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MODE BONE IMPLANT

1. Product Description

Mode Bone dental implants are part of Mode Dental Implant Systems, which is an integrated system with related abutments, healing abutments, cover screws, surgical and prosthetic parts and instruments; They are endoosseous screw type implants that have an internal conical octagon connection between the implant and the abutment.

Surface roughening of Bone implants produced from biocompatible Titanium Grade 4 (ASTM F 67) material is done with biphasic calcium phosphate (BCP).

They are packaged together with the cover screw produced using Ti6Al4V-ELI (ASTM F 136) material.

Mode Bone implants are produced in two different platforms as narrow platform (NP) and regular platform (RP).

Diameter and length options of Mode Bone implants according to their platforms are given in the table below.

Platform	NP	NP	RP	RP
Implant Ø(D)	Ø3.3	Ø3.7	Ø4.1	Ø4.7
Length (L)				
8 mm	01.03.08.33	01.03.08.37	01.03.08.41	01.03.08.47
10 mm	01.03.10.33	01.03.10.37	01.03.10.41	01.03.10.47
11,5 mm	01.03.115.33	01.03.115.37	01.03.115.41	01.03.115.47
13 mm	01.03.13.33	01.03.13.37	01.03.13.41	01.03.13.47
16 mm	01.03.16.33	01.03.16.37	01.03.16.41	01.03.16.47

2. Intended Use

Mode Bone implants are intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.

3. Target patient group and intended user

Mode Bone implants are intended to be used in patients with complete or partial edentulism who have completed their growth and development and do not have the conditions specified in the contraindications.

Mode dental implants are intended to be used by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode dental implants are indicated for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in fully or partially edentulous patients.

There is a wide range of indications, from the rehabilitation of single or multiple tooth deficiencies with fixed prosthetic applications in anterior and/or posterior regions where sufficient bone volume and quality is available, to the treatment of edentulous patients with fixed or removable prosthesis applications supported by implants.

After tooth extraction or loss, they can be applied as single or double-stage surgery with immediate, early or late implantation techniques.

Bone implants can be loaded immediately by adjusting appropriate occlusal forces in cases where sufficient primary stability is achieved.

5. Contraindications

The use of Mode Bone implants are contraindicated in the presence of the following conditions;

- The general systemic condition is not suitable for implant surgery
- Inadequate bone volume and/or quality
- Allergy or hypersensitivity to Titanium Grade 4 (ASTM F 67) and Ti6Al4V-ELI (ASTM F 136) materials
- Incomplete bone growth/development
- Alcohol and/or drug abuse
- Weak immune system
- Diseases requiring regular corticosteroid use
- Uncontrolled endocrine system diseases

6. Warnings / Cautions / Precautions

General

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! It is recommended to review the product-specific surgical technique before the surgeon performs the surgical procedure. MODE MEDİKAL can provide surgical technical information. Please contact MODE MEDİKAL sales representative.

! One hundred percent implant success cannot be guaranteed. Failure to comply with the specified use restrictions and operating steps may result in failure of implant therapy.

! Failure to recognize actual drill lengths based on radiographic measurements may result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for mandibular surgery can potentially cause permanent numbness of the lower lip and chin, or cause hemorrhage in the floor of the mouth.

! In implant operations, as in all surgeries, it is obligatory to comply with the rules of asepsis and antisepsis.

! Damage to nerves and vessels should be avoided by referring to anatomical information and preoperative radiographs in implant operations.

! In patients with atrophic mandible, fractures of the mandible may occur during the operation or during routine functions after the operation.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode dental implant system products cannot be applied to any part of the body other than the lower and upper jawbones.

! Due to the risk of prosthetic overload, it is recommended not to use implants with a diameter of less than 4 mm in the posterior regions.

! Mode dental implant system products should only be used with their system elements in the surgical and prosthetic stages. The use of products with different brands and materials may lead to mechanical problems, implant failure, tissue damage or aesthetic dissatisfaction.

! Check the expiry date of the product before use. Do not use Mode Dental implants after the expiry date on the package.

! Mode dental implants are in sterile packaging. Do not resterilize or process the implants. Cleaning and sterilization can damage material and design features, leading to implant failure.

! Do not reuse Mode dental implants. Reuse of single use products poses a risk of infection for the patient and user.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! Do not use the implant if the implant package is damaged or has been opened previously.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! The type, diameter, length, position and number of implants to be used should be chosen individually, taking into account the condition of the jawbones and anatomical structures.

! It is always recommended to choose the implant with the largest diameter that can be supported by available bone thickness, bone quality, interdental space and expected chewing forces. Where high loads are expected, proper implant alignment should be ensured.

! Placement of implants and design of prostheses should be specific to the patient. In the presence of extreme bruxism and other parafunctional habits and jaw relationship disorders, different treatment options can be planned.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases, bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

During the operation

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! Avoid getting close to the mandibular nerve canal while preparing the implant bed and placing the implant in the lower jaw. Possible nerve damage may result in anesthesia or paresthesia.

! Drills suitable for the size and diameter of the chosen implant should be used.

! Against the risk of contamination, as soon as the implant is taken out of the sterile package, it should be placed in the socket opened with the help of necessary equipment without touching its surface.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

! While inserting the implant, do not exceed the recommended torque values as it may cause bone necrosis.

! Inadequate cooling, incorrect implant bed preparation, use of incorrect instrument settings and excessive loading torque can result in implant failure.

! After implant placement, the clinician decides whether to use immediate or delayed loading protocols, based on the evaluation of the bone quality and primary stability in the operation.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Do not use damaged or blunted drills for implantation.

! Before use, avoid any contact of the implant with foreign materials. Do not touch the endosteal part of the implant.

! Patients should be advised to avoid activities that require excessive physical effort immediately after implant operations.

Post-operative

! For the long-term success of treatments with the Mode dental implants, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

! Patients should be monitored for peri-implant bone loss and/or changes in percussion responses. If more than 50% mobility or bone loss is observed in the implants, surgical removal of the implants can be considered.

! Patient records should be kept regularly using labels containing the type, diameter, length and lot number of the implant used.

7. Complications and side effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after implant treatment.

- Local pain
- Micro hemorrhages
- Swelling
- Bruising
- Local inflammations
- Gingival injuries
- Difficulty biting, chewing and talking
- Systemic or local infections (including Periimplantitis, periodontitis, gingivitis, fistulas)
- Paresthesia
- Chronic pain due to nerve damage
- Damage to the opposing or adjacent teeth
- Bone damage
- Bone resorption
- Sinus perforations
- Mandible fractures
- Trismus
- Hypersensitivity and/or allergic reactions
- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Implant fractures
- Implant failures
- Mandatory removal of implants
- Failure/fracture of prosthetic parts
- Undesirable aesthetic results

- Longer recovery times than expected

8. Surgical procedure

Preparing the implant bed

I. Determine the implant position with the lance drill.

II. Proceed to the implant length you have determined for the area with 2 mm diameter pilot drills with stoppers.

III. Using the appropriate implant drills, enlarge the implant bed to the diameter you have determined for the area.

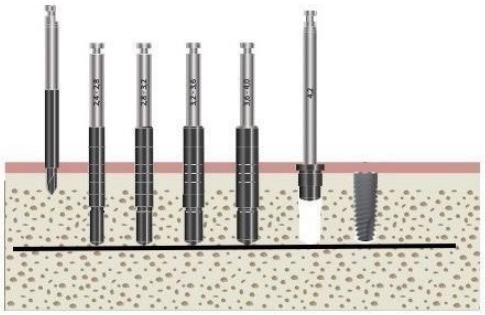
Note: Attention should be paid to bone quality during drilling. Bone quality is important for optimal primary stabilization. The drilling protocol of Mode Bone dental implants according to bone quality is given in the table below.

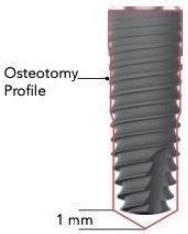
Platform	Implant Diameter	Soft Bone (D4)	Medium Bone (D2/D3)	Hard Bone (D1)
NP	⌀ **3.3**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 3.3 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.3 Bone Tap
NP	⌀ **3.7**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.7 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.7 Bone Tap
RP	⌀ **4.1**	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill

		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
			⌀ 4.1 Bone Tap	⌀ 3.6 / 4.0
				⌀ 4.1 Bone Tap
		⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
	⌀ **4.7**	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
RP		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
			⌀ 4.7 Bone Tap	⌀ 4.0 / 4.5
				⌀ 4.7 Bone Tap

- Drilling operations should be performed at a speed of 400-900 rpm/min by continuous cooling with sterile saline at room temperature in pilot and implant diameter drills.
- Bone taps should be used at low speed (maximum 25 rpm/min).
- For very compact bones, it is recommended to drill with back and forth motions.

Caution: Pilot and implant drills are driven 1 mm deeper than their actual implant length. Take this difference into account in order not to damage vital anatomical structures while preparing the implant bed.





Caution: In flapless surgical techniques, drilling should be done by taking the gingival height into account.

- In cases where the drills cannot reach the desired depth due to neighboring teeth, you can use a drill extender adapter.

Insertion of the implant

I. Open the packaging of the implant and place the sterile inner pack on the surgical area.
II. Mode dental implants are removed from the inner package with the implant carrier. You can use the implant carrier with the help of a hand adapter, a ratchet, a handpiece or a handle.

Note: The implant carrier should be used with a maximum speed of 25 rpm/min when used with a surgical motor.

III. Insert the implant into the implant bed with a maximum torque of 45 Ncm. Exceeding the recommended torque value may cause bone necrosis or damage/fracture of the implant.
IV. Non-compliance with the drill protocol during drilling may cause the implant to to be stucked without being fully inserted. In this case, use the implant motor in reverse mode or manually rotate it counterclockwise with the ratchet to remove the implant and return it to the inner package. Re-insert the implant by completing the drill protocol.

Attention: In order to be able to load immediately, at least 35Ncm torque value must be achieved.

Soft tissue management and wound closure

Depending on the selected loading protocol, place a cover screw, healing abutment or an abutment on the implant and perform the wound closure with suture.

9. Healing Phase

- The healing phase varies depending on the patient and the treatment. It is the clinician's sole responsibility when to load the implant. It is recommended to perform a radiographic control before loading.
- It is generally recommended to wait between 8 and 12 weeks in the two-stage surgical technique..
- In cases of partial edentulism, implants with immediate loading should be splinted to each other during the healing phase and kept without any occlusal contact. In cases of total edentulism, at least 6 implants in the maxilla and at least 4 implants in the mandible should be splinted together and kept in a balanced occlusal contact

10. Compatibility Information

Mode dental implants are compatible with Mode surgical sets.

Do not use implants and components made of different metals and supplied from different manufacturers with Mode dental implant system products.

Mode healing abutments and prosthetic parts can only be used with those with the corresponding connection on Mode Bone implants.

11. MRI Safety Information

Mode dental implants have been shown to be MRI conditional through testing in non-clinical tests. Patients using this device can be safely screened in an MRI system if the following conditions are met:

• 1.5 T and 3.0 T static magnetic field

• Maximum surface area gradient of 3,000 gauss/cm (^{30} T/m)

• At maximum MRI system, average specific absorption rate (SAR) of the whole body 2 W/kg (Normal Operating Mode)

Under the scanning conditions described above, Mode dental implants are expected to have a maximum temperature rise of 4°C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical tests, device-induced image artifact expands radially up to 2.7 cm and 2.2 cm from the implant when scanned with a gradient echo pulse array at 3.0 T and 1.5 T, respectively.

12. Cleaning And Sterilization

Mode dental implants are delivered sterile and for single use only. They should not be cleaned or sterilized. Mode Medikal does not accept any responsibility for the processing of devices that are initially delivered as sterile.

Surgical sets and drills are delivered non-sterile. Cleaning and sterilization of these parts are the responsibility of the users.

The protected packaging system protects the sterilized device from external factors and if the device is stored correctly, it maintains its sterility until the expiry date. When removing the device from its packaging, the rules of asepsis should be followed. The sterile package should not be opened until just before the insertion of the implant. Inspect the devices for damage before opening the sterile packaging. Products with damaged packaging system should not be used. A previously used or non-sterile implant should not be used under any circumstances.

13. Storage

The products should be stored at room temperature, in a dry place protected from direct sunlight. The products must be kept in their original packaging. Improper storage conditions may affect the product's characteristics and cause failure.

The expiry date of the product must be checked before using it. In case of damage to the sterile package, the product should not be used.

See labelings for specific storage and handling rules.

14. Disposal

Disposal of the products should be done in accordance with the rules within the framework of legal procedures and environmental requirements. Contaminated products and sharp parts are hazardous and should be disposed of as medical waste in appropriate conditions.

15. Information That Should Be Provided To The Patient

Patients should be informed about the contraindications, warnings, precautions, side effects and complications of Mode dental implants.

Patients should also be informed about MR safety information, and the diameter-height and serial number information of the implants used should be provided to the patient.

16. Disclaimer Of Liability

These products are part of a general concept and should only be used together with the relevant original products, in accordance with Mode Medikal's instructions and recommendations. The use of products that are not distributed by Mode Medikal and made by third parties will void any expressed or implied warranty or other obligations of Mode Medikal.

Mode Medikal products should be used in accordance with the instructions for use provided by the manufacturer. It is the clinician's responsibility to use products in accordance with these instructions and to determine whether the product is appropriate for the individual patient situation. The clinician is also responsible for regularly following the latest updates on the relevant Mode Medikal product and its applications. Mode Medikal is not responsible for any direct, indirect, punitive or other damages arising out of or in connection with any errors in professional judgment or application related to the use of Mode Medikal products; disclaims any liability, express or implied.

18. Additional Information

The shelf life of sterile products is 5 years.

Life Time:
it remains in the patient's mouth for life

The SSCP link of the products is in the link below;

https://modeimplant.com/images/SSCP-Dental-Implant-Systems.pdf

NOTICE REGARDING SERIOUS INCIDENT

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Manufacturer Name: Mode Medikal Sanayi ve Ticaret Limited Şirketi

Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

Mail: info@modeimplant.com

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

Related Person: Melis AKYÜZ

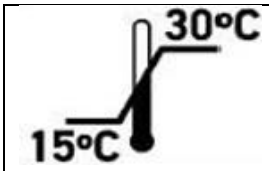
Mail: melis@modemed.com

Phone: 0553 373 36 42

19. Symbols

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
CE 2696	Notified Body Number		Expiry Date
	Do not subject to a second sterilisation		Date of Production
	Do not use a second time		Do not expose to direct sunlight
	Please refer to the user manual		Do not use if package is damaged
REF	Reference Number		Keep away from contact with water
	Barcode Number	MR	MR Safe
STERILE R	Sterilised with radiation	LOT	Batch code/Lot number
UDI	Specifies a bearer containing Unique Device Identifier information.	60% 40%	Indicates the humidity range to which the medical device can be safely exposed.

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

	Indicates the temperature limits to which the medical device can be safely exposed.		Medical device

Symbol	Symbol Description
	Patient name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer
	Information website for patients
	Device name
	Lot Number/Batch Code
	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data capture format (e.g. linear or 2D-Barcodes)*

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/Türkiye

MODE LEVEL IMPLANT

1. Product Description

Mode Level dental implants are part of Mode Dental Implant Systems, which is an integrated system with related abutments, healing abutments, cover screws, surgical and prosthetic parts and instruments; They are endoosseous screw type implants that have an internal conical octagon connection between the implant and the abutment.

Surface roughening of Level implants produced from biocompatible Titanium Grade 4 (ASTM F 67) material is done with biphasic calcium phosphate (BCP).

They are packaged together with the cover screw produced using Ti6Al4V-ELI (ASTM F 136) material.

Mode Level implants are produced in three different platforms as narrow platform (NP), regular platform (RP) and wide platform (WP).

Diameter and length options of Mode Level implants according to their platforms are given in the table below.

Platform	NP	NP	RP	RP	RP	WP
Implant Ø(D)	Ø3.3	Ø3.7	Ø4.1	Ø4.7	Ø5.2	Ø5.3
Length (L)						
8 mm	01.07.08.33	01.07.08.37	01.07.08.41	01.07.08.47	01.07.08.52	01.07.08.53

10 mm	01.07.10.33	01.07.10.37	01.07.10.41	01.07.10.47	01.07.10.52	01.07.10.53
11,5 mm	01.07.115.33	01.07.115.37	01.07.115.41	01.07.115.47	01.07.115.52	01.07.115.53
13 mm	01.07.13.33	01.07.13.37	01.07.13.41	01.07.13.47	01.07.13.52	01.07.13.53
16 mm	01.07.16.33	01.07.16.37	01.07.16.41	01.07.16.47	01.07.16.52	01.07.16.53

2. Intended Use

Mode Level implants are intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.

3. Target Patient Group And İntended User

Mode Level implants are intended to be used in patients with complete or partial edentulism who have completed their growth and development and do not have the conditions specified in the contraindications.

Mode dental implants are intended to be used by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode dental implants are indicated for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in fully or partially edentulous patients.

There is a wide range of indications, from the rehabilitation of single or multiple tooth deficiencies with fixed prosthetic applications in anterior and/or posterior regions where sufficient bone volume and quality is available, to the treatment of edentulous patients with fixed or removable prosthesis applications supported by implants.

After tooth extraction or loss, they can be applied as single or double-stage surgery with immediate, early or late implantation techniques.

Level implants can be loaded immediately by adjusting appropriate occlusal forces in cases where sufficient primary stability is achieved.

5. Contraindications

The use of Mode Level implants are contraindicated in the presence of the following conditions;

- The general systemic condition is not suitable for implant surgery
- Inadequate bone volume and/or quality
- Allergy or hypersensitivity to Titanium Grade 4 (ASTM F 67) and Ti6Al4V-ELI (ASTM F 136) materials
- Incomplete bone growth/development
- Alcohol and/or drug abuse
- Weak immune system
- Diseases requiring regular corticosteroid use
- Uncontrolled endocrine system diseases

6. Warnings / Cautions / Precautions

General

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! It is recommended to review the product-specific surgical technique before the surgeon performs the surgical procedure. MODE MEDİKAL can provide surgical technical information. Please contact MODE MEDİKAL sales representative.

! One hundred percent implant success cannot be guaranteed. Failure to comply with the specified use restrictions and operating steps may result in failure of implant therapy.

! Failure to recognize actual drill lengths based on radiographic measurements may result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for mandibular surgery can potentially cause permanent numbness of the lower lip and chin, or cause hemorrhage in the floor of the mouth.

! In implant operations, as in all surgeries, it is obligatory to comply with the rules of asepsis and antisepsis.

! Damage to nerves and vessels should be avoided by referring to anatomical information and preoperative radiographs in implant operations.

! In patients with atrophic mandible, fractures of the mandible may occur during the operation or during routine functions after the operation.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode dental implant system products cannot be applied to any part of the body other than the lower and upper jawbones.

! Due to the risk of prosthetic overload, it is recommended not to use implants with a diameter of less than 4 mm in the posterior regions.

! Mode dental implant system products should only be used with their system elements in the surgical and prosthetic stages. The use of products with different brands and materials may lead to mechanical problems, implant failure, tissue damage or aesthetic dissatisfaction.

! Check the expiry date of the product before use. Do not use Mode Dental implants after the expiry date on the package.

! Mode dental implants are in sterile packaging. Do not resterilize or process the implants. Cleaning and sterilization can damage material and design features, leading to implant failure.

! Do not reuse Mode dental implants. Reuse of single use products poses a risk of infection for the patient and user.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! Do not use the implant if the implant package is damaged or has been opened previously.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! The type, diameter, length, position and number of implants to be used should be chosen individually, taking into account the condition of the jawbones and anatomical structures.

! It is always recommended to choose the implant with the largest diameter that can be supported by available bone thickness, bone quality, interdental space and expected chewing forces. Where high loads are expected, proper implant alignment should be ensured.

! Placement of implants and design of prostheses should be specific to the patient. In the presence of extreme bruxism and other parafunctional habits and jaw relationship disorders, different treatment options can be planned.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases,

bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

During the operation

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! Avoid getting close to the mandibular nerve canal while preparing the implant bed and placing the implant in the lower jaw. Possible nerve damage may result in anesthesia or paresthesia.

! Drills suitable for the size and diameter of the chosen implant should be used.

! Against the risk of contamination, as soon as the implant is taken out of the sterile package, it should be placed in the socket opened with the help of necessary equipment without touching its surface.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

! While inserting the implant, do not exceed the recommended torque values as it may cause bone necrosis.

! Inadequate cooling, incorrect implant bed preparation, use of incorrect instrument settings, and excessive loading torque can result in implant failure.

! After implant placement, the clinician decides whether to use immediate or delayed loading protocols, based on the evaluation of the bone quality and primary stability in the operation.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Do not use damaged or blunted drills for implantation.

! Before use, avoid any contact of the implant with foreign materials. Do not touch the endosteal part of the implant.

! Patients should be advised to avoid activities that require excessive physical effort immediately after implant operations.

Post-operative

! For the long-term success of treatments with the Mode dental implants, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

! Patients should be monitored for peri-implant bone loss and/or changes in percussion responses. If more than 50% mobility or bone loss is observed in the implants, surgical removal of the implants can be considered.

! Patient records should be kept regularly using labels containing the type, diameter, length and lot number of the implant used.

7. Complications And Side Effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after implant treatment.

- Local pain
- Micro hemorrhages
- Swelling
- Bruising
- Local inflammations
- Gingival injuries
- Difficulty biting, chewing and talking
- Systemic or local infections (including Periimplantitis, periodontitis, gingivitis, fistulas)
- Paresthesia
- Chronic pain due to nerve damage
- Damage to the opposing or adjacent teeth
- Bone damage
- Bone resorption
- Sinus perforations
- Mandible fractures
- Trismus
- Hypersensitivity and/or allergic reactions
- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Implant fractures
- Implant failures
- Mandatory removal of implants
- Failueres/fractures of prosthetic parts
- Undesirable aesthetic results
- Longer recovery times than expected

8. Surgical Procedure

Preparing the implant bed

I. Determine the implant position with the lance drill.

II. Proceed to the implant length you have determined for the area with 2 mm diameter pilot drills with stoppers.

III. Using the appropriate implant drills, enlarge the implant bed to the diameter you have determined for the area.

Note: Attention should be paid to bone quality during drilling. Bone quality is important for optimal primary stabilization. The drilling protocol of Mode Level dental implants according to bone quality is given in the table below.

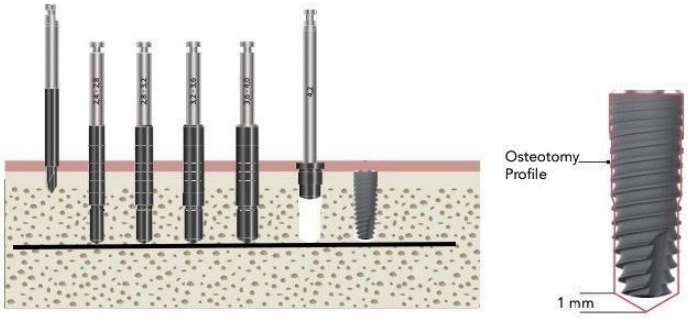
Platform	Implant Diameter	Soft Bone (D4)	Medium Bone (D2/D3)	Hard Bone (D1)
NP	⌀ **3.3**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 3.3 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.3 Bone Tap
NP	⌀ **3.7**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.7 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.7 Bone Tap
RP	⌀ **4.1**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6

			⌀ 4.1 Bone Tap	⌀ 3.6 / 4.0
				⌀ 4.1 Bone Tap
RP	⌀ **4.7**	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
			⌀ 4.7 Bone Tap	⌀ 4.0 / 4.5
				⌀ 4.7 Bone Tap
RP	⌀ **5.2**	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
		⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5
			⌀ 5.2 / 5.3 Bone Tap	⌀ 4.5 / 5.0
				⌀ 5.2 / 5.3 Bone Tap
WP	⌀ **5.3**	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
		⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5

	⌀ 5.2 / 5.3 Bone Tap	⌀ 4.5 / 5.0 ⌀ 5.2 / 5.3 Bone Tap

- Drilling operations should be performed at a speed of 400-900 rpm/min by continuous cooling with sterile saline at room temperature in pilot and implant diameter drills.
- Bone taps should be used at low speed (maximum 25 rpm/min).
- For very compact bones, it is recommended to drill with back and forth motions.

Caution: Pilot and implant drills are driven 1 mm deeper than their actual implant length. Take this difference into account in order not to damage vital anatomical structures while preparing the implant bed.



Caution: In flapless surgical techniques, drilling should be done by taking the gingival height into account.

- In cases where the drills cannot reach the desired depth due to neighboring teeth, you can use a drill extender adapter.

Insertion of the implant

I. Open the packaging of the implant and place the sterile inner pack on the surgical area.
II. Mode dental implants are removed from the inner package with the implant carrier. You can use the implant carrier with the help of a hand adapter, a ratchet, a handpiece or a handle.

Note: The implant carrier should be used with a maximum speed of 25 rpm/min when used with a surgical motor.

III. Insert the implant into the implant bed with a maximum torque of 45 Ncm. Exceeding the recommended torque value may cause bone necrosis or damage/fracture of the implant.
IV. Non-compliance with the drill protocol during drilling may cause the implant to be stucked without being fully inserted. In this case, use the implant motor in reverse mode or manually rotate it counterclockwise with the ratchet to remove the implant and return it to the inner package. Re-insert the implant by completing the drill protocol.
Attention: In order to be able to load immediately, at least 35Ncm torque value must be achieved.

Soft tissue management and wound closure
Depending on the selected loading protocol, place a cover screw, healing abutment or an abutment on the implant and perform the wound closure with suture.

9. Healing Phase

- The healing phase varies depending on the patient and the treatment. It is the clinician's sole responsibility when to load the implant. It is recommended to perform a radiographic control before loading.
- It is generally recommended to wait between 8 and 12 weeks in the two-stage surgical technique..
- In cases of partial edentulism, implants with immediate loading should be splinted to each other during the healing phase and kept without any occlusal contact. In cases of total edentulism, at least 6 implants in the maxilla and at least 4 implants in the mandible should be splinted together and kept in a balanced occlusal contact

10. Compatibility information

Mode dental implants are compatible with Mode surgical sets.

Do not use implants and components made of different metals and supplied from different manufacturers with Mode dental implant system products..

Mode healing abutments and prosthetic parts can only be used with those with the corresponding connection on Mode Level implants.

11. MRI safety information

Mode dental implants have been shown to be MRI conditional through testing in non-clinical tests. Patients using this device can be safely screened in an MRI system if the following conditions are met:

• 1.5 T and 3.0 T static magnetic field

• Maximum surface area gradient of 3,000 gauss/cm (30 T/m)

• At maximum MRI system, average specific absorption rate (SAR) of the whole body 2 W/kg (Normal Operating Mode)

Under the scanning conditions described above, Mode dental implants are expected to have a maximum temperature rise of 4°C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical tests, device-induced image artifact expands radially up to 2.7 cm and 2.2 cm from the implant when scanned with a gradient echo pulse array at 3.0 T and 1.5 T, respectively.

12. Cleaning and sterilization

Mode dental implants are delivered sterile and for single use only. They should not be cleaned or sterilized. Mode Medikal does not accept any responsibility for the processing of devices that are initially delivered as sterile.

Surgical sets and drills are delivered non-sterile. Cleaning and sterilization of these parts are the responsibility of the users.

The protected packaging system protects the sterilized device from external factors and if the device is stored correctly, it maintains its sterility until the expiry date. When removing the device from its packaging, the rules of asepsis should be followed. The sterile package should not be opened until just before the insertion of the implant. Inspect the devices for damage before opening the sterile packaging. Products with damaged

packaging system should not be used. A previously used or non-sterile implant should not be used under any circumstances.

13. Storage

The products should be stored at room temperature, in a dry place protected from direct sunlight. The products must be kept in their original packaging. Improper storage conditions may affect the product's characteristics and cause failure.

The expiry date of the product must be checked before using it. In case of damage to the sterile package, the product should not be used.

See labelings for specific storage and handling rules.

14. Disposal

Disposal of the products should be done in accordance with the rules within the framework of legal procedures and environmental requirements. Contaminated products and sharp parts are hazardous and should be disposed of as medical waste in appropriate conditions.

15. Information That Should Be Provided To The Patient

Patients should be informed about the contraindications, warnings, precautions, side effects and complications of Mode dental implants.

Patients should also be informed about MR safety information, and the diameter-height and serial number information of the implants used should be provided to the patient.

16. Disclaimer Of Liability

These products are part of a general concept and should only be used together with the relevant original products, in accordance with Mode Medikal's instructions and recommendations. The use of products that are not distributed by Mode Medikal and made by third parties will void any expressed or implied warranty or other obligations of Mode Medikal.

Mode Medikal products should be used in accordance with the instructions for use provided by the manufacturer. It is the clinician's responsibility to use products in accordance with these instructions and to determine whether the product is appropriate for the individual patient situation. The clinician is also responsible for regularly following the latest updates on the relevant Mode Medikal product and its applications. Mode Medikal is not responsible for any direct, indirect, punitive or other damages arising out of or in connection with any errors in professional judgment or application related to the use of Mode Medikal products; disclaims any liability, express or implied.

18. Additional Information

The shelf life of sterile products is 5 years.

Life Time:
it remains in the patient's mouth for life

The SSCP link of the products is in the link below;

https://modeimplant.com/images/SSCP-Dental-Implant-Systems.pdf

NOTICE REGARDING SERIOUS INCIDENT

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Manufacturer Name: Mode Medikal Sanayi ve Ticaret Limited Şirketi

Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

Mail: info@modeimplant.com

Related Person: Melis AKYÜZ

Mail: melis@modemed.com

Phone: 0553 373 36 42

19. Symbols

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol

CE 2696	Notified Body Number		Expiry Date
	Do not subject to a second sterilisation		Date of Production
	Do not use a second time		Do not expose to direct sunlight
	Please refer to the user manual		Do not use if package is damaged
REF	Reference Number		Keep away from contact with water
	Barcode Number	MR	MR Safe
STERILE R	Sterilised with radiation	LOT	Batch code/Lot number
UDI	Specifies a bearer containing Unique Device Identifier information.	60% 40%	Indicates the humidity range to which the medical device can be safely exposed.
30°C 15°C	Indicates the temperature limits to which the medical device can be safely exposed.	MD	Medical device

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

Symbol	Symbol Description
	Patient name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer
	Information website for patients
	Device name
	Lot Number/Batch Code
	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data capture format (e.g. linear or 2D-Barcodes)*

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/Türkiye

MODE MINI IMPLANT

1. Product Description

Mode Mini implants are endosteal implants in which the implant and abutment are produced in one piece (monoblock) and are part of Mode Dental Implant Systems, which is an integrated system with related healing abutments, surgical and prosthetic parts and instruments.

Surface roughening of Mini implants produced from biocompatible Ti6Al4V-ELI (ASTM F 136) material is done with biphasic calcium phosphate (BCP).

Implant Ø(D)	Ø2.2	Ø2.5	Ø2.9
Length (L)			
8 mm			01.05.08.29
10 mm	01.05.10.22	01.05.10.25	01.05.10.29
12 mm	01.05.12.22	01.05.12.25	01.05.12.29
14 mm	01.05.14.22	01.05.14.25	01.05.14.29

2. Intended Use

Mode Mini implants are intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower or upper jaw bones.

3. Target Patient Group And İntended User

Mode Mini implants are intended for use in patients with complete or partial edentulism who have completed their growth and development and do not have the conditions specified in the contraindications.

Mode Mini implants are intended for use only in patients undergoing a one-stage surgery and loading protocol.

Mode dental implants are intended to be used by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode dental implants are indicated for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in fully or partially edentulous patients.

In cases where there is sufficient bone volume after tooth extraction or loss, they can be applied with immediate, early or late implantation techniques as only one-stage surgery, and only in cases where optimum primary stabilization can be achieved by immediate loading.

It is used as a support for removable restorations with immediate loading in the upper and lower jaws. It is also indicated in cases with excessively resorbed ridges, narrow tooth spacing and insufficient distance between two roots. Implants may be placed with or without flaps. The abutment part of mini-implants is designed as spherical (O-Ball) for removable prosthetic restorations.

5. Contraindications

The use of Mode Mini implants are contraindicated in the presence of the following conditions;

- The general systemic condition is not suitable for implant surgery
- Inadequate bone volume and/or quality
- Allergy or hypersensitivity to Titanium Grade 4 (ASTM F 67) and Ti6Al4V-ELI (ASTM F 136) materials
- Incomplete bone growth/development
- Alcohol and/or drug abuse
- Weak immune system
- Diseases requiring regular corticosteroid use
- Uncontrolled endocrine system diseases

Special contraindications:

– Mini implants should not be used in D4 type cancellous bone types.

– Mini implants should not be used in cases where 35Ncm torque value cannot be obtained due to the necessity of immediate loading.

6. Warnings / Cautions / Precautions

General

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! It is recommended to review the product-specific surgical technique before the surgeon performs the surgical procedure. MODE MEDİKAL can provide surgical technical information. Please contact MODE MEDİKAL sales representative.

! Mode Mini implants are designed for immediate loading and should not be used in soft bone types.

! One hundred percent implant success cannot be guaranteed. Failure to comply with the specified use restrictions and operating steps may result in failure of implant therapy.

! Failure to recognize actual drill lengths based on radiographic measurements may result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for mandibular surgery can potentially cause permanent numbness of the lower lip and chin, or cause hemorrhage in the floor of the mouth.

! In implant operations, as in all surgeries, it is obligatory to comply with the rules of asepsis and antisepsis.

! Damage to nerves and vessels should be avoided by referring to anatomical information and preoperative radiographs in implant operations.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode dental implant system products cannot be applied to any part of the body other than the lower and upper jawbones.

! Mode dental implant system products should only be used with their system elements in the surgical and prosthetic stages. The use of products with different brands and materials may lead to mechanical problems, implant failure, tissue damage or aesthetic dissatisfaction.

! Check the expiry date of the product before use. Do not use Mode Dental implants after the expiry date on the package.

! Mode dental implants are in sterile packaging. Do not resterilize or process the implants. Cleaning and sterilization can damage material and design features, leading to implant failure.

! Do not reuse Mode dental implants. Reuse of single use products poses a risk of infection for the patient and user.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! Do not use the implant if the implant package is damaged or has been opened previously.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! The type, diameter, length, position and number of implants to be used should be chosen individually, taking into account the condition of the jawbones and anatomical structures.

! It is always recommended to choose the implant with the largest diameter that can be supported by available bone thickness, bone quality, interdental space and expected chewing forces. Where high loads are expected, proper implant alignment should be ensured.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases, bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

During the operation

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! Avoid getting close to the mandibular nerve canal while preparing the implant bed and placing the implant in the lower jaw. Possible nerve damage may result in anesthesia or paresthesia.

! Drills suitable for the size and diameter of the chosen implant should be used.

! Against the risk of contamination, as soon as the implant is taken out of the sterile package, it should be placed in the socket opened with the help of necessary equipment without touching its surface.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

! While inserting the implant, do not exceed the recommended torque values as it may cause bone necrosis.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Do not use damaged or blunted drills for implantation.

! Before use, avoid any contact of the implant with foreign materials. Do not touch the endosteal part of the implant.

! Patients should be advised to avoid activities that require excessive physical effort immediately after implant operations.

Post-operative

! For the long-term success of treatments with the Mode dental implants, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

! Patient records should be kept regularly using labels containing the type, diameter, length and lot number of the implant used.

! Patients should be monitored for peri-implant bone loss and/or changes in percussion responses. If more than 50% mobility or bone loss is observed in the implants, surgical removal of the implants can be considered.

7. Complications And Side Effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after implant treatment.

- Local pain
- Micro hemorrhages
- Swelling
- Bruising
- Local inflammations
- Gingival injuries
- Difficulty biting, chewing and talking
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- Paresthesia
- Chronic pain due to nerve damage
- Damage to the opposing or adjacent teeth

- Bone damage
- Bone resorption
- Sinus perforations
- Trismus
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- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Implant fractures
- Implant failures
- Mandatory removal of implants
- Failures/fractures of prosthetic parts
- Undesirable aesthetic results
- Longer recovery times than expected

8. Surgical Procedure

Preparing the implant bed

I. Determine the implant position with the marking bur.

II. If you are going to perform the flapless surgical technique, remove the gingiva in the area using a tissue punch.

III. Proceed to the implant length you have determined for the area with 1.5 mm diameter pilot drill.

IV. Using the appropriate implant drills, enlarge the implant socket to the diameter you specified for the area. The drill protocol of Mode Mini implants is given in the table below.

Implant Diameter	Drill Protocol
⌀ 2.2	1.5 Pilot Drill
⌀ 2.5	1.5 Pilot Drill 1.8 Pilot Drill
⌀ 2.9	1.5 Pilot Drill 1.8 Pilot Drill

2.4 Final Drill

- Drilling operations should be performed at a speed of 400-900 rpm/min by continuous cooling with sterile saline at room temperature in pilot and implant diameter drills.
- For very compact bones, it is recommended to drill with back and forth motions.

Caution: Pilot and implant drills are driven 1 mm deeper than their actual implant length. Take this difference into account in order not to damage vital anatomical structures while preparing the implant bed.

Caution: In flapless surgical techniques, drilling should be done by taking the gingival height into account.

Insertion of the implant

I. Open the packaging of the implant and place the sterile inner pack on the surgical area.
II. Mini implants are removed from the inner package with adapters specific to the abutment shape.

III. Implants that are placed directly in the implant socket are hand tightened until their stability is achieved.

IV. Finally, the implant is sent to the prepared socket with the help of a ratchet. Insert the implant into the socket with a maximum torque of 45 Ncm. Exceeding the recommended torque value may cause bone necrosis or damage/fracture of the implant.

Attention: In order to be able to load immediately, at least 35Ncm torque value must be achieved.

9. Healing phase

Mini-implants can be loaded immediately depending on the insertion torque and bone condition, or the relevant parts of the prosthesis can be emptied and left to heal without loading.

10. Compatibility information

Mode dental implants are compatible with Mode surgical sets.

Do not use implants and components made of different metals and supplied from different manufacturers with Mode dental implant system products.

11. MRI safety information

Mode dental implants have been shown to be MRI conditional through testing in non-clinical tests. Patients using this device can be safely screened in an MRI system if the following conditions are met:

• 1.5 T and 3.0 T static magnetic field

• Maximum surface area gradient of 3,000 gauss/cm (30 T/m)

• At maximum MRI system, average specific absorption rate (SAR) of the whole body 2 W/kg (Normal Operating Mode)

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13. Storage

The products should be stored at room temperature, in a dry place protected from direct sunlight. The products must be kept in their original packaging. Improper storage conditions may affect the product's characteristics and cause failure.

The expiry date of the product must be checked before using it. In case of damage to the sterile package, the product should not be used.

See labelings for specific storage and handling rules.

14. Disposal

Disposal of the products should be done in accordance with the rules within the framework of legal procedures and environmental requirements. Contaminated products and sharp parts are hazardous and should be disposed of as medical waste in appropriate conditions.

15. Information that should be provided to the patient

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Patients should also be informed about MR safety information, and the diameter-height and serial number information of the implants used should be provided to the patient.

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17. Additional Information

The shelf life of sterile products is 5 years.

Life Time:
it remains in the patient's mouth for life

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Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

Manufacturer Name: Mode Medikal Sanayi ve Ticaret Limited Şirketi

Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

Mail: info@modeimplant.com

Related Person: Melis AKYÜZ

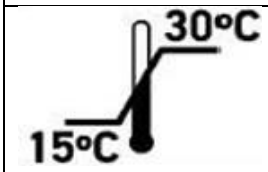
Mail: melis@modemed.com

Phone: 0553 373 36 42

19. Symbols

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
CE 2696	Notified Body Number		Expiry Date
	Do not subject to a second sterilisation		Date of Production
	Do not use a second time		Do not expose to direct sunlight
	Please refer to the user manual		Do not use if package is damaged
REF	Reference Number		Keep away from contact with water
	Barcode Number	MR	MR Safe

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

	Sterilised with radiation		Batch code/Lot number
	Specifies a bearer containing Unique Device Identifier information.		Indicates the humidity range to which the medical device can be safely exposed.
	Indicates the temperature limits to which the medical device can be safely exposed.		Medical device

Symbol	Symbol Description
	Patient name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer
	Information website for patients
	Device name
	Lot Number/Batch Code
	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data*

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

	capture format (e.g. linear or 2D-Barcodes)

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/Türkiye

MODE PROVO IMPLANT

1. Product Description

Mode Provo implants are endosteal implants in which the implant and abutment are produced in one piece (monoblock) and are part of Mode Dental Implant Systems, which is an integrated system with related healing abjutments, surgical and prosthetic parts and instruments.

Surface roughening of Provo implants produced from biocompatible Ti6Al4V-ELI (ASTM F 136) material is done with biphasic calcium phosphate (BCP).

Provo implants with a diameter of 2.5 produced for temporary implantation do not have surface roughening in order to prevent osseointegration, these implants are presented with a polished surface.

Implant Ø(D)	Ø2.5	Ø3	Ø3.5	Ø4	Ø4.5
Length (L)					
8 mm		01.06.08.30	01.06.08.35	01.06.08.40	01.06.08.45

10 mm	01.06.10.25	01.06.10.30	01.06.10.35	01.06.10.40	01.06.10.45
12 mm	01.06.12.25	01.06.12.30	01.06.12.35	01.06.12.40	01.06.12.45
15 mm	01.06.15.25	01.06.15.30	01.06.15.35	01.06.15.40	01.06.15.45

2. Intended Use

Mode Provo implants are intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower or upper jaw bones.

3. Target Patient Group And İntended User

Mode Provo implants are intended for use in patients with complete or partial edentulism who have completed their growth and development and do not have the conditions specified in the contraindications.

Mode Provo implants are intended for use only in patients undergoing a one-stage surgery and loading protocol.

Provo implants with a diameter of 2.5 are intended to be used only to support temporary prostheses that will meet the aesthetic expectations of the patient during implant treatments.

Mode dental implants are intended to be used by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode dental implants are indicated for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in fully or partially edentulous patients.

In cases where there is sufficient bone volume after tooth extraction or loss, they can be applied with immediate, early or late implantation techniques as only one-stage surgery, and only in cases where optimum primary stabilization can be achieved by immediate loading.

Provo implants are used for partial and total fixed restorations with immediate loading on upper and lower jaws with sufficient bone volume. Implants can be placed with or without a flap. The abutment part of Provo implants is designed only for cemented prostheses.

The use of Provo implants with a diameter of 2.5 is indicated only to support temporary prostheses that will meet the aesthetic expectations of the patient during implant treatments.

5. Contraindications

The use of Mode Provo implants are contraindicated in the presence of the following conditions;

- The general systemic condition is not suitable for implant surgery
- Inadequate bone volume and/or quality
- Allergy or hypersensitivity to Titanium Grade 4 (ASTM F 67) and Ti6Al4V-ELI (ASTM F 136) materials
- Incomplete bone growth/development
- Alcohol and/or drug abuse
- Weak immune system
- Diseases requiring regular corticosteroid use
- Uncontrolled endocrine system diseases

Special contraindications:
– Provo implants should not be used in D4 type cancellous bone types.
– Provo implants should not be used in cases where 35Ncm torque value cannot be obtained due to the necessity of immediate loading.
– Provo implants should not be used in a single tooth deficiency.

6. Warnings / Cautions / Precautions

General

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! It is recommended to review the product-specific surgical technique before the surgeon performs the surgical procedure. MODE MEDİKAL can provide surgical technical information. Please contact MODE MEDİKAL sales representative.

! Mode Provo implants are designed for immediate loading and should not be used in soft bone types.

! Provo implants with a diameter of 2.5 should only be used temporarily, they cannot be used to support permanent prostheses.

! One hundred percent implant success cannot be guaranteed. Failure to comply with the specified use restrictions and operating steps may result in failure of implant therapy.

! Failure to recognize actual drill lengths based on radiographic measurements may result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for mandibular surgery can potentially cause permanent numbness of the lower lip and chin, or cause hemorrhage in the floor of the mouth.

! In implant operations, as in all surgeries, it is obligatory to comply with the rules of asepsis and antisepsis.

! Damage to nerves and vessels should be avoided by referring to anatomical information and preoperative radiographs in implant operations.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode dental implant system products cannot be applied to any part of the body other than the lower and upper jawbones.

! Mode dental implant system products should only be used with their system elements in the surgical and prosthetic stages. The use of products with different brands and materials may lead to mechanical problems, implant failure, tissue damage or aesthetic dissatisfaction.

! Check the expiry date of the product before use. Do not use Mode Dental implants after the expiry date on the package.

! Mode dental implants are in sterile packaging. Do not resterilize or process the implants. Cleaning and sterilization can damage material and design features, leading to implant failure.

! Do not reuse Mode dental implants. Reuse of single use products poses a risk of infection for the patient and user.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! Do not use the implant if the implant package is damaged or has been opened previously.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! The type, diameter, length, position and number of implants to be used should be chosen individually, taking into account the condition of the jawbones and anatomical structures.

! It is always recommended to choose the implant with the largest diameter that can be supported by available bone thickness, bone quality, interdental space and expected chewing forces. Where high loads are expected, proper implant alignment should be ensured.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases, bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

During the operation

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! Avoid getting close to the mandibular nerve canal while preparing the implant bed and placing the implant in the lower jaw. Possible nerve damage may result in anesthesia or paresthesia.

! Drills suitable for the size and diameter of the chosen implant should be used.

! Against the risk of contamination, as soon as the implant is taken out of the sterile package, it should be placed in the socket opened with the help of necessary equipment without touching its surface.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

! While inserting the implant, do not exceed the recommended torque values as it may cause bone necrosis.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Do not use damaged or blunted drills for implantation.

! Before use, avoid any contact of the implant with foreign materials. Do not touch the endosteal part of the implant.

! Patients should be advised to avoid activities that require excessive physical effort immediately after implant operations.

Post-operative

! For the long-term success of treatments with the Mode dental implants, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

! Patient records should be kept regularly using labels containing the type, diameter, length and lot number of the implant used.

! Patients should be monitored for peri-implant bone loss and/or changes in percussion responses. If more than 50% mobility or bone loss is observed in the implants, surgical removal of the implants can be considered.

7. Complications And Side Effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after implant treatment.

- Local pain
- Micro hemorrhages
- Swelling
- Bruising
- Local inflammations
- Gingival injuries
- Difficulty biting, chewing and talking
- Systemic or local infections (including Periimplantitis, periodontitis, gingivitis, fistulas)
- Paresthesia
- Chronic pain due to nerve damage
- Damage to the opposing or adjacent teeth
- Bone damage
- Bone resorption
- Sinus perforations
- Trismus
- Hypersensitivity and/or allergic reactions
- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Implant fractures
- Implant failures
- Mandatory removal of implants
- Failures/fractures of prosthetic parts
- Undesirable aesthetic results
- Longer recovery times than expected

8. Surgical Procedure

Preparing the implant bed

I. Determine the implant position with the marking bur.

II. Proceed to the implant length you have determined for the area with 1.5 mm diameter pilot drills.

III. Using the appropriate implant drills, enlarge the implant bed to the diameter you have determined for the area.

Note: Attention should be paid to bone quality during drilling. Bone quality is important for optimal primary stabilization. The drilling protocol of Mode Provo implants according to bone quality is given in the table below.

Implant Diameter	Medium Bone (D2/D3)	Hard Bone (D1)
⌀ 3.0	⌀ 1.5 Pilot Drill ⌀ 3.0	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.0 Bone Tap
⌀ 3.5	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.5	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.5 ⌀ 3.5 Bone Tap
⌀ 4.0	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.5 ⌀ 4.0	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.5 ⌀ 4.0 ⌀ 4.0 Bone Tap

	⌀ 1.5 Pilot Drill	⌀ 1.5 Pilot Drill
	⌀ 3.0	⌀ 3.0
	⌀ 3.5	⌀ 3.5
⌀ 4.5		
	⌀ 4.0	⌀ 4.0
	⌀ 4.5	⌀ 4.5
		⌀ 4.5 Bone Tap

▪ Drilling operations should be performed at a speed of 400-900 rpm/min by continuous cooling with sterile saline at room temperature in pilot and implant diameter drills.
▪ For very compact bones, it is recommended to drill with back and forth motions.

Caution: Pilot and implant drills are driven 1 mm deeper than their actual implant length. Take this difference into account in order not to damage vital anatomical structures while preparing the implant bed.

Caution: In flapless surgical techniques, drilling should be done by taking the gingival height into account.

Insertion of the implant

I. Open the packaging of the implant and place the sterile inner pack on the surgical area.
II. Provo implants are removed from the inner package with adapters specific to the abutment shape.

III. Implants that are placed directly in the implant socket are hand tightened until their stability is achieved.

IV. Finally, the implant is sent to the prepared socket with the help of a ratchet. Insert the implant into the socket with a maximum torque of 45 Ncm. Exceeding the recommended torque value may cause bone necrosis or damage/fracture of the implant.

Attention: In order to be able to load immediately, at least 35Ncm torque value must be achieved.

Procedure for use on Provo implants with a diameter of 2.5:

I. Prepare the implant socket using the ⌀ 1.5 pilot drill

II. Remove the implant from the inner package with the special adapters and hand-tighten the socket until its initial stability is achieved.

III. Tighten to a minimum torque of 35Ncm using a torque ratchet.

9. Healing Phase

▪ In partial edentulism, Provo implants with immediate loading should be splinted to each other during the healing phase and kept without any occlusal contact. In cases of total edentulism, at least 6 implants in the maxilla and at least 4 implants in the mandible should be splinted together and kept in a balanced occlusal contact.

10. Compatibility Information

Mode dental implants are compatible with Mode surgical sets.

Do not use implants and components made of different metals and supplied from different manufacturers with Mode dental implant system products.

11. MRI Safety Information

Mode dental implants have been shown to be MRI conditional through testing in non-clinical tests. Patients using this device can be safely screened in an MRI system if the following conditions are met:

• 1.5 T and 3.0 T static magnetic field

• Maximum surface area gradient of 3,000 gauss/cm (30 T/m)

• At maximum MRI system, average specific absorption rate (SAR) of the whole body 2 W/kg (Normal Operating Mode)

Under the scanning conditions described above, Mode dental implants are expected to have a maximum temperature rise of 4°C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical tests, device-induced image artifact expands radially up to 2.7 cm and 2.2 cm from the implant when scanned with a gradient echo pulse array at 3.0 T and 1.5 T, respectively.

12. Cleaning And Sterilization

Mode dental implants are delivered sterile and for single use only. They should not be cleaned or sterilized. Mode Medikal does not accept any responsibility for the processing of devices that are initially delivered as sterile.

Surgical sets and drills are delivered non-sterile. Cleaning and sterilization of these parts are the responsibility of the users.

The protected packaging system protects the sterilized device from external factors and if the device is stored correctly, it maintains its sterility until the expiry date. When removing the device from its packaging, the rules of asepsis should be followed. The sterile package should not be opened until just before the insertion of the

implant. Inspect the devices for damage before opening the sterile packaging. Products with damaged packaging system should not be used. A previously used or non-sterile implant should not be used under any circumstances

13. Storage

The products should be stored at room temperature, in a dry place protected from direct sunlight. The products must be kept in their original packaging. Improper storage conditions may affect the product's characteristics and cause failure.

The expiry date of the product must be checked before using it. In case of damage to the sterile package, the product should not be used.

See labelings for specific storage and handling rules.

14. Disposal

Disposal of the products should be done in accordance with the rules within the framework of legal procedures and environmental requirements. Contaminated products and sharp parts are hazardous and should be disposed of as medical waste in appropriate conditions.

15. Information That Should Be Provided To The Patient

Patients should be informed about the contraindications, warnings, precautions, side effects and complications of Mode dental implants.

Patients should also be informed about MR safety information, and the diameter-height and serial number information of the implants used should be provided to the patient.

16. Disclaimer Of Liability

These products are part of a general concept and should only be used together with the relevant original products, in accordance with Mode Medikal's instructions and recommendations. The use of products that are not distributed by Mode Medikal and made by third parties will void any expressed or implied warranty or other obligations of Mode Medikal.

Mode Medikal products should be used in accordance with the instructions for use provided by the manufacturer. It is the clinician's responsibility to use products in accordance with these instructions and to determine whether the product is appropriate for the individual patient situation. The clinician is also responsible for regularly following the latest updates on the relevant Mode Medikal product and its applications. Mode Medikal is not responsible for any direct, indirect, punitive or other damages arising out of or in connection with any errors in professional judgment or application related to the use of Mode Medikal products; disclaims any liability, express or implied.

17. Additional Information

The shelf life of sterile products is 5 years.

Life Time:
it remains in the patient's mouth for life

The SSCP link of the products is in the link below;

https://modeimplant.com/images/SSCP-Dental-Implant-Systems.pdf

NOTICE REGARDING SERIOUS INCIDENT

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Manufacturer Name: Mode Medikal Sanayi ve Ticaret Limited Şirketi

Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

Mail: info@modeimplant.com

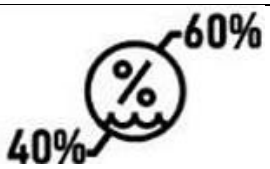
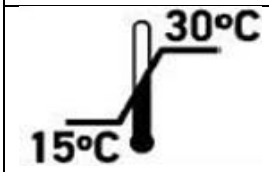
Related Person: Melis AKYÜZ

Mail: melis@modemed.com

Phone: 0553 373 36 42

19. Symbols

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
CE 2696	Notified Body Number		Expiry Date
	Do not subject to a second sterilisation		Date of Production
	Do not use a second time		Do not expose to direct sunlight

	Please refer to the user manual		Do not use if package is damaged
	Reference Number		Keep away from contact with water
	Barcode Number		MR Safe
	Sterilised with radiation		Batch code/Lot number
	Specifies a bearer containing Unique Device Identifier information.		Indicates the humidity range to which the medical device can be safely exposed.
	Indicates the temperature limits to which the medical device can be safely exposed.		Medical device

Symbol	Symbol Description
	Patient name or patient ID
	Date of implantation

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	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer
	Information website for patients
MD	Device name
LOT	Lot Number/Batch Code
UDI	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data capture format (e.g. linear or 2D-Barcodes)*

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/Türkiye

MODE RAPID IMPLANT

1. Product Description

Mode Rapid dental implants are part of Mode Dental Implant Systems, which is an integrated system with related abutments, healing abutments, cover screws, surgical and prosthetic parts and instruments; They are endoosseous screw type implants that have an internal conical octagon connection between the implant and the abutment.

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

Surface roughening of Rapid implants produced from biocompatible Titanium Grade 4 (ASTM F 67) material is done with biphasic calcium phosphate (BCP).

They are packaged together with the cover screw produced using Ti6Al4V-ELI (ASTM F 136) material.

Mode Rapid implants are produced in three different platforms as narrow platform (NP), regular platform (RP) and wide platform (WP).

Diameter and length options of Mode Rapid implants according to their platforms are given in the table below.

Platform	NP	NP	RP	RP	RP	WP
Implant Ø(D)	Ø3.3	Ø3.7	Ø4.1	Ø4.7	Ø5.2	Ø5.3
Length (L)						
8 mm	01.08.08.33	01.08.08.37	01.08.08.41	01.08.08.47	01.08.08.52	01.08.08.53
10 mm	01.08.10.33	01.08.10.37	01.08.10.41	01.08.10.47	01.08.10.52	01.08.10.53
11,5 mm	01.08.115.33	01.08.115.37	01.08.115.41	01.08.115.47	01.08.115.52	01.08.115.53
13 mm	01.08.13.33	01.08.13.37	01.08.13.41	01.08.13.47	01.08.13.52	01.08.13.53
16 mm	01.08.16.33	01.08.16.37	01.08.16.41	01.08.16.47	01.08.16.52	01.08.16.53

2. Intended Use

Mode Rapid implants are intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.

3. Target Patient Group And İntended User

Mode Rapid implants are intended to be used in patients with complete or partial edentulism who have completed their growth and development and do not have the conditions specified in the contraindications.

Mode dental implants are intended to be used by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode dental implants are indicated for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in fully or partially edentulous patients.

There is a wide range of indications, from the rehabilitation of single or multiple tooth deficiencies with fixed prosthetic applications in anterior and/or posterior regions where sufficient bone volume and quality is available, to the treatment of edentulous patients with fixed or removable prosthesis applications supported by implants.

After tooth extraction or loss, they can be applied as single or double-stage surgery with immediate, early or late implantation techniques.

Rapid implants can be loaded immediately by adjusting appropriate occlusal forces in cases where sufficient primary stability is achieved.

In addition to the above indications, with their enlarged thread cross-section and aggressive thread structure, they are indicated for primary stabilization in cancellous bones.

5. Contraindications

The use of Mode Rapid implants are contraindicated in the presence of the following conditions;

- The general systemic condition is not suitable for implant surgery
- Inadequate bone volume and/or quality
- Allergy or hypersensitivity to Titanium Grade 4 (ASTM F 67) and Ti6Al4V-ELI (ASTM F 136) materials
- Incomplete bone growth/development
- Alcohol and/or drug abuse
- Weak immune system
- Diseases requiring regular corticosteroid use
- Uncontrolled endocrine system diseases

6. Warnings / Cautions / Precautions

General

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! It is recommended to review the product-specific surgical technique before the surgeon performs the surgical procedure. MODE MEDİKAL can provide surgical technical information. Please contact MODE MEDİKAL sales representative.

! One hundred percent implant success cannot be guaranteed. Failure to comply with the specified use restrictions and operating steps may result in failure of implant therapy.

! Failure to recognize actual drill lengths based on radiographic measurements may result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for mandibular surgery can potentially cause permanent numbness of the lower lip and chin, or cause hemorrhage in the floor of the mouth.

! In implant operations, as in all surgeries, it is obligatory to comply with the rules of asepsis and antisepsis.

! Damage to nerves and vessels should be avoided by referring to anatomical information and preoperative radiographs in implant operations.

! In patients with atrophic mandible, fractures of the mandible may occur during the operation or during routine functions after the operation.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode dental implant system products cannot be applied to any part of the body other than the lower and upper jawbones.

! Due to the risk of prosthetic overload, it is recommended not to use implants with a diameter of less than 4 mm in the posterior regions.

! Mode dental implant system products should only be used with their system elements in the surgical and prosthetic stages. The use of products with different brands and materials may lead to mechanical problems, implant failure, tissue damage or aesthetic dissatisfaction.

! Check the expiry date of the product before use. Do not use Mode Dental implants after the expiry date on the package.

! Mode dental implants are in sterile packaging. Do not resterilize or process the implants. Cleaning and sterilization can damage material and design features, leading to implant failure.

! Do not reuse Mode dental implants. Reuse of single use products poses a risk of infection for the patient and user.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! Do not use the implant if the implant package is damaged or has been opened previously.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! The type, diameter, length, position and number of implants to be used should be chosen individually, taking into account the condition of the jawbones and anatomical structures.

! It is always recommended to choose the implant with the largest diameter that can be supported by available bone thickness, bone quality, interdental space and expected chewing forces. Where high loads are expected, proper implant alignment should be ensured.

! Placement of implants and design of prostheses should be specific to the patient. In the presence of extreme bruxism and other parafunctional habits and jaw relationship disorders, different treatment options can be planned.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases, bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

During the operation

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! Avoid getting close to the mandibular nerve canal while preparing the implant bed and placing the implant in the lower jaw. Possible nerve damage may result in anesthesia or paresthesia.

! Drills suitable for the size and diameter of the chosen implant should be used.

! Against the risk of contamination, as soon as the implant is taken out of the sterile package, it should be placed in the socket opened with the help of necessary equipment without touching its surface.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

! While inserting the implant, do not exceed the recommended torque values as it may cause bone necrosis.

! Inadequate cooling, incorrect implant bed preparation, use of incorrect instrument settings, and excessive loading torque can result in implant failure.

! After implant placement, the clinician decides whether to use immediate or delayed loading protocols, based on the evaluation of the bone quality and primary stability in the operation.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Do not use damaged or blunted drills for implantation.

! Before use, avoid any contact of the implant with foreign materials. Do not touch the endosteal part of the implant.

! Patients should be advised to avoid activities that require excessive physical effort immediately after implant operations.

Post-operative

! For the long-term success of treatments with the Mode dental implants, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

! Patients should be monitored for peri-implant bone loss and/or changes in percussion responses. If more than 50% mobility or bone loss is observed in the implants, surgical removal of the implants can be considered.

! Patient records should be kept regularly using labels containing the type, diameter, length and lot number of the implant used.

7. Complications And Side Effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after implant treatment.

- Local pain
- Micro hemorrhages
- Swelling
- Bruising
- Local inflammations
- Gingival injuries
- Difficulty biting, chewing and talking
- Systemic or local infections (including Periimplantitis, periodontitis, gingivitis, fistulas)
- Paresthesia
- Chronic pain due to nerve damage
- Damage to the opposing or adjacent teeth
- Bone damage
- Bone resorption

- Sinus perforations
- Mandible fractures
- Trismus
- Hypersensitivity and/or allergic reactions
- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Implant fractures
- Implant failures
- Mandatory removal of implants
- Failures/fractures of prosthetic parts
- Undesirable aesthetic results
- Longer recovery times than expected

8. Surgical Procedure

Preparing the implant bed

I. Determine the implant position with the lance drill.

II. Proceed to the implant length you have determined for the area with 2 mm diameter pilot drills with stoppers.

III. Using the appropriate implant drills, enlarge the implant bed to the diameter you have determined for the area.

Note: Attention should be paid to bone quality during drilling. Bone quality is important for optimal primary stabilization. The drilling protocol of Mode Rapid dental implants according to bone quality is given in the table below.

Platform	Implant Diameter	Soft Bone (D4)	Medium Bone (D2/D3)	Hard Bone (D1)
NP	⌀ **3.3**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 3.3 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.3 Bone Tap
NP	⌀ **3.7**	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill

		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
			⌀ 3.7 Bone Tap	⌀ 3.2 / 3.6
				⌀ 3.7 Bone Tap
RP	**⌀ 4.1**	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
			⌀ 4.1 Bone Tap	⌀ 3.6 / 4.0
				⌀ 4.1 Bone Tap
RP	**⌀ 4.7**	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
			⌀ 4.7 Bone Tap	⌀ 4.0 / 4.5
				⌀ 4.7 Bone Tap
RP	**⌀ 5.2**	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
		⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5

			⌀ 5.2 / 5.3 Bone Tap	⌀ 4.5 / 5.0 ⌀ 5.2 / 5.3 Bone Tap
WP	**⌀ 5.3**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.0 / 4.5	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.0 / 4.5 ⌀ 5.2 / 5.3 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.0 / 4.5 ⌀ 4.5 / 5.0 ⌀ 5.2 / 5.3 Bone Tap

- Drilling operations should be performed at a speed of 400-900 rpm/min by continuous cooling with sterile saline at room temperature in pilot and implant diameter drills.
- Bone taps should be used at low speed (maximum 25 rpm/min).
- For very compact bones, it is recommended to drill with back and forth motions.

Caution: Pilot and implant drills are driven 1 mm deeper than their actual implant length. Take this difference into account in order not to damage vital anatomical structures while preparing the implant bed.

Caution: In flapless surgical techniques, drilling should be done by taking the gingival height into account.

- In cases where the drills cannot reach the desired depth due to neighboring teeth, you can use a drill extender adapter.

Insertion of the implant

I. Open the packaging of the implant and place the sterile inner pack on the surgical area.
II. Mode dental implants are removed from the inner package with the implant carrier. You can use the implant carrier with the help of a hand adapter, a ratchet, a handpiece or a handle.

Note: The implant carrier should be used with a maximum speed of 25 rpm/min when used with a surgical motor.

III. Insert the implant into the implant bed with a maximum torque of 45 Ncm. Exceeding the recommended torque value may cause bone necrosis or damage/fracture of the implant.
IV. Non-compliance with the drill protocol during drilling may cause the implant to be stucked without being fully inserted. In this case, use the implant motor in reverse mode or manually rotate it counterclockwise with the ratchet to remove the implant and return it to the inner package. Re-insert the implant by completing the drill protocol.
Attention: In order to be able to load immediately, at least 35Ncm torque value must be achieved.

Soft tissue management and wound closure

Depending on the selected loading protocol, place a cover screw, healing abutment or an abutment on the implant and perform the wound closure with suture.

9. Healing phase

- The healing phase varies depending on the patient and the treatment. It is the clinician's sole responsibility when to load the implant. It is recommended to perform a radiographic control before loading.
- It is generally recommended to wait between 8 and 12 weeks in the two-stage surgical technique..
- In cases of partial edentulism, implants with immediate loading should be splinted to each other during the healing phase and kept without any occlusal contact. In cases of total edentulism, at least 6 implants in the

maxilla and at least 4 implants in the mandible should be splinted together and kept in a balanced occlusal contact.

10. Compatibility information

Mode dental implants are compatible with Mode surgical sets.

Do not use implants and components made of different metals and supplied from different manufacturers with Mode dental implant system products.

Mode healing abutments and prosthetic parts can only be used with those with the corresponding connection on Mode Rapid implants.

11. MRI safety information

Mode dental implants have been shown to be MRI conditional through testing in non-clinical tests. Patients using this device can be safely screened in an MRI system if the following conditions are met:

• 1.5 T and 3.0 T static magnetic field

• Maximum surface area gradient of 3,000 gauss/cm (30 T/m)

• At maximum MRI system, average specific absorption rate (SAR) of the whole body 2 W/kg (Normal Operating Mode)

Under the scanning conditions described above, Mode dental implants are expected to have a maximum temperature rise of 4°C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical tests, device-induced image artifact expands radially up to 2.7 cm and 2.2 cm from the implant when scanned with a gradient echo pulse array at 3.0 T and 1.5 T, respectively.

12. Cleaning and sterilization

Mode dental implants are delivered sterile and for single use only. They should not be cleaned or sterilized. Mode Medikal does not accept any responsibility for the processing of devices that are initially delivered as sterile.

Surgical sets and drills are delivered non-sterile. Cleaning and sterilization of these parts are the responsibility of the users.

The protected packaging system protects the sterilized device from external factors and if the device is stored correctly, it maintains its sterility until the expiry date. When removing the device from its packaging, the rules of asepsis should be followed. The sterile package should not be opened until just before the insertion of the implant. Inspect the devices for damage before opening the sterile packaging. Products with damaged packaging system should not be used. A previously used or non-sterile implant should not be used under any circumstances.

13. Storage

The products should be stored at room temperature, in a dry place protected from direct sunlight. The products must be kept in their original packaging. Improper storage conditions may affect the product's characteristics and cause failure.The expiry date of the product must be checked before using it. In case of damage to the sterile package, the product should not be used.See labelings for specific storage and handling rules.

14. Disposal

Disposal of the products should be done in accordance with the rules within the framework of legal procedures and environmental requirements. Contaminated products and sharp parts are hazardous and should be disposed of as medical waste in appropriate conditions.

15. Information that should be provided to the patient

Patients should be informed about the contraindications, warnings, precautions, side effects and complications of Mode dental implants.

Patients should also be informed about MR safety information, and the diameter-height and serial number information of the implants used should be provided to the patient.

16. Disclaimer of liability

These products are part of a general concept and should only be used together with the relevant original products, in accordance with Mode Medikal's instructions and recommendations. The use of products that are not distributed by Mode Medikal and made by third parties will void any expressed or implied warranty or other obligations of Mode Medikal.

Mode Medikal products should be used in accordance with the instructions for use provided by the manufacturer. It is the clinician's responsibility to use products in accordance with these instructions and to determine whether the product is appropriate for the individual patient situation. The clinician is also responsible for regularly following the latest updates on the relevant Mode Medikal product and its

applications. Mode Medikal is not responsible for any direct, indirect, punitive or other damages arising out of or in connection with any errors in professional judgment or application related to the use of Mode Medikal products; disclaims any liability, express or implied.

17. Additional Information

The shelf life of sterile products is 5 years.

Life Time:
it remains in the patient's mouth for life

The SSCP link of the products is in the link below;

https://modeimplant.com/images/SSCP-Dental-Implant-Systems.pdf

NOTICE REGARDING SERIOUS INCIDENT

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Manufacturer Name: Mode Medikal Sanayi ve Ticaret Limited Şirketi

Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

Mail: info@modeimplant.com

Related Person: Melis AKYÜZ

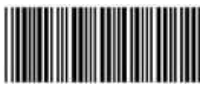
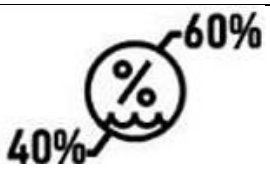
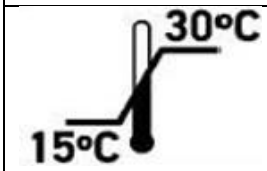
Mail: melis@modemed.com

Phone: 0553 373 36 42

19. Symbols

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
CE 2696	Notified Body Number		Expiry Date

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

	Do not subject to a second sterilisation		Date of Production
	Do not use a second time		Do not expose to direct sunlight
	Please refer to the user manual		Do not use if package is damaged
	Reference Number		Keep away from contact with water
	Barcode Number		MR Safe
	Sterilised with radiation		Batch code/Lot number
	Specifies a bearer containing Unique Device Identifier information.		Indicates the humidity range to which the medical device can be safely exposed.
	Indicates the temperature limits to which the medical device can be safely exposed.		Medical device

Symbol	Symbol Description

Hazırlayan/ Prepared By	Onaylayan/ Approverd By
Gonca Bakırcı	Saniye Özgür

	Patient name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer
	Information website for patients
	Device name
	Lot Number/Batch Code
	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data capture format (e.g. linear or 2D-Barcodes)*

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/Türkiye

Mode Short Implant

1. Product Description

Mode Short dental implants are part of Mode Dental Implant Systems, which is an integrated system with related abutments, healing abutments, cover screws, surgical and prosthetic parts and instruments; They are endoosseous screw type implants that have an internal conical octagon connection between the implant and the abutment.

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

Surface roughening of Short implants produced from biocompatible Titanium Grade 4 (ASTM F 67) material is done with biphasic calcium phosphate (BCP).

They are packaged together with the cover screw produced using Ti6Al4V-ELI (ASTM F 136) material.

Mode Short implants are produced in three different platforms as narrow platform (NP), regular platform (RP) and wide platform (WP).

Diameter and length options of Mode Short implants according to their platforms are given in the table below.

Platform	NP	RP	RP	RP	WP	WP
Implant Ø(D)	Ø3.7	Ø4.1	Ø4.7	Ø5.2	Ø5.3	Ø6
Length (L)						
6 mm	01.04.06.37	01.04.06.41	01.04.06.47	01.04.06.52	01.04.06.53	01.04.06.06

2. Intended Use

Mode Short implants are intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.

3. Target Patient Group And İntended User

Mode Short implants are intended to be used in patients with complete or partial edentulism who have completed their growth and development and do not have the conditions specified in the contraindications.

Mode Short implants can only be used in atrophic jaws with inadequate bone height.

Mode dental implants are intended to be used by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode dental implants are indicated for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in fully or partially edentulous patients.

There is a wide range of indications, from the rehabilitation of single or multiple tooth deficiencies with fixed prosthetic applications in anterior and/or posterior regions where sufficient bone volume and quality is available, to the treatment of edentulous patients with fixed or removable prosthesis applications supported by implants.

After tooth extraction or loss, they can be applied as single or double-stage surgery with immediate, early or late implantation techniques.

Mode Short implants are indicated for use in severely atrophic jaws where anatomical structures do not allow the placement of standard length implants due to insufficient bone height. It is indicated in cases where augmentations to increase the amount of vertical bone cannot be performed.

5. Contraindications

The use of Mode Short implants are contraindicated in the presence of the following conditions;

- The general systemic condition is not suitable for implant surgery
- Inadequate bone volume and/or quality
- Allergy or hypersensitivity to Titanium Grade 4 (ASTM F 67) and Ti6Al4V-ELI (ASTM F 136) materials
- Incomplete bone growth/development
- Alcohol and/or drug abuse
- Weak immune system
- Diseases requiring regular corticosteroid use
- Uncontrolled endocrine system diseases

6. Warnings / Cautions / Precautions

General

! Mode Short implants should not be loaded immediately. The largest possible diameter should be used for these implants by applying a two-stage surgical technique.

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! It is recommended to review the product-specific surgical technique before the surgeon performs the surgical procedure. MODE MEDİKAL can provide surgical technical information. Please contact MODE MEDİKAL sales representative.

! One hundred percent implant success cannot be guaranteed. Failure to comply with the specified use restrictions and operating steps may result in failure of implant therapy.

! Failure to recognize actual drill lengths based on radiographic measurements may result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for mandibular surgery can potentially cause permanent numbness of the lower lip and chin, or cause hemorrhage in the floor of the mouth.

! In implant operations, as in all surgeries, it is obligatory to comply with the rules of asepsis and antisepsis.

! Damage to nerves and vessels should be avoided by referring to anatomical information and preoperative radiographs in implant operations.

! In patients with atrophic mandible, fractures of the mandible may occur during the operation or during routine functions after the operation.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode dental implant system products cannot be applied to any part of the body other than the lower and upper jawbones.

! Due to the risk of prosthetic overload, it is recommended not to use implants with a diameter of less than 4 mm in the posterior regions.

! Mode dental implant system products should only be used with their system elements in the surgical and prosthetic stages. The use of products with different brands and materials may lead to mechanical problems, implant failure, tissue damage or aesthetic dissatisfaction.

! Check the expiry date of the product before use. Do not use Mode Dental implants after the expiry date on the package.

! Mode dental implants are in sterile packaging. Do not resterilize or process the implants. Cleaning and sterilization can damage material and design features, leading to implant failure.

! Do not reuse Mode dental implants. Reuse of single use products poses a risk of infection for the patient and user.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! Do not use the implant if the implant package is damaged or has been opened previously.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! The type, diameter, length, position and number of implants to be used should be chosen individually, taking into account the condition of the jawbones and anatomical structures.

! It is always recommended to choose the implant with the largest diameter that can be supported by available bone thickness, bone quality, interdental space and expected chewing forces. Where high loads are expected, proper implant alignment should be ensured.

! Placement of implants and design of prostheses should be specific to the patient. In the presence of extreme bruxism and other parafunctional habits and jaw relationship disorders, different treatment options can be planned.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases, bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

During the operation

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! Avoid getting close to the mandibular nerve canal while preparing the implant bed and placing the implant in the lower jaw. Possible nerve damage may result in anesthesia or paresthesia.

! Drills suitable for the size and diameter of the chosen implant should be used.

! Against the risk of contamination, as soon as the implant is taken out of the sterile package, it should be placed in the socket opened with the help of necessary equipment without touching its surface.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

! While inserting the implant, do not exceed the recommended torque values as it may cause bone necrosis.

! Inadequate cooling, incorrect implant bed preparation, use of incorrect instrument settings, and excessive loading torque can result in implant failure.

! After implant placement, the clinician decides whether to use immediate or delayed loading protocols, based on the evaluation of the bone quality and primary stability in the operation.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Do not use damaged or blunted drills for implantation.

! Before use, avoid any contact of the implant with foreign materials. Do not touch the endosteal part of the implant.

! Patients should be advised to avoid activities that require excessive physical effort immediately after implant operations.

Post-operative

! For the long-term success of treatments with the Mode dental implants, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

! Patients should be monitored for peri-implant bone loss and/or changes in percussion responses. If more than 50% mobility or bone loss is observed in the implants, surgical removal of the implants can be considered.

! Patient records should be kept regularly using labels containing the type, diameter, length and lot number of the implant used.

7. Complications and side effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after implant treatment.

- Local pain
- Micro hemorrhages
- Swelling
- Bruising
- Local inflammations
- Gingival injuries
- Difficulty biting, chewing and talking
- Systemic or local infections (including Periimplantitis, periodontitis, gingivitis, fistulas)
- Paresthesia
- Chronic pain due to nerve damage
- Damage to the opposing or adjacent teeth
- Bone damage
- Bone resorption

- Sinus perforations
- Mandible fractures
- Trismus
- Hypersensitivity and/or allergic reactions
- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Implant fractures
- Implant failures
- Mandatory removal of implants
- Failures/fractures of prosthetic parts
- Undesirable aesthetic results
- Longer recovery times than expected

8. Surgical procedure

Preparing the implant bed

I. Determine the implant position with the lance drill.

II. Proceed to the implant length you have determined for the area with 2 mm diameter pilot drills with stoppers.

III. Using the appropriate implant drills, enlarge the implant bed to the diameter you have determined for the area.

Note: Attention should be paid to bone quality during drilling. Bone quality is important for optimal primary stabilization. The drilling protocol of Mode Short dental implants according to bone quality is given in the table below.

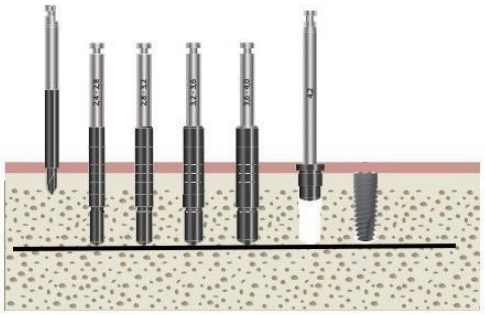
Platform	Implant Diameter	Soft Bone (D4)	Medium Bone (D2/D3)	Hard Bone (D1)
NP	⌀ **3.7**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.7 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.7 Bone Tap

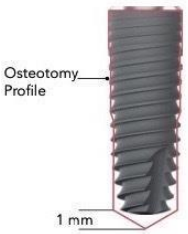
RP	**⌀ 4.1**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 4.1 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.1 Bone Tap
RP	**⌀ 4.7**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.7 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.0 / 4.5 ⌀ 4.7 Bone Tap
RP	**⌀ 5.2**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.0 / 4.5	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.0 / 4.5 ⌀ 5.2 / 5.3 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.0 / 4.5 ⌀ 4.5 / 5.0 ⌀ 5.2 / 5.3 Bone Tap
WP	**⌀ 5.3**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8

		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
		⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5
			⌀ 5.2 / 5.3 Bone Tap	⌀ 4.5 / 5.0
				⌀ 5.2 / 5.3 Bone Tap
		⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
WP	**⌀ 6.0**	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
		⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5
		⌀ 4.5 / 5.0	⌀ 4.5 / 5.0	⌀ 4.5 / 5.0
			⌀ 5.2 / 5.3 Bone Tap	⌀ 5.0 / 5.8
				⌀ 5.2 / 5.3 Bone Tap

- Drilling operations should be performed at a speed of 400-900 rpm/min by continuous cooling with sterile saline at room temperature in pilot and implant diameter drills.
- Bone taps should be used at low speed (maximum 25 rpm/min).
- For very compact bones, it is recommended to drill with back and forth motions.

Caution: Pilot and implant drills are driven 1 mm deeper than their actual implant length. Take this difference into account in order not to damage vital anatomical structures while preparing the implant bed.



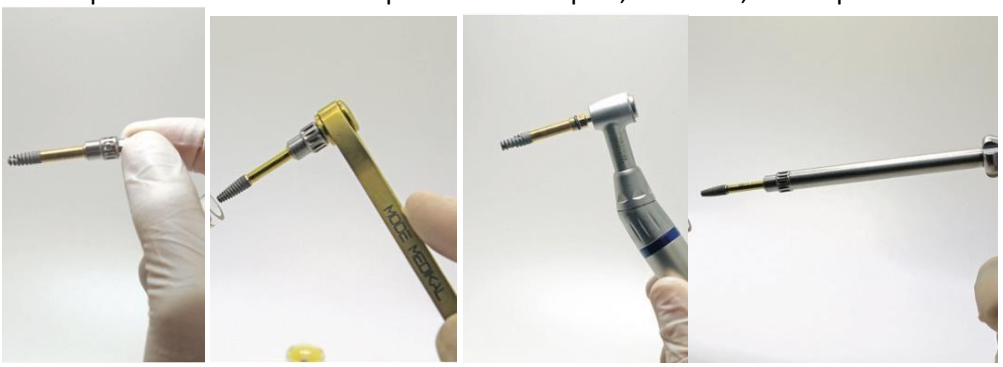


Caution: In flapless surgical techniques, drilling should be done by taking the gingival height into account.

- In cases where the drills cannot reach the desired depth due to neighboring teeth, you can use a drill extender adapter.

Insertion of the implant

I. Open the packaging of the implant and place the sterile inner pack on the surgical area.
II. Mode dental implants are removed from the inner package with the implant carrier. You can use the implant carrier with the help of a hand adapter, a ratchet, a handpiece or a handle.



Note: The implant carrier should be used with a maximum speed of 25 rpm/min when used with a surgical motor.

III. Insert the implant into the implant bed with a maximum torque of 45 Ncm. Exceeding the recommended torque value may cause bone necrosis or damage/fracture of the implant.
IV. Non-compliance with the drill protocol during drilling may cause the implant to be stucked without being fully inserted. In this case, use the implant motor in reverse mode or manually rotate it counterclockwise with the ratchet to remove the implant and return it to the inner package. Re-insert the implant by completing the drill protocol.

Soft tissue management and wound closure

Perform wound closure by suturing by placing the cover screw on the implant.

9. Healing phase

- The healing phase varies depending on the patient and the treatment. It is the clinician's sole responsibility when to load the implant. It is recommended to perform a radiographic control before loading.
- For Mode Short implants, it is recommended to wait for at least 12-16 weeks before loading.

10. Compatibility information

Mode dental implants are compatible with Mode surgical sets.

Do not use implants and components made of different metals and supplied from different manufacturers with Mode dental implant system products.

Mode healing abutments and prosthetic parts can only be used with those with the corresponding connection on Mode Short implants.

11. MRI Safety İnformation

Mode dental implants have been shown to be MRI conditional through testing in non-clinical tests. Patients using this device can be safely screened in an MRI system if the following conditions are met:

• 1.5 T and 3.0 T static magnetic field

• Maximum surface area gradient of 3,000 gauss/cm (30 T/m)

• At maximum MRI system, average specific absorption rate (SAR) of the whole body 2 W/kg (Normal Operating Mode)

Under the scanning conditions described above, Mode dental implants are expected to have a maximum temperature rise of 4°C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical tests, device-induced image artifact expands radially up to 2.7 cm and 2.2 cm from the implant when scanned with a gradient echo pulse array at 3.0 T and 1.5 T, respectively

12. Cleaning and sterilization

Mode dental implants are delivered sterile and for single use only. They should not be cleaned or sterilized. Mode Medikal does not accept any responsibility for the processing of devices that are initially delivered as sterile.

Surgical sets and drills are delivered non-sterile. Cleaning and sterilization of these parts are the responsibility of the users.

The protected packaging system protects the sterilized device from external factors and if the device is stored correctly, it maintains its sterility until the expiry date. When removing the device from its packaging, the rules of asepsis should be followed. The sterile package should not be opened until just before the insertion of the implant. Inspect the devices for damage before opening the sterile packaging. Products with damaged packaging system should not be used. A previously used or non-sterile implant should not be used under any circumstances.

13. Storage

The products should be stored at room temperature, in a dry place protected from direct sunlight. The products must be kept in their original packaging. Improper storage conditions may affect the product's characteristics and cause failure.

The expiry date of the product must be checked before using it. In case of damage to the sterile package, the product should not be used.

See labelings for specific storage and handling rules.

14. Disposal

Disposal of the products should be done in accordance with the rules within the framework of legal procedures and environmental requirements. Contaminated products and sharp parts are hazardous and should be disposed of as medical waste in appropriate conditions.

15. Information that should be provided to the patient

Patients should be informed about the contraindications, warnings, precautions, side effects and complications of Mode dental implants.

Patients should also be informed about MR safety information, and the diameter-height and serial number information of the implants used should be provided to the patient.

16. Disclaimer of liability

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NOTICE REGARDING SERIOUS INCIDENT

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Manufacturer Name: Mode Medikal Sanayi ve Ticaret Limited Şirketi

Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

Mail: info@modeimplant.com

Related Person: Melis AKYÜZ

Mail: melis@modemed.com

Phone: 0553 373 36 42

18. Symbols

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
CE 2696	Notified Body Number		Expiry Date
	Do not subject to a second sterilisation		Date of Production
	Do not use a second time		Do not expose to direct sunlight
	Please refer to the user manual		Do not use if package is damaged
REF	Reference Number		Keep away from contact with water
	Barcode Number	MR	MR Safe
STERILE R	Sterilised with radiation	LOT	Batch code/Lot number
UDI	Specifies a bearer containing Unique Device Identifier information.	60% 40%	Indicates the humidity range to which the medical device can be safely exposed.
30°C 15°C	Indicates the temperature limits to which the medical device can be safely exposed.	MD	Medical device

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

Symbol	Symbol Description
	Patient name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer
	Information website for patients
	Device name
	Lot Number/Batch Code
	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data capture format (e.g. linear or 2D-Barcodes)*

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/Türkiye

Mode Shorter Implant

1. Product description

Mode Shorter dental implants are part of Mode Dental Implant Systems, which is an integrated system with related abutments, healing caps, cover screws, surgical and prosthetic parts and instruments; They are endoosseous screw type implants that have an internal conical octagon connection between the implant and the abutment.

Surface roughening of Shorter implants produced from biocompatible Titanium Grade 4 (ASTM F 67) material is done with biphasic calcium phosphate (BCP).

They are packaged together with the cover screw produced using Ti6Al4V-ELI (ASTM F 136) material.

Mode Shorter implants are produced in three different platforms as narrow platform (NP), regular platform (RP) and wide platform (WP).

Diameter and length options of Mode Shorter implants according to their platforms are given in the table below.

Platform	NP	RP	RP	RP	WP	WP
Implant Ø(D)	Ø3.7	Ø4.1	Ø4.7	Ø5.2	Ø5.3	Ø6
Length (L)						
5 mm	01.04.05.37	01.04.05.41	01.04.05.47	01.04.05.52	01.04.05.53	01.04.05.06

2. Intended use

Mode Shorter implants are intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.

3. Target patient group and intended user

Mode Shorter implants are intended to be used in patients with complete or partial edentulism who have completed their growth and development and do not have the conditions specified in the contraindications.

Mode Shorter implants can only be used in atrophic jaws with inadequate bone height.

Mode dental implants are intended to be used by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode dental implants are indicated for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in fully or partially edentulous patients.

There is a wide range of indications, from the rehabilitation of single or multiple tooth deficiencies with fixed prosthetic applications in anterior and/or posterior regions where sufficient bone volume and quality is available, to the treatment of edentulous patients with fixed or removable prosthesis applications supported by implants.

After tooth extraction or loss, they can be applied as single or double-stage surgery with immediate, early or late implantation techniques.

Mode Shorter implants are indicated for use in severely atrophic jaws where anatomical structures do not allow the placement of standard length implants due to insufficient bone height. It is indicated in cases where augmentations to increase the amount of vertical bone cannot be performed.

They are also indicated in terms of achieving primary stabilization with aggressive thread structure in atrophic bones with cancellous structure.

5. Contraindications

The use of Mode Shorter implants are contraindicated in the presence of the following conditions;

- The general systemic condition is not suitable for implant surgery
- Inadequate bone volume and/or quality
- Allergy or hypersensitivity to Titanium Grade 4 (ASTM F 67) and Ti6Al4V-ELI (ASTM F 136) materials
- Incomplete bone growth/development
- Alcohol and/or drug abuse
- Weak immune system
- Diseases requiring regular corticosteroid use
- Uncontrolled endocrine system diseases

6. Warnings / Cautions / Precautions

General

! Mode Shorter implants should not be loaded immediately. The largest possible diameter should be used for these implants by applying a two-stage surgical technique.

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! It is recommended to review the product-specific surgical technique before the surgeon performs the surgical procedure. MODE MEDİKAL can provide surgical technical information. Please contact MODE MEDİKAL sales representative.

! One hundred percent implant success cannot be guaranteed. Failure to comply with the specified use restrictions and operating steps may result in failure of implant therapy.

! Failure to recognize actual drill lengths based on radiographic measurements may result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for mandibular surgery can potentially cause permanent numbness of the lower lip and chin, or cause hemorrhage in the floor of the mouth.

! In implant operations, as in all surgeries, it is obligatory to comply with the rules of asepsis and antisepsis.

! Damage to nerves and vessels should be avoided by referring to anatomical information and preoperative radiographs in implant operations.

! In patients with atrophic mandible, fractures of the mandible may occur during the operation or during routine functions after the operation.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode dental implant system products cannot be applied to any part of the body other than the lower and upper jawbones.

! Due to the risk of prosthetic overload, it is recommended not to use implants with a diameter of less than 4 mm in the posterior regions.

! Mode dental implant system products should only be used with their system elements in the surgical and prosthetic stages. The use of products with different brands and materials may lead to mechanical problems, implant failure, tissue damage or aesthetic dissatisfaction.

! Check the expiry date of the product before use. Do not use Mode Dental implants after the expiry date on the package.

! Mode dental implants are in sterile packaging. Do not resterilize or process the implants. Cleaning and sterilization can damage material and design features, leading to implant failure.

! Do not reuse Mode dental implants. Reuse of single use products poses a risk of infection for the patient and user.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! Do not use the implant if the implant package is damaged or has been opened previously.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! The type, diameter, length, position and number of implants to be used should be chosen individually, taking into account the condition of the jawbones and anatomical structures.

! It is always recommended to choose the implant with the largest diameter that can be supported by available bone thickness, bone quality, interdental space and expected chewing forces. Where high loads are expected, proper implant alignment should be ensured.

! Placement of implants and design of prostheses should be specific to the patient. In the presence of extreme bruxism and other parafunctional habits and jaw relationship disorders, different treatment options can be planned.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases, bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

During the operation

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! Avoid getting close to the mandibular nerve canal while preparing the implant bed and placing the implant in the lower jaw. Possible nerve damage may result in anesthesia or paresthesia.

! Drills suitable for the size and diameter of the chosen implant should be used.

! Against the risk of contamination, as soon as the implant is taken out of the sterile package, it should be placed in the socket opened with the help of necessary equipment without touching its surface.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

! While inserting the implant, do not exceed the recommended torque values as it may cause bone necrosis.

! Inadequate cooling, incorrect implant bed preparation, use of incorrect instrument settings, and excessive loading torque can result in implant failure.

! After implant placement, the clinician decides whether to use immediate or delayed loading protocols, based on the evaluation of the bone quality and primary stability in the operation.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Do not use damaged or blunted drills for implantation.

! Before use, avoid any contact of the implant with foreign materials. Do not touch the endosteal part of the implant.

! Patients should be advised to avoid activities that require excessive physical effort immediately after implant operations.

Post-operative

! For the long-term success of treatments with the Mode dental implants, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

! Patients should be monitored for peri-implant bone loss and/or changes in percussion responses. If more than 50% mobility or bone loss is observed in the implants, surgical removal of the implants can be considered.

! Patient records should be kept regularly using labels containing the type, diameter, length and lot number of the implant used.

7. Complications and side effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after implant treatment.

- Local pain
- Micro hemorrhages
- Swelling
- Bruising
- Local inflammations
- Gingival injuries
- Difficulty biting, chewing and talking
- Systemic or local infections (including Periimplantitis, periodontitis, gingivitis, fistulas)
- Paresthesia
- Chronic pain due to nerve damage
- Damage to the opposing or adjacent teeth
- Bone damage
- Bone resorption
- Sinus perforations
- Mandible fractures
- Trismus
- Hypersensitivity and/or allergic reactions
- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Implant fractures
- Implant losses
- Mandatory removal of implants
- Loss of prosthetic parts
- Undesirable aesthetic results
- Longer recovery times than expected

8. Surgical procedure

Preparing the implant bed

I. Determine the implant position with the lance drill.

II. Proceed to the implant length you have determined for the area with 2 mm diameter pilot drills with stoppers.

III. Using the appropriate implant drills, enlarge the implant bed to the diameter you have determined for the area.

Note: Attention should be paid to bone quality during drilling. Bone quality is important for optimal primary stabilization. The drilling protocol of Mode Shorter dental implants according to bone quality is given in the table below.

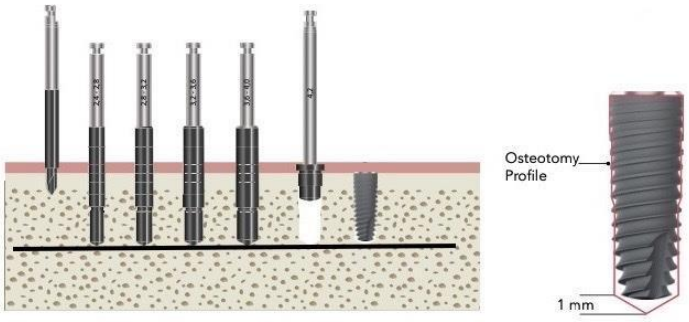
Platform	Implant Diameter	Soft Bone (D4)	Medium Bone (D2/D3)	Hard Bone (D1)
NP	⌀ **3.7**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.7 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.7 Bone Tap
RP	⌀ **4.1**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 4.1 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.1 Bone Tap
RP	⌀ **4.7**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.7 Bone Tap	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2 ⌀ 3.2 / 3.6 ⌀ 3.6 / 4.0 ⌀ 4.0 / 4.5 ⌀ 4.7 Bone Tap
RP	⌀ **5.2**	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill

		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
		⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5
			⌀ 5.2 / 5.3 Bone Tap	⌀ 4.5 / 5.0
				⌀ 5.2 / 5.3 Bone Tap
		⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
WP	**⌀ 5.3**	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
		⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5
			⌀ 5.2 / 5.3 Bone Tap	⌀ 4.5 / 5.0
				⌀ 5.2 / 5.3 Bone Tap
		⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
WP	**⌀ 6.0**	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
		⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5
		⌀ 4.5 / 5.0	⌀ 4.5 / 5.0	⌀ 4.5 / 5.0
			⌀ 5.2 / 5.3 Bone Tap	⌀ 5.0 / 5.8

⌀ 5.2 / 5.3 Bone Tap

- Drilling operations should be performed at a speed of 400-900 rpm/min by continuous cooling with sterile saline at room temperature in pilot and implant diameter drills.
- Bone taps should be used at low speed (maximum 25 rpm/min).
- For very compact bones, it is recommended to drill with back and forth motions.

Caution: Pilot and implant drills are driven 1 mm deeper than their actual implant length. Take this difference into account in order not to damage vital anatomical structures while preparing the implant bed.



Caution: In flapless surgical techniques, drilling should be done by taking the gingival height into account.

- In cases where the drills cannot reach the desired depth due to neighboring teeth, you can use a drill extender adapter.

Insertion of the implant

I. Open the packaging of the implant and place the sterile inner pack on the surgical area.
II. Mode dental implants are removed from the inner package with the implant carrier. You can use the implant carrier with the help of a hand adapter, a ratchet, a handpiece or a handle.

Note: The implant carrier should be used with a maximum speed of 25 rpm/min when used with a surgical motor.

III. Insert the implant into the implant bed with a maximum torque of 45 Ncm. Exceeding the recommended torque value may cause bone necrosis or damage/fracture of the implant.
IV. Non-compliance with the drill protocol during drilling may cause the implant to be stucked without being fully inserted. In this case, use the implant motor in reverse mode or manually rotate it counterclockwise with the ratchet to remove the implant and return it to the inner package. Re-insert the implant by completing the drill protocol.

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Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

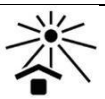
Mail: info@modeimplant.com

Related Person: Melis AKYÜZ

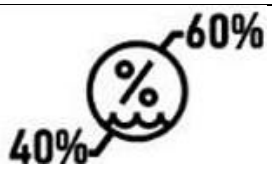
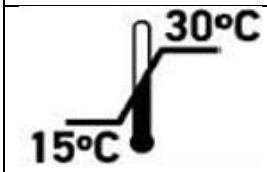
Mail: melis@modemed.com

Phone: 0553 373 36 42

18. Symbols

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
CE 2696	Notified Body Number		Expiry Date
	Do not subject to a second sterilisation		Date of Production
	Do not use a second time		Do not expose to direct sunlight
	Please refer to the user manual		Do not use if package is damaged

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

REF	Reference Number		Keep away from contact with water
	Barcode Number		MR Safe
STERILE R	Sterilised with radiation	LOT	Batch code/Lot number
UDI	Specifies a bearer containing Unique Device Identifier information.		Indicates the humidity range to which the medical device can be safely exposed.
	Indicates the temperature limits to which the medical device can be safely exposed.	MD	Medical device

Symbol	Symbol Description
	Patient name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider

Hazırlayan/ Prepared By	Onaylayan/ Approverd By
Gonca Bakırcı	Saniye Özgür

	Name and Address of the manufacturer
	Information website for patients
MD	Device name
LOT	Lot Number/Batch Code
UDI	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data capture format (e.g. linear or 2D-Barcodes)*

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/Türkiye

MODE TISSUE IMPLANT

1. Product Description

Mode Tissue dental implants are part of Mode Dental Implant Systems, which is an integrated system with related abutments, healing abutments, cover screws, surgical and prosthetic parts and instruments; They are endoosseous screw type implants that have an internal conical octagon connection between the implant and the abutment.

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

Surface roughening of Tissue implants produced from biocompatible Titanium Grade 4 (ASTM F 67) material is done with biphasic calcium phosphate (BCP).

They are packaged together with the cover screw produced using Ti6Al4V-ELI (ASTM F 136) material.

Mode Tissue implants are produced in two different platforms as regular platform (RP) and wide platform (WP).

Diameter and length options of Mode Tissue implants according to their platforms are given in the table below.

Platform	RP	RP	RP	WP	WP
Implant Ø(D)	Ø4.1	Ø4.7	Ø5.2	Ø5.3	Ø6
Length (L)					
8 mm	01.04.08.41	01.04.08.47	01.04.08.52	01.04.08.53	01.04.08.06
10 mm	01.04.10.41	01.04.10.47	01.04.10.52	01.04.10.53	01.04.10.06
11,5 mm	01.04.115.41	01.04.115.47	01.04.115.52	01.04.115.53	01.04.115.06
13 mm	01.04.13.41	01.04.13.47	01.04.13.52	01.04.13.53	01.04.13.06
16 mm	01.04.16.41	01.04.16.47	01.04.16.52	01.04.16.53	01.04.16.06

2. Intended use

Mode Tissue implants are intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.

3. Target patient group and intended user

Mode Tissue implants are intended to be used in patients with complete or partial edentulism who have completed their growth and development and do not have the conditions specified in the contraindications.

Mode dental implants are intended to be used by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode dental implants are indicated for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in fully or partially edentulous patients.

There is a wide range of indications, from the rehabilitation of single or multiple tooth deficiencies with fixed prosthetic applications in anterior and/or posterior regions where sufficient bone volume and quality is available, to the treatment of edentulous patients with fixed or removable prosthesis applications supported by implants.

After tooth extraction or loss, they can be applied as single or double-stage surgery with immediate, early or late implantation techniques.

Tissue implants can be loaded immediately by adjusting appropriate occlusal forces in cases where sufficient primary stability is achieved.

Implants are indicated in cases where the gingival level in the implant area is high in order to move the implant-abutment connection coronally.

5. Contraindications

The use of Mode Tissue implants are contraindicated in the presence of the following conditions;

- The general systemic condition is not suitable for implant surgery
- Inadequate bone volume and/or quality
- Allergy or hypersensitivity to Titanium Grade 4 (ASTM F 67) and Ti6Al4V-ELI (ASTM F 136) materials
- Incomplete bone growth/development
- Alcohol and/or drug abuse
- Weak immune system
- Diseases requiring regular corticosteroid use
- Uncontrolled endocrine system diseases

6. Warnings / Cautions / Precautions

General

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! It is recommended to review the product-specific surgical technique before the surgeon performs the surgical procedure. MODE MEDİKAL can provide surgical technical information. Please contact MODE MEDİKAL sales representative.

! One hundred percent implant success cannot be guaranteed. Failure to comply with the specified use restrictions and operating steps may result in failure of implant therapy.

! Failure to recognize actual drill lengths based on radiographic measurements may result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for mandibular surgery can potentially cause permanent numbness of the lower lip and chin, or cause hemorrhage in the floor of the mouth.

! In implant operations, as in all surgeries, it is obligatory to comply with the rules of asepsis and antisepsis.

! Damage to nerves and vessels should be avoided by referring to anatomical information and preoperative radiographs in implant operations.

! In patients with atrophic mandible, fractures of the mandible may occur during the operation or during routine functions after the operation.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode dental implant system products cannot be applied to any part of the body other than the lower and upper jawbones.

! Due to the risk of prosthetic overload, it is recommended not to use implants with a diameter of less than 4 mm in the posterior regions.

! Mode dental implant system products should only be used with their system elements in the surgical and prosthetic stages. The use of products with different brands and materials may lead to mechanical problems, implant failure, tissue damage or aesthetic dissatisfaction.

! Check the expiry date of the product before use. Do not use Mode Dental implants after the expiry date on the package.

! Mode dental implants are in sterile packaging. Do not resterilize or process the implants. Cleaning and sterilization can damage material and design features, leading to implant failure.

! Do not reuse Mode dental implants. Reuse of single use products poses a risk of infection for the patient and user.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! Do not use the implant if the implant package is damaged or has been opened previously.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! The type, diameter, length, position and number of implants to be used should be chosen individually, taking into account the condition of the jawbones and anatomical structures.

! It is always recommended to choose the implant with the largest diameter that can be supported by available bone thickness, bone quality, interdental space and expected chewing forces. Where high loads are expected, proper implant alignment should be ensured.

! Placement of implants and design of prostheses should be specific to the patient. In the presence of extreme bruxism and other parafunctional habits and jaw relationship disorders, different treatment options can be planned.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases, bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

During the operation

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! Avoid getting close to the mandibular nerve canal while preparing the implant bed and placing the implant in the lower jaw. Possible nerve damage may result in anesthesia or paresthesia.

! Drills suitable for the size and diameter of the chosen implant should be used.

! Against the risk of contamination, as soon as the implant is taken out of the sterile package, it should be placed in the socket opened with the help of necessary equipment without touching its surface.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

! While inserting the implant, do not exceed the recommended torque values as it may cause bone necrosis.

! Inadequate cooling, incorrect implant bed preparation, use of incorrect instrument settings, and excessive loading torque can result in implant failure.

! After implant placement, the clinician decides whether to use immediate or delayed loading protocols, based on the evaluation of the bone quality and primary stability in the operation.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Do not use damaged or blunted drills for implantation.

! Before use, avoid any contact of the implant with foreign materials. Do not touch the endosteal part of the implant.

! Patients should be advised to avoid activities that require excessive physical effort immediately after implant operations.

Post-operative

! For the long-term success of treatments with the Mode dental implants, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

! Patients should be monitored for peri-implant bone loss and/or changes in percussion responses. If more than 50% mobility or bone loss is observed in the implants, surgical removal of the implants can be considered.

! Patient records should be kept regularly using labels containing the type, diameter, length and lot number of the implant used.

7. Complications and side effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after implant treatment.

- Local pain
- Micro hemorrhages
- Swelling
- Bruising
- Local inflammations
- Gingival injuries
- Difficulty biting, chewing and talking
- Systemic or local infections (including Periimplantitis, periodontitis, gingivitis, fistulas)
- Paresthesia
- Chronic pain due to nerve damage
- Damage to the opposing or adjacent teeth
- Bone damage
- Bone resorption

- Sinus perforations
- Mandible fractures
- Trismus
- Hypersensitivity and/or allergic reactions
- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Implant fractures
- Implant failures
- Mandatory removal of implants
- Failures/fractures of prosthetic parts
- Undesirable aesthetic results
- Longer recovery times than expected

8. Surgical procedure

Preparing the implant bed

I. Determine the implant position with the lance drill.

II. Proceed to the implant length you have determined for the area with 2 mm diameter pilot drills with stoppers.

III. Using the appropriate implant drills, enlarge the implant bed to the diameter you have determined for the area.

Note: Attention should be paid to bone quality during drilling. Bone quality is important for optimal primary stabilization. The drilling protocol of Mode Tissue dental implants according to bone quality is given in the table below.

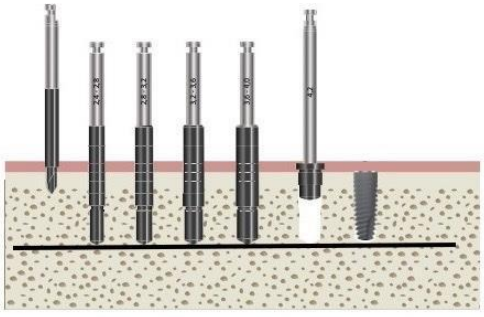
Platform	Implant Diameter	Soft Bone (D4)	Medium Bone (D2/D3)	Hard Bone (D1)
RP	⌀ **4.1**	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2	⌀ 2.0 Pilot Drill ⌀ 2.4 / 2.8 ⌀ 2.8 / 3.2

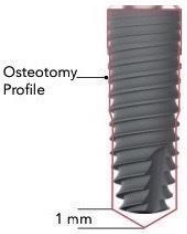
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
			⌀ 4.1 Bone Tap	⌀ 3.6 / 4.0
				⌀ 4.1 Bone Tap
		⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
	⌀ **4.7**	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
RP		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
			⌀ 4.7 Bone Tap	⌀ 4.0 / 4.5
				⌀ 4.7 Bone Tap
		⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
		⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
WP	⌀ **5.3**	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0
		⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5
			⌀ 5.2 / 5.3 Bone Tap	⌀ 4.5 / 5.0
				⌀ 5.2 / 5.3 Bone Tap
		⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill	⌀ 2.0 Pilot Drill
		⌀ 2.4 / 2.8	⌀ 2.4 / 2.8	⌀ 2.4 / 2.8
WP	⌀ **6.0**	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2	⌀ 2.8 / 3.2
		⌀ 3.2 / 3.6	⌀ 3.2 / 3.6	⌀ 3.2 / 3.6
		⌀ 3.6 / 4.0	⌀ 3.6 / 4.0	⌀ 3.6 / 4.0

⌀ 4.0 / 4.5	⌀ 4.0 / 4.5	⌀ 4.0 / 4.5
⌀ 4.5 / 5.0	⌀ 4.5 / 5.0	⌀ 4.5 / 5.0
	⌀ 5.2 / 5.3 Bone Tap	⌀ 5.0 / 5.8
		⌀ 5.2 / 5.3 Bone Tap

- Drilling operations should be performed at a speed of 400-900 rpm/min by continuous cooling with sterile saline at room temperature in pilot and implant diameter drills.
- Bone taps should be used at low speed (maximum 25 rpm/min).
- For very compact bones, it is recommended to drill with back and forth motions.

Caution: Pilot and implant drills are driven 1 mm deeper than their actual implant length. Take this difference into account in order not to damage vital anatomical structures while preparing the implant bed.





Caution: In flapless surgical techniques, drilling should be done by taking the gingival height into account.

- In cases where the drills cannot reach the desired depth due to neighboring teeth, you can use a drill extender adapter.

Insertion of the implant

I. Open the packaging of the implant and place the sterile inner pack on the surgical area.
II. Mode dental implants are removed from the inner package with the implant carrier. You can use the implant carrier with the help of a hand adapter, a ratchet, a handpiece or a handle.




Note: The implant carrier should be used with a maximum speed of 25 rpm/min when used with a surgical motor.

III. Insert the implant into the implant bed with a maximum torque of 45 Ncm. Exceeding the recommended torque value may cause bone necrosis or damage/fracture of the implant.
IV. Non-compliance with the drill protocol during drilling may cause the implant to be stucked without being fully inserted. In this case, use the implant motor in reverse mode or manually rotate it counterclockwise with the ratchet to remove the implant and return it to the inner package. Re-insert the implant by completing the drill protocol.
Attention: In order to be able to load immediately, at least 35Ncm torque value must be achieved.

Soft tissue management and wound closure

Depending on the selected loading protocol, place a cover screw, healing abutment or an abutment on the implant and perform the wound closure with suture.

9. Healing phase

- The healing phase varies depending on the patient and the treatment. It is the clinician's sole responsibility when to load the implant. It is recommended to perform a radiographic control before loading.
- It is generally recommended to wait between 8 and 12 weeks in the two-stage surgical technique..
- In cases of partial edentulism, implants with immediate loading should be splinted to each other during the healing phase and kept without any occlusal contact. In cases of total edentulism, at least 6 implants in the maxilla and at least 4 implants in the mandible should be splinted together and kept in a balanced occlusal contact

10. Compatibility information

Mode dental implants are compatible with Mode surgical sets.

Do not use implants and components made of different metals and supplied from different manufacturers with Mode dental implant system products.

Mode healing abutments and prosthetic parts can only be used with those with the corresponding connection on Mode Tissue implants.

11. MRI safety information

Mode dental implants have been shown to be MRI conditional through testing in non-clinical tests. Patients using this device can be safely screened in an MRI system if the following conditions are met:

• 1.5 T and 3.0 T static magnetic field

• Maximum surface area gradient of 3,000 gauss/cm (30 T/m)

• At maximum MRI system, average specific absorption rate (SAR) of the whole body 2 W/kg (Normal Operating Mode)

Under the scanning conditions described above, Mode dental implants are expected to have a maximum temperature rise of 4°C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical tests, device-induced image artifact expands radially up to 2.7 cm and 2.2 cm from the implant when scanned with a gradient echo pulse array at 3.0 T and 1.5 T, respectively.

12. Cleaning and sterilization

Mode dental implants are delivered sterile and for single use only. They should not be cleaned or sterilized. Mode Medikal does not accept any responsibility for the processing of devices that are initially delivered as sterile.

Surgical sets and drills are delivered non-sterile. Cleaning and sterilization of these parts are the responsibility of the users.

The protected packaging system protects the sterilized device from external factors and if the device is stored correctly, it maintains its sterility until the expiry date. When removing the device from its packaging, the rules of asepsis should be followed. The sterile package should not be opened until just before the insertion of the implant. Inspect the devices for damage before opening the sterile packaging. Products with damaged

packaging system should not be used. A previously used or non-sterile implant should not be used under any circumstances.

13. Storage

The products should be stored at room temperature, in a dry place protected from direct sunlight. The products must be kept in their original packaging. Improper storage conditions may affect the product's characteristics and cause failure.

The expiry date of the product must be checked before using it. In case of damage to the sterile package, the product should not be used.

See labelings for specific storage and handling rules.

14. Disposal

Disposal of the products should be done in accordance with the rules within the framework of legal procedures and environmental requirements. Contaminated products and sharp parts are hazardous and should be disposed of as medical waste in appropriate conditions.

15. Information that should be provided to the patient

Patients should be informed about the contraindications, warnings, precautions, side effects and complications of Mode dental implants.

Patients should also be informed about MR safety information, and the diameter-height and serial number information of the implants used should be provided to the patient.

16. Disclaimer of liability

These products are part of a general concept and should only be used together with the relevant original products, in accordance with Mode Medikal's instructions and recommendations. The use of products that are not distributed by Mode Medikal and made by third parties will void any expressed or implied warranty or other obligations of Mode Medikal.

Mode Medikal products should be used in accordance with the instructions for use provided by the manufacturer. It is the clinician's responsibility to use products in accordance with these instructions and to determine whether the product is appropriate for the individual patient situation. The clinician is also responsible for regularly following the latest updates on the relevant Mode Medikal product and its applications. Mode Medikal is not responsible for any direct, indirect, punitive or other damages arising out of or in connection with any errors in professional judgment or application related to the use of Mode Medikal products; disclaims any liability, express or implied.

17. Additional Information

The shelf life of sterile products is 5 years.

Life Time:
it remains in the patient's mouth for life

The SSCP link of the products is in the link below;

https://modeimplant.com/images/SSCP-Dental-Implant-Systems.pdf

NOTICE REGARDING SERIOUS INCIDENT

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Manufacturer Name: Mode Medikal Sanayi ve Ticaret Limited Şirketi

Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

Mail: info@modeimplant.com

Related Person: Melis AKYÜZ

Mail: melis@modemed.com

Phone: 0553 373 36 42

18. Symbols

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
CE 2696	Notified Body Number		Expiry Date
	Do not subject to a second sterilisation		Date of Production

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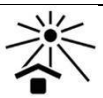
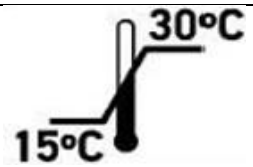
	Do not use a second time		Do not expose to direct sunlight
	Please refer to the user manual		Do not use if package is damaged
	Reference Number		Keep away from contact with water
	Barcode Number		MR Safe
	Sterilised with radiation		Batch code/Lot number
	Specifies a bearer containing Unique Device Identifier information.		Indicates the humidity range to which the medical device can be safely exposed.
	Indicates the temperature limits to which the medical device can be safely exposed.		Medical device

Symbol	Symbol Description
	Patient name or patient ID

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer
	Information website for patients
MD	Device name
LOT	Lot Number/Batch Code
UDI	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data capture format (e.g. linear or 2D-Barcodes)*

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/TURKEY

MODE PROVO S IMPLANT

1. Product Description

Mode Provo S implants are endosteal implants in which the implant and abutment are produced in one piece (monoblock) and are part of Mode Dental Implant Systems, which is an integrated system with related healing abjutments, surgical and prosthetic parts and instruments.

Surface roughening of Provo S implants produced from biocompatible Ti6Al4V-ELI (ASTM F 136) material is done with biphasic calcium phosphate (BCP).

Implant Ø(D)	Ø3	Ø3.5	Ø4	Ø4.5
Length (L)				
8 mm	01.09.08.30	01.09.08.35	01.09.08.40	01.09.08.45
10 mm	01.09.10.30	01.09.10.35	01.09.10.40	01.09.10.45
12 mm	01.09.12.30	01.09.12.35	01.09.12.40	01.09.12.45
15 mm	01.09.15.30	01.09.15.35	01.09.15.40	01.09.15.45

2. Intended Use

Mode Provo S implants are intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower or upper jaw bones.

3. Target Patient Group And İntended User

Mode Provo S implants are intended for use in patients with complete or partial edentulism who have completed their growth and development and do not have the conditions specified in the contraindications.

Mode Provo S implants are intended for use only in patients undergoing a one-stage surgery and loading protocol.

Mode dental implants are intended to be used by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode dental implants are indicated for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in fully or partially edentulous patients.

In cases where there is sufficient bone volume after tooth extraction or loss, they can be applied with immediate, early or late implantation techniques as only one-stage surgery, and only in cases where optimum primary stabilization can be achieved by immediate loading.

Provo S implants are used for partial and total fixed restorations with immediate loading on upper and lower jaws with sufficient bone volume. Implants can be placed with or without a flap. The abutment part of Provo S implants is designed only for screwed prostheses.

5. Contraindications

The use of Mode Provo S implants are contraindicated in the presence of the following conditions;

- The general systemic condition is not suitable for implant surgery
- Inadequate bone volume and/or quality
- Allergy or hypersensitivity to Titanium Grade 4 (ASTM F 67) and Ti6Al4V-ELI (ASTM F 136) materials
- Incomplete bone growth/development
- Alcohol and/or drug abuse
- Weak immune system
- Diseases requiring regular corticosteroid use
- Uncontrolled endocrine system diseases

Special contraindications:
– Provo S implants should not be used in D4 type cancellous bone types.
– Provo S implants should not be used in cases where 35Ncm torque value cannot be obtained due to the necessity of immediate loading.
– Provo S implants should not be used in a single tooth deficiency.

6. Warnings / Cautions / Precautions

General

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! It is recommended to review the product-specific surgical technique before the surgeon performs the surgical procedure. MODE MEDİKAL can provide surgical technical information. Please contact MODE MEDİKAL sales representative.

! Mode Provo S implants are designed for immediate loading and should not be used in soft bone types.

! One hundred percent implant success cannot be guaranteed. Failure to comply with the specified use restrictions and operating steps may result in failure of implant therapy.

! Failure to recognize actual drill lengths based on radiographic measurements may result in permanent injury to nerves and other vital structures. Drilling beyond the depth intended for mandibular surgery can potentially cause permanent numbness of the lower lip and chin, or cause hemorrhage in the floor of the mouth.

! In implant operations, as in all surgeries, it is obligatory to comply with the rules of asepsis and antisepsis.

! Damage to nerves and vessels should be avoided by referring to anatomical information and preoperative radiographs in implant operations.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode dental implant system products cannot be applied to any part of the body other than the lower and upper jawbones.

! Mode dental implant system products should only be used with their system elements in the surgical and prosthetic stages. The use of products with different brands and materials may lead to mechanical problems, implant failure, tissue damage or aesthetic dissatisfaction.

! Check the expiry date of the product before use. Do not use Mode Dental implants after the expiry date on the package.

! Mode dental implants are in sterile packaging. Do not resterilize or process the implants. Cleaning and sterilization can damage material and design features, leading to implant failure.

! Do not reuse Mode dental implants. Reuse of single use products poses a risk of infection for the patient and user.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! Do not use the implant if the implant package is damaged or has been opened previously.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! The type, diameter, length, position and number of implants to be used should be chosen individually, taking into account the condition of the jawbones and anatomical structures.

! It is always recommended to choose the implant with the largest diameter that can be supported by available bone thickness, bone quality, interdental space and expected chewing forces. Where high loads are expected, proper implant alignment should be ensured.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases, bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

During the operation

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! Avoid getting close to the mandibular nerve canal while preparing the implant bed and placing the implant in the lower jaw. Possible nerve damage may result in anesthesia or paresthesia.

! Drills suitable for the size and diameter of the chosen implant should be used.

! Against the risk of contamination, as soon as the implant is taken out of the sterile package, it should be placed in the socket opened with the help of necessary equipment without touching its surface.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

! While inserting the implant, do not exceed the recommended torque values as it may cause bone necrosis.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Do not use damaged or blunted drills for implantation.

! Before use, avoid any contact of the implant with foreign materials. Do not touch the endosteal part of the implant.

! Patients should be advised to avoid activities that require excessive physical effort immediately after implant operations.

Post-operative

! For the long-term success of treatments with the Mode dental implants, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

! Patient records should be kept regularly using labels containing the type, diameter, length and lot number of the implant used.

! Patients should be monitored for peri-implant bone loss and/or changes in percussion responses. If more than 50% mobility or bone loss is observed in the implants, surgical removal of the implants can be considered.

7. Complications And Side Effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after implant treatment.

- Local pain
- Micro hemorrhages
- Swelling
- Bruising
- Local inflammations
- Gingival injuries
- Difficulty biting, chewing and talking
- Systemic or local infections (including Periimplantitis, periodontitis, gingivitis, fistulas)
- Paresthesia
- Chronic pain due to nerve damage
- Damage to the opposing or adjacent teeth
- Bone damage
- Bone resorption
- Sinus perforations
- Trismus
- Hypersensitivity and/or allergic reactions
- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Implant fractures
- Implant failures
- Mandatory removal of implants
- Failures/fractures of prosthetic parts
- Undesirable aesthetic results
- Longer recovery times than expected

8. Surgical Procedure

Preparing the implant bed

I. Determine the implant position with the marking bur.

II. Proceed to the implant length you have determined for the area with 1.5 mm diameter pilot drills.

III. Using the appropriate implant drills, enlarge the implant bed to the diameter you have determined for the area.

Note: Attention should be paid to bone quality during drilling. Bone quality is important for optimal primary stabilization. The drilling protocol of Mode Provo S implants according to bone quality is given in the table below.

Implant Diameter	Medium Bone (D2/D3)	Hard Bone (D1)
⌀ 3.0	⌀ 1.5 Pilot Drill ⌀ 3.0	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.0 Bone Tap
⌀ 3.5	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.5	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.5 ⌀ 3.5 Bone Tap
⌀ 4.0	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.5 ⌀ 4.0	⌀ 1.5 Pilot Drill ⌀ 3.0 ⌀ 3.5 ⌀ 4.0 ⌀ 4.0 Bone Tap

	⌀ 1.5 Pilot Drill	⌀ 1.5 Pilot Drill
	⌀ 3.0	⌀ 3.0
	⌀ 3.5	⌀ 3.5
⌀ 4.5		
	⌀ 4.0	⌀ 4.0
	⌀ 4.5	⌀ 4.5
		⌀ 4.5 Bone Tap

▪ Drilling operations should be performed at a speed of 400-900 rpm/min by continuous cooling with sterile saline at room temperature in pilot and implant diameter drills.
▪ For very compact bones, it is recommended to drill with back and forth motions.

Caution: Pilot and implant drills are driven 1 mm deeper than their actual implant length. Take this difference into account in order not to damage vital anatomical structures while preparing the implant bed.

Caution: In flapless surgical techniques, drilling should be done by taking the gingival height into account.

Insertion of the implant

I. Open the packaging of the implant and place the sterile inner pack on the surgical area.
II. Provo S implants are removed from the inner package with adapters specific to the abutment shape.

III. Implants that are placed directly in the implant socket are hand tightened until their stability is achieved.

IV. Finally, the implant is sent to the prepared socket with the help of a ratchet. Insert the implant into the socket with a maximum torque of 45 Ncm. Exceeding the recommended torque value may cause bone necrosis or damage/fracture of the implant.

Attention: In order to be able to load immediately, at least 35Ncm torque value must be achieved.

Attention: Using the torque ratchet, tighten the prosthetic screw until a torque value of 15Ncm is obtained.

9. Healing Phase

▪ In partial edentulism, Provo S implants with immediate loading should be splinted to each other during the healing phase and kept without any occlusal contact. In cases of total edentulism, at least 6 implants in the maxilla and at least 4 implants in the mandible should be splinted together and kept in a balanced occlusal contact.

10. Compatibility Information

Mode dental implants are compatible with Mode surgical sets.

Do not use implants and components made of different metals and supplied from different manufacturers with Mode dental implant system products.

11. MRI Safety Information

Mode dental implants have been shown to be MRI conditional through testing in non-clinical tests. Patients using this device can be safely screened in an MRI system if the following conditions are met:

• 1.5 T and 3.0 T static magnetic field

• Maximum surface area gradient of 3,000 gauss/cm (30 T/m)

• At maximum MRI system, average specific absorption rate (SAR) of the whole body 2 W/kg (Normal Operating Mode)

Under the scanning conditions described above, Mode dental implants are expected to have a maximum temperature rise of 4°C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical tests, device-induced image artifact expands radially up to 2.7 cm and 2.2 cm from the implant when scanned with a gradient echo pulse array at 3.0 T and 1.5 T, respectively.

12. Cleaning And Sterilization

Mode dental implants are delivered sterile and for single use only. They should not be cleaned or sterilized. Mode Medikal does not accept any responsibility for the processing of devices that are initially delivered as sterile.

Surgical sets and drills are delivered non-sterile. Cleaning and sterilization of these parts are the responsibility of the users.

The protected packaging system protects the sterilized device from external factors and if the device is stored correctly, it maintains its sterility until the expiry date. When removing the device from its packaging, the rules of asepsis should be followed. The sterile package should not be opened until just before the insertion of the implant. Inspect the devices for damage before opening the sterile packaging. Products with damaged packaging system should not be used. A previously used or non-sterile implant should not be used under any circumstances

13. Storage

The products should be stored at room temperature, in a dry place protected from direct sunlight. The products must be kept in their original packaging. Improper storage conditions may affect the product's characteristics and cause failure.

The expiry date of the product must be checked before using it. In case of damage to the sterile package, the product should not be used.

See labelings for specific storage and handling rules.

14. Disposal

Disposal of the products should be done in accordance with the rules within the framework of legal procedures and environmental requirements. Contaminated products and sharp parts are hazardous and should be disposed of as medical waste in appropriate conditions.

15. Information That Should Be Provided To The Patient

Patients should be informed about the contraindications, warnings, precautions, side effects and complications of Mode dental implants.

Patients should also be informed about MR safety information, and the diameter-height and serial number information of the implants used should be provided to the patient.

16. Disclaimer Of Liability

These products are part of a general concept and should only be used together with the relevant original products, in accordance with Mode Medikal's instructions and recommendations. The use of products that are not distributed by Mode Medikal and made by third parties will void any expressed or implied warranty or other obligations of Mode Medikal.

Mode Medikal products should be used in accordance with the instructions for use provided by the manufacturer. It is the clinician's responsibility to use products in accordance with these instructions and to determine whether the product is appropriate for the individual patient situation. The clinician is also responsible for regularly following the latest updates on the relevant Mode Medikal product and its applications. Mode Medikal is not responsible for any direct, indirect, punitive or other damages arising out of or in connection with any errors in professional judgment or application related to the use of Mode Medikal products; disclaims any liability, express or implied.

17. Additional Information

The shelf life of sterile products is 5 years.

Life Time:
it remains in the patient's mouth for life

The SSCP link of the products is in the link below;

https://modeimplant.com/images/SSCP-Dental-Implant-Systems.pdf

NOTICE REGARDING SERIOUS INCIDENT

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Manufacturer Name: Mode Medikal Sanayi ve Ticaret Limited Şirketi

Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

Mail: info@modeimplant.com

Related Person: Melis AKYÜZ

Mail: melis@modemed.com

Phone: 0553 373 36 42

18. Symbols

CE 269(	Notified Body Number		Expiration date
	Do Not Sterilize For The Second Time		Production date
	Do Not Use For The Second Time		Do not expose to direct sunlight
	See User Manual	Dikkat, birlikte verilen belgelere danışın	Consult the accompanying documentation

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

Do Not Use If The Package Is Damaged

Keep Away From Contact With Water

MRI Safety Information

Barcode number

Referance number

Symbol	Symbol Description
	Patient name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Name and Address of the manufacturer
	Information website for patients

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

MD	Device name
LOT	Lot Number/Batch Code
UDI	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data capture format (e.g. linear or 2D-Barcodes)*

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/Türkiye

MODE IMPLANT COVER SCREWS

NP Cover Screws RP Cover Screws WP Cover Screws

1. Product Description

Mode cover screws are part of Mode Dental Implant Systems, an integrated system with Mode dental implants and related abutments, healing abutments, surgical and prosthetic parts and instruments; It is produced as a single piece using Ti6Al4V-ELI (ASTM F 136) material.

Mode cover screws are components that cover the implant-abutment connection area during the healing process and prevent soft and hard tissue growth in this area.

While the upper part of the cover screw tightly covers the implant, the threaded part fits into the internal screw thread of the implant.

Mode cover screws are packaged with Mode dental implants and are supplied sterile.

Mode cover screws are designed to be compatible with all the following Mode dental implants in three different platforms, narrow platform (NP), normal platform (RP), and wide platform (WP):

Implant / Platform	Narrow Platform (NP)	Regular Platform (RP)	Wide Platform (WP)
Level Implant	NP Cover screw REF: 03.01.00.03	RP Cover screw REF: 03.01.00.35	WP Cover screw REF: 03.01.00.45
Rapid Implant			
Bone Implant			
Tissue Implant			
Short Implant			
Shorter Implant			

2. Intended use

They are intended to used with the relevant Mode dental implants in the lower and/or upper jaws in partially or completely edentulous patients by covering the implant-abutment connection for preventing soft and hard tissue growth in this area during the healing process area in cases where two-stage surgical technique is used.

3. Target Patient Group And İntended User

Mode cover screws are intended for use with Mode dental implants in patients with complete or partial edentulism who have completed growth and development and do not have the conditions specified in the contraindications.

Mode cover screws are intended for use by dentists only.

Clinicians must have sufficient knowledge of implantology and practice skills, as well as comply with the instructions for use, in order to use Mode dental implants safely and properly.

4. Indications

Mode cover screws are indicated for use with Mode dental implants placed for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in totally or partially edentulous patients.

5. Contraindications

The use of Mode cover screws is contraindicated in the presence of the following conditions;

– Patients who are medically unfit for implant treatment

– Allergy or hypersensitivity to Ti6Al4V-ELI (ASTM F 136) materials

Note: For implant treatment contraindications, refer to the respective Mode implant intructions for use.

6. Warnings / Cautions / Precautions

General

! Mode dental implant systems products should be applied by paying attention to the instructions for use provided by Mode Medikal. It is the clinician's responsibility to use the products according to these instructions and to determine whether the implants are appropriate for the individual patient situation.

! Treatments with implants may lead to biological and mechanical problems, including bone loss and fatigue fracture of implants.

! Close collaboration between the surgeon, the prosthodontist and the dental laboratory technician is essential for successful implant treatment.

! Mode cover screws should only be used with their own system elements and paired with the correct platform during the surgical and prosthetic phases. The use of products with different brands and materials may lead to mechanical problems, failure of implants, tissue damage or aesthetic dissatisfaction.

! Mode cover screws are in sterile packaging. Do not resterilize or process the cover screws. Cleaning and sterilization can damage material and design features, leading to treatment failure.

! Sterile handling is essential. Never use potentially contaminated components. Contamination can cause infections.

! All surgical instruments and tooling used must be kept in good condition and care must be taken not to damage the implants or other components of the instruments.

Pre-operative

! A comprehensive clinical and radiological examination is necessary to determine the psychological and physical condition of the patient.

! Preoperative hard and soft tissue deficiencies may result in undesirable aesthetic results and/or negative implant angulation.

! Particular attention should be paid to patients with local or systemic factors that may affect hard tissue healing, soft tissue healing, or osseointegration of implanted implants. (eg Type 1 Diabetes, bone metabolism diseases, bleeding disorders, anticoagulant therapy, parafunctional habits such as bruxism, smoking, poor oral hygiene, pregnancy, acute periodontal diseases, orofacial radiotherapy, adjacent tissue infections, etc.)

! Particular attention should be paid to patients receiving bisphosphonate treatment.

! Implant treatment should not be applied to patients who have not completed bone growth and development.

! Placement of implants and design of prostheses should be specific to the patient. In the presence of extreme bruxism and other parafunctional habits and jaw relationship disorders, different treatment options can be planned.

During the operation

! Before placing the Mode cover screws, ensure that the inner surface of the implant is clean and free from blood.

! Be careful against the risk of aspiration and swallowing due to the size of the products during intraoral application. Aspiration of products can lead to infection or unwanted physical injury.

! After implant placement, the clinician decides whether to use immediate or delayed loading protocols, based on the evaluation of the bone quality and primary stability in the operation.

! Quality and/or quantity of remaining bone, distubed initial healing, local infections and general systemic diseases can be counted as causes of implant failures that occur immediately after the operation or after initial osseointegration has been achieved.

! Against the risk of contamination, it should be placed on the implant with the help of necessary equipment as soon as it is removed from the sterile package. Impairment of sterility may adversely affect the treatment outcome.

Post-operative

! For the long-term success of implant treatments, it is important to follow up the patient regularly and to give the necessary oral hygiene training to the patient.

7. Complications and side effects

Dental implant treatment outcomes can be affected by many variables. Possible complications and side effects listed below may be observed after the use of Mode cover screws.

- Hypersensitivity and/or allergic reactions
- Other toxicity reactions
- Aspiration or swallowing of parts during operation
- Triggering of the pharyngeal reflex during the insertion of the product
- Growth of bone tissue on the cover screws during the healing process
- In some cases, it becomes visible early as exposure during the healing process.

8. Procedure

I. Take the Mode cover screw from the sterile package with the Mode screwdriver.
II. Connect the cover screw to the implant you placed in the socket and tighten it by hand.
III. Loosen the Mode cover screw by hand using the screwdriver to remove it.

NOTE: When using the mode cover screws, it is recommended to ensure that the screwdriver is firmly seated on the screw to avoid the risk of aspiration/swallowing of the screw.

NOTE: The recommended tightening torque is 5-10 Ncm manually by hand.

9. Compatibility information

Mode cover screws are compatible with Mode Medikal implant systems products and components.

Do not use implants and components made of different metals and supplied from different manufacturers with Mode dental implant system products.

Mode cover screws can be used on all Mode dental implants only with the corresponding connection.

10. MRI safety information

Mode cover screws have been shown to be MRI conditional through testing in non-clinical tests. Patients using this device can be safely screened in an MRI system if the following conditions are met:

• 1.5 T and 3.0 T static magnetic field

• Maximum surface area gradient of 3,000 gauss/cm (30 T/m)

• At maximum MRI system, average specific absorption rate (SAR) of the whole body 2 W/kg (Normal Operating Mode)

Under the scanning conditions described above, Mode dental implants are expected to have a maximum temperature rise of 4°C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical tests, device-induced image artifact expands radially up to 2.7 cm and 2.2 cm from the implant when scanned with a gradient echo pulse array at 3.0 T and 1.5 T, respectively.

11. Cleaning and sterilization

Mode cover screws are delivered sterile and for single use only with Mode dental implants. They should not be cleaned or sterilized. Mode Medikal does not accept any responsibility for the processing of devices that are initially delivered as sterile.

Surgical sets and drills are delivered non-sterile. Cleaning and sterilization of these parts are the responsibility of the users.

The protected packaging system protects the sterilized device from external factors and if the device is stored correctly, it maintains its sterility until the expiry date. When removing the device from its packaging, the rules of asepsis should be followed. The sterile package should not be opened until just before the insertion of the cover screw. Inspect the devices for damage before opening the sterile packaging. Products with damaged packaging system should not be used. A previously used or non-sterile cover screws should not be used under any circumstances.

12. Storage

The products should be stored at room temperature, in a dry place protected from direct sunlight. The products must be kept in their original packaging. Improper storage conditions may affect the product's characteristics and cause failure.

The expiry date of the product must be checked before using it. In case of damage to the sterile package, the product should not be used.

See labelings for specific storage and handling rules.

13. Disposal

Disposal of the products should be done in accordance with the rules within the framework of legal procedures and environmental requirements. Contaminated products and sharp parts are hazardous and should be disposed of as medical waste in appropriate conditions.

14. Information that should be provided to the patient

Patients should be informed about the contraindications, warnings, precautions, side effects and complications of Mode cover screws.

Patients should also be informed about MR safety information.

15. Disclaimer of liability

These products are part of a general concept and should only be used together with the relevant original products, in accordance with Mode Medikal's instructions and recommendations. The use of products that are not distributed by Mode Medikal and made by third parties will void any expressed or implied warranty or other obligations of Mode Medikal.

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17. Additional Information

The shelf life of sterile products is 5 years.

Life Time:
it remains in the patient's mouth for life

The SSCP link of the products is in the link below;

https://modeimplant.com/images/SSCP-Dental-Implant-Systems.pdf

NOTICE REGARDING SERIOUS INCIDENT

For a patient/user/third party in the European Union and in countries with an identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Manufacturer Name: Mode Medikal Sanayi ve Ticaret Limited Şirketi

Adress: Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa/İstanbul

Phone: 0212 612 64 09

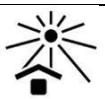
Mail: info@modeimplant.com

Related Person: Melis AKYÜZ

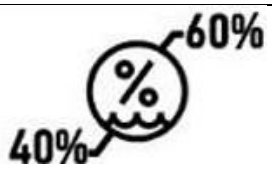
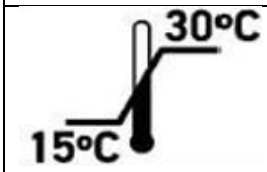
Mail: melis@modemed.com

Phone: 0553 373 36 42

18. Symbols

Symbol	Explanation of Symbol	Symbol	Explanation of Symbol
CE 2696	Notified Body Number		Expiry Date
	Do not subject to a second sterilisation		Date of Production
	Do not use a second time		Do not expose to direct sunlight
	Please refer to the user manual		Do not use if package is damaged

Hazırlayan/ Prepared By Gonca Bakırcı	Onaylayan/ Approverd By Saniye Özgür

REF	Reference Number		Keep away from contact with water
	Barcode Number		MR Safe
STERILE R	Sterilised with radiation	LOT	Batch code/Lot number
UDI	Specifies a bearer containing Unique Device Identifier information.		Indicates the humidity range to which the medical device can be safely exposed.
	Indicates the temperature limits to which the medical device can be safely exposed.	MD	Medical device

Symbol	Symbol Description
	Patient name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider

Hazırlayan/ Prepared By	Onaylayan/ Approverd By
Gonca Bakırcı	Saniye Özgür

	Name and Address of the manufacturer
	Information website for patients
	Device name
	Lot Number/Batch Code
	Explanation of unique device identifier as AIDC Format *AIDC: Automatic identification and data capture format (e.g. linear or 2D-Barcodes)*

Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/TURKEY