CONTENTS

MODE BALL ABUTMENT INSTRUCTIONS FOR USE

1. Product Description

The Mode Medikal prosthesis series consists of abutments in different types of diameters, lengths and platforms that are used in the restoration of Mode dental implants.They are available in a variety of shapes and sizes to suit the patient's needs. These instructions for use are valid for Mode Medikal's products specified in section 3.

Mode Medikal Ball abutments are manufactured using Ti6Al4V-ELI (ASTM F 136) material.

		Narrow Platform		Regular Platform		
	Platform/H (mm)	Ø3.3mm	Ø3.7mm	Ø4.1mm	Ø4.7mm	Ø5.2mm
MODE Ball Abutment	H0,5	02.06.050.03		02.06.050.35		
	H1,0	02.06.01.03		02.06.01.35		
	H2,0	02.06.02.03		02.06.02.35		
	H3,0	02.06.03.03		02.06.03.35		
	H4,0	02.06.04.03		02.06.04.35		
	H6,0	02.06.06.03		02.06.06.35		

2. Intended Use

Mode Medikal Ball abutments are used to support dentures in order to fulfill the chewing function and to eliminate tooth deficiencies. One-piece Ball abutments are screwed to Mode Medikal implants and form a basis for overdenture structures.

3. Target Patient Group And Intended User

Mode dental 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 may only be used by dentists.

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

4. Indications

They are screwed directly to the intraosseous implants to support the removable overdentures.

5. Contraindications

Its use is contraindicated in individuals with hypersensitivity to titanium and titanium alloys.

For implant treatment contraindications, refer to the relevant Mode Medikal implant instructions for use.

6. Warnings and Precautions

The patient may swallow or aspirate the prosthetic parts. Care must be taken when working inside the mouth.

It is recommended that the clinician review the product-specific technique before performing the procedure. MODE MEDİCAL can provide technical information. Please contact MODE MEDICAL sales representative.

Mode Medikal abutments should only be used with Mode brand implants on the appropriate platform.

Before the delivery of the prosthesis, the Ball abutment placed in the patient's mouth should be torqued with a torque value of 35 Ncm. Torque values greater than 35 Ncm may damage the prosthetic parts. Torque values less than the recommended value may cause abutment loosening.

Abutments are disposable devices.

Mode Medikal products should be used according to the instructions for use provided by the manufacturer. It is the physician's responsibility to decide whether the device is suitable for use according to these instructions and for the individual patient situation.

For a successful implant treatment, it is important that the dentist and dental technician work in harmony.

In order for the implant treatment to be successful in the long term, it is important that the patient's routine controls and oral hygiene training are given after the treatment is completed.

7. Complications And Side Effects

The following reactions may occur during implant treatment:

• Hypersensitivity/allergic reactions

• Swallowing or aspiration of prosthetic components

• Peri-implantitis

• Implant component or prosthesis failure/fracture

• Poor aesthetic result

• Repetition of prosthetic treatment

• Minor bleeding

• Implant loss

8. Compatibility Information

Metal and plastic matrices used with ball abutments are compatible with Rhein 83.

All abutments can be used with the same abutment screwdriver.

There are different shapes of abutments in the Mode two-piece implant series. Abbreviations and color codes indicating the compatibility of implant and abutment platforms are available on the packages.

Implant Platform	Abbreviation	Color Code	Implant Diameter
Narrow Platform	NP	Yellow	Ø 3.3 – Ø3.7
Regular Platform	RP	Blue	Ø4.1 – Ø4.7 – Ø 5.2
Wide Platform	WP	Green	Ø5.3- Ø6.0

9. Cleaning

Mode Medikal abutments and parts are delivered unsterile. Before placing the products in the patient's mouth, they must be disassembled, cleaned and sterilized.

Mode Medikal recommends the following for cleaning and sterilization of abutments before use.

1. Clean by brushing inside and outside with a brush under running water.

2. The pre-treated product can be cleaned by hand, ultrasonic cleaner, or an automatic cleaning method.

3. When selecting the automatic cleaning method, the appropriate detergent should be selected and the manufacturer's instructions should be followed.

10. Sterilization

Mode Medikal abutments and parts are delivered unsterile. Mode Medikal recommends the following for sterilization of abutments prior to use:

Method	Conditions	Drying
Humidity temperature (autoclave) pre-vacuum	121° C 30 min	Local

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

11. Procedure

11.1. Laboratory Procedure

Note: Screw the abutment to the analog during all laboratory procedures to preserve the abutment's attachment site to the implant.

1. Combine the impression coping with the implant analogue.

2. Obtain the plaster working model by using soft gingival silicone around the analogues.

3. Determine the abutment gingival height according to the amount of gingiva in the relevant region in the plaster model obtained.

4. Select the abutment suitable for the diameter of the dental implant used.

5. Connect the selected abutment with suitable diameter and gingival height to the analog in the plaster model with the help of screws.

6. Simply tighten the abutment screw by hand.

7. Plan your prosthesis in accordance with the selected abutment type and fabricate it with the preferred fabrication method.

9.2. Clinical Procedure

1. Remove the healing abutment located in the relevant area of the patient's mouth with the help of a screwdriver.

2. Select the abutment at the appropriate gingival height, insert it into the related implant in the mouth and screw the abutment with 35Ncm torque.

3. If the prosthesis and metal housing are to be combined in a laboratory environment, take the

impression with the relevant impression copings and custom impression tray.

4. At the delivery of the prosthesis, select the appropriate retention plastic and place it in the metal housing.

5. Place the prosthesis in the mouth and check the occlusal contacts, make the necessary adjustments.

Oral and Prosthetic Care: Good oral hygiene is extremely important for the success of the attachment. Ball attachments should be thoroughly cleaned daily to prevent plaque buildup, and the patient should use a soft, nylon-bristled toothbrush and non-abrasive toothpaste to clean the abutments. Plastic retension materials are subject to wear as part of normal use and may need to be replaced. Patients should be asked to continue routine follow-up visits for hygiene and attachment function evaluation. Follow-up visits are recommended at 6-month intervals. Patients should be examined for signs of inflammation around the implant abutments and for implant mobility.

Placing and Removing Overdentures: The patient should be given instructions on how to properly place the overdenture. The patient should ensure that the prosthesis is correctly placed on the abutments before applying pressure. Using both hands, the patient should press both sides of the overdenture prosthesis to firmly seat it.

The patient should not bite the overdenture prosthesis into place; otherwise the applied force will cause improper wear of the abutments, including the plastic retainers in the overdenture. To remove the overdenture, the patient should place their thumbs under the edges of the overdenture and remove the prosthesis by pushing from both sides.

12. Magnetic Resonance Imaging (MRI) Safety Information

Non-clinical testing has demonstrated that Titanium Dental Materials are MR Compatible.

A patient with these system parts in his body can safely be scanned in MR systems if the following conditions are met:

Only 1.5 and 3.0 Tesla static magnetic fields

Magnetic spatial drop field up to 970 Gauss/cm (9.7 T/m) or less

Average specific absorption rate (SAR) for the whole body 2 W/kg (Normal Use Mode)

Under the above-mentioned scanning conditions, after 15 minutes of continuous scanning, our products are expected to generate a maximum temperature rise of 3°C.

13. Disposal

Disposal should be done in an environmentally sustainable manner according to local regulations. Hazardous waste and cutting/drilling tools for contaminated devices should be disposed of in suitable containers that meet special technical requirements.

14. Disclaimer of Liability

These products are part of a general concept and should only be used with the relevant original products in accordance with Mode Medikal's instructions and recommendations. The use of products 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, penal or other damages arising from or in connection with any errors in professional judgment or practice related to the use of Mode Medikal products; assumes no liability, express or implied.

15.Additional Information

Non Sterile products do not have a specified shelf life.

Life Time

The useful life of the products is determined as 10 years.

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

16. Symbols

ISO 15223-1: 2021 Symbols and Meanings Prepared According to the Standard

CE 2696	Notified Body Number	NON STERILE	Non Sterile
	Attention		
	Do Not Use For The Second Time		Barcode
	See User Manual		
REF	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/TURKEY

MODE LOCATOR ABUTMENT INSTRUCTIONS FOR USE

1. Product Description

The Mode Medikal prosthesis series consists of abutments in different types of diameters, lengths and platforms that are used in the restoration of Mode dental implants. They are available in a variety of shapes and sizes to suit the patient's needs. These instructions for use are valid for Mode Medikal's products specified in section 3.

Mode Medikal Locator abutments are manufactured using Ti6Al4V-ELI (ASTM F 136) material.

		Narrow Platform		Regular Platform		
	Platform/H (mm)	Ø3.3mm	Ø3.7mm	Ø4.1mm	Ø4.7mm	Ø5.2mm
MODE Locator Abutment	H0,5	02.07.050.03		02.07.050.35		
	H1,0	02.07.01.03		02.07.01.35		
	H2,0	02.07.02.03		02.07.02.35		
	H3,0	02.07.03.03		02.07.03.35		
	H4,0	02.07.04.03		02.07.04.35		
	H6,0	02.07.06.03		02.07.06.35		

2. Intended use

Mode Medikal Locator abutments are used to support dentures in order to fulfill the chewing function and to eliminate tooth deficiencies. One-piece Locator abutments are screwed to Mode Medikal implants and form a basis for overdenture structures.

3. Target Patient Group And İntended User

Mode dental 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 may only be used by dentists.

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

4. Indications

They are screwed directly to the intraosseous implants to support the removable overdentures.

5. Contraindications

Its use is contraindicated in individuals with hypersensitivity to titanium and titanium alloys.

For implant treatment contraindications, refer to the relevant Mode Medikal implant instructions for use.

6. Warnings and Precautions

The patient may swallow or aspirate the prosthetic parts. Care must be taken when working inside the mouth.

It is recommended that the clinician review the product-specific technique before performing the procedure. MODE MEDİCAL can provide technical information. Please contact MODE MEDICAL sales representative.

Mode Medikal abutments should only be used with Mode brand implants on the appropriate platform.

Before the delivery of the prosthesis, the Locator abutment placed in the patient's mouth should be torqued with a torque value of 35 Ncm. Torque values greater than 35 Ncm may damage the prosthetic parts. Torque values less than the recommended value may cause abutment loosening.

Abutments are disposable devices.

Mode Medikal products should be used according to the instructions for use provided by the manufacturer. It is the physician's responsibility to decide whether the device is suitable for use according to these instructions and for the individual patient situation.

For a successful implant treatment, it is important that the dentist and dental technician work in harmony.

In order for the implant treatment to be successful in the long term, it is important that the patient's routine controls and oral hygiene training are given after the treatment is completed.

7. Complications And Side Effects

The following reactions may occur during implant treatment:

- Hypersensitivity/allergic reactions
- Swallowing or aspiration of prosthetic components
- Peri-implantitis
- Implant component or prosthesis failure/fracture
- Poor aesthetic result
- Repetition of prosthetic treatment
- Minor bleeding

• Implant loss

8. Compatibility Information

Metal and plastic matrices used with Locator abutments are compatible with Zest Locator and Kerator.

All abutments can be used with the same abutment screwdriver.

There are different shapes of abutments in the Mode two-piece implant series. Abbreviations and color codes indicating the compatibility of implant and abutment platforms are available on the packages.

Implant Platform	Abbreviation	Color Code	Implant Diameter
Narrow Platform	NP	Yellow	Ø 3.3 – Ø3.7
Regular Platform	RP	Blue	Ø4.1 – Ø4.7 – Ø 5.2
Wide Platform	WP	Green	Ø5.3- Ø6.0

9. Cleaning

Mode Medikal abutments and parts are delivered unsterile. Before placing the products in the patient's mouth, they must be disassembled, cleaned and sterilized.

Mode Medikal recommends the following for cleaning and sterilization of abutments before use.

1. Clean by brushing inside and outside with a brush under running water.

2. The pre-treated product can be cleaned by hand, ultrasonic cleaner, or an automatic cleaning method.

3. When selecting the automatic cleaning method, the appropriate detergent should be selected and the manufacturer's instructions should be followed.

10. Sterilization

Mode Medikal abutments and parts are delivered unsterile. Mode Medikal recommends the following for sterilization of abutments prior to use:

Method	Conditions	Drying
Humidity temperature (autoclave) pre-vacuum	121° C 30 min	Local

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

11. Procedure

11.1. Laboratory Procedure

Note: Screw the abutment to the analog during all laboratory procedures to preserve the abutment's attachment site to the implant.

1. Combine the impression coping with the implant analogue.

2. Obtain the plaster working model by using soft gingival silicone around the analogues.

3. Determine the abutment gingival height according to the amount of gingiva in the relevant region in the plaster model obtained.

4. Select the abutment suitable for the diameter of the dental implant used.

5. Connect the selected abutment with suitable diameter and gingival height to the analog in the plaster model with the help of screws.

6. Simply tighten the abutment screw by hand.

7. Plan your prosthesis in accordance with the selected abutment type and fabricate it with the preferred fabrication method.

9.2. Clinical Procedure

1. Remove the healing abutment located in the relevant area of the patient's mouth with the help of a screwdriver.

2. Select the abutment at the appropriate gingival height, insert it into the related implant in the mouth and screw the abutment with 35Ncm torque.

3. If the prosthesis and metal housing are to be combined in a laboratory environment, take the

impression with the relevant impression copings and custom impression tray.

4. At the delivery of the prosthesis, select the appropriate retention plastic and place it in the metal housing.

5. Place the prosthesis in the mouth and check the occlusal contacts, make the necessary adjustments.

Oral and Prosthetic Care: Good oral hygiene is extremely important for the success of the attachment. Locator attachments should be thoroughly cleaned daily to prevent plaque buildup, and the patient should use a soft, nylon-bristled toothbrush and non-abrasive toothpaste to clean the abutments. Plastic retension materials are subject to wear as part of normal use and may need to be replaced. Patients should be asked to continue routine follow-up visits for hygiene and attachment function evaluation. Follow-up visits are recommended at 6-month intervals. Patients should be examined for signs of inflammation around the implant abutments and for implant mobility.

Placing and Removing Overdentures: The patient should be given instructions on how to properly place the overdenture. The patient should ensure that the prosthesis is correctly placed on the abutments before applying pressure. Using both hands, the patient should press both sides of the overdenture prosthesis to firmly seat it.

The patient should not bite the overdenture prosthesis into place; otherwise the applied force will cause improper wear of the abutments, including the plastic retainers in the overdenture. To remove the overdenture, the patient should place their thumbs under the edges of the overdenture and remove the prosthesis by pushing from both sides.

12. Magnetic Resonance Imaging (MRI) Safety Information

Non-clinical testing has demonstrated that Titanium Dental Materials are MR Compatible.

A patient with these system parts in his body can safely be scanned in MR systems if the following conditions are met:

Only 1.5 and 3.0 Tesla static magnetic fields

Magnetic spatial drop field up to 970 Gauss/cm (9.7 T/m) or less

Average specific absorption rate (SAR) for the whole body 2 W/kg (Normal Use Mode)

Under the above-mentioned scanning conditions, after 15 minutes of continuous scanning, our products are expected to generate a maximum temperature rise of 3°C.

13. Disposal

Disposal should be done in an environmentally sustainable manner according to local regulations. Hazardous waste and cutting/drilling tools for contaminated devices should be disposed of in suitable containers that meet special technical requirements.

14. Disclaimer of Liability

These products are part of a general concept and should only be used with the relevant original products in accordance with Mode Medikal's instructions and recommendations. The use of products 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, penal or other damages arising from or in connection with any errors in

professional judgment or practice related to the use of Mode Medikal products; assumes no liability, express or implied.

15.Additional Information

Non Sterile products do not have a specified shelf life.

Life Time

The useful life of the products is determined as 10 years.

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

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

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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

16. Symbols

ISO 15223-1: 2021 Symbols and Meanings Prepared According to the Standard

CE 2696	Notified Body Number	NON STERILE	Non Sterile
	Attention		

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

Do Not Use For The Second Time

Barcode

See User Manual

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
	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)*

MODE MULTI BASE ABUTMENT INSTRUCTIONS FOR USE

1. Product Description

The Mode Medikal prosthesis series consists of abutments in different types of diameters, lengths and platforms that are used in the restoration of Mode dental implants.They are available in a variety of shapes and sizes to suit the patient's needs. These instructions for use are valid for Mode Medikal's products specified in section 3.

Mode Medikal Multi Base abutments are composed of two components. It consists of an abutment body and an abutment cover in different designs. Multi Base abutments are offered in two different angles, 17° and 30°.

Multi Base abutments offers a wide range of prosthetic solutions such as ball, Locator, bar-retained overdenture prostheses; and screwed fixed restorations.

Multi Base abutments, covers and copings are manufactured using Ti6Al4V-ELI (ASTM F 136) material.

		Narrow Platform		Normal Platform			Wide Platform	
	Platform/H (mm)	Ø3.3mm	Ø3.7mm	Ø4.1mm	Ø4.7mm	Ø5.2mm	Ø5.3mm	Ø6.0mm
 17° Multi Base Abutment	H2,5	02.14.01.03		02.14.01.35			02.14.01.45	
	H3,5	02.14.02.03		02.14.02.35			02.14.02.45	
 30° Multi Base Abutment	H3,5	02.14.03.03		02.14.03.35			-	
	H4,0	02.14.04.03		02.14.04.35			-	
 Multi Base Cover		36.00.00.02						
 Multi Base Ball Cover	H1	02.16.00.01						
	H2	02.16.00.02						
 Multi Base Locator Cover	H1	02.17.00.01						
	H2	02.17.00.02						
 Multi Base Ti Base Engaged Coping		02.07.00.03						
 Multi Base Ti Base Non Engaged Coping		02.07.00.04						

2. Intended use

Mode Medikal abutments are used for support in eliminating tooth deficiencies in order to fulfill the chewing function. Two-piece Mode Medikal Multi Base abutments and covers are attached to the implants with the help of screws and form the basis of prosthetic structures on implants such as screw retained fixed restorations and implant supported overdentures.

Multi Base Ti Base engaged and non engaged copings are supporting parts that provide a compatible interface with the Multi Base Cover by cementing the screwed final restoration or Geçici restoration in the laboratory environment.

3. Target patient group and intended user

Mode dental 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 may only be used by dentists.

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

4. Indications

They are screwed directly to the intraosseous implants with the help of screws in order to support the implant-supported prostheses. They provide support for screw retained fixed restorations or overdenture prostheses in edentulous or partially edentulous dental arches. Ball or Locator abutment cover is used to connect the removable overdentures with the implant. Multi Base abutments are used to connect bar-retained overdenture prostheses with the implant.

5. Contraindications

Its use is contraindicated in individuals with hypersensitivity to titanium and titanium alloys.

For implant treatment contraindications, refer to the relevant Mode Medical implant instructions for use.

6. Warnings and Precautions

The patient may swallow or aspirate the prosthetic parts. Care must be taken when working inside the mouth.

It is recommended that the clinician review the product-specific technique before performing the procedure. MODE MEDİCAL can provide technical information. Please contact MODE MEDICAL sales representative.

Mode Medikal abutments should only be used with Mode brand implants on the appropriate platform.

The abutment screw should be torqued with a torque value of 25 Ncm. Torque values greater than 25 Ncm may damage the prosthetic parts. Torque values less than the recommended value may cause abutment loosening. The prosthetic screws used in the Multi Base Abutment series should be torqued with a torque value of 15 Ncm.

Abutments are disposable devices.

Mode Medikal products should be used according to the instructions for use provided by the manufacturer. It is the physician's responsibility to decide whether the device is suitable for use according to these instructions and for the individual patient situation.

For a successful implant treatment, it is important that the dentist and dental technician work in harmony.

In order for the implant treatment to be successful in the long term, it is important that the patient's routine controls and oral hygiene training are given after the treatment is completed.

7. Complications and side effects

The following reactions may occur during implant treatment:

• Hypersensitivity/allergic reactions

• Swallowing or aspiration of prosthetic components

• Peri-implantitis

• Implant component or prosthesis failure/fracture

• Poor aesthetic result

• Repetition of prosthetic treatment

• Minor bleeding

• Implant loss

8. Compatibility Information

Metal housing and retention plastics used with Multi Base Locator Cover are compatible with Zest Locator and Kerator. Metal and plastic matrices used with Multi Base Ball Cover are compatible with Rhein 83.

All abutments can be used with the same abutment screwdriver.

There are different shapes of abutments in the Mode two-piece implant series. Abbreviations and color codes indicating the compatibility of implant and abutment platforms are available on the packages.

Implant Platform	Abbreviation	Color Code	Implant Diameter
Narrow Platform	NP	Yellow	Ø 3.3 – Ø3.7

Regular Platform	RP	Blue	Ø4.1 – Ø4.7 – Ø 5.2
Wide Platform	WP	Green	Ø5.3- Ø6.0

9. Cleaning

Mode Medikal abutments and parts are delivered unsterile. Before placing the products in the patient's mouth, they must be disassembled, cleaned and sterilized.

Mode Medikal recommends the following for cleaning and sterilization of abutments before use.

1. Clean by brushing inside and outside with a brush under running water.

2. The pre-treated product can be cleaned by hand, ultrasonic cleaner, or an automatic cleaning method.

3. When selecting the automatic cleaning method, the appropriate detergent should be selected and the manufacturer's instructions should be followed.

10. Sterilization

Mode Medikal abutments and parts are delivered unsterile. Mode Medical recommends the following for sterilization of abutments prior to use:

Method	Conditions	Drying
Humidity temperature (autoclave) pre-vacuum	121° C 30 min	Local

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

11. Procedure

11.1. Clinical Procedure

Impression

1. Multi Base abutments are selected in accordance with implant location, angle and gingival height.
2. The abutment body is placed in the appropriate position to the implant. The abutment carrier is flexible and can be bent if necessary.
3. The abutment body is fixed to the implant with a torque ratchet. The abutment body should be torqued with a torque value of 25 Ncm.
4. The abutment carrier is removed by turning.

5. The abutment cover is placed on the abutment body and torqued with a standard hex wrench with a torque value of 25 Ncm.
6. It is recommended to check the fit of the abutment by radiography.
7. Implant impression is taken with open tray, closed tray or digital impression techniques.
8. If Geçici restoration will not be used, protective healing abutments are placed.
9. If a Geçici restoration is to be used, the Geçici restoration is placed on the abutments and the prosthetic screw is tightened by hand.

11.2. Laboratory Procedure

1. Combine the impression coping with the implant analogue.
2. Obtain the plaster working model by using soft gingival silicone around the analogues.
3. Produce the prosthetic infrastructure according to the preferred method. Infrastructure can be produced as casting, CAD/CAM or metal sintering.
4. Fabricate the final prosthesis according to the preferred laboratory technique.

11.3. Clinical Procedure

Restoration delivery

Screw Retained Fixed Restoration

1. Remove the healing abutment located in the relevant area of the patient's mouth in order to be able to try-in the prosthesis produced by the technician.
2. If the patient has a Geçici prosthesis with an occlusal screw, loosen the screws of the Geçici prosthesis with the help of a screwdriver and remove the Geçici prosthesis from the mouth.
3. Loosen the prosthetic screw with a screwdriver to remove the prosthesis on the abutment in the plaster model.
4. Remove the restoration from the model.
5. Place the prosthesis on the relevant implants on the patient in the same position as the model and tighten the prosthetic screw with the help of a screwdriver and a torque ratchet. The prosthetic screw should be torqued with a torque value of 15 Ncm.

Overdenture Restoration with Locator or Ball Attachment

1. Select the Multi Base abutment at the appropriate gingival height, place it in the mouth to the relevant implant and screw the abutment with 25 Ncm torque.
2. Insert the Multi Base Ball Cover or Multi Base Locator Cover and tighten with 25 Ncm torque value.
3. If the prosthesis and metal housing are to be processed in a laboratory environment, take an impression with the relevant impression coping and custom impression tray.
4. At the delivery of the prosthesis, select the appropriate retention plastic and place it in the metal housing.

12. Magnetic Resonance Imaging (MRI) Safety Information

Non-clinical testing has demonstrated that Titanium Dental Materials are MR Compatible.

A patient with these system parts in his body can safely be scanned in MR systems if the following conditions are met:

Only 1.5 and 3.0 Tesla static magnetic fields

Magnetic spatial drop field up to 970 Gauss/cm (9.7 T/m) or less

Average specific absorption rate (SAR) for the whole body 2 W/kg (Normal Use Mode)

Under the above-mentioned scanning conditions, after 15 minutes of continuous scanning, our products are expected to generate a maximum temperature rise of 3°C.

13. Disposal

Disposal should be done in an environmentally sustainable manner according to local regulations. Hazardous waste and cutting/drilling tools for contaminated devices should be disposed of in suitable containers that meet special technical requirements.

14. Disclaimer of Liability

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

Mode Medical 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, penal or other damages arising from or in connection with any errors in professional judgment or practice related to the use of Mode Medikal products; assumes no liability, express or implied.

15.Additional Information

Non Sterile products do not have a specified shelf life.

Life Time

The useful life of the products is determined as 10 years.

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

16. Symbols

ISO 15223-1: 2021 Symbols and Meanings Prepared According to the Standard

CE 2696	Notified Body Number	NON STERILE	Non Sterile
	Attention		
	Do Not Use For The Second Time		Barcode
	See User Manual		
REF	Referance number		

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
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

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

MODE MULTI UNIT ABUTMENT INSTRUCTIONS FOR USE

1. Product Description

The Mode Medikal prosthesis series consists of abutments in different types of diameters, lengths and platforms that are used in the restoration of Mode dental implants.They are available in a variety of shapes and sizes to suit the patient's needs. These instructions for use are valid for Mode Medikal's products specified in section 3.

Multi Unit abutments are designed as one piece.

Mode Medikal Multi Unit abutments are manufactured using Ti6Al4V-ELI (ASTM F 136) material.

		Narrow Platform		Regular Platform			Wide Platform	
	Platform/H (mm)	Ø3.3mm	Ø3.7mm	Ø4.1mm	Ø4.7mm	Ø5.2mm	Ø5.3mm	Ø6.0mm
Multi-Unit Abutment	H0,5	02.05.00.03		02.05.01.35			02.05.00.45	
	H1,0	02.05.01.03		02.05.02.35			02.05.01.45	
	H2,0	02.05.02.03		02.05.03.35			02.05.02.45	
	H3,0	02.05.03.03		02.05.04.35			02.05.03.45	
	H4,0	02.05.04.03		02.05.05.35			02.05.04.45	

2. Intended Use

Mode Medikal abutments are used for support in eliminating tooth deficiencies in order to fulfill chewing function. It is attached to the two-piece Mode Medikal implants with the help of screws and forms the basis for screw retained fixed implant restorations.

3. Target Patient Group And Intended User

Mode dental 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 may only be used by dentists.

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

4. Indications

They are attached directly to the intraosseous implants with the help of screws in order to support the implant-supported prostheses. They provide support for fixed prostheses in edentulous or partially edentulous dental arches.

5. Contraindications

Its use is contraindicated in individuals with hypersensitivity to titanium and titanium alloys.

For implant treatment contraindications, refer to the relevant Mode Medikal implant instructions for use.

6. Warnings and Precautions

The patient may swallow or aspirate the prosthetic parts. Care must be taken when working inside the mouth.

It is recommended that the clinician review the product-specific technique before performing the procedure. MODE MEDİCAL can provide technical information. Please contact MODE MEDICAL sales representative.

Mode Medikal abutments should only be used with Mode brand implants on the appropriate platform.

The Multi Unit abutment should be torqued to 25 Ncm. Torque values greater than 25 Ncm may damage the prosthetic parts. Torque values less than the recommended value may cause abutment loosening. The prosthetic screws used in the Multi Unit abutment series should be torqued with a torque value of 15 Ncm.

Abutments are disposable devices.

Mode Medikal products should be used according to the instructions for use provided by the manufacturer. It is the physician's responsibility to decide whether the device is suitable for use according to these instructions and for the individual patient situation.

For a successful implant treatment, it is important that the dentist and dental technician work in harmony.

In order for the implant treatment to be successful in the long term, it is important that the patient's routine controls and oral hygiene training are given after the treatment is completed.

7. Complications And Side Effects

The following reactions may occur during implant treatment:

- Hypersensitivity/allergic reactions
- Swallowing or aspiration of prosthetic components
- Peri-implantitis
- Implant component or prosthesis failure/fracture
- Poor aesthetic result
- Repetition of prosthetic treatment
- Minor bleeding

• Implant loss

8. Compatibility Information

All abutments and prosthetic screws can be used with the same screwdriver.

There are different shapes of abutments in the Mode two-piece implant series. Abbreviations and color codes indicating the compatibility of implant and abutment platforms are available on the packages.

Implant Platform	Abbreviation	Color Code	Implant Diameter
Narrow Platform	NP	Yellow	Ø 3.3 – Ø3.7
Regular Platform	RP	Blue	Ø4.1 – Ø4.7 – Ø 5.2
Wide Platform	WP	Green	Ø5.3- Ø6.0

9. Cleaning

Mode Medikal abutments and parts are delivered unsterile. Before placing the products in the patient's mouth, they must be disassembled, cleaned and sterilized.

Mode Medikal recommends the following for cleaning and sterilization of abutments before use.

1. Clean by brushing inside and outside with a brush under running water.

2. The pre-treated product can be cleaned by hand, ultrasonic cleaner, or an automatic cleaning method.

3. When selecting the automatic cleaning method, the appropriate detergent should be selected and the manufacturer's instructions should be followed.

10. Sterilization

Mode Medikal abutments and parts are delivered unsterile. Mode Medikal recommends the following for sterilization of abutments prior to use:

Method	Conditions	Drying
Humidity temperature (autoclave) pre-vacuum	121° C 30 min	Local

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

11. Procedure

11.1. Clinical Procedure

Impression

1. The Multi Unit abutment is selected in accordance with the gingival height.
2. The abutment is attached and tightened to the implant with a torque ratchet. The abutment should be torqued with a torque value of 25 Ncm.
3. It is recommended to check the fit of the abutment by radiography.
4. Implant impression is taken with open tray, closed tray or digital impression techniques.
5. If Geçici restoration will not be used, protective healing abutments are placed.
6. If a Geçici restoration is to be used, the Geçici restoration is placed on the abutments and the prosthetic screw is tightened by hand.

11.2. Laboratory Procedure

1. Combine the impression transfer with the implant analogue.

2. Obtain the plaster working model by using soft gingival silicone around the analogues.

3. Produce the prosthetic infrastructure according to the preferred method. Infrastructure can be produced as casting, CAD/CAM or metal sintering.

4. Fabricate the final prosthesis according to the preferred laboratory technique.

11.3. Clinical Procedure

Restoration Delivery

6. Remove the healing abutment located in the relevant area of the patient's mouth in order to be able to try-in the prosthesis produced by the technician.
7. If the patient has a Geçici prosthesis with an occlusal screw, loosen the screws of the Geçici prosthesis with the help of a screwdriver and remove the Geçici prosthesis from the mouth.
8. Loosen the prosthetic screw with a screwdriver to remove the prosthesis on the abutment in the plaster model.
9. Remove the restoration from the model.
10. Place the prosthesis on the relevant implants on the patient in the same position as the model and tighten the prosthetic screw with the help of a screwdriver and a torque ratchet. The prosthetic screw should be torqued with a torque value of 15 Ncm.

12. Magnetic Resonance Imaging (MRI) Safety Information

Non-clinical testing has demonstrated that Titanium Dental Materials are MR Compatible.

A patient with these system parts in his body can safely be scanned in MR systems if the following conditions are met:

Only 1.5 and 3.0 Tesla static magnetic fields

Magnetic spatial drop field up to 970 Gauss/cm (9.7 T/m) or less

Average specific absorption rate (SAR) for the whole body 2 W/kg (Normal Use Mode)

Under the above-mentioned scanning conditions, after 15 minutes of continuous scanning, our products are expected to generate a maximum temperature rise of 3°C.

13. Disposal

Disposal should be done in an environmentally sustainable manner according to local regulations. Hazardous waste and cutting/drilling tools for contaminated devices should be disposed of in suitable containers that meet special technical requirements.

14. Disclaimer of Liability

These products are part of a general concept and should only be used with the relevant original products in accordance with Mode Medikal's instructions and recommendations. The use of products 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, penal or other damages arising from or in connection with any errors in professional judgment or practice related to the use of Mode Medikal products; assumes no liability, express or implied.

15.Additional Information

Non Sterile products do not have a specified shelf life.

Life Time

The useful life of the products is determined as 10 years.

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

16. Symbols

ISO 15223-1: 2021 Symbols and Meanings Prepared According to the Standard

CE 2696	Notified Body Number	NON STERILE	Non Sterile
	Attention		
	Do Not Use For The Second Time		Barcode
	See User Manual		
REF	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
	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

MODE CEMENT-RETAINED ABUTMENT INSTRUCTIONS FOR USE

1. Product Description

The Mode Medikal prosthesis series consists of abutments in different types of diameters, lengths and platforms that are used in the restoration of Mode dental implants. They are available in a variety of shapes and sizes to suit the patient's needs. These instructions for use are valid for Mode Medikal's products specified in section 3.

Mode Medikal abutments are manufactured using Ti6Al4V-ELI (ASTM F 136) material.





		Narrow Platform		Regular Platform			Wide Platform	
	Platform/H (mm)	Ø3.3mm	Ø3.7mm	Ø4.1mm	Ø4.7mm	Ø5.2mm	Ø5.3mm	Ø6.0mm
Profile Abutment	H1,0	02.01.01.03		02.01.01.35			02.01.01.45	
	H2,0	02.01.02.03		02.01.02.35			02.01.02.45	
	H3,0	02.01.03.03		02.01.03.35			02.01.03.45	
Esthetic Abutment	H1,0	02.13.01.03		02.13.01.35			02.13.01.45	
	H2,0	02.13.02.03		02.13.02.35			02.13.02.45	
	H3,0	02.13.03.03		02.13.03.35			02.13.03.45	
15° Esthetic Abutment	H1,0	02.08.01.03		02.08.01.35			02.08.01.45	
	H2,0	02.08.02.03		02.08.02.35			02.08.02.45	
	H3,0	02.08.03.03		02.08.03.35			02.08.03.45	
	H4,0	02.08.04.03		02.08.04.35			02.08.04.45	
25° Esthetic Abutment	H1,0	02.09.01.03		02.09.01.35			02.09.01.45	
	H2,0	02.09.02.03		02.09.02.35			02.09.02.45	
	H3,0	02.09.03.03		02.09.03.35			02.09.03.45	
	H4,0	02.09.04.03		02.09.04.35			02.09.04.45	
Premill Abutment		13.01.00.03		13.01.00.35			13.01.00.45	

		Narrow Platform		Regular Platform			Wide Platform	
	Platform/H (mm)	Ø3.3mm	Ø3.7mm	Ø4.1mm	Ø4.7mm	Ø5.2mm	Ø5.3mm	Ø6.0mm
	Abutment Diameter	Ø3,5mm	Ø4,0mm	Ø4,5mm		Ø5,0mm	Ø5,0mm	Ø6.0mm
Direct Abutment	H0,5	02.03.01.03	02.03.06.03	02.03.06.35		02.03.11.35	02.03.01.45	02.03.06.45
	H1,0	02.03.02.03	02.03.07.03	02.03.07.35		02.03.12.35	02.03.02.45	02.03.07.45
	H2,0	02.03.03.03	02.03.08.03	02.03.08.35		02.03.13.35	02.03.03.45	02.03.08.45
	H3,0	02.03.04.03	02.03.09.03	02.03.09.35		02.03.14.35	02.03.04.45	02.03.09.45

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

	H4,0	02.03.05.03	02.03.10.03	02.03.10.35	02.03.15.35	02.03.05.45	02.03.10.45

2. Intended Use

Mode Medikal abutments are used to support fixed implant supported prostheses in order to fulfill the chewing function and to eliminate tooth deficiencies. It is attached to the two-piece Mode Medikal implants with the help of abutment screws and forms a basis for cement retained prosthetic structures such as crowns and bridges.

3. Target Patient Group And İntended User

Mode dental 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 may only be used by dentists.

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

4. Indications

They are attached directly to the intraosseous implants with the help of abutment screws in order to support the implant-supported cement retained fixed prostheses.

		Indications	
Abutment type	**Retention**	**Crown**	**Bridge**
Profile Abutment	Cemented	✓	✓
Direct Abutment	Cemented	✓	✓
Esthetic Abutment	Cemented	✓	✓
15°/25° Esthetic Abutment	Cemented	✓	✓
Premill Abutment	Cemented	✓	✓

5. Contraindications

Its use is contraindicated in individuals with hypersensitivity to titanium and titanium alloys.

For implant treatment contraindications, refer to the relevant Mode Medikal implant instructions for use.

6. Warnings and Precautions

The patient may swallow or aspirate the prosthetic parts. Care must be taken when working inside the mouth.

It is recommended that the clinician review the product-specific technique before performing the procedure. MODE MEDİCAL can provide technical information. Please contact MODE MEDICAL sales representative.

Mode Medikal abutments should only be used with Mode brand implants on the appropriate platform.

Before the delivery of the prosthesis, the abutment placed in the patient's mouth should be torqued with a torque value of 35 Ncm. Torque values greater than 35 Ncm may damage the prosthetic parts. Torque values less than the recommended value may cause abutment loosening.

Abutments are disposable devices.

Mode Medikal products should be used according to the instructions for use provided by the manufacturer. It is the physician's responsibility to decide whether the device is suitable for use according to these instructions and for the individual patient situation.

For a successful implant treatment, it is important that the dentist and dental technician work in harmony.

In order for the implant treatment to be successful in the long term, it is important that the patient's routine controls and oral hygiene training are given after the treatment is completed.

7. Complications And Side Effects

The following reactions may occur during implant treatment:

- Hypersensitivity/allergic reactions
- Swallowing or aspiration of prosthetic components
- Peri-implantitis
- Implant component or prosthesis failure/fracture
- Poor aesthetic result
- Repetition of prosthetic treatment
- Minor bleeding
- Implant loss

8. Compatibility Information

All abutments can be used with the same abutment screwdriver.

There are different shapes of abutments in the Mode two-piece implant series. Abbreviations and color codes indicating the compatibility of implant and abutment platforms are available on the packages.

Implant Platform	Abbreviation	Color Code	Implant Diameter
Narrow Platform	NP	Yellow	Ø 3.3 – Ø3.7
Regular Platform	RP	Blue	Ø4.1 – Ø4.7 – Ø 5.2
Wide Platform	WP	Green	Ø5.3- Ø6.0

9. Cleaning

Mode Medikal abutments and parts are delivered unsterile. Before placing the products in the patient's mouth, they must be disassembled, cleaned and sterilized.

Mode Medikal recommends the following for cleaning and sterilization of abutments before use.

1. Clean by brushing inside and outside with a brush under running water.
2. The pre-treated product can be cleaned by hand, ultrasonic cleaner, or an automatic cleaning method.
3. When selecting the automatic cleaning method, the appropriate detergent should be selected and the manufacturer's instructions should be followed.

10. Sterilization

Mode Medikal abutments and parts are delivered unsterile. Mode Medikal recommends the following for sterilization of abutments prior to use:

Method	Conditions	Drying
Humidity temperature (autoclave) pre-vacuum	121° C 30 min	Local

Caution: Use devices immediately after sterilization. Do not store sterilizedk devices.

11. Procedure

11.1. Laboratory Procedure

Traditional Workflow in Implant Supported Fixed Dentures

Note: Screw the abutment to the analog during all laboratory procedures to preserve the abutment's attachment to the implant.

1. Combine the impression coping with the implant analogue.
2. Obtain the plaster working model by using soft gingival silicone around the analogues.
3. Determine the abutment gingival height according to the amount of gingiva in the relevant region in the plaster model obtained.
4. Select the abutment suitable for the diameter of the dental implant used.
5. Connect the selected abutment with suitable diameter and gingival height to the analog in the plaster model with the help of screws.

6. Simply tighten the abutment screw by hand.
7. Plan your prosthesis in accordance with the selected abutment type and fabricate it with the preferred fabrication method.

Digital Workflow in Implant Supported Fixed Dentures

1. Digital prosthetic workflow can be carried out by using STL data obtained with intraoral scanners or by obtaining STL data of impressions taken with traditional methods with a desktop scanner.
2. The use of software that includes Mode implants in their library for prosthesis design and production on the digital platform will ensure that the internal geometry of the abutment and restoration connection is matching (eg Exocad DentalCAD).

11.2. Clinical Procedure for Implant Supported Fixed Prostheses

1. For the try-in of the prosthesis produced by the technician, remove the healing abutment located in the relevant area of the patient's mouth with the help of a screwdriver.
2. Loosen the abutment screw with a screwdriver to remove from the model.
3. Remove the abutment from the model.
4. Place the abutment on the patient's implant in the same position as the model and tighten the screw with the help of a screwdriver.
5. Perform the prosthesis try-in.
6. After try-in, remove the prosthesis from the patient's mouth and loosen the abutment screw with the help of a screwdriver.
7. Place the abutment on the corresponding analog on the model and tighten the abutment screw with the help of the screwdriver.
8. Before cementation of the prosthesis, tighten the screw of the abutment placed in the relevant area of the patient's mouth with a torque value of 35 Ncm.
9. It is recommended to check the fit of the abutment by radiography.
10. Cover the screw hole with a suitable material and cement the prosthesis with the preferred luting cement.

Warning: After the abutment screw is torqued, the abutment screw hole should be closed with suitable materials. Correct closure of the screw hole makes it possible to access the screw in cases where the abutment needs to be separated from the implant.

Abutment Modification

When necessary, abutments can be modified according to the patient's anatomy by the technician in the dental laboratory or by the dentist in the clinic.

12. Magnetic Resonance Imaging (MRI) Safety Information

Non-clinical testing has demonstrated that Titanium Dental Materials are MR Compatible.

A patient with these system parts in his body can safely be scanned in MR systems if the following conditions are met:

Only 1.5 and 3.0 Tesla static magnetic fields

Magnetic spatial drop field up to 970 Gauss/cm (9.7 T/m) or less

Average specific absorption rate (SAR) for the whole body 2 W/kg (Normal Use Mode)

Under the above-mentioned scanning conditions, after 15 minutes of continuous scanning, our products are expected to generate a maximum temperature rise of 3°C.

13. Disposal

Disposal should be done in an environmentally sustainable manner according to local regulations. Hazardous waste and cutting/drilling tools for contaminated devices should be disposed of in suitable containers that meet special technical requirements.

14. Disclaimer of Liability

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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, penal or other damages arising from or in connection with any errors in professional judgment or practice related to the use of Mode Medikal products; assumes no liability, express or implied.

15.Additional Information

Non Sterile products do not have a specified shelf life.

Life Time

The useful life of the products is determined as 10 years.

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

16. Symbols

ISO 15223-1: 2021 Symbols and Meanings Prepared According to the Standard

CE 2696	Notified Body Number	NON STERILE	Non Sterile
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REF	Referance number		

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)*

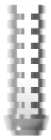
Yenidoğan Mah. Abdi İpekçi Cad. No:58 Bayrampaşa,İstanbul/TURKEY

MODE TEMPORARY ABUTMENT INSTRUCTIONS FOR USE

1. Product Description

The Mode Medikal prosthesis series consists of abutments in different types of diameters, lengths and platforms that are used in the restoration of Mode dental implants.They are available in a variety of shapes and sizes to suit the patient's needs. These instructions for use are valid for Mode Medikal's products specified in section 3.

Mode Medikal Temporary abutments are manufactured using Ti6Al4V-ELI (ASTM F 136) material.



		Narrow Platform		Regular Platform			Wide Platform	
	Platform/H (mm)	Ø3.3mm	Ø3.7mm	Ø4.1mm	Ø4.7mm	Ø5.2mm	Ø5.3mm	Ø6.0mm
Multi Temporary Abutment		33.00.00.04						
Immediate Temporary Abutment	H1,5	02.18.03.15		02.18.35.15			-	
	H3,0	02.18.03.03		02.18.35.03			-	
Temporary Abutment Non-Engage	H1,5	02.20.03.15		02.20.35.15			02.20.45.15	
	H3,0	-					02.20.45.30	
Temporary Abutment Engage	H1,5	02.19.03.15		02.19.35.15			02.19.45.15	
	H3,0	-					02.19.45.30	

2. Intended Use

Mode Medikal Temporary abutments are used to support Temporary prostheses to be used as an auxiliary tool in the treatment of tooth deficiencies. It attaches to the two-piece Mode Medikal implants with the help of screws and forms a basis for Temporary prosthetic structures such as crowns and bridges.

3. Target Patient Group And Intended User

Mode dental 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 may only be used by dentists.

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

3. Indications

They are attached directly to the intra-osseous implants with the help of screws in order to support the Temporary prosthesis on the implant. Temporary abutments are used as abutments in Temporary fixed prostheses.

	Indications	
Abutment type	**Crown**	**Bridge**
Multi Temporary Abutment		✓
Immediate Temporary Abutment	✓	✓
Temporary Abutment Engage	✓	
Temporary Abutment Non-Engage		✓

5. Contraindications

Its use is contraindicated in individuals with hypersensitivity to titanium and titanium alloys.

For implant treatment contraindications, refer to the relevant Mode Medikal implant instructions for use.

It is contraindicated in patients with parafunctional habits and in individuals who do not have sufficient implant number and diameter to meet the occlusal forces.

6. Warnings and Precautions

The patient may swallow or aspirate the prosthetic parts. Care must be taken when working inside the mouth.

It is recommended that the clinician review the product-specific technique before performing the procedure. MODE MEDİCAL can provide technical information. Please contact MODE MEDICAL sales representative.

Mode Medikal abutments should only be used with Mode brand implants on the appropriate platform.

Before the delivery of the prosthesis, Immediate Temporary Abutment , Temporary Abutment Engage, Temporary Abutment Non-Engage screw should be torqued with a torque value of 35 Ncm. Torque values greater than 35 Ncm may damage the prosthetic parts. The Multi Temporary abutment should be torqued with a torque value of 15 Ncm. Torque values less than the recommended value may cause abutment loosening.

Abutments are disposable devices.

Mode Medikal products should be used according to the instructions for use provided by the manufacturer. It is the physician's responsibility to decide whether the device is suitable for use according to these instructions and for the individual patient situation.

For a successful implant treatment, it is important that the dentist and dental technician work in harmony.

In order for the implant treatment to be successful in the long term, it is important that the patient's routine controls and oral hygiene training are given after the treatment is completed.

7. Complications and side effects

The following reactions may occur during implant treatment:

- Hypersensitivity/allergic reactions
- Swallowing or aspiration of prosthetic components
- Peri-implantitis
- Implant component or prosthesis failure/fracture
- Poor aesthetic result
- Repetition of prosthetic treatment
- Minor bleeding
- Implant loss

8. Compatibility Information

All abutments can be used with the same abutment screwdriver.

There are different shapes of abutments in the Mode two-piece implant series. Abbreviations and color codes indicating the compatibility of implant and abutment platforms are available on the packages.

Implant Platform	Abbreviation	Color Code	Implant Diameter
Narrow Platform	NP	Yellow	Ø 3.3 – Ø3.7
Regular Platform	RP	Blue	Ø4.1 – Ø4.7 – Ø 5.2
Wide Platform	WP	Green	Ø5.3- Ø6.0

9. Cleaning

Mode Medikal abutments and parts are delivered unsterile. Before placing the products in the patient's mouth, they must be disassembled, cleaned and sterilized.

Mode Medikal recommends the following for cleaning and sterilization of abutments before use.

4. Clean by brushing inside and outside with a brush under running water.
5. The pre-treated product can be cleaned by hand, ultrasonic cleaner, or an automatic cleaning method.
6. When selecting the automatic cleaning method, the appropriate detergent should be selected and the manufacturer's instructions should be followed.

10. Sterilization

Mode Medikal abutments and parts are delivered unsterile. Mode Medikal recommends the following for sterilization of abutments prior to use:

Method	Conditions	Drying
Humidity temperature (autoclave) pre-vacuum	121° C 30 min	Local

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

11. Procedure

1. Select the appropriate Temporary abutment for the planned Temporary prosthesis and connect it to the corresponding implant.
2. Check occlusal clearance and prepare out of the mouth for modification if necessary.
3. If preparation has been done, clean as specified in the cleaning and sterilization sections before inserting into the mouth and tighten the screw by hand.
4. Cement the clinical or laboratory prepared Temporary restoration to the abutment with a suitable material.
5. Drill a hole in the restoration for screw access. Loosen the screw with screwdriver and remove the restoration.
6. Finish and polish the restoration. Make the necessary occlusal adjustments.
7. Place the completed restoration in the mouth and torque the abutment screw with a ratchet to the appropriate torque.
8. After the abutment screw is torqued, close the abutment screw hole with suitable materials.

12. Magnetic Resonance Imaging (MRI) Safety Information

Non-clinical testing has demonstrated that Titanium Dental Materials are MR Compatible.

A patient with these system parts in his body can safely be scanned in MR systems if the following conditions are met:

Only 1.5 and 3.0 Tesla static magnetic fields

Magnetic spatial drop field up to 970 Gauss/cm (9.7 T/m) or less

Average specific absorption rate (SAR) for the whole body 2 W/kg (Normal Use Mode)

Under the above-mentioned scanning conditions, after 15 minutes of continuous scanning, our products are expected to generate a maximum temperature rise of 3°C.

13. Disposal

Disposal should be done in an environmentally sustainable manner according to local regulations. Hazardous waste and cutting/drilling tools for contaminated devices should be disposed of in suitable containers that meet special technical requirements.

14. Disclaimer of Liability

These products are part of a general concept and should only be used with the relevant original products in accordance with Mode Medikal's instructions and recommendations. The use of products 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, penal or other damages arising from or in connection with any errors in professional judgment or practice related to the use of Mode Medikal products; assumes no liability, express or implied.

15.Additional Information

Non Sterile products do not have a specified shelf life.

Life Time

The useful life of the products is determined as 10 years.

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

16. Symbols

ISO 15223-1: 2021 Symbols and Meanings Prepared According to the Standard

CE 2696	Notified Body Number	NON STERILE	Non Sterile
	Attention		
	Do Not Use For The Second Time		Barcode
	See User Manual		
REF	Referance number		

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
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 TI-BASE ABUTMENT INSTRUCTIONS FOR USE

1. Product Description

The Mode Medikal prosthesis series consists of abutments in different types of diameters, lengths and platforms that are used in the restoration of Mode dental implants. They are available in a variety of shapes and sizes to suit the patient's needs. These instructions for use are valid for Mode Medikal's products specified in section 3.

Mode Medikal Ti-base abutments are manufactured using Ti6Al4V-ELI (ASTM F 136) material.

		Narrow Platform		Regular Platform			Wide Platform	
	Platform/H (mm)	Ø3.3mm	Ø3.7mm	Ø4.1mm	Ø4.7mm	Ø5.2mm	Ø5.3mm	Ø6.0mm
Ti-Base Cerec Abutment	H0,7	17.00.01.03		17.00.01.35			17.00.01.45	
	H2,5	17.00.02.03		17.00.02.35			17.00.02.45	
Ti-Base Engaged (Digital) Abutment	H0,7	16.00.00.10		16.00.00.11			16.00.00.12	
	H2,5	16.00.00.13		16.00.00.14			16.00.00.15	
Ti-Base Non-Engaged (Digital) Abutment	H0,7	16.00.00.04		16.00.00.05			16.00.00.06	
	H2,5	16.00.00.07		16.00.00.08			16.00.00.09	

2. Intended Use

Mode Medikal Ti-base abutments are used to support fixed implant supported prostheses in order to fulfill the chewing function and to eliminate tooth deficiencies. It is attached to the two-piece Mode Medikal implants with the help of abutment screws and forms a basis for screw retained prosthetic structures such as crowns and bridges.

3. Target Patient Group And Intended User

Mode dental 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 may only be used by dentists.

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

4. Indications

They are attached directly to the intraosseous implants with the help of abutment screws in order to support the implant-supported cement or screw retained fixed prostheses.

Mode Medikal Ti-base abutments are titanium bases that can also be used in personal abutment construction.

		Indications	
Abutment type	**Retention**	**Crown**	**Bridge**
Ti-Base Cerec Abutment	Screw	✓	
Ti-Base Engaged (Digital) Abutment	Screw	✓	
Ti-Base Non-Engaged (Digital) Abutment	Screw		✓

5. Contraindications

Its use is contraindicated in individuals with hypersensitivity to titanium and titanium alloys.

For implant treatment contraindications, refer to the relevant Mode Medikal implant instructions for use.

6. Warnings and Precautions

The patient may swallow or aspirate the prosthetic parts. Care must be taken when working inside the mouth.

Mode Medical abutments should only be used with Mode brand implants on the appropriate platform.

It is recommended that the clinician review the product-specific technique before performing the procedure. MODE MEDİCAL can provide technical information. Please contact MODE MEDICAL sales representative.

Before the delivery of the prosthesis, the abutment placed in the patient's mouth should be torqued with a torque value of 35 Ncm. Torque values greater than 35 Ncm may damage the prosthetic parts. Torque values less than the recommended value may cause abutment loosening.

Abutments are disposable devices.

Mode Medikal products should be used according to the instructions for use provided by the manufacturer. It is the physician's responsibility to decide whether the device is suitable for use according to these instructions and for the individual patient situation.

For a successful implant treatment, it is important that the dentist and dental technician work in harmony.

In order for the implant treatment to be successful in the long term, it is important that the patient's routine controls and oral hygiene training are given after the treatment is completed.

7. Complications And Side Effects

The following reactions may occur during implant treatment:

- Hypersensitivity/allergic reactions
- Swallowing or aspiration of prosthetic components
- Peri-implantitis
- Implant component or prosthesis failure/fracture
- Poor aesthetic result
- Repetition of prosthetic treatment
- Minor bleeding
- Implant loss

8. Compatibility Information

All abutments can be used with the same abutment screwdriver.

There are different shapes of abutments in the Mode two-piece implant series. Abbreviations and color codes indicating the compatibility of implant and abutment platforms are available on the packages.

Implant Platform	Abbreviation	Color Code	Implant Diameter
Narrow Platform	NP	Yellow	Ø 3.3 – Ø3.7
Regular Platform	RP	Blue	Ø4.1 – Ø4.7 – Ø 5.2
Wide Platform	WP	Green	Ø5.3- Ø6.0

9. Cleaning

Mode Medikal abutments and parts are delivered unsterile. Before placing the products in the patient's mouth, they must be disassembled, cleaned and sterilized.

Mode Medikal recommends the following for cleaning and sterilization of abutments before use.

7. Clean by brushing inside and outside with a brush under running water.
8. The pre-treated product can be cleaned by hand, ultrasonic cleaner, or an automatic cleaning method.
9. When selecting the automatic cleaning method, the appropriate detergent should be selected and the manufacturer's instructions should be followed.

10. Sterilization

Mode Medikal abutments and parts are delivered unsterile. Mode Medikal recommends the following for sterilization of abutments prior to use:

Method	Conditions	Drying
Humidity temperature (autoclave) pre-vacuum	121° C 30 min	Local

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

11. Procedure

11.1. Laboratory Procedure

Note: Screw the abutment to the analog during all laboratory procedures to preserve the abutment's attachment to the implant.

1. Combine the impression coping with the implant analogue.

2. Obtain the plaster working model by using soft gingival silicone around the analogues.

3. Determine the abutment gingival height according to the amount of gingiva in the relevant region in the plaster model obtained.

4. Select the abutment suitable for the diameter of the dental implant used.

5. Connect the selected abutment with suitable diameter and gingival height to the analog in the plaster model with the help of screws.

6. Simply tighten the abutment screw by hand.

7. Plan your prosthesis with screw or cement retained in accordance with the selected abutment type and produce it with the preferred production method.

8. Place the fabricated restoration to the analog before cementing it to the Ti-base abutment.

9. Seal the screw channel with wax.

10. Apply a self-curing resin cement to the abutment. Use the resin cement in accordance with the manufacturer's instructions.

11. Place the restoration on the Ti-base abutment.

12. Immediately clean any cement overflowing from the abutment. Polish the joint after the cement has hardened.

Digital Workflow in Implant Supported Fixed Dentures

1. Digital prosthetic workflow can be carried out by using STL data obtained with intraoral scanners or by obtaining STL data of impressions taken with traditional methods with a desktop scanner.
2. The use of software that includes Mode implants in their library for prosthesis design and production on the digital platform will ensure that the internal geometry of the abutment and restoration connection is matching (eg Exocad DentalCAD).

11.2. Clinical Procedure for Implant Supported Fixed Prostheses

11. For the try-in of the prosthesis produced by the technician, remove the healing abutment located in the relevant area of the patient's mouth with the help of a screwdriver.
12. Loosen the abutment screw with a screwdriver to remove from the model.
13. Remove the abutment from the model.
14. Place the abutment on the patient's implant in the same position as the model and tighten the screw with the help of a screwdriver.
15. Perform the prosthesis try-in.
16. After try-in, remove the prosthesis from the patient's mouth and loosen the abutment screw with the help of a screwdriver.
17. Place the abutment on the corresponding analog on the model and tighten the abutment screw with the help of the screwdriver.
18. Before cementation of the prosthesis, tighten the screw of the abutment placed in the relevant area of the patient's mouth with a torque value of 35 Ncm.
19. It is recommended to check the fit of the abutment by radiography.
20. Cover the screw hole with a suitable material and cement the prosthesis with the preferred luting cement.

Warning: After the abutment screw is torqued, the abutment screw hole should be closed with suitable materials. Correct closure of the screw hole makes it possible to access the screw in cases where the abutment needs to be separated from the implant.

12. Magnetic Resonance Imaging (MRI) Safety Information

Non-clinical testing has demonstrated that Titanium Dental Materials are MR Compatible.

A patient with these system parts in his body can safely be scanned in MR systems if the following conditions are met:

Only 1.5 and 3.0 Tesla static magnetic fields

Magnetic spatial drop field up to 970 Gauss/cm (9.7 T/m) or less

Average specific absorption rate (SAR) for the whole body 2 W/kg (Normal Use Mode)

Under the above-mentioned scanning conditions, after 15 minutes of continuous scanning, our products are expected to generate a maximum temperature rise of 3°C.

13. Disposal

Disposal should be done in an environmentally sustainable manner according to local regulations. Hazardous waste and cutting/drilling tools for contaminated devices should be disposed of in suitable containers that meet special technical requirements.

14. Disclaimer of Liability

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15.Additional Information

Non Sterile products do not have a specified shelf life.

Life Time

The useful life of the products is determined as 10 years.

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

16. Symbols

ISO 15223-1: 2021 Symbols and Meanings Prepared According to the Standard

CE **2696**	Notified Body Number	NON STERILE	Non Sterile
	Attention		
	Do Not Use For The Second Time		Barcode
	See User Manual		
REF	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
	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

Mode Abutment and Prosthetic Screws

1. Product Description

Mode abutment and prosthetic screws are part of Mode Dental Implant Systems, which is an integrated system with Mode dental implants and related abutments, cover screws, healing abutments, surgical and prosthetic parts and instruments; It is produced as a single piece using Ti6Al4V-ELI (ASTM F 136).

Mode abutment screws are implant screws that allow abutments to be fixed to implants.

Mode prosthetic screws are implant screws that enable the fixation of patient-specific Geçici or permanent crowns to the relevant abutments.

The abutments that Mode abutments and prosthetic screws are compatible with are shown in Table 1 below.

Table 1

Screw	Abutment	Screwdriver
Abutment Screws	Direct Abutment	Mode Screwdriver
	Esthetic Abutment	
	Esthetic Abutment 15º	
	Esthetic Abutment 25º	
	Profile Abutment	
	Ti-base Non-Engaged Abutment	
	Ti-base Engaged Abutment	
	Ti-base Cerec Abutment	
	Premill Abutment	
Prosthetic Screws	Multi Unit Abutment	

	Multi Base Abutment	

PROSTHETIC SCREW	
Platform	NP/RP/WP
REF NO	06.01.01.03

ABUTMENT SCREW		
Platform	NP/RP	WP
REF NO	06.01.01.01	06.01.01.02

2. Intended Use

Mode abutment screws are intended to be used to fix Mode abutments to corresponding Mode dental implants.

Mode prosthetic screws are intended to be used to fix patient-specific Geçici or permanent crowns to the relevant abutments.

3. Target Patient Group And Intended User

Mode abutment and prosthetic screws are intended to be use with Mode dental implants and related abutments in patients with complete or partial edentulism who have completed growth and development and do not have the conditions specified in the contraindications.

Mode abutment and prosthetic screws 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 abutment screws are indicated to be used to fix the abutments which are related to the prostheses to be produced for the functional, phonetic and aesthetic rehabilitation of the upper and/or lower jaw in totally or partially edentulous patients, to the placed Mode dental implants.

Mode prosthetic screws are indicated for use to fix prostheses to Mode abutments designed 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 abutment and prosthetic screws is contraindicated in the presence of the following conditions;

– Patients medically unfit for implant treatment

– Allergy or hypersensitivity to Ti6Al4V-ELI (ASTM F 136) materials

Note: For contraindications to implant treatment, refer to the relevant Mode implant instructions for use; For the contraindications of the abutments where the screws will be used, refer to the relevant Mode abutment instructions 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.

It is recommended that the clinician review the product-specific technique before performing the procedure. MODE MEDİCAL can provide technical information. Please contact MODE MEDICAL sales representative.

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

! Mode abutment and prosthetic screws should only be used in prosthesis stages with their own system elements and compatible abutments. The use of products with different brands and materials may lead to mechanical problems, failure of implants, tissue damage or aesthetic dissatisfaction.

! Mode abutment and prosthetic screws are packaged non-sterile. It is the clinician's responsibility to ensure sterility prior to use.

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

! Mode abutments and prosthetic screws are for single use and should not be reused.

! The recommended torque value is 25 Ncm for abutment screws and 15 Ncm for prosthetic screws.

! 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 abutment and prosthetic 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.

Post-operative

! For the long-term success of treatments with the Mode dental implant system, 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 abutment and prosthetic screws.

- Local pain
- Micro hemorrhages
- Swelling
- Local inflammations
- Gingival injuries
- 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
- Screw fracture
- Screw loosening
- Component or prosthesis failure/fracture

8. Procedure

I. Use the implant screw suitable for the abutment you selected for treatment. (See Table 1)

II. Insert the Mode implant screw into the Mode screwdriver.

III. First, tighten the screw you placed on the abutment by hand.

IV. The Mode torque ratchet and Mode screwdriver should be used to fix the implant screws.

CAUTION: When using Mode abutment and prosthetic screws, it is recommended to ensure that the screwdriver is firmly seated on the screws to avoid aspiration/swallowing of the screws.

NOTE: The recommended torque value for tightening is 25 Ncm for abutment screws and 15 Ncm for prosthetic screws.

CAUTION: Torque of Mode abutment and prosthetic screws higher than the recommended torque values may cause screw fractures, and under-torque may cause loosening of the screws.

9. Compatibility Information

Mode abutment and prosthetic 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 abutments and prosthetic screws can only be used with the corresponding abutments.

10. MRI Safety Information

Mode abutment and prosthetic 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 abutment and prosthetic screws are packaged non-sterile. It is the clinician's responsibility to ensure sterility prior to use.

Sterile use is essential against the risk of contamination. Never use potentially contaminated components. Contamination can cause infections in the user and patient.

Previously used or non-sterile abutments and prosthetic screws should not be used under any circumstances.

Mode abutments and prosthetic screws can be cleaned manually or in an automatic washing unit. After cleaning, each device should be sealed and sterilized by placing it in a sterilization bag separately.

Mode Medikal recommends the following for cleaning abutment and prosthetic screws prior to use.

I. Clean under running water by brushing inside and outside with a brush.

II. The pre-treated product can be cleaned by hand, with ultrasonic assistance, or by an automatic cleaning method.

III. When choosing the automatic cleaning method, the appropriate detergent should be selected and the manufacturer's instructions should be followed.

Mode Medikal recommends the following for sterilization of abutment and prosthetic screws prior to use:

Method	Conditions	Drying
Humidity temperature (autoclave) Pre-vacuum	121°C 30 min.	Local

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

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.

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 abutment and prosthetic 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.

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.

16.Additional Information

Non Sterile products do not have a specified shelf life.

Life Time

The useful life of the products is determined as 10 years.

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

17.Symbols

ISO 15223-1: 2021 Symbols and Meanings Prepared According to the Standard

CE 2696	Notified Body Number	NON STERILE	Non Sterile
	Attention		
	Do Not Use For The Second Time		Barcode
	See User Manual		
REF	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
	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 HEALİNG ABUTMENTS

NP Healing Abutments

RP Healing Abutments

WP Healing Abutments

1. Product description

Mode healing abutments are part of Mode Dental Implant Systems, which is an integrated system with Mode dental implants and related abutments, cover screws, surgical and prosthetic parts and instruments; It is produced as a single piece using Ti6Al4V-ELI (ASTM F 136) material.

Mode healing abutments are components that support gingival healing on the implant, provide soft tissue contouring, and are directly connected to endoosseous dental implants.

Mode healing abutments 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	Dar Platform (NP)	Normal Platform (RP)	Geniş Platform (WP)
Level İmplant	NP Healing Abutments	RP Healing Abutments	WP Healing Abutments
Rapid İmplant			
Bone İmplant			
Tissue İmplant			
Short İmplant			
Shorter İmplant			

Diameter and length options of Mode healing abutments are shown in the table below.

Platform	NP	NP	RP	RP	RP	WP	WP	WP
Length (L)	Ø4	Ø4.5	Ø4.5	Ø5	Ø5.5	Ø5.5	Ø6	Ø6.5
2 mm	04.04.02.03	04.45.02.03	04.45.02.35	04.05.02.35	04.55.02.35	04.55.02.45	04.06.02.45	04.65.02.45
4 mm	04.04.04.03	04.45.04.03	04.45.04.35	04.05.04.35	04.55.04.35	04.55.04.45	04.06.04.45	04.65.04.45
6 mm	04.04.06.03	04.45.06.03	04.45.06.35	04.05.06.35	04.55.06.35	04.55.06.45	04.06.06.45	04.65.06.45

2. Intended Use

They are intended to used for supporting gingival healing on the implant and providing soft tissue contouring by placing them on the corresponding Mode dental implants.

3. Target Patient Group And Intended User

Mode healing abutments 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 healing abutments 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 healing abutments 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 healing abutments 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 therapy 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.

It is recommended that the clinician review the product-specific technique before performing the procedure. MODE MEDİCAL can provide technical information. Please contact MODE MEDICAL sales representative.

! 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 healing abutments 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 healing abutments should be used only during the healing process. They cannot be used to support a restoration.

! Mode healing abutments are packaged non-sterile. It is the clinician's responsibility to ensure sterility prior to use.

! 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 healing abutments, 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.

Post-operative

! For the long-term success of treatments with the Mode dental implant system, 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 healing abutments.

- Local pain
- Micro hemorrhages
- Swelling
- Local inflammations
- Gingival injuries
- 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 soft tissue on the healing abutments during the healing process
- Calculus formation on the healing abutments

8. Procedure

I. Select the appropriate healing abutment for the implant platform and gingival height.

II. Take the Mode healing abutment with the Mode screwdriver.

III. Connect the healing cap to the implant you placed and tighten it by hand.

IV. To remove the Mode healing abutment, loosen it by hand using the screwdriver.

CAUTION: When using Mode healing abutments, it is recommended to ensure that the screwdriver is firmly seated in the head to avoid the risk of aspiration/swallowing of the head.

NOTE: The recommended tightening torque is 5-10 Ncm manually by hand.

9. Compatibility Information

Mode healing abutments 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 healing abutments can only be used with those with the corresponding connection on all Mode dental implants.

11. MRI Safety Information

Mode healing abutments 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 healing abutments are packaged non-sterile. It is the clinician's responsibility to ensure sterility prior to use.

Sterile use is essential against the risk of contamination. Never use potentially contaminated components. Contamination can cause infections in the user and patient.

Previously used or non-sterile healing abutments should not be used under any circumstances.

Mode healing abutments can be cleaned manually or in an automatic washing unit. After cleaning, each device should be sealed and sterilized by placing it in a sterilization bag separately.

Mode Medikal recommends the following for cleaning healing abutments prior to use.

I. Clean under running water by brushing inside and outside with a brush.

II. The pre-treated product can be cleaned by hand, with ultrasonic assistance, or by an automatic cleaning method.

III. When choosing the automatic cleaning method, the appropriate detergent should be selected and the manufacturer's instructions should be followed.

Mode Medikal recommends the following for sterilization of healing abutments prior to use:

Method	Conditions	Drying
Humidity temperature (autoclave) Pre-vacuum	121°C 30 min.	Local

Caution: Use devices immediately after sterilization. Do not store sterilized devices.

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.

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 healing abutments.

Patients should also be informed about MR safety information.

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

Non Sterile products do not have a specified shelf life.

Life Time

The useful life of the products is determined as 10 years.

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

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

NOTICE REGARDING SERIOUS INCIDENT

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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 2696	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		Consult the accompanying documentation
	Do Not Use If The Package Is Damaged		Keep Away From Contact With Water

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

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
	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)*

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

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

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