Instructions for Use

This document contains the latest instructions for use. Please read it and keep it in a safe place.

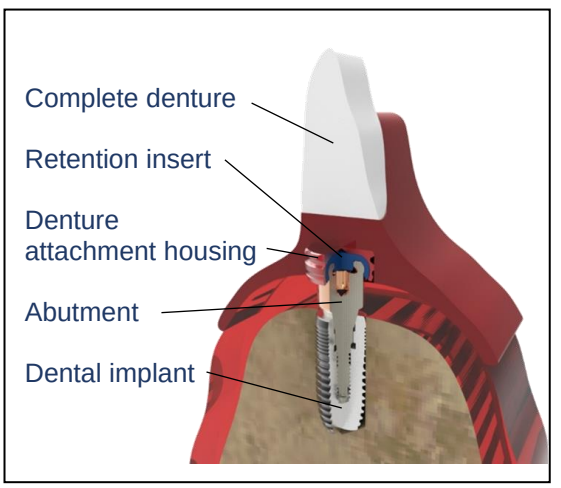
The instructions for use are also valid for Medealis products with trade names:
Anclator, Clic'n Loc, K-LOCK, LOcON, PrimeLOC, SICwhite+, Zantoloc, Overlock

1. SYSTEM DESCRIPTION

The Docklocs Attachment System for denture retention is designed for the fixation of complete dentures (overdentures) or partial dentures that are fully or partially supported by endosseous implants in the mandible or maxilla. With the Docklocs Attachment System, the patient has the possibility to remove and reinsert the denture.

2. SYSTEM COMPONENTS

The Docklocs Attachment System consists of the following components:



2.1 Secondary parts (abutments)

Docklocs secondary parts are prefabricated dental abutments that are used in combination with endosseous implants as a basis for retaining the dentures in the maxilla or mandible. They are available in different designs and gingival heights.

2.2 Matrix system

The matrix system includes two parts and consists of a Denture attachment housing that is fixed in the denture and a plastic retention insert that transfers the retention force to the abutment via its geometry (detachable snap connection). Denture attachment housings in different designs (geometry, material) and seven retention inserts in different colors are available to the user for the prosthetic restoration. The color indicates to the user the application range and the pull-off force that can be attained. A distinction is made between two areas of application in which the angular difference of the insertion direction between the abutments may be up to 20° or up to 40° and between three pull-off forces (retention forces) in light, medium and strong.

2.3 System tools

The system tools are designed for tightening and loosening the Docklocs abutments and retaining screws. They have a shaft for rotating dental instruments according to DIN EN ISO 1797-1. In the case of the screwdriver with holding sleeve, the abutment is held on the instrument via the holding sleeve. They are mechanically powered and reusable.

2.4 Auxiliary tools

2.4.1 Angle measuring device

The angle measuring device is used to determine the angulation difference of the insertion direction of abutments. It is used in the oral cavity or on the model and is reusable.

2.4.2 Universal instruments

The universal instruments are designed for changing the retention inserts in the Denture attachment housing. The rose gold attachment on the four-piece universal instrument is used to manually tighten and loosen the Docklocs abutments.

2.5 System accessories

The system accessories such as block-out spacer, laboratory analog, processing spacer, impression post with impression cap, impression coping with black processing insert and the selection abutments are available to the user as auxiliary parts for the prosthetic restoration.

3. INTENDED USE

The Docklocs Attachment System is designed to fully or partially attach removable full or partial dentures to abutments retained by dental implants in the mandible or maxilla.

3.1 INDICATIONS

- The Docklocs abutments are intended to be connected to endosseous dental implants in the maxilla or mandible.
- The Docklocs Bar abutment is intended as an additional retaining element on custom milled dental bars.
- Via the matrix system, the denture is attached to the abutments by means of a detachable snap connection.
- The screwdrivers are intended for tightening and/or loosening the abutments and retaining screws.
- The auxiliary instruments and accessories are intended for planning and fabricating the prosthetic restoration.

3.2 CONTRAINDICATIONS

- Not recommended for use with a single implant if the vertical divergence exceeds 20° or if the divergence between the implant axes exceeds 40°.
- Not suitable if permanent fixation of the denture is desired.
- The attachment system is not suitable for patients suffering from hypersensitivity or allergy to titanium (Ti-6Al-4V), a zirconium carbon-nitride coating (ZrCN) or polyamide PA (material of the retention inserts).

4. CAUTION

The laws of the USA and most other countries restrict the sale of this product by or on the order of a licensed dentist.

5. NOTICE FOR SERIOUS INCIDENTS

According to Regulation 2017/745/EU, the following applies to patients/users/third parties in the European Union and in countries with identical regulatory regimes:
The following applies to all products listed in these instructions for use:
Should a serious incident occur in relation to the product(s) or use, it must be reported to the manufacturer named in these instructions for use and to the national competent authority of the Member State in which the user and/or patient is established or resident.

6. INTENDED USERS AND PATIENT GROUP

- The Attachment System is to be used by dental professionals only!
- The Attachment System is intended for patients undergoing treatment with dental implants.

7. CLINICAL BENEFITS AND UNDESIRABLE ADVERSE EFFECTS

7.1 The clinical benefit

The clinical benefit of the Attachment System is to restore masticatory function for the patient.

7.2 Undesirable adverse effects

In principle, implantology and prosthetics cannot be considered independent from each other. Dental procedures can cause adverse effects such as bleeding, hematoma and infection. Further adverse effects can be inflammatory reactions (mucositis, peri-implantitis) in the soft tissue.
The materials used can trigger adverse effects in patients with intolerances in the form of an allergic reaction, which can be manifested locally by stomatitis, lichen ruber planus, gingivitis or periodontitis.
In sensitive patients, the insertion and removal of the abutments can trigger an urge to gag (pharyngeal reflex).

8. MRI SAFETY INFORMATION

The Docklocs Attachment System has not been tested for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration or image artefacts in the MR environment. The safety of the Docklocs Attachment System in the MR environment is unknown. Scanning a patient wearing this attachment system may cause injury to the patient.

9. STORAGE AND HANDLING

There are no special considerations for the Docklocs Attachment System, which is in its original undamaged packaging, with regard to transport and handling. Storage should be in a dry place at room temperature. Protect from direct sunlight.

10. WARNINGS AND PRECAUTIONS

The product should be checked for integrity and completeness before use. Products that are in damaged packaging should not be used in patients. If the packaging is damaged, the damaged packaging should be returned to the manufacturer together with the product. Replacement will only be provided if the damage to the packaging was caused by the shipment of the product.

If the Docklocs implant abutment is exposed to inappropriate loading conditions, there is a possible risk of metal fatigue.

As surgical instruments are susceptible to damage and wear, they should be checked before each use. Labels should be visible and legible. To ensure proper function, any reusable instrument should be replaced as soon as damage or wear is present. The number of uses varies and depends on a variety of factors including, but not limited to, the bone density, handling, proper cleaning, autoclave exposure and storage conditions (do not store tools or instruments wet). Over time, repeated sterilization may affect the appearance and visibility of the labels. If this applies to the surgical instrument, check the connection function for wear to ensure that the connection is not damaged.

Patient assessment, including determination of general health, oral hygiene habits and status, motivation for good dental care and anatomical acceptance are critical prior to placement of implant fixtures as part of the restorative procedure. A thorough assessment of the patient's medical status and history is mandatory. Treatment planning is crucial for the success of the implant and prosthesis.

Always follow the implant manufacturer's instructions for use! There are implant manufacturers who only allow a divergence of 10° per implant in order to avoid excessive mechanical stress.

The use of this attachment system requires the clinician to be familiar with the product and the method for its use and application. The clinician must use rational reasoning in deciding when and where to use the product.

During prosthetic treatment, the individual patient situation should always be taken into account. If parafunction or temporomandibular joint disorders such as bruxism are evident, it is essential that these are considered during treatment.

11. SINGLE-USE PRODUCTS

With the exception of tools and instruments, the Docklocs Attachment System components are all single-use products and delivered non-sterile. Single-use products must not be re-used or re-sterilized. If a product for single-use is reused, harm can be caused to the patient by transferring blood, tissue or salivary fluids that may contain infectious diseases. Single-use products that are re-sterilized may not function as intended and may result in an improper surgical procedure and product malfunction or failure.

Docklocs retention inserts: Docklocs retention inserts that are inadvertently reused may result in loss of overdenture retention due to wear from previous use or damage when removed with the Docklocs retention insert tool.

Docklocs Attachments: Docklocs attachments that are inadvertently reused could contain patient contamination, debris build-up and subsequent wear of the retention inserts. This would lead to improper fit and function resulting in loss of retention of the denture.

12. DEVICES FOR MULTIPLE-USE

The surgical instruments and tools of the Docklocs Attachment System are products intended for multiple-use. Reusable tools and instruments must be cleaned and sterilized before reuse on a patient.

Tools: The Docklocs Tools are designed for multiple-use and are supplied NON-STERILE. Follow the instructions for proper sterilization of non-sterile components and the instructions for the cleaning and re-sterilization process of reusable components.

13. CLEANING, DISINFECTION AND STERILIZATION

Instruments/prosthetic components must be cleaned and sterilized before each use. This also applies in particular to initial use following delivery, since the instruments/prosthetic components are delivered **non-sterile**.

The nylon (PA6.6) retention inserts, the processing inserts, and the parallelization post **cannot** be sterilized in an autoclave. The products must be chemically disinfected; otherwise, the function of the products may be impaired. This also includes the combination products such as the denture housings and the impression post with integrated black/yellow processing insert.

The following sterilization procedure should be carried out before use:

PLEASE ALSO READ THE MANUFACTURER'S INFORMATION AND INSTRUCTIONS ON THE CLEANING/STERILIZING OF MEDEALIS COMPONENTS, SURGICAL INSTRUMENTS AND DENTURES at:

https://www.medealis.de/service/downloads

13.1 Abutments, cap, system screws

Method 1	Procedure	Temperature	Minimum holding time*	Drying time
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	134°C	5 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary depending on the equipment.

Method 2	Procedure	Temperature	Minimum holding time*	Drying time
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary depending on the equipment.

13.2 Universal instruments, system tools, angle measuring tool, impression post

Method 1	Procedure	Temperature	Minimum holding time*	Drying time
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	134°C	5 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary depending on the equipment.

Method 2	Procedure	Temperature	Minimum holding time*	Drying time
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary depending on the equipment.

** Instruments should only be placed in the autoclave or sterilized in a disassembled state.*

13.3 HPP Retention Inserts (PA12-GB30), block-out spacer, scan cap

Method 1	Procedure	Temperature	Minimum holding time*	Drying time
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	134°C	5 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary depending on the equipment.

Method 2	Procedure	Temperature	Minimum holding time*	Drying time
Superheated steam	Vacuum process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary depending on the equipment.

13.4 Disinfection

Use only disinfectants with tested efficacy (e.g., VAH/DGHM or FDA approval or CE marking). Always follow the information, instructions, and warnings of the respective manufacturer of the disinfectant.

Validated procedure for the disinfection of products that cannot be sterilised:

Disinfectant: **Cidex® OPA** from JOHNSON & JOHNSON GmbH.

(Cidex® OPA is a registered trademark of Johnson & Johnson)

• Completely immerse the medical device in CIDEX® OPA solution at room temperature (20°C) for at least 5 minutes so that all lumens are filled and all air bubbles are eliminated. Remove the product from the solution and rinse thoroughly according to the following rinsing instructions.

• After removing the medical device from the CIDEX® OPA solution, immerse it completely in 1 litre of demineralised water. Then rinse the medical device under running water for 30 seconds.

• Repeat both steps: immersion and rinsing, once more so that the disinfectant is completely removed.

• After the second rinse, proceed with a final rinse for 10 seconds in isopropanol 70%

14. DISPOSAL

Dispose of used products that pose a risk of infection in accordance with the clinical waste procedures applicable to the facility and applicable local and state regulations.

15. PERFORMANCE REQUIREMENTS AND LIMITATIONS

15.1 Compatibility

The abutments of the Docklocs Attachment System may only be combined with the implant systems intended for them.
Check whether the products are compatible by looking at the identification on the products or product labels.
The implant systems compatible for the abutments are listed in the table below:
Table 1: Compatible implant systems and associated tightening torques

15.2 Performance

In order to achieve the desired performance of the Docklocs Attachment System, only products listed in these instructions for use may be combined with each other. Each product may only be used in accordance with its intended use. All specifications of parameters, which are mentioned in the instructions for use and are relevant for the respective product, must be observed.

16. Recommended tightening torque

Tighten the Docklocs abutment or abutment screw with a calibrated torque wrench to the tightening torque specified in the table.

Important! Check the specified tightening torque again after 5 minutes and correct if necessary.

Table 1: Compatible implant systems and associated tightening torque values

Implant system	One-piece abutments (in Ncm)	Retaining screw for angled abutment (in Ncm)
Straumann®		
Bone Level NC	30	30
Bone Level RC	30	30
Tissue Level NNC	30	30
Tissue Level RN	30	30
Tissue Level WN	30	30
LOGON®		
LOGON 3,3mm	30	30
LOGON 3,8mm	30	30
LOGON 4,3mm	30	30
LOGON 5,0mm	30	30
Camlog®		
iSy®	25	25
Camlog® Ø3.3mm	20	20
Camlog® Ø3.8mm	30	30
Camlog® Ø4.3mm	30	30
Camlog® Ø5.0mm	30	30
Conelog® Ø3.3mm	20	20
Conelog® Ø3.8mm	30	30
Conelog® Ø4.3mm	30	30
Conelog® Ø5.0mm	30	30
MegaGen		
AnyRidge®	30	30
AnyOne® Onestage	30	30
AnyOne® Internal	30	30
AnyOne® mini	30	30
BLUEDIAMOND® NC	30	30
BLUEDIAMOND® RC	30	30
Botticelli		
Botticelli small	25	25
Botticelli regular	25	25
Bego		
Sub-Tec S / RI / RS / RSX 3.75mm-4.1mm	30	30
Sub-Tec S / RI / RS / RSX 4.5mm	30	30
OSSTEM®/ HiOssen Implant®		
TS System Mini (yellow) ET-System Mini (yellow)	30	30
TS System Regular (green) ET-System Regular (green)	30	30
NEODENT®		
Grand Morse®	30	30
Champions		
Champions (R)evolution®	30	30

Dyna Dental®		
Helix	30	30
Medentis®		
ICX	30	30
Dentsply Sirona®		
Astra OsseoSpeed® TX Aqua 3.5mm/4mm	25	25
Astra OsseoSpeed® TX Lilac 4.5mm/5mm	30	30
Astra OsseoSpeed® Profile EV 3.6mm	25	25
Astra OsseoSpeed® EV und Profile EV 4.2mm	30	30
Astra OsseoSpeed® EV und Profile EV 4.8mm	30	30
Ankylos® C/X	25	25
Nobel Biocare®		
NobelReplace® Tri-Channel 3.5mm	35	35
NobelReplace® Tri-Channel 4.3mm	35	35
NobelReplace® Tri-Channel 5.0mm	35	35
NobelActive® Conical NP	35	35
NobelActive® Conical RP	35	35
Brånemark System® External Hex NP	35	35
Brånemark System® External Hex RP	35	35
Brånemark System® External Hex WP	35	35
ZimVie®		
Tapered Screw-Vent® 3.5mm	30	30
Tapered Screw-Vent® 4.5mm	30	30
Tapered Screw-Vent® 5.7mm	30	30
3i External Hex NP 3.25mm/3.4mm	30	30
3i External Hex RP 4,1mm	30	30
3.4mm Certain® Connection	30	30
4.1mm Certain® Connection	30	30
BioHorizons®		
Tapered Internal Implant System 3.5mm	30	30
Tapered Internal Implant System 4.5mm	30	30
Tapered Internal Implant System 5.7mm	30	30
LASAK		
BioniQ Regular	25	25
BioniQ Narrow	25	25
Bredent Medical		
SKY®	30	30
copaSKY®	30	30
Southern Implants®		
EXTERNAL HEX Ø 3,0mm	30	30
EXTERNAL HEX Ø 3,25mm	30	30
EXTERNAL HEX Ø 4,0mm	30	30
EXTERNAL HEX Ø 5,0mm	30	30
DEEP CONICAL Ø 3,0mm	20	20
DEEP CONICAL Ø 3,5/4,0mm	30	30
DEEP CONICAL Ø 5,0mm	30	30
TRI-NEX Ø3,5mm	30	30
TRI-NEX Ø4,3mm	30	30
TRI-NEX Ø5,0mm	30	30
SP1	30	30
Internal Hex/Provata	30	30
Internal Provata Ø3,3mm	30	30
IT **Connection** Ø4,8mm	30	30
IT **Connection** Ø6,5mm	30	30
C-Tech Implant		
EL/Esthetic Line	30	30

Products marked with ® are registered trademarks of the corresponding manufacturer.

17. PROSTHETIC PROCEDURES

Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate Docklocs abutment based on the implant type, diameter and gingival height.

It is imperative that all bone and soft tissue is removed from the crestal aspect of the implant body to ensure complete seating of the abutment.

17.1 Impression and Stone Model Fabrication

- When the Docklocs abutments are torqued in place, snap the impression copings on the abutments until they are firmly seated
- Proceed with taking an impression
- Remove the tray and snap a lab. analog into each impression coping
- Capture the abutment position in stone using standard methods for fabricating a laboratory stone model

17.2 Prosthesis Fabrication

- Seat the Docklocs Denture attachment housings with the black processing inserts on each of the abutments.
- Fabricate the prostheses using standard laboratory techniques.
- When inserting the prosthesis, initially use the retention insert with the lowest level of retention and increase the retention level as necessary.

17.3 Chair-side Denture Attachment Housing pick-up technique (optional)

- Place a block-out spacer around each abutment and press it down.
- Seat the Docklocs Denture attachment housing with the black processing insert on each of the abutments.
- Secure the Denture attachment housings to the prosthesis using light-cure, auto-polymerizing or composite resin, following the respective material guidelines for each pick-up technique.

17.4 Insertion of the prosthesis

- Once the fit of the prosthesis is verified, remove the black processing inserts from each Denture attachment housing using the Docklocs universal instrument (for further instructions, please refer to the instructions for use for the Docklocs universal instruments).
- Replace them with the lowest level retention insert to begin with and increase the retention level if needed. Insert the prosthesis firmly and make sure that each insert is fully engaged on each abutment.

17.5 Retention inserts

Retention insert clear, pink, blue, with dual retention When using the retention inserts with dual retention, the maximum divergence of the Docklocs abutments to be restored may be 20°			**Retention insert gray**	**Retention insert green, orange, red for the extended application range** If implant axis divergence exceeds 20° up to 40°, retention inserts from the extended pivot range should be used		
						
Clear, with strong retention (*2200g/22N)	Pink, with medium retention (*1200g/12N)	Blue, with light retention (*700g/7N)	Gray, without retention To be used for long-term restoration and protection of temporary Docklocs® abutments not included in the denture retention	Red, with light retention (*600g/6N)	Orange, with medium retention (*1000g/10N)	Green, with strong retention (*1900g/19N)
When initially inserting two or more Docklocs abutments, it is recommended to use the retention insert with the lowest retention. ** The retention (pull-off force) is determined under optimum conditions; factors such as dimensional tolerances, axle divergences and wear can influence the reference value!*						

Caution: The angled abutments can only be used in combination with the red/orange/green retention inserts.

17.6 HEALING PHASE

Delayed loading protocols: Relieve the prosthesis to ensure that the abutments do not come into contact with any denture acrylic. A soft liner may be added to the denture to ensure patient comfort during the healing phase.

18. UNIVERSAL INSTRUMENTS

A0019 Universal instrument (2-Piece)

A0020 Universal instrument (4-Piece)

Instructions for removing the retention inserts

To remove the retention inserts, the tip must be rotated far enough from the center section so that a small gap is visible between the two. This ensures that the release pin is far enough back in the tip.

The tip is then inserted vertically into the retention insert in the denture cap housing. The retention insert is removed from the denture housing with a slight tilting movement. The sharp edges of the tip hold the retention insert firmly on the tip. By turning the tip clockwise onto the center part, the release pin inside the tip is pushed forward and releases the retention insert off the tip.

19. PATIENT CARE

Good oral hygiene is crucial for success with the Docklocs Attachment System. The patient should be made aware of the following:

- Docklocs Attachments must be thoroughly cleaned every day to prevent the buildup of plaque biofilm. The patient should use a soft nylon brush or an end tufted toothbrush with a non-abrasive toothpaste to clean the abutments.
- The coarse particles in abrasive toothpastes may scratch the surface of the abutments and cause additional plaque accumulation.
- An irrigation system is recommended to flush out debris from the inside of the Docklocs retention inserts.
- The Docklocs retention inserts are made of a flexible plastic material so that the overdentures can be removed and reinserted regularly. Plastic materials are subject to a certain amount of wear in the course of normal use and may need to be replaced.
- Bruxism (grinding of the teeth) wears the Docklocs abutments and can reduce the longevity of the retention inserts.

Patients should be instructed to make routine follow-up visits for hygiene and to assess the attachment function. Should a patient experience any discomfort or loss of retention of the overdenture, they should consult a dentist.

Follow-up visits are recommended at 6-month intervals. The abutments must be retightened at follow-up visits according to the torque specifications provided above. Failure to retighten the abutments may result in screw loosening and fracture of the abutment. Patients should be examined for symptoms of inflammation around implant abutments and implant mobility at each follow-up visit.

20. Inserting and Removing Overdentures

The patient should be instructed on how to insert the overdenture correctly. The patient should ensure that they feel that it is correctly positioned over the abutments before applying pressure. The patient should use both hands and press down on each side until the overdenture snaps firmly into place.

NOTE: The patient must NOT bite their overdenture into place, as this force will cause improper wear of the abutments and retention inserts. The patient can remove the overdenture by placing their thumbs under the edges of the overdenture flanges and pulling both sides up (lower denture) or down (upper denture) simultaneously. Use of the tongue may assist in removal. Once removed, thorough cleaning is recommended.

21. Cleaning of implant-retained overdentures

Instruct the patient to follow the protocol below to ensure the longevity of their overdenture.

1. To prevent fracture of the overdenture, fill a sink with warm water. Apply non-abrasive toothpaste to a soft nylon brush or end tufted toothbrush and thoroughly clean each surface of the overdenture.
2. Remove the overdenture every night and rinse it with clear water.

22. Further information

Conventional restorative protocols should be followed to process the attachments into the patient's overdenture. To ensure the longevity of each restoration, standard overdenture care and maintenance should be followed.

Further information can be found in our Technical Manual, which is available in our download section:

https://www.medealis.de/service/downloads

23. Product Information

Secondary Parts		
Products	**Image**	**Material**
Abutment one-piece straight		Titanium alloy [1] with Zirconium Carbon Nitride (ZrCN)[2] coating,
Abutment angled 18° with retaining screw		Titanium alloy [1] with Zirconium Carbon Nitride (ZrCN)[2] coating,
Caution: The angled abutments can only be used in combination with the red/orange/green retention inserts.		
Abutment set A Abutment one-piece straight with denture housing with processing insert, retention inserts blue/pink/clear/red/orange/green, block-out spacer and parallel post		Titanium alloy [1] with Zirconium Carbon Nitride (ZrCN)[2] coating, polyethylene[5], polyamide[3] , TPE[6]/silicone[7]
Abutment set B Abutment angled 18° with retaining screw, denture housing with processing insert, retention inserts red/orange/green, block-out spacer and parallel post		Titanium alloy [1] with Zirconium Carbon Nitride (ZrCN)[2] coating, polyethylene[5], polyamide[3], TPE[6]/silicone[7]
Caution: The angled abutments can only be used in combination with the red/orange/green retention inserts.		

23.1 Basic UDI DI Information:

The following table contains the information for the base UDI-DI for the data included in this Instructions for Use for the described products.

Abutments/Abutment Sets				
Implant system	**One piece straight abutment**	**One piece angled abutment with system screw**	**One piece Straight Abutment set for denture restoration Set A**	**One piece Angled abutment set with system screw for denture restoration Set B**
GMDN	**44879**	**44879**	**44881**	**44881**
Straumann®				
Bone Level NC	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Bone Level RC	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Tissue Level NNC	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Tissue Level RN	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Tissue Level WN	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Camlog®				
iSy®	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Camlog® Ø3.3mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Camlog® Ø3.8mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Camlog® Ø4.3mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Camlog® Ø5.0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Conelog® Ø3.3mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Conelog® Ø3.8mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Conelog® Ø4.3mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Conelog® Ø5.0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
MegaGen				
AnyRidge®	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
AnyOne® Onestage	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
AnyOne® Internal	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
AnyOne® mini	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
BLUEDIAMOND® NC	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
BLUEDIAMOND® RC	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Botticelli				
Botticelli small	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Botticelli regular	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Bego				
Sub-Tec S / RI / RS / RSX 3.75mm-4.1mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Sub-Tec S / RI / RS / RSX 4.5mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
OSSTEM®/ HiOssen Implant®				
TS System Mini (gelb) ET-System Mini (gelb)	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
TS System Regular (grün) ET-System Regular (grün)	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
NEODENT®				
Grand Morse®	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Champions				
Champions (R)evolution®	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Dyna Dental®				
Helix	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Medentis®				
ICX	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Dentsply Sirona®				
Astra OsseoSpeed® TX Aqua 3.5mm/4mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Astra OsseoSpeed® TX Lilac 4.5mm/5mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Astra OsseoSpeed® EV 3.6mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Astra OsseoSpeed® EV und Profile EV 4.2mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Astra OsseoSpeed® EV und Profile EV 4.8mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Ankylos® C/X	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR

LOGON®				
LOGON 3,3mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
LOGON 3,8mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
LOGON 4,3mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
LOGON 5,0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Nobel Biocare®				
NobelReplace® Tri-Channel 3.5mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
NobelReplace® Tri-Channel 4.3mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
NobelReplace® Tri-Channel 5.0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
NobelActive® Conical NP	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
NobelActive® Conical RP	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Brånemark System® External Hex NP	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Brånemark System® External Hex RP	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Brånemark System® External Hex WP	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
ZimVie®				
Tapered Screw-Vent® 3.5mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Tapered Screw-Vent® 4.5mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Tapered Screw-Vent® 5.7mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
3i External Hex NP 3.25mm/3.4mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
3i External Hex RP 4,1mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
3.4mm Certain® Connection	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
4.1mm Certain® Connection	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
BioHorizons®				
Tapered Internal Implant System 3.5mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Tapered Internal Implant System 4.5mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Tapered Internal Implant System 5.7mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
LASAK				
BioniQ Regular	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
BioniQ Narrow	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Bredent Medical				
SKY®	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
copaSKY®	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Southern Implants®				
EXTERNAL HEX Ø 3,0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
EXTERNAL HEX Ø 3,25mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
EXTERNAL HEX Ø 4,0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
EXTERNAL HEX Ø 5,0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
DEEP CONICAL Ø 3,0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
DEEP CONICAL Ø 3,5/4,0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
DEEP CONICAL Ø 5,0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
TRI-NEX Ø3,5mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
TRI-NEX Ø4,3mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
TRI-NEX Ø5,0mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
SP1	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Internal Hex/Provata	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
Internal Provata Ø3,3mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
IT **Connection** Ø4,8mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
IT **Connection** Ø6,5mm	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR
C-Tech Implant				
EL/Esthetic Line	++EMESA001YM	++EMESA002YP	++EMESA003YR	++EMESA003YR

Secondary Parts

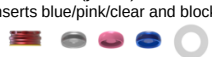
Products	Image	Material	GMDN	Basic UDI-DI
Docklocs Bar Abutment		Titanium alloy[1] with Zirconium Carbon Nitride[2] coating	44879	++EMESA001YM
Docklocs Bar Abutment Set		Titanium alloy[1] with Zirconium Carbon Nitride[2] coating Polyethylene[5], Polyamide (PA12)[3], TPE[6]/Silicone[7]	44881	++EMESA003YR

System Screws GMDN 44879						
Material: Titanium [1]						
Article number	**Description**	**Basic UDI-DI**		**Article number**	**Description**	**Basic UDI-DI**
A0120	M1.6x7.0mm with Hex 1.25mm	++EMESA004YT		A0140	M1.8x5.8mm with Hex 1.32mm	++EMESA004YT
A0121	M1.6x6.2mm with Hex 1.25mm	++EMESA004YT		A0141	M1.6x6.0mm with Hex 1.22mm	++EMESA004YT
A0122	M1.6x8.5mm with Hex 1.25mm	++EMESA004YT		P4301.1408	M1,4x8,0mm with Hex 1,25mm	++EMESA004YT
A0125	M1.8x5.5mm with Hex 1.25mm	++EMESA004YT		P4301.1609	M1.6x9.0mm with Hex 1.25mm	++EMESA004YT
A0126	M1.8x6.7mm with Hex 1.25mm	++EMESA004YT		AANMST	M1,8mm blue with Hex 1,20mm	++EMESA004YT
A0128	M2.0x6.5mm with Hex 1.25mm	++EMESA004YT		AANMSF	M1.8mm yellow with Hex 1.20mm	++EMESA004YT
A0129	M2.0x7.5mm with Hex 1.25mm	++EMESA004YT		APS-0001	M1.8mm short with Hex 1.20mm	++EMESA004YT
A0130	M2.0x8.5mm with Hex 1.25mm	++EMESA004YT		APS-0002	M1.8mm long with Hex 1.20mm	++EMESA004YT
A0131	M2.0x6.0mm with Hex 1.25mm	++EMESA004YT		00302943	M1.8x9.2mm with Torx	++EMESA004YT
A0134	M1.8x6.7mm with Hex 1.25mm	++EMESA004YT		00307537	M1.6x6.4mm with Torx	++EMESA004YT
A0135	M1.8x5.8mm with Hex 1.25mm	++EMESA004YT		A-P-S028	M1.6x0.25mm 8.1mm	++EMESA004YT
A0136	M1.6x5.7mm with Hex 1.25mm	++EMESA004YT		A-P-R028	M1.6x0.25mm 8.5mm	++EMESA004YT
A0137	M1.6x4.0mm with Hex 1.25mm	++EMESA004YT		QN 2191	M1,4 x 8,4mm	++EMESA004YT
A0138	M2.0x4.0mm with Hex 1.25mm	++EMESA004YT		QR 2103	M1,6x 8,6mm	++EMESA004YT
A0139	M1.6x7.6mm with Hex 1.25mm	++EMESA004YT		A0143	M1,8x 7,0mm	++EMESA004YT
A0140	M1,8x5,8mm with Hex 1,32mm	++EMESA004YT		A0148	M1.6x6.7mm with Hex 1.20mm	++EMESA004YT

Matrix System

Products	Products	Products
HPP Standard Pivot Processing Pack Denture housing anodized (red) with processing insert (black), retention inserts blue/pink/clear and block-out spacer  Titanium alloy[1] , Polyethylene[5] , Polyamide[3] (PA12), TPE[5] /Silicone [6]	**Standard Pivot Processing Pack** Denture housing with processing insert (black), retention inserts blue/pink/clear and block-out spacer  Titanium alloy[1] , Polyethylene[5] , Polyamide[4] (PA6.6), TPE[5] /Silicone[6]	**Standard Pivot Processing Pack with anodized denture housing** Denture housing anodized (pink) with processing insert (black), retention inserts blue/pink/clear and block-out spacer  Titanium alloy[1] , polyethylene[5] , Polyamide[4] (PA6.6), TPE[5] /Silicone[6]
Basic UDI-DI: ++EMESB004Z2	**Basic UDI-DI: ++EMESB004Z2**	**Basic UDI-DI: ++EMESB004Z2**

HPP Extended Pivot Processing Pack Denture housing anodized (red) with processing insert (black), retention inserts red/orange/green and block-out spacer  Titanium alloy[1] , Polyethylene[5] , Polyamide[3] (PA12), TPE[5] /Silicone[6]	**Extended Pivot Processing Pack** Denture housing with processing insert (black), retention inserts red/orange/green and block-out spacer  Titanium alloy[1] , Polyethylene[5] , Polyamide[4] (PA6.6), TPE[5] /Silicone[6]	**Extended Pivot Processing Pack with anodized denture housing** Denture housing anodized (pink) with processing insert (black), retention inserts red/orange/green and block-out spacer  Titanium alloy[1] , Polyethylene[5] , Polyamide[4] (PA6.6), TPE[5] /Silicone[6]
Basic UDI-DI: ++EMESB004Z2	**Basic UDI-DI: ++EMESB004Z2**	**Basic UDI-DI: ++EMESB004Z2**

HPP Processing Pack for Bar Denture housing anodized (red) with processing insert (yellow), retention inserts blue/pink/clear and block-out spacer  Titanium alloy[1] , Polyethylene[5] , Polyamide[3] (PA12), TPE[5] /Silicone[6]	**Processing Pack for Bar** Denture housing with processing insert (yellow), retention inserts blue/pink/clear and block-out spacer  Titanium alloy[1] , Polyethylene[5] , Polyamide[4] (PA6.6), TPE[5] /Silicone[6]	**Processing Pack for Bar with anodized denture housing** Denture housing anodized (pink) with processing insert (yellow), retention inserts blue/pink/clear and block-out spacer  Titanium alloy[1] , Polyethylene[5] , Polyamide[4] (PA6.6), TPE[5] /Silicone[6]
Basic UDI-DI: ++EMESB004Z2	**Basic UDI-DI: ++EMESB004Z2**	**Basic UDI-DI: ++EMESB004Z2**

HPP Processing Pack with zirconia housing Zirconia denture housing with processing insert (black), retention inserts blue/pink/clear and block-out spacer  Zirconia, polyethylene[5] , polyamide[3] (PA12), TPE[5] /silicone[6]	**HPP Extended Pivot Processing Pack with zirconia housing** Zirconia denture housing with processing insert (black),retention inserts red/orange/green and block-out spacer  Zirconia, polyethylene[5] , polyamide[3] (PA12), TPE[5] /silicone[6]
Basic UDI-DI: ++EMESB004Z2	**Basic UDI-DI: ++EMESB004Z2**

Matrix System			
Products	**Image**	**Material**	**Basic UDI-DI**
Retention inserts HPP		Polyamide12-GB30[3]	++EMESB001YU
Retention inserts standard		Polyamide 6.6[4]	++EMESB001YU
Denture housing titanium with processing insert (black)		Titanium alloy[1] and PE[5]	++EMESB002YW
Denture housing titanium with processing insert (yellow)		Titanium alloy[1] and PE[5]	++EMESB002YW
Zirconia denture housing with processing insert		Zirconia[13] and PE[5]	++EMESB003YY

System tool with contra-angle connection			
Products	**Image**	**Material**	**Basic UDI-DI**
Screwdriver for system abutments with shaft for contra-angle handpieces		Surgical steel[12]	++EMESG00122
Screwdriver with holding sleeve for Docklocs abutments with shaft for contra-angle handpieces		Surgical steel[12] and holding sleeve made of PEEK[8]	++EMESG00224
Hexagonal screwdriver 1.25mm for Docklocs abutments and retaining screws with shaft for contra-angle handpieces		Surgical steel[12]	++EMESG00122
Screwdriver with holding sleeve for Docklocs Zeramex abutments with shaft for contra-angle handpieces and ZrCN coating		Surgical steel[12] (ZrCN[2] - coating) and holding sleeve made of PEEK[8]	++EMESG00326

Auxiliary Parts			
Products	**Image**	**Material**	**Basic UDI-DI**
Universal instrument 2-Piece		Surgical steel[11] [12]	++EMESH00129
Universal instrument 4-Piece		Surgical steel[11] [12] with ZrCN[2] coating and PEEK holding sleeve[8]	++EMESH00129
Angle measuring aid		Surgical steel[10]	++EMESH00129

System Accessories			
Products	**Image**	**Material**	**Basic UDI-DI**
Processing insert		Polyethylene[5]	++EMESK0012W
Processing insert for bars		Polyethylene[5]	++EMESK0012W
Processing Spacer		Polyoxymethylene (POM) [9]	++EMESK0012W
Impression post		Titanium alloy[1] and polyethylene	++EMESK0022Y
Parallelization post		Polyethylene[6]	++EMESK0012W
Block-out spacer		Silicone[5] /TPE[6]	++EMESK0012W
Implant impression coping with retaining screw		Titanium alloy[1]	++EMESK0022Y
Impression cap		Polyoxymethylene (POM) [9]	++EMESK0012W
Laboratory analog straight		Titanium alloy[1]	++EMESK0022Y
Lab analog angled		Titanium alloy[1]	++EMESK0022Y
Scan Cap		PEEK MT[8]	++EMESK0012W

23.2 Material specifications:

The following table contains information about the materials used for the products.

Titanium alloy											
		Standards	Chemical composition (%Gew.)								
(1)	Titanium Grade 5 Titanium Grade 23 (titanium alloy)	Material No.: 3.7165 EN: TiAl6V4 ELI ISO: 5832-2	C	AL	V	Y	Fe	O	N	H	Ti
			max. 0.08	5.50- 6.50	3.50- 4.50	max. 0.005	max. 0.25	max. 0.13	max. 0.05	max. 0.012	Rest

Coating										
		Abbreviation	Chemical composition (%Gew.)							
(2)	Zirconium Carbon Nitride	ZrCN	Cr + FE	O	C	N	H	Zr			
			max. 0.20	max. 0.18	max. 0.50	max. 0.025	max. 0.005	min. 99.2			

Plastics			
		Abbreviation	Comment
(3)	Polyamide 12	PA12-GB30	Polyamide 12 with 30% glass beads
(4)	Polyamide 6.6	PA6.6	Nylon
(5)	Polyethylene	PE	
(6)	Thermoplastic elastomers	TPE	
(7)	Silicone	SI	
(8)	Polyether ether ketone	PEEK	
(9)	Polyoxymethylene	POM	

Surgical steel											
		Standards	Chemical composition (%Gew.)								
(10)	1.4301	Material No.: 1.4301 DIN EN 10088-3: X5CrNi 18-10	C	Si	Mn	P	S	Cr	Ni	N	FE
			max. 0.03	max. 1.00	max. 2.00	max. 0.045	max. 0.03	18.0- 19.5	10.0- 10.5	max. 0.10	Rest

		Standards	Chemical composition (%Gew.)										
(11)	1.4305	Material No.: 1.4305 DIN EN 10088-3: X8CrNiS18-9	C	Si	Mn	P	S	Cr	Ni	Cu	Mo	N	FE
			max. 0.10	max. 1.00	max. 2.00	max. 0.045	0.15- 0.35	17.0- 19.0	8.00- 10.00	max. 1.00	max. 0.70	max. 0.10	Rest

		Standards	Chemical composition (%Gew.)							
(12)	1.4035	Material No.: 1.4035 DIN EN 10088-3: X46CrS13	C	Si	Mn	P	S	Cr	Ni	FE
			0.43- 0.50	max. 1.00	max. 1.00	max. 0.04	max. 0.03	12,5- 14.5	max. 1.00	Rest

Zirconia						
		Abbreviation	Chemical composition (%Gew.)			
(13)	Zirconia	ZrO_2	ZrO_2	Y2O3	Al 2O 3	$SiO_2 + Fe_2O_3 + Na_2O$
			90.0- 95.0	4.0- 10.0	max. 2.00	max. 0.50

24. EXPLANATION OF OUTER PACKAGING LABEL SYMBOLS

The following symbols may be included on the product labels or in the accompanying information of the product. The applicable symbols can be found on the product labels or in the accompanying information.

Symbol	Title
	Manufacturer
EC REP	Authorized representative in the European Community
CH REP	Authorized representative in Switzerland
REF	Catalog number
LOT	Lot number
	Do not re-use
	Consult instructions for use
 XXXXX	Follow the instructions for use Link to the electronic instructions for use (eIFU): ***medealis.de/IFU***
	Do not re-sterilize
	Non-sterile
 JJJJ-MM-TT	Use-by date
	Conditionally MR safe

Symbol	Title
	Date of manufacture
	Do not use if package is damaged
	Attention, observe warnings
CE XXXX	European conformity mark with identification number of the notified body
CE	European conformity mark
Rx Only	According to U.S. federal law, this product may only be sold to or on the request of a dentist.
QTY	Quantity
UDI	Product identification number
MD	Medical device
	Protect from moisture
	Protect from light
„Made in Germany"	Designation of origin

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