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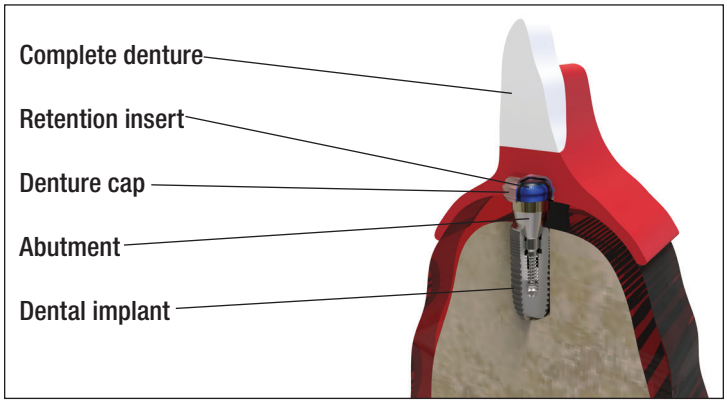
Instructions for Use
PreatLoc™ Attachment System

1. SYSTEM DESCRIPTION

The PreatLoc™ 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 PreatLoc™ Attachment System, the patient has the possibility to remove and reinsert the denture.

2. SYSTEM COMPONENTS

The PreatLoc™ Attachment System consists of the following components:



2.1 Secondary parts (abutments)

PreatLoc™ 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 Cap (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). 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 high .

2.3 Abutment Driver

The Abutment Driver is designed for tightening and loosening the PreatLoc™ abutments and retaining screws. It has a shaft for rotating dental instruments according to DIN EN ISO 1797-1. The driver holds the abutment via the holding sleeve. The driver is mechanically powered and reusable.

2.4 Auxiliary tools

2.4.1 Universal instrument

The universal instrument is 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 PreatLoc™ abutments.

2.5 System accessories

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

3. INTENDED USE

The PreatLoc™ 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 Indication

- The PreatLoc™ abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.
- The PreatLoc™ 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 auxiliary instruments and accessories are intended for planning and fabricating the prosthetic restoration.

3.2 Contraindications

- 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 nitride coating (ZrN) or polyamide PA (material of the retention inserts).

4. 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.

5. STORAGE AND HANDLING

Storage should be in a dry place at room temperature. Protect from direct sunlight.

6. 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 together with the product.

Please follow the instructions for use from the manufacturer of each compatible implant system for implant placement and allowed range of divergence for abutments. Use of a single implant with divergence of up to 10 degrees from vertical may not be allowed by the manufacturers of some of the compatible implant systems.

Not recommended for use with a single implant if the vertical divergence exceeds 20° or if the divergence between the implant axes exceeds 40°.

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

7. MAGNETIC RESONANCE (MR) SAFETY INFORMATION

MR CONDITIONAL

WARNING: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30cm from the implant, or ensuring the implant is located outside of the RF coil.

A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	PreatLoc™ Attachment System
Static Magnetic Field Strength (B0)	≤ 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Note: the removable restorations should be taken out prior to scanning.

8. SINGLE-USE PRODUCTS

With the exception of tools and instruments, the PreatLoc™ 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.

9. DEVICES FOR MULTIPLE-USE

The instruments and tools of the PreatLoc™ Attachment System are products intended for multiple-uses and supplied sterile. Reusable tools and instruments must be cleaned and sterilized before reuse on a patient.

10. CLEANING, DISINFECTION AND STERILIZATION

PreatLoc™ Attachment System products are supplied NON-STERILE. Always refer to the product label.

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 Polyamide (PA66) 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 PREAT COMPONENTS , SURGICAL INSTRUMENTS AND DENTURES

10.1 Abutments, cap, system screws , impression post, intruments and tools

Method	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.

10.2 Disinfection for Polyamide (PA66) Retention Inserts

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

The Polyamide (PA66) nylon retention inserts may be disinfected using an approved liquid chemical sterilant. They must be soaked for a minimum of 3 hours in the liquid sterilant at room temperature.

11. 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.

12. PERFORMANCE REQUIREMENTS AND LIMITATIONS

12.1 Compatibility

The abutments of the PreatLoc™ Attachment System may only be combined with the implant systems intended for them.

Check whether the products are compatible by looking at the product labels.

The implant systems compatible with the abutments are listed in Table 1: Compatible implant systems and associated tightening torques.

12.2 Performance

In order to achieve the desired performance of the PreatLoc™ 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.

13. RECOMMENDED TIGHTENING TORQUE

Tighten the PreatLoc™ abutment with a calibrated torque wrench to the tightening torque specified in Table 1.

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

14. PROSTHETIC PROCEDURES

Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate PreatLoc™ 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.

14.1 Impression and Stone Model Fabrication

- When the PreatLoc™ 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

14.2 Prosthesis Fabrication

- Seat the PreatLoc™ 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.

Table 1: Compatible implant systems and associated tightening torque values

Implant system	One-piece abutments (in Ncm)
BioHorizons®	
Tapered Internal Implant System 3.0mm	30
Tapered Internal Implant System 3.5mm	30
Tapered Internal Implant System 4.5mm	30
Tapered Internal Implant System 5.7mm	30
Dentsply Sirona®	
Ankylos® C/X	25
Astra OsseoSpeed® EV andProfile EV 4.2mm	30
Astra OsseoSpeed® EV and Profile EV 4.8mm	30
Astra OsseoSpeed® Profile EV 3.6mm	25
Astra OsseoSpeed® TX Aqua 3.5mm/4mm	25
Astra OsseoSpeed® TX Lilac 4.5mm/5mm	30
MIS C1 NP	30
MIS C1 SP	30
KEYSTONE	
TiLobe 3.5mm	30
TiLobe 4.1mm	30
TiLobe 5.0mm	30
MegaGen	
AnyRidge®	30
NEODENT®	
Grand Morse®	30
Nobel Biocare®	
Brånemark System® External Hex RP	35
NobelActive®/Conical 3.0mm	15
NobelActive®/Conical NP	35
NobelActive®/Conical RP	35
NobelBiocare™ Tri-Lobe NP	35
NobelBiocare™ Tri-Lobe RP	35
OSSTEM®/ Hiossen Implant®	
ET-System Mini (yellow)	30
ET-System Regular (green)	30
Straumann®	
BLX RB/WB	35
Bone Level NC	30
Bone Level RC	30
Tissue Level RN	30
ZimVie®	
Certain® 3.4mm	30
Certain® 4.1mm	30
Tapered Screw-Vent® 3.5mm	30
Tapered Screw-Vent® 4.5mm	30
Tapered Screw-Vent® 5.7mm	30

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

- Place a block-out spacer around each abutment and press it down.
- Seat the PreatLoc™ 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.

14.4 Insertion of the prosthesis

- Once the fit of the prosthesis is verified, remove the black processing inserts from each Denture attachment housing using the PreatLoc™ universal instrument.
- 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.

14.5 Retention Inserts

Retention Inserts (PA66)	
Standard pivot inserts with dual retention When using the retention inserts with dual retention, the maximum divergence of the PreatLoc™ abutments to be restored may be 20°	
	Clear, with strong retention (*5lbs/2270g/22N)
	Pink, with medium retention (*3lbs/1360g/13N)
	Blue, with light retention (*1.5lbs/700g/7N)
Processing insert	
	Grey, without retention To be used for long-term restoration and protection of temporary PreatLoc™ abutments not included in the denture retention
Extended pivot inserts for the extended application range If implant axis divergence exceeds 20° up to 40°, retention inserts from the extended pivot range should be used	
	Red, with light retention (*1lbs/450g/4N)
	Orange, with medium retention (*2lbs/910g/10N)
	Green, with strong retention (*4lbs/1810g/18N)

When initially inserting two or more PreatLoc™ 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!*

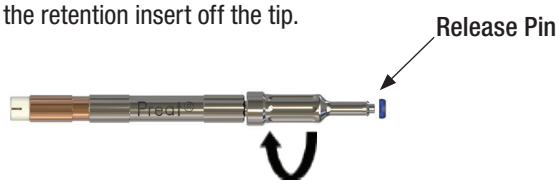
15. UNIVERSAL INSTRUMENTS

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.



16. PATIENT CARE

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

- PreatLoc™ 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 PreatLoc™ retention inserts.
- The PreatLoc™ 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 PreatLoc™ 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.

17. INSERTING AND REMOVING OVERDENTURES

The patient should be instructed on how to insert the overdenture correctly. The patient should ensure that they feel that the overdenture 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.

18. 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.

19. EXPLANATION OF OUTER PACKAGING LABEL SYMBOLS

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

Symbol	Title
	Manufacturer
	Catalog number
	Lot number
	Do not re-use
	Consult instructions for use
	Date of manufacture
	Do not use if package is damaged
	According to U.S. federal law, this product may only be sold to or on the request of a dentist.
	Non-sterile
	Conditionally MR safe
	Product identification number

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