

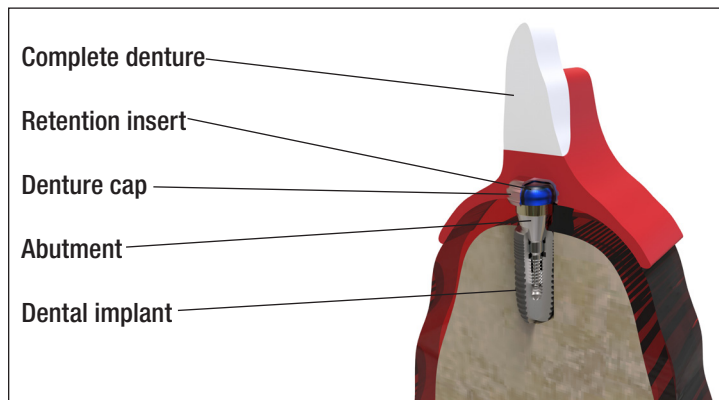
Instructions for Use PreatLoc™ Attachment System

1. SYSTEM DESCRIPTION

The PreatLoc™ Attachment System is designed for the retention of removable dental prostheses, including complete overdentures and partial dentures supported fully or partially by endosseous implants in the mandible and/or maxilla. The system enables the patient to independently insert and remove the prosthesis for routine use and oral hygiene maintenance.

2. SYSTEM COMPONENTS

The PreatLoc™ Attachment System consists of the following components:



2.1 Secondary Components (Abutments)

PreatLoc™ Abutments are prefabricated dental components intended for use in combination with endosseous implants. They serve as the prosthetic foundation for retaining removable prostheses in the mandible and/or maxilla and are available in various configurations and gingival heights to meet diverse clinical requirements.

The PreatLoc™ Angled Abutment features an angulation of 18° relative to straight abutments and is designed to compensate for implant divergence.

Table 1: Compatible implant systems

Compatible Implant System	Implant Diameter (mm)	Implant Platform Designation
Ankylos® C/X	3.5; 4.5; 5.5	3.5; 4.5; 5.5
Astra OsseoSpeed® EV	3.6	3.6
	4.2	4.2
	4.8	4.8
Astra OsseoSpeed® TX	3.5/4.0	Aqua
	4.5/5.0	Lilac
BioHorizons® Internal	3.0; 3.4; 3.8	3.0
	3.8; 4.6	3.5
	4.6; 5.8	4.5
	5.8	5.7
Biomet 3i Certain®	3.25	3.4
	4.0	4.1
Biomet 3i OSSEOTITE®	3.25	3.4
	3.75; 4.0	4.1
Keystone Prima Connex	3.3; 3.5	3.5
	4.0; 4.1	4.1
	5.0	5.0
MegaGen AnyRidge®	3.5; 4.0; 4.5; 5.0; 5.5	3.5
MIS Implants® C1	3.30	NP
	3.75; 4.20	SP
Neodent® Grand Morse®	3.5; 3.75; 4.0; 4.3; 5.0; 6.0; 7.0	Grand Morse (GM)
NobelActive® / NobelReplace® / NobelParallel Conical	3.0	3.0
	3.5	NP (3.5)
	4.3; 5.0	RP (3.9)
NobelReplace® Tri-Lobe	3.5	NP (3.5)
	4.3	RP (4.3)
Nobel Brånemark System®	3.75; 4.0	RP
OSSTEM®/Hiossen Implant® ET-System	3.2; 3.5	Mini (2.1)
	4.0; 4.5; 5.0; 5.5; 6.0; 7.0	Regular (2.5)
Straumann® BLX	3.5; 3.75; 4.0; 4.5	RB/WB
	5.0; 5.5; 6.5	WB
Straumann® Bone Level	3.3	NC
	4.1; 4.8	RC
Straumann® Tissue Level	3.3; 4.1; 4.8	RN
Zimmer Screw-Vent® / Tapered Screw-Vent®	3.7; 4.1	3.5
	4.7	4.5
	6.0	5.7

2.2 Matrix system

The matrix system includes two components and consists of a Denture Cap (attachment housing) that is secured within the prosthesis and a plastic retention insert that transmits the retention force to the abutment via a precision snap-fit connection. Denture attachment housings are available in various designs (geometry and material). Seven color-coded retention inserts are available, each indicating the applicable divergence range and corresponding pull-off force. Three retention force levels are provided: light, medium, and high. Refer to RETENTION INSERTS for further details.

2.3 Abutment Driver

The Abutment Driver is designed for tightening and loosening the PreatLoc™ straight abutments. 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.

For tightening the retaining screws of the PreatLoc™ angled abutments, only screwdrivers with a 1.25 mm hex interface may be used.

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™ straight 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, as well as the Scan Body for digital impression workflows.

3. INTENDED USE

The PreatLoc™ Attachment System is intended to fully or partially retain removable complete or partial dentures on implant-supported abutments 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™ Angled Abutment, with an angular correction, is designed to engage with endosseous implants and to be used with the PreatLoc™ Attachment System for the retention of removable complete or partial dentures in the mandible or maxilla.
- 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 retaining screw of the PreatLoc™ Angled Abutments is intended as a connecting component for mating the angled abutment to an endosseous implant.
- The auxiliary instruments and accessories are intended for planning and fabricating the prosthetic restoration.

3.2 Contraindications

- Contraindicated where permanent fixation of the denture is required.
- Contraindicated in patients with known hypersensitivity or allergy to titanium (Ti-6Al-4V), a zirconium nitride coating (ZrN) or polyamide PA (material of the retention inserts), or polyether ether ketone (PEEK).

4. INTENDED USERS AND PATIENT GROUP

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

5. STORAGE AND HANDLING

Store in a dry location at room temperature, away from direct sunlight.

6. WARNINGS AND PRECAUTIONS

Prior to use, inspect all products for integrity and completeness. Products with damaged packaging must not be used on patients. Damaged packaging should be returned to the manufacturer together with the product.

Clinicians must follow the instructions for use provided by the respective implant manufacturer regarding implant placement and the permissible range of abutment divergence. For certain compatible implant systems, a vertical divergence exceeding 10° for a single implant may not be permitted.

PreatLoc™ Abutments are intended for use under appropriate functional loading conditions only. Improper use or excessive loading may compromise the structural integrity of the components, potentially resulting in material fatigue and/or localized bone loss.

Implants placed at significant angulation may generate unfavorable stress distribution at the implant body, the implant–abutment interface, and the surrounding bone. Such conditions should be avoided where clinically possible. Clinicians must strictly adhere to the implant manufacturer’s specified limits for implant angulation.

The use of small-diameter implants in combination with PreatLoc™ Angled Abutments in the posterior (high-load) regions of the oral cavity is contraindicated due to elevated mechanical demands.

7. MAGNETIC RESONANCE (MR) SAFETY INFORMATION



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:

Parameter	Condition
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 instruments, tools and the Scan Body all components of the PreatLoc™ Attachment System are designated as single-use devices and are supplied non-sterile. Single-use devices must not be reused or resterilized.

Reuse of single-use devices poses a risk to patient safety, including the potential transmission of blood, tissue, or saliva containing infectious agents. Additionally, resterilization may adversely affect the functional integrity of the device, potentially resulting in malfunction or device failure.

PreatLoc™ Angled Abutments: Inadvertent reuse may result in the accumulation of biological contaminants and mechanical wear of the retention elements, leading to inadequate fit and potential loss of prosthesis retention.

Retaining Screws for PreatLoc™ Angled Abutments: Reuse may lead to contamination buildup and material degradation, negatively affecting fit and function at the abutment–implant interface and impairing connection stability.

9. REUSABLE DEVICES

The instruments, tools, and the Scan Body of the PreatLoc™ Attachment System are designed for multiple use. Prior to each patient use, all reusable devices must be cleaned, disinfected, and sterilized in accordance with applicable reprocessing guidelines.

10. CLEANING, DISINFECTION AND STERILIZATION

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

All instruments and prosthetic components must be cleaned and sterilized before each use. This requirement applies in particular to initial use after delivery, as all components are supplied non-sterile.

The Polyamide (PA66) retention inserts, the processing inserts, and the parallelization post **cannot** be sterilized by autoclave. The products must be chemically disinfected; failure to do so may impair product function. This applies equally to 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 PROSTHESES

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

Method	Procedure	Temperature	Minimum Exposure Time*	Drying Time
Steam sterilization	Pre-vacuum cycle (3x fractionated pre-vacuum)	132°C / 270°F	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., VAH/DGHM or FDA approval or CE marking). Always follow the information, instructions, and warnings of the respective manufacturer of the disinfectant.

Disinfect using the manufactures instructions of an FDA approved high level disinfection solution, CIDEX® OPA-suspension (Johnson & Johnson). The disinfection steps are as follows:

1. Soak for a minimum of 12 minutes in the liquid sterilant at room temperature. Ensure that the inserts are completely immersed in the high level disinfectant solution and that all air bubbles are removed from the surfaces of the device.
2. Rinse disinfection agent by submersing in an immersion bath of 1L demineralized water for 1 minute.
3. Rinse under running demineralized water for 30 seconds.
4. Repeat step 2 and 3 for removal of the disinfectant solution.
5. Rinse inserts with 70% Isopropanol for 10 seconds.
6. Allow to air dry or wipe using a lint-free cloth.
7. Store in clean or sterile container protecting the disinfected inserts from contamination until use.

11. DISPOSAL

Used products that pose an infection risk must be disposed of in accordance with the facility's clinical waste management procedures and all applicable local and national regulations.

12. PERFORMANCE REQUIREMENTS AND LIMITATIONS

12.1 Compatibility

PreatLoc™ Attachment System abutments may only be combined with the implant systems for which they are designated. Verify compatibility by checking the identification markings on the product or product label.

Compatible implant systems are listed in Table 1.

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 must be used strictly in accordance with its intended use, and all specified parameters must be observed.

13. RECOMMENDED TIGHTENING TORQUE

Tighten the PreatLoc™ abutment or retaining screw with a calibrated torque wrench to the tightening torque value specified in Table 2.

Important! Re-verify the specified tightening torque after 5 minutes and re-tighten if necessary.

Table 2: Compatible implant systems and associated tightening torque values	
Implant system	Tightening Torque (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 and Profile 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. PROSTHETIC PROCEDURES

Based on the pre-surgical patient assessment, the clinician should select the appropriate PreatLoc™ Abutment according to implant type, diameter, and gingival height. Reinforcement is recommended for provisional restorations.

All residual bone and soft tissue must be removed from the crestal aspect of the implant body to ensure complete abutment seating.

14.1 Abutment Placement

Straight Abutments

- Carry the abutment to the implant site with either the rose gold end of the Universal Instrument or the Abutment Driver. The holding sleeve on the rose gold end will securely hold the abutment.

Angled Abutments

- Insert the screwdriver with retention sleeve firmly into the abutment retaining screw until the abutment is engaged on the instrument. Transfer the abutment to the implant site and seat it in the desired orientation.
- Thread the retaining screw into the implant using the screwdriver without applying final torque.
- Verify the desired abutment orientation using the parallel post. If adjustment is required, loosen the screw, rotate the abutment to the correct position, and re-seat.

14.2 Abutment Tightening

- Hand-tighten the retaining screw or abutment. Using a calibrated torque wrench, tighten the PreatLoc™ Abutment to the torque value specified in Table 2 or to the value recommended by the implant manufacturer. **Note:** if using the Universal Instrument with straight abutments, insert a 1.25mm/0.050" hex tool into the top portion of the rose gold end and attach a torque wrench.
- Important:** Re-verify the tightening torque after 5 minutes and re-tighten if necessary.
- Following final tightening, seal the screw access channel of angled abutments with cotton pellets or PTFE tape over the screw head, then close with a composite material of choice. Do not overfill beyond the coronal margin of the abutment.

14.3 Abutment Removal

Straight Abutments

- To remove, use either the rose gold end of the Universal Instrument or the Abutment Driver. If using the Universal Instrument insert a 1.25mm/0.050" hex tool into the top portion of the rose gold end. Apply counterclockwise torque until the abutment disengages from the implant.

Angled Abutments

- To remove the abutment, carefully clear the access channel of sealing material using manual instruments such as a curette or a dental handpiece with a suitable bur, avoiding contact with the abutment walls or internal screw.
- Engage the screwdriver with retention sleeve firmly into the retaining screw and apply counterclockwise torque until the screw disengages from the implant. The abutment may then be removable by hand.
- If the abutment cannot be removed by hand, continue applying counterclockwise torque until the retaining screw is fully removed. Then use the abutment removal instrument to disengage and retrieve the abutment from the implant.

14.4 Impression Taking and Stone Model Fabrication

- Once the PreatLoc™ abutments have been tightened to the specified torque, snap the impression copings or scan bodies (if using a digital workflow) onto the abutments until securely seated.
- Proceed with impression taking or intraoral scan using the preferred clinical technique.
- Remove the impression tray and engage a laboratory analog into the intaglio of each impression coping.
- Register the abutment positions in dental stone using standard laboratory model fabrication procedures.

14.5 Prosthesis Fabrication

- Position the PreatLoc™ denture attachment housings with black processing inserts on each abutment.
- Fabricate the prosthesis using standard laboratory techniques.
- At initial delivery, use the retention inserts with the lowest retention level and increase as clinically appropriate.

14.6 Chairside Pick-Up Technique for Denture Attachment Caps (Optional)

- Place a block-out spacer around each abutment and press firmly into position.
- Seat the PreatLoc™ denture attachment cap with the black processing insert onto each abutment.
- Bond the caps to the prosthesis using light-curing, auto-polymerizing, or composite resin material in accordance with the applicable material manufacturer's guidelines.

14.7 Prosthesis Delivery

- Once prosthesis fit has been verified, remove the black processing inserts from each denture attachment cap using the PreatLoc™ universal instrument.
- Replace with the lowest available retention inserts and increase as clinically required. Seat the prosthesis firmly and confirm that each insert is fully engaged on its respective abutment.

14.8 Healing Phase – Delayed Loading

- Relieve the prosthesis to ensure the abutments are not in contact with the denture base material. A soft relining material may be applied to improve patient comfort during the healing period.

14.9 Healing Phase – Immediate Loading

- Immediate loading should only be performed once adequate primary stability has been achieved. An insertion torque of ≥ 30 Ncm may serve as a guideline; however, this threshold may vary depending on the implant system and individual clinical circumstances.
- The decision to proceed with immediate loading is at the clinician's discretion and must be based on a comprehensive evaluation of patient-specific factors.
- A soft diet is recommended throughout the osseointegration period to minimize functional loading on the implants.
- The prosthesis should be adjusted to avoid excessive implant loading during the healing phase.
- The prosthesis should be removed periodically for hygiene purposes as clinically indicated.

15. RETENTION INSERTS

Retention Inserts (PA66)	
Standard pivot inserts with dual retention. For use with straight abutments. 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. For use with straight and angled abutments. 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!*

16. SCAN BODY

PreatLoc™ Scan Body (PEEK)	
If used intraorally, the scan abutment must be sterilized in an autoclave prior to clinical use. Do not use the scan abutment for intraoral scanning unless it has been properly sterilized.	
	For proper processing, a PreatLoc™ digital library is needed. To download and install one of our libraries specific to your dental CAD system please visit our website https://www.preat.com

17. UNIVERSAL INSTRUMENTS

Universal instrument (4-Piece)

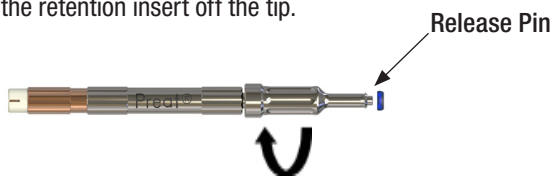


Instructions for removing the retention inserts

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.



18. PATIENT CARE

Meticulous oral hygiene is essential for the long-term success of the PreatLoc™ Attachment System. Patients should be informed of the following:

- PreatLoc™ attachments must be cleaned thoroughly each day to prevent plaque biofilm accumulation. A soft-bristled nylon toothbrush or end-tufted brush with a non-abrasive toothpaste should be used to clean the abutments.
- Abrasive toothpastes contain coarse particles that may scratch abutment surfaces and promote additional plaque retention.
- An oral irrigation device is recommended to flush debris from within the PreatLoc™ retention inserts.
- PreatLoc™ retention inserts are fabricated from a flexible polymer material to allow routine insertion and removal of the overdenture. Wear occurs under normal functional conditions and replacement may be required over time.
- Bruxism places increased functional demands on PreatLoc™ abutments and may reduce the service life of the retention inserts.

Patients should be instructed to make routine follow-up visits for hygiene and to assess the attachment function. Any discomfort or loss of overdenture retention should be reported to the dental professional promptly.

Follow-up appointments are recommended at 6-month intervals. The abutments must be retightened to the specified torque values at each visit. Failure to retighten the abutments may result in screw loosening and fracture of the abutment. Patients should be examined for signs of peri-implant inflammation and implant mobility at every follow-up appointment.

19. INSERTING AND REMOVING OVERDENTURES

Patients must be instructed on the correct technique for overdenture insertion. The prosthesis should be correctly positioned over the abutments before pressure is applied. Using both hands, the patient should apply even bilateral pressure until the prosthesis snaps firmly into place.

NOTE: Patients must NOT bite the overdenture into position. Biting forces will cause premature wear of the PreatLoc™ Abutments and retention inserts.

To remove the overdenture, the patient should place both thumbs beneath the flanges of the prosthesis and apply simultaneous upward pressure (mandibular denture) or downward pressure (maxillary denture) on both sides. Tongue movement may assist in disengagement. Thorough cleaning of the prosthesis is recommended following each removal.

20. CLEANING OF IMPLANT RETAINED OVERDENTURES

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

1. To minimize the risk of fracture, fill the sink with warm water before cleaning. Apply a non-abrasive toothpaste to a soft-bristled nylon brush or end-tufted toothbrush and clean all surfaces of the overdenture thoroughly.
2. Remove the overdenture every night and rinse it with clear water.

21. 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 packaging is damaged
	U.S. Federal law restricts this device to sale by, or on the order of, a licensed dentist.
	Non-sterile
	MR conditional
	Product identification number

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