MEDEALIS

PROFESSIONAL DENTAL SYSTEMS

PrimeLOC Overdenture Attachment System®

Technique Manual

The **PrimeLOC Overdenture Attachment System®** for hybrid dentures consists of precision fasteners that can be used on solitary implants. It is indicated for use with implant-retained overdentures in the maxilla and mandible on at least two to four implants.
The abutments are coated with an innovative protective layer of zirconium carbonitride. This is not only characterized by very high abrasion resistance but also by its highly aesthetic rose-gold color.

PrimeLOC abutments are compatible with the respective brands and manufacturers. Please note that the trademarks referenced here are the property of their respective owners.

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Content

1. Information about the PrimeLOC Overdenture Attachment System®

- **Biocompatible ceramic PVD hard coating**
  The coating is an extremely hard zirconium carbonitride layer (ZrCN). It has high abrasion and wear resistance. In addition to the functional surface properties, the rose-gold coloring is also impressive. Zirconia surfaces have the advantage that they have **half the plaque adhesion** as titanium and thus largely prevent inflammatory reactions of the soft tissue.

- **Additional screw-in mechanism**
  The industry standard .050"/1.25 mm* hexagonal screw mechanism simplifies insertion.

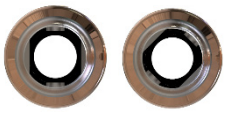
- **Optimized retention housing**
  The retention housing has additional horizontal grooves for improved resistance to vertical and horizontal movement. The red anodized surface improves aesthetics and prevents the grey surface shining through with the thin denture material.

PrimeLOC Abutments, straight

PrimeLOC Abutments, angled

- **Abutments with an 18° angulation**
  With these abutments, divergences between implants of up to 65° can be corrected. With the 18° angled abutments, the dentist is able to cover a wide range of clinical implant situations. The angled abutments are available in two connection variants. This makes it easier to compensate for the implant position.

- **Retention inserts made of a biocompatible high-performance plastic**
  The outstanding properties of the retention inserts include their very high hardness combined with high toughness and dynamic load-bearing capacity (number of load cycles). They are also highly resistant to chemicals and lipids (grease) and have a low tendency to absorb water. They have outstanding resistance to disinfectants containing alcohol.



example: indexation 0° and 45°

- **All-in-one packaging**
  There are two different packaging variants. One for the straight abutments and one for the angled 18° abutments. In both cases the abutment ordered is packed with the alignment post, the possible retention insert, the retention housing with the black processing insert and the block-out ring. The angled abutments also include the required retaining screw.

2. Intended purpose

Indication
The **PrimeLOC Overdenture Attachment System®** for denture fixation is intended for the attachment of overdentures or partial dentures that are wholly or partially supported by endosseous implants in the lower or upper jaw.

Contraindication
There are no absolute contraindications for the use of the attachment system for denture fixation. However, the product must not be used:

- if a complete fixation of the denture is requested.
- if only one implant is available to fix the denture.
- if the divergence between the implant axes is more than 40°.

3. System instructions

Please pay attention!

This work instruction contains the current operating instructions. Please read them before using the PrimeLOC Overdenture Attachment System®. The generally applicable planning principles apply for implant retained, combined mucosa/implant-supported, removable prosthetic restorations.

The PrimeLOC Overdenture Attachment System® may only be used by dentists and doctors as well as dental technicians who are familiar with dental surgery, including diagnosis and preoperative planning. If there is any uncertainty regarding the indication or the type of application, it should not be used until all points have been clarified. Before each operation, make sure that all necessary parts, instruments and aids are suitable, complete and functional. All clinically used parts and instruments must be secured against aspiration and ingestion.

The products are supplied **NON-STERILE**. Therefore, any prosthetic reconstruction must be cleaned and disinfected before use. The exact details can be found in section 16 Sterilization.

This product must not be used in patients suspected of being allergic to one or more elements of the materials used.
The product may only be used after prior allergological clarification and proof of the absence of an allergy.

Single use of products
In general, products marked for single use must not be used more than once to avoid functional losses of the system!
Retention inserts: Retention inserts that show signs of abrasion or have been removed from the retention housing with the universal instrument are damaged and must be replaced.
PrimeLOC abutments: Impurities on the abutment could lead to inflammation and infection in the patient or to increased wear in the retention area, which would result in a loss of retention of the denture.

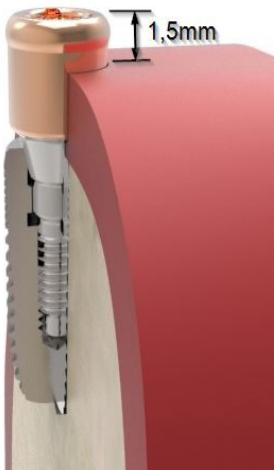
4.Work instruction for the PrimeLOC Overdenture Attachment System®

4.1 Position of the implant

The planning of implant positions is of decisive importance for optimal restoration and the resulting patient satisfaction.
The strategic alignment of the implant positions should be chosen in such a way that the implants are widely distributed, thus ensuring polygonal support for the denture.
The restoration can be placed on two implants in the lower jaw. Make sure that the implants are arranged as symmetrically as possible with sufficient interimplant space.
For the patient, the use of four instead of two implants is preferred. It reduces the risk of complications and stabilizes the prosthetic reconstruction against tensile, tilting and chewing forces.

At least four implants are required in the upper jaw. The distally planned implants should be placed as far distally as possible in order to achieve a maximum support polygon and to counteract any undesired tilting of the denture.

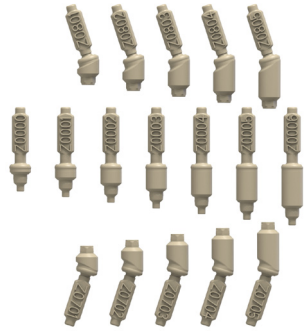
4.2 Selection of the PrimeLOC abutments

	The choice of PrimeLOC abutment depends on the implant used, the thickness of the gingiva and the axial divergence between the implants. If the axial divergence between the implants is greater than 20°, the angled PrimeLOC abutment with 18° angulation is preferred. The correct abutment height is selected when the functional area is 1.5 mm out of the gingiva. It is easier for the patient to insert the denture if the abutments are at the same horizontal level. Clean the implant configuration before inserting the PrimeLOC abutment. It must be ensured that the abutment is properly seated in the implant. Various instruments are available for inserting the abutment, which are described in sections 9, 10 and 11. The required tightening torque can be found in the table on page 29.

4.3 Determining the axial divergence between the implants

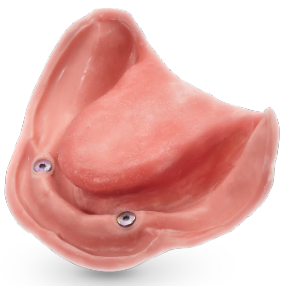
	First, the blue parallelization pins are placed on the abutments. The angle measuring aid is then placed behind the parallelization pins and the axial divergence is read off. The value read is used for the correct selection of the abutment variant and shows which retention inserts are to be used.

4.4. Selection of the abutments set

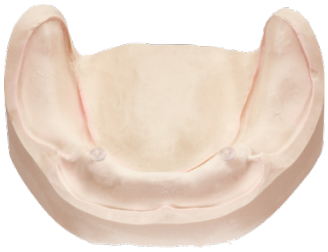
	The correct selection of the implant abutment for each individual patient case is an important aspect of treatment success. The selection abutment set helps the dental technician to select the optimal PrimeLOC abutment for the restoration. The appropriate angulation (straight or 18° angled) and connection indexing (type A or B if available) are determined. The label on the flag of the selection abutment stands for the respective PrimeLOC counterpart that the dental technician must order. Note: Abutment selection aids are not suitable for use on the patient!
	The flag on the selection abutment shows the dental technician whether there is a common insertion direction.

5. Fabrication of a new full denture with the PrimeLOC Overdenture Attachment System®

5.1 Situational impression

	After the implants have healed and the gingiva formers have been inserted, the anatomical impression is taken using alginate impression material and a pre-fabricated tray.
	

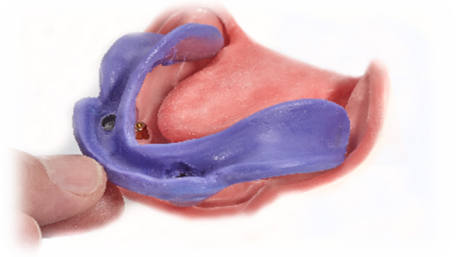
	

	The anatomical plaster model is fabricated in the laboratory, on the basis of which an individual tray is made.

	The dental technician applies a placeholder for the impression material in the form of a wax plate in the area of the recognizable gingiva former. They design this area to be cylindrical in order to gain sufficient space for the closed impression using the PrimeLOC impression caps.
	Now an individual tray made of dimensionally stable material is created, which serves for functional impression taking and transfer of the implant position.

5.2 Functional impression

<table>
<tr><td>  </td><td>After removing the healing caps, the appropriate PrimeLOC abutments are inserted (disinfection).
Make sure that the PrimeLOC abutments have a consistent horizontal height.
Select the corresponding gingiva heights to achieve a uniform horizontal height level for all PrimeLOC abutments. In unfavorable situations, you can also choose between straight and angled PrimeLOC abutments.
The selection made must be documented so that it can be recreated for the final bonding.</td></tr>
<tr><td>  </td><td rowspan="2">Now place the impression cap on the PrimeLOC abutments. Pay attention to a firm fit free of play, recognizable by an audible click.</td></tr>
<tr><td>  </td></tr>
<tr><td>  </td><td>Check the individual tray for its anatomical and tension-free fitting in the area of the PrimeLOC abutments.</td></tr>
</table>

	The impression should now be taken without compression using a stable impression material that allows the impression copings to be firmly located.
	After removing and checking the impression, the dental technician makes a master model from superhard plaster using the laboratory analogs, which are snapped in with an easily felt click.




	On this master model, the dental technician produces a bite registration whose base should be made of resin.
	In order to achieve optimum accuracy in bite registration, it makes sense to incorporate the PrimeLOC spacer sleeve, which serves as a placeholder for completion (small undercuts are used for retention). This ensures that the bite registration, as well as the subsequent wax placement, is definitely firm and stable in the mouth.

5.3 Bite registration

	With this stable bite plate, it is possible to implement all different bite registration systems.
	Back in the laboratory, the opposing jaw is articulated in relation to its position using the bite plate.
	Then the wax setup is made and its try-in takes place.
	

5.4 Aesthetic fitting

If it is aesthetically and functionally satisfactory for all parties, the dental technician can finish the denture using the placeholder.
Check the correct fit and seal between the placeholder housing and the laboratory analog. If there is a gap, it can be closed with a little wax.
After lifting off the polymerized denture, the placeholder is removed from the denture using the insertion and removal tool.

Removal of the placeholder:

	Use the tip of the Universal Instrument to remove the spacer sleeves from the finished denture. Use the same procedure when removing the spacer sleeve as you would when removing the colored retention insert from the retention housing. Do not angle the instrument, but hold it straight when pulling out the spacer sleeves. This holds the instrument more firmly in the sleeve. Remove the spacer from the instrument by turning the tip further to the middle of the instrument (clockwise). This activates the release pin that pushes the spacer sleeve off the instrument. Please point the instrument downwards and away from you. Now the denture is finished for bonding the retention housing in the mouth.

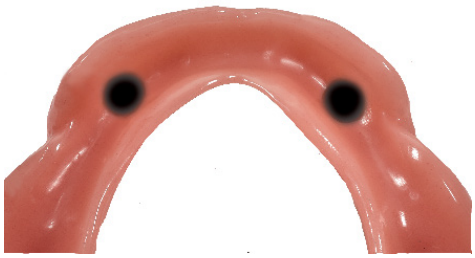
5.5 Bonding in the mouth

	Sterilize the PrimeLOC abutments as described in section 16 and screw in the appropriate sizes (according to their documentation during the function impression) with the prescribed torque and using the corresponding insertion tool. Slide the white block-out rings over the functional area of the PrimeLOC abutments and place the retention housing with the black processing insert on top. Check that the block-out ring between the retention housing and the PrimeLOC abutment is seated and sealed correctly. If there is a gap, it can be closed with a second block-out ring or some block-out wax. It is very important that no resin gets into the retention housing. Now check the tension-free fit of the denture over the retention housings.
	To enable controlled bonding, it is advantageous to drill a small opening in the area of the placeholder cavity to place the adhesive in the mouth under visual control of the correctly seated denture.
	

	This hole can be drilled on the lingual or buccal surface (depending on access).
	To ensure an optimal hold, we recommend an abutment cement (e.g. Quick UP® QuickMix syringe 7.5 g by VOCO or similar). According to the adhesive manufacturer's instructions, condition the housing and placeholder cavity of the denture, insert it and place the adhesive. After the cement has hardened, the denture can be removed and its function checked. Then the remaining hole can be closed with pink denture resin and cleaned.

6. Reworking an existing complete denture with the PrimeLOC Overdenture Attachment System®

<table>
<tr><td>  </td><td rowspan="2">Slide the white block-out rings over the functional area of the PrimeLOC abutments.</td></tr>
<tr><td>  </td></tr>
<tr><td>  </td><td rowspan="2">Now place the red retention housing with the black processing insert on each abutment. Check the correct fit and seal of the block-out ring between the retention housing and the mucous membrane. You can compensate for greater mucosal resilience with overlaying block-out rings.</td></tr>
<tr><td>  </td></tr>
<tr><td>  </td><td>Apply paint to the back of the retention housing for example by using a marker or articulating paper. Place the existing denture on the model.</td></tr>
</table>

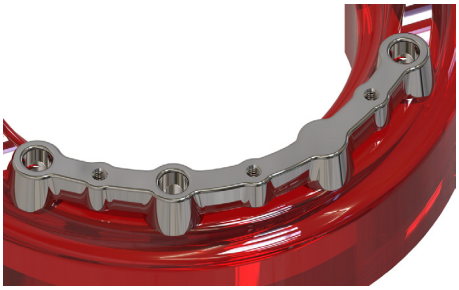
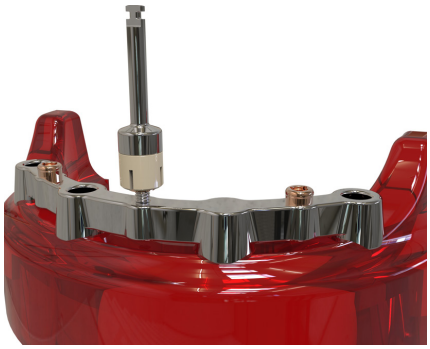
	The imprint of the ink on the denture base shows you the positions of the cavities for the fit of the retention housing.
	Grind out the cavities until the denture can be easily pushed over the retention housing and a passive fit of the denture is achieved. The cavities for the retention housings must be large enough to prevent direct contact between the retention housing and the denture with a passive denture seat. It is recommended to drill a connection hole to the cavities from the occlusal side. This allows for bonding to also take place from the occlusal side or for excess cement to escape through the hole.
	Bond the denture on the retention housings. For this purpose, place the denture over the retention housing in the oral cavity. The denture should have an optimal passive fit without exerting high pressure on the soft tissue. You can fill the cavity between the retention housing with denture resin through the connecting holes. For this purpose, use cold-curing or light-curing resin and observe the manufacturer's instructions. Alternatively, apply a small amount of this material to the milled cavities of the denture and coat slightly around the retention housings. Then place the denture in the oral cavity again. The position of the denture should not be changed until the resin has hardened. After curing, remove the denture from the oral cavity and remove the white block-out rings from the abutments. Now remove excess resin from the denture and re-polish it.

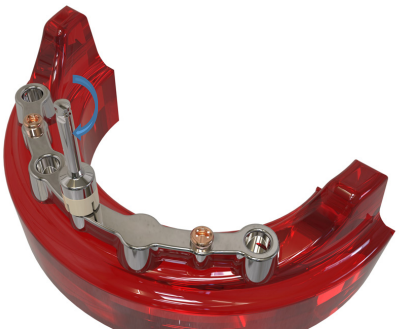
<table>
<tr><td>  </td><td rowspan="2">Replace the black processing inserts with the selected retention insert using the universal instrument (see retention insert application).</td></tr>
<tr><td>  </td></tr>
<tr><td>  </td><td>Insert the finished denture and check the occlusion. For initial treatment, you should choose a retention insert with lower retention force.
Removal and replacement of the denture for cleaning purposes must be practiced with the patient.</td></tr>
</table>

7. PrimeLOC bar abutment for milled bars

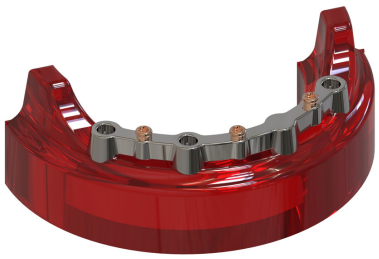
PrimeLOC bar abutment with M2 threaded pin and a head height of 2 mm

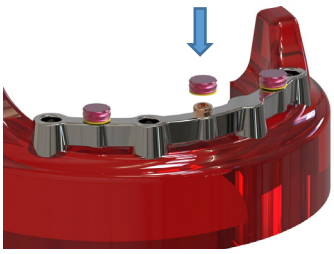
7.1 PrimeLOC bar abutment as an additional holding element on a milled bar in a new denture.

	Take an impression of the oral situation and fabricate a working cast according to the manufacturer's processing instructions.
	Design the bar using the CAD/CAM technique. Take into account the desired positions of the PrimeLOC bar abutment. A standard **M2** thread is required in the bar to attach the bar abutment. When designing the thread, pay attention to the insertion direction of the denture in the mouth. The bar abutment must rest on the bar.
	After fabrication of the CAD/CAM dental bar, the PrimeLOC bar abutment is screwed into the milled bar using the PrimeLOC screwdriver.

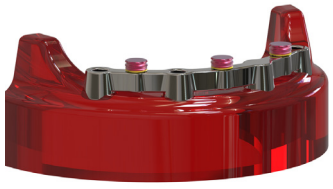


Tighten the PrimeLOC bar abutment to a torque of **35 Ncm**.

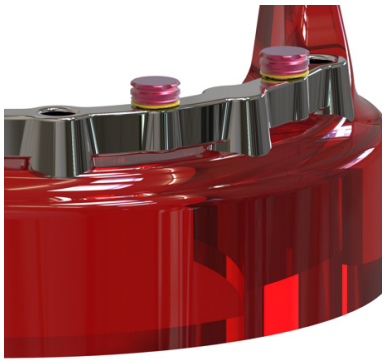




After mounting the milled bar with the assembled PrimeLOC bar abutments and the fixed retention housings on the master model, the denture can be fabricated according to the principle of modern full dentures.



7.2 Use of PrimeLOC CAD/CAM bar abutment as an additional retention element on a milled bar for an existing denture

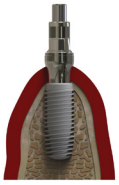
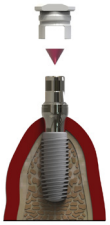
	Take a relining impression with the impression coping of the respective implant manufacturer and the denture to be remodeled. Fabricate the model in extra hard dental stone plaster in a dental laboratory. After fabricating the CAD/CAM dental bar, screw the PrimeLOC bar abutment into the milled bar using the PrimeLOC screwdriver. Tighten the PrimeLOC bar abutment to a torque of **35 Ncm**. After mounting the milled bar with the assembled PrimeLOC bar abutments and the fixed retention housings on the master model, the denture is fitted over the bar construction with polymerization of the retention housings. The denture is then checked for excess acrylic in the area of the matrices and for proper functionality.
	**Selection of retention inserts** Three different PrimeLOC retention inserts are available for selecting the desired retention. The retention inserts are color-coded. The color indicates the retention force that can be achieved with the retention inserts. yellow: processing insert blue: light retention (700 g), pink: medium retention (1200 g) clear: strong retention (2200 g) The data for the retention forces are approximate values. **Important:** When trying the denture on the patient, always start with the lowest retention force.

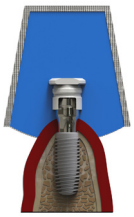
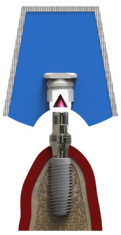
8. Impression coping, closed tray

For transferring the implant position to the master model using the reduction technique (closed tray)

	Impression copings in two lengths are available for taking the impression. The connecting screw is loosely connected to the impression coping.
	The impression cap (reduction cap) is supplied together with the impression coping.

Impression taking
Step by step

			
(1) The impression coping is inserted into the implant	(2) The retaining screw in the impression coping is tightened using the insertion tool	(3) The repositioning aid is applied to the impression coping after the correct fit has been rechecked	(4) Pressure is applied to the repositioning aid until it is fixed and locked in place

		
(5) The impression tray is applied to the repositioning aid and the impression coping.	(6) The impression tray is then removed, leaving the repositioning aid in the impression tray	(7) The impression coping is removed using the insertion tool

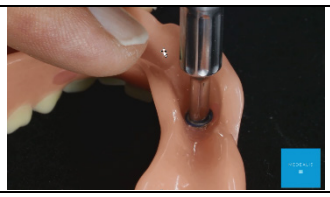
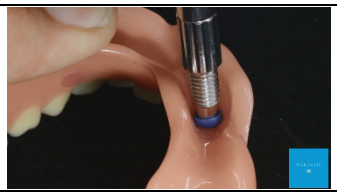
		
(8) The impression coping is placed in an analog and the retaining screw is tightened using the insertion tool	(9) The components are inserted into the repositioning aid, which is located in the impression tray, and fixed in place.	(10) The impression is moulded with the model material

9. Use of the retention inserts

The retention housing is supplied with a pre-assembled black processing insert, which is replaced by the selected retention insert with the PrimeLOC universal instrument after the denture has been fabricated.

If subsequent work has to be carried out on the denture, the retention insert must be replaced by the processing insert. This is the only way to ensure that no contamination enters the retention housing. After work has been completed, the processing insert is replaced by a new retention insert.

Retention insert clear, pink, blue, for dual retention When anchoring on two or more PrimeLOC abutments, the use of the blue or pink retention insert is recommended. When using the retention inserts with dual retention the maximum divergence of the accommodative PrimeLOC abutments may not exceed 20°.			**Retention insert grey**	**Retention insert green, orange, red, for extended application range** If there are implant axis divergences of more than 10-20° the replacement inserts come into effect for the extended range of application.		
						
A0004	A0003	A0002	A0001	A0005	A0006	A0007
clear with strong retention (*2200 g / 22N)	pink with medium retention (*1200 g / 12 N)	blue with light retention (*700 g / 7 N)	zero retention for temporary support and protection. Do not use in the anchoring with the PrimeLOC abutments included	red with light retention (*600 g / 6 N)	orange with medium retention (*1000 g / 10 N)	green with strong retention (*1900 g / 19 N)
The selection of the retention insert depends on the individually desired strength of the anchorage or retention. *Always start with the inserts with the least retention* ** Different factors can lead to a deviation from the guide values*						

		
Removing the process inserts To insert the retention inserts into the denture sockets you can remove the black processing inserts from the socket	**Inserting the retention inserts** Insert the retention inserts with the PrimeLOC tool (see section 9).	**Inserting the finished denture** Insert the finished denture and check the occlusion

10. Presentation of the universal instruments for the PrimeLOC Overdenture Attachment System®

10.1 PrimeLOC universal instrument four-piece A0020

The PrimeLOC universal instrument four-piece A0020 boasts additional features such as the easy-to-clean surface, a holding sleeve and additional friction, which ensures secure retention of the retention insert on the instrument and thus considerably facilitates the insertion of the retention insert into the housing.

Holding sleeve

The instrument holding sleeve is screwed onto the end piece. It simplifies insertion of a PrimeLOC abutment and holds it in place while it is screwed into the implant. The sleeve is made of PEEK and can be autoclaved.

Rose-gold end piece

The end piece of the instrument is used to screw the PrimeLOC abutments into the implants or lab analogs. It is hardened and additionally refined with a very hard zirconium carbonitride coating.

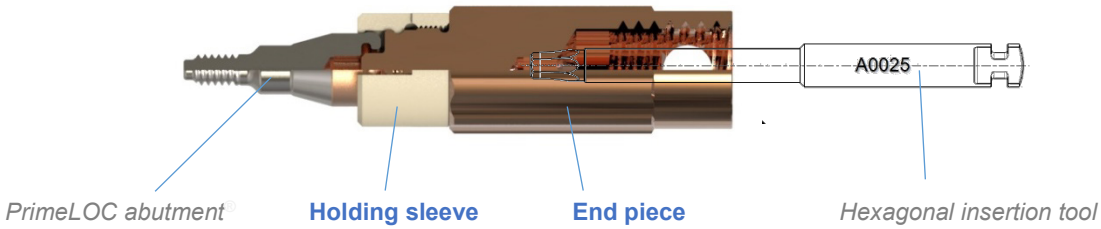
Body

The body of the instrument is used to insert the retention insert into the retention housing. To do this, the tip must be completely unscrewed from the body. With the end, the retention insert is pressed into the retention housing. Additional friction holds the retention insert on the end.

Tip

The tip is used to remove the replacement inserts from the retention housing. To do this, the tip must be loosened with two full turns.
A gap becomes visible between the tip and the body.

Rose-gold end piece with holding sleeve



Holding sleeve: The holding sleeve is screwed onto the end piece. It holds the PrimeLOC abutment on the instrument when it is inserted into the implant. The holding sleeve can be easily screwed off the end piece for cleaning. If the holding function is not required, the end piece can also be used without the sleeve. The holding sleeve can be autoclaved.

End piece: The end piece is fitted with a hexagon socket into which a hexagonal instrument with a size of 1.25 mm fits. A locking thread can be inserted through a cross hole. This can avoid aspiration.

10.2 PrimeLOC universal instrument practice A0019

The tool is designed for use in the dental practice with the main focus on replacing retention inserts.

End piece practice

The end piece of the instrument is used to insert the retention inserts into the housing. The tip does **not** have to be unscrewed from the body. With the end, the retention insert is pressed into the housing. Through additional friction, the retention insert is held at the end of the instrument.

Tip

The tip is used to remove the retention inserts from the housing. To do this, the tip must be loosened with two full turns. A gap becomes visible between the tip and the body.

11. Instructions for removing the retention inserts

To remove the retention inserts, the tip must be turned from the body until a small gap between the two becomes visible. 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 retention housing.
The retention insert is removed from the retention 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 on the body, the release pin inside the tip is pushed forward and thus pushes the retention insert from the tip.

Holding element for retention inserts

A very special feature of PrimeLOC universal instruments is the friction of the retention inserts on the instrument. The annoying dropping of the retention inserts during insertion into the housing is a thing of the past. With the instrument, the retention inserts can be removed directly from the MEDEALIS system packaging.

12. Instruments for the PrimeLOC Overdenture Attachment System®

12.1 Screwdrivers for PrimeLOC abutments with shank for contra-angle handpieces

The instrument is used to screw the one-piece straight PrimeLOC abutments into the intended implants or implant analogs. It engages with the triangular geometry at the upper end of the abutment heads.

Material: hardened stainless steel
Length: 30 mm
Art. no.: A0022

12.2 Screwdriver with holding sleeve for PrimeLOC Abutments with shank for contra-angle handpieces

The instrument is used to screw the one-piece straight PrimeLOC abutments into the intended implants or implant analogs. It engages with the triangular geometry at the upper end of the abutment heads. As an additional **feature**, the abutment is held on the instrument by the holding sleeve. The holding sleeve can be easily screwed off the end piece for cleaning. If the holding function is not required, the end piece can also be used without the sleeve. The holding sleeve can be autoclaved.

Material: hardened stainless steel; holding sleeve PEEK
Length: 23.2 mm
Diameter: Ø 5.8 mm
Art. no.: A0023

12.3 Hex screwdriver 1.25 mm with shank for contra-angle handpieces

For PrimeLOC abutments and retaining screws

This instrument can be used to screw the one-piece straight PrimeLOC abutments into the intended implants or implant analogs. The instrument is suitable for all PrimeLOC retaining screws.

Material: hardened stainless steel
Length: 27 mm
Art. no.: A0025

Not suitable for MEGAGEN screws AANMST and AANMSF
Not suitable for Botticelli screws A-P-S028 and A-P-R028

12.4 PrimeLOC angle measuring aid

The angle measuring aid can be used to determine the angles (axial divergence) between the individual implants.

Material: steel
Art. no.: A0013

Secure the angle measuring aid to the lateral holes with dental floss in order to avoid aspiration.

12.5 Screwdriver with holding sleeve for PrimeLOC ceramic abutments with shank for contra-angle handpieces

fits NobelPearl™ PrimeLOC and Zeramex® Docklocs® ceramic abutments

The instrument is used to screw the one-piece straight Docklocs ceramics abutments into the intended implants or implant analogs. It engages with the triangular geometry at the upper end of the abutment heads. As an additional feature, the abutment is held on the instrument by the holding sleeve. The holding sleeve can be easily screwed off the end piece for cleaning. If the holding function is not required, the end piece can also be used without the sleeve. The holding sleeve can be autoclaved.

Material: hardened stainless steel (1.4035); holding sleeve PEEK MT
Coating: ZrCN
Length: 23.2 mm
Diameter: Ø 5.8 mm
REF: A0027

13. System supplies

REF	Quantity pieces	Denomination		material
A0001.S.P	8	PrimeLOC retention insert, grey, no (0) retention		PA12-GB30
A0002.S.P	8	PrimeLOC retention insert, blue, light retention, 0°–10°		PA12-GB30
A0003.S.P	8	PrimeLOC retention insert, pink, medium retention, 0°–10°		PA12-GB30
A0004.S.P	8	PrimeLOC retention insert, clear, strong retention, 0°–10°		PA12-GB30
A0005.S.P	8	PrimeLOC retention insert, red, light retention, 10°–20°		PA12-GB30
A0006.S.P	8	PrimeLOC retention insert, orange, medium retention, 10°–20°		PA12-GB30
A0007.S.P	8	PrimeLOC retention insert, green, strong retention, 10°–20°		PA12-GB30
A0008.S.P	8	PrimeLOC processing insert black (not suitable for long-term use)		HD-PE Purell
A0001.SZ.P	4	PrimeLOC retention insert, grey, no (0) retention		PA 6.6
A0002.SZ.P	4	PrimeLOC retention insert, blue, light retention, 0°–10°		PA 6.6
A0003.SZ.P	4	PrimeLOC retention insert, pink, medium retention, 0°–10°		PA 6.6
A0004.SZ.P	4	PrimeLOC retention insert, clear, strong retention, 0°–10°		PA 6.6
A0005.SZ.P	4	PrimeLOC retention insert, red, light retention, 10°–20°		PA 6.6
A0006.SZ.P	4	PrimeLOC retention insert, orange, medium retention, 10°–20°		PA 6.6
A0007.SZ.P	4	PrimeLOC retention insert, green, strong retention, 10°–20°		PA 6.6
A0008.SZ.P	4	PrimeLOC processing insert black (not suitable for long-term use)		LD-PE Purell
A0009.S.P	20	PrimeLOC block-out ring		Santroprene® TPE
A0009.SZ.P	20	PrimeLOC block-out ring		Silicone
A0010.S.P	4	Titanium retention housing with processing insert		Housing Titanium G5 HD-PE Purell
A0010.SZ.P A0010.SZT.P	4 10	Titanium retention housing with processing insert		Housing titanium G5 LD-PE Purell
A0011.SZ.P A0011.SZT.P	4 10	Pink anodized titanium retention housing with processing insert		Housing pink Titan G5 LD-PE Purell

A0030.S.P	2	Zirconia retention housing with processing insert		Housing ZiO_2 HD-PE Purell
A0012.S.P	4	PrimeLOC spacer sleeve		Hostaform® POM
A0013.P	1	PrimeLOC angle measuring aid		Stainless steel
A0014.S.P	4	PrimeLOC Lab Analog straight		Titanium Grade 5
A0026.S.P	4	PrimeLOC Lab Analog angled 18°		Titanium Grade 5
A0015.S.P	4	PrimeLOC impression coping with black processing insert		Housing Titanium G5 HD-PE Purell
A0016.S.P	4	PrimeLOC parallelization posts		HD-PE Purell
A0019.P	1	PrimeLOC universal instrument practice		Stainless steel Silicone
A0020.P	1	PrimeLOC universal instrument four-part		Stainless steel ZrCN (red-gold) PEEK /Silicone
A0022.P	1	Screwdriver for PrimeLOC abutments with shank for contra-angled handpieces		Stainless Steel
A0023.P	1	Screwdriver with holding sleeve for PrimeLOC abutments with shank for contra-angled handpieces		Stainless Steel PEEK
A0027.P	1	Screwdriver with holding sleeve for PrimeLOC ceramic abutments with shank for contra-angled handpieces		Stainless steel ZrCN (red-gold) PEEK
A0025.P	1	Hex screwdriver 1.25 mm for PrimeLOC abutments and retaining screws with shank for contra-angled handpieces *Not suitable for MEGAGEN screws AANMST and AANMSF*		Stainless steel

A0050.S.T.P	1	PrimeLOC laboratory set, up to 20° divergence compensation: 2 titanium housings (A0010) (Ø 5.5 mm, height 2.5 mm) with black process insert (A0008) (height 1.9 mm), 2 block-out rings (A0009), 2 retention inserts, transparent (A0004), 2 retention inserts, pink (A0003), 2 retention inserts, blue (A0002)	
A0051.S.T.P	1	PrimeLOC laboratory set, up to 40° divergence compensation: 2 titanium housings (Ø 5.5 mm, height 2.5 mm) with black process insert (height 1.9 mm), 2 block-out ring (A0009), 2 retention inserts, green (A0007), 2 retention inserts, orange (A0006), 2 retention inserts, red (A0005),	
A0052.S.T.P	1	PrimeLOC laboratory set, up to 20° divergence compensation: 2 zirconia housings (Ø 5.5 mm, height 2.5 mm) with black process insert (height 1.9 mm), 2 block-out ring (A0009), 2 retention inserts, transparent (A0004), 2 retention inserts, pink (A0003), 2 retention inserts, blue (A0002)	
A0053.S.T.P	1	PrimeLOC laboratory set, up to 40° divergence compensation: 2 zirconia housings (Ø 5.5 mm, height 2.5 mm) with black process insert (height 1.9 mm), 2 block-out ring (A0009), 2 retention inserts, green (A0007), 2 retention inserts, orange (A0006), 2 retention inserts, red (A0005),	
A0055.S.ZT.P A0055.T.ZT.P	2 10	PrimeLOC laboratory set, up to 20° divergence compensation: 1 titanium housing (A0010.Z) (Ø 5.5 mm, height 2.5 mm) with black process insert (height 1.9 mm), 1 block-out ring (A0009.Z), 2 retention inserts, transparent (A0004), 1 retention insert, clear (A0004.Z), 1 retention insert, pink (A0003.Z), 1 retention insert, blue (A0002.)	

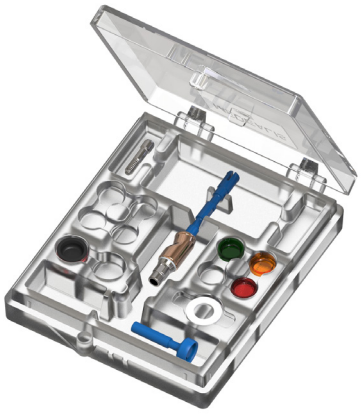
A0055.S.ZTA.P A0055.T.ZTA.P	2 10	PrimeLOC laboratory set, up to 20° divergence compensation: 1 titanium housing (A0011.Z), pink anodized (Ø 5.5 mm, height 2.5 mm) with black process insert (height 1.9 mm), 1 block-out ring (A0009.Z), 1 retention insert, clear (A0004.Z), 1 retention insert, pink (A0003.Z), 1 retention insert, blue (A0002.)	
A0056.S.ZT.P A0056.T.ZT.P	2 10	PrimeLOC laboratory set, up to 40° divergence compensation: 1 titanium housing (A0010.Z) (Ø 5.5 mm, height 2.5 mm) with black process insert (height 1.9 mm), 1 block-out ring (A0009.Z), 1 retention insert, green (A0007.Z), 1 retention insert, orange (A0006.Z), 1 retention insert, red (A0005.Z)	
A0056.S.ZTA.P A0056.T.ZTA.P	2 10	PrimeLOC laboratory set, up to 40° divergence compensation: 1 titanium housing (A0011.Z), pink anodized (Ø 5.5 mm, height 2.5 mm) with black process insert (height 1.9 mm), 1 block-out ring (A0009.Z), 1 retention insert, green (A0007.Z), 1 retention insert, orange (A0006.Z), 1 retention insert, red (A0005.Z)	

PrimeLOC Bar components

REF	Quantity pieces	Denomination	
A0102.S.T.P	1	PrimeLOC Abutment Set A, one-piece abutment 1 piece PrimeLOC bar abutment (A0102) 1 retention housing (Ø 5.5 mm, height 2.5 mm) with yellow processing insert (A0017) 1 block-out ring (A0009), 1 retention insert, blue (A0002), 1 retention insert, pink (A0003), 1 retention insert, transparent (A0004),	
A0102.S .P A0102.Z .P	2 10	PrimeLOC abutment for bar, 2.0 mm thread	
A0050.SB.T.P	1	PrimeLOC laboratory set, up to 20° divergence compensation: 2 titanium housings (A0010) (Ø 5.5 mm, height 2.5 mm) with yellow bar process insert (height 1.9 mm), 2 pieces block-out ring (A0009), 2 pieces retention inserts, transparent (A0004), 2 retention inserts, pink (A0003), 2 retention inserts, blue (A0002)	
A0057.S.ZT.P A0057.T.ZT.P	2 10	PrimeLOC laboratory set, up to 20° divergence compensation: 1 titanium housing (A0010.Z) (Ø 5.5 mm, height 2.5 mm) with yellow bar process insert (height 1.9 mm), 1 piece block-out ring (A0009.Z), 2 pieces retention inserts, transparent (A0004), 1 retention insert, clear (A0004.Z), 1 retention insert, pink (A0003.Z), 1 retention insert, blue (A0002.)	
A0057.S.ZTA.P A0057.T.ZTA.P	2 10	PrimeLOC laboratory set, up to 20° divergence compensation: 1 titanium housing (A0011.Z), pink anodized (Ø 5.5 mm, height 2.5 mm) with yellow bar process insert (height 1.9 mm), 1 block-out ring (A0009.Z), 1 retention insert, transparent (A0004.Z), 1 retention insert, pink (A0003.Z), 1 retention insert, blue (A0002.)	
A0017.SZ .P A0017.SZT.P	4 20	Yellow bar processing insert	
A0010.SB.P A0010.SBT.P	4 10	Red retention housing with processing insert for bar abutments	
A0010.SZB.P A0010.SZBT.P	4 10	Titanium retention housing with yellow processing insert for bar	
A0011.SZB.P A0011.SZBT.P	4 10	Pink titanium retention insert with yellow processing insert for bar	

14. Packaging variants

14.1 All-in-one-packaging

Set A	PrimeLOC Abutment Set A, one-piece abutment 1 PrimeLOC abutment (xxxxxx) 1 retention housing (Ø 5.5 mm, height 2.5 mm) with black processing insert 1 block-out ring (A0009), 1 PrimeLOC parallelization pin (A0016) 1 retention insert, blue (A0002), 1 retention insert, pink (A0003), 1 retention insert, transparent (A0004), 1 retention insert, red (A0005), 1 retention insert, orange (A0006), 1 retention insert, green (A0007), (*the black processing insert is not suitable for permanent use in the mouth*)	
Set B	PrimeLOC Abutment Set B, abutment with retaining screw 1 PrimeLOC abutment, angulation 18° (xxxxxx) 1 PrimeLOC retaining screw (A01xx) 1 holding pin (E0000), 1 retention housing (Ø 5.5 mm, height 2.5 mm) with black processing insert, 1 block-out ring (A0009), 1 PrimeLOC parallelization pin (A0016) 1 retention insert, red (A0005), 1 retention insert, orange (A0006), 1 retention insert, green (A0007), (*the black processing insert is not suitable for permanent use in the mouth*)	

For the MEGAGEN All-in-one packaging set B, a laboratory screw is additionally packed.

14.2 PrimeLOC abutments individually packed in plastic vials

- The straight PrimeLOC abutments are individually packaged in plastic vials.
- The angled PrimeLOC abutments are packaged in the plastic vial together with the retaining screw.

15. Tightening torque in Ncm

The current tightening torques can be found in the operating instructions Fo_00100

Important! The specified tightening torque must always be checked again after 5 minutes and corrected if necessary.

16. Sterilization

Please note that all abutments and components are supplied NON-STERILE. The following sterilization procedures should be used before use:

16.1 Abutments, cap, system screws:

Method	Procedure	Temperature	Minimum holding time *	Drying period
superheated steam	vacuum process (3x fractionated fore-vacuum)	134°C	5 minutes	20 minutes

* Indicated are the minimum holding times. The operating times are longer and may vary on the instrument side.

READ THE MANUFACTURER'S INFORMATION AND INSTRUCTIONS FOR CLEANING/STERILIZING MEDEALIS SURGICAL INSTRUMENTS AND PROSTHETIC COMPONENTS.

16.2 Universal instruments, system tools, angle measuring tool

Method	Procedure	Temperature	Minimum holding time *	Drying period
superheated steam	vacuum process (3x fractionated fore-vacuum)	134°C	5 minutes	20 minutes

* Indicated are the minimum holding times. The operating times are longer and may vary on the instrument side.

Instruments should only be autoclaved or sterilized when dismantled.

READ THE MANUFACTURER'S INFORMATION AND INSTRUCTIONS FOR CLEANING/STERILIZING MEDEALIS SURGICAL INSTRUMENTS AND PROSTHETIC COMPONENTS.

16.3 HPP retention inserts (PA12-GB30), block-out spacer

Method	Procedure	Temperature	Minimum holding time *	Drying period
superheated steam	vacuum process (3x fractionated fore-vacuum)	134°C	5 minutes	20 minutes

* Indicated are the minimum holding times. The operating times are longer and may vary on the instrument side.

READ THE MANUFACTURER'S INFORMATION AND INSTRUCTIONS FOR CLEANING/STERILIZING MEDEALIS SURGICAL INSTRUMENTS AND PROSTHETIC COMPONENTS.

16.4 PrimeLOC nylon retention insert, other plastic parts:

The nylon (PA6.6) retention inserts, the processing inserts and the parallelization pin **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 retention housings and the impression coping with integrated black/yellow processing insert.

Disinfection:
Use only disinfectants with tested efficacy according to EN ISO 15883 or with 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 sterilized:

Recommended 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 liter of demineralized 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%.

17. Prophylaxis

The long-term success of the PrimeLOC Overdenture Attachment System® depends in particular on the maintenance of the system. The system should be inspected every 6 months (if necessary also at shorter intervals). The system should be thoroughly checked on these occasions. It is important that the abutments are cleaned of any accumulations. These can lead to premature wear of the retention inserts. The abutments should only be cleaned with plastic instruments. Metal instruments can scratch or roughen the abutment surface, which can also lead to increased abrasion of the retention inserts. The sulcus area on the abutment and the implant shoulder should also be checked regularly and cleaned if necessary. Check the exact seating of the abutment in the implant and the tightening torque and correct it if necessary.
It is also very important to check the retention inserts for abrasion. Excessive abrasion of the retention inserts may indicate a malfunction that needs to be corrected. Particles that support abrasion of the abutments can adhere to the surface of the retention inserts.

18. Patient

The patient has a very large influence on the longevity of the system. This is why they in particular must learn how to use the PrimeLOC Overdenture Attachment System® correctly. Removal and replacement of the denture should be practiced. It is important to show the patient how to handle the individual components and how to clean them. The abutments and the retention inserts may only be cleaned with a soft dental brush and a tooth gel. Under no circumstances should cleaning agents with abrasive particles be used. Flushing systems are very well suited for the cleaning of gaps.

19. Description of symbols

	Manufacturer
	Catalogue number / Article number
	Batch number
	Consult instruction for use
	Do not reuse
	European conformity mark with identification number of the notified body
	European conformity mark
	Non-sterile
	Caution, consult accompanying documents
	Date of Manufacture (see packing)
	Protected from moisture
	Protection from light
MD	Medical device labeling according to MDR (Medical Device Regulation)
QTY	Quantity [piece] (see packing)
Rx only	Federal law (USA) restricts this product to sale by or on the order of a dentist or physician.

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