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INTRODUCTION


Please read this product description/ instruction manual before you use the Novaloc™-matrix system for the first time.

Correct adherence to the instructions below is the prerequisite and guarantee for the proper operational reliability of the system.

The manufacturer accepts no liability whatsoever for any damage caused by failure to observe these instructions.

Legend

 Conformity symbol


 Do not reuse

 manufacturer

 Article number

 Non- steril

 Batch code

 Instructions for use

Indication

The Novaloc™ matrix system may be used in a new or existing Novaloc™ compatible partial denture or overdenture.

Contraindication

The Novaloc™ matrix system cannot be used when there is a divergence of more than 40° between the implants.

Field of Application

Dentistry

Sterilisation

The product is delivered UNSTERILISED.

Every prosthetic reconstruction must be cleaned and disinfected before use.

Allergies

This product must not be used for patients with suspicion of an existing allergy to one or more elements of the materials used.

The product must be used only after an allergy test has been performed and proof obtained that no allergy exists.

Note

Using toothbrushes and toothpaste to clean products mechanically can lead to premature wear in functional areas.

SYSTEM DESCRIPTION

The Novaloc™ matrix system with its newly developed technology is a ready-made connective element to fix removable dentures to Locator® males or Locator® abutments.

The Novaloc™ matrix consists of a housing (choice between titanium or PEEK) and four interchangeable plastic retention inserts (PEEK) with differently color-coded retention values or pull-off weights.

The snap fit connection of the Novaloc™ matrix to the Locator® male placement is based on the locking mechanism of the retention insert across the functional range of the Locator® male placement. In particular thanks to the construction of the retention insert and the use of PEEK as a material, the Novaloc™ matrix is also able to cater for several extremely divergent abutment positions without wear and tear to the retention inserts.

The dilation area arranged between the matrix housing and the retention insert allows the retention insert to expand without any strain, thus significantly extending the life span.

Mindful of their use in daily practice, the specifically developed Novaloc™ user equipment for dentists and dental technicians includes all necessary system components and tools.

One of the absolutely Novaloc™-specific tools to be mentioned here is the mounting and demounting tool for retention inserts which permits retention inserts to be replaced or exchanged absolutely stress-free using specially developed technology.

Procedure for diverging implant positions

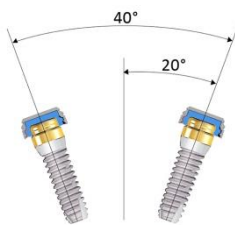


Fig. 1

The Novaloc™ matrix system offers the possibility of integrating a dental prosthesis for implantations bent by up to 20 degrees. This means that divergences between two implants of a maximum of 40 degrees can be corrected [Fig.1].

For this purpose, the four color-coded Novaloc™ retention inserts classified by impression weight can be used without the need for bent abutments.

Prosthesis base arrangement for use with anchoring elements (hybrid dental prosthesis)

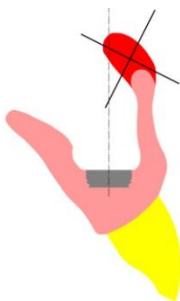


Fig.2

Attention!

In case of divergences in the alveolar ridge relative to the Novaloc™ matrix axis, it is essential that the affected prosthesis edges are shortened to the prosthetic equator [Fig.2].

This procedure is **absolutely necessary** for any type of hybrid dental prosthesis to ensure that the prosthesis can be inserted without any stress in combination with the supporting elements


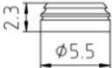
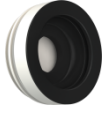
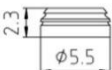






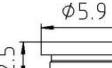

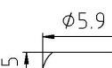


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SYSTEM OVERVIEW

Novaloc™ components




Image	Part no.	Description	Specifications	Quantity per unit
	2010.701	Matrix housing, titanium (including black mounting insert)  -disinfectable-	Matrix housing: Titanium T Mounting insert: PEEK P	4 pcs.
	2010.702	Matrix housing, PEEK (including black mounting insert)  -disinfectable-	Matrix housing: PEEK P Mounting insert: PEEK P	4 pcs.
	2010.711	Retention insert, white -disinfectable-	PEEK (P) Retention value: light	4 pcs.
	2010.712	Retention insert, yellow -disinfectable-	PEEK (P) Retention value: medium	4 pcs.
	2010.713	Retention insert, green -disinfectable-	PEEK (P) Retention value: strong	4 pcs.
	2010.714	Retention insert, blue -disinfectable-	PEEK (P) Retention value: extra-strong	4 pcs.
	2010.721	Model analog Ø4 blue -disinfectable-	Aluminum	4 pcs.
	2010.722	Forming/ fixing matrix, red  -disinfectable-	PEEK P	4 pcs.
	2010.723	Processing spacer, white  -disinfectable-	POM C	4 pcs.
	2010.724	Mounting collar, silicone -disinfectable-	Silicone	10 pcs.
	2010.725	Black mounting insert -disinfectable-	PEEK P	4 pcs.

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Novaloc™ instruments

Image	Part no.	Part description	Specifications	Quantity per unit
	2010.731	Demounting tool for mounting inserts + model analogue reposition aid (blue) -sterilizable-	Aluminum, steel	1 pc
	2010.741	Mounting and demounting tool for retention inserts (brown) -sterilizable-	Aluminum, steel	1 pc
	2010.751	Matrix housing extractor (gray) -sterilizable-	Aluminum, steel	1 pc

Novaloc™- special accessories



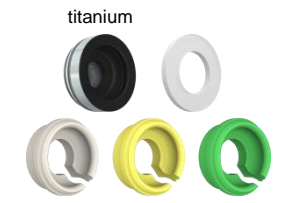

Image	Part no.	Part description	Specifications	Quantity per unit
	2010.703	Matrix housing with attachment option (including black mounting insert) -disinfectable-	Matrix: Titanium T Mounting insert: PEEK P	4 pcs.
	2010.710	Retention insert red -disinfectable-	PEEK (P) Retention value: extra-light	4 pcs.
	2010.715	Retention insert black -disinfectable-	PEEK (P) Retention value: ultra-strong	4 pcs.

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Novaloc™- Order overview

Image	Part no.	Part description	Quantity per unit
	2010.101	Equipment box with 3 tools	
	2010.731	Demounting tool for mounting insert + model analogue reposition aid (blue)	1 pc.
	2010.741	Mounting and demounting tool for retention inserts (brown)	1 pc.
	2010.751	Matrix housing extractor (gray)	1 pc.
	2010.201	Start-up inventory for equipment box	
	2010.701	Titanium matrix housing (including mounting insert)	4 pcs.
	2010.702	PEEK matrix housing (including mounting insert)	4 pcs.
	2010.711	Retention insert, white <i>light</i>	4 pcs.
	2010.712	Retention insert, yellow <i>medium</i>	4 pcs.
	2010.713	Retention insert, green <i>strong</i>	4 pcs.
	2010.714	Retention insert, blue <i>extra-strong</i>	4 pcs.
	2010.721	Model analog Ø4, blue	4 pcs.
	2010.722	Forming/fixing matrix, red	4 pcs.
	2010.723	Processing spacer, white	4 pcs.
2010.724	Mounting collar, silicone	10 pcs.	
 <p style="margin-left: 20px;">titanium</p>	2010.601	Processing package titanium	
	2010.701	Titanium matrix housing (including mounting insert)	2 pcs.
	2010.711	Retention insert, white <i>light</i>	2 pcs.
	2010.712	Retention insert, yellow <i>medium</i>	2 pcs.
	2010.713	Retention insert, green <i>strong</i>	2 pcs.
2010.724	Mounting collar, silicone	2 pcs.	
 <p style="margin-left: 20px;">PEEK</p>	2010.611	PEEK processing package	
	2010.702	PEEK matrix housing (including mounting insert)	2 pcs.
	2010.711	Retention insert, white <i>light</i>	2 pcs.
	2010.712	Retention insert, yellow <i>medium</i>	2 pcs.
	2010.713	Retention insert, green <i>strong</i>	2 pcs.
2010.724	Mounting collar, silicone	2 pcs.	

CLEANING

Responsibility for regular maintenance and monitoring of cleaning, disinfection and sterilization equipment rests with the operator, as does the corresponding validation.

The relevant product information by the manufacturer of the respective cleaning, disinfection and sterilization equipment is to be followed for all settings not listed here (e.g. pressure, time).

All surfaces have to be accessible to the disinfection and sterilization agents.

Note:

Novaloc™ components must under no circumstance be exposed to autoclave/steam sterilization because of the ensuing reduction in dimensional stability, resulting in a probable deformation of parts.

Disinfection

As a general rule, Novaloc™ components must only be disinfected loosely and not stacked in order to ensure that all surfaces are accessible to the disinfection agent.

If Novaloc™ components are prepared manually, the solution used has to be checked daily (contamination load). As a rule, disinfection solutions have to be replaced daily, unless the disinfection agent manufacturer can produce an independent expert assessment supporting a longer service life. Concentrations and contact times for the solutions as specified by the disinfection agent manufacturer have to be accurately adhered to.

Used Novaloc™ components have to be transferred from the treatment area to the preparation area. Under due observation of protective measures (such as gloves, safety glasses), any coarse contaminants have to be removed with care (e.g. by wiping with a cellulose swab or rinsing under running water).

Disassemblable Novaloc™ components have to be taken apart prior to further preparation. In order to prevent surface drying, all medical devices have to be immersed immediately after preparation carefully, completely and bubble-free into the prepared solution (instrument bath with strainer and lid).

Sterilization

New Novaloc™ instruments have to be cleaned and disinfected prior to autoclave/ steam sterilization. Novaloc™ instruments that have already been used must not be sterilized in the supplied protective pouch.

The recommended duration of autoclave/ steam sterilization is 18 minutes at a temperature of 134°C+3°C (273.2°F+5.4°F/ 407.15K+3K).

RISKS

Risks associated with cleaning

Only use Novaloc™ instruments that are completely clean and sterile!

Novaloc™ instruments must not come into contact with agents containing chloride or fluoride.

Aluminum or aluminous materials must never come into contact with any mercurial agents. Even the minutest traces of mercury can cause considerable corrosion. Novaloc™ instruments made from aluminous materials must only be wiped, cleaned or immersed in cleaning or disinfecting agents with a pH value between 4.5 and 8.5. The protective layer of aluminous materials dissolves at higher or lower pH values, resulting in corrosion.

Reusable Novaloc™ instruments have to be cleaned, disinfected and sterilized immediately after use.

No contamination must be allowed to dry on Novaloc™ instruments as this will make subsequent cleaning more difficult.

Novaloc™ instruments should not be immersed into physiological saline solution, as prolonged contact could lead to corrosion and surface changes.

Always use freshly prepared cleaning and sterilization agents.

Neither metal brushes nor abrasive agents must be used to clean the instruments.

For all Novaloc™ instruments with hollow spaces, extra care has to be taken specifically prior to sterilization to ensure that no residue is left inside these spaces.

Risks associated with the Novaloc™ system

Use of Novaloc™ instruments

General risks associated with the use of Novaloc™ instruments are allergic reactions to the material that the instrument is made of as well as loosening, wear and tear, corrosion and ageing of instrument parts.

Damage or improper handling can result in corrosion, oxidation, excessive wear or functional impairment of Novaloc™ instruments.

Instruments can have sharp edges or pointed ends. These can cause damage to plastic/latex gloves. Users need to be aware of the associated risk of infection.

Use of Novaloc™ components

No risks associated with Novaloc™ components are currently known.

In case of unexpected complications or pain, patients are advised to contact their dentist or dental prosthetician immediately.

PROSTHETIC PROCEDURE

Novaloc™ matrix housing (titanium/ PEEK)



Fig.3

The Novaloc™ matrix housing is available in titanium [Fig.3] and beige plastic (PEEK) [Fig.4].

The titanium matrix housing can be inserted in the usual manner.



Fig.4

The beige plastic (PEEK) version is used for extreme labial or buccal positions in relation to the Locator® (no gray irritation) as well as in holistic dentistry where treatment has to be provided without the use of metal.



The Novaloc™ mounting insert (PEEK/ black)

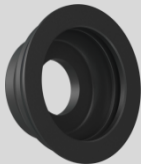


Fig.5

The black mounting insert [Fig.5] serves to protect the interior of the matrix housing and to secure the cap in place during processing.

Thanks to its outstanding fit and functionality, the mounting insert ensures the accurate positioning of the cap on the Locator® male; it also prevents any plastic from entering into the cap during polymerization.

The mounting insert must only be removed after polymerization of the cap into the denture, using Novaloc™ removal tool for mounting inserts [Fig.6.1] [Fig.6.2].



Fig.6.1

Removing mounting insert with removal tool version 1 (from 11/2012)

1. Use the stainless steel tip of the removal tool [Fig.6.1.1]
2. Insert the toe of the Novaloc™- removal tool into the mounting insert [Fig.6.1.2]. There is marking notch on the stainless steel tip as an orientation guide for the toe [Fig.6.1.1]. Insert the removal toe into the hole in the bottom of the mounting insert [Fig.6.1.3].
3. Tip the removal tool to the opposite side of the foot-shaped end and remove the mounting insert from the matrix housing by pulling [Fig.6.1.4]



Fig.6.1.1



Fig.6.1.2

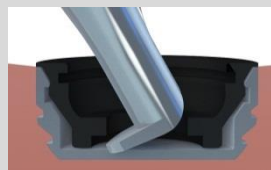


Fig.6.1.3

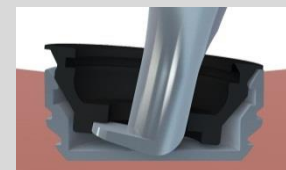


Fig.6.1.4



Fig.6.2

Removing mounting insert with removal tool version 0

1. Use the stainless steel tip of the removal tool [Fig.6.2.1]
2. Insert the beak-shaped laser-marked side of the Novaloc™- removal tool anywhere inside the protruding ring of the circular groove of the mounting insert [Fig.6.2.2] [Fig.6.2.3]
3. Tip the removal tool to the opposite side of the beak-shaped end and remove the mounting insert from the matrix housing by pulling [Fig.6.2.4]



Fig.6.2.1



Fig.6.2.2

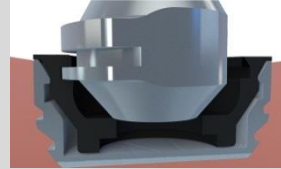


Fig.6.2.3

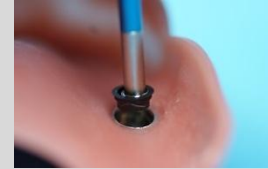
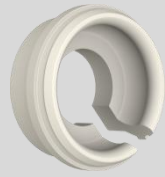


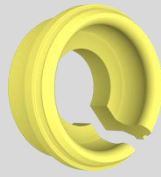
Fig.6.2.4

Novaloc™ retention insert (PEEK)

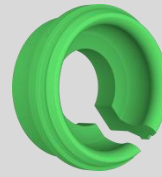
Fig.7



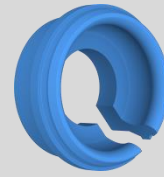
Retention value:
light
approx. 750g



Retention value:
medium
approx. 1200g



Retention value:
strong
approx. 1650g



Retention value:
extra-strong
approx. 2100g

Four retention inserts, color coded according to its pull-off weight or retention value [Fig.7], are available for the fixation of Novaloc™ matrices.



After the removal of the mounting insert, they are placed inside the matrix housing as required. The tool for this purpose is the Novaloc™ mounting and demounting tool for retention inserts [Fig. 8] which permits easy handling. In this way, retention inserts can be replaced without stress or damage:

Fig.8

Mounting:



Fig.8.1



Fig.8.2



Fig.8.3



Fig.8.4

1. Use the bright metal plunger of the tool to pick up the retention insert of your choice from the equipment box. You can feel the retention insert locking onto the plunger. [Fig.8.1;8.2]
2. Press the retention insert up axial to matrix housing into the matrix housing. You can hear and feel it "click"! [Fig.8.3;8.4]

Demounting:



Fig.8.5

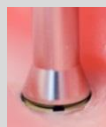


Fig.8.6



Fig.8.7

1. The bright metal gripper of the tool is aligned axial to the matrix housing and locked in place via the outside of the retention insert, using slight pressure, but no force, with a noticeable "click". In this procedure, the use of binocular loupes is advantageous. [Fig.8.5;8.6;8.7]
2. This unlocks the retention insert, which can then be removed from the matrix housing using a slight rotational movement. [Fig.8.7]
3. In order to release the removed retention inserts from the removal tool, the equipment box includes two removal devices. Insert the retention insert into the according device. [Fig.8.8]
4. With a sideways tilt, the retention insert is released from the tool. [Fig.8.9]



Fig.8.8



Fig.8.9

Novaloc™ forming/fixing matrix (PEEK/ red)

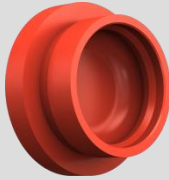


Fig.9

The Novaloc™ forming/fixing matrix [Fig.9] is slightly higher than the complete Novaloc™ matrix. In the transfer/ molding process into existing dentures, this provides clarity and an overview whether there will be sufficient space for the Novaloc™ matrix amongst potential obstructions such as metal reinforcements, artificial teeth etc. [Fig.9.1].

Inside the mouth, the Novaloc™ forming/fixing matrix is placed onto the Locator® abutment [Fig.9.2]. A perceptible and audible "click" ensures the accurate positioning of the forming/fixing matrix. Then proceed with the pickup impression as normal.

Thanks to its minimal space requirement, the Novaloc™ forming/fixing matrix is also ideally suited as a fixation cap for check-bites, templates, bars, provisional dentures etc. [Fig.9.3]



Fig.9.1



Fig.9.2



Fig.9.3

Novaloc™ processing spacer (POM C/ white)



Fig.10

The Novaloc™ white processing spacer [Fig.10] is the ideal space holder for the later polymer or glue fixation of the original matrix into model-cast or cast metal-reinforced dentures thanks to the slightly oversized dimensions of the matrix [Fig.10.1;10.2;10.3]

The outside surfaces of the processing spacer are slightly angled, thus creating a self-retentive gap for the admission of the matrix housing in the metal in model-cast or cast metal-reinforced structures.



Fig.10.1



Fig.10.2



Fig.10.3

Novaloc™ mounting collar (silicone/ white)



Fig.11

The Novaloc™ mounting collar - white - [Fig.11] is used in the direct matrix fixation in the patient's mouth.

To this end, the mounting collar is placed below the retentive molding at the Locator® male [Fig.11.1] and pushed flush with the matrix that is to be glued in place.

This prevents excessive polymer or glue from attaching itself to the cylindrical neck of the Locator® abutment, with the consequence of firmly locking the denture to the screwed in Locator® abutment.



Fig.11.1

The following rule applies when fitting matrixes directly into the mouth:

Better to use too little rather than too much polymer or glue. This means that all excesses have to be avoided.

If necessary, adding further glue outside of the mouth is the safest way to prevent lockages inside the mouth!

The Novaloc™ model analog (aluminum/ blue)



Fig.12

The neck area of the Novaloc™ model analog -blue- [Fig.12] is identical in size with the original Locator® abutment, thus ensuring that the impression material cannot cause irritation when positioning the model analog into the impression. [Fig.12.6]



Fig.12.1

To help with the positioning of the analog in the impression, Novaloc™ provides the model analog repositioning tool [Fig.12.1] which provides absolute safety in handling [Fig.12.2;12.3;12.4;12.5;12.6]



Fig.12.2

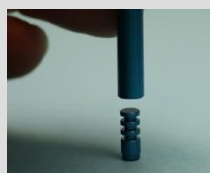


Fig.12.3



Fig.12.4

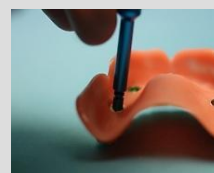


Fig.12.5

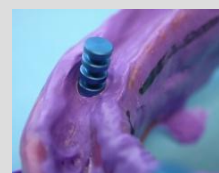


Fig.12.6

Novaloc™ matrix housing extractor + stripping equipment (gray) - only for titanium caps-

The Novaloc™ extractor stands out for its simplicity and efficiency. [Fig.13]



Fig.13

The three application steps:



Fig.13.1

1. Heat the extractor head over a flame [Fig.13.1]



Fig.13.2

2. Attach the beak-shaped side of the Novaloc™ extractor anywhere within the circular groove of the matrix housing and let the heat of the heated extraction head 2 to 3 seconds on the cap bottom briefly to soak. [Fig.13.2]



Fig.13.3

3. Apply leverage to the opposite of the beak-shaped side to remove both the Novaloc™ extractor and the matrix housing. [Fig.13.3]

Procedure for using stripping equipment:



Fig.13.4

For reasons of hygiene, it isn't recommended that retention inserts already used on patients are stripped off into the equipment box. This prevents the contamination of the unused retention inserts still in the equipment box.

1. To loosen the retention insert taken out of the dental prosthesis from the extraction instrument, a groove is cut into on the handle end. The retention insert must be pushed into the appliance notch. [Fig.13.4]
2. Tilting the instrument to the side releases the retention insert.

Novaloc™ equipment box incl. first equipment



Fig.14

The Novaloc™ equipment box [Fig.14], specifically designed for dentists and dental technicians, stands out for its clear and user-friendly lay-out. It contains the full range of system parts as well as the three corresponding tools.

The lay-out and fitting of the box ensures that all individual parts remain within their individual storage containers when the box is closed.

In addition, it was used for this box is an extremely shock-and shatter-resistant material, that the usual standards in the dental office and laboratory will provide fully sufficient.

The Novaloc™- special accessories

Matrix housing titanium with attachment option:

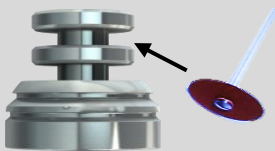


Fig.15

The matrix housing titanium with attachment option finds its indication in low-lying or not ideal selected abutment heights. Sufficient support in denture bases can be achieved by shortening the additional fixing steps. [Fig.15]

Retention insert red:



Fig.16

The retention insert red [Fig.16] is the most smooth-running retention insert.

Retention value: **extra-light** (approx. 300g)

Retention insert black:



Fig.17

The retention insert black [Fig.17] for extreme situations is recommended for the following indications:

- Heavily worn abutment
- Fixures with only one supporting element.

Retention value: **ultra-strong** (approx. 2550g)

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LEGEND OF MATERIALS

Symbol	Name	Physical properties							Melting range	Mechanical properties 0.2 % Proof Stress Rp 0.2 %	Information on use					
		Colour	Composition								Connexion possibilities					
										Casting-on	Soldering	Laser welding	Phaser welding	Resin-bonding	Polymerization	
T	Pure Titanium	Grey	C % (max.) 0.08	Fe % (max.) 0.5	O % (max.) 0.4	N % (max.) 0.05	H % (max.) 0.0125	Ti % Remainder	1600 – 1700°C	≥ 520 MPa			✓	✓	✓	✓
P	PEEK	Various	Polyetheretherketone 100 % Mouth-resistant plastic													