



Novaloc® Matrix System

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Manufacturer
Valoc AG
Bahnhofstrasse 64
CH-4313 Möhlin
Switzerland

Tel: +41 61 855 95 59
E-Mail: info@valoc.ch
www.valoc.ch

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
1 INTRODUCTION

Please read this product description/ instruction manual before you use the Novaloc® Matrix System.

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.

1.1 Legend

	Valoc products with the CE mark fulfil the requirements of the Medical Devices Directive 93/42 EEC		Do not reuse
	Manufacturer		Article number
	Non-sterile		Batch code
	Instructions for use		Do not expose to sunlight
	Caution: U.S. Federal law restricts this device to sale by or on the order of a dental professional.		

1.2 Indication

The Novaloc® Matrix System may be used in new or existing Novaloc® compatible partial dentures or overdentures.

1.3 Contraindication

The Novaloc® Matrix System cannot be used when there is a divergence of more than 40° between the implants. Not suitable if fixed connections are required. Lacking cooperation of the patient with respect to follow-up / recall instructions. Patients with bruxism or other para-functional habits. Unilateral free-end prosthesis without transversal support.

1.4 Field of Application

Dentistry

1.5 Sterilization

The product is delivered UNSTERILISED.

Every prosthetic reconstruction must be cleaned and disinfected before use.

1.6 Storage

Plastic parts must be protected from strong light and heat and stored at room temperature.

1.7 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.

1.8 Information regarding handling and after-care

Attachments with prosthetic restorations in the mouth are subjected to high loads in a constantly changing milieu and thus to wear and tear to a greater or lesser extent. Wear is an everyday occurrence and cannot be avoided, but only reduced. The degree of wear depends on the overall system. The perfect fit of the restoration on the mucosa should be checked at least once a year and the restoration must be relined, if necessary, to avoid rocking movements (overloading). We recommend initially checking the denture in three-month intervals and replacing the retention inserts, if required.

1.9 Compatibility

The Novaloc® matrix system is compatible with the following types of abutments:

- Novaloc®
- MedentiLOC®
- Locator®

Note: The retention force can vary on these abutments due different manufacturing tolerances and surfaces of the various abutments.

2 SYSTEM DESCRIPTION

The Novaloc® matrix system with its newly developed technology is a ready-made connective element to attach removable dentures to dental implants in conjunction with abutments.

The Novaloc® matrix consists of a housing (choice between titanium and PEEK) and six 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 Novaloc® abutment or Locator® male is based on the locking mechanism of the retention insert across the functional range of the Novaloc® abutment or the Locator® male. In particular, the construction of the retention insert and the use of PEEK as a material, enables the Novaloc® matrix 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 de-mounting tool for retention inserts which permits retention inserts to be replaced or exchanged absolutely stress-free using specially developed technology.

2.1 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 six color-coded Novaloc® retention inserts with different retention forces can be used without the need for angled abutments.

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

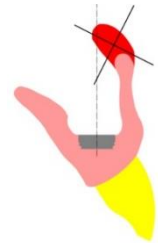










Fig. 2





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




3 SYSTEM OVERVIEW

3.1 Novaloc® Components




Image	Part no.	Description	Specifications	Quantity per unit
	2010.701	Matrix housing, titanium (including mounting insert) -disinfectable-	Matrix housing: Ti Mounting insert: POM	4 pcs.
	2010.701-STM			
	2010.702	Matrix housing, PEEK (including mounting insert) -disinfectable-	Matrix housing: PEEK Mounting insert: POM	4 pcs.
	2010.702-STM			
	2010.711	Retention insert, white -disinfectable-	PEEK Retention value: <i>light</i>	4 pcs.
	2010.711-STM			
	2010.712	Retention insert, yellow -disinfectable-	PEEK Retention value: <i>medium</i>	4 pcs.
	2010.712-STM			
	2010.713	Retention insert, green -disinfectable-	PEEK Retention value: <i>strong</i>	4 pcs.
	2010.713-STM			
	2010.714	Retention insert, blue -disinfectable-	PEEK Retention value: <i>extra-strong</i>	4 pcs.
	2010.714-STM			
	2010.720	Model analogue angled 15° -disinfectable-	Al	4 pcs.
	2010.720-STM			
	2010.721	Model analogue blue -disinfectable-	Al	4 pcs.
	2010.721-STM			

	2010.722	Forming/fixing matrix, red -disinfectable-	PEEK	4 pcs.
	2010.722-STM			
	2010.723	Processing spacer, white -disinfectable-	POM	4 pcs.
	2010.723-STM			
	2010.724	Mounting collar, silicone -disinfectable-	Silicone	10 pcs.
	2010.724-STM			
	2010.725	Mounting insert -disinfectable-	POM	4 pcs.
	2010.725-STM			




3.2 Novaloc® Instruments

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


3.3 Novaloc® Special Accessories


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

3.4 Novaloc® System Components

Image	Part no.	Part description	Quantity per unit
	2010.101	Equipment box incl. 3 tools	
	2010.101-STM		
	2010.731	Demounting tool for mounting insert + model analogue reposition aid (blue)	1 pc.
	2010.731-STM		
	2010.741	Mounting and demounting tool for retention inserts (brown)	1 pc.
	2010.741-STM		
	2010.751	Matrix housing extractor (gray)	1 pc.
2010.751-STM			
	2010.102	Equipment box with insert	1 pc.
	2010.201	Initial load 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 analogue, 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.

Instructions for Use

	2010.601	Processing package titanium	
	2010.601-STM		
	2010.701	Titanium matrix housing (including mounting insert)	2 pcs.
	2010.701-STM		
	2010.711	Retention insert, white <i>light</i>	2 pcs.
	2010.711-STM		
	2010.712	Retention insert, yellow <i>medium</i>	2 pcs.
	2010.712-STM		
	2010.713	Retention insert, green <i>strong</i>	2 pcs.
2010.713-STM			
2010.724	Mounting collar, silicone	2 pcs.	
2010.724-STM			

	2010.611	Processing package PEEK	
	2010.611-STM		
	2010.702	Matrix housing PEEK (including mounting insert)	2 pcs.
	2010.702-STM		
	2010.711	Retention insert, white <i>light</i>	2 pcs.
	2010.711-STM		
	2010.712	Retention insert, yellow <i>medium</i>	2 pcs.
	2010.712-STM		
	2010.713	Retention insert, green <i>strong</i>	2 pcs.
2010.713-STM			
2010.724	Mounting collar, silicone	2 pcs.	
2010.724-STM			

4 CLEANING

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.

Responsibility for regular maintenance and monitoring of cleaning, disinfection and sterilization of 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.

4.1 Disinfection / Sterilization

After each completion or modification, the prosthetic work, incl. matrix components must be cleaned and disinfected according to national guidelines. When selecting the disinfectant, make sure that it:

- Is suitable for cleaning and disinfection of dental prosthetic components.
- Is compatible with the materials of the products that are going to be cleaned and disinfected.
- Has a proven effectiveness of disinfection.

4.2 Disinfection

All plastic parts must be disinfected before use with a low or medium EPA registered disinfectant. The equipment box can also be disinfected and is used exclusively as a storage means for the supplied Valoc prosthetic products and their instruments.

4.3 Sterilization

All metallic Novaloc® components must be sterilized before use.

Plastic parts are not suitable for steam sterilization.

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).

5 RISKS

Instruments have to be sterilized and if necessary disinfected after use and before storage.

5.1 Risks associated with cleaning

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

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

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.

5.2 Risks associated with the Novaloc® system

5.2.1 Use of Novaloc® instruments

General risks associated with the use of Novaloc® instruments are allergic reactions to the materials from which they are 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.

5.2.2 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.

6 PROSTHETIC PROCEDURE

6.1 Novaloc® matrix housing (titanium / PEEK)



Fig. 3

The Novaloc® matrix housing is available in titanium [**Error! Reference source not found.**] and beige plastic (PEEK) [Fig. 4].

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

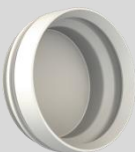


Fig. 4

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.



6.2 The Novaloc® mounting insert (POM)

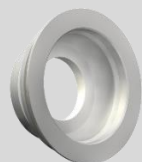


Fig. 5

The 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 abutment; 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].



Fig. 6

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

1. Use the stainless steel tip of the removal tool [Fig. 7]
2. Insert the toe of the Novaloc® removal tool into the mounting insert. There is a marking notch on the stainless steel tip which serves as an orientation guide for the toe [Fig. 7]. Insert the removal toe into the hole in the bottom of the mounting insert. [Fig. 8, Fig. 9]
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 [**Error! eference source not found.**].



Fig. 7



Fig. 8

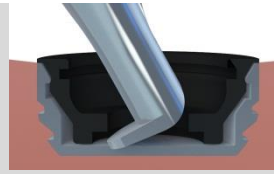


Fig. 9

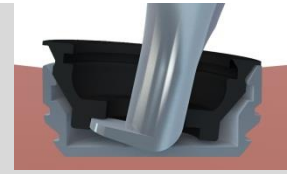


Fig. 10



Fig. 11



Fig. 12

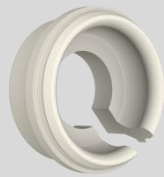
Removing mounting insert with removal tool version 0

Novaloc® removal tool version 0 [Fig. 11, Fig. 12] is not compatible with the mounting insert.

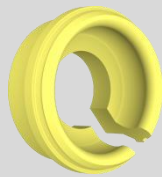
Novaloc® retention insert (PEEK)



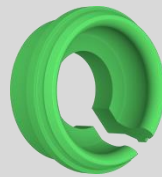
Retention value:
ultra-light
approx. 300



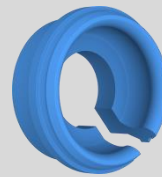
Retention value:
light
approx. 750g



Retention value:
medium
approx. 1200g



Retention value:
strong
approx. 1650g



Retention value:
extra-strong
approx. 2100g



Retention value:
ultra-strong
approx. 2550g

Six retention inserts, color coded according to their pull-off weights or retention values 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. 13] which permits easy handling. In this way, retention inserts can be replaced without stress or damage:

Fig. 13

Mounting:



Fig. 14



Fig. 16

1. Use the bright metal mounting part 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 instrument. [Fig. 14, Fig. 16]

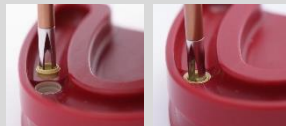


Fig. 15



Fig. 17

2. Push the retention insert axially to the matrix housing into the matrix housing. You can hear and feel it "click"! [Fig. 15, Fig. 17]

Mounting retention inserts with the old generation Novaloc® mounting and demounting tool

Old generation



Fig. 18

New generation



Fig. 19

The brown instrument of the old generation [Fig. 18] is forward-compatible and can be used to put retention inserts of the new generation into matrix housings. It is, however, to be expected that the new retention inserts will not stick to the mounting part of the old instrument during vertical pick-up. Thus, the retention inserts can be pressed lightly onto the mounting part to ensure them sticking to the instrument.

Demounting:



Fig. 20



Fig. 21



Fig. 22

1. The bright metal demounting part of the tool is aligned axially to the matrix housing and locks 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. 20; Fig. 21; Fig. 22]
2. This unlocks the retention insert, which can then be removed from the matrix housing using a slight rotational movement. [Fig. 22]

6.4 Novaloc® forming/fixing matrix (PEEK / red)

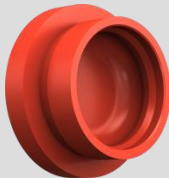


Fig. 23

The Novaloc® forming/fixing matrix [Fig. 23] 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. 24].

Inside the mouth, the Novaloc® forming/fixing matrix is placed onto the Locator® abutment [Fig. 25]. 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. 26].



Fig. 24



Fig. 25



Fig. 26

6.5 Novaloc® processing spacer (POM / white)



Fig. 27

The Novaloc® white processing spacer [Fig. 27] 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. 28; Fig. 29; Fig. 30]

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. 28



Fig. 29



Fig. 30

6.6 Novaloc® mounting collar (silicone / white)



Fig. 31

The Novaloc® mounting collar - white - [Fig. 31] 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. 32] 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. 32

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 lockage inside the mouth!

6.7 The Novaloc® model analogues (aluminum)

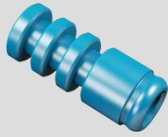


Fig. 33

The neck area of the Novaloc® model analog -blue- [Fig. 33] is identical in size with the original Locator® abutment, thus ensuring that the impression material cannot cause irritation when positioning the model analogue into the impression. [Fig. 40]



Fig. 34

The Novaloc model analogue angled 15° [Fig. 34] can be used as an alternative to the regular model analogue in conjunction with 15° angled Novaloc abutments.



Fig. 35

To help with the positioning of the analogue in the impression, Novaloc® provides the model analogue repositioning tool [Fig. 35] which provides absolute safety in handling [Fig. 36, Fig. 37, Fig. 38, Fig. 39, Fig. 40]



Fig. 36



Fig. 37



Fig. 38



Fig. 39

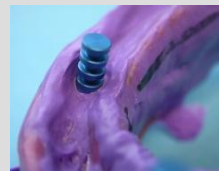


Fig. 40

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

The Novaloc® extractor stands out for its simplicity and efficiency. [Fig. 41]



Fig. 41

The three application steps:



Fig. 42

1. Heat the extractor head over a flame [Fig. 42]



Fig. 43

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. 43]



Fig. 44

3. Apply leverage to the opposite of the beak-shaped side to remove both the Novaloc® extractor and the matrix housing. [Fig. 44]

Procedure for using stripping equipment:



Fig. 45

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. 45]
2. Tilting the instrument to the side releases the retention insert.

6.9 Novaloc® equipment box



Fig. 46

The Novaloc® equipment box [Fig. 46], specifically designed for dentists and dental technicians, stands out for its clear and user-friendly lay-out. It contains the three Novaloc® instruments.

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, the material 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.

6.10 Novaloc® special accessories

Matrix housing titanium with attachment option:

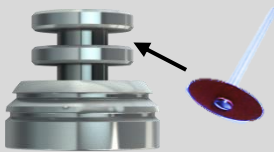


Fig. 47

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. 47]

Retention insert red:



Fig. 48

The retention insert red [Fig. 48] is the most smooth-running retention insert.

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

Retention insert black:



Fig. 49w

The retention insert black [Fig. 49w] for extreme situations is recommended for the following indications:

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

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