

# Novaloc® Abutments

## Instructions for Use



## Novaloc® Abutments

IFU 70 Rev. 2

Valid from 10/2018



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### 1. PRODUCT DESCRIPTION

The Novaloc® Abutments are designed to be used with the Thommen Medical dental implant lines SPI®ELEMENT and SPI®CONTACT, to retain overdentures or partial overdentures.

Thommen medical implant lines consist of implants of different types, diameters and lengths. The abutments are available in different sizes and angles to fit individual patient needs and to be compatible with all the platforms of the implant lines. The Novaloc® Abutments are screwed into the implants and have a defined geometry on the retention side for the Novaloc Matrix System®.

### 2. INTENDED USE

Novaloc® Abutments are intended for use as an aid in prosthetic rehabilitation for the attachment of overdentures or partial dentures on endosseous dental implants.

### 3. INDICATIONS

Novaloc® Abutments are indicated to be used for the attachment of full or partial dentures on Thommen dental implants of the implant lines SPI®ELEMENT and SPI®CONTACT.

### 4. CONTRAINDICATIONS

- Not suitable where a completely fixed connection (screw retained or cement retained) is required.
- Angled abutments should not be used to compensate for implant divergence angles greater than 35 degrees.
- Straight and angled abutments on small diameter implants (PF Ø3.5 mm) are not recommended for use in the posterior region in the lower and upper jaw, single tooth restorations of canines and single tooth restorations of incisors in the maxilla

### 5. MATERIAL

- Novaloc® Abutments: Titanium Grade 5 (Ti-6Al-4V-ELI)
- Novaloc® Abutment coating: ADLC (amorphous diamond-like carbon)
- Abutment Screw: Titanium Grade 5 (TiAl6Nb7)

### 6. COMPATIBILITY INFORMATION

Novaloc® Abutments are compatible with the following platform interfaces of the Thommen Medical implant lines SPI®ELEMENT and SPI®CONTACT:

- ELEMENT/CONTACT Implant PF Ø3.5 mm
- ELEMENT/CONTACT Implant PF Ø4.0 mm
- ELEMENT/CONTACT Implant PF Ø4.5 mm
- ELEMENT/CONTACT Implant PF Ø5.0 mm
- ELEMENT/CONTACT Implant PF Ø6.0 mm

### 7. WARNINGS

- Novaloc® Abutments are intended to be used only once. Re-use of the product can result in the product not meeting the performance specifications.

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- No torques other than those recommended by the manufacturer should be used to tighten the abutment on the implant interface. Torques greater than recommended may result in the failure of abutment and/or implant. Torques less than recommended may result in loosening of the abutment.
- Products must be secured against aspiration/swallowing when handled intraorally. Aspiration/swallowing of the product(s) may lead to infection or undesirable physical injury.
- Novaloc® Abutments can only be combined with the Thommen Medical implants of the SPI® ELEMENT and SPI® CONTACT implant lines.
- Improper selection, placement, positioning and fixation of the abutment can cause a subsequent undesirable result.
- Allergies and sensitivities in connection with the materials cannot be ruled out. The product must not be used for patients with suspicion/knowledge of existing allergies to one or more materials used. Improper cleaning using toothbrushes and toothpaste to clean the product mechanically can lead to premature wear in functional areas.
- The product must be inspected prior to use. The packaging must be sealed without any visible damage. The content must be checked for any visible damage. The product integrity cannot be guaranteed if the outer protective packaging is damaged. The contents of an opened or damaged outer protective pack may no longer be used.

### 8. CAUTION/PRECAUTIONS

- The clinician must supervise the abutment insertion and functional loading of the prosthetic construction very carefully. A stressed loading of the implant or abutment over and above its functional capacity can lead to excessive bone loss or fracture of the implant – abutment connection or damage to the restoration.
- Dentist Maintenance: During periodic visits, please inspect the state of each abutment. Always use plastic instruments during those visits. It is recommended to replace worn out abutments.
- Patient Maintenance: Please advise your patient with the following information: A good oral hygiene is necessary for the success of the denture. The abutments must be thoroughly cleaned daily by the patient to prevent adhesive plaque formation and wearing of the components. The use of soft nylon bristle or end-tufted toothbrushes with non-abrasive toothpaste is recommended.

### 9. MR SAFETY

The Novaloc® Abutments have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Novaloc® Abutments in the MR environment is unknown.

### 10. CLEANING AND STERILIZATION

Novaloc® Abutments and components (screws for angled abutments) are not supplied in a sterile state. The product must be cleaned and sterilized before use. The following procedure is recommended for cleaning and sterilization

Cleaning: Clean by rinsing under flowing water while brushing the inner and outer sides.

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**Sterilization:** Unless directed otherwise, a steam sterilization of the abutments and screws is recommended. Seal the product in suitable autoclave foil. Steam sterilization with fractionated vacuum procedure with at least 3 vacuum steps (with adequate product drying time: at least 20 minutes) with maximum sterilization temperature of 138 °C (280 °F; plus tolerance) in compliance with EN ISO 17665.

Sterilization time, exposure time at sterilization temperature, of at least 4 minutes at 132 °C (270 °F) or 18 minutes.

### Notes:

- *Do not store sterilized the product for later use.*
- *The user should ensure that the appropriate sterilizer with the above defined parameters is used for sterilization.*

The manufacturer does not accept any liability for regular maintenance and monitoring of cleaning, disinfection and sterilization equipment. This responsibility rests with the operator.

## 11. PROCEDURE/APPLICATION

The Novaloc® Abutments are directly screwed into the implant by using the specified Torque ratchet (Art. No. 3.03.160) from Thommen Medical.

For inserting the abutments into implants, 4-lobe screw drivers (Art. Nos. 3.03.165, 3.03.166, 3.03.167) should be used.

For the insertion of angled abutments, it is essential to use the abutment screw.

Recommended Torque values for the attachment of Novaloc Abutments:

- 15 Ncm for PF Ø3.5 mm
- 25 Ncm for PF Ø4.0 - 6.0 mm

*Note: The abutments should only be tightened with the specified instruments and conditions.*

The manufacturer does not accept any liability for complications that may arise from the use of other instruments or application of inappropriate torque values.

The right choice of abutment, correct positioning and fixation is crucially important for the sufficient amount of stability and a good fit. The user should be thoroughly familiar with the implants, abutments, instruments and relevant surgical techniques.

Sufficient experience in the field of dentistry is highly recommended.

## 12. STORAGE

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence the characteristics of the product.

## 13. VALIDITY

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### 14. SIGNS & SYMBOLS

 Valoc products with the CE mark fulfil the requirements of the Medical Devices Directive 93/42 EEC	 Article number
 0481	
 Do not reuse	 Batch code
 Manufacturer	 Do not expose to sunlight
 Non-sterile	 Caution: U.S. Federal law restricts this device to sale by or on the order of a dental professional
 Instructions for use	

Products indicated with ® are registered brand names of the manufacturers.

Notice: The product may be subjected to further development. In this connection we reserve the right to make product changes in relation to the design and composition.