

Sherlock Ti-Base And ASC Abutments

Instructions for Use

Caution: Federal law restricts this device to sale by or on the order of a dentist. For professional use only- RX Only



DESCRIPTION

Open Implants Sherlock Titanium Bases (Ti-Base) and Angled Screw Channel (ASC) Titanium Bases are intended for the restoration of compatible dental implants. They are for use by qualified, licensed clinicians and laboratory technicians fully trained in their application.

INDICATIONS FOR USE

Sherlock abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.

All digitally designed CAD/CAM customizations for Sherlock abutments are to be sent to an Open Implants-validated milling center for manufacture.

Sherlock abutments are compatible with the implant systems listed in the Compatibility Table:

Compatibility Table

Compatible Implant Systems	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
Nobel Biocare Nobel Active®	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)
Straumann Bone Level	3.3	3.3 (NC)
	4.1, 4.8	4.1, 4.8 (RC)
Zimmer Tapered Screw-Vent	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

CONTRAINDICATIONS

- Patients who are allergic or hypersensitive to commercially pure titanium or titanium alloy Ti-6Al-4V ELI
- Patients who are allergic or hypersensitive to Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).
- Patients in whom adequate size, number or desirable position of the implants are not attainable to achieve safe support of functional or parafunctional loads.
- Patients who are medically unfit for this procedure.

SIDE EFFECTS

The risks and complications with prosthetic components, include but are not limited to the following:

- Allergic reaction to abutment material
- Patients may swallow or aspirate components that are not secured
- Application of excessive torque may cause the fracture of an abutment screw
- Screws may loosen

STERILITY

Provided non-sterile. Single use only. Non-sterile abutments and screws must be cleaned and sterilized prior to clinical use, according to the following validated method.

Cleaning: The recommended process is as follows:

- 1) Rinse the article under running tap water.
- 2) While the article is being rinsed, brush the article using a soft-bristled brush.
- 3) Create a detergent bath using Enzol detergent at 1 oz per gallon of lukewarm tap water.
- 4) Immerse the article in the detergent bath and allow it to soak for a minimum of 5 minutes.
- 5) While the article is immersed, brush the article using a soft-bristled brush.
- 6) Rinse the article under running RO/DI water.
- 7) Allow the article to air dry.

Sterilization: The recommended process is based on the ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79 guidelines, as follows:

- Preconditioning Pulses 4
- Cycle Time 270°F (132°C) for 4 minutes
- Dry Time 20 minutes
- Packaging 510k-cleared sterilization pouch

NOTE: The validated procedures require the use of FDA-cleared sterilization trays, wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The healthcare facility should monitor the sterilizer for the facility according to an FDA-recognized sterility assurance standard such as ANSI/AAMI ST79.

DENTAL IMPLANT COMPATIBILITY

Sherlock Titanium Abutments manufactured by Open Implants are compatible with the Nobel Biocare Nobel Active®, Zimmer Tapered Screw-Vent (TSV), or Straumann Bone Level implant restorative platform configurations below. Individual products are labeled for each platform. See the product catalog online at: www.openimplants.com/downloads.

Compatibility Table

Compatible Implant System	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
Nobel Biocare Nobel Active®	3.5	3.5 (NP)
	4.3, 5.0	3.9 (RP)
Straumann Bone Level	3.3	3.3 (NC)
	4.1, 4.8	4.1, 4.8 (RC)
Zimmer TSV	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

MATERIALS

Component	Material
Open Implants Abutments and screws	Titanium: Ti-6Al-4V ELI
Scan body and Analog interface	Stainless Steel
Top crown ,coping , bridge for final restoration	Zirconium Dioxide

RECOMMENDED TORQUE VALUES

Use the recommended torque values below. These can also be found on the torque chart available for download or viewing at openimplants.com/downloads.

Components	REFs	Torque Value
Sherlock Ti-Base Abutment Screw for Nobel Active®	3758, 3759	35 N·cm
Sherlock ASC Abutment Screw for Nobel Active®	4909, 4910	
Sherlock Ti-Base Abutment Screw for Straumann Bone Level	3765	
Sherlock ASC Abutment Screw for Straumann Bone Level	4914	35 N·cm
Sherlock Ti-Base Abutment Screw for Zimmer Tapered Screw-Vent	3768	30 N·cm
Sherlock ASC Abutment screw Zimmer Tapered Screw-Vent	4916	30 N·cm
Sherlock ASC driver	5794	n/a

For best results, the following conditions must be meticulously met:

- Use the suitable driver size for tightening and unscrewing.
- Make sure the correct model of screw is used for each case. Check the compatibility of the screw with the implant model to which it will be connected.
- Check that the driver is in good condition and used with care
- Check that the screw threads are properly aligned with the analog or implant before tightening.
- Check that the abutment is properly seated prior to continuing the procedure.
- A new screw should be used when assembling a prosthesis for the first time and for every check thereafter.
- When transferring to the patient, do not use the same screw that was used in the laboratory.
- Position the patient to avoid aspiration in case a screw falls during screwing/unscrewing.
- Verify that the abutment is engaged in the proper position before tightening the screw.
- Avoid excessive torque to prevent damage to the screw or disruption of the implant.
- Verify the final abutment seating using radiographic imaging.

SHERLOCK Ti-BASE AND ASC ABUTMENTS

The Sherlock ASC Abutments are pre-manufactured dental implant abutments that directly connect to the dental implant and support the single multi unit prosthesis. Open Implants offers straight and angled screw channel abutments with various gingival heights.

All prosthetic copings (mesostructures) for use with the Subject device regular and ASC Titanium Bases will be made at an Open Implants validated milling center under FDA quality system regulations, and the material will conform to ISO 13356, Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).

The cement used to affix zirconia mesostructures to the Open Implants Titanium Bases and ASC Titanium Bases shall be Kuraray Noritake Dental PANAVIA™ V5 (K150704) based on the Bench Performance Testing performed as part of this premarket notification.

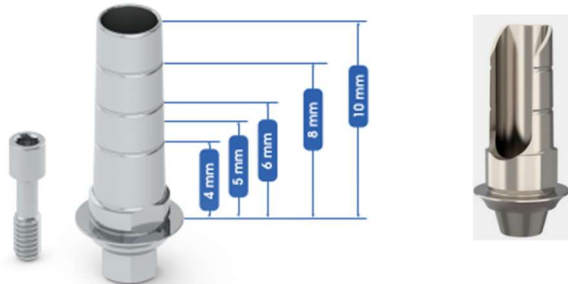
The straight Ti-Base abutments are in a two piece configuration where the screw is not part of the abutment. Use the appropriate driver to place the abutment screw and tighten the abutment using the proper torque and instructions included in this document. Use OEM compatible drivers to tighten the abutments.

The angled Angled Screw Channel abutments have a separate screw. The ASC allows for the driver to engage the screw from 0-30 degrees. Use OEM compatible drivers to tighten the abutment.

Design Parameters

The restoration fabricated to complete the abutment must be designed and manufactured using a CAD/CAM method and to the parameters listed in the tables in the Restorative Manual. The ti-base post height may be reduced to accommodate patient occlusion. If reduced, it shall be done by hand-milling and the post may not be reduced to less than 4 mm for the NobelActive and Zimmer titanium bases, and no less than 5 mm for the Straumann Titanium bases.

The restoration fabricated to complete the abutment must be designed and manufactured using a CAD/CAM method and to the parameters listed below.



The following is a summary of the design parameter restrictions for the zirconia portion of the finalized two-part abutment:

- Minimum Zirconia Wall Thickness – 0.5 mm
- Minimum Post Height for single-unit restoration – 4.0 mm, 5.0 mm for Straumann implant line
- Minimum Gingival Height – 0.5 mm (Titanium base + zirconia portion)
- Maximum Overall Gingival Height – 5 mm
- Maximum Correction Angle – 30°

Please refer to the Restorative Manual for detailed design parameter tables for each titanium base compatible implant system and titanium base type.

VALIDATED MILLING CENTERS

Open Implants has validated milling centers that can produce the final finished Sherlock CAD/CAM abutments. Please refer to the Open Implants website (www.openimplants.com) for a list/indication of validated milling centers and their milling capabilities.

SHERLOCK ACCESSORIES & OTHER PROSTHETIC COMPONENTS

Sherlock Titanium Abutments may also be used with compatible accessories such as analogs, scan bodies, prosthetic screws.

- Sherlock Screws secure the Sherlock Abutments to the Implant.
- Sherlock Scan Bodies are single use devices and should never be autoclaved under any circumstances.
- Sherlock Analogs aid with procedures in the laboratory and were not designed for intraoral use.

DISPOSAL

Dispose of any temporary components that have become in contact with blood or mucous membranes as a biohazard waste.

WARNINGS AND PRECAUTIONS

The guidelines presented herein are not intended to substitute for formal clinical or laboratory training. Sherlock devices should only be used by individuals with training and experience to their clinically accepted application. Open Implants, LLC is not liable for damages resulting from treatment outside of our control. The responsibility rests with the provider.

Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.

The patient-specific customized abutments are to be digitally designed using 510k-cleared dental implant abutment design software. An abutment library file for the dental implant abutment design software includes the maximum and minimum design parameters listed in this document.

The customized abutment design files are forwarded to an Open Implants-validated Milling Center for manufacture. Once the abutment has been customized, it is sent back to the dental laboratory for final restoration fabrication following traditional and/or CAD/CAM materials and technology.

If any modifications are made to the implant/abutment interface, the abutment may not properly interface with the implant. The FDA considers the modifier of the implant/abutment interface a medical device company subject to FDA rules and regulations.

Prosthetics are single patient use only. To eliminate the risk of cross-patient contamination re-use should not be attempted. Open Implants assumes no responsibility for attempted re-use or re-sterilization between patients.

Sherlock components may be small and require careful handling in the patient's mouth, according to this manual to avoid risk of aspiration and/or swallowing. These products should only be used by a trained professional.

Sherlock implant abutments and screws are not represented to be Pyrogen-free.

Reduction of Abutment wall thickness is not permitted.

MRI Safety Information: MR Conditional

The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant or ensuring the implant is located outside of the RF coil.

A patient with Sherlock device can be scanned safely in an MR system under the following conditions:

Device Name	Sherlock
Static Magnetic Field Strength (B0)	≤ 3.0
Maximum Spatial Field Gradient	17T/m (1700 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode is the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Symbols:

Symbol	Title of Symbol (Reference Number)
	Non-Sterile (5.2.7)
	For USA Only (Federal law (USA) restricts this device to sale by order of a licensed dentist)
	Manufacturer (5.1.1)
	Consult instructions for use (5.4.3)
	Do not reuse (5.4.2)
	MR Conditional



Manufacturer

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