

Sherlock Multi Unit Abutments

Instructions for use



DESCRIPTION

Open Implants Sherlock Multi Unit Abutments 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.

CONTRAINDICATIONS

- Patients who are allergic or hypersensitive to commercially pure titanium or titanium alloy Ti-6Al-4V ELI.
- 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.

For multi unit abutments, remove the pre-loaded holder and clean and sterilize following the same procedure. Then, reassemble prior to placing the abutment.

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 are manufactured by Open Implants and are compatible with the Nobel Biocare NobelActive implant restorative platform configurations below. Individual products are labeled for each platform. See the product catalog online at www.openimplants.com/downloads.

Implant Manufacturer	Restorative Platform Diameter (mm)	Implant Body Diameter (mm)
Nobel Biocare	NobelActive NP (3.5)	3.5
Nobel Biocare	NobelActive RP (3.9)	4.3/5.0

MATERIALS

Component	Material
Open Implants Multi Unit Abutments and screws	Titanium: Ti-6Al-4V ELI
Scan body interface	Stainless Steel

SCREWDRIVER USAGE & 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	Compatible Driver	Torque Value
Sherlock Straight Multi Unit Abutment with integral screw	Open Implants REF 4944	35 N·cm
Sherlock Angled Multi Unit Abutment Screw	Open Implants REF 5328	20 N·cm
Multi Unit Prosthetic Screw REF 3894	Nobel Biocare NobelActive	15 N·cm

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.
- Check that the screw threads are properly aligned with the analog or implant before tightening.
- 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 MULTI UNIT ABUTMENTS

The Sherlock Multi Unit Abutments (MUA) are pre-manufactured dental implant abutments that directly connect to the dental implant and support the multi unit prosthesis. Open Implants offers straight and angled Multi Unit abutments with various gingival heights.

The straight Multi-unit abutments are in a one piece configuration where the screw is part of the abutment. Use the preloaded holder to place the abutment. Unscrew the holder to remove it and tighten the abutment using the Open Implants multi unit driver and the proper torque and instructions included in this document.

The angled Multi Unit abutments have a separate screw. The preloaded holder 1) keeps the screw from falling out and 2) aids in the placement of the abutment. Place the abutment using the preloaded holder. Tighten the screw using the proper torque and the Open Implants driver. Once the screw is tightened, remove the preloaded holder by unscrewing it. Take an impression using a standard procedure with the abutments in place.

SHERLOCK ACCESSORIES & OTHER PROSTHETIC COMPONENTS

Sherlock Titanium Abutments may also be used with compatible accessories such as analogs, scan bodies, prosthetic screws, titanium inserts and temporary titanium cylinders.

Sherlock Multi Unit Titanium inserts and Temporary Cylinders are non-engaging. They interface with compatible multi unit abutments. The external surface of these devices is cemented to the multi-unit prosthesis.

- Sherlock Multi Unit Temporary Non-Engaging Cylinders are not indicated for permanent restorations.
- Sherlock Multi Unit Prosthetic Screws secure the prosthesis to the MU Abutments.
- Open Implant Scan Bodies are single use devices and should never be autoclaved under any circumstances.
- Sherlock Multi Unit analogs aid with procedures in the laboratory and were not designed for intraoral use.

Note: Temporary abutments are intended for use for a period of less than 6 months.

DISPOSAL

Dispose of any temporary components that have come in contact with blood or mucous membranes as biohazardous 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 the molar region.

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

Prosthetic components are small and special care should be taken to prevent swallowing or choking. Use instructions for use for handling instructions.

MRI Safety Information: Sherlock abutments have not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Open Implants Sherlock abutments in the MR environment is unknown. Scanning a patient who bears this device may result in patient injury.

Manufacturer:

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SYMBOLS:



Do not Re-use



Consult
Instructions
for Use



Manufacturer



Non Sterile



Federal Law
restricts this
device to
sale by or on
the order of
a licensed
dentist

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