

Sherlock Multi Unit Abutments

Instructions for use

DESCRIPTION

Open Implants Sherlock Multi Unit Abutments and Pre-Milled Titanium Blanks 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.

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 with permanent or temporary restorations, 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 manufactured by Open Implants are compatible with the Nobel Biocare NobelActive, Zimmer Tapered Screw-Vent (TSV), Straumann Bone Level, or Biomet 3i Certain implant restorative platform configurations below. Individual products are labeled for each platform. See the product catalog online at www.openimplants.com/downloads.

MATERIALS	
Component	Material
Open Implants Multi Unit Abutments, multi unit abutment inserts, temporary cylinders, screws, prosthetic screws, and pre-milled blanks	Titanium; Ti-6Al-4V ELI
Scan body interface, impression copings	Stainless Steel
Top crown or bridge for the temporary restoration	Polymethyl Methacrylate (PMMA)
Top crown or bridge for final restoration	Zirconium Dioxide

COMPATIBILITY TABLE		
Compatible Implant Systems	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
Nobel Biocare NobelActive	3.5	3.5 (NP)
	4.3/ 5.0	3.9 (RP)
	3.25	3.4
	4.0	4.1
Biomet 3i Certain	5.0	5.0
	6.0	6.0
	3.3	3.3 (NC)
	4.1, 4.8	4.1, 4.8 (RC)
Straumann Bone Level	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7
Zimmer Tapered Screw-Vent		

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. NobelActive products may use Open Implants Driver REF 4944 for straight abutments or REF 5328 for Angled abutments.

Components	REFs	Torque Value
Sherlock Straight Abutment Screw for NobelActive (for single abutments)	3756, 3759	35 N cm
Sherlock Straight Multi Unit Abutment with integral screw for NobelActive	4926-4933	
Sherlock Straight Multi Unit Abutment with integral screw for Straumann Bone Level NC	0099-6101	
Sherlock Straight Multi Unit Abutment with integral screw for Straumann Bone Level RC	6102-6104	
Sherlock Abutment Screw for Straumann Bone Level	3765	
Sherlock Angled Multi Unit Abutment Screw Straumann Bone Level	6141, 6143	
Sherlock Abutment Screw for Zimmer Tapered Screw-Vent	3769	30 N cm
Sherlock Straight Multi Unit Abutment Screw with integral Zimmer Tapered Screw-Vent 3.5	6105-6109	
Sherlock Straight Multi Unit Abutment Screw with integral Zimmer Tapered Screw-Vent 4.5	6110-6112	
Sherlock Angled Multi Unit Abutment Screw Zimmer Tapered Screw-Vent	6145, 6145	
Sherlock Angled Multi Unit Abutment Screw for NobelActive	5326, 5327	20 N cm
Sherlock Multi Unit Prosthetic Screw for NobelActive	3694	
Sherlock Straight Multi Unit Abutment with integral screw for Biomet 3i Certain 3.4	6091-6094	
Sherlock Straight Multi Unit Abutment with integral screw for Biomet 3i Certain 4.1	6095-6098	
Sherlock Abutment Screw for Biomet 3i Certain	3763	
Sherlock Angled Multi Unit Abutment Screw for Biomet 3i Certain	6130-6140	
Sherlock Multi Unit Prosthetic Screw for Biomet 3i	3900	15 N cm
Sherlock Multi Unit Prosthetic Screw for Straumann Bone Level	3901	
Sherlock Multi Unit Prosthetic Screw for Zimmer Tapered Screw-Vent	3902	

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 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 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.

Multi unit abutments are not intended to be modified manually or by CAD/CAM methods. Gingival Heights, gingival diameters and correction angles are pre-determined by the base portion of a multi-unit abutment. Additional angle correction or increases to gingival height arm are not permitted.

Fabrication of temporary restorations for use on Multi-Unit abutments can be performed using traditional chairside or laboratory methods. The temporary cylinder can be reduced using hand milling to accommodate patient occlusion, but must be a minimum of 4 mm tall. Temporary cylinders may not be used for angle correction.

CORRECTION ANGLE AND IMPLANT DIVERGENCE; NOBEL ACTIVE IMPLANTS

For angle correction, use the abutment with the angle closest to the implant angulation. The maximum correction angle of Sherlock Multi Unit Abutments and the implant placement is 30°. Under no conditions can the divergence angles between implants exceed 60 degrees. To allow for the path of insertion, the following limitations apply.

Abutment A	Abutment B	Max Implant Divergence Angle
0°	0°	19°
0°	17°	36°
0°	24°	43°
0°	30°	49°
17°	17°	53°
17°	24°	60° *
17°	30°	60° *
24°	30°	60° *
24°	24°	60° *
30°	30°	60° *

* Limited to a maximum of 30° per implant.

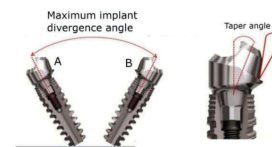
CORRECTION ANGLE AND IMPLANT DIVERGENCE; ZIMMER, BIOMET, AND STRAUMANN IMPLANTS

Multi Unit Abutments have a 21 degrees taper angle on the coronal aspect of the abutment which enables clinicians to compensate for the divergence of seated implants or to otherwise accommodate an angled path of insertion. However, fatigue testing of the Subject device limits implant placement and correction angle of the abutment to 30 degrees.

Abutment A	Abutment B	Max Implant Divergence Angle
0°	0°	0°
17°	17°	34°
17°	30°	47° *
30°	30°	60° *

* Restricted/determined by correlation angle of each implant of the multi unit abutment

Limited to a maximum of 30° per implant.



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 Screws secure the MU Abutments to the Implant. Screws may be straight or angled to support the MU Abutment selected for use.
- 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.
- Sherlock Multi Unit Abutment Screws secure the customized Ti-blank abutments to the implant.
- Sherlock Angled Multi Unit Abutment Screws secure the angled MU Abutments to the implant.

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

SHERLOCK PRE-MILLED TITANIUM BLANKS

Open Implants Sherlock Pre-Milled Titanium Blanks allow the production of a one-piece abutment specific to a patient's needs. Abutments may only be milled by an Open Implants certified milling center. 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 in the table below. 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. Contact us at 1-888-800-8369 or visit www.openimplants.com for a list of validated milling centers.

Compatible Implant System	Sherlock Prosthetic Platform Diameter (mm)	Min GH (mm)	Max GH (mm)	GD (mm)	Min WT (mm)	Max CA	Min PH (mm)	Max PH (mm)
NobelActive	3.5 (NP), 3.9 (RP)	0.5	5	11.9 (max)	0.42	30	4	10
Biomet 3i Certain	3.4	0.8	5	3.4 - 11.9	0.65	30	4	10
Biomet 3i Certain	4.1, 5.0, 6.0	0.5	5	4 - 11.9	0.95	30	4	10
Straumann Bone Level	3.3 (NC)	0.8	5	3.0 - 11.9	0.41	30	4	10
Straumann Bone Level	4.1, 4.8 (RC)	0.8	5	3.45 - 11.9	0.57	30	4	10
Zimmer Tapered Screw-Vent	3.5	0.8	5	3.5 - 11.9	0.48	30	4	10
Zimmer Tapered Screw-Vent	4.5	0.5	5	4.5 - 11.9	1	30	4	10
Zimmer Tapered Screw-Vent	5.7	0.5	5	5.7 - 11.9	1.6	30	4	10

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- Sherlock Multi Unit Temporary Non-Engaging Cylinders are not indicated for permanent restorations.
- Sherlock Multi Unit Screws secure the MU Abutments to the Implant. Screws may be straight or angled to support the MU Abutment selected for use.
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- Sherlock Multi Unit analogs aid with procedures in the laboratory and were not designed for intraoral use.
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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 posterior region.

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.

Prosthetic 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.

Prosthetic components are small and special care should be taken to prevent swallowing or choking. Use Instructions for Use for handling instructions. Reduction of Multi Unit Abutment wall thickness is not permitted.

Angle correction using a straight Multi Unit Abutment is not permitted. Angled Multi unit abutments are to be used for angle correction.

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 artifacts in the MR environment. The safety of Open Implants Sherlock abutments in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.



Manufactured by:

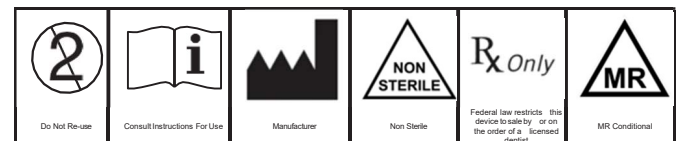
Open Implants, LLC

2850 Redhill Ave, Suite 210, Santa Ana, CA 92705

TEL 781.587.3242; 1.888.800.8369 (toll free)

www.openimplants.com

SYMBOLS:



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