Instructions for Use

Implant-One™ Titanium Base Abutments

Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed dentist or physician.

Device Description:

The Implant-One™ Titanium Base Abutments are premanufactured prosthetic components directly connected to the endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. Implant-One Ti Base Abutments are intended to be used with the following system(s):

- **Implant-One™ 300, 400, and 500 Series implant systems**

Intended Use:

Intended to be used in the maxilla and mandible and use to support prosthetics for the restoration of chewing function.

Indications:

Implant-One™ System Abutments are intended to provide support for prosthetic restorations for use as an aid in prosthetic rehabilitation in the mandible or maxilla for support of single-unit or multi-unit restorations.

The Implant-One™ Ti Base Abutment consists of the titanium base and a mesostructure component, making up a two-piece abutment, and will be attached to the implant using an abutment screw. The mesostructure for use with the Implant-One Ti-Base is intended only to be designed and manufactured according to digital dentistry workflow that integrates scan files from intraoral scanners and lab scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Contraindications:

It is contraindicated to place Implant-One™ Ti Base Abutments in:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers, or desirable positions of implants are not reachable to achieve safe support of static and dynamic loads.
- Patients who are allergic or hypersensitive to titanium alloy Ti-6AL4V (90% titanium, 6% aluminum, 4% vanadium)

Cautions:

Close cooperation between the surgeon, restorative dentist and a dental laboratory technician is essential for a successful implant treatment.

Procedure:

The digital workflow requires the use of the following equipment and materials following the standard procedure according to the instructions of the system provider:

Equipment/Material	Minimum Requirements
Scanner	CEREC Primescan (Dentsply Sirona Systems GmbH) Medit/Identica T500 3D Scanner (Medit Corp.)
Design Software	3Shape™ Dental Designer (3Shape A/S) exoCAD™ AbutmentCAD (exoCAD GmbH)
Restorative Material	Katana™ Zirconia (Kuraray Noritake)
Milling Unit	Ceramill Motion II (Amann-Girrbach)
Bonding Cement	RexyX™ Luting Plus Automix (3M ESPE Dental Products)

When using the digital workflow, the standard procedure according to the system provider instructions apply.

The instructions for use of the material manufacturer shall be followed. For set-up, validation, use, tools, maintenance, and lifetime information on scanners, ovens, and milling machines, please refer to the manufacturer's instructions.

Warning: Do not use any dental cements, restorative material, scanners, milling unit and CAD/CAM software, other than those specifically identified for the Implant-One™ Ti Base Abutment.

The diameter or the height of the Ti Base Abutment must not be reduced.

Restorative design specifications for the Implant-One™ Ti Base Abutment are as follows:

Parameter	Specification
Maximum Angle from implant axis	20°
Minimum Wall Thickness	0.50mm
Minimum Post Height	4.00mm
Maximum Total Height	10.75mm

<u>Designing and manufacturing the restoration using the digital workflow:</u>

Clinical procedure; (when using an Intra-Oral Scanner)

- Remove cover screw, healing cap, or temporary restoration from the implant.
- Select the appropriate series Implant-One™ Scan Body and connect it to the implant. Hand-tighten the provided screw and check for proper seating.
- Take a digital impression of the scan body and surrounding teeth following the scanner manufacturer's instructions.
- Remove the Scan Body and re-connect the cover screw, healing cap, or temporary restoration to the implant.
- Send the digital impression to the dental laboratory along with scan body, restorative material, and patient information.

Laboratory Procedure: (when provided with cast patient model, go to (1). When provided a scan file, go to (2)

1. Scan the patient model.

- Select the appropriate Implant-One™ Scan Body and connect it to the analog. Hand tighten the provided screw and check for proper seating.
- Scan the patient model following the scanner manufacturer's instructions.

2. Design the restoration.
    - Import the scan file into the CAD software and choose the proper Ti Base abutment from the digital library.
    - Design the abutment using the CAD tools within the design limitations specified.
3. Produce the restoration.
    - Send the output file to a milling unit or authorized production facility.
4. Bonding and Cleaning
    - After milling the restoration, finalize it following the restorative material manufacturer's instructions.
    - Clean the restoration using the bonding material manufacturer's instructions.
    - Protect the screw channel from adhesive then apply the adhesive to the contact surfaces of the Ti Base and the zirconia restoration.
    - Press the zirconia restoration onto the Ti Base while maintaining proper orientation until fully seated. Remove excess adhesive from the outside of the abutment with a clean cloth. Follow the adhesive manufacturer's instructions for curing.
    - Clear any materials from the screw channel and finalize the restoration.
    - Send the Restoration to the clinician along with the abutment screw.

5. Clinical Procedure
    - **Caution: The final restoration and abutment screw must be cleaned and sterilized prior to placement into a patient's mouth according to the instructions of the material manufacturer.**
    - Remove the cover screw, healing cap, or temporary restoration from the implant.
    - Connect the completed Ti Base abutment into the implant. Torque the abutment screw to the following specifications:

Implant-One™ Connection	Torque Value
300 Series	20Ncm
400/500 Series	30Ncm

Materials:

Implant-One™ Ti base Abutments and abutment screws are made from titanium alloy Ti-6AL4V per ASTM F136 or ASTM F1472

Sterility and Reusability Information:

The Implant-One™ Ti Base Abutments and abutment screws are provided non-sterile and are intended for single-use only. Prior to use in the patient, sterilize the finalized patient-specific product using the following Sterilization Instructions.

Sterilization Instructions:

- Reassemble the screw into the abutment and enclose the device in an FDA cleared sterilization wrap.
- Place the sealed wrap into the autoclave/sterilizer. Sterilize using the following parameters which have been validated.

Method	Steam
Cycle	Pre-vacuum
Exposure Time	4 Minutes
Temperature	132°C (270°F)
Dry Time	30 Minutes

Magnetic resonance (MR) Safety Information

MR Conditional

Warning: 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 this device can be scanned safely in an MR system under the following conditions:

Device Name	Implant-One™ System
Static Magnetic Field Strength (B_0)	≤ 3.0T
Maximum Field Strength Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularity Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmark 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 in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operation Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Storage, Handling, and Transportation

This device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, county and government legislation or policy.

Manufacturer and Distributer Information

Digital libraries are available from the following:

- 3Shape™ - Available on line at www.implantlogistics.com. Choose “Lab Downloads” from the Resources menu, and select Implant-One 3Shape Library
- Exocad™ - Available on line at www.exocad.com. Choose Implant Logistics from an alphabetical list in the “Implant Libraries for CAD” menu. Add to the download list and provide dongle serial number as instructed.

Ti Base Abutments are manufactured by:

Implant Logistics Inc.

711 Spartan Drive

Sparta, WI 54656

www.Implantlogistics.com

Symbols Glossary

Symbols Glossary		
Symbol	Title	ISO 15223-1 Ref No.
	Manufacturer	5.1.1
	Use by Date	5.1.4
	Lot Number	5.1.5
	Catalog Number	5.1.6
	Sterilize using Irradiation	5.2.4
	Do Not Re-use	5.4.2
	Non-sterile	5.2.7
	Caution	5.4.4
	Consult instructions for use	5.4.3
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	-
	MR Conditional	-