Instructions for Use

Implant-One™ Multi-Unit 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™ Multi-Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. The Implant-One Multi-Unit 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 used to support multi-unit 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 and maxilla for support of single-unit or multi-unit restorations.

The Implant-One™ Multi-Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for prosthetic rehabilitation of the mandible or maxilla with a multi-unit restoration.

Contraindications:

It is contraindicated to place Implant-One™ Multi-Unit 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:

Ensure that the implants have sufficient stability before beginning the prosthetic procedure.

Caution: Never exceed the recommended tightening torque. Over tightening may lead to a screw failure.

Straight Multi-Unit Abutments

- Remove cover screw, healing cap, or temporary restoration from the implant.
- Select the Multi-Unit abutment with the appropriate cuff height.
- Straight Multi-Unit Abutments have an integral thread. Place the abutment into the implant and turn until lightly seated.
- Torque the abutment using the Implant-One™ MUA Driver to the following specifications:

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

- It is recommended to verify seating using radiographic imaging.

Angled Multi-Unit Abutments

- Remove cover screw, healing cap, or temporary restoration from the implant.
- Select the Multi-Unit abutment with the appropriate cuff height and angulation.
- Place the abutment into the implant with the desired orientation.
- Torque the abutment screw using the Implant-One™ Hex Driver to the following specifications:

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

- It is recommended to verify seating using radiographic imaging.

Materials:

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

Sterility and Reusability Information:

The Implant-One™ Multi-Unit 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 according to the following sterilization instructions.

Sterilization Instructions:

Sterilization

- 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 (B0)	≤ 3.0T
Maximum Spatial Field 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 Operating 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

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	-