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Implant-One™ Implants Instructions for Use

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

IMPORTANT NOTE TO CLINICIAN
For safe and effective use of these products or devices they should only be used by trained professionals. Poor technique can result in implant failure and loss of supporting bone.

It is expected that clinicians placing Implant-One Dental Implants have a good understanding of the principals of implant surgery and final restorations before surgically placing these implants. Individual indications and the type of implant placement will dictate any pre- medications required. Depending on the type of surgical event (flapless or flapped, bone graft or not) some patients may be given an antibiotic prior to the surgical appointment.

Post-surgical antibiotics may also be given at the clinician's discretion.

Local anesthesia is required at time of placement and possibly during the surgical event based on the complexity of the case. Draping sterile sheets over the patient at the time of surgery is also recommended.

Device Description
The Implant-One™ Dental Implant System consists of endosseous dental implants, cover screws, healing caps, abutments and abutment screws in a variety of sizes to accommodate differing patient anatomy.

Endosseous implants are self-tapping and threaded, and offered having root form or wide thread form. Root-form implant diameters range from 3.25mm to 5.5mm having lengths from 8mm to 14mm. Wide thread implant diameters are available in 4.1 and 4.5mm (8mm to 14mm lengths), 5.5mm (8mm to 12mm lengths) and 6.5mm (8mm to 10mm lengths). Cover screws and healing caps provide protection to the threads of the abutment connection during endosseous and gingival healing. Cover screws are pre- packaged with each implant. Healing caps are provided as an alternative to the cover screw and are packaged separately. The Implant-One™ dental implants and cover screws are provided sterile.

Implant-One™ abutments are fastened to the implant using either an abutment screw or integral retaining threads. Abutment options include standard, ball, conical, angled conical, custom blank, glueless, locator, post, anatomical angled (15° and 30°), solid, straight, temporary and wide post having various heights. Specific instructions for the clinical use of these abutments can be found in the Implant Logistics online Resource Library at implantlogistics.com.

The standard, solid, straight, temporary and wide post abutment barrels can be modified chairside. Please refer to the online information sheet at the Implant Logistics Resource Library at implantlogistics.com.

Not all abutments ca n be used for single-unit restorations. The conical, angled conical, ball, locator and glueless abutments are intended only for multi-unit loaded restorations. The ball, locator and glueless abutments are to be used in fully removable dentures. The conical and angled conical abutments are to be used in screw retained dentures. A titanium sleeve will be used to allow for screw retention.

The final design parameters for the custom blank abutment are as follows: maximum total height, 12.5mm; minimum/maximum gingival height, 0.5mm/6mm; minimum post height , 4mm; maximum angulation, 30°; minimum wall thickness, 0.78mm (at 1.5mm above the proximal end); minimum diameter, 3.75 mm for the 300 Series, 4.25 mm for the 400 Series and 4.75 mm for the 500 Series.

All Implant-One™ components (implants, abutments, cover screws, healing caps and abutment screws) are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 or wrought titanium alloy (Ti-6Al-4V) as described by ASTM F1472.

How Supplied
The Implant-One™ dental implants, cover screws, and carrier/Impression Posts are supplied sterile. All sterile products are labeled 'STERILE' – the individual package labels contain sterilization information. All products sold sterile are for single use before the expiration date printed on the product label. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave sterilized implants. Do not reuse implants.

The Implant-One™ abutments, healing caps, abutment screws and instruments are supplied non-sterile. These components must be removed from the packaging then thoroughly cleaned and sterilized prior to surgery. Do not reuse abutments (including cover screws, healing abutments, abutment screws and abutments).

Cleaning and Sterilization
Reusable devices must be cleaned before their first use and then between uses. The non-sterile abutments and screws must be cleaned before their first use. The following validated steps are recommended as the cleaning protocol. These instructions are not intended for implants or single-use surgical instruments.

Cleaning:

1. Prepare All-in-One 4 Enzyme Detergent, per manufacturer's instructions
2. Rinse in cold water (<43°C) to remove gross debris and to prevent coagulation of blood
3. Place instruments in container ensuring sufficient amount of Enzymatic Cleaner to cover instruments with solution.
4. Sonicate instruments for a minimum of ten (10) minutes in an ultrasonic cleaner containing enzymatic detergent at 40°C.
5. Remove additional soil from challenging design feature (i.e. holes, lumens, hinged/mating surfaces, interfaces, crevices, serrations) using common hospital cleaning tools.
    a. Move and/or retract all moveable parts and remove soil using a brush.
    b. Scrub lumens or holes with a brush of an appropriate size to ensure that the full width and depth is accessed. Use a twisting action with the brush. Small diameter lumens may be irrigated with the cleaning solution using a syringe.
    c. Open hinged devices and scrub hinged area with a brush.
    d. Scrub crevices with a brush.
6. Rinse thoroughly with warm water, making sure to irrigate the challenging design features. Note: Final rinsing should be carried out using demineralized water. If the components of the instrument are moveable or can be retracted, it is necessary to retract or open the part for thorough rinsing at these locations. Blind holes should be repeatedly filled and emptied.
7. Inspect device under adequate lighting for visible soil. Repeat step 6 until all visible soil has been removed.

Sterilization:

- Return the reusable devices to their appropriate locations within the surgical tray.
- Enclose the surgical tray in an FDA cleared sterilization wrap or autoclave bags twice.
- Sterilization validation has shown these recommendations for sterilization are effective to a sterility assurance level (SAL) of 10^{-6}:

Method:	*Steam*	Temperature:	*132°C (270°F)*
Cycle:	*Pre-vacuum*	Dry Time:	*30 minutes*
Exposure time:	*4 minutes*		

Storage and Handling
Implant components and sterile implant packaging should be handled and stored appropriately to protect them from unintentional damage.

Indications for Use
The Implant-One™ system is indicated for surgical placement in partially or completely edentulous upper or lower jaws to provide a means for prosthetic attachment to restore a patient's chewing function. The Implant-One™ system is indicated for immediate loading only when primary stability is achieved and with the appropriate occlusal loading.

Contraindications

Some general contraindications for placement include:

- Alcohol and drug abuse
- Recently radiated placement sites
- Patients with uncontrolled diabetes
- Patients with mental psychosis
- Medical conditions such as blood disorders or uncontrolled hormonal conditions.

Local contraindications for placement:

- Inadequate bone quantity and/or quality necessary for implant support.
- Clinical signs of pathology in or near the implant site.
- Poor oral hygiene.

Procedural Precautions, Bone-Implant Relationship

- The prepared osteotomy must be prepared so that heat necrosis is minimized.
- The prepared osteotomy must be prepared so that pressure necrosis is minimized.
- Primary stability is achieved at time of placement.
- Vital structures must not be compromised at time of placement. These include cortical plates, nasal cavities and the inferior alveolar nerve canal. Some bone-implant factors to consider at time of placement:
    - Diameter of the implant site.
    - Depth of the implant site.
    - Bone quality and quantity.
    - Cone Beam Computed Tomographic images are highly recommended to evaluate implant sites relative to available bone, position of vital structures and adjacent dentition.
    - It is recommended that small diameter implants not be restored with angled abutments in the molar region.

Warnings

- Excessive bone loss or breakage of a dental implant or restorative device may occur when an implant or abutment is loaded or tightened beyond its functional capability. Physiological and anatomic conditions may negatively affect the performance of dental implants.
- Mishandling of small components inside the patient's mouth carries a risk of aspiration and/or swallowing.
- Forcing the implant into the osteotomy deeper than the depth established by the drills can result in stripping the driver hex interface inside the implant, stripping the driver, or stripping the walls of the osteotomy that may prevent an effective initial implant fixation.
- Small diameter implants and angled abutments may not be used in the premolar or molar region.

MRI Safety Information
The Implant-One™ System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Implant-One™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Procedural Precautions, Surgery
During the planning phase, it is important to determine the vertical dimension, the actual space available between the alveolar crest and the opposing dentition, in order to confirm that the available space will accommodate the proposed abutment and the final crown restoration. This information varies with each patient and abutment; therefore, it should be carefully evaluated before placing any dental implant. The final prosthesis should be considered prior to the placement of the dental implant. Utilize continuous irrigation with a cool, sterile irrigating solution to avoid excessive damage to the surrounding tissue and to prevent compromising Osseo integration. This is mandatory during all procedures. Avoid excessive pressure during preparation of the bone site. As the drilling speed varies based on the instrument and the surgical procedure, recommendations for speed can be found in the Surgical Manual.

Only sharp instruments of the highest quality should be used for any surgical procedure involving bone. Minimizing trauma to the bone and surrounding tissue enhances the potential for successful Osseo integration. In order to eliminate contaminants and other sources of infection, all nonsterile devices should be cleaned and/or sterilized prior to use, per the instructions on the individual product labels.

Procedural Precautions, Post-Operative Care
If the patient experiences any unusual discomfort after implant placement they should be seen immediately. The decision as to when to load the implants should be left up to the clinician and should incorporate the following clinical considerations:

- Initial primary stability.
- Mandibular (shorter time period) or maxillary (longer time period) arch placement.
- Status of occlusal forces being in balance.

Long term clinical success can be best achieved if the final restorations are not placed until 4 to 6 months after placement. This gives the bone adequate time to integrate with the implant. The bone is undergoing remodeling for the first four to ten weeks and should not be loaded during this time.

Potential Adverse Events
Potential adverse events associated with the use of dental implants may include:

- Failure to integrate.
- Persistent pain, numbness, paresthesia.
- Loss of integration.
- Hyperplasia.
- Dehiscence of the implant, requiring bone grafting.
- Perforation of the maxillary sinus, inferior border of the mandible, lingual plate or labial plate.
- Implant breakage or fracture.
- Nerve injury from violation of the inferior alveolar canal space during surgery.
- Temporary or permanent paresthesia.
- Systemic infection.
- Infection as reported by: abscess, fistula, suppuration, inflammation, radiolucency.

Symbols Glossary

Symbol	Title	Ref. No.
	Manufacturer	5.1.1
	Use-by date	5.1.4
	Sterilized using irradiation	5.2.4
	Do not re-use	5.4.2
	Consult instructions for use	5.4.3
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	N/A