Instructions For Use

1. Instructions For Use

1.1. Device Description (Principles of operation)

INOSS Fixture of INOSS System is specially designed for use in dental implant surgery. A successfully osseointegrated dental implant will achieve a firm implant when the fixture is operated under controlled conditions per well-known clinical studies. There are intended for use in partially or fully edentulous mandibles and maxillae, in support of single-unit restorations. The Fixture is made of Unalloyed Titanium Grade 4 (ASTM F67) which has a SAT (Sandblasted Acid-etched Treatment) treated surface. These Fixtures can be used in one-stage surgery method or two-stage surgery method. The Fixture is a surgical component that interfaces with the bone of the jaw to support a dental prosthesis such as a crown, bridge and denture. Fixture connects with other components in order to function. The Fixture design includes two types. The difference between the two fixture types is the platform diameter. One type features a reduced platform diameter that enables platform switching.

[The dimension of INOSS Fixture]

- Ø3.9 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm
- Ø4.3 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm
- Ø4.9 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm
- Ø5.4 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm
- Ø6.2 : 8.0mm, 10.0mm, 11.5mm, 13.0mm, 16.0mm

The INOSS Abutments are intended for use in the recovery of the patient's masticatory function and are upper components of the implant to support dental prostheses. It consists of Healing Abutment, Cover Screw, Stock Abutment and Abutment Screw.

[The dimension of INOSS Abutments]

No.	Product Name	Dimension
1	Cover Screw	Ø3.5 : Length 5.1mm Ø4.5 : Length 5.1mm Ø5.7 : Length 5.1mm
2	Healing Abutment	Ø3.5 : Height 3mm, 5mm, 7mm Ø4.0 : Height 3mm, 4mm, 5mm, 6mm, 7mm Ø4.5 : Height 3mm, 5mm, 7mm Ø5.0 : Height 3mm, 4mm, 5mm, 6mm, 7mm Ø5.5 : Height 3mm, 5mm, 7mm Ø5.9 : Height 3mm, 4mm, 5mm, 6mm, 7mm Ø6.5 : Height 3mm, 5mm, 7mm Ø7.0 : Height 3mm, 4mm, 5mm, 6mm, 7mm
3	Stock Abutment	Ø4.5 : Height 5.5mm (Cuff 1.0, 2.0, 3.0, 4.0, 5.0) Ø5.5 : Height 5.5mm (Cuff 1.0, 2.0, 3.0, 4.0, 5.0) Ø6.5 : Height 5.5mm (Cuff 1.0, 2.0, 3.0, 4.0, 5.0)
4	Abutment Screw	Ø1.95 x 8.2mm

The INOSS Fixture, Healing Abutment and Cover Screw are provided sterile, and other prosthetic components are provided non-sterile. All non-sterile products shall be sterilized by the end user before use.

1.2. Indications for use

INOSS System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single-units' prosthetic attachment to restore a patient's chewing function. INOSS System can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading.

1.3. Instruction for use

1) Preparation before use

① Prior to use, verify that the outer carton box, sterile barrier system, and primary packaging are intact and have not been damaged, opened, or compromised.

② Open the sterile packaging using standard aseptic technique in an appropriate clinical environment. The device shall be handled only by qualified dental professionals familiar with implant procedures and sterile handling techniques.

During package opening and device preparation:

- Maintain sterile conditions throughout the procedure
- Avoid unnecessary contact with the implant and connection areas
- Avoid contact with non-sterile surfaces
- Handle the device using appropriate sterile instruments and techniques
- Prepare the device for implantation in accordance with standard sterile procedures

③ After opening the packaging, maintain sterile conditions throughout implant handling and preparation. Avoid unnecessary contact with the implant and connection areas, and avoid contact with non-sterile surfaces. The implant and packaging components shall be handled using appropriate sterile instruments and techniques. If visible contamination, foreign material, or damage is observed, the device shall not be used.

④ Appropriate products shall be selected for the implant site.

⑤ The expiration date indicated on the label shall be checked. Expired products shall not be used.

⑥ The cleanliness of the operating room environment shall be maintained. The surgical instruments shall be sterilized by the user before use.

2) Instructions and procedure sequence

[Dental implant placement]

To implant the fixture, various drills are used in sequence for site preparation during osteotomy. To place the fixture accurately in the selected site, a hole must be prepared according to the size of the fixture, using the appropriate instruments (drilling, tapping). Rotational speed during these procedures shall be adjusted taking into consideration the condition of the recipient bone and the type of equipment used. The procedure shall be performed using adequate normal saline to reduce heat generation in the bone tissue.

① Remove the blister packaging from the outer box.

② Open the blister packaging and remove the ampoule packaging using aseptic handling techniques.

③ Open the ampoule packaging while maintaining sterile conditions and remove the outer body to expose the implant body secured by the apical connecting implant pin holder.

④ Prior to separation from the apical connecting implant pin holder, securely engage the designated fixture driver with the INOSS Fixture.

⑤ With the fixture driver fully engaged, gently tilt the implant body toward the open side of the ampoule until it separates from the apical connecting implant pin holder.

⑥ After separation, visually inspect the implant and connection area and prepare the implant for placement while maintaining aseptic conditions.

⑦ The fixture can be implanted using a ratchet or a low-speed handpiece.

⑧ The fixture connected to the driver shall be placed into the prepared implant site.

⑨ Transfer the implant to the surgical field using aseptic handling techniques while maintaining sterile conditions throughout transfer and preparation.

⑩ The fixture shall be implanted by rotating clockwise in the osteotomy site.

[Drilling procedure]

① An X-ray image of the patient shall be used to determine the appropriate osteotomy site for the implant.

② On a selected surgical site, an incision shall be made in the gingiva.

③ After the gingiva is incised and the bone is exposed, the implant position shall be established using a point drill.

④ The initial drill shall be used to prepare an initial hole corresponding to the length of the fixture.

⑤ The final drill shall be selected according to the diameter of the fixture and drilling shall be performed at an appropriate speed.

⑥ Detailed drilling sequences shall be referenced in the applicable catalog or drilling protocol.

[Healing]

① After implantation, blood and other substances that are inside the fixture have to be removed, cleanly, and the fixture shall be closed with the cover screw using the hex driver, then the gingiva is sutured, or the gingiva can be formed by connecting a healing abutment to the fixture.

② Healing time is expected in 3 - 6 months, but it depends on the patient's bone condition.

③ Maintenance after initial use

a. This product is for single use only. Reuse is prohibited.

b. The chart label has to be kept in order to ensure that the information of the product that is implanted in the patient is controlled.

[Prosthesis]

After the healing period, an impression shall be taken by attaching the dental impression post. Use the impression to create a dental model and prepare the final prosthesis.

3) Storage

① The INOSS System product shall be stored in a dry place in the original packaging, protected from direct sunlight, and kept at room temperature.

② Improper storage may compromise essential material and design characteristics leading to device failure.

③ Do not re-use the INOSS System product. Reuse of single-use devices may increase the risk of infection to the patient or user.

④ Do not use the INOSS Fixture, Healing Abutment, and Cover Screw after the expiration date indicated on the packaging. Use of these devices after the expiration date may lead to infections.

1.4. Cautions in use

1) General instructions

① This product should not be used in contraindicated cases.

② The user should use this product safely and in accordance with the instructions for use.

③ The user is responsible for selecting and using the product based on the patient's condition.

④ This product is for single use only. Reuse is prohibited.

⑤ Do not use the product after the expiration date indicated on the label.

⑥ Do not use the product if the packaging is damaged or if contamination is suspected.

2) Contraindication

Serious systemic medical conditions, Uncontrolled high blood pressure, Uncontrolled bleeding disorders, Diabetes, Inadequate wound healing capacity, Inadequate bone volume or bone quality, Incomplete maxillary or mandibular growth, Poor general health condition, Bone disease and bone metabolism disorder, Bruxism, Uncooperative or unmotivated patient, Drug or alcohol abuse, Psychosis, Prolonged therapy-resistant functional disorders, Xerostomia, Compromised immune system, Conditions requiring periodic use of steroids, Uncontrolled endocrine disorders, Hypersensitivity or allergy to materials used (e.g., titanium)

3) Adverse effect

Dental implant placement is a surgical procedure that should be performed by adequately trained and qualified clinicians. Patients are advised to avoid excessive physical activity after implant placement.

Potential adverse events which may occur after dental implant placement include:

① Bone and soft tissue dehiscence, temporary hypersensitivity, delayed healing, edema, hematoma, gingivitis, mastication difficulties, bone damage, postoperative discomfort, allergic reactions, poor esthetic outcomes, bruising, and bleeding

② This may cause gingival mucous membrane (gum tissue) ulcer and infection of cellular tissues. However, these are generally reactions from local treatment.

③ Accidental swallowing or aspiration of small components during the procedure

4) Warning

① This procedure must be performed by a trained and qualified clinician. Improper handling may result in damage to the implant and surrounding bone.

② Do not use damaged implants or components. Damaged products must be removed and replaced.

③ Avoid proximity to the inferior alveolar nerve during implant site preparation and placement. Nerve damage may result in anesthesia, paresthesia, or dysesthesia.

④ Products shall be handled carefully to prevent aspiration during use. In case of aspiration, it may lead to infection or physical injury.

⑤ Improper selection, positioning, or unstable fixation may compromise the long-term performance of the implant.

⑥ Do not exceed the recommended insertion torque, as this may cause bone necrosis.

⑦ Implants are only to be placed straight in line with occlusal forces. Not intended for angulation or angle correction.

⑧ Inspect the implant and connection area prior to implantation. Do not use the device if visible damage, deformation, contamination, debris, or residue is observed.

⑨ Abutment or prosthetic components may fracture under excessive loading or improper use.

5) Caution

① Proper planning is essential to the long-term success of both the prosthesis and the implant.

② Overload is one of the key contributors to implant failure.

③ Ensure that the implant size is appropriate for the occlusal load.

④ Appropriate tightening of the screw is essential to prevent premature loosening.

⑤ Sterile handling shall be maintained throughout packaging opening, implant handling, transfer, and implantation procedures. Contact with non-sterile surfaces shall be avoided. Never use potentially contaminated components. Contamination may lead to infections.

⑥ Do not re-sterilize the product, because re-cleaning, disinfection and re-sterilization may compromise material and design characteristics leading to device failure.

⑦ Only place final abutments in occlusion when sufficient primary stability is achieved or when the implant is completely osseointegrated.

⑧ Ensure that the implant-abutment surface is clean before the placement of any prosthetic parts.

⑨ To install the superstructure in the patient's mouth, the operator must check the degree of osseointegration of the implanted fixture with X-ray images and percussion before the operation.

⑩ An open product or a damaged product must not be used. The implant and connection area shall be visually inspected prior to implantation. Do not use the device if visible damage, deformation, contamination, debris, or residue is observed.

⑪ A product contaminated by the operator's mistake during operation must not be used.

⑫ Implant surgery must be considered in terms of side effects and restrictions.

⑬ Pay special attention to patients who have local or systemic factors that could interfere with either the healing process of bone or soft tissue or the osseointegration process, such as the following:
(Bone disease and bone metabolism disorder, Diabetes, Inadequate oral hygiene, Tobacco abuse, Pregnancy, Taking anticoagulation drugs, Untreated periodontal diseases etc.)

⑭ The blister packaging must not be opened until immediately prior to the insertion of sterilized products.

⑮ As these devices are disposable, they shall not be reused.

6) Sterilization

① INOSS Fixture, Healing Abutment, and Cover Screw are provided sterile.

② Before using non-sterile abutments, they shall be sterilized with an autoclave for 15 minutes at 132℃ and the dry time is 20 minutes in gravity type.

1.5. Magnetic Resonance (MR) Safety Information

INOSS System is labeled as MR Conditional with recommended scanning conditions listed below and in the instructions for use.

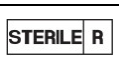
MR Conditional
Warning : Non-clinical evaluation supports the following conditions for safe scanning. The patient may only be imaged by landmarking at least 30cm from the implant, or ensuring the implant is located outside of the RF coil.

A patient with this device can be scanned safely in an MR system under the following conditions :

Device Name	INOSS System
Static Magnetic Field Strength (B_0)	≤ 3.0T
Maximum Spatial Field Gradient	20 T/m
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking 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 applicable - head landmarking not permitted under these conditions.
Scan Duration	No specific constraints due to implant heating

1.6. Symbols

Symbol	Title	Description	Source
	Date of manufacturer	Indicates the date when the medical device was manufactured	ISO 15223-1
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1
	Do not re-use	Indicates a medical device that is intended for one single use only	ISO 15223-1
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1
	Medical device	Indicates the item is a medical device	ISO 15223-1
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1
	Prescription devices	U.S. federal law restricts this device to sale by or on the order of a dentist	21 CFR 801.109(b)(1)
	MR Conditional	Magnetic resonance warning : Device is MR conditional	FDA Guidance Document Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment

Manufactured for INOSYS, INC.
545 W 45th St Fl 11, New York, NY 10036, USA
Tel: 845.562.1555

End of Document