Prosthetic Manual

1. Purpose and Scope

This Prosthetic Manual provides detailed instructions for the use of the INOSS System prosthetic components following successful osseointegration.

It is intended for use by licensed dental professionals trained in implant prosthodontics and is designed to enable the safe and effective restoration of function and esthetics in accordance with the intended use of the system.

2. Prosthetic System Overview

The INOSS System includes a range of prosthetic components designed to be used with INOSS implants for fixed dental restorations.

The prosthetic system consists of:

• Prosthetic Abutments (Stock Abutment)

• Abutment Screw

• Prosthetic accessories compatible with the INOSS System

Only prosthetic components specified for use with the INOSS System should be used.

Use of non-specified components may result in improper fit, mechanical failure, or adverse clinical outcomes.

3. 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.

4. Prosthetic Restoration Options

The INOSS System supports the following prosthetic restoration options :

4.1. Screw-Retained Restorations

1) Preferred where retrievability is desired

2) Allows direct access to the abutment screw

4.2. Cement-Retained Restorations

1) May be used based on prosthetic design and clinician preference

2) Requires careful cement handling to prevent residual cement

5. Abutment Selection

The hex engaging abutments achieve a friction-fit with the implant, regardless of the implant’s design or type of connection. The abutments are assemblies that consist of a two-piece abutment and an abutment screw. The abutment contains a hex that interdigitates with the mating hex of the implant. This engagement prevents rotation when the abutment screw is threaded into the implant. To complete seating and fully engage the friction-fit, the abutment screw must be tightened to 30Ncm.

Abutment selection should be based on :

• Implant position

• Soft tissue height and contour

• Prosthetic restoration design

• Occlusal considerations

Proper abutment selection is critical to ensure optimal fit, load distribution, and esthetic outcomes.

6. Torque Specifications

Component	Torque Value
Cover Screw	Hand Torque
Healing Abutment	10 ~ 15 Ncm
Abutment Screw	30 Ncm

7. Temporary Components

7.1. Healing Abutment

1) Determine the size of the implant platform

2) Select the emergence profile that best suits the site being restored. The profile should match the transfer and the abutment to be used.

3) Select the cuff height so that the top of the component protrudes slightly above the surrounding tissue. The gingival height options are 3.0mm, 4.0mm, 5.0mm, 6.0mm, or 7.0mm.

8. Impression Procedure

8.1. Open-tray Impression Technique

1) Select the appropriate Pick-up Impression Coping corresponding to the implant platform.

2) Connect the Pick-up Impression Coping to the fixture using the coping screw and appropriate driver.

3) Verify that the coping is fully seated and securely connected to the implant.

4) Prepare a perforated impression tray allowing access to the coping screw.

5) Apply impression material around the coping and within the impression tray according to the manufacturer′s instructions.

6) Position the impression tray intraorally and allow the impression material to set completely.

7) After the impression material has set, loosen the coping screw through the access opening of the tray.

8) Remove the impression tray carefully. The Pick-up Impression Coping shall remain embedded within the impression.

9) Connect the fixture analog to the Pick-up Impression Coping within the impression using the coping screw.

10) Verify proper seating and positioning of the fixture analog prior to model fabrication.

8.2. Closed-tray Impression Technique

1) Select the appropriate Transfer Impression Coping corresponding to the implant platform.

2) Connect the Transfer Impression Coping to the fixture using the coping screw and appropriate driver.

3) Verify that the coping is fully seated and securely connected to the implant.

4) Apply impression material around the coping and within the impression tray according to the manufacturer′s instructions.

5) Position the impression tray intraorally and allow the impression material to set completely.

6) After the impression material has set, carefully remove the impression tray. The Transfer Impression Coping shall remain connected to the implant within the mouth.

7) Remove the Transfer Impression Coping from the implant.

8) Connect the Transfer Impression Coping to the corresponding fixture analog.

9) Reposition the coping and fixture analog assembly into the corresponding area of the impression.

10) Verify proper seating and positioning prior to model fabrication.

9. Screw-Retained Restoration Procedures

9.1. Laboratory Model Preparation :

1) In the dental laboratory, a fixture analog is connected to the impression, and a final working model is fabricated using dental stone.

2) Artificial gingival material may be applied to replicate the soft tissue contours of the patient's oral condition.

9.2. Restoration Design and Fabrication

1) Design and fabricate the screw-retained restoration in accordance with standard laboratory procedures.

① Ensure a passive fit of the restoration on the fixture analog.

② Verify the alignment of the screw access channel.

③ Check occlusal and proximal contacts on the working model.

9.3. Clinical Try-In : In the clinical setting, seat the screw-retained restoration intraorally.

1) Verify complete seating and passive fit.

2) Check occlusion and interproximal contacts.

3) Make necessary adjustments prior to final screw tightening.

9.4. Final Placement and Screw Tightening

1) Seat the screw-retained restoration onto the implant or abutment.

① Insert the prosthetic screw through the screw access channel.

② Tighten the screw using a calibrated torque wrench.

2) Recommended torque value: 30 Ncm

9.5. Screw Access Hole Sealing

1) After final tightening :

① Fill the screw access channel with a retrievable material.

② Seal the access opening using an appropriate restorative material.

9.6. Final Evaluation : Make final adjustments as required prior to dismissal of the patient.

1) Occlusion

2) Proximal contacts

3) Overall stability of the restoration

10. Cement-Retained Restoration Procedures

10.1. Laboratory Model Preparation

1) In the dental laboratory, a fixture analog is connected to the impression, and a final working model is fabricated using dental stone.

2) Artificial gingival material may be applied to replicate the soft tissue contours of the patient's oral condition.

10.2. Abutment Selection and Placement on Fixture Analog

1) Select a Stock Abutment with an appropriate height based on the prosthetic requirements.

2) Attach the abutment to the corresponding fixture analog using a screwdriver.

10.3. Abutment Modification and Margin Preparation : Mark the areas requiring modification for vertical clearance and gingival contouring.

1) Maintain a minimum occlusal clearance of 1.5–2.0 mm for metal and porcelain restorations.

2) For cement-retained restorations, the minimum abutment post height above the gingival collar is 4.0 mm for intraoral clinical use.

When preparing a margin on the abutment for cement retention, the soft tissue contours should be respected rather than relying solely on the pre-defined abutment margin.

10.4. Wax-Up Procedure

1) Perform a diagnostic wax-up of the crown on the working model.

2) The wax-up should approximate up to 80% of the natural crown size, allowing adequate space for final material application and contour refinement.

10.5. Framework Fabrication and Evaluation

1) Remove porosities and sprue remnants from the fabricated framework.

2) Seat the framework on the working model and verify proper fit, margin adaptation, and occlusal relationships.

10.6. Final Prosthesis Fabrication : Complete fabrication of the final prosthesis according to standard laboratory procedures, ensuring proper esthetics, occlusion, and structural integrity.

10.7. Clinical Cementation Procedure

In the clinical setting :

1) Apply an appropriate amount of dental cement inside the final prosthesis.

2) Seat the prosthesis onto the abutment following standard cementation techniques.

3) Remove all excess cement to minimize the risk of peri-implant complications.

10.8. Final Prosthesis Placement

1) Verify complete seating of the final prosthesis in the patient's mouth.

2) Check occlusion, proximal contacts, and overall stability of the restoration prior to dismissal of the patient.

11. Occlusal Considerations

11.1. Adjust the occlusion to minimize excessive lateral forces.

11.2. Avoid premature contacts, particularly during initial loading.

11.3. Periodically reassess the occlusion during follow-up visits.

12. Maintenance and Follow-Up

12.1. Routine clinical and radiographic evaluations are recommended.

12.2. Inspect prosthetic components for screw loosening or wear.

12.3. Reinforce the patient's oral hygiene instructions.

13. Cautions in use

13.1. 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.

13.2. 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)

13.3. 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

13.4. 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.

13.5. 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.

14. Storage

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

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

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

14.4. 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.

15. Sterilization

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

15.2. 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.

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

End of Document