

## EN IMPORTANT PRODUCT INFORMATION

This document applies to BIOMET 3i Dental Implants.

**Instructions for Use:** For a detailed explanation of the osteotomy preparation and implant placement guidelines, please refer to the appropriate Surgical Manual(s).

**Description:** BIOMET 3i Dental Implants are manufactured from biocompatible titanium or titanium alloy. BIOMET 3i Dental Implants include various surface treatments. For specific product descriptions, please refer to individual product labels.

**Indications for Use:** BIOMET 3i Dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. The BIOMET 3iT3®, NanoTite™ and OSSEOTITE® Dental Implants may also utilize immediate loading for these indications. BIOMET 3iT3®, NanoTite™ and OSSEOTITE® Dental Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

**Contraindications:** Placement of dental implants may be precluded by both patient conditions that are contraindications for surgery as well as hypersensitivity to commercially pure titanium or titanium alloy (including vanadium, aluminum, and calcium phosphate).

BIOMET 3i Dental Implants should not be placed in patients where the remaining jaw bone is too diminished to provide adequate implant stability.

**Warnings:** Excessive bone loss or breakage of a dental implant may occur when an implant is loaded beyond its functional capability. Physiological and anatomical conditions may 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 damage to the implant, driver, or osteotomy.

For short implants, clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to the implant's response to percussion or radiographic changes in bone-to-implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. If a clinician chooses a short implant, then the clinician should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. In addition, the clinician should allow longer periods for osseointegration and avoid immediate loading.

Reuse of BIOMET 3i products that are labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

**MRI Statement:** BIOMET 3i Dental Implants have not been evaluated for safety, heating, migration, or compatibility in the Magnetic Resonance Imaging (MRI) environment.

**Precautions:** These devices are only to be used by trained professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration. When the clinician has determined adequate primary stability is achieved, immediate functional loading can be considered.

The following should be taken into consideration when placing dental implants: bone quality, oral hygiene, and medical conditions such as blood disorders or uncontrolled hormonal conditions. The healing period varies depending on the quality of the bone at the implantation site, the tissue response to the implanted device and the surgeon's evaluation of the patient's bone density at the time of the surgical procedure. Proper occlusion should be evaluated on the implant restoration to avoid excessive force during the healing period on the implant.












It is recommended that implants less than 4mm diameter **NOT** be placed in the posterior regions.

**Sterility:** All dental implants are supplied sterile and are labeled "STERILE". 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.

**Storage and Handling:** Devices should be stored at room temperature. Refer to individual product labels and the Surgical Manual for special storage or handling conditions.

**Potential Adverse Events:** Potential adverse events associated with the use of dental implants may include: failure to integrate, loss of integration, dehiscence requiring bone grafting, perforation of the maxillary sinus, inferior border, lingual plate, labial plate, inferior alveolar canal, or gingiva, infection as reported by abscess, fistula, suppuration, inflammation, or radiolucency, persistent pain, numbness, paresthesia, hyperplasia, excessive bone loss requiring intervention, implant breakage or fracture, systemic infection, nerve injury, and aspiration.

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

 Date of Manufacture	 Use by date
 Catalogue number	 By prescription only
 Batch code	 Do not use if package is damaged
 Caution, consult accompanying documents	 Consult Instructions for Use
 Do not re-use	 Do not re-sterilize
 Sterilized using gamma irradiation	

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**EC REP**

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