Product Label Symbols	Product Label Legend	Product Label Symbols	Product Label Legend
	Do not reuse		Use by date
	Do not re-sterilize		Do not use if package is damaged
STERILE R	Sterilized using irradiation	MD	Medical device
	manufacturer	Rx only	By prescription only
	Date of manufacture	CE 1639	Conformité Européene
REF	Catalog number	EC REP	Authorized representative in the European Union
LOT	Batch code	www.ifu.biomet3i.com	Consult instruction for use

aZure® Implant System

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VIE01-01

English

Instruction for use aZure Implant System

This document applies to aZure Dental Implants.

1. Product Description

aZure Implant System dental implants are manufactured from biocompatible titanium (commercially pure) and are surgically inserted into the upper and/or lower jawbone; which serves as a replacement for a patient's tooth and provides a stable foundation for prosthetic attachment.

For detailed information on the specific procedure for the product you are using, please refer to the appropriate manual/ guide on the website www.zimmerbiometdental.com.

2. Indications for Use

aZure Implant System dental implants are intended for surgical placement in the maxilla or mandible 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 with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. aZure Implant System 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.

aZure Implant System is indicated for adult patients.

3. Directions for Use

The implantation procedure should be done under aseptic conditions with specifically designed sterile surgical instruments. Implant placement should follow the specified drill sequence while using a gentle up and down pumping motion and external irrigation to prevent bone heating.

Tapping is recommended when insertion torque exceeds 45 Ncm. Caution: too much insertion torque may cause deformation of double hex in the implant. After completing the insertion procedure, place the cover screw into the implant. Close and suture the tissue flap.

4. 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)

aZure Implant System dental implants should not be used in cases where the remaining alveolar bone is insufficient to provide adequate width or height to stabilize the implant.

5. Warnings and Precautions

Determine local anatomy and suitability of the available bone for implant placement.

Thorough screening of prospective implant candidates must be performed. Visual inspections as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT scans, and CBCT may also be beneficial. Adequate radiographs, direct palpation, and visual inspection of the implant site are necessary prior to treatment, planning, and use of aZure Implant System dental implants.

Lack of osseointegration or subsequent implant failure may occur in cases where there is insufficient bone, poor bone quality, poor oral hygiene, heavy smoking, tobacco use, or medical conditions such as blood disorders or uncontrolled diabetes.

Dental implant placement is a highly specialized and complex procedure. For safe and effective use of aZure Implant System dental implants, it is strongly suggested that specialized training be undertaken.

Dental implants must not be altered in any way.

The use of electro-surgical instruments or lasers around metallic implants and their abutments is not recommended due to the risk of electric shock and/or burns.

Implant mobility, bone loss, and/or chronic infection may indicate implant failure.

Reuse of aZure Implant System dental Implants may result in product contamination, patient infection and/or failure of the device to perform as intended.

The implant operation requires high accuracy and careful attention, we must try to minimize damage to the cell tissue and pay special attention to the temperature, surgical trauma, and/or removal of the source of contamination and infection.

Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening, ingestion (aspiration or swallowing).

When the clinician has determined adequate primary stability is achieved, functional loading in single and/or multiple tooth applications can be consider.

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 3.5 mm in diameter NOT be placed in the posterior regions.

The healing period varies depending on the quality/density of the bone at the implantation site, and the tissues response to the implanted device.

6. Sterility

The implant along with the packaged cover screw has been cleaned and sterilized by gamma irradiation and are labeled "STERILE."Product that is labeled "STERILE"should be opened onto a sterile field and handled with sterilized tools only. All products sold sterile are for single-use before the expiration date printed on the product label. Do not use if package is opened, damaged, or expired. Do not resterilize. Discard any and all open, unused products.

Sterility guaranteed only when the package is not opened or damaged. The accompanying label for medical treatment should be used for care of patient.

7. MRI Safety Information

Although aZure Implant System implants are made of nonmagnetic material, the safety and compatibility in the magnetic resonance imaging (MRI) environment have not been evaluated. Image artifact may be created by the device.

Intai Technology Corp. is not liable for damages resulting from MRI usage.

8. 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, ingestion, aspiration and/or swallowing.

Storage and Handling

aZure implant system implants, abutments, and instrument should be stored at room temperature.