| Product Label Symbols | Product Label Legend | Product Label Symbols | Product Label Legend |
|---|---|---|---|
| | Do not reuse | | Use by date |
| www.ifu.biomet3i.com | Consult instruction for use | | Do not use if package is damaged |
| NON STERILE | Non sterile | MD | Medical device |
| | manufacturer | CE | Conformité Européene |
| | Date of manufacture | EC REP | Authorized representative in the European Union |
| REF | Catalog number | LOT | Batch code |

CE 1639 The CE mark is valid only if it is also printed on the product label

aZure® Implant System

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EC REP

European Authorised Representative(E.A.R): **Lotus NL B.V.**
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VIE04-01

English

## Instruction for use aZure Implant System
## Abutment & Prosthetic Components

This document applies to aZure restorative products.

**1. Product Description**

aZure Implant System abutment and prosthetic components are manufactured from biocompatible titanium alloy (Ti-6Al-4V), medical grade stainless steel, and medical grade plastic. aZure Implant System abutment and prosthetic components consist of the following:
abutment and prosthetic components
aZure Implant System abutment and prosthetic components are only compatible with the aZure Implant System dental implant. They cannot be used with other fixture systems.
Refer to product manual, catalogue of aZure Implant System for details. For the product code, specification, manufacturing date, and expiration date see the product label.
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 restorative products are intended for use as an accessory to endosseous dental implants for placement in the maxilla and mandible.
Provisional abutments are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. The prosthesis will be either cement, mechanically or screw-retained to the abutment system based on individual product design.

**3. Contraindications**

Placement of aZure Implant System restorative products are precluded by known patient hypersensitivity to any of the materials listed in the Product Description section of this document.
Additional Contraindications include, but are not limited to the following:
* Patients with Hemophilia
* Patients experiencing difficulties related to bone and wound healing
* Patients with uncontrollable diabetes, tissue disease influencing bone wound healing; heavy smokers or heavy consumers of alcohol.
* Patients whose immunity system is compromised due to chemotherapy and/or radiation therapy
* Patients with active oral infection or inflammation, or other adverse oral conditions (improper oral hygiene, bruxism)
* Patients with untreatable occlusion/joint disorder, insufficient dental arch space
* Patient with insufficient bone height or width

**4. Warning and Precautions**

aZure Implant System abutment and prosthetic components should only be used by trained professionals. The surgical and restorative techniques required to properly utilize these products are highly specialized and complex procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw lossening, ingestion and aspiration and/or swallowing.
aZure Implant System abutment and prosthetic components labeled as single use cannot be reused and if not followed may result in product contamination, patient infection and/or failure of the device to perform as intended.
Stress distribution and occlusal stability are especially important in implant placement as well as the fit of prosthesis and abutment on bridges. Avoid use excessive force horizontally, especially during immediate implantation following tooth extraction. Fracture of a restoration may occur when an abutment is loaded beyond its functional capability.
Patients should be instructed to keep the oral cavity thoroughly clean. Do not apply excessive stress on the teeth until the final prosthesis is placed.

**5. Sterility**

Products provided non-sterile may need to be cleaned and sterilized prior to use.
Intai recommends the following Sterilization parameters for wrapped items:

**autoclaves (vaccum type)**

| Optimal sterilization temperature | Minimally required sterility time | Minimally required drying time |
|---|---|---|
| 135℃ | 10 minutes | 30 minutes |

Do not re-sterilize or autoclave components except where indicated on the individual product label,

**6. 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.

## Storage and Handling

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