Prosthetic Fixtures for Dental Implants

ENGLISH (US Only)

INSTRUCTIONS FOR USE

CAUTION – PLEASE READ CAREFULLY

Products covered in this document should only be used by dental specialists with experience in dental implantology and other specialties, such as dental diagnosis, planning, dental surgery, or prosthetic techniques.

Products covered in this document designed for single use only must never be re-used. If reused, there is risk of product damage and possible prosthetic failure, which may cause health risks to the patient.

All products covered in this document should be dry fitted before use to check that they fit correctly. The clinician is responsible for the correct use of the products, as both the planning and the procedures are under their control. Only dental specialists with appropriate experience and training should work with these products.

Please contact the manufacturer or distributor with any questions.

U.S. Federal law restricts these devices to be sold by or on the order of a licensed dentist / physician.

An annual inspection of the prosthetic restoration and the screw by the dentist and/or the laboratory is recommended. If the screws are subject to unusual wear, the complete integrity of the implant abutment should be checked. Failure to follow these instructions puts the patient at risk.

During any intraoral use and handling, all Azure products must be secured to prevent them from being swallowed or aspirated by the patient.

Compatible Implant Systems

AZURE SYSTEM	*COMPATIBLE WITH:*
AA-CONICAL	*AXIOM® BONE LEVEL & TISSUE LEVEL*
BS-INTERNAL	*BEGOS SEMADOS®* SC/SCX/RS/RSX/S/RI*
BHI-INTERNAL	*BIOHORIZONS TAPERED INTERNAL*
BHEX-EXTERNAL	*BIOHORIZONS TAPERED EXTERNAL HEX*
BK-CONICAL	*BIOTECH KONTACT®*
BI-INTERNAL	*BTI® INTERNA®*
CCA-INTERNAL	*CAMLOG®*
CCO-CONICAL	*CONELOG®*
DT-CONICAL	*DENTIUM SUPERLINE, IMPLANTIUM, IMPLANTIUM II*
DAEV-CONICAL	*DENTSPLY SIRONA ASTRA TECH IMPLANT SYSTEM® OSSEOSPEED® EV*
DATX-INTERNAL	*DENTSPLY SIRONA ASTRA TECH IMPLANT SYSTEM® OSSEOSPEED® TX*
DX-INTERNAL	*DENTSPLY SIRONA XIVE®*
DA-INTERNAL	*DENTSPLY SIRONA ANKYLOS®* C/X*
GD-CONICAL	*GLOBAL D IN-KONE®*
MI-CONICAL	*MEDENTIS ICX®*
MA-CONICAL	*MEGAGEN ANYRIDGE®*
MSC-CONICAL	*MIS® C1 CONICAL*
MSV-CONICAL	*MIS® V3 CONICAL*
MSCV-CONICAL	*MIS® C1 & V3 CONICAL*
MSH-INTERNAL	*MIS® SEVEN® INTERNAL HEXAGON*
NG-CONICAL	*NEODENT GRAND MORSE®*
NRT-TRILOBE	*NOBELREPLACE® & REPLACE SELECT™ TAPERED*
NAC-CONICAL	*NOBELACTIVE® & NOBELREPLACE® CONICAL*
NB-EXTERNAL	*NOBEL BRÅNEMARK SYSTEM®*
NBI-INTERNAL	*NEOBIOTECH IS-II*
OH-CONICAL	*OSSTEM TS, KS & HIOSSEN ET NH, ET SA*
PB-EXTERNAL	*PHIBO® TSH®*
SBL-CONICAL	*STRAUMANN BONE LEVEL*
SBLX-CONICAL	*STRAUMANN BLX®*
STL-TISSUE	*STRAUMANN TISSUE-LEVEL*
ZTSV-INTERNAL	*ZIMVIE TAPERED SCREW-VENT®*
ZC-CERTAIN®	*ZIMVIE CERTAIN®*
ZEX-EXTERNAL	*ZIMVIE EXTERNAL HEX*

US ONLY

All digitally designed custom abutments for use with Azure Tibases or Pre-Milled Blanks are to be sent to a TerratsMedical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

APPLICATIONS AND DIRECTIONS FOR USE

Analogs

Analogs are used to simulate the connection of the dental implant and its placements in a plaster model.
Caution: Before any laboratory manipulation, make sure that the anti-rotational and retentive parts are properly connected. Before tightening check that the analog and the prosthesis match in size and type of connection. A sealed connection with passive fit is desirable. Do not reuse an analog, as this connection may be altered, and its technical specifications modified.

Impression Coping/ Transfer

The impression coping is used to transfer the implant position from the intraoral environment to the model in the dental laboratory. Azure impression copings can be used in the closed and open tray technique.
Caution: Before use, make sure that the implant connection seat is clean. Any trace of dirt could affect the subsequent fit of the prosthesis. Ensure compatibility to the implant system it will be connected to.
Procedure: Remove the healing abutment, clean the connection with water and air dry. Select the impression coping compatible with the implant system, connection, and platform size. Place on the implant and check its correct position. Place the screw and tighten manually.

- For the closed tray technique, choose the short screw. After tightening, block the screw hexagon with wax. Use hydrocolloid, polyethylene, or soft silicone. Once hardened, place the impression coping in the impression and check its stability before sending it to the laboratory. This technique is only recommended for implants without axial divergence.
- For the open-tray technique, choose the long screw. Before mixing the impression material, try the tray in the mouth to check the access to the screws from the outside. Before taking the impression, the impression copings can be splinted with acrylic resin placed on top of the dental floss between adjacent implants. After hardening, remove all screws and remove the tray.

Scanbody

Scanning abutments are used for prosthetic restorations prepared by dental technicians in the laboratory or by dentists in the clinic throughout the CAD/CAM process. It is suitable for obtaining geometric data from the model using a desktop 3D scanner in the laboratory or for optical impressions using an intraoral 3D scanner. An Azure digital library is required for proper operation. To download and install one of our specific libraries for your CAD system, please visit www.azuredental.com/digital-library.

For best scanning accuracy, it is recommended to place the flat surface of the analog body in a palatal/lingual orientation. Fix the abutment with the corresponding screw (indications in our catalog) by hand or with a maximum torque of 10 Ncm. In case of intraoral abutment, fix it by hand-tightening the integrated screw. For most scanners, no spray is required. Scanning should be performed according to the CAD/CAM system manufacturer's instructions. It is crucial to choose the correct implant connection in the software. After scanning, the abutment can be disassembled by gently leaving it in the tray or case. To complete the scan, it may be necessary to collect additional information (e.g., silicone bite, gingival shape, etc.).

Caution: Before scanning, visually check the abutment and analog for surface damage or tissue debris on the implant connection. The scanning abutment is a precision tool and over tightening can change its geometry causing errors in the scanning process and discrepancy in accuracy.

Healing abutment

The healing abutment is used as an auxiliary transmucosal abutment. It is placed on the implant prior to the prosthetic restoration to facilitate the formation of a soft tissue sulcus.

Caution: Choose the correct height to ensure proper function and prevent transmission of masticatory forces. Prior to placement, ensure that the implant platform is free of tissue debris. Use gentle hand torque.

Temporary Cylinder

The temporary abutment is used for prosthetic restorations prepared by the dentist in the clinic, it functions as a support for screw-retained temporary prostheses: Crowns, bridges, and complete dentures.

Caution: Make sure that the abutment is correctly aligned with the retentive parts of the implant. We recommend taking a periapical radiograph to verify proper fit after tightening the screws. Any grinding should be performed outside the mouth. If this is not possible, use adequate suction. Position the patient so that debris are not inhaled or swallowed. Use carbide burs and water-cooled carborundum discs. Before fixing the restoration, check the torque according to the connection and implant size. It is important to seal the chimney with Teflon tape or gutta percha and composite. Clean any excess cement near the platform to avoid peri-implantitis or other complications, which can lead to implant loss. It is important to check the static and dynamic occlusion avoiding excessive loads, which can prolong or prevent osseointegration, especially in cases of immediate loading.

Castable Abutment

The castable abutment is used for prosthetic restorations prepared by dental technicians in the laboratory. For a better sealing of the connection, we recommend metal abutments which have been pre-milled. However, if you decide to use the casting method take the following precautions:

- Add enough was to create a layer that can compensate for the expansion of the castable.
- Press gently to avoid deformation.
- Cast parts to a size and shape that promotes cavity filling and avoids air bubbles.
- Use high flowing alloys in cases of complicated modeling.

Tibase-T (Straight Titanium Tibase)

The Tibase-T is used for prosthetic restorations prepared by dental technicians in the laboratory. The main use of the titanium Tibase-T is to support a bridge or zirconium dioxide restoration fabricated with CAD/CAM techniques, or on the manual milling-copying machine. It can also be used as a connector between screw-retained full crowns (of any material) and an implant, or in some cases as a narrow clinical abutment.

To use this product in with a digital workflow, the Azure libraries and the use of scanbodies are required.

Some CAD/CAM systems require a double scan of the diagnostic wax-up. If you need additional assistance with the installation and/or correct use of the libraries, or with the use of the part itself, please contact your local customer service.

Caution: To improve cement adhesion, it is recommended to clean and degrease the surfaces prior to cementation. For cementation on the model any implant cement (dual-curing or self-adhesive) can be used following the cement manufacturer's instructions. The inner surface of the zirconia framework (cementation area) should be sandblasted and cleaned/degreased. For secure bonding, reduction of the interface diameter and height is not recommended.

Contraindications: Do not use the titanium interface for single-unit restorations with extensions on a single implant, patients with bruxism, in cases of insufficient vertical space or for metal overlays.

Tibase-A (Angled Screw Channel Tibase)

The angled **Tibase-A** is used for prosthetic restorations prepared with axially divergent implants. The main use of the titanium interface is to correct this axis to support the bridge or individual zirconium dioxide restorations fabricated with CAD/CAM techniques, or on the manual milling-copying machine. It can also be used as a connector between screw-retained full crowns (of any material) and an implant, or in some cases as a narrow clinical attachment.

To use this product with a digital workflow, the Azure libraries and the use of scan bodies are required.

Some CAD/CAM systems require a double scan of the diagnostic wax-up. If you need additional assistance with the installation and/or correct use of the libraries, or with the use of the part itself, please contact your local customer service.

Caution: To improve cement adhesion it is recommended to clean and degrease the surfaces prior to cementation. For cementation on the model any implant cement (dual-curing or self-adhesive) can be used following the cement manufacturer's instructions. The inner surface of the zirconia framework (cementation area) should be sandblasted and cleaned/degreased. For secure bonding, reduction of the interface diameter and height is not recommended.

Contraindications: Do not use the titanium Ti-Base for single-unit restorations with extensions on a single implant, patients with bruxism, in cases of insufficient vertical space or for metal overlays.

Tibase-C (Tibase Compatible with Cerec® System)

These tibases function in the same way as Tibase-T (straight titanium tibase). They are used for prosthetic restorations fabricated with CAD/CAM techniques within the CEREC and INLAB SW systems from Dentsply® Sirona. The function of theses Ti-Bases is to support cores of different materials (zirconium oxide, PMMA, …) and screw them to the implant. These restorations can also be crowns or anatomical bridges. To use this product in digital dentistry you have two options, use the Azure library together with Azure scanbodies, or to design within the Sirona Cerec® or in-lab software with Sirona® scanbodies.

The CAD design of the elements to be fabricated will be carried out with the same Dentsply® Sirona software and library. To improve the adhesion of the cement, it is recommended to clean and degrease the surfaces prior to cementation. Any implant cement (dual-curing or self-adhesive) can be used for cementing on the model according to the cement manufacturer's instructions The ceramic surface in the cementation area should be sandblasted and cleaned/degreased. For secure bonding, reduction of the interface diameter and height is not recommended.
Caution: To improve the adhesion of the cement, it is recommended to clean and degrease the surfaces prior to cementation. Any implant cement (dual-curing or self-adhesive) can be used for cementation on the model following the cement manufacturer's instructions. The inner surface of the zirconia framework (cementation area) should be sandblasted and cleaned/degreased. For secure bonding, reduction of the interface diameter and height is not recommended.

Straight and Angled Cement-Retained Abutments

The straight and angled cement-retained abutments are used for prosthetic restorations prepared by dental technicians in the laboratory or by dentists in a dental office where cementable attachments form the core of supporting crowns or bridges.

Caution: Make sure that the attachment is correctly aligned with the retentive parts of the implant and that they are in the correct place in relation to the secondary parts. We recommend taking a periapical radiograph to verify the correct fit after tightening the screws. If customization of the abutment is necessary, do not thin the walls to less than 0.5 mm thickness. Any grinding should be done outside the mouth. If this is not possible, use adequate suction. Position the patient so that debris are not inhaled or swallowed, and before cementing the definitive restoration check the torque according to the connection and implant size. Use definitive or temporary cement after sealing the chimney with Teflon tape or gutta percha. Clean the excess cement on the edge of the crown to avoid peri-implantitis that can lead to implant loss. After cementation remember to check the static and dynamic occlusion using the conventional protocol.

Multi-Unit Abutments (includes abutments compatible with Dentsply Sirona's UniAbutments)

These abutments are used for prosthetic restorations prepared by the dentist in a dental clinic. It is a prefabricated abutment directly connected to the dental implant and intended to serve as a transepithelial auxiliary fixation in screw-retained prosthetic restorations. It is highly recommended to verify its position by means of periapical radiographs.

Azure offers two systems: Multi-Unit and the systems compatible with Dentsply Sirona's UniAbutment, U-EV/ARDAEVMU, U-20/ARDA20MU, and U-45/ARDA45MU.

In the case of straight Multi-Unit abutments,is a suitable abutment using the plastic holder that facilitates placement. Tighten the abutment using the appropriate wrench. For angled Multi-Unit abutments, place the appropriate abutment in its desired location and position using the metal holder and then tighten the abutment screw using the implant system specific driver tip on a torque ratchet. Take an impression with the usual procedure and place a provisional prosthesis on the patient. If the provisional prosthesis is not necessary, place healing caps.

In case of UniAbutment, ix a suitable abutment choosing the different heights and types (20° or 45° - depending on the divergence of the implant). Use the support screw to facilitate placement. Tighten the abutment with the compatible wrench for UniAbutment and take the impression with the usual procedure

For torque recommendations refer to the Azure Screw Recommended Torque Document or the Azure Catalog.

Pre-milled blank

The Pre-milled blank abutment is used for prosthetic restorations prepared by prosthetists in the laboratory. The Pre-milled blank abutment interface is fabricated on an industrial lathe to provide consistent and accurate results. The connection is more precise, and the abutment shape can be milled to the patient's specific needs.

An Azure adapter is required for proper machining.

Caution: The minimum wall thickness of the milled attachment must not be less than 0.45 mm. CoCr: Material classified by ECHA as CMR 1B hazardous substance (possibly carcinogenic, mutagenic, or toxic for reproduction).

US ONLY. PROSTHETIC PROCEDURE (APPROVED MILLING CENTER DIGITAL DENTISTRY WORKFLOW)

Using digital workflow (intra-oral scanning)

1. For detection of the precise implant position during scanning, use the Azure scanbody.
2. For a correct digitization, scan the patient's teeth by using an intra oral scanner.

Model creator (optional step)

3. With design software, create a digital working model.
4. Export the stl file and send it to 3D print provider.
5. Place Azure analog in the working model.

Using digital workflow (desktop scanning):

1. Obtain conventional impression of patient teeth setup and create working model with placed enclosed analog to representing the implant.
2. Place a Azure scanbody in the analog to identify the position and orientation of the implant.
3. Scan the working model by use of a dental desktop scanner.

Designing the zirconia superstructure. The zirconia superstructure must be designed using appropriate design software with appropriate library files installed. Refer to Section 10 APPLICATIONS – ABUTMENTS for design limitations.

1. Import the digital file from the scanner into the design software.
2. Import library file and select relevant implant platform from the library.
3. Design the zirconia superstructure in the design software.
4. The digital file must be sent to a Terrats validated milling center for manufacture.
5. The Base abutment and zirconia superstructure will be sent to the dental lab with a prosthetic screw.

Pre-milled Blank (Custom) abutment

The Pre-milled blank abutment must be designed using appropriate design software with appropriate library files installed. Refer to Section APPLICATIONS – ABUTMENTS for design limitations.

1. Import the digital file from the scanner into the design software.
2. Import library file and select relevant implant platform from the library.
3. Design Pre-milled Blank abutment in the design software.
4. The digital file must be sent to a Terrats validated milling center for manufacture.
5. The Pre-milled Blank abutment will be sent to the dental lab with a prosthetic screw.

US ONLY. PROSTHETIC PROCEDURE (GENERAL DIGITAL DENTISTRY WORKFLOW)

Using digital workflow (intra-oral scanning)

1. For detection of the precise implant position during scanning, use the Azure Scan body.
2. For a correct digitization, scan the patient's teeth by using an intra oral scanner that has an accuracy of 10 µm or better (i.e intraoral Trios-series).

Model creator (optional step)

3. With design software, create a digital working model.
4. Export the stl file and send it to 3D print provider.
5. Place Azure analog on the working model.

Using digital workflow (desktop scanning):

1. Obtain conventional impression of patient teeth setup and create working model with placed enclosed analog to represent the implant.
2. Place an Azure Scan body in the analog to identify the position and orientation of the implant.
3. Scan the working model by use of a dental desktop scanner that has an accuracy of 10 µm or better, ie. 3Shape D900).

Designing the zirconia superstructure

The zirconia superstructure must be designed using 3Shape Dental System design software with the relevant Azure library files installed.

The Azure library file can be obtained via the 3Shape server in the software. Operation manual for 3Shape Dental System can be access from www.3shape.com.

The Azure library file has built-in design limitations, and the user is not allowed to exceed the limitations. Refer to Section APPLICATIONS – ABUTMENTS for design limitations.

Manufacturing the zirconia superstructure

1. Import the digital file from the scanner into the design software.
2. Import library file and select relevant implant platform from the library.
3. Design the zirconia superstructure using 3Shape Dental system design software with Azure libraries installed.
4. Send the zirconia superstructure file to milling machine VHF R5 By vhf camfacture AG with DentalCAM & DentalCNC 7 software, using the preset settings and fabricating the part with dental zirconia tooling (i.e. Z060, Z100, Z120, Z200) according to the manufacturer's instructions.
5. The zirconia superstructure must be created from VITA YZ® ST and sintered according to manufactures instruction.
6. The zirconia superstructure shall be cemented to the abutment using the cement recommended in the labeling (Multi-Link cement by Ivoclar Vivadent).

Manufacturing Pre-Milled Blank (Custom) abutment

1. Import the digital file from the scanner into the design software.
2. Import library file and select relevant implant platform from the library.
3. The Pre-Milled custom abutment must be design using 3Shape Dental system design software with Azure libraries installed.
4. Azure libraries can be download from: www.azuredental.com/digital-library
5. Send Pre-milled Blank abutment file to milling machine VHF R5 By vhf camfacture AG with DentalCAM & DentalCNC 7 software, using the preset settings and fabricating the part with a Cobalt chrome or Titanium tooling (i.e. M060, M100, M120, M200) according to the manufacturer's instructions.
6. Visually inspect the implant-abutment connection of the Pre-milled Blank for any damage which may have been caused during the machining process.

US ONLY - CEMENTING

Preparing the dental restoration for cementing:

To aid in cement adhesion we recommend that the tibase abutment be thoroughly cleaned before cementation (i.e. Monobond® Plus Cleaner by Ivoclar Vivadent). The ceramic surface of the superstructure in the cementing zone should be sandblasted and cleaned. For secure grip the diameter of Base abutment and its height should not be reduced (e.g. by grinding).

Cementing the dental restoration:

Base abutment and corresponding zirconia superstructure are provided to the clinician either with the superstructure cemented to the abutment by the milling center or the dental laboratory, or separately for the clinician to bond together chairside or intraorally using the cement recommended in the labeling (Multi-Link cement by Ivoclar Vivadent). Reminder: sterilization of the components (either bonded together or separately) shall be completed prior to placement in the mouth. If cementing the superstructure intraorally, be careful to maintain sterility while handling.

US ONLY. APPLICATIONS - ABUTMENTS

TIBASES

Base abutments are used for support of prosthetic restorations prepared by dental technicians in a dental laboratory with CAD/CAM technology. The Base abutments can be used to support a direct crown, and each Base abutment can be used with a POM (polyoxymethylene) sleeve that can burn out when fabricating a direct crown. The Base abutments can also be used to support a zirconia superstructure plus crown. The design parameters for the CAD/CAM zirconia superstructures (including direct crown and zirconia superstructure plus crown) are:

- Minimum wall thickness – 0.4 mm
- Minimum post height for single-unit restorations Ti Base Interface – 4.2 mm
- Tibase A – 4.0 mm
- C-Base – 4.7 mm CoCr Base – 4.5 mm
- Minimum gingival height – 0.5 mm Maximum gingival height – 6.0 mm
- All zirconia superstructures are for straight abutments only.

PRE-MILLED BLANK ABUTMENTS

Pre-milled Blank abutment is used for support of prosthetic restorations prepared by dental technicians in a dental laboratory with CAD/CAM technology. Pre-milled Blank abutments are manufactured in grade 5 titanium or CoCr. The design parameters for the CAD/CAM Pre-milled Blank abutments are:

Parameter	Min (mm)	Max (mm)

Total Height	4.3	19
Post Height for Single-Unit Restoration	4.0	19
Wall Thickness	0.45	N/A
Gingival height	0.5	6
Diameter	Based on minimum wall thickness	14
Angulation	n/a	0°

The CAD/CAM Pre-Milled Blank abutments that are compatible with Astra Tech EV (except 3.0), Astra Tech OsseoSpeed (except 3.0), Biomet 3i Certain, Nobel Active/NobelParallel Conical (except for 3.0 mm implants), Nobel-Replace Tri-Lobe, Nobel Brånemark, Straumann Bone Level, and Zimmer Screw-Vent/Tapered Screw-Vent, may use the following design parameters:

Parameter	Min (mm)	Max (mm)
Total Height	4.3	19
Post Height for Single-Unit Restoration	4.0	19
Wall Thickness	0.45	N/A
Gingival height	0.5	6
Diameter	Based on minimum wall thickness	14
Angulation	n/a	30°

Screw

The screw is used to fix prostheses and auxiliary prosthetics to the implant or analog.
To obtain the best results, the following conditions must be carefully observed:

- For tightening or loosening use the correct model and size of wrench. In case of doubt, check if the larger size wrench fits the seat. The tip must be positioned in the longitudinal axis of the prosthesis/implant assembly. It is essential to use a new screw when mounting the prosthesis for the first time, as well as in each subsequent revision of the prosthesis.
- In cases of immediate loading, screw manually, avoiding excessive torque, and secure the implant so that it does not rotate when screwed.
- When transferring the patient, do not use the same screw used in the laboratory.
- Make sure that the screw used for each case is the correct model.
- **Place the patient in a safe position to avoid aspiration in case the screw falls out during handling.**
- Check the compatibility of the screw with the implant model to which it is to be connected.

Caution: Make sure to fix the parts with the corresponding screw and follow the torque value specified on the Azure catalog.

Instruments

Azure instruments are intended to be used to support prosthetic restorations in the dental laboratory.

Precautions: Azure instruments intended exclusively for laboratory use and should never be used during surgical procedures.

Adapters

Azure adapters are designed to be connected to a contra-angle handpiece to assist in prosthetic rehabilitation in the dental clinic. The adapters incorporate a contra-angle handpiece connection for torque and rotational speed control with the surgical motor.

Screwdriver: The screwdriver is used to tighten and loosen the clinical or prosthetic screws that secure the implant and prosthetic components to the dental implant.

Caution: Make sure that the tip of the screwdriver matches the size and shape of the screw head. Never exceed the maximum recommended torque for the surgical or prosthetic component. Excessive tightening of the screw may result in screw fracture and/or damage to the component.

Device	Reference	Material	Sterilization	Reuse	
ANALOG	x-SAx x-DAx	Surgical steel s AISI-303	In autoclave prior to use on the patient	Not recommended	⊘
TRANSFER	x-ICx	Body: Surgical steel AISI-303 Screw: Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	In autoclave prior to use on the patient	Use after sterilization	-
SCANNING ABUTMENT	x-ISx x-DSx x-xxSBx x-xxDSx	Polyetheretherketone (PEEK) ANK sysem: Ti ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3) Screw: Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	In autoclave prior to use on the patient	Use after sterilization	-
HEALING ABUTMENT	x-HAx	Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	In autoclave prior to use on the patient	Single use	⊘
		Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	Sterile by radiation		
		Polyetheretherketone (PEEK)	In autoclave prior to use on the patient		
TEMPORARY ABUTMENT	x-TCx	Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	In autoclave prior to use on the patient	Single use	⊘
		Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	Sterile by radiation		
		Polyetheretherketone (PEEK)	In autoclave prior to use on the patient		
CASTABLE ABUTMENTs	x-CAx x-CPx	Polyoxymethylene (POM)	N/A	Single use	⊘
Ti-BASE	x-TBx x-TBT x-TTx x-TBAx x-TBCx x-UTAx	Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	In autoclave prior to use on the patient	Single use	⊘
STRAIGHT AND ANGLED CEMENT-RETAINED ABUTMENT	x-CRx	Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	In autoclave prior to use on the patient	Single use	⊘
MULTI-UNIT ABUTMENT	x-MUx x-UAx x-xUAx x-xxUAx x-OAx	Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	In autoclave prior to use on the patient	Single use	⊘
		Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	Sterile by radiation		
PRE-MILLED BLANK	x-BTx	x-BTx: Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	In autoclave prior to use on the patient	Single use	⊘

SCREW	x-SHx x-SNx x-STx x-SUGx	Titanium ELI Ti-6Al-4V (according to ASTM F136 and ISO 5832-3)	In autoclave prior to use on the patient	Single use	⊘
INSTRUMENTS	x-BHx x-xTD x-xPD x-ADx x-UAD x-MUADx x-OAD x-TWx	Handles: surgical stainless steel 316L Tips: stainless steel AISI 420 MOD (according toASTM F899)	N/A	Reusable	-
ADAPTER	x-CA7STR x-CA8NBL x-DTx x-DT8NBL x-DT7STR x-DTSQ x-SDISO x-SQDx	Stainless steel AISI 420 MOD (according to ASTM F899) Stainless steel 465 (according to ASTM F899-12B)	In autoclave prior to use on the patient	Use after sterilization	-

INDICATIONS – PLEASE READ CAREFULLY

Products indicated for prosthetic restorations of dental implants or to assist procedures in the dental laboratory.

WARNINGS – PLEASE READ CAREFULLY

- tibases must never be changed or modified.
- pre-milled blank and tibases are for single-use only.
- Reuse of the products can result in loss of functionality and/ or infections.
- The pre-milled blank and tibases must be attached to the implant using the compatible screw.
- During any intraoral use and manipulation all products must be secured to prevent aspiration due to their small size and shape.
- Place implant-borne restorations in occlusion only when the implant is fully osseointegrated.
- Azure products must be used by dental specialists with experience in dental implantology and other specialties, such as dental diagnosis, planning, dental surgery, or prosthetic techniques.
- The use of a different torque other than the recommended by the manufacturer can damage the restorations and the implant.
- The non-engaging connections are not intended for singled tooth dental restorations.
- The use of any abutment device, dental cement, superstructure or other ceramic materials, scanners, milling units, CAD / CAM tools and software other than those specifically identified as compatible on these instructions, may result in improper fit and / or damage to the dental restoration

CONTRAINDICATIONS

All the materials used are biocompatible; however, some patients may present allergies or hypersensitivity to any of the materials and their components. The use of these products is contraindicated in patients with known allergy or hypersensitivity to any of the components used in the manufacture of Azure products.
The use of these products is contraindicated in patients who are medically unfit for oral surgery.
All tibases are contraindicated for any angular correction to be fabricated into the ceramic component of the two-piece abutment.
Do not use the Base abutments for restorations with cantilever on a single implant, with patients who brux, with insufficient space, with direct metal-to-interface casting.

PRECAUTIONS – PLEASE READ CAREFULLY

Implants with diameters of 3.7 mm or below with angled abutments are recommended for incisors region only. Small diameter implants and angled abutments are not recommended for the posterior region.

Products covered in this document should only be used by dental specialists with experience in dental implantology and other specialties, such as dental diagnosis, planning, dental surgery, or prosthetic techniques.

All products covered in this document should be dry fitted before use to check that they fit correctly. The clinician is responsible for the correct use of the products, as both the planning and the procedures are under their control. Only dental specialists with appropriate experience and training should work with these products.

Please contact the manufacturer or distributor with any questions.

U.S. Federal law restricts these devices to be sold by or on the order of a licensed dentist / physician.

An annual inspection of the prosthetic restoration and the screw by the dentist and/or the laboratory is recommended. If the screws are subject to unusual wear, the complete integrity of the implant abutment should be checked. Failure to follow these instructions puts the patient at risk.

During any intraoral use and handling, all Azure products must be secured to prevent them from being swallowed or aspirated by the patient.

POTENCIAL ADVERSE EVENTS – PLEASE READ CAREFULLY

Potential adverse events associate with the use of the pre-milled blank and tibases products may include loss of integration and infection.

INTENDED USERS AND PATIENT GROUPS

Products covered in this document should only be used by dental specialists with experience in dental implantology and other specialties, such as dental diagnosis, planning, dental surgery, or prosthetic techniques. Their use is limited to dental laboratories and clinics.

Indicated for edentulous patients (totally or partially) who require oral rehabilitation by means of implant-supported prostheses. Rehabilitation can be unitary, multiple or overdentures, both in the upper and lower jaw. Its use is indicated in patients with complete dentofacial development. There are no differences in end users by age group, sex, ethnicity, family predisposition or genetic aspects. It is not indicated for use in patients without dental problems.

CLINICAL BENEFITS AND UNDESIRABLE SIDE EFFECTS

As a clinical benefit, patients can expect full or partial rehabilitation of the dentition, allowing them to regain proper masticatory function.
No side effects directly related to the use of Azure implantology products have been described, however, the use of these devices may be part of an invasive treatment that may be associated with typical side effects such as inflammation, bleeding, hematoma, pain or swelling.

Serious Incident Notice

For patients / users / third parties in the European Union with an identical regulatory regime (Regulation 2017/745/EU) if, due to the use of the product, a serious incident occurs, notify ZimVie Dental at

ZimVie Dental – Headquarters
Monday - Friday 7:30AM - 7:00PM EST
Address: 4555 Riverside Drive. Palm Beach Gardens, Florida 33410

USA: 1-800-342-5454
Canada: 1-800-363-1980

To notify manufacturer please contact
Terrats Medical SL
75-99 Mogoda Street
08210 - Barberá del Vallés -Barcelona (Spain)
Tel + 34935646006
cesar.escribano@dessdental.com

Outside of USA:
1-561-776-6700

GLOBAL FAX
Fax: 1-561-776-1272

Email: DentalCS@zimvie.com

STERILITY AND REUSABILITY INFORMATION

Non-sterile products

In general, abutments, screws and instruments are supplied non-sterile. Before use, clean and sterilize the product following the recommended autoclave treatment at 121 °C for 30 minutes, drying 30 minutes (according to ISO 17665-1 and ISO/TS 17665-2). For sterilization of surgical drills and screw taps it is recommended to follow the steam autoclave treatment at 134 °C for a minimum of 6 minutes. Wait for the complete end of the drying cycle. The use of sterilization tokens is recommended, recording date and expiration date, in addition to periodic controls of the sterilization process by means of biological indicators. The presence of corrosion after sterilization is the main factor to discourage the use of the instruments, regardless of whether they have cutting capacity. Inspect instruments after sterilization for depreciation after sterilization cycles. Caution: Surgical drills and screw taps should not be sterilized in their original packaging, use the specific pouches for sterilization.
Warning: Products supplied non-sterile must be sterilized before use in the oral cavity. The use of a non-sterile device may result in tissue infection or infectious diseases.

Abutments and screws are devices intended for Single use.
Caution: These products are Single use devices and cannot be reprocessed. Reuse may cause damage or deterioration of product characteristics that may result in prosthetic solution inadequacies and/or other impairment of patient health, such as tissue infection.

All Azure instruments are reusable instruments that should be inspected prior to each reuse to ensure that the integrity and performance of the product is maintained. Check the instrument for visible wear, deformation, or corrosion. Instruments showing these signs should be discarded.
For reuse of instruments intended for use during procedures in the dental clinic, they should be cleaned prior to sterilization. Here are some tips for cleaning:

- Never place instruments of different types of materials together.
- Do not use metallic brushes to remove impurities.
- Use disposable syringes for cleaning instrument cavities.
- When selecting detergents and disinfectants, make sure that they are products intended for this purpose and always follow the manufacturer's instructions.

Sterile products

Transepithelial abutment (Multi-Unit), temporary abutments and healing abutments can also be supplied in sterile condition. The decision to purchase them in sterile or non-sterile condition is at the discretion of the practitioner. Products supplied in sterile condition have been sterilized by irradiation and are intended for Single use.
Warning: Do not re-sterilize. Do not use the device after the expiration date stated on the label. Do not use the device if the packaging is damaged or has been previously opened.
Caution: sterile transepithelial abutments, sterile temporary abutments and sterile healing abutments are single use devices and cannot be reprocessed. Reuse may cause damage or deterioration of product characteristics that may result in prosthetic solution inadequacies and/or other impairment of patient health, such as tissue infection.

US only - MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Warning: The RF safety of the device has not been tested. A patient with this device can be safely scanned on an MRI system under the following conditions:
- Static magnetic field strength (BO) less than or equal to 3.0T.
- Special gradient magnetic fields of maximum 3000 gauss/cm (30 T/m).
- RF excitation: Circular Polarization (CP)
- For the body transmitting coil, a reference point must be marked at least 30 cm from the implant or ensure that the implant is outside the coil. Extremity T/R coils are allowed. Head T/R coil excluded.
- Normal mode of operation in the allowed imaging zone.
- Maximum whole body specific absorption rate of 2 W/kg (Normal mode of operation).
- Maximum head specific absorption rate not evaluated.
- Scan duration without specific limitations due to implant heating.

Note: removable restorations must be removed prior to scanning.

STORAGE, HANDLING AND TRANSPORT

Products supplied non-sterile are not susceptible to variations in environmental conditions and therefore no special storage, handling and/or transport conditions are required. Products supplied in sterile packaging should be stored and transported in dry conditions, in their original packaging, at room temperature and not exposed to direct sunlight. Improper storage and transport may affect the sterile barrier of the product.

DISPOSAL

Disposal of the devices should follow local regulations and environmental requirements, taking into account the different levels of contamination.

COMPATIBILITY INFORMATION

All Azure components are available in different connections. For compatibility with dental implants and analogs, please refer to our catalog and guidelines or contact your local distributor.

Special conditions Internal ANK (ANKYLOS® C/X System)

The thickness of the anti-rotation elements is reduced due to the widening of the screw channel in order to accommodate the use of a normal screw. To avoid bending of these parts under the applied pressure, make sure that the screw is threaded through the attachment while the restoration is being carried out and before placing it in the analog or implant. If this precaution is taken, the anti-rotation elements will remain supported and safe from shear and compressive forces. If, for any reason, it is necessary to remove the screw, place it back in position before applying any load on the attachment.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

The Summary of Safety and Clinical Performance (RSFC) for products belonging to the families of devices is available in the European Database on Medical Devices (EUDAMED). You can consult the document linked to the basic UDI-DI 84354572Q0102F3 on the EUDAMED public website: https://ec.europa.eu/tools/eudamed

GLOSSARY OF SYMBOLS

MD Medical device	UDI Unique device identification	LOT Batch	REF Reference
CE CE Marking	CE 0051 CE marking with Notified Body number	Do not reuse	Do not re-sterilize
NON STERILE Non-sterile product	STERILE R Product sterilized by irradiation	Do not use if package is damaged	Manufacturing date
Expiration date	Rx only Prescription only	Contains CoCr	MR Conditional MRI
Keep away from sunlight	See Instructions for use Download link ifu.biomet3i.com		Distributor

For any information about Products distributed by ZimVie Dental, LLC, please contact your local Territory Manager.

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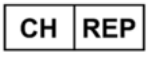

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