ArgenIS Ti bases and screws

Instructions For Use

℞ ONLY REF MD

For Sale in the U.S. Only

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

1. Intended Use

ArgenIS Ti bases and screws are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed custom restorations for use with Ti bases are 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.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)
Astra Tech EV™*	3.0	3.0
	3.6	3.0
	4.2	4.0
	4.8	4.0
	5.4	5.0
Astra Tech OsseoSpeed™*	3.0	3.0
	3.5/4.0	3.5, 4.0
	4.5/5.0	4.5, 5.0
BioHorizons®*	3.0, 3.4, 3.8	3.0
	3.8, 4.6	3.0
	4.6, 5.8	4.0
	5.8	5.0
Biomet 3i Certain®*	3.25	3.0
	4.0	4.0
	5.0	5.0
Camlog®*	3.3	3.0
	3.8	3.0
	4.3	4.0
	5.0	5.0
MegaGen AnyRidge®*	3.5, 4.0, 4.5, 5.0, 5.5	3.0

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Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)
Neodent Grand Morse®*	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse
NobelActive®* NobelReplace®*/Nobel Parallel Conical	3.0	3.0 (3.0)
	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
	5.5	WP (5.1)
NobelReplace®* Trilobe	3.5	NP (3.5)
	4.3	RP (4.3)
	5.0	WP (5.0 mm)
	6.0	6.0 (6.0 mm)
Osstem®* TS	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Straumann®* BLX	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann®* Bone Level	3.3	NC (3.3 mm)
	4.1, 4.8	RC (4.1/4.8 mm)
Straumann®* Tissue Level	3.3	NNC (3.5 mm)
	3.3, 4.1, 4.8	RN (4.8 mm)
	4.8	WN (6.5 mm)
Zimmer Screw-Vent®*/Tapered Screw-Vent®*	3.3, 3.7, 4.1	3.5 mm
	4.7	4.5 mm
	6.0	5.7 mm

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2. CONTRAINDICATIONS

All materials used are biocompatible; however, some patients may present allergies or hypersensitivity to any of the materials and their components (specified in the table).

All Ti bases are contraindicated for any angular correction to be fabricated into the ceramic component of the two-piece abutment.

Do not use the Ti bases for restorations with cantilever on a single implant, with patients who brux, with insufficient space, with direct metal-to-interface casting.

3. WARNINGS – PLEASE READ CAREFULLY

- The Ti bases and screws must never be changed or modified and are for single use only.
- Reuse of the products can result in loss of functionality and/or infections.
- The Ti bases must be attached to the implant using the compatible Prosthetic Screw.
- During any intraoral use and manipulation all ArgenIS components 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.
- This type of product must be used by dental specialists with experience in maxillofacial implantology and other specialties, such as dental diagnosis, planning, dental surgery, or prosthetic techniques.

- The use of a different torque other than that recommended by the manufacturer can damage the restorations and the implant.
- The non-engaging connections are not intended for single 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.

Magnetic Resonance (MR) Safety Information

MR Conditional

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

A patient with this device can be scanned safely in an MR system under the following conditions:

Device Name	Argen IS
Static Magnetic Field Strength (B0)	≤ 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Note: the removable restorations should be taken out prior to scanning.

4. PRECAUTIONS – PLEASE READ CAREFULLY

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

All ArgenIS components must be dry fitted before use to check the correct fitting. The clinician will be responsible for correct application of those restorative products as planning and procedures are under his/her control. This is the reason why only dental specialists with the appropriate experience and training should work with these products. In case of doubt please call : (800) 255-5524 (Toll-free).

Annual inspection of the prosthetic restoration by the dentist and the laboratory is recommend. This inspection must include a screw check. If the screws have suffered unusual wear, the complete integrity of the implant-abutment should be checked. New screws must be used for any revision, correction, or replacement. Failure to follow this instruction puts the patient at risk and will void the warranty.

5. POTENTIAL ADVERSE EVENTS – PLEASE READ CAREFULLY

Potential adverse events associated with the use of the Ti base products may include loss of integration and infection.

6. STERILIZATION

All ArgenIS components are supplied NON-STERILE. Prior to installation of the prosthetic restoration in the patient's mouth, it must be sterilized. The recommended sterilization cycle is standard gravity autoclave, exposure at 121 °C/250 °F for 30 minutes with a drying time of 30 minutes, using a sterilization wrap that is FDA cleared for the indicated cycle.

7. PROSTHETIC PROCEDURE (DIGITAL DENTISTRY WORKFLOW)

Using digital workflow (intra-oral scanning)

1. For detection of the precise implant position during scanning, use the ArgenIS 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 ArgenIS analog on the working model.

Using digital workflow (desktop scanning):

6. Obtain conventional impression of patient teeth setup and create working model with placed enclosed analog to represent the implant.
7. Place an ArgenIS Scan body in the analog to identify the position and orientation of the implant.
8. 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 ArgenIS library files installed.

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

The ArgenIS library file has built-in design limitations, and the user is not allowed to exceed the limitations. Refer to Section 9 APPLICATIONS 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 ArgenIS library installed.
4. Send the zirconia superstructure file to one of the milling machines in the chart below, using the preset settings and fabricating the part with dental zirconia tooling (i.e. Z060, Z100, Z120, Z200) according to the manufacturer's instructions.

Milling Machine	CAM software
Arum 200	SUM 3D
Arum 500	SUM 3D
Roland 52D	SUM 3D
Roland 53D	SUM 3D
Imes 350i	SUM 3D
Dyamach AS1	SUM 3D
VHF S5	SUM 3D

5. The zirconia superstructure must be created from ArgenZ zirconia and sintered according to the manufacturer's instructions. The zirconia superstructure shall be cemented to the abutment using the cement recommended in the labeling (Multi-Link cement by Ivoclar Vivadent).

8. CEMENTING

Preparing the dental restoration for cementing:

To aid in cement adhesion we recommend that the Ti base 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 the Ti base and its height should not be reduced (e.g. by grinding).

Cementing the dental restoration:

The Ti base 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.

9. APPLICATIONS

Ti-bases

Ti bases are used for support of prosthetic restorations prepared by dental technicians in a dental laboratory with CAD/CAM technology. The Ti bases can be used to support a direct crown, and each Ti base can be used with a POM (polyoxymethylene) sleeve that can burn out when fabricating a direct crown. The Ti bases 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
Angled Ti Base – 4.0 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm

SCREWS

The screw is for fixing prosthetic restorations and auxiliary abutments onto implant or analog. Make sure to secure the parts with corresponding screw and observe specified torque value placed on the label.
For best results, the following conditions must be meticulously met:

- Position the patient to avoid aspiration in case the screw falls during screwing/unscrewing.
- Check compatibility of the screw with the implant model to which it will be connected.
- Make sure the correct model of screw is used for each case.
- When transferring to the patient, do not use the same screw that was used in the laboratory.
- Use the suitable size for tightening and unscrewing. If in doubt, check that the next size does not fit into the seat. The driver should be appropriately aligned with the screw head inside the screw channel of the prosthesis/implant assembly. A new screw must be used when assembling a prosthesis for the first time and for every check thereafter.
- For immediate load prostheses screw manually, avoiding excessive torque, and prevent the implant from turning while screwing.

Screws are provided with each abutment for the corresponding implant line. Also, screws are provided separately.
If you have any doubts about the fit of the screw, call: (800) 255-5524 (Toll-free).

10. COMPATIBILITY INFORMATION

All ArgenIS components are available for a variety of connections, as listed in Section 1.
For any questions concerning compatibility with dental implants and implant analogs please contact: (800) 255-5524 (Toll-free).

Ti bases are provided with the screw corresponding to the compatible implant line.

Implant System Compatibility	Recommended Abutment Screw Torque (Ncm)
Astra Tech EV™*	25
Astra Tech OsseoSpeed™*	20 (3.5/4.0)
	25 (4.5/5.0)
BioHorizons®*	30
Biomet 3i Certain®*	20
Camlog®*	20
MegaGen AnyRidge®*	35
Neodent®* Grand Morse	20
NobelActive®*/NobelReplace®* Conical	35
NobelReplace®* Trilobe	35
Osstem®* TS	30 (Regular)
Straumann®* BLX	35
Straumann®* Bone Level	35
Straumann®* Tissue Level	35
Zimmer Screw-Vent®*/Tapered Screw-Vent®	30

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11. INSTRUCTION FOR USE AND MAINTENANCE OF MILLING EQUIPMENT

The original operating manual and maintenance guide for the milling machines can be requested by contacting the manufacturer

12. FURTHER INFORMATION

For additional information about the use of ArgenIS products, please contact:
(800) 255-5524 (Toll-free) or info@argen.com

13. SYMBOLS GLOSSARY

The following table describes the symbols that may be printed on the packaging label. Please refer to the packaging label for the applicable symbols related to the product.

Symbol	Title	Description
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.

Symbol	Title	Description
	Prescription use only per US FDA	Caution: Federal law restricts this device to sale by or on the order of a licensed dentist.
	Manufacturer	Indicates the medical device manufacturer.
	MR Conditional	Conditional use for magnetic resonance imaging.
	Medical device	Indicates the item is a medical device.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
QTY	Quantity	Indicates the quantity

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