# Abutment & Final / Clinical / Prosthetic Screw
Instructions for use (IFU)

*To request a printed copy call toll free: 800-255-5524*

## Abutment

*It is important that you carefully read the disclaimer statement at the end of this document*

**Description:**
The Titanium Abutment also referred to as "The Product" is a Titanium Abutment designed specifically for an individual patient and then milled from a titanium blank with a pre-milled interface correlating to a specific implant system. This abutment can be fixed in the laboratory model work containing the implant analog for final construction of the related prosthetic restoration. The ArgenIS Titanium Abutments are then intended to be fixed in the mouth with the included prosthetic screw. The ArgenIS Titanium Abutments are supplied with two final screws. The final screw must be torqued on the endosseous implant with the specific torque setting provided.

**Material:**
Titanium alloy Ti 6Al-4V ELi (Grade 23)
**(90% Titanium, 6% Aluminum, 4% Vanadium)**

**Adverse Effects:**
ArgenIS Titanium Abutments can only be used with the corresponding implant system and cannot be combined with implants from a different type, size or manufacturer. The diameter of the titanium abutment interface must match the implant diameter in order to prevent peri-implant tissue irritation. ArgenIS Titanium Abutments are intended for single use only; multiple uses could cause damage to the implant and/or harm to the patient. ArgenIS Titanium Abutments should not be used unless the dental implants are stable and there are no signs of infection or severe bone loss. Poor bone quality, poor patient oral hygiene, heavy tobacco use, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction, and psychological instability may contribute to lack of integration and/or subsequent implant failure. Severe bruxism, clenching, and overloading may cause bone loss, screw loosening, component fracture, and/or implant failure. Exposure to radiation and chemotherapy may impact health of the implant. Dental implant patients should be instructed to consult with their physician prior to undergoing such treatment options.

**Series Compatibility / Recommended Torque Settings**

| Implant System | Series | Standard Abutment | ISBridge Abutment | ISBridge Cap Screw |
|---|---|---|---|---|
| ASTRA TECH EV™* | SEV Series | 25 Ncm | - | - |
| ASTRA TECH OsseoSpeed TX™* | S Series / AO Series | 20 Ncm (3.5/4.0), 25 Ncm (4.5/5.0) | 15 Ncm | 15 Ncm |
| BioHorizons®* | BIO Series | 30 Ncm | - | - |
| Biomet 3i Certain®* | H Series / BC Series | 20 Ncm | 20 Ncm | 15 Ncm (3.4, 4.1) |
| Biomet 3i OSSEOTITE®* | I Series / BO Series | 35 Ncm | - | - |
| CAMLOG®* | CAM Series | 20 Ncm | - | - |
| Dentsply Friadent XiVE®* | T Series / DX Series | 25 Ncm | 25 Ncm | 20 Ncm (3.8/4.5), 15 Ncm (3.4) |
| Hiossen ET / HG®* | HIO Series | 20 Ncm | - | - |
| Neoss®* | NEO Series | 30 Ncm | - | - |
| NobelActive®* | F Series/ NC Series | 25 Ncm (3.5), 35 Ncm (4.3/5.0) | 25 Ncm (3.9), 35 Ncm (4.3/9.0) | 30 Ncm |
| NobelReplace Select®* | E Series/ NR Series | 35 Ncm | 35 Ncm | 30 Ncm (4.3/5.0), 20 Ncm (3.5) |
| Nobel Brånemark®* | K Series/ NB Series | 35 Ncm | - | - |
| Straumann Bone Level®* | L Series/ SB Series | 35 Ncm | 35 Ncm | 30 Ncm |
| Straumann SynOcta®* | N Series/ SS Series | 35 Ncm | 35 Ncm | 30 Ncm |
| Zimmer Tapered Screw-Vent®* | R Series/ ZS Series | 30 Ncm | 30 Ncm | 15 Ncm (3.5, 4.5) |

* Not trademarks of the Argen Corporation

**Indications/Intended use:**
ArgenIS Titanium Abutments are intended to be single use available by prescription only in the construction of dental restorations supported by the endosseous dental implant. The ArgenIS Titanium Abutments are designed to specifically fit an individual patient's needs of the final restoration. Digitally designed abutments files are intended to be sent to Argen for milling. The ArgenIS Titanium Abutments are compatible with the implant systems listed in the Series Compatibility chart in this document.

**Precautions:**
The manufacturing of dental prosthesis must be carried out by qualified personnel only. Always use the recommended torque settings to ensure the implant screw has securely fixed to the implant. Proper case planning is essential to the long-term success of both the prostheses and the implants. Overload is one of the key contributors to implant failure. Ensure the implant angle corrections are appropriate for the occlusal load.

**Single Use:**
Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

**Packaging:**
ArgenIS Titanium Abutments are packaged in non-sterile packaging. Parts need to be removed from packaging prior to autoclaving and placed in an autoclavable pouch or plastic tray that is FDA cleared for steam sterilization.

**Cleaning and Sterilization:**
ArgenIS Titanium Abutments and prosthetic screws are supplied in unsterile condition and should be cleaned, disinfected and, if necessary, sterilized prior to use. To avoid potential damage, be sure to use only plastic instruments and maintain control over the components at all times. Always place the components in a germicidal bath immediately after removal from packaging. Use distilled water and neutral cleaning agents to rinse and clean the parts. The internal irrigation tube should be cleaned with distilled water using a disposable syringe (min. 10 mil) and oil-free compressed air (if necessary). All components must be rinsed three times with distilled water after removal from the germicidal bath and dried thoroughly with a lint-free cloth. Check parts for damage and corrosion after cleaning. To disinfect, use a high-level disinfectant such as Cidex OPA (Johnson & Johnson). Follow the instructions for use and make sure to rinse all components thoroughly prior to drying. Sterilize devices prior to use using the parameters below.

It is the responsibility of the user to establish whether or not their sterilizer has been cleared by the FDA to meet these recommended parameters, and to use accessories (BI's, CI's, and wraps/pouches, containers) cleared by FDA and labeled for use with these recommended sterilization parameters.

Device is for single use only and is supplied non-sterile. Device must be sterilized prior to use by the end user.

**Method of Sterilization:**
Parts shall be sterilized in individual autoclaving pouches using steam sterilization and a gravity placement autoclave. The following sterilization parameters (method, temperature and time) are required to achieve a 10- sterility assurance level (SAL).To ensure autoclave is performing effectively, periodic use of biologic indicators should be considered.

**Cleaning and sterilization:**
Warning: Use of non-sterile components will lead to infection of tissues and or infectious diseases. Do not use if package seems adulterated or damaged.
The Final Screw is shipped non-sterile. It is the responsibility of the user to clean, disinfect and sterilize The Product based on generally accepted protocols used by dentists and implantologists.

Seal single device in a pouch and steam sterilize at 270°F, max 279°F (132°C, max 137°C) for three minutes.

**Contraindications:**
ArgenIS Titanium Abutments should have a smooth conical shape without undercuts, which could result in areas of inadequate wall thickness. Angled customized abutments and thin implants are not intended for use in the posterior area of the mouth. Abutments should be inspected and the orientation should be appropriately marked by an experienced and qualified laboratory technician. ArgenIS Titanium Abutments should not be used by anyone with allergies or hypersensitivity to titanium alloy, Ti 6Al 4V.

**Magnetic Resonance (MR) safety information:**
Please note that The Product has not been evaluated for safety in and compatibility with MR equipment including issues related to heating or migration while MR equipment is in active use and magnetic rays are emitted.

**Storage and handling:**
Place devices in a dry place to prevent damage and/or deterioration.

Caution: Federal (USA) law restricts this device to the sale by or on the order of a dentist (or other licensed practitioner).

**Software:**
The ArgenIS Titanium Abutments do not contain or utilize software.

**EMC and Electrical Safety:**
The ArgenIS Titanium Abutments do not require EMC and Electrical Safety Evaluation.

**Disposal:**
Disposal of the device shall follow local and national regulations and environmental requirements, taking various levels of contamination levels into account.

**General Cautionary Statement:**
All instruments and tooling used in oral surgery must be maintained in good, clean and sterile condition and care must be taken that The Product or instrumentation does not damage the implant or other components. Due to the small size of The Product and the associated abutment, care must be taken that they are not swallowed or aspirated by the patient.

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# Final / Clinical / Prosthetic Screw

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## Description:

The Final Screw (aka Abutment Screw, Clinical Screw or Prosthetic Screw) and also referred to as "The Product" is a pre-manufactured device designed to connect the dental abutment or framework to a dental implant. The Final Screw is made of biocompatible Titanium alloy and has the appropriate dimensions and thread design to perfectly mate with the threaded hole of the implant.

## Material:

Titanium alloy Ti 6Al-4V ELi (Grade 23)
(90% Titanium, 6% Aluminum, 4% Vanadium)

## Intended use:

Caution: The Product is a Prescription Device – Rx only. Federal law restricts use of this device to licensed physician or dentist. Sale of The Product can only be done on the order of a licensed dentist or physician. The Final Screw is intended to secure a dental abutment or framework to a dental implant in the upper or lower jaw.

## Indications:

The Final Screw is to be directly inserted into the dental abutment or framework, intended for use as an aid in prosthetic rehabilitation.

## General Cautionary Statement:

All instruments and tooling used in oral surgery must be maintained in good, clean and sterile condition and care must be taken that The Product or instrumentation does not damage the implant or other components. Due to the small size of The Product and the associated abutment, care must be taken that they are not swallowed or aspirated by the patient.

## Series Compatibility / Recommended Torque Settings

| Implant System | Series | Standard Abutment | ISBridge Abutment | ISBridge Cap Screw |
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| Biomet 3i Certain®* | H Series / BC Series | 20 Ncm | 20 Ncm | 15 Ncm (3.4, 4.1) |
| Biomet 3i OSSEOTITE®* | I Series / BO Series | 35 Ncm | - | - |
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| NobelReplace Select®* | E Series/ NR Series | 35 Ncm | 35 Ncm | 30 Ncm (4.3/5.0), 20 Ncm (3.5) |
| Nobel Brånemark®* | K Series/ NB Series | 35 Ncm | - | - |
| Straumann Bone Level®* | L Series/ SB Series | 35 Ncm | 35 Ncm | 30 Ncm |
| Straumann SynOcta®* | N Series/ SS Series | 35 Ncm | 35 Ncm | 30 Ncm |
| Zimmer Tapered Screw-Vent®* | R Series/ ZS Series | 30 Ncm | 30 Ncm | 15 Ncm (3.5, 4.5) |

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## Handling procedure:

**Caution:** Never exceed recommended maximum tightening torque detailed in this document. Over tightening of the Final Screw may lead to fracture of the screw inside the implant.

1. Final Screw is for single use only and must not be reprocessed.
2. Only use the Final Screw provided with the abutment to affix it to the implant. Consult information on the Argen website or contact Argen with any questions with regards to type of Final Screw.
3. Tightening of the Final Screw must be done with the correct torque wrench and insert. Use of incorrect insert will lead to stripping of the drive features in the screw head. Use of incorrect torque wrench will cause over or under tightening of the screw, both of which can cause failure of the device.

## Cleaning and sterilization:

**Warning:** Use of non-sterile components will lead to infection of tissues and or infectious diseases. Do not use if package seems adulterated or damaged.
The Final Screw is shipped **non-sterile**. It is the responsibility of the user to clean, disinfect and sterilize The Product based on generally accepted protocols used by dentists and implantologists.

Seal single device in a pouch and steam sterilize at 270°F, max 279°F (132°C, max 137°C) for three minutes.

## Contraindications:

It is contraindicated placing the Final Screw in:
– Patients who are medically unfit for an oral surgical procedure.
– Patients who are allergic or hypersensitive to titanium alloy Ti 6Al-4V ELI (Grade 23)
Magnetic Resonance (MR) safety information:
Please note that The Product has not been evaluated for safety in and compatibility with MR equipment including issues related to heating or migration while MR equipment is in active use and magnetic rays are emitted.

## Storage and handling:

The Product must be stored at room temperature in a dry place and in the original packaging. Direct exposure to sunlight and or incorrect storage may influence product characteristics and could lead to failure.

## Disposal:

Disposal of the device shall follow local and national regulations and environmental requirements, taking various levels of contamination levels into account.

## Important! Please read carefully

### Disclaimer of liability:

This Product may only be used in conjunction with the specifically designed associated products according to the instructions and recommendation of Argen Corp. (hereafter Argen). The user of Argen products in general and this product specifically, has the responsibility to determine whether or not the product is suitable for the particular patient and the professionally planned treatment.

Argen disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Argen products. The user is responsible for keeping abreast of the latest developments with regard to this Argen product and its applications. In cases of uncertainty related to specification, intended use, application or manner of use, the user must contact Argen prior to use. Argen does not assume any liability whatsoever for damage arising thereof.

Please note that The Product detailed in this Instruction for Use (IFU) may not be regulatory cleared, released or licensed for sale in all markets.


**Do not re-sterilize**

**Do Not Use if package is damaged**

Consult Instructions for Use
**efiu.argen.com**

**Do not reuse**

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