Argen Titanium Scan Bodies

Instructions for Use

℞ONLY MD

For Sale in the U.S. and Canada

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

This IFU is only applicable for the products specified.

INTENDED USE

Argen titanium scan bodies are intended to be used during digital impression procedures in order to obtain the exact position and orientation of the respective dental implant or laboratory analogue and transfer this position digitally during CAD / CAM scanning procedures. This aids the CAD / CAM software to align the CAD / CAM restorations to the implant digitally. These devices are reusable and supplied non-sterile.

INTENDED USER

Dental professionals use only such as Dental Technicians, Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users

INTENDED ENVIRONMENT

This device is intended to be used in a dental laboratory for making the restoration, and in a clinical environment such as an operating room or a dentist consultation room for in a dental laboratory.

DESCRIPTION

Argen Ti intraoral scan bodies are available in different connections. The items are to be fitted directly onto implants or to the laboratory analog on a dental model. The scan bodies are made from Ti6Al4V-ELI titanium alloy and are supplied with a captured screw used to secure the scan body onto the dental implant or analog. The scan bodies are provided non-sterile in a foil bag.

Argen Ti intraoral scan bodies are used to transfer the position and orientation of implants installed in the mouth or analogs installed on a dental model. They can be used for intraoral scanning and in the laboratory with a desktop scanner. The scan bodies have a zirconium nitride surface treatment, which will allow for proper scanning. They are cylindrical and contain 1 flat surface at the upper end, indexed with the hexagon face of the interface which allows for the correct positioning of the digital model scan file. On their lower end, they have a shape compatible with the respective implants of the same lines. The captured screw has a hexalobe interface for torque application with the appropriate connections. The scan bodies are laser marked with the respective implant series and size for the correct application with the corresponding implant and/or analog.

INDICATIONS FOR USE

Argen Ti intraoral scan bodies are indicated for use with intraoral and desktop scanners as part of planning and design software using CAD / CAM systems. Argen Ti intraoral scan bodies are indicated for use on partially or fully edentulous patients in support of single or multiple unit restorations

CONTRAINDICATIONS

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ARGEN®

It is contraindicated placing the Argen Ti intraoral scan body 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)
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.

CAUTIONS

All instruments and tooling used 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 screw, care must be taken that they are not swallowed or aspirated by the patient.

COMPATIBILITY INFORMATION

Compatible implant systems and sizes are summarized in table A.

Table A

Implant System	Interference Design	Sizes
Astra Tech EV*	Round with 6 channels	3.0, 3.6, 4.2, 5.4
BioHorizons® Internal*	Hex	3.0, 3.5, 4.5, 5.7
Camlog®*	Round with 3 channels	3.3, 3.8, 4.3, 5.0
NobelReplace®*	Tri-Lobe (Tri-channel)	3.5, 4.3, 5.0
Hiossen ET*	Hex	3.5, 4.0-6.0
MegaGen AnyRidge®*	Hex	3.5
Neodent® Grand Morse™*	Hex	3.5
Biomet 3i Certain®	Hex	3.4, 4.1, 5.0
Straumann® synOcta®*	Octagon (w/shoulder)	3.5, 4.8, 6.5
Straumann® Bone Level*	4 flat connection (square with radius corners)	3.3, 4.1,4.8
Astra Tech OsseoSpeed® TX*	Hex	3.5, 4.0, 4.5, 5.0
Zimmer Tapered Screw-Vent®*	Hex	3.5, 4.5, 5.7
NobelActive®*	Hex	3.5, 4.3, 5.0, 5.5

*Not a registered trademark of Argen

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 Ti scan body 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.
Recommended cycle:
Seal single device in a pouch and steam sterilize at 134°C for 3 minutes with a 20 minute dry time.

NOTE: Users in the USA must ensure that the sterilizer, wrap or pouch, and all sterilizer accessories are cleared by the FDA, for the intended sterilization cycle.

PROCEDURE FOR USE

Before placing the scan body ensure all items are clean and suitable for intraoral use. If the item is being re-used, inspect the fitting surface to ensure that there is no damage.

1. Attach the matching scan body to the dental implant or lab analog. Check proper fit and hand tighten the screw with the appropriate driver.
2. The patient is scanned using an intraoral scanner, or the laboratory model is scanned using a desktop scanner.
3. The scan body is removed from the implant or analog.
4. The scan body in the digital form is now matched and aligned with the corresponding scan flag from the library file that was imported into the software.
5. The software recognizes the position of the scan flag to the implant or analog, this allows the software to know where to place the abutment for the design step.

NOTE: Follow the instructions of the scanner used.

MATERIALS

Scan body:	Titanium alloy (Ti6Al4V-ELI Grade 23)
Screw	Titanium alloy (Ti6Al4V-ELI Grade 23)

DISPOSAL

Disposal of the device and its packaging; follow national, state, regional, or local regulations and environmental requirements, taking different contamination levels into account. Sufficient PPE must be used at all times.

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.

CLINICAL BENEFITS

Through this procedure patients can expect to have their missing teeth replaced and/or crowns restored.

NOTICE REGARDING SERIOUS INCIDENTS

Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device (The Argen Corporation).

LIFE CYCLE

This product is validated for up to 100 cycles of use with reprocessing (one use equals to one surgical or clinical procedure), provided that the conditions of use recommended by Argen are observed. The medical professional should always assess the product's condition before and after each use.
Reusing is defined by the applicable cleaning, disinfection and sterilization cycle for the product.

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
	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
	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
	Importer	Indicates the entity importing the medical device into the locale
	Medical device	Indicates the item is a medical device
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	Quantity	Indicates the quantity

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