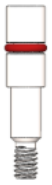
ICam 5 System Accessories – U.S.A Version

All Imetric products are delivered non-sterile. Please note the instructions for reprocessing.

1 Product Description

The Imetric ICam 5 System Accessories are used together with the Imetric ICam 5 System to obtain and output the 3D coordinates of endosseous implants to aid in the design and fabrication of dental prosthetic restorations. The ICam 5 System Accessories consist of ScanBodies (ICamBodies and ICamRefs), ICamBody Screws, and the ICBD-Torx-8-11 Driver (also known as Torx-6). The ScanBodies are mounted onto endosseous implant interfaces at the multi-unit level or at the implant level.

ICam System Accessories - ScanBodies		
ICamBody	The ICamBodies are mounted directly onto a compatible implant interface and used with the ICam System to obtain 3D coordinates of implant locations	
ICamRef	The ICamRefs are mounted directly onto a compatible implant interface and used with an intraoral scanner, CBCT scanner, or oral impression equipment to relate the implant positions to the gingiva	
ICam System Accessories: ICamBody Screws and Driver		
ICBD-Torx-8-11	Driver used to fasten the ICamBody to the interface	
ICamBody Screw	Placed inside the ICamBody lumen to fasten it to the specific interface	

2 Compatibility

The Imetric ICamBodies, ICamRefs, and ICamBody Screws may only be used with compatible implant or multi-unit abutment interfaces. Please review the compatibility list to select ICamBodies, ICamRefs, and ICamBody Screws that are compatible with the implant system used.

2 Intended Use

- **ICamBodies:** Intended for use to locate the position of an implant in relation to the prosthetic restoration.
- **ICamBody Screws:** Intended for use to connect ICamBodies to the interfaces at the implant or multi-unit level.
- **ICBD-Torx-8-11:** Intended for use to tighten and loosen the ICamBody Screws.
- **ICamRefs:** Intended for use to relate implant positions to the gingiva.

3 Indications for Use

- **ICamBodies:** The ICamBodies are indicated for use with the Imetric ICam 5 System to locate the positions of implants after they have been placed in the maxilla or mandible.

- **ICamBody Screws:** The ICamBody Screws are indicated for use to connect ICamBodies to the implant or multi-unit interfaces.
- **ICBD-Torx-8-11:** The ICBD-Torx-8-11 is indicated for use to tighten and loosen the ICamBody Screws.
- **ICamRefs:** The ICamRefs are indicated for use with an intraoral scanner, CBCT scanner, or oral impression equipment to relate the implant positions to the patient's post-operative gingiva.

5 Maximum Number of Usage Cycles

5.1 ICamBodies

The ICamBodies may be used for a maximum of 50 reprocessing cycles. After this, the accuracy of the implant location data is no longer guaranteed and the ICamBodies must be replaced. If an ICamBody shows signs of wear (e.g visible aluminum, illegible markings, greyish discoloration of white target pattern) before the 50 reprocessing cycles have been reached, the ICamBody may no longer be used.

CAUTION: Improper handling or reprocessing can damage the ICamBodies or reduce the maximum number of usage cycles.

5.2 ICamBody Screws

There is no defined maximum number of reprocessing cycles for the ICamBody Screws. However, the ICamBody Screws must be replaced when a new set of ICamBodies is used. In addition, if the ICamBody Screw show signs of wear (e.g broken O-ring, damage to the screw threads, damage to the screw head), then the ICamBody Screw must be replaced.

5.3 ICamRefs

There is no defined maximum number of reprocessing cycles for the ICamRefs. If the ICamRefs show signs of wear (e.g corrosion, poor fit on the implant interface), then the ICamRefs must be replaced.

6 Multiple-Use Devices

The Imetric ICamBodies, ICamRefs, ICamBody Screws, and ICBD-Torx-8-11 are multi-use devices. Reusable products and instruments must be cleaned and sterilized prior to reuse on patients. Please follow the reprocessing instructions at the end of this IFU.

CAUTION: Improper handling or reprocessing can damage the ICamBodies, ICamRefs, and ICamBody Screws or reduce the maximum number of usage cycles.

7 Contraindications

It is contraindicated to use the ICam 5 System Accessories if:

- The patient is medically unfit for oral surgery
- The number, size, or position of implants is not sufficient to support the forces exerted by the prosthesis
- The patient is allergic or hypersensitive to commercially pure titanium alloy Ti6Al4V, unalloyed commercially pure titanium (CP), or aluminum
- The interface is not compatible with the ICam System Accessories
- The product shows signs of wear or discoloration, such as visible bare aluminum, fading of the white target pattern markings, greyish discoloration of the white target pattern markings, and illegible markings
- The ICamBody Screw shows signs of wear, such as a broken or loose o-ring, damage to the screw threads, or damage to the screw head

8 Cautions

Inaccurate implant position data may lead to a poor fit of the prosthesis. To avoid inaccurate implant position data, please consider the following:

- Close collaboration between the surgeon, restorative dentist and dental laboratory technician is essential for successful treatment.
- It is strongly recommended to use only instruments and accessories that are intended to be used in combination with the ICam System Accessories to avoid product failure, damage to tissue, or unsatisfactory aesthetic results.
- When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications.
- Ensure the implant is stable prior to mounting ICamBodies or ICamRefs.
- Each time an ICamBody is connected to an implant interface, ensure the ICamBody Screw is not loose and retighten with a torque of no greater than 10 Ncm if necessary

Damage to the ICam 5 System Accessories may lead to decreased accuracy of implant location data or mechanical failure of parts. To avoid damaging the ICam 5 System Accessories, please consider the following:

- Never exceed the recommended torque. Excessive torque may cause the screw, abutment or implant to break.
- The ICamBody screws are mounted with an O-ring. This O-ring prevents the screw from slipping out of the ICamBody. If the O-ring is damaged, the entire screw must be discarded.
- It is not permitted to mechanically modify Imetric products. The accuracy of measurements and compatibility of components is then no longer guaranteed.

9 Recommended Torques

Attention: The specified torques apply to the clinical area and must not be used in the laboratory.

It is recommended to tighten the ICamBody Screws with the following torque values:

Torque [Ncm]	Product
Recommended	5 Ncm
Maximum	10 Ncm

10 Handling Instructions

It is recommended to check the final fit of the abutment in the implant with the help of an X-ray.

10.1 Assembly of the ICamBodies and Screws

- Prior to mounting the ICamBodies on the implant or multi-unit interface, insert the threaded end of the ICamBody Screw into the top of the ICamBody lumen.
- When the ICamBody Screw is pushed all the way into the ICamBody lumen, the bottom of the ICamBody Screw will be visible, as shown in Figure 1.

Figure 1. Assembly of ICamBody and ICamBody Screw

10.2 Mounting ICamBodies

Figure 2. Orientation of the ICam-

- Position the ICamBody so that the bottom sits flush with the top of the implant interface.
- Orient the ICamBody so that it sits at an angle. Two faces of the ICamBody should be visible when viewing from the opening of the patient's mouth (see Figure 2).
- Verify that no tissue is trapped between the ICamBody and the implant or multi-unit interface and ensure that there is no visible gap.
- While holding the ICamBody in place with one hand, use the ICBD-Torx-8-11 driver to fasten the ICamBody Screw with a torque no greater than 10 Ncm.
- Ensure there is no gap between the ICamBody and the implant or multi-unit interface (see Figure 3)

CAUTION: A gap between the ICamBody and the implant interface may affect the accuracy of 3D implant measurements and result in a poor fit of the prosthetic.

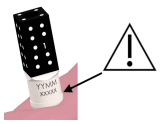


Figure 3. Placement of ICamBody

10.3 Removing ICamBodies

- Use the ICBD-Torx-8-11 to unscrew the ICamBody Screw and remove it from the ICamBody.

10.5 Disassembling the ICamBody and ICamBody Screw

- Remove the ICamBody screw from the top end of the ICamBody.
- The tip of the ICBD-Torx-8-11 can be used to help push the ICamBody Screw out through the bottom of the ICamBody.

10.4 Mounting ICamRefs

- Place the ICamRef on the interface.
- Hand-tighten until the base of the ICamRef sits flush on top of the interface.

CAUTION: A gap between the ICamRef and the interface may affect the accuracy of the relation of the implant location to the gingiva

11 Materials

- **ICamBodies:** The ICamBodies are made of a titanium alloy (Ti6Al4V) base and an aluminum alloy upper body.
- **ICamBody Screws:** The ICamBody Screws are made of a titanium alloy (Ti6Al4V.)
- **ICBD-Torx-8-11:** The torque driver ICBD-Torx-8-11 is made of titanium alloy (Ti6Al4V).
- **ICamRefs:** The ICamRefs are made of pure titanium.

12 Sterility and Reusability Information

All ICamBodies, ICamRefs, ICBD-Torx-8-11, and ICamBody Screws are supplied non-sterile. Non-sterile products must be cleaned and sterilized before use. Do not use the device if the packaging has been damaged or previously opened.

WARNING: Use of a non-sterile device may lead to infection of tissues or infectious diseases.

13 Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging and not exposed to direct sunlight. Incorrect storage and transportation may compromise the integrity of the packaging or the legibility of the labelling.

14 Disposal

The products that are to be disposed of must be treated as clinical waste and decontaminated in compliance with the relevant regulations.

15 Cleaning and Disinfection

Multiple-use devices like instruments and some accessories must be cleaned in between patient uses according to the following instructions:

WARNING:

- Do not use makeshift chemicals or excessive force. Under no circumstances should metal brushes or metal pads be used to prevent damage.
- Use cleaning and disinfecting agents with a neutral to mildly alkaline pH (7 to 11).
- When using cleaning agents and disinfectants, the manufacturer's instructions must be followed (e.g. intended use, dosage, exposure time and renewal of the solution).
- Non-sterile parts must be completely prepared before they are used for the first time.

15.1 Limitations on Reprocessing:

- Frequent but careful reprocessing has little effect on the life of the parts. The end of product life is usually determined by wear and tear during use and treatment.

15.2 Pre-Cleaning:

Pre-cleaning of the parts should be performed prior to both manual and automatic cleaning and disinfection.

1. Disassemble all ICamBodies and ICamBody Screws prior to cleaning.
2. Pre-clean the individual parts with a soft non-metallic brush under running cold tap water. Do not allow blood residues and other build-up to dry.
3. Rinse the ICamBody lumen intensively for >30 seconds using a water pressure gun or disposable syringe (without cannula).

Warning: Do not attempt to remove the black upper body from the ICamBody. This would destroy it.

15.3 Manual Cleaning, Disinfection, and Drying

The pre-cleaned parts can be cleaned, disinfected, and dried manually as follows:

1. **Soak**
   - 1.1. Prepare a fresh cleaning solution using an enzymatic detergent with a neutral pH (e.g ENZOL™ Enzymatic Detergent) according to the manufacturer's instructions with lukewarm tap water.
   - 1.2. Fully immerse the parts in the detergent. Ensure that the ICamBody lumens are filled with the cleaning solution.
   - 1.3. At the conclusion of the soaking time, gently brush all part surfaces with a soft non-metallic brush.
   - 1.4. Use a disposable syringe to flush the ICamBody lumens with the cleaning solution.
   - 1.5. Check the lumens for any residual soil or debris.

CAUTION: Ensure that the enzymatic detergent used is compatible with anodized aluminum. Do not allow the parts to make contact with the cleaning solution for longer than is specified in the manufacturer's instructions.

2. **Rinsing**
   2.1. Rinse all parts with room-temperature distilled water for at least 30 seconds using a water pressure gun or disposable syringe.
   2.2. Use a disposable syringe to rinse all ICamBody lumens with room-temperature distilled water.
3. **Disinfection**
   3.1. Disinfect the parts using a high-level ortho-phthalaldehyde based disinfecting solution with a neutral pH (e.g CIDEX™ OPA).
   3.2. Prepare the disinfecting solution according to the manufacturer's instructions.
   3.3. Per the manufacturer's recommendations, immerse the device in the disinfecting solution, ensuring all ICamBody lumens are filled. Allow the parts to soak in the disinfecting solution for the required time at the appropriate temperature.
   3.4. Thoroughly rinse and flush all parts and lumens with running tap water.
   CAUTION: Ensure that the disinfectant used is compatible with anodized aluminum. Do not allow the parts to make contact with the disinfecting solution for longer than is specified in the manufacturer's instructions.
4. **Drying**
   4.1. Drain the excess water from the parts.
   4.2. Dry all parts using a clean lint-free cloth immediately after rinsing.
   4.3. Dry the ICamBody lumens with oil-free compressed air.

15.4 Automatic Cleaning, Disinfection, and Drying

The pre-cleaned parts can be cleaned, disinfected, and dried automatically as follows:

1. **Load Parts into the Washer/Disinfector**
   Carefully load the pre-cleaned parts into the brackets/strainer of the washer/disinfector.
2. **Automatic Cleaning Cycle**
   Program the washer using the following parameters:

Phase	Recirculation Time	Water Temperature	Detergent Type	Concentration
Pre-Cleaning	1 minute	Cold Tap Water < 40° C	N/A	N/A
Cleaning	10 minutes	55° C ± 5° C	Alkaline Cleaning Agent (e.g neodisher® Medi-Clean)	0.5 %
Neutralization	3 minutes	Cold Tap Water < 40° C	N/A	N/A
Rinse	3 minutes	Distilled Water	N/A	N/A

3. **Automatic Disinfection Cycle**
   Use a thermal disinfection program that meets the national requirements for the A0 value (Recommendation: A0 > 3000).

15.5 Maintenance, Inspection, and Testing:

- Allow the parts to cool at room temperature and check macroscopically for residues of protein and other contaminants.
- Parts with visible residue must go through the entire cleaning and disinfection process again.
- If any of the rubber O-rings on the screws are damaged, the entire screw must be replaced.

15.6 Packaging

- Standard packing of the parts for sterilization according to ISO 11607 and EN 868.
- The bag must be large enough and the seal must not be under tension.

15.7 Sterilization

The ICam System Accessories are reusable devices and must be sterilized prior to reuse on patients. All Imetric products are delivered non-sterile. After performing the cleaning instructions specified above, perform the following sterilization cycle:

Sterilization Type	Fractionated Pre-Vacuum
Pre-Vacuum Cycles	3
Sterilization Temperature	132°C
Sterilization Holding Time	4 Minutes
Drying Time	20 Minutes

Use a sterilization pouch that is FDA cleared for the indicated cycle.

16 Signs and Symbols

REF	Catalogue number	LOT	Batch code		Caution
	Manufacturer		Consult instructions for use		Keep away from sunlight
UDI	Unique Device Identifier	NON STERILE	Non-sterile	MD	Medical device
	Date of manufacture		Distributor	Rx only	For prescription use only
	Keep dry	EC REP	Authorized representative in the European Union		

17 Serious Incident

Every serious incident that has occurred in connection with an Imetric product must be reported to the manufacturer (complaints@imetric4d.com) and the competent authority in the respective country.

18 Manufacturer

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19 US Contact

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