1 ICam System Accessories

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

2 Product Description

The Imetric ICam System Accessories are used together with the Imetric ICam System to obtain and output the 3D coordinates of endosseous implants to aid in the design and fabrication of dental prosthetic restorations. The ICam System Accessories consist of Scanbodies (ICamBodies and ICamRefs), Screws and a Driver. The Scanbodies are mounted onto endosseous implant interfaces at Multi-Unit level or at implant level.

ICam System Accessories		
ICamBody (ICB)	The ICamBodies are mounted directly onto a compatible implant interface or Multi-Unit interface and used with the ICam System to obtain 3D coordinates of implant locations.	
ICamRef (ICR)	The ICamRefs are mounted directly onto a compatible Multi-Unit interface and used with an intraoral scanner, CBCT scanner, or oral impression equipment to relate the implant positions to the gingiva.	
ICamBody Screw (ICBS & ICBSI)	Placed inside the ICamBody lumen to fasten it to the implant interface or Multi-Unit interface.	
ICamBody Driver (ICBD)	Driver used to fasten/loosen the ICamBody Screw.	

3 Compatibility

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

Link https://imetric4d.com/ifu/

4 Intended Use

Product	Intended use
ICamBody (ICB)	Optical localization of the dental implant.
ICamRef (ICR)	Optical localization of the dental implant relate to gingiva.
ICamBody Screw (ICBS & ICBSI)	Connect ICamBodies to the implant interfaces or Multi-Unit abutment interfaces.
ICamBody Driver (ICBD)	Loosening and / or tightening screws/ICamRefs.

5 Indications for Use

Product	Indications for use
ICamBody (ICB)	Indicated for use with the Imetric ICam System to locate the 3D coordinates of endosseous implants after they have been placed in the maxilla or mandible.
ICamRef (ICR)	Indicated for use with an intraoral scanner, CBCT scanner or oral impression equipment to relate the implant positions that to the patient's post-operative gingiva.
ICamBody Screw (ICBS & ICBSI)	Indicated for use to connect ICamBodies to the implant or Multi-Unit interfaces.
ICamBody Driver (ICBD)	Indicated for use to tighten and loosen the ICamBody Screws and/or ICamRefs.

6 Maximum Number of Usage Cycles

6.1 ICamBodies

The ICamBodies may be used for a maximum of 50 reprocessing cycles. After this, the accuracy of the measurements may decrease and the ICamBodies must be replaced. If an ICamBody shows signs of wear (e.g. frayed dot pattern, illegible markings, grayish discoloration of the dot pattern) before the 50 reprocessing cycles have been reached, the ICamBody must no longer be used.

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

6.2 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 shows 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.

6.3 ICamRefs

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

7 Multiple-Use Devices

The Imetric ICamBodies, ICamRefs, ICamBody Screws, and ICamBody Driver are multi-use devices. Reusable products and instruments must be cleaned, disinfected 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.

8 Contraindications

It is contraindicated to use the ICam 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.
- Do not use two or more ICamBodies with the same dot pattern in a scan process.
- 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.
- The ICamBody has been dismantled.

CAUTION: It is not permitted to mechanically process Imetric products. This can reduce accuracy. Correct application is no longer possible. Only Imetric screws may be used for the ICamBodies. Never use screws from other manufacturers.

9 Cautions

Inaccurate measurements of the implant coordinates may lead to a poor fit of the prosthesis. To avoid inaccurate measurements, 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 10 Ncm if necessary.

Damage to the ICam System Accessories may lead to decreased accuracy of measurements or mechanical failure of parts. To avoid damaging the ICam 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 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 no longer guaranteed.

10 Recommended Torques

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

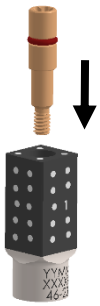
It is recommended to tighten the ICamBody Screws with the following torque values:

Product	Torque
ICamBody (ICB) + ICamBody Screw (ICBS & ICBSI)	10 Ncm
ICamRef (ICR)	10 Ncm

11 Handling Instructions

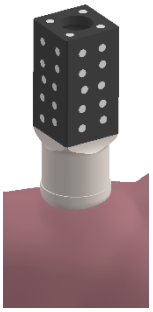
It is recommended to check the final fit of the abutment in the implant with the help of an X-ray.

11.1 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 right.

11.2 Mounting ICamBodies



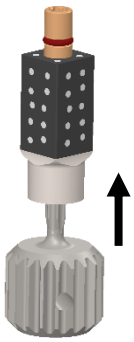
- Position the ICamBody so that the bottom sits flush with the top of the specific interface.
- Orient the ICamBody so that it sits at an angle, corner facing outside the mouth. Two faces of the ICamBody should be visible when viewing from the opening of the patient's mouth (see Figure right).
- Verify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

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.

CAUTION: Make sure that there is no blood or saliva on the surface of the ICamBody. If necessary, use oil-free compressed air to remove blood or saliva from the ICamBody.

11.3 Removing ICamBodies

- Use the ICamBody Driver to unscrew the ICamBody Screw and remove it from the ICamBody.



11.4 Disassembling the ICamBody and ICamBody Screw

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

CAUTION: Never use compressed air to blow the screw out of the ICamBody.

11.5 Mounting ICamRefs

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

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

12 Materials

Product	Material
ICamBody (ICB) base	Titanium alloy (Ti6Al4V)
ICamBody (ICB) upper part	Aluminum alloy
ICamRef (ICR)	Pure titanium
ICamBody Screw (ICBS & ICBSI)	Titanium alloy (Ti6Al4V)
ICamBody Driver (ICBD)	Titanium alloy (Ti6Al4V)

13 Sterility and Reusability Information

All Imetric parts 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.

14 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.

15 Disposal

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

16 Cleaning and Disinfection

Multiple-use devices like instruments and 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.

16.1 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.

16.2 Pre-Cleaning

Pre-cleaning of the parts should be performed prior to disinfection.

- Disassemble all ICamBodies and ICamBody Screws prior to cleaning.
- 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.
- 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.

16.3 Manual Cleaning, Disinfection, and Drying

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

16.3.1 Ultrasonic bath

- Neodisher® LM 2 should be used as a cleaning agent. Please note the safety data sheet and the leaflet for neodisher® LM 2. The dosage depends on the degree of soiling. According to the manufacturer, the following parameters must be observed: 0.5 - 2.0 vol.% (2 - 10 ml / l), e.g. B. at room temperature for 10 min.
- Place all parts in a sieve, avoid acoustic shadows. Add the detergent to the water and clean the parts at room temperature in an ultrasonic bath (35-40 kHz) for 10 minutes.
- It must be ensured that the parts are completely immersed in the water without bubbles. Pay attention to small parts.
- The O-ring on the ICBS (screw) must not be removed.

CAUTION: Make sure that the parts in the ultrasonic bath do not touch each other if you are cleaning several parts at the same time. Make sure that the parts do not lie directly on a metal sieve. Friction between metallic parts will damage the parts.

16.3.2 Manual treatment

- After treatment in an ultrasonic bath, clean all surfaces with a soft, non-metallic brush under running demineralized water and rinse all surfaces, inside and outside, for at least 30 seconds with a water pressure gun or disposable syringe (without cannula).
- Drain water.

⚠ **CAUTION**: The O-ring on the ICBS (screw) must not be removed. Please ensure that no residue remains between the screw and the O-ring. Clean again if necessary.

16.3.3 Manual disinfection

- Immerse the products in an RKI or VAH listed disinfectant.
- The instructions of the disinfectant manufacturer must be followed. Ensure that the disinfectant reaches all areas of the product (dismantled parts). Rinse all surfaces with the disinfectant at least 5 times using a disposable syringe (without cannula) (in the immersed disinfectant bath).
- The process is **validated** with the following disinfectant: 3% DESOMEDAN ID (15 minutes). Rinse the products (complete rinsing inside, outside and cavities) in demineralized water > 20 seconds.

16.3.4 Drying

Dry parts with lint-free, soft cloths and blow dry with oil-free compressed air.

16.3.5 Maintenance, inspection and testing

Allow the parts to cool at room temperature and check macroscopically for residues of protein and other contaminants. Parts that are not clean must go through the entire reprocessing process again.

16.3.6 Packaging

Standard packing of the parts with stericlin® bags (STEAM, EO, FORM) for sterilization according to ISO 11607 and EN 868. The bag must be large enough and the seal must not be under tension.

⚠ **CAUTION**: Reusable products and instruments must be sterilized prior to reuse on patients. Use parameters below.

17 Sterilization

All Imetric products are delivered non-sterile. Please note the instructions for reprocessing. The recommended sterilization cycle is fractionated prevacuum with the following parameters:

- Methode: Fractionated pre-vacuum process (according to ISO 17665)
- Pre-Vacuum cycles: 3 pre-vacuum phases with at least 60 mbar pressure
- Sterilization temperature: Heating up to 134 °C; max. 137 °C
- Sterilization holding time: min. 5 Minutes, max 25 minutes
- Drying time: min. 10 minutes

After sterilization, check the sterile packaging for damage and check the sterilization indicators.

18 Side effects

Allergic reactions and hypersensitivity in connection with the alloy cannot be ruled out in very rare individual cases. Furthermore, side effects such as pain, swelling and inflammation can occur, as this is an invasive treatment concept.

19 Interactions

Different types of alloys in the same oral cavity can lead to galvanic reactions with occlusal or approximal contact.

20 Serious incident

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

21 Manufacturer

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22 Authorized representative in the European Union

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23 EU Importer

Imetric 4D GmbH, Im Schwarzenbach 4, 79576 Weil am Rhein, Germany

24 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	EC REP	Authorized representative in the European Union	Rx only	For prescription use only
	Keep dry	CE	CE sign		