

Intraoral Scanbody, Scanbody

Instructions for use



Description

Scanbodies are premanufactured dental prosthetic components which are connected to an endosseous dental implant placed in the patient's mouth, or to an implant replica embedded in a master cast, to facilitate the design and fabrication of a dental implant restoration.

Materials

Scanbody: Stainless steel 303F according to JIS G4318.

Intraoral Scanbody and Screw: titanium alloy 90%, 6% Al, 4% V according to ASTM F136.

Jig: polyetheretherketone (PEEK) according to ASTM F2026-17.

Intended Use

Intended for use to transfer the direction, position, or orientation of a dental implant to a patient model.

Indication for Use

Scanbodies are indicated for use in combination with an intra-oral or desktop scanner to confirm the location, position and angulation of a dental implant or dental implant replica, to support creation of the digital model to facilitate the design and fabrication of a dental prosthesis using CAD/CAM technology.

Contraindications

Do not use in patients:

- Patients who are medically unfit for an oral surgical procedure.

- Patients in whom adequate sizes, numbers and desirable positions of implant are not reachable to achieve safe support of functional or eventually parafunctional loads.

- Patients who are allergic or hypersensitive to any of the materials which are included in the device. Refer to Materials section of this IFU for the material composition specific to each device.

Cautions

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment. Scanbody must only be used with compatible ARUM DENTISTRY instruments and components. Use of instruments and components that are not intended to be used in combination with the scanbody can lead to product failure, damage to tissue, or unsatisfactory esthetic results.

Warnings

To ensure the accuracy of the scan, the scanbody must not be modified.

Any modifications may impact the accuracy of the scan.

Sterilization

Intraoral Scanbody is delivered non-sterile. Prior to use clean and sterilize the product following the procedure in the Cleaning and Sterilization Instructions. Scanbody is connected to an implant replica in a master cast (not intended for intraoral use) and has no cleaning and/or sterilization requirements.

※ How to sterilization

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Gravity	121°C (250°F)	30 mins	30 mins

Standard for the autoclave: autoclave at 121°C, pressure of 1.5 for 30 minutes.

1) Supply power to the auto-clave.

2) Place the product in the autoclave.

3) Set the autoclave. (Temperature: 121°C, time: 30 minutes)

4) When finished, take out the product.



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

Do not use device if the packaging has been damaged or previously opened.

Before surgery

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

During surgery

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

※ Handling procedure



Do not re-use scanbody which have been damaged or disassembled.

[Intraoral Scanbody]

1) Connect the Intraoral Scanbody to the implant by hand-tightening the screw using the screw driver.

2) Take an intra-oral scan of the patient following the scanner manufacturer's instructions.

3) Remove the Intraoral Scanbody by untightening the screw.

4) Send the scan file to the laboratory.

[Scanbody]

1) Connect and hand-tighten the Scanbody by tightening the screw to the implant replica embedded in the master cast using the screw driver.

2) Scan the master cast following the scanner manufacturer's instructions.

Manufacturer Information



ARUM DENTISTRY Co., Ltd.

23, Gukjegwahak 11-ro, Yuseong-gu, Daejeon, 34002, Republic of Korea

Tel: +82-42-935-3644 Fax: +82-42-935-3633

<http://www.arumdentistry.com>

MedNet EC-REP Iib GmbH



Borkstrasse 10, 48163 Muenster, Germany

Tel: +49-251-32266-61

<http://www.mednet-ecrep.com/>



Note: Refer to the product label to determine the applicable CE mark for each device.

Basic UDI-DI Information












Product	Basic UDI-DI Number
Intraoral Scanbody	88000557ISBXH
Scanbody	88000557MSBY5

Symbol Glossary

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

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	Catalog Number		Consult Instructions for Use
	Batch Code		Do Not re-use
	Date of Manufacture		Non-Sterile
	Legal Manufacturer	Rx Only	Use by prescription only
	CE marking		Medical Device
	Caution		Authorized representative in the European Community