



ATTENTION: The images are merely illustrative. They do not correspond to the actual dimensions of the product.

INSTRUCTIONS FOR USE

This device is intended for a specialized procedure, which must be performed by qualified professionals in Dental Implants. For best results, use the product knowing the appropriate techniques. Always apply them in appropriate conditions, also in an operating room environment.

INDICATIONS FOR USE

The components of the SCANBODY TI DSP FAMILY are indicated for intraoral scanning or for tabletop (extraoral) scanners, in order to accurately determine the positioning of the tooth in relation to other teeth or implants.

The fixation screws that come with the components of the TI DSP Scanbody family are intended to secure the scanbody to the implant, abutment or analogue. The Scanbody with the set screw remains in contact with the patient for less than 30 minutes.

DESCRIPTION

The Scanbody TI DSP are intra- and extraoral scanning components, manufactured with F136 titanium. They are available for HE, HIM, HIL, HIS, CMI, CMH, CMF, FC and FCM and CEREC implant models.

System Compatibility: DSP Digital Scanner Post are compatible with CEREC Bluecam®, Exocad®, 3shape®, Dental Wings® systems. CEREC References

Platform	Ref. Scan Post	Ref. Interface
Slim	6430891	6460476
Standard	6431022	6460518

CONTRAINDICATIONS

This product is contraindicated for patients who show signs of allergy or hypersensitivity to the chemical ingredients of the material: titanium Ti6Al4V.

HOW TO USE

1. Choose the DSP SCANBODY TI according to the diameter and platform of the implant, abutment or analogue.
2. Clean and sterilize the DSP Digital Scanner Post in an oven or autoclave according to the manufacturer's recommendations before using on the patient.
3. Place the screw inside the Scanbody, snap into the implant, analogue or abutment. Use the Hex Wrench to thread the screw and secure the scanbody. Hand tighten the screw.
It is recommended that the flat (facet) side of the Scanbody point to the buccal side.
4. Perform the intraoral scan and, using the system of your choice, obtain the topographic situation of the patient's mouth.
5. After scanning, remove the Scanbody Ti.

PRECAUTIONS

Non-sterile product. The use of non-sterile components may lead to tissue infection or infectious diseases. Scanbody DSPs can be reused. However, before reuse, the user must inspect the component to verify that it does not have any damage. If any malfunction is detected, DSP does not recommend re-use, and the component should be discarded. DSP is not responsible for components damaged during use, which may incur in manufacturing errors of the prosthesis; The use of these products requires knowledge in CAD/CAM technology. DSP is not responsible for misuse or misuse

ADVERSE EFFECTS

No adverse effects are expected as long as the product is used according to its instructions for use.

ADDITIONAL INFORMATION FOR THE PROFESSIONAL

Instruct the patient about the need for professional medical follow-up after surgery and obey the guidelines regarding care, hygiene and prescription of medications. These guidelines are the responsibility of the responsible professional.

MAGNETIC RESONANCE IMAGING (MRI) - SAFETY INFORMATION

The DSP implant system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MRI environment. The safety of the DSP implant system in the MR environment is unknown. Scanning a patient who has this device may result in injury to the patient.

PRESENTATION

This product is supplied non-sterile and can be reprocessed. It should be cleaned and sterilized before use.

PRODUCT CLEANING

This product must be properly sanitized and sterilized before use.

Use only the following manual cleaning process. Automated cleaning has not been validated. Do not use automated cleaning for scanbody DSP.

1. Disassemble the product (if applicable).
2. Prepare Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner according to the manufacturer's recommendation of 1ml/L of warm tap water.
3. Soak the items in the prepared detergent solution and let them soak for at least 1 minute. While soaking, brush the items with a soft-bristled brush.
4. Prepare Prolystica® 2X Presoak and Cleaner Enzyme Concentrate according to the manufacturer's recommendation of 1ml/L in warm tap water in a sonication unit.
5. Soak the articles in the prepared detergent solution and let them sonicate for 10 minutes.
6. Visually inspect each test article for visible soil. If any visible dirt remains, repeat the cleaning process (steps 4-8) until there is no more visible dirt.

STERILIZATION

Sterilize the products the day before or on the day of the procedure.

ATTENTION: It is not recommended to autoclave these products in their original packaging. The product must be packaged with a wrap approved by legislation.

Please use for sterilization only steam sterilization according to the following parameters:

DYNAMIC/FRACTIONATED VACUUM AIR REMOVAL PARAMETERS¹	
Sterilization time	4 minutes
Temperature	132°C
Drying time	20 minutes ²

¹ At least three vacuum steps.

² The drying time actually required depends directly on the parameters of the user's sole responsibility (load configuration and density, sterilizer conditions) and must therefore be determined by the user. However, drying times of less than 20 min should not be applied.

TRACEABILITY LABEL

This product is accompanied by three labels that allow its traceability and must be attached to the following documents: • patient record;

- prosthetic records;
- implant card;

Identification and traceability are carried out through the REF and LOT codes.

STORAGE CONDITIONS

This product should be stored, in its original packaging, in a clean and dry place, at a maximum temperature of 45°C and protected from direct sunlight.

MATERIAL DISPOSAL

Every product and consumable used during surgery for the installation of dental implants can put the health of those who handle them after use at risk. Before disposing of them in the environment, it is recommended to observe current legislation and comply with it.

EXPIRATION DATE

See on label

PRODUCT WARRANTY

























DSP Biomedical provides product warranty against any manufacturing defect. The presence of any defect must be immediately reported to the manufacturer, respecting the legal deadline. The warranty of products manufactured by DSP Biomedical is strictly linked to following the information described in the instructions for use. Improper use of the product in disregard of the indications exempts the manufacturer and/or seller from any responsibility.

Note: the warranty does not cover wear and tear resulting from the use of the product.

SERVICE INFORMATION

If there is a need for more information, or the product presents any adverse effect, with potential risk to the patient, which generates or has the potential for injury or threat to public health, or any customer dissatisfaction, please contact DSP at 0800 600 88 66, or send an email to sac@dspbiomedical.com.br.

SYMBOLOLOGY

SYMBOLOLOGY	DESCRIPTION	SYMBOLOLOGY	DESCRIPTION
	Batch number		Refer to the instructions for use or refer to the electronic instructions for use
	Date manufacturing		Keep dry
	Manufacturer		Keep out of sunlight
	Non-sterile		Unique sterile barrier system
	Product Code		Expiration date
	Model Number		Unique Device Identifier
	Maximum temperature limit		Country of manufacturer
	Authorized representative in the European Community		Do not use if packaging is damaged and refer to instructions for use
	Care		Humidity limits
	Importer		Medical Device
	Fragile, handle with care		FDA-Required Prescription Notification for the United States States Market
	CE Mark		CE marking with Notified Body number; SIQ, number 1304

REF :Goods

Medical Device Description	Code
HE SLIM TITANIUM INTRAORAL SCANBODY	9.3300T
HE SLIM EXTRAORAL TITANIUM SCANBODY	9.3300TE
HE INTRAORAL TITANIUM SCANBODY	9.4000T
HE EXTRAORAL TITANIUM SCANBODY	9.4000TE
INTRAORAL TITANIUM SCANBODY CMI	79.4050T
CMI SCANBODY TITANIUM EXTRAORAL	79.4050TE
FCM INTRAORAL TITANIUM SCANBODY	77.3092T
FCM EXTRAORAL TITANIUM SCANBODY	77.3092TE
FC INTRAORAL TITANIUM SCANBODY	77.3392T
FC EXTRAORAL TITANIUM SCANBODY	77.3392TE
CMH SLIM TITANIUM INTRAORAL SCANBODY	69.3300T
CMH SLIM EXTRAORAL TITANIUM SCANBODY	69.3300TE
CMH INTRAORAL TITANIUM SCANBODY	69.4000T
CMH EXTRAORAL TITANIUM SCANBODY	69.4000TE
INTRAORAL TITANIUM SCANBODY	59.4000RT
HIM EXTRAORAL TITANIUM SCANBODY	59.4000TE
HIS INTRAORAL TITANIUM SCANBODY	59.4000ST
HIS EXTRAORAL TITANIUM SCANBODY	59.4000STE
HIL SCANBODY TITANIUM INTRAORAL	59.4000TT
HIL SCANBODY TITANIUM EXTRAORAL	59.4000TTE
CMF INTRAORAL TITANIUM SCANBODY	79.4050FT
CMF EXTRAORAL TITANIUM SCANBODY	79.4050FTE
MPC INTRAORAL TITANIUM SCANBODY	6.4090T
EXTRAORAL TITANIUM SCANBODY	6.4090TE
SCANPOST SLIM (CEREC)	4.3601IT
SCANPOST STANDARD (CEREC)	4.4601IT

MANUFACTURER

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