

Instruction for Use – Scan Body

1. Product Description

The Scan Body is a dental implant surgical instrument used during the impression-taking process to scan and identify the position of the area where a prosthesis will be placed. It is intended for use in the fabrication of the final dental prosthesis in partially or fully edentulous patients.

2. Intended Use

The device is intended to transfer the 3D position and orientation of the dental implant to a digital model through intraoral scanning or laboratory scanning. It serves as a positional indicator during CAD/CAM prosthetic design.

3. Sterility

- Supplied non-sterile.
- Must be sterilized in an autoclave at 132°C for 15 minutes, followed by a minimum 15-minute drying time before use.
- Do not use if packaging is damaged.
- Dispose of products in open or damaged packaging.

4. Procedure

A. Preparation Before Use

- 1) Dental implant surgery is highly specialized and requires a complex procedure. It is strongly recommended to perform the procedure only after completing a professional training course.
- 2) As this product is a medical device, it must be sterilized by moist heat in an autoclave before use (Temperature: 132 °C, Time: 15 minutes).

B. Applications

- 1) Scan Body: Connect the Scan Body to the Multi Abutment, tighten with a screw, and take the impression using an intraoral scanner.
- 2) Screw: Connect the Scan Body to the Multi Abutment and tighten using a 1.2 Hex driver.
- 3) Rod: Connect to the Main Scan Body, then take the impression using an intraoral scanner.
- 4) Bite Table: Connect to the Main Scan Body, then use an intraoral scanner to verify the bite.

C. Management after use

- 1) After the procedure, immediately disassemble all used instruments, wash them under running water, dry thoroughly, and store at room temperature.
- 2) Do not store in areas where there is a risk of contamination.

5. Warning

- Improper patient selection and surgical procedures may lead to implant failure or bone loss.
- Mobility of the implanted implant, bone loss, and chronic infection can cause implant failure.
- The implant must be handled carefully to prevent damage or deformation.

6. Caution

- Do not use products that have been contaminated due to operator error during the procedure.
- As this product is a medical device, it must be sterilized in an autoclave before use (Temperature: 132°C, Time: 15 minutes).
- Do not use hydrogen peroxide as a disinfectant or cleaning agent, as it may cause damage or discoloration to coatings or anodized surfaces.

7. Contraindication

Do not use in the following patients:

- Patients with a history of heart attack or arteriosclerosis
- Patients who are uncooperative or who have mental or physical disabilities that may cause instability, fixation failure or other complications regarding the implant during post-surgical management.
- Patients with conditions affecting bone formation, microcirculation, or blood.
- Pregnant patient.
- Patients with hypertension or diabetes.

8. Side Effects

- Bone loss, loss of stability, damage to prosthetics, inflammation, and nerve damage can lead to implant surgery failure.
- Local complications such as swelling, hematoma, bleeding, infection, inflammation, ulceration, and wound dehiscence may occur.

9. MR Safety Information

This product has not been evaluated for safety and compatibility in a magnetic resonance (MR) environment. Tests for heating, migration, and image artifacts in the MR environment have not been conducted. Therefore, the safety of this product in the MR environment is unknown. Scanning patients with this medical device implanted may result in patient injury.
















10. Storage

Store at room temperature (1~30°C).

11. Disposal

Follow local regulations and laws for the disposal of medical devices.

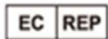
[Pictogram]

Symbol	Description	Symbol	Description
	Batch code		Manufacture Date
	Catalog number		Do not re-use
	Temperature limit		Consult instructions for use
	Keep dry		Medical Device
	Caution		Manufacturer
	Non-Sterile		Unique device identifier
	Do not use if package is damaged		CE Mark
	European Authorized Representative		



Manufacturer: HUB Biotech Co., Ltd.

181, Oksan-ro, Wonmi-gu, Bucheon-si, Gyeonggi-do, Republic of Korea
 Tel: +82-2-529-8857 Fax: +82-2-529-8859



Authorized representative: OBELIS S.A

Bd. Général Wahis, 53, 1030 Brussels, Belgium
 Tel: +32 2 732 5954, Fax +32 2 732 6003