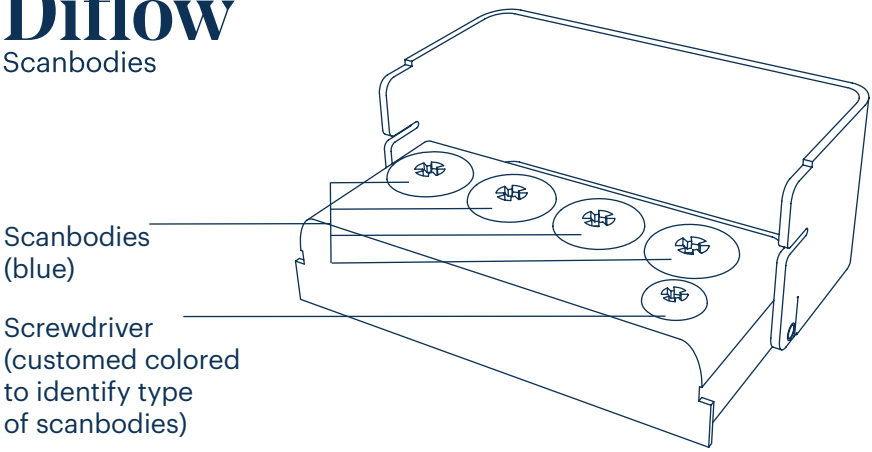
Diflow

Scanbodies

Technical leaflet

The Diflow Scanbodies System was created to help you in your daily practice and facilitate 100% digital implant works. The system brings together the specific scanbodies and the Diflow Scanbodies Box.

Diflow
Scanbodies



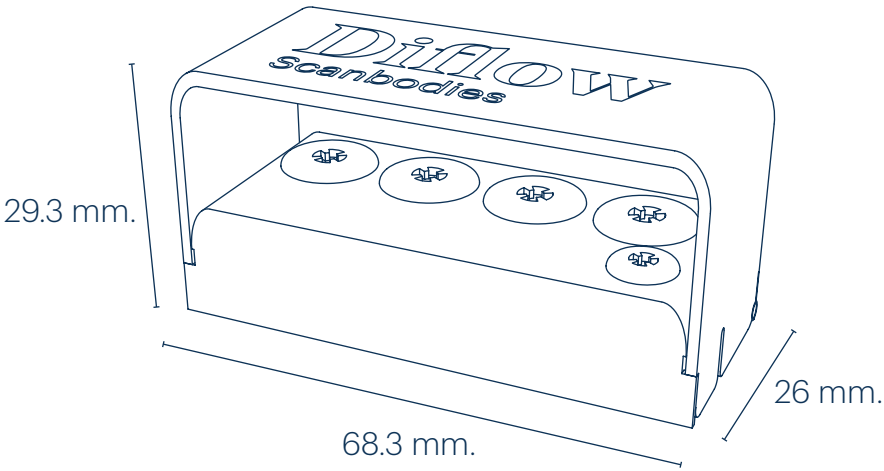
The Diflow Scanbodies Box is an aluminium box designed to help you keep your scanbodies and screwdriver organised and create a working protocol that lets you have everything ready for each patient.

To help you to easily identify the scanbodies, we have provided four different coloured rubber caps that you can place on each screwdriver part, allowing you to create an organisational system that works for you.

The box is designed so that it is easy to sterilise. Please read the instructions carefully.

Diflow Scanbodies Box specifications

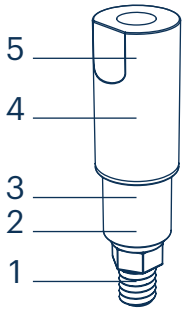
- Dimensions: 68.3 x 26 x 29.3 mm.
- Aluminium product.
- Do not put in dishwasher.
- Do not use with ultrasonic bath.
- Be careful with disinfecting liquids as some are incompatible with aluminium.
- Read the instructions carefully.
- This product is made of aluminium with a coloured coating. The colour of the product may be altered by using chemical cleaners.



Scanbodies specifications

Scanbodies are extremely precise components that determine the position and orientation of the digital "impression" of dental implants.

- Compatible with intra-oral (clinical) and extra-oral (laboratory) systems.
- Also compatible with the Renishaw® Stylus System.
- Includes captive screw to prevent loss and facilitate assembly.
- TiN coating offers antibacterial properties to protect the gingiva.
- Titanium base ensures a durable connection and enables Rx use.
- PEEK upper part, a polymer that facilitates the reading and placement of the implant.
- Maximum Z-precision when resting in the sagittal plane of the implant or analogue.
- Tolerance of ± 5 microns throughout the manufacturing process.
- Inscribed reference with laser marking.
- 2-unit heights: 10mm for most cases, and 15mm for situations where the implant is deeply submerged.



1. Captive screw.
2. TiN coating.
3. Titanium base.
4. Upper part made from PEEK.
5. The highest possible precision on the Z-axis.

Important

Before fitting the Scan Body, it is necessary to decide whether a single or multiple prosthesis must be made so that the correct one can be chosen. In the event of an error, the scan must be carried out again.

The technician must be informed of the reference used in each job so that he/she can record it in the library and avoid making mistakes.

Check radiologically that the Scan Abutment is correctly positioned.

In connections with conical support, we manufacture the Scan Body connection without this cone, forcing it to sit flat on the outside of the implant to ensure zero closure and to be able to guarantee the 5 microns in Z in a repetitive manner.

THEY ARE SUPPLIED NON-STERILE.

INSTRUCTIONS FOR USE

Symbol and labelling

Batch number


Consult the instructions for use

Not been subjected to a sterilisation process

Catalogue number


Cautionary note


Date of manufacture

Medical device


Complies with EU regulations


Manufacturer

DIFLOW SCANBODIES BOX

NICHROMINOX
18, rue des Frères LUMIERE
69720 Saint-Bonnet-de-Mure / FRANCE
Tel: 33 (0)4-78-74-04-15 - Fax: 33 (0)4-78-01-61-80
www.nichrominox.fr
E-Mail: office@nichrominox.fr

Indications

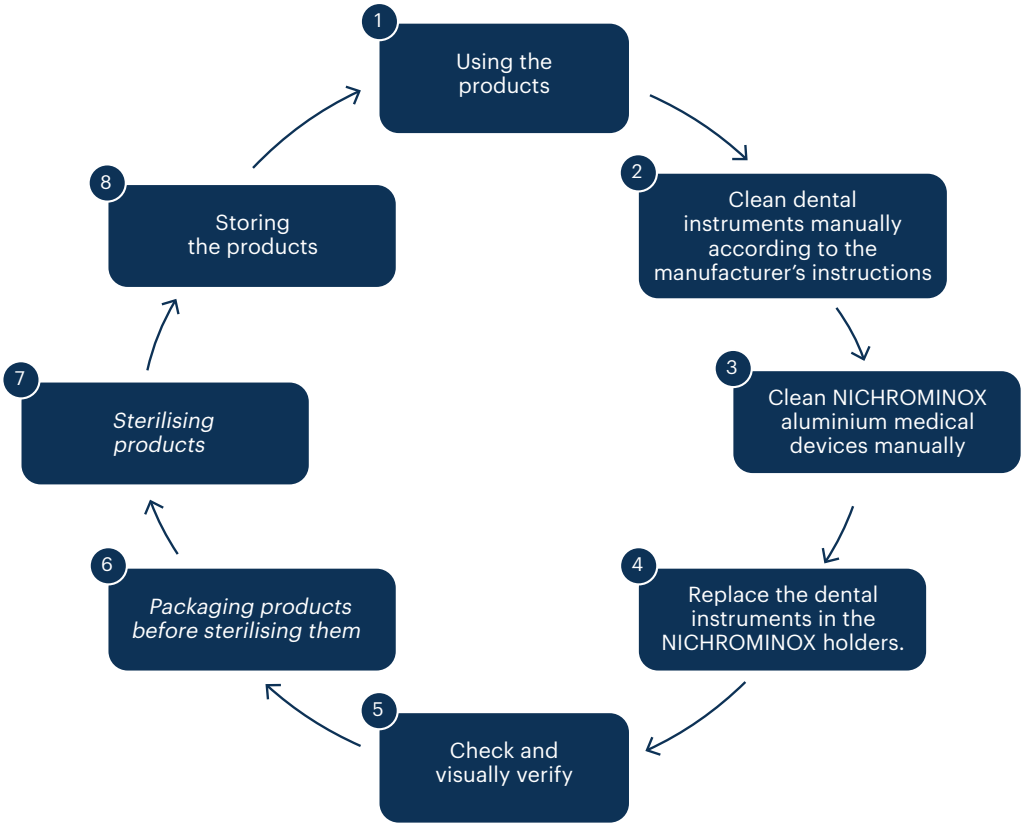
Medical devices made of aluminium are used for the storage and mechanical protection of dental instruments, as well as for the sterilisation of these instruments.

These devices are intended to be used by qualified dental professionals (dentist, dental surgeon, orthodontist, stomatologist, etc.) in a healthcare environment such as dental practices, hospitals, clinics and university laboratories, in a dedicated area for any type of dental procedure.

The health care staff (i.e. the reprocessor) is responsible for the proper reprocessing of medical devices using the equipment on site and the validated safety procedures for cleaning and sterilization. It is essential that the sterilisation equipment is also maintained and controlled in accordance with the manufacturer's recommendations and the validated parameters applied to each sterilisation cycle.

In addition, the legal provisions in force in the country in question and the instructions on hygiene in the practitioner's office or health care facility must be taken into account.

Stages of Reprocessing



Step 1: Using the products

Step 2: Clean dental instruments outside the NICHROMINOX holders according to the manufacturers' instructions before replacing them in the NICHROMINOX holders.

Step 3: Clean the NICHROMINOX supports manually, carefully following the instructions for use of the cleaning products used and taking into account possible incompatibilities with aluminium:

- Do not put in washing machine
- Do not use ultrasound
- Some decontamination products are incompatible with aluminium: refer to the instructions for use.

Step 4: Place the dental instruments back into the NICHROMINOX holders.

Step 5: Check and verify visually, ensuring that all dirt has been removed during cleaning and that the devices are completely dry.

Step 6: Packing products before sterilisation. All instruments must be completely dry before packaging. Once dry, pack them immediately in medical sterilisation bags suitable for NICHROMINOX medical devices and complying with medical device packaging standards (AAMI ST79, ISO 11607, Regulation (EU) 2017/745, FDA).

Step 7: Sterilise the products. Use only the recommended sterilisation procedures described

Stages of Reprocessing

below. Other sterilisation procedures are the responsibility of the user:

- It is imperative to follow the manufacturer's instructions for routine inspection and regular maintenance of the sterilizer.
- It is imperative that the steriliser is maintained in accordance with the manufacturer's recommendations.
- Use only low-contaminated and deionised water (i.e. purified water).
- Sterilized instruments must be completely dry after sterilization and before handling. Sterilizers with an automatic drying programme are recommended.
- Minimum exposure time to sterilisation temperature: **3 minutes at 132°C and 16 minutes drying time.**

The suitability of the instruments for effective sterilisation has been demonstrated by an approved independent testing laboratory under the following conditions:

Sterilisation method	Steam sterilisation
Sterilizer	Tuttnauer ELARA 11-D (K090783) The steriliser used meets the requirements of EN 13060 and is a standard device for the sterilisation of dental instruments and accessories.
Sterilisation temperature	132°C
Waiting (full cycle)	3 minutes
Drying time	16 minutes
Validation report	Laboratory test identification: SN 33693 Test number: 2021-3656

Stages of Reprocessing

A longer sterilisation time or a higher sterilisation temperature will microbiologically increase the safety of the sterilisation process; therefore, the sterility assurance level of 10^{-12} can for example be confirmed for the following sterilisation conditions:

- 132ºC; sterilisation time 4min, drying time 20min
- 135ºC; sterilisation time 3min, drying time 16min
- 134ºC; sterilisation time 3min, drying time 16min
- 134ºC; sterilisation time 18min, drying time 16min

The responsibility for reprocessing NICHROMINOX instruments with parameters not specified in this document lies with the customer.

Step 8: Store the products.

- Place the sterilized material in the area designated for its storage, in a dry and dust-free place.
- Ensure that sterile material is kept separate from non-sterile material for safety reasons.
- Check that the conditions of humidity, temperature and cleanliness of the environment are respected.
- Ensure that the protocol is followed to ensure that an effective sterile barrier is maintained as required by the facility.
- Check labelling, markers and packaging for tampering before reusing an instrument.

Recommendations

- Do not use alkaline or overly acidic products, or products that include soda or potash.
- Do not put in the washing machine.
- Do not use ultrasound.
- Some decontamination products are incompatible with aluminium: refer to the instructions for use of these products.

Precautions

- The use of ultrasonic tanks for cleaning may damage the anodising and colour.
- A pH of 4 to 8 does not present any particular risk.
- It is important to select enzyme solutions intended for the dissolution of blood and body tissues and fluids. Some enzyme solutions are specifically designed for the dissolution of faeces or other organic contaminants and may not be suitable for use with dental instruments or accessories.
- Repeated treatment according to the instructions in this manual has a minimal effect on NICHROMINOX medical devices, unless otherwise stated. The end of life of these aluminium medical devices is determined by wear and tear due to intended medical use and not by reprocessing.

Precautions

- NICHROMINOX does not specify the maximum number of times that stainless steel, Teflon and silicone DM instruments and accessories can be reused. The life span of products depends on a number of factors, including the type of handling and processing that occurs between uses. The best way to determine when a device should no longer be reused is to carry out a visual and functional inspection to ensure that there is no deterioration on the medical device.

Complaints and Requests for Information

NICHROMINOX makes every effort to design and supply safe and effective devices, in accordance with its quality policy. However, in the event of a serious incident involving a NICHROMINOX device or a manufacturing defect, the healthcare professional (user, prescriber, etc.) or the patient should contact NICHROMINOX immediately.

Complaints or any other reason for dissatisfaction concerning NICHROMINOX devices must be indicated by specifying the reference, the batch number and a complete description of the incident.

For any information, please contact customer service directly via the contact details below:

NICHROMINOX
18, rue des Frères LUMIERE
69720 Saint-Bonnet-de-Mure / FRANCE
Tel: 33 (0)4-78-74-04-15 - Fax: 33 (0)4-78-01-61-80
www.nichrominox.fr
E-Mail: office@nichrominox.fr

SCANBODIES
IPD INSTRUCTIONS FOR USE

Indication for Use

Implant Abutments and Screws are used for prosthetic restorations of dental implants or for assisting procedures in the dental laboratory.

Manufacturer

All the products that commercialize and distribute Implant Protesis Dental 2004 S.L. have been manufactured in the facilities of IPD2004.

IMPLANT PROTESIS DENTAL 2004
Cami del mig 71, Bajos 08302 Mataró, Barcelona
www.ipd2004.com. Tel: +34 93 278 84 91.

Storage and Handling

All products manufactured by Implant Protesis Dental 2004 S.L. should be stored at a temperature between 15-25 ° C and 40-60% humidity. The products must be kept away from direct sunlight and any artificial ultraviolet light. The product is well packaged and sealed. A defect on the packaging may involve the loss of the properties of decontamination and disinfection, it is recommended to avoid their use. The material must not be unpacked and handled it if is not going to be immediately used.

Implant Protesis Dental 2004 S.L. products are delivered in a non-sterile state.

Contraindicaton

All materials used are biocompatible; however, some patients may present allergies or hypersensitivity to any of the materials and its components.

All IPD Abutments and Screws can only be combined with the corresponding compatible implant system. No abutments inappropriate in connection geometry should be used. Any post processing at the connection geometry to the implant may result in fitting inaccuracies prohibiting further use.

The reuse of single-use products carries a possible deterioration of its characteristics, which implies the risk of infection of the tissues and /or deterioration of the patient's health.

There is a contraindication to the use of the products for patients with conditions that rule out the use of surgery for placement of dental implants. Check the integrity of the packaging, and do not use in case of alteration.

Warning

Items supplied Implant Protesis Dental 2004 SLU are intended to be used by qualified health professionals (dental technicians, doctors and dentists).

The safety and efficacy of the products supplied by Implant Protesis Dental 2004 S.L., is guaranteed only when trained professionals use them.

There is a risk of aspiration or ingestion of the products when used intra-orally, so that appropriate measures be taken to prevent it.

Sterilization

ALL PRODUCTS ARE SUPPLIED NON-STERILE. For sterilization, we recommend autoclaving the product at 121°C for 30 minutes, drying time 30 minutes (in accordance with standard UNE-EN ISO 17665-1:2007). Some devices are marked for “Single use only” because it is difficult or impossible to clean and decontaminate a used device, reuse can lead to cross-infection. Furthermore, any attempt to reuse a device greatly increases the risk of mechanical failure caused by material fatigue. Any warranty claim resulting from the reuse of a single-use device will not be accepted.

Autoclave is the most commonly used method in clinics and dental laboratories. A physical agent, moist heat, which causes protein denaturation and coagulation, produces sterilization. These effects are mainly due to two reasons:

- Water is a very reactive chemical and many biological structures (DNA, RNA, proteins, etc.) are produced by reactions that remove water. Therefore, reverse reactions may damage the cell to cause the production of toxic products. Furthermore, intermolecular hydrogen bridge bonds that can be broken and replaced by water at high temperatures stabilize the secondary and tertiary structures of proteins.

- Water steam has a much higher heat transfer tcoefficient than air. Wet materials, which conduct heat faster than dry materials, due to the energy released during condensation.

ADVANTAGES

· Fast heating and penetration
· Destruction of bacteria and spores in a short time
· Does not leave toxic waste
· Low deterioration of exposed material
· Economic

DISADVANTAGES

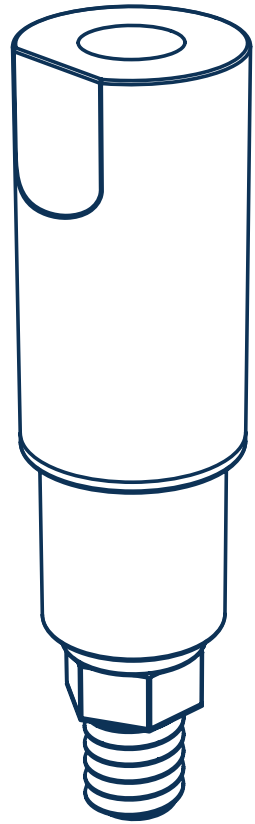
· It does not allow to sterilize solutions that form emulsions with water
· It is corrosive to certain metallic instruments

Scan Abutment

Material: PEEK / Titanium grade 5 Ti6Al4V

Indicated for obtaining geometric data from the master model using a desktop laboratory 3D scanner or for optical impressions using intraoral 3D scanner. Prior to use, ensure cleanliness of the implant connection seat. Any dirt could affect the subsequent alignment of the prosthesis. Verify the compatibility of the connection, in type and size, between the impression coping and the implant.

For greater scanning precision, we recommend locating the flat surface of the scan abutment in palatine/ lingual orientation. Fasten the abutment using the corresponding screw by hand or with maximum 10 Ncm. Scan abutment is a precision tool and over-tightening may change its geometry causing errors in scanning process and discrepancy in accuracy.
Two different heights are available, 10 mm and 15 mm depending on the gum height. If it is used for an intraoral scan, it is important to sterilize first.



For inquiries or information, please send an email to: support.diflow@corusdental.com

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