

Diver Family with Coating are intended for surgical procedures for installation of prosthetic components, which must be performed by qualified professionals. The way the product is used and surgical techniques are inherent to the professional's training. The use of the product must be carried out in a surgical environment and in conditions suitable for the health and safety of the patient.



PROUDCT DESCRIPTION

The drivers are produced in stainless steel and have a DLC (Diamond-Like Carbon) surface, at one of its ends it has a specific active tip for fitting prosthetic components, screws or other instruments. Wrenches can be used in conjunction with torque wrenches or manually.



ATTENTION

The Driver Family with Coating are intended for specialized procedures, which must be performed by qualified professionals in implantology. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

INDICATIONS OF USE

The Driver Family with Coating are indicated for installation of prosthetic components, as they assist in the fixation/removal of prosthetic components.

OPERATION PRINCIPLE

The purpose is to enable the installation of prosthetic components, through assistance in the surgical procedure, transport or fixation of the component. All switches work based on mechanical power transmission principles to actuate secondary elements.

PRECAUTIONS

Before starting the procedure, check the fit of the wrench on the contra-angle and the adjustment of the motor in relation to rotation and torque. The wrench should be selected in accordance with the implant/component installation recommendations. Use of excessive force or disengagement between parts can damage the product. Before each procedure, make sure of the perfect fit between the pieces, and the conditions of the instruments, always respecting their useful life. It is necessary to replace the instruments in case of damage, erased markings, compromised sharpening, deformations and wear.

HOW TO USE

The Driver Family with Coating is indicated for the installation of prosthetic components. The braces help to capture the primary packaging, transport to the dental implant and have the function of fixing/removal of prosthetic components.

RECOMMENDATIONS

The product should only be used by qualified dentistry professionals who already have all the scientific information necessary for the correct use of the product. Always perform cleaning and sterilization as recommended before the surgical procedure. It is necessary to verify the functionality, fitting capacity or accuracy of these products after each procedure and if there is natural wear and tear generated by use, they must be replaced and discarded.

1. Open the package and remove the driver;
2. Perform the cleaning and sterilization procedures contained in this Instruction for Use.
3. After the cleaning and sterilization process, the driver can be used.

CONTRAINDICATIONS

The Driver Family with Coating does not present contraindications as long as its recommendations are followed correctly and used by a specialized professional.

SIDE EFFECTS

Failure may result from factors intrinsic to the surgical procedure, such as the local and health conditions of the implanted individual and the skill and knowledge of the professional who practices it.

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of the instruments. All items may exhibit natural wear and tear and should be replaced whenever the professional identifies loss of fit or accuracy of these products as they may interfere with the end result of the work.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches that allow traceability, thus promoting greater safety to the professional skilled in the procedure. Through this lot number it is possible to know all product history from the manufacturing process to the time of distribution.

STORAGE

The Drills Family with Coating should be stored in a cool, dry place at a maximum temperature of 35°C and protected from direct sunlight.

HANDLING

Once sterilized, the instruments should be handled only in a sterile environment by properly attired professionals and in appropriate clothing at the time of surgery to install implants. Scratches or notches of the instruments should be avoided as such factors may increase the possibility of corrosion of the products.

DISPOSAL OF MATERIAL

The disposal of materials should comply with local hospital regulations and applicable local laws.

TRANSPORTATION

The Driver Family with Coating must be transported adequately to avoid falling and stored under a maximum temperature of 35°C, protected from heat and moisture. Carriage must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Reprocessing Allowed. Refer to the cleaning and sterilization conditions contained in these Instructions. In case of an incident caused by the product, the professional must immediately inform the manufacturer.

CLEANING INSTRUCTIONS

1. Disassemble the product (if applicable). Remove all the internal organic matter using tap water and follow to the next step only after performing such procedures.
2. Prepare the enzymatic detergent according to the manufacturer's recommendation.
3. Immerse all parts of the product into the prepared detergent solution and keep in contact for at least 5 minutes, then using soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove parts from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each.
5. Visual inspection of each part for cleaning process residue or organic waste from product use.
6. If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
7. Dry with a soft, clean, dry cloth or disposable paper.
8. Follow to sterilization process.

RECOMMENDATIONS

- a. Use the proper PPEs (gloves, masks, goggles, caps, etc.).
- b. Start the cleaning right after the surgical use.
- c. Never let the instruments dry with organic waste after the surgical use.
- d. Never let the instrument dry naturally after cleaning.
- e. Never use saline solutions, include sodium hypochlorite, disinfectant, hydrogen peroxide or alcohol to cleaning or rinsing the surgical instruments and Kits.
- f. Never use steel wool and abrasive products, so that the instruments are not damaged.
- g. Do not stack the instruments in lots to avoid the deformation of smaller and delicate pieces.

LIFE TIME

The Driver Family with Coating can be used as below depending on the proper handling, cleaning and sterilization.

Driver: Used up to 250 times.

STERILIZATION

Reusable product and provided non-sterile. It must be clean and sterilized in autoclave before use.

1. Dry all instruments before the steam sterilization cycle.
2. The product must be enclosed in a steam sterilizable wrap.
3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. Always accommodate the case in autoclave over a plane surface and away of device walls.
5. Never stack objects or other cases.

RECOMMENDATIONS

- a. Sterilize the products in the same day or one day earlier the procedure.
- b. The chemical sterilization is not recommended, once some products may cause the discoloration and damages to the case.
- c. Do not use temperature higher than 60°C to drying process.
- d. Do not use dry heat stoves for sterilization of the instruments and kits from S.I.N. - Implant System

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|  | NÃO ESTÉRIL | NON-ESTERILE | NO ESTÉRIL |
|  | CONSULTAR AS INSTRUÇÕES DE USO | CONSULT INSTRUCTIONS FOR USE | CONSULTE LAS INSTRUCCIONES DE USO |
|  | MANTENHA SECO | KEEP DRY | MANTÉNGALO SECO |
|  | MANTENHA AO ABRIGO DO SOL | KEEP AWAY FROM SUNLIGHT | MANTÉNGALO LEJOS DE LA LUZ SOLAR |
|  | NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA | DO NOT USE IF PACKAGE IS DAMAGED | NO LO UTILICE SI EL ENVOLTORIO ESTÁ DAÑADO |
|  | ATENÇÃO | CAUTION | PRECAUCIÓN |
|  | LIMITE SUPERIOR DE TEMPERATURA | UPPER LIMIT OF TEMPERATURE | LÍMITE SUPERIOR DE TEMPERATURA |
| Rx only | ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTE DISPOSITIVO POR OU POR ORDEM DE UM PROFISSIONAL DE SAÚDE LICENCIADO. | CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PRACTITIONER. | PRECAUCIÓN: LAS LEYES FEDERALES (USA) RESTRINGEN LA VENTA DE ESTE DISPOSITIVO POR O EN EL ORDEN DE UN PROFESIONAL DE LA SALUD LICENCIADO. |
|  | FABRICANTE | MANUFACTURER | FABRICANTE |
|  | DATA DE FABRICAÇÃO | DATE OF MANUFACTURE | FECHA DE FABRICACIÓN |
| REF | CÓDIGO DE REFERÊNCIA | REFERENCE CODE | CÓDIGO DE REFERÊNCIA |

DEVELOPED AND MANUFACTURED BY:
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PRODUCT:
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