SURGICAL INSTRUMENTALS

Non-articulated, non-cutting instrument with connection to equipment

Non-articulated, non-cutting instruments with connection to equipment are intended for specialized procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

PRODUCT DESCRITION

Non-articulated, non-cutting instruments with connection to equipment are produced in stainless steel, at one end it has a fitting for contra angle (active device) and at the other end a specific active tip fitting with implants, components or screws.

INDICATIONS OF USE

Non-articulated, non-cutting instruments with connection to equipment are indicated for installation of implants and prosthetic components, assist in the capture of the implant for transport between the primary packaging and the surgical socket or assist in the fixation / removal of implants and components.

OPERATION PRINCIPLE

The finality is to enable the installation of dental implants, through the aid in the surgical procedure, in the transport or fixation of the implant or component. All driver function based on mechanical principles of force transmission, for the activation of secondary elements.

HOW TO USE

Non-articulated, non-cutting instruments with connection to equipment must be selected according to the specificity of the implant and/or component and must be connect to contra-angle and the motor for use.

It is necessary to adjust the rotation and torque of the motor according to the recommendation of the implant/component to be installed.

ATTENTION

Non-articulated, non-cutting instruments with connection to equipment 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.

PRECAUTIONS

The driver should be selected according to the implant/component installation recommendations. Use of excessive force or disengagement between parts can damage the product. Before each procedure, make sure the perfect fit between the parts, 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.

RECOMMENDATIONS

The product should be used only by qualified dental 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 check the functionality, fitability 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.

CONTRAINDICATIONS

Use for purposes other than installing or removing implants and prosthetic components.

SIDE EFFECTS

Failure may occur due to 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. products - Implant System 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

Non-articulated, non-cutting instruments with connection to equipment 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

Scratche 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

Non-articulated, non-cutting instruments with connection to equipment 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. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplante.com.br or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Remove all internal organic material with running water, and move on to the next step only when you have done this;
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.

STERILIZATION

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

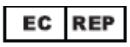
1. Dry all instruments before the steam sterilization cycle;
2. The product must be enclosed in a steam sterilizable wrap;
3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes;
4. Always accommodate the case in autoclave 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.

LIFE TIME

It is estimated that the instruments that are not articulated, with connection to equipment, non-cutting, can be submitted to 250 uses. It is necessary to check the functionality, fitting capacity or precision of these products after each procedure and if there is natural wear generated by use, they must be replaced and discarded.

	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	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
	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
	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	MANUFACTURE	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERENCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DISTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE

DEVELOPED AND MANUFACTURED BY:
S.I.N. Sistema de Implante Nacional S/A
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ANVISA REGISTRATION: 80108910048