DRILLS FAMILY

SYMBOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON ESTERILE	NO ESTÉRIL
	CONSULTAR 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
EC REP	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
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.

DEVELOPED AND MANUFACTURED BY:

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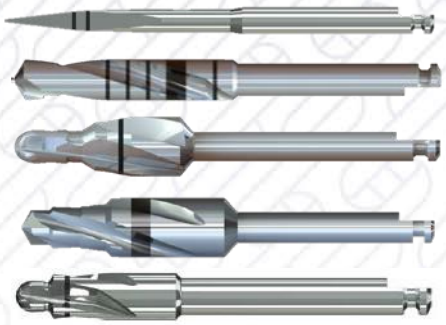
PRODUCT:

Drills Family
Anvisa Registration: 80108910024

CE

Drilling Cutters are intended to 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 DESCRIPTION

Drills are recommended for the removal of material in restorative procedures (dental/oral and maxillofacial/orthodontic).

INDICATIONS OF USE

The related drilling cutters have the same objective of performing a stepped and controlled drilling, in order to have a correct insertion of the implant.

Lance/ Spherical Drill: These Drills have the purpose of marking the place where the implant will be installed, and promoting a descorticalization of the bone in that area, in order to facilitate the insertion of other drills.

Helical / Conic Drill: The purpose of these Drills is the progressive extension of drilling, to promote greater control of the work performed until the final drilling dimension allows the implant to be installed.

Pilot Drill: Pilot Drills are used as intermediaries between the helical Drills, so that the it has the diameter of the previous drill on the edge (as a guide) and the diameter of the next drill in the active part.

Countersink Drill: These drills have the purpose of making a bevel at the entrance of the perforation for a correct seating of the implant head

Trephine Drill: These Drills have the purpose of facilitating the removal of bone in areas where the dimensions of helical or conic drills do not reach, and can be used to remove osseointegrated implants according to each need.

Bone Profile Drill: These drills are intended to facilitate the removal of bone created on the implant cover during the osseointegration period.

Extracting Drill: These drills have the purpose of facilitating the removal of the mucosa, so that the professional can have access to the implant to finalize the work.

OPERATION PRINCIPLE

Drilling cutters base their working principle on the mechanical action of bone/mucosa cutting, by the surface of the drilling cutter. As the material from which the drills are manufactured is harder than these, by printing the rotational movement to the drills, they cut the tissue promoting the removal of material according to the geometry of the drill.

HOW TO USE

1. Select the set of drills necessary to obtain the proper drilling of the place taking into account the desired length and width.
2. Ensure that the drills are properly sterilized before the procedure (see sterilization conditions contained in this use instruction manual).
3. At the appropriate time, insert the drill into the motor or wrench and ensure that it is properly secured.
4. Perform the desired drilling.
5. Continue the surgical procedures.

CONTRAINDICATIONS

Drills do not present contraindications since they follow their recommendations correctly and used by specialized professionals.

SIDE EFFECTS

Not Applicable. Adverse effects will only occur if the drill is unsuitable.

PRECAUTIONS AND RECOMMENDATIONS

1. 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.
2. Carry out the Cleaning and Sterilization according to the recommendations contained in these Instructions.
3. It is recommended to use up to 20 to 30 perforations, including:

- 20 high-density bone perforations;
- 30 low-density bone perforations.

WARNING

Do not use the drills if you notice cracks, wear or oxidation/corrosion points. This may cause instrument performance problems. All items may appear a natural wear due use and they should be replaced whenever the professional identifies loss of fitting capacity or accuracy of these products, as they may interfere with final work results.

TRACEABILITY

All S.I.N. products - Implante System products have sequential batches that allow traceability, which promotes greater safety for the professional qualified to the procedure. Through this batch number, it is possible to know the entire history of the product from the manufacturing process to the distribution time.

STORAGE

Drills should be stored in a dry, fresh and ventilated place, away from direct sunlight;

TRANSPORTATION

Drills should be transported at room temperature away from direct sunlight, avoiding locations where greater variations in temperature and humidity occur. The transportation must be carried out properly to avoid falls and it must be carried out in its original package.

HANDLING CONDITIONS

Once sterilized, drills should only be handled in a sterile environment by properly trained professionals and in suitable suits at the time of the surgical procedure.

COMPLEMENTARY INFORMATION

Multiple use product. Reprocessing Allowed. Refer to the cleaning and sterilization conditions contained in these Use Instructions.

DISPOSAL OF MATERIAL

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

EXPIRATION DATE

Indicated on the label.

CLEANING INSTRUCTIONS

1. Pre-cleaning or De-embedding

a. Remove the organic matter from the instruments without manual contact.
b. Begin cleaning or de-embed quickly after surgical use.

Recommendations

a. Wear appropriate scrubs (gloves, masks, goggles, caps, etc.).
b. Use enzyme solutions at the concentration and time of exposure determined by the manufacturer of these chemical solutions
c. Perform a single rinse, directly in a stream of water, without the handling of the instruments

2. Decontamination

a. The cleaning of microorganisms in vegetative form
b. This type of cleaning offers occupational hazards.

Recommendations

a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
b. Never use saline solutions, especially sodium hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

3. Washing

a. It is the removal of debris from surgical instruments through manual brushing or ultrasonic vibrations.

Recommendations

a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
b. Use neutral soap at 1% or neutral detergent, both at pH 7.0.
c. Always use brushes with natural or Nylon bristles for cleaning racks, serrations and fittings.
d. Never use steel straws or sponges and abrasive products not to damage the instruments.
e. Do not accumulate instruments in large quantities on top of one another to avoid deformation of minor and delicate parts.

Try to handle a few pieces at a time.
Ultrasonic cleaning, if used, should have the washing solution heated to at least 45°C and the instruments should be placed in the open position for 3 to 5 minutes of immersion at a frequency of 35 KHz.
There may also be the need to brush the serrated parts and joints.

4. Rinse

a. It is the removal of chemical residues, detergents and foams still present in the instruments.

Recommendations

a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
b. Never use saline solutions, especially sodium hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

5. Drying

a. It is the removal of residual water and moisture, after the rinsing procedure..

Recommendations

a. Never let the instrument dry naturally.
b. Always use soft, absorbent fabric (e.g. compresses) or moisture-free compressed air.
c. Never use dry heaters to dry the S.I.N. Instruments.

STERILIZATION

It is the procedure that aims at the total elimination of microorganisms (viruses, bacteria, microorganisms, and fungi), either in vegetative or sporulated form.

Recommendations

a. Dry all instruments before the steam sterilization cycle.
b. Use mechanical and chemical indicators (place the internal chemical indicator between instruments or materials to be sterilized) for each sterilization cycle.
c. Allow instruments to dry and cool in the sterilizer before handling to prevent contamination and oxidation of materials.
d. The autoclavable case can be sterilized at 121°C at 1 ATM pressure for 30 minutes or at 134°C at 2 ATM pressure for 20 minutes.
e. Always place the case in an autoclave on a flat surface and away from the edges of the device.
f. Never overlap objects or even other cases.
g. Chemical sterilization is not recommended as some products may cause discoloration and damage to the case.