SURGICAL INSTRUMENTS

Safe Drill Limiters

The Safe Drill Limiters are intended for specialized procedures, which must be performed by qualified professionals. The way to use the product and surgical techniques are inherent to the professional's training. The product use must be performed in a surgical environment and under adequate conditions for the patient's health and safety.

PROUDCT DESCRITION

The Safe Drill Limiters are instruments manufactured in Polyacetal, used as accessories for surgical cutters, during the dental implant installation procedure.

INDICATIONS OF USE

The Safe Drill Limiters are indicated to assist in the installation of dental implants. Their function is to limit the depth of bone tissue drilling for implant installation.

OPERATION PRINCIPLE

The Safe Drill Limiters are based on mechanical action. All instruments are indicated to aid bone tissue drilling in dental implant placement and should be used following the appropriate dental techniques.

HOW TO USE

The Dental Surgeon should use the Safe Drill Limiters in bone tissue drilling procedures, following the aseptic and appropriate surgical techniques for each case. Described below is a suggested guideline for the use of Safe Drill Drill Limiters. After the use of the Limiters, separate them from the other materials, wash and sterilize them following the guidelines described in this Instruction of Use.

Safe Drill Sequence:

1. Select the Safe Drill Stopper appropriate for the cutter being used (diameter and bore length);
2. Mount the Safe Drill Stop on the desired cutter, making sure that it is seated properly on the cutter;
3. Check that the chosen Safe Drill Stop length matches the laser marking on the cutter;
4. Drill to the desired depth;
5. Remove the Safe Drill Stopper.

ATTENTION

The Safe Drill Limiters are intended for specialized procedures, which must be performed by qualified professionals in Implant Dentistry. The use of the product must be performed in a surgical environment and under adequate conditions for the health and safety of the patient.

PRECAUTIONS

The Safe Drill Boundaries require specialized surgical procedures and should only be used by qualified dental surgeons to make diagnosis, preoperative planning and surgical protocol. The use of the product without knowledge of the adequate techniques and/or inadequate procedures and conditions, may harm the final result of the treatment and the patient, leading to unsatisfactory results. It is recommended that after use, Safe Drill Stoppers be washed and sterilized immediately

RECOMMENDATIONS

Wear the appropriate clothing (gloves, masks, goggles, caps, etc.). Start cleaning immediately after the surgical use. Never let the product dry containing organic residues after surgical use. Never let the product dry naturally after cleaning. Never use saline solutions, especially sodium hypochlorite and saline solution

disinfectants, hydrogen peroxide or alcohol for cleaning or rinsing the products. Never use steel wool or sponges and abrasive products, so that the products are not damaged. Do not pile the stoppers in large quantities on top of each other to avoid deformation of smaller and delicate parts.

CONTRAINDICATIONS

The Safe Drill Limiters do not present contraindications as long as its recommendations are correctly followed and used by a specialized professional, who will be responsible for the adequate planning of the surgical procedure in which the instruments will be used. None of the instruments are for permanent/implantable use, only for transitory use during surgery.

SIDE EFFECTS

Safe Drill Limiters are used to assist in the installation of dental implants, so adverse effects will only occur if the choice or use of instrumentation is inappropriate.

WARNING

Do not use the instruments if you notice cracks, wear, or deformation. This can cause problems in the functioning of Safe Drill Limiters. All items can present natural wear and tear generated by use, and must be replaced whenever the professional identifies loss of fitting capacity or precision of these products, because they can interfere in the final result of the work. Safe Drill Stoppers can only be used with S.I.N. - Implant System cutters that contain the stopper pocket. These stoppers are not compatible with any other drilling system. The clinician must make sure that the Safe Drill Stop is fully seated in the cutter to minimize the possibility of the stop disengaging from the cutter.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches that allow for traceability, thus providing greater security to the professional who is qualified for the procedure. Through this lot number it is possible to know the entire history of the product from the manufacturing process to the moment of distribution.

STORAGE

Safe Drill Limiters should be stored in a dry, cool, well-ventilated place away from direct sunlight.

HANDLING

Once sterilized, the instruments should be handled only in a sterile environment by properly dressed professionals in appropriate attire at the time of implant installation surgery.

DISPOSAL OF MATERIAL

The disposal of materials must be done according to hospital standards and local legislation in force.

TRANSPORTATION

The Safe Drill Limiters must be transported at room temperature, away from direct sunlight, avoiding places where there are large variations in temperature and humidity. The transportation must be done properly, to avoid falling and must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for Odontological use. Passible of Reprocessing. See cleaning and sterilization conditions contained in this Use Instruction. 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. Disassemble the product (if applicable). For the torque wrench, disassembly it completely, 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.

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 non-articulated, equipment-connected, non-cutting instruments can be subjected to 50 uses.

	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	RECYCLABLE PACKAGING	EMBALAJE RECICLABLE

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