SURGICAL INSTRUMENTS

Safe Drill Limiters

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

PRODUCT DESCRIPTION

Safe Drill Limiters are instruments made of Polyacetal, used as accessories for surgical drills, during the dental implant installation procedure.

INDICATIONS OF USE

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

PURPOSE AND OPERATION PRINCIPLE

Safe Drill Limiters base their operating principle on mechanical action. All instruments are indicated to assist in drilling bone tissue when placing dental implants and must be used following appropriate dental techniques.

HOW TO USE THE INSTRUMENT

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

Safe Drill Sequence

1. Select the appropriate Safe Drill Limiter for the cutter used (perforation diameter and length);
2. Mount the Safe Drill Limiter on the desired cutter, paying attention to placing it properly on the cutter;
3. Check that the chosen Safe Drill Limiter length matches the laser marking of the cutter;
4. Drill to the desired depth;
5. Remove the Safe Drill Limiter.

⚠ ATTENTION

Safe Drill Limiters 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

Safe Drill Limiters require specialized surgical procedures and should only be used by dental surgeons qualified to carry out diagnosis, pre-operative planning and surgical protocol. Using the product without knowledge of the appropriate techniques and/or inappropriate procedures and conditions may harm the final result of the treatment and lead to unsatisfactory results for the patient. It is recommended that after use, Safe Drill Limiters are washed and sterilized immediately

RECOMMENDATIONS

Wear appropriate clothing (gloves, masks, glasses, hats, etc.). Begin cleaning immediately after 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, disinfectants, hydrogen peroxide or alcohol to clean or rinse products. Never use steel straws or sponges and abrasive products, so that the products are not damaged. Do not accumulate the limiters in large quantities on top of each other to avoid deformation of smaller and delicate pieces.

CONTRAINDICATION

Safe Drill Limiters do not present contraindications as long as their recommendations are followed correctly 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 transient use during surgery.

SIDE EFFECTS

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

WARNING

Do not use the instrument if you notice cracks, wear or deformation. This may cause problems in the operation of the Safe Drill Limiters. All items may show natural wear and tear caused by use and must be replaced whenever the professional identifies loss of fitting capacity or precision of these products, as they may interfere with the final result of the work. Safe Drill Limiters can only be used with S.I.N. cutters that contain housing for the limiter. These limiters are not compatible with any other drilling system. The clinical manager must make sure to fully seat the Safe Drill Limiter on the drill to reduce the possibility of the limiter disengaging from the drill.

TRACEABILITY

All S.I.N. products have sequential batches that allow traceability, thus promoting greater safety for professionals skilled for 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 Safe Drill Limiters should be stored in a cool dry place at a temperature of 15°C to 35°C and protected from direct sunlight in their original unopened packaging and should not be damaged.

HANDLING

Once sterilized, the instruments should be handled 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 can 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 Safe Drill Limiters must be transported adequately to avoid falling and stored at a maximum temperature of 35ºC, protected from heat and moisture. Transport must be carried out in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for dental use. Reprocessing allowed. Refer to the cleaning and sterilization conditions contained in this instruction for use. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the country in which the dentist and/or patient is established. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplantsystem.com or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Prepare the enzymatic detergent according to the detergent manufacturer's instructions.
2. Immerse all parts of the product into the prepared detergent solution and leave for 5 minutes. Then, using a soft bristle brush, scrub the parts for at least 2 minutes until complete remove organic matter from the products.

3. Remove the parts from the detergent solution and rinse with tap water for 1 minute until the residue is completely removed. Repeat the rinse two more times.
4. Visually inspect each part to check for process residues or organic residues from the used of the product.
5. If residue in detect in the product, repeat the cleaning process until the residue is completely removed.
6. Dry with a soft, clean, dry cloth or disposable paper.
7. Proceed to the sterilization process.

RECOMMENDATIONS

a. Wear appropriate clothing (gloves, masks, glasses, hats, etc.)
b. Begin cleaning immediately after surgical use.
c. Never let the instrument dry containing organic residues after surgical use.
d. Never let the instrument dry naturally after cleaning.
e. Never use saline solutions, especially sodium hypochlorite and saline, disinfectants, hydrogen peroxide or alcohol to clean or rinse surgical instruments and Kit trays.
f. Never use steel wool or sponges or abrasive products, so that the instruments are not damaged.
g. Do not accumulate instruments in large quantities on top of each other to avoid 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.

LIFE TIME

It is estimated that non-articulated instruments, connected to equipment, and non-sharp 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 DE TEMPERATURA	TEMPERATURE LIMIT	LÍMITE 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
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERÊNCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DESTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCABLE PACKAGING	EMBALAJE RECICABLE

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PRODUCT
Safe Drill Limiters