

Kit Safe Drill Epikut – KESD 02

The Kit Safe Drill is intended for specialized procedures, which must be performed by qualified professionals. The way of using 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 conditions suitable for the health and safety of the patient.



PROUDCT DESCRIPTION

The Kit Safe Drill is a composite of materials needed to install implants in the Epikut and Epikut Plus line.

Safe Drill Stopper: It is an instrument made of polyacetal, used to assist the drilling of the surgical socket, during the dental implant installation procedure.

Box: Support for storing, transporting and sterilizing all items in the kit.

INDICATIONS OF USE

The Kit Safe Drill is intended to be used together with cutters to install dental implants. Its function is to limit the drilling depth of the bone tissue for the implant installation.

OPERATION PRINCIPLE

Its purpose is to assist in the correct drilling of the surgical socket, its use allows a more precise drilling, as it works as a depth limiter for when the desired perforation is achieved.

HOW TO USE

The implantodontist must use the Kit Safe Drill in bone tissue drilling procedures, following aseptic and appropriate surgical techniques for each case. Described below, follows a suggested roadmap for using safe drill stopper. After using the safe drill stopper, separate them from other materials, wash and sterilize them following the guidelines described in this instruction for use.

Sequence Safe Drill:

1. Select the appropriate safe drill stopper for the cutter used (diameter and length of the hole).
2. Mount the safe drill stopper on the desired cutter, taking care to fit it properly on the cutter.
3. Check that the length of the chosen safe drill stopper matches the laser marking of the cutter.
4. Drill to the desired depth.
5. Remove the safe drill stopper.



ATTENTION

Kit Safe Drill are intended for expert procedures, which must be performed by qualified professionals in implant Dentistry. The product must be used in a surgical environment and in proper conditions for the health and safety of the patient.

PRECAUTIONS

Safe drill stopper require specialized surgical procedures, should only be used by qualified dental surgeons, including: diagnosis, preoperative planning and surgical protocol.

The use of the product without knowledge of the appropriate techniques and/or inadequate procedures and conditions, may harm the final result of the treatment and the patient leading to unsatisfactory results.

Do not stick labels, adhesive tapes, write or mark the surface of the product.

RECOMMENDATIONS

Before using the safe drill stopper, the professional must sterilize it, according to the recommendations contained in this instruction for use.

It is recommended that after use, the kit and its components are washed and sterilized immediately.

CONTRAINDICATIONS

Safe drill stopper are not contraindicated as long as their recommendations are correctly followed and used by a specialized professional, who will be responsible for the proper planning of the surgical procedure in which the instruments will be used.

SIDE EFFECTS

The safe drill stopper is used to assist in the installation of implants, so adverse effects will only occur if the choice of instruments is inadequate.

WARNING

Do not use the instruments 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 generated by use and should be replaced whenever the professional identifies a loss of fit or accuracy of these products, as they may interfere with the final result of the work.

Safe drill stopper can only be used with S.I.N. containing the accommodation for the limiter. These stopper are not compatible with any other drilling system. The clinician must ensure that the safe drill stopper is fully seated on the cutter to reduce the possibility of the limiter being disengaged from the cutter.

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 Kit Safe Drill 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.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

The Kit Safe Drill 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. Remove manually all surgical instruments from the kit. Remove the kit box parts (lid, tray and bottom).
2. Prepare the enzymatic detergent, according to manufacturer's recommendation.
3. Immerse the trays into the prepared detergent solution and keep in contact for at least 5 minutes, then using a soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove trays 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.

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 3. 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








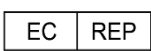




- a. Sterilize the products in the same day or one day earlier the procedure.
- b. The chemical sterilization is not recommended, once some products may cause the discoloration and damages to the case.
- c. Do not use temperature higher than 60°C to drying process.
- d. Do not use dry heat stoves for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

LIFE TIME


The Kit Safe Drill can be used as below depending on the proper handling, cleaning and sterilization.

Safe Drill Stopper: Use up to 50 times.

Box: The box can be cleaned and sterilized up to 250 times.

	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 DESTES 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

DEVELOPED AND MANUFACTURED BY:
 **S.I.N. Sistema de Implante Nacional S/A**
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PRODUCT:
 Kit Safe Drill – KESD 02

ANVISA REGISTRATION 80108910095

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