SURGICAL KIT

Sinus Lifting Kit S.I.N. - KLEV 02

The Sinus Lifting Kit S.I.N. – KLEV 02 is intended for expert 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

The Sinus Lifting Kit S.I.N. – KLEV 02 is a set of Dental Picks of Maxillary Sinus composed by:
01 - CRT 01 Dental Pick of Maxillary Sinus nº1;
01 - CRT 02 Dental Pick of Maxillary Sinus nº2;
01 - CRT 03 Dental Pick of Maxillary Sinus nº3;
01 - CRT 04 Dental Pick of Maxillary Sinus nº4;
01 - CRT 05 Dental Pick of Maxillary Sinus nº5;

INDICATIONS OF USE

The Sinus Lifting Kit S.I.N. – KLEV 02 is composed by surgical instruments used in the lifting surgery of the maxillary sinus for the increase in the osseous height in the posterior region of the jaw, enabling the immediate installation of osseous implants.

OPERATION PRINCIPLE

The working principle applicable to the Sinus Lifting Kit S.I.N. – KLEV 02 Instruments is mechanical, being used for detaching and pulling away the sinus membrane so that the graft can be accommodated.

HOW TO USE

Since this is an advanced surgical technique, it is recommended that the professional has in-depth technical knowledge about sinus floor elevation surgery, acquired through a specialization course in Implant Dentistry or Oral and Maxillofacial Surgery. The Dental Surgeon must use the Sinus Lifting Kit in lateral bone window procedures, which must be performed using instruments rotary instruments to access the maxillary sinus. After carefully performing the lateral osteotomy, the professional must select and use the curettes available in the kit for detachment and separation of the sinus membrane. This procedure should be performed carefully and progressively to avoid perforation or rupture of the sinus membrane. Then the professional must accommodate the graft material under the sinus membrane using the instruments available in the kit for this purpose. Once this procedure is concluded, the professional must perform the suture of the operated area.

ATTENTION

The Sinus Lifting Kit S.I.N. - KLEV 02 is 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

For the use of the Sinus Lifting Kit S.I.N. - KLEV 02 it is recommended that the professional have a specialization course in the area. The professional must submit the patient to a thorough clinical evaluation to diagnose cases cited below in contraindications.

RECOMMENDATIONS

The professional must be aware of the force exerted when using the product in order not to cause damage to the patient and the product.

Before using the S.I.N. Sinus Lift Kit - KLEV 02, the professional must sterilize it, according to the standard sterilization protocol, observing the drying cycle. The S.I.N. Sinus Lift Kit - KLEV 02 should be cleaned after use under running water with neutral detergent and a soft sponge. After washing, the instruments of the Sinus Lift Kit S.I.N. - KLEV 02 should be dried with air jets to prevent its oxidation. The professional must: prepare a sterile environment with sterile surgical dressing and field, submit the patient to a good buccal asepsis, avoid that during the application the product has contact with any non-sterile object in order to reduce to a minimum the risk of contamination. The professional must inform the patient of the possible complications of the sinus lift surgery, the proper way to clean the mouth, the need for periodic monitoring, and the need to avoid physical effort after the surgery.

CONTRAINDICATIONS

The maxillary sinus lift surgery must be preceded by a detailed anamnesis performed by the dental surgeon, with special attention to the diagnosis of sinus pathologies such as the presence of acute or chronic sinusitis, sinus cysts or polyps and other alterations in the health of the maxillary sinuses, which contraindicate the performance of this procedure. Whenever detected, the sinus pathologies must be treated by the dentist or otorhinolaryngologist, previously to the maxillary sinus lift surgery.

SIDE EFFECTS

The Sinus Lifting Kit S.I.N. - KLEV 02 has no 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 it will be used.

WARNING

Do not use the instruments if you notice cracks, wear or oxidation/corrosion spots. This may cause problems in the instrumentals functioning. All items may present natural wear generated by use and must be replaced whenever the professional identifies a loss of fitting capacity or precision of these products, because they can interfere with the final result of the work.

TRACEABILITY

All S.I.N. products - Implant System - have sequential lots that allow 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

The Sinus Lifting Kit S.I.N. - KLEV 02 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 must be handled only in a sterile environment by properly dressed professionals in appropriate attire at the time of surgery for installation of orthodontic mini-implants. Avoid scratching, bending or notching the instruments as these factors may increase the possibility of corrosion of the products.

DISPOSAL OF MATERIAL

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

TRANSPOTATION

The Sinus Lifting Kit S.I.N. - KLEV 02 should 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 in an appropriate way to avoid falls 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 Instruction for Use.

If you need the printed version of this Instruction for Use, free of charge, please request it by e-mail to sin@sinimplante.com.br or call 0800 770 8290 and you will receive it within 7 calendar days.

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.

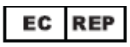
1. Dry all instruments before the steam sterilization cycle.
1. The product must be enclosed in a steam sterilizable wrap.
2. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
3. Always accommodate the case in autoclave over a plane surface and away of device walls.
4. 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 S.I.N. Sinus Lifting Kit - KLEV 02 can be reprocessed, depending on proper handling, cleaning, and sterilization, 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 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

DEVELOPED AND MANUFACTURED BY:
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