SURGICAL KIT

S.I.N. Expander Kit - KEXP

The S.I.N. Expander Kit – KEXP is intended for specialized procedure, 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 S.I.N. Expander Kit - KEXP is a Kit consisting of four different expansion rods with Stop.

INDICATIONS OF USE

Expanders are used as surgical instruments during bone compaction procedures or partial elevation of the maxillary sinus and are not implantable. They allow the placement of osseointegrated implants, without or with little use of drills, to take advantage of the remaining bone tissue of the patient, often avoiding the need for bone grafting.

OPERATION PRINCIPLE

The working principle applicable to Expanders is that of Lever, that is, purely mechanical. The force exerted at the distal (wider) end is transferred throughout the body of the instrument, to the proximal end, which acts at the surgical site by compacting the bone tissue.

HOW TO USE

The Dental Surgeon should use the Expander in procedures of bone Compaction or partial elevation of the maxillary sinus, following the aseptic and appropriate surgical techniques to each case. In the items described below, there is a suggested route for the use of Expanders, in cases of bone compaction and partial elevation of the maxillary sinus. After using the Expanders, separate them from other materials, wash and sterilize them following the instructions in this Instructions Manual.

Bone compaction:

1. First, the bone is drilled at the implant site to be installed with the milling cutter, followed by the milling cutter to the planned depth. This process assumes an exact planning in the radiological image;
2. Before using the instruments, it is recommended to mount the depth limiters, in order not to exceed the pre-determined working depth.
3. Straight instruments allow easier access in the back area;
4. The larger diameter instruments are manually introduced, with slightly rotating movements or with slight hammer strokes, according to the length and diameter of the desired implant.
5. Careful insertion of the implant is recommended.

Partial elevation of maxillary sinus:

1. First, the bone is drilled at the implant area to be installed with the milling cutter, followed by the helical milling cutter, to the maxillary sinus floor, with due care not to break this cortical with the milling cutter. This process assumes an exact planning in the radiological image;
2. Before using the instruments, it is recommended to mount the depth Stop in order not to exceed the pre-determined working depth. Depth Stops are manually mounted on the instruments. Straight instruments allow easier access in the back area;
3. After milling, the floor of the maxillary sinus is fractured using the 2mm diameter expander, which requires accurate radiological planning. It is recommended to work with depth limiters, in order not to exceed the one previously defined in the planning. The instrument is advanced with slight hammer strokes, according to the desired length of the implant;

4. During elevation, a filling material (autogenous bone or bone replacement) may be applied to the implant bed prior to its installation. The material introduced has the effect of a cushion that lifts the maxillary sinus membrane, according to the hydraulic principle;
5. Careful insertion of the implant is recommended.
6. Depending on availability and bone density at the site, alternate use of expanders and burrs with progressive diameters may be required to obtain satisfactory clinical results.

ATTENTION

The S.I.N. Expander Kit - KEXP 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 S.I.N. Expander Kit - KEXP, it is recommended that the professional have a specialization course in the area of Implant Dentistry or Oral and Maxillofacial Surgery. Excessive use of the expanders, bad positioning, added to the lever effort caused during their use, can compromise the active tip of the expanders.

RECOMMENDATIONS

The professional should 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 Kit, the professional should sterilize it, according to the recommendations contained in this instruction for use. The professional should: prepare an 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 risks related to the surgical procedure, the appropriate way to clean the mouth, the need for periodic monitoring, and the need to avoid physical effort after the surgery.

Do not stick labels, adhesive tapes, write on or demarcate the surface of the product. It is recommended that after use, the kit and its components be washed and sterilized immediately.

CONTRAINDICATIONS

The S.I.N. Expander Kit - KEXP has no contraindications as long as its recommendations are correctly followed and it is used by a specialized professional who will be responsible for the adequate planning of the surgical procedure.

SIDE EFFECTS

The S.I.N. Expander Kit - KEXP is used to assist in implant installation, so adverse effects will occur only if the choice of instrumentation is inadequate.

WARNING

Do not use the instruments if you notice cracks, wear or oxidation/corrosion spots. This can cause problems in the functioning of the instruments. All the items may 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, as they may interfere in 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 since its manufacturing process until the moment of distribution.

STORAGE

The S.I.N. Expander Kit - KEXP should be stored in a dry, cool, well-ventilated place away 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.

TRANSPORTATION

The S.I.N. Expander Kit - KEXP should be transported at room temperature, away from direct sunlight, avoiding places where there are wide variations in temperature and humidity. The transport must be done in an appropriate way 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. 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.

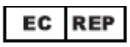
1. Dry all instruments before the steam sterilization cycle.
2. 2. The product must be enclosed in a steam sterilizable wrap.
3. 3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. 4. Always accommodate the case in autoclave over a plane surface and away of device walls.
5. 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 S.I.N. Expander Kit - KEXP 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

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