

S.I.N. Rotary Expander Kit

The S.I.N. Rotary Expander Kit is for specialized 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 DESCRIPTION

The Rotary Expander Kit is a Kit consisting of rotary expanders, wrenches and a spear cutter.

INDICATIONS OF USE

Rotatory Expanders are used as surgical instruments during bone alveolar ridge and bone compaction procedures. They allow the placement of osseointegrated implants, without or with little use of drills, to better take advantage of the remaining bone tissue of the patient, often avoiding the need for bone grafting.

OPERATION PRINCIPLE

The operating principle applicable to Rotary Expansion Units is rotating and leverage, ie purely mechanical. Torque exerted in the square socket is transferred throughout the body of the instrument, to the proximal end that acts in the surgical site compacting the bone tissue.

HOW TO USE

The dentist should use the Rotary Expander in procedures of expansion of the alveolar ridge or bone compaction, following the surgical techniques appropriate to each case, its use follows the following steps:

1. Firstly, the bone is perforated, breaking the cortical bone at the implant site to be installed with the shaft milling drill, followed by the milling drill to the planned depth.
2. Before using the instruments, it is recommended to observe carefully the height markings of the instruments, in order not to exceed the predetermined working depth;
3. The instruments are introduced, in increasing diameter, with variable rotational movements according to the case, with the aid of a torque wrench, digital key or contra-angle, according to the length and the diameter of the desired implant;
4. Careful insertion of the implant is recommended.



ATTENTION

The S.I.N. Rotational Expander Kit is intended for specialized procedures, which must be performed by qualified dental professionals. 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 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. Rotary Expander Kit, it must be sterilized.

RECOMMENDATIONS

For the use of the S.I.N. Rotatory Expander Kit it is recommended that the professional has experience in the area of bone reconstructions. The excessive use of the Rotatory Expanders, bad positioning, added to the lever effort caused during the use, can compromise the active tip of the expanders.

CONTRAINDICATIONS

The S.I.N. Rotary Expander Kit has no contraindications provided its recommendations are properly followed and used by a specialized professional who will be responsible for the proper planning of the surgical procedure in which the SIN Rotary Expander Kit will be used.

SIDE EFFECTS

The S.I.N Rotary Expander Kit is used to assist in the installation of dental implants, thus adverse effects may occur only if the instrument choice is not appropriate.

WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of Rotary Expanders. All items may present natural wear due use and they should be replaced whenever the professional identifies loss of fitting capacity or accuracy of these products, as they may interfere with final work results.

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

The S.I.N. Rotatory Expander Kit 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 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 S.I.N. Rotary Expander Kit should be transported in a suitable manner to avoid falls and stored at a maximum temperature of 35°C, protected from heat and moisture. It must be transported 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. In case of any incident caused by the product, the professional must inform the manufacturer immediately. 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. 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

The S.I.N. Rotary Expander Kit 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:

S.I.N. Sistema de Implante Nacional S/A

CNPJ: 04.298.106/0001-74

Rua Soldado Ocimar Guimarães da Silva, 2445 - Vila
Rio Branco CEP: 03348-060 - São Paulo - SP - Brazil

SERVICES TO THE PROFESSIONAL

0800 770 8290 +55 (11) 2169-3000

www.sinimplantsystem.com

e-mail: sin@sinimplante.com.br

EC REP

OBELIS S.A.

Bd. General Wahis, 53
1030 Brussels, Belgium

CE 2460

RESPONSIBLE TECHNICIAN:

Alessio Di Risio
CREA-SP: 5061207169

PRODUCT: S.I.N. Rotatory Expander Kit

ANVISA REGISTRATION: 80108910062