SURGICAL KIT

Cheek Retractor – SGA 01

The Cheek Retractor 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 DESCRIPTION

The Cheek Retractor is a composite of materials necessary for aerosol suction, so that the dentist can work without interruption.

Lip Retractor: keep the lips apart.

E-Connector: keep the suction ducts fixed.

Vacuum Lip Retractor: assist in the suction of aerosol particles generated during the procedure.

T-Connector: allows the suction to be divided into 2 different tubes.

Suction Tube: tube that drains the collected aerosol.

INDICATIONS OF USE

The Cheek Retractor is indicated to aid aerosol suction generated by dental devices that require irrigation such as: high-speed pen.

OPERATION PRINCIPLE

The materials contained in the Cheek Retractor base its principle of operation on the mechanical action of the correct fitting between the parts and coupling on the vacuum pump outlet.

HOW TO USE

The Cheek Retractor must be used according to the surgical planning programmed by a qualified dentistry professional.

ATTENTION

The Cheek Retractor are intended for specialized procedures, which must be performed by qualified professionals in odontology. 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

1. The product should only be used by qualified dental professionals who already have all the scientific information necessary for the correct use of the product.
2. Always perform cleaning and sterilization as recommended before the surgical procedure.
3. Keep the environment where the devices are stored always clean and adopt an adequate hygiene procedure during handling.
4. Do not stick labels, adhesive tapes, write or mark the surface of the product.

RECOMMENDATIONS

Before each procedure, check the condition of the materials, always respecting their useful life. It is necessary to replace the materials in case of damage, erased markings, deformations and wear. The Cheek Retractor can be cleaned and sterilized up to 30 times. All items are subject to reprocessing, with the exception of the suction tube (TSG 01), which must be discarded after use. Each time the Cheek Retractor is used, a new suction tube must be used.

CONTRAINDICATIONS

If the instructions for use are followed correctly, no contraindications or adverse effects related to the use of this product are observed.

SIDES EFFECTS

They will not occur as long as the handling is done according to the instructions for use.

WARNING

Do not use the materials if you notice cracks or wear. This may cause problems in the operation of the products. All items are subject to reprocessing, with the exception of the suction tube (TSG 01), which must be discarded after use. Each time the Cheek Retractor is used, a new suction tube must be used.

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 Cheek Retractor should be stored in a cool, dry place at a maximum temperature of 35°C and protected from direct sunlight.

HANDLING

Once sterilized the materials should only be handled in a sterile environment by professionals who are properly attired 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 Cheek Retractor 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. Exclusive for dental use. Possible of reprocessing. Consult cleaning and sterilization conditions contained in this instruction for use. 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.

RECOMMENDATION

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.

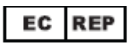
RECOMMENDATION

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 Aerosol Sucker can be used as follows depending on proper handling, cleaning and sterilization:

Tubing for Sucker (TSG 01): Single use only;
All other items: 30 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
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PRODUCT: Cheek Retractor – SGA 01

ANVISA REGISTRATION: 80108910098