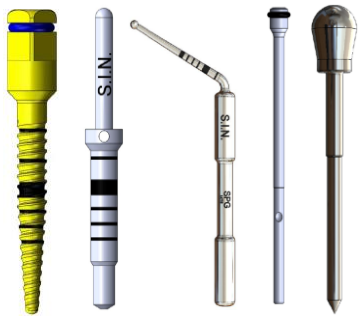
SURGICAL INSTRUMENTALS

TI Instrumentals

The TI Instrumentals are intended for surgical procedures for installing dental implants, 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 DESCRITION

TI Instrumentals are manufactured in grade 5 titanium and are intended to be used in humans to assist in the placement of implants and other surgical procedures following appropriate dental techniques.

INDICATIONS OF USE

Assemblers: Used during the process of transporting and installing the implant in the surgical alveolus.

Depth Rod: Indicated to assist and guide correct drilling.

Direction Indicator: Indicated to assist and guide correct drilling.

Driver: Indicated for installation of implants and prosthetic components, assist in the surgical procedure or in the fixation / removal of implants and components.

Expanders: Used as surgical instruments for bone compaction procedures in regions with lower bone volume. They allow the placement of implants, without or with little use of drills for better utilization of the remaining bone tissue of the patient, often avoiding the need for bone grafting.

Guide Drill: Use with drills for installing dental implants. Its function is to guide the drilling of bone tissue for implant installation.

Guide Fixer: used in the surgical guide to assist in fixing there for the correct perforation of the alveolus, during the dental implant installation procedure using the guided surgery technique.

Surgical Tweezers: Used to facilitate the handling of components and implants in the surgical procedure.

Stabilizer: Used in the surgical guide to assist in fixing the surgical guides for the correct perforation of the alveolus, during the dental implant installation procedure using the guided surgery technique.

Washer head: Used in the surgical guide to assist in the correct perforation of the alveolus during the dental implant installation procedure through the guided surgery technique.

OPERATION PRINCIPLE

TI Instrumentals base their operating principle on mechanical action. All instruments are indicated for use in implant placement and must be used following the appropriate dental techniques.

HOW TO USE

1. Open the original packaging and remove the instrument.
2. Before the first use or after being used in surgical procedures, perform the cleaning and sterilization procedures contained in this instruction for use.
3. After sterilized, the instrument will be ready for use.

ATTENTION

The TI Instrumentals are intended for specialized procedures, which must be performed by qualified professionals in implantology. 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

The TI Instrumentals requires specialized surgical procedures, it should only be used by qualified dental surgeons, including: diagnosis, preoperative planning and surgical protocol.
Use of the product without knowledge of proper techniques and / or procedures and
Inadequate conditions may impair the end result of the treatment and the patient leading to unsatisfactory results.
Do not stick labels, tape, write or demarcate the surface of the product.

RECOMMENDATIONS

Before using the instrumentals, the professional should sterilize it according to the recommendations contained in this Instruction for Use.
It is recommended that after use, the kit and its components should be washed and sterilized immediately

CONTRAINDICATIONS

The instrumentals has no contraindications as long as its recommendations are followed correctly 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 instrumentals is used to assist with implant installation, so adverse effects will occur only if the choice of instruments is inadequate.

WARNING

Do not use the instrument 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 and should be replaced whenever the professional identifies loss of fit or accuracy of these products as they may interfere with the end result of the work.

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 TI Instrumentals 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. Scratche or notches of the instruments should be avoided as such factors may increase the possibility of corrosion of the products.

DISPOSAL OF MATERIAL

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

TRANSPORTATION

The TI Instrumentals 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 all the internal organic matter using tap water and follow to the next step only after performing such procedures.
2. Prepare the enzymatic detergent according to the manufacturer's recommendation.
3. Immerse all parts of the product into the prepared detergent solution and keep in contact for at least 5 minutes, then using soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove parts 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.
8. Follow to sterilization process.

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

1. Product reusable and provided non-sterile. It must be clean and sterilized in autoclave before use.
2. Dry all instruments before the steam sterilization cycle.
3. The product must be enclosed in a steam sterilizable wrap.
4. 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.
5. Always accommodate the case in autoclave over a plane surface and away of device walls.
6. 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.

LIFE TIME

The TI Instrumentals can be used as below depending on the proper handling, cleaning and sterilization.

Assemblers and Washer Head: Use only once.

Driver: Use up to 50 times.

Expanders: 20 perforations in high density bones; 30 low density boné perforations.

Depth Rod, Direction Indicator, Guide Drill, Guide Fixer, Stabilizer and Surgical Tweezers: Use 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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