

SYMBOLGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE UTILIZACIÓN
	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
<b>Rx only</b>	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.

## DEVELOPED AND MANUFACTURED BY: S.I.N. Sistema de Implante Nacional S/A

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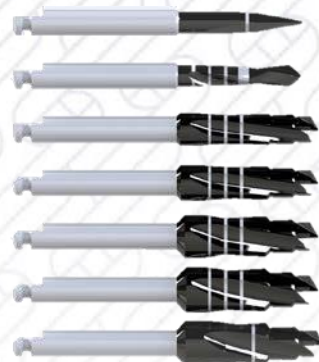
Alessio Di Risio  
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## PRODUCT:

SW Short Drill Kit – KSDSW  
**Anvisa Registration:** 80108910072

**CE**

The SW Short Drill Kit is intended to 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

This Kit consists of the complete line of surgical drilling required for the placement of Strong SW implants.

As the material from which the drills are manufactured is harder and more resistant than these, by printing the rotational movement to the drills cuts the tissue promoting the removal of material that varies according to the geometry of each commercial model in this presentation.

## INDICATIONS OF USE

The SW Short Drill Kit is indicated to perform the necessary drilling for the surgical alveolar socket, with the aim of performing a stepped and controlled drilling, in order to have a correct insertion of the implant.

**Lance Pilot Drill:** It is intended to perform the marking of the place where the implant will be installed, in addition to promote the bone decorticalization in that area to ease the insertion of other drills.

**Helical Drill:** Its purpose is to deepen the drilling in the bone tissue according to the planning performed by the professional.

**Conical Drill:** It aims at progressive enlargement of the drilling and to promote a greater control of the performed work, until the final dimension of the drilling allows the installation of the implant.

## HOW TO USE

1. Select the correct models of drills that will be used in the surgical procedure.
2. Open the original product package and remove the selected drills;
3. Before first use or after having been used in previous surgical procedures, correctly follow the Cleaning and Sterilization Instructions contained in this Use Instructions.
4. Once cleaned and sterilized, the drills are ready for use in surgical procedures.

## OPERATION PRINCIPLE

Drilling contained in the SW SHORT DRILL KIT base their working principle on the mechanical action of cutting bone/mucosa through their surface.

## CONTRAINDICATIONS

The SHORT DRILL SW KIT does not present contraindications if its recommendations are followed correctly and used by a specialized and skilled professional, who will be responsible for the proper planning of the surgical procedure in which it will be used. None of the instruments are for permanent/implantable use, but only for transient use during the surgical procedure.

## SIDE EFFECTS

The SW Short Drill Kit has no adverse effects provided that the choice of instrument and technique is appropriate to the procedure.

## PRECAUTIONS AND RECOMMENDATIONS

The SW SHORT DRILL KIT requires specialized surgical procedures, only to be used by qualified dental surgeons.

It is recommended to use between 20 to 30 perforations, which are:  
20 high-density bone perforations;  
30 low-density bone perforations.

It is recommended that immediately after use, the kit and its components are washed and sterilized.

Do not stick labels, tapes, as well as write, or mark the surface of the product.

## WARNING

Do not use the instrument if you notice cracks, wear or oxidation/corrosion points. This may cause problems in the operation of dental drilling. All items may appear a 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. products - The Implant System has sequential batches that allow traceability, thus promoting, greater security to the professional qualified to the procedure. Through this batch number, it is possible to know the entire history of the product, from the manufacturing process to the distribution time.

## STORAGE

The SW Short Drill Kit should be stored in a dry, fresh, ventilated place away from direct sunlight;

## TRANSPORTATION

The SW Short Drill Kit should be transported at room temperature, away from direct sunlight, avoiding locations where large variations in temperature and humidity occur. The transportation must be carried out properly, in order to avoid falls and it must be carried out in its original package.

## HANDLING CONDITIONS

Once sterilized, instruments should be handled only in a sterile environment by properly trained professionals and in appropriate attire at the time of surgery to install dental implants.

## ADDITIONAL INFORMATION

Multiple use product. Reprocessing Allowed. Check Cleaning and Sterilization Conditions included in these Use Instructions.

## CLEANING INSTRUCTIONS

### 1. Pre-cleaning or De-embedding

- a. Remove the organic matter from the instruments without manual contact.
- b. Begin cleaning or de-embed quickly after surgical use.

### Recommendations

- a. Wear appropriate scrubs (gloves, masks, goggles, caps, etc.).
- b. Use enzyme solutions at the concentration and time of exposure determined by the manufacturer of these chemical solutions.
- c. Perform a single rinse, directly in a stream of water, without the handling of the instruments.

## 2. Decontamination

- a. The cleaning of microorganisms in vegetative form
- b. This type of cleaning offers occupational hazards.

### Recommendations

- a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
- b. Never use saline solutions, especially sodium Hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

## 3. Washing

- a. It is the removal of debris from surgical instruments through manual brushing or ultrasonic vibrations.

### Recommendations

- a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
- b. Use neutral soap at 1% or neutral detergent, both at pH 7.0.
- c. Always use brushes with natural or Nylon bristles for cleaning racks, serrations and fittings.
- d. Never use steel straws or sponges and abrasive products not to damage the instruments.
- e. Do not accumulate instruments in large quantities on top of one another, to avoid deformation of minor and delicate parts.
- f. Try to handle a few pieces at a time.
- g. Ultrasonic cleaning, if used, should have the washing solution heated to a temperature of at least 45°C and the instruments should be placed in the open position for 3 to 5 minutes of immersion at a frequency of 35 KHz.
- h. There may also be the need to brush the serrated parts and joints.

## 4. Rinse

- a. It is the removal of chemical residues, detergents and foams still present in the instruments.

### Recommendations

- a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated, to facilitate cleaning, this temperature should be between 40°C and 45°C.
- b. Never use saline solutions, especially sodium Hypochlorite and physiological saline, disinfectants, hydrogen peroxide, or alcohol for cleaning or rinsing surgical instruments.

## 3. Drying

- a. It is the removal of residual water and moisture, after the rinsing procedure.

### Recommendations

- a. Never let the instrument dry naturally.
- b. Always use soft, absorbent fabric (e.g. Compressed material) or moisture-free compressed air.
- c. Never use dry heaters to dry the S.I.N. Instruments.

## STERILIZATION

It is the procedure that aims at the total elimination of microorganisms (viruses, bacterias, microorganisms, and fungi), either in vegetative or sporulated form.

### Recommendations

- a. Dry all instruments before the steam sterilization cycle.
- b. Use mechanical and chemical indicators (place the internal chemical indicator between the instruments or materials to be sterilized) for each sterilization cycle.
- c. Allow instruments to dry and cool in the sterilizer before handling, to prevent contamination and oxidation of materials.

- d. The autoclavable case can be sterilized at 121°C at 1 ATM pressure for 30 minutes or at a temperature of 134°C at 2 ATM pressure for 20 minutes.
- e. Always place the case in an autoclave on a flat surface and away from the edges of the device.
- f. Never overlap objects or even other cases.
- g. The chemical sterilization is not recommended as some products may cause discoloration and damage to the case.

### DISPOSAL OF MATERIALS

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

### EXPIRATION DATE

Indicated on the label.