






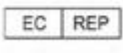


SYMBOLOLOGY	DESCRIÇÃO	DESCRIPTION	DESCRIPCIÓN
	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO 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
Rx only	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTES 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:

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TECHNICIAN RESPONSIBLE:

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CREA-SP: 5061207169

PRODUCT:

Male Thread

Anvisa Registration: 80108910032

CE

Male Threads are intended 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

Male Threads, also known in the market as Thread Mills, are instruments used in surgeries for the installation of dental implants.

INDICATIONS OF USE

The Male Thread is indicated for the formation of type I and II bone threads during the surgical procedure. They are suitable for all implant models.

OPERATION PRINCIPLE

The principle of operation of the Male Thread is based on the formation of threads in the alveolus for a better insertion of the dental implant.

DIRECTIONS

1. Select the Male Thread necessary to obtain the proper drilling of the place taking into account the desired length and width.
2. Prior to first use or after having been used in surgical procedures, follow the cleaning and sterilization recommendations contained in these use Instructions.
3. Ensure that the male thread is properly sterilized at the time of the procedure;
4. Perform the desired drilling;
5. Continue the surgical procedures.

CONTRAINDICATIONS

Male Threads are better used where the following situations do not exist:

- Atrophic bone ridge, where the quantity and quality of the remaining bone cannot provide adequate height and thickness of bone tissue around the implant;
- Places with bone diseases or infections;
- Individuals addicted to tobacco, alcohol or chemicals;
- Individuals with poor health (eg.: Blood disorders, diabetes);
- Individuals with exacerbated functional habits (eg.: bruxism).

SIDE EFFECTS

Failure to do so may occur due to factors intrinsic to the surgical procedure in the mouth, such as the local conditions and health of the implanted individual and the skill and knowledge of the professional who practices it.

PRECAUTIONS AND RECOMMENDATIONS

1. The product should only be used by qualified dentistry professionals who already have all the scientific information necessary for the correct use of the product.
2. The professional should sterilize it by autoclaving.

WARNING

Do not use male threads if you notice cracks, wear or oxidation/corrosion points. This may cause instrument performance problems. All items may present natural wear due to 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 traceability, which promotes greater safety for 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 until the moment of distribution

STORAGE

Male Threads must be stored in a cool and dry place, keep away from sunlight.

TRANSPORTATION

Male Threads must be transported in room temperature, away from direct sunlight, avoiding places with great temperature and humidity instability. The transportation must be carried out properly to avoid falls and it must be carried out in its original package.

HANDLING CONDITIONS

Once sterilized, male threads should only be handled in a sterile environment by properly trained professionals and in appropriate attire at the time of the surgical procedure.

COMPLEMENTARY INFORMATION

Multiple use product. Reprocessing Allowed. Refer to the cleaning and sterilization conditions contained in these Instructions.

DISPOSAL OF MATERIAL

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

EXPIRATION DATE

Indicated on the label.

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 shortly 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. Cleaning

- 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 for easy 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.

Try to handle a few pieces at a time.

Ultrasonic cleaning, if used, should have the washing solution heated to 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.

There may also be the need to brush the serrated parts and joints.

4. Rinsing

- 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.

5. 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. compresses) 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, bacteria, microorganisms, and fungi), either in vegetative or sporulated form.

Recommendations

- a. Dry all instruments before the steam sterilization cycle.
- a. Use mechanical and chemical indicators (place the internal chemical indicator between instruments or materials to be sterilized) for each sterilization cycle.
- b. Allow instruments to dry and cool in the sterilizer before handling to prevent contamination and oxidation of materials.
- c. 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.
- d. Always place the case in an autoclave on a flat surface and away from the walls of the unit.
- e. Never overlap objects or even other cases.
- f. Chemical sterilization is not recommended as some products may cause discoloration and damage to the case.