








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
<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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## PRODUCT:

Impression Trays

**Anvisa Registration:** 80108910021

**IMPRESSION TRAYS** 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

Impression Trays are produced in polycarbonate and available in sizes small in yellow, medium in color green and large in color blue.

## INDICATIONS OF USE

Impression Trays are indicated in the molding of total upper and lower dental arches; Moldings for the confection of prosthesis over implants and modeling of orthodontic, study and prosthetic documentation;

## OPERATION PRINCIPLE.

The working principle of the Impression Trays is based on the reproduction of impression molds from the impression material.

## HOW TO USE

1. Autoclave the impression tray prior to use;
2. Check the dental arch characteristic of the patient;
3. Select the size that best suits the patient without hurting him/her.
4. Fill with suitable molding material;
5. Take the tray to the patient's mouth with the impression material and wait for it to set, then remove it.
6. For implant molding, establish the cutting area of the impression tray and proceed cut with rotary instruments in low rotation.

## CONTRAINDICATIONS

Not applicable.

## SIDE EFFECTS

Not applicable.

## PRECAUTIONS AND RECOMMENDATIONS

Impression trays are available in non-sterile form and sterilization is recommended prior to use.

## WARNING

It must be used by qualified professionals, who have the technical and scientific information necessary for the correct use of the Impression Tray.

The type of tray should be selected according to the dental arch of the patient;

## TRACEABILITY

All S.I.N. products - 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 to the distribution time.

## STORAGE

Impression Trays should be stored in a dry, fresh and ventilated place away from direct sunlight;

## TRANSPORTATION

Impression Trays must be transported at room temperature away from direct sunlight, avoiding places where greater 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, the trays should only be handled in a sterile environment by properly trained professionals in suitable clothing.

## COMPLEMENTARY INFORMATION

Multiple use product. Reprocessing Allowed. Refer to the cleaning and sterilization conditions contained 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 under a stream of water, without handling 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 dirt from surgical instruments by manual brushing or ultrasonic vibrations.

#### Recommendations

- a. Always use distilled, deionized or demineralized water for this procedure. If the water is heated for easier washing, 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.

For ultrasonic cleaning, a wash solution should be heated to a temperature of at least 45°C and 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. 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.

### 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. 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 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 may be sterilized at 121°C at 1 ATM pressure for 30 minutes or at 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.