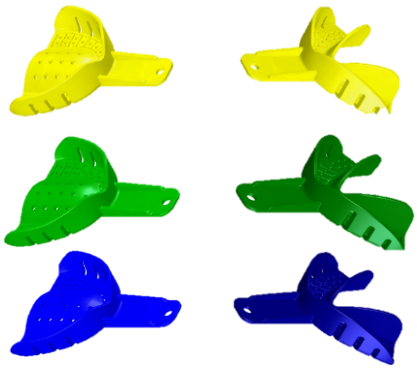
IMPRESSION TRAYS

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 artery 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.

ATTENTION

The molds are intended for specialized procedures, which must be performed by qualified professionals in implant dentistry. The use of the product must be performed in a surgical environment and under adequate conditions for the patient's health and safety.

PRECAUTIONS

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

RECOMMENDATIONS

It is recommended to sterilize the trays before use.

CONTRAINDICATIONS

Not applicable.

SIDE EFFECTS

Not applicable.

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. - Implant System products have sequential batches that allow for traceability, thus providing greater security to the professional who is qualified for the procedure. Through this lot number it is possible to know the entire history of the product from the manufacturing process to the moment of distribution.

STORAGE

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

HANDLING

Once sterilized, trays should be handled only in a sterile environment by properly dressed professionals in appropriate attire.

DISPOSAL OF MATERIAL

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

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.

COMPLEMENTARY INFORMATIONS

Single use product. Reprocessing prohibited. Product for odontological use only. In case of any incident caused by the product, the professional must immediately inform the manufacturer. 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 all the molding material under running water and only proceed to the next step when you have done this.
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

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.

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. - Implant System.

	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	NÃO REUTILIZAR	DO NOT REUSE	NO LO REUTILICE
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	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
	NÃO REESTERILIZE	DO NOT RESTERILIZE	NO LO REESTERILIZAR
	ATENÇÃO	CAUTION	PRECAUCIÓN
	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
	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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PRODUCT: Impression Trays

ANVISA REGISTRATION: 80108910021