



SOUTHERNIMPLANTS®

Innovative Treatment Solutions

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Intended Use

The perforated trays are used to hold dental tools and instruments in place during transport, steam sterilization and storage. The instrument trays are reusable devices. The instrument trays are medical device.

Intended User

Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists, and other appropriately trained and experienced implant users.

Intended Environment

The devices are intended to be used in any standard autoclave as well as in the clinical environment such as an operating theatre or a dental consultation room.

Intended Patient Population

Patients that have lost one tooth or multiple teeth.

Description

The device 'instrument tray' is a reusable rigid container or organizing tray intended for use in health care facilities for the purpose of organising, containing, and transporting reusable medical devices for sterilization. It is composed of multiple pieces, designed to be integrated into a single unit which contains and protects the interior components during steam sterilization. Each tray consists of three components: a base tray, a lid and an internal individualized insert tray. All three of the tray's components are perforated for steam sterilization, with the insert tray allowing steam to penetrate through the retention sockets (grommets) which are made from silicone. The internal insert tray and base has the ability to hold individualized pieces and accessories which include dental tools, drills and ratchets / wrenches.

The lid is made from Radel R-5800 and is tinted a transparent blue or gray. The base and insert tray are made of Radel R-5000 and has a white colour. The Radel material is a polymer resin. The base and insert trays are layered with medical grade silicon layers to locate and hold the various tools and instruments.

Table 1 - Corresponding instrument tray with implant system

Product Code	Implant System
CH-I-ZYG	ZAGA®
I-HEX-EG	External Hex, PROVATA®
I-T-EG	IT (Internal Octagon)
I-PROS-EG	Applicable to all Southern Implant systems
I-TRI-NEX-EG	TRI-NEX®
I-DC-EG	Deep Conical
I-INT-HEX-EG	Internal (M) Hex
I-MAX-EG	Tri-Max, Max, ProMax, IT-Max
I-PROS-MINI	Applicable to all Southern Implant systems
I-ZYG-1	Zygomatic
I-IV-EG	INVERTA® Deep Conical & INVERTA® External Hex

Indications for Use

Southern Implants Instrument trays are designed to hold various dental surgical drills and tools in order to organize, steam sterilize and transport the tools and instruments between uses.

Contraindications

- Patients under the age of 18
- Poor bone quality
- Blood disorders
- Infected implant site
- Vascular impairment
- Uncontrolled diabetes
- Drug or alcohol abuse
- Chronic high dose steroid therapy
- Anti-coagulant therapy
- Metabolic bone disease

- Radiotherapy treatment
- Sinus pathology

Warnings

THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.

- For the safe and effective use of dental implants it is suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.
- Responsibility for proper patient selection, adequate training, experience in the placement of implants, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves/vessels and/or loss of supporting bone.

Cautions

New and experienced Implant users should do training before using a new system or attempt to do a new treatment method. Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue (i.e. poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone and patients who had oro-facial radiotherapy). Thorough screening of prospective implant candidates must be performed including:

- a comprehensive medical and dental history.
- visual and radiological inspection to determine adequate bone dimensions, anatomical landmarks, occlusal conditions and periodontal health.
- bruxism and unfavourable jaw relations must be taken into account.
- proper pre-operative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- minimizing the trauma to the host tissue increases the potential for successful osseointegration.
- electro-surgery should not be attempted around metal implants, as they are conductive.

Principles of Operation

The rigid multi-piece tray holds dental device apparatus and accessories before, during and after the sterilization process. The tray set has a locking lid to contain the products. The trays are designed to fit any standard autoclave, which allows it to be effective for sterilization and be able to withstand the environment of repeated steam sterilization and be able to withstand the environment of repeated steam sterilization cycles in normal operating room. Since the trays are perforated, an FDA cleared sterilization wrap must be used for sterilization purposes to maintain the sterility of the contents. Please refer to product catalogues for tray layouts. The instrument trays are intended to be reusable, however they cannot be repaired or serviced if damaged.

Storage, cleaning and sterilisation

The trays are reusable and the tray material allows repeated sterilization cycles and supplied non-sterile. If packaging is damaged do not use the product and contact your Southern representative/ or return to Southern Implants. The devices must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

The Southern Implants Instrument Tray is designed to hold various dental surgical drills and tools in order to organize, steam sterilize, and transport the instruments between uses. The tray is to be enclosed in an FDA cleared steam sterilizable wrap and sterilized in an FDA Cleared sterilizer for one of the following cycles:

- Pre-vacuum Steam – At 132°C for 4 minutes with a 20 minutes dry time.
- Pre-vacuum Steam – At 135°C for 3 minutes with a 20 minutes dry time.

The trays are not intended for sterilization of non-porous loads.

The trays are recommended not to be stacked during sterilization.

The Complete Surgical Trays represent the worst-case validated load due to number of components (Large: 21 Medium: 90 and Small: 25

instruments) and the weight (Large: 752; Medium: 672 and Small 280 grams).

Southern Implants (Pty.) Ltd. does not make any lumen claims for the Southern Implants Instrument Trays.

Place the pre-cleaned devices in the instrument trays. Load devices into a thermo-disinfector. Run the cleaning and disinfection cycle, followed by the drying cycle. Always follow the instructions for use of the manufacturers of cleaning agents and disinfectants.

Sterilization

Southern Implants recommends the following procedure to sterilise the restoration prior to use:

Methods to sterilize the restoration and abutment screw

1. Pre-vacuum sterilization method: Steam sterilise the abutments at 132°C (270°F) at 180-220kPa for 4minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilization must be used.
2. Pre-vacuum sterilization method: Wrapped, steam sterilize at 135°C (275°F) for 3minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilization cycle.

NOTE: Users in the USA must ensure that the sterilizer, wrap or pouch, and all sterilizer accessories are cleared by the FDA, for the intended sterilization cycle.

Materials

Lid: Radel R-5800
Base and insert tray: Radel R-5000
Grommets: Medical grade silicone

Disposal

Disposal of the device and its packaging; Follow local regulations and environmental requirements, taking different contamination levels into account. When disposing of spent items, take care of sharp drills and instruments. Sufficient PPE must be used at all times.

Disclaimer of liability

This product is part of the Southern Implants product range and should only be used with the associated original products and according to the recommendations as in the individual product catalogues. The user of this product has to study the development of the Southern Implants product range and take full responsibility for the correct indications and use of this product. Southern Implants does not assume liability for damage due to incorrect use. Please note that some Southern Implants products may not be cleared or released for sale in all markets.

Notice regarding serious incidents

Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device and the competent authority in the member state in which the user and / or patient is established.

The contact information for the manufacturer of this device to report a serious incident is as follows:

sicomplaints@southernimplants.com

Basic UDI

Product	Basic-UDI Number
Basic-UDI for Surgical Trays	600954403877

Symbols and Warnings

 Manufacturer: Southern Implants 1 Albert Rd, P.O Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046	 2797	 Prescription device*	 Sterilization using Irradiation	 Non-sterile	 Caution	 Consult instruction for use	 Use by date (mm-yy)	 Do not reuse	 Do not re-sterilize	 Batch code	 Do not use if package is damaged	 Medical Device
* Prescription device: Rx only. Caution: Federal Law restricts this device to sale by or on the order of a licenced physician or dentist.						Canada licence exemption: Please note that not all products may have been licensed in accordance with Canadian law.						
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Related literature & catalogues

CAT-2004 - Tri-Nex® Implants Product Catalogue
 CAT-2005 - IT Implants Product Catalogue
 CAT-2010 - Osseointegrated Fixtures Catalogue
 CAT-2020 - External Hex Implants Product Catalogue
 CAT-2042 - Deep Conical Implants Product Catalogue
 CAT-2043 - Internal Hex Implants Product Catalogue
 CAT-2060 - PROVATA® Implants Product Catalogue
 CAT-2069 - INVERTA® Implants Product Catalogue
 CAT-2070 - Zygomatic Implants Product Catalogue