

English

INSTRUCTIONS FOR USE: Southern Implants® Instrument Trays



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Intended use

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

Description

The Southern Implants® Instrument Trays are reusable, multi-piece rigid containers or organizing trays designed for use in healthcare facilities to hold various surgical drills and instruments. Their primary purpose is to organize, contain, and transport non-porous, reusable medical devices for sterilization between uses. Each tray can consist of multiple components, including a base tray, a locking lid and an internal individualized insert tray, which are designed to integrate into a single unit that securely contains and protects the interior components during steam sterilization.

The components of the Southern Implants® Instrument Trays are perforated and/or have sufficient air gaps to facilitate steam sterilization. Additionally, select insert trays features retention sockets (grommets) made from silicone to allow steam penetration. The Instrument Trays are available in various dimensions enabling them to fit in any standard autoclave.

The lid is constructed from Radel R-5800 (a polymer resin), Stainless Steel, or Aluminium. The base and insert trays are made from Radel R-5000 or Aluminium.

The instruments to be sterilized in the proposed tray, are all non-porous devices and include dental surgical drills and tools. The instrument trays are intended to be reusable, however they cannot be repaired or serviced if damaged. Since the trays are perforated, an FDA cleared sterilization wrap must be used for sterilization purposes to maintain the sterility of the contents. The trays are reusable and the tray material allows repeated sterilization cycles.

Table A – Corresponding instrument tray with implant system

Product Code	Implant System
CH-I-ZYG	Straumann Zygomatic Implant System
I-ZYG-1	Southern Implants Zygomatic Implant System
I-HEX-EG	External Hex and PROVATA® Implant Systems
I-IT-EG	Internal Octagon (IT) Implant System
I-TRI-NEX-EG	TRI-NEX® Implant System
I-DC-EG	Deep Conical Implant System
I-INT-HEX-EG	Internal (M-Series) Hex Implant System
I-MAX-EG	MAX Implants including TRI-MAX®, MAX, PROMAX®, MAXIT®
I-IV-EG	INVERTA® Deep Conical & INVERTA® External Hex Implants
I-SP-EG	Single Platform (SP1) Implant System
I-SP-GS1-EG	Single Platform (SP1) Implant System
I-SP-GS2-EG	Single Platform (SP1) Implant System
I-PTN-EG	Pterygoid and Nazalus External Hex Implants
I-PROS-EG	Applicable to all Southern Implant systems
I-PROS-MINI	Applicable to all Southern Implant systems
I-EO-EG	Osseointegrated Fixtures
I-PT-MT	External Hex Pterygoid Implants
I-BG-MT	Bhora Guided Surgery System

Table B – Tray Accessories

Product Code	Corresponding Trays
I-GS-TP	All Radel Trays with silicone grommets

Indications for use

The Southern Implants' Instrument Tray is designed to hold various dental surgical drills and tools in order to organise, steam sterilise, and transport the instruments between uses. The tray is to be enclosed in an FDA cleared steam sterilisable wrap and sterilised in an FDA Cleared steriliser 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 sterilisation of non-porous loads. The trays are recommended not to be stacked during sterilisation.

The Complete Surgical Trays represent the worst-case validated load due to number of components (Large: 25 instruments; Medium: 90 instruments; Small: 47 instruments) and the weight (Large: 752 grams; Medium: 672 grams; Small: 339 grams). Southern Implants (Pty) Ltd does not make any lumen claims for the Southern Implants' Instrument Trays.

Size (L x W x H)	Product Code	Number of Instruments	Weight of Tray (g)	Weight of Full Tray (g)	Vent to Volume Ratio (in ² /in ³)	For Use With
Large 26.8 x 14.7 x 5.5 cm	CH-I-ZYG	19	485.5	752	0.01	ZAGA Zygomatic Implants (K192651)
	I-ZYG-1	25	485	746	0.01	Zygomatic Implants (K093562; K173343)
Large (Milled) 25 x 14 x 3.4 cm	I-PT-MT	22	1742	1930.7	1.505	External Hex Implants (K232726)
Medium 18.7 x 13.5 x 5.5 cm	I-HEX-EG	90	348	672	0.013	External Hex Implants (K163634; K173706; K003620; K020617; K033171; K052490; K070841), Provata Implants (K180465)
	I-IT-EG	49	434	541	0.013	IT Implants (K061169)
	I-TRI-NEX-EG	60	390	547	0.013	Tri-Nex Implants (K070905)
	I-DC-EG	55	386	541	0.013	DC Implants (K163060)
	I-INT-HEX-EG	46	392	555	0.013	Provata Implants (K180465)
	I-MAX-EG	50	386	546	0.013	MAX Implants (K071161; K191054)
Small 14.8 x 9.5 x 5.5 cm	I-IV-EG	47	228	339	0.013	Inverta Implants (K181850)
	I-SP-EG	44	204.5	310	0.014	SP1 Implant System (K232418)
	I-SP-GS1-EG	47	204.5	339	0.014	SP1 Implant System (K232418)
	I-SP-GS2-EG	47	204.5	339	0.014	SP1 Implant System (K232418)
	I-PTN-EG	37	204.5	303	0.014	External Hex Implants (K232726) and DC Implants (K163060)
	I-PROS-EG	25	180.5	280	0.014	Abutments (K003620; K020617; K033171; K052490; K053478; K061169; K070841; K070905; K071161; K082651; K093562; K163634; K172160; K173343; K173706; K180465; K181850; K191054; K191250; K192651; K193084)
	I-PROS-MINI	7	122.5	147	0.056	
	I-EO-EG	55	180.5	304	0.013	Osseointegrated Fixtures (K161548)
Small (Milled) 13.0 x 7.0 x 5.4 cm	I-BG-MT	26	310	335	0.73	External Hex Implants (K232726); Tri-Nex Implants (K070905); DC Implants (K163060);

						Provata Implants (K180465); Inverta Implants (K181850); SP1 Implant System (K232418)
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Intended user

Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontists, 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.

Storage, cleaning and sterilisation

The trays are reusable and the tray material allows repeated sterilisation 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 device must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

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.

Sterilisation

The Southern Implants Instrument Tray is designed to hold various dental surgical drills and tools in order to organise, steam sterilise, and transport the instruments between uses. The tray is to be enclosed in an FDA cleared steam sterilisable wrap and sterilised in an FDA Cleared steriliser for one of the following cycles:

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

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

The trays are recommended not to be stacked during sterilisation.

The Complete Surgical Trays represent the worst-case validated load due to number of components (Large trays: between 19 and 25 instruments; Medium trays: between 46 and 90 instruments; Small trays: between 7 and 47 instruments) and the weight (Large trays: 746 to 752 grams; Medium trays: 540 to 672 grams; Small trays: 147 to 339 grams).

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

Contraindications

This product range does not present any contraindications as long as it is properly used for the indicated purpose.

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

- This product must be used sterile.
- The trays are not intended for sterilisation of non-porous loads.
- The trays are not recommended to be stacked during sterilisation.
- The trays are not recommended for sterilisation of loads containing devices with lumens.
- Instruments intended for sterilisation should be subjected to a validated cleaning process prior to sterilisation.
- Instrument loading should not exceed the worst-case validated loads, and instruments must not be double-loaded into spaces designed to accommodate only one device.
- Ensure that the instrument tray does not touch the walls of the autoclave to prevent melting.
- Ensure the instructions for use as stipulated by the autoclave manufacturer are followed.
- For sterilisation, the instrument tray should be wrapped in a sterilisable wrap that is FDA-cleared for the indicated cycles.
- Do not use the product if packaging is damaged.
- It is the clinician's responsibility to ensure that Southern Implants' products are used responsibly and according to the specified instructions for use.

Principles of operation

The rigid multi-piece tray holds dental device apparatus and accessories before, during and after the sterilisation process. The tray set has a locking lid to contain the products and is designed to fit any standard autoclave. Since the trays are perforated, an FDA cleared sterilisation wrap must be used for sterilisation purposes to maintain the sterility of the contents. The trays are reusable and the tray material allows repeated sterilisation cycles.

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.

Materials

Lid:	Radel R-5800 or Stainless Steel 304 or Aluminium 6082
Base and Insert Tray:	Radel R-5000 or Aluminium 6082
Grommets:	Medical Grade Silicone
Tray Accessories:	Titanium Grade 5 or Stainless Steel

Disposal

Before disposal of the device and its packaging, it is recommended to check and 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.

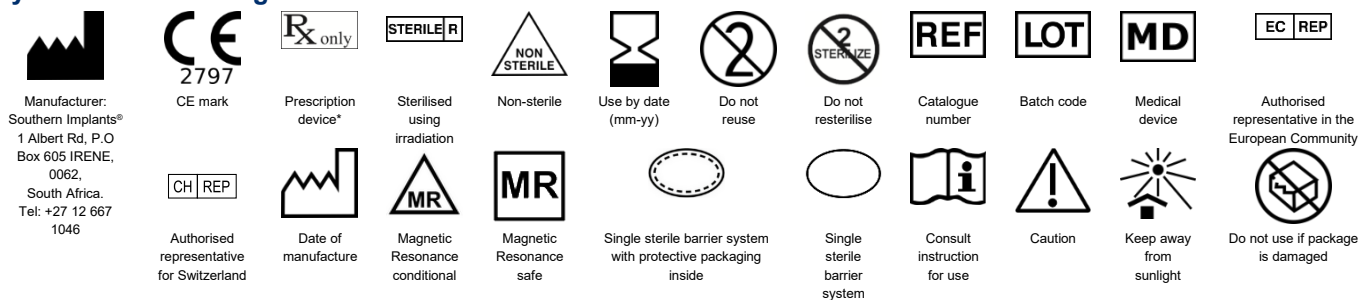
Basic UDI

Product	Basic-UDI Number
Basic-UDI for Instrument Trays	6009544039118P

Related literature and 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 - Deep Conical INVERTA® Implants Product Catalogue
 CAT-2070 - Zygomatic Implants Product Catalogue
 CAT-2088M - Nazalus Product Catalogue and Surgical Manual
 CAT-2089M - SIREAL Guided Surgery System Product Catalogue
 CAT-2092 - Deep Conical Pterygoid Implants Product Catalogue
 CAT-2093 - Single Platform Implants Product Catalogue
 CAT-2095 - External Hex INVERTA® Implants Product Catalogue
 CAT-2096 - External Hex Pterygoid Implants Product Catalogue

Symbols and warnings



* 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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