English

INSTRUCTIONS FOR USE: Southern Implants® Instrument Tray

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Description

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

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

Intended use

The Instrument Trays are intended to aid in the treatment of partially or fully edentulous patients eligible for placement of one or more dental implants as a means of fixing a permanent ore removable single crown, partial or full-arch dental prosthesis in the upper or lower jaw.

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), Pravata Implants (KI80465)
	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	Pravata Implants (KI80465)
	I-MAX-EG	50	386	546	0.013	MAX Implants (K071161; K191054)
Small 14.8 x 9.5x 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)

Intended user

The intended user for this system includes Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontists, Prosthodontists, and other appropriately trained and experienced implant users.

Intended environment

This device is intended to be used in a clinical environment such as an operating theatre or a dentist consultation room.

Intended patient population

The intended patient population for dental implant therapy includes partially or fully edentulous patients eligible or, otherwise, not contraindicated for implant placement that require prosthetic restoration or revision of existing restorations in the upper or lower jaw; where the planned restorations are to be fixed and comprise of single teeth, partial or full bridges.

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. In the Southern Implants' range there are 11 implant systems. The implant code and connection type can be identified by specific abbreviations in the product codes. Range identifiers are summarised in Table A.

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

Clinical benefits

The Instrument Trays are used as part of dental implant therapy, a procedure in which a patient's missing teeth and/or crowns are restored. As a result, the indirect clinical benefits of the Instrument Trays mirror those of dental implant therapy in general, including improved chewing function, speech, aesthetics, and patient psychological wellbeing.

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. prevacuum 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. for users in the USA: prevacuum sterilisation method: wrapped, steam sterilise at 135°C (275°F) at 180 - 220 kPa 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: between19 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.

Storage

Maintain packaging integrity to ensure sterility in storage. Packaging should be completely dry before storage to avoid corrosion and degradation of cutting edges.

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.

Side effects

Since the device is required or utilized as part of dental implant surgery, the side effects of the device are not dissimilar to those of dental implant therapy as a whole. Common side effects of dental implant therapy include pain, inflammation, phonetic difficulties and gingival inflammation. Other, less common side effects or complications to dental implant therapy include, but are not limited to: (1) wound dehiscence; (2) peri-implantitis; (3) transient weakness, numbness, and/or pain associated with mild nerve injury; (4) fat emboli formation; (5) marginal bone loss within acceptable limits; (6) allergic reaction(s) to implant and/or abutment material; (7) unspecified infection; (8) implant failure due to insufficient levels of osseointegration; (9) breakage of the implant and/or abutment; (10) loosening of the abutment screw and/or retaining screw; (11) complications requiring revision of the dental implant; (12) nerve damage resulting in permanent weakness, numbness, or pain; (13) loosening of the implant requiring revision surgery; (14) perforation of the maxillary sinus; (15) perforation of the labial and/or lingual plates and (16) bone loss possibly resulting in revision or removal of the implant.

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
Base and Insert Tray	Radel R-5000 or Aluminium
Grommets	Medical Grade Silicon

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.

Summary of Safety and Clinical Performance (SSCP)

As required by the European Medical Device Regulation (MDR; EU2017/745), a Summary of Safety and Clinical Performance (SSCP) is available for perusal with regard to Southern Implants® product ranges.

The relevant SSCP can be accessed at https://ec.europa.eu/tools/eudamed.

NOTE: the above website will be available upon the launch of the European Database on Medical Devices (EUDAMED).

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.

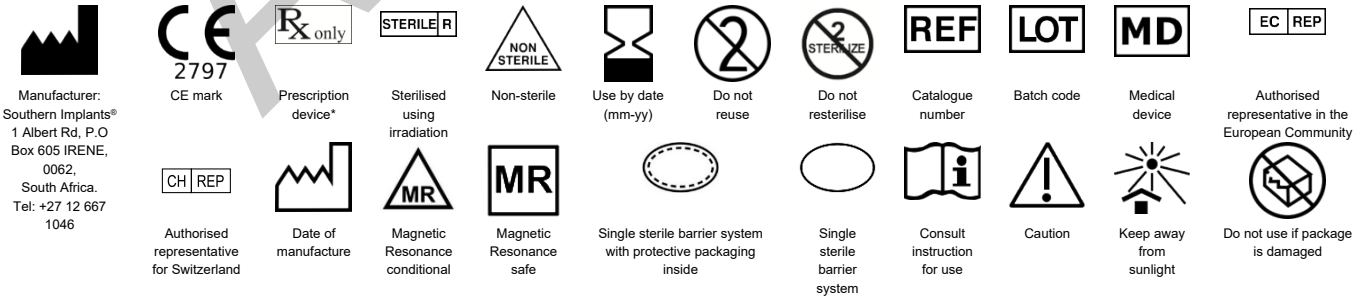
Basic UDI

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 - INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue
CAT-2093 - Single Platform 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.