

English

INSTRUCTIONS FOR USE: Straumann® ZAGA™ Instrument Trays



South Africa - Headquarters: 1 Albert Road, Irene, 0062, RSA
T: +27-12-667-1046 | E: info@southernimplants.com

Subsidiaries

United Kingdom and Ireland

Southern Implants UK
T: +44-20 8059 4490
E: info@southernimplants.co.uk

USA and Canada

Southern Implants North America Inc.
T: +1-561-472-0990
E: customercare@southernimplants.com

EC REP

Southern Implants Europe AB: Holmgatan 30, S-791 71 Falun, Sweden
T: +46 23 13300 | E: ecrep@southernimplants.com

CH REP

MedEnvoy Switzerland: Gotthardstrasse 28, 6302 Zug, Switzerland

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 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 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 has the ability to hold individualised 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 is white in 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 A – Corresponding instrument tray with implant system

| Product Code | Implant System |
|--------------|---|
| CH-I-ZYG | Straumann ZAGA™ Zygomatic Implant System |
| I-ZYG-1 | Southern Implants Zygomatic Implant System |
| I-PROS-EG | Applicable to all Southern Implants Systems |

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 9.5x 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) |
| 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) |

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. 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: 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
Base and Insert Tray: Radel R-5000
Grommets: Medical Grade Silicone

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-8049-STR - IFU - Straumann® ZAGA™ Zygomatic Implants
CAT-8047-STR - IFU - Straumann® ZAGA™ Screw-Retained Abutments
CAT-8051-STR - IFU - Straumann® ZAGA™ Cover Screws
CAT-8048-STR - IFU - Straumann® ZAGA™ Drills & Handpiece Instruments
CAT-8080-STR - IFU - Straumann® ZAGA™ Reusable Instruments
CAT-8083-STR - IFU - Straumann® ZAGA™ General Use Instruments

Symbols and warnings

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| Manufacturer: Southern Implants® 1 Albert Rd, P.O Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046 | CE mark 2797 | Prescription device* | Sterilised using irradiation | Non-sterile | Use by date (mm-yy) | Do not reuse | Do not resterilise | Catalogue number | Batch code | Medical device | Authorised representative in the European Community |
| |  |  |  |  |  |  |  |  |  |  | |
| | Authorised representative for Switzerland | Date of manufacture | Magnetic Resonance conditional | Magnetic Resonance safe | Single sterile barrier system with protective packaging inside | Single sterile barrier system | Consult instruction for use | Caution | Keep away from sunlight | Do not use if package is damaged | |

* 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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