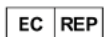


English

INSTRUCTIONS FOR USE: Southern Implants® Cover Screws



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Description

Cover screws are pre-manufactured temporary dental implant components used during the initial healing phase following implant insertion. They connect to the implant and seal the connection of the implant. The cover screw has a low profile so that soft tissue can be sutured closed over it. Cover screws have built in screws for retention to the implant and are made of commercially pure titanium. All Southern Implants cover screws are provided sterile.

Intended use

Abutments are intended to aid in the treatment of partially or fully edentulous patients eligible for placement of one or more dental implants in the maxilla and/or mandible. Specifically, a cover screw is intended to be connected to an endosseous dental implant to seal the internal screw thread and implant platform during the healing phase and keep the soft tissue clear of the implant interface.

Cover screws are classified as medical devices and are intended for single use on a single patient.

Indications for use

Southern Implants Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- replacing single and multiple missing teeth in the mandible and maxilla,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
- loading in all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

Intended user

Dental Technicians, 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 a clinical environment such as an operating theatre or a dentist consultation room.

Intended patient population

This device is used in the dental restoration of partially or fully edentulous patients in the upper or lower jaw. Restorations may comprise of single teeth, partial or full bridges, and may be fixed or removable.

Compatibility information

Southern Implants' implants should be restored with Southern components. In the Southern Implants range there are 8 implant connections. 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

| Implant connection type | Compatible device |
|------------------------------------|---|
| External Hex (EX) | Parts labelled SCP-2, SCNU2, SCU2, SCAU5, SCU6, SC7, CS-ZYG* |
| Tri-Nex (EL) (Lobe) | Parts labelled CS-L-(Ø) |
| Deep Conical (DC) | Parts labelled CS-DC(Ø) |
| Internal Hex (M) | Parts labelled CS-M (used with Ø3.75, 4.2 and 5.0 mm platforms) |
| Internal Hex PROVATA® (M) (Z) | Parts labelled CS-3M (used with Ø3.3 mm platform) |
| | Parts labelled CS-M (used with Ø4.0, 5.0 and 6.0 mm platforms) |
| | Parts labelled CS-Z (used with Ø7.0, 8.0 and 9.0 mm platforms) |
| IT (ITS) (ITS6) - Internal Octagon | Parts labelled TT0 (used with Ø4.8 mm platforms) |
| | Parts labelled TT6-0 (used with Ø6.5 mm platforms) |
| External Hex ZAGA™ Zygomatic (CH) | Parts labelled CH-CS |
| Single Platform (SP) | Parts labelled CS-SP (used with Ø3.5, 4.0 and 5.0 mm implants) |

NOTE: *CS-ZYG is only for use with the ZYGIN Zygomatic Implants

NOTE: Internal Hex (M-Series) implants are packaged with a cover screw (CS-M) except for IM-T4218 (18 mm length) implant.

Clinical benefits

The clinical benefits of the device are not dissimilar to that of dental implant therapy.

Clinical benefits of dental implant therapy include improved chewing function, speech, aesthetics, and patient psychological wellbeing. Through this procedure patients can expect to have their missing teeth replaced and/or crowns restored.

Storage, cleaning and sterilisation

The component is supplied sterile (sterilised by gamma irradiation) and intended for single-use prior to the expiration date (see packaging label). Sterility is assured unless the container or seal is damaged or opened. 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. Do not reuse components indicated for single-use only. Reusing these components may result in:

- damage to the surface or critical dimensions, which may result in performance and compatibility degradation.
- adds the risk of cross-patient infection and contamination if single-use items are reused.

Southern Implants® does not accept any responsibility for complications associated with reused single-use components.

Contraindications

Do not use in patients:

- who are medically unfit for dental implant procedures.
- where adequate numbers of implants could not be placed to achieve full functional support of the prosthesis.
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6Al-4V), gold, palladium, platinum or iridium.
- who are under the age of 18, have 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 and sinus pathology.

Warnings and precautions

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

- For the safe and effective use of dental implants it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.
- Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.

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. Implant failure increases when implants are placed in irradiated bone as radiotherapy can result in progressive fibrosis of vessels and soft tissue, leading to diminished healing capacity.

It is important to be aware and avoid damage to vital structures such as nerves, veins and arteries. Injuries to vital anatomical structures may cause serious complications such as injury to the eye, nerve damage and excessive bleeding. It is essential to protect the infraorbital nerve. Failing to identify actual measurements relative to the radiographic data could lead to complications.

New and experienced implant users should do training before using a new system or attempting 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 orofacial 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 preoperative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- minimising the trauma to the host tissue increases the potential for successful osseointegration.
- electrosurgery should not be attempted around metal implants as they are conductive.

Should the device not operate as intended, it must be reported to the manufacturer of the device. The contact information for the manufacturer of this device to report a change in performance is: sicomplaints@southernimplants.com.

Side effects

The side effects of the use of the system are not dissimilar to those of dental implant therapy. Possible side effects to implant therapy include:

- pain.
- swelling.
- phonetic difficulties.
- gingival inflammation.

Less common but more persistent symptoms include, but are not limited to:

- allergic reaction(s) to implant and/or abutment material.
- breakage of the implant and/or abutment.
- loosening of the abutment screw and/or retaining screw.
- infection requiring revision of the dental implant.
- nerve damage resulting in permanent weakness, numbness, or pain.
- histologic responses with possible macrophage and/or fibroblast involvement.
- fat emboli formation.
- loosening of the implant requiring revision surgery.
- perforation of the maxillary sinus.
- perforation of the labial and lingual plates.
- bone loss possibly resulting in revision or removal of the implant.

Precaution: maintaining sterility protocol

Implants are packaged as follows:

1. An outer package consisting of a rigid, clear box which acts as protection for the inner package.
2. The inner package consisting of a blister pack (clear plastic-formed blister base with a TYVEK “peel-back” lid).
3. Within the inner package, there is a hollow tube which contains one implant suspended from a titanium ring, this ensures the implant never touches the inside of the plastic tube.
4. Labelling information is located on the surface of the peel-back lid and on the outside of the rigid box.

Care must be taken to maintain the sterility of the implant by proper opening of the packaging and handling of the implant.

1. Open the implant package in the non-sterile field, with non-sterile gloves, tear the address label to open the box.
2. With non-sterile gloves, remove the inner blister pack. Do not place the plastic box or blister pack-lid onto the sterile field. The contents of this inner package are sterile.
3. The sealed blister is to be opened by an assistant (with nonsterile gloves): remove the TYVEK lid and drop or place the sterile tube onto the sterile field, open the tube cap and attach the implant placement tool onto the implant and carefully remove from the sterile tube. Do not touch the sterile implant.

Other sterile components are packed in a peel pouch or blister base with a “peel-back” lid. Labelling information is located on the bottom half of the pouch, inside the packet or on the surface of the peel-back lid. Sterility is assured unless the pouch is damaged or opened. Non-sterile components are supplied clean but not sterile in a peel pouch or blister base with peelback lid. Labelling information is located on the bottom half of the pouch or on the surface of the peel-back lid.

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

Material type Commercially Pure Titanium (Grade 4)

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.

MR safety

Nonclinical testing has demonstrated that the Southern Implants® dental implants, metallic abutments and prosthetic screws are MR conditional.

A patient with these devices can be safely scanned in a MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 3000 Gauss/cm (30 T/m).
- Maximum MR system reported SAR corresponding to Normal Operating mode for all landmarks (Head SAR of 2 W/kg for head landmark, 1 W/kg whole body (for landmarks within 30 cm of the implant) or 2 W/kg whole body (for landmarks more than 30 cm from the implant), and appropriate partial body SAR for other landmarks). For imaging landmarks above the thorax, 15 min of scanning at normal operating mode for landmarks greater than 30 cm from the implant with a whole body SAR of 1W/kg for imaging landmarks within 30 cm of the implant.
- In the non-clinical testing, the image artifact caused by the device extends approximately 20 mm from the Southern Implants dental implants, abutments and prosthetic screws, when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

Removable restorations should be taken out prior to scanning, as is done for watches, jewellery etc. Should there be no MR symbol on the product label, please note that this device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

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.

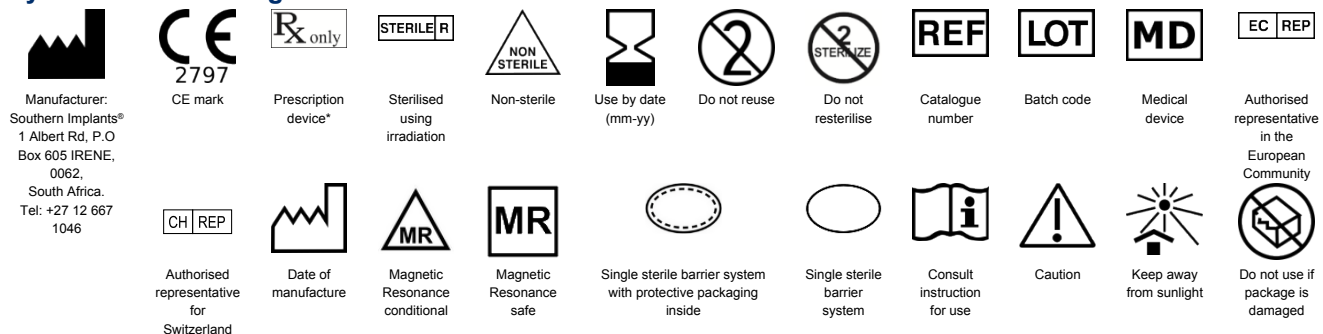
Basic UDI

| Product | Basic-UDI Number |
|-------------------------------|------------------|
| Basic-UDI for Metal Abutments | 60095440387296. |

Related literature and catalogues

CAT-2004 - Tri-Nex Implants Product Catalogue
 CAT-2005 - IT Implants Product 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-2010 - Osseointegrated Fixtures 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.

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