English

INSTRUCTIONS FOR USE: Southern Implants® Single Platform (SP1) implants

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

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

Subsidiaries

Australia
Southern Implants Australia
T: +61-(0)-8-9466-2627
E: info@southernimplants.com.au

Spain and Portugal
Southern Implants Iberica
T: +34 935 053 507
E: info@southernimplants.es

United Kingdom and Ireland
Southern Implants UK
T: +44-20-8899-6845 / 6 / 7
E: info@southernimplants.co.uk

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

Description

The Single Platform (SP1) implant is a self-tapping tapered implant made of commercially pure Grade 4 Titanium (UTS≥ 900 MPa). All implants are surface-roughened using Southern Implants' proven surface. The surface has an average Sa value of 1.4 microns. Tapered implants facilitate good stability for cases involving immediate loading and/or soft bone. Cover screws and healing abutments are supplied separately.

Intended use

This system is 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 or removable single crown, partial or full-arch dental prosthesis in the upper or lower jaw. These devices are intended to be placed into a pre-drilled site in the alveolar bone where they osseointegrate (form a rigid connection with bone), and an abutment is attached for retention of a prosthesis.

Indications for use

The Single Platform (SP1) Implant System is intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. The Single Platform (SP1) Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

The Single Platform SP1 implants in lengths 20, 22 and 24 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

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 a clinical environment such as an operating theater or a dentist consultation room.

Intended patient population

Patients that have lost one tooth or multiple teeth.

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. Use components that correspond to the connection type and prosthetic platform when restoring the Single Platform (SP1) implants. For further information see the Single Platform (SP1) Product Catalogue (CAT-2093).

Table A – Single Platform (SP1) implant range

Item Code	Implant Length Codes	Implant Lengths (mm)	Implant Diameter (mm)
MSC-SP35	08/ 10/ 11/ 13/ 16/ 18/ 20	8.0/ 10.0/ 11.5/ 13.0/ 16.0/ 18.0/ 20.0	Ø3.5
MSC-SP40	08/ 10/ 11/ 13/ 16/ 18/ 20/ 22/ 24	8.0/ 10.0/ 11.5/ 13.0/ 16.0/ 18.0/ 20.0/ 22.0/ 24.0	Ø4.0
MSC-SP50	08/ 10/ 11/ 13/ 16/ 18	8.0/ 10.0/ 11.5/ 13.0/ 16.0/ 18.0	Ø5.0

Clinical benefits

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.

Before surgery

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

During surgery
Take care that parts are not swallowed or aspirated during any of the procedures and apply the correct tightening torque to abutments and abutment screws.

CAUTION: identify and protect vital structures like nerves, veins, arteries and especially the infraorbital nerve during surgical exposure of the lateral maxillary wall. Injury to any of these anatomical structures can lead to complications like nerve dysfunction or bleeding. It is recommended that a minimal distance of 2 mm be maintained between the implant and critical anatomical structures. Additionally, it is recommended that a minimal of 1.5 mm of bone be maintained around each implant.

Post-surgery
Regular patient follow-up and proper oral hygiene must be achieved to ensure favourable long-term results.

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.

Observe the conditions of the intraoral tissue, bone quality and quantity of the site receiving the implant, through radiographic and/or tomography examinations. Not performing the pre-surgical assessment may compromise the success of the procedure. As for the systemic aspect, consider the general health of the patient. In particular, one must be careful in cases of patients who have allergies to drugs, local or systemic factors that may interfere with the healing

process of the bone tissues or soft tissues, or the process of osseointegration. Patient selection should consider the contraindications of the implant system and patients should exhibit sufficient mouth opening capacity to facilitate dental implant procedures.

Inadequate preoperative planning may compromise the performance of the implant/prosthesis assembly, resulting in system failure, such as loss or fracture of the implant, loosening or fracture of abutments and/or prosthetic screws. It is recommended that 3D imaging/ CBCT scanning be used to evaluate the proposed implant site and used to determine the required implant angulation, trajectory and depth prior to surgery.

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. It is recommended to raise a full thickness mucoperiosteal flap to aid in effective visualisation and irrigation of the site. It is recommended that a minimal distance of 2 mm be maintained between the implant and critical anatomical structures. Additionally, it is recommended that a minimal of 1.5 mm of bone be maintained around each implant.

Care must be taken to minimize damage to the host tissue and avoid bone overheating. In particular, special attention must be paid to thermal and surgical trauma and to the elimination of contaminants and sources of infection. All instruments used in surgery must be maintained in good condition and care must be taken that the instruments do not damage the implants or other components. All drilling procedures should be performed at maximum 1000-1500 rpm with copious irrigation. The use of sharp drills, sufficient irrigation, an in-and-out drilling motion, short cutting cycles, waiting for the bone to cool, and use of drills in successively increasing sizes are essential.

The use of postoperative radiography is recommended, where appropriate, to monitor trajectory during long dental implant placement and to verify final implant and abutment position/ seating.

The longer length implants (i.e. implant lengths ≥ 18 mm) are not intended for any specialized surgical technique or anatomic placements outside of the alveolar arches. The longer length implants should be restored using multiple-unit restorations with at least two (2) splinted implants.

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.

Application for longer length implants

The longer length Single Platform SP1 Implants (lengths ≥ 18 mm) are intended for surgical intraoral installation into bone types III/IV, for cases of total or partial edentulism, for multiple-unit prostheses. The longer length implants are not intended for any specialized surgical technique or anatomic placements outside of the alveolar arches. Refer to the product catalogue (listed under Related literature and catalogues) for the compatible abutments indicated for multiple-unit loading.

Note: For the purposes of immediate loading, good primary stability must be achieved (≥ 35 Ncm) with appropriate occlusal loading.

Preoperative Evaluation

A thorough clinical assessment must be done to determine the physical health of the patient. Take care when treating patients with local or systemic factors that could affect the healing process of the tissues or interfere with the osseointegration process (e.g. smoking, uncontrolled diabetes, radiotherapy, steroid therapy, poor oral hygiene, infection of the oral tissue and/or bisphosphonate therapy etc.).

Before surgery a proper radiographic examination should be done. Panoramic and CBCT should be taken. Analysis of the structure and shape of the intended placement site should be done with regard to vital anatomical structures and landmarks (e.g. maxillary sinus, nasal cavities, inferior alveolar nerve, infraorbital nerve, mental foramen, natural tooth positions, veins and arteries), as well as evaluating the bone quality and shape.

The model, diameter, length, position and quantity of implants must be selected for each clinical case, considering the anatomy, quality and quantity of bone and space available. When necessary, execute the wax-up diagnostic of the patient. In situations in which there are relatively high loads, special care must be taken to ensure the suitable alignment of the implant(s), abutment(s) prosthetics(s) and prosthesis.

Cautions:

- In cases of soft bone and minimal bone height, it is recommended to do a 2 stage procedure with prolonged healing time before the implants are loaded.
- Ensure that the mouth opening capacity of the patient is sufficient for implant surgery.
- Choose the appropriate size implant for the volume of bone available.

Handling procedures

Step 1: Initiate the osteotomy
NOTE: it is recommended to raise a full thickness mucoperiosteal flap to aid in effective visualisation and irrigation of the site.

The cortical perforator and leveller (D-GS-CP/D-GS-CP-4) or spade initiation drill (D-3SPADE-1.8) is used to initiate the osteotomy by perforating and levelling the cortical plate at the desired location (Fig. 1). All drilling should be performed at a speed of 1000-1500 rpm with copious irrigation. An intermittent technique should be used to avoid overheating of the bone.

Figure 1

Step 2: Ø2 mm Twist Drill
Drill with the Ø2 mm twist drill (D-20T-M10/15/20) to the implant length corresponding to the laser markings on the twist drills and direction indicator (Fig. 2 and Fig. 3).

NOTE: depth should allow the implant to inserted level or slightly submerged in the surrounding bone.

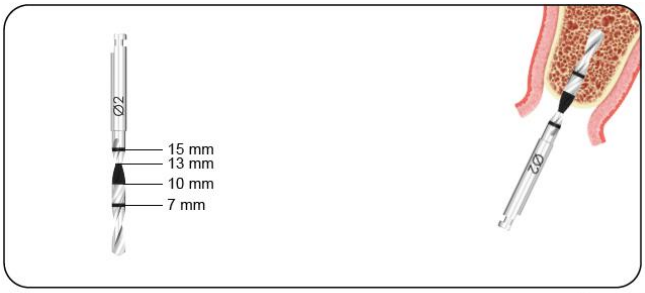


Figure 2

After using the Ø2 mm twist drill to verify the alignment with adjacent teeth/implants, insert the direction indicator (I-DI/I-DI-17D/I-DI-30D) (Fig. 3). A radiograph is taken at this point to verify the depth and angulation. If the drilling direction is incorrect, start a new osteotomy in the correct direction with the Ø2 mm twist drill.

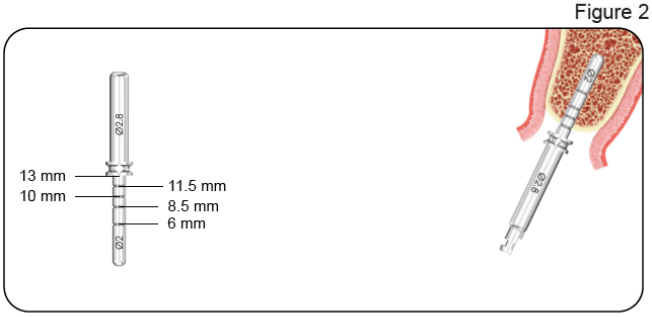


Figure 3

Step 3: Gradually enlarge the osteotomy
The Single Platform (SP1) tapered drills are diameter and bone density specific. Use the diameter drill corresponding to the implant that is selected. Widen the osteotomy intermittently to the desired diameter corresponding to the patient bone density (i.e., type I/II or type III/IV) (Fig. 4). Follow the recommended drill protocols for bone density by referring to catalogue.

NOTE: The Southern Implants drills must be used in accordance with their own instructions for use. For more information, consult the product catalogue (listed under **Related literature and catalogues**).

Caution
All drilling procedures should be performed at maximum 1000-1500 rpm with copious irrigation. The use of sharp drills, sufficient irrigation, an in-and-out drilling motion, short cutting cycles, waiting for the bone to cool, and use of drills in successively increasing sizes are essential.

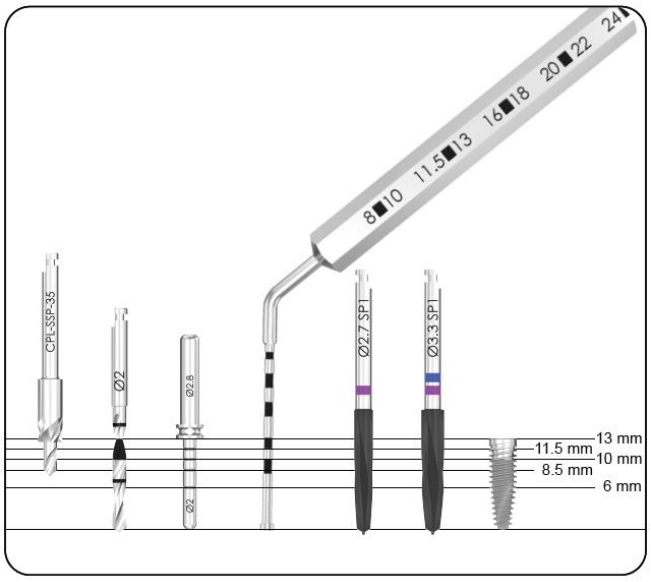


Figure 4: Illustrating the drilling protocol for the placement of a 13 mm implant

Step 4: Implant placement (tapered implants)
NOTE: see CAT-8056 for instructions on how to use placement tools.

Single Platform (SP1) placement tools have laser markings on them to indicate and assist in implant placement depth up to handpiece. Additionally, these placement tools have dimples aligning to the internal hex corners to aid to exact implant alignment for desired prosthetic placement. Connect the handpiece insertion tool (I-HSP-S/M) to the handpiece. Engage the internal hex of the implant with the insertion tool and carefully remove the implant from the sterile vial (the hexagon of the insertion tool must be fully engaged in the implant before torque is applied to prevent any damage (Fig. 5).

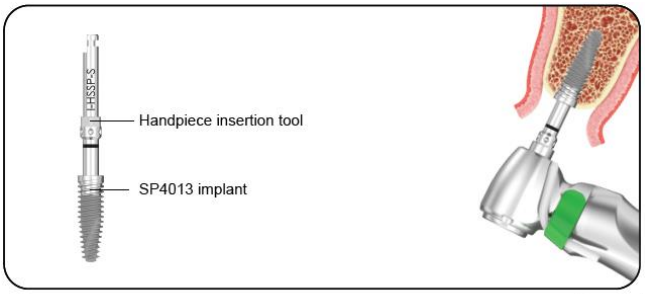


Figure 5

Alternatively, the wrench insertion tool (I-WI-SP-S/M) can be connected to the ratchet wrench (I-TWS), with wrench insert converter (I-WI-SS) and used to extract the implant from its packaging (Fig. 6). Insert the implant at 15 – 20 rpm while applying downward pressure.

Step 5: Fully seat the implant.
For the Single Platform (SP1) implants, the ratchet and torque attachment wrench (I-TWS with I-TWS-B100), in combination with the wrench converter (I-WI-CST) and hand-piece insertion tool (I-HSP-S/M) or the wrench insertion tool (I-WI-SP-S/M) with wrench insert converter (I-WI-SS) may be used for final manual seating of tapered implants (Fig. 6).

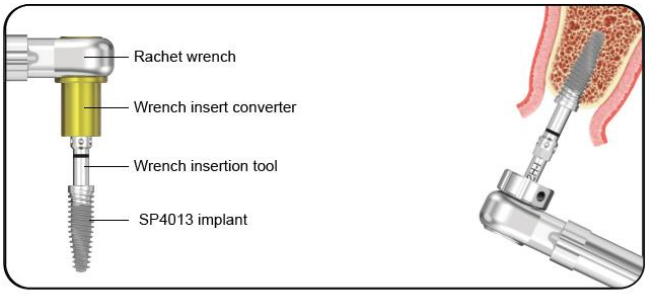


Figure 6

NOTE: use light finger force on the wrench when levelling the implant. Excessive torque (>70 Ncm) with the wrench should be avoided, as this will cause too much compression in the bone or damage to the implant. The implant should be retrieved and additional drilling should be performed in the site to widen the osteotomy site before reinsertion of the implant.

NOTE: as the implants are self-tapping, it is recommended to stop rotation once the implant has reached the prepared depth. The implant may continue to advance beyond the drilled depth with further rotations, owing to the effective self-tapping thread. Care should be taken not to countersink the implant too far, especially in soft bone. There is also a risk that the implant may spin.

Step 6: Prosthetic application
Restore the implant(s) using compatible mating abutments. It is recommended that should sufficient primary stability not be achieved for the implant, a cover screw should be placed for a two-stage protocol/ delayed loading.

The longer length implants are intended to be used in a multiple-unit configuration, with at least two implants splinted together. Prosthetic components used in these cases should be suitable for multiple-unit cases (i.e. prosthetic components should be non-engaging components).

Refer to the product catalogue (listed under **Related literature and catalogues**) for the compatible abutments.

Loading times

Healing period is generally 3-4 months in the mandible and 4-6 months in the maxilla; however, healing periods may vary for each patient. When a shorter healing time or immediate loading is being considered, the assessment must be based on the individual clinical situation (i.e., bone quality, bone quantity, primary stability achieved, loading conditions, design of superstructure, etc.). Implants may be immediately temporized on single or splinted multiple-unit restorations, if good primary stability is achieved. Immediately temporized restorations should be kept out of occlusion. The patient should adhere to a soft diet and place minimal forces on the restoration for 6-12 weeks.

Troubleshooting

- Implant mobility: if the fixture is very loose, consider removal and replacement with a wider diameter fixture, without further drilling.

- Poor fixture alignment: If the angular misalignment is less than 30°, the problem can be addressed using angulated abutments. If the angle is greater than 30°, remove the implant and allow the surgical site to heal for approximately six months.
- Exposed threads: if the implant threads are exposed in the coronal region, perform a bone augmentation procedure.
- Over countersinking: over countersinking can cause complications with primary stability in cortical bone. The countersink should not extend beyond the cortical region whenever possible. Continue with normal treatment protocol, but it is recommended to avoid immediate or early loading and to pay special attention to the stability of the implant in the first 3-6 months after placement.

Precaution: maintaining sterility protocol

Implants are packaged as follows:

1. An outer package consisting of a carton 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 carton 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, ASTM F67 and ISO5832-2, UTS≥ 900 MPa)

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 3.2 W/kg for head landmark, 2 W/kg whole body, and appropriate partial body SAR for other landmarks). For imaging landmarks above the thorax, a continuous scan time of 15 minutes will require a cooling delay of at least 5 minutes.
- 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.

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.

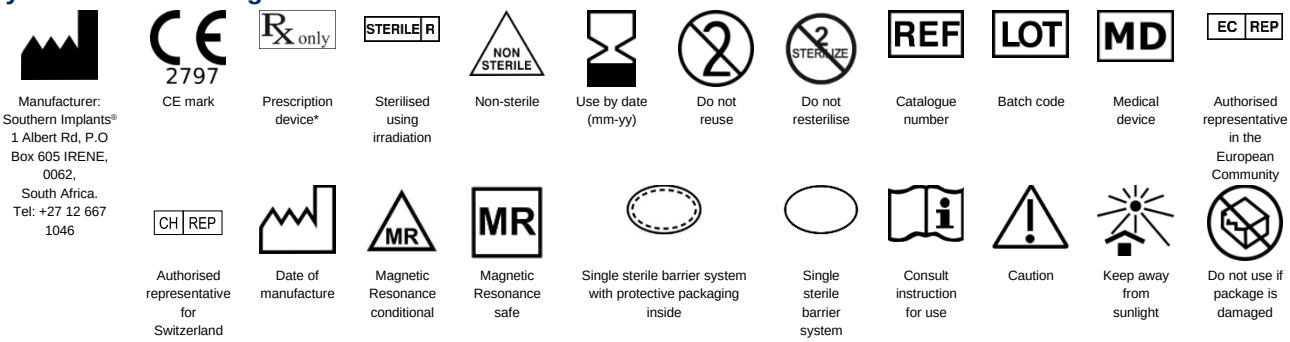
Basic UDI

Product	Basic-UDI Number
Basic-UDI for General Dental Implants	6009544038699H

Related literature and catalogues

CAT-2093 - Single Platform (SP1) 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.