English

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

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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

Southern Implants® Dental Implants are intended to be surgically placed in the upper or lower jaw to provide a support structure and point of attachment for prosthetic devices.

Indications for use

Southern Implants' dental implants are 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.

Southern Implants' dental implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

Intended user

Maxillofacial Surgeons, General Dentists, Orthodontists, Periodontists, Prosthodontists, and other appropriately trained and/or experienced medical professionals.

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

The intended patient population for dental implant therapy includes partially or fully edentulous patients eligible or, otherwise, not contraindicated for implant placement.

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/ 22/ 24	8.0/ 10.0/ 11.5/ 13.0/ 16.0/ 18.0/ 20.0/ 22.0/ 24.0	Ø3.5
MSC-SP37	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	Ø3.75
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
PT-SP40	10/ 11/ 13/ 15/ 18/ 20/ 22/ 24	10.0/ 11.5/ 13.0/ 15.0/ 18.0/ 20.0/ 22.0/ 24.0	Ø4.0
MSC-SP45	08/ 10/ 11/ 13/ 16/ 18	8.0/ 10.0/ 11.5/ 13.0/ 16.0/ 18.0	Ø4.5
MSC-SP50	08/ 10/ 11/ 13/ 16/ 18	8.0/ 10.0/ 11.5/ 13.0/ 16.0/ 18.0	Ø5.0
MSC-SP60	08/ 10/ 11/ 13/ 16	8.0/ 10.0/ 11.5/ 13.0/ 16.0	Ø6.0

Clinical performance

The General Dental Implants are intended to provide a support structure and point of attachment for prosthetic devices in the functional and aesthetic treatment of the partially or fully edentulous upper or lower jaw. The rigid and secure retention of the prosthetic devices are accomplished through the stability of the implant itself. This stability is achieved through the implant's surgical implantation into the bone and subsequent successful osseointegration. Consequently, the clinical performance of the General Dental Implants is primarily defined by the degree of osseointegration achieved. This performance can be quantitatively assessed through implant survival, which serves as an important indicator of the implant's effectiveness and long-term success in clinical practice.

Clinical benefits

Due to the critical role that the General Dental Implants play in the functional and aesthetic restoration of partially or fully edentulous patients, the clinical benefit associated with these devices is closely related to the outcome of the overall restorative treatment and not merely the clinical performance of the device itself.

The clinical benefits associated with the prosthetic restoration of edentulism are significant, as this treatment can greatly enhance the functional and aesthetic outcomes of the patient. Therefore, in defining the clinical benefit of the General Dental Implants, consideration should be given to the successful restoration of the edentulous state and the patient's satisfaction with the outcome. As such, in order to provide an overall measure of the clinical benefit, both the treatment/implant success rate and the patient's satisfaction should be considered. Patient satisfaction includes patient feedback and other Patient Reported Outcome Measures (PROMs) such as aesthetic and functional satisfaction surveys and quality of life questionnaires.

Furthermore, since this treatment addresses the functional and/or aesthetic impact of partial or full edentulism, it is anticipated that a successfully restored patient will experience an improvement in masticatory function and improved psychosocial wellbeing. However, these are considered indirect clinical benefits of the treatment and are difficult to measure and quantify. Therefore, with a successful treatment outcome, it is assumed that these also occur.

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

The contraindications of all device groups used as part of the specific treatment or procedure apply. Therefore, the contraindications of the systems/medical devices utilized as part of implant surgery/therapy should be noted and the relevant documents consulted.

The contraindications specific to this device group include:

- patients medically unfit for oral surgical procedures,
- cases where an adequate number of implants cannot be placed to provide full functional support of the prosthesis,
- patients with inadequate bone quality/quantity,
- patients with uncontrolled bleeding disorders,
- presence of infection at the implant site,

- patients with severe vascular impairment,
- patients with uncontrolled endocrine disorders,
- patients undergoing high dose steroid therapy,
- patients with metabolic bone disease,
- patients with incomplete mandibular or maxillary growth,
- patients with a weakened immune system or inadequate wound healing capacity
- patients with allergies or hypersensitivity to the material used (titanium).

Warnings and precautions

IMPORTANT NOTICE: THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQAUTE TRAINING

- To ensure the safe and effective use of dental implants, new technologies/systems and the Metal Abutment devices, it is strongly recommended that specialised training be undertaken. This training should include hands-on methods to gain competency on the proper technique, the system's biomechanical requirements and radiographic evaluations required for the specific system.
- Improper technique can result in implant failure, damage to nerves/vessels and/or loss of supporting bone.
- Use of the device with incompatible or non-corresponding devices can result in the poor performance or failure of the device.
- When handling devices intraorally, it is imperative that they are adequately secured to prevent aspiration, as aspiration of products may lead to infection or physical injury.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.
- Failure to adhere to appropriate cleaning, re-sterilization, and storage procedures as outlined in the Instructions for Use can result in device damage, secondary infections, or patient harm.
- Exceeding the number of recommended uses for reusable devices can result in device damage, secondary infection or patient harm.
- The use of blunt drills may cause damage to the bone, potentially compromising osseointegration.

It is crucial to emphasize that training should be undertaken by both new and experienced implant users prior to utilizing a new system or attempting a new treatment method.

Patient Selection and Preoperative Planning

A comprehensive patient selection process and meticulous preoperative planning are essential for successful implant treatment. This process should involve consultation among a multidisciplinary team, including well-trained surgeons, restorative dentists, and laboratory technicians.

Patient screening should include, at a minimum, a thorough medical and dental history, as well as visual and radiological inspections to assess the presence of adequate bone dimensions, the positioning of anatomical landmarks, the presence of unfavourable occlusal conditions, and the periodontal health status of the patient.

For successful implant treatment, it is important to:

1. Minimize trauma to the host tissue, thereby increasing the potential for successful osseointegration.
2. Accurately identify measurements relative to radiographic data, as failure to do so may lead to complications.
3. Be vigilant in avoiding damage to vital anatomical structures, such as nerves, veins, and arteries. Injury to these structures may result in serious complications, including ocular injury, nerve damage, and excessive bleeding.
4.

The responsibility for proper patient selection, adequate training and experience in implant placement, and the provision of appropriate information required for informed consent rests with the practitioner. By combining thorough screening of prospective implant candidates with a practitioner possessing a high level of competence in the use of the system, the potential for complications and severe side effects can be significantly reduced.

High Risk Patients

Special care should be exercised when treating patients with local or systemic risk factors that may adversely affect the healing of bone and soft tissue or otherwise increase the severity of side effects, the risk of complications, and/or the likelihood of implant failure. Such factors include:

- poor oral hygiene
- history of smoking/vaping/tobacco use
- history of periodontal disease
- history of orofacial radiotherapy**
- bruxism and unfavourable jaw relations
- use of chronic medications that may delay healing or increase the risk of complications including, but not limited to, chronic steroid therapy, anti-coagulant therapy, TNF-α blockers, bisphosphonate and cyclosporin

*** The potential for implant failure and other complications increases when implants are placed in irradiated bone, as radiotherapy can lead to progressive fibrosis of blood vessels and soft tissue (i.e., osteoradionecrosis), resulting in diminished healing capacity. Contributing factors to this increased risk include the timing of implant placement in relation to radiation therapy, the proximity of radiation exposure to the implant site, and the radiation dosage at that site.*

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

Side effects

The clinical outcome of treatment is influenced by various factors. The following side effects and residual risks are associated with the device group and may necessitate further treatment, revision surgery or additional visits to the relevant medical professional's office.

- Allergic reaction(s) to the implant material
- Anaesthesia, paraesthesia, hyperesthesia, and hypoesthesia (transient or permanent)
- Anatomical landmark damage
- Bleeding on probing
- Bruising
- Complications requiring revision surgery
- Damage to adjacent dentition
- Dental injury during surgery
- Hyperplastic sift tissue response
- Implant failure
- Implant fracture
- Improper implant positioning resulting in prosthetic compromise
- Infection (acute and/or chronic)
- Insufficient levels of osseointegration resulting in instability, mobility and/or failure
- Localized inflammation
- Loosening of the abutment screw and/or retaining screw
- Loss or damage to adjacent teeth
- Marginal bone loss
- Micromovements and implant instability
- Misfit or improper connection at the implant-abutment interface
- Overloading of the abutment/implant

- Pain or discomfort
- Peri-implantitis, peri-mucositis or otherwise poor peri-implant soft tissue health
- Periodontal inflammation
- Phonetic difficulties
- Prosthetic failure
- Soft tissue irritation
- Sub-optimal aesthetic result
- Surgical side effects such as pain, inflammation, bruising and mild bleeding
- Wound dehiscence or poor healing

Additionally, the normal side effects associated with anaesthesia should also be expected.

Note: these side effects and residual risks can vary in both severity and frequency.

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.

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 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 General Dental Implants	6009544038699H

Related literature and catalogues

CAT-2093 - Single Platform (SP1) Implants Product Catalogue

Symbols and warnings

Manufacturer: Southern Implants® 1 Albert Rd, P.O Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046

CE mark

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.