SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	**INSTRUCTIONS FOR USE: Southern Implants® Scan Flags**
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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

Intended use
Southern Implants® scan flags are intended to be used during digital impression procedures in order to obtain the exact position and orientation of the respective dental implant or laboratory analogue and transfer this position digitally during CAD/CAM scanning procedures. This aids the CAD/CAM software to align the CAD/CAM restorations to the implant digitally. These devices are intended for single use on a single patient and supplied nonsterile.

Description
The scan flags are premanufactured and are available in different connections. The items are to be fitted directly onto implants or indirectly, to the compact conical abutment or to the laboratory analogue on a dental model.The scan flags are made from titanium and are supplied with a screw to secure the scan flag onto the dental implant or analogue. The scan flags are provided nonsterile with the exception of the multipurpose fixture mount (SFT-PRO3) which is provided sterile.

Indications for use
Scan flags are indicated for use with intraoral - and desktop scanners as part of planning and design software using 3Shape, Dental Wings and Exocad, CAD/CAM systems.

A digital impression can be taken at different stages during treatment:
- at time of implant placement – for immediate loading techniques, to deliver a provisional restoration and in certain cases a final restoration on the same day.
- at second stage surgery – after soft tissue healing following second stage surgery procedures.
- at the dental laboratory – after taking impressions digitally for printed models or taking impressions using conventional methods to produce a dental model with laboratory analogues.

Intended user
Dental Technicians, Maxillofacial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users.

Intended environment
This device is intended to be used in a dental laboratory to aid in making the restoration by obtaining a digital impression or in a clinical environment, such as an operating theatre or a dentist consultation room, for taking a digital impression.

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 single teeth, partial or full bridges and may be fixed or removable.

Compatibility information
Southern Implants® should be restored with Southern components. In the Southern Implants® range there are 5 implant connections, the implant code and connection type, can be identified by specific abbreviations in the product codes. Range identifiers are summarised in *Table 1*.

Table 1

Implant connection type	Compatible device
External Hex (EX)	Parts labelled SFT-EX-(Ø).
TRI-NEX® (EL)(Lobe)	Parts labelled SFT-EL-(Ø).
Deep Conical (DC)	Parts labelled SFT-DC-(Ø).
Internal Hex (M)	Parts labelled SFT-M (used with Ø3.75, 4.20 and 5.00 mm platforms).
Internal Hex PROVATA® (M) (Z)	Parts labelled SFT-PRO3 (used with Ø3.3 mm platforms). Parts labelled SFT-M (used with Ø4.0, 5.0 and 6.0 mm platforms).
	Parts labelled SFT-Z (used with Ø7.0, 8.0 and 9.0 mm platforms).
IT (ITS) (ITS6) - Octagon	Parts labelled SFT-IT (used with Ø4.8 mm platforms).
	Parts labelled SFT-IT6 (used with Ø6.5 mm platforms).
Abutment level	Parts labelled SFT-MC-48 (used with Ø4.8 mm abutment platforms).
	Parts labelled SFT-MC-60 (used with Ø6.0 mm abutment platforms).

Clinical benefits
Through this procedure patients can expect to have their missing teeth replaced and/or crowns restored.

During surgery
Care must be taken that parts are not swallowed during any of the procedures, a rubber-dam application is recommended when appropriate. Care must be taken to apply the correct tightening torque of abutments and abutment screws.

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

Storage, cleaning and sterilisation
The implants, cover screws and healing abutments are 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. Incorrect storage may influence device characteristics. Do not reuse implants, cover screws, temporary abutments and abutments. Reusing these components may result in:
- damage on 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 components.

Cleaning and disinfection
Before intraoral use the device needs to be disinfected, as they are supplied nonsterile.

Sterilisation
Southern Implants® recommends the following procedure to sterilise the restoration prior to use:

Methods to sterilise the restoration and abutment screw:
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. Prevacuum sterilisation method: wrapped, steam sterilise at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilisation cycle.

NOTE: users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA for the intended sterilisation cycle.

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, iridium, stainless steel and radel.
- 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, anticoagulant therapy, metabolic bone disease, radiotherapy treatment.

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

New and experienced Implant users should do training before using a new system or attempt 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.

Side effects

Potential side effects and temporary symptoms: pain, swelling, phonetic difficulties, gingival inflammation. More persistent symptoms: The risks and complications with implants include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) breakage of the implant and/or abutment; (3) loosening of the abutment screw and/or retaining screw; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts; (7) formation of fat emboli; (8) loosening of the implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates; and (11) bone loss possibly resulting in revision or removal.

Breakage

Implant and abutment fractures can occur when applied loads exceed the normal functional torque strength of the material. Potential overloading conditions may result from; deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g. bruxing or clenching) loss or changes indentition or functionality, inadequate prosthesis fit and physical trauma.

Additional treatment may be necessary when any of the above conditions are present to reduce the possibility of hardware complications or failure.

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

Scan Flag: Titanium or Titanium alloy (Ti-6AL-4V)

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.

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.

Healing

The healing time required for osseointegration depends on the individual and treatment protocol. It is the responsibility of the practitioner to decide when the implant can be restored. Good primary stability will govern if immediate loading can be done.

Implant care and maintenance

Potential implant patients should establish an adequate oral hygiene regime prior to Implant therapy. Proper postoperative, oral hygiene and implant maintenance instructions must be discussed with the patient, as this will determine the longevity and health of the Implants. The patient should maintain regular prophylaxis and evaluation appointments.

Procedure for use

Before placing the scan flag ensure all items are clean and suitable for intraoral use.

1. Attach the matching scan flag to the dental implant or lab analogue. Check proper fit and hand tighten the screw with the appropriate driver see *Table 2*.
2. The patient is scanned using an intraoral scanner or the laboratory model is scanned using a desktop scanner. The seating of the scan flag must be verified before intra-oral scanning procedures by an X-ray.
3. The scan flag is removed from the implant or analogue.
4. The scan flag in the digital form is now matched and aligned with the corresponding scan flag from the library file that was imported into the software. 3Shape, Dental Wings and Exocad libraries can be downloaded after registering on www.southernimplants.com.
5. The software recognises the position of the scan flag to the implant or analogue, this allows the software to know where to place the abutment for the design step.

NOTE: follow the instructions of the scanner used and for scan procedures.

Table 2

Driver type	External Hex	DC	TRI-NEX®	Internal Hex	IT	Compact conical screw
1.22 /1.27 mm universal driver	✓	✓		✓		✓
1.27 mm hex driver	✓			✓		
Quad driver			✓			
Blade driver					✓	

Changes in performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g. looseness of the prosthesis, infection or exudate around the implant pain or any other unusual symptoms that the patient has not been told to expect).

Basic UDI

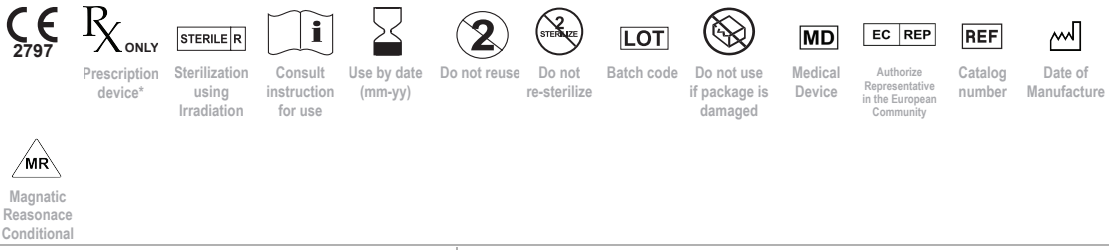
Product	Basic-UDI Number
Basic-UDI for Impression Coping	600954403878

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

Symbols and Warnings

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



* 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.