

English

**INSTRUCTIONS FOR USE: Southern Implants® Deep Conical Implants**



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## Description

Deep Conical (DC) implants from Southern Implants are made from biocompatible, commercially pure, Grade 4 Titanium and are available in a range of lengths and diameter configurations to be used with a range of prosthetic components (see the DC Implant product catalogue).

## 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,
- immediate loading in all indications, except in single tooth situations on implants shorter than 8mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.

The intended use for 3.0 Deep Conical implants is limited to replacement of maxillary lateral incisors and mandibular incisors

## Contraindications

Do not use in patients:

- who are medically unfit for dental implant procedures.
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6AL-4V).
- with inadequate bone volume.
- where adequate numbers of implants could not be placed to achieve full functional support for a prosthesis.

## 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.
- 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.
- For short implants, clinicians should closely monitor patients for any of the following conditions: peri implant bone loss, changes to implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. If the clinicians choose a short implant, then clinicians should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. Allow longer periods for osseointegration and avoid immediate loading.

## 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 oro-facial 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, periodontal status, and adequacy of bone.
  - Bruxism and unfavourable jaw relations must be taken into account.
- Proper pre-operative planning with a good team approach between well trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.

- Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.
- Minimizing the trauma to the host tissue increases the potential for successful osseointegration.
- Electro-surgery should not be attempted around metal implants, as they are conductive.

#### During surgery

- Care must be taken that parts are not swallowed during any of the procedures, thus 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 are essential for favourable long-term results.

#### Surgical procedures

Refer to the DC Implant product catalogue for details regarding the drill sequence, prosthetic compatibility and instrument availability of the DC range of Implants.

#### Materials

Material type                      Commercially pure titanium (grade 4)

#### Magnetic Resonance (MR) safety information

Deep Conical implants have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artefact in the MR environment. The safety of Deep Conical implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

#### Storage, Cleaning & sterilization

The implants are supplied sterile 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. Do not re-sterilize or autoclave these components.























#### Disposal

Disposal of the device and its packaging shall follow local regulations and environmental requirements, taking different contamination levels into account.

#### 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.

## Symbols and warnings

											
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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