English

INSTRUCTIONS FOR USE: Southern Implants® MAX Dental Implants

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Description

MAX 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 MAX Implant product catalogue). These implants are tapered, self-taping, screw type endosseous dental implants. The MAX Dental Implants are available in diameters ranging from 6 mm to 10 mm and lengths from 6 mm to 13 mm. These implants are available in two surface treatment options: fully roughened or Machined Surface Coronal (MSC).

Intended use

To stabilize fixed or removable dental prosthesis in single teeth, partially edentulous prosthesis, or full arch prosthesis.

Indications for use

Southern Implants MAX implant is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. In the Southern Implants' MAX Dental Implants range there are 4 implant connections. The implant code and connection interface type can be identified by specific abbreviations in the product codes. Range identifiers are summarised in Table A.

Table A – MAX Dental Implant Range

Range Identifier	Connection Interface	Item Codes	MSc	Implant Diameter (mm)	Implant Lengths (mm)
MAX	External Hex	MAX-6-(XX)		6	6/7/9/11
		MSC-MAX-6-(XX)	✓	6	6/7/9/11
		MAX-7-(XX)		7	7/9/11
		MSC-MAX-7-(XX)	✓	7	7/9/11
		MAX-8-(XX)		8	7/9/11/13
		MSC-MAX-8-(XX)	✓	8	7/9/11
		MAX-9-(XX)		9	7/9/11/13
		MSC-MAX-9-(XX)	✓	9	7/9/11
		MAX-10-(XX)		10	7/9/11/13
PROMAX	Internal Hex	PROMAX6(XX)		6	7/9/11
		MSC-PROMAX6(XX)	✓	6	7/9/11
		PROMAX7(XX)		7	7/9/11
		MSC-PROMAX7(XX)	✓	7	7/9/11
		PROMAX8(XX)		8	7/9/11
		MSC-PROMAX8(XX)	✓	8	7/9/11
		PROMAX9(XX)		9	7/9/11
		MSC-PROMAX9(XX)	✓	9	7/9/11
TRI-MAX®	Tri-lobe	TRI-MAX7-(XX)		7	7/9/11
		TRI-MAX8-(XX)		8	7/9/11
		TRI-MAX9-(XX)		9	7/9/11
MAXIT	Internal Octagon (IT)	MAXIT7-(XX)		7	7/9/11
		MAXIT8-(XX)		8	7/9/11
		MAXIT9-(XX)		9	7/9/11

Storage, cleaning and sterilisation

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.

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

Contraindications

Do not use in patients:

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

Warnings

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.

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.
- 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 and are essential for favourable long-term results.

Surgical procedures

Refer to the MAX Implant product catalogues (see the *Related literature and catalogues* section of this document) for details regarding the drill sequence, prosthetic compatibility and instrument availability for the MAX range of Implants.

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

Implant: Commercially pure titanium (Grade 4)

Disposal

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

Magnetic Resonance (MR) Safety

Non clinical 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.

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 MAX Dental Implants	60095440387092

Related literature and catalogues

CAT-2020 - External Hex Implants Product Catalogue
CAT-2004 - Tri-Nex Implants Product Catalogue
CAT-2060 - Provata Implants Product Catalogue
CAT-2005 - IT 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.