

Description:

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

Indications for Use:

The Piccolo Implants and Accessories are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:

- replacing maxillary lateral incisors and mandibular incisors,
- immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
- immediate loading, except in soft bone (type IV) where implant stability may be difficult to obtain.

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:

- **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.

Images are for illustration purposes only and do not necessarily accurately represent the product.

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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 are essential for favourable long-term results.

Surgical Procedures:

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

Materials:

Implant: Commercially pure titanium (grade 4)

Magnetic Resonance (MR) Safety Information:

Piccolo Implants and Accessories 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 Piccolo Implants and Accessories 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.

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.

Disposal:

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

Symbols & Warnings:

 Manufacturer: Southern Implants 1 Albert Rd, P.O. Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046 Fax: +27 12 667 1029	 	 Prescription device *	 Sterilization using Irradiation	 Non-sterile	 Caution	 Consult instruction for use	 Use by date (mm-yy)	 Do not reuse	 Do not Re-sterilize	 Batch code	 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 licensed physician or dentist.						Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.					
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For Technical Assistance or additional product literature, please contact Southern Implants.

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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.