English

INSTRUCTIONS FOR USE: Southern Implants® PROVATA® Implants

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Description

The PROVATA® 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). The PROVATA® implant is also available with the 12° angulated platform Co-Axis® design. This design enables tilting of the implant without compromising the restorative emergence angle. Cover screws and healing abutments are supplied separately.

Intended use

The devices are intended to treat partially or fully edentulous patients eligible for placement of one or more dental implants as a means of fixing a permanent or removable single crown, partial or full-arch dental prosthesis in the upper or lower jaw. The devices allow for immediate or delayed prosthetic restoration based on the user's evaluation of the patient's eligibility.

Indications for use

The PROVATA® Implant System is 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. The PROVATA® Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

The intended use for the Ø3.30 PROVATA® implants is limited to replacement of maxillary and mandibular lateral and central incisors.

The 12° angled Co-Axis PROVATA® Implants are intended to only be used with straight abutments.

Intended user

Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontists, Prosthodontists and other appropriately trained and experienced implant users.

Intended environment

The devices are intended to be used in a clinical environment such as an operating theatre or a dentist consultation room.

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

Pre-operative examination and planning

A full medical and dental history must be taken, with emphasis on the presence of soft and/or hard tissue pathology. The patient must have clinically symptom-free sinuses and no pathology in surrounding bone or soft tissue. It is recommended that a CT scan and/or CBCT analysis be performed as part of the planning process in order to:

- detect the presence of any pathology in the maxillary sinuses.
- bone volume and condition.
- jaw relationships.
- choose an appropriate size implant for the amount of bone available, without violating the biological width, and evaluate sufficient bone volume surrounding the implant body. In dense bone, use new drills and profuse irrigation. In low-density bone, it is recommended to undersize the osteotomy by drilling with a smaller final drill (i.e. If placing a Ø4.0 mm implant, final shaping drill would be Ø3.3 mm).

NOTE: implant selection and implant restoration is determined by the clinician. It is imperative that the clinician determines the correct implant diameter and prosthetic component in order to achieve the most desirable prosthetic

emergence and ideal crown-implant ratio. PROVATA® Ø5 mm implants can utilise platform matched components and are indicated when:

- the patient is known to have a very strong bite force and bruxism is present.
- the occlusal table of the crown will be significantly larger than that of the implant and abutment.
- crown design results in an excessive cantilevel requiring a larger platform for optimal crown emergence and ideal crown-implant ratio.

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 PROVATA® implants. For further information see the PROVATA® Product Catalogue (CAT-2060).

Table A – PROVATA® Implant range

Item Code	Implant Length Codes	Implant Lengths (mm)	Implant Diameter (mm)
Straight			
PRO3 MSC-PRO3	08/ 10/ 11/ 13/ 15/ 18	8.5/ 10.0/ 11.5/ 13.0/ 15.0/ 18.0	Ø3.3
PRO4 MSC-PRO4	06/ 08/ 10/ 11/ 13/ 15/ 18	6.4/ 8.5/ 10.0/ 11.5/ 13.0/ 15.0/ 18.0	Ø4.0
PRO5 MSC-PRO5	08/ 10/ 11/ 13/ 15/ 18	8.5/ 10.0/ 11.5/ 13.0/ 15.0/ 18.0	Ø5.0
MSC-PRO6	08/ 10/ 11/ 13/ 15	8.5/ 10.0/ 11.5/ 13.0/ 15.0	Ø6.0
Co-Axis			
PRO12D3 MSC-PRO12D3	08/ 10/ 11/ 13/ 15/ 18	8.5/ 10.0/ 11.5/ 13.0/ 15.0/ 18.0	Ø3.3
PRO12D4 MSC-PRO12D4	08/ 10/ 11/ 13/ 15/ 18	8.5/ 10.0/ 11.5/ 13.0/ 15.0/ 18.0	Ø4.0
PRO12D5 MSC-PRO12D5	08/ 10/ 11/ 13/ 15/ 18	8.5/ 10.0/ 11.5/ 13.0/ 15.0/ 18.0	Ø5.0

Clinical benefits

Patients can expect to have their missing teeth replaced and/or crowns restored.

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. Do not reuse implants, cover screws, temporary abutments and abutments. Re-using 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.

Packaging and precautions to maintain the sterility of the implant

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.

Other sterile components are packed in a peel pouch or bubble-type base with a “peel-back” lid. Labelling information is located on the bottom half of the pouch, inside the packet or on the surface of the peel-back lid. Sterility is assured unless the pouch is damaged or opened. Non-sterile components are supplied clean but not sterile in a peel pouch or bubble-type base with peel-back lid. Labelling information is located on the bottom half of the pouch or on the surface of the peel-back lid.

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 or iridium, 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, anti-coagulant therapy, metabolic bone disease, radio therapy treatment and sinus pathology.

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.
- 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 and periodontal health.
- 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.
- minimising 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.

Side effects

Potential side effects and temporary symptoms: pain, swelling, phonetic difficulties and 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.

Warnings and Cautions for use of short implants (<7 mm length)

For short implants (i.e., strictly shorter than 7 mm), immediate restoration or loading on a single implant has not been studied and is not recommended for a terminal molar in an arch or cantilevering more than one pontic off a single implant.

Because of the reduced surface area for anchorage in the bone, implants shorter than 7 mm length should be used with caution because they present greater risks to failures compared to standard implants, and are recommended for the following situations:

i. As an additional implant together with longer implants to support implant-borne reconstructions;
ii. As an auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible.

When a short implant is the treatment of choice, consider a two-stage surgical approach, splinting of implants, and placement of the widest possible implant. For short implants (i.e., strictly shorter than 7 mm), clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes in the 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. Allow longer periods for osseointegration.

Short implants (i.e., strictly shorter than 7 mm), should not be placed in patients who demonstrate untreated occlusal parafunction, such as bruxism or clenching.

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).

Loading times

Healing period is generally 3-4 months in the mandible and 4-6 months in the maxilla; however, healing periods may vary for each patient. When a shorter healing time or immediate loading is being considered, the assessment must be based on the individual clinical situation (i.e. bone quality, bone quantity, primary stability achieved, loading conditions, design of super- structure, etc). Implants may be immediately temporized on single or splinted multiple-unit restorations, if good primary stability is achieved. Immediately temporized restorations should be kept out of occlusion. The patient should adhere to a soft diet and place minimal forces on the restoration for 6-12 weeks.

Troubleshooting

Implant mobility: if the fixture is very l oose, consider removal and replacement with a wider diameter fixture, without further drilling. Poor fixture alignment: If the angular misalignment is less than 30°, the problem can be addressed using angulated abutments. If the angle is greater than 30°, remove the implant and allow the surgical site to heal for approximately six months. Repeat surgery on the same area after the healing period or use a Co-Axis® implant to take full advantage of available bone. Exposed threads: if the implant threads are exposed in the coronal region, perform a bone augmentation procedure. Over-countersinking: over-countersinking can cause complications with primary stability in cortical bone. The countersink should not extend beyond the cortical region whenever possible. Continue with normal treatment protocol, but it is recommended to avoid immediate or early loading and to pay special attention to the stability of the implant in the first 3-6 months after placement.

Clinical procedure

Step 1: Initiate the osteotomy *(Fig. 1)*

NOTE: it is recommended to raise a full thickness mucoperiosteal flap.

The 3Spade drill (D-3Spade-1.8M) is used to initiate the osteotomy by perforating the cortical plate at the desired location (Fig. 1). All drilling should be performed at a speed of 1000-1500 rpm with copious irrigation. An intermittent technique should be used to avoid overheating of the bone.

(Fig. 1)

Step 2: Ø2 mm Twist Drill
(Fig. 2)

Drill with the Ø2 mm twist drill (D-20T-M10/15/20) to the implant length corresponding to the laser markings on the twist drills and direction indicator (Fig. 2 and Fig. 7).

NOTE: depth should allow the implant to inserted level or slightly submerged in the surrounding bone.

(Fig. 2)

After using the Ø2 mm twist drill to verify the alignment with adjacent teeth/implants, insert the direction indicator (I-DI) (Fig. 3). A radiograph is taken at this point to verify the depth and angulation. If the drilling direction is incorrect, start a new osteotomy in the correct direction with the Ø2 mm twist drill.

(Fig. 3)

Ø2 mm twist drilling for Co-Axis® implants

Drill in the planned direction to the appropriate depth, as indicated by the depth markings on the Ø2 mm twist drill (D-20T-M10/15/20). If an anterior implant is being placed, ***align the drill to the incisal edge of the adjacent tooth.*** (Fig. 4).

(Fig. 4)

With the 12° Co-Axis® angulation, the screw access hole will come out on the palatal side in the area of the cingulum if aligned correctly. If the osteotomy is angulated too much to the palatal side (e.g. normal direction when preparing for a screw retained restoration) there is a risk of a sub-optimal restoration angle, with soft and hard tissue being compromised on the palatal side. Insert the Co-Axis® direction indicator (I-DI-12d) to verify the alignment (Fig. 5). A radiograph is taken at this point to verify the depth and angulation. If the drilling direction is incorrect, start a new osteotomy in the correct direction with the Ø2 mm twist drill.

NOTE: vertical positioning is dependent on soft tissue height and the jump gap between the buccal wall and implant.

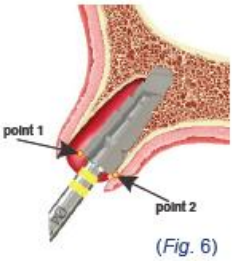
(Fig. 5)

Step 3: Gradually enlarge the osteotomy

The PROVATA® tapered drills are length and diameter specific. Use the length and diameter drill corresponding to the implant that is selected. Widen the osteotomy intermittently to the desired diameter (Fig.6). Follow the recommended drill protocols for soft, medium and dense bone by referring to catalogue.

NOTE: caution should be taken to not over prepare the implant site, especially for shorter length implants (9 mm and shorter).

NOTE: with a probe, check the soft tissue height, prepare final step at least 1 mm subcrestal. Depending on the gap between planned implant and buccal bone plate, deeper countersinking may be appropriate.



(Fig. 6)

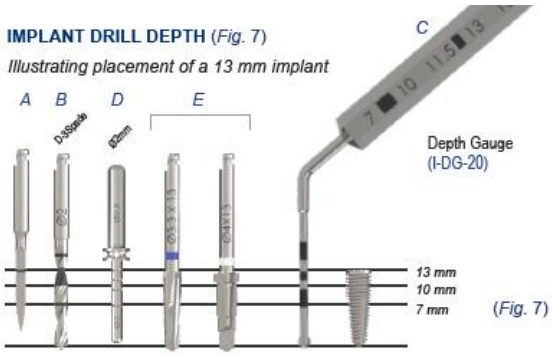
* Final Tapered Drill Position (Co-Axis®)

NOTE:
Point 1
This corner of the drill is to be at bone level.

Point 2
This corner of the drill will be subcrestal.

IMPLANT DRILL DEPTH *(Fig. 7)*

Illustrating placement of a 13 mm implant



(Fig. 7)

Step 4: Implant placement (tapered implants)

NOTE: see CAT-8056 for instructions on how to use placement tools.

PROVATA® placement tools and PROVATA® Co-Axis® implant fixture mounts have laser markings on them to indicate and assist in implant placement depth up to handpiece. Connect the handpiece insertion tool (I-HM-S / M / L or I-H3M-M / L) to the handpiece. Engage the internal hex of the implant with the insertion tool and carefully remove the implant from the sterile vial (the hexagon of the insertion tool must be fully engaged in the implant before torque is applied to prevent any damage. The hexagon is fully engaged when the straight portion of the hexagon tool is almost completely sunken in the implant) (Fig. 8).

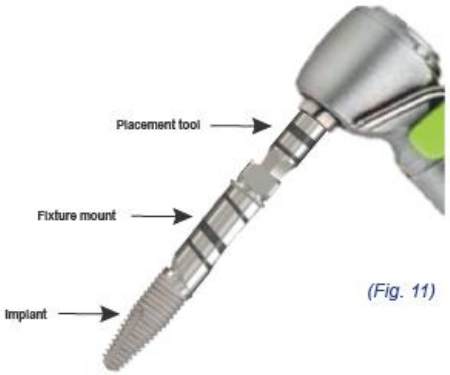
(Fig. 8)

Alternatively, the wrench insertion tool (I-WI-M-S / M / L or I-WI-3M-S / M / L) can be connected to the ratchet wrench (I-TWS), with wrench insert converter (I-WI-SS) and used to extract the implant from its packaging (Fig. 9). Insert the implant at 15-20 rpm while applying downward pressure.

(Fig. 9)

Implant placement (Co-Axis® Implants)
PROVATA® Co-Axis® implants are pre-mounted with a fixture mount and placed with an insertion tool, that fits into the hex in the fixture mount. Connect the insertion tool (I-HM-S / M / L) to the handpiece (Fig. 10). Push the tool into the fixture mount. The hexagon of the insertion tool in the fixture mount must be fully engaged before torque is applied, to prevent any damage. The hexagon is fully engaged when the straight portion of the hexagon tool is almost completely sunken in the fixture mount (Fig. 11).

(Fig. 10)



(Fig. 11)

Step 5: fully seat the implant.
For tapered implants, the ratchet and torque attachment wrench (I-TWS with I-TWS-B100), in combination with the wrench converter (I-WI-CST) and hand-piece insertion tool (I-HM-S / M / L or I-H3M-M / L) or the wrench insertion tool (I-WI-M-S / M / L or I-WI-3M-S / M / L) with wrench insert converter (I-WI-SS) may be used for final manual seating of tapered implants (Fig. 12).

For Co-Axis® implants, the insertion tool is removed from the fixture mount and the ratchet and torque attachment wrench (I-TWS with I-TWS-B100) in combination with the wrench insert converter (I-WI-SS), may also be used on the fixture mount for final manual seating of the implant (Fig. 13). Once the implant is placed and the position verified using a radiograph, remove the fixture mount by unscrewing the fixture mount screw using a 1.27 mm hex hand-held (I-HD-27-S / M / L) driver (Fig. 14).

(Fig. 12)

NOTE: if the fixture mount is removed before final placement, then the Ø 4.0 and 5.0 mm implant/s can alternatively be placed with the PROVATA® Co-Axis® handpiece insertion tool (I-H-PRO12D-S / M / L).

NOTE: use light finger force on the wrench when levelling the implant. Excessive torque (>70 Ncm) with the wrench should be avoided, as this will cause too much compression in the bone or damage to the implant. The implant should be retrieved and additional drilling should be performed in the site to widen the osteotomy site before reinsertion of the implant.

(Fig. 13)

NOTE: because the implants are self-tapping, it is recommended to stop rotation once the implant has reached the prepared depth. The implant may continue to advance beyond the drilled depth with further rotations, owing to the effective self-tapping thread. Care should be taken not to countersink the implant too far, especially in soft bone. There is also a risk that the implant may spin.

(Fig. 14)

Breakage

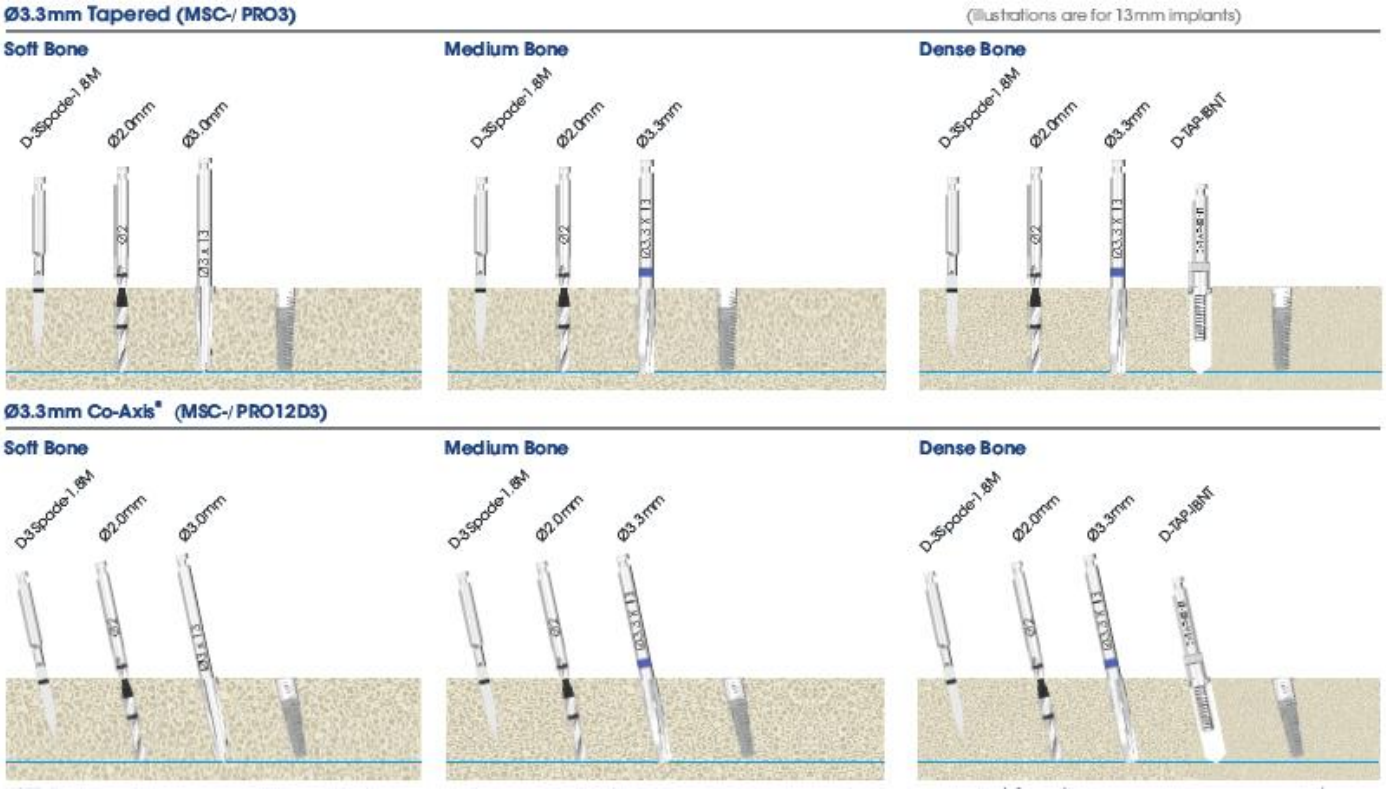
Implant and abutment fractures can occur when applied loads exceed the tensile or compressive strength of the material. Potential overloading conditions may result from: deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30°, occlusal interferences causing excessive lateral forces, patient parafunction (e.g. bruxing, clenching), loss or changes in dentition 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.

Drilling/Surgical Protocol for implants



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.

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 post-operative, 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.

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 4000 Gauss/cm (40 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.

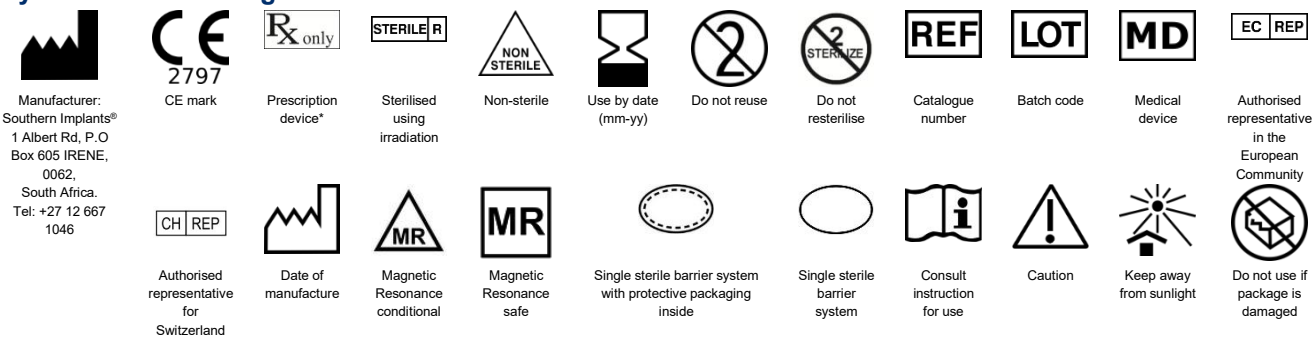
Basic UDI

Product	Basic-UDI Number
Basic-UDI for General Dental Implants	6009544038699H

Related literature and catalogues

CAT-2060- PROVATA® Implants Product Catalogue

Symbols and warnings



* 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.