English

INSTRUCTIONS FOR USE: Southern Implants® Gold Abutments

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

CH REP
MedEnvoy Switzerland: Gotthardstrasse 28, 6302 Zug, Switzerland

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 8059 4490
E: info@southernimplants.co.uk

USA and Canada
Southern Implants North America Inc.
T: +1-561-472-0990
E: customercare@southernimplants.com

Description

The gold abutment is a pre-manufactured abutment, made of a gold alloy (Au-60%, Pd-20%, Pt-19%, Ir-1%), and supplied with a plastic sleeve to assist in the fabrication of a prosthesis in the dental laboratory procedure. The gold abutment can either be connected direct to an endosseous implant, or connect the prosthesis to a compact conical abutment for use as an aid in prosthetic rehabilitation. The plastic sleeve is not for clinical use but is used to aid in the laboratory procedure. This abutment has the advantage of a gold base that is pre-machined to give a precise fit to the implant, together with a waxing sleeve, to facilitate an easy wax up process.

Gold Abutments are available in engaging and non-engaging versions. Engaging versions are indicated for single implant cases. And, non-engaging versions are indicated for multi-unit implant cases.

Note: Screws are sold separately for all abutments.

Table 1 – Compatibility table for Gold Abutments

Implant connection type	Compatible device	Prosthetic Screw	Final Screw Torque (Ncm)	Driver
External Hex (EX)	Parts labelled GC-EX-(Ø) for engaging items	3 Series TS-P-16	32-40 25-32	1.22 Hex
	Parts labelled GC-NX-(Ø) for non-engaging items			
TRI-NEX® (EL) (Lobe)	Parts labelled GC-EL-(Ø) for engaging items	TS-L-18 or GS-L-18 TS-L-20 or GS-L-20	32 32-40	Unigrip
	Parts labelled GC-NL-(Ø) for non-engaging items			
Deep Conical (DC)	Parts labelled GC-DC-(Ø) for engaging items	TS-DC3-14 TS-DC4-16 TS-DC5-20	20 30 32	1.22 Hex
	Parts labelled GC-NDC-(Ø) for non-engaging items			
Internal Hex/PROVATA® (M/ Z)	Parts labelled GC-EM or GC-EZ for engaging items	TS-Z-18, or GS-Q-18	32	1.27 Hex or Quad
	Parts labelled GC-NM or GC-NZ for non-engaging items			
Internal Octagon IT (ITS/ ITS6)	Parts labelled ITS-GC1 (used with Ø4.8 mm platforms) for engaging items	TSIT2 or GSIT2	32-40	Torx
	Parts labelled ITS-GC1ne (used with Ø4.8 mm platforms) for non-engaging items			
	Parts labelled ITS6-GC1 (used with Ø6.5 mm platforms) for engaging items			
	Parts labelled ITS6-GC1ne (used with Ø6.5 mm platforms) for non-engaging items			
Compact Conical Abutment	Parts labelled GMC1 (used with Ø4.8 mm abutment platforms) for non-engaging items	1 Series	10 - 15	1.22 Hex
	Parts labelled GMCW1 (used with Ø6.0 mm abutment platforms) for non-engaging items			
Standard Abutment	Parts labelled GCP3 (used with Ø4.5 mm abutment platforms) for non-engaging items	1 Series	10 - 15	1.22 Hex

Intended use

Gold abutments for direct connection to Implants: Southern Implants dental abutments are intended to be used in the Maxilla or Mandible for supporting a prosthesis on endosseous implants in order to restore chewing function for the patient.

Gold abutments for connection to compact conical abutments: These Southern Implants' gold abutments are intended to attach directly to the compact conical abutment by means of a screw, and used to create multi-unit substructures to stabilize a removal prosthesis or multi-unit fixed prosthesis.

Indications for use

For External Hex & Tri-Nex System:

Intended to be implanted into the upper or lower jaw arches to provide support for fixed or removable dental prosthesis in a single tooth, partially edentulous prostheses or full arch prosthesis.

For Deep Conical System:

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 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.

For MAX system:

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.

For Provata System:

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.

Contraindications

Do not use in patients:

- who are medically unfit for dental implant procedures.
- who are allergic or have hypersensitivity to titanium or titanium alloy (Ti-6Al-4V) and gold alloy (Au-60%, Pd-20%, Pt-19%, Ir-1%)
- 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, patients 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.

- The abutments are intended for single use. Re-use may result in damage on the surface or critical dimensions. This may result in performance and compatibility degradation. The removal of proteins from the surface of the components is extremely difficult and these proteins, when implanted, can lead to secondary infections.
- The abutment post height (with attached plastic sleeve) must not be reduced below a minimum height of 4mm in single implant cases.
- No Additional Angular correction is intended for these abutments.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.
- 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.

Procedures for Use

First clinical procedure:

1. Connect the impression coping/s to the dental implant/s (or compact conical abutments, if applicable).
2. Take an open or closed tray impression. When closed tray procedure is used, transfer the copings to the impression.
3. Connect the healing abutment or temporary restoration direct to the dental implant/s (or compact conical abutments, if applicable).

First laboratory procedure:

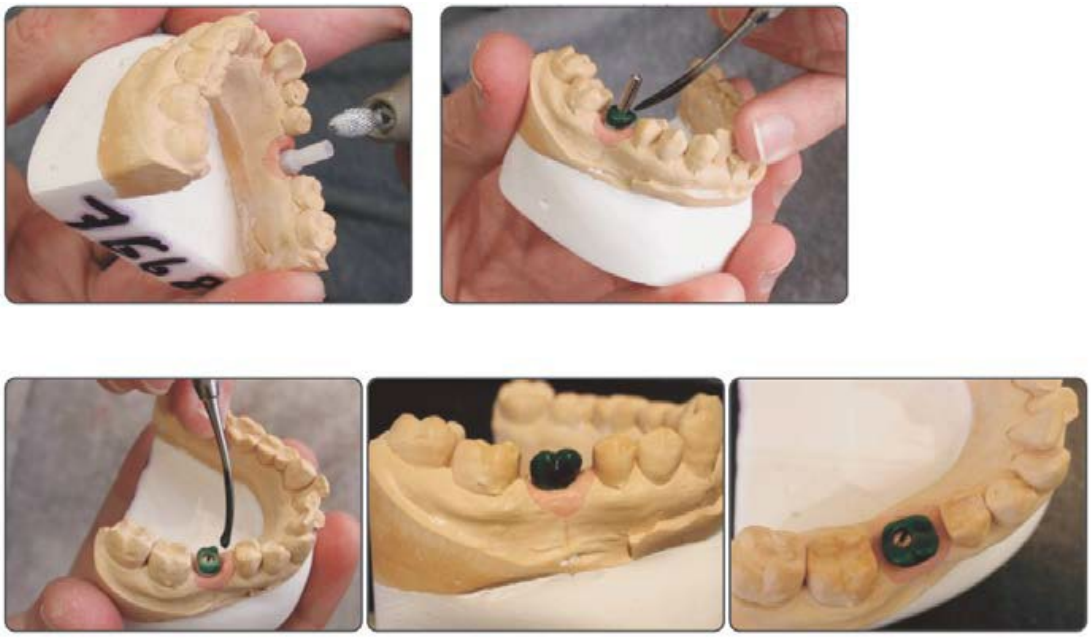
This abutment has a machined gold base, together with a plastic waxing sleeve. The plastic sleeve aids in the wax up process.

1. Prepare the master model and obtain the correct Gold Abutment, with laboratory screw
2. The gold abutment is screwed onto the model. And, the plastic sleeve must be trimmed to the correct occlusal height, with no additional angular correction, ensuring that this post height is more than 4mm in single tooth cases. The plastic sleeve is then reduced out of occlusion and wax is added until the ideal shape of the substructure is achieved (the Impression Coping Pin can be used as a waxing sleeve). A normal wax-up is done around the waxing sleeve.

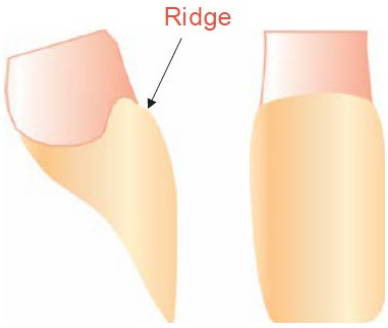
Note: illustrations are for a single-tooth restoration, but the same steps apply for multi-unit restorations.

Dimensional Parameter Requirements for Gold Abutment Fabrication.

Parameter	Limits of Customization
Wall thickness	No customization allowed
Gingival margin diameter	No customization allowed
Gingival margin height	No customization allowed
Total height	Do not shorten to exceed the limit of the abutment post height
Abutment post height (above the gingival collar)	Do not shorten the abutment post height to less than 4 mm
Angulation	No customization allowed to provide angulation

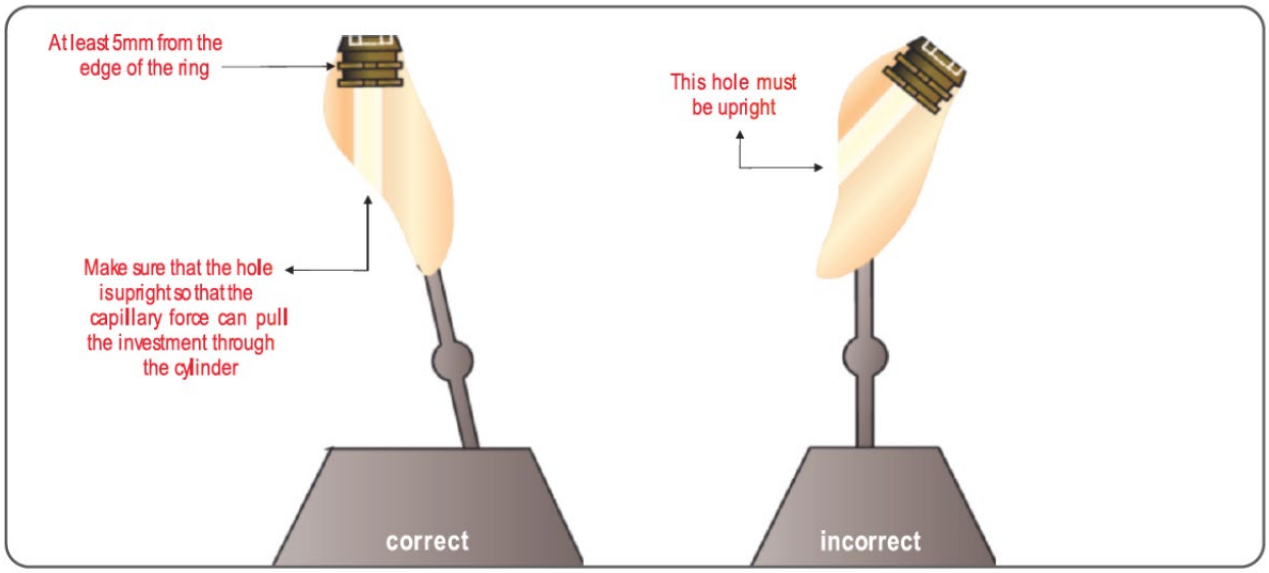


NOTE: The technician can determine the place where the soft tissue will settle against the tooth by making a slight ridge as shown on the left. This must be done to match the adjacent teeth.

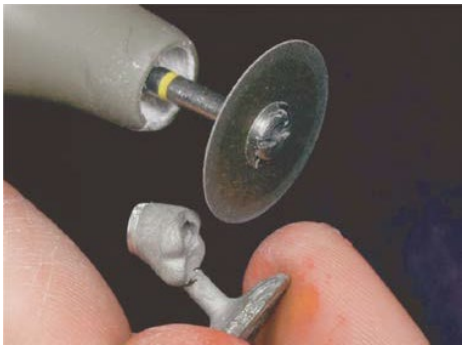


NOTE: The shape of teeth is seldom “round”. The shape of the root of the tooth must be developed sub-gingival so that where it emerges through the tissue it is the right shape and there must be no ridge-lap. This is referred to as the “emergence profile”.

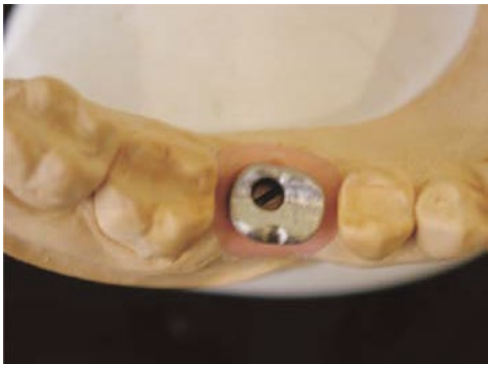
3. Add the sprue to the abutment with its wax and then invest it.



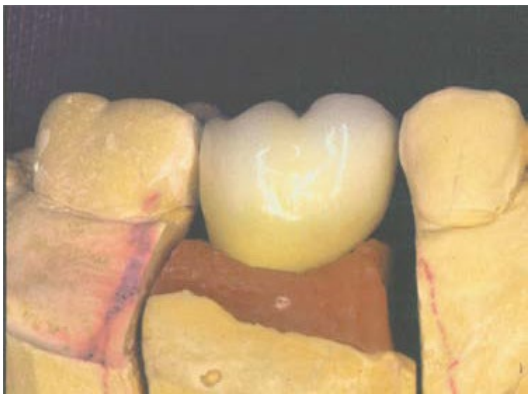
4. Burn out the wax and plastic by placing the model into the furnace according to the investment manufacturer's specifications and leave at final temperature for at least one hour. The plastic sleeve requires more time to burn out than does wax. It is advisable not to leave these rings at low burnout temperatures, i.e. 400° to 500°C, as this is the optimum temperature for investment to expand. Too much expansion on an implant case could result in a metal creep on the gold abutment.
5. After casting, the removal of the investment material is most critical. IT MUST BE REMOVED ULTRASONICALLY. DO NOT sandblast or blast with glass beads, the fitting surface which must fit on the implant. If this surface is blasted in any way, the precision-machined gold part will not fit the implant as intended. If the abutment is to be sandblasted cover it with a thin layer of wax or a policing protector cap.
6. Work off the coping as normal. Take care not to damage the fitting surface.



7. After de-oxidising and opaqueing, the porcelain (or composite) can now be added. NOTE: It is not only important to get the shade match correct, but also the surface texture of the crown. Replicate the surface texture of the adjacent tooth as much as possible and a slight shade mismatch will probably not be noticeable.



8. At the screw access hole, a porcelain margin must be built up. This will enable the dentist to do a composite closure of the screw access hole without an unsightly grey metal ring showing.
9. Before sending the crown and model to the dentist, clean the model thoroughly with soap, water, and a toothbrush, or steam clean. Then clean the abutment crown and its screw, preferably in the Ultrasonic bath. Assemble the crown to the model and send it to the dentist.



Occlusion:
Implant borne crowns are usually kept out of occlusion by about one-tenth of a millimetre. This is because implants are 100% rigid. When masticating, clenching or grinding, the natural teeth move on their periodontal ligament. The implant does not, and therefore if it is in occlusion, it will bear 100% of all loads, causing it to eventually break.

Second clinical procedure:

1. Remove the restoration from the laboratory model/analogue.
2. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
    a. For single-unit: Place and tighten the restoration screw. Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a torque wrench, to the torque value specified for the applicable prosthetic screw. (Refer to Table 1).
    b. For multi-unit: Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a torque wrench, to the torque value specified for the applicable prosthetic screw. (Refer to Table 1).
3. Close the screw access hole.
4. Cement the final prosthesis, if applicable.

Gold Abutment casting specifications:
The Gold abutments are not made of porcelain-bonding alloy. The alloy is designed to have oxidation during cast-on procedures. Some labs do bond porcelain directly onto the gold abutments. This could result in the porcelain turning slightly green or chipping off due to a poor bond. The melting temperature of the gold alloy is approx. 1475 °C. Labs cast on at ±920°C – no higher. As this could result in the edges of the cylinder distorting. The furnace should run up straight to the casting temperature (reduces investment expansion – too much expansion could result in overflow of metal onto the fitting surface of the abutments). The co-efficient of expansion are:

- 25-500 °C – 11.9
- 25-600 °C – 12.2

Caution: Casting temperatures at 650 °C result in a high chance of miscast. Usual casting temperature is 900°C. A Phosphate bonded investment must be used. When investing, avoid the use of a tension reliever as it leaves a residue, which can result in metal creep.

Once the cast metal has been oxidized, it needs to be sandblasted before applying opaque, the seating surface of the gold abutment should be blocked out with a thin layer of wax to avoid any damage during blasting procedure. An alternative is to protect this surface by attaching a polishing protector cap.

Recommended casting alloys:
Commonly used metals, which are used for custom posts (non-ceramic bonding):

- Contact your restorative material supplier for a compatible material to Southern Implants gold abutments. Some of them are: Stabilor, Procast Y45-Argen, Argeno 1.

Ceramic bonding alloys:

- Contact your restorative material supplier for a compatible material to Southern Implants gold abutments. Some of them are: Argeno 1, Degudent U, Argident 3, Degunorm-Gold gate system, Bond-on 4, and Degudent G.

Materials

Gold Abutment:	Ceramicor®, Gold Alloy (Au-60%, Pd-20%, Pt-19%, Ir-1%) or Gold
Plastic Sleeve:	Polyoxymethylene (POM)
Abutment screws:	Titanium alloy (Ti-90%, Al-6%, V-4%) or Gold Alloy (Au-61%, Ag-16.5%, Pt-13.5%, Cu-9%)

Magnetic Resonance (MR) Safety

Nonclinical 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 2 W/kg for head landmark, 1 W/kg whole body (for landmarks within 30 cm of the implant) or 2 W/kg whole body (for landmarks more than 30 cm from the implant), and appropriate partial body SAR for other landmarks). For imaging landmarks above the thorax, 15 min of scanning at normal operating mode for landmarks greater than 30 cm from the implant with a whole-body SAR of 1W/kg for imaging landmarks within 30 cm of the implant.
- 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. This device has not been tested for heating or migration in the MR environment.

Storage, cleaning & sterilization

These abutments are supplied non-sterile and are intended for single use prior to the expiration date (see packaging label). Final restoration should be cleaned and disinfected, as per restorative material manufacturer's instructions, before intra oral use.

Southern Implants® recommends one of the following procedures to sterilise the restorations and non-sterile single-use components prior to use:

- Pre-vacuum sterilization method: Steam sterilise the abutments at 135°C (275°F) at 180-220kPa for 3 minutes. Dry for at least 20 minutes in the chamber.
- Pre-vacuum sterilization method: Steam sterilise the abutments at 132°C (270°F) at 180-220kPa for 3-7 minutes. Dry for at least 20 minutes in the chamber.

Note: Only an appropriate regulatory authority approved wrap or pouch for steam sterilization must be used. It is the responsibility of the user to establish whether or not their sterilizer is approved by an appropriate regulatory authority to meet recommended parameters.

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: follow local regulations and environmental requirements, taking different contamination levels into account.

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.

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.

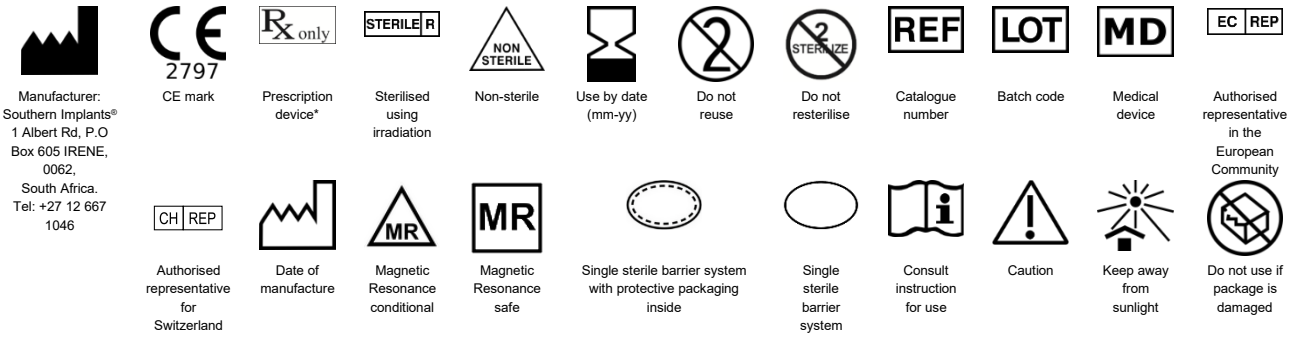
Basic UDI

Product	Basic-UDI Number
Basic-UDI for Metal Abutments	60095440387296
Basic-UDI for Direct Abutments	60095440500985 6009544050107N 6009544050117Q

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 - Deep Conical INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue
CAT-2088M - Nazalus Product Catalogue and Surgical Manual
CAT-2092 - Deep Conical Pterygoid Implants Product Catalogue
CAT-2095 - External Hex INVERTA® Implants Product Catalogue
CAT-2096 - External Hex Pterygoid 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.