English

INSTRUCTIONS FOR USE: Southern Implants® Healing abutments

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Description

Healing abutments are used during the healing phase following implant insertion. They can be connected to either the implant or connected to a compact conical abutment for use as a temporary aid in prosthetic rehabilitation. The healing abutments are available in different diameters and lengths to create a suitable emergence profile in the soft tissue for the final prosthesis. All Southern Implants Healing Abutments are provided sterile.

Intended use

The Healing abutments are premanufactured prosthetic components directly connected to endosseous dental implants and intended for use in fully edentulous or partially edentulous maxilla and/or mandible to provide support for crowns, bridges or overdentures.

Indications for use

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Intended user

Dental Technicians, 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 theater or a dentist consultation room.

Intended patient population

Patients that have lost one tooth or multiple teeth.

Compatibility information

Southern Implants' implants should be restored with Southern Implants' components. In the Southern Implants' range there are 8 implant / abutment connections. The implant code and connection type can be identified by specific abbreviations in the product codes. Range identifiers are summarised in Table A.

Table A - Compatible

Implant connection type	Compatible device
External Hex (EX)	Parts labelled TPW*, TBN*, WBN*, TV4B*, TB*, WB*, T4B*, T5B*, TBA*, XBA*, WBA*, TV5BA*, T5BA*, T6BA*, T7BA*, TBBB*, WBBB*, T6BBB, T7BBB*, TB9MAX*, TMAX9* and TPN*
TRI-NEX® (EL) (Lobe)	Parts labelled HA-L-(Ø)-* and HA-L-(Ø)W-*
Deep Conical (DC)	Parts labelled HA-DC(Ø)-*, HA-DC(Ø)-W* and HA-DC(Ø)-N*
Internal Hex (M)	Parts labelled HA-M-37-*, HA-M-45-* and HA-M-55-* (used with Ø3.75, 4.2 and 5.0 mm platforms)
	Parts labelled HA-M-P45-* (used with Ø5.0 and 6.0 mm during platform matching procedures)
Internal Hex PROVATA® (3M/ M/ Z)	Parts labelled HA-3M-35-* and HA-3M-45-* (used with Ø3.3 mm platform
	Parts labelled HA-M-37-*, HA-M-45-* and HA-M-55-*(used with Ø4.0, 5.0 and 6.0 mm platforms)
	Parts labelled HA-M-P45-* (used with Ø5.0 and Ø6.0 mm platforms during platform matching procedures)
	Parts labelled HA-Z6-* and HA-Z8-* (used with Ø7.0, 8.0 and 9.0 mm platforms)
Internal Octagon IT (ITS/ ITS6)	Parts labelled TT* (used with Ø4.8 mm platforms)
	Parts labelled TT6* (used with Ø6.5 mm platforms)
Single Platform (SP)	Parts labelled HA-SP45-* and HA-SP50-* (used with Ø3.5, 4.0 and 5.0 mm platforms)
	Parts labelled HA-SP55-PM-* and HA-SP65-PM-* (used with Ø5.0 mm platforms during platform matching procedures)
Compact Conical Abutments	Parts labelled HMC* and HMCT7* (used with Ø4.8 mm abutment platforms)
	Parts labelled HMCW* and HMCTW9* (used with Ø6.0 mm abutment platforms)

*indicates the collar height

Clinical benefits

Clinical benefits of dental implant therapy include improved chewing function, speech, aesthetics and patient psychological wellbeing. Through this procedure patients can expect to have their missing teeth replaced and/or crowns restored.

Before surgery

All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

During surgery

Take care that parts are not swallowed or aspirated during any of the procedures and apply the correct tightening torque to abutments and abutment screws.

CAUTION: identify and protect vital structures like nerves, veins, arteries and especially the infraorbital nerve during surgical exposure of the lateral maxillary wall. Injury to any of these anatomical structures can lead to complications like nerve dysfunction or bleeding.

Post-surgery

Regular patient follow-up and proper oral hygiene must be achieved to ensure favourable long-term results.

Storage, cleaning and sterilisation

The component is 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®. The devices must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics. Do not reuse components indicated for single-use only. Reusing these components may result in:

- damage to 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 single-use components.

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, radiotherapy treatment and sinus pathology.

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.
- Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.

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. Implant failure increases when implants are placed in

irradiated bone as radiotherapy can result in progressive fibrosis of vessels and soft tissue, leading to diminished healing capacity.

It is important to be aware and avoid damage to vital structures such as nerves, veins and arteries. Injuries to vital anatomical structures may cause serious complications such as injury to the eye, nerve damage and excessive bleeding. It is essential to protect the infraorbital nerve. Failing to identify actual measurements relative to the radiographic data could lead to complications.

New and experienced implant users should do training before using a new system or attempting 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 orofacial 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 preoperative 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.
- electrosurgery should not be attempted around metal implants as they are conductive.

Should the device not operate as intended, it must be reported to the manufacturer of the device. The contact information for the manufacturer of this device to report a change in performance is: sicomplaints@southernimplants.com.

Side effects

The side effects of the use of the system are not dissimilar to those of dental implant therapy. Possible side effects to implant therapy include:

- pain
- swelling
- phonetic difficulties
- gingival inflammation

Less common but more persistent symptoms include, but are not limited to:

- allergic reaction(s) to implant and/or abutment material
- breakage of the implant and/or abutment
- loosening of the abutment screw and/or retaining screw
- infection requiring revision of the dental implant
- nerve damage resulting in permanent weakness, numbness, or pain
- histologic responses with possible macrophage and/or fibroblast involvement
- fat emboli formation
- loosening of the implant requiring revision surgery
- perforation of the maxillary sinus
- perforation of the labial and lingual plates
- bone loss possibly resulting in revision or removal of the implant.

Precaution: maintaining sterility protocol

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.

Care must be taken to maintain the sterility of the implant by proper opening of the packaging and handling of the implant.

1. Open the implant package in the non-sterile field, with non-sterile gloves, tear the address label to open the box.
2. With non-sterile gloves, remove the inner blister pack. Do not place the plastic box or blister pack-lid onto the sterile field. The contents of this inner package are sterile.
3. The sealed blister is to be opened by an assistant (with nonsterile gloves): remove the TYVEK lid and drop or place the sterile tube onto the sterile field, open the tube cap and attach the implant placement tool onto the implant and carefully remove from the sterile tube. Do not touch the sterile implant.

Other sterile components are packed in a peel pouch or blister 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 blister base with peelback lid. Labelling information is located on the bottom half of the pouch or on the surface of the peel-back lid.

Handling procedures

1. Select the appropriate healing abutment or cap and ensure vertical clearance to opposing dentition or opposing implant components.
2. Connect the healing abutment to the implant, or the healing cap to the compact conical abutment and tighten the healing abutment, with the applicable driver (Table B).

Table B

Driver type	External Hex	DC	TRI-NEX®	Internal Hex	IT	Single Platform	Compact Conical screw
1.22 mm/1.27 mm Universal driver	✓	✓		✓		✓	✓
1.22 mm hex driver	✓	✓				✓	✓
1.27 mm hex Driver				✓			
Unigrip driver			✓				✓
Torx driver					✓		

3. Torque the healing abutment or cap down to the value indicated in Table C.
4. Reposition the flap margins together and suture closed.

Table C

Direct to Implant	Torque
External Hex	
Ø3.0 mm	10 – 15 Ncm
Ø3.25, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	10 – 15 Ncm
TRI-NEX®	
Ø3.5 mm	10 – 15 Ncm
Ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	10 – 15 Ncm
DC	
Ø3.0 mm	5 – 10 Ncm
Ø3.5 and 4.0 mm	5 – 10 Ncm
Ø5.0 mm	5 – 10 Ncm
Internal Hex (M-Series & PROVATA®)	
Ø3.75, 4.2 and 5.0 mm M-Series	10 – 15 Ncm
Ø3.3, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm PROVATA® Implants	10 – 15 Ncm
IT Octagon	
Ø3.3, 4.1, 4.9, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	10 – 15 Ncm
Single Platform (SP1)	
Ø3.5, 4.0 and 5.0 mm	10 – 15 Ncm
Compact Conical Abutment	
All Healing abutments on Compact Conical abutments	10 – 15 Ncm

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

Material type Commercially Pure Titanium (Grade 4)

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.

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 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.

Summary of Safety and Clinical Performance (SSCP)

As required by the European Medical Device Regulation (MDR; EU2017/745), a Summary of Safety and Clinical Performance (SSCP) is available for perusal with regard to Southern Implants® product ranges.

The relevant SSCP can be accessed at https://ec.europa.eu/tools/eudamed.

NOTE: the above website will be available upon the launch of the European Database on Medical Devices (EUDAMED).

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.

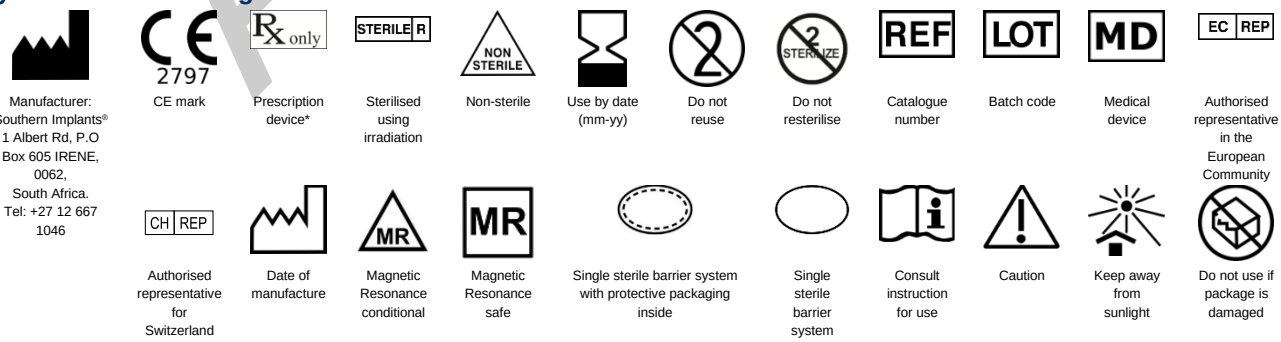
Basic UDI

Product	Basic-UDI Number
Basic-UDI for Metal Abutments	60095440387296

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 - INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue
CAT-2093 - Single Platform (SP1) 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.