English

INSTRUCTIONS FOR USE: Southern Implants® Overdenture Abutments

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Description

Overdenture abutments are premanufactured abutments that is connected directly to an endosseous implant and is used in multiple unit reconstructions to retain a tissue-supported overdenture in patients with extensive bone or soft tissue loss. These components are supplied non-sterile.

Intended use

This device is 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. This device constituents are classified as medical devices and are intended for single use on a single patient.

Indications for use

The Overdenture 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.

Intended user

The intended user for this system includes Dental Technicians, Maxillofacial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users.

Intended environment

This device is intended to be used in a dental laboratory for making of the restoration and in a clinical environment such as an operating theatre 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 5 implant 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 EQ-IP- (*), EQ-IBN- (*) and EQ-IB- (*)
Tri-Nex® (EL) (Lobe)	Parts labelled Z-EQ-131TN35(*), Z-EQ-131TN43(*) and Z-EQ-131TN5(*),LOB-35-(*), LOB-43-(*), LOB-50-(*), and LOB-60-(*)
Deep Conical (DC)	Parts labelled EQ-DC(ø)-(L)
Internal Hex (M)	Parts labelled EQ-M-(*) (used with ø3.75,4.2 and 5.0mm platforms)
Internal Hex PROVATA® (3M) (M)	Parts labelled EQ-3M-(*) (used with Ø3.3 mm platform)
	Parts labelled EQ-M-(*) (used with ø4.0, 5.0 and 6.0mm platforms)
IT (ITS) (ITS6) - Internal Octagon	Parts labelled Z-EQ-131IT48(*) (used with ø4.8mm platforms)
Single Platform (SP1)	Parts labelled EQ-SP-(*) (used with Ø3.5, 3.75, 4.0 4.5, 5.0 and 6.0 mm implants)

(*) is indicative of various lengths available.

NOTE: TRI-NEX® (Lobe) and IT (Octagon) implant equator abutments are supplied with a smart box housing and retention caps. For External Hex, Internal Hex (M-Series and PROVATA®), DC (Deep Conical) and Single Platform (SP1) ranges the housing and retentive caps needs to be ordered separately.

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

This component is supplied non-sterile and is indicated for single use. 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. Re-using these components may:

- 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 single-use components.

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

1. prevacuum sterilisation method: wrapped, steam sterilise at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilisation cycle.

NOTE: users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

Contraindications

Contraindications to implant therapy include:

- patients who are medically unfit for oral surgical procedures.
- where adequate numbers of implants cannot be placed to achieve full functional support of a prosthesis.
- patients under the age of 18.
- 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.
- allergy or hypersensitivity to pure titanium, titanium alloy (Ti6Al4V), gold, palladium or iridium.

Other than the above, there are no side effects or contraindications unique to this system.

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

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:

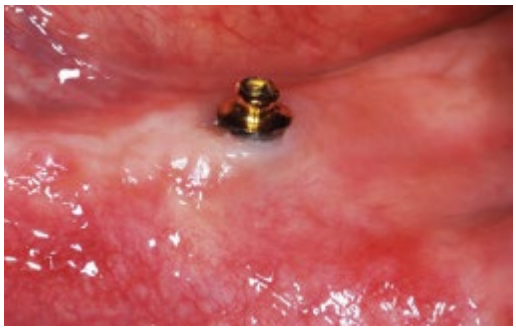
- allergic reaction(s) to implant and/or abutment material.
- breakage of the implant and/or abutment.
- loosening of the abutment screw and/or retaining screw.
- infection requiring revision of the dental implant.

- nerve damage that could cause permanent weakness, numbness or pain.
- histologic responses possibly involving macrophages and/or fibroblasts.
- formation of a fat emboli.
- 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.

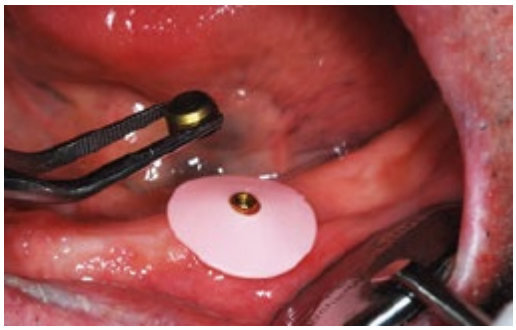
Handling procedures

Surgical procedure

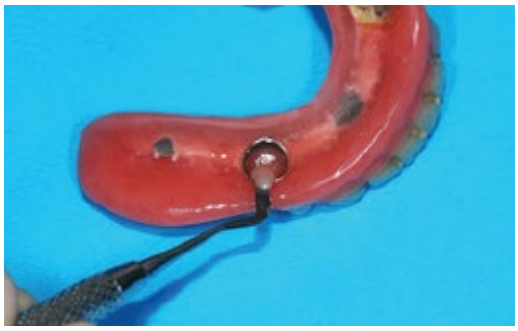
1. Select the OT Equator with the appropriate cuff height. Screw the OT Equator into the implant.



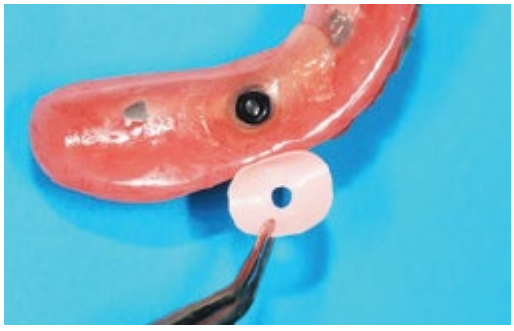
2. Place the protective disk over the OT Equator. Then, place the stainless-steel housing with cap on the attachment.



3. Fill the space corresponding to the housings with self curing resin. Insert the prosthesis into the final position.

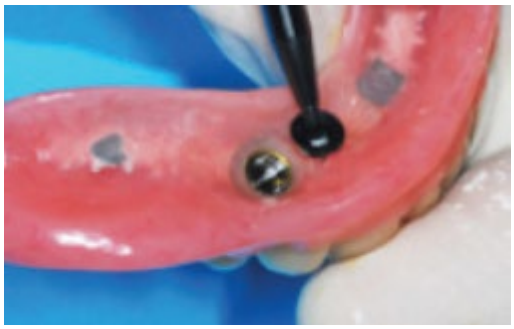


4. Once the resin has cured, remove the protective disk.

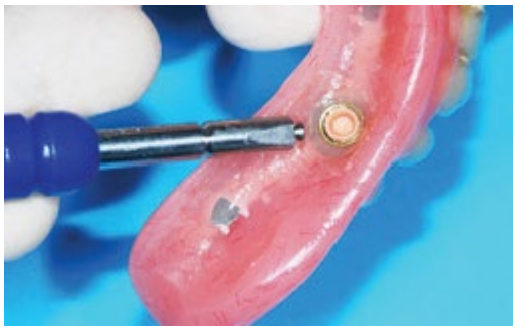


5. Remove excess resin with bur and polish for passive connection.

6. Remove black protector cap with cap extractor tool.

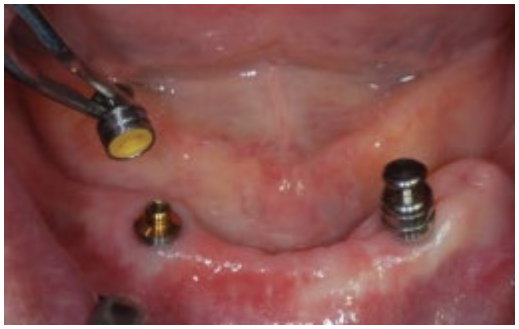


7. Using the cap insertion tool, select 1 of 4 OT Equator female caps for desired retention.



Laboratory procedure (analogue technique)

1. Place the pick-up impression coping onto the equator abutment, take the impression.



2. Place the laboratory analogues into the impression copings and pour the laboratory model.
3. Proceed with waxing, teeth set-up of the denture and try-ins.
4. Before curing the resin, connect the retentive housing with the black positioning cap on the equator lab analogue.
1. After curing remove the Black positioning cap from the metal housing with the cap extractor tool. Insert the retentive cap of choice.
2. Return to the dentist office.

Retentive cap information

Torque values and driver information

Table B

Direct to Implant	Torque	Driver
External Hex		
Ø3.0 mm	20 Ncm	I-QDI-S/M/L, I-HQD-S/M/L and I-WI-QS/M/L
Ø3.25, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	20 – 25 Ncm	
TRI-NEX®		
Ø3.5 mm	20 – 25 Ncm	Z-I-EQ25
Ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	20 – 25 Ncm	
DC		
Ø3.0 mm	5 – 10 Ncm	I-QDI-S/M/L, I-HQD-S/M/L and I-WI-QS/M/L
Ø3.5 and 4.0 mm	20 Ncm	
Ø5.0 mm	20 – 25 Ncm	
Internal Hex (M-Series & PROVATA®)		
Ø3.75, 4.2 and 5.0 mm M-Series	20 – 25 Ncm	I-QDI-S/M/L, I-HQD-S/M/L and I-WI-QS/M/L
Ø4.0, 5.0 and 6.0 mm PROVATA® Implants	20 – 25 Ncm	
IT Octagon		
Ø4.8 mm platform IT implants	20 – 25 Ncm	Z-I-EQ25
Single Platform (SP1)		
Ø3.5, 4.0 and 5.0 mm	20 Ncm	I-QDI-S/M/L, I-HQD-S/M/L and I-WI-QS/M/L

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

Overdenture Abutments	Commercially Pure Titanium (Grade 4) and Titanium Alloy (Grade 5)

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.

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 (30T/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
Basic-UDI for MA Overdenture Abut Titanium	60095440501682

Related literature and catalogues

CAT-2004 - Tri-Nex® Implants Product Catalogue
CAT-2005 - IT Implants Product Catalogue
CAT-2010 - Osseointegrated Fixtures 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 Implants Product Catalogue

Symbols and warnings

Manufacturer:
Southern Implants®
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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.