English **INSTRUCTIONS FOR USE: Southern Implants® Compact Conical Abutments**

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Description

The Compact Conical is a pre-manufactured abutment that is connected directly to an endosseous implant and is used in multiple unit reconstructions when it is desirable to raise the prosthetic interface to a more coronal position than that of an implant head, for a screw retained restoration. Compact Conical abutments are indicated for multi-unit cases only. These abutments are Titanium Nitride (TiN) coated and available in straight, 17°, 20° and 30° angles.

NOTE: angled compact conical abutments are not available for all implant interfaces, please consult product catalogues. Angled Compact Conical abutments are not indicated to be used with Southern Implants' Zygomatic implant ranges or with Southern Implants' angled or Co-Axis® implants. No additional angular correction may be fabricated into the design of the Compact Conical abutments (straight or angled) when combined with abutment cylinder components (e.g. gold cylinder, titanium cylinder, passive abutment) during the patient-specific customization. The Compact Conical abutments are provided sterile.

Intended use

The Compact Conical Abutments are intended to be used in the Maxilla or Mandible connected to an endosseous dental implant to support multiple-unit screw retained prosthetic restorations. These abutments extend the prosthetic interface above the implant platform interface (i.e. to tissue-level).

The angled Compact Conical abutments are not intended to be used with Co-Axis® implants.

Indications for use

These devices 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

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 6 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

Implant connection type	Compatible prosthetic device	
	Non-Angled	Angled
External Hex (EX)	Parts labelled APMC(*), ABNMCZ(*), AMCZ(*), ABAMCZ(*), ABBBMCZ(*) and MC-ZYG(*)(**)	Parts labelled ABNMC17d, AMC17d-3, AMC30d-4, ABAMC17d-3, ABAMC30d-4, ABBBMC17d-3 and ABBBMC30d-4
TRI-NEX (EL) (Lobe)	Parts labelled MC-L-(Ø)-(*) and MCN-L-50-(*)	Parts labelled MCL-(Ø)-17d and MCL-(Ø)-30d
Deep Conical (DC)	Parts labelled MC-DC(Ø)-(*) and MCNDC5-(*)	Parts labelled MC-DC(Ø)-20d and MC-DC(Ø)-30d
Internal Hex (M)	Parts labelled MC-M-(*) (used with Ø3.75, 4.2 and 5.0 mm platforms)	Parts labelled MC-M-20d and MC-M-30d (used with Ø3.75, 4.2 and 5.0 mm platforms)
Internal Hex PROVATA® (3M) (M) (Z)	Parts labelled MC-3M-(*) (used with Ø3.3 mm platform)	Parts labelled MC-3M-20d (used with Ø3.3 mm platform)
	Parts labelled MC-M-(*) (used with Ø4.0, 5.0 and 6.0 mm platforms)	Parts labelled MC-M-20d and MC-M-30d (used with Ø4.0, 5.0 and 6.0 mm platforms)

	Parts labelled MC-Z-(*) (used with Ø7.0, 8.0 and 9.0 mm platforms)	N/A
Single Platform (SP1)	Parts labelled MC-SP-(*) (used with Ø3.5, 4.0 and 5.0 mm implants)	Parts labelled MC-SP-17D-(*) and MC-SP-30D-(*) (used with Ø3.5, 4.0 and 5.0 mm implants)

NOTE: (*) is indicative of various lengths available.
NOTE: (**) The MC-ZYG components are only for use with the ZYGIN Zygomatic Implants

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

First clinical procedure

For straight Compact Conical abutments

1. Select and connect appropriate abutment to the implant, using the abutment driver indicated in Table B.
2. Torque the Compact conical abutment to the implant, to the value indicated in Table C.

Table B

Abutment driver	
Handheld	I-AD
Handpiece	I-HAD
Wrench	I-WI-A

For angled Compact Conical abutments: (17°, 20° and 30°)

1. Place the abutment screw in the abutment prior to bringing it to the implant. (It is not possible to seat the abutment on top of the implant and thereafter to introduce the abutment screw).
2. For Angled Compact Conical abutments (17°, 20° and 30°) use handle (supplied with the abutment) to position the abutment about 2 mm above the implant.
3. Screw the abutment screw into the implant until the abutment is pulled down to about 1 mm above the implant (refer to figure below). Now seat the abutment down on the implant.

4. Torque the angled Compact Conical abutment to the Implant, to the value indicated in Table C.

NOTE: angled Compact Conical abutments are supplied with a Titanium screw. (Screws are also available separately, consult product catalogue for codes. Gold angled Compact Conical screws must be torqued to 20 Ncm only).

Table C

Direct to Implant	Torque
External Hex	
Ø3.0 mm	20 Ncm
Ø3.25, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	20 Ncm
TRI-NEX®	
Ø3.5 mm	20 Ncm
Ø4.3, 5.0, 6.0, 7.0, 8.0 and 9.0 mm	20 Ncm
DC	
Ø3.0 mm	15 Ncm
Ø3.5 and 4.0 mm	20 Ncm
Ø5.0 mm	32 Ncm
Internal Hex (M-Series & PROVATA®)	
Ø3.75, 4.2 and 5.0 mm M-Series	32 Ncm
Ø3.3, 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 mm PROVATA® Implants	32 Ncm
Single Platform (SP1)	
Non-angled abutment onto Ø3.5, 4.0 and 5.0 mm implants.	32 Ncm
Angled abutment onto Ø3.5, 4.0 and 5.0 mm implants.	20 Ncm

The following steps are the same for both straight and angled Compact Conical abutments.

1. Verify the correct seating of the abutments using radiographic imaging.
2. Connect impression copings to the Compact Conical abutments.
3. Take an open or closed tray impression and remove/transfer the impression copings to the impression.
4. Connect the healing cap or temporary restoration direct to the Compact Conical abutments.

Laboratory procedures

1. Attach the laboratory analogues to the impression coping in the impression.
2. Fabricate a working model with removable gingival mask or soft tissue material.
3. Fabricate the restoration, consult product catalogue for prosthetic abutments options.

Clinical procedures

The clinician receives the restoration from the laboratory.

1. Remove the healing abutments or temporary restoration.
2. Clean, disinfect and sterilise the restoration.
3. Insert the restoration into the patient's mouth.
4. Position the restoration on the Compact Conical abutment, making sure that the retentive elements of the abutment connections are properly aligned.

Table D

Driver type	External Hex	DC	TRI-NEX®	Internal Hex	Single Platform
1.22 mm/1.27 mm Universal driver	✓	✓		✓	✓
1.22 mm hex driver	✓	✓			✓
1.27 mm hex Driver				✓	

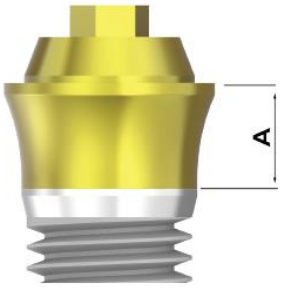
Unigrip driver	✓		✓		

5. Fix the restoration to the Compact Conical abutment with the prosthetic screw (Table E) and appropriate driver (Table D). Torque the screw down to 10-15 Ncm.
6. Verify the correct seating of the restoration using radiographic image.
7. Do not exceed the recommended torque value as this may result in failure of the screw, abutment or implant. Do not torque less than the recommended value, this may result in loosening of the abutment that can lead to abutment or implant failure.
8. Close the screw access hole.
9. Cement the final prosthesis if applicable.

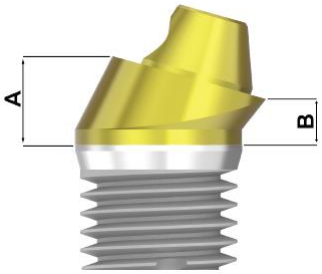
Table E

Prosthetic screw connection	**1.22 mm Hex**	**Slotted**	**Unigrip**
Screws	TSH1/ GSH1	TSS1/ GSS1	TSU1/ GSU1

Table F - Compact Conical collar height

External Connection		
External Hex Straight 		
Implant Range	**Part No.**	**Collar Height A (mm)**
Ex Hex Ø3.0	AMPC1	1.7
	AMPC3	3.0
	AMPC4	4.0
	AMPC5.5	5.5
Ex Hex Ø3.25	ABNMCZ1	1.5
	ABNMCZ2	2.0
	ABNMCZ3	3.0
	ABNMCZ4	4.0
	ABNMCZ5	5.5
Ex Hex Ø4.0	AMCZ1	1.5
	AMCZ2	2.0
	AMCZ3	3.0
	AMCZ4	4.0
	AMCZ5	5.5
Ex Hex Ø5.0	ABAMCZ1	1.5
	ABAMCZ2	2.0
	ABAMCZ3	3.0
	ABAMCZ4	4.0
	ABAMCZ5	5.5
Ex Hex Ø6.0	ABBBMCZ1	1.5
	ABBBMCZ2	2.0
	ABBBMCZ3	3.0
	ABBBMCZ4	4.0
	ABBBMCZ5	5.5

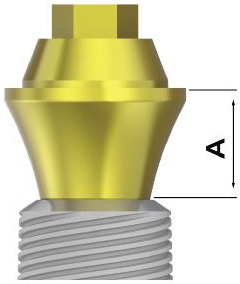
External Connection
External Hex Angled



Implant Range	Part No.	Collar Height A (mm)	Collar Height B (mm)
Ex Hex Ø3.25	ABNMC-17D	3.0	1.60
Ex Hex Ø4.0	AMC17D-3	2.90	1.50
	AMC17D-4	3.70	1.30
Ex Hex Ø5.0	ABAMC17D-3	2.90	1.50
	ABAMC17D-4	3.70	1.30
Ex Hex Ø6.0	ABBBMC17D-3	3.0	1.30
	ABBBMC17D-4	4.0	1.0

Internal Connection

Internal Hex Straight

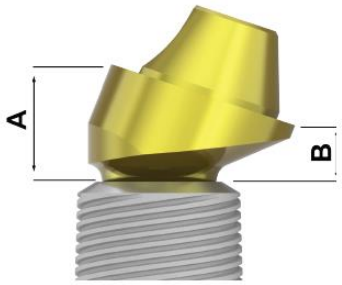


Implant Range	Part No.	Collar Height A (mm)
PROVATA® Narrow	MC-3M-1	1.0
	MC-3M-3	3.0
	MC-3M-5	5.0
PROVATA® Standard	MC-M-1	1.0
	MC-M-2	2.0
	MC-M-3	3.0
	MC-M-4	4.0
	MC-M-5	5.0
PROVATA® Wide	MC-Z-1	1.0
	MC-Z-3	3.0
	MC-Z-5	5.0
TRI-NEX® Ø3.5	MC-L-35-1	1.0
	MC-L-35-3	3.0
	MC-L-35-5	5.0
TRI-NEX® Ø4.3	MC-L-43-1	1.0
	MC-L-43-2	2.0
	MC-L-43-3	3.0
	MC-L-43-4	4.0
	MC-L-43-5	5.0
TRI-NEX® Ø5.0	MCN-L-50-1	1.0
	MCN-L-50-2	2.0
	MCN-L-50-3	3.0
	MC-L-50-1	1.0
	MC-L-50-2	2.0
	MC-L-50-3	3.0
DC Ø3.0	MC-DC3-1	1.70
	MC-DC3-3	3.20
	MC-DC3-4	4.20
	MC-DC3-5	5.20
DC Ø3.5/Ø4.0	MC-DC4-1	1.70
	MC-DC4-3	3.20

	MC-DC4-4	4.20
	MC-DC4-5	5.20
DC Ø5.0	MC-DC5-1	1.75
	MC-DC5-3	3.25
	MC-DC5-4	4.25
	MC-DC5-5	5.25
	MCN-DC5-1	1.75
	MCN-DC5-3	3.25
	MCN-DC5-4	4.25
	MCN-DC5-5	5.25
Single Platform (SP1) Ø3.5, 4.0 and 5.0 mm implants.	MC-SP-1.5	1.50
	MC-SP-2.5	2.50
	MC-SP-3.5	3.50
	MC-SP-4.5	4.50

Internal Connection

Internal Hex Angled



Implant Range	Part No.	Collar Height A (mm)	Collar Height B (mm)
PROVATA® Narrow	MC-3M-20D	3.20	1.60
PROVATA® Standard	MC-M-20D	2.85	1.20
	MC-M-30D	3.0	0.60
TRI-NEX Ø3.5	MCL-35-17D-2	2.20	0.80
	MCL-35-17D-3	3.0	1.60
TRI-NEX Ø4.3	MCL-43-17D-2	2.20	0.80
	MCL-43-17D-3	3.0	1.60
	MCL-43-17D-4	4.0	2.60
	MCL-43-30D-4	4.0	1.60
DC Ø3.0	MC-DC3-20	3.10	1.50
	MC-DC3-30	3.10	0.70
DC Ø3.5/Ø4.0	MC-DC4-20	3.15	1.50
	MC-DC4-30	3.15	0.70
Single Platform (SP1) Ø3.5, 4.0 and 5.0 mm implants.	MC-SP-17D-1.5	2.90	1.50
	MC-SP-17D-2.5	3.90	2.50
	MC-SP-17D-3.5	4.90	3.50
	MC-SP-30D-2.5	4.90	2.50
	MC-SP-30D-3.5	5.90	3.50

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); Titanium Alloy (Ti-6Al-4V)

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-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®
1 Albert Rd, P.O Box 605 IRENE, 0062,
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.