



SOUTHERNIMPLANTS®

Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Deep Conical Inverta™ and External Hex Inverta™
Español	INSTRUCCIONES DE USO: Deep Conical Inverta™ and External Hex Inverta™
Italiano	ISTRUZIONI PER L'USO: Deep Conical Inverta™ and External Hex Inverta™
Français	MODE D'EMPLOI: Deep Conical Inverta™ and External Hex Inverta™



South Africa - Headquarters:
1 Albert Road, Irene, 0062, RSA
T: +27-12-667-1046
E: info@southernimplants.com

Subsidiaries

Australia
Southern Implants Australia
T: +61-(0)-8-9466-2627
E: info@southernimplants.com.au

United Kingdom
Southern Implants UK
T: +44 20 8899 6845 / 6 / 7
E: info@southernimplants.co.uk

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

Indications for use

Southern Implants® Inverta™ Implants are intended for placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures.

Southern Implants' Inverta Implants are intended for immediate function with appropriate occlusal loading, provided good primary stability is achieved.

Description

Southern Implants Inverta implants are made from biocompatible, commercially pure, Grade 4 Titanium and are available in a range of lengths and diameters and are to be used with a range of prosthetic components (see the Inverta Implant product catalogue CAT-2069).

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,
- or who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6Al-4V).

Warnings

THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.

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, 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.
- 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 to ensure favourable long-term results.

Compatibility information

Southern Implants® Inverta™ implant range are available in two connections. It is essential to only use Southern Implants components corresponding to the connection type and prosthetic platform when restoring the dental implant. For further information please see Inverta product catalogue CAT-2069. Summarized in Table 1 is information to help you identify whether a particular part is compatible with the implant you are restoring.

IMPLANT TYPE	CONNECTION TYPE	NON-ANGLED IMPLANTS LABELLED	ANGLED IMPLANTS LABELLED	PROSTHETIC PLATFORM TYPE	COMPATIBLE PARTS
Inverta	Deep Conical	IV-DC35-45xx	IV-DC3512D-45xx	ø4,0mm	Parts labelled blue, with DC4 in product code
		IV-DC40-50xx	IV-DC4012D-50xx		
Inverta	External Hex	IV-EX35-45xx	IV-EX3512D-45xx	ø3,25	Parts labelled blue, "N" & ø3,4mm in product code
		IV-EX40-50xx	IV-EX4012D-50xx		

Table 1

Sterilization, cleaning and disinfection

The implants are supplied sterile 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. Do not re-sterilize or autoclave these components. Southern Implants does not accept any responsibility for re-sterilized implant.

Procedure

Consult CAT-2069 (Inverta catalogue) for the step by step Osteotomy preparation procedure and product information.

Drill at the recommended speed using an intermittent technique with adequate cooling to minimize thermal trauma to the implant site.

Implant placement

Inverta Deep Conical implants, non angled (IV-DC35-45xx & IV-DC40-50xx) are picked up and placed with a placement tool (I-HDC4-S/M).

Inverta 12° Co-Axis Deep Conical implants (IV-DC3512D-45xx & IV-DC4012D-50xx) are supplied with a fixture mount, the placement tool (I-HDC4-S/M) is inserted into the fixture mount to pick up and place the implant.

Inverta non angled and 12° Co-Axis External Hex implants are supplied with a Fixture mount, the placement tool (I-CON-X/S) is placed onto the fixture mount to pick up and place the implant.

Implants placement speed: 15rpm for all implants.

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. Inverta Implants are suitable for immediate placement in an extraction socket. Good primary stability will govern if immediate loading can be done, Inverta implants are suitable for implantation in edentulous or partially edentulous Maxilla and Mandible to replace missing teeth.

A radiographic check must be done after a healing phase or during immediate loading, before starting the prosthetic restoration.

Magnetic Resonance (MR) safety information

Southern Implants have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artefact in the MR environment. The safety of Southern implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Disposal

Disposal of the device and its packaging shall follow local regulations and environmental requirements, taking different contamination levels into account.

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.

Symbols and Warnings

 Manufacturer: Southern Implants 1 Albert Rd, P.O Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046 Fax: +27 12 667 1029	 2797	 Prescription device*	 Sterilization using Irradiation	 Non-sterile	 Caution	 Consult instruction for use	 Use by date (mm-yy)	 Do not reuse	 Do not re-sterilize	 Batch code	 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.					
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