

English

**INSTRUCTIONS FOR USE: Southern Implants® Inverta Implants**



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## Description

Inverta® implants are narrow platform implants with wider external threads at the apical end to provide greater bone contact and assist in initial stability in immediate extraction sockets.

## Indications for use

Inverta® 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. Inverta® Implant System is intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

## Contraindications

Do not use an Inverta® implant:

- In cases where the remaining bone anatomy is not suitable to allow for implant placement
- In patients with hypersensitivities to pure titanium or titanium alloy (Ti-6AL-4V)
- In patients with insufficient mental health precluding patient cooperation
- In patients with a history of drug or alcohol abuse
- In patients with conditions such as, but not limited to:
  - Myocardial infarction within the last year
  - Infections around the implant site
  - Malignancies
- In patients with uncontrolled diabetes or blood disorders
- Inverta® Co-Axis Implants are not intended for use with angled abutments

## Precautions:

New and experienced Implant users should undergo training before using a new system or attempting a new treatment protocol.

Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue. (e.g. poor oral hygiene, uncontrolled diabetes, steroid therapy, etc.)

Proper pre-operative planning must be conducted to deal with hard and soft tissue defects that could affect the functional and aesthetic outcomes. In case of bruxism or unfavorable jaw relation, re-evaluation of the treatment plan must be considered.

Care must be taken that parts are not swallowed during any of the procedures, thus rubber-dam application, when appropriate is recommended at all times.

All dental implant rehabilitations require proper home care and regular follow-up appointments to ensure a successful long-term outcome.

## The Concept

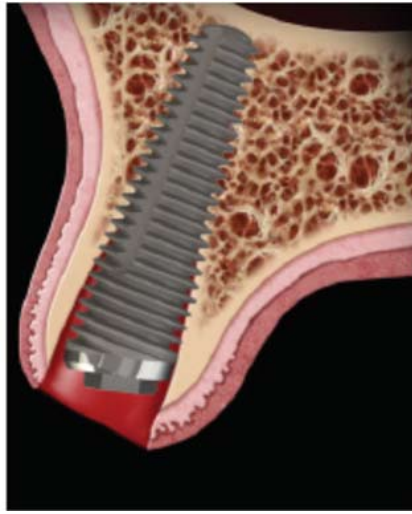
The Inverta implant's unique design combines the advantage of high initial stability achieved with a large-diameter implant apically, with maintenance of a 2-3 mm gap distance between the facial bone plate and the implant achieved with a narrow diameter implant coronally. This gap allows for a blood clot and new labial bone plate formation through secondary healing, as well as preventing "palatal bounce" typically seen with conventional tapered implants in immediate extraction sockets. "Palatal bounce" is a situation in which the apical portion of a dental implant is placed into the extraction socket and the wider neck engages the palatal bone plate creating deflection to the facial aspect of the extraction socket. This can result in undesirable labial positioning and potentially decrease the gap distance between the dental implant and the facial aspect of the extraction socket.

Inverta®'s body shift (A) enables the surgeon to take advantage of the stability provided by a large diameter implant (B), while retaining the gap distance provided by a narrow diameter implant (C), in order for stabilization grafting to be placed to maintain socket volume and protect against labial bone plate collapse. In comparative testing in synthetic

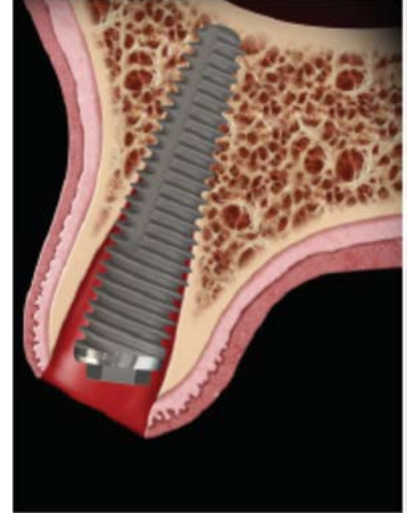
bone, Inverta® Co-Axis implant shows an increase in mean insertion torque of at least 163% over the standard Co-Axis External Hex implant having a similar coronal diameter.



**Fig A:** Ø3.5/Ø5.0 12° Co-Axis Inverta® Implant



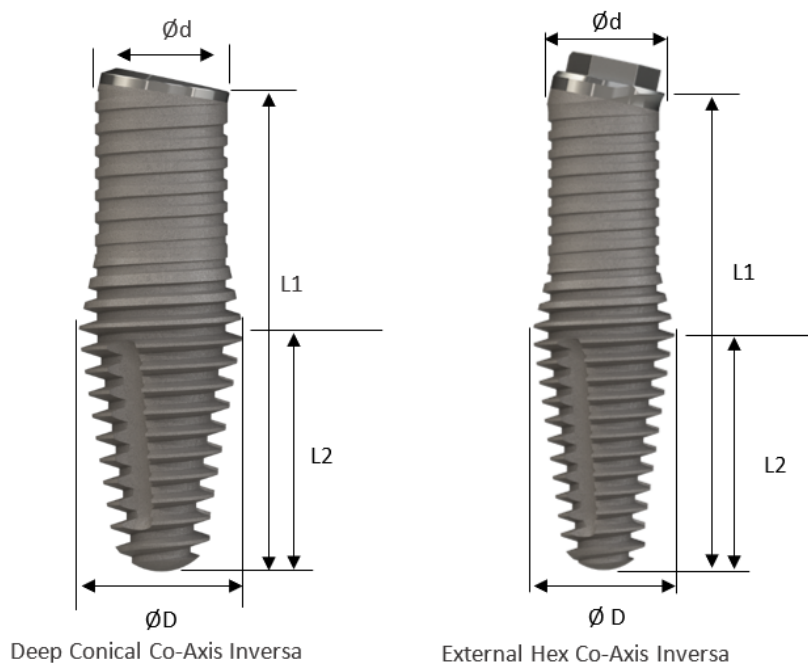
**Fig B:** Ø5.0 12° Co-Axis BAR Implant



**Fig C:** Ø4.0 12° Co-Axis IBR Implant

#### Available sizes and prosthetic compatibility

Unlike regular implants, the size of an Inverta® implant is characterized by the length, the diameter at the coronal end, as well as the body shift diameter. Inverta® implants are available in 4 different lengths and multiple coronal/ body shift diameter configurations (see Table A and Figure D).



**Fig D:** Size definitions for Table A

**Table A - List of available Co-Axis Inverta® implants**

Product code	Description	Coronal diameter (d) mm	Apical diameter (D) mm	L1 mm	L2 mm
IVM/IV-DC3512D-4511	Implant, Ø3.5/Ø4.5 Inverta® Deep Conical, 12° Co-Axis	3.6	4.5	11.5	5.75
IVM/IV-DC3512D-4513				13	6.5
IVM/IV-DC3512D-4515				15	7.5
IVM/IV-DC3512D-4518				18	9
IVM/IV-DC4012D-5011	Implant, Ø4.0/Ø5.0 Inverta® Deep Conical, 12° Co-Axis	4.0	5.0	11.5	5.75
IVM/IV-DC4012D-5013				13	6.5
IVM/IV-DC4012D-5015				15	7.5
IVM/IV-DC4012D-5018				18	9
IVM/IV-EX3012D-3711	Implant, Ø3.50/Ø3.75 Inverta® External Hex, 12° Co-Axis	3.09	3.75	11.5	5.75
IVM/IV-EX3012D-3713				13	6.5
IVM/IV-EX3012D-3715				15	7.5
IVM/IV-EX3512D-4511	Implant, Ø3.5/Ø4.5 Inverta® External Hex, 12° Co-Axis	3.5	4.5	11.5	5.75
IVM/IV-EX3512D-4513				13	6.5
IVM/IV-EX3512D-4515				15	7.5
IVM/IV-EX3512D-4518				18	9
IVM/IV-EX4012D-5011	Implant, Ø4.0/Ø5.0 Inverta® External Hex, 12° Co-Axis	4.0	5.0	11.5	5.75
IVM/IV-EX4012D-5013				13	6.5
IVM/IV-EX4012D-5015				15	7.5
IVM/IV-EX4012D-5018				18	9
IV-EX4212D-5011	Implant, Ø4.2/Ø5.0 Inverta® External Hex, 12° Co-Axis	4.2	5.0	11.5	5.75
IV-EX4212D-5013				13	6.5
IV-EX4212D-5015				15	7.5
IV-EX4212D-5018				18	9
IVM/IV-EX5212D-6011	Implant, Ø5.2/Ø6.0 Inverta® External Hex, 12° Co-Axis	4.2	5.0	11.5	5.75
IVM/IV-EX5212D-6013				13	6.5
IVM/IV-EX5212D-6016				15	7.5
IVM/IV-EX5212D-6018				18	9

\* IVM denotes the MSC version of the implant

Dedicated tapered drills are also provided for each length and body shift diameter version of the Inverta®. A complete list of the prosthetic compatibility, dedicated drill and recommended insertion torque for each version of the Inverta® is provided in Table B.

**Table B - Connection system interface, prosthetic component compatibility, dedicated drill and recommended insertion torque for Co-Axis Inverta® implants**

Product code	Connection system interface and prosthetic compatibility	Dedicated drill	Recommended insertion torque range (Ncm)
IV-EX3012D-37SET	Ø3.0 External Hex (IP) <sup>1</sup>	D-IV37SET	25-35

IV-EX3512D-45SET	Ø3.43 External Hex (IBN) <sup>1</sup>	D-IV45SET	25-35
IV-EX4012D-50SET	Ø3.43 External Hex (IBN) <sup>1</sup>	D-IV50SET	32-45
IV-EX4212D-50SET	Ø3.43 External Hex (IBN) <sup>1</sup>	D-IV50SET	32-45
IV-EX5212D-60SET	Ø5.0 External Hex (BA) <sup>1</sup>	D-IV60SET	35-50
IV-DC3512D-45SET	Ø3.5/4.0 Deep Conical (DC) <sup>1</sup>	D-IV45SET	25-35
IV-DC4012D-50SET	Ø3.5/4.0 Deep Conical (DC) <sup>1</sup>	D-IV50SET	32-45

<sup>1</sup>Please refer to Southern Implants' INVERTA® implant Prosthetic Flow Chart (CAT-2069 and CAT-2095) for a full list of available prosthetic components and screws.

**Table C - List of available Straight Inverta® implants**

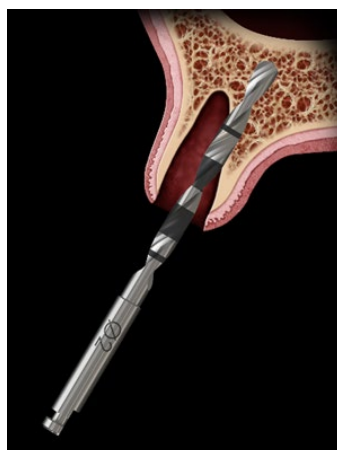
Item Code	MSc	Tapered/Cylindrical	Implant Diameter (mm)	Implant Lengths (mm)
<b>DC Inverta® Implants</b>				
IV-DC30-35		Tapered	Ø3.0 – Ø3.5	8/ 10/ 11.5/ 13/ 15
IV-DC30-37		Tapered	Ø3.0 – Ø3.7	8/ 10/ 11.5/ 13/ 15
IV-DC35-45		Tapered	Ø3.5 – Ø4.5	8/ 10/ 11.5/ 13/ 15/ 18
IV-DC40-50		Tapered	Ø4.0 – Ø5.0	8/ 10/ 11.5/ 13/ 15/ 18
IV-DC50-60		Tapered	Ø5.0 – Ø6.0	10/ 11.5/ 13/ 15/ 18
IVM-DC30-37	✓	Tapered	Ø3.0 – Ø3.7	8/ 10/ 11.5/ 13/ 15
IVM-DC35-45	✓	Tapered	Ø3.5 – Ø4.5	8/ 10/ 11.5/ 13/ 15/ 18
IVM-DC40-50	✓	Tapered	Ø4.0 – Ø5.0	8/ 10/ 11.5/ 13/ 15/ 18
IVM-DC50-60	✓	Tapered	Ø5.0 – Ø6.0	10/ 11.5/ 13/ 15/ 18
<b>External Hex Inverta® Implants</b>				
IV-EX30-37		Tapered	Ø3.0 – Ø3.7	10/ 11.5/ 13/ 15
IV-EX35-45		Tapered	Ø3.5 – Ø4.5	10/ 11.5/ 13/ 15
IV-EX40-50		Tapered	Ø4.0 – Ø5.0	10/ 11.5/ 13/ 15
IV-EX52-60		Tapered	Ø5.2 – Ø6.0	10/ 11.5/ 13/ 15
IVM-EX30-37	✓	Tapered	Ø3.0 – Ø3.7	10/ 11.5/ 13/ 15
IVM-EX35-45	✓	Tapered	Ø3.5 – Ø4.5	10/ 11.5/ 13/ 15
IVM-EX40-50	✓	Tapered	Ø4.0 – Ø5.0	10/ 11.5/ 13/ 15
IVM-EX52-60	✓	Tapered	Ø5.2 – Ø6.0	10/ 11.5/ 13/ 15

### Surgical Procedure for Inverta® implants with a Ø4.5 apical body shift diameter

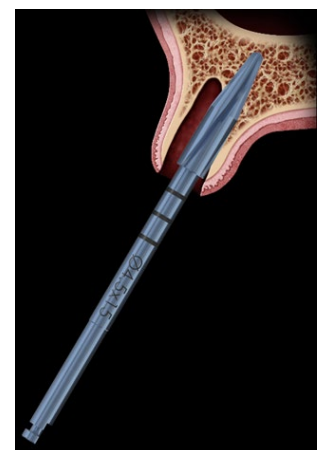
Site preparation sequence (shown here for an IV-EX3512D-4515 implant):



Initiate site preparation with the spade drill D-3SPADE-1.8M



Drill a Ø2.0mm pilot hole using the D-20T-M15 twist drill



Complete the site preparation using the dedicated D-IV4515 final drill



Place the implant with a speed of 20rpm or less. Expect insertion torque between 30-50Ncm

### Surgical Procedure for Inverta® implants with a Ø5.0 apical body shift diameter

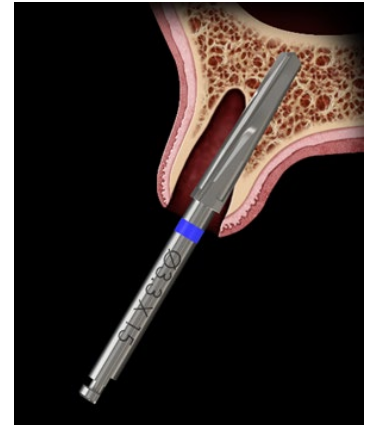
Site preparation sequence (shown here for a IV-EX4012D-5015 implant):



Initiate site preparation with the spade drill D-3SPADE-1.8M



Drill a Ø2.0mm pilot hole using the D-20T-M15 twist drill



Expand the osteotomy with a D-33TP tapered drill



Expand the osteotomy with a D-40TP tapered drill

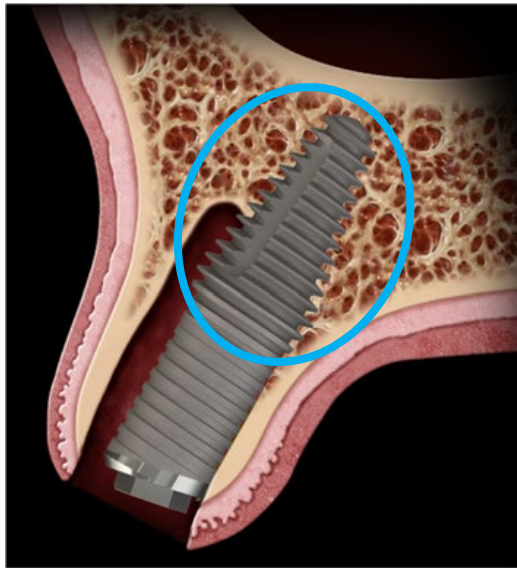


Complete the site preparation using the dedicated D-IV5015 final drill

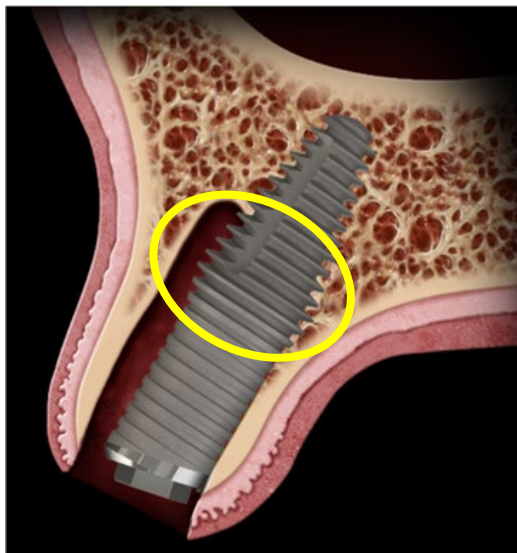


Place the implant with a speed of 20rpm or less. Expect insertion torque between 30-50Ncm



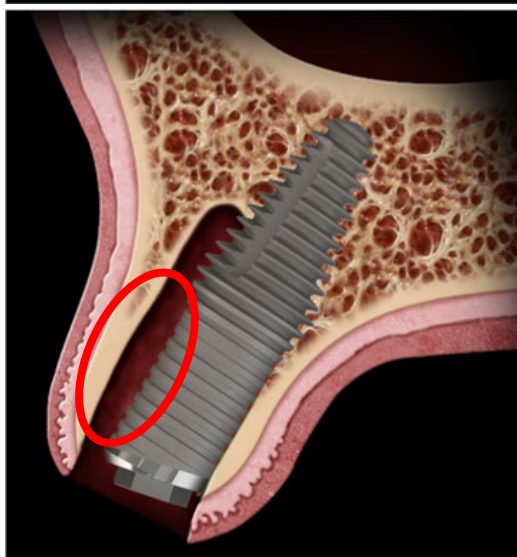
**Body shift concept (shown for an IV-EX4012D-5015 implant)**

The wide tapered apical section of the Inverta® implant (highlighted by the blue ellipse) provides high bone to implant contact and high initial stability



The body shift feature (highlighted by the yellow ellipse) applies the theory of platform shifting to the body of the implant by shifting the external diameter of the implant body from a wide section to a narrow cylindrical section.

Hence the name: body shift



By shifting the external diameter of the implant body from a wide section to a narrow cylindrical section, a gap between the implant and the buccal bone plate is created, allowing a blood clot to form, or grafting material to be placed.

The decision whether or not to graft is left to the discretion of the user

## Magnetic Resonance (MR) safety information

This product has 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 this product in the MR environment is unknown. MR scanning a patient with one of these devices may result in patient injury.

## Storage, Cleaning & sterilization

Inverta® implants are also supplied sterile, for single use. The packaging consists of rigid, clear boxes which provide protection for the inner package. The inner package consists of a clear plastic-formed bubble type base with “peel-back” lid. The contents of this inner package are sterile. Within the inner package there is a hollow tube which contains a single implant. Labelling information is located on the surface of the inner package’s peel-back lid and on the outside of the rigid box. Please refer to individual product label for more information and expiration date. Sterility is assured unless the container or seal is damaged or opened.

## Disposal

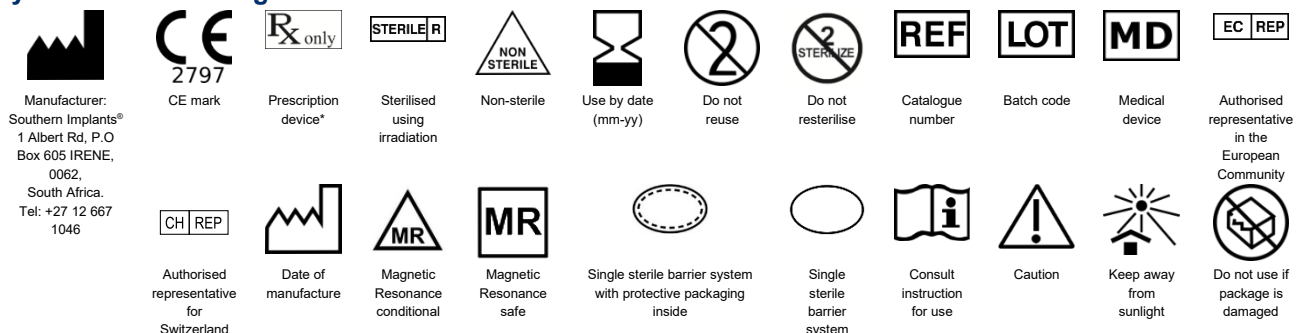
Disposal of this device and its packaging shall follow local regulations and environmental requirements, taking different contamination levels into account.

## Disclaimer of liability

Southern Implants products have only been validated for use with the corresponding implants in the specific product range referred to in Table B. Although care has been taken to create dimensions that are common to the industry, Southern Implants cannot guarantee outcomes obtained using components from other manufacturers. Please refer to individual product catalogues. 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 and/or loss of supporting bone.

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 Southern Implants product documentation. The user of this product undertakes to remain abreast of development of the Southern Implants product range and assumes full responsibility for the correct 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



\* Prescription device: Rx only. Caution: Federal Law restricts this device to sale by or on the order of a licenced physician or dentist.

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