SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English

INSTRUCTIONS FOR USE: Southern Implants® External Hex Implants

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Description

The External Hex implant is a self-tapping implant made of commercially pure special Grade 4 Titanium (UTS ≥900 Mpa). Implants are available with either a tapered or parallel walled body shape. All implants are surface-roughened up to the collar using Southern Implants' proven surface. The surface has a S_a value of a 1.4 microns. The External Hex implant is also available in the angulated platform Co-Axis® design. With a built-in platform angulation of 12°, 24° and 36°, this design enables tilting of the implant without compromising the restorative emergence angle.

Intended use

This system is intended to aid in the treatment of 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.

These devices are intended to be placed into a pre-drilled site in the alveolar bone where they osseointegrate (form a rigid connection with bone), and an abutment is attached for retention of a prosthesis.

The devices allow for immediate or delayed prosthetic restoration based on the user's evaluation of the patient's eligibility.

The system constituents are classified as medical devices and are intended for single use on a single patient.

Indications for use

Southern Implants' External Hex implants are 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. Southern Implants' External Hex implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

<u>For Standard Length IBR36d Implant Range:</u>
Southern Implants' External Hex Implants are 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. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

When using Southern Implants' Standard Length IBR36D Implants with angulation of 36° a minimum of 4 implants must be used and splinted

The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.

<u>For Extra Length IBR36d Implant Range:</u>
Southern Implants' External Hex Implants are 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. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

Extra Length IBR36d Implants can be placed bicortically in cases of reduced bone density. Extra Length IBR36d Implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Extra Length IBR36d Implants are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.

The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.

For Extra Length IBR24d Implant Range:
Southern Implants' External Hex Implants are intended for surgical placement in the upper jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

Southern Implants' Extra Length IBR24d Implant Range when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.

Intended user
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 theatre or a dentist consultation room.

Intended patient population
This device is used in the dental restoration of partially or fully edentulous patients in the upper or lower jaw. Restorations may comprise of single teeth, partial or full bridges, and may be fixed or removable.

Compatibility information
Southern Implants' implants should be restored with Southern Implants' components. Use components that correspond to the connection type and prosthetic platform when restoring the External Hex implants.

- Ø4.1mm IBR 12°and 24°Co-Axis® implants, in lengths 8-18mm, use External Hex Ø3.25mm prosthetic components.
- Ø4.1 IBR 24° Co-Axis® implants, in lengths 20-24mm, are restricted to use with the ABNMCZ-SET multi-unit abutments and use External Hex Ø3.25mm cover screws and healing abutments.
- Ø4.2 IBR 36° Co-Axis® implants are restricted to use with the ABNMCZ-SET multi-unit abutments and use External Hex Ø3.25mm cover screws and healing abutments.
- Ø5.0mm BAR 12°, 24°, and 36° Co-Axis® implants use External Hex Ø4.0mm prosthetic components.
- Ø3.5/Ø4.5mm INVERTA® Co-Axis® implants use External Hex Ø3.25mm prosthetic components.
- Ø4.0/Ø5.0mm INVERTA® Co-Axis® implants use External Hex Ø4.0mm prosthetic components.
- Ø5.2/Ø6.0mm INVERTA® Co-Axis® implants use External Hex Ø5.0mm prosthetic components.

For further information see the product catalogues (CAT-2020 & CAT-2095).

Table A – External Hex implant range

Item Code	MSc	Tapered/Cylindrical	Implant Diameter (mm)	Implant Lengths (mm)
Regular Implants				
Straight				
IP	✓	Tapered	Ø3.0	8.5/ 10/ 11.5/ 13/ 15
IBN		Cylindrical	Ø3.25	8.5/ 10/ 11.5/ 13/ 15/ 18
IBNT	✓	Tapered	Ø3.25	8.5/ 10/ 11.5/ 13/ 15/ 18
IBS	✓	Cylindrical	Ø3.75	7/ 8.5/ 10/ 11.5/ 13/ 15/ 18/ 20
I4B		Cylindrical	Ø4.0	7/ 8.5/ 10/ 11.5/ 13/ 15
IBT	✓	Tapered	Ø4.0	6/ 8.5/ 10/ 11.5/ 13/ 15/ 18
IBPS		Tapered	Ø4.0	8.5/ 10/ 11.5/ 13/ 15
BA	✓	Cylindrical	Ø5.0	6/ 7/ 8.5/ 10/ 11.5/ 13/ 15/ 18
BAT	✓	Tapered	Ø5.0	6/ 8.5/ 10/ 11.5/ 13/ 15/ 18
BBBT		Tapered	Ø6.0	6/ 8.5/ 10/ 11.5/ 13/ 15/ 18

Co-Axis®				
IBNT12D	✓	Tapered	Ø3.25	8.5/ 10/ 11.5/ 13/ 15/ 18
IBT12D	✓	Tapered	Ø4.0	8.5/ 10/ 11.5/ 13/ 15/ 18
IBR12D	✓	Tapered	Ø4.0	8.5/ 10/ 11.5/ 13/ 15/ 18
IBR24D	✓	Tapered	Ø4.0	8.5/ 10/ 11.5/ 13/ 15/ 18/ 20/ 22/ 24
IBR36D		Tapered	Ø4.0	8.5/ 10/ 11.5/ 13/ 15/ 18/ 20/ 22/ 24
BAT12D	✓	Tapered	Ø5.0	8.5/ 10/ 11.5/ 13/ 15/ 18
BAR12D	✓	Tapered	Ø5.0	8.5/ 10/ 11.5/ 13/ 15/ 18
BAR24D	✓	Tapered	Ø5.0	8.5/ 10/ 11.5/ 13/ 15/ 18
BAR36D		Tapered	Ø5.0	8.5/ 10/ 11.5/ 13/ 15/ 18/ 20/ 22/ 24
BBBT12D		Tapered	Ø6.0	10/ 11.5/ 13/ 15/ 18
BBBT24D		Tapered	Ø6.0	10/ 11.5/ 13/ 15/ 18
INVERTA® Implants				
Straight				
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
Co-Axis®				
IV-EX3012D-37		Tapered	Ø3.0 – Ø3.7	11.5/ 13/ 15
IV-EX3512D-45		Tapered	Ø3.5 – Ø4.5	11.5/ 13/ 15/ 18
IV-EX4012D-50		Tapered	Ø4.0 – Ø5.0	11.5/ 13/ 15/ 18
IV-EX5212D-60		Tapered	Ø5.2– Ø6.0	11.5/ 13/ 15/ 18
IVM-EX3012D-37	✓	Tapered	Ø3.0 – Ø3.7	11.5/ 13/ 15
IVM-EX3512D-45	✓	Tapered	Ø3.5 – Ø4.5	11.5/ 13/ 15/ 18
IVM-EX4012D-50	✓	Tapered	Ø4.0 – Ø5.0	11.5/ 13/ 15/ 18
IVM-EX5212D-60	✓	Tapered	Ø5.2– Ø6.0	11.5/ 13/ 15/ 18
Internal Drive External Hex Implants				
INPI		Cylindrical	Ø3.3	8.5/ 10/ 11.5/ 13/ 15
IBI		Cylindrical	Ø3.75	7/ 8.5/ 10/ 11.5/ 13/ 15/ 18/ 20
IBTI		Tapered	Ø4.0	8.5/ 10/ 11.5/ 13/ 15/ 18
BAI		Cylindrical	Ø5.0	6/ 7/ 8.5/ 10/ 11.5/ 13/ 15/ 18
BATI		Tapered	Ø5.0	10/ 11.5/ 13/ 15/ 18
BBBI		Cylindrical	Ø6.0	7/ 8.5/ 10/ 11.5/ 13/ 15
BBBTI		Tapered	Ø6.0	8.5/ 10/ 11.5/ 13/ 15/ 18

Clinical benefits

The 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.

Surgical Protocol

1. Extra Length IBR36d Implants (Pterygoid placement)

Procedural Precautions – Surgery

Surgical placement of pterygoid implants is to be performed by an experienced clinician and can be performed under local anesthesia in a dental office. The disadvantages of the pterygoid implant are the learning curve and technique sensitivity associated with the procedure and proximity to certain vital anatomic structures, including the middle cranial fossa and cerebellar structures. Clinicians must understand surgical anatomy before placement of implants in this region. Additionally, use of cone beam computed tomography (CBCT) imaging is recommended during treatment planning.

Patient Selection

A thorough clinical assessment must be done to determine the physical and psychological health of the patient. Take care when treating patients with local or systemic factors that could affect the healing process of the tissues or interfere with the osseointegration process (e.g. smoking, uncontrolled diabetes, radiotherapy, steroid therapy, poor oral hygiene, infection of the oral tissue and/or bisphosphonate therapy etc.).

Preoperative Evaluation

Before surgery, a proper radiographic examination should be done. Panoramic and CBCT should be taken. Analysis of the structure and shape of the maxillary region should be done concerning the intranasal sinus morphology and alveolar bone quality and shape. When analysing the patient morphology to determine if a Pterygoid implant would be a potential treatment solution, it is important to classify the pterygomaxillary region shape and sinus morphology.

Cautions:

- In cases of soft bone and minimal bone height, it is recommended to do a 2-stage procedure with prolonged healing time before the implants are loaded.
- Ensure that the patient's mouth opening capacity is sufficient for implant surgery.
- Choose the appropriate size implant for the volume of bone available.

Surgical Placement

Step 1: Tabling the bone at the insertion point.

NOTE: it is recommended to raise a full-thickness mucoperiosteal flap.

A round burr (D-RB-MS) is used to prepare the osteotomy insertion point by flattening the alveolar ridge at the desired location.

All drilling should be performed at a speed of 1000-1500 rpm with copious irrigation.

An intermittent technique should always be used to avoid overheating of the bone. Care should be taken not to perforate the sinus.

Step 2: Initiate the osteotomy and drill to the posterior wall of the maxillary sinus.

Initiate the osteotomy by perforating the cortical plate at the desired location using the dual-diameter drill (D-20PT-M16). The drilling angle should not be greater than 36°.

Continue drilling in the planned direction through the alveolar bone, into and across the sinus (should the surgical approach planned be a trans-sinus protocol), until the tip of the drill engages the hard cortical bone of the posterior wall of the maxillary sinus (just before entering the pterygoid fossa).

Should the markings at the alveolar bone be between the 12 and 18 mm lines, proceed to step 5.

Step 3: Adjust the entry point.

Use the side cutting drill (D-18PT-M18) to adjust the entry point of the osteotomy either mesially or distally in order to move the osteotomy entrance between the 12 and 18 mm length from the posterior wall of the maxillary sinus. This can be validated by aligning it to the laser markings on the drill.

Step 4: Confirm drilling orientation.

Insert the direction indicator (I-DI-36D) to verify the alignment with adjacent teeth/implants and opposing dentition.

A radiograph may be taken at this point to verify depth and direction.

If the drilling direction is incorrect, either start a new osteotomy or adjust using the side-cutting burr mentioned in step 3.

Step 5: Enlarging the osteotomy on the alveolar ridge.

Enlarge the alveolar osteotomy using the ⌀2.8 mm drill.

Step 6: Drill to final depth.

Drill to depth using the twist drill initially used in Step 2 (D-20PT-M16).

Continue drilling in the planned direction and perforate the cortical bone entering the pterygoid fossa. Do not drill past the pterygoid process.

Once the drill has just entered the pterygoid fossa, determine the desired implant length by the corresponding laser marking on the drill (20, 22 or 24 mm).

Step 7: Final osteotomy shaping drill.

Pterygoid implants are available in 20, 22 and 24 mm lengths which each have a corresponding tapered drill. The dedicated tapered drills are length and diameter-specific (D-40TP-20/22/24).

Drill using the dedicated tapered drill to widen the osteotomy to full depth.

WARNING: it is essential to use the dedicated Ø4.0 tapered drills (i.e., D-40TP-20/22/24) and no other tapered drills to prevent over-preparation of the apical portion of the osteotomy which may be caused by the larger apical diameter of non-dedicated tapered drills.

Step 8: Implant placement.

The Pterygoid Co-Axis® implants are supplied premounted with a fixture mount. This enables the Co-Axis® implant to be placed in the same manner as a straight implant.

Connect the fixture mount driver (I-CON-X/XS) to the handpiece. Carefully remove the implant and fixture mount assembly from the sterile vial.

The fixture mount is laser-marked 3 mm above the implant platform to indicate depth of placement. One full turn of the implant corresponds to 0.6 mm in placement depth.

Insert the implant at low speed (15 - 25 rpm) with no irrigation. Set the maximum torque to 50 Ncm. The implant should engage the pterygoid plate in the pterygoid process to allow for bicortical anchorage with the cortical plate of the alveolar bone.

Step 9: Fully seat the implant.

The implant can be fully seated in 3 methods:

- The ratchet and torque attachment wrench (I-TWS with I-TWS-B100), in combination with the wrench converter (I-WI-SS), is used on the fixture mount.
- Use of the hand driver (I- IMP-INS-2 or I-ZYG-INS-2)
- Use of the motor unit handpiece.

Use light force on the wrench when levelling the implant.

Avoid excessive torque (>50 Ncm) with the wrench, as this can cause damage to the implant. A torque exceeding the maximum limit indicates that the implant should be retrieved, and additional drilling should be performed to increase the depth and diameter of the osteotomy site. It is advised to ensure that the fixture mount is tightened using a 1.22 mm hex driver before proceeding with this step.

NOTE: since the implants are self-tapping, it is recommended to stop rotation once the implant has reached the prepared depth. The implant may continue to advance beyond the drilled depth with further rotations. Care should be taken not to sink the implant too far, especially in soft bone.

Once the implant is placed and the position verified with a final radiograph, remove the fixture mount by using a 1.22 mm hex driver.

NOTE: a useful tool to indicate the direction of the prosthetic axis of a Co-axis® implant is by inserting the 1.22 mm Hex driver in the fixture mount screw before removal.

Step 10: Proceed with either an immediate loading protocol, one-stage or two-stage protocol.

Depending on the primary stability, patient factors and clinical decision, the treatment can proceed following either an immediate loading protocol, one-stage or two-stage protocol.

Should a two-stage procedure be followed, place the cover screw with a 0.9 mm hex driver (white idler). Tighten to 10 Ncm.

Should a one-stage procedure be followed, place the healing abutment with a 1.22 mm hex driver (grey or blue idler). Tighten to 15 Ncm. Alternatively, should good primary stability be achieved, the permanent abutment, a compact conical abutment, can be placed and tightened to 20 Ncm using the dedicated abutment driver (I-AD).

Caution: These guidelines serve as informational instructions only, and it is crucial for clinicians to exercise their experience and judgment in establishing the most appropriate treatment protocol for the patient.

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2. Standard Length IBR36d Implants

SURGICAL GUIDELINES

A thorough clinical assessment must be done to determine the physical and psychological health of the patient. Take care when treating patients with local or systemic factors that could affect the healing process of the tissues or interfere with the osseointegration process (e.g. smoking, uncontrolled diabetes, radiotherapy, steroid therapy, poor oral hygiene, infection of the oral tissue and/or bisphosphonate therapy etc.).

PREOPERATIVE EVALUATION

Before surgery, a proper radiographic examination should be done. Panoramic and CBCT should be taken. Analysis of the structure and shape of the maxillary or mandibular region should be done concerning the intranasal sinus morphology, alveolar bone quality and shape and important vessel identification (such as the Inferior Alveolar nerve).

When analysing the patient morphology to determine if an IBR36D implant would be a potential treatment solution, it is important to classify the pterygomaxillary region shape and sinus morphology. The 36° Co-Axis® feature ensures that the prosthetic platform is angled at the implant level, allowing easier accessibility and angle correction of a tilted implant at the implant level to avoid complex bone grafting procedures.
Cautions:

- In cases of soft bone and minimal bone height, it is recommended to do a 2-stage procedure with prolonged healing time before the implants are loaded.
- Ensure that the patient's mouth opening capacity is sufficient for implant surgery.
- Choose the appropriate size implant for the volume of bone available.

SURGICAL PLACEMENT

The IBR36D implant can be placed used either conventional surgery with a raised flap or using a guided approach with a raised flap or flapless approach. These two approached are described briefly below. The drilling protocol utilised to place the implants will remain the same for both approaches.

When utilising a conventional approach, the I-ADG drill guide can be used to ensure the implants are placed at correct angulations. After making an incision for flap elevation, a Ø2mm osteotomy must be made to insert the pin of the I-ADG Angled Drill Guide into. Drilling may then commence using the Angled Drill Guide to prepare the site at correct angulations.

When utilising a guided surgery approach, a surgical guide transfers pre-operative, software planned dental implant placement, to the patient intraoperatively to ensure that implants are placed at correct angulations but also with enough spacing to maximize anterior-posterior spread and decrease distal cantilevers. There are three types of surgical guides: bone supported, mucosa supported, and tooth supported. All surgical guides are patient specific, and the choice of surgical guide type selection depends on the dental professional's preference, patient anatomy and available planning software. The surgical guide consists of a 3D printed/milled acrylic guide and metal guide sleeves. Additional spoons are inserted through the metal guide sleeves during surgery to facilitate drilling sequences and implant placement. For more information on Southern Implants' guided surgery solution "SIGuided" please see CAT-2068.

Drilling Protocol

Step 1: Tabling the bone at the insertion point.

NOTE: it is recommended to raise a full-thickness mucoperiosteal flap if it is required for better visibility of the intended implant site.

A round burr (D-RB-MS) is used to prepare the osteotomy insertion point by flattening the alveolar ridge at the desired location.

All drilling should be performed at a speed of 1000-1500 rpm with copious irrigation.

An intermittent technique should always be used to avoid overheating of the bone. Care should be taken not to perforate the sinus or damage important surrounding structures.

Step 2: Initiate the osteotomy.

Initiate the osteotomy by perforating the cortical plate at the desired location using the Pilot Spade drill (D-3Spade-1.8M). Adjust the entry point of the osteotomy to the desired location to plan for the ideal emergence point of the implant.

Step 3: Drill to depth using a 2 mm twist drill.

Drill to the desired depth using the 2 mm twist drill (D-20T-M24). Use the laser markings on the drill to determine the drilling depth. It is recommended to take several radiographs at this point to verify depth and direction whilst proceeding to drill to the desired depth.

Step 4: Confirm drilling orientation.

Insert the direction indicator (I-DI-36D) to verify the alignment with adjacent teeth/implants and opposing dentition. A radiograph may be taken at this point to verify depth and direction.

If the drilling direction is incorrect, either start a new osteotomy or adjust the angulation using the 2 mm twist drill.

Step 5: Depth gauge – implant length selection.

The 24 mm depth gauge (I-DG-24) can be used to palpate the osteotomy site for implant selection.

Step 6: Enlarging the osteotomy.

After confirming the trajectory with the direction indicator and the implant length with the depth gauge, use the appropriate drill protocol depending on the bone quality and dental practitioners' preference.

The IBR36D implants are available in lengths ranging from 8 mm to 18 mm which each have a corresponding tapered drill. The dedicated tapered drills are length and diameter-specific.

Care should be taken to drill to the planned depth. The implant should be placed at the same vertical level as the prepared osteotomy.

If the maxillary bone is dense or the bone is brittle in texture, widening of the osteotomy can be done with a short 4 mm diameter tapered drill (D-40TP-8.5) to avoid the risk of fractures of the buccal bone plate.

In cases where the bone is very dense (i.e. hard bone), the use of the counter sink (D-CSS-M) can be used to widen the alveolar bone.

Drill up to the line on the countersink. This will prevent the implant head/fixture mount from interfering with the alveolar bone.

Step 7: Implant placement

The IBR36D implants are supplied premounted with a fixture mount. This enables the Co-Axis® implant to be placed in the same manner as a straight implant.

Connect the fixture mount driver (I-CON-X/XS) to the handpiece. Carefully remove the implant and fixture mount assembly from the sterile vial.

The fixture mount is laser-marked 3 mm above the implant platform to indicate depth of placement. One full turn of the implant corresponds to 0.6 mm in placement depth.

Insert the implant at low speed (15 - 25 rpm) with no irrigation. Set the maximum torque to 50 Ncm.

Grafting

If it is indicated that grafting is needed to support the implant, the grafting procedure can be applied either before or after implant placement.

Step 8: Fully seat the implant.

The implant can be fully seated in 3 methods:

- The ratchet and torque attachment wrench (I-TWS with I-TWS-B100), in combination with the wrench converter (I-WI-SS), is used on the fixture mount.
- Use of the hand driver (I-IMP-INS-1/2)
- Use of the motor unit handpiece and the handpiece implant insertion tool (I-CON-X).

Use light force on the wrench when levelling the implant.

Avoid excessive torque (>50 Ncm) with the wrench, as this can cause damage to the implant. A torque exceeding the maximum limit indicates that the implant should be retrieved and additional drilling should be performed to increase the depth and diameter of the osteotomy site. It is advised to ensure that the fixture mount is tightened using a 1.22 mm hex driver before proceeding with this step.

NOTE: since the implants are self-tapping, it is recommended to stop rotation once the implant has reached the prepared depth. The implant may continue to advance beyond the drilled depth with further rotations. Care should be taken not to sink the implant too far, especially in soft bone.

Once the implant is placed and the position verified with a final radiograph, remove the fixture mount by using a 1.22 mm hex driver.

NOTE: a useful tool to indicate the direction of the prosthetic axis of a Co-axis® implant is by inserting the 1.22 mm Hex driver in the fixture mount screw before removal.

Step 9: Proceed with either an immediate loading protocol, one-stage or two-stage protocol.

Depending on the primary stability, patient factors and clinical decision, the treatment can proceed following either an immediate loading protocol, one-stage or two-stage protocol.

Should a two-stage procedure be followed, place the cover screw with a 0.9 mm hex driver (white idler). Tighten to 10 Ncm.

Should a one-stage procedure be followed, place the healing abutment with a 1.22 mm hex driver (grey or blue idler). Tighten to 15 Ncm. Alternatively, should good primary stability be achieved, the permanent abutment, a compact conical abutment, can be placed and tightened to 20 Ncm using the dedicated abutment driver (I-AD).

Caution: These guidelines serve as informational instructions only, and it is crucial for clinicians to exercise their experience and judgment in establishing the most appropriate treatment protocol for the patient.

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3. Extra Length IBR24d Implants

Patient Selection

A thorough clinical assessment must be done to determine the physical and psychological health of the patient. Take care when treating patients with local or systemic factors that could affect the healing process of the tissues or interfere with the osseointegration process (e.g. smoking, uncontrolled diabetes, radiotherapy, steroid therapy, poor oral hygiene, infection of the oral tissue and/or bisphosphonate therapy etc.).

Surgical Placement

Step 1: Initiate the osteotomy.

NOTE: it is recommended to raise a full-thickness mucoperiosteal flap.

The spade/lance drill (D-3Spade-1.8M) is used to initiate the osteotomy by perforating the cortical plate at the desired location.

All drilling should be performed at a speed of 1000 - 1500 rpm with copious irrigation.

An intermittent technique should always be used to avoid overheating of the bone.

Step 2: Pilot drilling – Ø2 mm twist drill

Drill in the planned direction to the appropriate depth, as indicated by the depth markings on the Ø2 mm twist drill (D-20T-M24).

Drill through the alveolar bone, into and across the sinus (should the surgical approach planned be a trans-sinus protocol), engaging the lateral nasal wall.

NOTE: the planned drilling depth should be in accordance with aiming to place the trans-sinus implant either level or 1 - 2 mm subcrestal to the alveolar bone ridge.

Step 3: Check alignment

Insert the direction indicator (I-DI-24D) to verify the alignment with adjacent teeth or implants and opposing dentition.

A radiograph may be taken at this point to verify depth and direction.

If the drilling direction is incorrect, start a new direction with the pilot drill as in step 2 and continue with the remaining steps.

Step 4: Depth gauge – implant length selection

The 24 mm depth gauge (I-DG-24) can be used to palpate the osteotomy site for implant selection.

Make sure that the maxillary alveolar bone height is more than 3 mm in thickness. If not, it is recommended to perform a sinus lift and bone grafting procedure.

Step 5: Enlarge the osteotomy (final drill).

After confirming the trajectory with the direction indicator and implant length with the depth indicator, use the appropriate drill protocol depending on the bone quality and dental practitioners' preference.

The trans-sinus implants are available in 20 mm, 22 mm and 24 mm lengths which each have a corresponding tapered drill. The dedicated tapered drills are length and diameter-specific.

Care should be taken to drill to the planned depth. The implant should be placed at the same vertical level as the prepared osteotomy. If the implant is forced deeper, there is a risk of perforating the nasal bone.

If the maxillary bone is dense or the bone is brittle in texture, widening of the osteotomy can be done with a short 4 mm diameter tapered drill (D-40TP-8.5) to avoid the risk of fractures of the buccal bone plate.

Step 5.1: Soft bone protocol

Widen the osteotomy to full depth with the Ø3.3 mm tapered drill (D-33TP-xx).

Step 5.2: Medium bone protocol.

Use the counter sink (D-CS-IBN) (Fig. A) to widen the alveolar bone slightly before commencing with the Ø3.3 mm tapered drill (D-33TP-xx). In medium bone, this will allow the tapered drill to be inserted easily in the Ø2.0 mm pilot drill hole (Fig. B).

Widen the alveolar bone with the Ø4.0 tapered drill, 8.5 mm length, (D-40TP-8.5).

Step 5.3: Hard bone protocol.

For hard bone, perform the drilling steps indicated in step 5.2 followed by use of the counter sink (D-CSS-M) (Fig. D) to widen the alveolar bone.

Drill up to the line on the countersink. This will prevent the implant head/fixture mount from interference with the alveolar bone.

Step 6: Implant placement.

The Co-Axis® implants are supplied premounted with a fixture mount. This enables the Co-Axis implant to be placed in the same manner as a straight implant.

Connect the fixture mount driver (I-CON-X/XS) to the handpiece.

Carefully remove the implant and fixture mount assembly from the sterile vial.

The fixture mount is laser marked 3 mm above the implant platform to indicate depth of placement. One full turn of the implant corresponds to 0.6 mm in placement depth.

Insert the implant at low speed (15 – 25 rpm) with no irrigation. Set the maximum torque to 50 Ncm.

Step 7: Fully seat the implant.

The ratchet and torque attachment wrench (I-TWS with I-TWS-B100), in combination with the wrench converter (I-WI-SS), is used on the fixture mount for final manual seating of the implant.

Use light finger force on the wrench when levelling the implant.

Avoid excessive torque (>50 Ncm) with the wrench, as this can cause damage to the implant. A torque exceeding the maximum limit indicates that the implant should be retrieved and additional drilling should be performed to increase the depth and diameter of the osteotomy site.

NOTE: As the implants are self-tapping, it is recommended to stop rotation once the implant has reached the prepared depth. The implant may continue to advance beyond the drilled depth with further rotations. Care should be taken not to sink the implant too far, especially in soft bone.

Once the implant is placed and the position verified with a final radiograph, remove the fixture mount by using a 1.22 mm hex driver.

In the event that immediate loading criteria is not met, a conventional one or two-stage protocol can be adopted.

Step 8: Two-Stage Procedure: cover screw placement.

After the implant is fully seated in the osteotomy, place the cover screw with a 0.9 mm hex driver.

Tighten to 10 Ncm.

Step 9: Suture closed.

Reposition the flap margins together and suture closed.

Step 10: Place healing abutments.

After an appropriate healing period, locate and expose the cover screw. Proceed to remove the cover screw using the 0.9 mm hex driver.

Place the selected healing abutment or appropriate definitive abutment, using the 1.22 mm hex driver.

Tighten to 15 Ncm.

Step 11: One-Stage Procedure: healing abutment placement.

If high primary stability is achieved, a one-stage protocol can be followed.

After the implant is fully seated in the osteotomy, place the selected healing abutment with a 1.22 mm hex driver.

Tighten to 15 Ncm.

Step 12: Suture around healing abutments.

Arrange the flap margins around the healing abutment for a tight seal and suture.

Bone Milling

Should the cover screw or healing abutment not seat fully due to bone structures protruding on the implant platform, a bone mill can be used to remove the excess bone around the implant (I-BNM-45 / I-BPM-55).

Secure the protector cap (I-BNM-CAP) on the implant with a 1.22 mm hex driver.

Connect the bone mill to the handpiece and set the speed to 20 rpm. Proceed to use the mill over the protector cap to remove any impinging bone surrounding the implant.

After the surrounding bone has been removed, ensure that the implant platform is clean of any bone particles.

Reposition the cover screw, healing abutment or prosthesis.

Warning: The extra length IBR24D implants (i.e. implant lengths > 18mm) are not intended for any specialized surgical technique or anatomical placements outside of the alveolar arches. These guidelines serve as informational instructions only, and it is crucial for clinicians to exercise their experience and judgment in establishing the most appropriate treatment protocol for the patient.

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

Contra-indications to implant therapy include:

- patients medically unfit for oral surgical procedures.
- where an inadequate number of implants can be placed limiting the functional support of the prosthesis.
- patients under the age of 18 years.

- patients with poor bone quality.
- patients with blood disorders.
- presence of infection at the implant site.
- patients with vascular impairment.
- patients with uncontrolled diabetes.
- patients with drug or alcohol abuse dependencies.
- patients undergoing chronic high dose steroid therapy.
- patients undergoing anti-coagulant therapy.
- patients with metabolic bone disease.
- patients undergoing radiotherapy treatment.
- patients with pure titanium, titanium alloy (Ti6Al4V), gold, palladium, polyether ether ketone (PEEK), or iridium allergies or hypersensitivities.

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 peel-back lid. Labelling information is located on the bottom half of the pouch or on the surface of the peel-back lid.

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, ASTM F67 and ISO5832-2, UTS≥ 900 MPa)

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 General Dental Implants	6009544038699H

Related literature and catalogues

CAT-2020 - External Hex Implants Product Catalogue
CAT-2095 - External Hex INVERTA® 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.