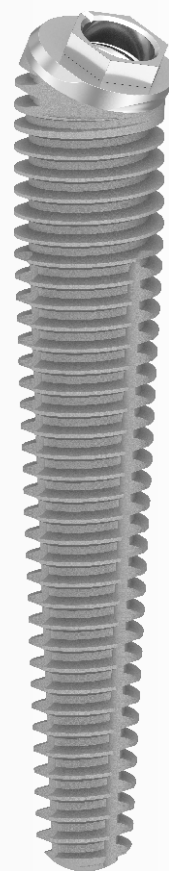


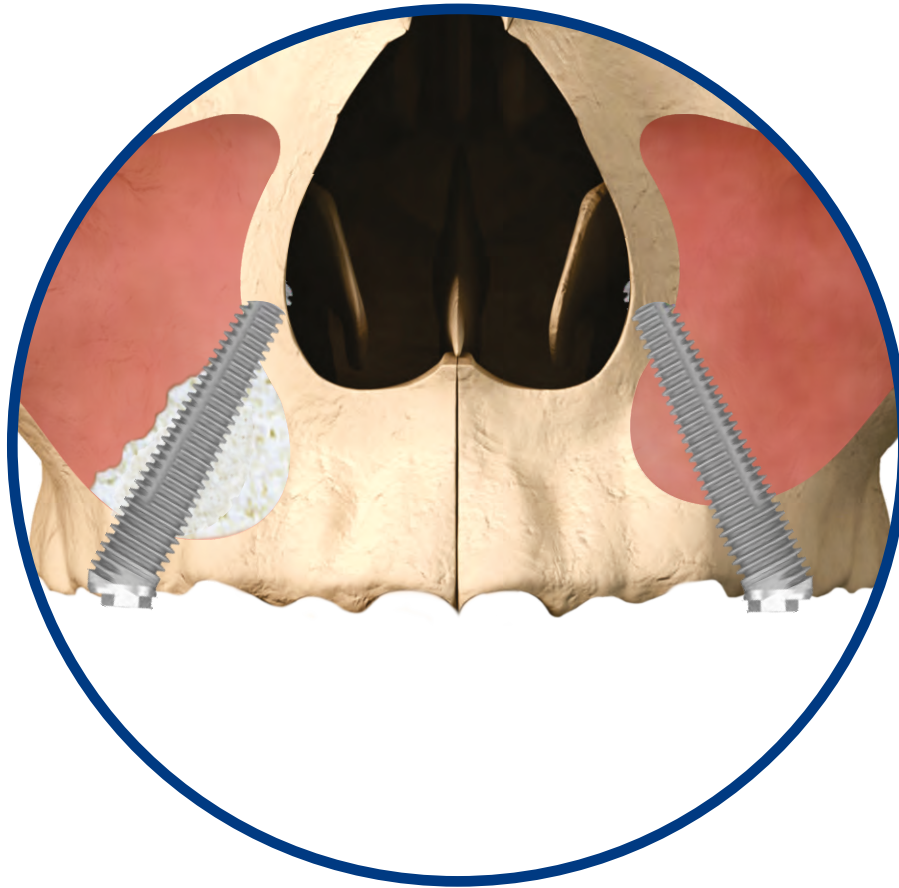


SOUTHERNIMPLANTS®

Innovative Treatment Solutions

NAZALUS Implants
Product Catalogue
and Surgical Manual





Southern Implants® is a leading provider of unique and innovative dental implant products with a focus on top-end professional users who want more choices. Southern's expertise in research, development and manufacturing of dental implants allows us to provide Innovative Treatment Solutions that will reduce treatment times and improve patient outcomes.

Striving for excellence and meeting customer needs, has led to our wide product range characterised by Unique and Innovative products which include:

- Multiple interfaces, to suit customer preference.
- INVERTA® implant, featuring a Body-Shift™ design, engineered for primary stability and suitable for immediate loading.
- Co-Axis®, Subcrestal Angle Correction® implants, available in angulations of 12°, 24° and 36° and various internal and external connections.
- MAX implant, specifically designed for immediate molar tooth replacement.
- The ZYGAN®, ZYGEX and ZYGIN implants for severely resorbed maxilla and craniofacial reconstruction.
- The Machined Surface Coronally (MSC) dental implant surface treatment offers practitioners an innovative way to take advantage of the best characteristics of both smooth and moderately rough implant surfaces.

Our product portfolio is in synchronised evolution with protocol improvements and technological advances.

My sincere thanks to all specialists, dentists and technicians who put their trust in our company.


Graham Blackbeard
Managing Director, Southern Implants

CONTENTS

NAZALUS Concept.....	Page 05
Surgical Guidelines.....	Page 06
NAZALUS Ø4.0 mm, External Hex, 24° Co-Axis® Implant (Tapered)	
Implants and Surgical Components.....	Page 08
Prosthetic Flowchart.....	Page 09
Implant Drill Depth.....	Page 12
Surgical Placement.....	Page 13
Loading Times.....	Page 18
Troubleshooting.....	Page 18
Two-Stage Procedure.....	Page 19
One-Stage Procedure.....	Page 20
Torque Table for Southern Screws.....	Page 21
Instrument Trays	
I-HEX-EG.....	Page 22
I-PROS-EG.....	Page 24
Implant Dimensions and Information.....	Page 25
Key Features and Benefits.....	Page 26
Explanation of Symbols.....	Page 27

For more information scan the below



or visit

SOUTHERNIMPLANTS.COM

NOTE: • images are for illustration purposes only and do not necessarily accurately represent the product.
• all dimensions in this catalogue are in mm, unless otherwise specified.
• not all products are cleared for sale in all countries.

NAZALUS CONCEPT

This innovative implant technology allows full arch rehabilitation using the maxillary bone surrounding the nasal cavity.

Because of inadequacies in both the quantity and quality of available bone in the maxilla, it can be challenging for full arch rehabilitation with implants, especially when immediate loading is considered. For this reason, bone augmentation or sinus floor elevation is often prescribed, followed by delayed placement.

To avoid complex bone grafting procedures, Pterygoid or Zygomatic implants have been advocated, but these surgical approaches have some limitations and potential for complications.

The Nazalus implant was developed as an alternative to the Zygomatic and Pterygoid implants. The Nazalus concept is based on utilising an extra long 24° Co-Axis® implant that will be anchored in the cortical bone mass of the lateral nasal wall.

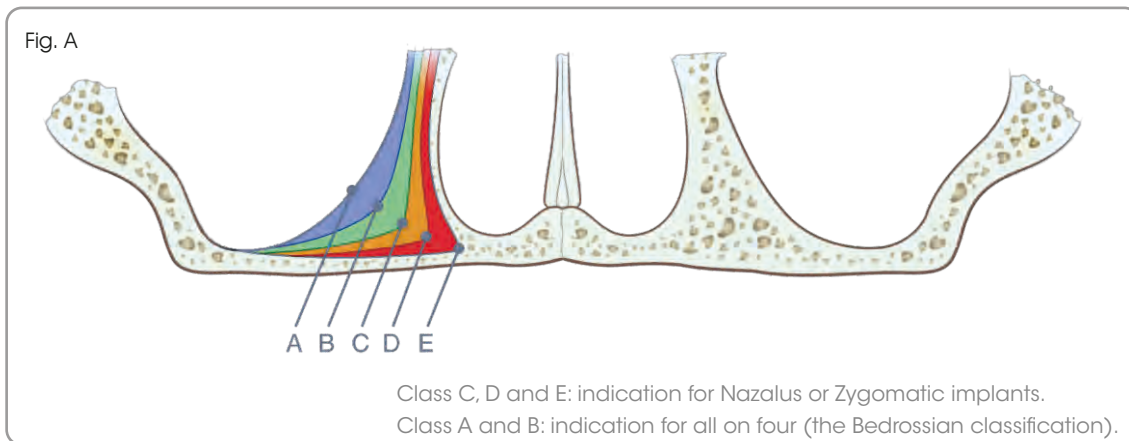
The Nazalus implants are designed for either trans-sinus placement or in combination with a sinus lift procedure. They are equipped with an angled platform to improve fixation at the alveolar process.

SURGICAL GUIDELINES

A thorough clinical assessment must be done to determine 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.).

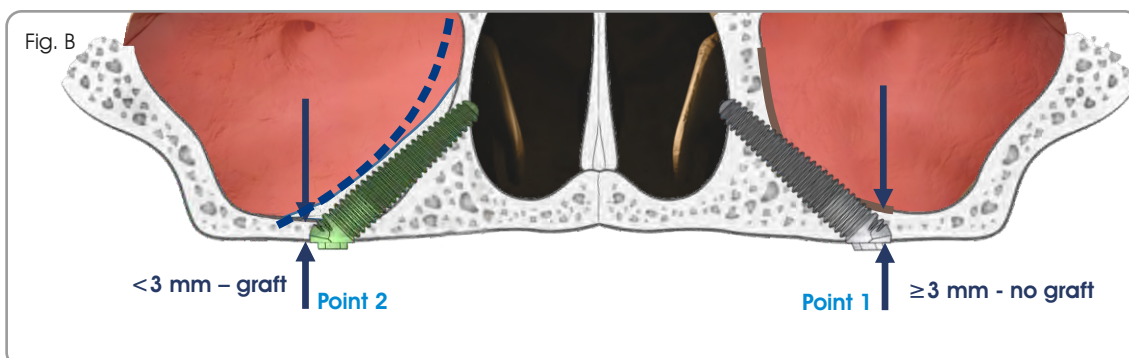
PREOPERATIVE EVALUATION

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 with regards to the intranasal sinus morphology and alveolar bone quality and shape (Fig.A).



When analysing the patient morphology to determine if a Nazalus implant would be a potential treatment solution, it is important to consider the below criteria:

Patient morphology	Potential treatment solution
Amount of bone in the alveolar ridge and/or lateral nasal wall.	In cases with insufficient bone in these areas, it is contraindicated to place a Nazalus implant.
If the alveolar crest has more than 3 mm (Fig. B, point 1).	No grafting of the sinus cavity is necessary.
If available bone is less than 3 mm (Fig. B, point 2) or if the available bone is soft.	It is recommended to do a sinus-lift procedure. Open a window in the lateral sinus wall in the area where the implant is crossing the sinus cavity. Gently reflect the membrane and apply the bone graft.



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.
- make sure that the mouth opening capacity is sufficient for implant surgery.
- choose the appropriate size implant for the volume of bone available.

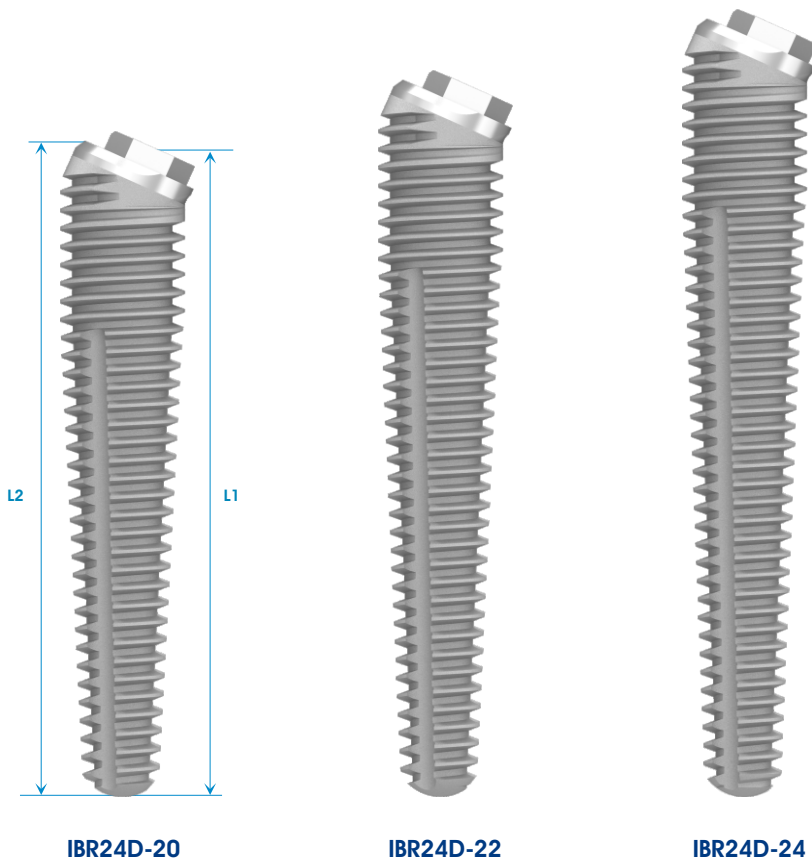
EXTERNAL HEX

Ø4.0 mm

24° Co-Axis®

REDUCED PLATFORM

 Restore with External Hex
Ø3.25 mm prosthetics



Implants are premounted and available in lengths of:

NOTE: implant dimensions and information - page 21.

ITEM CODE	IMPLANT LENGTHS (in mm)	
	L1	L2
IBR24D-20	20.0	21.6
IBR24D-22	22.0	23.6
IBR24D-24	24.0	25.6

Surgical Components

Cover Screw

SCNU2



Healing Abutments

TBN



2/3/4/6/8
lengths

WBN



2/3/4/6
lengths

DIRECT

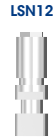
Healing Abutments



Impression Copings



Laboratory Analogues



DIRECT
Abutments

SCANNABLE
Abutments

PASSIVE
Abutment

Prosthetic Components

GC-EX-34
(engaging)
GC-NX-34
(non-engaging)



Gold

TCBN1H/5H
(engaging)
TCBN1NH/5NH
(non-engaging)



Titanium

Uses 2 Series Screws

PKBN2H
(engaging)
PKBN2NH
(non-engaging)



PEEK*

*Screw torque:
15 Ncm

TIB-EX-34
TIB-EX-34-C1.5
TIB-EX-34-C3
(engaging)



TIB abutments available in 3 cuff height variants:
0.6 mm, 1.5 mm and 3 mm

TIB-NX-34
TIB-NX-34-C1.5
TIB-NX-34-C3
(non-engaging)



CIA-EX-34
(engaging)
CIA-NX-34
(non-engaging)



SBN16
(engaging)
SBN-17-TT
(non-engaging)



Retaining Screws

3 Series
Screws

TORQUE:
32 - 40 Ncm

2 Series
Screws

TORQUE:
32 - 40 Ncm

NOTE: for Vertical Passive abutment refer to CAT-1120. For Ball and Equator Overdenture abutments refer to CAT-1019 and CAT-1189. For Anatomical abutments refer to CAT-1138.

INDIRECT

Compact Conical Abutments

ABNMCZ



1/2/3/4/5.5

ABNMC17D



TSUZ9 **GSUZ9**
Packed with titanium screw.
Optional gold screw available.

Healing Caps

HMC



4/6

OR

HMCT7



4/6

Impression Copings

CMC1
(pick-up)



CMC2
(transfer)



CMC-ZG-2
(transfer)



SFT-MC-48
(scanning flag)



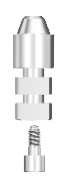
Titanium

Laboratory Analogues

LSMC1



LAD-MC



(digital analogue)

Prosthetic Components

GMC1



Gold

TMC1 / 5



Titanium
TMCSL
(long version)

PKC-MC



PEEK*
*Screw torque:
10 - 15 Ncm

PA-MC-48
(passive abutment)



ASC-TMC1
(angulated screw channel abutment)



(packed with screw)

Retaining Screws

1 Series
Screws

TORQUE:
10 - 15 Ncm

TST1-ASC

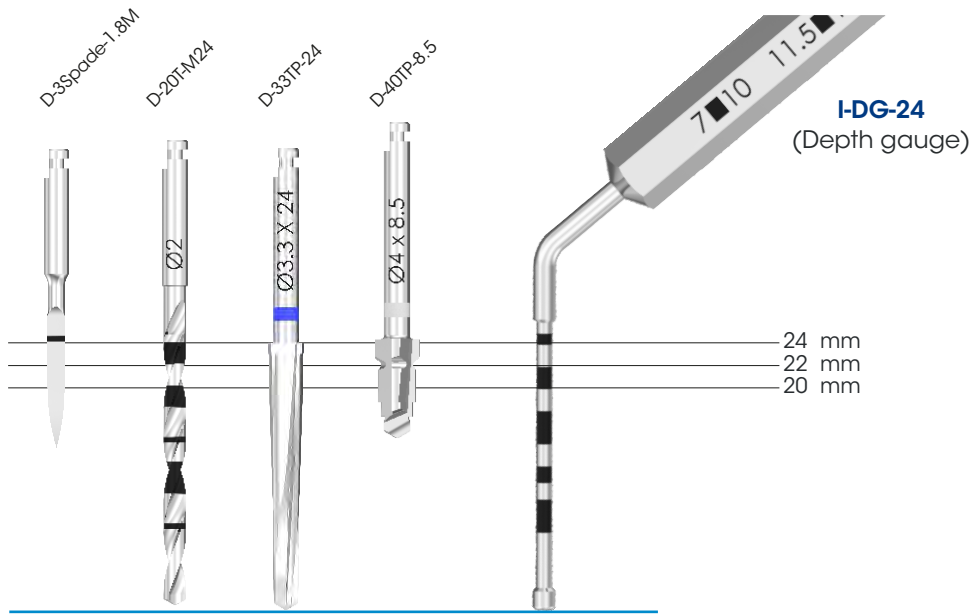


TORQUE:
10 - 15 Ncm

SURGICAL PROCEDURES

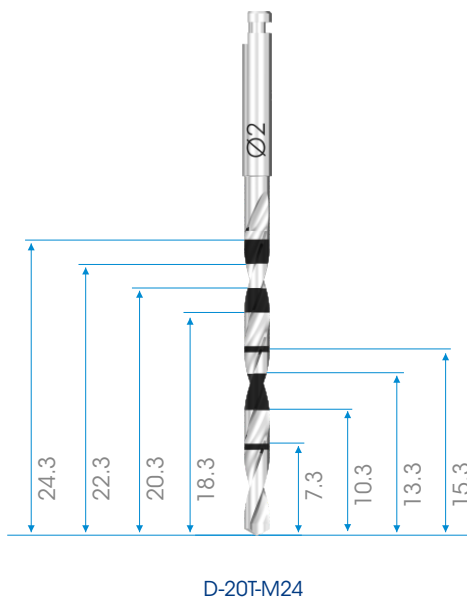
IMPLANT DRILL DEPTH

Illustrating placement of a 24 mm implant.



TWIST DRILL MARKINGS

The laser markings on the twist drills indicate millimeter lengths.



SURGICAL PLACEMENT

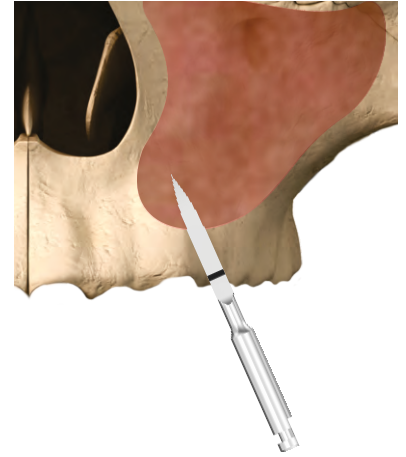
Step 1: initiate the osteotomy

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.

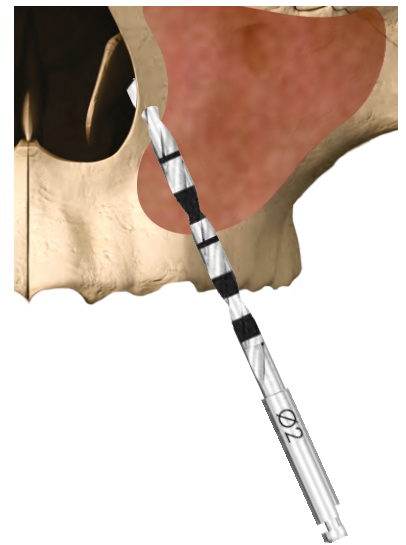


Step 2: pilot drilling - Ø2 mm twist drill

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 Nazalus implant either level or 1 - 2 mm subcrestal to the alveolar bone ridge.

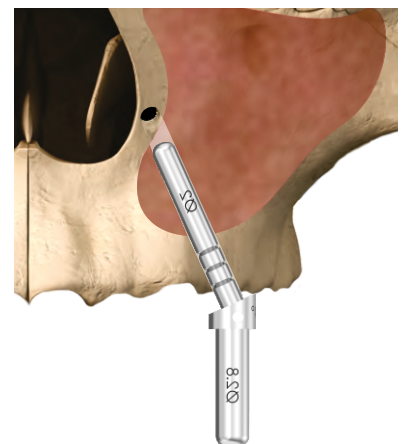


Step 3: check alignment

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.

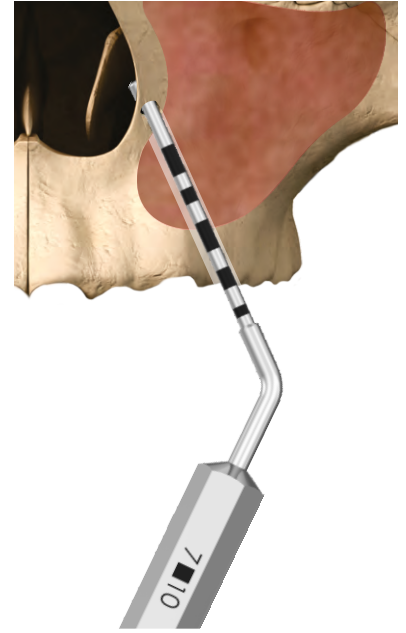


SURGICAL PLACEMENT

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, use the appropriate drill protocol depending on the bone quality and dental practitioners' preference.

The Nazalus 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.

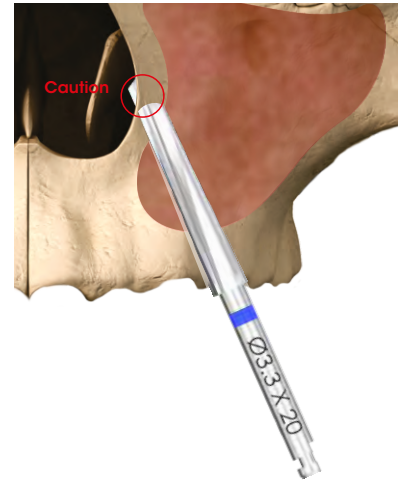
Care should be taken to drill to the planned depth. The implant should be placed at the same vertical level as the prepared osteotomy. If the implant is forced deeper, there is a risk of perforating the nasal bone.

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.

SURGICAL PLACEMENT

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 to hard 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) (Fig. C). This will prevent the implant

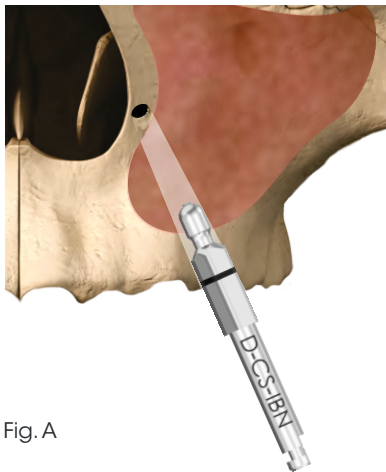


Fig. A

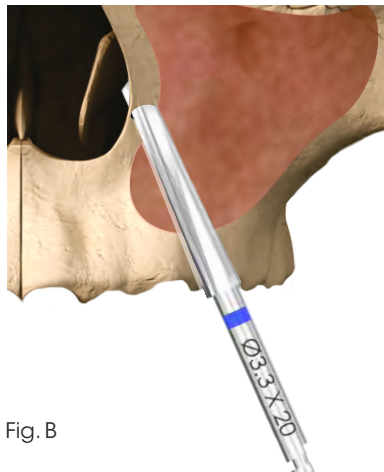


Fig. B

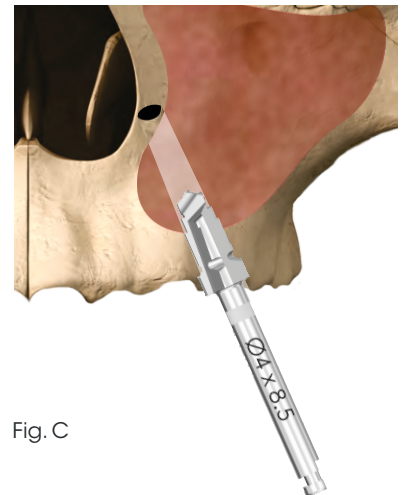


Fig. C

Step 5.3: hard bone protocol

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

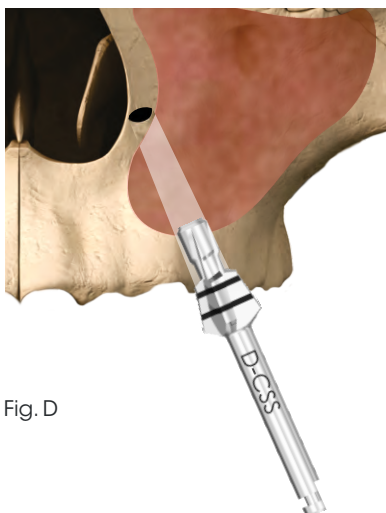
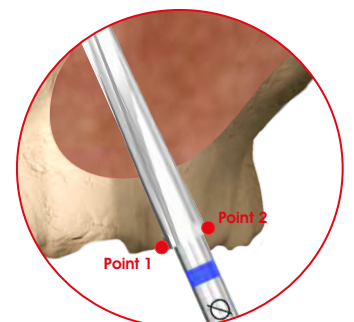


Fig. D



NOTE:

Point 1

This corner of the drill is to be at bone level.

Point 2

This corner of the drill will be subcrestal.

SURGICAL PLACEMENT

Step 6: implant placement

The Nazalus 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.

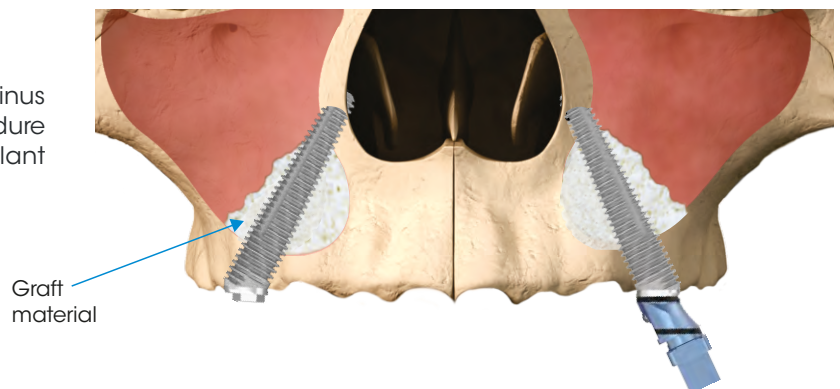
The fixture mount is laser marked 3 mm above the implant platform to indicate depth of placement. One full turn of the implant corresponds to 0.6 mm in placement depth.

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



Grafting

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



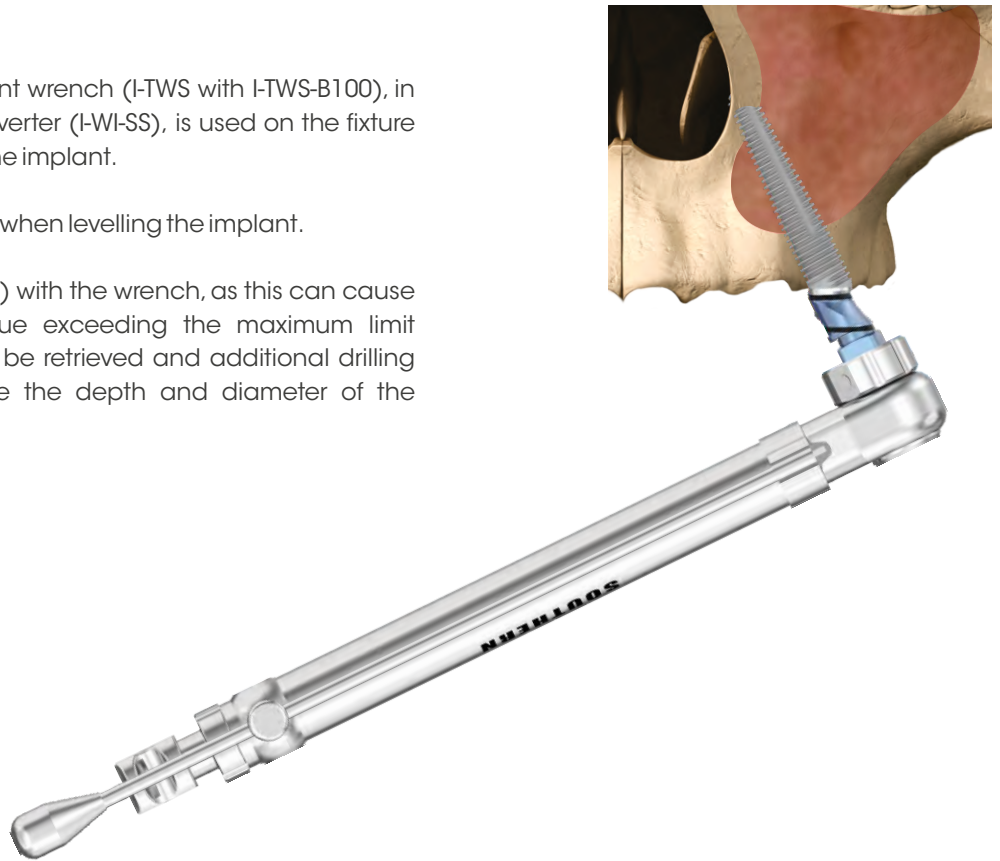
SURGICAL PLACEMENT

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.

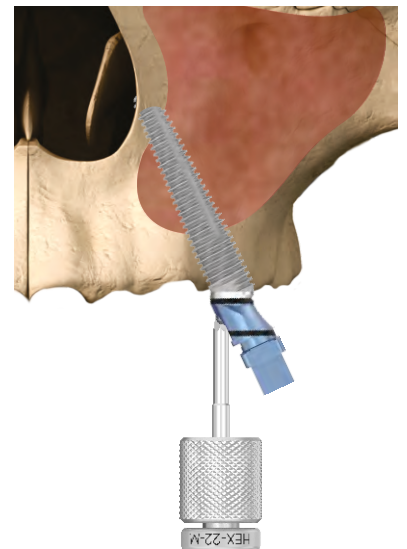
Use light finger force on the wrench when levelling the implant.

Avoid excessive torque (>100 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: because 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 for stabilising the Co-Axis® implant, is the Southern spanner (I-SP-X) in combination with the 1.22 mm hex driver as a direction indicator to show the prosthetic axis (direction).



LOADING TIMES

Healing periods may vary for each patient. When a shorter healing time or immediate loading is being considered, the assessment must be based on the individual clinical situation (i.e. bone quality, bone quantity, primary stability achieved, loading conditions and design of super-structure etc.).

If good primary stability is achieved and sufficient anchorage is present at the coronal part of the implant, the implants may be immediately temporised on splinted multiple unit restorations. Immediately temporised restorations should have good occlusal profile, limited cantilevers and flattened cusps in order to minimise prosthetic load on the implants.

The patient should adhere to a soft diet and place minimal force on the restoration for 12 weeks.

TROUBLESHOOTING

Implant mobility: if the implant is very loose, remove the implant and allow the surgical site to heal for approximately six months. Repeat surgery on the same area after the healing period.

Poor implant alignment: if the angular misalignment is less than 35°, the problem can be addressed using angulated abutments. If the angle is greater than 35°, remove the implant and allow the surgical site to heal for approximately six months. Repeat surgery on the same area after the healing period with improved placement.

Exposed threads: if the implant threads are exposed in the coronal region, perform a bone augmentation procedure.

Over countersinking: avoid countersinking in soft and medium bone. Over countersinking can cause complications with primary stability in cortical bone.

Lack of primary stability: this might cause misalignment due to soft bone, error in site preparation or volume of bone in implant contact. In such cases immediate loading is to be avoided.

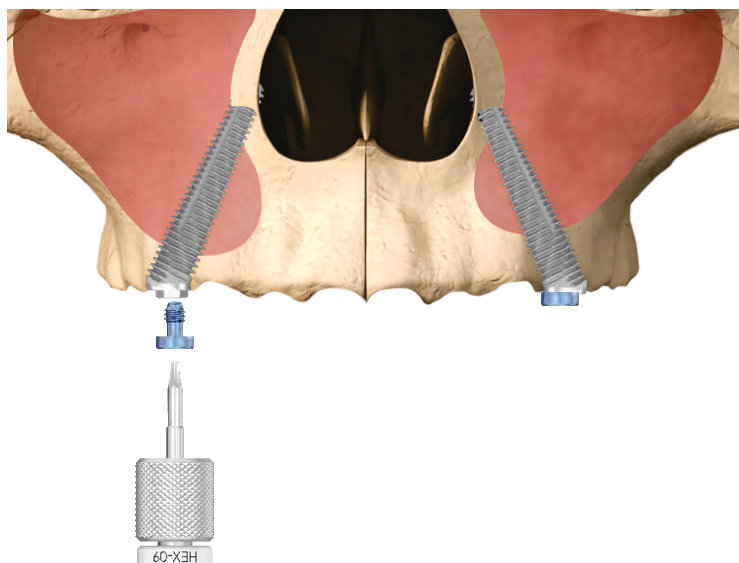
TWO-STAGE PROCEDURE

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

Step 8

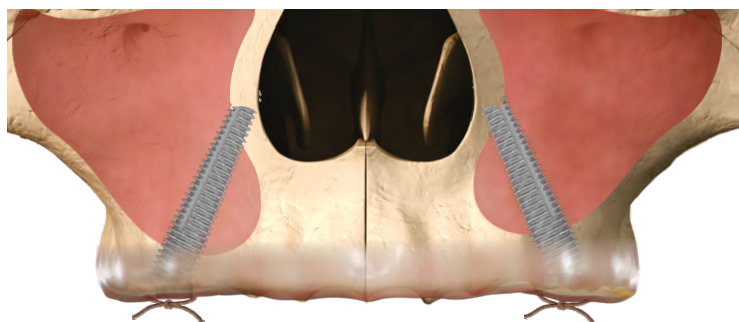
After the implant is fully seated in the osteotomy, place the cover screw with a 0.9 mm hex driver.

Tighten to 10 Ncm.



Step 9

Reposition the flap margins together and suture closed.

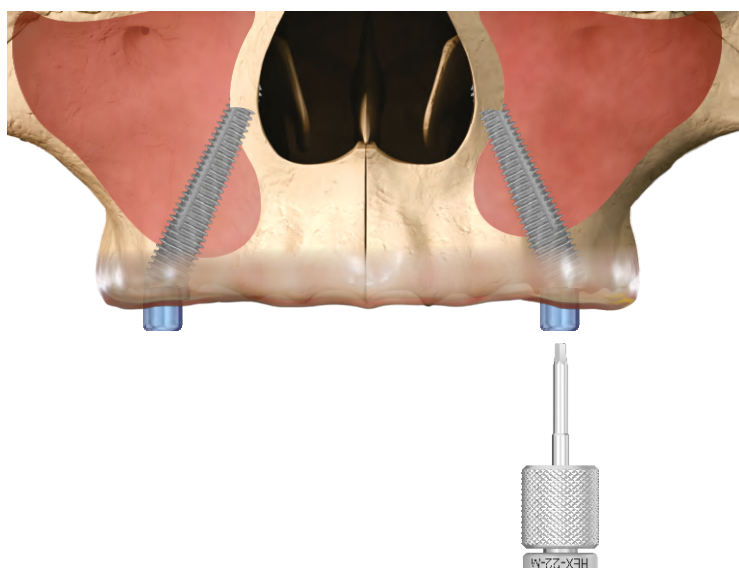


Step 10

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.



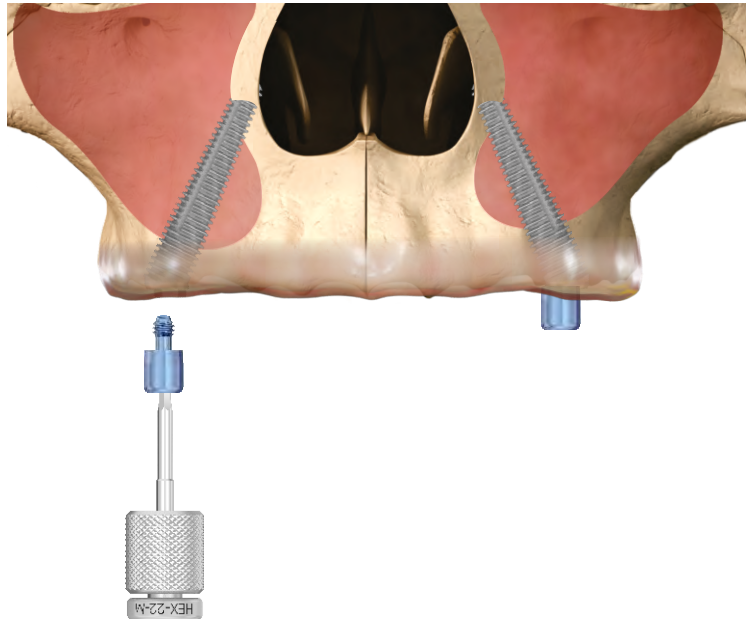
ONE-STAGE PROCEDURE

Step 11

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

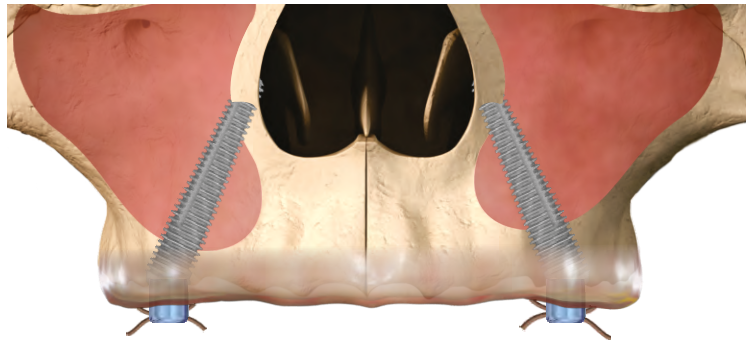
After the implant is fully seated in the osteotomy, place the selected healing abutment with a 1.22 mm hex driver.

Tighten to 15 Ncm.



Step 12

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



Bone milling

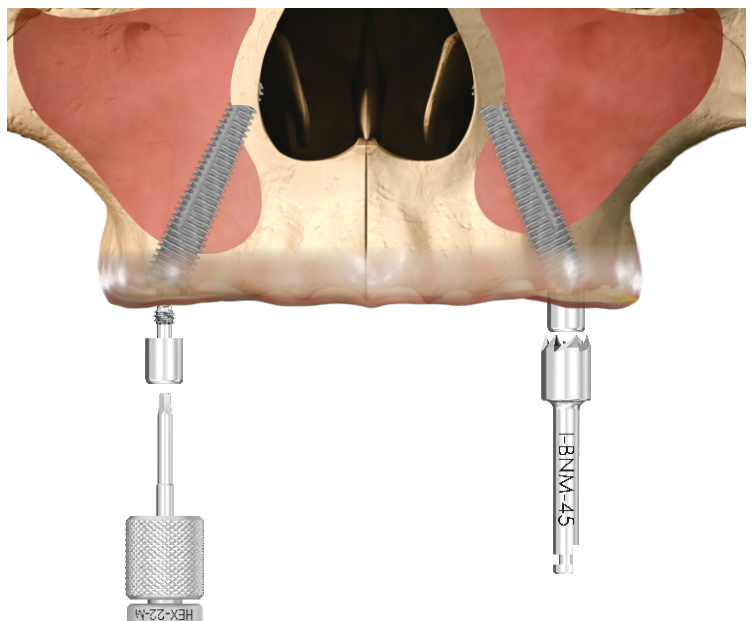
Should the cover screw or healing abutment not seat fully due to bone structures protruding on the implant platform, a bone mill can be used to remove the excess bone around the implant (I-BNM-45 / I-BPM-55).

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.



TORQUE TABLE FOR SOUTHERN SCREWS

2 Series screws (M2)

1.22 Hex



TSHZ2



BSH2*

QUAD



GSQZ2

SLOTTED



TSSZ2



GSSZ2



BSS2*

UNIGRIP



TSUZ2



GSUZ2

TORQUE:
32 - 40 Ncm
Head diameter:
2.70 mm

3 Series screws (M2)



TSHZ3



BSH3*



GSQZ3



TSSZ3



GSSZ3



BSS3*



TSUZ3



GSUZ3

TORQUE:
32 - 40 Ncm
Head diameter:
2.40 mm

NOTE: screw TORQUE with PEEK prosthetics: $\lt; \varnothing 4.0 \text{ mm}$ implant interfaces: 15 Ncm
>math>\ge \varnothing 4.0 \text{ mm}</math> implant interfaces: 20 Ncm

Digital Laboratory Analogue screw

1.22 Hex



LAD-S

TORQUE:
Finger tighten
Head diameter:
2.40 mm

(screw supplied with all digital analogues).

ASC 1 Series compact conical screw

M1.4



TST1-ASC

TORQUE:
10 - 15 Ncm
Head diameter:
2.30 mm

1 Series screws (M1.4)

1.22 Hex



TSH1



GSH1



BSH1*

Slotted



TSS1



GSS1



BSS1*

Unigrip



TSU1



GSU1

TORQUE:
10 - 15 Ncm
Head diameter:
2.25 mm
Screw TORQUE with
PEEK prosthetics:
10 - 15 Ncm

9 Series, Angled Compact Conical Abutment screws (M2)

Unigrip



TSUZ9



GSUZ9

TORQUE:
20 Ncm
Head diameter:
2.50 mm

NOTE:

- due to design revisions screw tips may be flat or rounded.
- always ensure that the correct screw is used for the relevant implant and component.
- refer to CAT-8068 for alternative slotted 1 Series screws.
- * blackened and for laboratory use only.
- universal drivers are compatible with both 1.22 and 1.27 Hex screws:
 - IHD22U-S/M/L
 - IHH22U-S/M/L
 - IWI22U-S-/M/L

Screw Head Connections

Hex



Slotted



Unigrip



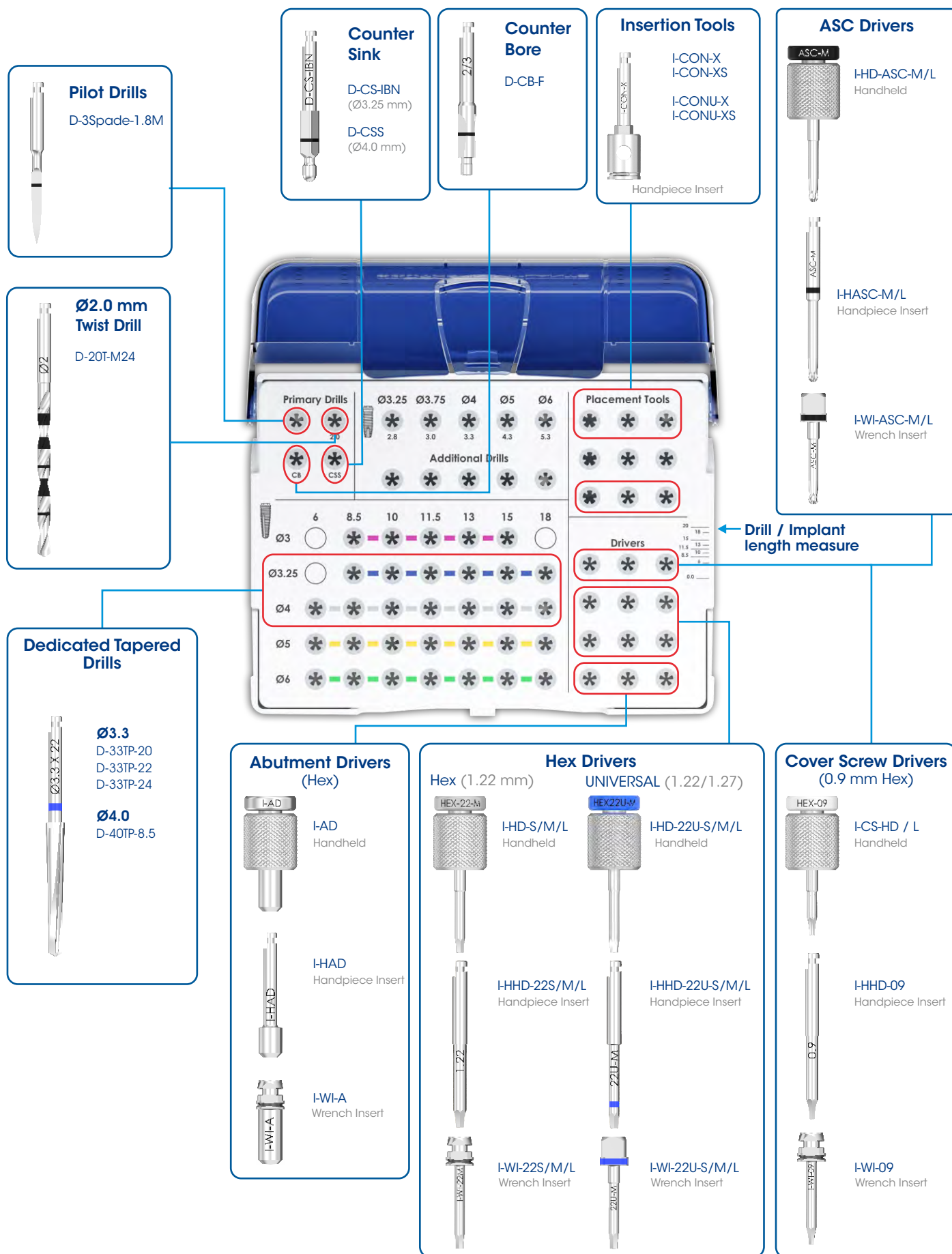
Quad



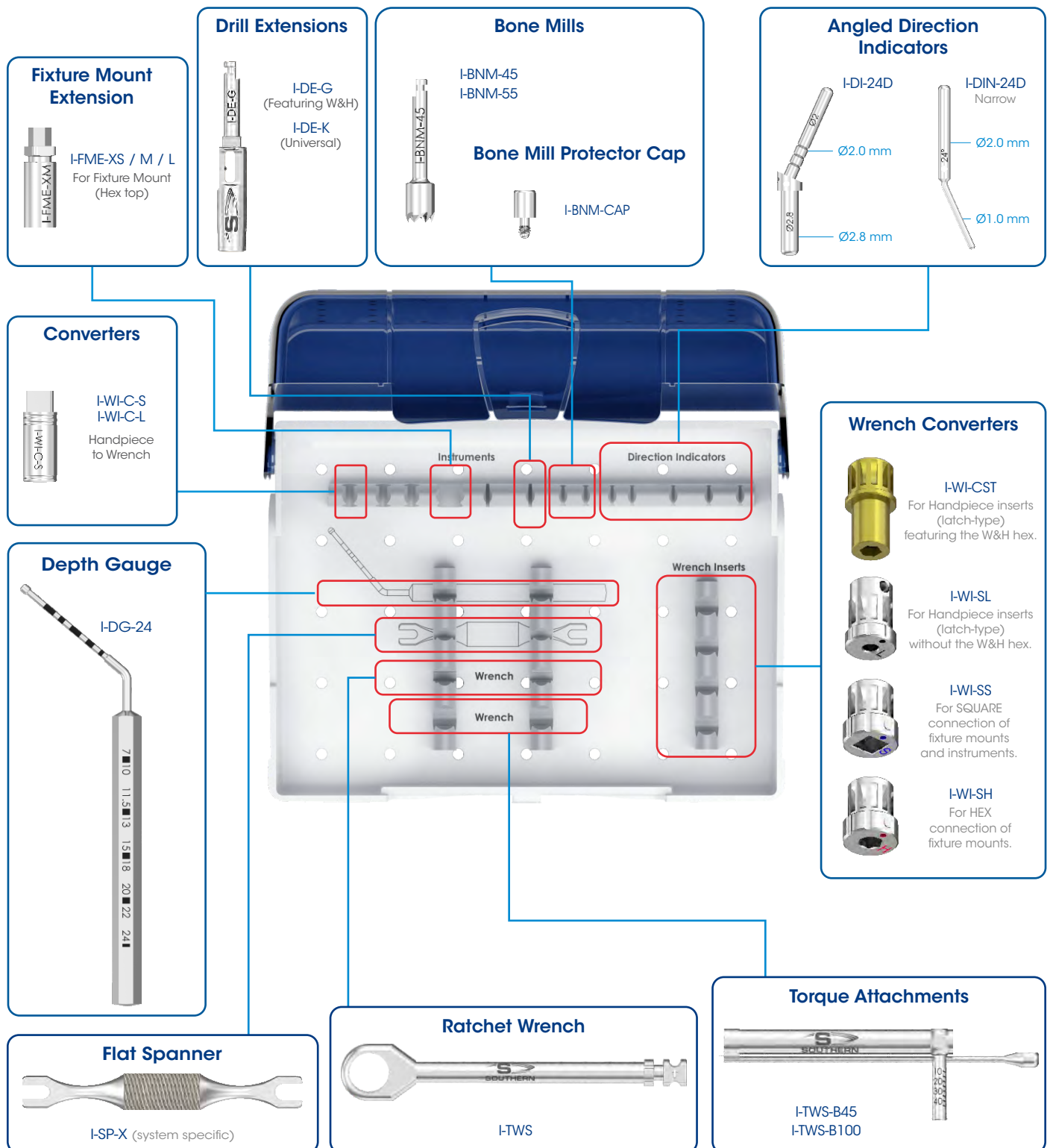
ASC



TOP TRAY



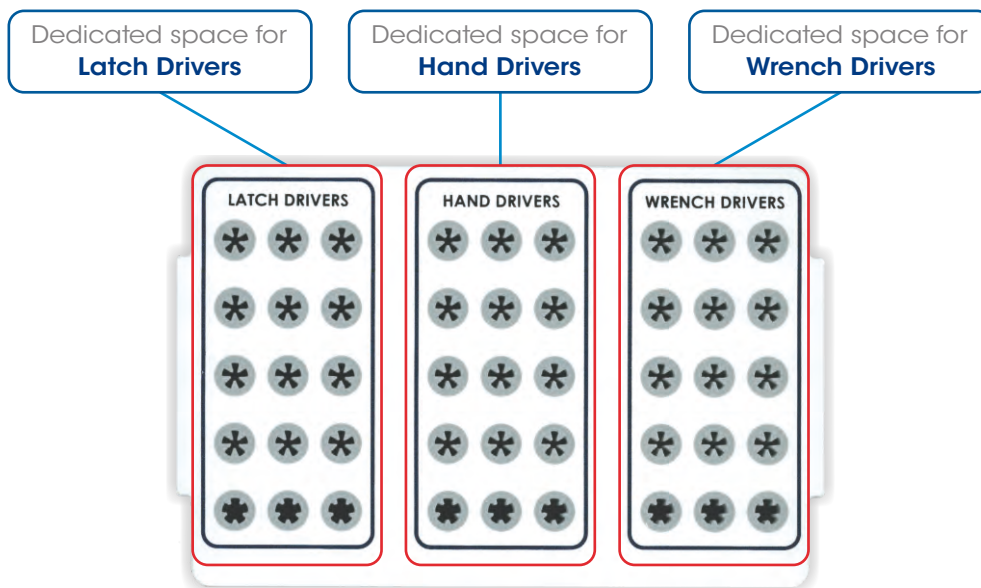
BOTTOM TRAY



NOTE:

- the surgical kit has an intuitive layout to guide the surgeon through the drill sequence.
- most instruments are available in various lengths.
- all instruments and tooling used during the procedure must be maintained in good condition, cleaned and sterilised prior to use. Please consult the Instructions for Use: Southern Implants instrument tray and reusable instruments (CAT-8003 and CAT-8070) for guidance concerning the maintenance of instruments and surgical trays. Please consult the corresponding drill Instructions for Use regarding care and maintenance of drills.
- refer to CAT-8021 for more information on bone mills and polishing protector caps.

TOP TRAY



BOTTOM TRAY

Flat Spanner
I-SP-X (system specific)

Ratchet Wrench
I-TWS

Wrench Converters

- I-WI-CST**
For Handpiece inserts (latch-type) featuring the W&H hex.
- I-WI-SL**
For Handpiece inserts (latch-type) without the W&H hex.
- I-WI-SS**
For SQUARE connection of fixture mounts and instruments.
- I-WI-SH**
For HEX connection of fixture mounts.

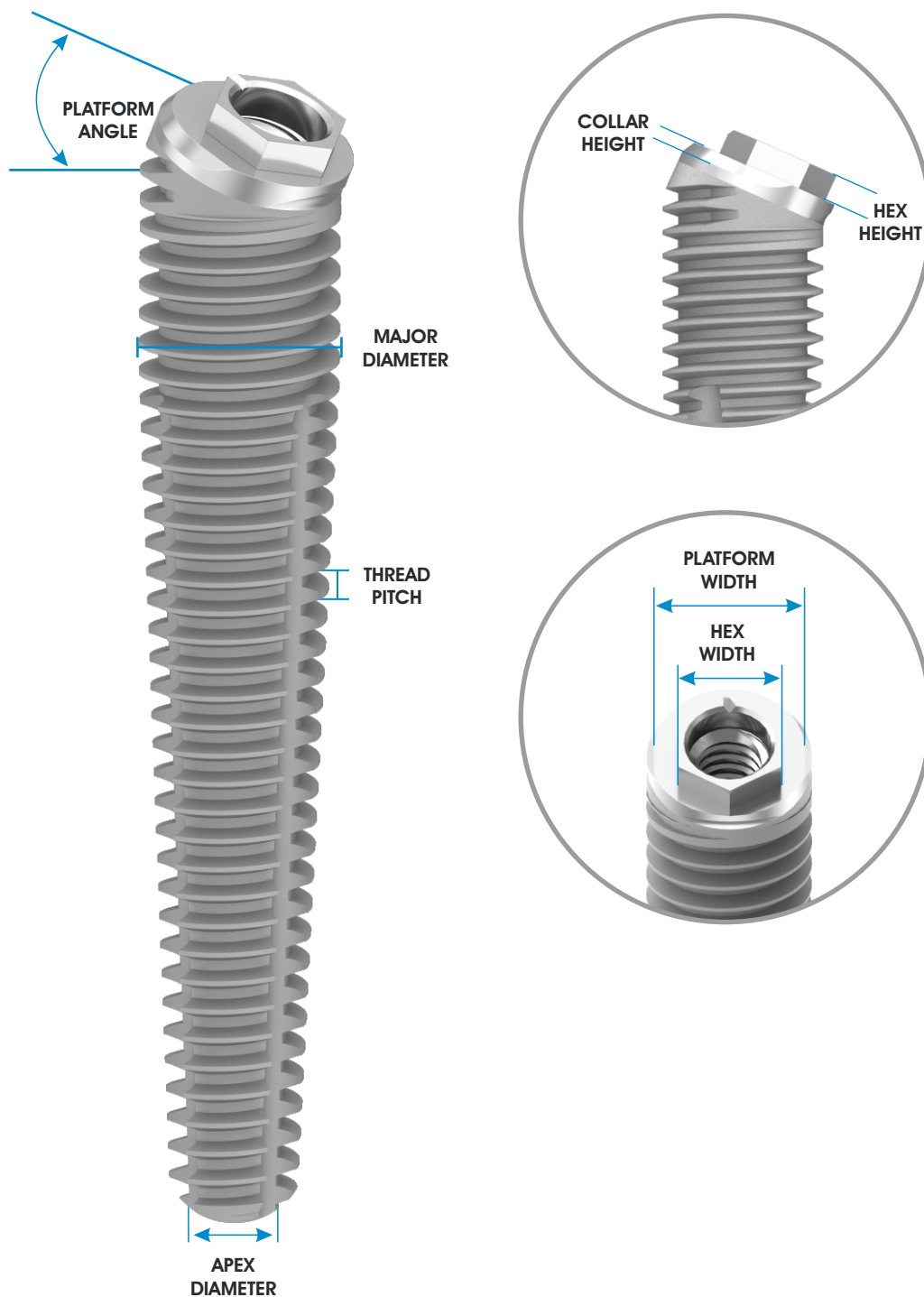
Torque Attachments
I-TWS-B45
I-TWS-B100

NOTE:

- this instrument tray is to be customised by the user to be suitable for use with the preferred implant system and its surgical or prosthetic items.
- most instruments are available in various lengths.

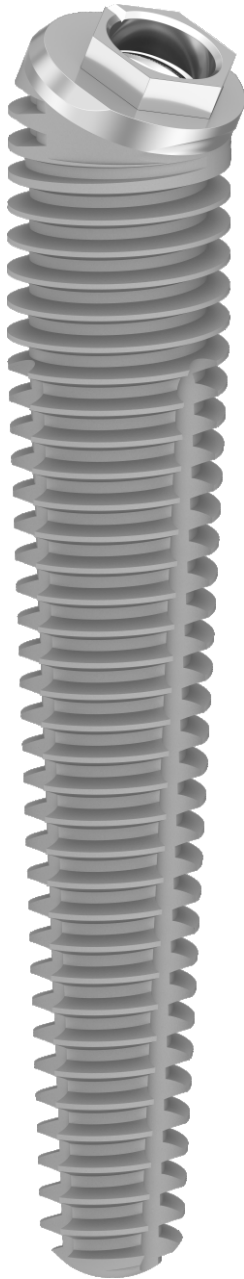
IMPLANT DIMENSIONS AND INFORMATION

RANGE	MAJOR DIAMETER	PLATFORM WIDTH	PROSTHETICS	HEX WIDTH	HEX HEIGHT	COLLAR HEIGHT	THREAD PITCH	APEX DIAMETER	CYLINDRICAL OR TAPERED (C/T)	PLATFORM ANGLE	IMPLANT LENGTH CODES		
											20	22	24
IBR24D	Ø4.0 mm	4.0		2.54	0.7	0.6	0.6	2.6	T	24°	✓	✓	✓



NOTE:

- all dimensions in this catalogue are in mm, unless otherwise specified.
- not all products are cleared for sale in all countries.



EXTERNAL HEX CONNECTION

The most established and versatile connection system.



CO-AXIS® ENABLED

24° angled platform to utilise existing bone while maintaining a restorative platform at an angle that ensures an optimal aesthetic result.

Biomechanically effective to eliminate the need for angled abutments.



INCREASED PARALLELISM AND AP SPREAD

Allows for simplified restorations in multi-implant cases.



LONGER TAPERED BODY

Enabling the use of the maxillary bone surrounding the nasal cavity.



DIFFERENT LENGTHS

Available in 18 mm, 20 mm, 22 mm and 24 mm implant variants.















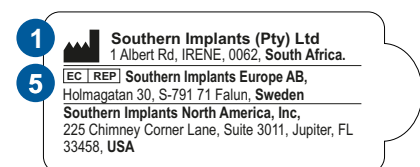
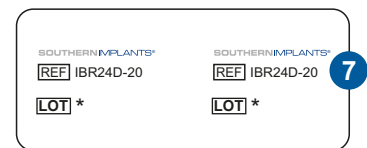
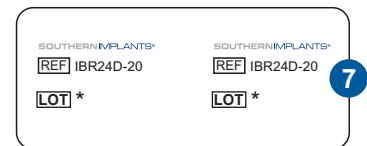
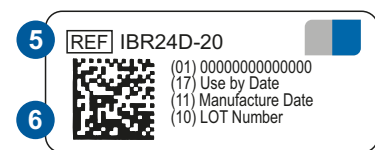
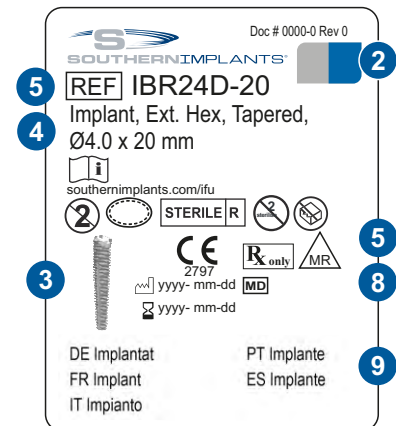
SINERGY SURFACE

Over 20 years of documented successful clinical results, manufactured from grade 4 commercially pure titanium (> 920 MPa).

EXPLANATION OF SYMBOLS

The following symbols are used on packaging labels and they indicate the following:

- 1  Manufacturer
- 2  Colour code indicating platform diameter
- 3  Implant image
- 4  Implant details and size
- 5  Sterilisation using irradiation
-  European representative
-  Catalogue number
-  Batch code
-  Do not resterilise
-  Consult instruction for use
-  Do not reuse
-  CE mark and notified body number
-  Use by date
-  Date of manufacture
-  Do not use if package is damaged
-  Identifies the product as a medical device
-  MR conditional / Magnetic resonance conditional
-  Single sterile barrier system
-  Double sterile barrier
- 6 **2D Bar coding**
Contains the GTIN, Use by date and LOT number
- 7 **Patient sticker for documentation purposes**
(to be used by health care provider on patient file)
- 8  Prescription device
CAUTION: FEDERAL LAW RESTRICTS THE DEVICE TO SALE BY OR ON THE ORDER OF A LICENCED HEALTH CARE PROVIDER.
- 9 **Product description**
(translated as per international standards)



For more information on Instructions for Use of our products, please scan the below,



or visit our website
southernimplants.com/ifu

For more information scan the below



to contact your Southern Implants Representative
or visit southernimplants.com



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