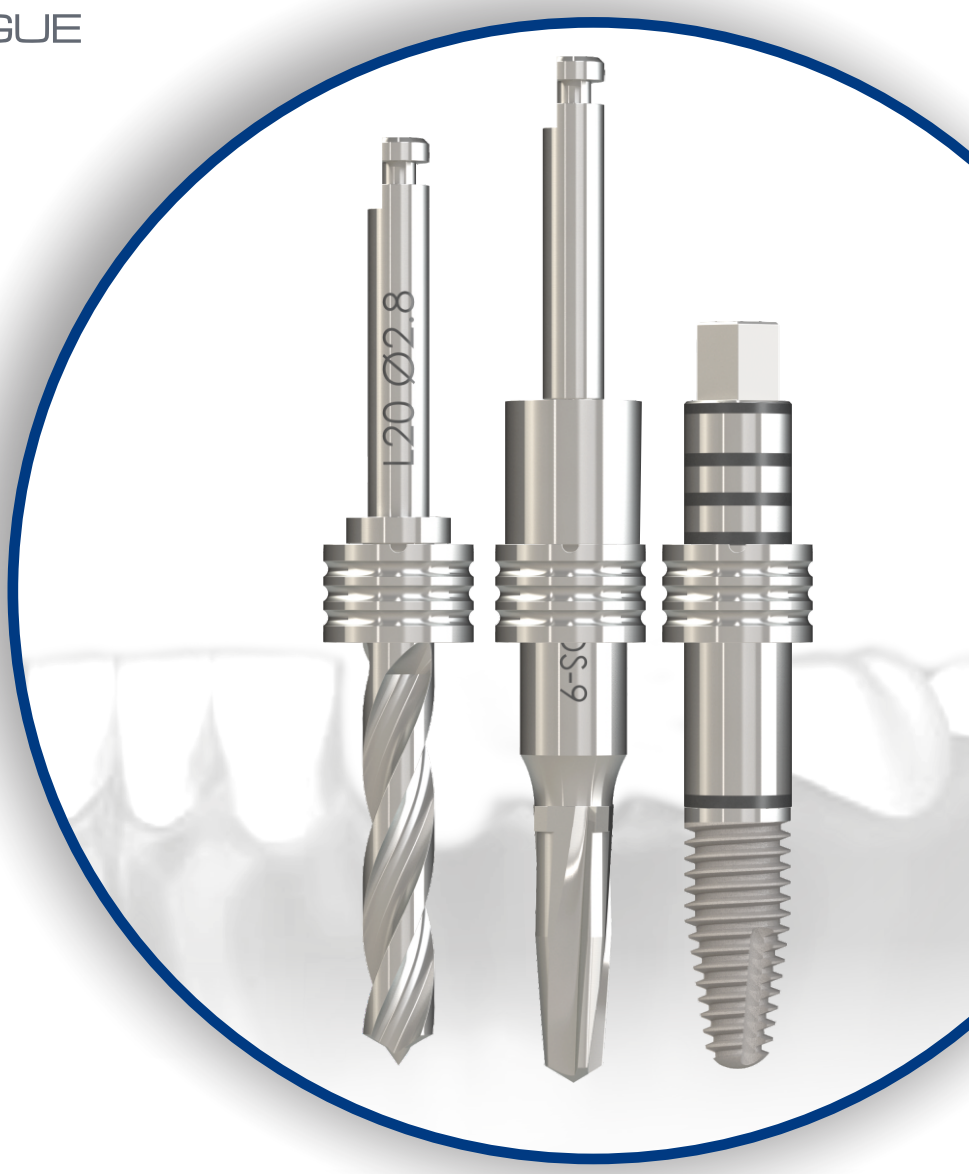
SOUTHERNIMPLANTS®

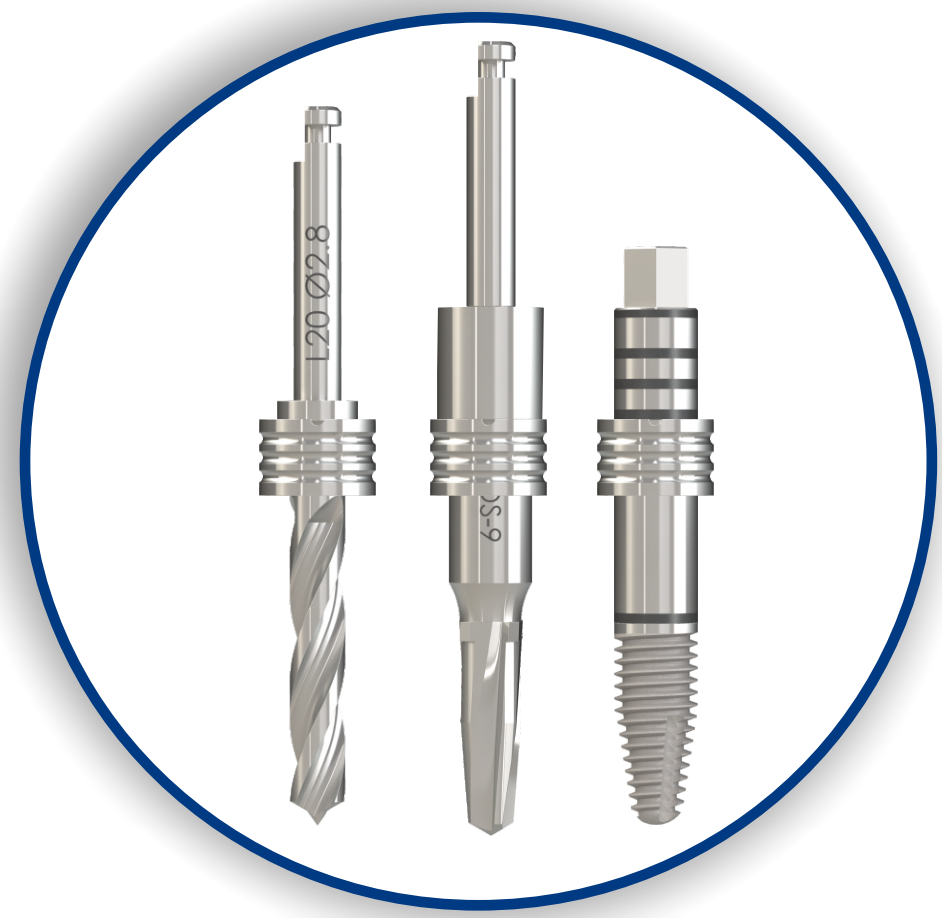
Innovative Treatment Solutions

SIGUIDED

PRODUCT CATALOGUE



Version 1.0



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 characterized 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®, sub-crestal angle correcting implant, available in angulations of 12, 24 & 36° and various internal and external connections.
- MAX implant, specifically designed for immediate molar tooth replacement.
- The ZYGAN and ZYGEX implants for severely resorbed maxilla and craniofacial reconstruction.

Our product portfolio is in synchronized 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

Various Data Sheets and information are available on our website
SOUTHERNIMPLANTS.COM

Please 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.

The Southern Implants guided surgery solution "SIGuided" provides the complete computer-assisted dental implant planning and placement solution for the External Hex and PROVATA™ implant systems. This is by virtual prosthesis and on-screen design of surgical guides, allowing prosthetically driven implant placements.

Solution Description

A surgical guide transfers pre-operative, software planned dental implant placement to the patient intraoperatively. There are three types of surgical guides: Bone supported, Mucosa supported and Tooth-supported. All surgical guides are patient specific.
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.
There are two guided surgery options available:

- Fully guided
- Pilot drill guided

Fully Guided

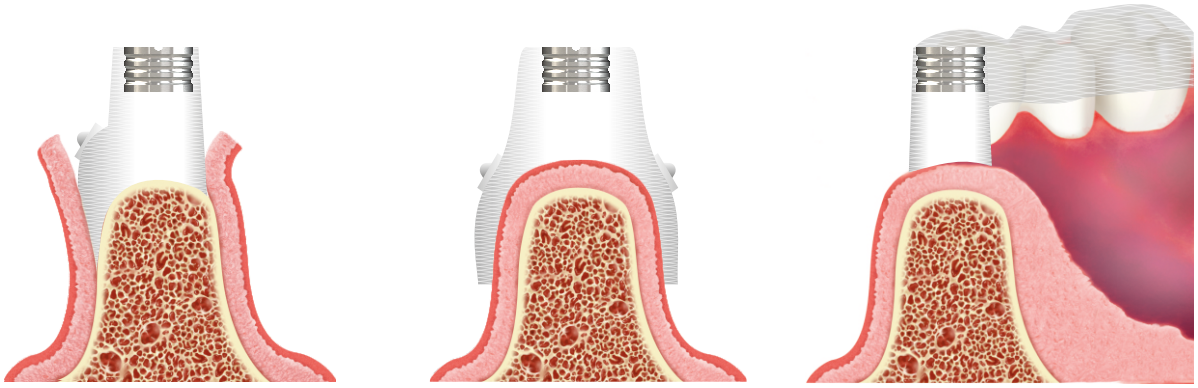
This is for placement of Southern Implants tapered and Co-Axis® External Hex and PROVATA implants. Implant diameters include Ø3.25, Ø4.0 and Ø5.0, in lengths from 8.5 to 15mm.

Pilot Drill Guided

This is the guided solution for ONLY the initial pilot drill, where optimal osteotomy angulation, direction and depth can be planned and initiated.

Surgical Guide Types

The surgical guide type selection depends on the dental professional's preference, patient anatomy and the available planning software.



Bone supported guide

Mucosa/tissue supported guide

Tooth-Supported guide

Surgical Guide Fixation

To stabilise the surgical guide, Southern Implants fixation pins, or fixation screws are available.

For the safe and effective use of dental implants, it is strongly suggested that specialized training be undertaken, including practical training to learn proper technique, biomechanical requirements, and radiographic evaluation.

Instructions for handling of Southern Implants External Hex and PROVATA implants should be studied, refer to our website.

Indications and intended use

Southern Implants External Hex and PROVATA implant systems are indicated for immediate replacement of compromised teeth in the mandible or maxilla, and are intended to provide support for fixed or removable dental prosthesis in the form of a single tooth, partial-arch or full arch restoration.

Southern Implants Guided range of instruments and implant libraries are available for various 3rd party software companies. For detailed information and instructions for use please contact these companies directly.

CONTRAINDICATIONS

Do not use in patients:

- who are medically unfit for dental implant procedures (e.g. uncontrolled diabetes and untreated infection in nearby bone).
- who are allergic to or have hypersensitivity to Titanium.
- where adequate numbers of implants cannot be placed to achieve full functional support for a prosthesis.
- where site specific contraindications exist.
- with insufficient vertical opening.

Treatment planning
Diagnostic and patient specific conditions influence the guided treatment plan. The type of restoration, provisionals, number of implants and imaging procedures must be taken into consideration during planning.

The following considerations should be reviewed during pre-planning:
- Quantity, quality and health of soft and hard tissues
- Occlusal analysis
- Oral hygiene assessment
- The patient's vertical opening of the mouth needs to be sufficient to accommodate the instruments used during guided surgery.

CT scanning
Several imaging technologies are available in order to get accurate scan data, the dental professional or radiologist and patient needs to follow the instructions of the imaging system used.

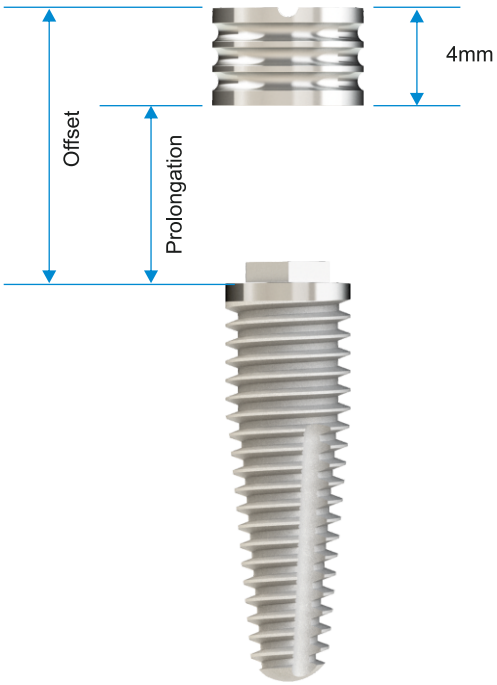
Warning: There may be distortion in the CT image data. These distortions could lead to fit and trajectory problems. It is recommended to validate the guide fit and trajectory, by taking a CT scan of the patient wearing the guide before surgery. Open the CT scan image and review the guide sleeve positions and orientations. Measure guide sleeve distance and orientation in the CT scan and compare to the offset / prolongation selected during the planning phase.

The dental professional must follow Southern Implants sleeve offsets and prolongations, failing to do so could result in patient injury. The guide manufacturer ensures compatibility with Southern Implants guided instruments by using SIGuided sleeves and instruments positioned according to offsets and prolongations described in this manual.

Guided surgery
Verify the fit of the guide by seating it on the patients jaw. It is recommended to validate the fit and sleeve positions with a CT scan of the patient with the guide in-situ. If the guide was manufactured on a stone model, the inaccuracy of the model or poor image quality from the scan data may result in the guide not fitting. Do not proceed, remake the guide.

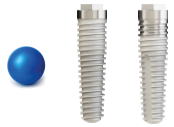
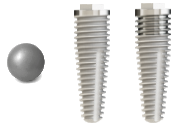
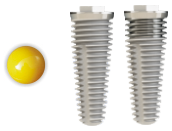
After fixing the guide into place, proceed using SIGuided drills and instrumentation to prepare the osteotomy. The surgical protocol together with the surgical guide will govern which instruments are required to prepare each implant site.

- The offset is measured from the implant platform to the top of the guide sleeve
- The prolongation is measured from the implant platform to the bottom of the guide sleeve

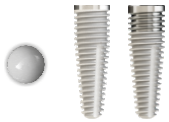
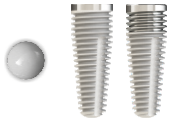


POST-PLACEMENT PROCEDURES
The following considerations should be reviewed prior to the restorative phase:
- Implant stability
- Implant position and abutment selection

EXTERNAL HEX

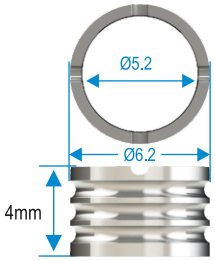
		8.5mm	10mm	11.5mm	13mm	15mm
	Ø3.25mm	IBNT8.5 MSc-IBNT-8.5	IBNT10 MSc-IBNT-10	IBNT11.5 MSc-IBNT-11.5	IBNT13 MSc-IBNT-13	IBNT15 MSc-IBNT-15
	Ø4.0mm	IBT8.5 MSc-IBT-8.5	IBT10 MSc-IBT-10	IBT11.5 MSc-IBT-11.5	IBT13 MSc-IBT-13	IBT15 MSc-IBT-15
	Ø5.0mm	BAT8.5 MSc-BAT-8.5	BAT10 MSc-BAT-10	BAT11.5 MSc-BAT-11.5	BAT13 MSc-BAT-13	BAT15 MSc-BAT-15

PROVATA™

		8.5mm	10mm	11.5mm	13mm	15mm
	Ø4.0mm	PRO408 MSc-PRO408	PRO410 MSc-PRO410	PRO411 MSc-PRO411	PRO413 MSc-PRO413	PRO415 MSc-PRO415
	Ø5.0mm	PRO508 MSc-PRO508	PRO510 MSc-PRO510	PRO511 MSc-PRO511	PRO513 MSc-PRO513	PRO515 MSc-PRO515

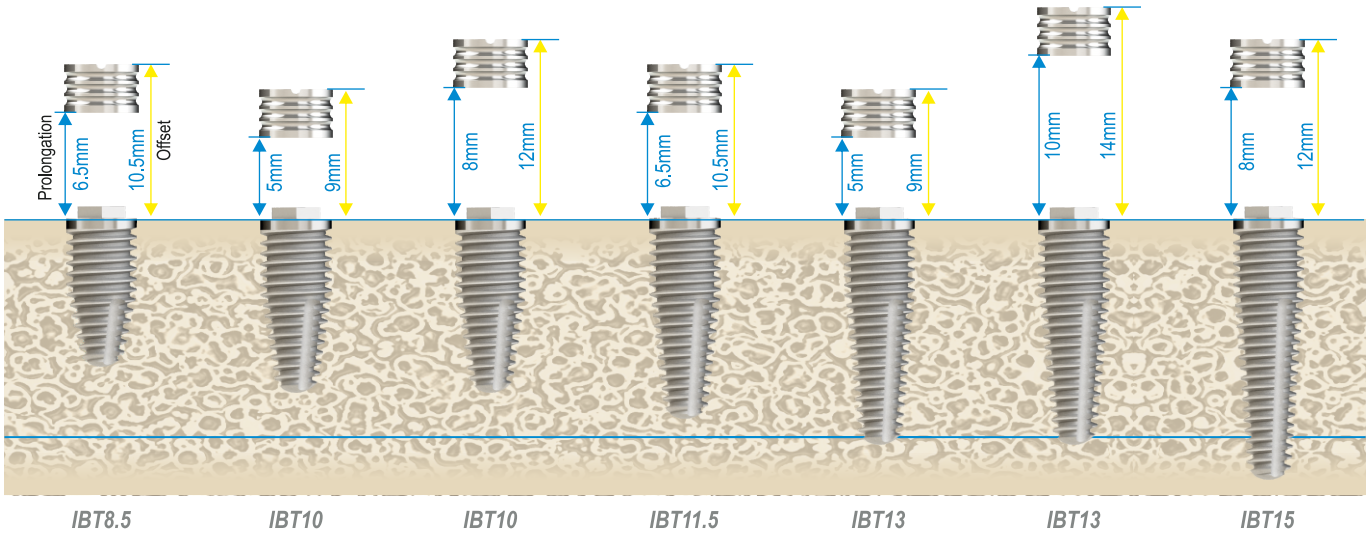
GUIDE SLEEVES

Guide sleeves have a specific inner diameter, Ø5.2, which accommodates all Southern Implants instruments used during the guided procedure. Tapered implants can be placed through closed sleeves, GSS. The instruments used to prepare a site and place an implant is determined by the offset of the guide sleeves. It is therefore crucial that cases are planned using the specific offset heights.



	Order Number	Sleeve inner diameter	Sleeve outer diameter	Sleeve height
	GSS	Ø5.2mm	Ø6.2mm	4mm

External Hex IBT implants used for illustration



EXTERNAL HEX

	8.5mm	10mm	11.5mm	13mm	15mm
 Ø3.25mm Co-Axis	IBNT12d-8.5 MSc-IBNT12d-8.5	IBNT12d-10 MSc-IBNT12d-10	IBNT12d-11.5 MSc-IBNT12d-11.5	IBNT12d-13 MSc-IBNT12d-13	IBNT12d-15 MSc-IBNT12d-15
 Ø4.0mm Co-Axis REDUCED PLATFORM	IBR12d-8.5 MSc-IBR12d-8.5	IBR12d-10 MSc-IBR12d-10	IBR12d-11.5 MSc-IBR12d-11.5	IBR12d-13 MSc-IBR12d-13	IBR12d-15 MSc-IBR12d-15
 Ø5.0mm Co-Axis REDUCED PLATFORM	BAR12d-8.5 MSc-BAR12d-8.5	BAR12d-10 MSc-BAR12d-10	BAR12d-11.5 MSc-BAR12d-11.5	BAR12d-13 MSc-BAR12d-13	BAR12d-15 MSc-BAR12d-15

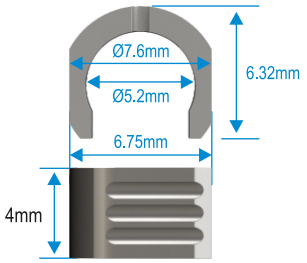
PROVATA™

	8.5mm	10mm	11.5mm	13mm	15mm
 Ø4.0mm Co-Axis	PRO12D408 MSc-PRO12D408	PRO12D410 MSc-PRO12D410	PRO12D411 MSc-PRO12D411	PRO12D413 MSc-PRO12D413	PRO12D415 MSc-PRO12D415
 Ø5.0mm Co-Axis	PRO12D508 MSc-PRO12D508	PRO12D510 MSc-PRO12D510	PRO12D511 MSc-PRO12D511	PRO12D513 MSc-PRO12D513	PRO12D515 MSc-PRO12D515

Guide sleeves have a specific inner diameter, Ø5.2, which accommodates all Southern Implants instruments used during the guided procedure. Co-Axis implants can be placed through open sleeves, GSS-C, to allow access for placement and removal of the Co-Axis fixture mount.

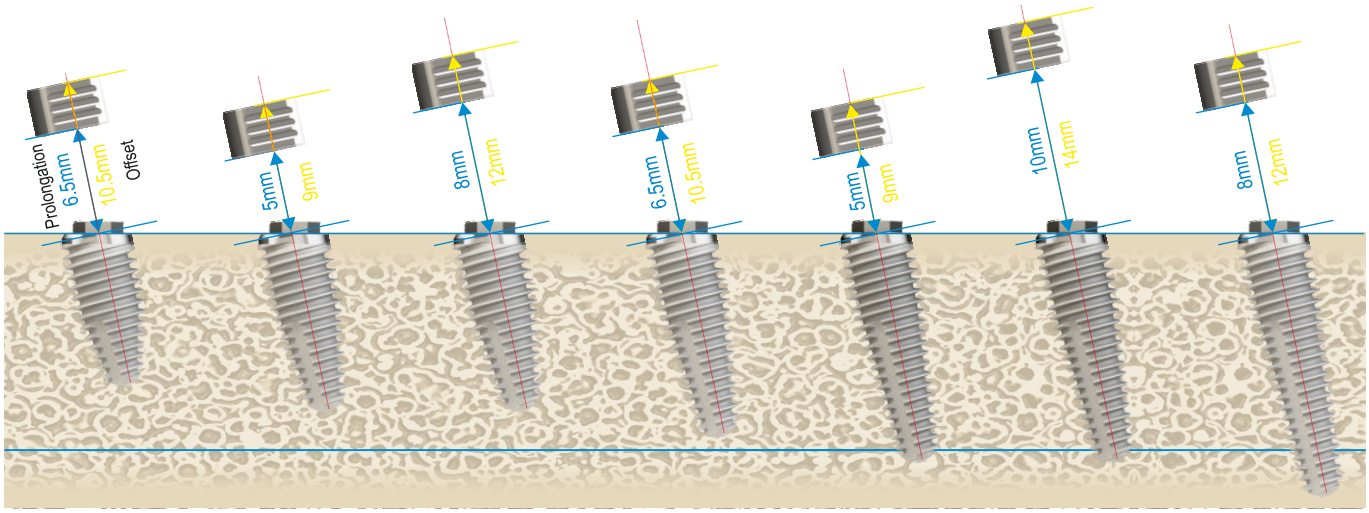
The instruments used to prepare a site and place an implant is determined by the offset of the guide sleeves. It is therefore crucial that cases are planned using the specific offset heights.

Note: Offset & Prolongation for the Co-Axis implants are indicated through the centre of the guide sleeve and implant.



	Order Number	Sleeve inner diameter	Sleeve outer diameter	Sleeve height
	**GSS-C**	Ø5.2mm	Ø7.6mm	4mm

External Hex IBR12d implants used for illustration



IBR12d-8.5 *IBR12d-10* *IBR12d-10* *IBR12d-11.5* *IBR12d-13* *IBR12d-13* *IBR12d-15*

Step 1: Preparing for the osteotomy

Note: It is recommended to raise a full-thickness mucoperiosteal flap. Alternatively, a tissue cutter can be used.

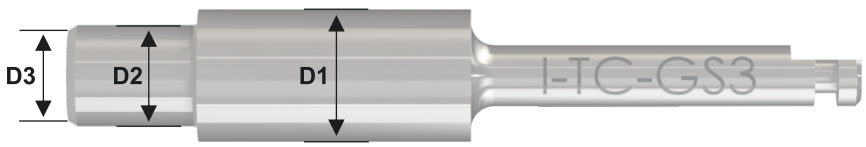
The Tissue Cutter is used to remove the soft tissue to the required diameter as indicated in the table below.

Recommended tissue cutting speed: 1200rpm.

Insert the Tissue Cutter, I-TC-GSx, through the guide sleeve.

TISSUE CUTTER *(Optional)*

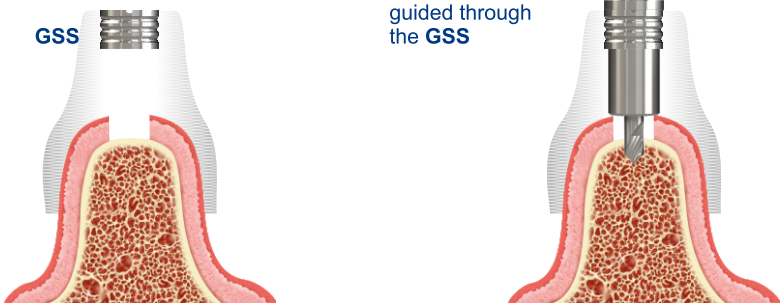
	Order Number	Used with	D1	D2	D3
	I-TC-GS3	Ø3.25mm implants	Ø5.1	Ø3.9	Ø3.5
	I-TC-GS4	Ø4.0mm implants	Ø5.1	Ø4.5	Ø4.1
	I-TC-GS5	Ø5.0mm implants	Ø5.1	Ø5.1	Ø4.7



Step 2: Initiate the osteotomy

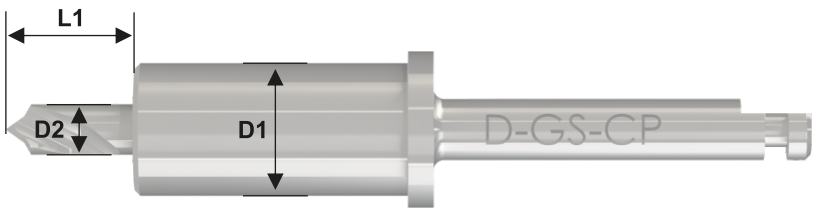
The cortical perforator, D-GS-CP, is used to initiate the osteotomy by perforating the cortical plate at the planned implant position.

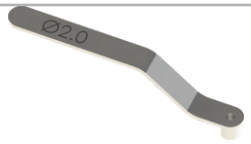
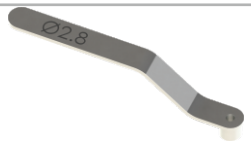
Drill at a speed of 1000-1500rpm with copious irrigation. An intermittent technique is highly recommended to avoid overheating the bone.



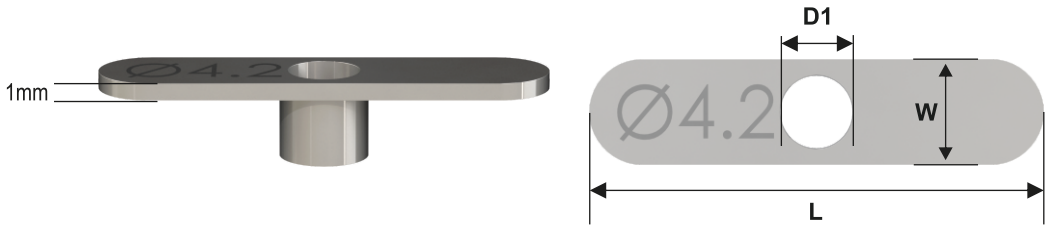
CORTICAL PERFORATOR

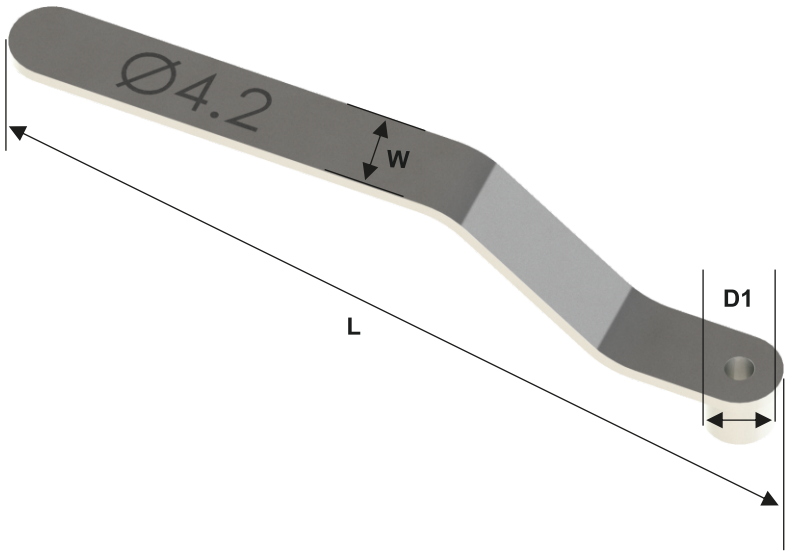
	Order Number	Used with	D1	D2	L1
	D-GS-CP	All implants	Ø5.1	Ø1.95	4.7mm



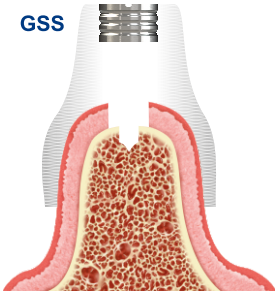
Long Guide Spoons	Order Number	Used with	D1	Width	Length
	DGS-L-2	Ø2.0mm Pilot drills	Ø2.0	6mm	56.65mm
	DGS-L-2.8	Ø2.8mm Twist drills	Ø2.8	6mm	56.65mm
	DGS-L-4.2	Ø3.25mm, Ø4.0mm External Hex implants during fully guided implant placement	Ø4.2	6mm	56.65mm

Short Guide Spoons	Order Number	Used with	D1	Width	Length
	DGS-S-2	Ø2.0mm Pilot drills	Ø2.0	6mm	26mm
	DGS-S-2.8	Ø2.8mm Twist drills	Ø2.8	6mm	26mm
	DGS-S-4.2	Ø3.25mm, Ø4.0mm External Hex implants during fully guided implant placement	Ø4.2	6mm	26mm



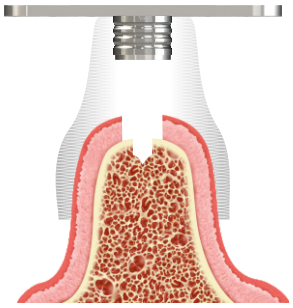


Guide spoons are placed through the guide sleeve, GSS / GSS-C, to assist with guiding the different diameter drills during the site preparation.

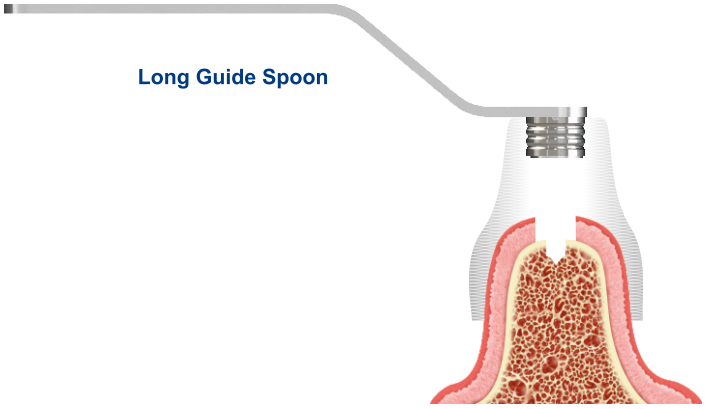


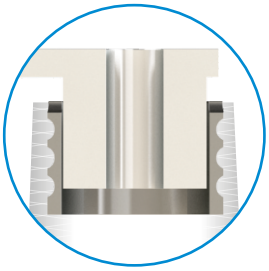
Guide Spoon inserted into GSS

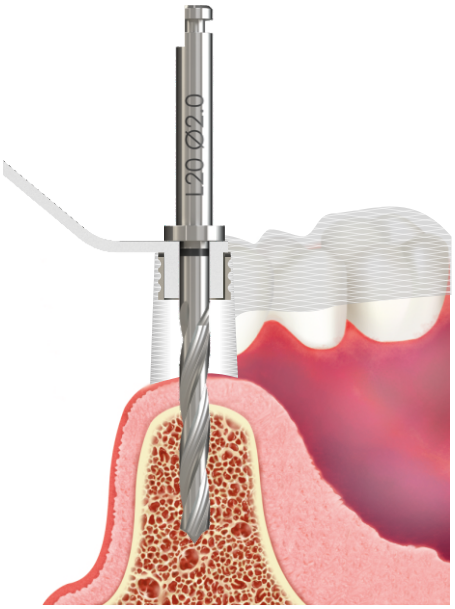
Short Guide Spoon



Long Guide Spoon

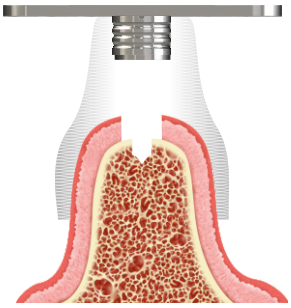






Step 3: Pilot drilling – Ø2mm Pilot Drill

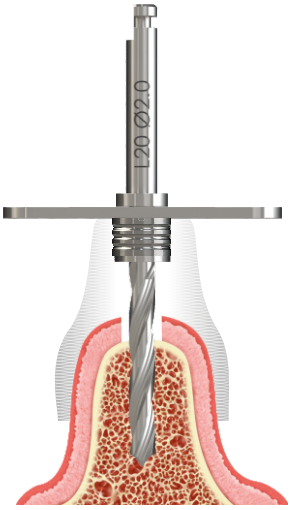
Place either the short or long Ø2.0mm guide spoon, DGS-S-2 / DGS-L-2, through the guide sleeve.



Drill through the spoon and guide sleeve in the pre-determined direction with the Ø2.0mm pilot drill.

The Ø2.0mm drills are length specific and are available in lengths related to the planned implant length and guide offset.

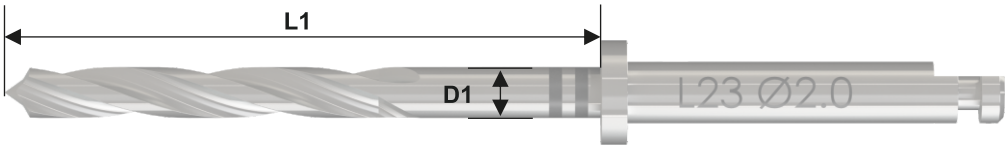
The built-in drill stop prevents the drill from drilling past the planned depth.



PILOT DRILLS

Pilot drills are available in three lengths.

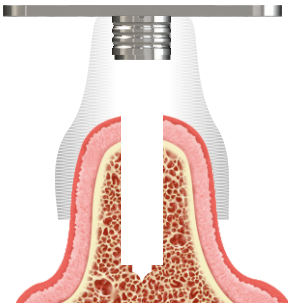
Implant Length	Prolongation	Offset	Order Number	Spoon	D1	L1
8.5mm	6.5mm	10.5mm	D-20T-GS-20	DGS-L-2 DGS-S-2	Ø1.95	20mm
10mm	5mm	9mm	D-20T-GS-20	DGS-L-2 DGS-S-2	Ø1.95	20mm
10mm	8mm	12mm	D-20T-GS-23	DGS-L-2 DGS-S-2	Ø1.95	23mm
11.5mm	6.5mm	10.5mm	D-20T-GS-23	DGS-L-2 DGS-S-2	Ø1.95	23mm
13mm	5mm	9mm	D-20T-GS-23	DGS-L-2 DGS-S-2	Ø1.95	23mm
13mm	10mm	14mm	D-20T-GS-28	DGS-L-2 DGS-S-2	Ø1.95	28mm
15mm	8mm	12mm	D-20T-GS-28	DGS-L-2 DGS-S-2	Ø1.95	28mm



NOTE: The number of laser marked rings around the pilot drill help to identify the drill length.

Step 4: Gradually enlarge the osteotomy - Ø2.8mm Twist Drill

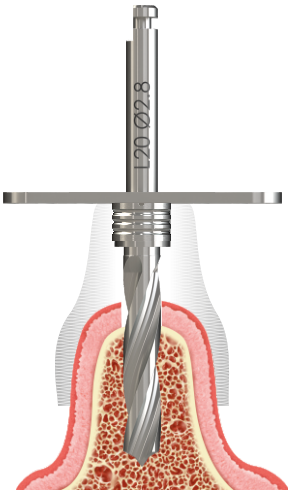
Place either the short or long Ø2.8mm guide spoon, DGS-S-28 / DGS-L-28, through the guide sleeve.



Gradually enlarge the osteotomy by drilling through the spoon and guide sleeve with the Ø2.8mm twist drill.

The Ø2.8mm Twist drills are length specific and are available in lengths related to the planned implant length and guide offset.

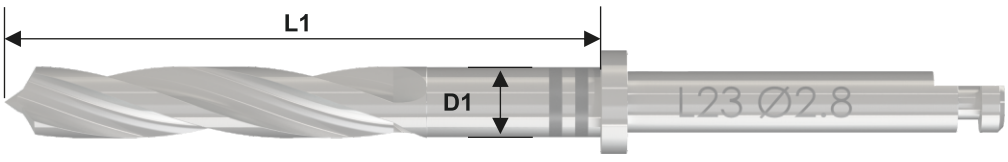
The built-in drill stop prevents the drill from drilling past the planned depth.



TWIST DRILLS

Twist drills are available in three lengths.

Implant Length	Prolongation	Offset	Order Number	Spoon	D1	L1
8.5mm	6.5mm	10.5mm	D-28T-GS-20	DGS-L-2.8 DGS-S-2.8	Ø2.75	20mm
10mm	5mm	9mm	D-28T-GS-20	DGS-L-2.8 DGS-S-2.8	Ø2.75	20mm
10mm	8mm	12mm	D-28T-GS-23	DGS-L-2.8 DGS-S-2.8	Ø2.75	23mm
11.5mm	6.5mm	10.5mm	D-28T-GS-23	DGS-L-2.8 DGS-S-2.8	Ø2.75	23mm
13mm	5mm	9mm	D-28T-GS-23	DGS-L-2.8 DGS-S-2.8	Ø2.75	23mm
13mm	10mm	14mm	D-28T-GS-28	DGS-L-2.8 DGS-S-2.8	Ø2.75	28mm
15mm	8mm	12mm	D-28T-GS-28	DGS-L-2.8 DGS-S-2.8	Ø2.75	28mm

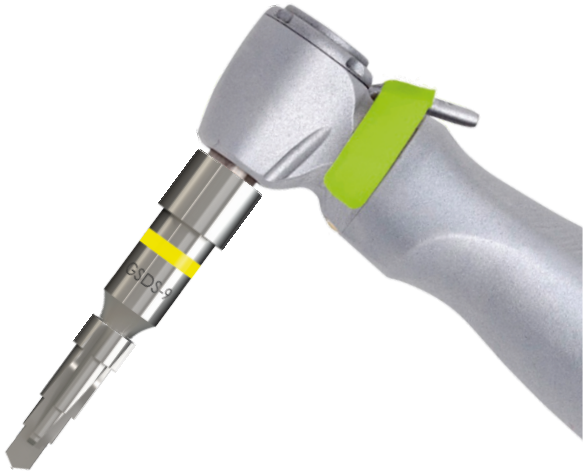


NOTE: The number of laser marked rings around the twist drill help to identify the drill length.

After initial drilling, the drilling sequence will continue with the use of drill stabilisers.

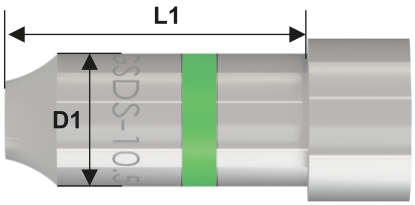
The drill stabilizer is placed over the tapered drill shaft, and secured with the hand piece. The stabiliser is used to guide the drill through the guide sleeve, GSS / GSS-C. The drill stabilisers have set stopper heights which are dependent on the guide offset .

NOTE: Drill stabilisers are colour coded for ease of identification. **The colour coding does not correspond to diameter, but to prolongation and offsets.**

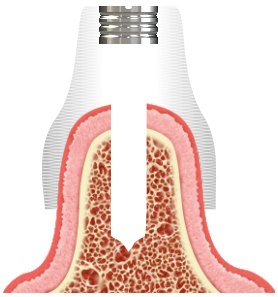


DRILL STABILIZERS

Ø5.0mm	Prolongation	Offset	Order Number	D1	L1
	5mm	9mm	**GSDS-5-9**	Ø5.1	9mm
	6.5mm	10.5mm	**GSDS-5-10.5**	Ø5.1	10.5mm
	8mm	12mm	**GSDS-5-12**	Ø5.1	12mm
	10mm	14mm	**GSDS-5-14**	Ø5.1	14mm



Step 4: Gradually enlarge the osteotomy with Tapered drills



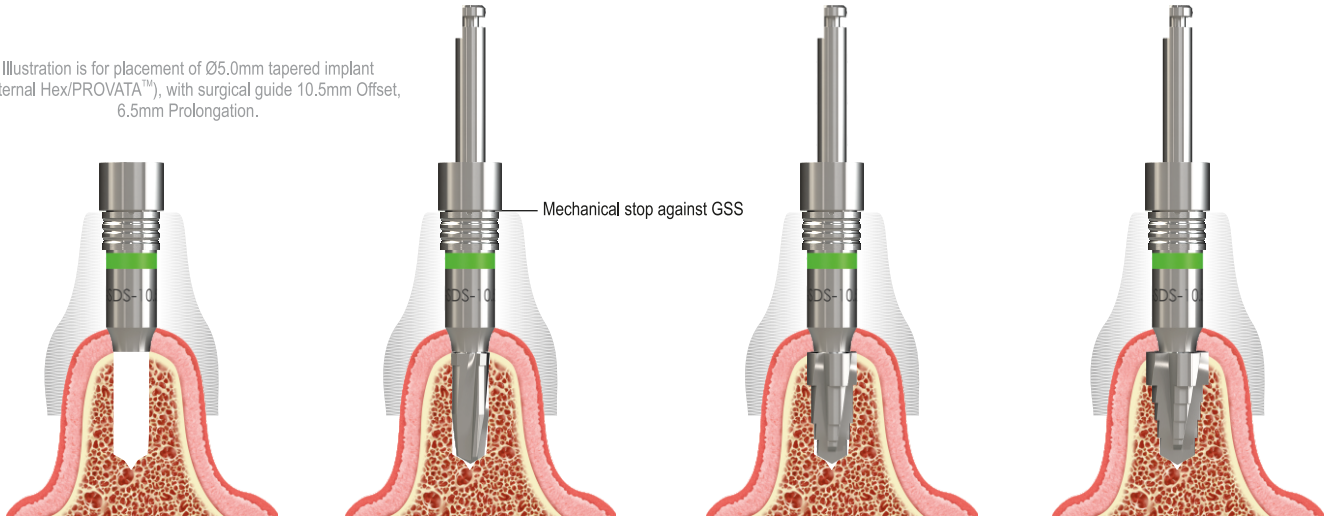
Tapered shaping drills are length and diameter specific. **Note:** Southern Implants tapered drills do not have built-in drill stops. Tapered drills used for guided surgery have "L" in the product code for identification (e.g. D-40TP-8.5-L)

Use the appropriate length and diameter drills, corresponding to the selected implant. Slide the drill stabilizer, GSDS-5-xx, over the drill shaft.

See page 16 for drill stabiliser selection. Connect the drill to the hand piece.

Widen the osteotomy intermittently, with copious irrigation, with the tapered drill and stabiliser through the guide sleeve, GSS / GSS-C. Drilling speed is recommended at max. 800rpm.

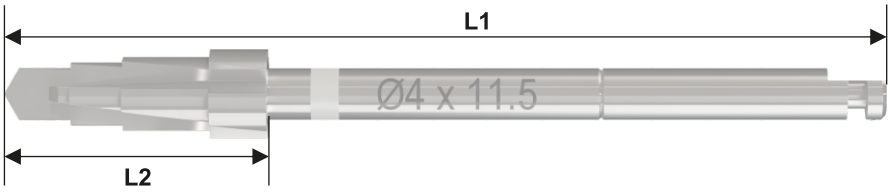
Illustration is for placement of Ø5.0mm tapered implant (External Hex/PROVATA™), with surgical guide 10.5mm Offset, 6.5mm Prolongation.



Ø3.3mm Tapered drill | Ø4.0mm Tapered drill | Ø5.0mm Tapered drill

TAPERED DRILLS

Ø3.3mm Tapered drills | Ø4.0mm Tapered drills | Ø5.0mm Tapered drills



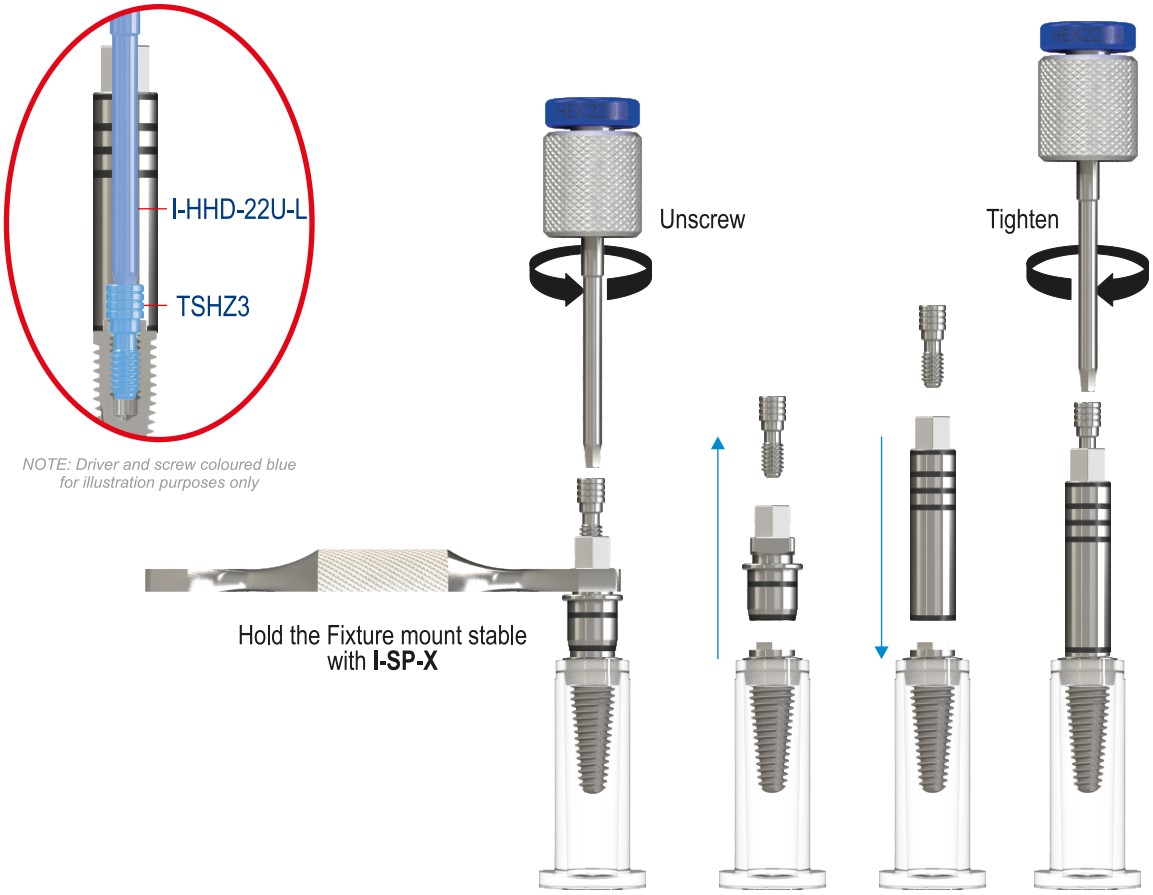
Order Number	L1	L2
D-33TP-8.5-L	37.71	8.5
D-33TP-10-L	39.21	10
D-33TP-11.5-L	40.71	11.5
D-33TP-13-L	42.21	13
D-33TP-15-L	44.21	15
D-40TP-8.5-L	37.71	8.5
D-40TP-10-L	39.21	10
D-40TP-11.5-L	40.71	11.5
D-40TP-13-L	42.21	13
D-40TP-15-L	44.21	15
D-50TP-8.5-L	37.71	8.5
D-50TP-10-L	39.21	10
D-50TP-11.5-L	40.71	11.5
D-50TP-13-L	42.21	13
D-50TP-15-L	44.21	15

IMPLANT PLACEMENT
EXTERNAL HEX

External Hex implants are supplied with a standard fixture mount. The standard fixture mount must be replaced with the guided surgery fixture mount. Keep the implant stable, with the I-SP-X (spanner) when removing the fixture mount screw.

The fixture mount screw, TSHZ3, is removed by using a long universal hex driver, I-HHD-22U-L. The guided surgery fixture mount is then attached and tightened using the TSHZ3 screw.

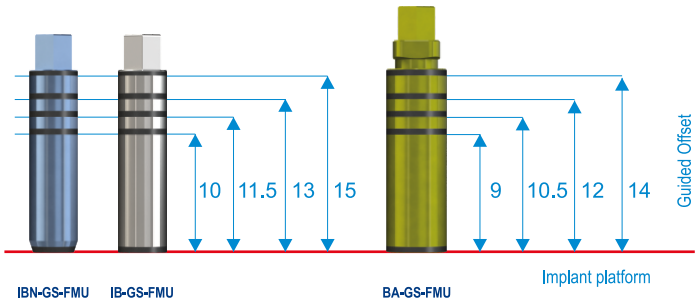
Tighten screw to:
15Ncm for straight External Hex implants.
25Ncm for Co-Axis® External Hex implants.



Note: Due to the length of the guided fixture mount, only long drivers can be used. Available in handheld, hand-piece and wrench insert versions.

TAPERED IMPLANTS

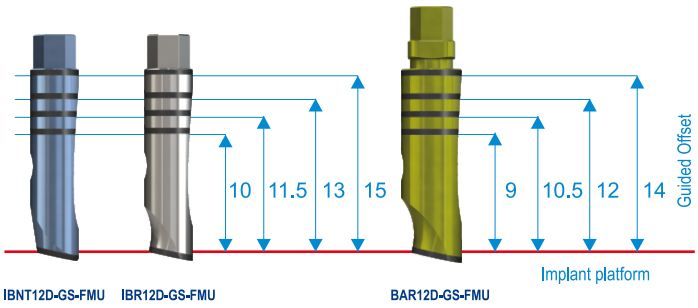
Laser markings



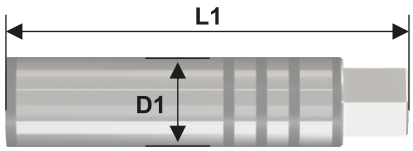
Order Number	Used with implant	D1	L1 (Total Length)
IBN-GS-FMU	IBNT	Ø4.1	18.5mm
IB-GS-FMU	IBT	Ø4.1	18.5mm
BA-GS-FMU	BAT	Ø5.1	20.9mm

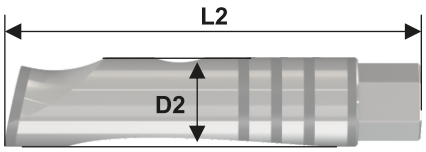
CO-AXIS™ IMPLANTS

Co-Axis Laser markings



Order Number	Used with implant	D2	L2 (Total Length)
IBNT12D-GS-FMU	IBNT12d	Ø4.1	19.2mm
IBR12D-GS-FMU	IBR12d	Ø4.1	19.2mm
BAR12D-GS-FMU	BAR12d	Ø5.1	21.8mm

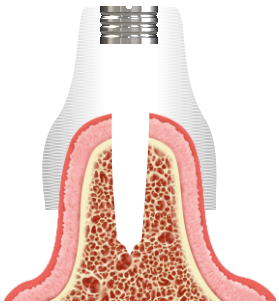


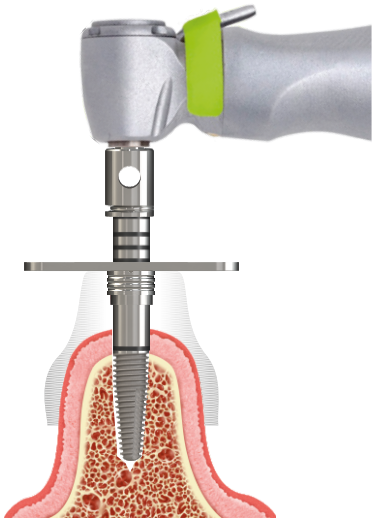


Step 7: Placement of External Hex Ø3.25 & Ø4.0mm implants (Tapered and Co-Axis®).

Once the guided fixture mount is attached, connect the Hand Piece insertion tool, I-CON-X/XS, to the hand piece.

Engage the fixture mount and carefully remove the implant from the sterile vial.





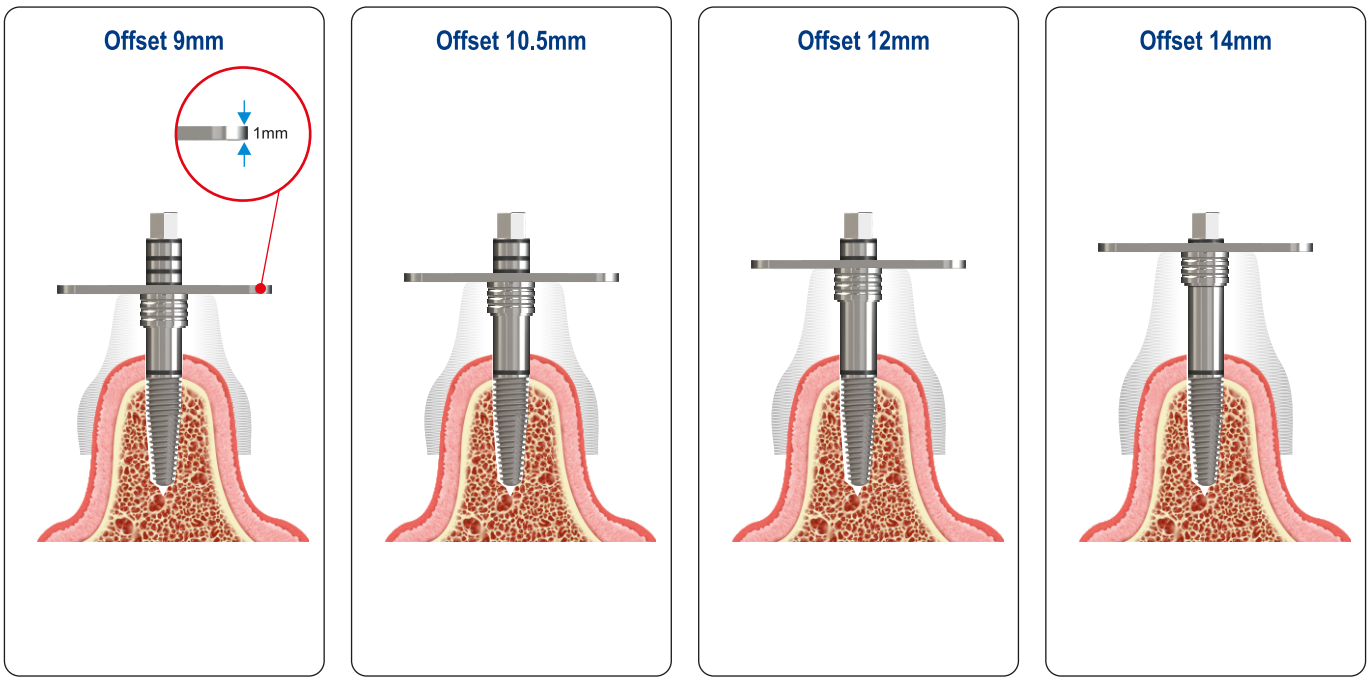
Place either the long or short **Ø4.2mm** guide spoon, DGS-L-4.2 / DGS-S-4.2, into the guide sleeve, (GSS / GSS-C). Carry the implant to the prepared implant site.

Insert the implant at low speed (15-25rpm), set the maximum torque to 70Ncm.

Guided fixture mounts do not have a drill stop. The stop is a visual stop only.
The laser markings on the guided fixture mounts correspond to the surgical guide offset. Place the implant so that the bottom line of the appropriate laser marking is in line with the spoon, DGS-L-4.2 / DGS-S-4.2.

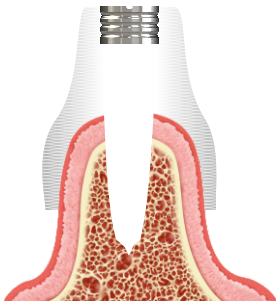
Avoid applying bending moments to the fixture mount while inserting the implant. Check the fixture mount screw for loosening periodically and re-tighten if necessary.

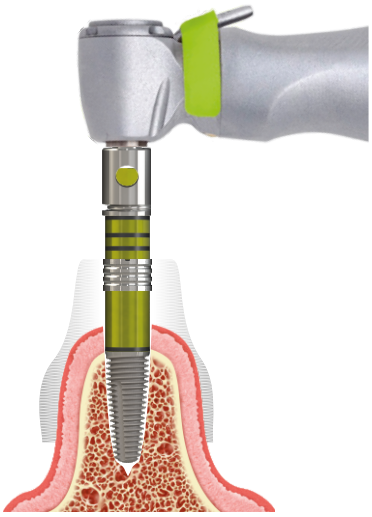
Detach the insertion tool from the fixture mount. Then use the long universal driver, I-HHD-22U-L, to remove the fixture mount screw. Slide the guide spoon, DGS-L-4.2 / DGG-S-4.2, over the fixture mount and remove the fixture mount.



Step 7: Placement of External Hex Ø5mm implants (Tapered and Co-Axis®).
Once the guided fixture mount has been attached, connect the hand piece insertion tool, I-CON-X / XS, to the hand piece.

Engage the fixture mount and carefully remove the implant from the sterile vial.





NOTE: Ø5mm implants are placed directly through the guide sleeve, GSS / GSS-C, and **not through a spoon.**

Carry the implant to the prepared implant site.

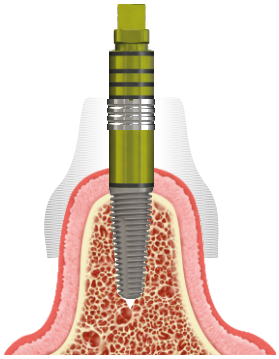
Insert the implant at low speed (15-25rpm), set the maximum torque to 70Ncm.

Guided fixture mounts do not have a stop on them, the stop is a visual stop. The laser markings correspond to the offset selected during the planning phase. Place the implant with the bottom line of the laser marking in line with the guide sleeve, GSS / GSS-C. The planned depth is now reached.

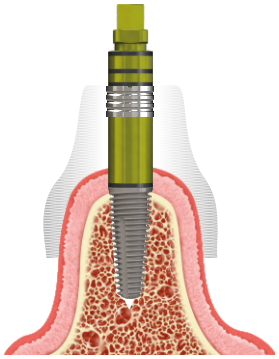
Avoid applying bending moments to the fixture mount while inserting the implant. Check the fixture mount screw for loosening periodically and re-tighten if necessary.

Use the long universal driver, I-HHD-22U-L, to remove the fixture mount screw and remove the guided fixture mount.

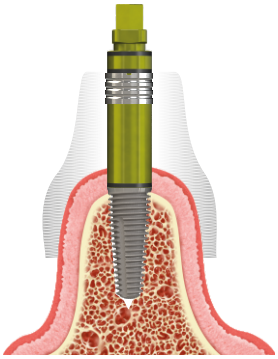
Offset 9mm



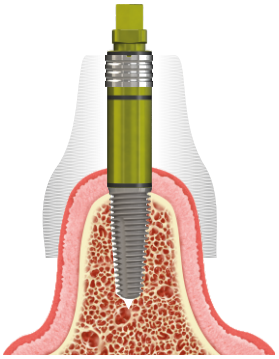
Offset 10.5mm



Offset 12mm

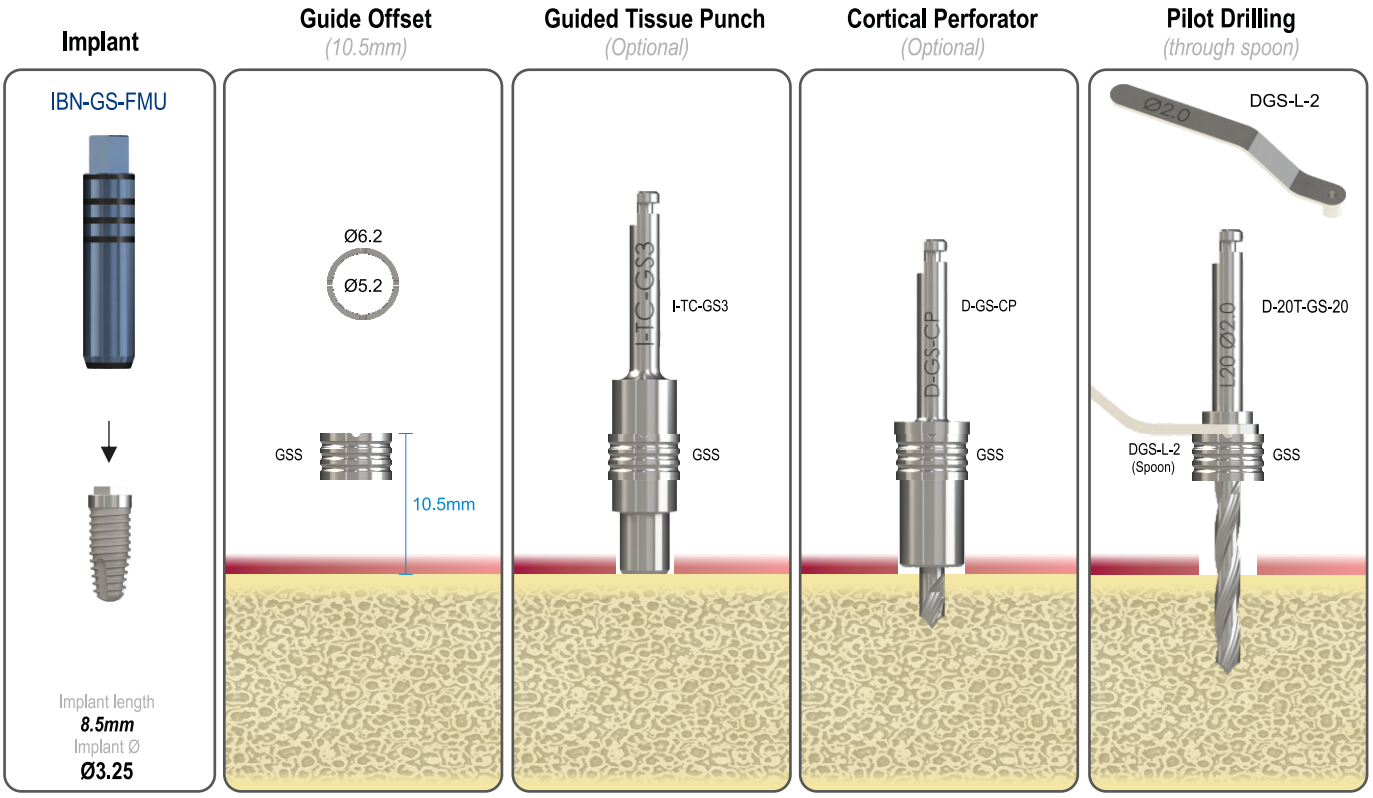


Offset 14mm



IBNT8.5

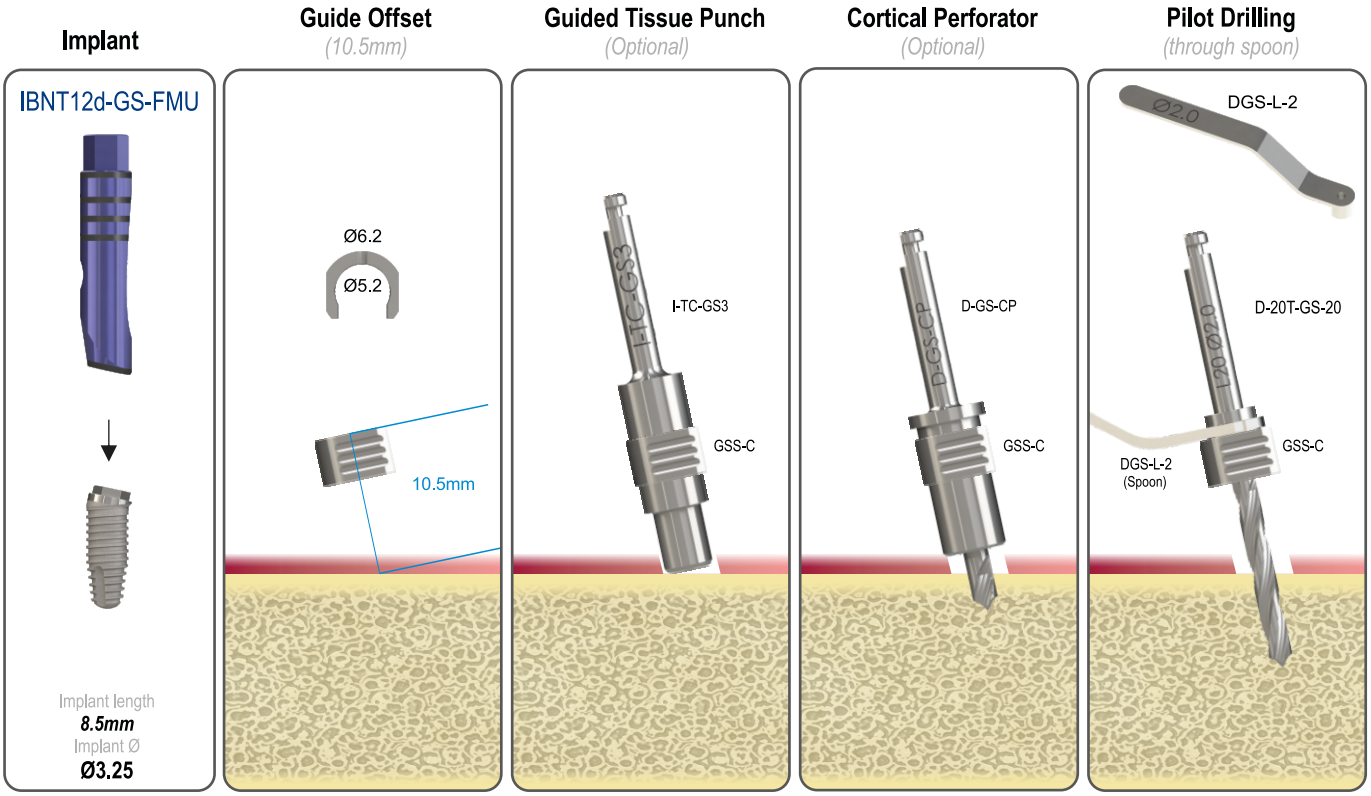
PROCESS



NOTE: IBNT8.5 is shown with an offset of 10.5mm to illustrate the workflow for Ø3.25mm implants.

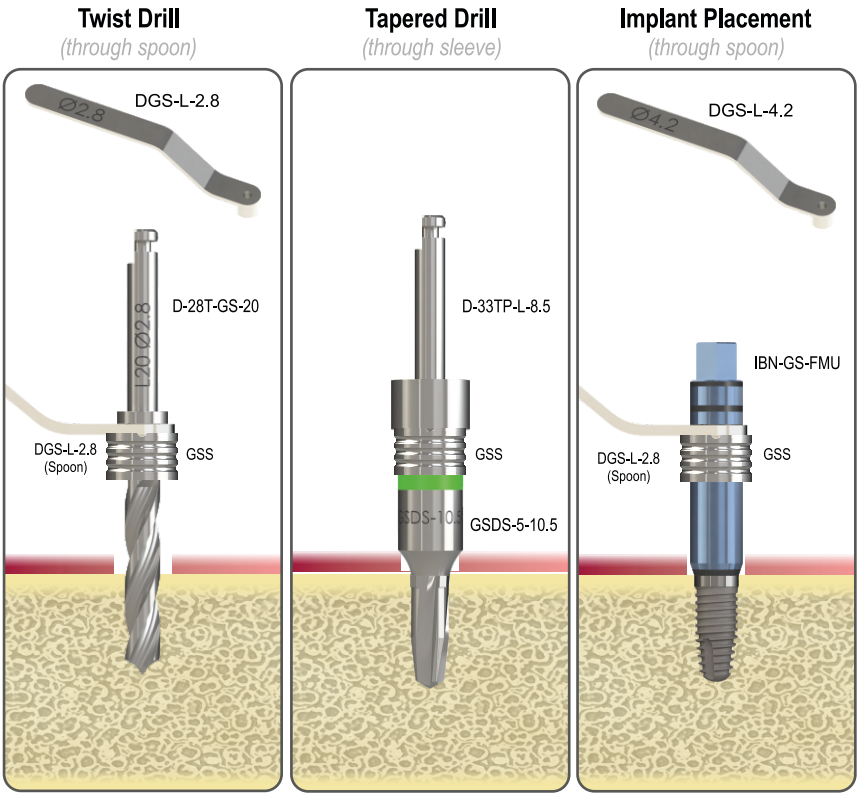
IBNT12d-8.5

PROCESS



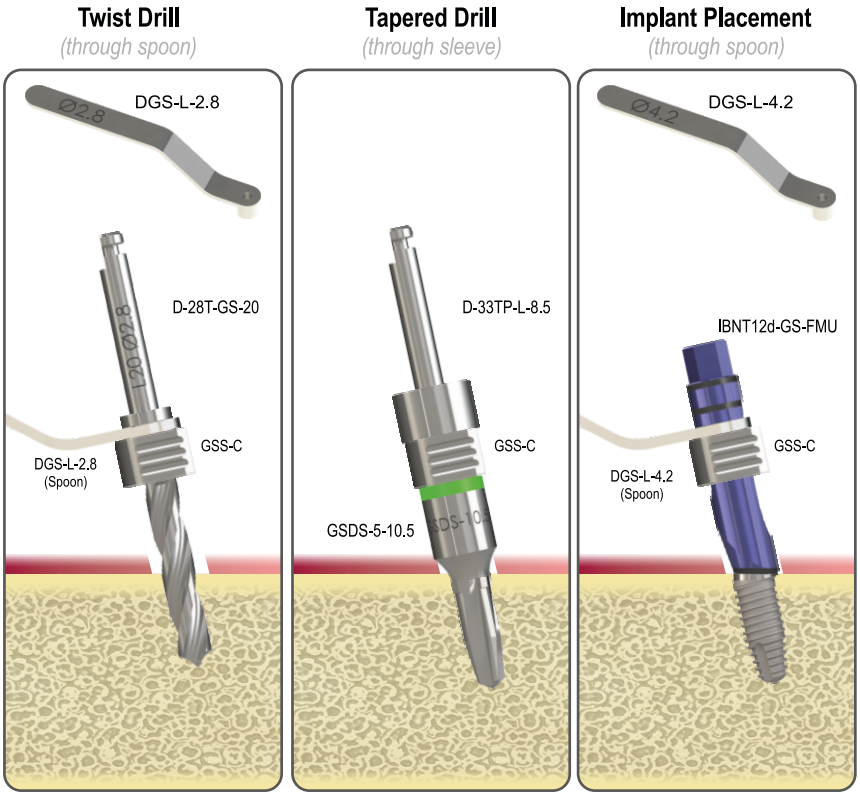
NOTE: IBNT12d-8.5 is shown with an offset of 10.5mm to illustrate the workflow for Ø3.25mm Co-Axis implants.

Ø3.25mm External Hex



Refer to pages 8 & 9 for full implant range, offsets and prolongations

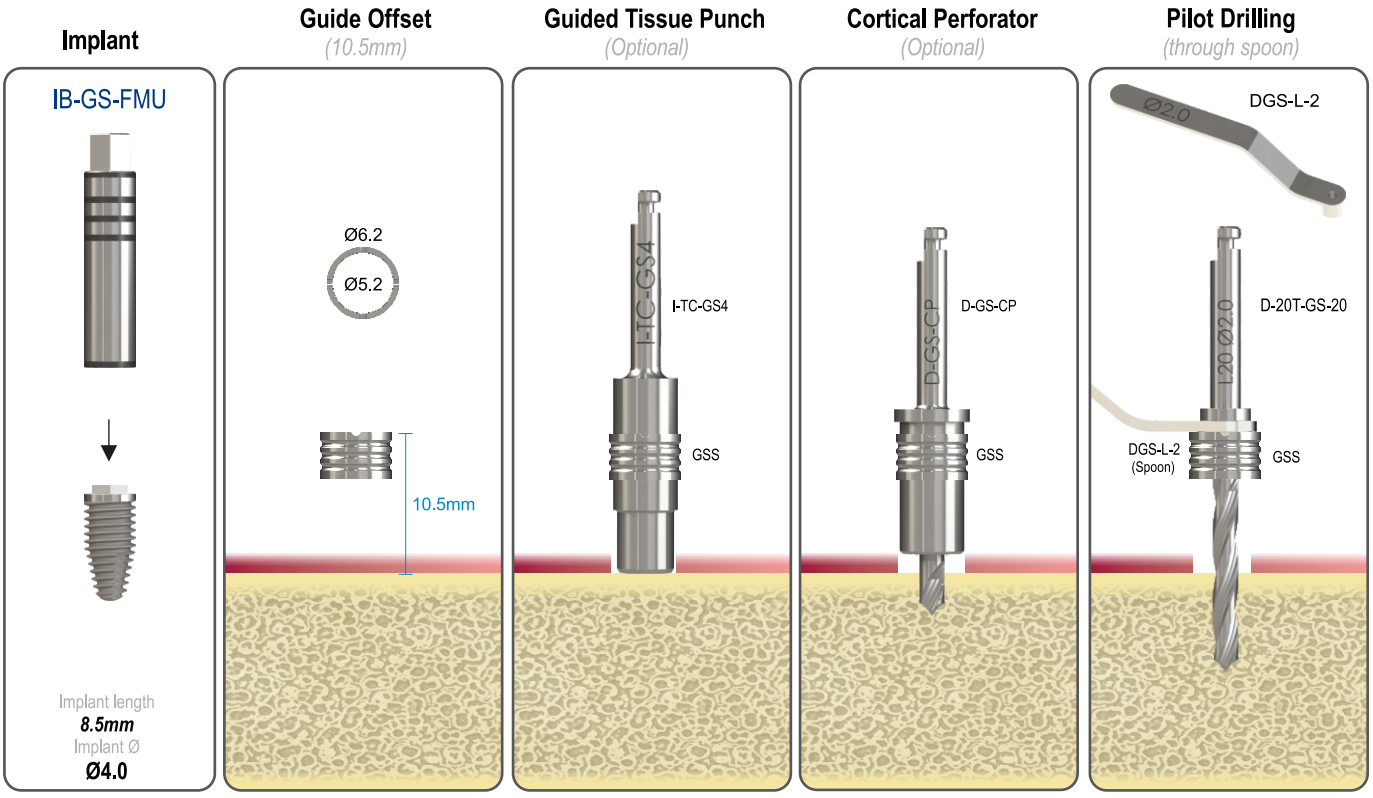
Ø3.25mm External Hex Co-Axis®



Refer to pages 10 & 11 for full Co-Axis implant range, offsets and prolongations

IBT8.5

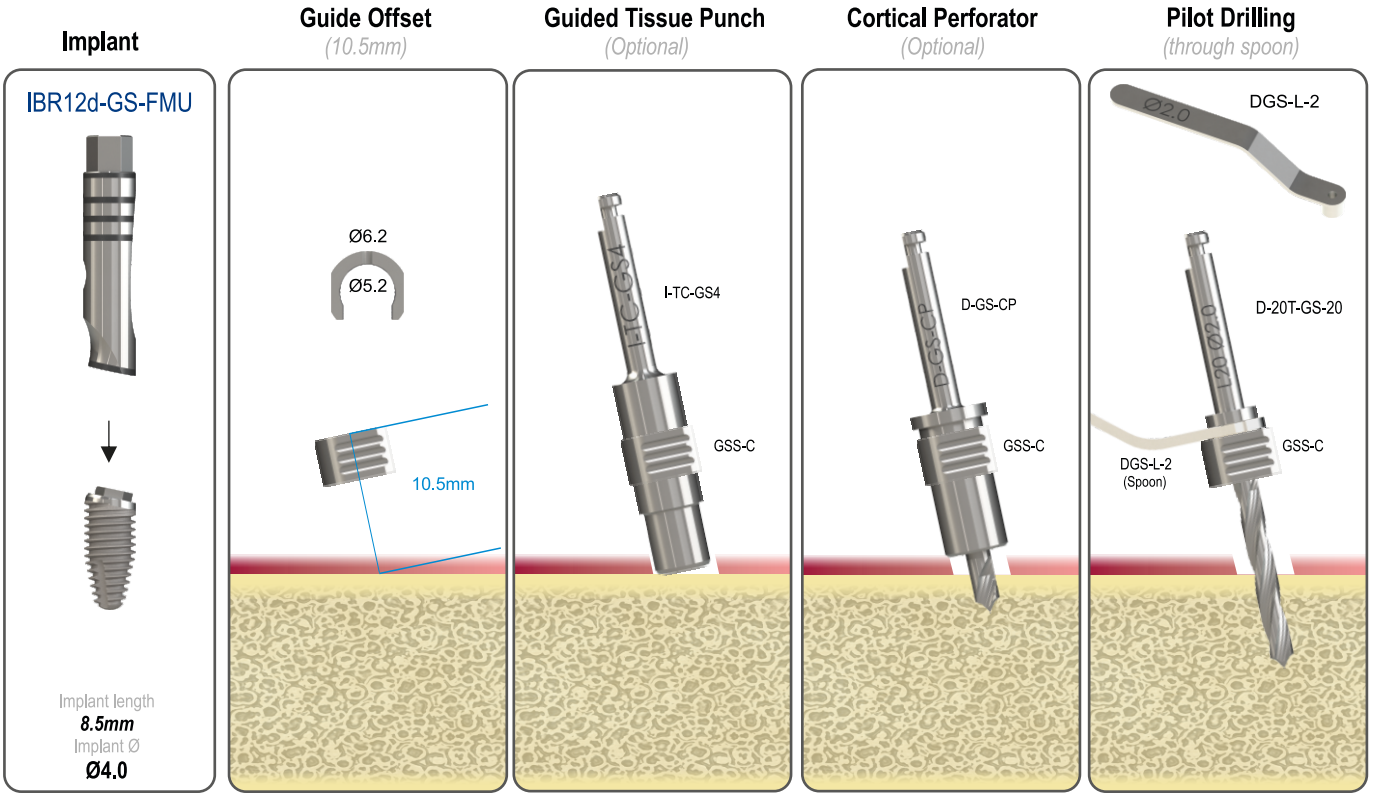
PROCESS



NOTE: IBT8.5 is shown with an offset of 10.5mm to illustrate the workflow for Ø4.0mm implants.

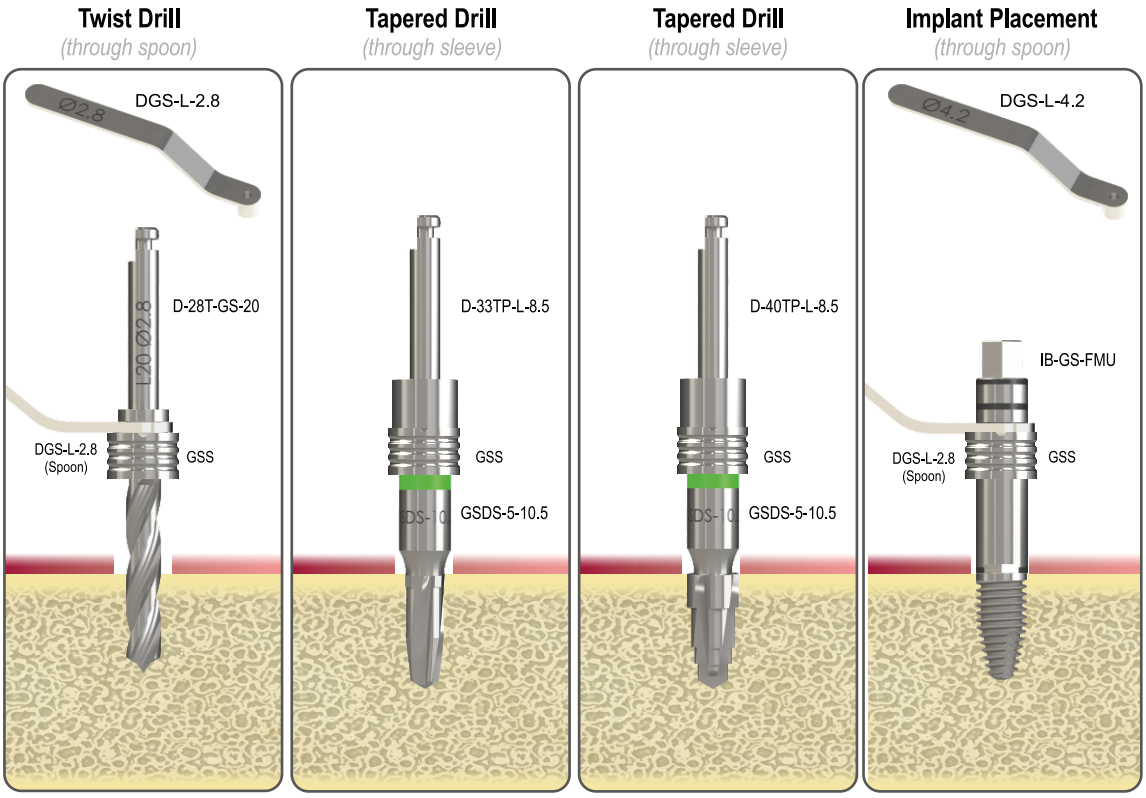
IBR12d-8.5

PROCESS



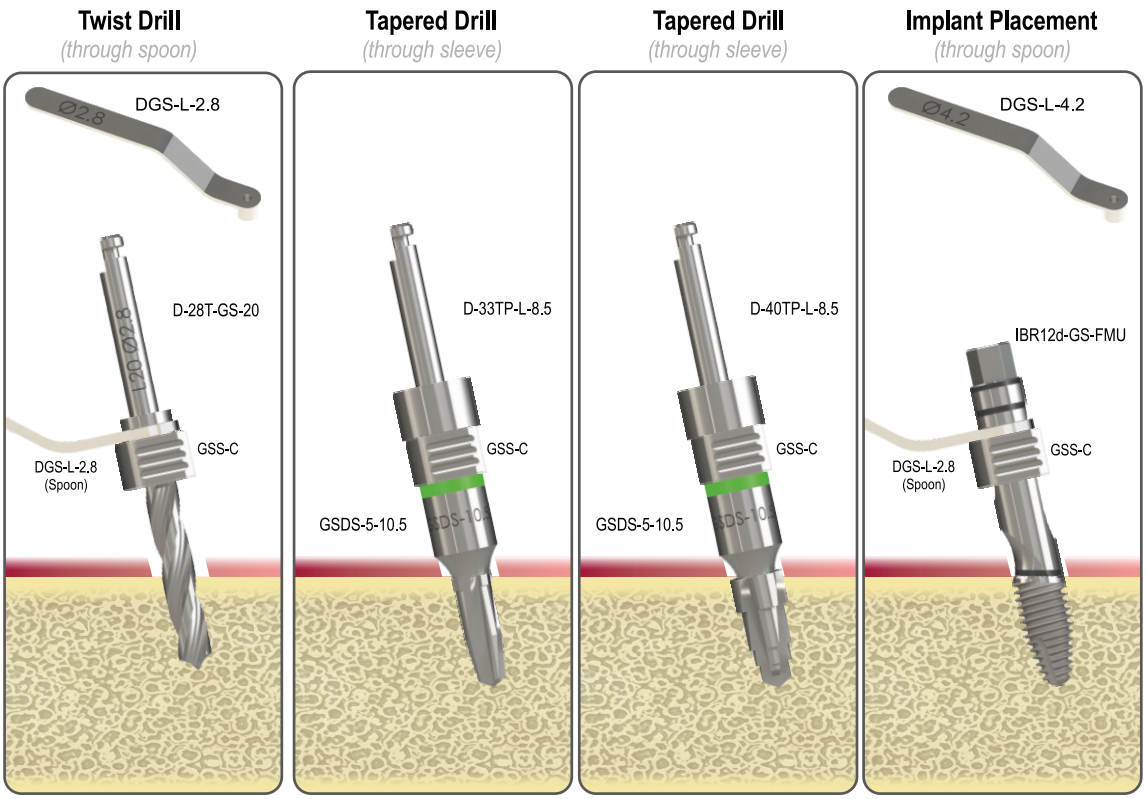
NOTE: IBR12d-8.5 is shown with an offset of 10.5mm to illustrate the workflow for Ø4.0mm Co-Axis implants.

Ø4.0mm External Hex



Refer to pages 8 & 9 for full implant range, offsets and prolongations

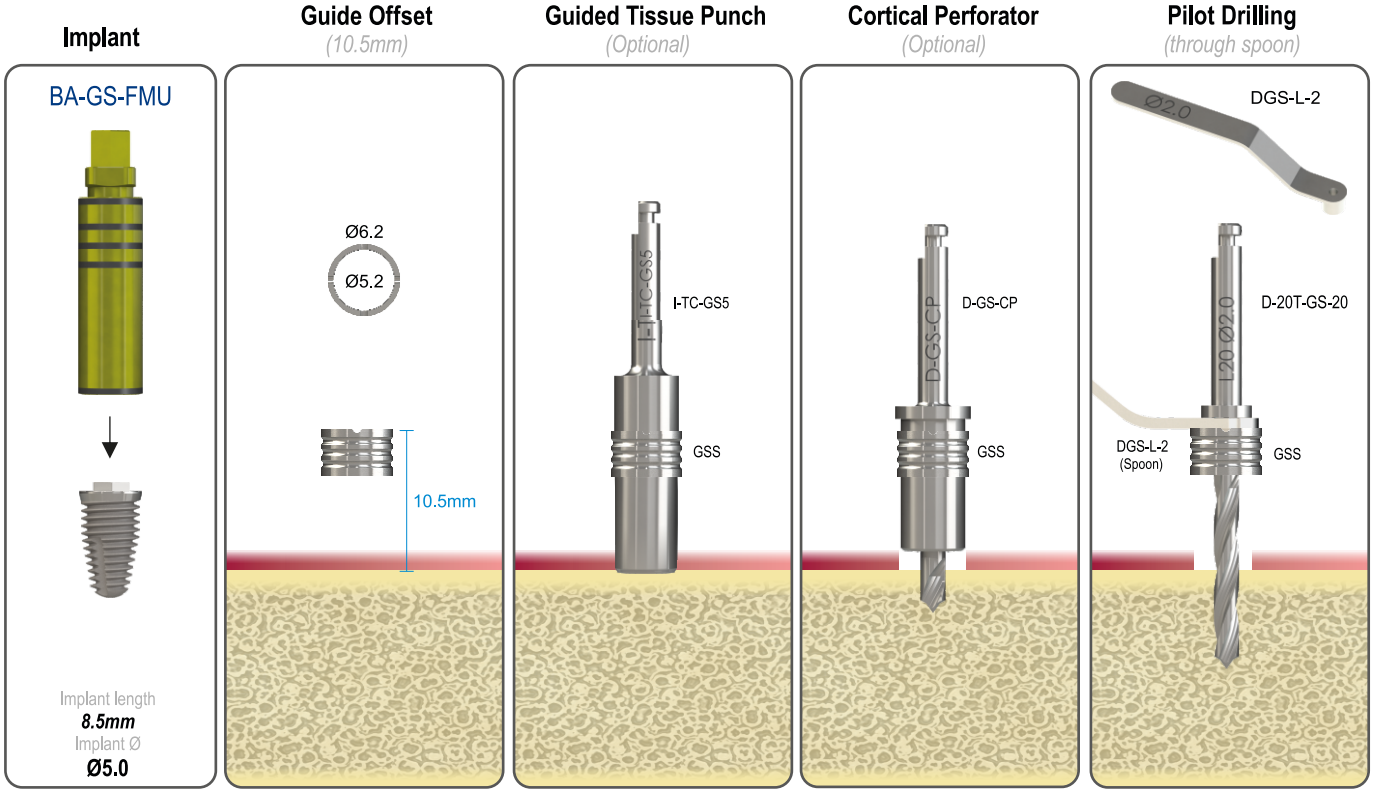
Ø4.0mm External Hex Co-Axis®



Refer to pages 10 & 11 for full Co-Axis implant range, offsets and prolongations

BAT8.5

PROCESS

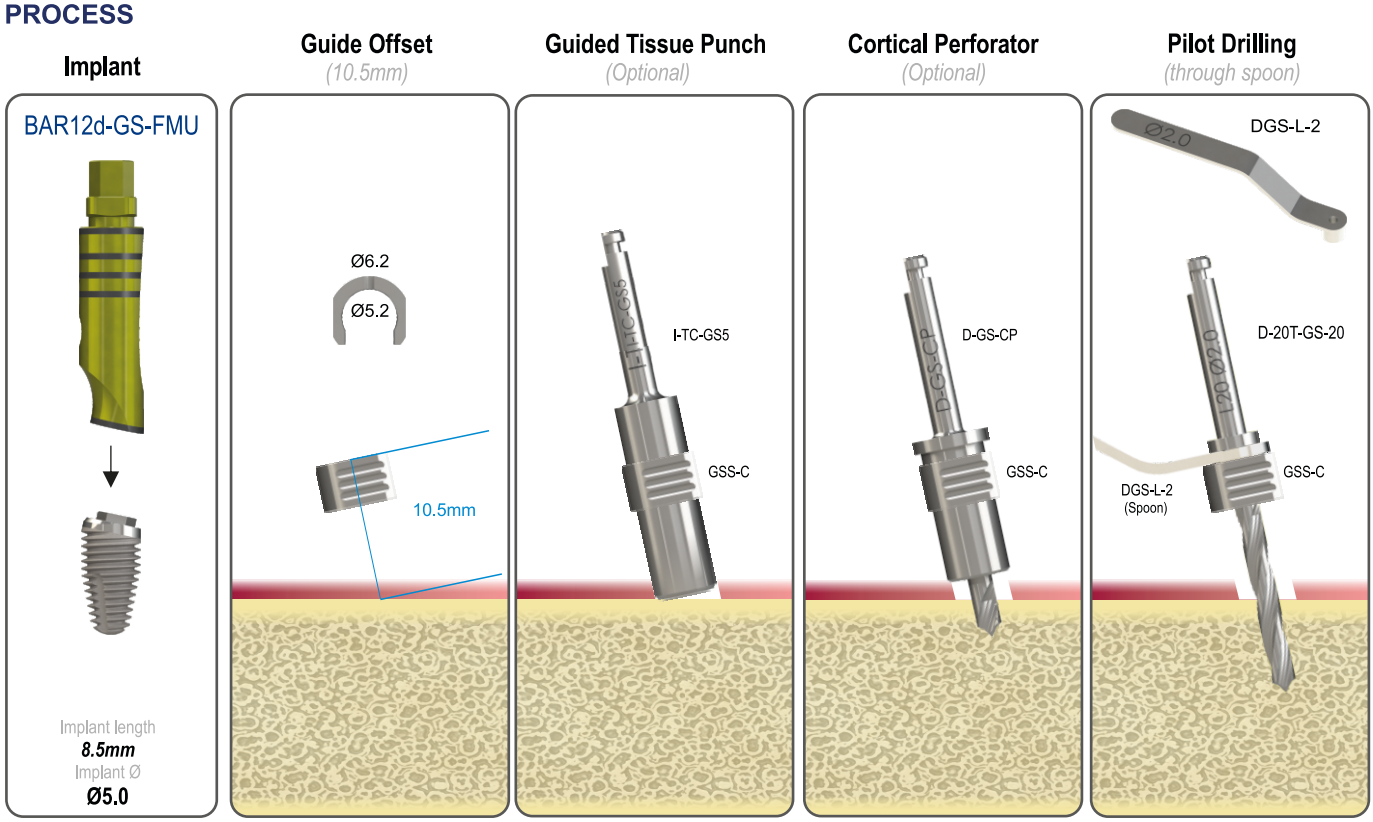


NOTE: BAT8.5 is shown with an offset of 10.5mm to illustrate the workflow for Ø5.0mm implants.

BAR12d-8.5

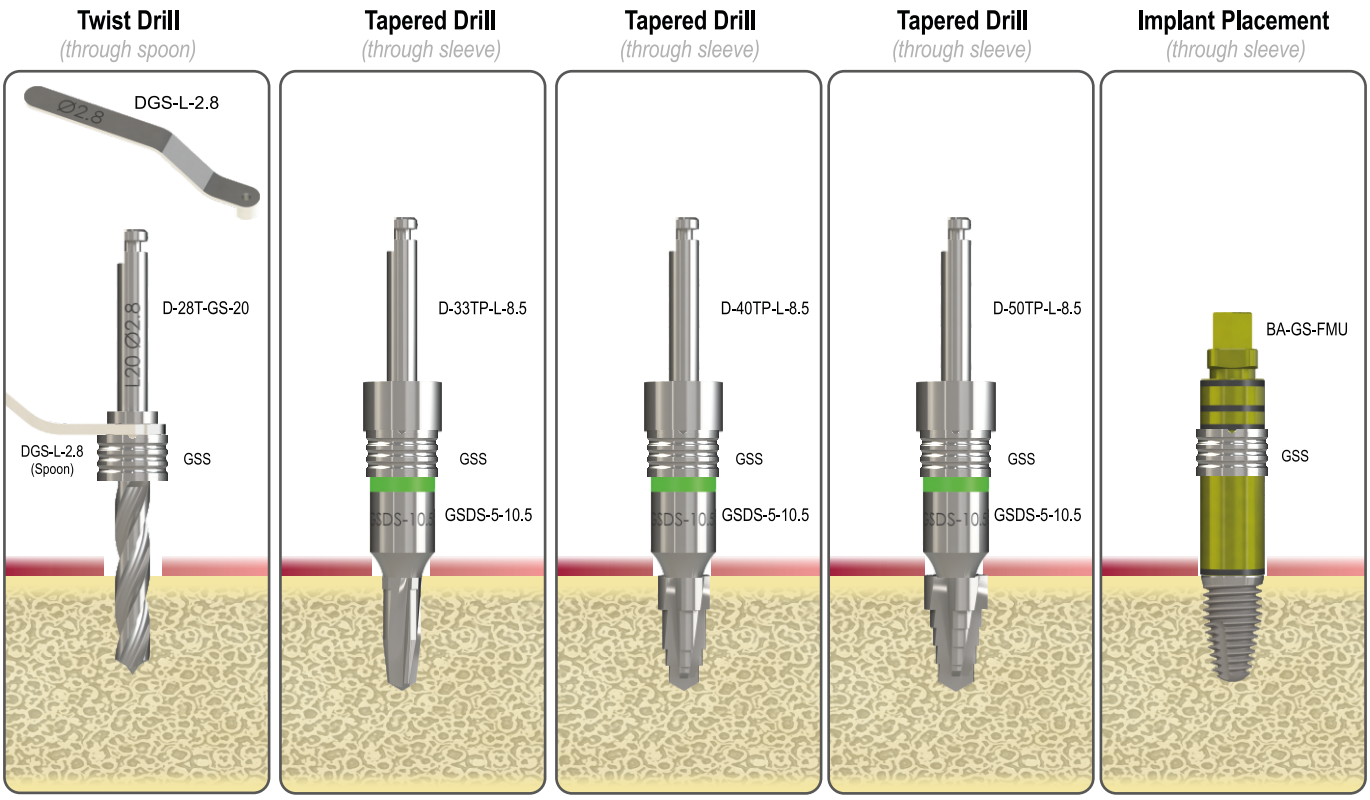
Ø5.0mm External Hex Co-Axis®

PROCESS



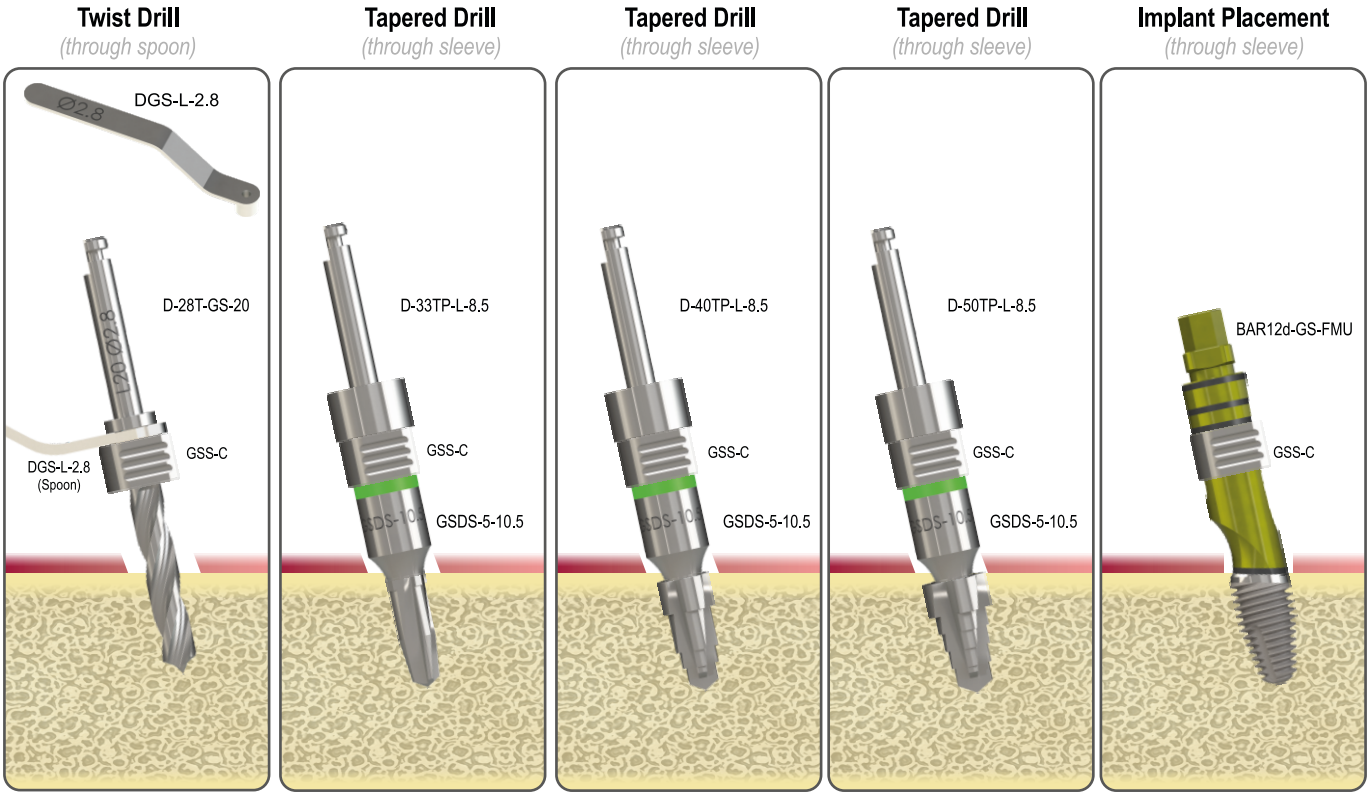
NOTE: BAR12d-8.5 is shown with an offset of 10.5mm to illustrate the workflow for Ø5.0mm Co-Axis implants.

Ø5.0mm External Hex



Refer to pages 8 & 9 for full implant range, offsets and prolongations

Ø5.0mm External Hex Co-Axis®



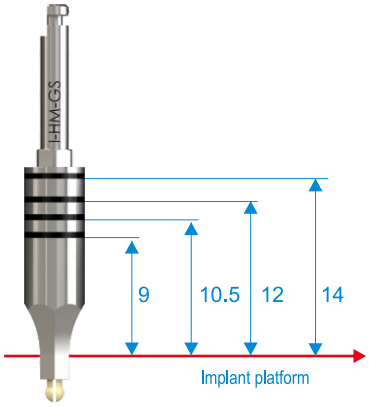
Refer to pages 10 & 11 for full Co-Axis implant range, offsets and prolongations

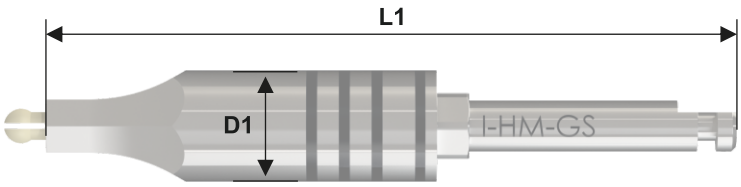
IMPLANT PLACEMENT
PROVATA™

PROVATA tapered implants are supplied without a fixture mount. The placement tool, I-HM-GS, is used for guided implant placement.

GUIDED SURGERY PLACEMENT TOOL

Order Number	Used with implants	D1	L1 (Total Length)
I-HM-GS	PRO4xx PRO5xx	Ø5.1mm	31.85mm





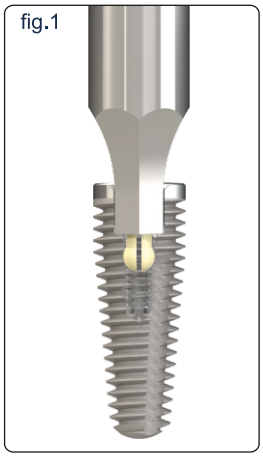
IMPLANT PLACEMENT - PROVATA

Step 7: Placement of PROVATA Ø4mm & Ø5mm Tapered implants.

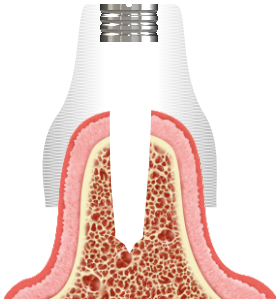
Connect the hand piece insertion tool, I-HM-GS, to the hand piece. Engage the implant and carefully remove from the sterile vial.

NOTE: The insertion tool must be fully engaged in the implant before torque is applied, to prevent any damage, to the internal hex.

The hexagon is fully engaged when the straight portion of the hexagon tool is almost completely sunken in the implant (fig.1).



PROVATA tapered implants are placed directly through the guide sleeve, GSS, and **not through a spoon**. Carry the implant to the prepared implant site.



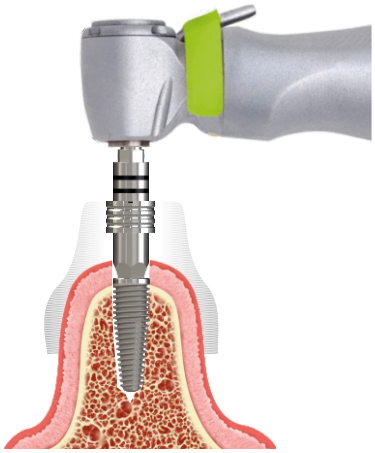
Insert the implant at low speed (15-20rpm), set the maximum torque to 70Ncm.

The Guided Placement tool do not have a stop, the stop is a visual stop. The laser markings correspond to the offset selected during the planning phase.

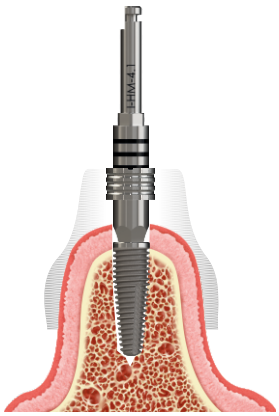
The laser markings on the placement tool correspond to the surgical guide offset. Place the implant so that the bottom line of the appropriate laser marking is in line with the guide sleeve, GSS.

Avoid applying bending moments while inserting the implant.

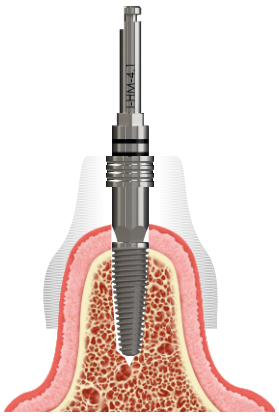
Detach the insertion tool from the implant.



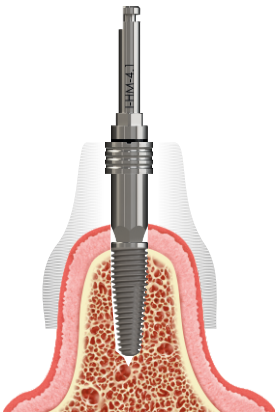
Offset 9mm



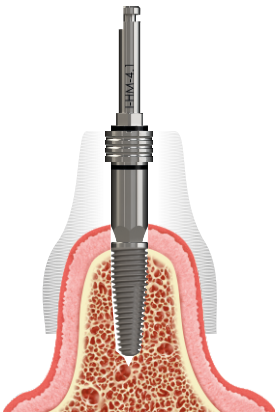
Offset 10.5mm



Offset 12mm



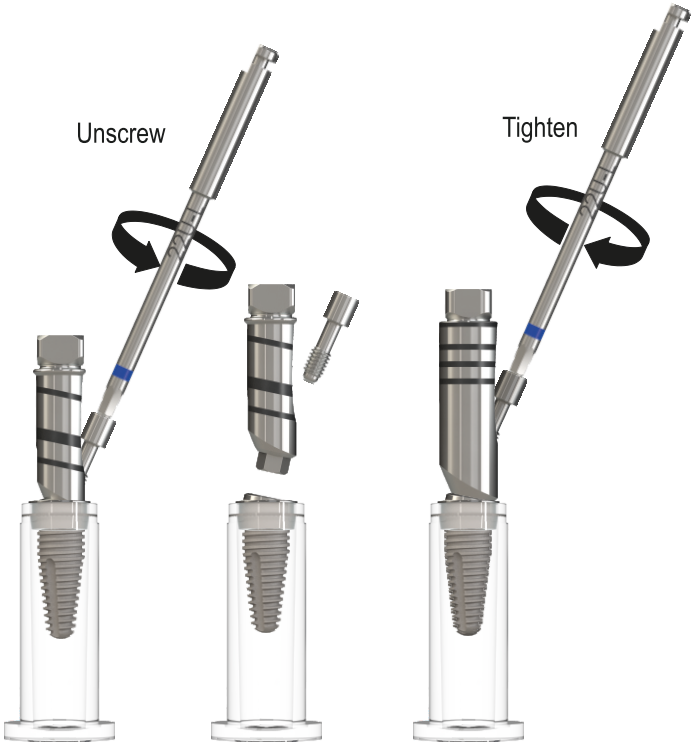
Offset 14mm



PROVATA Co-Axis implants are supplied with a fixture mount. The standard fixture mount must be replaced with the guided surgery fixture mount.

The fixture mount screw, TS-Z-18, is removed by using a long universal hex driver, I-HHD-22U-L, the guided surgery fixture mount is then attached and tightened using the same TS-Z-18 screw.

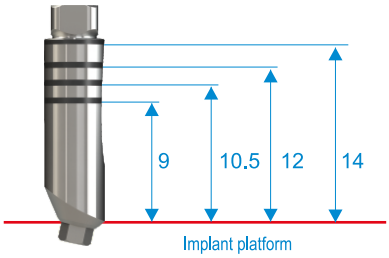
Tighten screw to 25Ncm.

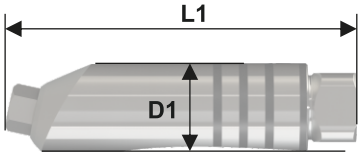


Note: Due to the length of the guided fixture mount, only long drivers can be used. Available in handheld, hand-piece and wrench insert versions.

FIXTURE MOUNTS

Co-Axis Laser markings	Order Number	Used with IMPLANT	D1	L1 (Total Length)
	PRO12D-GS-FMU	PRO12D4xx PRO12D5xx	Ø5.1	20.40mm

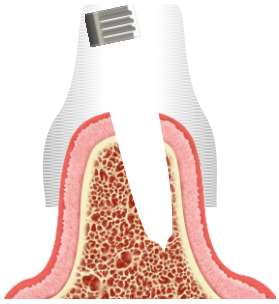


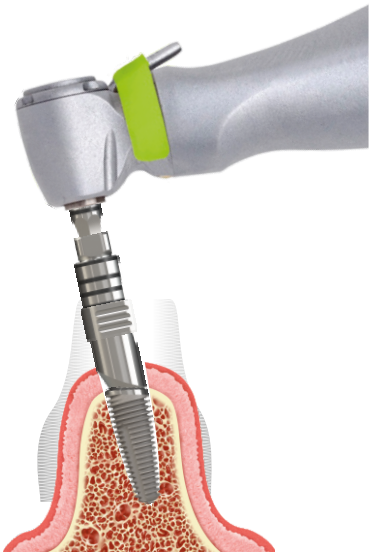


Step 7: Placement of PROVATA Co-Axis Ø4mm & Ø5mm implants.

Once the guided fixture mount is attached, connect the standard hand piece insertion tool, I-HM-S / M / L, to the hand piece.

Engage the fixture mount and carefully remove the implant from the sterile vial.





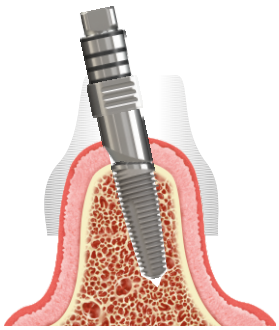
PROVATA Co-Axis implants are placed directly through the guide sleeve, GSS-C, and not through a spoon. Carry the implant to the prepared implant site.

Insert the implant at low speed (15-25rpm), set the maximum torque to 70Ncm.

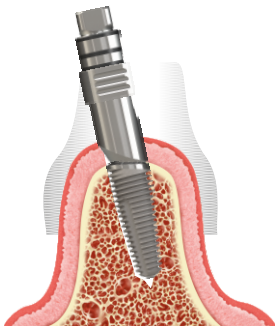
Guided fixture mounts do not have a physical stop, but a visual stop. The laser markings correspond to the offset selected during the planning phase. Place the implant with bottom line of the laser marking in line with the guide sleeve, GSS-C. The planned depth is now reached.

Important Note: Check the fixture mount screw for loosening periodically and re-tighten if necessary.

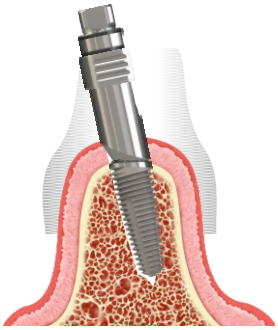
Offset 9mm



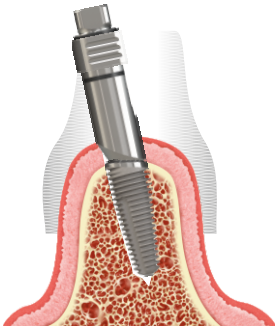
Offset 10.5mm



Offset 12mm

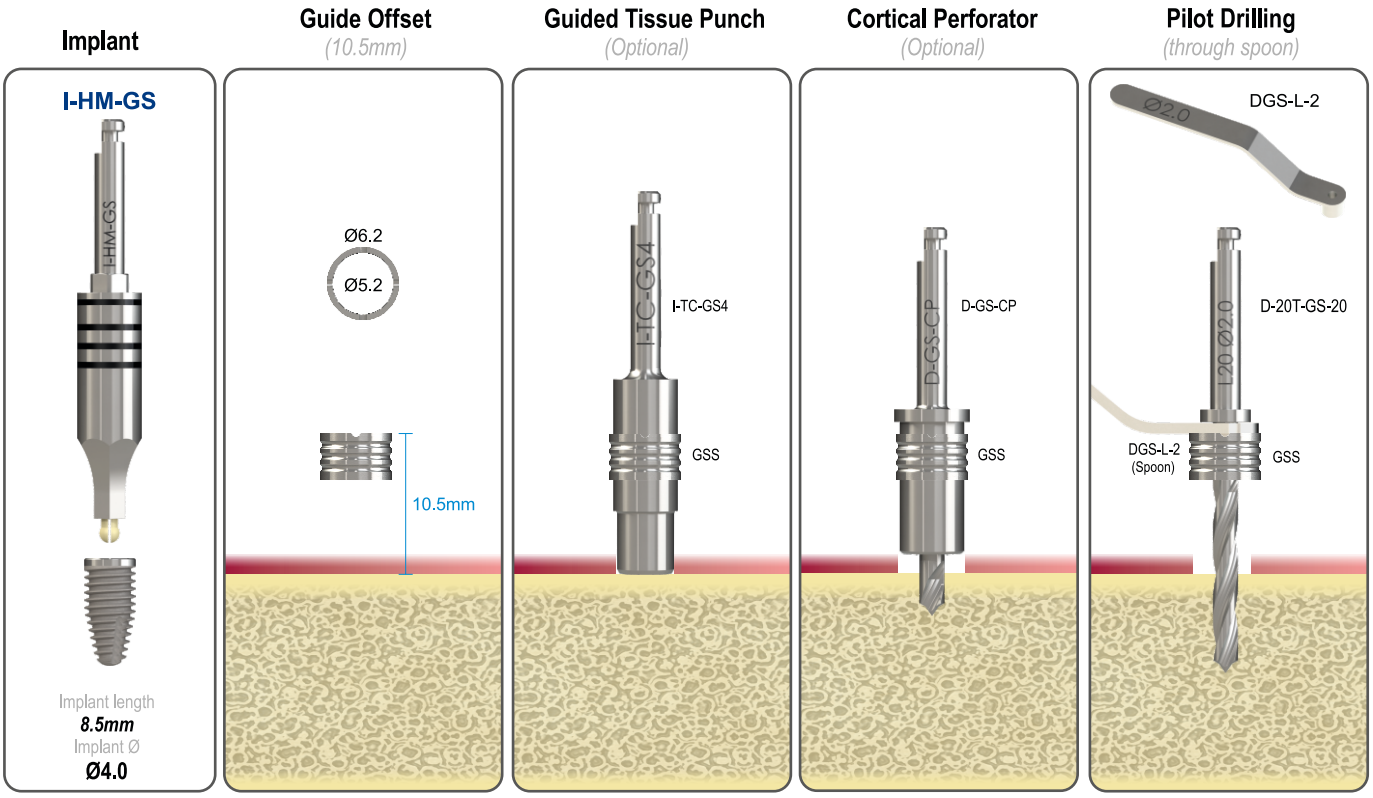


Offset 14mm



PRO408

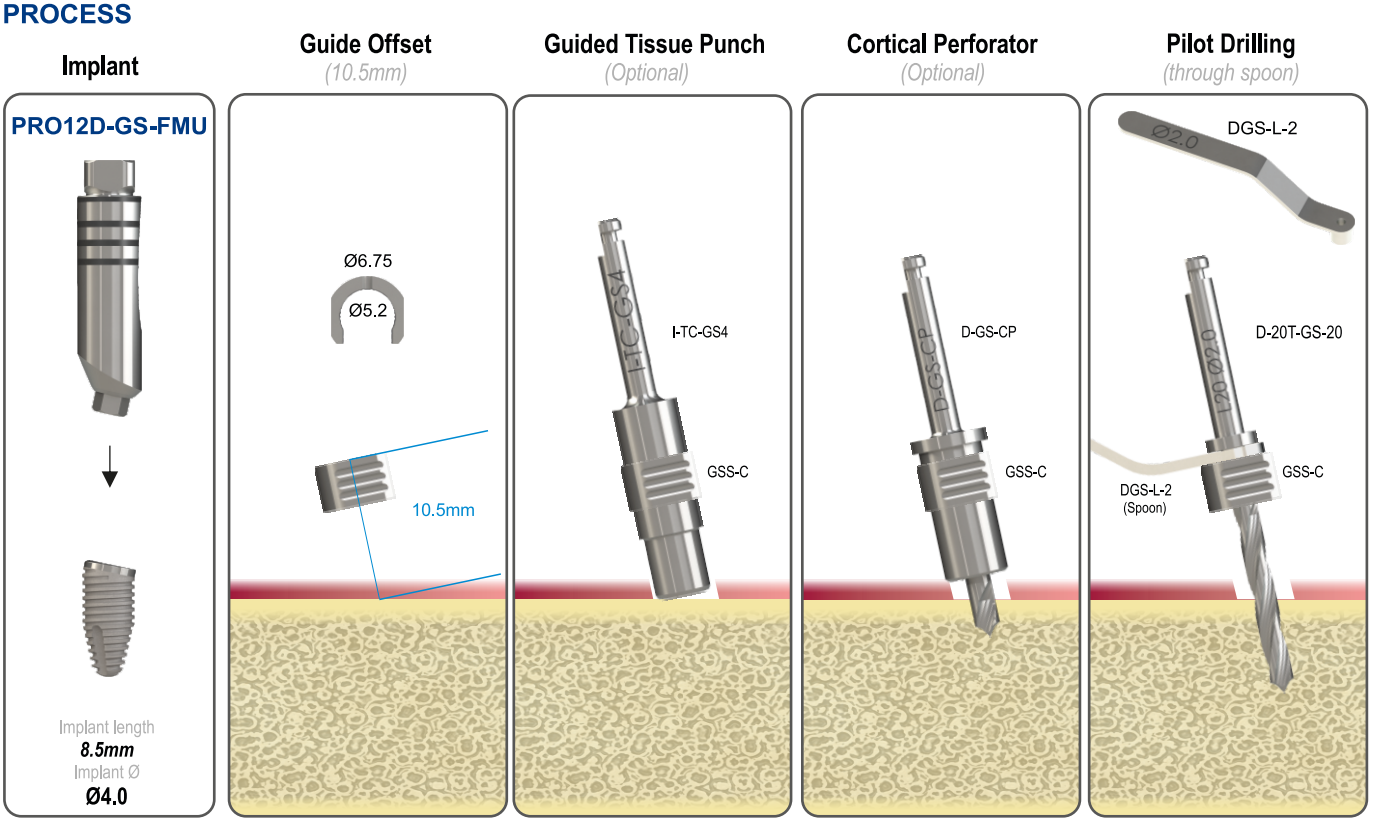
PROCESS



NOTE: PRO408 is shown with an offset of 10.5mm to illustrate the workflow for Ø4.0mm PROVATA implants.

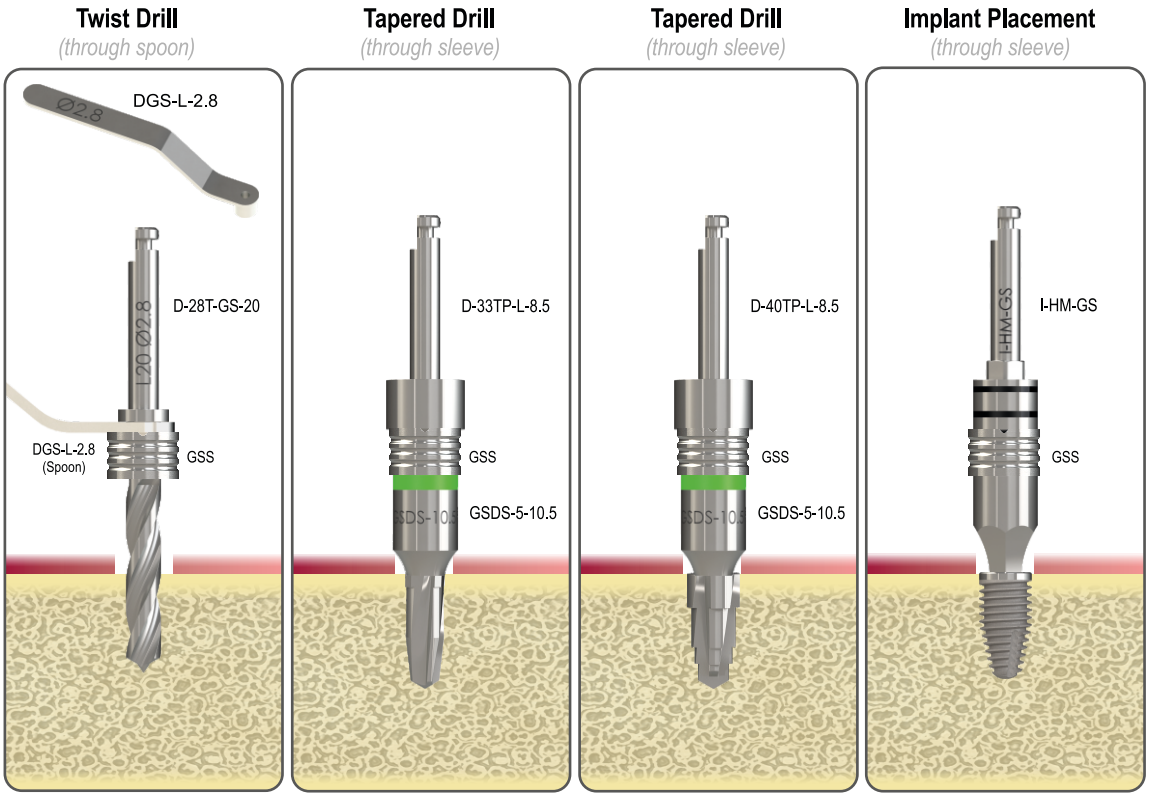
PRO12D408

PROCESS



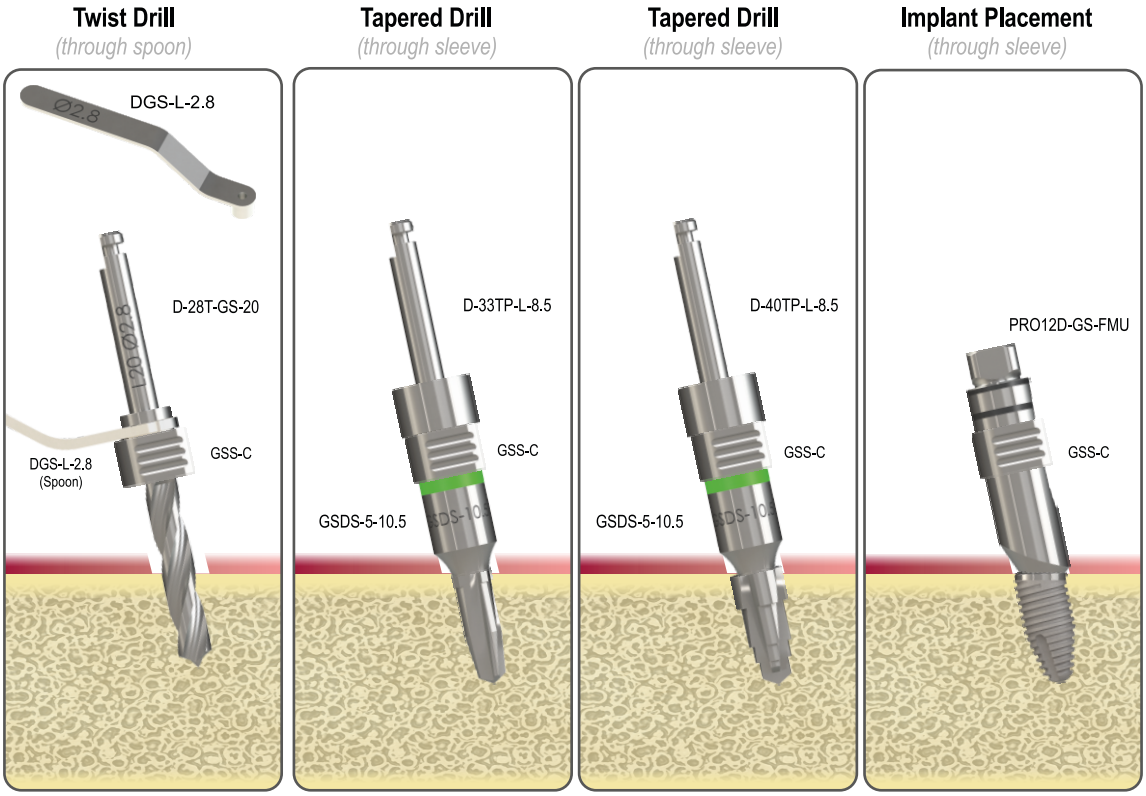
NOTE: PRO12D408 is shown with an offset of 10.5mm to illustrate the workflow for Ø4.0mm PROVATA Co-Axis implants.

Ø4.0mm PROVATA



Refer to pages 8 & 9 for full implant range, offsets and prolongations

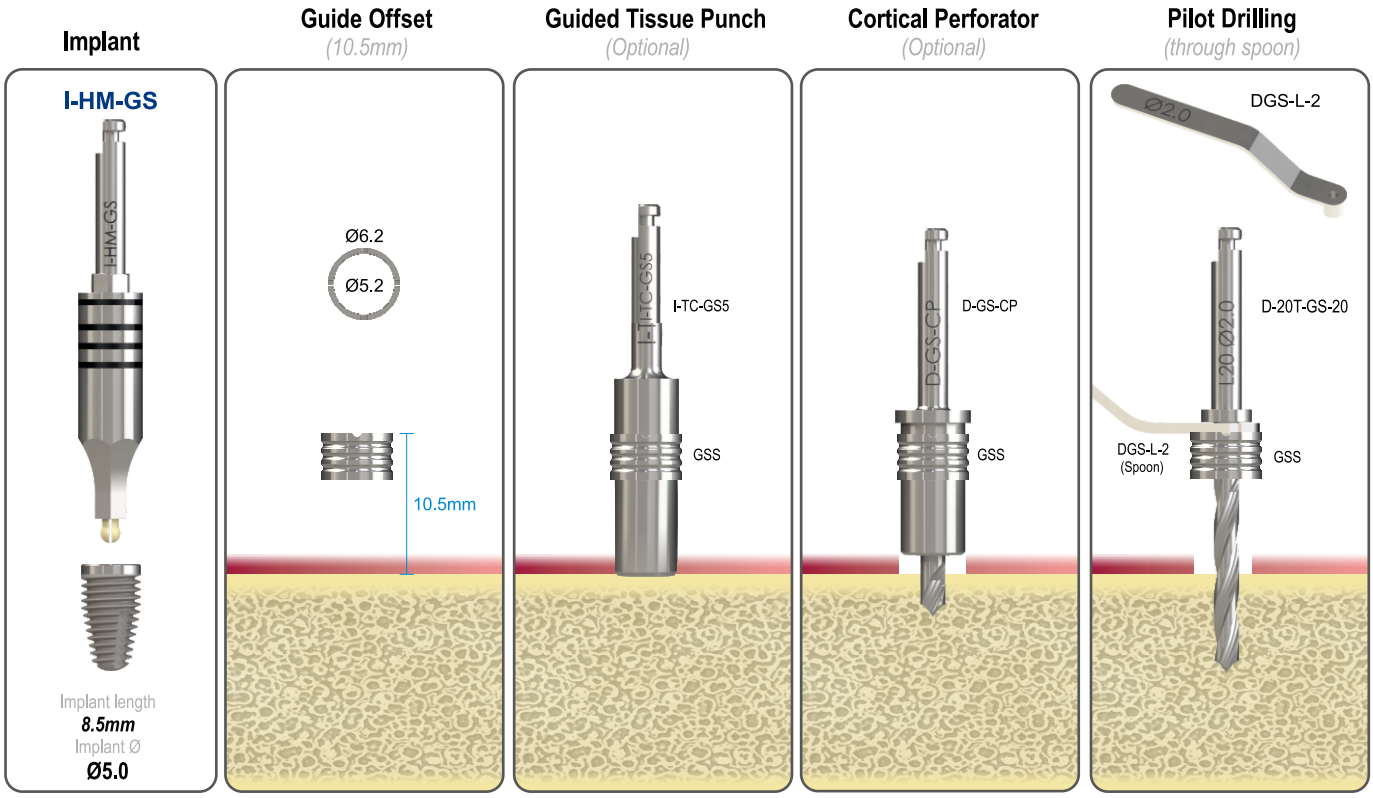
Ø4.0mm PROVATA Co-Axis®



Refer to pages 10 & 11 for full Co-Axis implant range, offsets and prolongations

PRO508

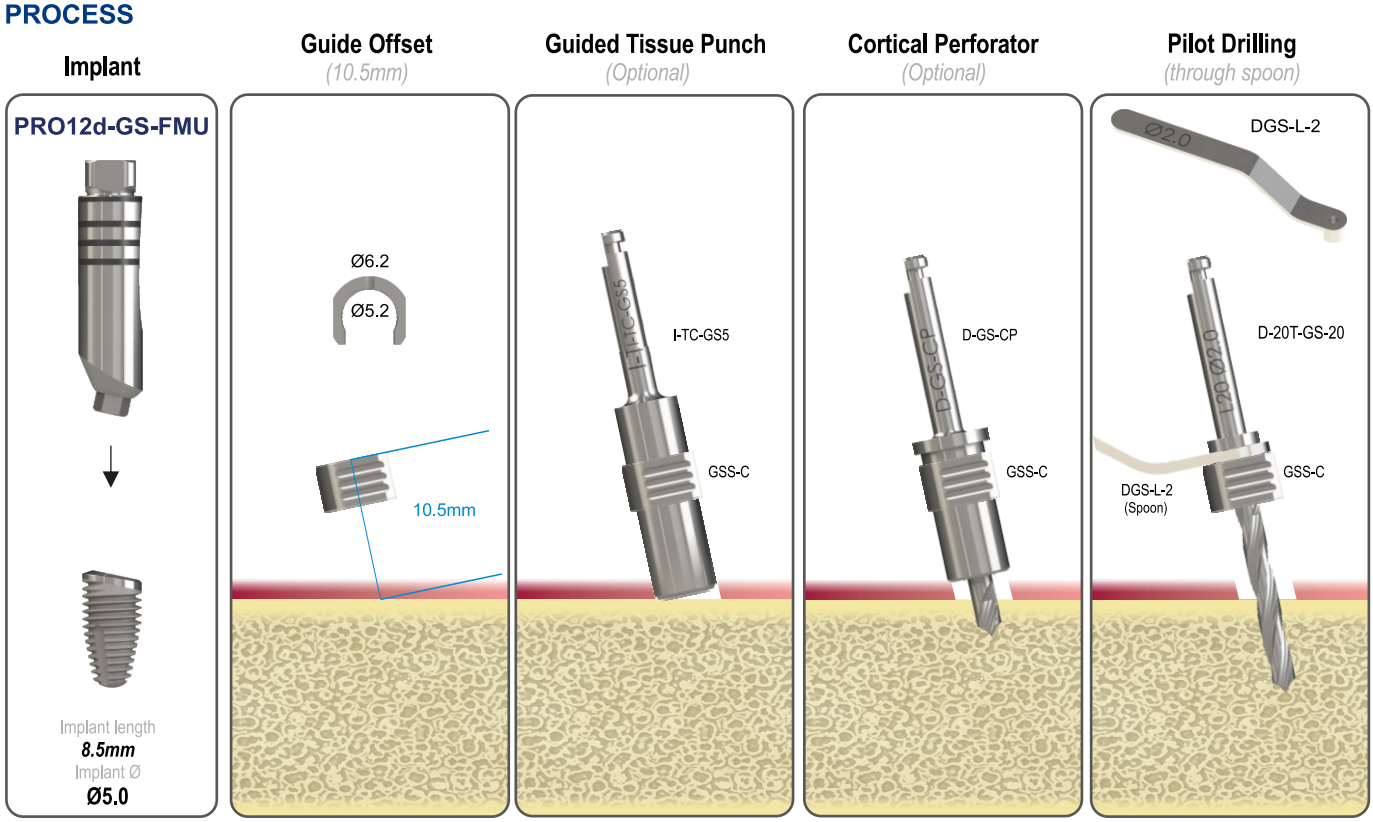
PROCESS



NOTE: PRO508 is shown with an offset of 10.5mm to illustrate the workflow for Ø5.0mm PROVATA implants.

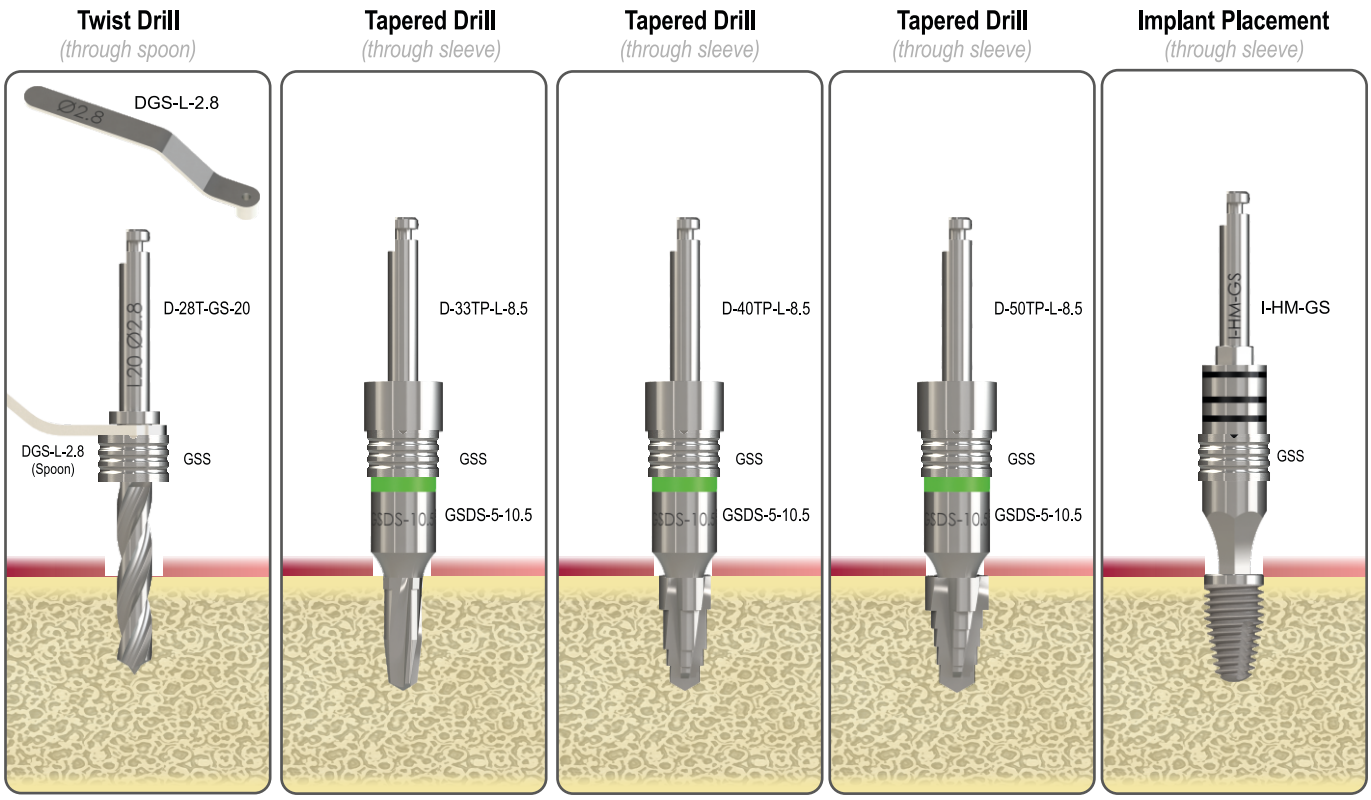
PRO12D508

PROCESS



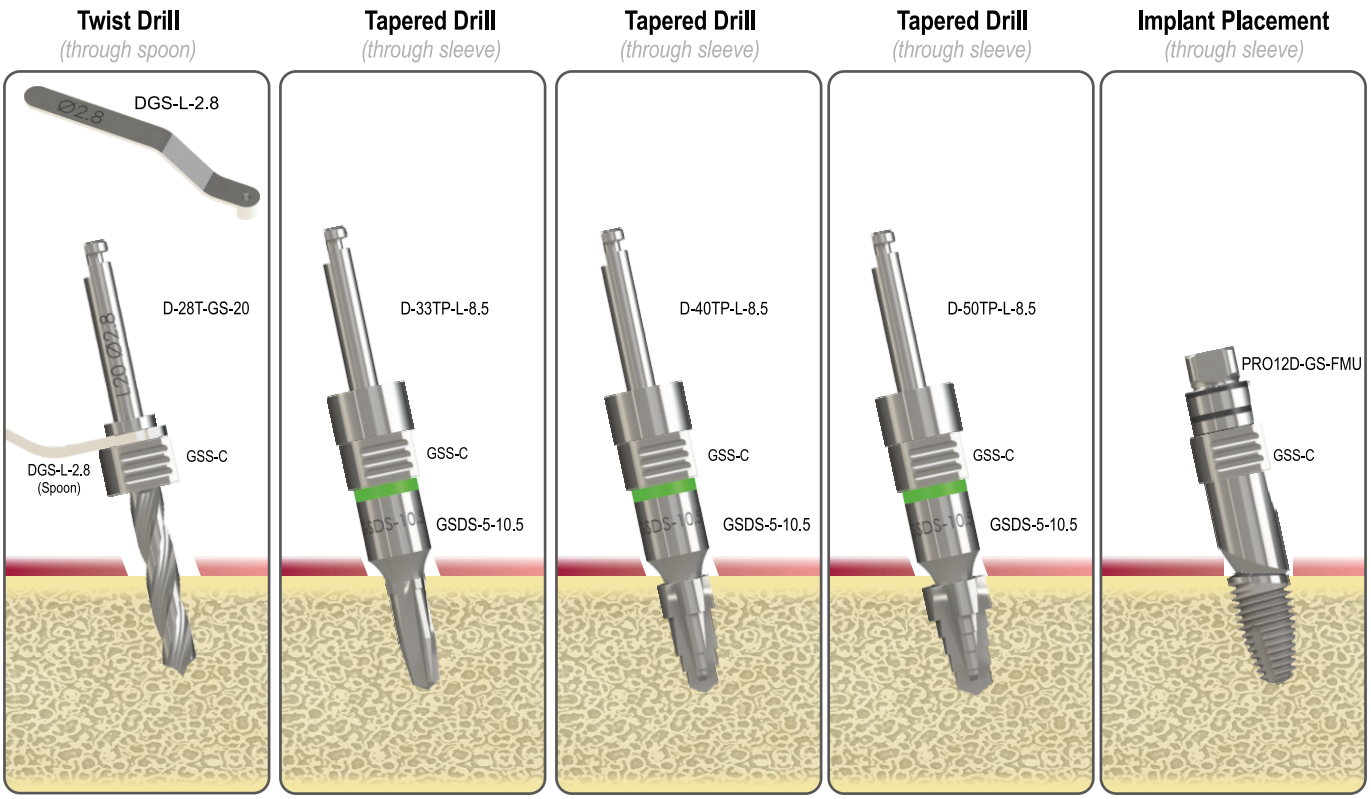
NOTE: PRO12D508 is shown with an offset of 10.5mm to illustrate the workflow for Ø5.0mm PROVATA Co-Axis implants.

Ø5.0mm PROVATA



Refer to pages 8 & 9 for full implant range, offsets and prolongations

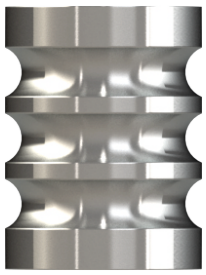
Ø5.0mm PROVATA Co-Axis®



Refer to pages 10 & 11 for full Co-Axis implant range, offsets and prolongations

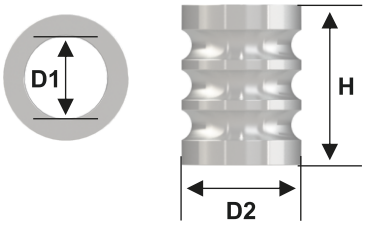
Pilot sleeve guided surgery ensures correct angulation, direction and depth from the very first drill and allowing the dental practitioner to confidently continue with freehand surgery.

Pilot drill guide sleeves have a specific inner diameter of Ø2.0mm, that accommodates Ø2.0mm pilot drills.

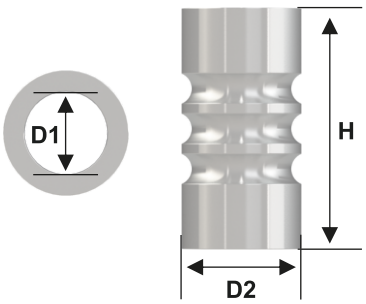


PILOT GUIDE SLEEVES

	Order Number	D1	D2	H
	GSS-ID4	2.0mm	3.0mm	4mm



	Order Number	D1	D2	H
	GSS-ID6	2.0mm	3.0mm	6mm



The instruments used to prepare a site and place the implant is determined by the implant length and guide offset. It is therefore crucial that cases are planned using the specific prolongation and guide offset heights.

IMPLANT SELECTION: GSS-ID4 — EXTERNAL HEX

		Implant Length				
Implant	**Implant Ø**	**10**	**11.5**	**13**	**13**	**15**
IP	Ø3.00mm	✓	✓	✓	✓	✓
IBN	Ø3.25mm	✓	✓	✓	✓	✓
IBNT	Ø3.25mm	✓	✓	✓	✓	✓
IBS	Ø4.00mm	✓	✓	✓	✓	✓
IBT	Ø4.00mm	✓	✓	✓	✓	✓
BA	Ø5.00mm	✓	✓	✓	✓	✓
BAT	Ø5.00mm	✓	✓	✓	✓	✓
BBBS	Ø6.00mm	✓	✓	✓	✓	✓
BBBT	Ø6.00mm	✓	✓	✓	✓	✓
IBNT12D	Ø3.25mm	✓	✓	✓	✓	✓
IBT12D	Ø4.00mm	✓	✓	✓	✓	✓
IBR12D	Ø4.00mm	✓	✓	✓	✓	✓
IBR24D	Ø4.00mm	✓	✓	✓	✓	✓
BAT12D	Ø5.00mm	✓	✓	✓	✓	✓
BAR12D	Ø5.00mm	✓	✓	✓	✓	✓
BAR24D	Ø5.00mm	✓	✓	✓	✓	✓
BAR36D	Ø5.00mm	✓	✓	✓	✓	✓
BBBT12D	Ø6.00mm	✓	✓	✓	✓	✓
BBBT24D	Ø6.00mm	✓	✓	✓	✓	✓
PROLONGATIONS		6	4,5	3	6	4
OFFSETS		10	8,5	7	10	8
PILOT DRILL		D-20T-GS-20	D-20T-GS-20	D-20T-GS-20	D-20T-GS-23	D-20T-GS-23

IMPLANT SELECTION — PROVATA™

		Implant Length				
Implant	**Implant Ø**	**10**	**11.5**	**13**	**13**	**15**
PRO4	Ø4.00mm	✓	✓	✓	✓	✓
PRO5	Ø5.00mm	✓	✓	✓	✓	✓
PRO12D4	Ø4.00mm	✓	✓	✓	✓	✓
PRO12D5	Ø5.00mm	✓	✓	✓	✓	✓
PROLONGATIONS		6	4,5	3	6	4
OFFSETS		10	8,5	7	10	8
PILOT DRILL		D-20T-GS-20	D-20T-GS-20	D-20T-GS-20	D-20T-GS-23	D-20T-GS-23

IMPLANT SELECTION: GSS-ID6 — EXTERNAL HEX

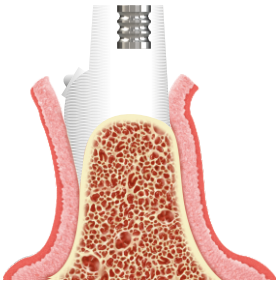
		Implant Length					
Implant	**Implant Ø**	**8.5**	**10**	**11.5**	**11.5**	**13**	**15**
IP	Ø3.00mm	✓	✓	✓	✓	✓	✓
IBN	Ø3.25mm	✓	✓	✓	✓	✓	✓
IBNT	Ø3.25mm	✓	✓	✓	✓	✓	✓
IBS	Ø4.00mm	✓	✓	✓	✓	✓	✓
IBT	Ø4.00mm	✓	✓	✓	✓	✓	✓
BA	Ø5.00mm	✓	✓	✓	✓	✓	✓
BAT	Ø5.00mm	✓	✓	✓	✓	✓	✓
BBBS	Ø6.00mm	✓	✓	✓	✓	✓	✓
BBBT	Ø6.00mm	✓	✓	✓	✓	✓	✓
IBNT12D	Ø3.25mm	✓	✓	✓	✓	✓	✓
IBT12D	Ø4.00mm	✓	✓	✓	✓	✓	✓
IBR12D	Ø4.00mm	✓	✓	✓	✓	✓	✓
IBR24D	Ø4.00mm	✓	✓	✓	✓	✓	✓
BAT12D	Ø5.00mm	✓	✓	✓	✓	✓	✓
BAR12D	Ø5.00mm	✓	✓	✓	✓	✓	✓
BAR24D	Ø5.00mm	✓	✓	✓	✓	✓	✓
BAR36D	Ø5.00mm	✓	✓	✓	✓	✓	✓
BBBT12D	Ø6.00mm	✓	✓	✓	✓	✓	✓
BBBT24D	Ø6.00mm	✓	✓	✓	✓	✓	✓
PROLONGATIONS		5,5	4	2,5	5,5	4	2
OFFSETS		11,5	10	8,5	11,5	10	8
PILOT DRILL		D-20T-GS-20	D-20T-GS-20	D-20T-GS-20	D-20T-GS-23	D-20T-GS-23	D-20T-GS-23

IMPLANT SELECTION — PROVATA™

		Implant Length					
Implant	**Implant Ø**	**8.5**	**10**	**11.5**	**11.5**	**13**	**15**
PRO4	Ø4.00mm	✓	✓	✓	✓	✓	✓
PRO5	Ø5.00mm	✓	✓	✓	✓	✓	✓
PRO12D4	Ø4.00mm	✓	✓	✓	✓	✓	✓
PRO12D5	Ø5.00mm	✓	✓	✓	✓	✓	✓
PROLONGATIONS		5,5	4	2,5	5,5	4	2
OFFSETS		11,5	10	8,5	11,5	10	8
PILOT DRILL		D-20T-GS-20	D-20T-GS-20	D-20T-GS-20	D-20T-GS-23	D-20T-GS-23	D-20T-GS-23

Step 1: Initiate the osteotomy

Note: It is recommended to raise a full-thickness mucoperiosteal flap.

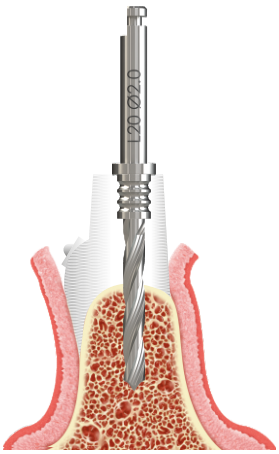


Step 2: Pilot drilling - Ø2mm pilot drill

Pilot drills are available in three lengths, the 20mm, 23mm & 28mm, and are used with pilot guide sleeves. The drill length corresponds to the planned implant length and guide offset.

Drill through the pilot guide sleeve in the predetermined guided direction. The drill has a stop that will prevent the drill from drilling past the planned depth.

All drilling should be performed at speed of 1000-1500rpm with copious irrigation, an intermitted technique should be used to avoid overheating of the bone.



D-20T-GS-20
20mm length

D-20T-GS-23
23mm length

D-20T-GS-28
28mm length

NOTE: The number of laser marked rings around the pilot drill help to identify the drill length.
If fully guided surgery is not possible, or if only pilot drill guided surgery is performed, consult CAT-2020 (External Hex) or CAT-2060 (PROVATA™).

I-HEX-GS-EG For surgical placement of External Hex & PROVATA™ Implants -

Universal 1.22/1.27 Hex Drivers

UNIVERSAL 1.22/1.27 Hex
I-HD-22U-L
Handheld
I-HHD-22U-L
Handpiece
I-WI-22U-L
Wrench

Cortical Perforator

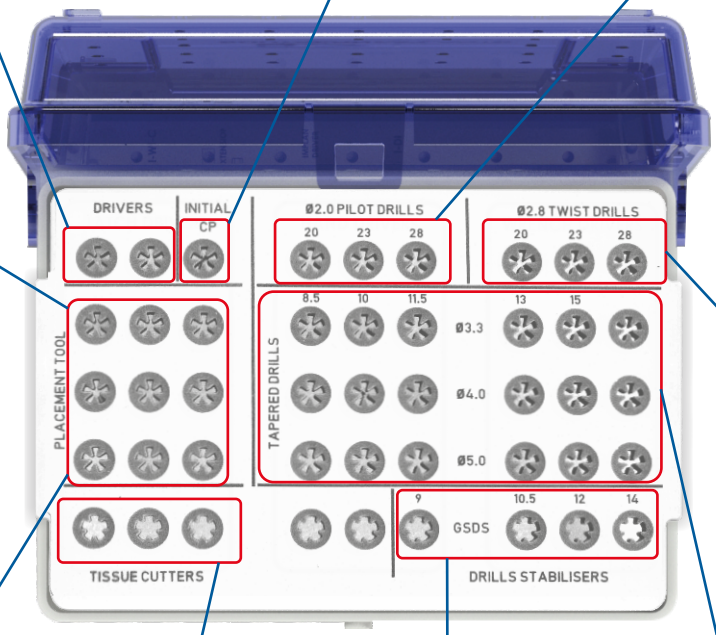
D-GS-CP

Ø2.0mm Twist Drill

D-20T-GS-20
D-20T-GS-23
D-20T-GS-28

Ø2.8mm Twist Drill

D-28T-GS-20
D-28T-GS-23
D-28T-GS-28



Insertion Tools

I-CON-X / XS
Fixture Mount (Hex) Driver with W&H

I-CONU-X / XS
Fixture Mount (Universal) Driver

I-HM-S/M/L

Guided Fixture Mounts

IB-GS-FMU
IBN-GS-FMU
BA-GS-FMU

IBNT12d-GS-FMU
IBR12d-GS-FMU
BAR12d-GS-FMU

I-HM-GS
PRO12D-GS-FMU

Tissue Cutters

I-TC-GS3
I-TC-GS4
I-TC-GS5

Drill Stabilizers

GSDS-5-9
GSDS-5-10.5
GSDS-5-12
GSDS-5-14

Dedicated Tapered Drills

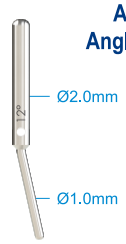
Ø3.3
D-33TP-8.5-L
D-33TP-10-L
D-33TP-11.5-L
D-33TP-13-L
D-33TP-15-L

Ø4.0
D-40TP-8.5-L
D-40TP-10-L
D-40TP-11.5-L
D-40TP-13-L
D-40TP-15-L

Ø5.0
D-50TP-8.5-L
D-50TP-10-L
D-50TP-11.5-L
D-50TP-13-L
D-50TP-15-L

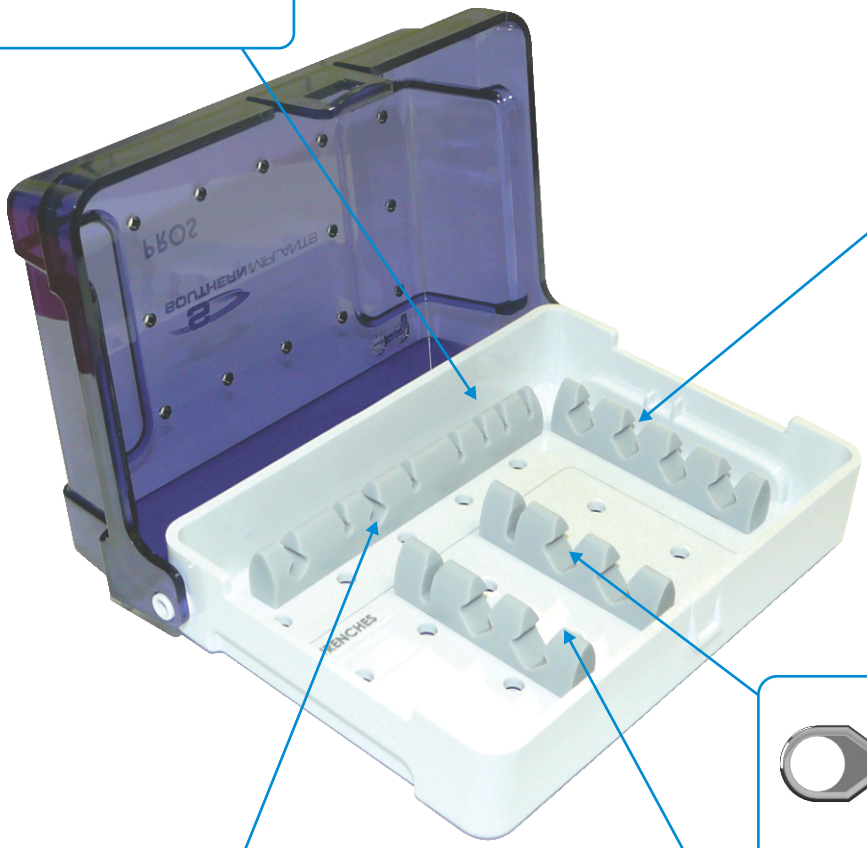
The surgical kit has an intuitive layout to guide the surgeon through the drill sequence.
All instruments and tooling used during the procedure must be maintained in good condition, and cleaned and sterilized prior to to use. Please consult the Southern Implants Cleaning and Sterilization Procedure Guidelines (CAT-1039) for guidance concerning the maintenance of drills, instruments, and surgical trays.

Additional Instruments
Angled Direction Indicators



I-DIN-12d
I-DIN-24d
I-DIN-36d

I-DIN-12d



Wrench Insert 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

Ratchet Wrench

I-TWS

Guide spoons

DGS-S-2
DGS-S-2.8
DGS-S-4.2

DGS-L-2
DGS-L-2.8
DGS-L-4.2

Torque Attachments

I-TWS-B45
I-TWS-B100

EXTERNAL HEX

Implant Code	Prolongation	Offset	Master sleeve	Cortical Perforator	Pilot Drill	Spoon for Pilot Dill (Long or Short)	Twist Drill	Spoon for Twist Dill (Long or Short)	Tapered drill Ø3.3	Drill stabilizer to use with Tapered drill
IBNT8.5	6,5	10,5	GSS	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
IBNT10	5	9	GSS	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
IBNT10	8	12	GSS	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
IBNT11.5	6,5	10,5	GSS	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
IBNT13	5	9	GSS	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
IBNT13	10	14	GSS	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
IBNT15	8	12	GSS	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12
IBNT12D-8.5	6,5	10,5	GSS-C	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
IBNT12D-10	5	9	GSS-C	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
IBNT12D-10	8	12	GSS-C	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
IBNT12D-11.5	6,5	10,5	GSS-C	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
IBNT12D-13	5	9	GSS-C	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
IBNT12D-13	10	14	GSS-C	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
IBNT12D-15	8	12	GSS-C	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12
IBT8.5	6,5	10,5	GSS	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
IBT10	5	9	GSS	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
IBT10	8	12	GSS	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
IBT11.5	6,5	10,5	GSS	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
IBT13	5	9	GSS	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
IBT13	10	14	GSS	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
IBT15	8	12	GSS	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12
IBR12D-8.5	6,5	10,5	GSS-C	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
IBR12D-10	5	9	GSS-C	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
IBR12D-10	8	12	GSS-C	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
IBR12D-11.5	6,5	10,5	GSS-C	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
IBR12D-13	5	9	GSS-C	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
IBR12D-13	10	14	GSS-C	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
IBR12D-15	8	12	GSS-C	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12
BAT8.5	6,5	10,5	GSS	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
BAT10	5	9	GSS	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
BAT10	8	12	GSS	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
BAT11.5	6,5	10,5	GSS	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
BAT13	5	9	GSS	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
BAT13	10	14	GSS	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
BAT15	8	12	GSS	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12
BAR12D-8.5	6,5	10,5	GSS-C	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
BAR12D-10	5	9	GSS-C	D-GS-CP	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
BAR12D-10	8	12	GSS-C	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
BAR12D-11.5	6,5	10,5	GSS-C	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
BAR12D-13	5	9	GSS-C	D-GS-CP	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
BAR12D-13	10	14	GSS-C	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
BAR12D-15	8	12	GSS-C	D-GS-CP	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12

Tapered drill Ø4.0	Drill stabilizer to use with Tapered drill	Tapered drill Ø5.0	Drill stabilizer to use with Tapered drill	Implant placed with guided fixture mount or Placement tool	Through spoon (Long or Short)	Through Master sleeve	Place up to
				IBN-GS-FMU	DGS-L-4.2 / DGS-S-4.2		2nd line on Fixture Mount
				IBN-GS-FMU	DGS-L-4.2 / DGS-S-4.2		1st line on Fixture Mount
				IBN-GS-FMU	DGS-L-4.2 / DGS-S-4.2		3rd line on Fixture Mount
				IBN-GS-FMU	DGS-L-4.2 / DGS-S-4.2		2nd line on Fixture Mount
				IBN-GS-FMU	DGS-L-4.2 / DGS-S-4.2		1st line on Fixture Mount
				IBN-GS-FMU	DGS-L-4.2 / DGS-S-4.2		4th line on Fixture Mount
				IBN-GS-FMU	DGS-L-4.2 / DGS-S-4.2		3rd line on Fixture Mount
				IBNT12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		2nd line on Fixture Mount
				IBNT12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		1st line on Fixture Mount
				IBNT12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		3rd line on Fixture Mount
				IBNT12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		2nd line on Fixture Mount
				IBNT12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		1st line on Fixture Mount
				IBNT12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		4th line on Fixture Mount
				IBNT12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		3rd line on Fixture Mount
D-40TP-L-8.5	GSDS-5-10.5			IB-GS-FMU	DGS-L-4.2 / DGS-S-4.2		2nd line on Fixture Mount
D-40TP-L-10	GSDS-5-9			IB-GS-FMU	DGS-L-4.2 / DGS-S-4.2		1st line on Fixture Mount
D-40TP-L-10	GSDG-5-12			IB-GS-FMU	DGS-L-4.2 / DGS-S-4.2		3rd line on Fixture Mount
D-40TP-L-11.5	GSDS-5-10.5			IB-GS-FMU	DGS-L-4.2 / DGS-S-4.2		2nd line on Fixture Mount
D-40TP-L-13	GSDS-5-9			IB-GS-FMU	DGS-L-4.2 / DGS-S-4.2		1st line on Fixture Mount
D-40TP-L-13	GSDS-5-14			IB-GS-FMU	DGS-L-4.2 / DGS-S-4.2		4th line on Fixture Mount
D-40TP-L-15	GSDS-5-12			IB-GS-FMU	DGS-L-4.2 / DGS-S-4.2		3rd line on Fixture Mount
D-40TP-L-8.5	GSDS-5-10.5			IBR12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		2nd line on Fixture Mount
D-40TP-L-10	GSDS-5-9			IBR12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		1st line on Fixture Mount
D-40TP-L-10	GSDG-5-12			IBR12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		3rd line on Fixture Mount
D-40TP-L-11.5	GSDS-5-10.5			IBR12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		2nd line on Fixture Mount
D-40TP-L-13	GSDS-5-9			IBR12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		1st line on Fixture Mount
D-40TP-L-13	GSDS-5-14			IBR12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		4th line on Fixture Mount
D-40TP-L-15	GSDS-5-12			IBR12D-GS-FMU	DGS-L-4.2 / DGS-S-4.2		3rd line on Fixture Mount
D-40TP-L-8.5	GSDS-5-10.5	D-50TP-L-8.5	GSDS-5-10.5	BA-GS-FMU		GSS	2nd line on Fixture Mount
D-40TP-L-10	GSDS-5-9	D-50TP-L-10	GSDS-5-9	BA-GS-FMU		GSS	1st line on Fixture Mount
D-40TP-L-10	GSDG-5-12	D-50TP-L-10	GSDG-5-12	BA-GS-FMU		GSS	3rd line on Fixture Mount
D-40TP-L-11.5	GSDS-5-10.5	D-50TP-L-11.5	GSDS-5-10.5	BA-GS-FMU		GSS	2nd line on Fixture Mount
D-40TP-L-13	GSDS-5-9	D-50TP-L-13	GSDS-5-9	BA-GS-FMU		GSS	1st line on Fixture Mount
D-40TP-L-13	GSDS-5-14	D-50TP-L-13	GSDS-5-14	BA-GS-FMU		GSS	4th line on Fixture Mount
D-40TP-L-15	GSDS-5-12	D-50TP-L-15	GSDS-5-12	BA-GS-FMU		GSS	3rd line on Fixture Mount
D-40TP-L-8.5	GSDS-5-10.5	D-50TP-L-8.5	GSDS-5-10.5	BAR12D-GS-FMU		GSS-C	2nd line on Fixture Mount
D-40TP-L-10	GSDS-5-9	D-50TP-L-10	GSDS-5-9	BAR12D-GS-FMU		GSS-C	1st line on Fixture Mount
D-40TP-L-10	GSDG-5-12	D-50TP-L-10	GSDG-5-12	BAR12D-GS-FMU		GSS-C	3rd line on Fixture Mount
D-40TP-L-11.5	GSDS-5-10.5	D-50TP-L-11.5	GSDS-5-10.5	BAR12D-GS-FMU		GSS-C	2nd line on Fixture Mount
D-40TP-L-13	GSDS-5-9	D-50TP-L-13	GSDS-5-9	BAR12D-GS-FMU		GSS-C	1st line on Fixture Mount
D-40TP-L-13	GSDS-5-14	D-50TP-L-13	GSDS-5-14	BAR12D-GS-FMU		GSS-C	4th line on Fixture Mount
D-40TP-L-15	GSDS-5-12	D-50TP-L-15	GSDS-5-12	BAR12D-GS-FMU		GSS-C	3rd line on Fixture Mount

PROVATA™

Implant Code	Prolongation	Offset	Master sleeve	Pilot Drill	Spoon for Pilot Dill (Long or Short)	Twist Drill	Spoon for Twist Dill (Long or Short)	Tapered drill Ø3.3	Drill stabilizer to use with Tapered drill
PRO408	6,5	10,5	GSS	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
PRO410	5	9	GSS	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
PRO410	8	12	GSS	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
PRO411	6,5	10,5	GSS	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
PRO413	5	9	GSS	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
PRO413	10	14	GSS	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
PRO415	8	12	GSS	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12
PRO12D408	6,5	10,5	GSS-C	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
PRO12D410	5	9	GSS-C	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
PRO12D410	8	12	GSS-C	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
PRO12D411	6,5	10,5	GSS-C	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
PRO12D413	5	9	GSS-C	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
PRO12D413	10	14	GSS-C	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
PRO12D415	8	12	GSS-C	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12
PRO508	6,5	10,5	GSS	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
PRO510	5	9	GSS	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
PRO510	8	12	GSS	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
PRO511	6,5	10,5	GSS	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
PRO513	5	9	GSS	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
PRO513	10	14	GSS	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
PRO515	8	12	GSS	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12
PRO12D508	6,5	10,5	GSS-C	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-8.5	GSDS-5-10.5
PRO12D510	5	9	GSS-C	D-20T-GS-20	DGS-L-2 / DGS-S-2	D-28T-GS-20	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDS-5-9
PRO12D510	8	12	GSS-C	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-10	GSDG-5-12
PRO12D511	6,5	10,5	GSS-C	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-11.5	GSDS-5-10.5
PRO12D513	5	9	GSS-C	D-20T-GS-23	DGS-L-2 / DGS-S-2	D-28T-GS-23	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-9
PRO12D513	10	14	GSS-C	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-13	GSDS-5-14
PRO12D515	8	12	GSS-C	D-20T-GS-28	DGS-L-2 / DGS-S-2	D-28T-GS-28	DGS-L-2.8 / DGS-S-2.8	D-33TP-L-15	GSDS-5-12

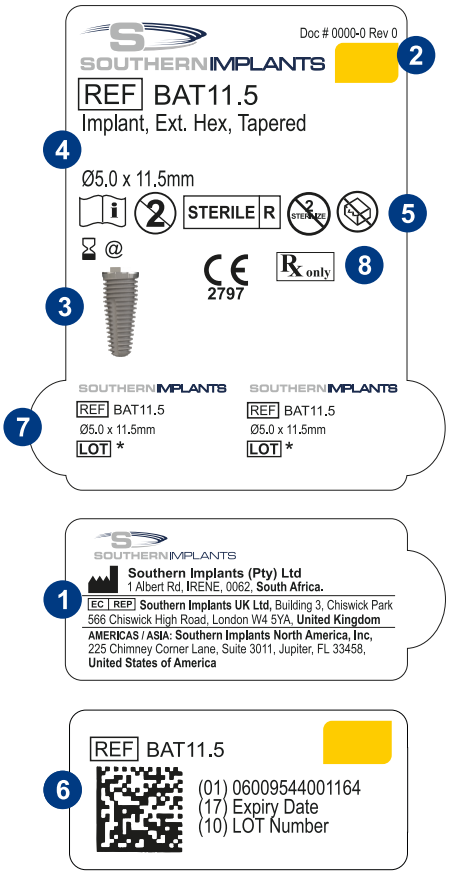
Tapered drill Ø4.0	Drill stabilizer to use with Tapered drill	Tapered drill Ø5.0	Drill stabilizer to use with Tapered drill	Implant placed with guided fixture mount or Placement tool	Through spoon (Long or Short)	Through Master sleeve	Place up to
D-40TP-L-8.5	GSDS-5-10.5			I-HM-GS		GSS	2nd line on Fixture Mount
D-40TP-L-10	GSDS-5-9			I-HM-GS		GSS	1st line on Fixture Mount
D-40TP-L-10	GSDG-5-12			I-HM-GS		GSS	3rd line on Fixture Mount
D-40TP-L-11.5	GSDS-5-10.5			I-HM-GS		GSS	2nd line on Fixture Mount
D-40TP-L-13	GSDS-5-9			I-HM-GS		GSS	1st line on Fixture Mount
D-40TP-L-13	GSDS-5-14			I-HM-GS		GSS	4th line on Fixture Mount
D-40TP-L-15	GSDS-5-12			I-HM-GS		GSS	3rd line on Fixture Mount
D-40TP-L-8.5	GSDS-5-10.5			PRO12D-GS-FMU		GSS-C	2nd line on Fixture Mount
D-40TP-L-10	GSDS-5-9			PRO12D-GS-FMU		GSS-C	1st line on Fixture Mount
D-40TP-L-10	GSDG-5-12			PRO12D-GS-FMU		GSS-C	3rd line on Fixture Mount
D-40TP-L-11.5	GSDS-5-10.5			PRO12D-GS-FMU		GSS-C	2nd line on Fixture Mount
D-40TP-L-13	GSDS-5-9			PRO12D-GS-FMU		GSS-C	1st line on Fixture Mount
D-40TP-L-13	GSDS-5-14			PRO12D-GS-FMU		GSS-C	4th line on Fixture Mount
D-40TP-L-15	GSDS-5-12			PRO12D-GS-FMU		GSS-C	3rd line on Fixture Mount
D-40TP-L-8.5	GSDS-5-10.5	D-50TP-L-8.5	GSDS-5-10.5	I-HM-GS		GSS	2nd line on Fixture Mount
D-40TP-L-10	GSDS-5-9	D-50TP-L-10	GSDS-5-9	I-HM-GS		GSS	1st line on Fixture Mount
D-40TP-L-10	GSDG-5-12	D-50TP-L-10	GSDG-5-12	I-HM-GS		GSS	3rd line on Fixture Mount
D-40TP-L-11.5	GSDS-5-10.5	D-50TP-L-11.5	GSDS-5-10.5	I-HM-GS		GSS	2nd line on Fixture Mount
D-40TP-L-13	GSDS-5-9	D-50TP-L-13	GSDS-5-9	I-HM-GS		GSS	1st line on Fixture Mount
D-40TP-L-13	GSDS-5-14	D-50TP-L-13	GSDS-5-14	I-HM-GS		GSS	4th line on Fixture Mount
D-40TP-L-15	GSDS-5-12	D-50TP-L-15	GSDS-5-12	I-HM-GS		GSS	3rd line on Fixture Mount
D-40TP-L-8.5	GSDS-5-10.5	D-50TP-L-8.5	GSDS-5-10.5	PRO12D-GS-FMU		GSS-C	2nd line on Fixture Mount
D-40TP-L-10	GSDS-5-9	D-50TP-L-10	GSDS-5-9	PRO12D-GS-FMU		GSS-C	1st line on Fixture Mount
D-40TP-L-10	GSDG-5-12	D-50TP-L-10	GSDG-5-12	PRO12D-GS-FMU		GSS-C	3rd line on Fixture Mount
D-40TP-L-11.5	GSDS-5-10.5	D-50TP-L-11.5	GSDS-5-10.5	PRO12D-GS-FMU		GSS-C	2nd line on Fixture Mount
D-40TP-L-13	GSDS-5-9	D-50TP-L-13	GSDS-5-9	PRO12D-GS-FMU		GSS-C	1st line on Fixture Mount
D-40TP-L-13	GSDS-5-14	D-50TP-L-13	GSDS-5-14	PRO12D-GS-FMU		GSS-C	4th line on Fixture Mount
D-40TP-L-15	GSDS-5-12	D-50TP-L-15	GSDS-5-12	PRO12D-GS-FMU		GSS-C	3rd line on Fixture Mount

EXPLANATION OF SYMBOLS

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

1. **Manufacturer**
2. **Colour code indicating platform diameter**
3. **Implant image**
4. **Implant details and size**
5. **Sterilization using Irradiation**
   - **Do not Resterilize**
   - **Consult instruction for use**
   - **Do not reuse**
   - **CE mark and notified body number**
   - **Expiry date**
   - **Sterile unless package is opened or damaged**
6. **2D Bar coding**
   Contains the GTIN, Expiry 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.



WARNINGS

All Southern Implants products are intended to be used by appropriately trained and licensed professionals. For safe and effective use, it is strongly suggested that specialised training be undertaken, including hands-on training to learn proper technique and radiographic evaluations. THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING. 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 damage to anatomical structures during placement, implant failure and/or loss of supporting bone. Southern Implants will not accept liability for damage caused by improper implant treatment.

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended in the mandible may potentially result in permanent numbness to the lower lip and/or chin or lead to a haemorrhage in the floor of the mouth.

Blunt drills may cause damage to the bone, which can compromise osseointegration.

The SIGuided solution has only been approved for use with NSK and W&H hand pieces

Southern Implants' Dental Implants have only been validated for use with the corresponding Southern Implants' abutments and accessories. Although care has been taken to create interfaces that are equivalent to similar products on the market, Southern Implants cannot guarantee outcomes obtained using components from other manufacturers. Please refer to individual product catalogues for interface requirements. Southern Implants will not accept liability for damage caused by selection of incompatible abutments and accessories.

Do not re-use Implants, Cover screws, Temporary or Permanent Abutments. These are single-use products. DO NOT re-sterilize or autoclave these components unless otherwise indicated. Re-using these components may result in damage on the surface or critical dimensions. This may result in performance and compatibility issues. The removal of proteins from metal (such as Titanium) is extremely difficult and re-use can lead to secondary infections.
Electro-surgery should not be attempted around metal implants, as they are conductive.

One hundred percent implant success cannot be guaranteed. Non-observance of the indicated limitations of use and working steps may result in failure.

CAUTION

Before surgery:
A thorough radiological and clinical assessment must be done to determine the psychological and physical 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 (i.e. smoking, uncontrolled diabetes, radiotherapy treatment, steroid therapy, poor oral hygiene, infection of nearby tissue, systemic bi-phosphonate therapy).

Treatment planning (surgical and prosthetic design) must accommodate patient specific conditions. In cases of bruxism or unfavorable jaw relationships the treatment option may have to be reassessed and adjusted.

Implant treatment is not recommended in juvenile patients, until the mature jaw bone growth phase has been reached.

Hard or soft tissue defects may result in compromised treatment outcomes.

At surgery:
Validate the guide fit and trajectory.

Do not place narrow implants in the posterior region. Avoid the risk of prosthetic overload, that could lead to implant failure or fracture.

All instruments and tooling used during procedures must be maintained in good condition, and care must be taken not to damage the implant or other components.

Surgical procedure:
Assess bone quality during drilling procedures and follow the appropriate drill sequence to ensure optimal primary stability.

Drill at 1000 -1500 rpm for twist drills and 800 rpm for tapered drills. Use copious irrigation (saline at room temperature), and drill with a continuous intermittent motion, to avoid overheating of the bone. The laser marking on the shaft of the Pilot and Twist drills indicate drill diameters and length.

The implants are ideally placed with low speed, max. 25 rpm, when using an implant motor unit and Hand-Piece insert.

Never exceed insertion torque of 70Ncm when placing these implants. Over tightening an implant may lead to damage of the implant or fracture of the bone.

If the implant gets stuck during implant placement or 70Ncm of insertion torque is reached before the implant is fully seated, rotate the implant counter clockwise (handpiece in reverse mode) and remove implant from site. Adjust the osteotomy before placing the implant again.

HANDLING

Refer to the individual product packaging label and the corresponding IFU's for special handling instructions.

IMPLANTS MUST NOT BE TOUCHED DIRECTLY. They must be handled and placed by the instruments provided. If an implant is dropped onto a non-sterile surface, it should not be used.

PACKAGING

1) Implants: The outer packaging consists of a rigid, clear box which acts as protection for the inner packaging. The inner packaging consists of a clear plastic-formed bubble-type base with a "peel-back" lid. The contents of this inner package are sterile. Labeling Information is located on the surface of the peel-back lid and on the outside of the rigid box. Within the inner packaging there is a hollow tube which contains one implant. Sterility is assured unless the container or seal is damaged or opened.
2) Other sterile components are packed in a peel pouch and sterilized by gamma irradiation. Labeling information is located on the bottom half of the pouch, inside the packet. Sterility is assured unless the pouch is damaged or opened.
3) Other non-sterile components used in the laboratory are supplied clean but not sterile. These are laboratory analogues, some Ti abutments, CIA abutments, TIB abutments, cast waxing sleeves and gold abutments with plastic sleeves. Labeling information is located on the bottom half of the pouch, inside the packet.

Implants and abutments are supplied sterile and intended for single use. DO NOT re-sterilize or autoclave these components.

CLEANING

- Refer to CAT-1039
- Used instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva and tissue residue.
- Used surgical trays including grommets must be cleaned with suitable disinfectants.
- Multiple-part instruments must be disassembled prior to cleaning and sterilization.
- Internal debris/residue on instruments must be removed with a soft brush.
- Instruments should be inspected, cleaned separately and discarded if damaged.
- Best results are achieved if surgical instruments are cleaned by material type.
- Instruments and trays can be cleaned and disinfected in a dedicated instrument washer or alternatively by hand, followed by an ultrasonic bath with a detergent appropriate for surgical instruments.
- Instruments and trays must be rinsed and dried thoroughly.

STERILIZATION

- Products provided non-sterile must be cleaned and sterilized prior to use.
- Pre-vacuum sterilization method: Steam sterilise the component at 132°C (270°F) at 180-220 kPa for 4 minutes, or at 135° C (275°F) at 180-220 kPa for 3 minutes. Dry for at least 20 minutes in the chamber. Only an appropriate regulatory authority approved sterilizer and wrap or pouch for steam sterilization must be used.
- It is the responsibility of the user to establish whether or not their sterilizer is appropriate regulatory authority approved to meet the recommended parameters.
- The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

MAGNETIC RESONANCE (MR) SAFETY INFORMATION

External Hex & PROVATA™ 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 External Hex and PROVATA™ implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CAUTION: (USA ONLY)

United States Federal Law restricts this device to sale to, or on the order of, a licensed dentist or physician.

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.

For more information, please call your Southern Implants Representative or visit southernimplants.com

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SOUTHERNIMPLANTS®
Innovative Treatment Solutions

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

Southern Implants are distributed world-wide, please visit southernimplants.com for a list of Distributors.

CAT-2068-00 (C1053)