

A less-invasive
surgical option for
pedicle screw placement

AnyPlus

Long Arm
Screw System

SURGICAL TECHNIQUE GUIDE

Minimal invasive spine surgery has several advantages over traditional open techniques. Smaller incisions and minimal muscle resection, markedly decrease operating time, blood loss and postoperative pain.

The AnyPlus LONG ARM SCREW System was created to offer a less invasive surgical option for pedicle screw placement. The system incorporates anatomically driven solutions such as self-tapping cannulated polyaxial screws and pre-lordosed rods. The instrumentation is ergonomically designed to allow for true percutaneous. The AnyPlus LONG ARM SCREW System offers a simple, precise and efficient solution to spinal fixation.

Intended Use

When used as a posterior, non-cervical pedicle screw system, the AnyPlus LONG ARM SCREW System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine:

- ▶ Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- ▶ Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebrae
- ▶ Degenerative spondylolisthesis
- ▶ Trauma (i.e., fracture or dislocation)
- ▶ Spinal stenosis
- ▶ Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- ▶ Tumor
- ▶ Pseudoarthrosis
- ▶ Failed previous fusion

Preoperative Planning

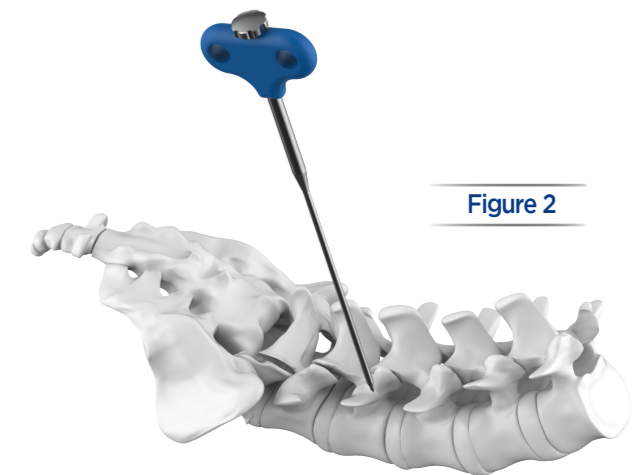
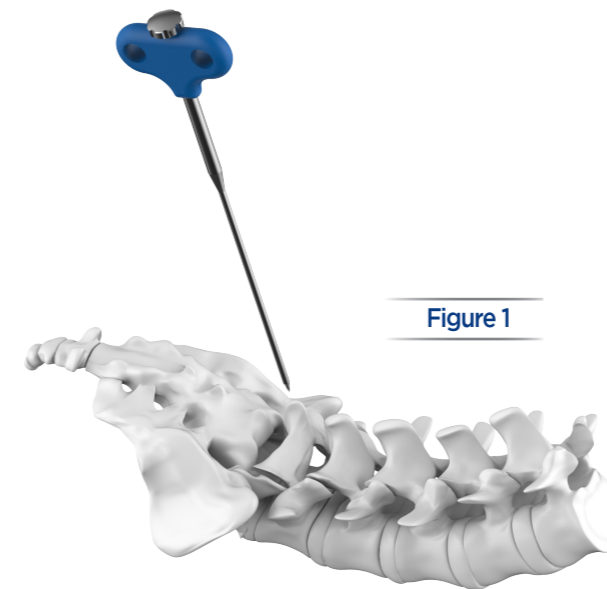
When using the AnyPlus LONG ARM SCREW System, the patient should be positioned prone on a radiolucent table. Chest rolls may be used, but the knee-to-chest position should be avoided.

Using fluoroscopic imaging, it should be verified that the true views of both anterior-posterior (A/P) and lateral images of the spine (views which adequately delineate pedicle morphology and geometry) are obtainable. It is also recommended that preoperative planning be used to help determine a proper entry point and trajectory.

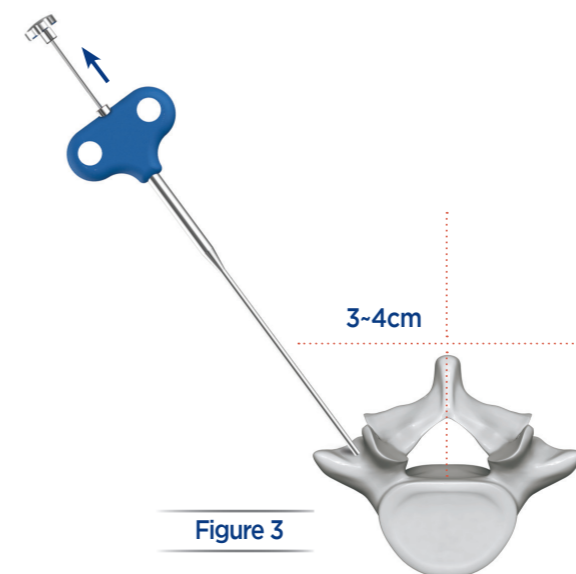
After identifying the pedicle entry point, a targeting needle and a guide should be used to initiate the starting entry point. Adjustments to the entry angle and the trajectory should be made as often as needed with the assistance of fluoroscopic imaging until the proper position is attained.

This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warning.

Pedicle Targeting & Guidewire Placement



▶ Target needle positioning



GS114-0210 Targeting needle

It is recommended that preoperative planning is used to help determine the proper entry point and trajectory as the starting point is not usually at the point directly over the pedicle.

Identify the operative levels using A/P and lateral fluoroscopy. Plan the entry point to target the pedicle from a transverse trajectory lateral to the facet.

Make an incision through the skin and fascia. The typical starting point is 3-4cm off the midline.

Insert the Targeting Needle and the Guide down to the surface of the pedicle and dock the tip on the bony anatomy of the desired level and confirm placement with A/P fluoroscopy. Adjustments to the entry angle and the trajectory should be made until the proper position is attained.

Advance the Targeting Needle and the Guide down through the pedicle. Once proper placement is confirmed, remove the inner stylet of the targeting needle.

Pedicle Targeting & Guidewire Placement(Cont.)

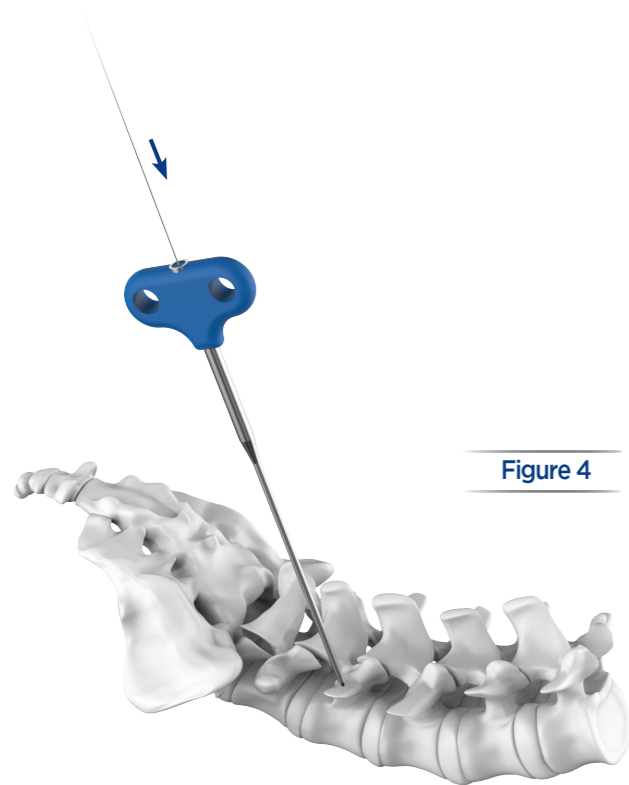


Figure 4

GS114-0115 Nitinol Guide Wire

Insert the Guidewire through the cannulated target needle sheath and advance the Guidewire just past the tip of the Targeting Guide. Use caution when advancing the Guidewire under fluoroscopy ensure the location of the Guidewire. Once the Guidewire is in place remove the Targeting needle and leave the Guidewire in place.

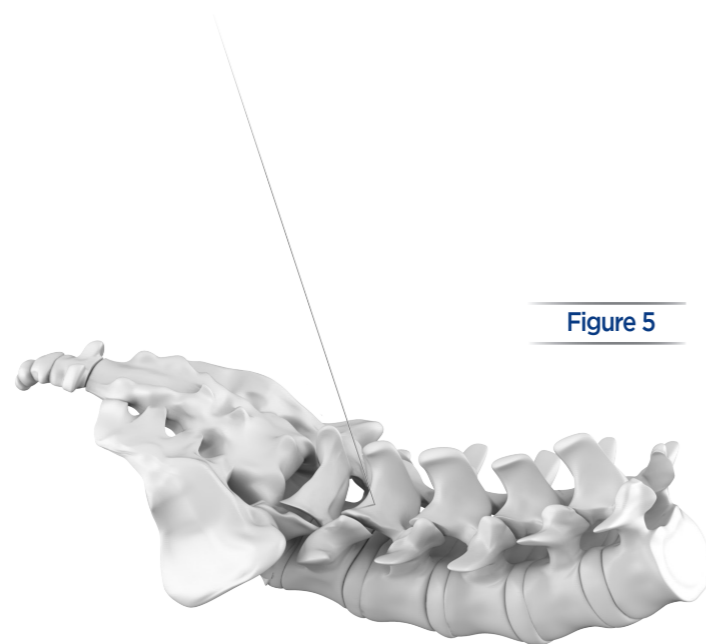


Figure 5

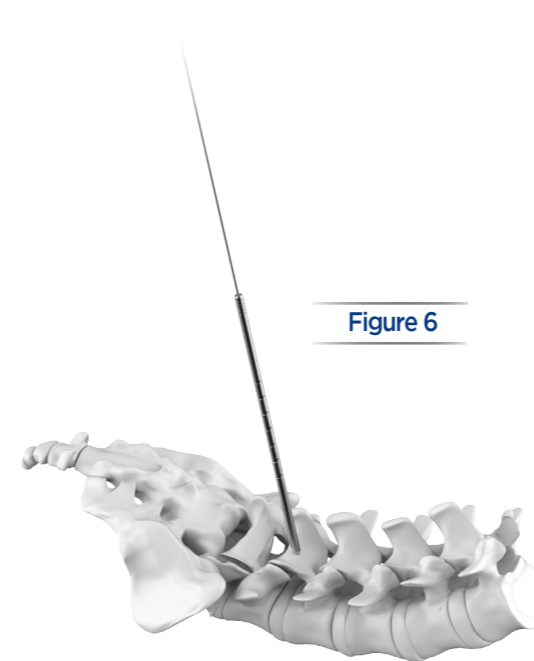


Figure 6

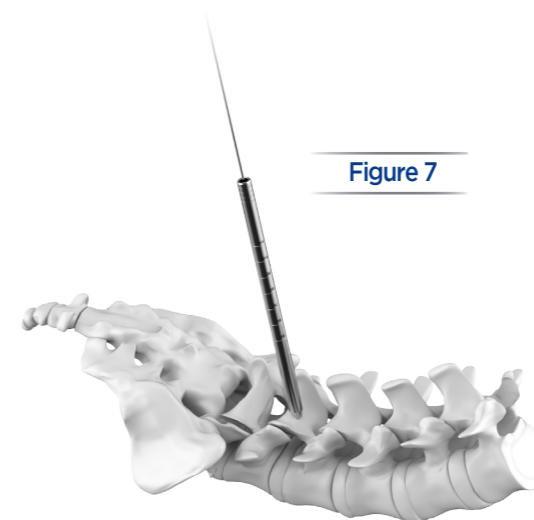


Figure 7

Facilitates Advancement

Tissue Dilation & Tapping

- GS114-0520 Dilator (Ø1.8/6mm)
- GS114-0522 Dilator (Ø6/10mm)
- GS114-0524 Dilator (Ø10/14mm)

A longitudinal incision about 1.5cm is made through the skin and fascia. An incision of 1.5cm will facilitate the insertion of the Dilators used later in the procedure. Prepare a pathway to the pedicle by sequentially using dilators 1,2 and 3. Once the Large Dilator is placed remove the inner Dilators and place them over the adjacent Guidewire. Leave the Large Dilator in place to protect the soft tissue while tapping.

Caution: Use fluoroscopy to monitor guidewire advancement during dilation.

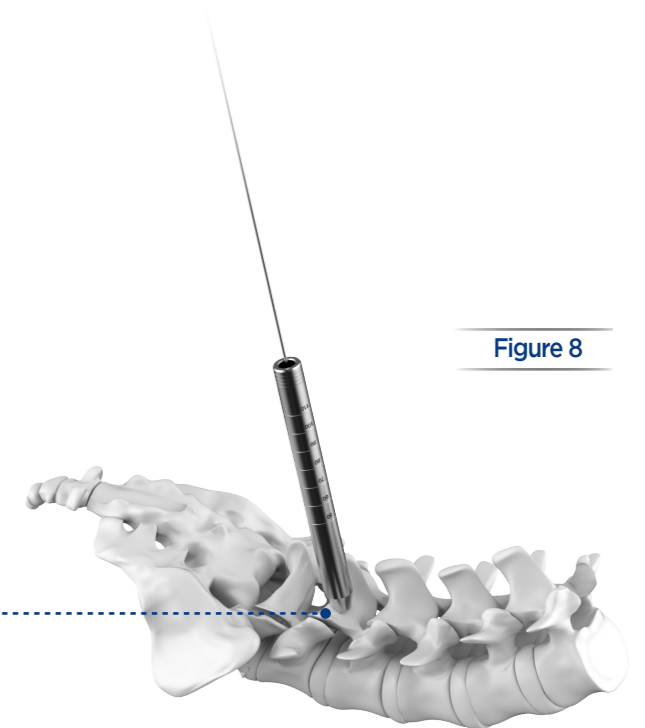


Figure 8

Tissue Dilation & Tapping(Cont.)

GS114-2120 Cannulated Awl

The AnyPlus LONG ARM SCREW SYSTEM offers a cannulated Awl for pedicle preparation. Advance the Awl till breaching the pedicle cortex. Once positioned and confirmed under fluoroscopy the guide wire can be delivered. The Awl can then be removed while maintaining control of the guidewire.

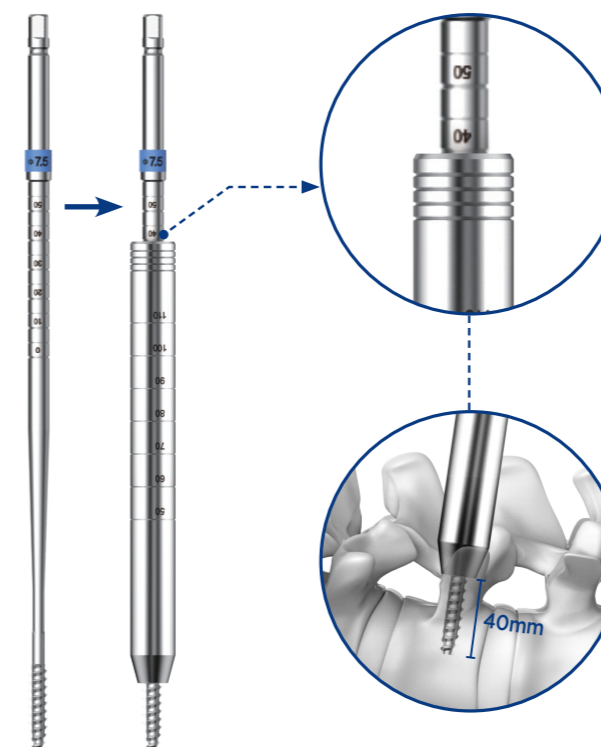
Caution: Use fluoroscopy to monitor guidewire advancement during the following step.



Figure 9



Figure 10



Tissue Dilation & Tapping(Cont.)

- GS114-0651 Cannulated Tap, 5.0mm
- GS114-0656 Cannulated Tap, 5.5mm
- GS114-0661 Cannulated Tap, 6.0mm
- GS114-0666 Cannulated Tap, 6.5mm
- GS114-0671 Cannulated Tap, 7.0mm
- GS114-0676 Cannulated Tap, 7.5mm

Attach the appropriate Tap size to the preferred handle. Place the tap over the Guidewire and through the Large Dilator to the surface of the pedicle. The depth markers on the Tap shaft where the Tap shaft meets the top of the Large Dilator are used to monitor insertion. They can also be used to determine screw length. Once desired depth has been achieved remove tap while maintaining control of guidewire.

Caution: Use fluoroscopy to monitor guidewire advancement during tapping.

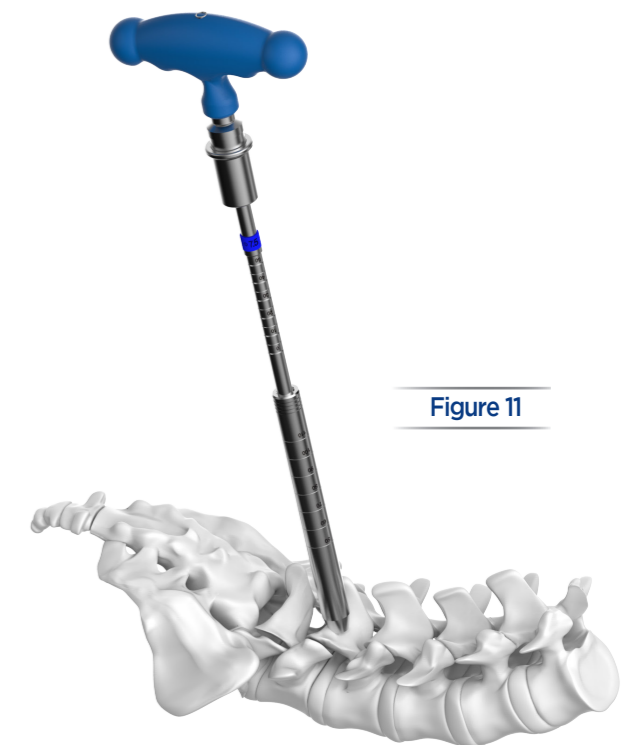


Figure 11

Screw Driver Assembly & Screw Insertion

GS114-2320 Long Arm Locking Cap
GS114-0930 Long Arm Cannulated Screw Driver

Screw driver assembly

Insert the screwdriver with the preferred handle through the blades of The AnyPlus LONG ARM SCREW and engage the tip of the screwdriver with torx head of the screw. Rotate the black screwdriver knob in a clockwise to assemble the tip of screw driver into the head of the screw. Ensure the screw is firmly attached to the screw driver

Screw implanting

Guide the screwdriver assembly over the guide wire and into pedicle. advance the screw to the desired depth and verify placement under fluoroscopy.

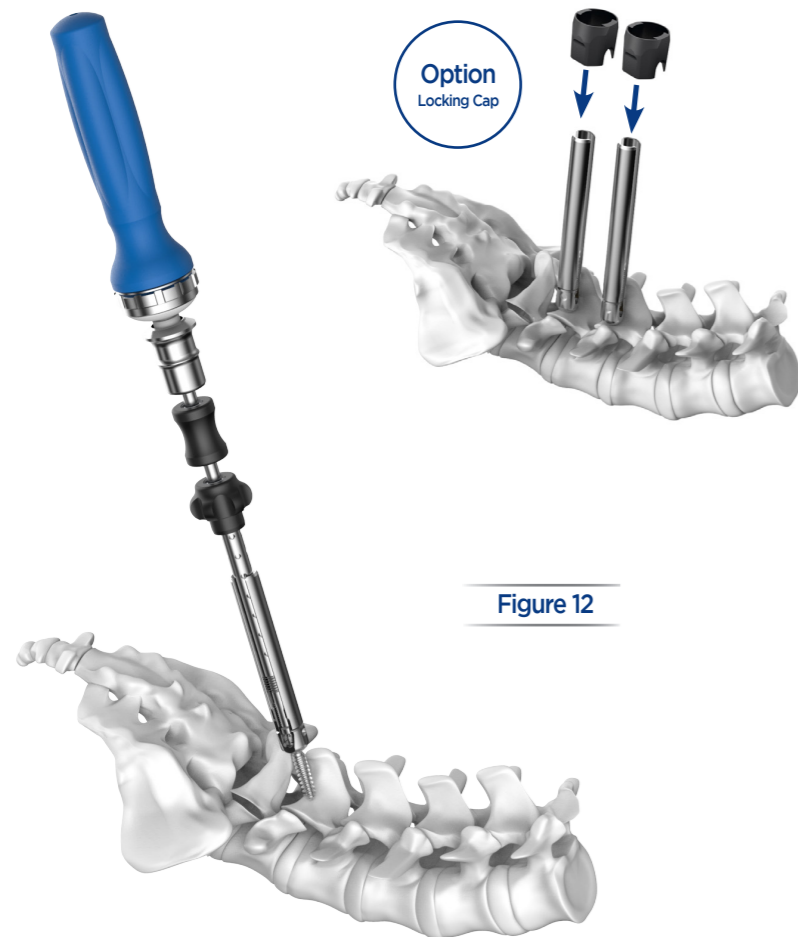


Figure 12

After screw placement, remove the screwdriver and the guidewire. Rotate the black screwdriver knob in a counter clockwise and gently pull out the screwdriver through the blade of the screw. Gently tug the guidewire in an upward motion with a guide wire driver.

Option: Locking Cap

Use a Locking Cap to protect for pliable blades of The AnyPlus LONG ARM SCREW

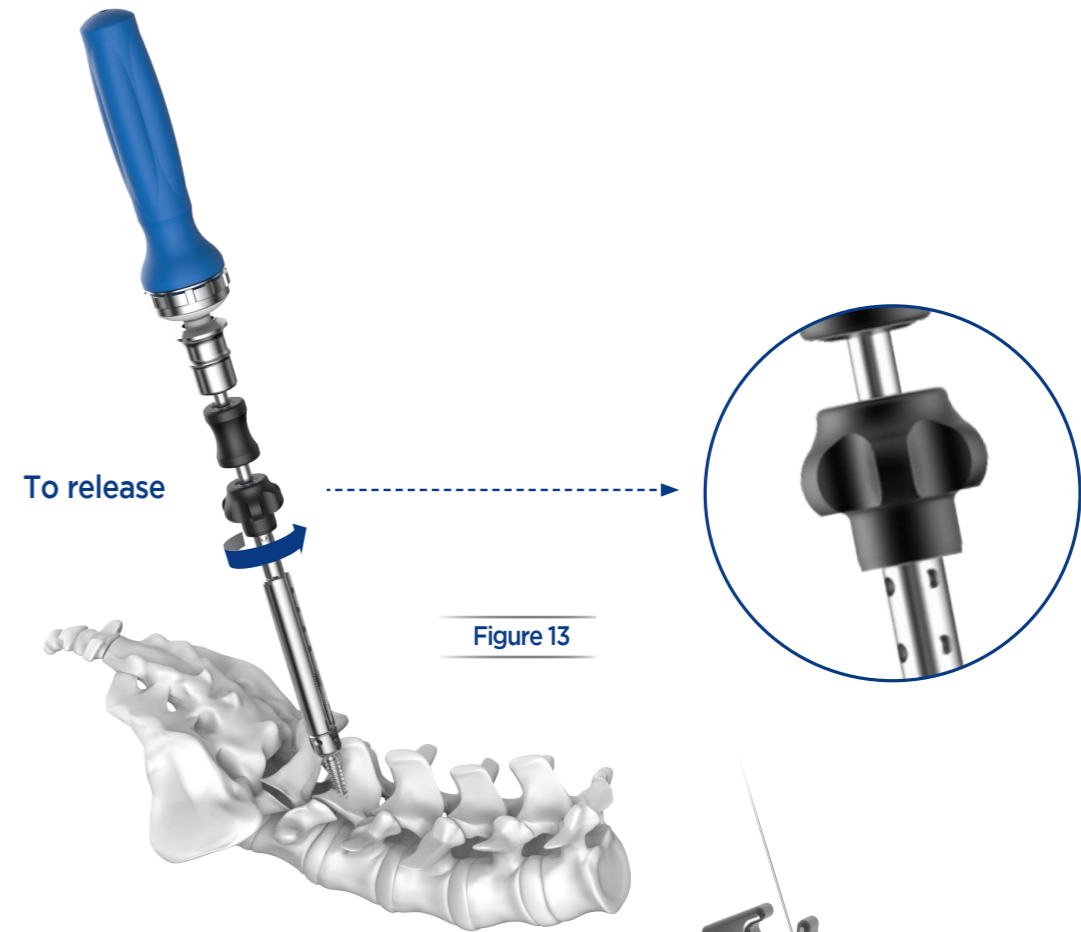
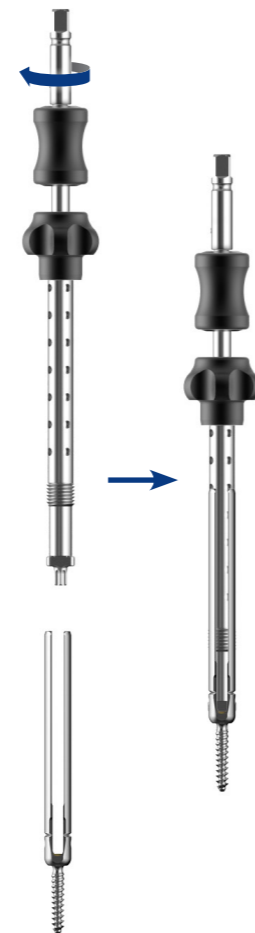


Figure 13

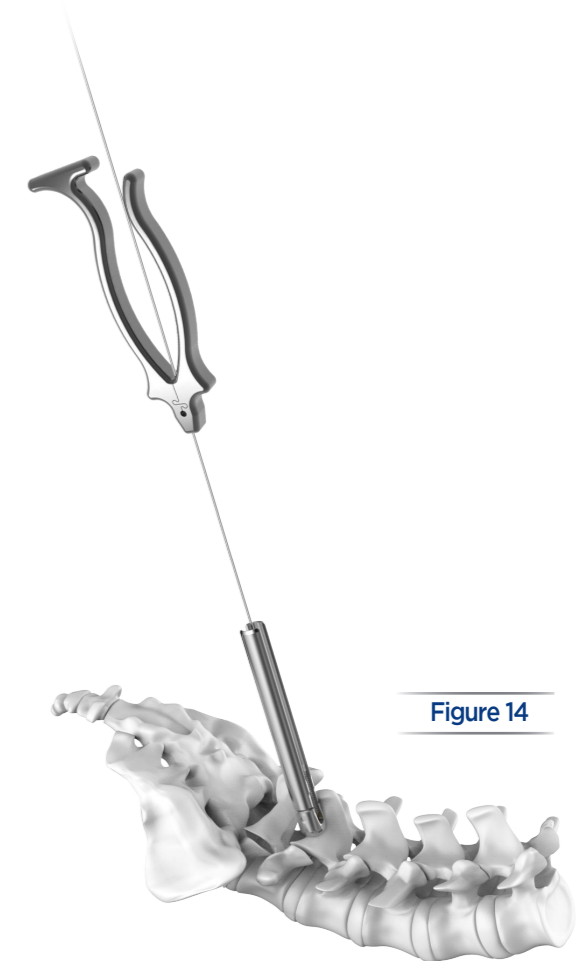
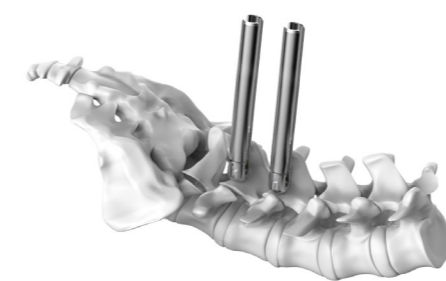
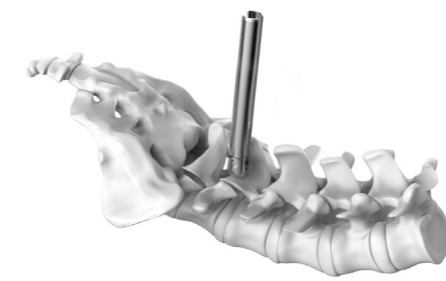


Figure 14

Rod Measurements

GS114-1120 Rod Length Gauge

Align the screws and the Rod Length Gauge will allow you to measure the exact length of the Rod needed. Assemble the Rod Length Gauge to the proximal end of the screws.

Based on the Screw positions the pointer will indicate the appropriate Rod length on the Gauge. Read rod measurement length from size marking on caliper, if the pointer falls between measurements the measurement should be rounded up to the next rod length. After determining the Rod length, remove the Rod Gauge.

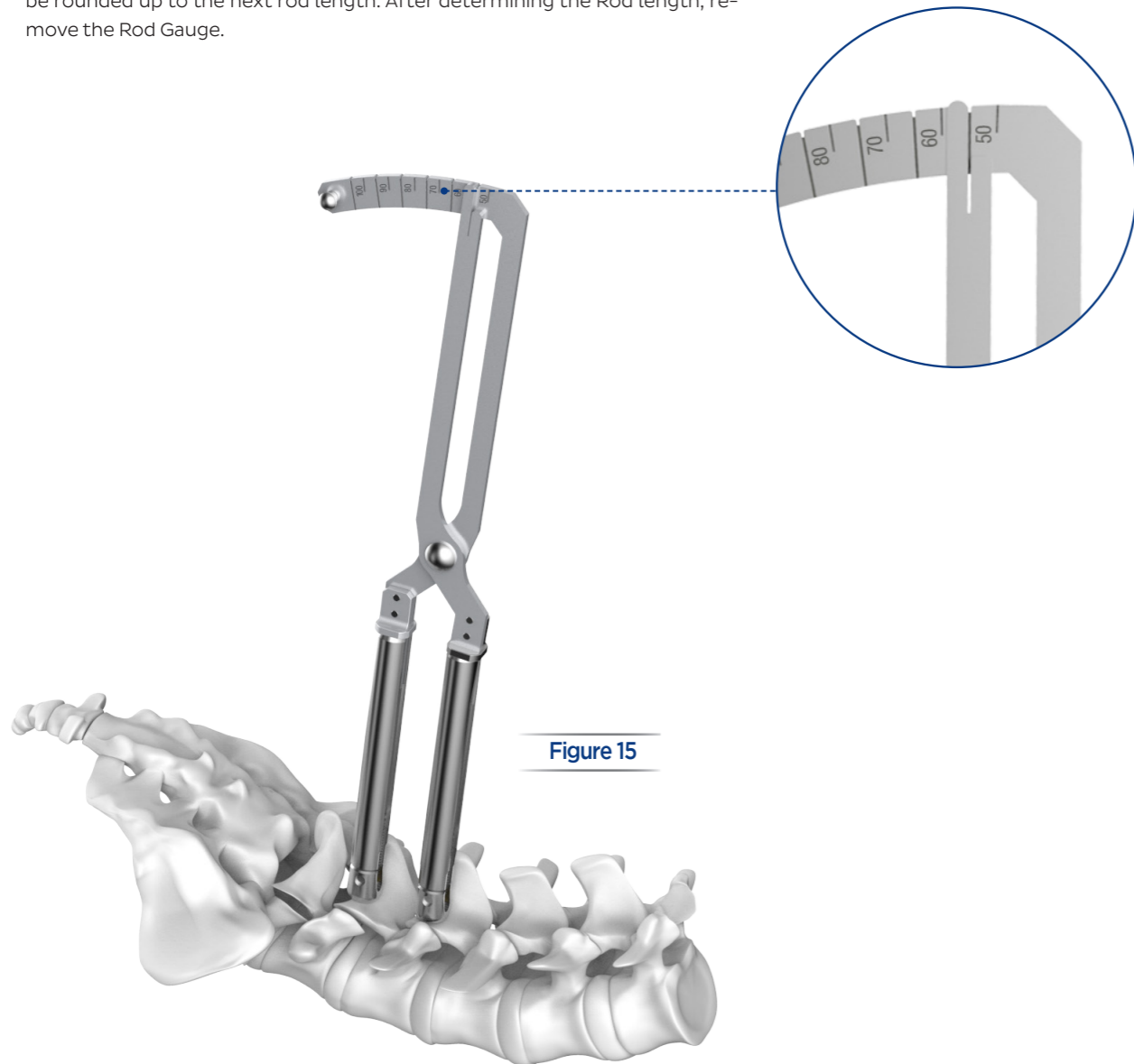


Figure 15

Rod Bending & Guide

GS110-1526 French Rod Bender GS114-1010 Rod Holder Guide

The French Rod Bender is allowed to contour the pre-determined rod if necessary



Figure 16

The Rod Holder Guide may be used to create a pathway of the rod to ensure the rod placement



Figure 17

Rod Insertion

GS114-1240 Rod Holder

Place an appropriate length of the pre-bent rod at the end tip of the Rod holder and and rotate the handle on the top of the Rod Holder clock-wise.

This will securely lock the rod in the insertion position.

In order to facilitate proper placement of the rod, it is necessary to extend the incision at the entry point by 5mm. Pass the pre-bent rod through the window of the first screw blade. When the tip of the rod reaches the top of the screw head, advance the rod through the muscle to the top of the next screw and confirm the rod position using fluoroscopy.

End rod attachment

At the position of the Rod Holder for the angle of 90 degrees, pushing downward the rod through the Rod Holder will be achieved to seat the rod into the pedicle screw heads.

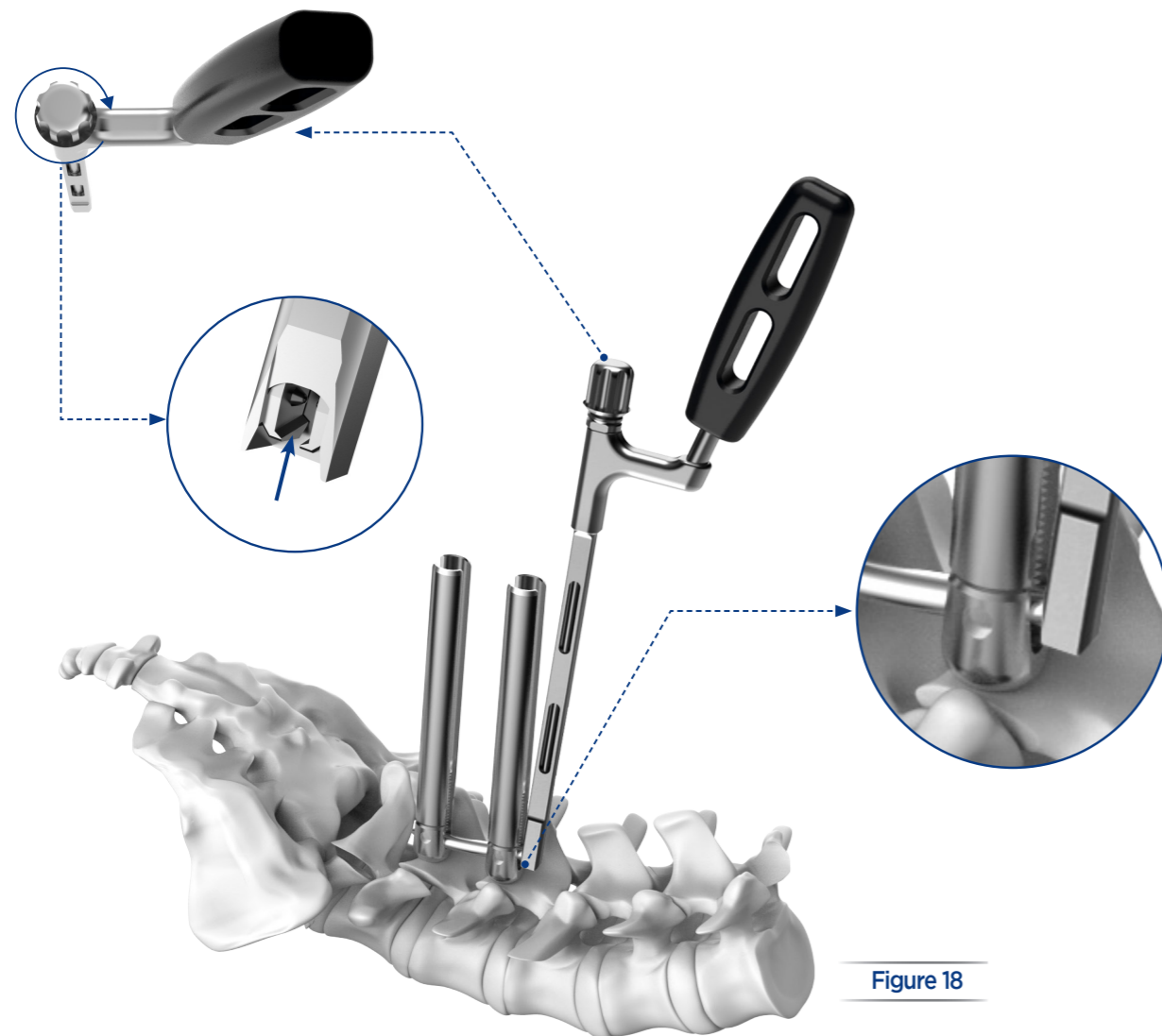


Figure 18

Rod Placement

GS114-2020 Set screw driver starter GS114-1320 Rod Pusher

Set Screw Driver Starter

Load the Set screw on the Set Screw Driver Starter, and the set screw is inserted into the each screw head until it is fully seated.

The etched line marking on the Set Screw Driver Starter allows to indicated that the set screw is placed properly.

Rod Pusher

The Rod Pusher may be used to introduce the set screw into set screw head.

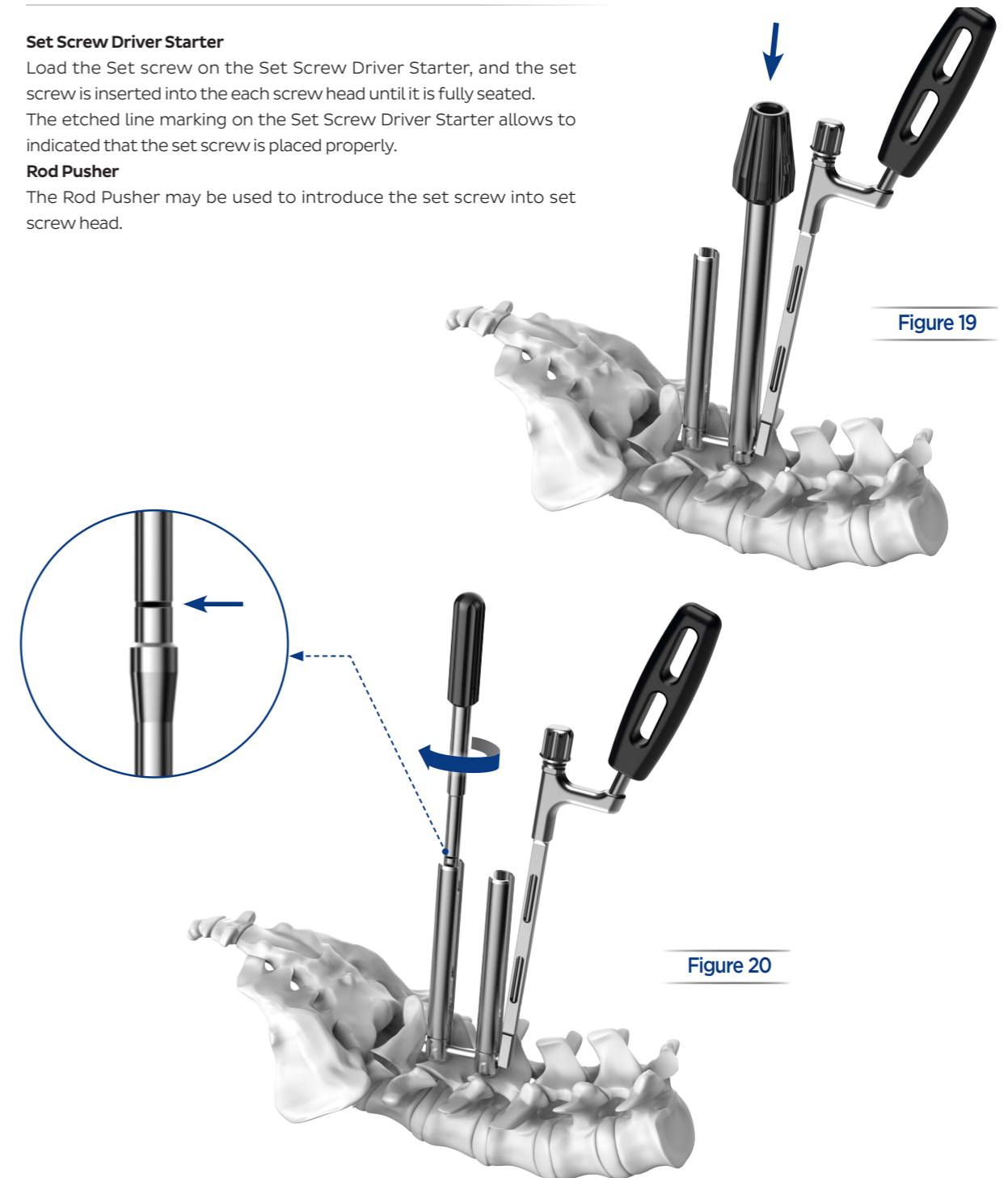


Figure 19

Figure 20

Compression & Distraction

GS114-1510 Compressor
GS114-1530 Sleeve

Compression & Distraction

The Compression-Distraction tool will allow you to compress or distract the operable level and maintaining position

Put a Sleeve over a blade of AnyPlus LONG ARM SCREW and apply another Sleeve over a blade of adjacent AnyPlus LONG ARM SCREW.

Compression : Attach the tool as close as possible to the surface of the skin. The bar, which acts as a fulcrum, is inserted and above the pivot point between the two sleeve.

Distraction : Attach the tool as close as possible to the surface of the skin. The bar, which acts as a fulcrum, is inserted and below the pivot point between the two sleeves.

Provisionally tighten one of the set screws and then apply force to the handle of the Compression-Distraction tool.

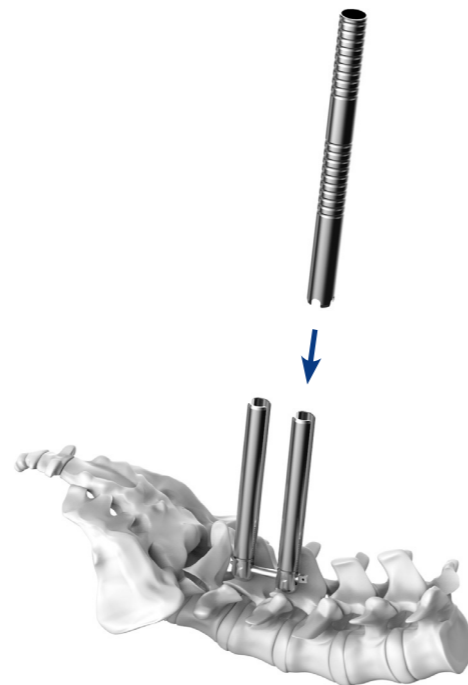


Figure 21

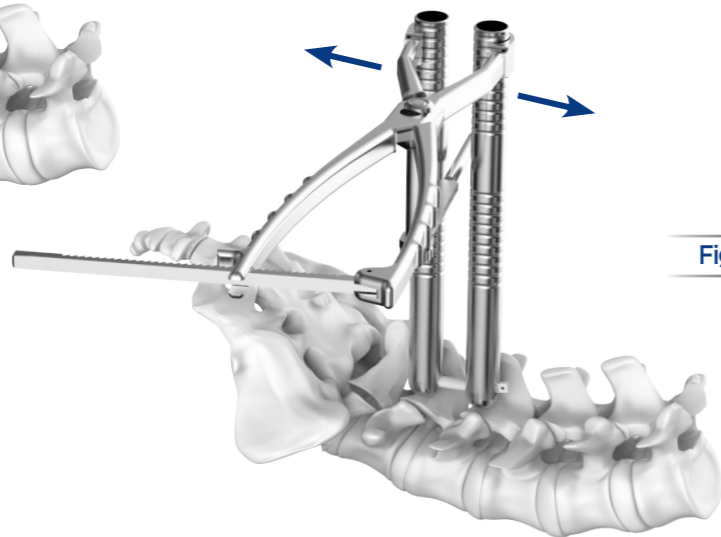


Figure 22

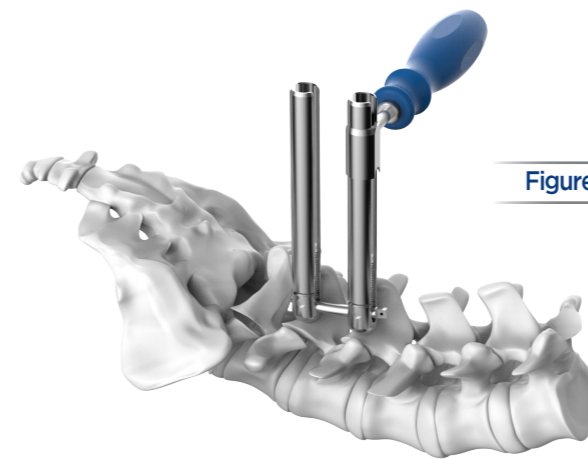


Figure 23

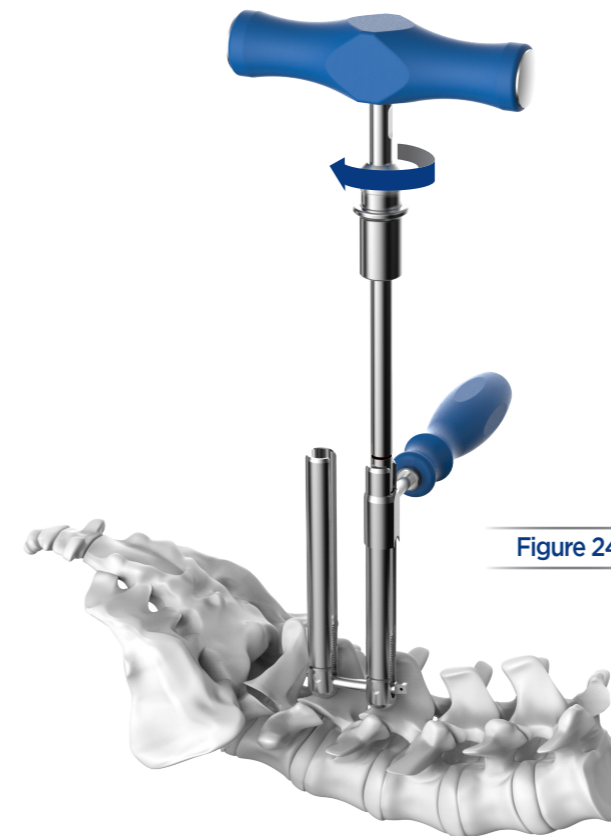


Figure 24

Final Tightening

GS114-1630 Anti Torque Wrench
GS114-1420 Set Screw Driver, Final
GS110-0652 Torque Limiting Handle

Slide the Anti torque wrench over the screw engaging the slots as the tool advances.

Assemble the 10.5 N-m Torque Limiting Handle with the Set Screw Driver, Final and guide it through the screw into the set screw.

Turn the Torque Limiting Handle clockwise. Final tightening is achieved when the "Click" indication.

Remove Torque Limiting Handle and the Anti Torque Wrench. Repeat same procedure for each screw.

The etched line marking on the Set Screw Driver, Final Allows to indicate that the set screw is placed properly.



Blade Removal

GS114-1730 Tab Breaker

Gently put the Tab breaker over the AnyPlus LONG ARM SCREW after final tightening has taken place. Rock the Breaker in a back and forth motion until tabs are away from the screw and it may be required a repeated procedure a few times to ensure the breakage.

Caution: Confirm final tightening of all construct screws before removing the tabs.

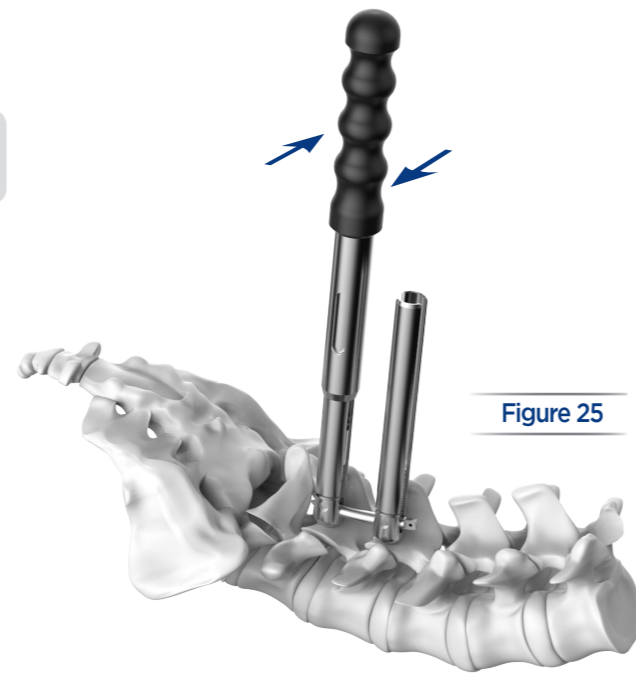
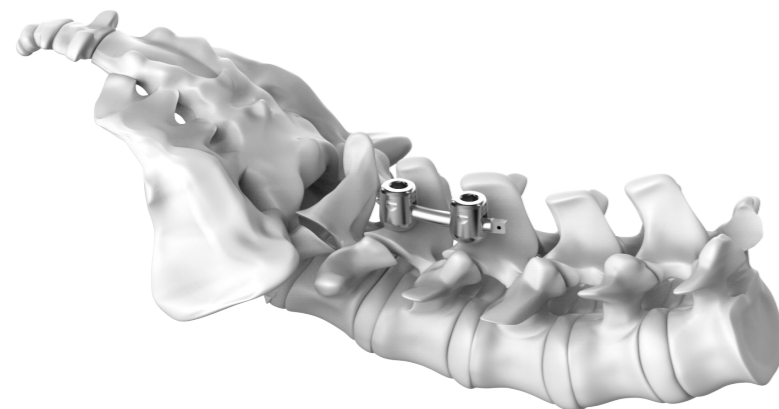


Figure 25



Product Specification

Dia=5.0mm



AnyPlus Long Arm Screw(Self)

No.	Part No.	Length(mm)
1	2712-5025	25
2	2712-5030	30
3	2712-5035	35
4	2712-5040	40
5	2712-5045	45
6	2712-5050	50
7	2712-5055	55
8	2712-5060	60
9	2712-5065	65
10	2712-5070	70

Dia=5.5mm



AnyPlus Long Arm Screw(Self)

No.	Part No.	Length(mm)
1	2712-5525	25
2	2712-5530	30
3	2712-5535	35
4	2712-5540	40
5	2712-5545	45
6	2712-5550	50
7	2712-5555	55
8	2712-5560	60
9	2712-5565	65
10	2712-5570	70

Dia=6.0mm



AnyPlus Long Arm Screw(Self)

No.	Part No.	Length(mm)
1	2712-6025	25
2	2712-6030	30
3	2712-6035	35
4	2712-6040	40
5	2712-6045	45
6	2712-6050	50
7	2712-6055	55
8	2712-6060	60
9	2712-6065	65
10	2712-6070	70
11	2712-6075	75
12	2712-6080	80
13	2712-6085	85
14	2712-6090	90
15	2712-6095	95
16	2712-6000	100

Dia=6.5mm



AnyPlus Long Arm Screw(Self)

No.	Part No.	Length(mm)
1	2712-6525	25
2	2712-6530	30
3	2712-6535	35
4	2712-6540	40
5	2712-6545	45
6	2712-6550	50
7	2712-6555	55
8	2712-6560	60
9	2712-6565	65
10	2712-6570	70
11	2712-6575	75
12	2712-6580	80
13	2712-6585	85
14	2712-6590	90
15	2712-6595	95
16	2712-6500	100

Dia=7.0mm



AnyPlus Long Arm Screw(Self)

No.	Part No.	Length(mm)
1	2712-7025	25
2	2712-7030	30
3	2712-7035	35
4	2712-7040	40
5	2712-7045	45
6	2712-7050	50
7	2712-7055	55
8	2712-7060	60
9	2712-7065	65
10	2712-7070	70
11	2712-7075	75
12	2712-7080	80
13	2712-7085	85
14	2712-7090	90
15	2712-7095	95
16	2712-7000	100

Dia=7.5mm



AnyPlus Long Arm Screw(Self)

No.	Part No.	Length(mm)
1	2712-7525	25
2	2712-7530	30
3	2712-7535	35
4	2712-7540	40
5	2712-7545	45
6	2712-7550	50
7	2712-7555	55
8	2712-7560	60
9	2712-7565	65
10	2712-7570	70
11	2712-7575	75
12	2712-7580	80
13	2712-7585	85
14	2712-7590	90
15	2712-7595	95
16	2712-7500	100

AnyPlus®

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