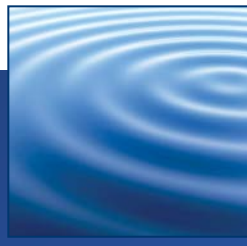
Life moves us

SURGICAL TECHNIQUE



PLYMOUTH®

Thoracolumbar Plate System

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

PLYMOUTH®

Thoracolumbar Plate System

PLYMOUTH® is a minimally invasive thoracolumbar plate system that provides stabilization through a single lateral approach.

Innovative anchoring and keying instruments align the plate with various interbody devices and the vertebral endplates, allowing controlled placement with minimal retraction.

PLYMOUTH®
THORACOLUMBAR PLATE SYSTEM

Reduced Retraction

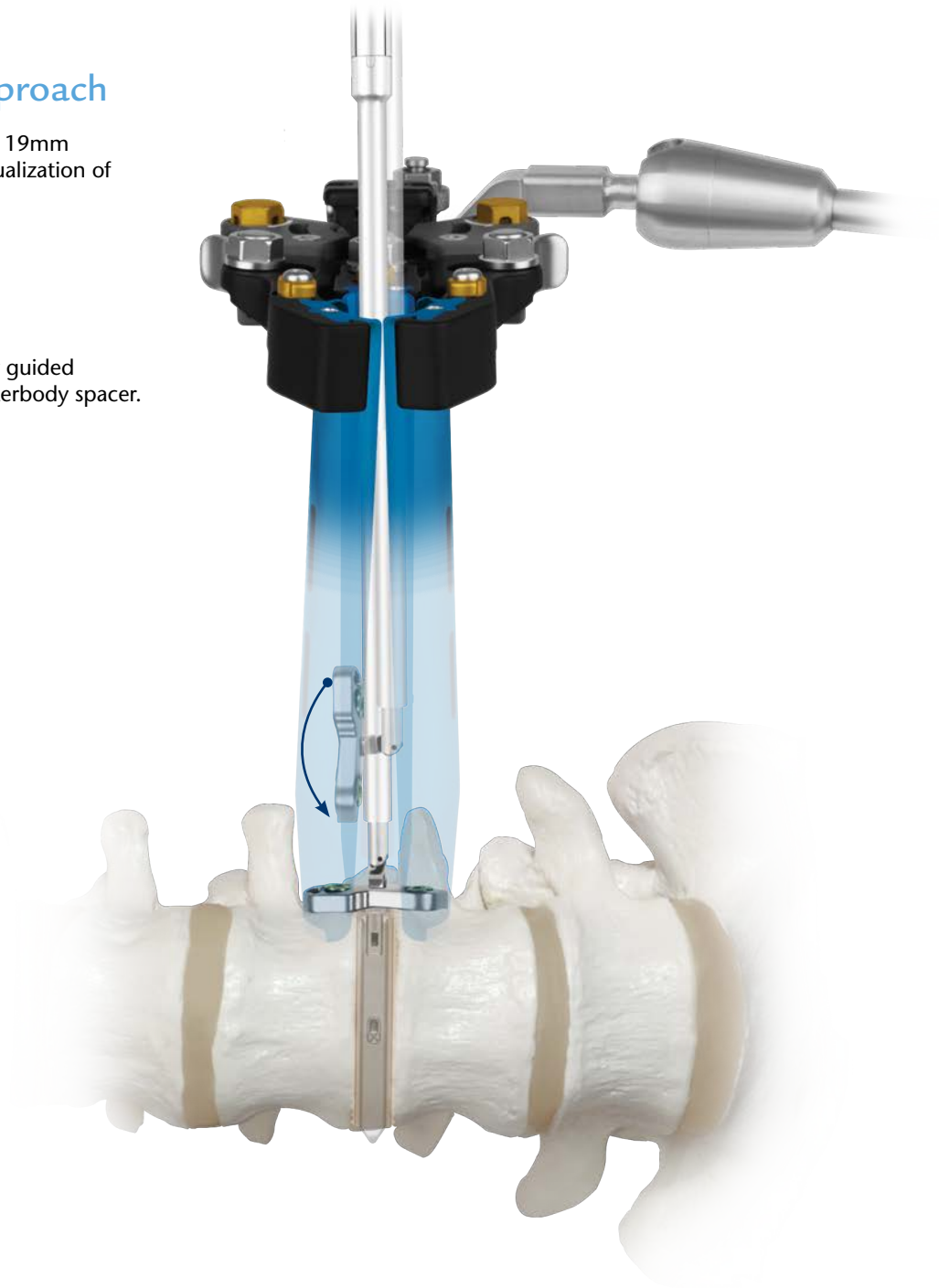
Compact design enables placement with less retraction required

Minimally Invasive Approach

The plate can be delivered through a 19mm opening while maintaining direct visualization of the operative level

Ease of Placement

Anchor and keying instruments allow guided placement and alignment with an interbody spacer.



CONTENTS

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

IMPLANT OVERVIEW

Plates

- 17mm width allows placement through a minimally invasive retractor
- 4.0mm profile
- Two screw and four screw plate designs
- L4-L5 plate eases screw insertion at challenging angles
- Lengths from 15–24mm (hole-to-hole)

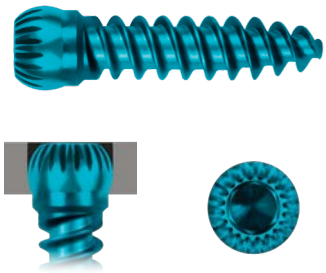
2 Screw Plate

4 Screw Plate

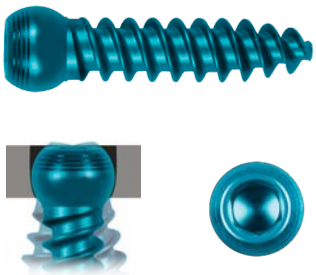
L4/L5 Plate

Bone Screws

- 5.5mm and 6.5mm diameter
- Variable angle and fixed angle
- Lengths from 22–57mm
- Self-tapping
- Variable angle screws allow for ±10° of angulation
- Fixed angle screws with pre-set trajectory 5° cephalad/caudal

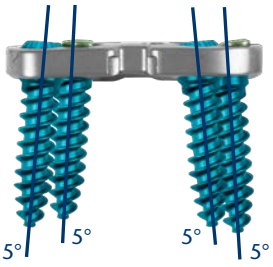


Fixed Angle Screw



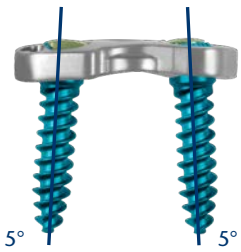
Variable Angle Screw

End View
4 Screw Plate



4 Screw Plate

End View
2 Screw Plate



2 Screw Plate

Blocking Mechanism

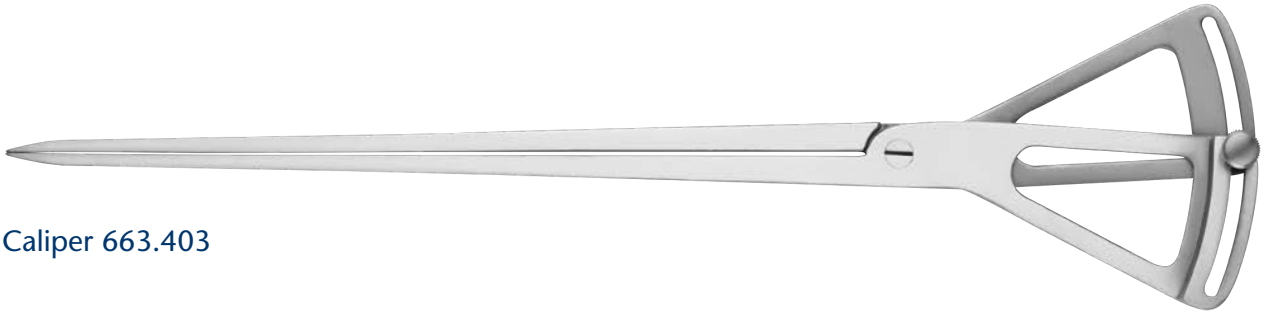
- Simple and reliable locking set screw
- Preassembled to the plate
- Provides direct visual confirmation of locked bone screws

Blocking Mechanism
Open

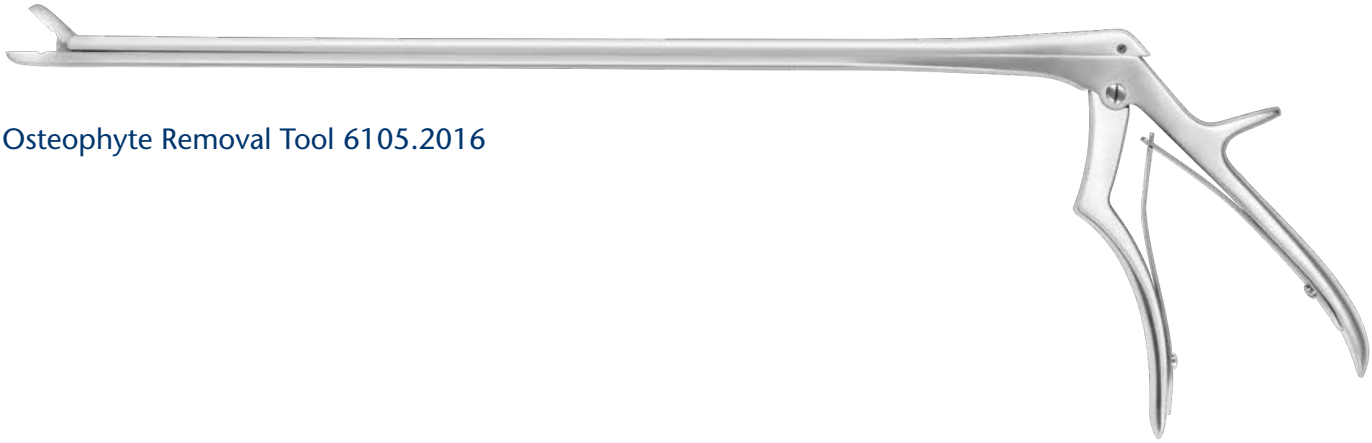
Blocking Mechanism
Closed

INSTRUMENT OVERVIEW

Plate Preparation Instruments



Caliper 663.403



Osteophyte Removal Tool 6105.2016

Anchors and Keying Instruments

Anchor Weight 6105.3016

Anchor Wrench 6105.3030

Offset Handle 6105.3040

Anchors and Keying Instruments (cont'd)

Anchor Threaded 6105.3010

Keying Sleeve for Threaded Anchor 6105.3020

Anchor Press Fit 6105.3012

Anchor for Hex 6105.3050

Keying Sleeve for Hex, 18mm 6105.3055

Keying Sleeve for Hex, 22mm 6105.3057

Offset Keying Tool 6105.3022

Plate Holders

Threaded Plate Holder 6105.5010

Plate Inserter 6105.5012

Articulating Holder 6105.5030

Screw Preparation Instruments

Cortex Awl, 1/4" QC 630.316

DTS Guide Awl, Adjustable Depth 6105.4010

DTS Guide Sleeve, Awl 6105.4012

Screw Preparation Instruments (cont'd)

DTS Guide Drill Bit, Adjustable Depth 6105.4020

DTS Guide Sleeve, Drill Bit 6105.4022

DTS Guide Tap, Adjustable Depth 6105.4030

DTS Guide Sleeve, Tap 6105.4032

Screwdriver Sleeve 6105.4040

Quick Release 1/4", Ratchet, Straight Handle 630.407

Quick Connect Handle, Cannulated 648.400

Screw Preparation Instruments (cont'd)

DTS Guide, Preset Angle 6105.4000

DTS Guide, Preset Angle, 4 Screw 6105.4004

Quick Release 1/4", Ratchet, T-Handle 630.401

Drill Guide, Variable Angle, Adjustable Depth 663.401

Screw Preparation Instruments (cont'd)

Drill Bit, Adjustable Depth 663.402

Screwdriver 3.5mm Hex, Self-Retaining 630.410

Screwdriver Shaft, 3.5mm Hex, 1/4" QC, Self-Retaining 630.414

Locking Instrument

Set Screw Positioner, Torque Limiting, 1.5Nm 630.503

RESCUE® Instrument

3.5mm Hex Screw Extractor 6105.6000

PLYMOUTH® SURGICAL TECHNIQUE

Please refer to the package insert printed at the back of this technique guide for device description, indications, contraindications, warnings and precautions.

Refer to the LLIF (GMTGD32) or the CALIBER®-L (GMTGD78) Surgical Technique Guides for instructions on retractor and interbody device insertion.

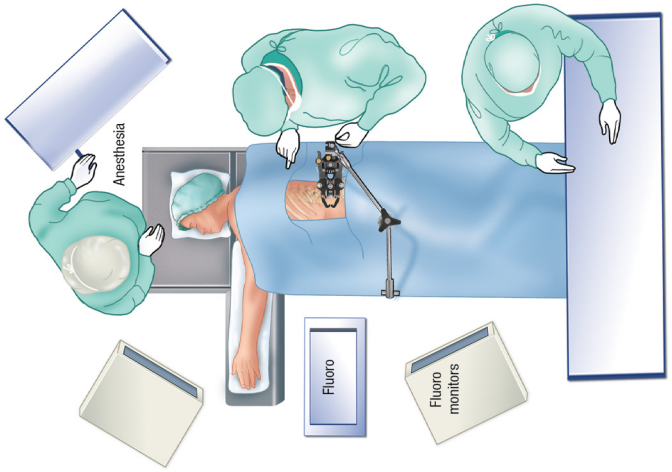
Step 1 Patient Preparation

Patient Positioning

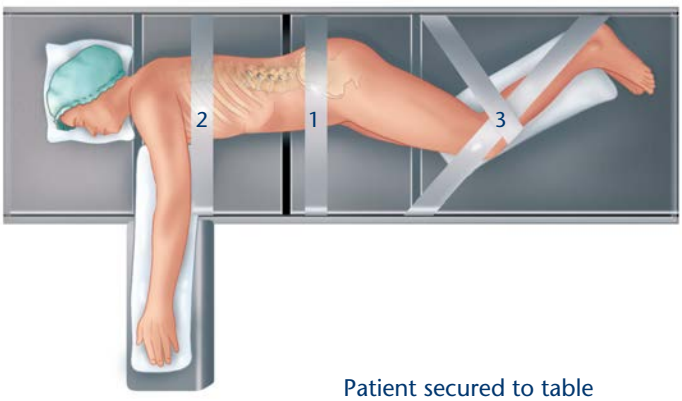
The patient is placed on a flexible surgical table in a straight 90° right lateral decubitus position so that the iliac crest is just over the table break, as shown below.

The patient is then secured to the table at the following locations: 1) Just beneath the iliac crest; 2) Over the thoracic region, just under the shoulder; 3) From the back of the table, over the ankle, and past the knee to the front of the table.

The table should be flexed to open the interval between the 12th rib and iliac crest, and provide direct access to the disc space as shown below.



Patient positioning



Patient secured to table

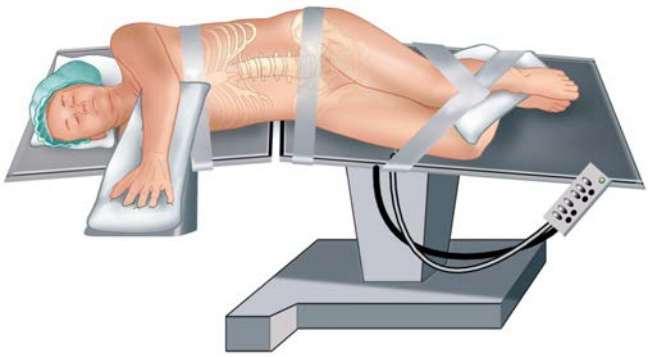


Table flexed

Patient Preparation (cont'd)

X-Ray Confirmation

Fluoroscopy is used to ensure that the spine is oriented in a straight lateral position. The table should be adjusted so that the C-arm provides straight AP images when at 0° and straight lateral images at 90°.

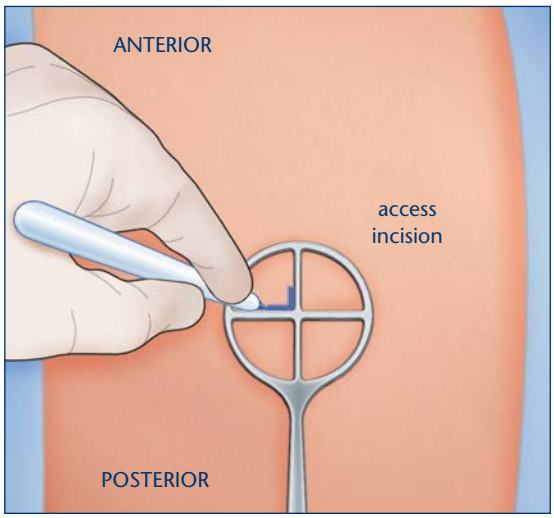
Lateral image

AP image

Incision Location

The operative area is carefully cleaned and the Incision Locator is used under fluoroscopy to identify the middle of the disc space to be fused. An access incision mark is then traced on the patient's skin to indicate the position and insertion site for the retractor. Position the desired retractor.

Using Incision Locator



Marking the incision locations

Step 2 Plate Preparation

A **Caliper** may be used to determine the appropriate plate length. Plate length is measured from the center of the cephalad hole to the center of the caudal hole.

Osteophyte Removal

Use the **Osteophyte Removal Tool** or other standard surgical instruments for osteophyte removal.

Osteophyte removal may aid in plate placement against the vertebral bodies.

Using the Osteophyte Removal Tool

Step 3 Plate Placement

The PLYMOUTH® Thoracolumbar Plate System has seven options to achieve plate placement and alignment:

A. Anchor Threaded with TransContinental®
B. Anchor Press Fit with TransContinental®
C. Anchor for Hex with CALIBER®-L
D. Keying Sleeve with Anchors
E. Plate Inserter with Anchors
F. Articulating Holder
G. Offset Keying Tool

Anchors are instruments designed to guide the plate into position. Once the plate is secured to the vertebrae, the anchors are removed. The plate is not attached to the spacer at final implantation.

All anchors should be placed with the Anchor Wrench as described on page 16.

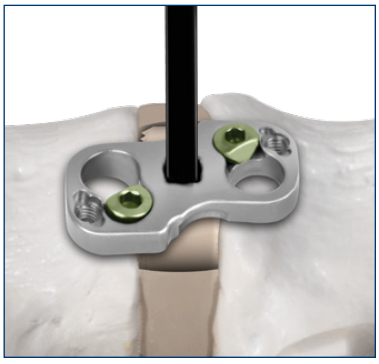
Option A: Plate Placement Using Anchor Threaded with TransContinental®

Place the **Anchor Threaded** into the TransContinental® Spacer. It is fully seated when resistance is felt. Placing the plate over this anchor enables it to rotate about the anchor. Guide and rotate the plate into place with the **Keying Sleeve for Threaded Anchor**. The keying sleeve slides over the anchor and through the square in the center of the plate, positioning the plate perpendicular to the spacer.

The Anchor Threaded and Keying Sleeve have black tips for identification.

Anchor Threaded inserted into TransContinental®

Positioning plate over anchor



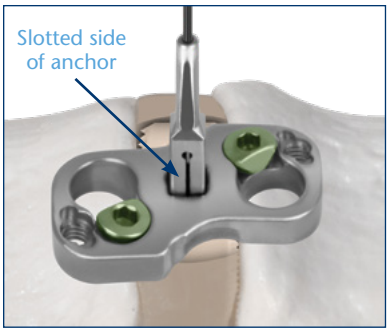
Placing the plate with the keying sleeve

Option B: Plate Placement Using Anchor Press Fit with TransContinental®

The **Anchor Press Fit** engages into the TransContinental® Spacer with a press fit. Align the slotted sides of these anchors in the anterior/posterior direction for a rigid fit.

The Anchor Press Fit aligns the plate to the spacer in the cephalad/caudal direction and does not require a keying sleeve for positioning, as shown at right.

Note: The Anchor Press Fit has a silver tip.

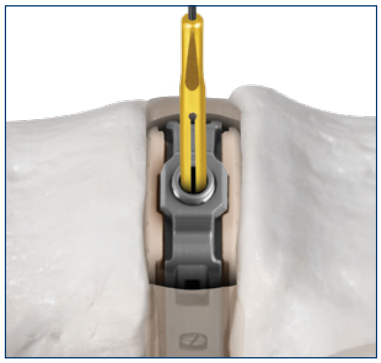


Anchor Press Fit in TransContinental®

Option C: Plate Placement Using Anchor for Hex with CALIBER®-L

The **Anchor for Hex** has a press fit connection that fits into the hex of the CALIBER®-L Spacer and enables the plate to rotate about the anchor. The **Keying Sleeve for Hex** may be placed over this anchor to position the plate, using the arm to guide the plate into place. The arm will key into a slot on the side of the spacer. A keying sleeve for each width (18mm and 22mm) is provided.

The Anchor for Hex and Keying Sleeves for Hex have a gold tip for identification.



Anchor for Hex inserted into CALIBER®-L

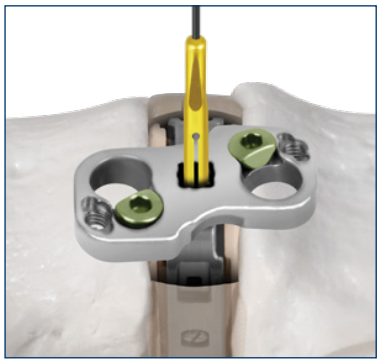
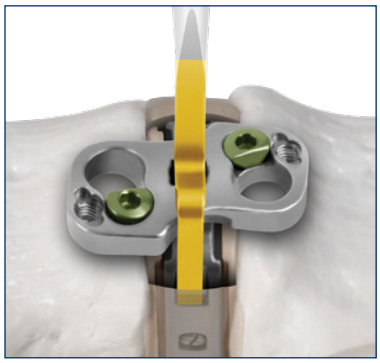


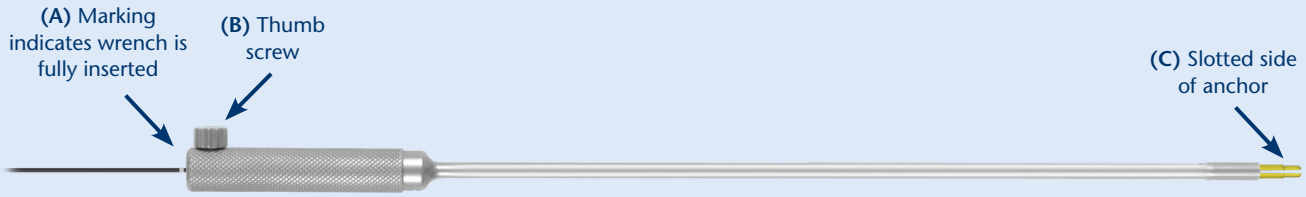
Plate placed over anchor



Positioning plate with keying sleeve

Using the Anchor Wrench

All anchors should be placed with the **Anchor Wrench**.



Ensure the Anchor Wrench is open by rotating the thumb screw counterclockwise. Slide the wrench over the desired anchor. When the marking on the anchor wire **(A)** meets the top of the wrench, the Anchor Wrench is fully inserted.

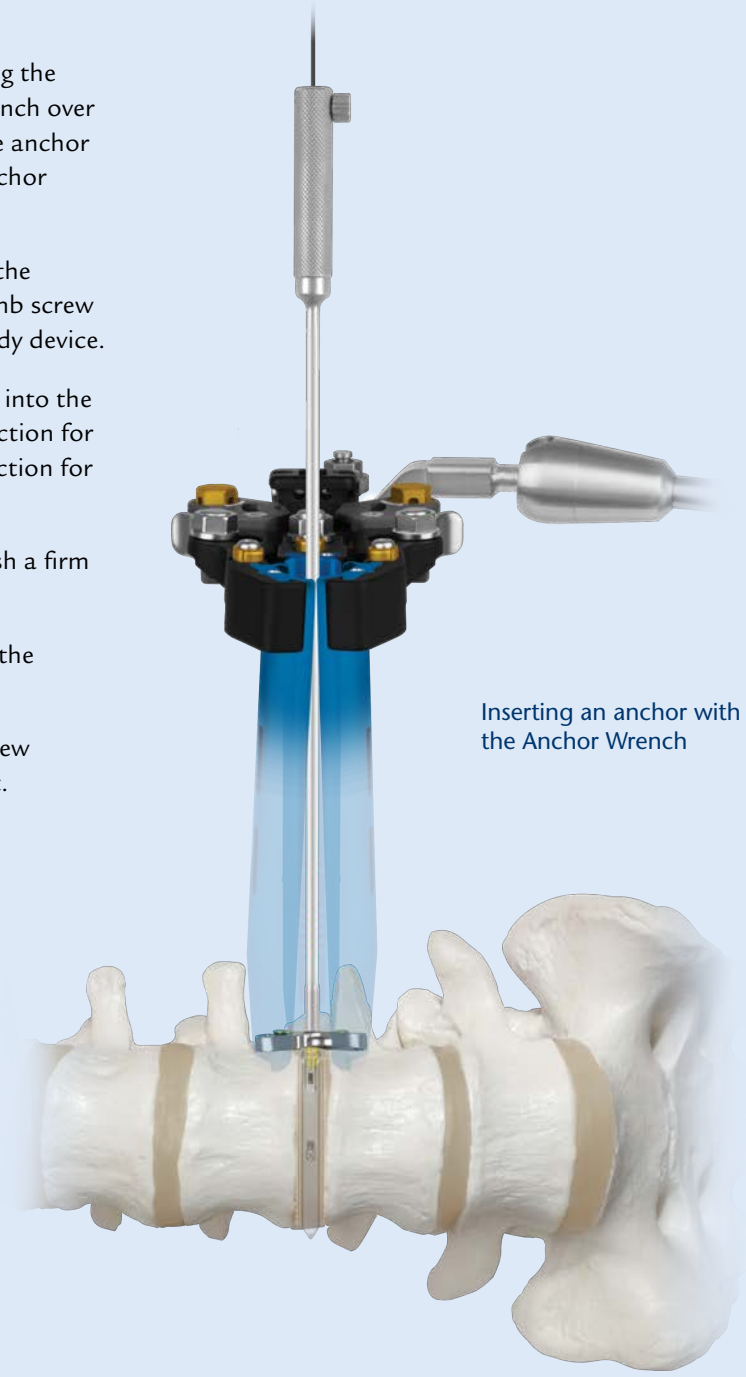
Align the thumb screw **(B)** on the wrench to the slotted side of the anchor **(C)**, using the thumb screw as a reference for placement into the interbody device.

Align the slotted sides of the selected anchor into the interbody device in the cephalad/caudal direction for a toggle fit and in the anterior/posterior direction for a more rigid fit.

Rotate the thumb screw clockwise to establish a firm connection with the anchor.

Using the wrench, insert the anchor through the retractor and into the interbody device.

Unlock the wrench by rotating the thumb screw counterclockwise and remove the instrument.



Inserting an anchor with the Anchor Wrench

Plate Placement (cont'd)

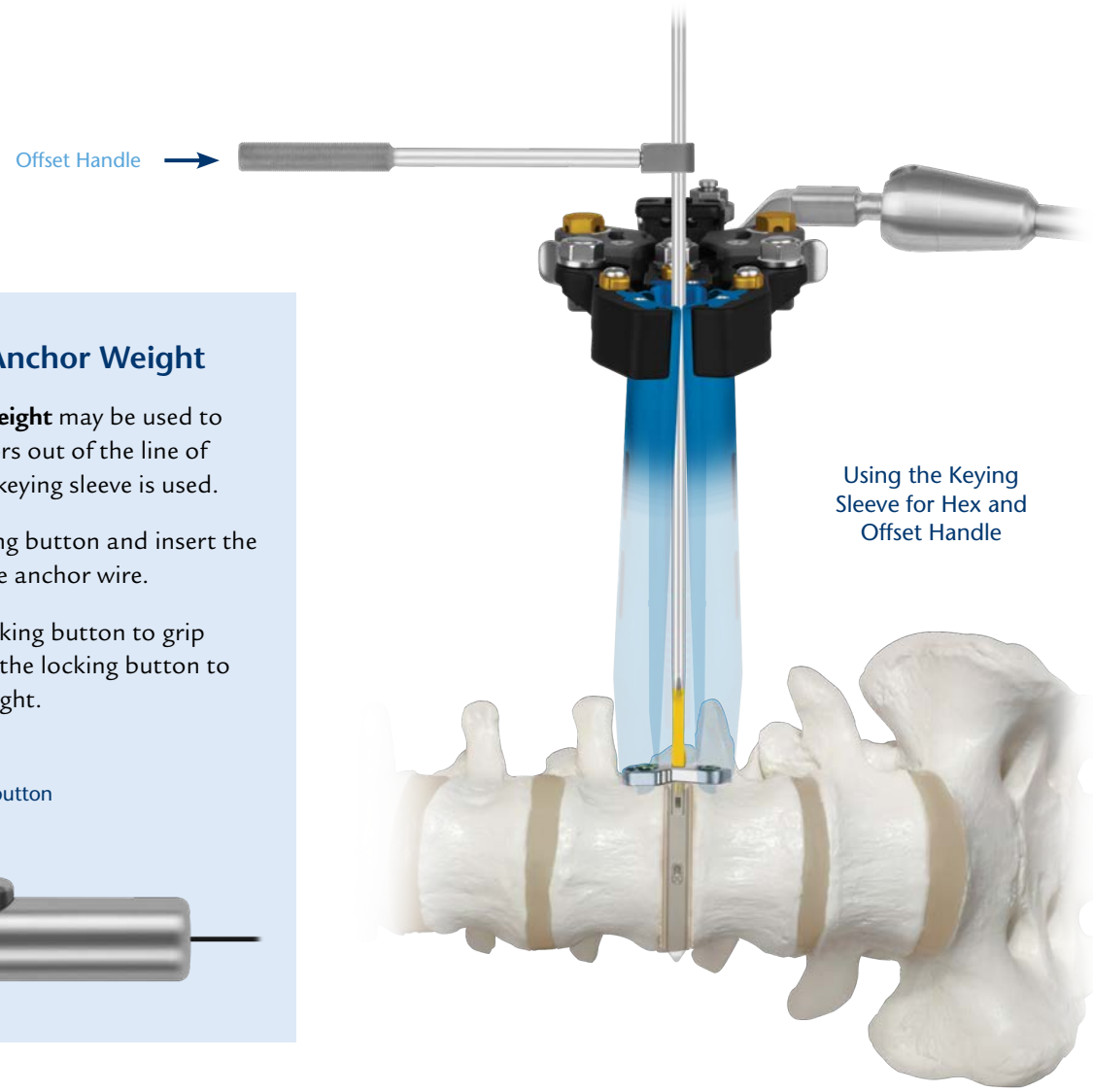
Option D: Plate Placement Using Keying Sleeves

Keying sleeves are used with either the Anchor Threaded or Anchor for Hex.

Once the anchor is in place and the plate has been placed, the Keying Sleeve for Threaded Anchor or Keying Sleeve for Hex (18mm or 22mm) may be placed over the anchor to assist in holding the plate in the desired position for screw insertion, as shown below.

The **Offset Handle** may be used to assist in holding the sleeve. Slide the handle over the keying sleeves for added stability.

Note: The Keying Sleeve for Threaded Anchor is used with the Threaded Anchor and TransContinental®.
The Keying Sleeve for Hex is used only with the Anchor for Hex and CALIBER®-L.
The Hex Keying Sleeves match the CALIBER®-L widths (18mm and 22mm).



Using the Keying Sleeve for Hex and Offset Handle

Using the Anchor Weight

The **Anchor Weight** may be used to hold the anchors out of the line of sight when no keying sleeve is used.

Press the locking button and insert the weight onto the anchor wire.

Release the locking button to grip the wire. Press the locking button to remove the weight.

Plate Placement (cont'd)

Option E: Plate Placement Using the Plate Inserter with Anchors

The **Plate Inserter** may be used with the Anchor Press Fit, Anchor for Hex or the Anchor Threaded.

Place the Plate Inserter around the waist of the plate and lock into position by rotating the knurled knob clockwise. The plate will be loaded perpendicular to the inserter and should be articulated to the vertical position for insertion.

Note: For ease of loading, place the plate on a table and attach the Plate Inserter.

Insert the plate over the anchor, as shown. Once in position, release the plate by rotating the knurled knob of the Inserter counterclockwise.

The **Threaded Plate Holder** may be secured into the threaded holes of the plate to guide the plate over the anchor.

Self-Positioning Plate Inserter

Threaded holes in plate

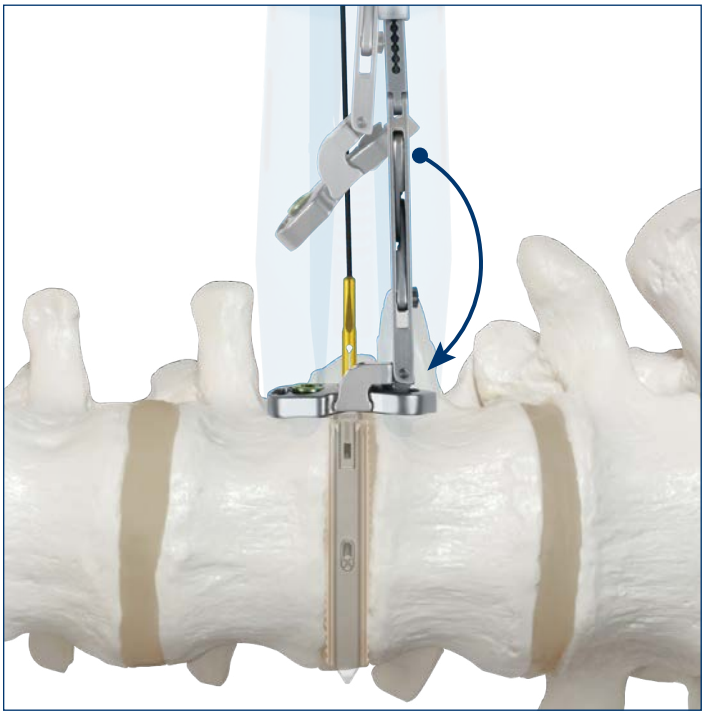


Plate Inserter sliding over the Anchor for Hex

Option F: Plate Placement Using the Articulating Holder

If plate placement is not intended to be aligned with the spacer, the **Articulating Holder** may be used. The Articulating Holder holds the plate parallel to the instrument shaft to allow insertion with minimal retraction and then rotates the plate into the desired position.

Slide the outer sleeve forward (A) to compress the holder tips and insert into the central hole within the plate. The markings on the holder should face the screw holes (B).

Once the plate is loaded, slide the outer sleeve back (C) and press the lock (D) to secure the connection. Rotate the knurled knob clockwise (E) to move the plate into the parallel position.

Place the plate through the retractor and rotate the knurled knob counterclockwise to move the plate onto the vertebrae. To release the plate, slide the outer sleeve forward.

Placing the plate with the Articulating Holder freehand

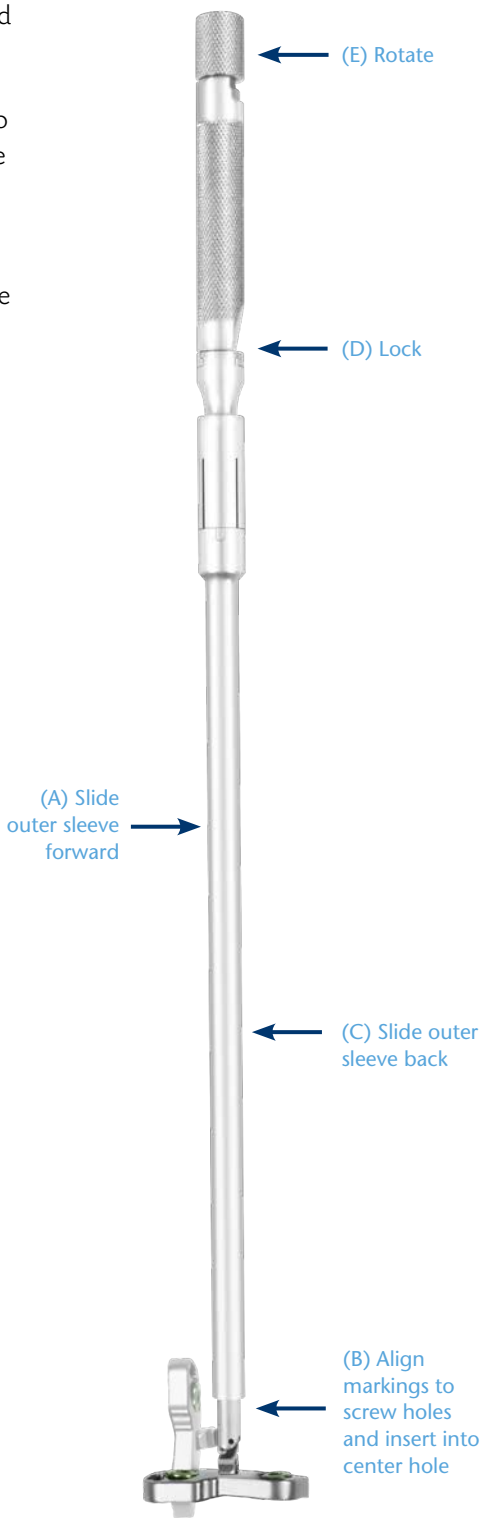


Plate Placement (cont'd)

Option G: Plate Placement Using the Offset Keying Tool

The **Offset Keying Tool** may also be used to assist in holding the plate in position for screw insertion. This keying tool allows the plate to be placed 7–12.5mm offset from the center of the interbody device.

Place the plate with the Threaded Plate Holder and insert the Offset Keying Tool.

The short arm of the Offset Keying Tool should be inserted into the central hole of the plate and the long arm should be placed into the interbody device.

Remove the holder and adjust plate placement as needed.

Note: The Offset Keying Tool is compatible with TransContinental® only.

Using the Offset Keying Tool

Anchor inserted into Plate

Step 4 Screw Hole Preparation

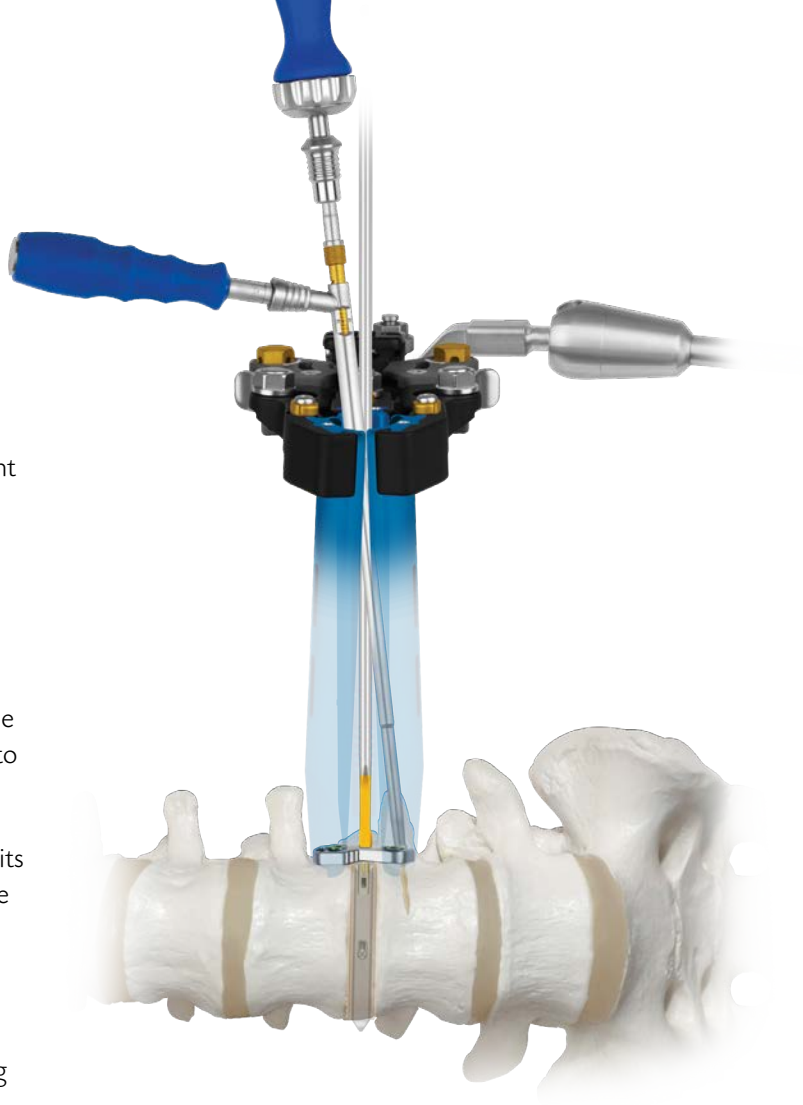
Screw hole preparation can be performed with or without anchoring. The following describes how to achieve screw hole preparation using any of the anchored plate placement options as demonstrated in step 3.

Option A: Drill Guide Variable Angle, Adjustable Depth

Use the **Cortex Awl, 1/4" QC** and **Quick Release Ratcheting Handle** assembly to perforate the cortex of the vertebral body. Press down on the awl to allow the sleeve to retract while the tip penetrates the vertebral body.

The **Drill Guide Variable Angle, Adjustable Depth** permits full angulation of the drill through the plate. This drill guide should only be used to create a trajectory for the variable angle screws. Adjust the depth as described below.

Place the drill guide into the plate hole. Attach the **Drill Bit, Adjustable Depth** to a 1/4" Quick Release Ratcheting Handle, and insert through the drill guide. Drill until it reaches the stop.

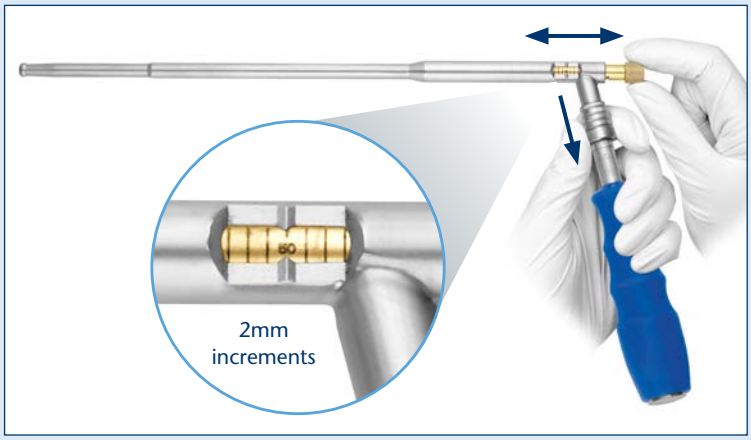


Using the Drill Guide, Variable Angle, Adjustable Depth to prepare pilot hole

Using the Drill Guide Variable Angle, Adjustable Depth

Pull down on the tapered sleeve to release the ratchet. Adjust the drill stop until the appropriate depth is indicated.

Release the sleeve to lock the drill guide at the appropriate depth. Ensure that the ratchet is full engaged by pressing on the drill stop.



Drill Guide Variable Angle, Adjustable Depth

Drill Bit Adjustable Depth

Screw Hole Preparation (cont'd)

Option B: Preset Angulation

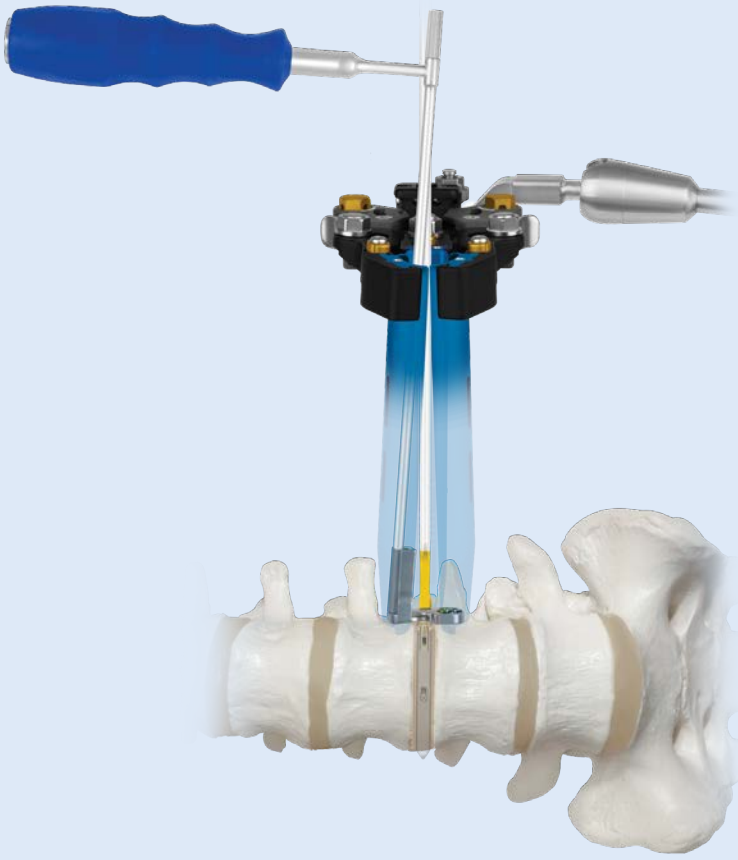
Secure the **DTS Guide, Preset Angle** into a threaded hole in the plate. The DTS guides provide a pre-set angulation of 5° in the cephalad/caudal directions. Positioning tabs assist in placing the guide. The DTS guide can be attached to the plate with an anchor and keying sleeve in place.

Note: To minimize retraction, attach the DTS guide after the plate is in place.

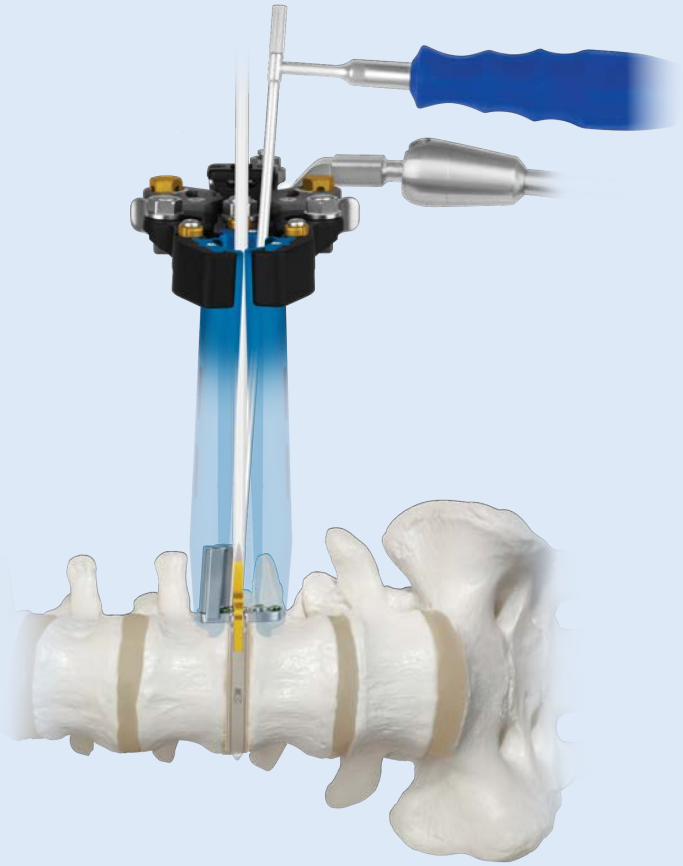
Attaching the DTS Guides

The DTS Guide, Preset Angle is designed to be used with 2 screw hole plates. The DTS Guide, Preset Angle, 4 Screw is designed to be used with 4 screw hole plates.

When using the DTS guides, the handle should be oriented in the cephalad/caudal direction. Direct the handle of the DTS Guide, Preset Angle away from the center of the plate. Direct the handle of the DTS Guide, Preset Angle, 4 Screw toward the center of the plate.



2-SCREW
Handle orientation for the DTS Guide, Preset Angle



4-SCREW
Handle orientation for the DTS Guide, Preset Angle, 4 Screw

Option B: Preset Angulation (cont'd)

DTS guides may be used to awl, drill and tap for screw hole preparation.

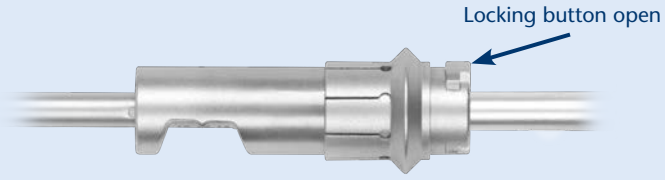
Choose the appropriate **DTS Guide Sleeve** and slide it over the awl, drill or tap, with the slotted end of the sleeve towards the back of the instrument.

Adjust the depth stop as shown at right and insert the guide sleeve assembly into the DTS guide.

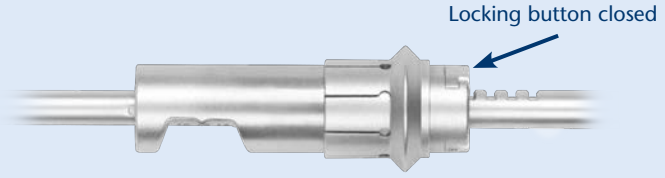
Using the adjustable depth drill bit through the DTS guide

Using the Awl, Drill and Tap with Adjustable Stop

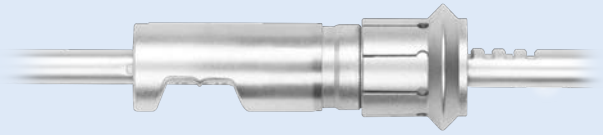
Slide the locking sleeve towards the tip of the instrument to expose the release button. Press the release button forward and slide the depth indicator to the desired depth.



Once depth has been selected, press the release button back to its initial position so it is flush with the indicator.

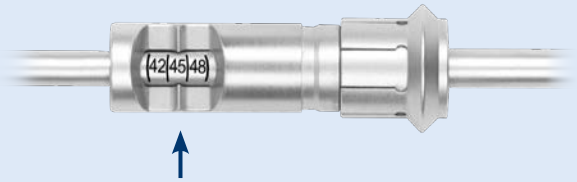


Slide the locking sleeve over the flush release button to position at the desired depth.



Attach the corresponding sleeve before using the awl, drill, or tap.

The sleeve acts as a stop and must be used with an awl, drill or tap. Ensure the distal tip of the sleeve is fully seated into the plate to achieve the appropriate depth.



Adjustable stop set to 45mm

Drill Bit and DTS Guide Sleeve assembly

Screw Hole Preparation (cont'd)

Option C: Adjustable Depth Awl, Drill and Tap, Freehand

Alternatively, the **Adjustable Depth Awl, Drill** and **Tap** can be used without a drill guide to achieve variable angulation.

Ensure the appropriate depth is set and the sleeve is attached before using.

Using the adjustable depth drill

Step 5 Screw Insertion

Bone screws are available in variable angle and fixed angle options. Screw lengths are measured by bone engagement and range from 22mm to 57mm, in 2mm increments (3mm increments for screws longer than 30mm).

Note: Anchors are removed before the screws are fully seated.

Select the appropriate screw length. Use the **Screwdriver, 3.5mm Hex, Self-Retaining** to load the screw from the screw module. Alternately, the **Screwdriver Shaft, 3.5mm Hex, 1/4" QC, Self-Retaining** may be used in conjunction with a 1/4" Quick Release Ratcheting Handle to insert the screws.

Inserting screw with 3.5mm Hex Driver

Screw Insertion (cont'd)

Before screw insertion, confirm screw length using the gauge provided in the screw module.

The **Screwdriver Sleeve** may be attached to the 3.5mm Hex Driver for soft tissue protection.

Using the
Screwdriver Sleeve

Step 6 Blocking Set Screw

Once all of the screws are fully seated within the plate, the blocking set screw can be rotated into position.

Insert the **Set Screw Positioner, Torque Limiting, 1.5Nm** into the blocking set screw, ensuring that the hex is fully seated in the screw head. Rotate the Set Screw Positioner clockwise to the click. The flat on the blocking set screw should be facing away from the screw head when locked, as shown below.

Unlocked

Locked

Final Construct: Two Screw Plate

Lateral View

Anterior View

Final Construct: Four Screw Plate

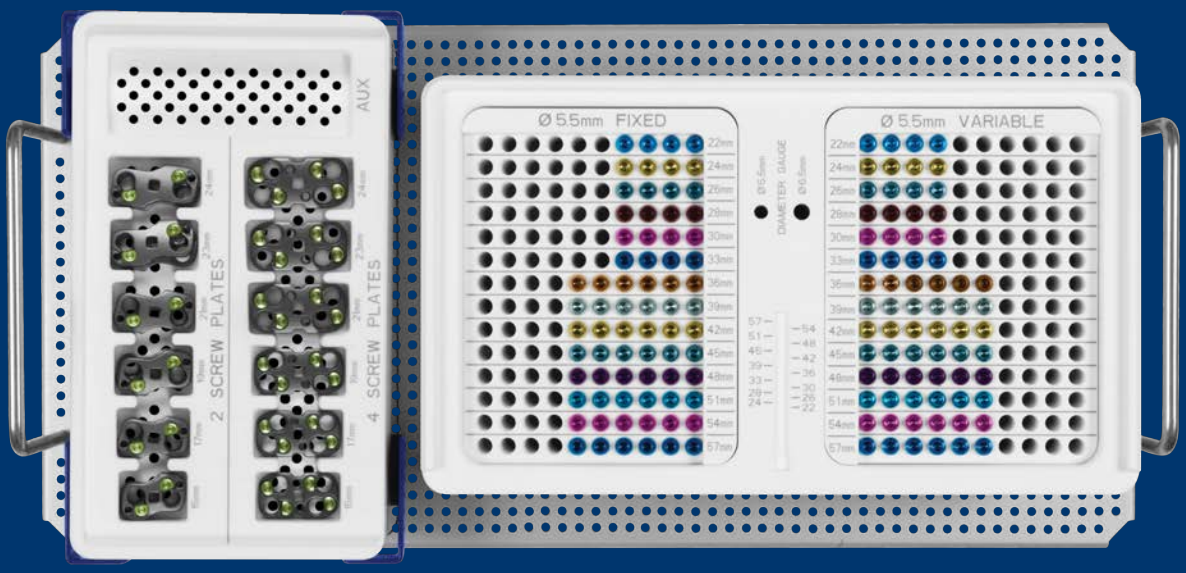
Lateral View

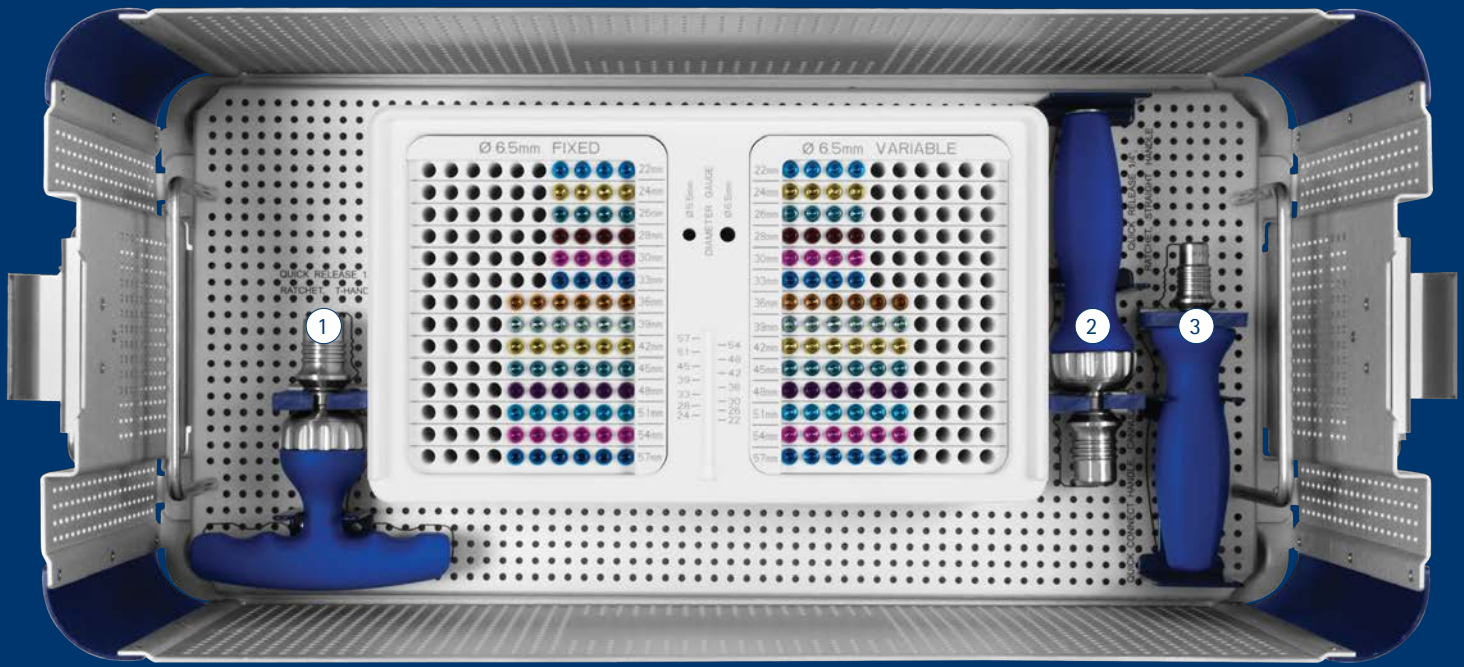
Anterior View

Optional: Implant Removal

To remove the plates, unlock the blocking set screw using the Set Screw Positioner, Torque Limiting, 1.5Nm. Loosen and remove the bone screws using the 3.5mm Hex Driver. Once all screws have been removed, the plate can be removed using a grasping instrument, plate holder, or DTS guide.

PLYMOUTH® IMPLANT SET





PLYMOUTH® Implant Set 9105.9002

PLYMOUTH® Two Screw Plates

Description		Qty
1105.1009	PLYMOUTH® Plate, 15mm	2
1105.1011	PLYMOUTH® Plate, 17mm	2
1105.1013	PLYMOUTH® Plate, 19mm	2
1105.1015	PLYMOUTH® Plate, 21mm	2
1105.1017	PLYMOUTH® Plate, 23mm	2
1105.1018	PLYMOUTH® Plate, 24mm	2

PLYMOUTH® Four Screw Plates

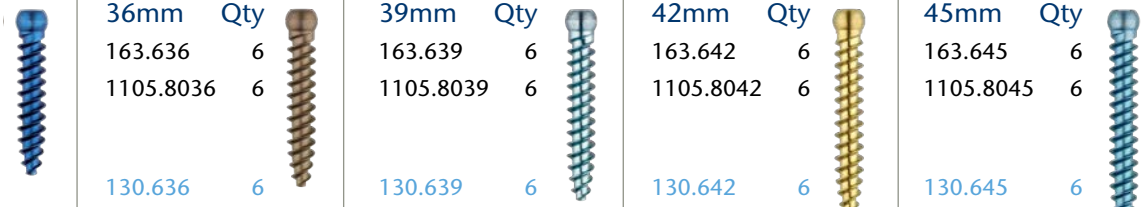
Instruments		Qty
1105.2009	PLYMOUTH® Plate, 4-Screw, 15mm	1
1105.2011	PLYMOUTH® Plate, 4-Screw, 17mm	1
1105.2013	PLYMOUTH® Plate, 4-Screw, 19mm	1
1105.2015	PLYMOUTH® Plate, 4-Screw, 21mm	1
1105.2017	PLYMOUTH® Plate, 4-Screw, 23mm	1
1105.2018	PLYMOUTH® Plate, 4-Screw, 24mm	1

PLYMOUTH® Screws

Variable angle screw part numbers start with 130.xxx and 163.xxx
Fixed angle screw part numbers start with 1105.xxxx

	22mm	Qty	24mm	Qty	26mm	Qty	28mm	Qty	30mm	Qty
5.5mm										
Variable	163.622	4	163.624	4	163.626	4	163.628	4	163.630	4
Fixed	1105.8022	4	1105.8024	4	1105.8026	4	1105.8028	4	1105.8030	4
6.5mm										
Variable	130.622	4	130.624	4	130.626	4	130.628	4	130.630	4
Fixed	1105.9022	4	1105.9024	4	1105.9026	4	1105.9028	4	1105.9030	4

	33mm	Qty	36mm	Qty	39mm	Qty	42mm	Qty	45mm	Qty
5.5mm										
Variable	163.633	4	163.636	6	163.639	6	163.642	6	163.645	6
Fixed	1105.8033	4	1105.8036	6	1105.8039	6	1105.8042	6	1105.8045	6
6.5mm										
Variable	130.633	4	130.636	6	130.639	6	130.642	6	130.645	6
Fixed	1105.9033	4	1105.9036	6	1105.9039	6	1105.9042	6	1105.9045	6

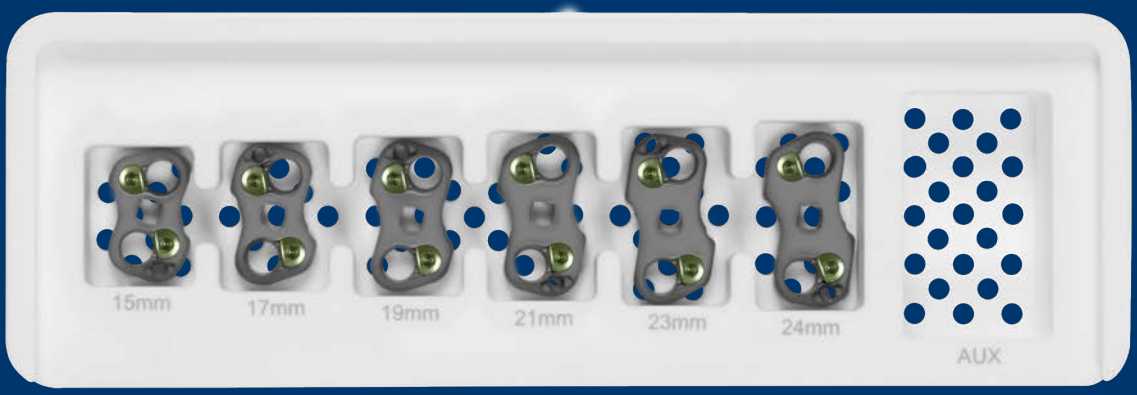


	48mm	Qty	51mm	Qty	54mm	Qty	57mm	Qty
5.5mm								
Variable	163.648	6	163.651	6	163.654	6	163.657	6
Fixed	1105.8048	6	1105.8051	6	1105.8054	6	1105.8057	6
6.5mm								
Variable	130.648	6	130.651	6	130.654	6	130.657	6
Fixed	1105.9048	6	1105.9051	6	1105.9054	6	1105.9057	6

PLYMOUTH® Instruments

	Description		Qty	Description	
1	630.401	Quick Release 1/4", Ratchet, T-Handle	1	9105.0004	Plate Module
2	630.407	Quick Release 1/4", Ratchet, Straight Handle	1	963.006	5.5mm Screw Module
3	648.400	Quick Connect Handle, Cannulated	1	9105.0008	6.5mm Screw Module
	9105.0002	Implant Graphic Case			

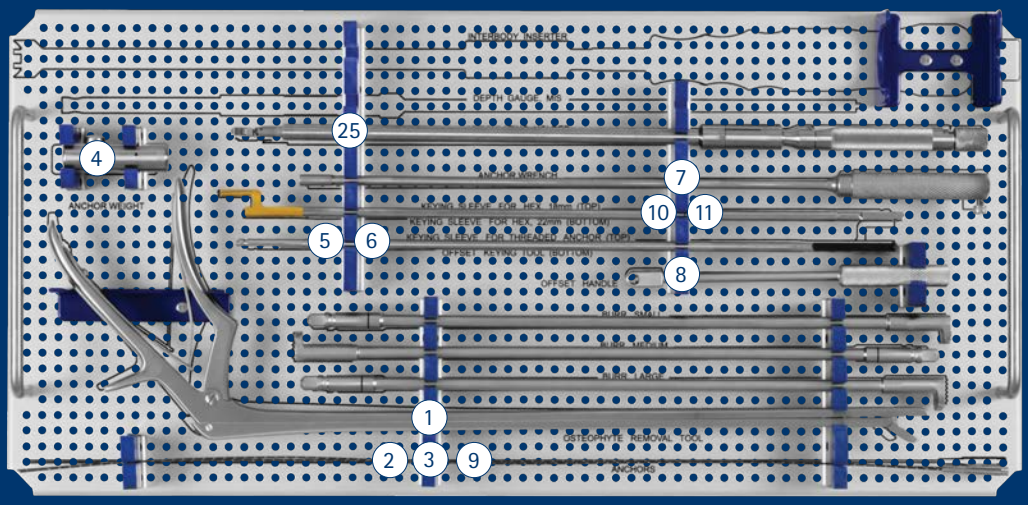
PLYMOUTH® L4-L5 PLATE SET

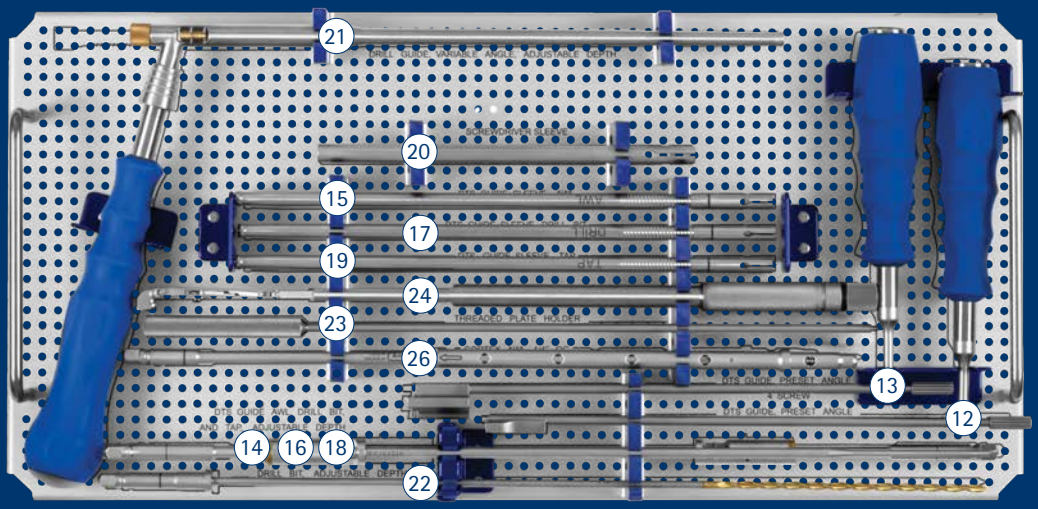


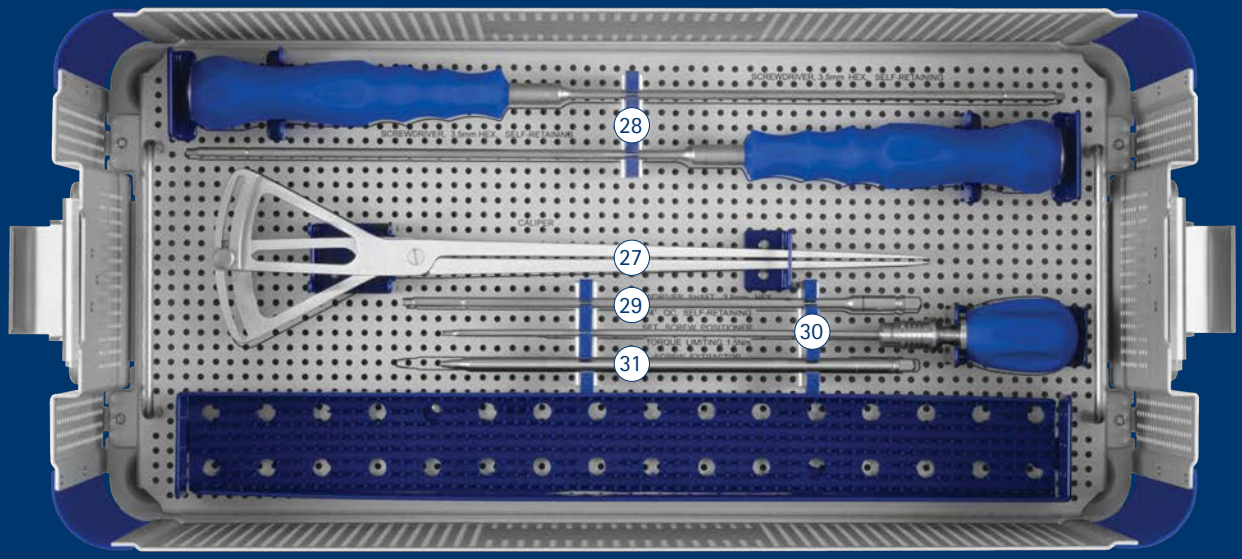
PLYMOUTH® L4-L5 Plate Set 9105.9005

Description		Qty
1105.3009	PLYMOUTH® Plate, L4-L5, 15mm	1
1105.3011	PLYMOUTH® Plate, L4-L5, 17mm	1
1105.3013	PLYMOUTH® Plate, L4-L5, 19mm	1
1105.3015	PLYMOUTH® Plate, L4-L5, 21mm	1
1105.3017	PLYMOUTH® Plate, L4-L5, 23mm	1
1105.3018	PLYMOUTH® Plate, L4-L5, 24mm	1
9105.0005	PLYMOUTH® Plate Module, L4-L5	1

PLYMOUTH® INSTRUMENT SET







PLYMOUTH® Instrument Set 9105.9001

	Instruments		Qty
1	6105.2016	Osteophyte Removal Tool	1
2	6105.3010	Anchor Threaded	1
3	6105.3012	Anchor Press Fit	1
4	6105.3016	Anchor Weight	1
5	6105.3020	Keying Sleeve for Threaded Anchor	1
6	6105.3022	Offset Keying Tool	1
7	6105.3030	Anchor Wrench	1
8	6105.3040	Offset Handle	1
9	6105.3050	Anchor for Hex	1
10	6105.3055	Keying Sleeve for Hex, 18mm	1
11	6105.3057	Keying Sleeve for Hex, 22mm	1
12	6105.4000	DTS Guide, PreSet Angle	1
13	6105.4004	DTS Guide, PreSet Angle, 4 Screw	1
14	6105.4010	DTS Guide Awl, Adjustable Depth	1
15	6105.4012	DTS Guide Sleeve, Awl	1
16	6105.4020	DTS Guide Drill, Adjustable Depth	1
17	6105.4022	DTS Guide Sleeve, Drill	1
18	6105.4030	DTS Guide Tap, Adjustable Depth	1
19	6105.4032	DTS Guide Sleeve, Tap	1
20	6105.4040	Screwdriver Sleeve	1
21	663.401	Drill Guide Variable Angle, Adjustable Depth	1
22	663.402	Drill Bit, Adjustable Depth	1
23	6105.5010	Threaded Plate Holder	1
24	6105.5012	Plate Inserter	1
25	6105.5030	Articulating Holder	1
26	630.316	Cortex Awl, 1/4” QC	1
27	663.403	Caliper	1
28	630.410	Screwdriver, 3.5mm Hex, Self-Retaining	2
29	630.414	Screwdriver Shaft, 3.5mm Hex, 1/4” QC, Self-Retaining	1
30	630.503	Set Screw Positioner, Torque Limiting, 1.5Nm	1
31	6105.6000	3.5mm Hex Screw Extractor	1
	9105.0001	PLYMOUTH® Instrument Graphic Case	

Additionally Available

6105.1011	Depth Gauge, MIS
6105.2010	Burr, Small
6105.2012	Burr, Medium
6105.2014	Burr, Large
630.403	Quick Release 1/4”, Palm Handle (Non-Ratcheting)

IMPORTANT INFORMATION ON THE PLYMOUTH® THORACOLUMBAR PLATE SYSTEM

DESCRIPTION

The PLYMOUTH® Thoracolumbar Plate System consists of rigid plates of various lengths that are used with variable or fixed angle bone screws. These plates attach to the anterolateral or lateral portion of the vertebral body of the thoracolumbar spine (T1-L5). These implants are manufactured from titanium alloy, as specified in ASTM standards F136, F1295 and F1472.

INDICATIONS

The PLYMOUTH® Thoracolumbar Plate System is intended for use in the treatment of thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or failed previous spine surgery.

WARNINGS

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Possible adverse effects which may occur and may require additional surgery include: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; loss of fixation; vertebral fracture; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

The components of this system are manufactured from titanium alloy or stainless steel. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons. Components of this system should not be used with components of any other system or manufacturer, unless specifically stated.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

PRECAUTIONS

The implantation of screw and plate systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting screw diameter and length.

The PLYMOUTH® Thoracolumbar Plate System has not been evaluated for safety and compatibility in the MR environment. The PLYMOUTH® Thoracolumbar Plate System has not been tested for heating or migration in the MR environment.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

CONTRAINDICATIONS

Use of PLYMOUTH® Thoracolumbar Plate System is contraindicated in patients with the following conditions:

1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis, which may prevent adequate fixation.
4. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
5. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
6. Any condition not described in the indications for use.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

IMPORTANT INFORMATION ON THE PLYMOUTH® THORACOLUMBAR PLATE SYSTEM

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.* It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132° C (270° F)	4 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal Law (USA) Restricts this Device to Sale by or on the order of a Physician.

DI163A
REV B

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