Life moves us

SURGICAL TECHNIQUE




TRUSS™

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's 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

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TRUSS™

Thoracolumbar Plate System

The TRUSS™ Thoracolumbar Plate System has a slim, low profile design to accommodate the entire thoracolumbar spine. Intra-operative compression and optimal screw placement are achieved by way of an integrated Slider™ mechanism, while fixed or variable screws are used to lag the plate to the bone.

TRUSS™
THORACOLUMBAR PLATE SYSTEM

Slim Plate Design

TRUSS™ offers a slim plate design that fits the lateral aspect of the upper thoracic vertebra, and is able to withstand lumbar loads.

Integrated Intra-operative Compressibility

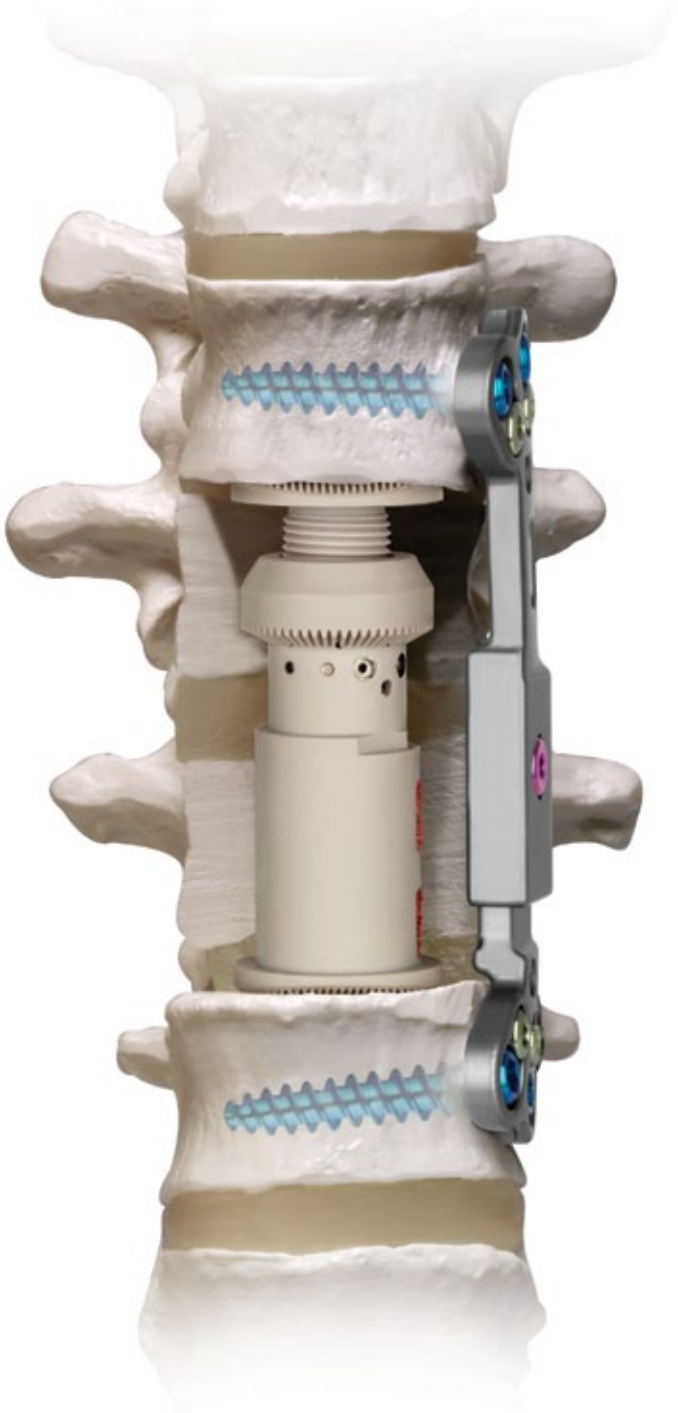
The TRUSS™ plate has an integrated Slider™ mechanism that provides up to 7.5mm of compression.

Minimal Steps for Installation

Five implants (one plate and four screws) to install, then simply block and lock with a single instrument.

Comprehensive Offering

TRUSS™ offers two low profile plate options with fixed or variable screws that are inserted with easy to use instrumentation.



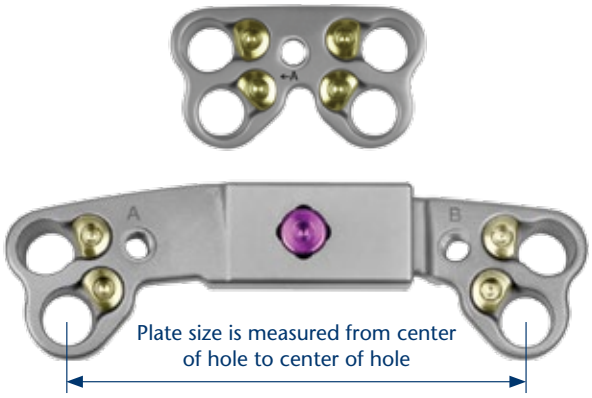
CONTENTS

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

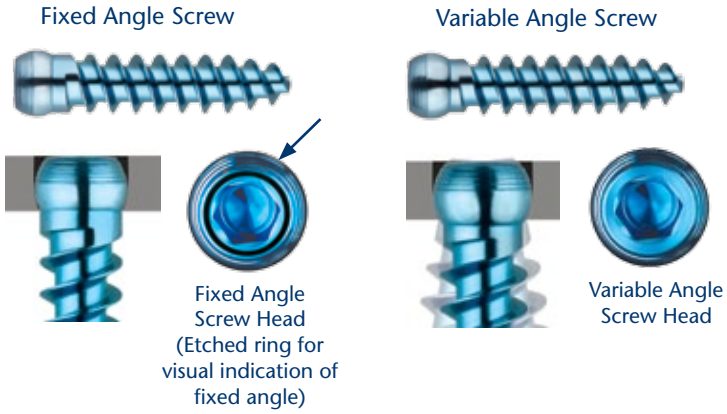
Plates

- Low-profile – 4.0mm thick
- 21mm width
- Lengths range from 22mm to 99.5mm
- Compressible plate lengths range from 45mm to 99.5mm

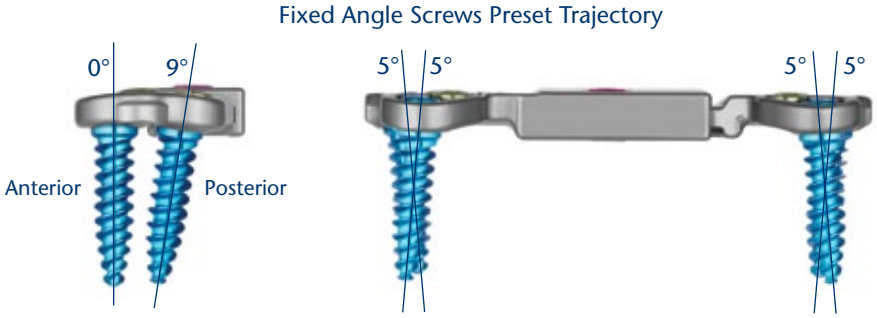


Bone Screws

- Lengths from 22mm-57mm
- 5.5mm and 6.5mm* diameter
- Self-tapping screws
- Variable angle screws allow for ±10° of angulation



- Fixed angle screws pre-set trajectory
  - 0° anterior
  - 9° posterior
  - 5° cephalad/caudal



Locking Mechanism

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

* Recommended for use in the lumbar spine

INSTRUMENT OVERVIEW

Screw Preparation Instruments

Cortex Awl, 1/4" QC 630.316

Awl Sleeve Retracted

Awl, 1/4" QC 630.317

Drill Bit, 22mm, 1/4" QC 630.400*

Ø6.4mm, Tap 22mm, 1/4" QC 630.405

Ø4.4mm, Tap 1/4" QC 663.410

Ø5.4mm, Tap 1/4" QC 663.412

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

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

Screw Preparation Instruments (cont'd)

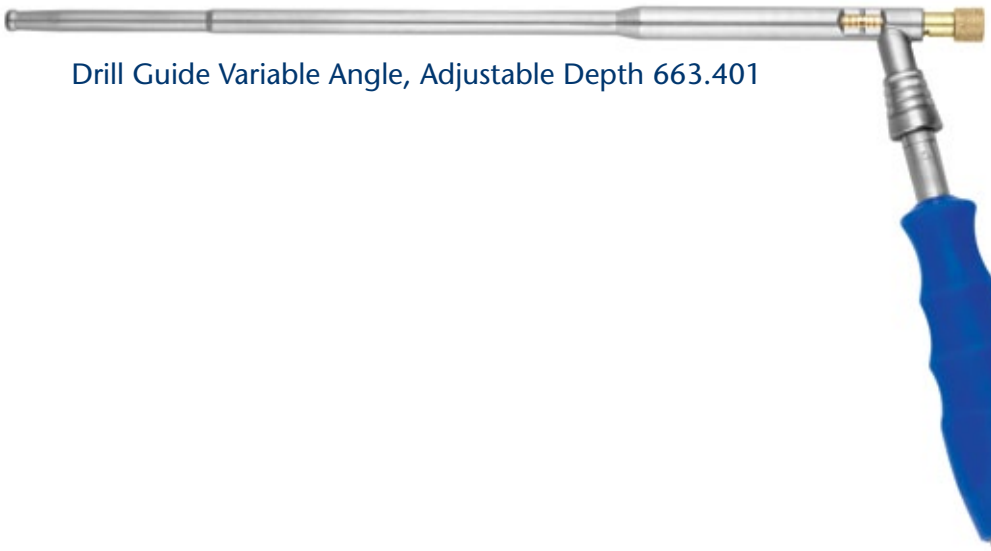
Ball Tip Probe 602.105

Plate Holder, DTS Guide Handle 663.340

Plate Holder DTS Guide, A Barrel 663.342

Plate Holder DTS Guide, B Barrel 663.344

Drill Guide, Freehand 630.336



Drill Guide Variable Angle, Adjustable Depth 663.401

Drill Bit, Adjustable Depth 663.402*

Plate Instruments

Caliper 663.403

Simple Plate Holder 663.338

Temporary Screw for Screw Holes, 16mm 663.500

Screwdriver, 2.5mm Hex, Self Retaining 650.301

Screwdriver, 3.5mm Hex, Self-Retaining 630.410

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

Universal Joint Instruments

Awl, 1/4” QC, U-Joint 630.493

Drill Bit, 22mm, 1/4” QC, U-Joint 630.495*

Screwdriver, 3.5mm Hex, 1/4” QC, U-Joint 630.495

Ø6.4mm Tap, 22mm, 1/4” QC, U-Joint 630.496

Drill Bit, 25mm, 1/4” QC, U-Joint 663.497*

Drill Bit, 30mm, 1/4” QC, U-Joint 663.498*

Drill Bit, 35mm, 1/4” QC, U-Joint 663.499*

* Drill bits are not intended for connection to power drill sources.

Ø4.4mm, Tap 1/4" QC, U-Joint 663.414

Ø5.4mm, Tap 1/4" QC, U-Joint 663.416

Hammer 603.977

Compression Instrument

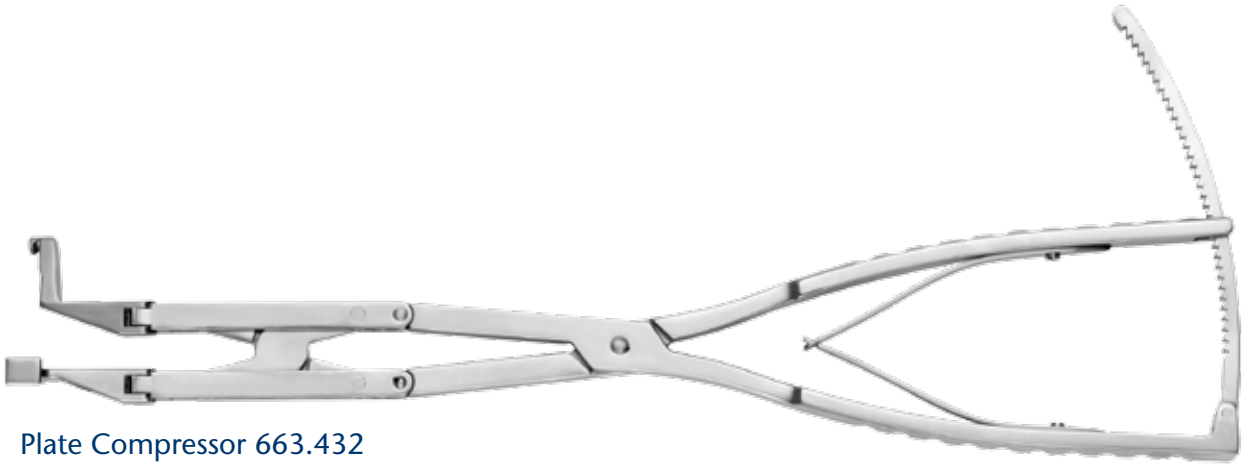


Plate Compressor 663.432

Locking Instrument

Set Screw Positioner, Torque Limiting, 1.5Nm 630.503

TRUSS™ SURGICAL TECHNIQUE

Step 1 Approach and Preparation

The patient is placed under general anesthesia and positioned in a true lateral position. It is important to maintain patient position throughout the procedure. In general, a left-sided approach is used for the thoracolumbar junction, while a right-sided approach is more common at higher thoracic levels.

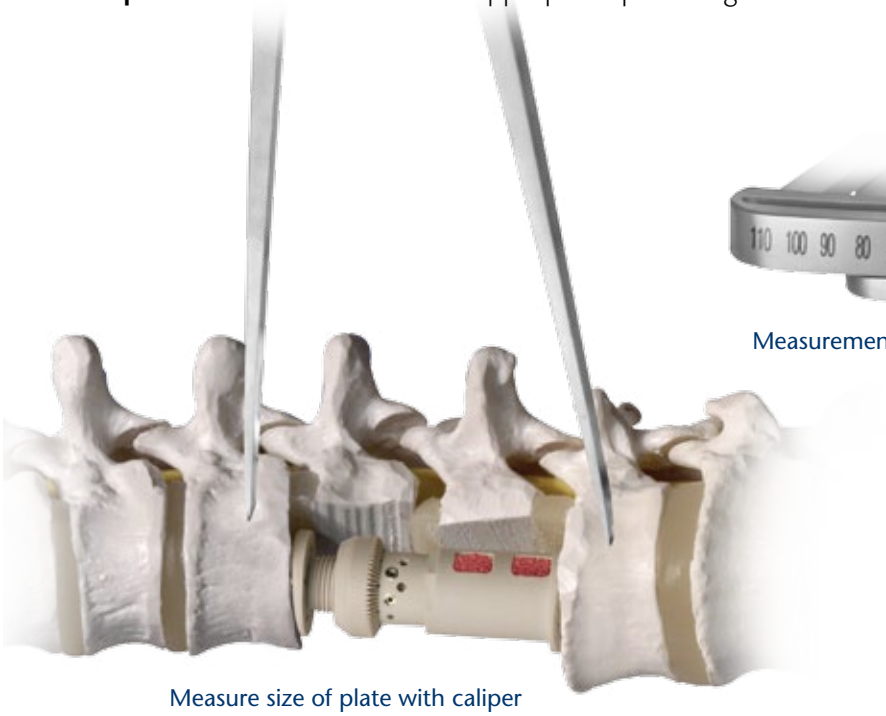
The operative area is carefully cleaned and an incision is made at the appropriate fusion level(s). TRUSS™ plate fixation may be used in the thoracolumbar spine between T1-L5. Please refer to the product insert for complete description, indications and warnings.

Perform a corpectomy (if needed) and remove the adjacent intervertebral discs. Distraction can be performed at this point using a vertebral body spreader.

Insert the desired veterbral body replacement device. The XPand® Radiolucent Corpectomy Spacer is shown below. Distraction can be achieved by using the XPand® R device. Refer to the XPand® Surgical Technique Guide for the recommended surgical technique.

Step 2 Plate Placement

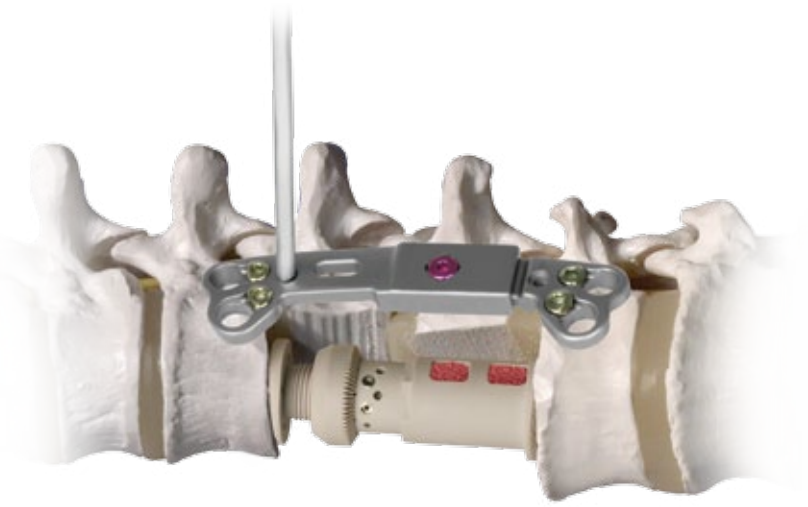
A **Caliper** is used to determine the appropriate plate length.



Measure size of plate with caliper

Measurement is read from the top of the caliper

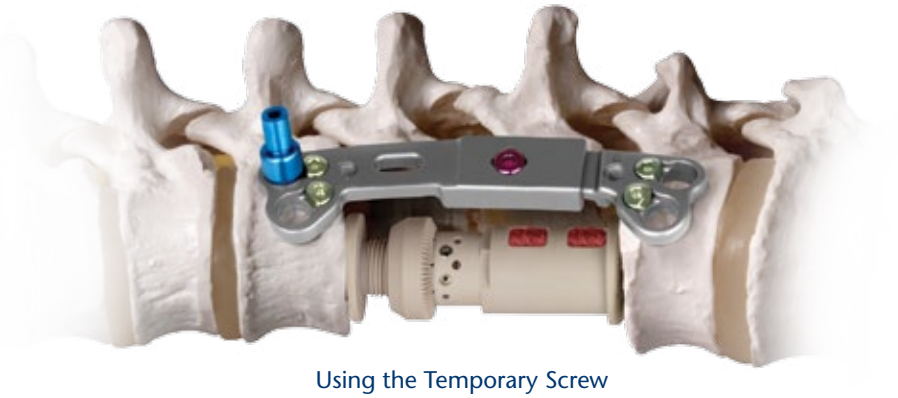
Using the **Simple Plate Holder**, remove the desired TRUSS™ plate from the plate module. Place over the vertebrae and confirm appropriate plate length. Alternately the **Plate Holder DTS Guide Assembly** can be used to insert the plate, as described on page 12.



Using the Simple Plate Holder

Once plate placement has been established, use the **Screwdriver, 2.5mm Hex, Self-Retaining** to insert the **Temporary Screw for Screw Holes, 16mm**.

The temporary screw can be inserted through the DTS Guide Barrels, if desired.



Using the Temporary Screw

Removing the Temporary Screw

The temporary screw may be removed with the Screwdriver, 2.5mm Hex, Self-Retaining. If a firmer connection is needed, load the **Temporary Pin Driver, External Grip** as descibed below.

Ensure the outer sleeve of the Temporary Pin Driver, External Grip is retracted before placing the inner shaft over the temporary screw head.

Engage the inner shaft of the Temporary Pin Driver, External Grip over the temporary screw head.

Slide the outer sleeve down over the temporary screw head and pull upwards on the handle to remove the screw.

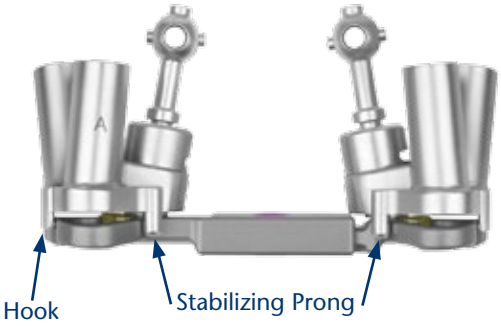
Step 3 Screw Hole Preparation

Option A: Pre-Set Angulation

Attach the Plate Holder DTS Guide Handle to the guide barrels as described at right. Two Plate Holder DTS (Drill-Tap-Screw) Barrels are available to securely hold the plate and provide a preset screw trajectory. Fixed screws should always be inserted through these barrels.

The barrels are labeled A and B to coincide with plate sides A and B.

To install the appropriate barrels on the corresponding side of the plate place the hook into the notch on the end of the plate, and place the threaded end of the barrels into the small hole on the plate. The stabilizing prong should be on the anterior side of the plate, as shown below.



Turn the blue handle clockwise to thread the barrels into the plate. Once the guide is securely connected to the plate, the knurled knob on the back of the Plate Holder DTS Guide Handle can be rotated clockwise to secure desired angle of the handle.

Connecting the DTS Guide Handle to DTS Guide Barrels

Retract on trigger of the DTS Guide handle.

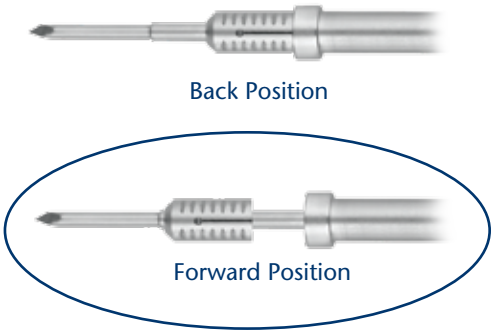
Engage prongs of DTS Guide handle around the sphere of the barrel. Release the trigger to connect the handle with the sphere on the DTS Guide.

DTS Guide Handle is now connected to the barrel.

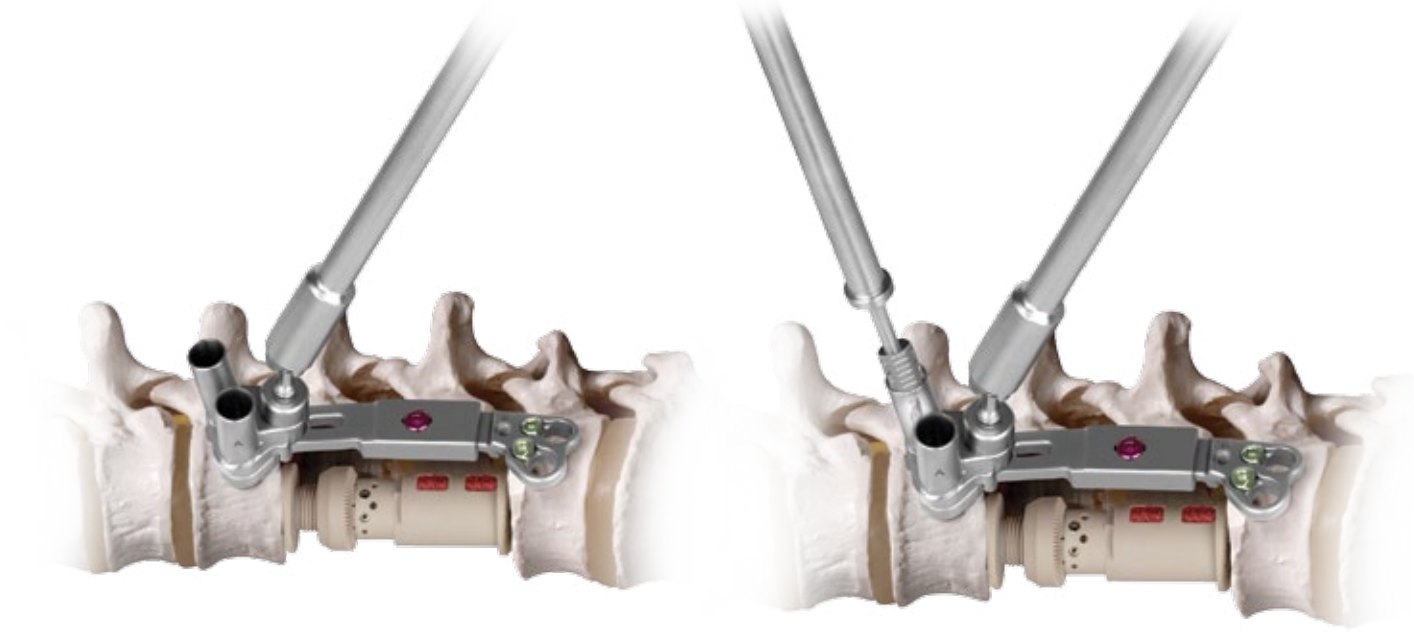
Attach the **Awl, 1/4" QC** to a **1/4" Quick Release Ratcheting Handle** and insert through the drill guide to perforate the cortex of the vertebral body. Drill the screw hole using the **Drill Bit, 22mm, 1/4" QC** and handle assembly.

Note: When connecting instruments to the Quick Release 1/4" Ratchet Handles, the instrument shaft should be inserted into the handles so that the black etch line is no longer visible.

When inserting the Drill Bit, 22mm, 1/4" QC or Awl, 1/4" QC through the DTS Guide Barrels, move the positioning sleeve to the forward position as shown at right. This will ensure the instrument is centered through the guide.



Awl or drill the hole until the shoulder stop contacts the top of the guide barrel.



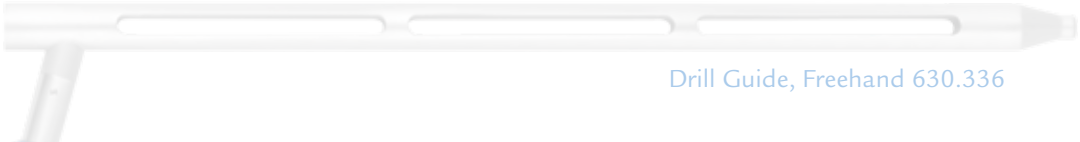
The screws are self-tapping, however the vertebral body may be tapped if desired. Attach the tap of appropriate diameter to one of the quick release ratcheting handles, and tap through the drill guide. To avoid stripping the screw hole, stop rotating the tap when its shoulder contacts the barrel of the guide.

Screws may be inserted through the Plate Holder DTS Guide. See page 16 for screw insertion.

Note: Only the DTS Guide A Barrel may be used with the 22mm and 25mm plates.

Universal Joint Instrumentation

A series of universal joint tools are provided for added flexibility. The **Awl, 1/4" QC, U-Joint** and **Drill Bit, 1/4" QC, U-Joint** can be used through all the drill guides provided, except the Adjustable Depth Drill Guide. The **Tap, 1/4" QC, U-Joint** can be used through the Plate Holder DTS Guide Barrels. Insert Universal Joint Instruments through the Plate Holder DTS Guide Barrel in the same manner as described above. A universal joint screwdriver is also provided and can be used for screw insertion through the Plate Holder DTS Guide Barrels.



Option B. Variable Angulation

Using the DTS Guide, Freehand

Prepare the pilot screw hole on the anterior-most portion of the plate, or opposite to the temporary screw. Use the **Cortex Awl, 1/4" QC** and 1/4" 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 cortex.

Alternately the Awl, 1/4" QC or Drill Bit, 22mm 1/4" QC can be connected to a 1/4" Quick Release Ratcheting Handle and inserted through the **Drill Guide, Freehand.**

The Drill Guide, Freehand 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.

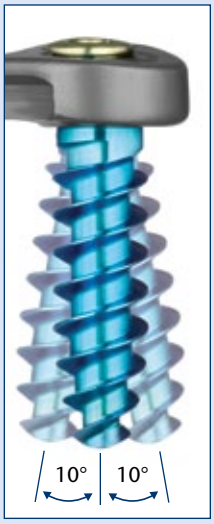
When inserting the Awl, 1/4" QC or Drill Bit, 22mm 1/4" QC through the Drill Guide, Freehand, move the positioning sleeve to the back position to be fully inserted. See image below.

Back Position

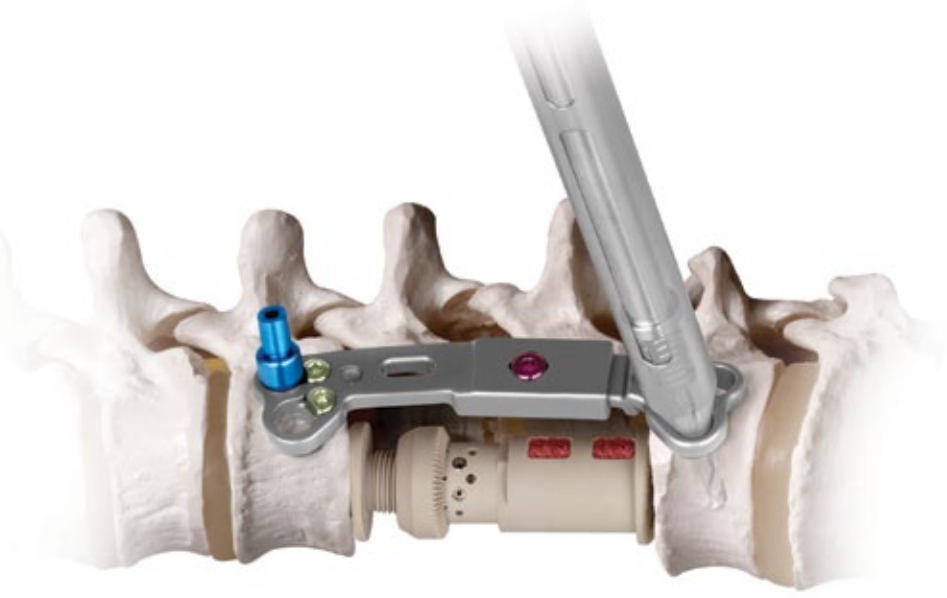
Place the drill guide into the plate hole. Attach the Drill Bit, 22mm, 1'/4" QC to a 1/4" Quick Release Ratcheting Handle, and insert through the drill guide. Drill until it reaches the stop.

Variable Angle Drill Guides

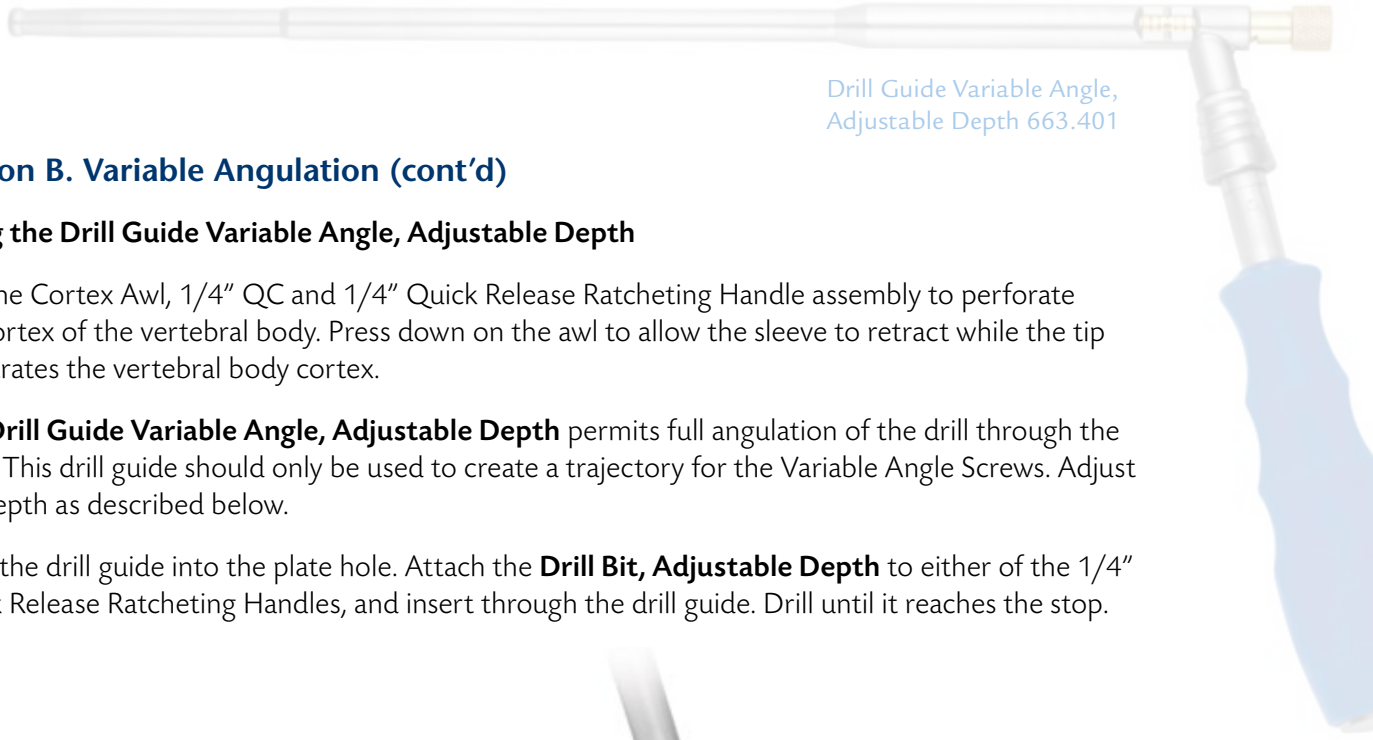
Provide screw angulation of ±10° in all directions for drilling screw pilot holes.



Note: Care should be taken to prevent interference in medial angulation.



Using the Drill Guide, Freehand to prepare screw pilot hole



Drill Guide Variable Angle,
Adjustable Depth 663.401

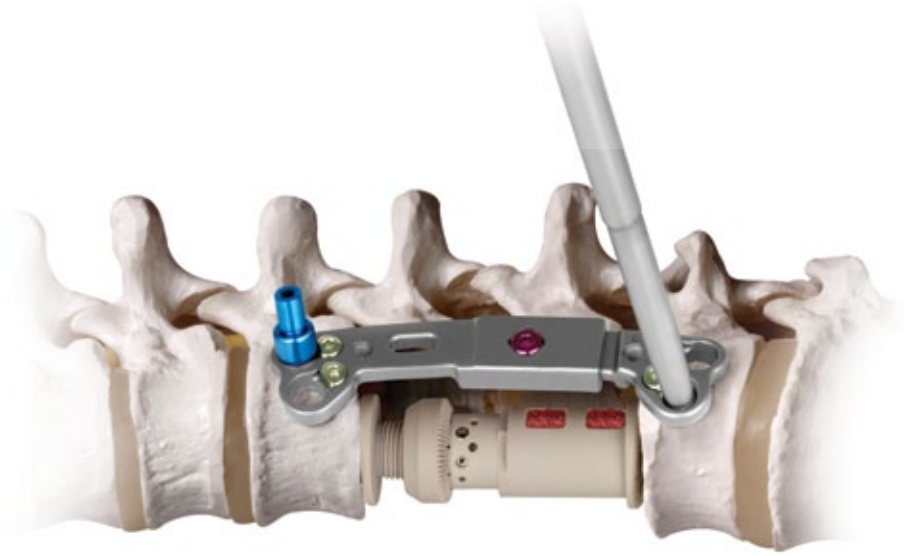
Option B. Variable Angulation (cont'd)

Using the Drill Guide Variable Angle, Adjustable Depth

Use the Cortex Awl, 1/4" QC and 1/4" 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 cortex.

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 either of the 1/4" Quick Release Ratcheting Handles, and insert through the drill guide. Drill until it reaches the stop.

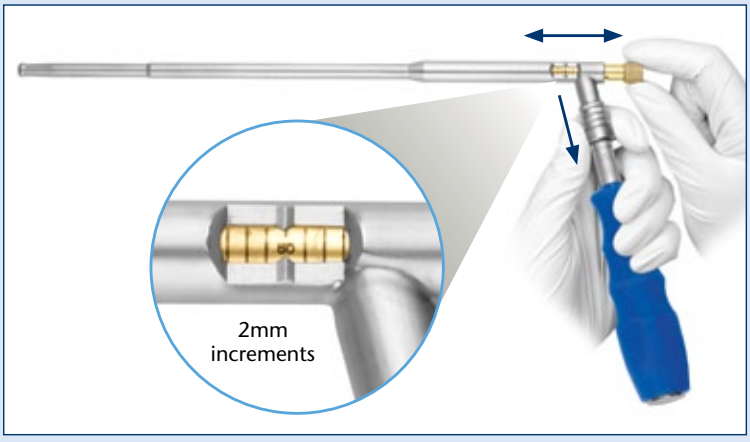


Using the Drill Guide, Variable Angle, Adjustable Depth
to prepare screw pilot hole

Using the Drill Guide with Adjustable Stop

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 fully engaged by pressing on the drill stop.



Drill Guide Variable Angle, Adjustable Depth

Drill Bit Adjustable Depth

Step 4 Screw Insertion

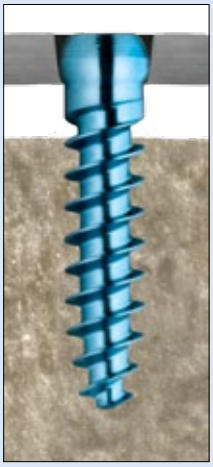
Bone screws are available in variable angle and fixed angle variations. Lengths vary from 22mm to 57mm in 2mm increments (3mm increments after 30mm).

Note: Screw lengths are measured by bone engagement.

To determine screw length after drilling and/or tapping, use the **Ball Tip Probe**. Demarcations every 10mm on the probe indicate depth to help determine screw length.

Ball Tip Probe

Screw Lags Plate to the Bone



As screw is inserted plate lags to bone

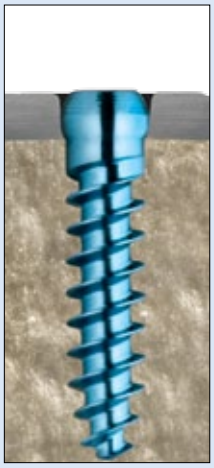
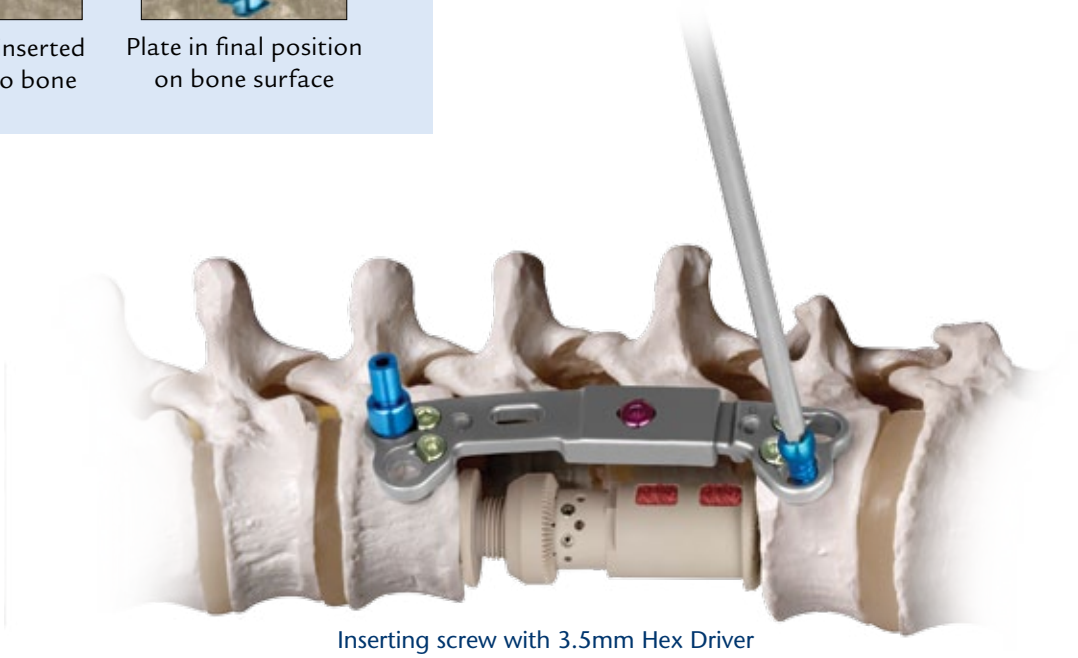


Plate in final position on bone surface

Before bone screw insertion, verify that the flat of the Locking Set Screw is oriented to permit the bone screw to pass through the plate hole. See the initial position of Locking Set Screw on the opposite page.

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 either of the 1/4" Quick Release Ratcheting Handles to insert the screws. Before insertion, confirm screw length using the gauges provided on the screw module. As the screws are inserted, the plate will lag to the bone as shown at left.



Inserting screw with 3.5mm Hex Driver

Step 5 Locking Set Screw

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

Insert the **Set Screw Positioner, Torque Limiting, 1.5Nm** into the locking set screw, making sure the hex is fully seated in the screw head, and turn the Set Screw Positioner clockwise to the click. As shown at right, the flat on the locking set screw should be facing away from the screw head when locked.

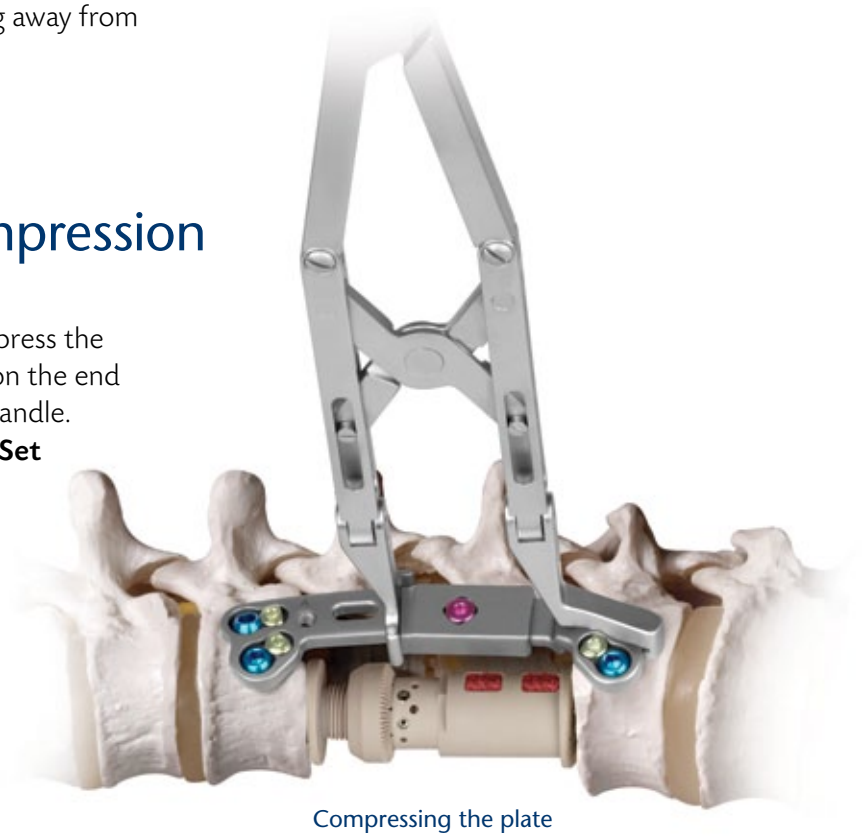
Unlocked

Locked

Step 6 Construct Compression

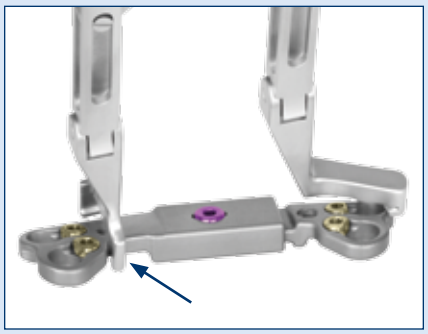
The **Plate Compressor** can be used to compress the construct. Place the tips of the compressor on the end of plate as shown below and compress the handle. Final tighten the fuchsia **TRUSS™ Clamping Set Screw** as described on page 18.

Notch on side of plate

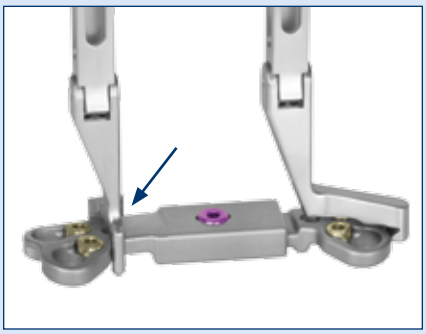


Compressing the plate

Loading the Plate Compressor



Engage the pin of the compressor with the curve of the compressible plate.

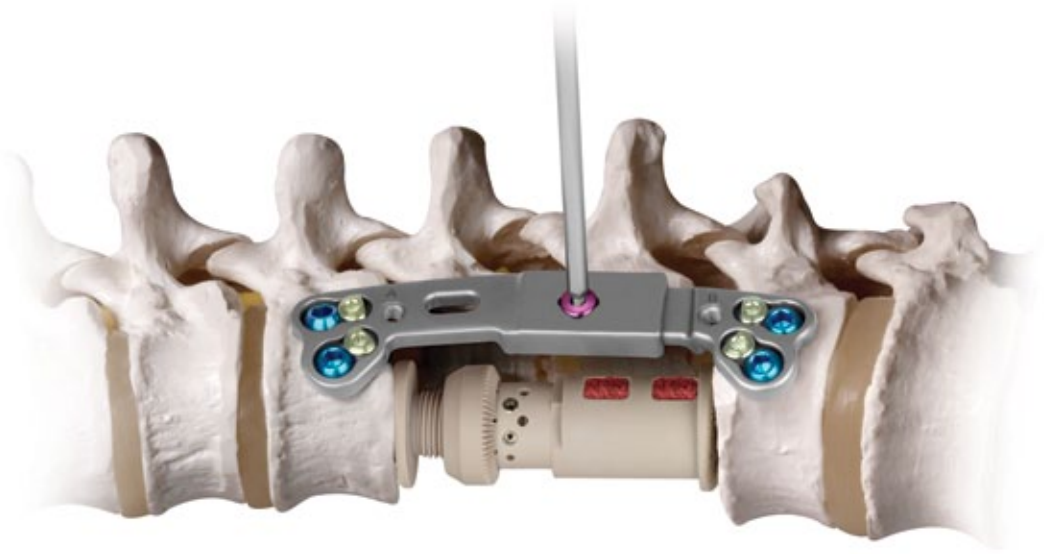


Rock the compressor around the plate so that the flat portion of the compressor engages under the plate.

Squeeze the compressor handle to engage the hook of the compressor into the notch on the plate.

Step 7 Locking the Clamping Set Screw

Insert the Set Screw Positioner, Torque Limiting, 1.5Nm into the set screw, making sure the hex is fully seated in the screw head, and turn the Set Screw Positioner clockwise to the click.



Final Construct

Lateral View

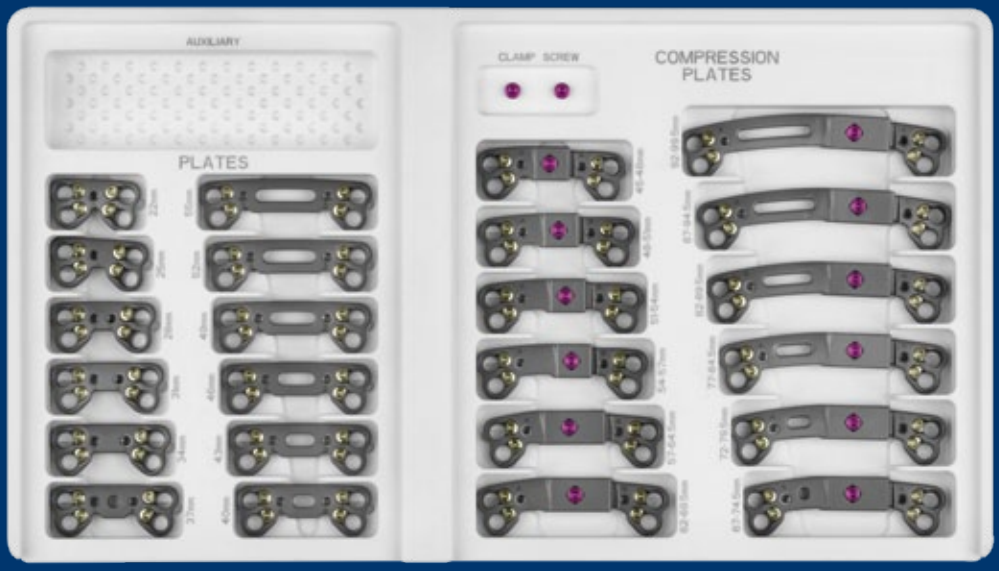
Final Construct

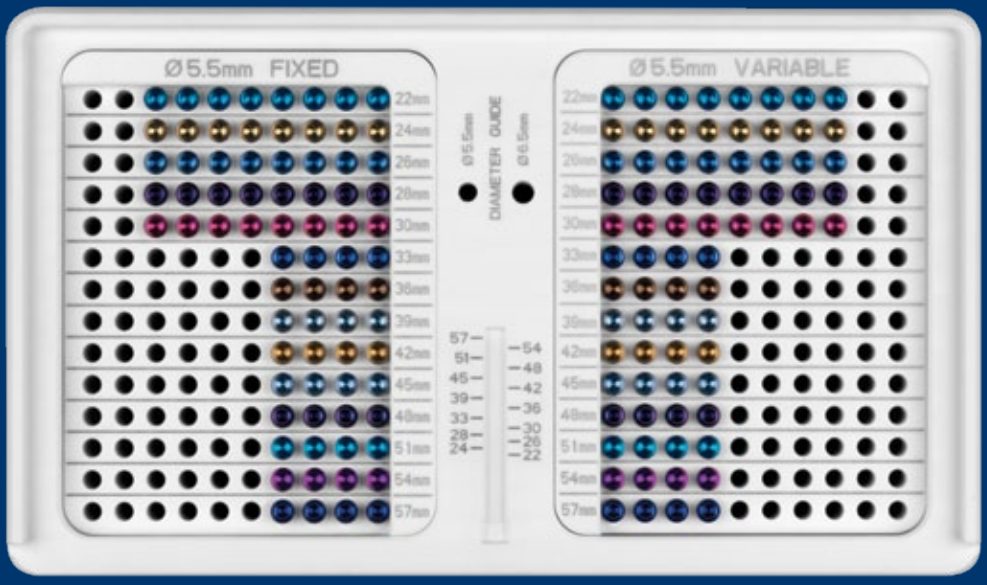
Anterior View

Optional: Implant Removal

To remove the plates, unlock the locking set screw with the Set Screw Positioner, Torque Limiting 1.5Nm. Take out the bone screws with the 3.5mm Hex Driver.

TRUSS™ IMPLANT SET





TRUSS™ Implant Set List 963.904

TRUSS™ Plate Module 963.002

TRUSS™ Plates (Qty 1 each)

163.122	22mm
163.125	25mm
163.128	28mm
163.131	31mm
163.134	34mm
163.137	37mm
163.140	40mm
163.143	43mm
163.146	46mm
163.149	49mm
163.152	52mm
163.155	55mm

TRUSS™ Compressible Plates (Qty 1 each)

163.345	45-48mm
163.348	48-51mm
163.351	51-54mm
163.354	54-57mm
163.357	57-64.5mm
163.362	62-69.5mm
163.367	67-74.5mm
163.372	72-79.5mm
163.377	77-84.5mm
163.382	82-89.5mm
163.387	87-94.5mm
163.392	92-99.5mm

TRUSS™ 5.5mm Bone Screws

(All 5.5mm screws start with the prefix 163 are contained within set 963.904)

TRUSS™ 6.5mm Bone Screws

(All 6.5mm screws start with the prefix 130 and are contained within set 963.906)

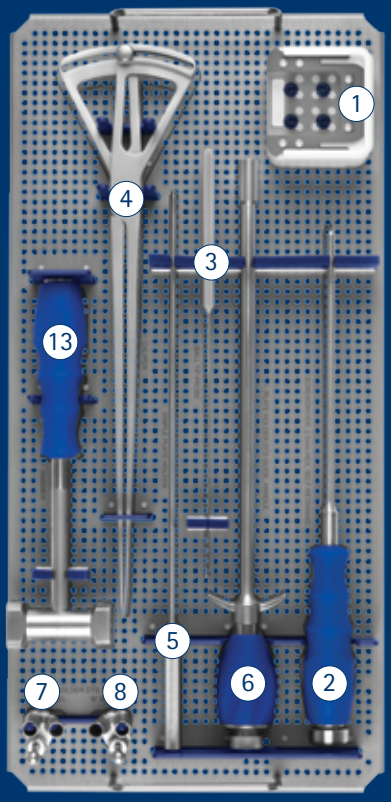
	22mm	Qty	24mm	Qty	26mm	Qty	28mm	Qty	30mm	Qty
Variable Angle 5.5mm	163.622	8	163.624	8	163.626	8	163.628	8	163.630	8
Fixed Angle 5.5mm	163.822	8	163.824	8	163.826	8	163.828	8	163.830	8
Variable Angle 6.5mm	130.622	8	130.624	10	130.626	10	130.628	8	130.630	8
Fixed Angle 6.5mm	130.822	8	130.824	10	130.826	10	130.828	8	130.830	8

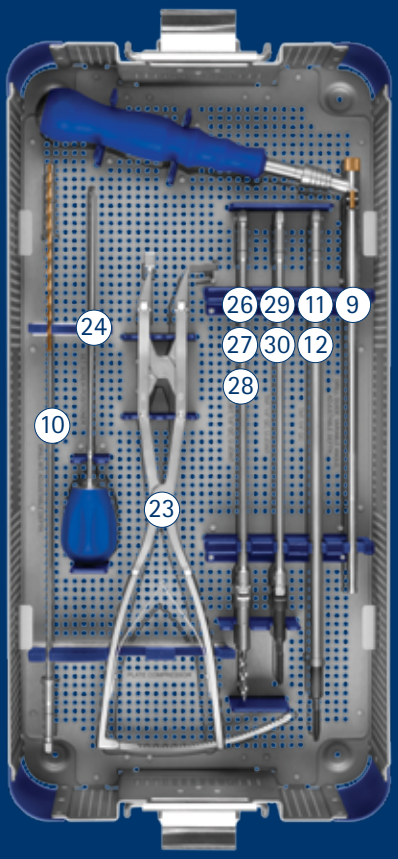
	33mm	Qty	36mm	Qty	39mm	Qty	42mm	Qty	45mm	Qty
Variable Angle 5.5mm	163.633	4	163.636	4	163.639	4	163.642	4	163.645	4
Fixed Angle 5.5mm	163.833	4	163.836	4	163.839	4	163.842	4	163.845	4
Variable Angle 6.5mm	130.633	4	130.636	4	130.639	4	130.642	4	130.645	4
Fixed Angle 6.5mm	130.833	4	130.836	4	130.839	4	130.842	4	130.845	4

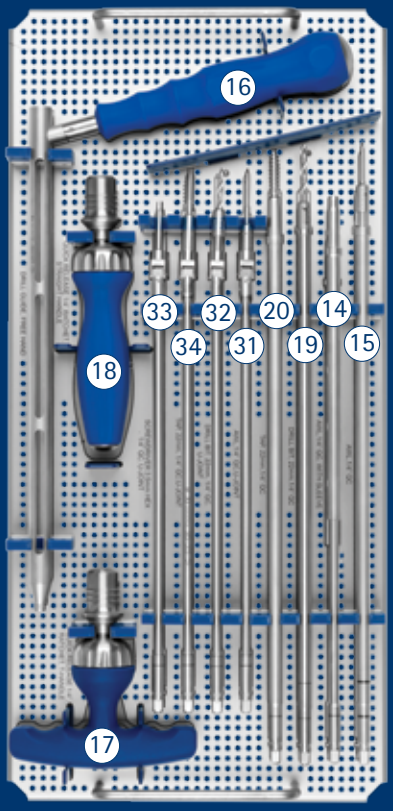
	48mm	Qty	51mm	Qty	54mm	Qty	57mm	Qty
Variable Angle 5.5mm	163.648	4	163.651	4	163.654	4	163.657	4
Fixed Angle 5.5mm	163.848	4	163.851	4	163.854	4	163.857	4
Variable Angle 6.5mm	130.648	4	130.651	4	130.654	4	130.657	4
Fixed Angle 6.5mm	130.848	4	130.851	4	130.854	4	130.857	4

TRUSS™ INSTRUMENT SET

TRUSS™/GATEWAY®/CITADEL® BONE SCREW INSTRUMENT SET







TRUSS™ Instrument Set 963.901
TRUSS™/GATEWAY®/CITADEL® Bone Screw Instrument Set 963.906

Temporary Fixation Instruments			Qty
1	663.500	Temporary Screw for Screw holes, 16mm	4
2	650.301	Screwdriver, 2.5mm Hex, Self Retaining	1

Preparation Instruments			Qty
3	602.105	Ball Tip Probe	1
4	663.403	Caliper	1
5	663.338	Simple Plate Holder	1
6	663.340	Plate Holder, DTS Guide, Handle	1
7	663.342	Plate Holder DTS Guide, A Barrel	1
8	663.344	Plate Holder DTS Guide, B Barrel	1
9	663.401	Drill Guide Variable Angle, Adjustable Depth	1
10	663.402	Drill Bit, Adjustable Depth	2
11	663.410	Ø4.4mm Tap, 1/4" QC	1
12	663.412	Ø5.4mm Tap, 1/4" QC	1
13	603.977	Hammer	1
14	630.316	Cortex Awl, 1/4" QC	1
15	630.317	Awl, 1/4" QC	1
16	630.336	Drill Guide, Freehand	1
17	630.401	Quick Release 1/4", Ratchet, T-Handle	1
18	630.407	Quick Release 1/4", Ratchet, Straight Handle	1
19	630.400	Drill Bit, 22mm, 1/4" QC	2
20	630.405	Ø6.4mm Tap, 22mm, 1/4" QC	2

Screw Insertion Instruments			Qty
21	630.410	Screwdriver, 3.5mm Hex, Self-Retaining	2
22	630.414	Screwdriver Shaft, 3.5mm Hex, 1/4" QC, Self-Retaining	1

Compression Instruments			Qty
23	663.432	Plate Compressor	1

Screw Locking Instruments			Qty
24	630.503	Set Screw Positioner, Torque Limiting, 1.5Nm	1
25	630.501	Set Screw Positioner	1

Universal Joint Instruments			Qty
26	663.497	Drill Bit, 25mm, 1/4" QC, U-Joint	1
27	663.498	Drill Bit, 30mm, 1/4" QC, U-Joint	1
28	663.499	Drill Bit, 35mm, 1/4" QC, U-Joint	1
29	663.414	Ø4.4mm Tap, 1/4" QC, U-Joint	1
30	663.416	Ø5.4mm Tap, 1/4" QC, U-Joint	1
31	630.493	Awl, 1/4" QC, U-Joint	1
32	630.494	Drill Bit, 22mm, 1/4" QC, U-Joint	1
33	630.495	Screwdriver, 3.5mm Hex, 1/4" QC, U-Joint	1
34	630.496	Ø6.4mm Tap, 22mm, 1/4" QC, U-Joint	1

963.001	TRUSS™ Instrument Graphic Case	1
963.006	TRUSS™/GATEWAY®/CITADEL® Bone Screw and Instrument Case	1

Additionally Available Instruments

630.006	Temporary Pin Driver, External Grip
630.403	Quick Release 1/4", Palm Handle (Non Ratcheting)

*Items highlighted in gray are additionally available.

IMPORTANT INFORMATION ON THE TRUSS™ THORACOLUMBAR PLATE SYSTEM

DESCRIPTION

The TRUSS™ Thoracolumbar Plate System consists of rigid and compression 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 bodies of the thoracolumbar spine (T1-L5). Implants are composed of titanium alloy, as specified in ASTM F136, F1295 and F1472.

INDICATIONS

The TRUSS™ 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.

CONTRAINDICATIONS

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.

CLEANING

Cleaning instruments by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

1. Clear any corners or recesses of all debris (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
2. Remove all traces of blood and other such residues immediately. Do not allow these to dry.
3. The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Instraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
6. Dry instruments immediately after cleaning.

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

TRUSS™ implants and instruments have been validated to assure a Sterility Assurance Level (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.*

Implants:
These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time
Steam	Gravity Displacement (Wrapped)	132° - 135°C (270° - 275°F)	28 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132° - 135°C (270° - 275°F)	4 Minutes

Instruments:
These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time
Steam	Gravity Displacement (Wrapped)	132° - 135°C (270° - 275°F)	25 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132° - 135°C (270° - 275°F)	15 Minutes

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

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

Notes

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

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