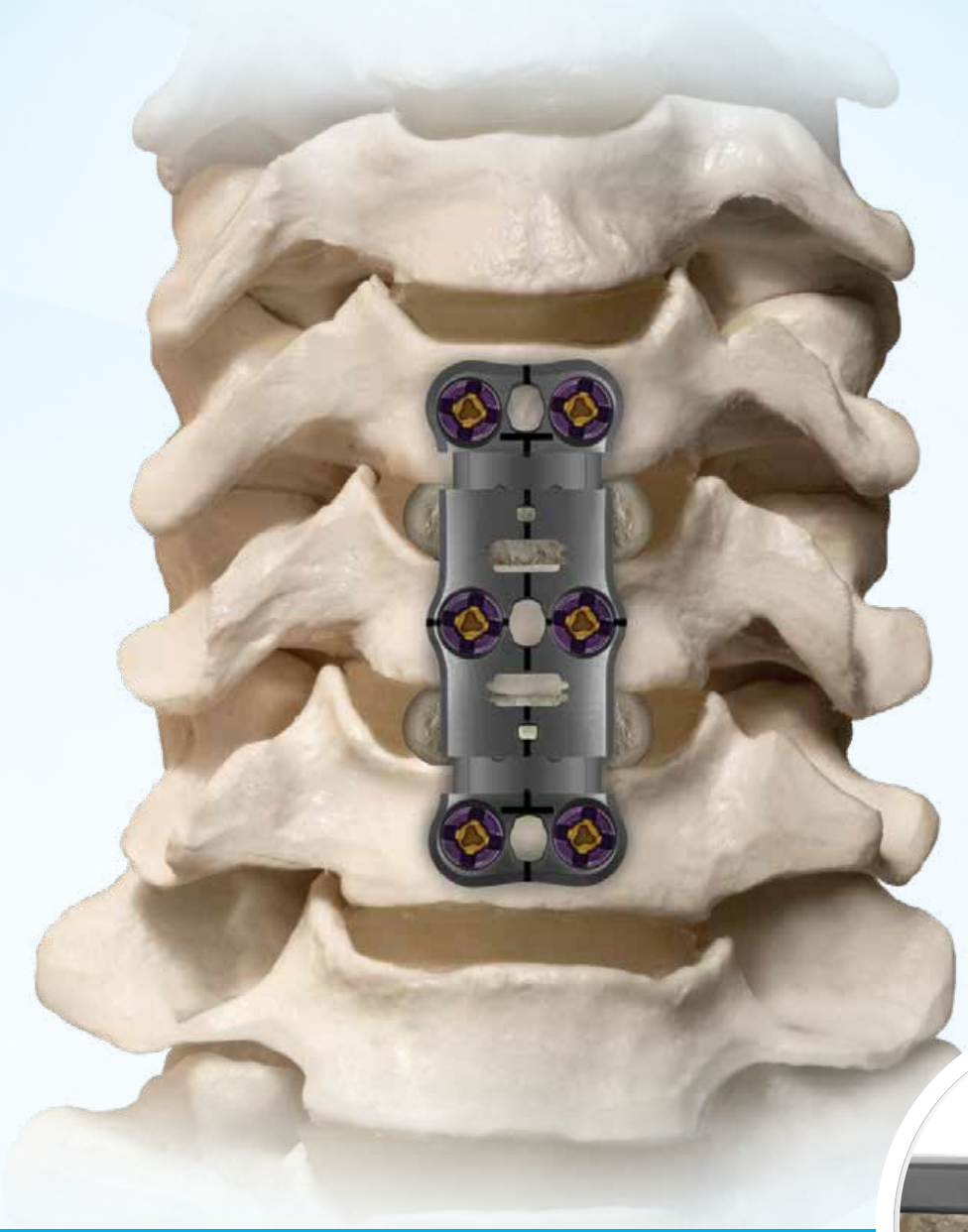

UNIFY®

Dynamic Anterior Cervical Plate System

SURGICAL TECHNIQUE GUIDE

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Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

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SURGICAL TECHNIQUE GUIDE

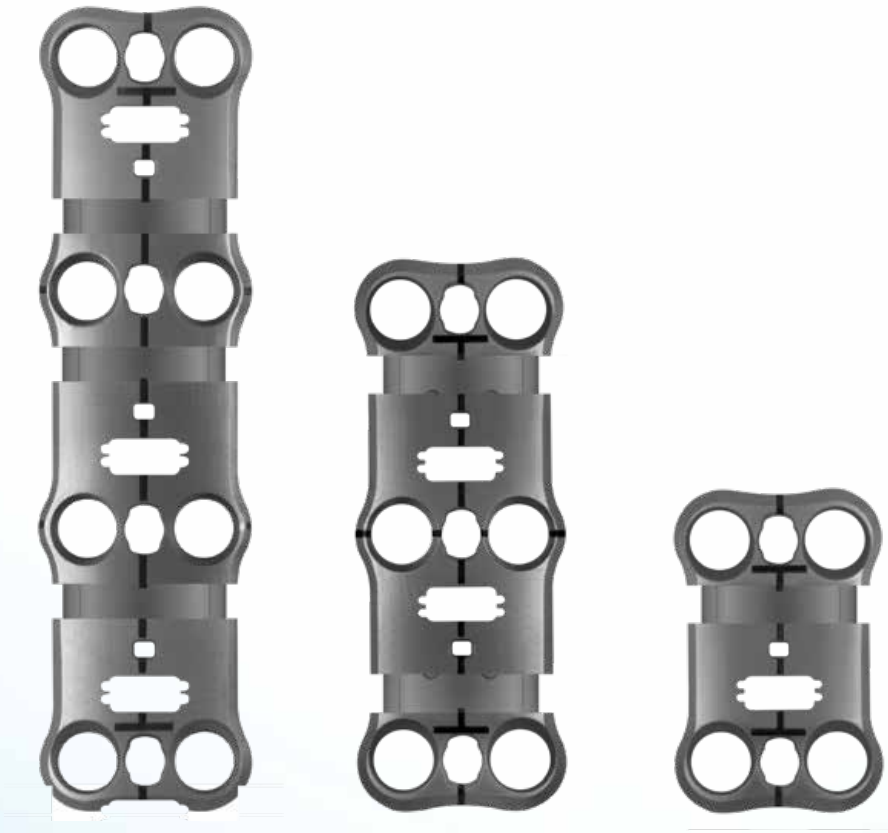
UNIFY®

UNIFY®

Dynamic Anterior Cervical Plate System

The UNIFY® plate system utilizes internal dynamization and optimized compression to maximize the principles of Wolff's Law and help promote fusion.

The pre-assembled expanding screws are quickly driven and securely locked using one instrument.



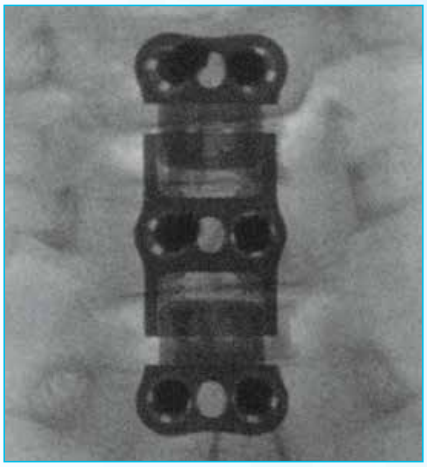
Optimized Compression

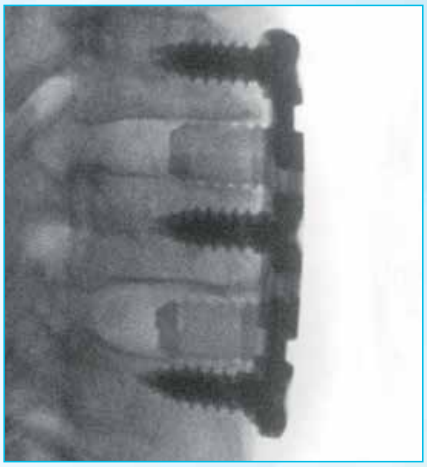
Intraoperative compression of 1mm per level helps provide a precise fit, allowing immediate graft loading to aid in promoting fusion.

Postoperatively, up to 2mm of adjustment per level permits physiologic loading to help promote fusion.

Internal Dynamization

Telescoping adjustment at each level may help prevent adjacent level impingement.





Secure Locking

A single instrument to quickly drive and securely lock the screw.

Unlocked

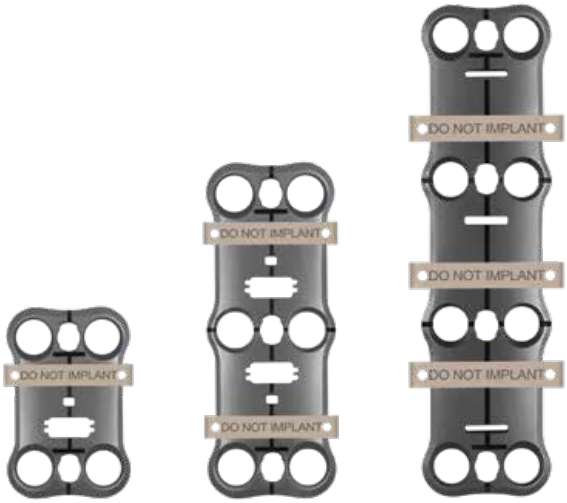
Locked

Screwdriver

IMPLANT OVERVIEW

Plates

- 2.8mm profile
- 16.6mm width
- Internal dynamization
- Lengths from 10–100mm
- 1, 2, 3, and 4-level plates
- Optimized compression
- Temporary spacers

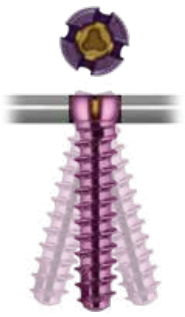


Pre-Assembled Expanding Screws

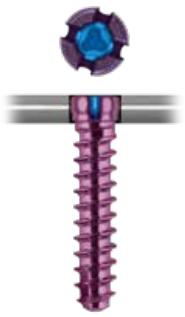
- 4.2mm and 4.6mm diameters
- Self-drilling and self-tapping
- Lengths from 10–20mm, in 2mm increments
- Variable angle and fixed angle

Screw Angulation

- Variable angle screw provides ±14.5° angulation
- Pre-set angulation with drill guides
- 6° medial
- 10° cephalad/caudal

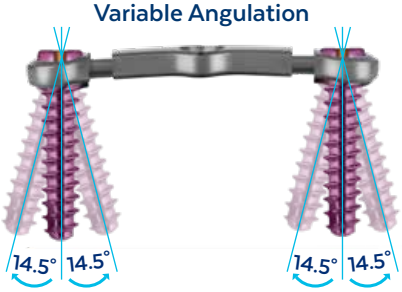


Variable Angle Screw



Fixed Angle Screw

Variable Angulation



Pre-Set Angulation

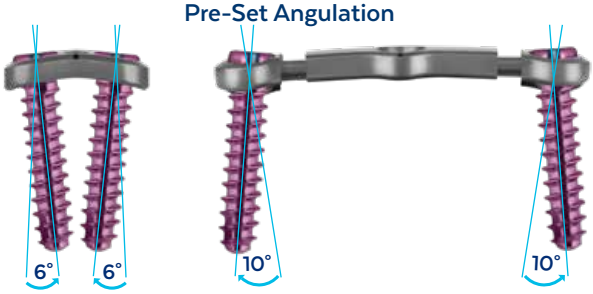


Plate Offerings

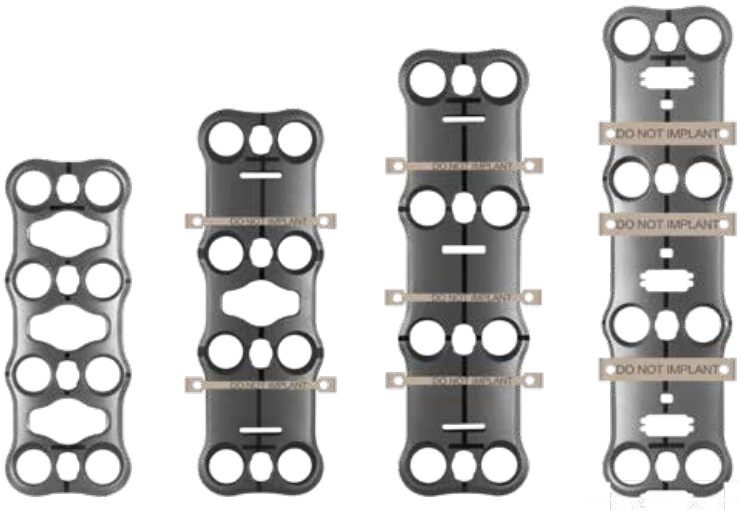
1-Level Plates

Static | 1mm dynamic compression | Standard

2-Level Plates

Static | 1mm dynamic compression, 1 level only | 1mm dynamic compression | Standard

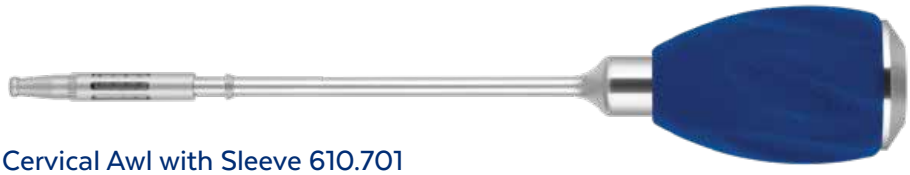
3-Level Plates



Static | 1mm dynamic compression, 2 levels only | 1mm dynamic compression | Standard

INSTRUMENT OVERVIEW

SCREW HOLE PREPARATION INSTRUMENTS



Cervical Awl with Sleeve 610.701

Awl Sleeve Retracted

Cervical Awl, for Drill Guide 610.704

Drill Bits

610.710	10mm	
610.712	12mm	
610.714	14mm	
610.716	16mm	
610.718	18mm	
610.720	20mm	

Easy Connect Handle, Small 697.705

ACDF Tap 610.740

PLATE INSTRUMENTS

Temporary Plate Spacer, 1mm 697.001

Temporary Plate Spacer, 2mm 697.002

Temporary Plate Spacer, 3mm 697.003

Simple Plate Holder 697.810

Fixation Pin Driver 697.020

Temporary Fixation Pin 697.010

Temporary Fixation Screw 610.804

2.5mm Hex Driver, Quick-Connect 610.831

PLATE INSTRUMENTS

Screwdriver 697.820

Trilobular Driver 697.821

Counter-Torque 697.822

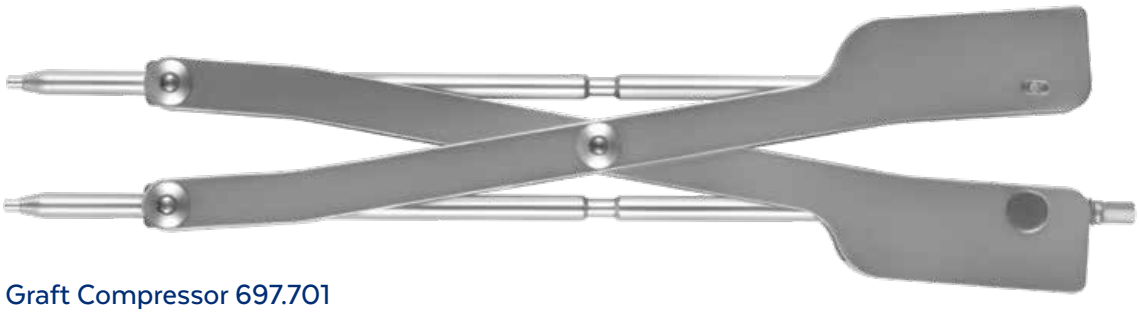
PLATE INSTRUMENTS (CONT'D)

DTS Guide, Pre-Set Angle Plate Holder, Single Barrel 697.206

Variable Angle Drill Guide, Short Barrel 610.832

Torque-Limiting, Quick-Connect Handle, 0.3N-m 697.312

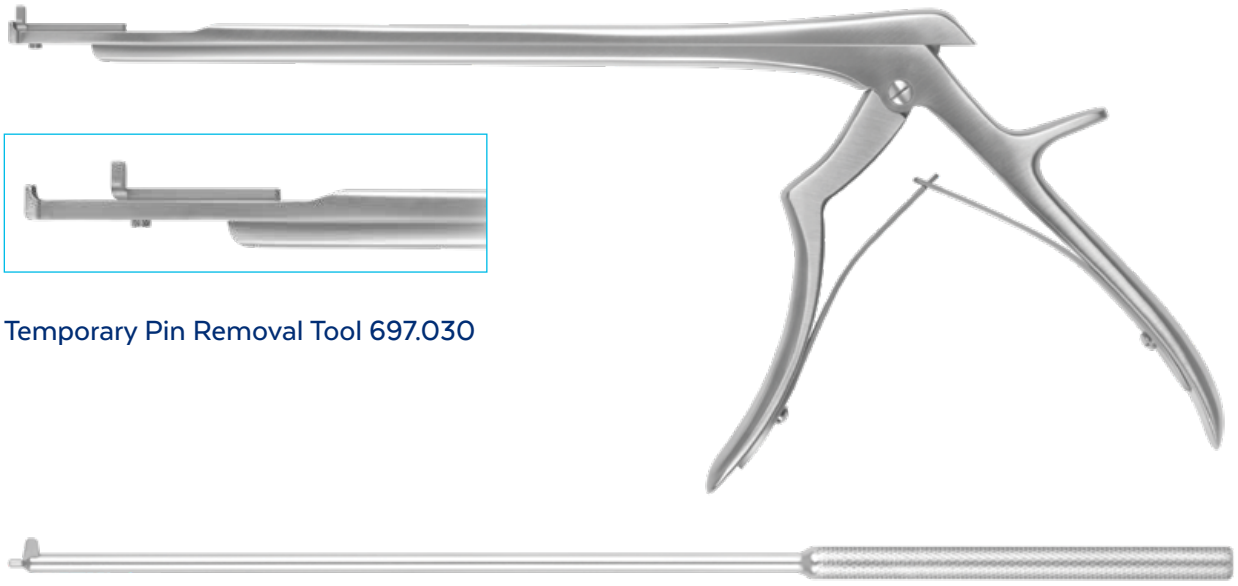
COMPRESSION INSTRUMENTS



Graft Compressor 697.701

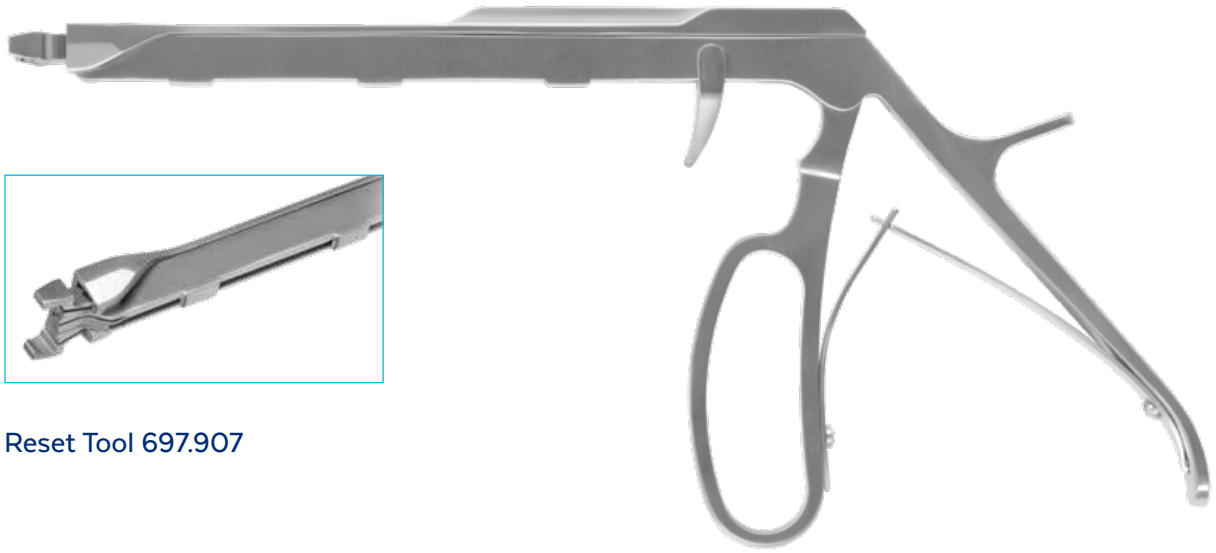
Graft Compressor, Torque-Limiting Handle 697.702

REMOVAL INSTRUMENTS



Temporary Pin Removal Tool 697.030

Spacer Removal Tool 697.903



Reset Tool 697.907

SURGICAL TECHNIQUE

UNIFY®

STEP 1 APPROACH AND PREPARATION

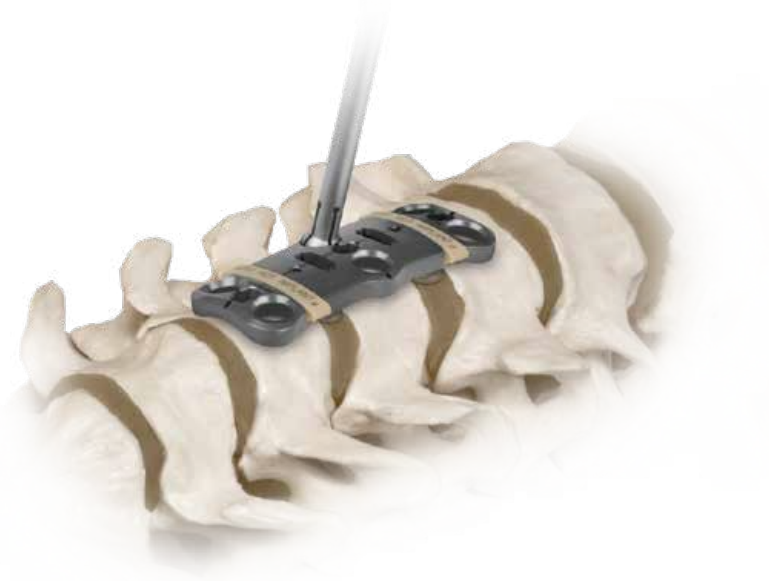
The patient is placed under anesthesia and positioned supine. The operative area is cleaned and an incision is made at the appropriate fusion level(s). UNIFY® plate fixation may be used in the cervical spine from C2 to C7. Please refer to the product insert for complete description, indications, contraindications, warnings, and precautions.

Distraction may be accomplished using a standard distractor or other standard methods. Prepare the disc space and insert bone graft or an interbody fusion device. Refer to the COLONIAL® ACDF Surgical Technique Guide (GMTGD27) for recommended techniques. Remove anterior osteophytes to allow the plate to sit flush on the vertebral body.

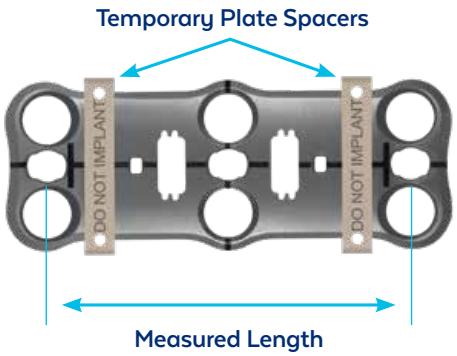
STEP 2 PLATE PLACEMENT

Choose the appropriate plate size. Plate length is measured from the center of the cephalad hole to the center of the caudal hole in the extended (open) position. The **Temporary Plate Spacers** should be left in place until all screws are inserted and locked.

Use the **Simple Plate Holder** to place the selected plate. Press the holder tip into a screw hole. Remove by pulling up on the holder.



Using Simple Plate Holder to place plate



The plate may be temporarily secured by using **Temporary Fixation Pins**. Use the **Fixation Pin Driver** to insert the pin through the midline pin hole, as shown below.

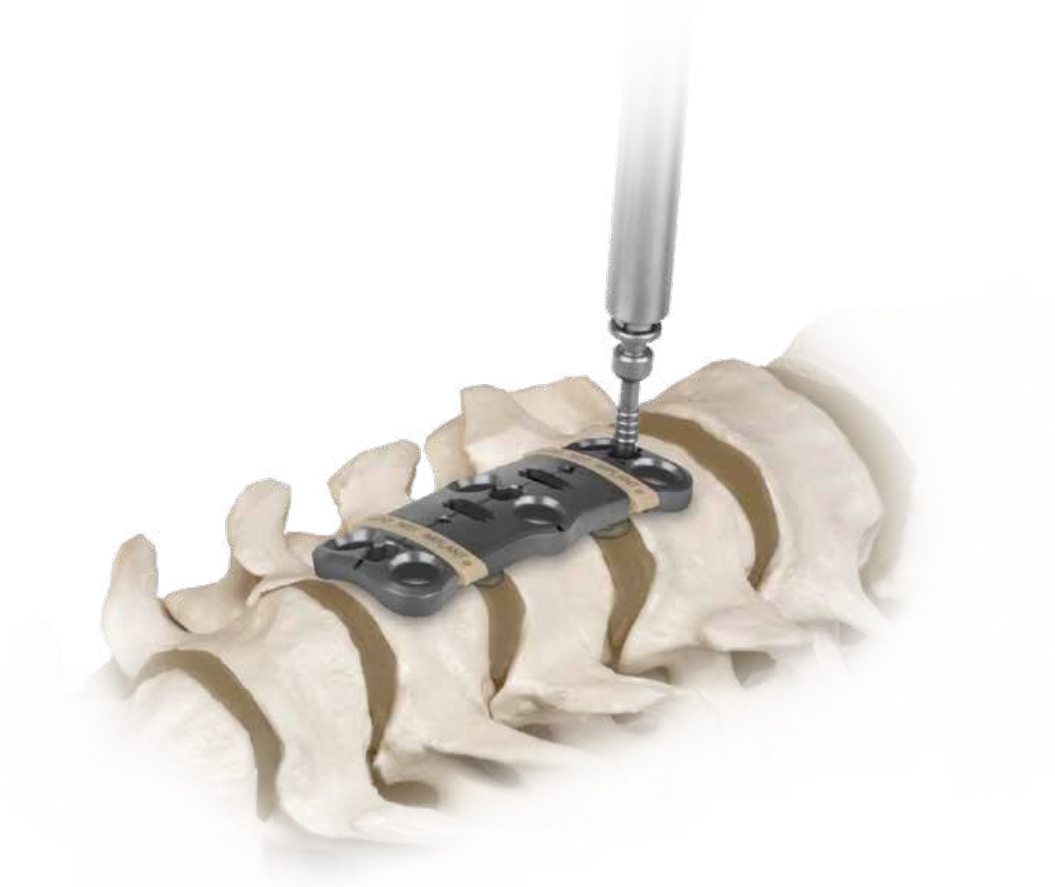
To load the pin to the pin driver, pull back on the outer sleeve. Once a pin is loaded, press down on the outer sleeve to achieve a tight fit.

To unload the pin from the pin driver, rock the instrument off of the pin.

The pin holes on the cephalad and caudal ends of the plate are angled at 10°, respectively. Insert and remove the pins and DTS guides at this angle. The center pin hole is perpendicular to the plate. Instruments can be inserted perpendicular to the plate in this hole.

Alternately, the **Temporary Fixation Screw** may be inserted into a screw hole and removed with the **2.5mm Hex Driver, Quick-Connect**.

Loading Temporary Fixation Pin onto Pin Driver



Inserting Temporary Fixation Pin

STEP 3 SCREW HOLE PREPARATION

Option A: Pre-Set Angulation

When using the **DTS Guide, Pre-Set Angle Plate Holder, Single Barrel**, ensure that the DTS guide is in the unlocked position. Insert the DTS guide tip into a midline pin hole. After insertion into the midline pin hole, rotate the knob at the top of the DTS guide clockwise to establish a rigid connection.

Start each pilot screw hole by inserting the **Cervical Awl, for Drill Guide** into the DTS guide.

Determine the desired drill depth and select the appropriate fixed length **Drill Bit**. Assemble the Drill Bit to the **Easy Connect Handle, Small** and insert into the DTS guide. Drill to the stop.

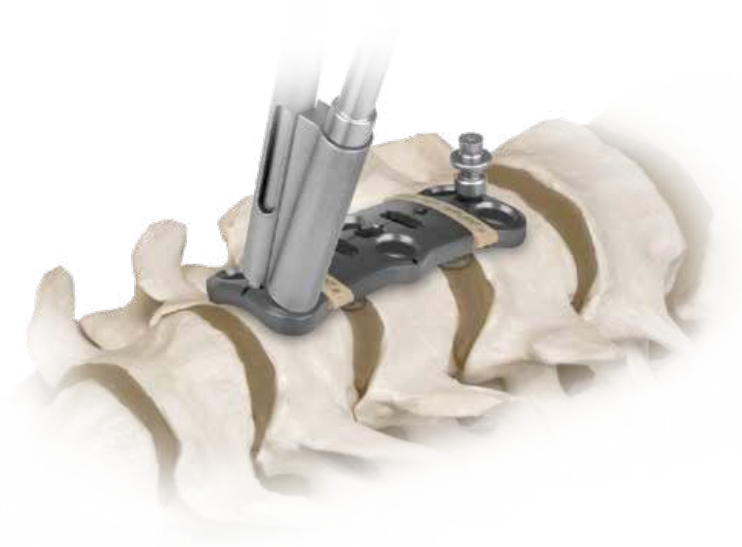
Screw holes may be tapped through the DTS guide using the **ACDF Tap**.

Screws may also be inserted through this DTS guide. See Step 4, page 16 for screw insertion.

To remove the DTS guide, rotate to the unlocked position, rock laterally to disengage, and pull the DTS guide from the plate.

Note: Drill Bits are not intended for connection to power drill sources.

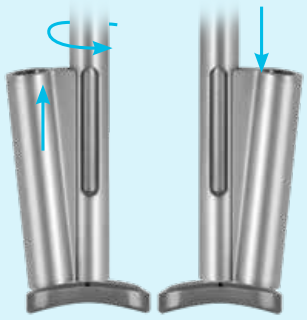
Unlocked Locked



Using DTS Guide, Pre-Set Angle Plate Holder to prepare screw pilot hole

ROTATING THE DTS GUIDE BARREL

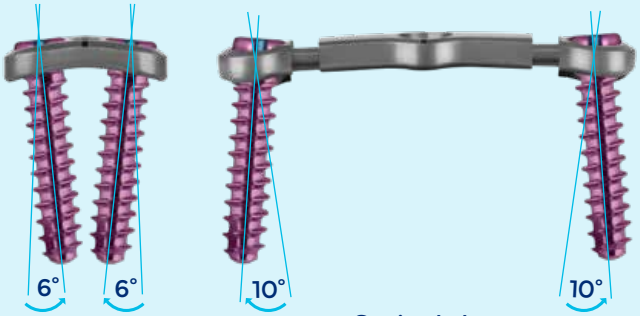
The barrel of the DTS guide rotates to conveniently switch to the contralateral screw hole. Pull the sleeve up toward the handle, rotate, and release the sleeve to change barrel position.



USING THE DTS AND DRILL GUIDES WITH PRE-SET ANGULATION

Line up the arrows on the T-Handle and Trial Shaft. Press the “DETACH” button on the T-Handle and attach the Trial Shaft.

Note: Care should be taken when using screws longer than 14mm to prevent medial interference.



Sagittal plane

Option A: Pre-Set Angulation (Cont'd)

Using the Pre-Set Angle Drill Guide

Place the **Pre-Set Angle Drill Guide** into the desired screw hole. Start each pilot screw hole by inserting the **Cervical Awl, with Sleeve**.

Determine the desired drill depth and select the appropriate fixed length Drill Bit. Assemble the Drill Bit to the Easy Connect Handle, Small and insert into the drill guide. Drill to the stop. Screw holes may be tapped using the ACDF Tap after the drill guide is removed.

Option B: Variable Angulation

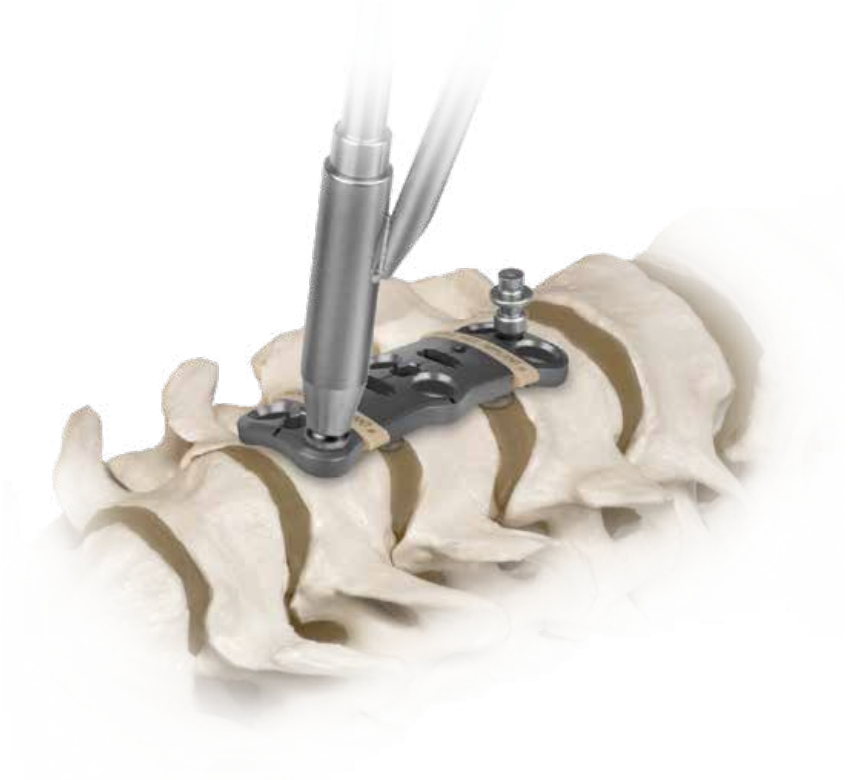
Using the Variable Angle Drill Guide

Start each screw hole by inserting the Cervical Awl, with Sleeve into a screw hole within the plate. Alternately, the Cervical Awl, for Drill Guide may be inserted through the **Variable Angle Drill Guide, Short Barrel**.

Place the drill guide into the desired screw hole. This drill guide permits full angulation of the Drill Bit through the plate.

Determine the desired drill depth and select the appropriate fixed length Drill Bit. Assemble the Drill Bit to the easy connect handle and insert into the drill guide. Drill to the stop. Screw holes may be tapped using the ACDF Tap after the drill guide is removed.

Note: Variable angle guides should not be used to prepare screw holes for fixed angle screws.



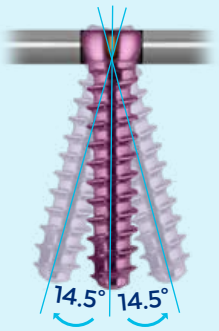
Using Variable Angle Drill Guide to prepare screw pilot hole

USING THE VARIABLE ANGLE DRILL GUIDE

Screw Angulation

This guide allows screw angulation of 14.5° in any direction for drilling screw pilot holes.

Note: Care should be taken to prevent medial interference.

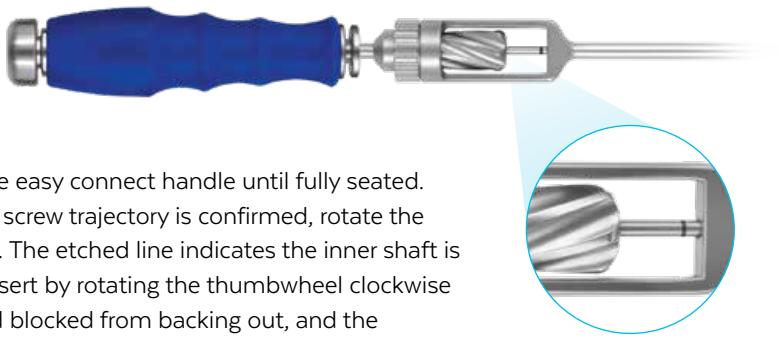


STEP 4 SCREW INSERTION

Option A: Pre-Set Angulation

Pre-assembled expanding UNIFY® screws use a locking insert to prevent backout. The **Screwdriver** is used to insert and lock the screws in the plate. The outer shaft of the Screwdriver engages and retains the screw. The inner shaft and thumbwheel position the blocking insert. The Screwdriver is assembled with the Easy Connect Handle, Small before use.

Select the desired screw, engage the Screwdriver outer shaft, and remove the screw from the module. Alignment of the inner shaft is not required at this step. Verify screw length and diameter using the gauges within the screw module.



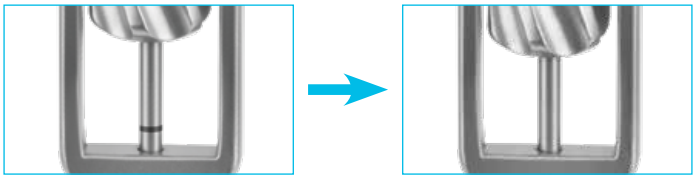
Insert the screw through the screw hole and drive with the easy connect handle until fully seated. As the screw is inserted, the plate lags to the bone. Once screw trajectory is confirmed, rotate the thumbwheel to engage the inner shaft and locking insert. The etched line indicates the inner shaft is fully engaged in the locking insert. Position the locking insert by rotating the thumbwheel clockwise until finger tight. The screw is now locked in the plate and blocked from backing out, and the Screwdriver may be removed from the screw. Repeat for all screws.

Alternately, the Cruciform Driver, Self-Retaining may be used for screw insertion. The Driver Sleeve may be used for additional rigidity to the screw during insertion. Snap the sleeve onto the screw head in the module and insert the cruciform driver into the sleeve, engaging the screw head. Insert the screw through the screw hole and drive until fully seated. Final tightening steps will still need to be completed as described below.

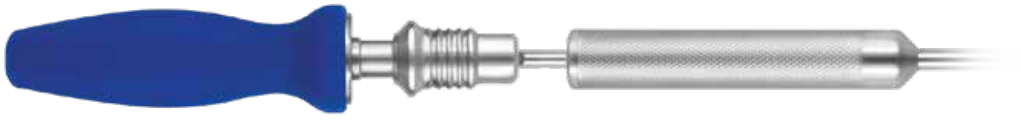
Locking Confirmation (Final Tightening)

Assemble the **Trilobular Driver** and **Torque-Limiting, Quick-Connect Handle, 0.3Nm**. Insert the driver into the **Counter-Torque**. Fully engage the Counter-Torque into the screw and slide the driver into the locking insert. Rotate the Torque-Limiting handle clockwise until it reaches its torque limit of 0.3Nm. Repeat for all screws.

Note: All screw lengths are measured by bone engagement.



Disengaged Engaged



SCREW IDENTIFICATION

Screw Module Gauges

Verify screw diameter by inserting the selected screw into the gauge in the screw module, adjacent to the indicated diameter.

Verify screw length by resting the selected screw in the length gauge with the bottom of the screw head resting on the side of the module.

Locking Insert

Variable angle and fixed angle screws can be confirmed by the color of the locking insert. The body of the screw is color-coded by screw length.

The screw is locked when the locking insert is flush with the top surface of the screw.

If inserting a screw through a DTS guide, the etched line on the Screwdriver aligns with the top of the DTS barrel when the screw is fully seated.

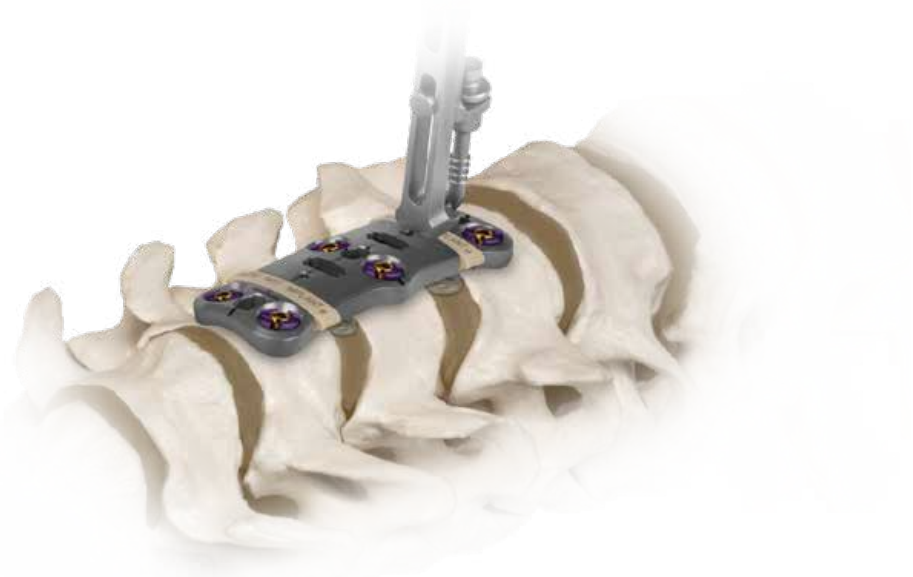
Variable GOLD | *Fixed* LIGHT BLUE

Unlocked | Locked

STEP 5 TEMPORARY FIXATION REMOVAL

Use the **Temporary Pin Removal Tool** to remove the Temporary Fixation Pins. The removal tool engages between the plate and bottom of the pin head.

Once engaged, compress the handles to pull the pin out of the vertebral body.

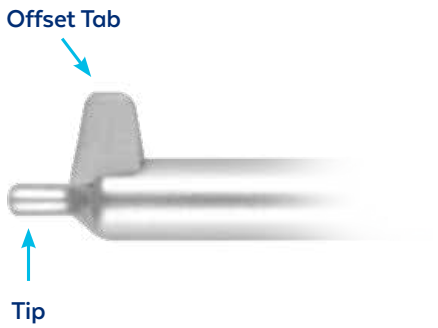


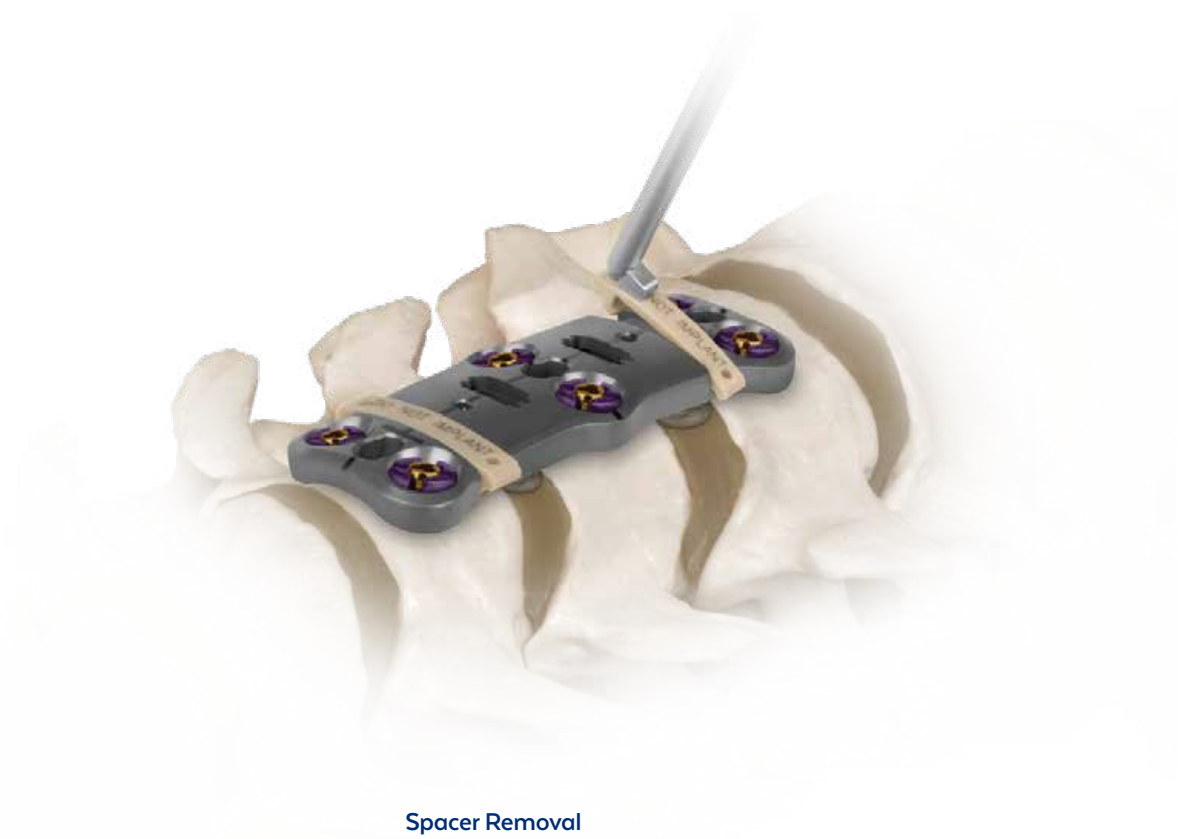
Removing a Temporary Fixation Pin

STEP 6 TEMPORARY SPACER REMOVAL

Once all screws have been inserted and locked, remove the Temporary Plate Spacers with the **Spacer Removal Tool**.

Insert the tip of the removal tool into the spacer, with the offset tab against the spacer, and gently rock the spacer toward the midline of the plate to remove, as shown.





Spacer Removal

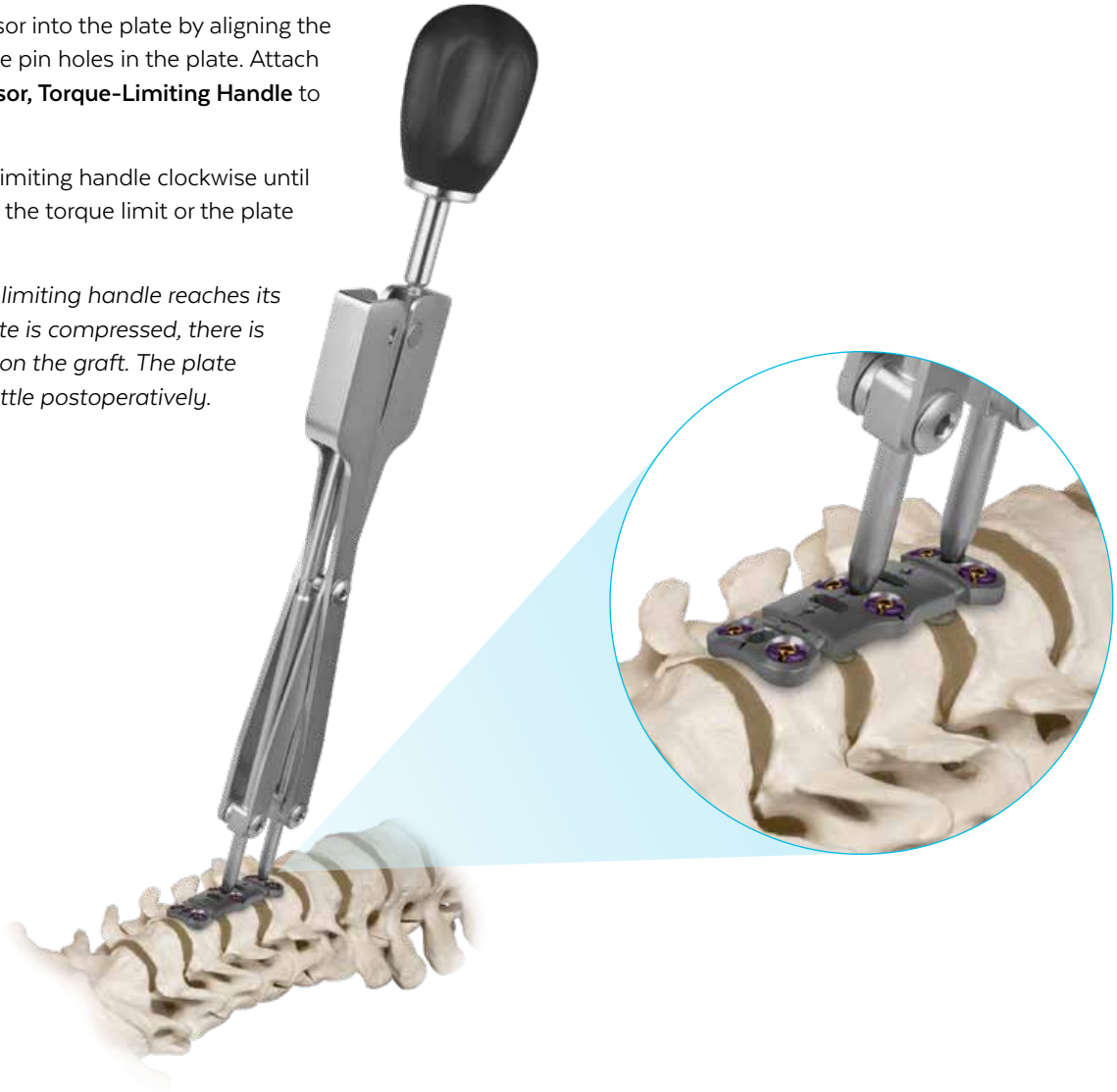
STEP 7 COMPRESSION

Once the spacers have been removed, the plate may be compressed with the **Graft Compressor**. Compress only one level at a time.

Insert the compressor into the plate by aligning the tips with the midline pin holes in the plate. Attach the **Graft Compressor, Torque-Limiting Handle** to the compressor.

Rotate the torque-limiting handle clockwise until the handle clicks at the torque limit or the plate compresses.

Note: If the torque-limiting handle reaches its limit before the plate is compressed, there is sufficient pre-load on the graft. The plate should be left to settle postoperatively.

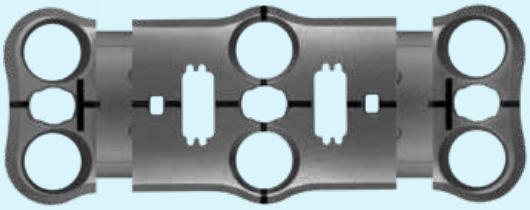


Using Compressor

OPTIONAL COMPRESSION TECHNIQUE

If 1mm of intraoperative compression is not required, the plate can be compressed prior to plate placement and the length is maintained by using the Temporary Spacer, 2mm.

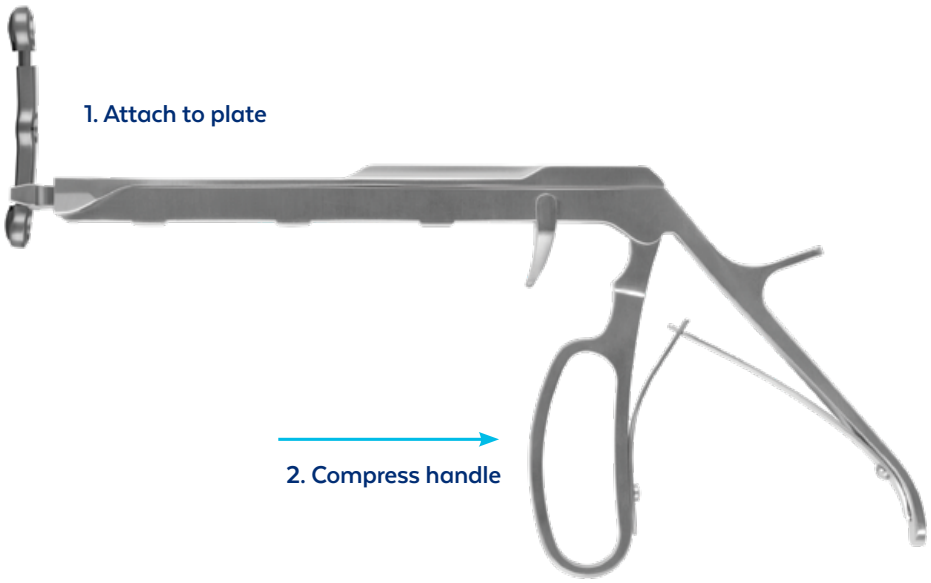
Remove the Temporary Spacer, 3mm and compress the plate by pushing the plate together. Place the Temporary Spacer, 2mm between each dynamic component to maintain the length during plate placement.

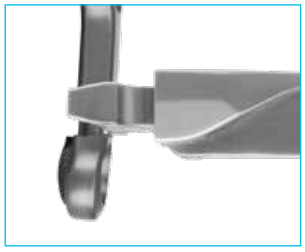


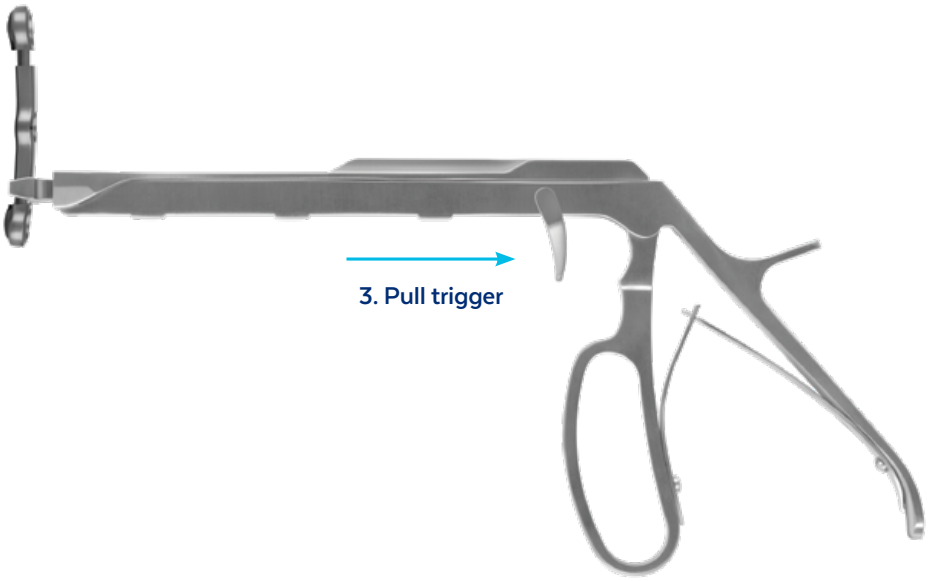
RESET TOOL

If the plate has compressed prior to implantation, it may be opened with the **Reset Tool**. Engage the tool into a midline pocket and around the waist of the plate. Once attached, compress the handle to engage the compression mechanism and hold the plate. While compressing the handles, pull the trigger and the plate will reset.

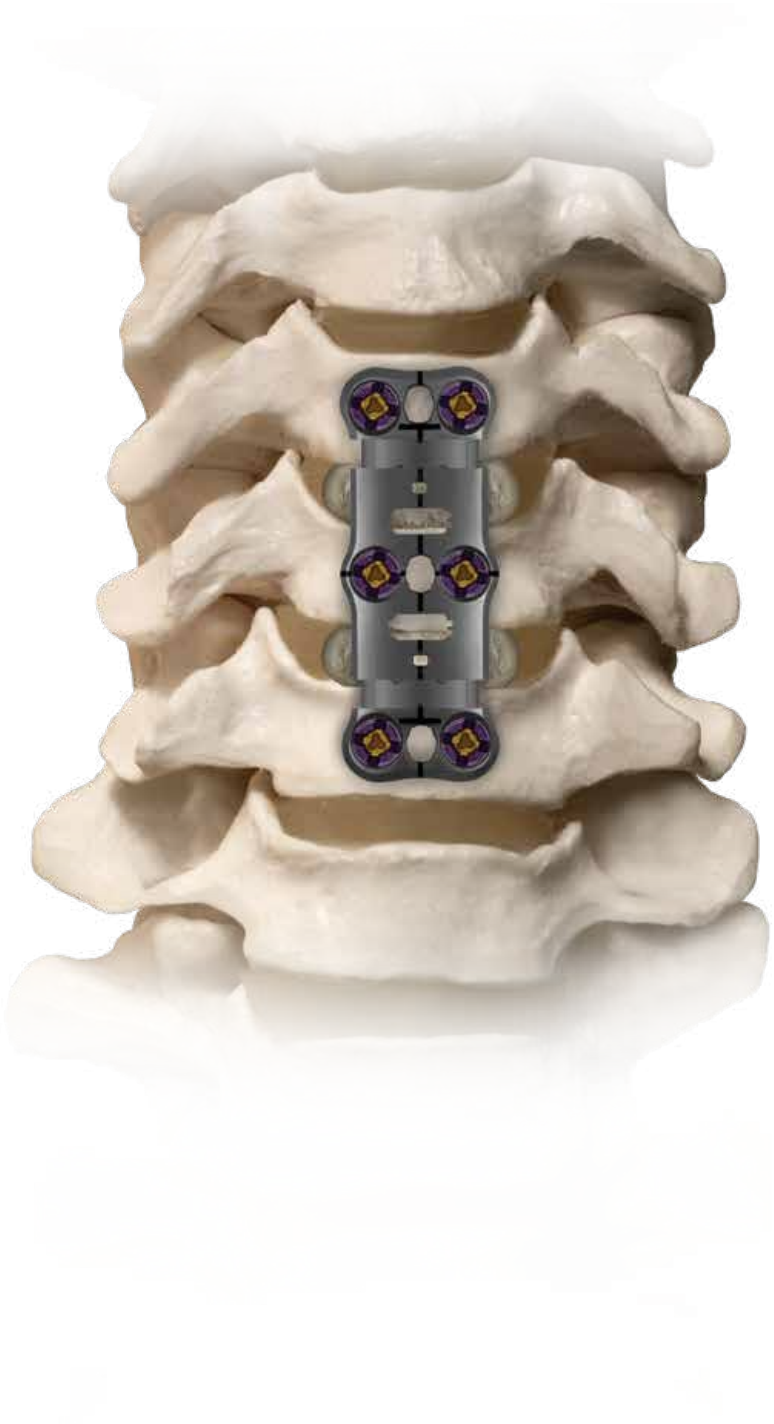
Note: It is recommended that the plate be reset prior to implantation.







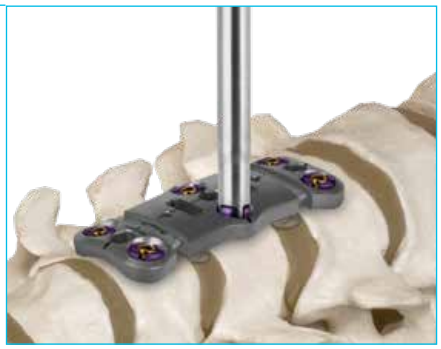
FINAL CONSTRUCT



OPTIONAL: SCREW UNLOCKING AND REMOVAL

If screws require removal, the Counter-Torque and Trilobular Driver may be used. First ensure that the Easy Connect Handle, Small is connected to the driver.

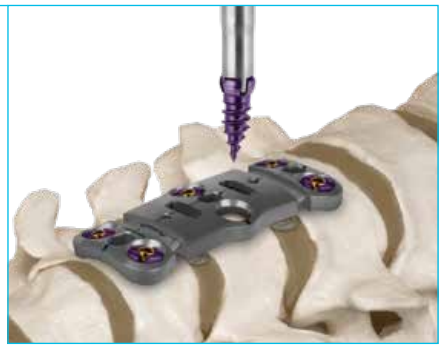
Engage the outer diameter of the screw with the Counter-Torque.



Once the Counter-Torque is engaged, slide the driver through the Counter-Torque into the locking insert. Rotate the easy connect handle counterclockwise to unlock the screw.

After the screw is unlocked, disengage the Counter-Torque and remove the screw with the Screwdriver by rotating counterclockwise.

Repeat for all screws.



SCREWDRIVER DISASSEMBLY

The Screwdriver is designed to easily disassemble for cleaning.

Disassembly for Cleaning

1. Disengage the Easy Connect Handle, Small from the Screwdriver.

2. Rotate the retaining cap counterclockwise until it is fully removed from the outer shaft.

3. Remove the connector.

4. Remove the inner shaft.

The Screwdriver is now fully disassembled and ready for cleaning.

Reassembly

Note: Reverse the above procedure and ensure that the retaining cap is fully tightened.

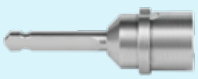
Easy Connect Handle, Small

Outer Shaft Screwdriver

Inner Shaft

Thumbwheel

Retaining Cap



Connector

UNIFY®
DYNAMIC CERVICAL PLATE SET 997.902

1-3 Level Standard Plate Set

UNIFY® 1 Level Plates

Part No.	Length	Qty
197.110	10mm	1
197.112	12mm	1
197.114	14mm	1
197.116	16mm	1
197.118	18mm	1
197.120	20mm	1
197.122	22mm	1
197.124	24mm	1
197.126	26mm	1
197.128	26mm	1

UNIFY® 2 Level Plates

Part No.	Length	Qty
197.226	26mm	1
197.228	28mm	1
197.230	30mm	1
197.232	32mm	1
197.234	34mm	1
197.236	36mm	1
197.238	38mm	1
197.240	40mm	1
197.242	42mm	1
197.244	44mm	1
197.246	46mm	1
197.248	48mm	1

UNIFY® 3 Level Plates

Part No.	Length	Qty
197.337	37mm	1
197.340	40mm	1
197.343	43mm	1
197.346	46mm	1
197.349	49mm	1
197.352	52mm	1
197.355	55mm	1
197.358	58mm	1
197.361	61mm	1
197.364	64mm	1
197.367	67mm	1
197.370	70mm	1

997.002	UNIFY® 1-3 Level Plate Module

Plate Key (Amount of Compression):

Static (no compression)

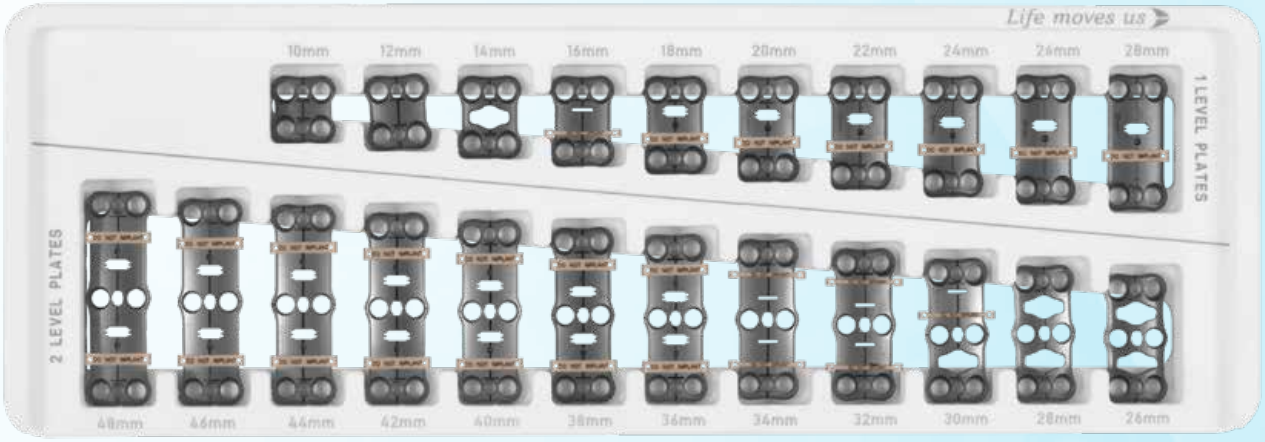
1mm dynamic compression only

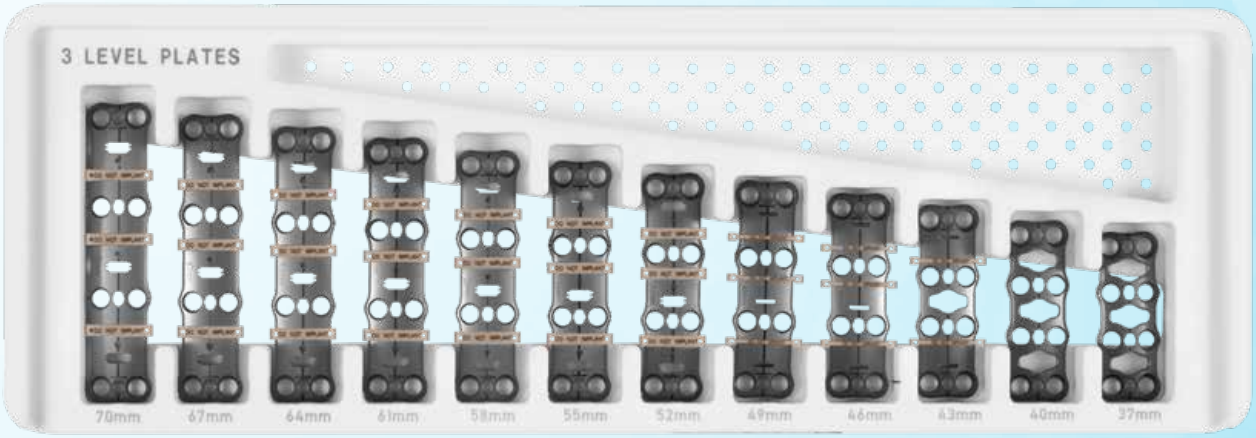
Standard (1mm compression, 2mm dynamic)

Special (2-level plates allow 1mm compression on one end only; 3-level plates allow 1mm compression on each end and a static middle level)

Refer to page 7 for visual reference.

UNIFY®
DYNAMIC CERVICAL PLATE SET 997.902





UNIFY®
SCREW SET 997.908

Variable Angle Screws Self-Drilling

Part No.	4.2mm	Qty
597.610	10mm	4
597.612	12mm	10
597.614	14mm	10
597.616	16mm	10

Part No.	4.6mm	Qty
597.710	10mm	4
597.712	12mm	10
597.714	14mm	10
597.716	16mm	10

Fixed Angle Screws Self-Drilling

Part No.	4.2mm	Qty
597.010	10mm	4
597.012	12mm	10
597.014	14mm	10
597.016	16mm	10

Part No.	4.6mm	Qty
597.510	10mm	4
597.512	12mm	10
597.514	14mm	10
597.516	16mm	10

Variable Angle Screws Self-Tapping

Part No.	4.2mm	Qty
597.810	10mm	4
597.812	12mm	10
597.814	14mm	10
597.816	16mm	10
597.818	18mm	4
597.820	20mm	4

Part No.	4.6mm	Qty
597.910	10mm	4
597.912	12mm	10
597.914	14mm	10
597.916	16mm	10
597.918	18mm	4
597.920	20mm	4

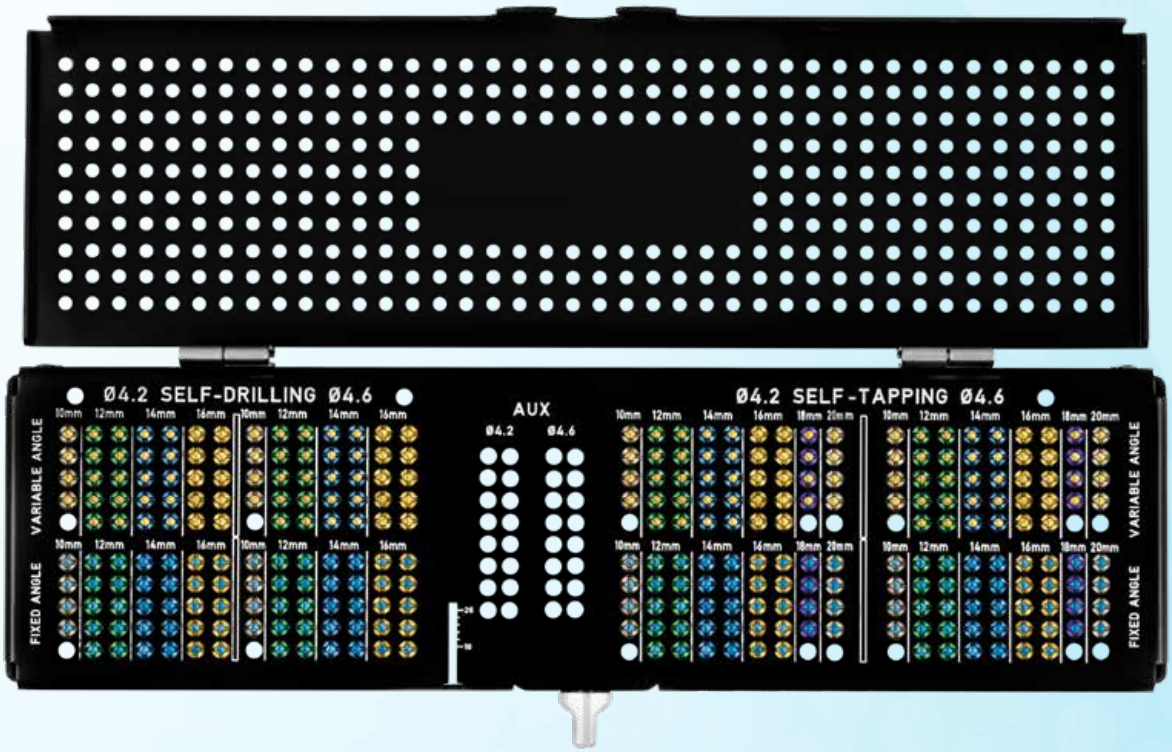
Fixed Angle Screws Self-Tapping

Part No.	4.2mm	Qty
597.030	10mm	4
597.032	12mm	10
597.034	14mm	10
597.036	16mm	10
597.038	18mm	4
597.040	20mm	4

Part No.	4.6mm	Qty
597.530	10mm	4
597.532	12mm	10
597.534	14mm	10
597.536	16mm	10
597.538	18mm	4
597.540	20mm	4

997.008	UNIFY® Screw Module

UNIFY®
SCREW SET 997.908



UNIFY®
INSTRUMENT SET 997.901

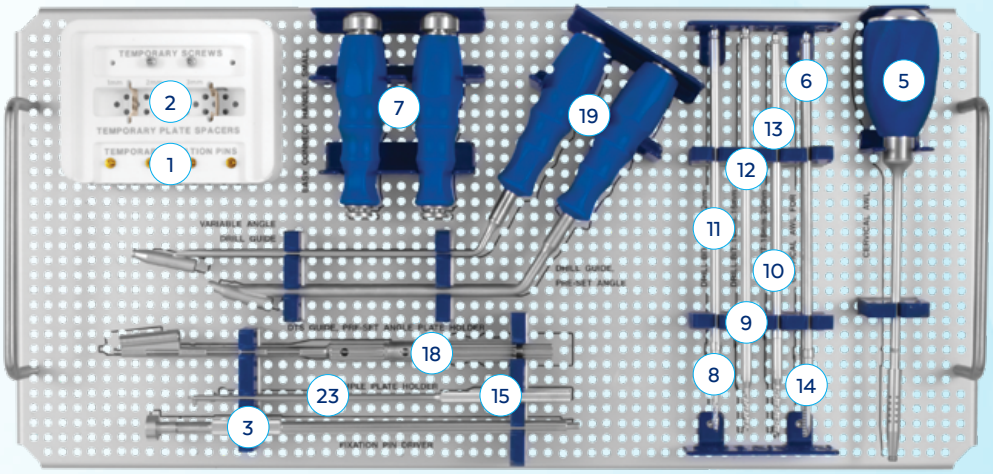
	Part No.	Description	Qty
1	697.010	Temporary Fixation Pin	4
2	697.001	Temporary Plate Spacer, 1mm	1
	697.002	Temporary Plate Spacer, 2mm	1
	697.003	Temporary Plate Spacer, 3mm	1
3	697.020	Fixation Pin Driver	1
4	697.030	Temporary Pin Removal Tool	1
5	610.701	Cervical Awl, with Sleeve	1
6	610.704	Cervical Awl, for Drill Guide	1
7	697.705	Easy Connect Handle, Small	2
8	610.710	Drill Bit, 10mm	1
9	610.712	Drill Bit, 12mm	1
10	610.714	Drill Bit, 14mm	1
11	610.716	Drill Bit, 16mm	1
12	610.718	Drill Bit, 18mm	1
13	610.720	Drill Bit, 20mm	1
14	610.740	ACDF Tap	1
15	697.810	Simple Plate Holder	1
16	697.701	Graft Compressor	1
17	697.702	Graft Compressor, Torque-Limiting Handle	1
18	697.206	DTS Guide, Pre-Set Angle Plate Holder, Single Barrel	1
19	610.832	Variable Angle Drill Guide, Short Barrel	1
20	697.820	Screwdriver	2
21	697.821	Trilobular Driver	2
22	610.831	2.5mm Hex Driver, Quick-Connect	1
23	697.903	Spacer Removal Tool	1
24	697.822	Counter-Torque	1
25	697.907	Reset Tool	1
26	697.312	Torque-Limiting, Quick-Connect Handle, 0.3Nm	1
	997.100	UNIFY® Graphic Case	

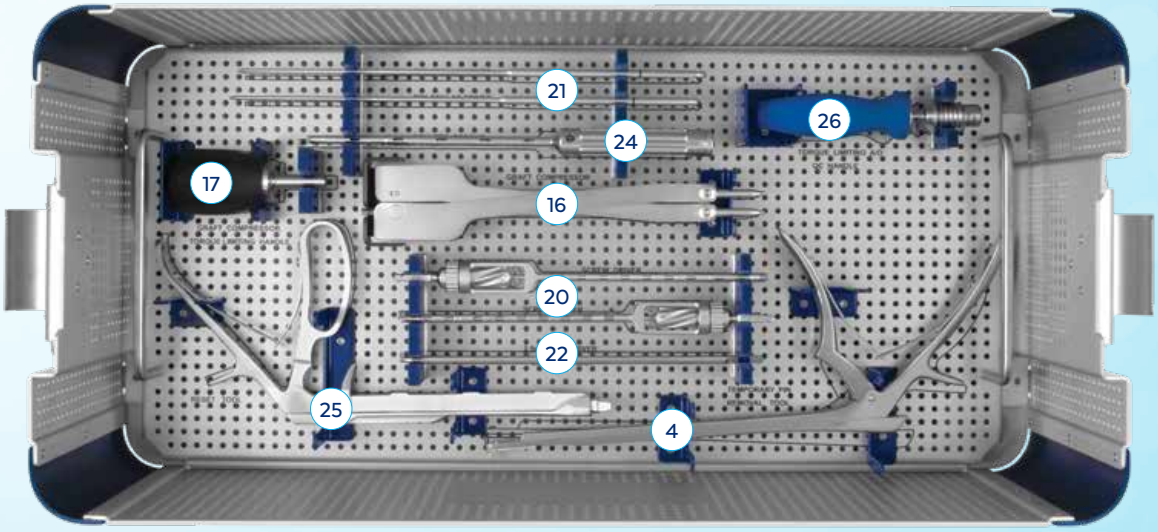
Additionally Available

610.801	Caliper
610.804	Temporary Fixation Screw
610.811	Cervical Depth Gauge
610.813	Drill Guide, Variable Angulation
697.203	DTS Guide, Pre-Set Angle Plate Holder, Double Barrel
697.823	Cruciform Driver, Self-Retaining
697.824	Driver Sleeve

*Additionally available

UNIFY®
INSTRUMENT SET 997.901





IMPORTANT INFORMATION ON THE UNIFY® SYSTEM

DESCRIPTION

The UNIFY® Dynamic Anterior Cervical Plate System consists of plates and variable or fixed angle screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (C2-C7). The plate allows translation to accommodate bone graft resorption.

The UNIFY® Dynamic Anterior Cervical Plate System implants are manufactured from titanium alloy, as specified in ASTM standards F136, F1472, and F1295.

INDICATIONS

The UNIFY® Dynamic Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks, which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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

Possible adverse effects that may occur include: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; 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. 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.

Plate contouring is not recommended due to the plate's translational components.

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 implant size, screw diameter and length.

Surgical implants 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.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Adequately instruct the patient. Mental or physical impairment that compromises or prevents 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.

MRI SAFETY INFORMATION

UNIFY® Dynamic Anterior Cervical Plate Systems are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Quadrature Body Coil only

Under the scan conditions defined above, the UNIFY® Dynamic Anterior Cervical Plate Systems are expected to produce a maximum temperature rise of less than or equal to 3.5°C after 15 minutes of continuous scanning.

The image artifact is not expected to extend beyond 55mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS

Use of this 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. Severe osteoporosis, which may prevent adequate fixation.
3. 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.
4. 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.
5. Any condition not described in the indications for use.

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 AND USE

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.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

IMPORTANT INFORMATION ON THE UNIFY® SYSTEM

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.

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 pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

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 (U.S.A.) Law Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	Quantity		

DI159A Rev F

Globus Medical
Valley Forge Business Center
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Audubon, PA 19403
www.globusmedical.com

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

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