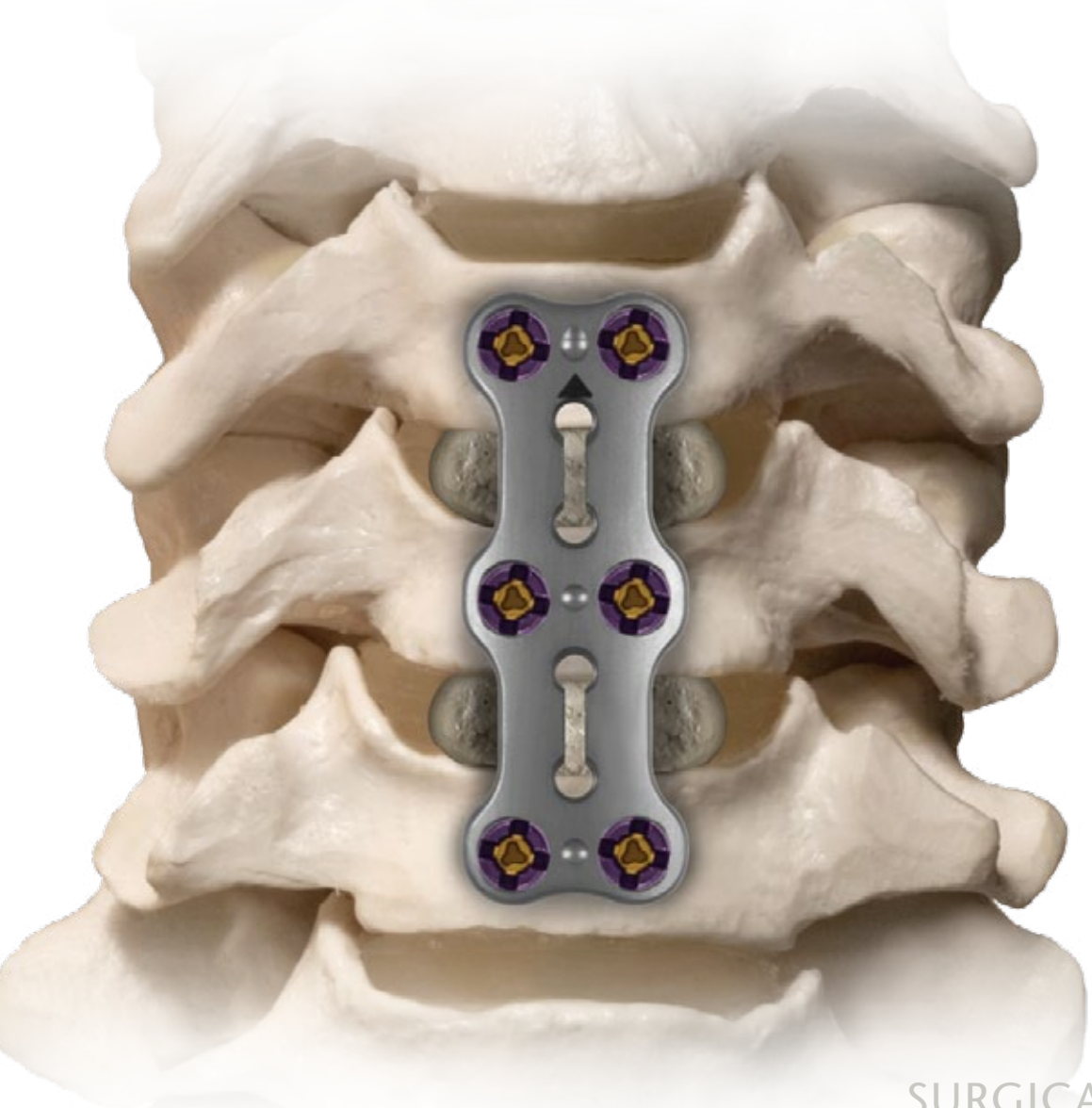
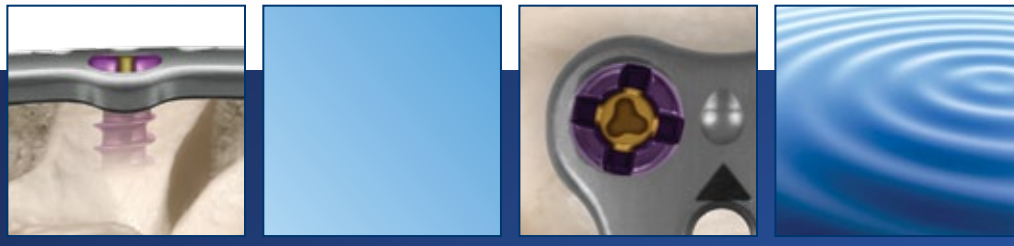
Life moves us



SURGICAL TECHNIQUE



ASSURE®-X

Anterior Cervical 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

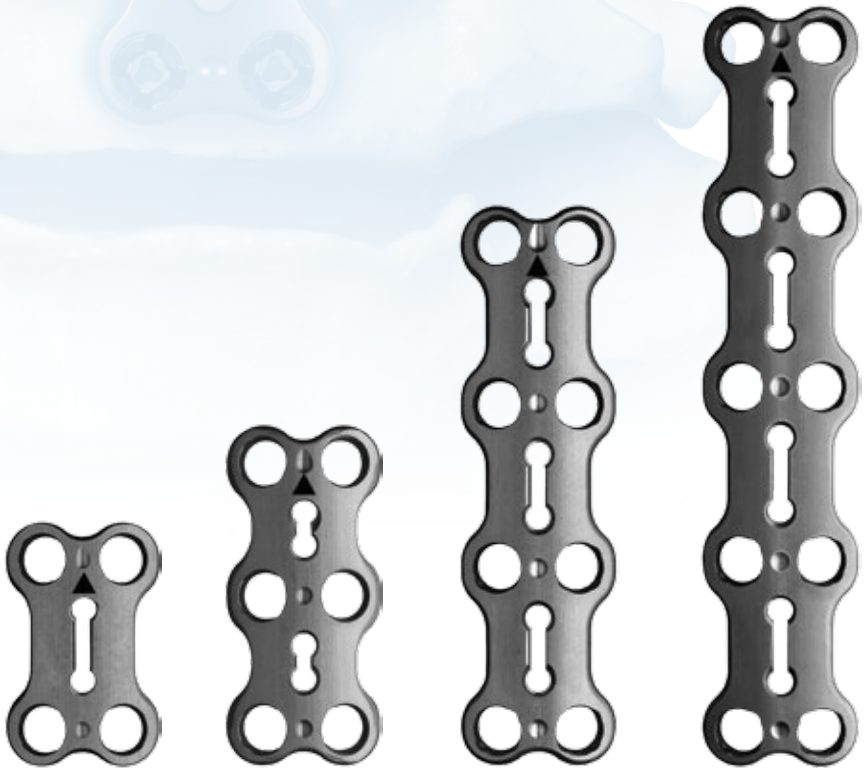
www.globusmedical.com

ASSURE® -X

Anterior Cervical Plate System

ASSURE®-X combines the proven success of a low-profile anterior cervical plate with audible, tactile, and visual screw locking.

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



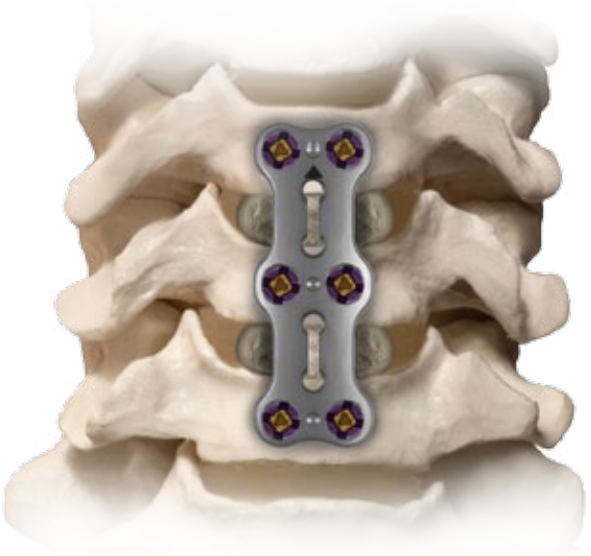
ASSURE®-X
DISTINGUISHING CHARACTERISTICS

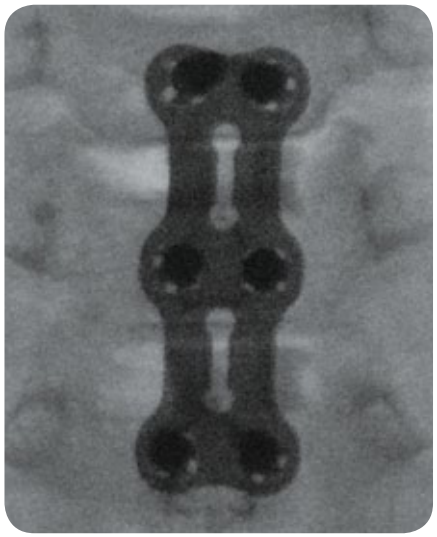
Proven Success

The cornerstone of ASSURE®-X is the ASSURE® Plate, launched in 2004, which has a proven track record of strength and reliability.

Low Profile

The plate has a low profile and smooth surface designed to help reduce esophageal irritation.





Secure Locking

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

Unlocked

Locked

Screwdriver

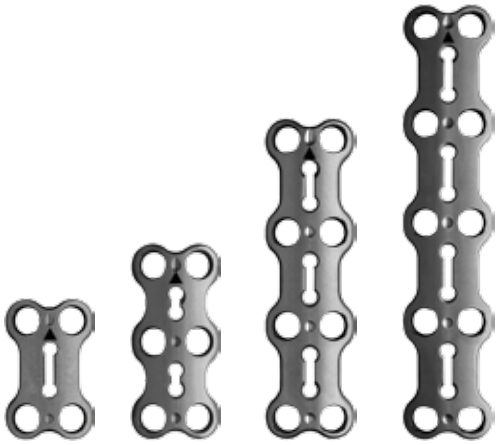
CONTENTS

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

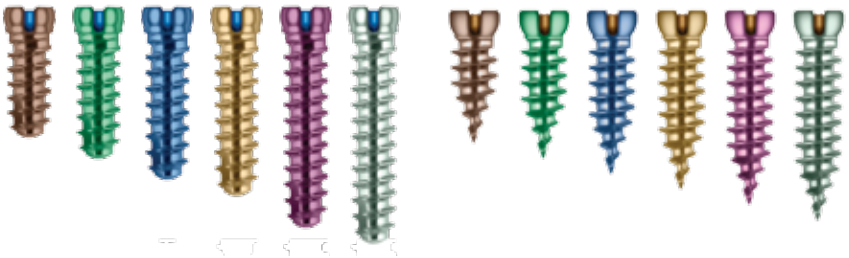
ASSURE®-X Plates

- 1.8mm profile
- 16mm width (11mm at waist)
- Textured undersurface
- Lengths from 10-100mm
- 1, 2, 3 and 4-Level plates



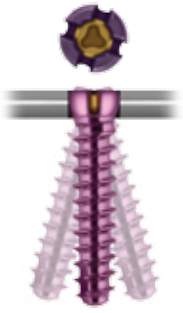
Pre-Assembled Expanding Screws

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

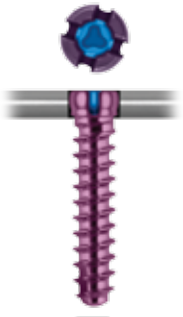


Screw Angulation

- Variable angle screw provides ±18˚angulation
- Pre-set angulation with drill guide
  - 11.5˚ medial
  - Cephalad/caudal angulation is perpendicular to the plate

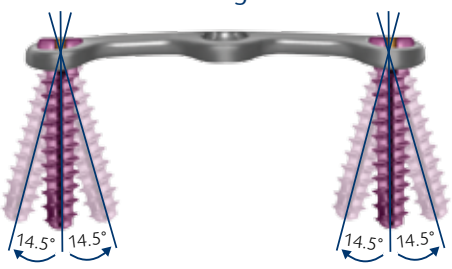


Variable Angle Screw

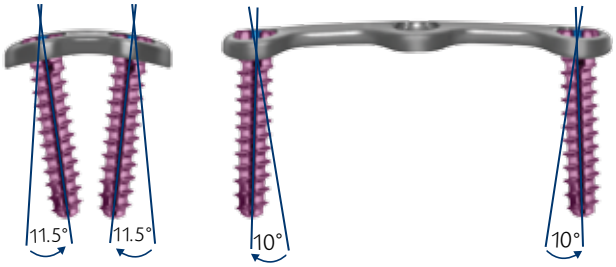


Fixed Angle Screw

Variable Angulation



Pre-Set Angulation



INSTRUMENT OVERVIEW

Screw Hole Preparation Instruments

Cervical Awl, with Sleeve 610.701

Awl Sleeve Retracted

Cervical Awl, for Drill Guide 610.704

Drill Bits

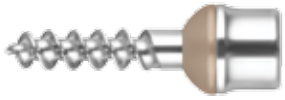
610.710	10mm	
610.712	12mm	
610.714	14mm	
610.716	16mm	
610.718	18mm	
610.720	20mm	

Easy Connect Handle, Small 610.705

ACDF Tap 610.740

Plate Insertion Instruments

Simple Plate Holder 697.810



Temporary Fixation Screw 610.804

2.5mm Hex Driver, Quick-Connect 610.831

Plate Bender, Large 610.806

Screw Instruments

Screwdriver 697.820

Screw Instruments (cont'd)

DTS Guide, Pre-Set Angulation, Cephalad 610.840

DTS Guide, Pre-Set Angulation 610.841

Variable Angle Drill Guide, Short Barrel 610.832

Torque Limiting, Quick-Connect Handle, 0.3Nm 697.312

Trilobular Driver 697.821

Counter Torque 697.822

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). ASSURE®-X 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.

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 the Simple Plate Holder to place the plate

Plate Placement (cont'd)

All plates are pre-contoured in the sagittal plane to provide lordosis and in the axial plane to fit the cervical vertebrae. However, additional contouring may be accomplished using the **Plate Bender, Large**.

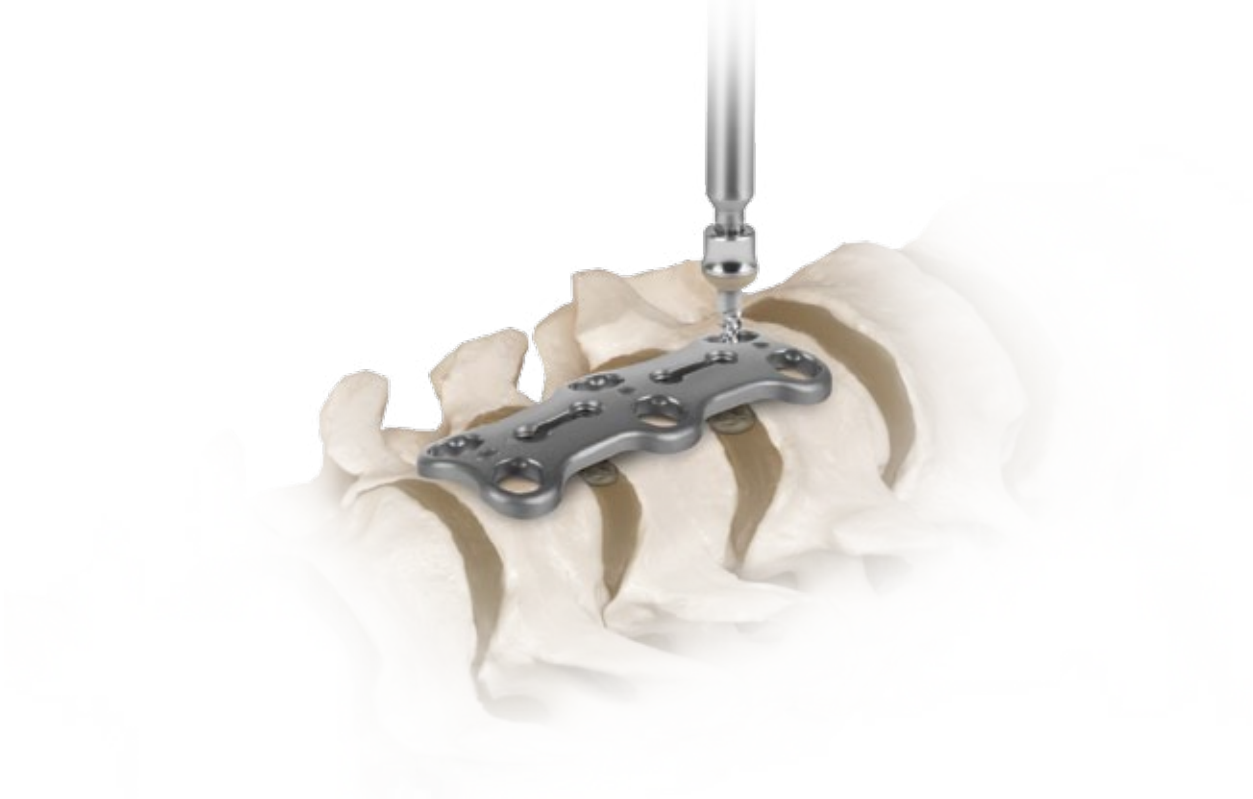
To add lordosis, insert the plate onto the bender with the top of the plate facing the bottom anvil and ensure that the top anvil is not covering the screw holes.

For multi-level plates, incrementally bend sections and slide the plate along the bottom anvil to the next level. At every level, check to ensure that the top anvil is not covering the screw holes.

Note: Plates may be bent to increase lordosis only. Repeated bending may weaken the plate.

Step 3 Screw Hole Preparation

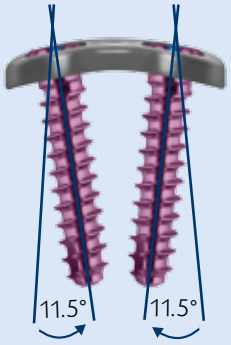
The plate may be temporarily secured by using **Temporary Fixation Screws**. Use the **2.5mm Hex Driver, Quick-Connect** to insert and remove the temporary screw from the screw holes.



Inserting the Temporary Fixation Screw

Using the DTS and Drill Guides with Pre-Set Angulation

These instruments provide the pre-set screw angulation shown below for awling, drilling, tapping and screw insertion.

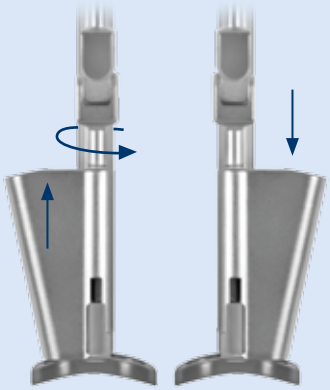


Axial plane

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

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.



Option A: Pre-Set Angulation

Secure either the **DTS Guide, Pre-Set Angulation** or the **DTS Guide, Pre-Set Angulation, Cephalad** into the threaded central hole in the plate. The DTS Guide, Pre-Set Angulation, Cephalad is only to be used in the cephalad bone screw holes. The DTS Guide, Pre-Set Angulation may be used for the remaining bone screw holes of the plate.

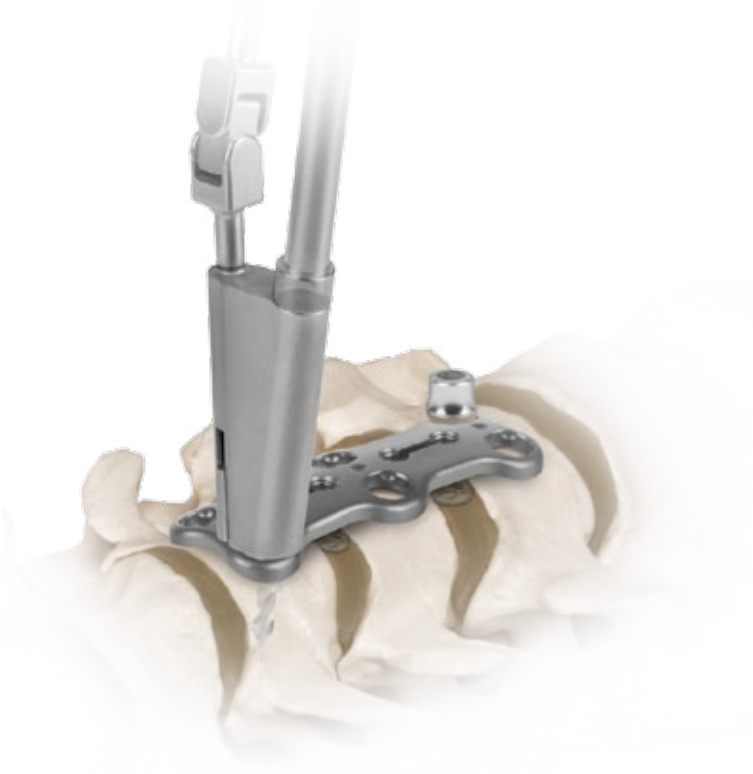
Start each pilot screw hole by inserting the **Cervical Awl, for Drill Guide** into the DTS guide.

Determine the desired drill depth and select the appropriate fixed length **Drill Bit**. Assemble the bit to the **Easy Connect Handle, Small** and insert it 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 12 for screw insertion.

To remove the DTS guide, rotate the back knob counterclockwise and pull the guide from the plate.



Using DTS Guide, Pre-Set Angulation, Cephalad to prepare screw pilot hole

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

Option B: Variable Angulation

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.

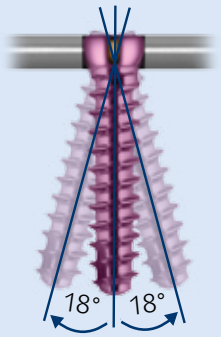
Determine the desired drill depth and select the appropriate fixed length Drill Bit. Assemble the bit to the easy connect handle and insert into the drill guide. Drill to the stop. Screw holes may be tapped using the ACDF Tap, once the drill guide is removed.

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

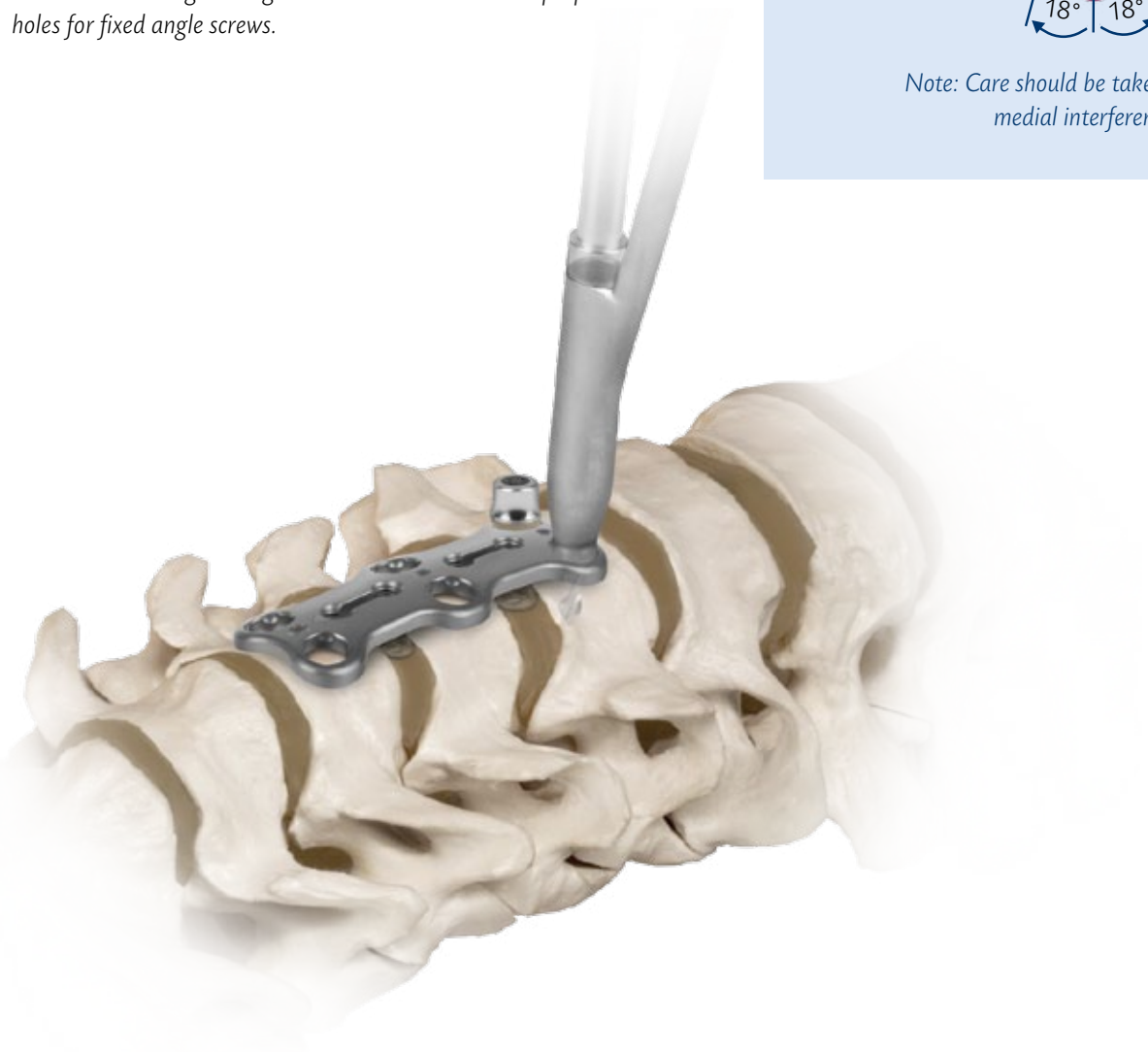
Using the Variable Angle Drill Guide

Screw Angulation

This guide allows screw angulation of 18° in any direction for drilling screw pilot holes.



Note: Care should be taken to prevent medial interference.



Using Variable Angle Drill Guide to prepare screw pilot hole

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 into the length gauge with the bottom of the screw head resting on the side of the module.

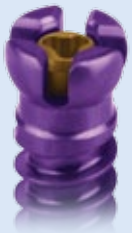
Locking Insert

Confirm variable angle or fixed angle screw by the color of the locking insert. The body of the screw is color-coded by screw length.

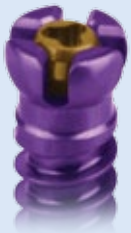
Variable
GOLD

Fixed
LIGHT BLUE

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



Unlocked



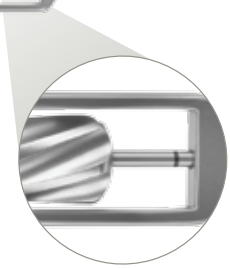
Locked

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

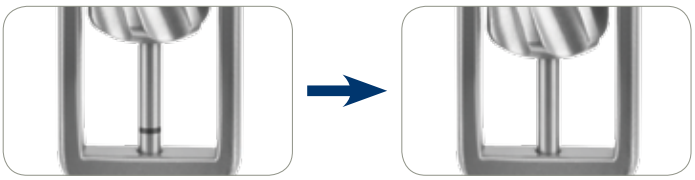
Step 4 Screw Insertion

Pre-assembled expanding 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.



Disengaged

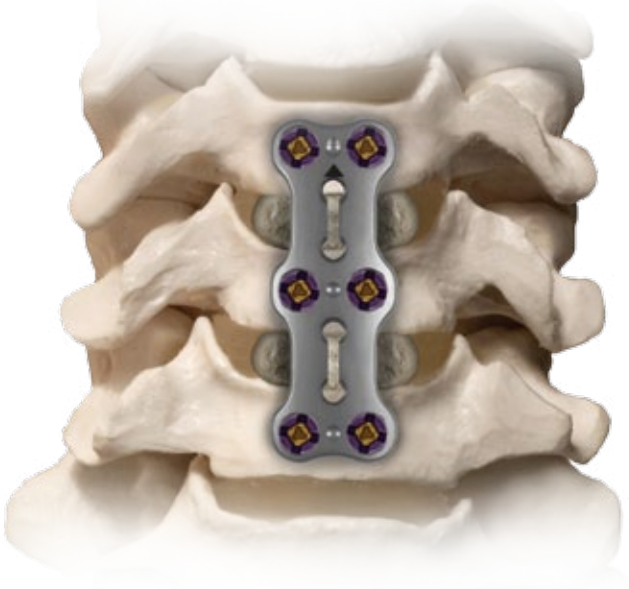
Engaged

Locking Confirmation (Final Tightening)

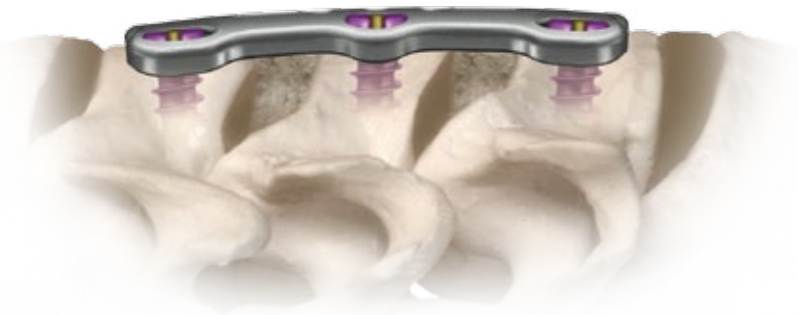
Assemble the Trilobular Driver and Torque Limiting Quick-Connect Handle, 0.3Nm. Insert the driver into the Counter Torque. Fully engage the Counter Torque into the screw and slide the driver into the locking insert. Rotate the easy connect handle clockwise until it reaches its torque limit of 0.3Nm.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

Note: All screw lengths are measured by bone engagement.

Final Construct



AP View

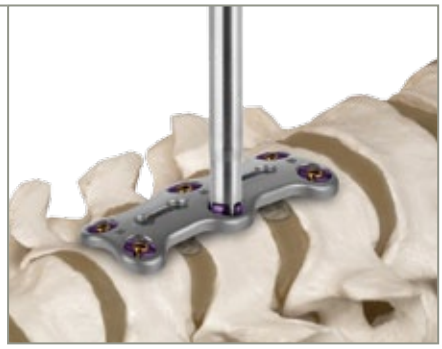


Lateral View

Optional Technique: Screw 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.

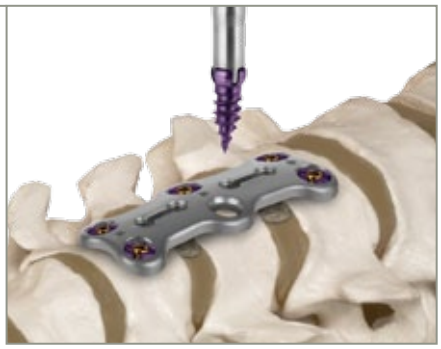
Engage the outer diameter of the screw with the Counter Torque.



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 self-retaining Screwdriver by rotating counterclockwise.

Repeat for all screws.

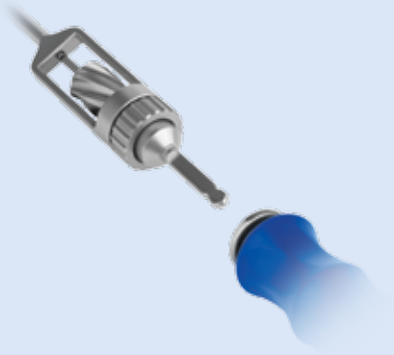


Screwdriver Disassembly

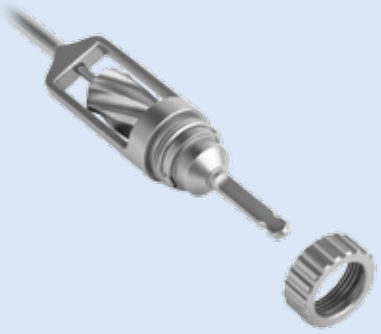
The Screwdriver is designed to easily disassemble for cleaning.

Disassembly for Cleaning

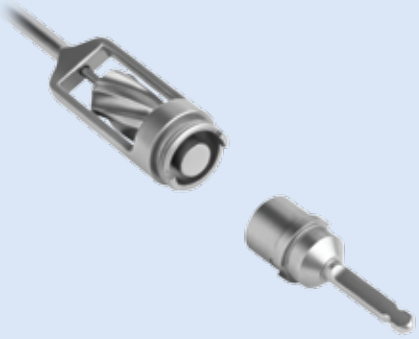
1. Disengage the Easy Connect Handle, Small from the Screwdriver.



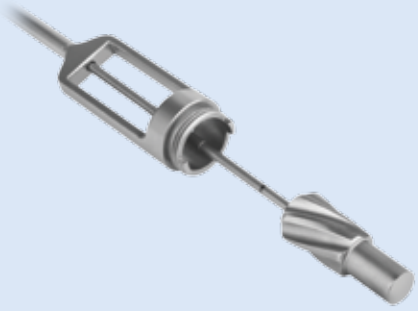
2. Rotate the retaining cap counterclockwise until it is fully removed from the outer shaft.



3. Remove the connector.



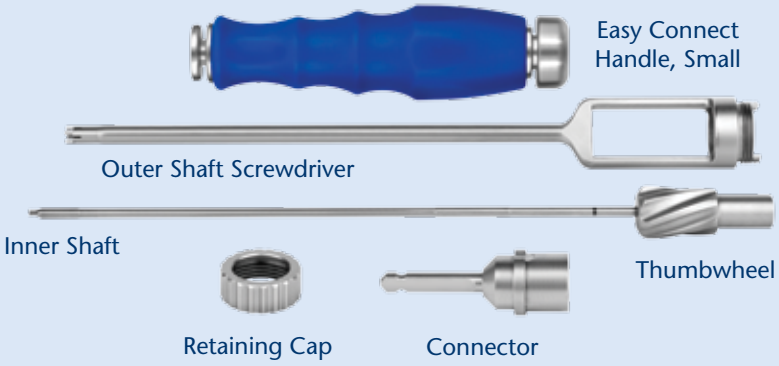
4. Remove the inner shaft.



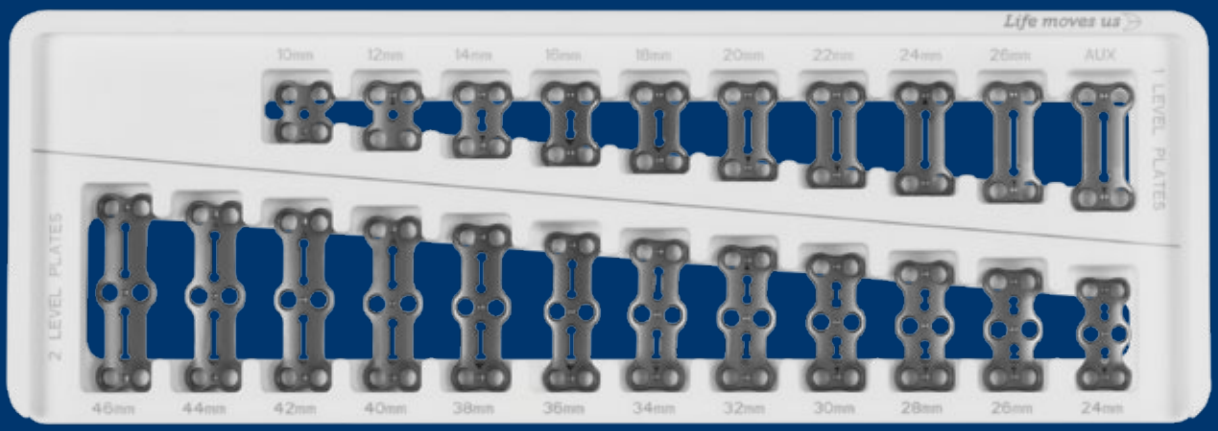
The Screwdriver is now fully disassembled and ready for cleaning.

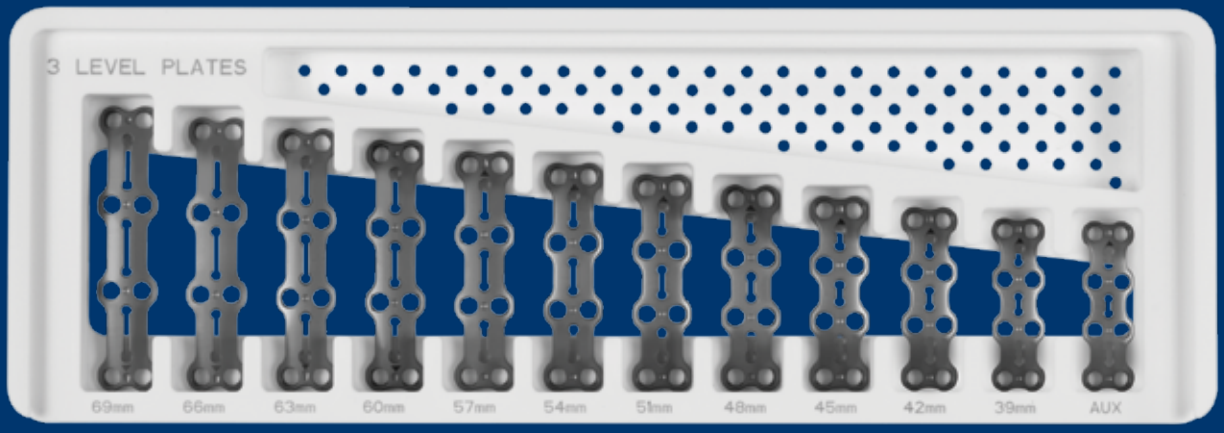
Reassembly

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



ASSURE®-X PLATE SET





ASSURE®-X Cervical Plate Sets

ASSURE®-X 1-3 Level Plate Set 910.912

1-Level

Part No.	Length	Qty
110.110	10mm	1
110.112	12mm	1
110.114	14mm	1
110.116	16mm	1
110.118	18mm	1
110.120	20mm	1
110.122	22mm	1
110.124	24mm	1
110.126	26mm	1

2-Level

Part No.	Length	Qty
110.226	26mm	1
110.228	28mm	1
110.230	30mm	1
110.232	32mm	1
110.234	34mm	1
110.236	36mm	1
110.238	38mm	1
110.240	40mm	1
110.242	42mm	1
110.244	44mm	1
110.246	46mm	1

3-Level

Part No.	Length	Qty
110.339	39mm	1
110.342	42mm	1
110.345	45mm	1
110.348	48mm	1
110.351	51mm	1
110.354	54mm	1
110.357	57mm	1
110.360	60mm	1
110.363	63mm	1
110.366	66mm	1
110.369	69mm	1

910.012 ASSURE®-X 1-3 Level Plate Module

ASSURE®-X 4 Level Plate Set 910.914

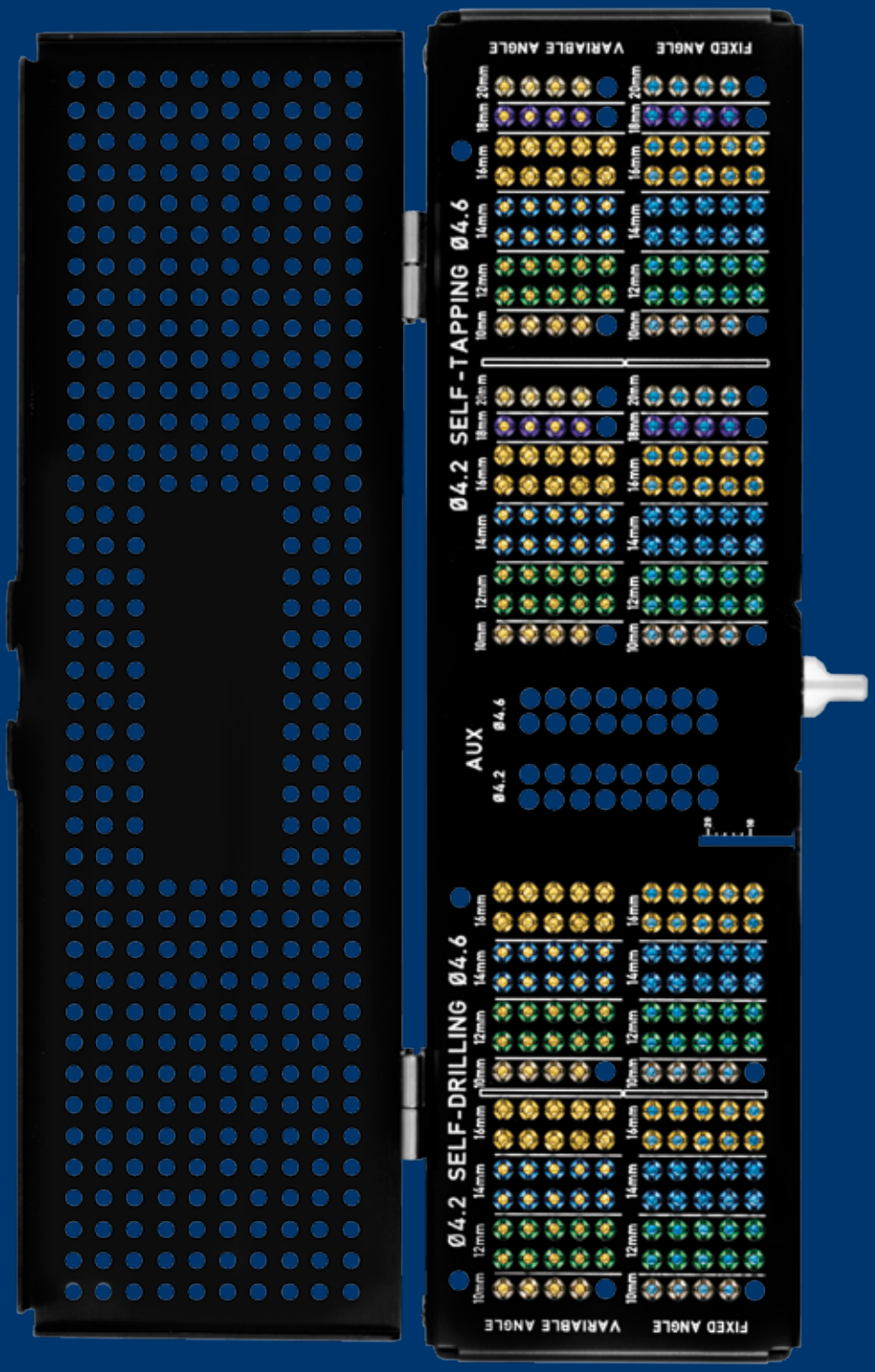
4-Level

Part No.	Length	Qty
110.460	60mm	1
110.464	64mm	1
110.468	68mm	1
110.472	72mm	1
110.476	76mm	1
110.480	80mm	1
110.484	84mm	1
110.488	88mm	1
110.492	92mm	1
110.496	96mm	1
110.500	100mm	1

Additionally Available Instruments

910.014 ASSURE®-X 4 Level Plate Module

UNIFY™ SCREW SET



UNIFY™ Screw Set 997.908

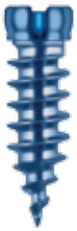
Variable Angle Screws Self-Drilling

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

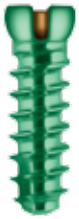


Part No.	4.6mm	Qty
597.510	10mm	4
597.512	12mm	10
597.514	14mm	10
597.516	16mm	10

Variable Angle Screws Self-Tapping

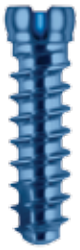
Part No.	4.2mm	Qty
597.810	10mm	4
597.812	12mm	10
597.814	14mm	10
597.816	16mm	10
597.818	18mm	4
597.820	20mm	4

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

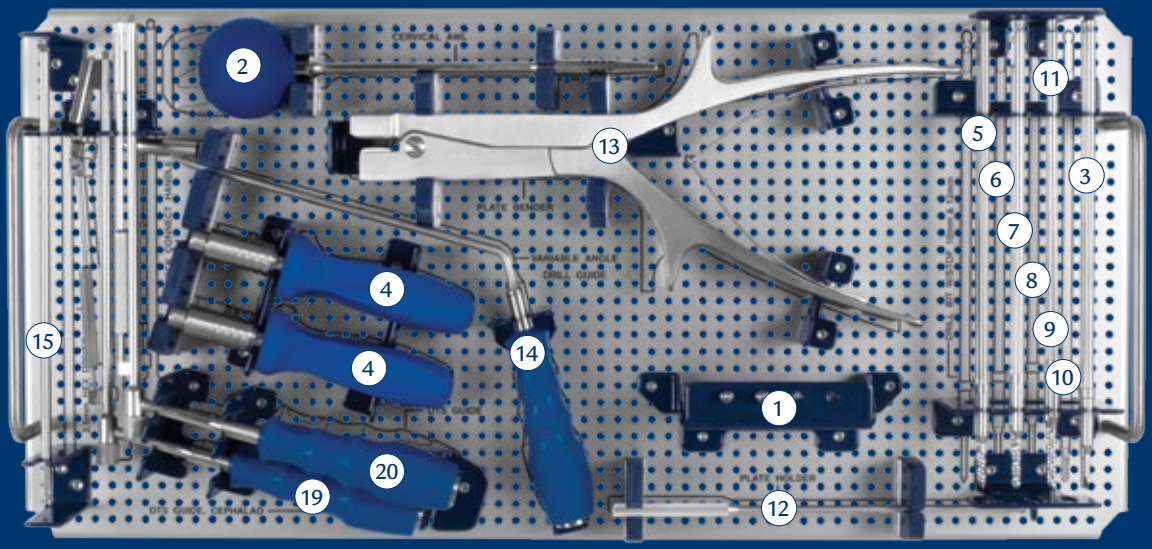
Part No.	4.2mm	Qty
597.030	10mm	4
597.032	12mm	10
597.034	14mm	10
597.036	16mm	10
597.038	18mm	4
597.040	20mm	4

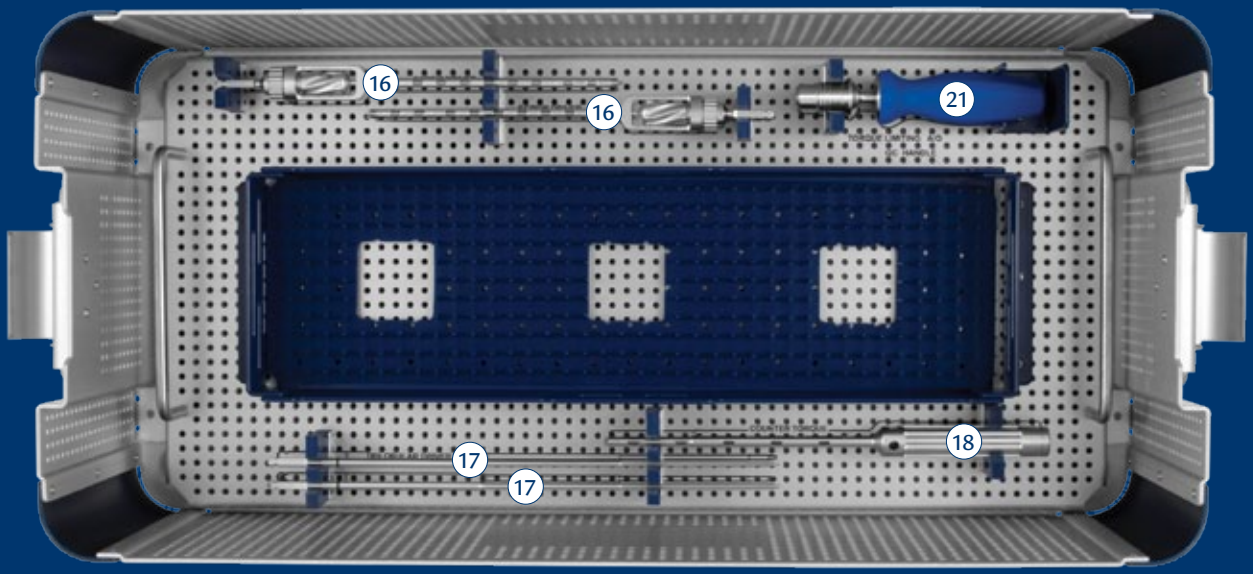


Part No.	4.6mm	Qty
597.530	10mm	4
597.532	12mm	10
597.534	14mm	10
597.536	16mm	10
597.538	18mm	4
597.540	20mm	4

997.008 UNIFY™ Screw Module

ASSURE®-X INSTRUMENT SET





ASSURE®-X Instrument Set 997.901

		Instruments	Qty
1	697.804	Temporary Fixation Screw	2
2	610.701	Cervical Awl	1
3	610.704	Cervical Awl, for Drill Guide	1
4	697.705	Easy Connect Handle, Small	2
5	610.710	Drill Bit with Stop, 10mm	1
6	610.712	Drill Bit with Stop, 12mm	1
7	610.714	Drill Bit with Stop, 14mm	1
8	610.716	Drill Bit with Stop, 16mm	1
9	610.718	Drill Bit with Stop, 18mm	1
10	610.720	Drill Bit with Stop, 20mm	1
11	610.740	ACDF Tap	1
12	697.810	Simple Plate Holder	1
13	610.806	Plate Bender, Large	1
14	610.832	Variable Angle Drill Guide, Short Barrel	1
15	610.831	2.5mm Hex Driver, Quick-Connect	1
16	697.820	Screwdriver	2
17	697.821	Trilobular Driver	2
18	697.822	Counter Torque	1
19	610.840	DTS Guide, Pre-set Angulation, Cephalad	1
20	610.841	DTS Guide, Pre-set Angulation	1
21	697.312	Torque Limiting, Quick-Connect Handle, 0.3Nm	1
	910.200	ASSURE®-X Graphic Case	

Additionally Available Instruments

610.801	Caliper
610.811	Cervical Depth Gauge
610.817	Counter Torque for Rigid Screws
610.825	Screwdriver, for Set Screw, without Sleeve
610.829	Cruciform Driver, Self-Retaining

IMPORTANT INFORMATION ON THE ASSURE® ANTERIOR CERVICAL PLATE SYSTEM

DESCRIPTION

The ASSURE® Anterior Cervical Plate System consists of plates used with either standard screws or rigid screws and set screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (levels C2-C7). The implants of this system are manufactured from titanium alloy.

INDICATIONS

The ASSURE® 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 (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

WARNING

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

ATTENTION

See Warnings, Precautions and Potential Adverse Events sections of the insert entitled "Suggestions Concerning Orthopaedic Metallic Internal Fixation Devices" for a complete list of potential risks.

CLEANING

Cleaning instructions 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.

STERILIZATION

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 the 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.

REV D

IMPORTANT INFORMATION ON THE UNIFY™ DYNAMIC ANTERIOR CERVICAL PLATE 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.

WARNING

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.

UNIFY™ implants have not been evaluated for safety and compatibility in the MR environment. UNIFY™ has not been tested for heating and migration in the MR environment.

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.

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

UNIFY™ implants and instruments are available nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. All components should be carefully checked to ensure that there is no damage prior to use. Damaged products should not be used, and should be returned to Globus Medical. 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. Instruments should be checked to ensure that they are in working order prior to surgery. All instruments 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.

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,

IMPORTANT INFORMATION ON THE UNIFY™ DYNAMIC ANTERIOR CERVICAL PLATE SYSTEM (CONT'D)

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

UNIFY™ Dynamic Anterior Cervical Plate implants and instruments are available nonsterile.

Nonsterile UNIFY™ Dynamic Anterior Cervical Plate implants and instruments have been validated to ensure 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. 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 (USA) Law Restricts this Device to Sale by or on the order of a Physician.

REV B

Notes

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Audubon, PA 19403
www.globusmedical.com

Customer Service:
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