GLOBUS MEDICAL

ASSURE®

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

ASSURE®

ASSURE®

Anterior Cervical Plate System

ASSURE® is an anterior cervical plate that requires only one step for inserting and locking screws into place. The plate design allows for a smooth anterior surface while maintaining a low profile.

One-Step Locking Mechanism

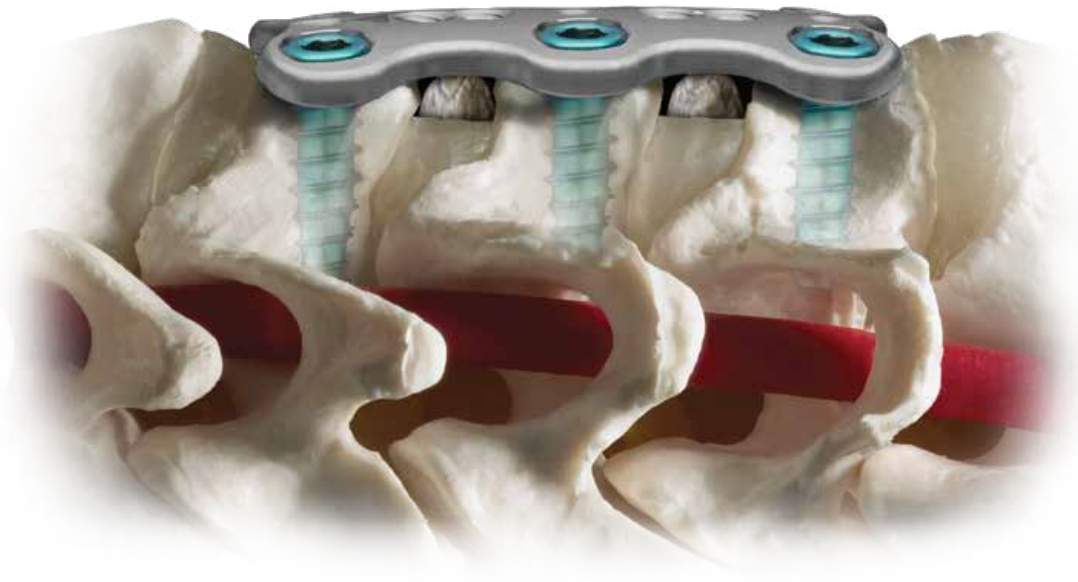
One instrument to insert and lock screw into plate.

Low Profile Design

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

Unique Design

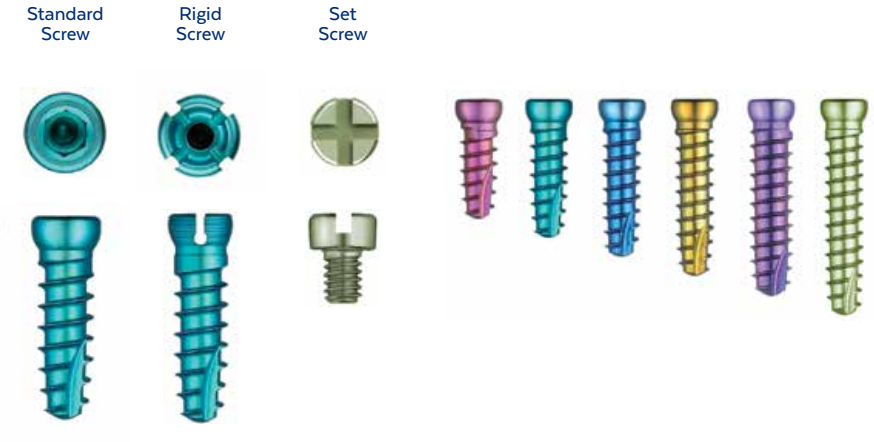
- Lags plate to bone
- Rigid screw option
- Hybrid constructs
- Titanium alloy (TAV)



IMPLANT OVERVIEW

Screws

- 4.0mm or 4.5mm diameter
- Self-drilling or self-tapping
- Lengths 10, 12, 14, 16, 18, 20mm

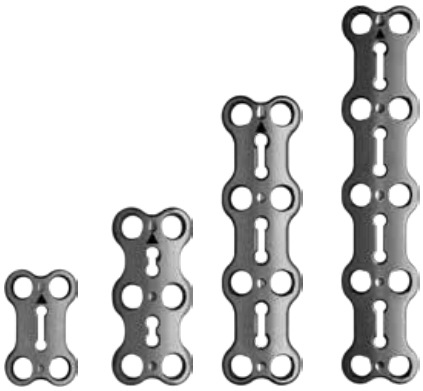


Screw Angulation

- ±18° angulation for all screws
- Pre-set angulation with Drill Guide
- 6° medial angle
- 10° cephalad angle
- 0° caudal angle

ASSURE® Plates

- Low profile: 1.8mm thick
- Narrow width 16mm (11mm at the waist)
- Textured undersurface
- 1, 2, 3 and 4 level plates
- Lengths 10–100mm (hole to hole)
- Titanium alloy (TAV)



ASSURE®-T Plates

- 2.3mm thick
- 16.5mm width
- Textured undersurface
- 1, 2, 3 and 4 level plates
- Lengths 12-100mm (hole to hole)
- Titanium alloy (TAV)

INSTRUMENT OVERVIEW

SCREW PREPARATION INSTRUMENTS

610.701 Cervical Awl

610.702 Small Quick Connect Handle

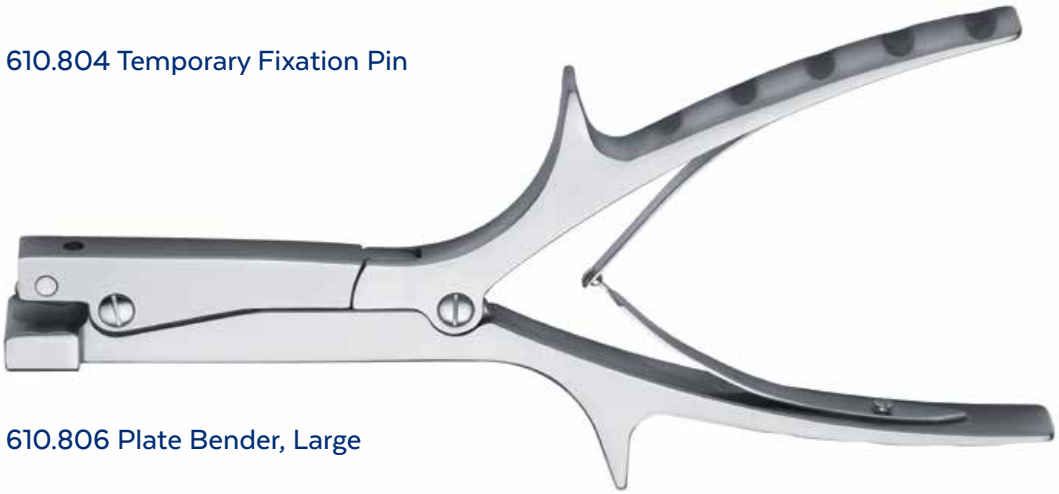
Drill Bits with Stop for 4.0/4.5mm Screws

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

610.740 Tap for 4.0/4.5mm Screws

PLATE INSTRUMENTS

610.804 Temporary Fixation Pin



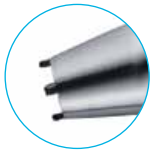
610.806 Plate Bender, Large

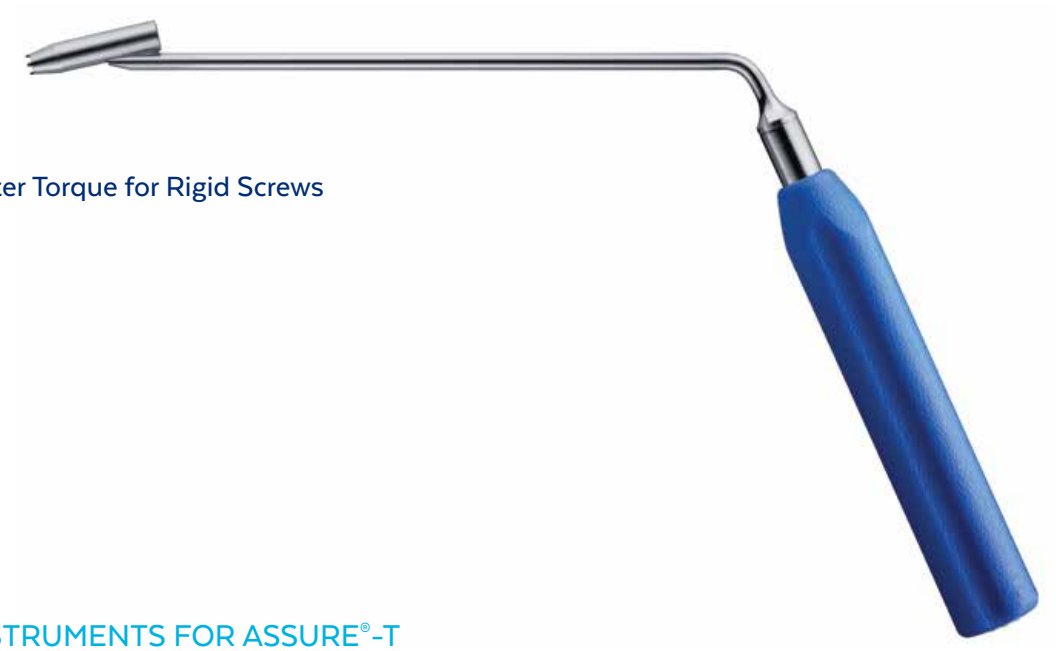
SCREW INSTRUMENTS

610.812 Drill and Screw Guide, Pre-Set Angulation

610.813 Drill Guide, Variable Angulation

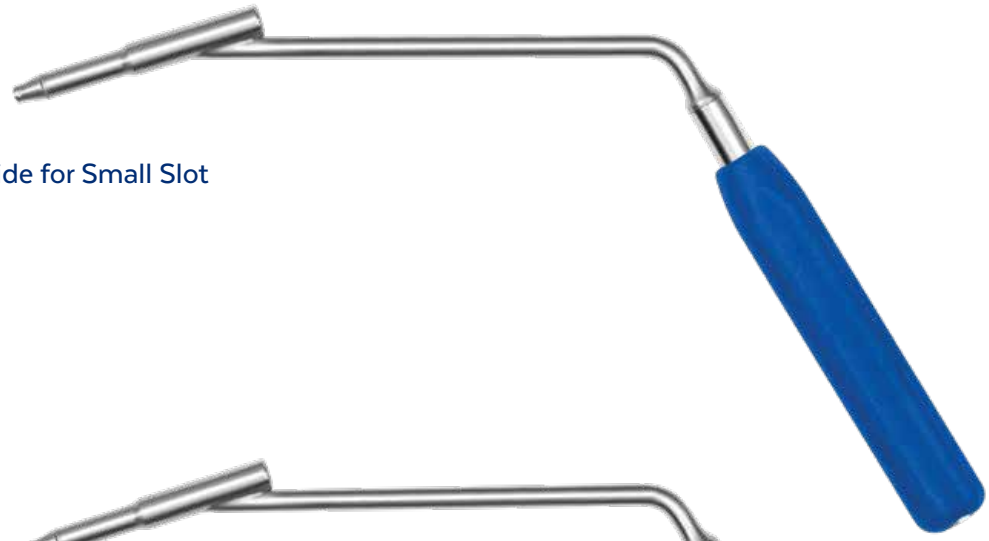
SCREW INSTRUMENTS (CONT'D)



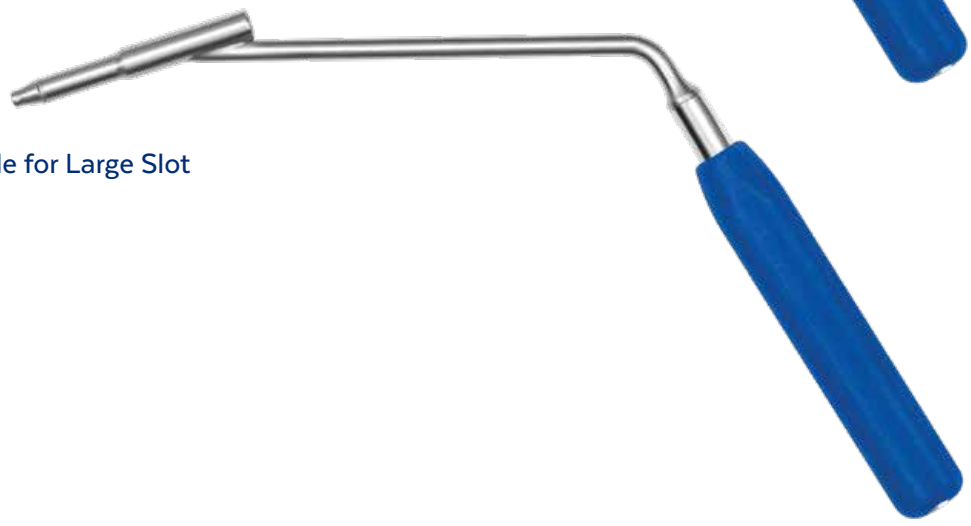


610.817 Counter Torque for Rigid Screws

SCREW INSTRUMENTS FOR ASSURE®-T



617.813 Drill Guide for Small Slot

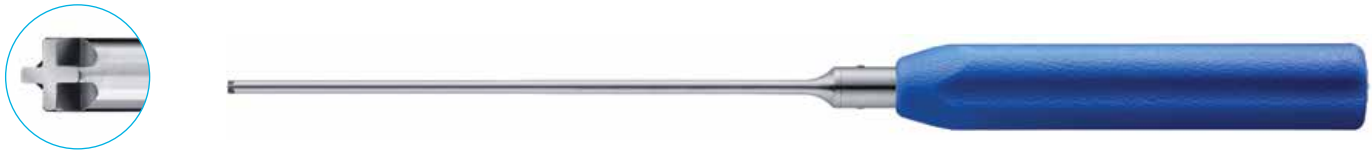


617.814 Drill Guide for Large Slot

SCREW INSTRUMENTS (CONT'D)

610.814 Self-Retaining Screwdriver

610.829 Cruciform Driver, Self-Retaining



610.825 Screwdriver for Set Screws, without Sleeve

610.819 Screw Removal Tool

610.820 Rigid Screw Extractor

SURGICAL TECHNIQUE

ASSURE®

Refer to the package insert printed in the back of this technique guide for information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

STEP 1 APPROACH AND PREPARATION

The patient is placed under anesthesia and positioned supine with support of the posterior cervical spine to maintain cervical lordosis. The operative area is carefully cleaned and an incision is made at the appropriate fusion level(s). ASSURE® plate fixation may be used in the cervical spine between C2 and C7.

Distraction may be accomplished using the Distractor available in the COLONIAL® ACDF System 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 for the recommended technique. Remove any anterior osteophytes to allow the plate to sit flush on the vertebral body.

STEP 2 PLATE PLACEMENT

To determine appropriate plate length, additionally available **Calipers** may be used. Place the Caliper between the centers of the end vertebrae to be fused. Plate lengths are measured between screw hole centers (cephalad to caudal). Determine the appropriate plate length using the gauge on the back of the Caliper.

28mm measurement shown

To remove the desired ASSURE® plate from the plate module, one of three instruments may be used. The **Pre-Set Angulation Drill and Screw Guide** may be secured to the plate by threading the tip of the guide into the center hole on the plate. Alternatively, one of the additionally available plate holders may be used.

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.**

Note: The plate should not be bent at screw hole locations. Repeated bending may weaken the plate.

Removing plate from module using
Pre-Set Angulation Drill and Screw Guide

Removing plate from module using
additionally available Plate Holder

Placing plate on vertebrae using the
Pre-Set Angulation Drill and Screw Guide

STEP 3 SCREW HOLE PREPARATION

Once the plate is positioned over the vertebrae, prepare the screw pilot holes. If needed, **Temporary Fixation Pins** may be used to hold the plate in position. For temporary plate stability, it is recommended that the pin is placed diagonal to the first hole being prepared. Alternatively, the first two screws can be partially inserted and diagonally placed to provide temporary fixation.

Prepare the pilot hole by inserting the **Awl** into the screw hole within the plate. Push down on the awl to allow the sleeve to retract and the tip to break the cortex.

Preparation of the screw hole may be accomplished using one of two guided options. Guided preparation can be accomplished using either variable angulation or pre-set angulation drill guides.

Using the Variable Angle Drill Guide to prepare screw pilot hole

Option A: Variable Angulation

Place the **Variable Angulation Drill Guide** into the desired plate hole. This drill guide permits full angulation of the drill through the plate.

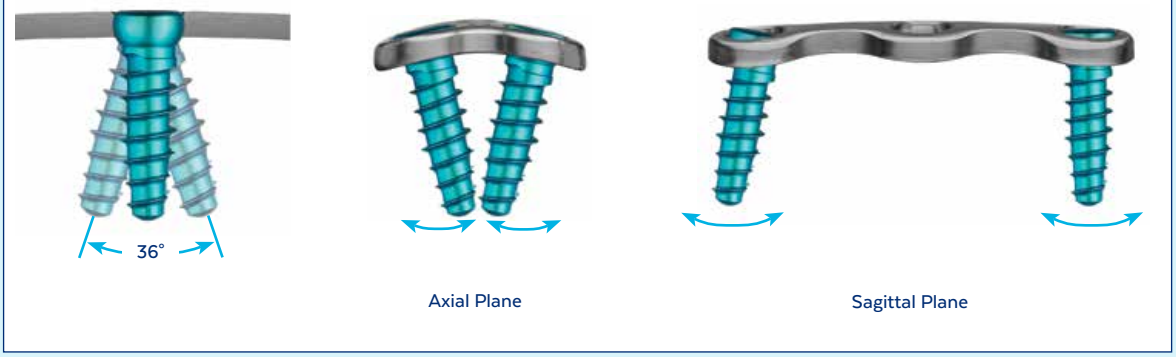
Determine the desired drill depth (10, 12, 14, 16, 18, or 20mm), select the corresponding **Drill Bit**, and assemble to the **Small Quick Connect Handle**. Insert the drill into the drill guide, and drill until it reaches the stop. The **Cervical Depth Gauge** may be used to verify depth.

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

Screws are available in self-drilling and self-tapping designs, both of which are fluted to tap pilot holes. However, holes may be tapped using the **Tap for 4.0/4.5mm Screws**.

VARIABLE ANGULATION DRILL GUIDE

The drill guide allows screw angulation of ±18° in all directions for drilling screw pilot holes.



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

Option B: Pre-Set Angulation

Secure the Pre-Set Angulation Drill and Screw Guide into threaded central hole in plate. Place the drill guide into the desired plate hole. This drill guide provides pre-set angulation of the drill and screw through the plate. The etched triangle indicates the 10° cephalad angle, as shown below.

Determine the desired drill depth (10, 12, 14, 16, 18, or 20mm), select the corresponding Drill Bit, and assemble to the Small Quick Connect Handle. Insert the drill into the drill guide, and drill until it reaches the stop. The Cervical Depth Gauge may be used to verify depth.

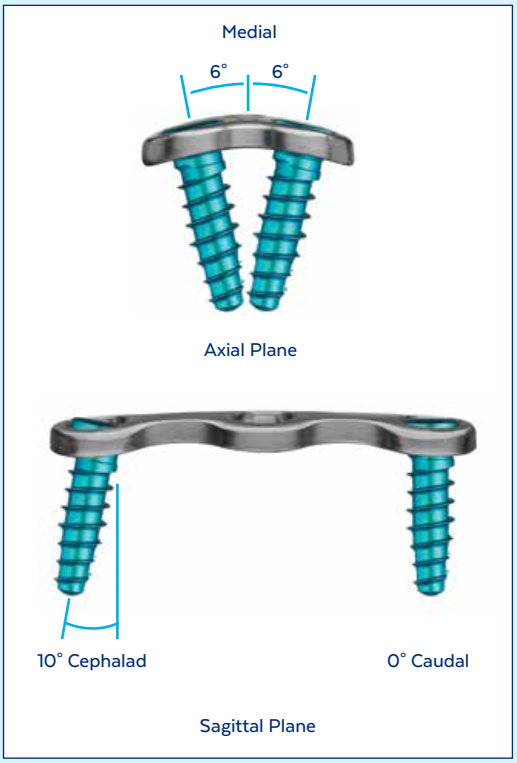
Screws are available in self-drilling and self-tapping designs, both of which are fluted to tap pilot holes. However, holes may be tapped through the drill guide using the **Tap for 4.0/4.5mm Screws**.

The drill guide is designed for left or right rotation to conveniently switch to the contralateral side. Slide the sleeve upward and rotate the guide to the opposite side, as shown below. Screws may also be inserted through this drill guide.

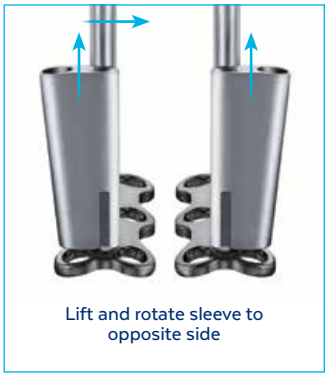
Using the Pre-Set Angulation Drill and Screw Guide to prepare screw pilot hole

PRE-SET ANGULATION DRILL AND SCREW GUIDE

The drill provides pre-set screw angulation for drilling, tapping, and inserting screws.



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



STEP 4 SCREW INSERTION

ASSURE® plates are designed for one-step insertion with standard screws. These screws lag the plate to the vertebral body and provide automatic blocking to help minimize screw backout. Standard screws are not recommended for weak or osteoporotic bone; rigid screws may instead be used as described in Optional Techniques, page 17.

Standard screws are available in 4.0mm and 4.5mm diameters, as self-tapping or self-drilling, and in 10, 12, 14, 16, 18, and 20mm lengths. The 4.0mm screws are recommended for standard use, while the 4.5mm diameter screws are recommended for inferior bone quality or as replacement screws. The 18mm and 20mm screws are available only in the self-tapping design and are recommended for bicortical applications; careful imaging needs to be used with bicortical screws. All screw lengths are measured by bone engagement.

Select the desired screw and use the **Self-Retaining Screwdriver (2.5mm Hex Tip)** to remove it from the screw module. Insert the screw into the plate and prepared pilot hole. Drive the screw partially in, stopping just as the screw head makes contact with the plate. Repeat Step 3 and partial screw insertion for all screws.

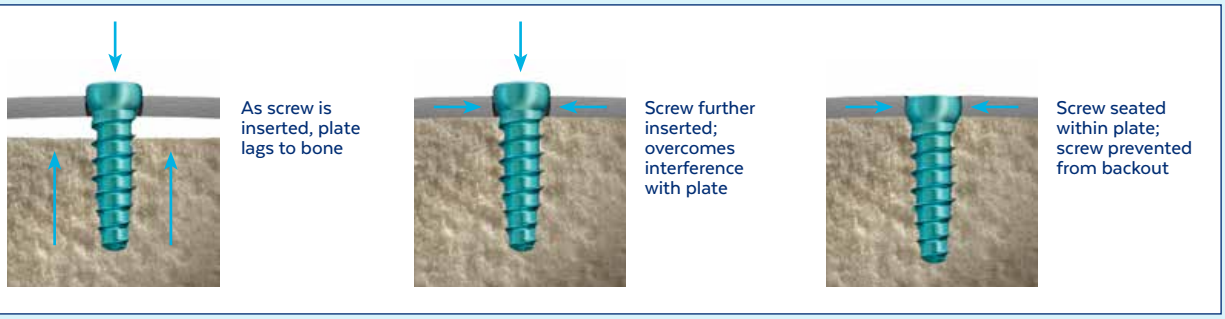
Finish driving screws. As the screw is inserted, the plate lags to the bone as shown below. When the screw overcomes its interference with the plate, it provides a tactile feel and is flush with the plate, indicating that the screw is seated. No additional tightening is necessary. The screw is now automatically blocked from backing out. Further tightening of the screw may result in stripping the bone.

Partial insertion of first standard screw

Seating of the first standard screw

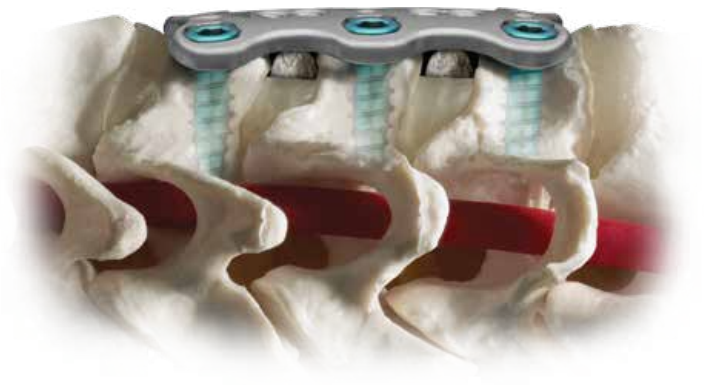
AUTOMATIC BLOCKING WITH STANDARD SCREWS

The tactile feel of the screws seating into the plate may vary depending on angulation and surrounding fluid lubricants. Once the screw head is flush with plate, the screw has reached its final locked position.

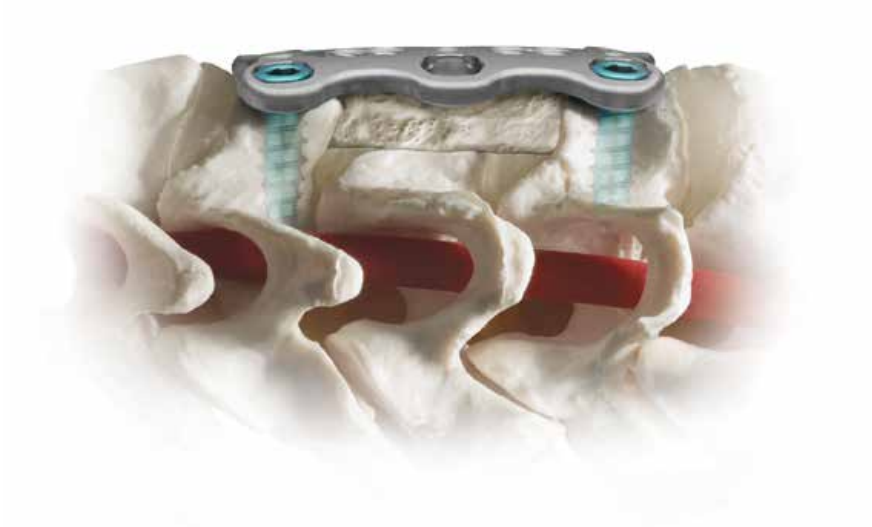


FINAL CONSTRUCTS

Final ASSURE® 2-level construct with standard screws (anterior view)



Final ASSURE® 2-level construct with standard screws (lateral view)



ASSURE® corpectomy construct with standard screws (lateral view)

OPTIONAL TECHNIQUE: USING RIGID SCREWS

Rigid screws may be used with ASSURE® cervical plates as an alternative to standard screws. These screws are recommended for weak or osteoporotic bone.

Rigid screws are available in the same options as the standard screws, as described in Step 4.

Select the desired screw and use the **Self-Retaining Cruciform Driver** with the cruciform tip to remove from the screw module. Insert the screw into the plate and prepared pilot hole. Drive screw fully until seated within the plate. Repeat for all screws.

Insert the **Screwdriver for Set Screws, without Sleeve** into the set screw within the screw module. For final tightening, place the loaded driver through the **Counter Torque for Rigid Screws** and into the rigid screw head. Tighten with the driver. Repeat for all screws. The screws are now locked to the plate and blocked from backing out.

Hybrid constructs may also be created with rigid screws and standard screws as shown below.

Insertion of rigid screw

Insertion of set screw into rigid screw

Final ASSURE® construct with rigid screws

Final ASSURE® hybrid construct with both rigid screws and standard screws

OPTIONAL: ASSURE®-T TRANSLATIONAL PLATE

The ASSURE®-T plate adjusts as the graft settles, promoting fusion by maintaining endplate contact to optimize load sharing. This low profile anterior cervical plate incorporates the same automatic blocking mechanism as the ASSURE® plate. Slotted holes allow up to 1.5mm of translation per level while centralized static screw holes are designed to control settling.

Follow Steps 1-4 for placement of ASSURE® plates. Additional instructions for ASSURE®-T plates are described below.

Insert the awl at the most extremes (towards the ends) of the elongated holes.

Only standard screws may be used in the elongated translational screw holes of the ASSURE®-T plate.

Rigid screws may not be used with ASSURE®-T. Rigid screws fit in the ASSURE®-T plate, however they are designed to lock to the plate and do not allow translation.

Drill guides for small and large slots may be used to insert screws into elongated holes (slots). For large slots, insert screws at the most extremes (towards the ends) of the elongated holes.

Screw insertion location
for maximum translation

Drill guide in enlongated hole

Final Construct - ASSURE®-T Plate

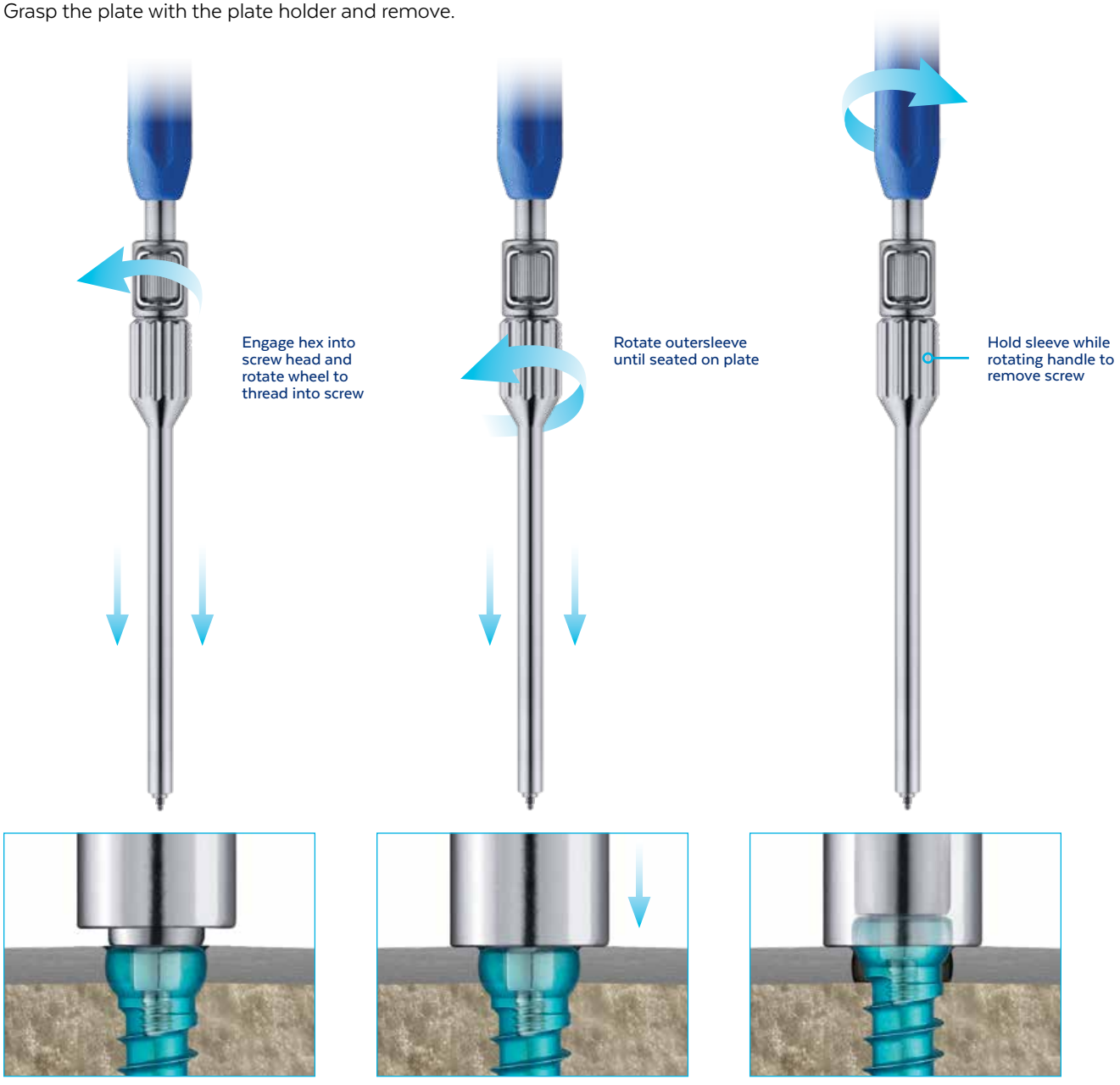
OPTIONAL TECHNIQUE: SCREW REMOVAL

If rigid screws require removal, remove the set screw using the Screwdriver for Set Screws and Counter Torque for Rigid Screws, and remove the rigid screw with the Screwdriver for Rigid Screws.

If standard screws require removal, the **Screw Removal Tool** can be used as shown below. Engage the hexagonal tip into the screw head. Rotate the small wheel clockwise to engage the threaded portion into the screw head. Rotate the outer sleeve clockwise until seated on the plate. Hold the sleeve while rotating the handle counterclockwise until the screw is removed from the plate.

Alternatively, the **Rigid Screw Extractor** may be used for rigid screw removal. Using the sleeve of the Screw Removal Tool and the Quick Connect Handle, insert the extractor into the screw head and remove in the same manner as described above. Discard the screw extractor portion and screw after use.

Grasp the plate with the plate holder and remove.



ASSURE®
CERVICAL PLATE IMPLANT SETS

Cervical Plates* (QTY 1 Each)

1-Level

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

2-Level

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

3-Level

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

4-Level

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

910.902	ASSURE® 1-,2- and 3-Level Plate Implant Set
910.904	ASSURE® 4-Level Plate Implant Set

**All plate lengths are measured from hole to hole.*


1 LEVEL
3 LEVEL
110.114
110.116
110.118
110.120
110.122
110.124
110.126
2 LEVEL
110.226
110.228
110.230
110.232
110.234
110.236
110.238
110.240
110.242
110.244
110.246


3 LEVEL
110.345
110.348
110.351
110.354
110.357
110.360
110.363
110.366
110.369


4 LEVEL
110.460
110.464
110.468
110.472
110.476
110.480
110.484
110.488
110.492
110.496
110.500

ASSURE®
TRANSLATIONAL PLATE IMPLANT SETS

Cervical Plates* (QTY 1 Each)

1-Level

Part No.	Length
117.112	12mm
117.114	14mm
117.116	16mm
117.118	18mm
117.120	20mm
117.122	22mm
117.124	24mm
117.126	26mm

2-Level

Part No.	Length
117.224	24mm
117.226	26mm
117.228	28mm
117.230	30mm
117.232	32mm
117.234	34mm
117.236	36mm
117.238	38mm
117.240	40mm
117.242	42mm
117.244	44mm
117.246	46mm

3-Level

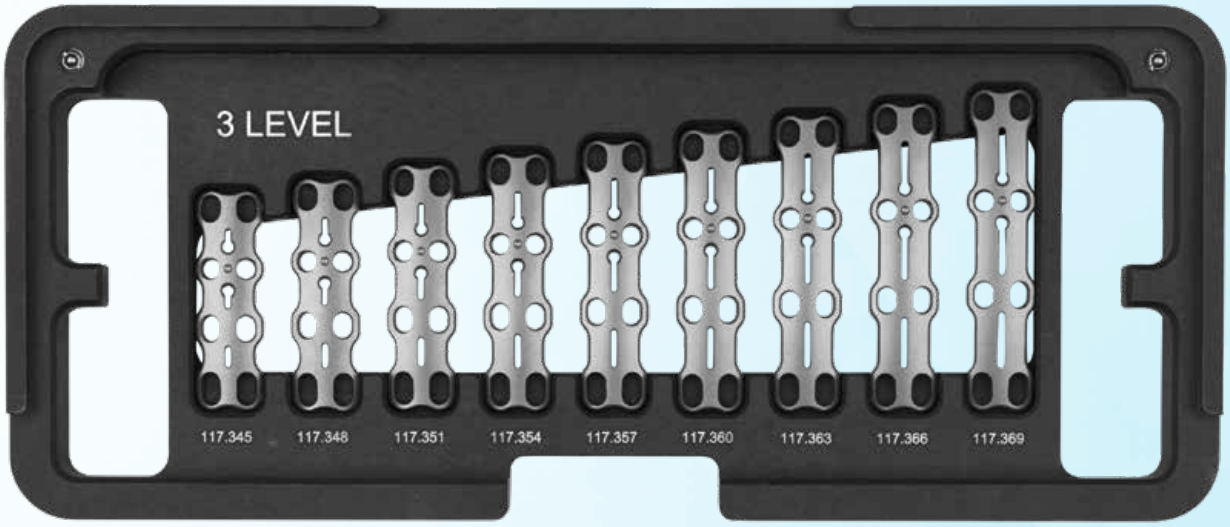
Part No.	Length
117.339	39mm
117.342	42mm
117.345	45mm
117.348	48mm
117.351	51mm
117.354	54mm
117.357	57mm
117.360	60mm
117.363	63mm
117.366	66mm
117.369	69mm

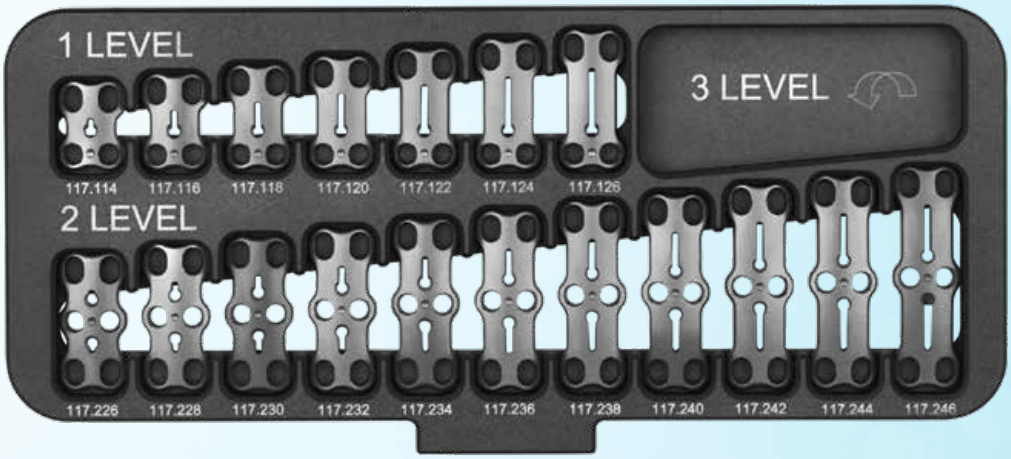
4-Level

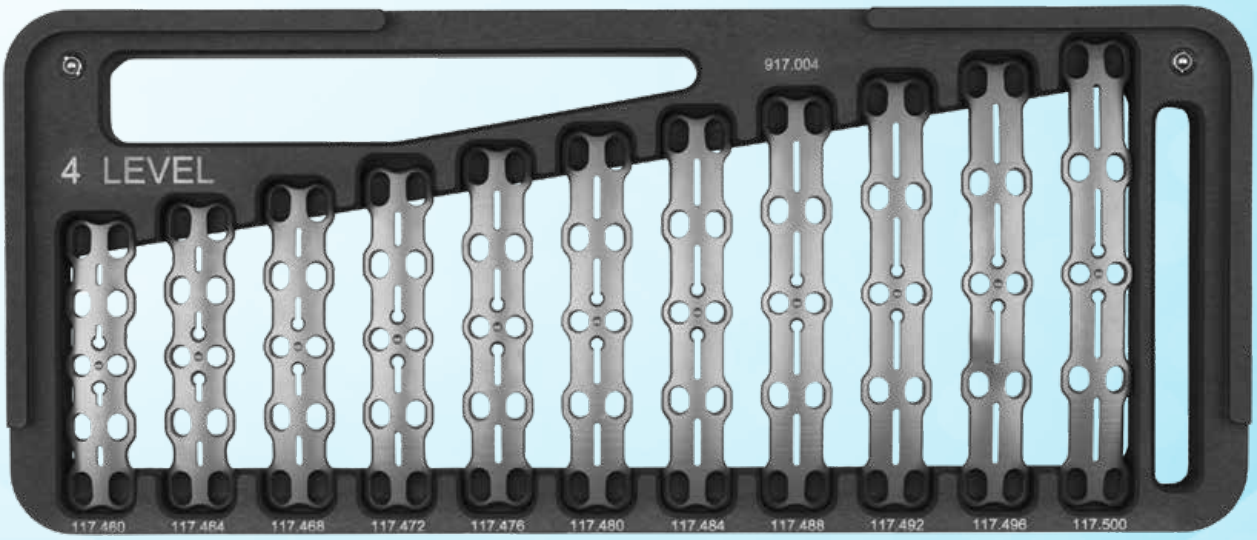
Part No.	Length
117.460	60mm
117.464	64mm
117.468	68mm
117.472	72mm
117.476	76mm
117.480	80mm
117.484	84mm
117.488	88mm
117.492	92mm
117.496	96mm
117.500	100mm

917.902	ASSURE® Translational 1-, 2-, 3-Level Cervical Plate Set
917.904	ASSURE® Translational 4-Level Cervical Plate Set

**All plate lengths measured from hole to hole*


3 LEVEL
117.345
117.348
117.351
117.354
117.357
117.360
117.363
117.366
117.369


1 LEVEL
3 LEVEL
117.114
117.116
117.118
117.120
117.122
117.124
117.126
2 LEVEL
117.226
117.228
117.230
117.232
117.234
117.236
117.238
117.240
117.242
117.244
117.246


917.004
4 LEVEL
117.460
117.464
117.468
117.472
117.476
117.480
117.484
117.488
117.492
117.496
117.500

ASSURE®
IMPLANT MODULE FOR SCREWS 910.906

Standard Screws

Self-drilling	10mm	QTY	12mm	QTY	14mm	QTY	16mm	QTY	18mm	QTY	20mm	QTY
4.0mm	110.610	4	110.612	10	110.614	10	110.616	10	–		–	
4.5mm	–		110.712	10	110.714	10	110.716	10	–		–	
Self-tapping												
4.0mm	110.810	4	110.812	10	110.814	10	110.816	10	110.818	4	110.820	4
4.5mm	–		110.912	10	110.914	10	110.916	10	110.918	4	110.920	4

Rigid Screws

Self-drilling	10mm	QTY	12mm	QTY	14mm	QTY	16mm	QTY	18mm	QTY	20mm	QTY
4.0mm	110.010	4	110.012	10	110.014	10	110.016	10	–		–	
4.5mm	–		110.512	10	110.514	10	110.516	10	–		–	
Self-tapping												
4.0mm	110.030	4	110.032	10	110.034	10	110.036	10	110.038	4	110.040	4
4.5mm	–		110.532	10	110.534	10	110.536	10	110.538	4	110.540	4

Additionally Available Standard Screws, Fixed

Self-drilling	10mm	12mm	14mm	16mm	18mm	20mm
4.0mm	510.610	510.612	510.614	510.616	–	–
4.5mm	–	510.712	510.714	510.716	–	–
Self-tapping						
4.0mm	510.810	510.812	110.814	510.816	510.818	510.820
4.5mm	–	510.912	110.914	510.916	510.918	510.920

Additionally Available Fixed Screws

Self-drilling	10mm	12mm	14mm	16mm	18mm	20mm
4.0mm	510.010	510.012	510.014	510.016	–	–
4.5mm	–	510.512	510.514	510.5166	–	–
Self-tapping						
4.0mm	510.030	510.032	110.034	510.036	510.038	510.040
4.5mm	–	510.532	110.534	510.536	510.538	510.540

Part No.	Description
910.030	Screw Rack for Auxiliary Screws
110.050	Set Screw for Rigid Screws

*Items in gray are additionally available

STANDARD SCREWS
Ø 4.0
Ø 4.5
RIGID SCREWS
Ø 4.0
Ø 4.5
SELF DRILLING
SELF TAPPING
Ø4.0 SELF DRILLING 12mm 14mm 16mm
110.612 110.614 110.616
Ø4.5 SELF DRILLING 12mm 14mm 16mm
110.712 110.714 110.716
Ø4.0 SELF TAPPING 12mm 14mm 16mm
110.812 110.814 110.816
Ø4.5 SELF TAPPING 12mm 14mm 16mm
110.912 110.914 110.916
AUX Ø4.5 Ø4.0 18mm 20mm AUX
Ø4.0 SELF DRILLING 12mm 14mm 16mm
110.012 110.014 110.016
Ø4.0 SELF TAPPING 12mm 14mm 16mm
110.032 110.034 110.036
Ø4.5 SELF DRILLING 12mm 14mm 16mm
110.512 110.514 110.516
Ø4.5 SELF TAPPING 12mm 14mm 16mm
110.532 110.534 110.536

ASSURE® ANTERIOR CERVICAL PLATE
IMPLANT AND INSTRUMENT SET 910.901

		Instrument	QTY
1	610.701	Cervical Awl	1
2	610.702	Quick Connect Handle, Small	2
3	610.710	Drill Bit with Stop, 10mm	1
	610.712	Drill Bit with Stop, 12mm	1
	610.714	Drill Bit with Stop, 14mm	1
	610.716	Drill Bit with Stop, 16mm	1
	610.718	Drill Bit with Stop, 18mm	1
	610.720	Drill Bit with Stop, 20mm	1
4	610.740	Tap for 4.0/4.5mm Screws	1
5	615.104	Drill 2.4mm Diameter	1
6	610.806	Plate Bender, Large	1
7	610.804	Temporary Fixation Pin	4
8	610.809	Drill Guide, Variable Angulation, Adjustable Depth	1
9	610.813	Drill Guide, Variable Angulation	1
10	610.812	Drill and Screw Guide, Pre-Set Angulation	1
11	610.814	Screwdriver, Self-Retaining	2
12	610.817	Counter Torque for Rigid Screws	1
13	610.819	Screw Removal Tool	1
14	610.820	Rigid Screw Extractor	1
15	610.825	Screwdriver, for Set Screws without Sleeve	2
16	610.829	Cruciform Driver, Self-Retaining	2
	910.002	ASSURE® Implant Module for 1-, 2-, and 3-Level Plates	
	910.004	ASSURE® Implant Module for 4-Level Plates	
	910.006	ASSURE® Implant Module for Screws	
	910.050	ASSURE® Auxiliary Case	

Additionally Available Instruments

610.510	Small Drill Bit with Stop, 10mm
610.512	Small Drill Bit with Stop, 12mm
610.514	Small Drill Bit with Stop, 14mm
610.516	Small Drill Bit with Stop, 16mm
610.518	Small Drill Bit with Stop, 18mm
610.520	Small Drill Bit with Stop, 20mm
610.703	Handle, Quick Connect, Ratcheting
610.704	Cervical Awl for Drill Guides
610.741	Tap with Stop
610.801	Caliper
610.803	Plate Holder
610.805	Temporary Fixation Pin, Straight
610.807	Plate Holder Drill Guide
610.808	Drill Guide, Double Barrel, Variable Angulation
610.810	Simple Plate Holder
610.811	Cervical Depth Gauge
610.815	Screwdriver for Rigid Screws, Threaded
610.816	Screwdriver, Self-Retaining, for Rigid Screws
610.818	Screwdriver, for Set Screw
610.821	Screwdriver, 2.5mm Hex, with Sleeve
610.822	Screwdriver, 2.5mm Hex, with Cap
610.823	Screwdriver, for Rigid Screws, with Sleeve
610.824	Screwdriver, for Rigid Screws, with Cap
610.826	Screwdriver, 2.5mm Hex, Self-Retaining, Small
610.827	Screwdriver, For Rigid Screws, Self-Retaining, Small
610.828	Screwdriver, For Set Screws, Small
610.831	2.5mm Hex Driver, Quick Connect
610.832	Variable Angle Drill Guide, Short Barrel

Additionally Available Instruments ASSURE®-T

617.813	Drill Guide for Small Slot
617.814	Drill Guide for Large Slot

**Items in gray are additionally available*


13
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IMPORTANT INFORMATION ON THE ASSURE® ANTERIOR CERVICAL PLATE SYSTEM

CLEANING

The ASSURE® Anterior Cervical Plate System consists of plates used with either standard screws or rigid screws and set screws. ASSURE-T plates allow translation to accommodate graft subsidence. 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 per ASTM F136 and F1295.

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.

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.

CONTRAINDICATIONS

Use of this system is contraindicated in patients with the following conditions:

- 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.
- Severe osteoporosis, which may prevent adequate fixation.
- 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.
- 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.
- Any condition not described in the indications for use

MRI SAFETY INFORMATION

ASSURE® 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 ASSURE® 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.

PACKAGING

These implants 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.

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 may be available sterile or nonsterile.

Sterile implants 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 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 Law (USA) Restricts this Device to Sale by or on the order of a Physician.

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

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www.globusmedical.com

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Fax 1-866-GLOBUS3 (or 1-866-456-2873)

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