



# ASSURE<sup>®</sup>

## Anterior Cervical Plate System

Outside the US Only



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

*Life moves us* 

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.

# SURGICAL TECHNIQUE GUIDE

## ASSURE<sup>®</sup>

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# ASSURE<sup>®</sup>

## Anterior Cervical Plate System

ASSURE<sup>®</sup> 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

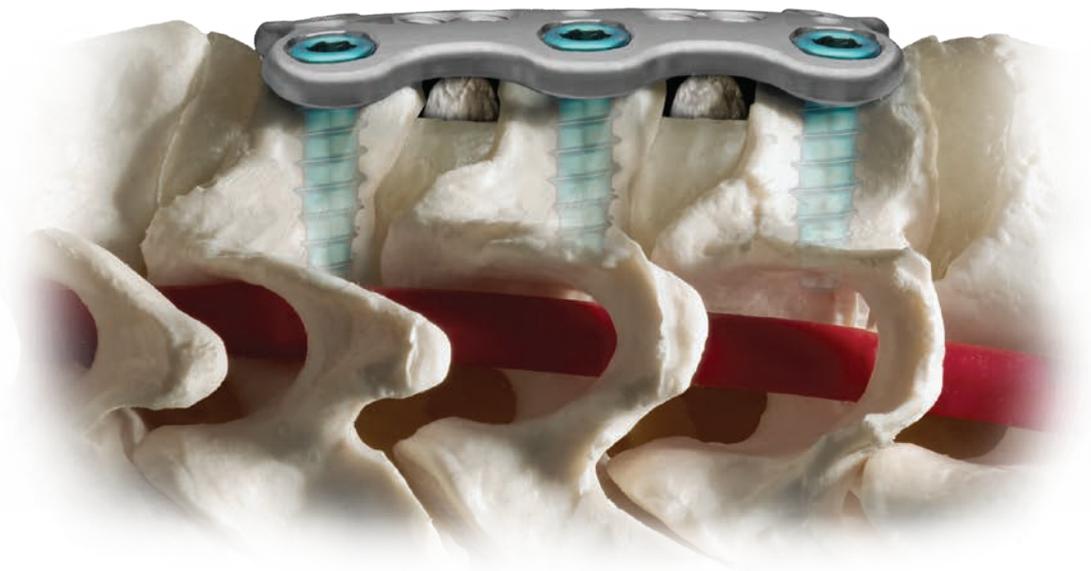
One instrument to insert and lock screw into plate.

## 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



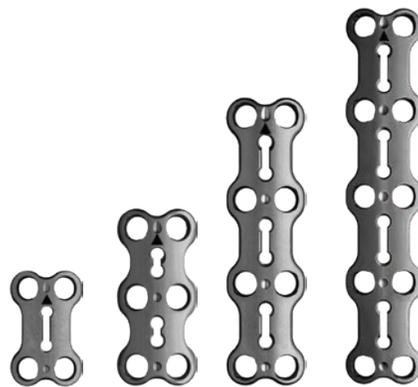
## Screw Angulation

- $\pm 18^\circ$  angulation for all screws
- Pre-set angulation with Drill Guide
- $6^\circ$  medial angle
- $10^\circ$  cephalad angle
- $0^\circ$  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

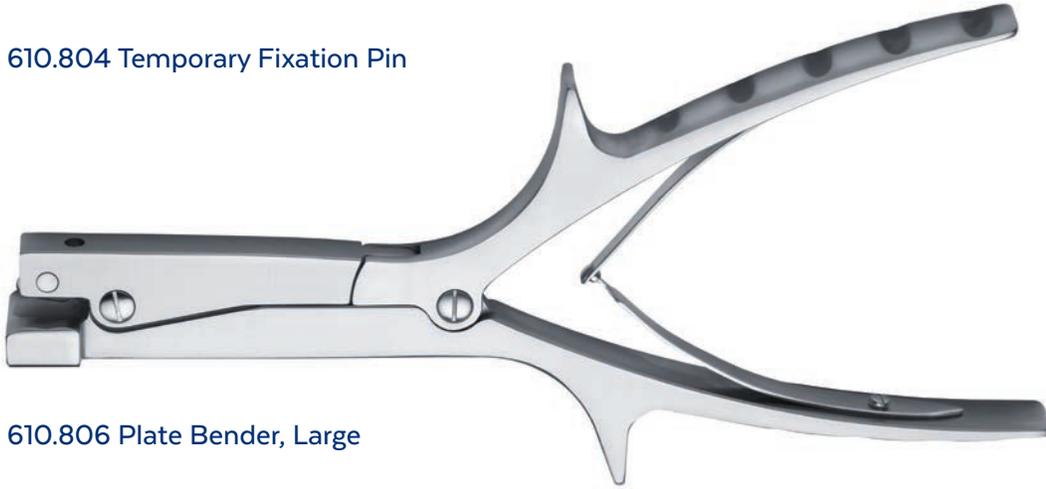


610.740 Tap for 4.0/4.5mm Screws

## PLATE INSTRUMENTS



610.804 Temporary Fixation Pin



610.806 Plate Bender, Large

## SCREW INSTRUMENTS

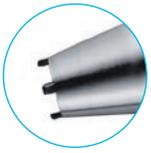


610.812 Drill and Screw Guide, Pre-Set Angulation

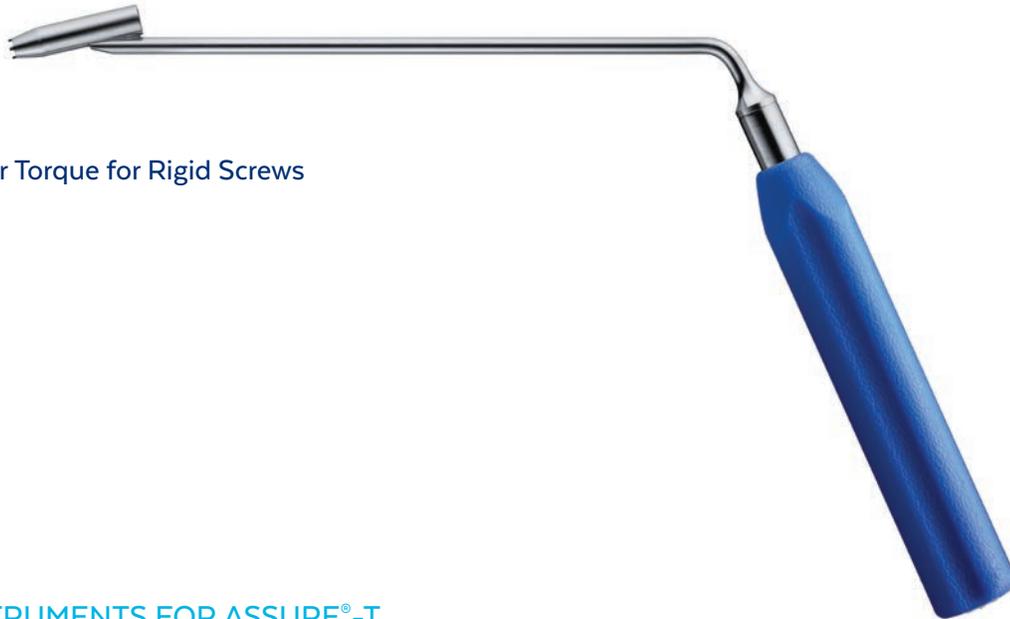


610.813 Drill Guide, Variable Angulation

## SCREW INSTRUMENTS (CONT'D)



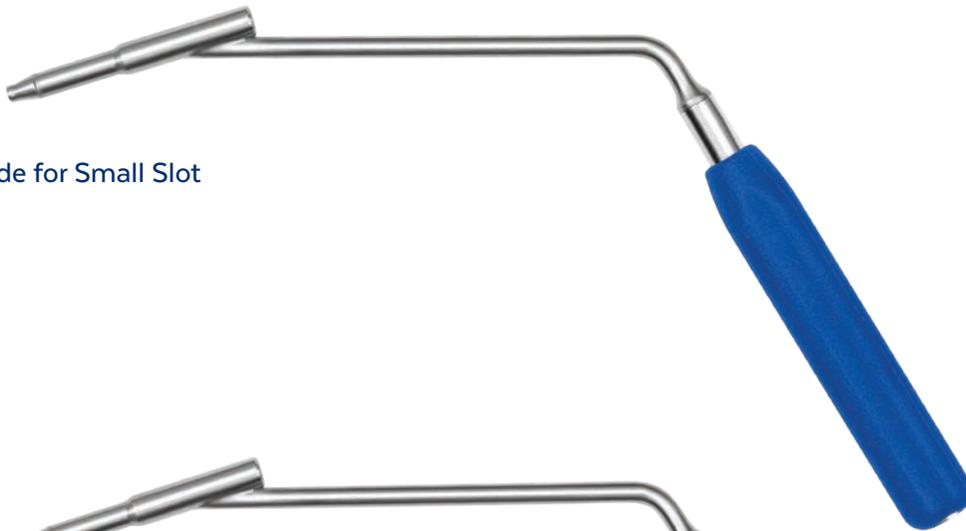
610.817 Counter Torque for Rigid Screws



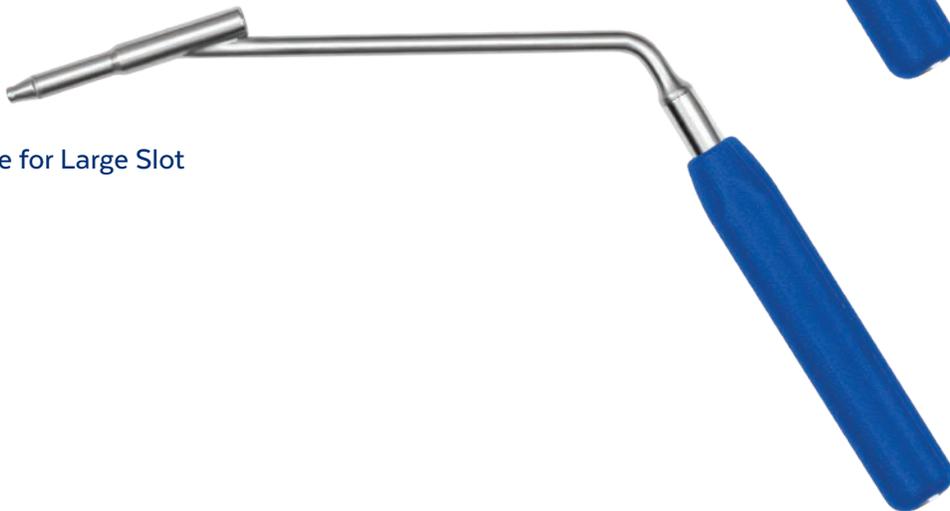
## SCREW INSTRUMENTS FOR ASSURE®-T



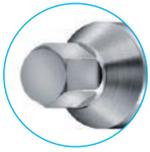
617.813 Drill Guide for Small Slot



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<sup>®</sup>

## 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<sup>®</sup> plate fixation may be used in the cervical spine between C2 and C7.

Distraction may be accomplished using the Distractor available in the COLONIAL<sup>®</sup> ACDF System or other standard methods. Prepare the disc space and insert bone graft or an interbody fusion device. Refer to the COLONIAL<sup>®</sup> 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.

### 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.*

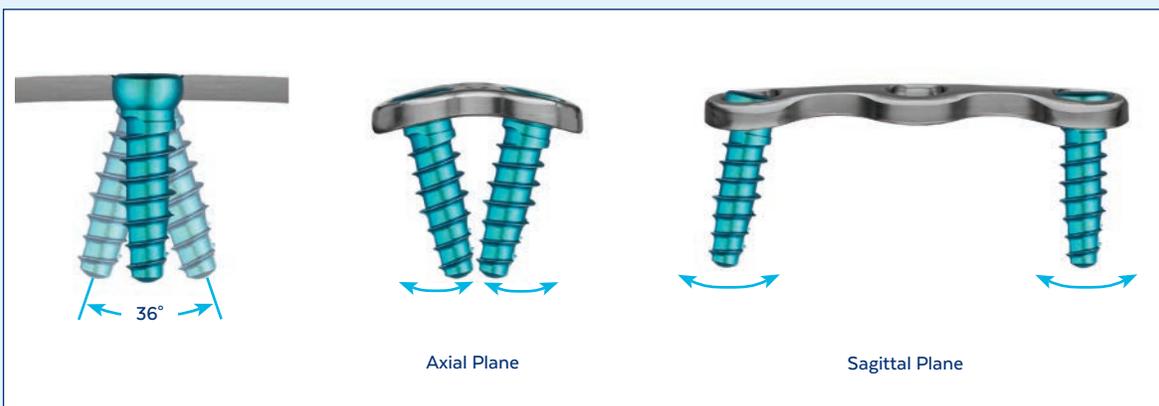
Screws are available in self-drilling and self-tapping designs, both of which are fluted to tap pilot holes. However, holes may be tapped using the **Tap for 4.0/4.5mm Screws**.



Using the Variable Angle Drill Guide to prepare screw pilot hole

### VARIABLE ANGLATION DRILL GUIDE

The drill guide allows screw angulation of  $\pm 18^\circ$  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.

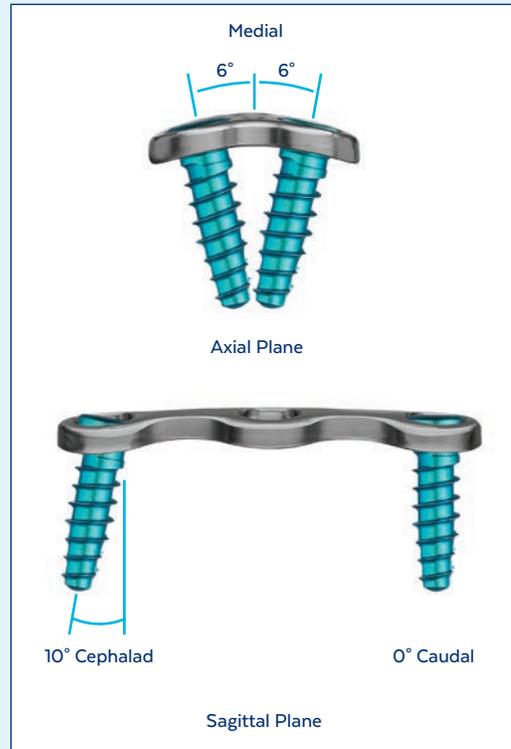
Determine the desired drill depth (10, 12, 14, 16, 18, or 20mm), select the corresponding Drill Bit, and assemble to the Small Quick Connect Handle. Insert the drill into the drill guide, and drill until it reaches the stop. The Cervical Depth Gauge may be used to verify depth.

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.

## 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.*



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



## STEP

## 4

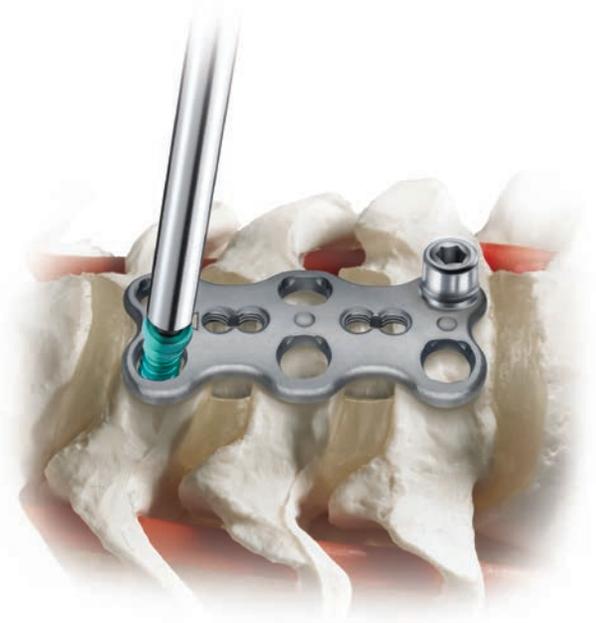
# SCREW INSERTION

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

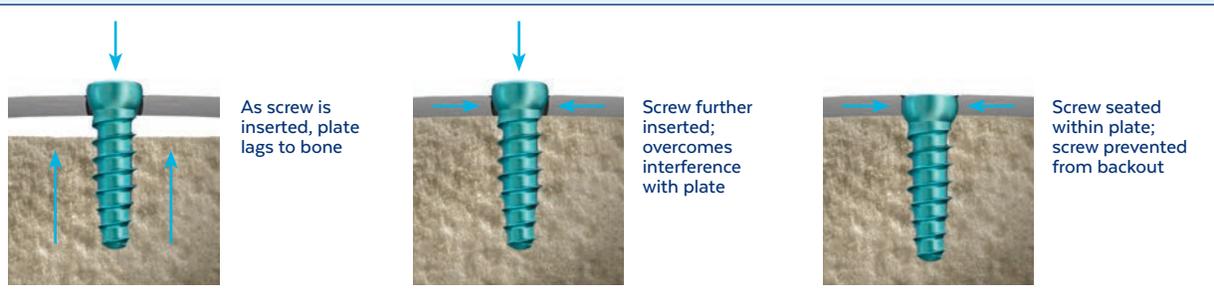


Seating of the first standard screw



### AUTOMATIC BLOCKING WITH STANDARD SCREWS

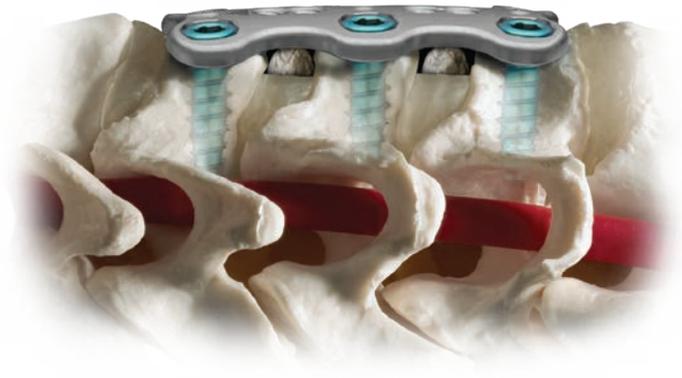
*The tactile feel of the screws seating into the plate may vary depending on angulation and surrounding fluid lubricants. Once the screw head is flush with plate, the screw has reached its final locked position.*



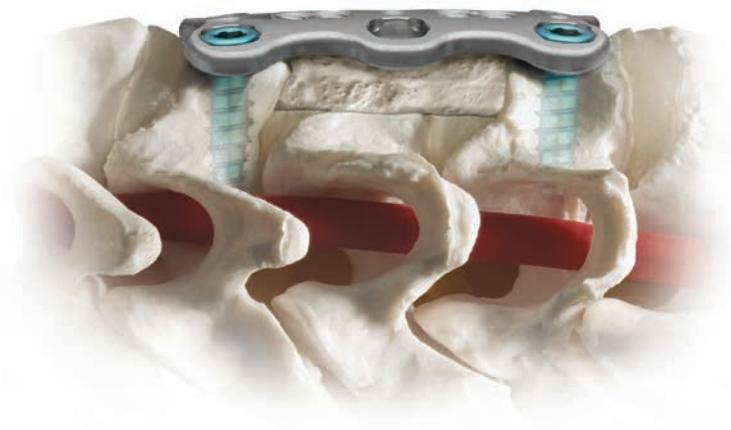
# FINAL CONSTRUCTS



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 elongated hole



Final Construct - ASSURE®-T Plate

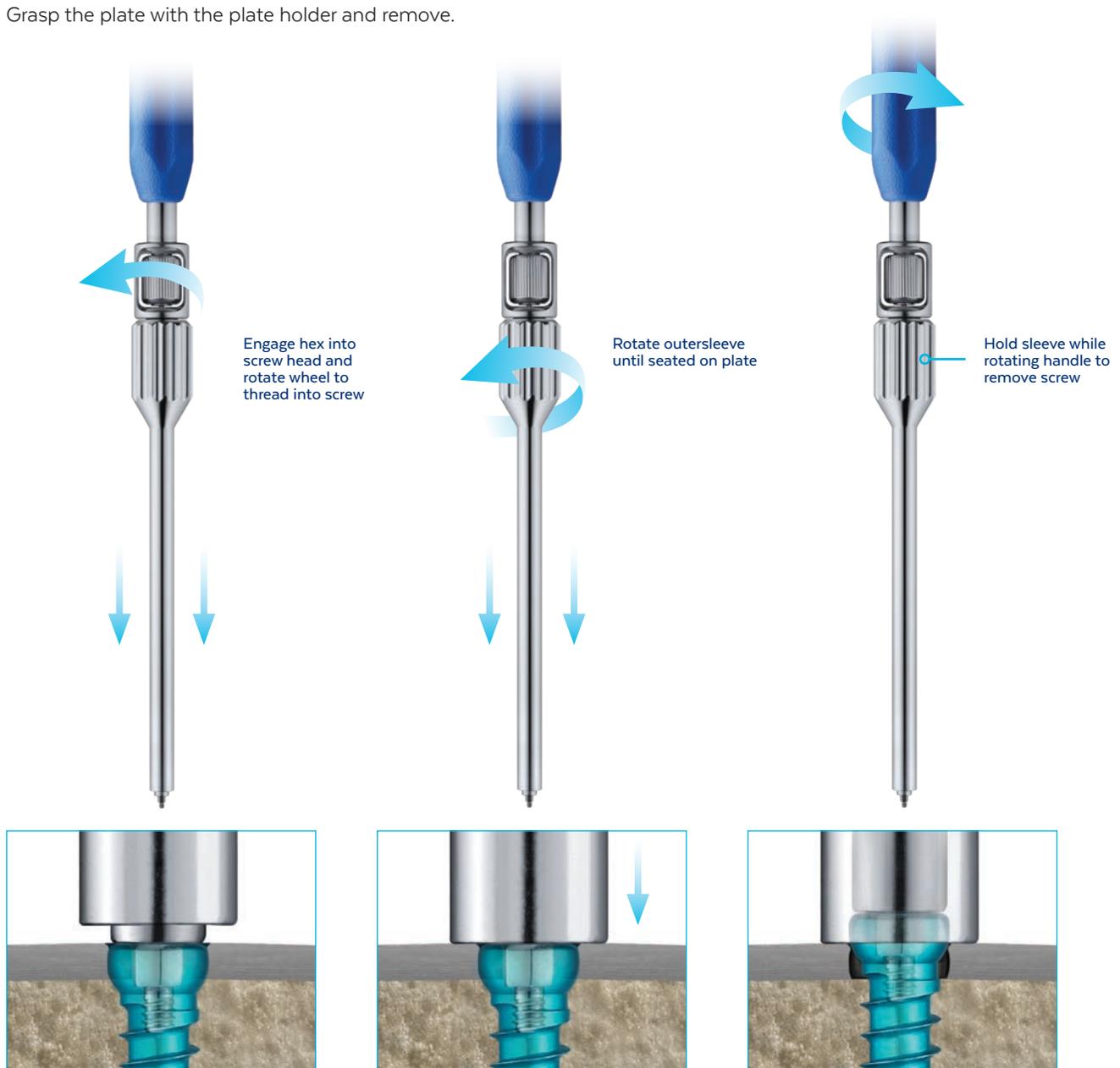
# OPTIONAL TECHNIQUE: SCREW REMOVAL

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<sup>®</sup>

## 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<sup>®</sup> 1-,2- and 3-Level Plate Implant Set

910.904 ASSURE<sup>®</sup> 4-Level Plate Implant Set

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

NOTE: Set configuration may vary depending on location. Please consult your Globus Medical Sales Representative.



# ASSURE<sup>®</sup>

## 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

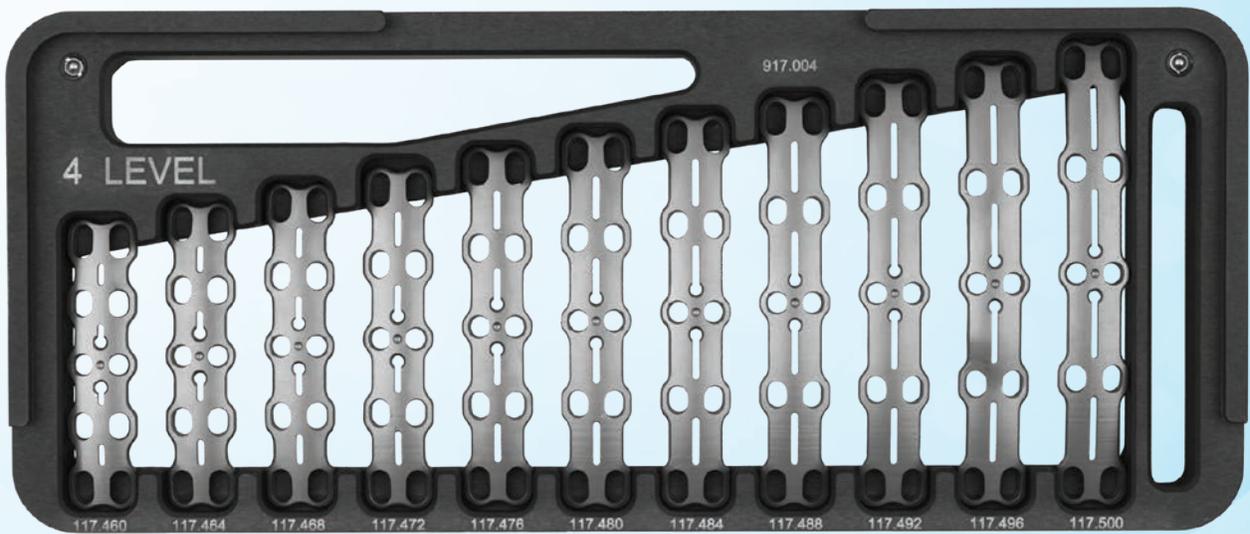
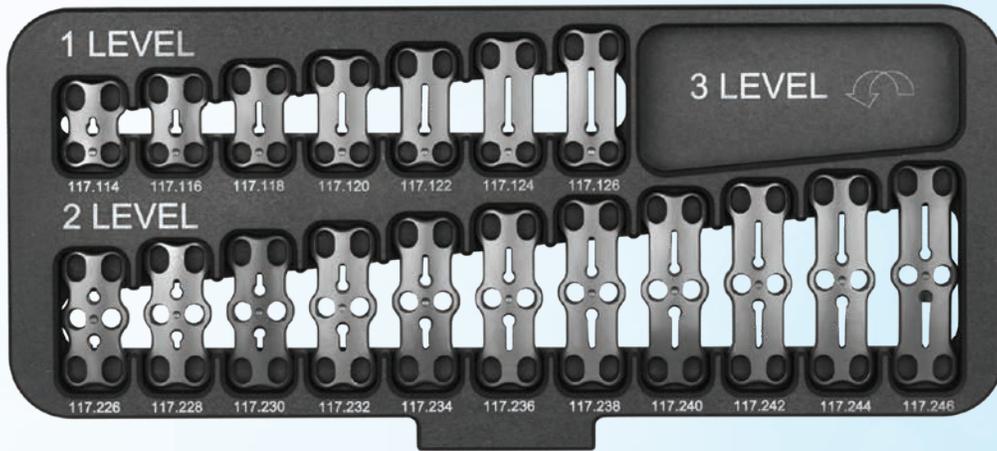


917.902 ASSURE<sup>®</sup> Translational 1-, 2-, 3-Level Cervical Plate Set

917.904 ASSURE<sup>®</sup> Translational 4-Level Cervical Plate Set

\*All plate lengths measured from hole to hole

NOTE: Set configuration may vary depending on location. Please consult your Globus Medical Sales Representative.



# ASSURE<sup>®</sup>

## 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	10mm	Qty	12mm	Qty	14mm	Qty	16mm	Qty	18mm	Qty	20mm	Qty
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	10mm	Qty	12mm	Qty	14mm	Qty	16mm	Qty	18mm	Qty	20mm	Qty
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	10mm	12mm	14mm	16mm	18mm	20mm
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	10mm	12mm	14mm	16mm	18mm	20mm
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

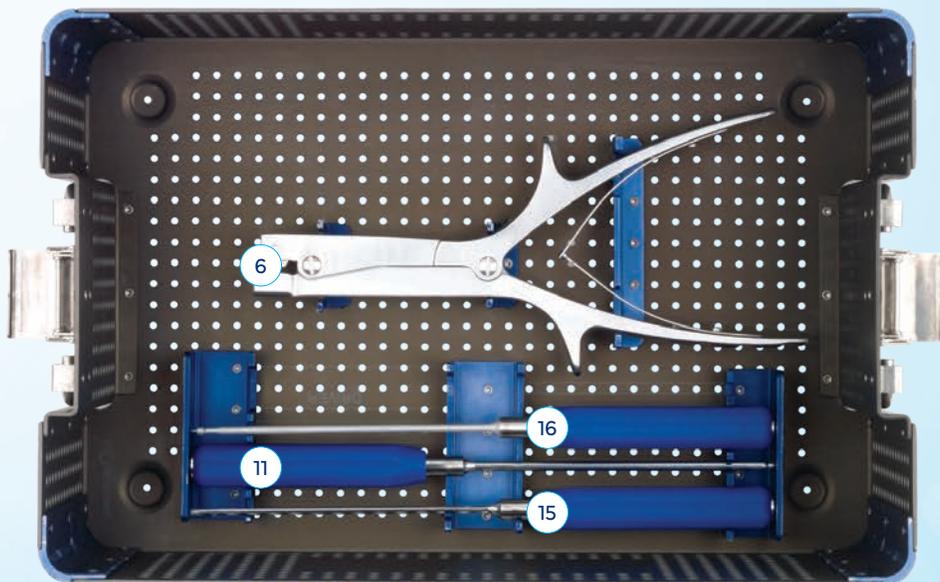
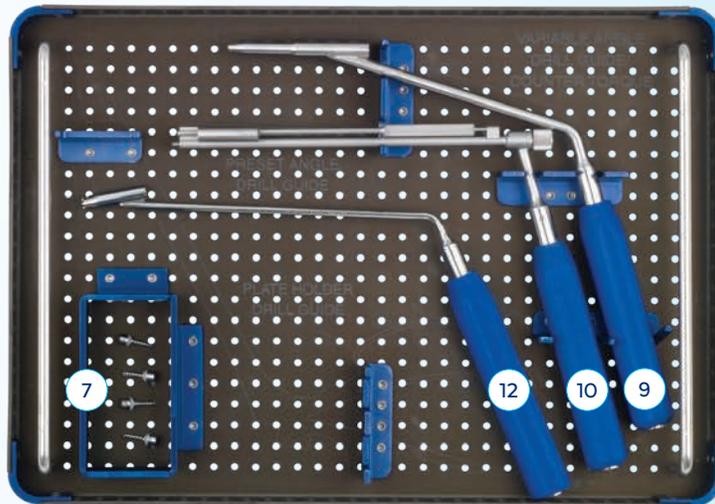
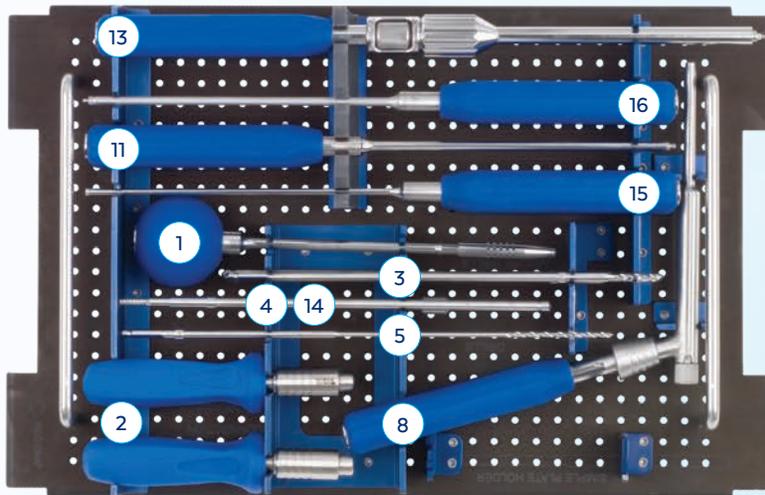
NOTE: Set configuration may vary depending on location. Please consult your Globus Medical Sales Representative.



# ASSURE® ANTERIOR CERVICAL PLATE IMPLANT AND INSTRUMENT SET 910.901

	Instrument	Qty	Additionally Available Instruments
1	610.701 Cervical Awl	1	610.510 Small Drill Bit with Stop, 10mm
2	610.702 Quick Connect Handle, Small	2	610.512 Small Drill Bit with Stop, 12mm
3	610.710 Drill Bit with Stop, 10mm	1	610.514 Small Drill Bit with Stop, 14mm
	610.712 Drill Bit with Stop, 12mm	1	610.516 Small Drill Bit with Stop, 16mm
	610.714 Drill Bit with Stop, 14mm	1	610.518 Small Drill Bit with Stop, 18mm
	610.716 Drill Bit with Stop, 16mm	1	610.520 Small Drill Bit with Stop, 20mm
	610.718 Drill Bit with Stop, 18mm	1	610.703 Handle, Quick Connect, Ratcheting
	610.720 Drill Bit with Stop, 20mm	1	610.704 Cervical Awl for Drill Guides
4	610.740 Tap for 4.0/4.5mm Screws	1	610.741 Tap with Stop
5	615.104 Drill 2.4mm Diameter	1	610.801 Caliper
6	610.806 Plate Bender, Large	1	610.803 Plate Holder
7	610.804 Temporary Fixation Pin	4	610.805 Temporary Fixation Pin, Straight
8	610.809 Drill Guide, Variable Angulation, Adjustable Depth	1	610.807 Plate Holder Drill Guide
9	610.813 Drill Guide, Variable Angulation	1	610.808 Drill Guide, Double Barrel, Variable Angulation
10	610.812 Drill and Screw Guide, Pre-Set Angulation	1	610.810 Simple Plate Holder
11	610.814 Screwdriver, Self-Retaining	2	610.811 Cervical Depth Gauge
12	610.817 Counter Torque for Rigid Screws	1	610.815 Screwdriver for Rigid Screws, Threaded
13	610.819 Screw Removal Tool	1	610.816 Screwdriver, Self-Retaining, for Rigid Screws
14	610.820 Rigid Screw Extractor	1	610.818 Screwdriver, for Set Screw
15	610.825 Screwdriver, for Set Screws without Sleeve	2	610.821 Screwdriver, 2.5mm Hex, with Sleeve
16	610.829 Cruciform Driver, Self-Retaining	2	610.822 Screwdriver, 2.5mm Hex, with Cap
	910.002 ASSURE® Implant Module for 1-, 2-, and 3-Level Plates		610.823 Screwdriver, for Rigid Screws, with Sleeve
	910.004 ASSURE® Implant Module for 4-Level Plates		610.824 Screwdriver, for Rigid Screws, with Cap
	910.006 ASSURE® Implant Module for Screws		610.826 Screwdriver, 2.5mm Hex, Self-Retaining, Small
	910.050 ASSURE® Auxiliary Case		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
			<b>Additionally Available Instruments ASSURE®-T</b>
			617.813 Drill Guide for Small Slot
			617.814 Drill Guide for Large Slot

NOTE: Set configuration may vary depending on location. Please consult your Globus Medical Sales Representative.





Globus Medical  
Valley Forge Business Center  
2560 General Armistead Avenue  
Audubon, PA 19403  
[www.globusmedical.com](http://www.globusmedical.com)

Customer Service:

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

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