

PROVIDENCE™

Anterior Cervical Plate System



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.

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PROVIDENCE™

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PROVIDENCE™

Anterior Cervical Plate System



PROVIDENCE™ is an anterior cervical plate with large windows that allow graft access and visualization.

The technologically advanced screw blocking mechanism provides audible, tactile and visual confirmation when the mechanism is engaged.

Advanced Blocking Mechanism

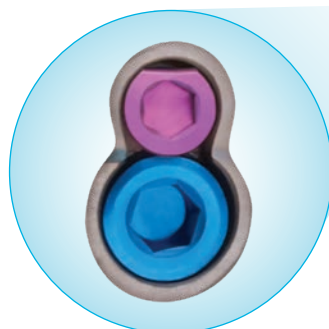
Provides audible, tactile, and visual confirmation that the screws are blocked in place

Large Graft Windows

Allow for visualization of graft placement intraoperatively and fusion status postoperatively

Streamlined Instrumentation

Facilitates and eases implant placement to help reduce surgery time



IMPLANT OVERVIEW

Blocking Set Screw

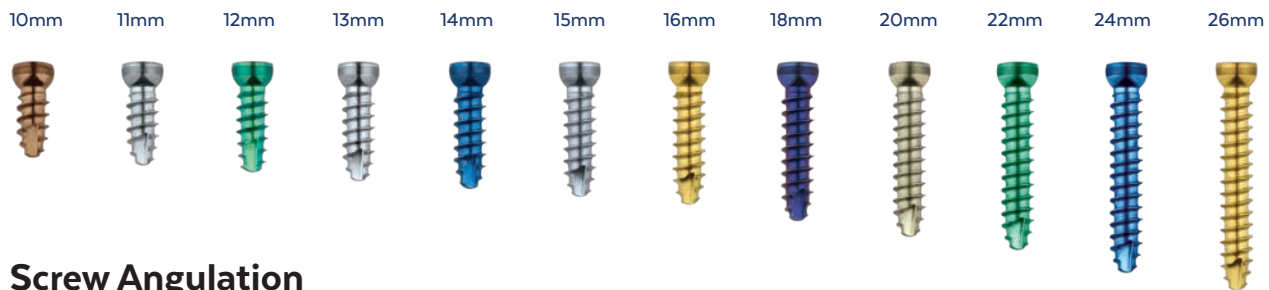
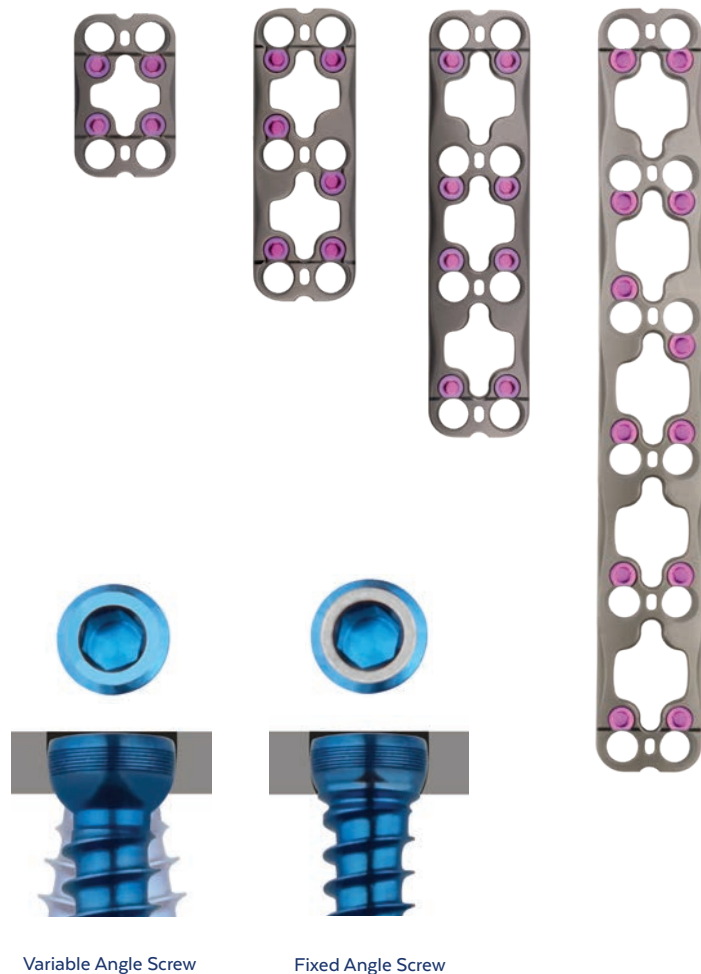
- Provides audible, tactile, and visual confirmation of blocking
- Preassembled into the plate
- Prevents screw backout

Plates

- 2.3mm low profile
- 16mm width
- Large graft visualization windows
- 1, 2, 3, 4 and 5-level plates
- Lengths from 10mm to 104mm

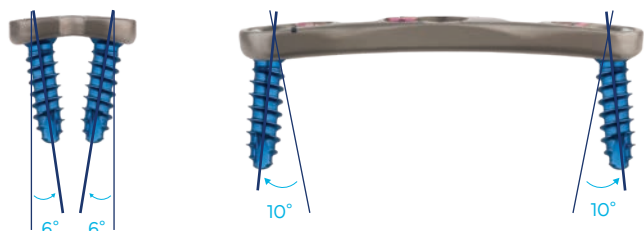
Variety of Screw Sizes

- 4.2mm or 4.6mm diameter
- Self-drilling or self-tapping
- Lengths from 10mm to 26mm
- Variable and Fixed Angle Screws



Screw Angulation

- Variable angle screws provide $\pm 20^\circ$ angulation
- Pre-set angulation with drill guide
- 6° medial
- 10° cephalad/caudal, respectively



INSTRUMENT OVERVIEW

SCREW PREPARATION INSTRUMENTS



Cervical Awl, with Sleeve 650.100



Cervical Awl, for Drill Guide 650.102



Drill Bits

Drill Bit, 10mm 650.110	
Drill Bit, 12mm 650.112	
Drill Bit, 14mm 650.114	
Drill Bit, 16mm 650.116	
Drill Bit, 18mm 650.118	
Drill Bit, 20mm 650.120	

SCREW PREPARATION INSTRUMENTS (CONT'D)



Quick-Connect Handle, Small, with Cap 650.105



Cervical Tap 650.160

PLATE INSERTION INSTRUMENTS



Temporary Fixation Pin 650.010



Temporary Screw 650.012



Fixation Pin Driver 650.020



Push Button Holder 650.200



Plate Bender 650.806



SCREW INSERTION INSTRUMENTS



Drill Bit, 2.4mm 650.150



Adjustable Depth Guide Drill Bit

Adjustable Depth Guide Drill Bit, 10mm 650.130	
Adjustable Depth Guide Drill Bit, 12mm 650.132	
Adjustable Depth Guide Drill Bit, 14mm 650.134	
Adjustable Depth Guide Drill Bit, 16mm 650.136	
Adjustable Depth Guide Drill Bit, 18mm 650.138	
Adjustable Depth Guide Drill Bit, 20mm 650.140	



DTS Guide, Pre-Set Angle Plate Holder 650.203



DTS Guide, Variable Angle 650.206

SCREW INSTRUMENTS (CONT'D)



Drill Guide, Variable Angle, Short Barrel 650.210

Drill Guide Variable Angulation,
Adjustable Depth 650.211



Screwdriver, 2.5mm Hex, Self-Retaining, with Cap 650.301

BLOCKING SET SCREW INSTRUMENTS



Set Screw Positioner, 2.0mm Hex, Torque Limiting 650.312



2.1mm Hex Screwdriver 650.313

SURGICAL TECHNIQUE

PROVIDENCE™

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). PROVIDENCE™ Plate Fixation may be used in the cervical spine from C2 to C7. Please refer to the product insert for complete description, contraindications, indications, warnings and precautions.

Distraction may be accomplished using a standard distractor (see 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 (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. Laser marked lines on the plate assist in positioning.

Plate Bending and Placement

All plates are pre-contoured in the sagittal plane to provide lordosis; however, additional contouring may be accomplished using the Plate Bender.

Option A: Removable Bottom Anvil

To add lordosis, insert the plate into the prongs as shown at right. Ensure that the bottom anvil is loaded onto the bender so that the “+ LORDOSIS” laser mark aligns with the arrow as shown below. Rotate the top anvil down and compress the handles to achieve the desired curvature.

Note: Do not bend the plate at the bone screw hole and adjacent set screw interface. Repeated bending may weaken the plate.



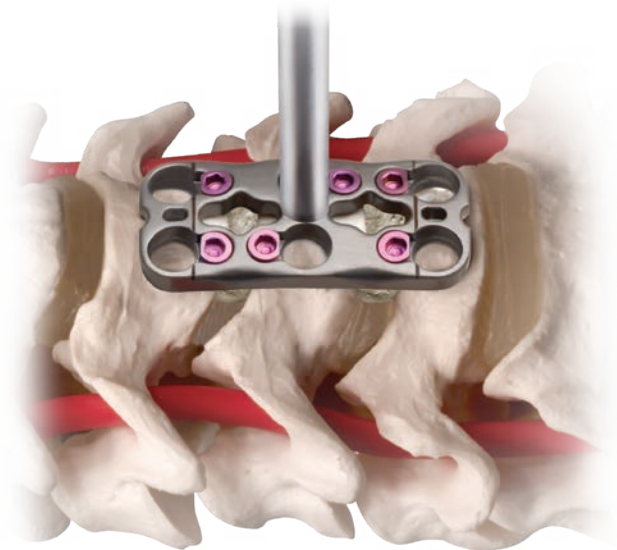
Plate properly inserted



Anvil rotated to final position

The Plate Bender may also be used to decrease lordosis. Insert the plate, top surface facing in, and load the bottom anvil so that the “- LORDOSIS” laser mark aligns with the arrow.

Use the **Push Button Holder** to place the plate. Press the holder tip into a midline pin hole at the appropriate angle, as described on page 12. To remove the holder, press the button at the top of the handle. Alternately, the **DTS Guide, Pre-Set Angle Plate Holder** may be used.



Using Push Button Holder to place plate

Option B: Plate Bender – New Design

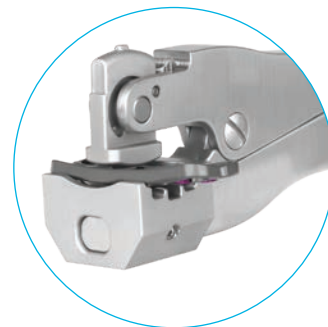
To add lordosis, insert the plate with set screws facing the bottom anvil. In most situations, the top anvil should be rotated to the standard position (wider tip facing the plate), as shown. This will provide the most gradual bend over multiple levels.

Several plates do not have sufficient surface area to fit this side of the anvil without interfering with the set screws (see chart below). When using these plates, rotate the anvil to the narrow tip to bend the plate. These plates are as follows:

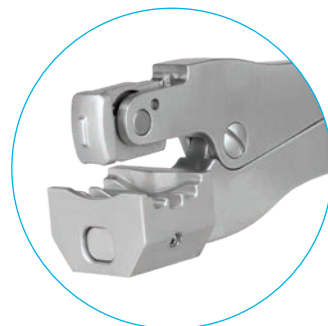
- 1 Level:** 16–18mm (150.116–150.118)
- 2 Level:** 32–36mm (150.232–150.236)
- 3 Level:** 48–54mm (150.348–150.354)
- 4 Level:** 63–72mm (150.463–150.472)
- 5 Level:** 80–89mm (150.580–150.589)

Do not bend the plate at the bone screw hole and adjacent set screw interface. This is avoided by placing the plate on the bender in the correct position, as described above.

Plates may be bent to decrease lordosis. To decrease lordosis, insert the plate with set screws facing the upper anvil and rotate the anvil to the neutral position.



Standard



Neutral



Narrow

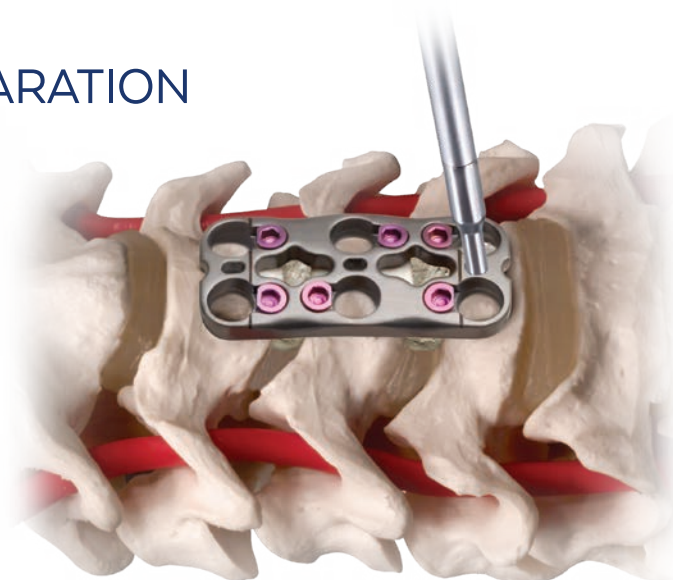
STEP

3

SCREW HOLE PREPARATION

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

Note: When removing Temporary Fixation Pins, rock the driver in a cephalad/caudal motion while pulling upwards.



Option A: Pre-Set Angulation

Using the DTS Guide, Pre-Set Angle Plate Holder

Ensure that the blue handle is rotated counterclockwise until the stop. Insert guide tip into the pin hole. Rotate the blue handle clockwise until a rigid connection is established.

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

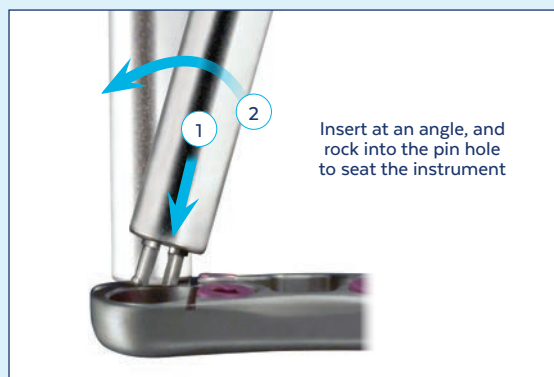
Determine the desired drill depth and select the appropriate fixed length **Drill Bit**. The bits are color coded corresponding to the screw length. Assemble the bit to the **Quick-Connect Handle, Small, with Cap** and insert into the drill guide. Drill to the stop.

Inserting Temporary Fixation Pin

⚙️ INSERTING INSTRUMENTS INTO THE PIN HOLES

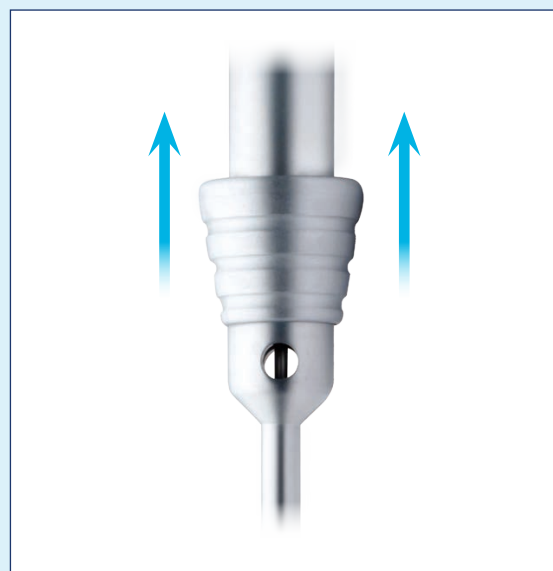
The pin holes on the cephalad and caudal ends of the plate are angled at 10°, respectively. Insert the Push Button Holder and DTS guides at this angle.

The pin hole in the center of the plate is not angled and the Push Button Holder and DTS guides may be inserted perpendicular to the plate.



🔧 LOADING THE TEMPORARY FIXATION PIN

To load and unload the pin from the Fixation Pin Driver, pull back on the sleeve as shown below.

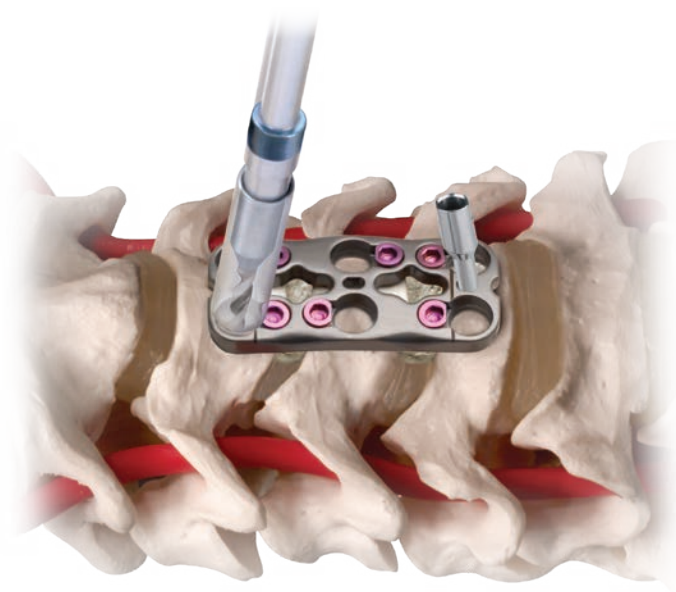


Screw holes may be tapped through the drill guide using the **Cervical Tap**.

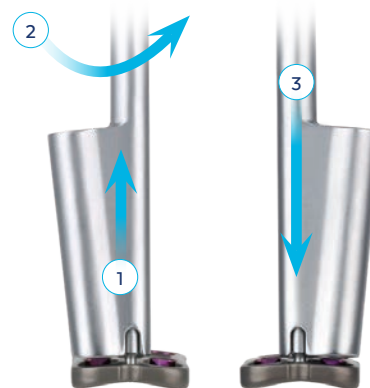
The barrel of the DTS guide rotates to conveniently switch to the contralateral side. Pull the sleeve up toward the handle, rotate, and release the sleeve to change barrel position.

Screws may also be inserted through the DTS guide. See Step 4, page 17 for screw insertion.

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



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

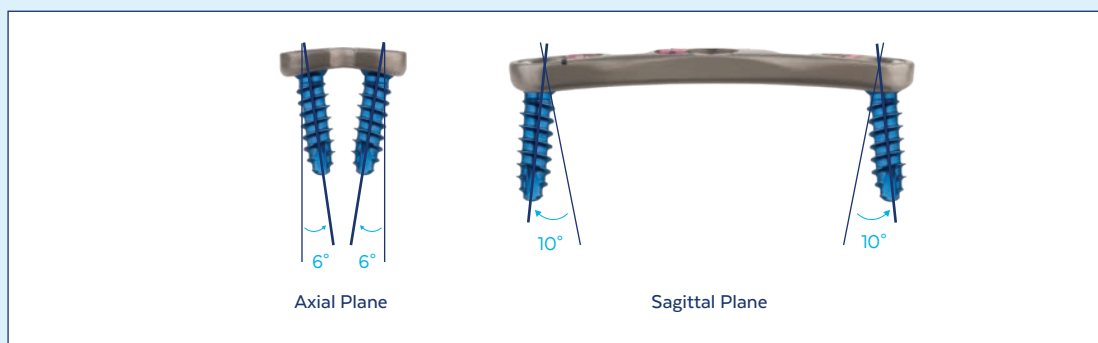


Lifting and rotating sleeve to contralateral side

DTS GUIDE, PRE-SET ANGLE PLATE HOLDER

The DTS guide provides the pre-set screw angulation for awling, drilling, tapping and inserting screws.

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



Option B: Variable Angulation

Using the DTS Guide, Variable Angle

The **DTS Guide, Variable Angle** may be used to insert the drill bit, tap and screws, while still maintaining a variable screw trajectory. The tip of the DTS guide sits within the pin hole and allows angulation in the cephalad/caudal direction.

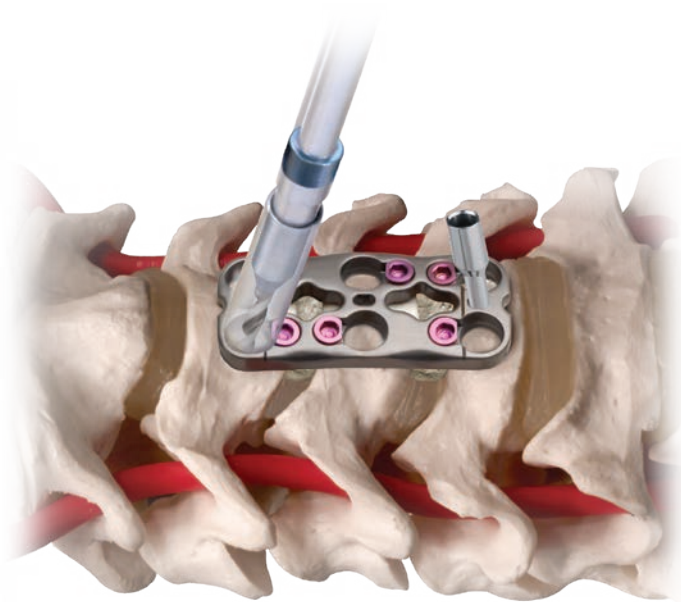
Start each pilot screw hole by inserting the Cervical Awl, for Drill Guide into the DTS guide.

Determine the desired drill depth and select the appropriate fixed length Drill Bit. The bits are color-coded corresponding to screw length. Assemble the bit to the Quick-Connect Handle, Small, with Cap and insert into the DTS guide. Drill to the stop.

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

The barrel of the DTS guide rotates to conveniently switch to the contralateral side. Pull the sleeve toward the handle and rotate the barrel, as shown on page 13.

Note: Variable angle guides should not be used to prepare screw holes for Fixed Angle Screws.



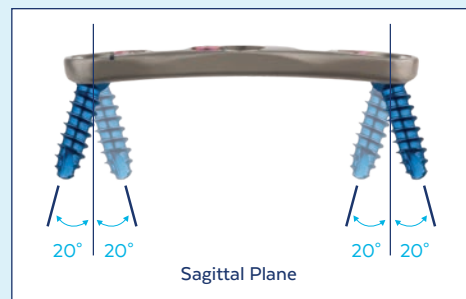
Note: The DTS Guide, Variable Angle has a rotating handle. To change the angle, retract the tapered sleeve and rotate the handle about the axis of the shaft.

Using DTS Guide, Variable Angle to prepare screw pilot hole

DTS GUIDE, VARIABLE ANGLE

The DTS guide allows screw angulation in the cephalad/caudal directions for awling, drilling, tapping and screw insertion.

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



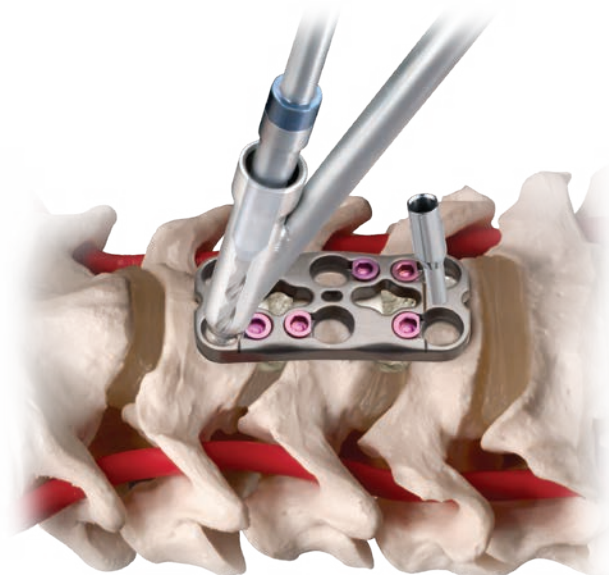
Using the Variable Angle Drill Guide

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

Place the drill guide into the desired plate hole. This guide permits full angulation of the drill bit through the plate.

Determine the desired drill depth and select the appropriate fixed length Drill Bit. The bits are color-coded corresponding to screw length. Assemble the bit to the Quick-Connect Handle, Small and insert into the drill guide. Drill to the stop.

Screw holes may be tapped using the Cervical Tap.



Using Variable Angle Drill Guide to prepare screw pilot hole

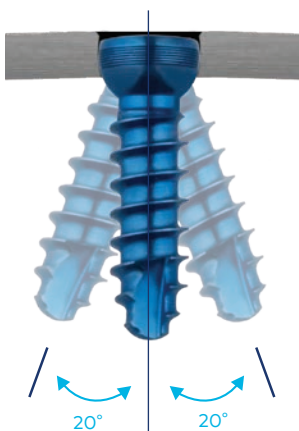
Using the Drill Guide Variable Angulation, Adjustable Depth

The **Drill Guide Variable Angulation, Adjustable Depth** allows drill depth from 10mm to 20mm, in 2mm increments. Adjust the drill guide depth as described at right.

Note: Variable angle guides should not be used to prepare screw holes for Fixed Angle Screws.

VARIABLE ANGLE DRILL GUIDES

Allow screw angulation of 20° in any direction for drilling screw pilot holes.

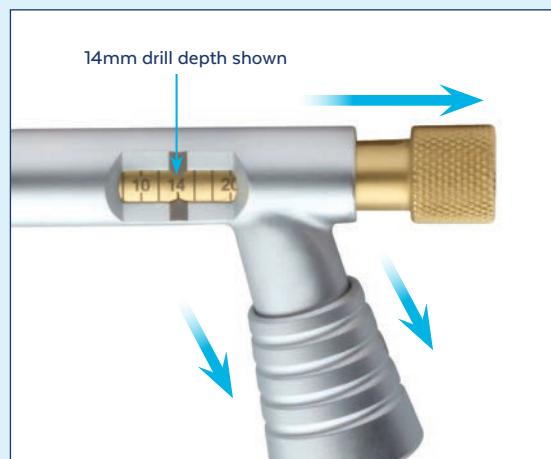


Note: Care should be taken to prevent medial interference.

ADJUSTING DRILL GUIDE DEPTH

Pull down the tapered sleeve to release the ratchet. Adjust the drill stop until the appropriate depth is indicated.

Release the sleeve to lock the drill guide at the appropriate depth. Ensure that the ratchet is fully engaged by pressing on the drill stop.



Option B. Variable Angulation (Cont'd)

Drill Guide Variable Angulation, Adjustable Depth, Cont'd

Attach the **Drill Bit, 2.4mm** to the Quick-Connect Handle, Small, with Cap and insert the bit through the drill guide. Drill to the stop. The Drill Bit 2.4mm has a gold tip, indicating that it is to be used with the Drill Guide Variable Angulation, Adjustable Depth (gold stop).



**Drill Guide Variable Angulation, Adjustable Depth
with Drill Bit, 2.4mm inserted**

Alternatively, the Drill Guide Variable Angulation, Adjustable Depth may be used with fixed depth bits. Pull back the tapered sleeve to disengage the ratchet. The drill stop can be removed from the drill guide and the **Adjustable Depth Guide Drill Bit** of the appropriate length inserted.



**Variable Angulation, Adjustable Depth Drill Guide with
Adjustable Depth Guide Drill Bit, 14mm inserted**

The fixed depth drill bits are additionally available and also have a gold tip to indicate that they are to be used with the Drill Guide Variable Angulation, Adjustable Depth.



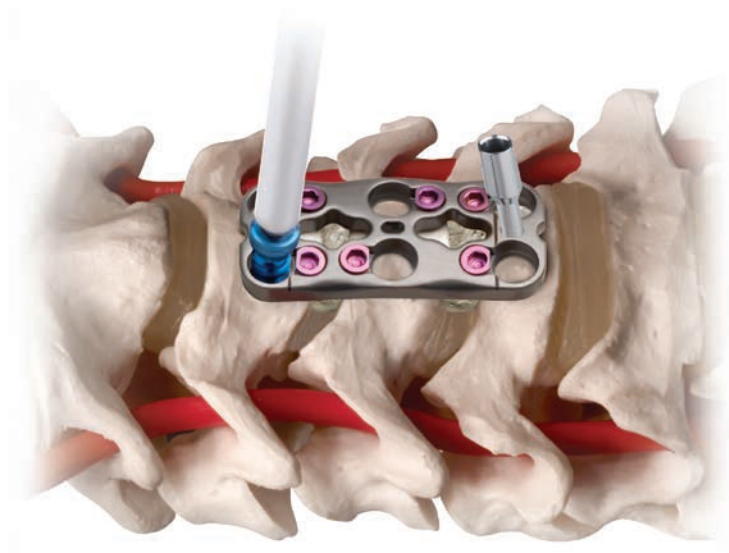
STEP

4

SCREW INSERTION

Load the desired screw from the module using the Screwdriver, 2.5mm Hex, Self-Retaining. Verify screw length and diameter using the gauges within the screw module. Insert the screw through the screw hole. As the screw is inserted, the plate will lag to the bone.

Note: All screw lengths are measured by bone engagement.



Screw insertion

STEP

5

SCREW BLOCKING

Once the screws are fully seated within the plate, insert the **Set Screw Positioner, 2.0mm Hex, Torque Limiting** into the blocking set screw and rotate clockwise approximately 180°. The set screw positioner will provide audible and tactile confirmation that the screw is blocked from backing out. As a final confirmation, visually confirm that the blocking set screw is correctly rotated approximately 180°, as shown below.

Initial Position



Blocking set screw in unblocked position - Flat facing screw

Final Position



Blocking set screw in blocked position - Flat facing away from screw

FINAL CONSTRUCT



Lateral View



AP View

OPTIONAL: SCREW REMOVAL

For screw removal, simply reverse the steps for insertion. Use the Set Screw Positioner, 2.0mm Hex, Torque Limiting to rotate the blocking set screws counterclockwise 180°. Remove the screws from the plate using the 2.5mm Hex Screwdriver.

In the event the blocking set screw hex becomes stripped, use the 2.1mm Hex Screwdriver. A **Screw Extractor for 2.5mm Hex** is additionally available and may be used if a screw hex becomes stripped.

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CERVICAL PLATE SET 950.902

1-Level (Qty 1 Each)

Part No. Length

150.110	10mm
150.112	12mm
150.114	14mm
150.116	16mm
150.118	18mm
150.120	20mm
150.122	22mm
150.124	24mm
150.126	26mm

2-Level (Qty 1 Each)

Part No. Length

150.224	24mm
150.226	26mm
150.228	28mm
150.230	30mm
150.232	32mm
150.234	34mm
150.236	36mm
150.238	38mm
150.240	40mm
150.242	42mm
150.244	44mm
150.246	46mm

3-Level (Qty 1 Each)

Part No. Length

150.339	39mm
150.342	42mm
150.345	45mm
150.348	48mm
150.351	51mm
150.354	54mm
150.357	57mm
150.360	60mm
150.363	63mm
150.366	66mm
150.369	69mm

Part No. Description

950.002	PROVIDENCE™ Plate Module
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PROVIDENCE™ Cervical Plates Extra Lordotic

1-Level

Part No. Length

150.130	10mm
150.132	12mm
150.134	14mm

2-Level

Part No. Length

150.254	24mm
150.256	26mm

3-Level

Part No. Length

150.379	39mm
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4-Level

Part No. Length

150.460	60mm
150.463	63mm
150.466	66mm
150.469	69mm
150.472	72mm
150.475	75mm
150.478	78mm
150.481	81mm
150.484	84mm
150.487	87mm
150.490	90mm
150.493	93mm

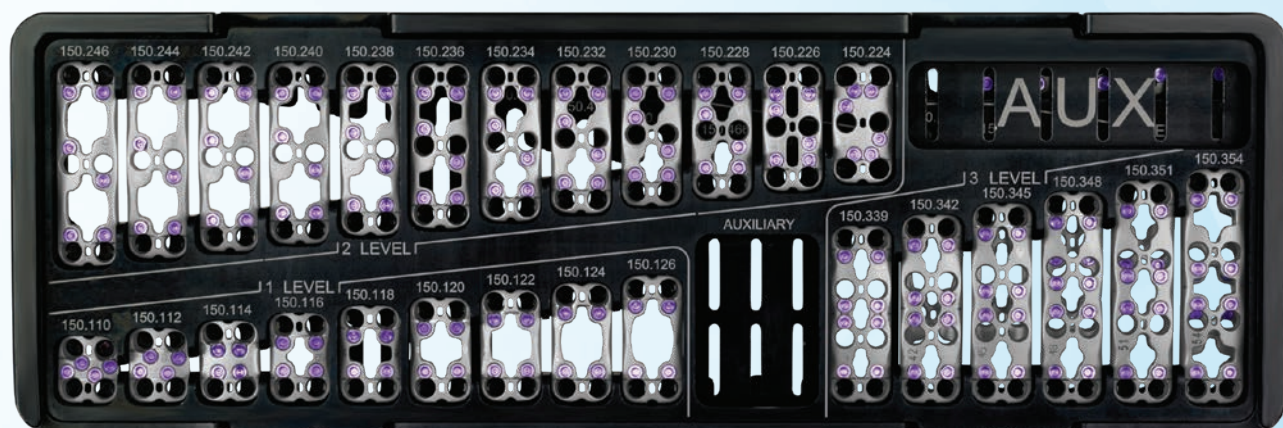
5-Level

Part No. Length

150.580	80mm
150.583	83mm
150.586	86mm
150.589	89mm
150.592	92mm
150.595	95mm
150.598	98mm
150.601	101mm
150.604	104mm

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CERVICAL PLATE SET 950.902



PROVIDENCE™

SCREW SET 950.906






Fixed Angle Screws

Self-drilling	10mm Qty		12mm Qty		14mm Qty		16mm Qty		18mm Qty		20mm Qty
4.2mm diameter	150.010	4	150.012	10	150.014	10	150.016	10	-	-	-
4.6mm diameter	150.510		150.512	10	150.514	10	150.516	10	-	-	-

Self-tapping

4.2mm diameter	150.030	4	150.032	10	150.034	10	150.036	10	150.038	4	150.040	4
4.6mm diameter	150.530		150.532	10	150.534	10	150.536	10	150.538	4	150.540	4

Variable Angle Screws

Self-drilling	10mm Qty		12mm Qty		14mm Qty		16mm Qty		18mm Qty		20mm Qty
4.2mm diameter	150.610	4	150.612	10	150.614	10	150.616	10	-	-	-
4.6mm diameter	150.710		150.712	10	150.714	10	150.716	10	-	-	-

Self-tapping

4.2mm diameter	150.810	4	150.812	10	150.814	10	150.816	10	150.818	4	150.820	4
4.6mm diameter	150.910		150.912	10	150.914	10	150.916	10	150.918	4	150.920	4

Part No. Description

950.006	PROVIDENCE™ Implant Module for Screws
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Additionally Available Fixed Angle Screws

Self-drilling	11mm	13mm	15mm	22mm	24mm	26mm
4.2mm diameter	150.011	150.013	150.015	-	-	-
4.6mm diameter	150.511	150.513	150.515	-	-	-

Self-tapping

4.2mm diameter	150.031	150.033	150.035	150.042	150.044	150.046
4.6mm diameter	150.531	150.533	150.535	150.542	150.544	150.546

Additionally Available Variable Angle Screws

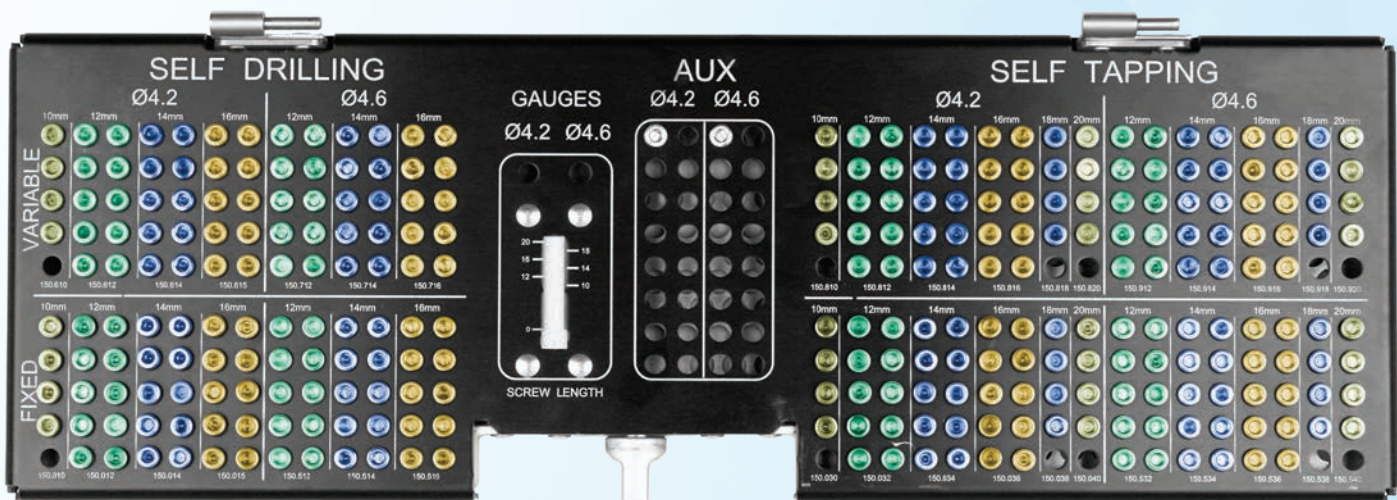
Self-drilling	11mm	13mm	15mm	22mm	24mm	26mm
4.2mm diameter	150.611	150.613	150.615	-	-	-
4.6mm diameter	150.711	150.713	150.715	-	-	-

Self-tapping

4.2mm diameter	150.811	150.813	150.815	150.822	150.824	150.826
4.6mm diameter	150.911	150.913	150.915	150.922	150.924	150.926

PROVIDENCE™

SCREW SET 950.906



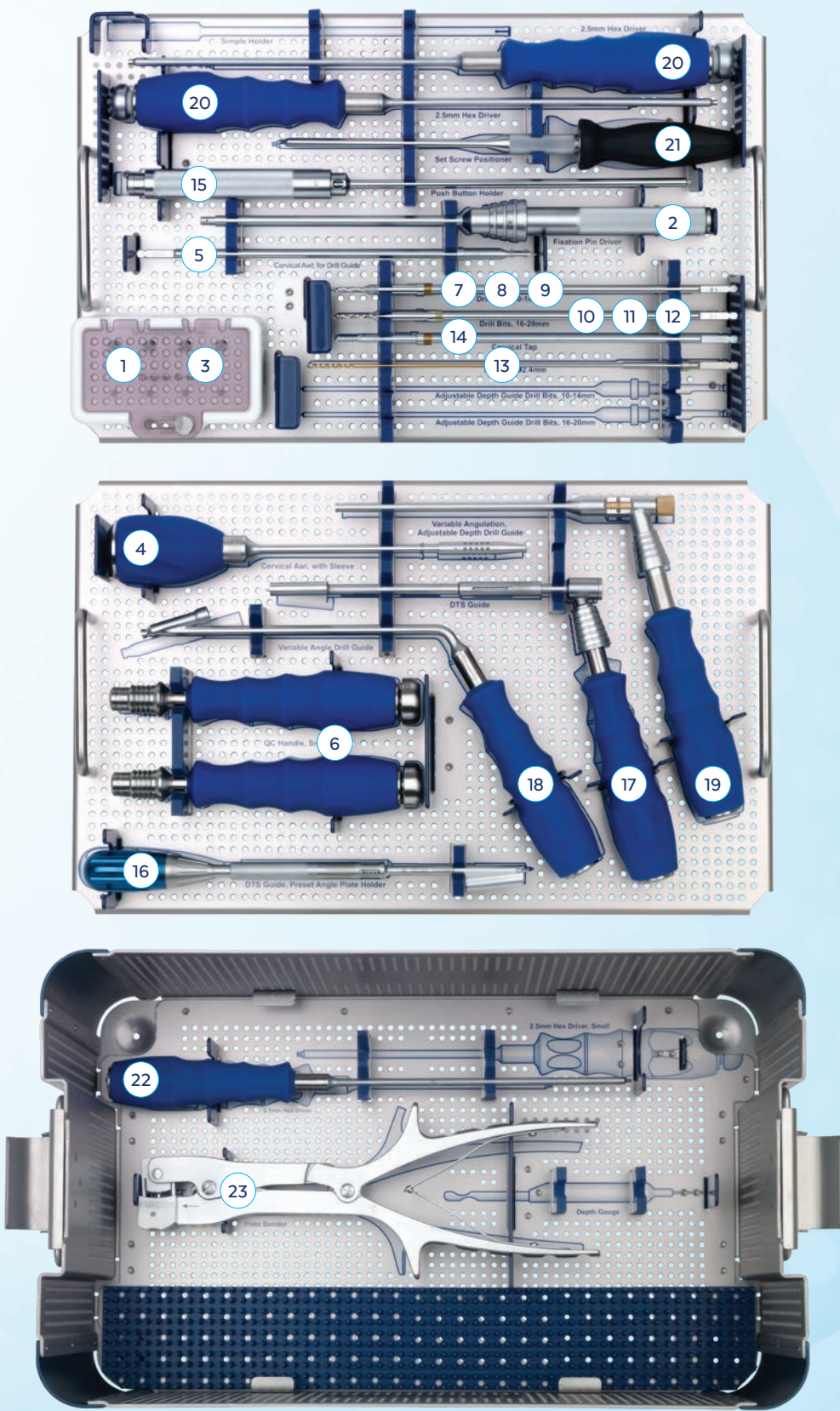
PROVIDENCE™

CERVICAL PLATE INSTRUMENT SET 950.900

	Part No.	Description	Qty	Additionally Available	
1	650.010	Temporary Fixation Pin	4	610.811	Cervical Depth Gauge
2	650.020	Fixation Pin Driver	1	650.011	Temporary Fixation Pin, Smooth
3	650.012	Temporary Screw	4	650.013	Temporary Fixation Screw, Long
4	650.100	Cervical Awl, with Sleeve	1	650.021	Slap Hammer
5	650.102	Cervical Awl, for Drill Guide	1	650.106	QC Handle, Small Ratcheting, with Cap
6	650.105	QC Handle, Small, with Cap	2	650.130	Adjustable Depth Guide Drill Bit, 10mm
7	650.110	Drill Bit, 10mm	1	650.132	Adjustable Depth Guide Drill Bit, 12mm
8	650.112	Drill Bit, 12mm	1	650.134	Adjustable Depth Guide Drill Bit, 14mm
9	650.114	Drill Bit, 14mm	1	650.136	Adjustable Depth Guide Drill Bit, 16mm
10	650.116	Drill Bit, 16mm	1	650.138	Adjustable Depth Guide Drill Bit, 18mm
11	650.118	Drill Bit, 18mm	1	650.140	Adjustable Depth Guide Drill Bit, 20mm
12	650.120	Drill Bit, 20mm	1	650.201	Simple Holder
13	650.150	Drill Bit, 2.4mm	1	650.208	DTS Guide, Pin Connection
14	650.160	Cervical Tap	1	650.212	Drill Guide, Variable Angle, Long Barrel
15	650.200	Push Button Holder	1	650.213	Drill Guide, Fixed Angle
16	650.203	DTS Guide, Pre-Set Angle Plate Holder	1	650.223	Double Barrel DTS Guide, Preset Angle, Plate Holder
17	650.206	DTS Guide, Variable Angle	1	650.226	Double Barrel DTS Guide, Variable Angle
18	650.210	Drill Guide, Variable Angle, Short Barrel	1	650.302	Screwdriver, 2.5mm Hex, Self-Retaining with Cap, Small
19	650.211	Drill Guide Variable Angulation, Adjustable Depth	1	650.314	Screw Extractor, for 2.5mm Hex
20	650.301	Screwdriver, 2.5mm Hex, Self-Retaining, with Cap	1	650.510	Small Drill Bit, 10mm
21	650.312	Set Screw Positioner, 2.0mm Hex, Torque Limiting	1	650.512	Small Drill Bit, 12mm
22	650.313	2.1mm Hex Screwdriver	1	650.514	Small Drill Bit, 14mm
23	650.806	Plate Bender	1	650.516	Small Drill Bit, 16mm
				650.518	Small Drill Bit, 18mm
				650.520	Small Drill Bit, 20mm
	950.100	PROVIDENCE™ Graphic Case			

PROVIDENCE™

CERVICAL PLATE INSTRUMENT SET 950.900



IMPORTANT INFORMATION ON PROVIDENCE™

DESCRIPTION

The PROVIDENCE™ Anterior Cervical Plate System consists of plates used with either variable or fixed angle 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, as specified in ASTM F136, F1295.

INDICATIONS

The PROVIDENCE™ 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.

CONTRAINDICATIONS

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

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

WARNINGS

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

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.

Possible adverse effects which may occur include: failed fusion or pseudarthrosis 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.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

PRECAUTIONS

The implantation of screw and plate systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting screw diameter and length.

Surgical implants must never be reused. An explanted metal 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.

Correct handling of the implant is extremely important. Contouring of metal implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

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.

MRI SAFETY INFORMATION



PROVIDENCE™ 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 PROVIDENCE™ 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 and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING AND USE

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

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

IMPORTANT INFORMATION ON PROVIDENCE™

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6} . Sterile products are packaged in a heat sealed, double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6} . The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:










- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² 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.

SYMBOL TRANSLATION			
	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		

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