GLOBUS MEDICAL

# XTEND®

## 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.*

***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

# XTEND®


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# XTEND®

## The Complete ACDF

XTEND® presents a new approach to treating the effects of degenerative disease on the cervical spine. XTEND® is a complete ACDF system that allows for adjacent level treatment. The XTEND® Primary Plate provides a low profile solution with verifiable screw blocking. A Universal Extender Plate may be added without disruption to the Primary Plate, potentially reducing surgery time and tissue damage.

## Designed for Quality Care

Low profile XTEND® plates may reduce postoperative discomfort sometimes reported after an ACDF. Screws that lag the plate to bone and integrated set screws maintain a low profile and smooth surface.

## Designed for Versatility

While maintaining the most desired features in an anterior cervical plate, XTEND® allows for future treatment of adjacent levels as needed.

**Adjacent Level Treatment**

When treating an adjacent level, the Primary Plate and screws remain in place, preserving bone purchase. Universal Extenders can be placed adjacent to any plate without disrupting the primary screws.

The single screw hole provides up to 30° angulation around the 15° insertion point.

# LESS DISRUPTIVE TREATMENT FOR ADJACENT SEGMENT DISEASE

**Angle the single screw up to 30° for ease of placement**

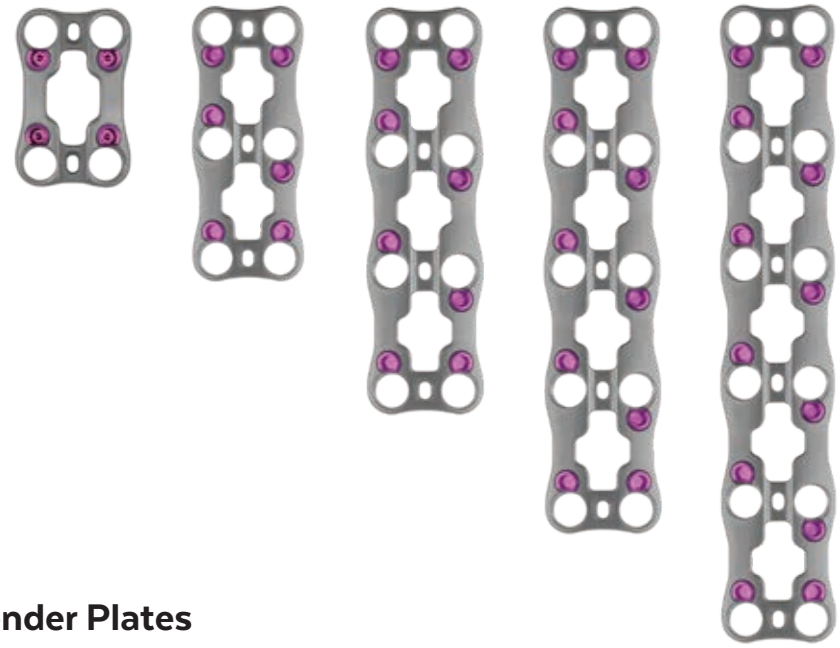
**No disruption of existing construct**

# IMPLANT OVERVIEW

## XTEND® Primary Plates

- Add a Universal Extender for adjacent level stabilization
- 2.3mm profile
- 17.5mm width
- Large centralized windows provide access and visualization to intervertebral space
- Integrated blocking set screw provides audible, tactile, and visual confirmation of blocking
- Lordotic and extra lordotic plates to match patient anatomy
- Lengths from 10mm to 104mm in 2mm increments
- 1, 2, 3, 4, and 5 level plates available

**XTEND® Primary Plates**



## Universal Extender Plates

- Treat adjacent levels without disrupting the primary construct
- Universal Extender can be placed adjacent to any Primary Plate
- Lordotic and extra lordotic plates to match patient anatomy
- Lengths from 10mm to 46mm in 2mm increments
- 1 and 2 level plates available

**Universal Extender**

## Screws

- 4.2mm and 4.6mm diameters
- 4.6mm and 5.1mm diameter for single Universal Extender screw hole
- Self-drilling and self-tapping
- Lengths from 10mm to 20mm in 2mm increments
- Variable and Fixed Angle Screws

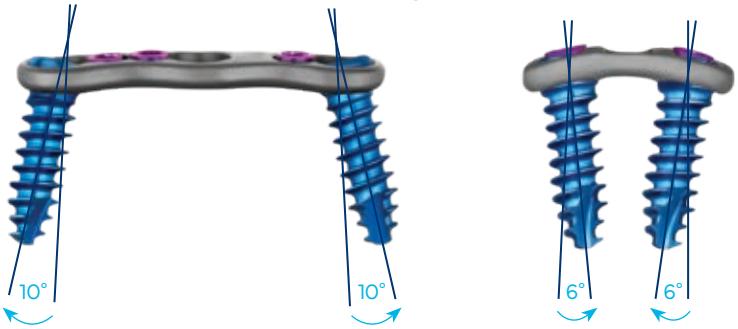
**Variable Angle Screw**

**Fixed Angle Screw**

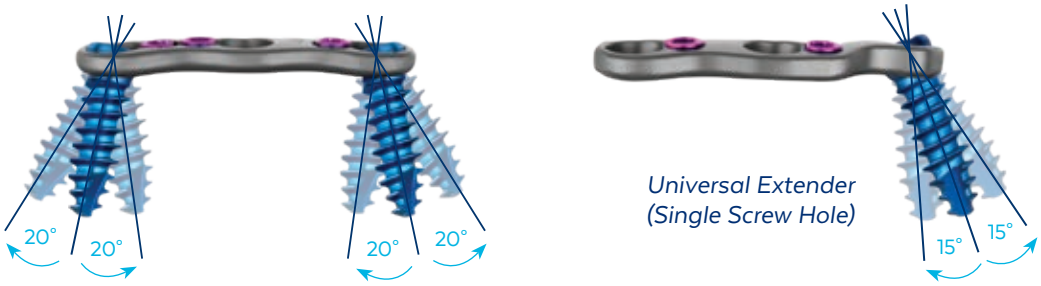
## Screw Angulation

- Variable angle screws provide ±20° angulation
- Single screw hole on Universal Extender provides ±15° angulation around the fixed 15° insertion point
- Pre-set angulation with Drill Guides
- 6° medial
- 10° cephalad/caudal
- Single screw hole on Universal Extender is angled 15° away from the plate

**Pre-Set Angulation**




**Variable Angulation**




*Universal Extender (Single Screw Hole)*

*Angulation includes all screw holes on primary XTEND® plate and remaining dual screw holes on the Universal Extender Plate.*

# **INSTRUMENT** OVERVIEW

## SCREW PREPARATION INSTRUMENTS

Cervical Awl, with Sleeve 650.100

Awl Sleeve Retracted


Cervical Awl, for Drill Guide 650.102

| Drill Bits | |
|---|---|
| Part No. | Size |
| 650.110 | 10mm |
| 650.112 | 12mm |
| 650.114 | 14mm |
| 650.116 | 16mm |
| 650.118 | 18mm |
| 650.120 | 20mm |

Quick Connect Handle, Small, with Cap 650.105

Cervical Tap 650.160

## SCREW INSTRUMENTS

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

DTS Guide, Pre-Set Angle Plate Holder 661.204

Drill Guide, Variable Angle, Short Barrel 650.210

Drill Guide, Pre-Set Angle 661.214

## PLATE INSTRUMENTS

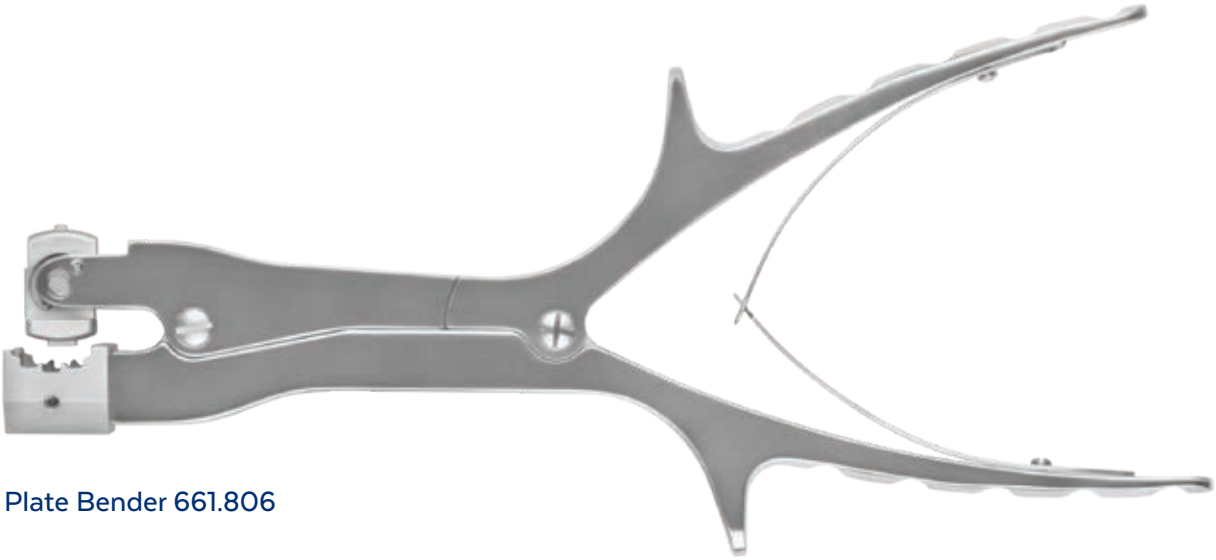


Plate Bender 661.806

Simple Plate Holder 661.303

Fixation Pin Driver 650.020

Temporary Fixation Pin 650.010

## BLOCKING SET SCREW INSTRUMENTS

Set Screw Positioner, 2.0mm Hex, Torque Limiting 650.312

## RESCUE INSTRUMENTS

Screw Extractor, for 2.5mm Hex 650.314

## UNIVERSAL EXTENDER INSTRUMENTS

Caliper 610.801

Cleaning Tool, Curette 661.402

Cleaning Tool, Angled 661.404

Cleaning Tool, Straight 661.406

DTS Guide, Pre-Set Angle Plate Holder, Extender 661.208

# SURGICAL TECHNIQUE

# XTEND®

## XTEND® Primary Plate

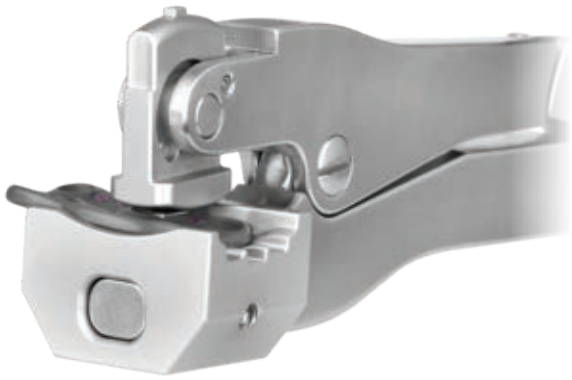
## STEP 1 APPROACH AND PREPARATION

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). XTEND® plate fixation may be used in the cervical spine from C2 to C7. Please refer to the product insert for complete description, indications, and warnings.

Distraction may be accomplished using a standard distractor or other standard methods. Prepare the disc space and insert bone graft or an interbody fusion device. Refer to the **COLONIAL® ACDF Spacer Surgical Technique Guide** for recommended techniques. Remove any 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.



### Plate Bending

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

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 above and on the following page to provide the most gradual bend over multiple levels. Compress the handles to achieve the desired curvature.

Several plates do not have sufficient surface area to fit this side of the anvil without interfering with the set screws (see table on next page). When using these plates, rotate the anvil to the more narrow tip to bend the plate. See images as shown on the next page.

For multi-level plates, incrementally bend sections and slide the plate along the bottom anvil to the next level. At every level, check to ensure the top anvil is not touching any set screws.

*Note: Avoid bending the plate at the bone screw hole and adjacent set screw interface by placing the plate on the bender in the correct position, as shown.*

*Plates may not be bent to decrease lordosis. If additional lordosis is required on a plate that cannot be bent due to placement of the blocking set screws, an extra lordotic plate is recommended.*

**Anvil rotated to standard position**

| Narrow Anvil Plate Sizes | |
|---|---|
| 1 Level | 16-18mm |
| 2 Level | 28-36mm |
| 3 Level | 42-54mm |
| 4 Level | 60-72mm |
| 5 Level | 80-89mm |

**Anvil rotated to narrow tip**

## INSERTING INSTRUMENTS INTO THE PIN HOLES

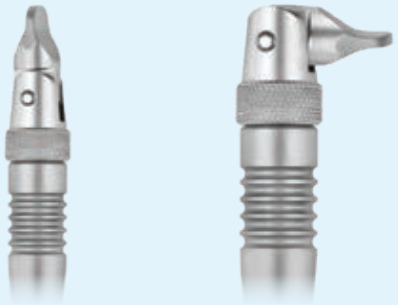
The pin holes on the cephalad and caudal ends of the plate are angled at 10° respectively.

Insert the Simple Plate Holder and DTS guides at this angle.

The center pin hole is perpendicular to the plate. Instruments can be inserted perpendicular to the plate into this hole.

## LOCKING THE SIMPLE PLATE HOLDER

Rotate the lock up to remove or down to rigidly lock the holder to the plate.

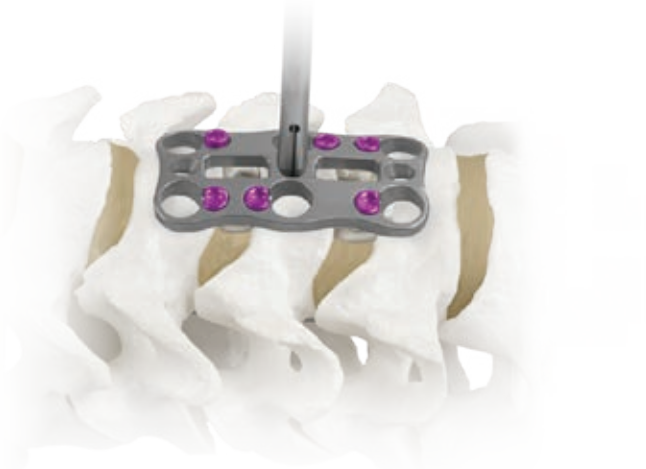


**Unlocked** **Locked**

## Plate Placement

Use the **Simple Plate Holder** to place the selected plate. Ensure that the plate holder locking mechanism is unlocked and press the holder tip into a midline pin hole at the appropriate angle, as described at right. Flip the locking mechanism down to secure the holder to the plate.

Release the plate holder by rotating the lock up and pulling back at the appropriate angle. Alternately, the **DTS Guide, Pre-Set Angle Plate Holder** may be used.



**Using the Simple Plate Holder to place the plate**

# STEP 3 SCREW HOLE PREPARATION

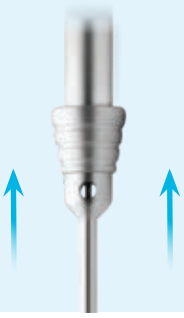
The plate may be temporarily secured by using **Temporary Fixation Pins**. Use the **Fixation Pin Driver** to insert the pin through the midline pin hole as shown below.

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

**Inserting the Temporary Fixation Pin**

### LOADING THE TEMPORARY FIXATION PIN

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



## Option A: Pre-Set Angulation

***Using the Pre-Set Angle Drill Guide***

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

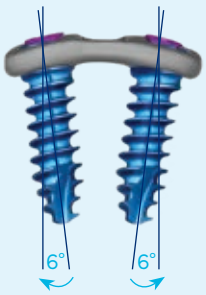
Determine the desired drill depth and select the appropriate fixed length **Drill Bit**. The Drill Bits are color-coded corresponding to the screw length. Assemble the Drill Bit to the **Quick Connect Handle, Small, with Cap** and insert into the drill guide. Drill to the stop.

Screw holes may be tapped using the **Cervical Tap** once the drill guide is removed.

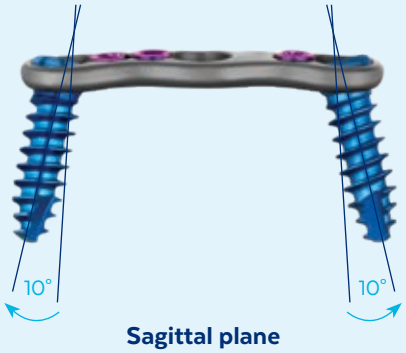
*Note: Drill bits are not intended for connection to power drill sources.*

### USING THE DTS AND DRILL GUIDES WITH PRE-SET ANGULATION

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




**Axial plane**




**Sagittal plane**

***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 Drill Bits are color-coded corresponding to the screw length. Assemble the Drill 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 drill guide using the Cervical Tap.

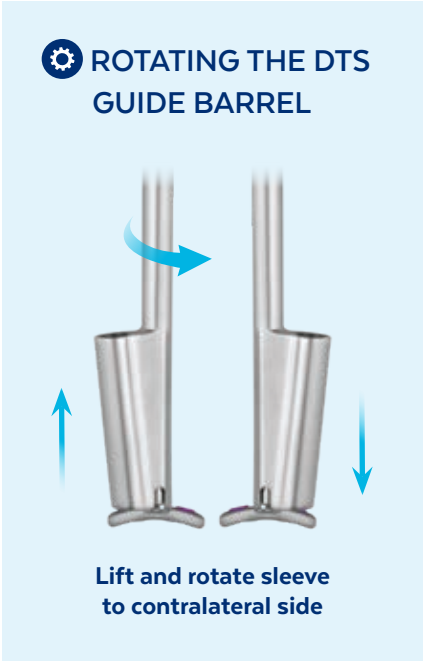
The barrel of the DTS Guide rotates to conveniently switch to the contralateral side. Pull the sleeve up toward the handle, rotate and release the sleeve to change barrel position.

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

*Note: When using instruments through a DTS Guide, hold the guide firmly in the area below the blue handle to prevent the instrument from rotating.*

*The blue handle rotates to lock and unlock the guide to the plate and has the ability to rotate during drill, tap, or screw insertion.*

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



## Option B: Variable Angulation

***Using the Variable Angle Drill Guide***

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

Place the Variable Angle 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 drill bits are color-coded corresponding to screw length. Assemble the Drill Bit to the Quick Connect Handle and insert into the drill guide. Drill to the stop.

Screw holes may be tapped using the Cervical Tap once the drill guide is removed.

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

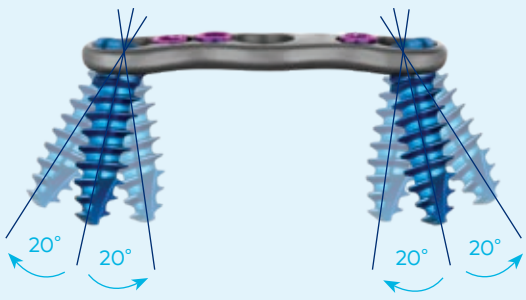
**Using the Variable Angle Drill Guide to prepare screw pilot hole**

### USING THE VARIABLE ANGLE DRILL GUIDE

**Screw Angulation**

This guide allows screw angulation of 20° in any direction for drilling screw pilot holes.

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



# 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 - XTEND®**

## USING THE SCREW MODULE GAUGES

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


Verify screw length by resting the selected screw into the length gauge with the bottom of the screw head resting on the side of the module. A 14mm screw is shown.


# 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 turn clockwise approximately 180°. The Set Screw Positioner provides audible and tactile confirmation that the screw is blocked from backing out. As a final check, visually confirm that the blocking set screw is correctly rotated approximately 180°, as shown below.

**Initial Position**

**Flat of blocking set screw facing bone screw**

**Final Position**

**Flat of blocking set screw facing away from bone screw**

# FINAL CONSTRUCT

**SURGICAL** TECHNIQUE

# XTEND®

## Universal Extender Plates

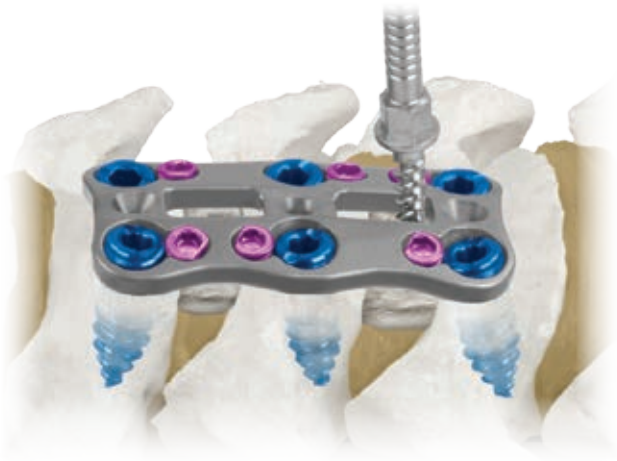
## STEP 1 APPROACH AND PREPARATION

Follow the same approach and preparation steps as outlined on page 12.

Cleaning tools (Curette, Angled or Straight) may aid in removing bone or soft tissue growth in and around the XTEND® connection area.

If distraction is required when inserting a Universal Extender Plate, a distraction pin may be placed either within the graft window or against the existing plate if space allows. Placement will depend on the position of the Primary Plate. See images below.

**Using the Cleaning Tool, Angled to remove excess bone in and around the plate.**



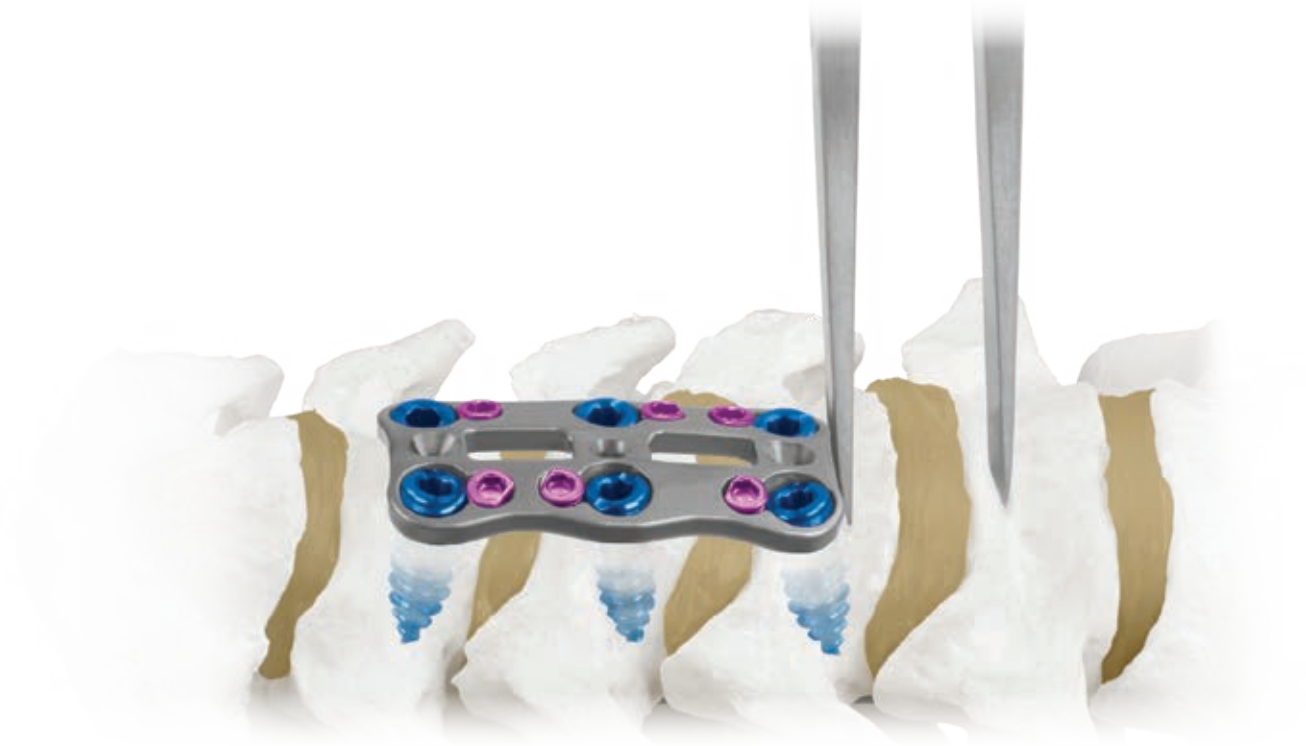
**Distraction pin within existing plate window**

**Distraction pin against existing plate**

# STEP 2 PLATE PLACEMENT

Choose the appropriate Universal Extender Plate size. Plate length is measured from the center of the single screw hole to the center of the most distal hole.

A caliper may be used to measure the appropriate plate length. Place one tip of the caliper against the Primary Plate and the other tip on the last surgical level where the screws are to be placed, as shown below. Subtract 3mm from the indicated measurement to account for the plate material around the end of the single screw hole.



**Using the Caliper to measure for a Universal Extender Plate**

## 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. To add lordosis, follow the steps described on page 13.

The Simple Plate Holder can be used to place the plate. See page 13 for instructions on using the Simple Plate Holder.

# STEP 3 SCREW HOLE PREPARATION

The plate may be temporarily secured by using Temporary Fixation Pins. Follow the steps outlined on page 14 for temporary fixation.

## Option A: Pre-set Angulation

***Using the DTS Guide, Pre-Set Angle Plate Holder, Extender***

The **DTS Guide, Pre-Set Angle Plate Holder, Extender** should be used on the single screw hole only. The DTS Guide, Pre-Set Angle Plate Holder should be used on the remaining screw holes.

The DTS Guide, Extender is inserted at a 15° angle to accommodate the screw insertion angle. See page 15 for instructions on using the DTS Guide, Pre-Set Angle Plate Holder and inserting instruments into the pin holes.

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

## Option B: Variable Angulation

See page 16 for instructions on using the Variable Angle Drill Guide. The Variable Angle Drill Guide may be used on any Universal Extender screw hole.

# STEP 4 SCREW INSERTION AND BLOCKING

When inserting screws into the Universal Extender Plate, the single screw hole should be filled first. See page 17 for screw insertion and blocking instructions.

# FINAL CONSTRUCT

### XTEND® Primary Plate and Universal Extender Plate

# OPTIONAL: REMOVAL

For implant removal, simply reverse the steps for insertion. Use the Torque Limiting Set Screw Positioner to turn the Blocking Set Screws counterclockwise 180°. Remove the screws from the plate using the 2.5mm Screwdriver. If the screw hex is stripped, use the **Screw Extractor, for 2.5mm Hex**. If the blocking set screw hex is stripped, use the **2.1mm Hex Screwdriver**.

# XTEND® Anterior Cervical Plate
# IMPLANT SETS

## XTEND® Cervical Plate Set 961.902 (Qty 1 each)

### 1-Level

| Part No. | Length |
|---|---|
| 161.110 | 10mm |
| 161.112 | 12mm |
| 161.114 | 14mm |
| 161.116 | 16mm |
| 161.118 | 18mm |
| 161.120 | 20mm |
| 161.122 | 22mm |
| 161.124 | 24mm |
| 161.126 | 26mm |

### 2-Level

| Part No. | Length |
|---|---|
| 161.224 | 24mm |
| 161.226 | 26mm |
| 161.228 | 28mm |
| 161.230 | 30mm |
| 161.232 | 32mm |
| 161.234 | 34mm |
| 161.236 | 36mm |
| 161.238 | 38mm |
| 161.240 | 40mm |
| 161.242 | 42mm |
| 161.244 | 44mm |
| 161.246 | 46mm |

### 3-Level

| Part No. | Length |
|---|---|
| 161.339 | 39mm |
| 161.342 | 42mm |
| 161.345 | 45mm |
| 161.348 | 48mm |
| 161.351 | 51mm |
| 161.354 | 54mm |
| 161.357 | 57mm |
| 161.360 | 60mm |
| 161.363 | 63mm |
| 161.366 | 66mm |
| 161.369 | 69mm |

## Additionally Available

### 4-Level

| Part No. | Length |
|---|---|
| 161.460 | 60mm |
| 161.463 | 63mm |
| 161.466 | 66mm |
| 161.469 | 69mm |
| 161.472 | 72mm |
| 161.475 | 75mm |
| 161.478 | 78mm |
| 161.481 | 81mm |
| 161.484 | 84mm |
| 161.487 | 87mm |
| 161.490 | 90mm |
| 161.493 | 93mm |

### 5-Level

| Part No. | Length |
|---|---|
| 161.580 | 80mm |
| 161.583 | 83mm |
| 161.586 | 86mm |
| 161.589 | 89mm |
| 161.592 | 92mm |
| 161.595 | 95mm |
| 161.598 | 98mm |
| 161.601 | 101mm |
| 161.604 | 104mm |

## Extra-Lordotic

### 1-Level

| Part No. | Length |
|---|---|
| 161.130 | 10mm |
| 161.132 | 12mm |
| 161.134 | 14mm |

### 2-Level

| Part No. | Length |
|---|---|
| 161.254 | 24mm |
| 161.256 | 26mm |

### 3-Level

| Part No. | Length |
|---|---|
| 161.379 | 39mm |

## 961.902 XTEND® Cervical Plate Set

961.002 XTEND® Plate Module

## 961.906 XTEND® Screw Set

961.006 XTEND® Screw Module

## 961.906 XTEND® Screw Set

### Variable Angle Screws

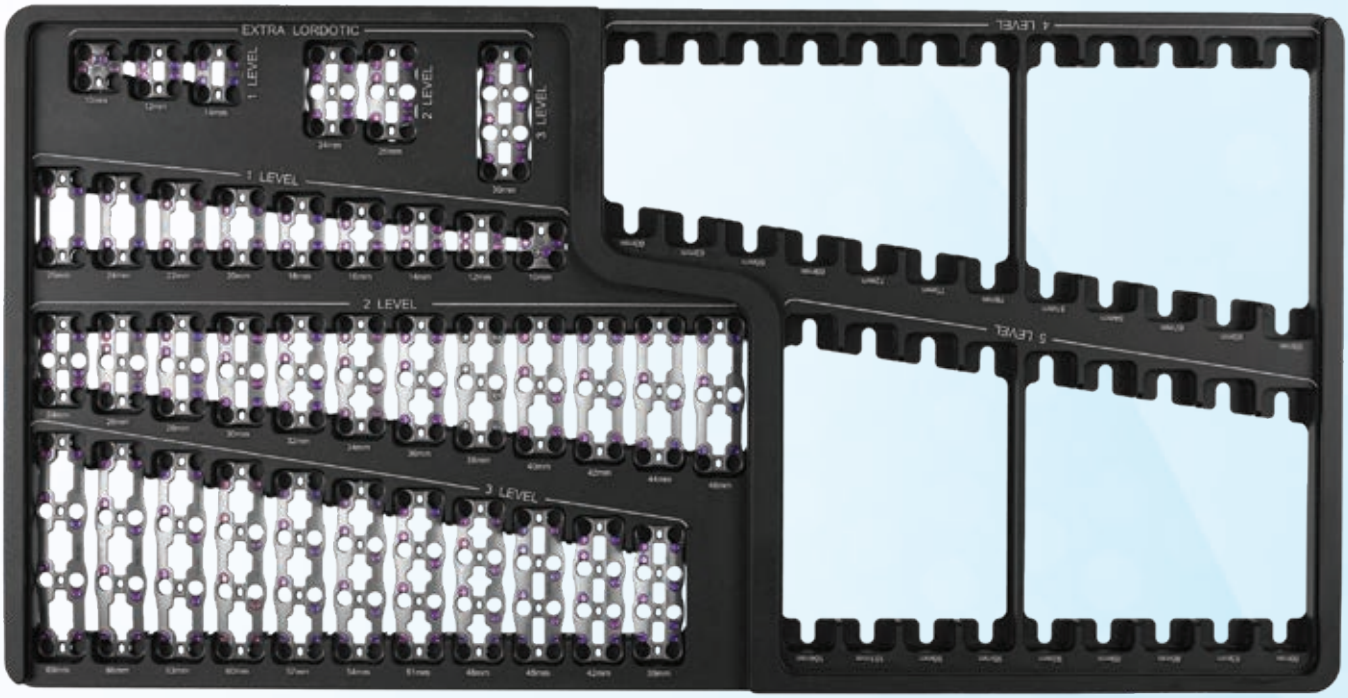
| Self-drilling | 10mm | Qty | 12mm | Qty | 14mm | Qty | 16mm | Qty | 18mm | Qty | 20mm | Qty |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 4.2mm | 161.010 | 4 | 161.012 | 10 | 161.014 | 10 | 161.016 | 10 | - | - | - | - |
| 4.6mm | - | - | 171.012 | 10 | 171.014 | 10 | 171.016 | 10 | - | - | - | - |
| **Self-tapping** | | | | | | | | | | | | |
| 4.2mm | 161.310 | 4 | 161.312 | 10 | 161.314 | 10 | 161.316 | 10 | 161.318 | 4 | 161.320 | 4 |
| 4.6mm | - | - | 171.312 | 10 | 171.314 | 10 | 171.316 | 10 | 171.318 | 4 | 171.320 | 4 |

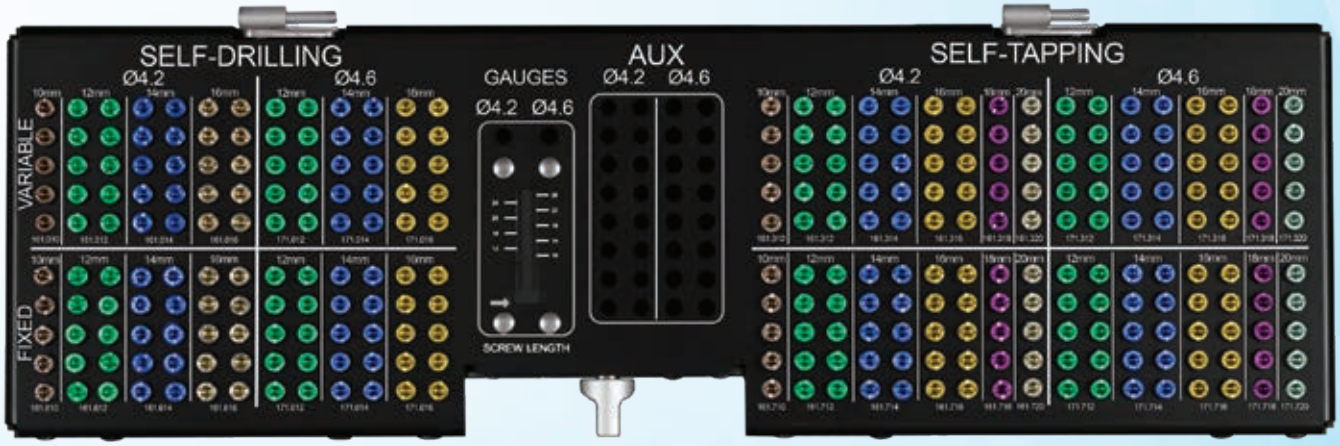
### Fixed Angle Screws

| Self-drilling | 10mm | Qty | 12mm | Qty | 14mm | Qty | 16mm | Qty | 18mm | Qty | 20mm | Qty |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 4.2mm | 161.610 | 4 | 161.612 | 10 | 161.614 | 10 | 161.616 | 10 | - | - | - | - |
| 4.6mm | - | - | 171.612 | 10 | 171.614 | 10 | 171.616 | 10 | - | - | - | - |
| **Self-tapping** | | | | | | | | | | | | |
| 4.2mm | 161.710 | 4 | 161.712 | 10 | 161.714 | 10 | 161.716 | 10 | 161.718 | 4 | 161.720 | 4 |
| 4.6mm | - | - | 171.712 | 10 | 171.714 | 10 | 171.716 | 10 | 171.718 | 4 | 171.720 | 4 |



*Items in gray are additionally available


EXTRA LORDOTIC
1 LEVEL
2 LEVEL
3 LEVEL
4 LEVEL
5 LEVEL


SELF-DRILLING
Ø4.2
Ø4.6
VARIABLE
FIXED
GAUGES
Ø4.2 Ø4.6
SCREW LENGTH
AUX
Ø4.2 Ø4.6
SELF-TAPPING
Ø4.2
Ø4.6

# XTEND® Anterior Cervical Plate
# IMPLANT SETS (CONT'D)

## XTEND® Extender Plate Set 961.912

### Universal Extender Plate

#### 1-Level

| Part No. | Length |
|---|---|
| 561.310 | 10mm |
| 561.312 | 12mm |
| 561.314 | 14mm |
| 561.316 | 16mm |
| 561.318 | 18mm |
| 561.320 | 20mm |
| 561.322 | 22mm |
| 561.324 | 24mm |
| 561.326 | 26mm |

#### 2-Level

| Part No. | Length |
|---|---|
| 561.424 | 24mm |
| 561.426 | 26mm |
| 561.428 | 28mm |
| 561.430 | 30mm |
| 561.432 | 32mm |
| 561.434 | 34mm |
| 561.436 | 36mm |
| 561.438 | 38mm |
| 561.440 | 40mm |
| 561.442 | 42mm |
| 561.444 | 44mm |
| 561.446 | 46mm |

### Extra-Lordotic

#### 1-Level

| Part No. | Length |
|---|---|
| 561.330 | 10mm |
| 561.332 | 12mm |
| 561.334 | 14mm |

#### 2-Level

| Part No. | Length |
|---|---|
| 561.454 | 24mm |
| 561.456 | 26mm |

## 961.906 XTEND® Screw Set

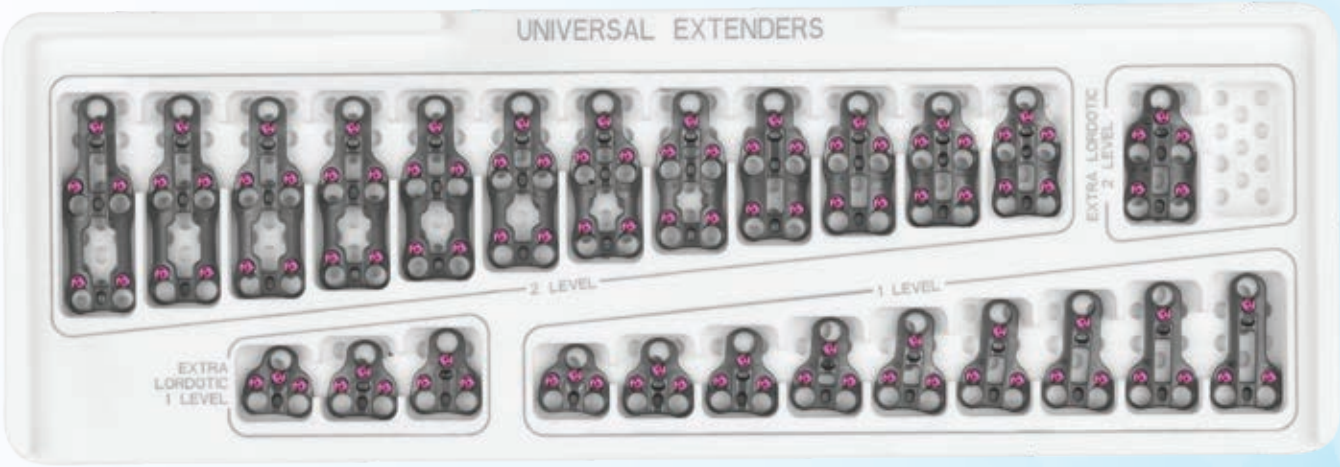
*(5.1mm Diameter)*

### Variable Angle Screws

| | 12mm | 14mm | 16mm | 18mm | 20mm |
|---|---|---|---|---|---|
| **Self-drilling** | 171.412 | 171.414 | 171.416 | - | - |
| **Self-tapping** | 171.512 | 171.514 | 171.516 | 171.518 | 171.520 |

### Fixed Angle Screws

| | 12mm | 14mm | 16mm | 18mm | 20mm |
|---|---|---|---|---|---|
| **Self-drilling** | 171.812 | 171.814 | 171.816 | - | - |
| **Self-tapping** | 171.912 | 171.914 | 171.916 | 171.918 | 171.920 |


UNIVERSAL EXTENDERS
EXTRA LORDOTIC 2 LEVEL
2 LEVEL
1 LEVEL
EXTRA LORDOTIC 1 LEVEL

# XTEND® Anterior Cervical Plate
# INSTRUMENT SET 961.901

| | | Temporary Fixation | QTY |
|---|---|---|---|
| 1 | 650.010 | Temporary Fixation Pin | 4 |
| 2 | 650.020 | Fixation Pin Driver | 1 |

| | | Drilling and Tapping | QTY |
|---|---|---|---|
| 3 | 650.100 | Cervical Awl, with Sleeve | 1 |
| 4 | 650.102 | Cervical Awl, for Drill Guide | 1 |
| 5 | 650.105 | QC Handle, Small, with Cap | 2 |
| 6 | 650.110 | Drill Bit, 10mm | 1 |
| | 650.112 | Drill Bit, 12mm | 1 |
| 7 | 650.114 | Drill Bit, 14mm | 1 |
| | 650.116 | Drill Bit, 16mm | 1 |
| 8 | 650.118 | Drill Bit, 18mm | 1 |
| | 650.120 | Drill Bit, 20mm | 1 |
| 9 | 650.160 | Cervical Tap | 1 |

| | | Plate and Screw Instruments | QTY |
|---|---|---|---|
| 10 | 661.303 | Simple Plate Holder | 1 |
| 11 | 661.204 | DTS Guide, Pre-Set Angle Plate Holder | 1 |
| 12 | 650.210 | Drill Guide, Variable Angle, Short Barrel | 1 |
| 13 | 661.214 | Drill Guide, Pre-Set Angle | 1 |
| 14 | 650.301 | Screwdriver, 2.5mm Hex, Self-Retaining, with Cap | 2 |
| 15 | 650.312 | Set Screw Positioner, 2.0mm Hex, Torque Limiting | 1 |
| 16 | 650.314 | Screw Extractor, for 2.5mm Hex | 1 |
| 17 | 661.806 | Plate Bender | 1 |
| | 961.100 | XTEND® Graphic Case | |

### Extender Instruments

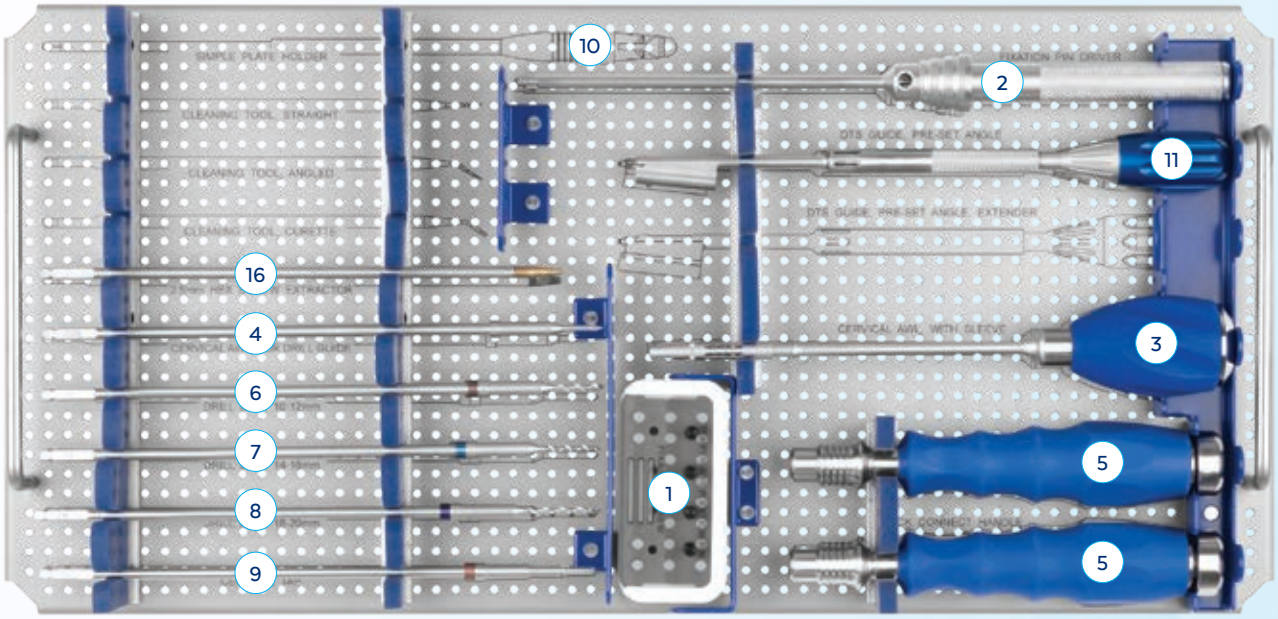
| | |
|---|---|
| 661.402 | Cleaning Tool, Curette |
| 661.404 | Cleaning Tool, Angled |
| 661.406 | Cleaning Tool, Straight |
| 661.208 | DTS Guide, Pre-Set Angle Plate Holder, Extender |
| 610.801 | Caliper |

### Additionally Available

| | |
|---|---|
| 636.450 | Quick Connect Handle, Swivel |
| 636.451 | Quick Connect Handle |
| 650.012 | Temporary Screw |
| 650.106 | QC Handle, Small Ratcheting, with Cap |
| 650.510 | Small Drill Bit, 10mm |
| 650.512 | Small Drill Bit, 12mm |
| 650.514 | Small Drill Bit, 14mm |
| 650.516 | Small Drill Bit, 16mm |
| 650.518 | Small Drill Bit, 18mm |
| 650.520 | Small Drill Bit, 20mm |
| 650.212 | Drill Guide, Variable Angle, Long Barrel |
| 650.302 | Screwdriver, 2.5mm Hex, Self-Retaining with Cap, Small |
| 610.811 | Cervical Depth Gauge |
| 650.313 | 2.1mm Hex Screwdriver |
| 671.303 | Screwdriver Sleeve |



**Items in gray are additionally available*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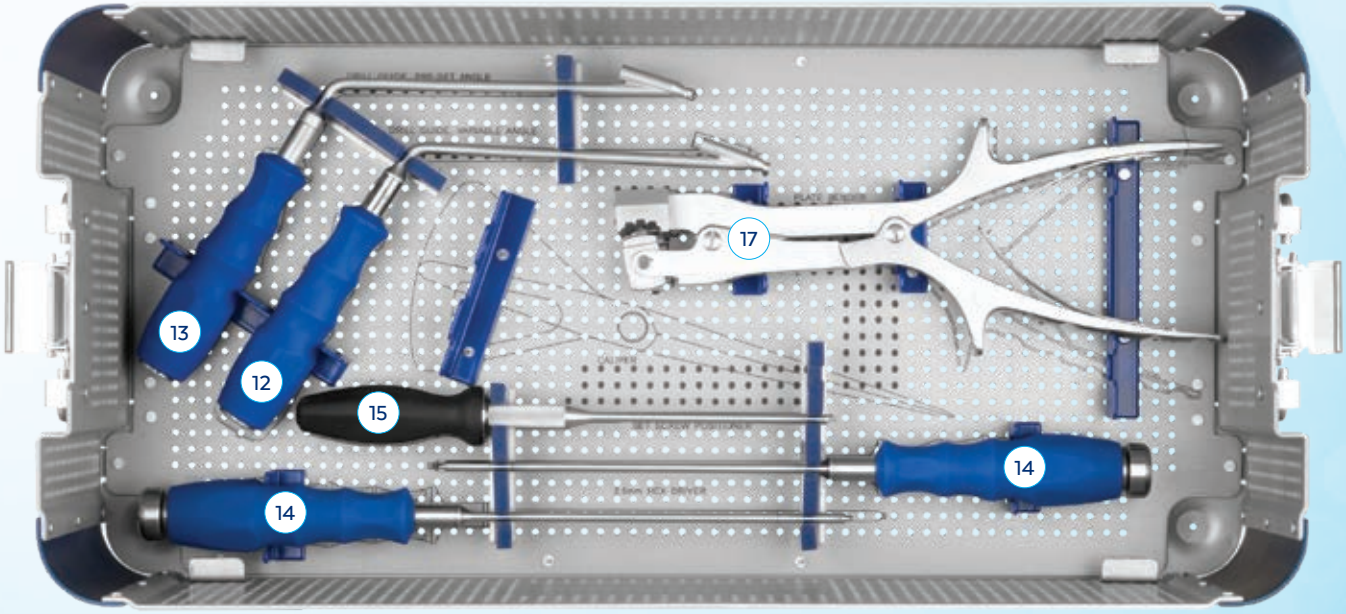
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# IMPORTANT INFORMATION ON THE XTEND® ANTERIOR CERVICAL PLATE SYSTEM

**DESCRIPTION**

The XTEND® Anterior Cervical Plate System consists of standard plates and Universal Extender plates. Universal Extender plates may be used for revision surgery in which additional stabilization is required. Universal Extender plates are inserted adjacent to XTEND® plates or other plates. XTEND® plates are available in various lengths to be used with either variable angle screws or fixed angle screws. Each XTEND® plate is attached to the anterior portion of the vertebral body of the cervical spine (levels C2-C7). The XTEND® Anterior Cervical Plate System implants are composed of titanium alloy, as specified in ASTM F136 and F1295.

**INDICATIONS**

The XTEND® 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**

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 pseudarthosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; loss of fixation; device migration or loosening; decrease in bone density; vertebral fracture; 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.

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.

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.

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

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

**MRI SAFETY INFORMATION**


Non-clinical testing has demonstrated the XTEND® 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 XTEND® Anterior Cervical Plate Systems are expected to produce a maximum temperature rise of less than or equal to 3.5°C after 15 minutes of continuous scanning.

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

**CONTRAINDICATIONS**

Use of these implants is contraindicated in patients with the following conditions:

1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis, which may prevent adequate fixation
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
5. Any condition not described in the indications for use.

**PACKAGING**

These implants 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 and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

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

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

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 $in^2$ total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

| Method | Cycle Type | Temperature | Exposure Time | Drying Time |
|---|---|---|---|---|
| Steam | Pre-vacuum | 132°C (270°F) | 4 Minutes | 30 Minutes |

*These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.*

**CAUTION:** Federal 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 | AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY |
| ⚠ | CAUTION | | MANUFACTURER |
| | SINGLE USE ONLY | | USE BY (YYYY-MM-DD) |
| QTY | QUANTITY | | |

**DI144A REV J**

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