INTRODUCTION

The EXPEDIUM® SFX™ Cross Connector System redefines ease-of-use, implant versatility, and construct security with an advanced top-loading design and uniquely designed snap-fit feature. The benchmark for speed, security, and simplicity is the EXPEDIUM Spine System. Note: Please note the actual colour of the implant is Gold.
CONTENTS
IMPLANT SIZING 2
CONTOURING 4
INSERTION/PROVISIONAL TIGHTENING 6
FINAL TIGHTENING 7
ADDITIONAL CROSS CONNECTORS 8
**STEP 1: IMPLANT SIZING**

The EXPEDIUM SFX Cross Connector Systems are designed to transversely connect two rods upon the completion of posterior spinal instrumentation constructs. Cross connectors increase the torsional stability of posterior constructs to aid in spinal fusion.

Two sizing options are available.

- Determine the proper cross connector size using either the Forcep-Style Measuring Device or the rod size specific Plate Measuring Device.

  **Note:** Implant sizes F1-F9 are fixed and A1-A7 are adjustable.

**Option 1: (Figure 1)**

- Fully seat the Forcep-Style Measuring Device around the outside of the rods at the desired cross connector location and note the implant size as it appears at the intersection of the instrument arms (see example, Figure 1a). The proper implant size for the fixed and adjustable connectors are seen on the right and left instrument arms, respectively.

  **Note:** The instrument tips represent a run-on-rod template for the connectors and can be used as a guide to determine necessary bone and tissue removal for proper implant fit.

**Option 2: (Figure 2)**

- Place the rod size specific Plate Sizing Device over the two rods, setting the notched end over one rod and reading the size as it appears over the second rod. The short sides of the device are for sizing the fixed size cross connectors (F1-F9) and the long side of the device is for gauging the adjustable size cross connectors (A1-A7).

  **If implant contouring is necessary to accommodate non-parallel, non-planar rods, or increased clearance, proceed to Step 2. If no contouring is needed, proceed to Step 3.**

  **Note:** If the size indicated is at the transition between two sizes, it is recommended to choose the larger of the two sizes and contour the implant to fit.
STEP 2: CONTOURING

If contouring of the implant is desired, the Implant Benders should be used.

There are two types of benders.

- The double-ended Fixed Implant Benders can be used to bend and twist the fixed implants in the transverse and coronal planes to accommodate different rod positions.
- The single-ended Adjustable Implant Benders can be used to bend the implants in the transverse plane to provide dural clearance.
- Both sets of benders have sliding tabs to hold the implants in place (Figure 3).

Fixed Implants:

- For contouring a fixed implant in the transverse plane, place the implant into the proper silhouetted end of the Fixed Implant Benders and slide the tabs into place (Figure 4). This contouring is commonly performed to provide additional dural clearance.

- For contouring a fixed implant in the coronal plane, place the implant into the opposite end of the Fixed Implant Benders and slide the tabs into place. This contouring is commonly performed for (Figure 4a) non-parallel and (Figure 4b) non-planar rods.

Note: The smallest fixed implant (F1) is not bendable and will not fit into the benders.

Note: It is not recommended to bend or twist more than Figure 3: 20° in any direction.
STEP 2: CONTOURING (CONTINUED)

Adjustable Implants:
- For contouring an adjustable implant in the transverse plane, place the lower end of the implant into the proper silhouetted end of the Adjustable Implant Benders and slide the tab into place (Figure 5).

• Only one side of the implant body is placed into the bender. The other bender fits the middle segment of the implant (Figure 5a). Load the middle segment and slide the tab into place.

Note: Only the lower end of the implant fits into the Implant Benders.

Note: Use only the benders included in the SFX Cross Connector System set to prevent damage to the implants during contouring.
STEP 3: INSERTION/PROVISIONAL TIGHTENING

Two insertion options are available.

Note: If the implant will not engage the rod, back out the setscrew slightly to provide additional rod clearance.

Option 1:
- If the screw heads are tightly spaced, choose the X20 Self-Retaining Inserter option.
- Place the two self-retaining drivers into the two outer setscrews on the properly sized implant (Figure 6).
- Use the drivers to pick up the implant from the caddy, snap it onto the two rods, and provisionally tighten the setscrews (Figure 6a).

Option 2:
- If more space is available between the screw heads, choose the Forcep-Style Inserter option.
- The forcep tips engage with the implant insertion feature for a secure grip. Use the Forcep-Style Inserter to pick up the implant and snap the attached end onto the rod first (Figure 7).
- Then, use the X20 Self-Retaining Inserter to snap the second side of the implant onto the other rod and provisionally tighten both outer setscrews (Figure 7a).
- For adjustable implants only: After the outer two setscrews are provisionally tightened, provisionally tighten the middle setscrew.
STEP 4: FINAL TIGHTENING

- Place the X20 Torque Driver Shaft, with the Torque Handle attached, through the Stabiliser so that the X20 tip extends past the end of the Stabiliser (Figure 8).
- Fully engage the X20 driver tip with either outer setscrew of the implant (Figure 8a).

- Slide the Stabiliser down over the implant (Figure 8b).

  Note: To orient the Stabiliser, the notched side of the Stabiliser tip should face the rod.

- Tighten to 65 in-lbs (7.3Nm) by turning the Torque Handle clockwise until it clicks (Figure 8c).
- Repeat tightening process on the second outer setscrew.
STEP 4: FINAL TIGHTENING

To tighten the centre setscrew of an adjustable implant, place the Centre Screw Alignment Guide down over the centre setscrew (Figure 9).

Place the X20 Torque Driver Shaft, with the Torque Handle attached, through the Centre Screw Alignment Guide, fully engaging the driver tip with the setscrew (Figure 9a).

Tighten to 65 in-lbs (7.3Nm) by turning the Torque Handle clockwise until it clicks (Figure 8c).

For long posterior constructs, it is recommended to stabilise the instrumentation with two cross connectors by placing one on the upper third and one on the lower third of the construct (Figure 10).

Repeat Steps 1-4 for each additional connector added to the construct.

Tighten to 65 in-lbs (7.3Nm) by turning the Torque Handle clockwise until it clicks (Figure 8c).
INDICATIONS
The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in posterior spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available EXPEDIUM, VIPER® F2 Facet Fixation System, VSP, ISOLA, MONARCH, MOSS MIAMI, and TIMX Spine Systems.

LIMITED WARRANTY AND DISCLAIMER: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS: This product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.