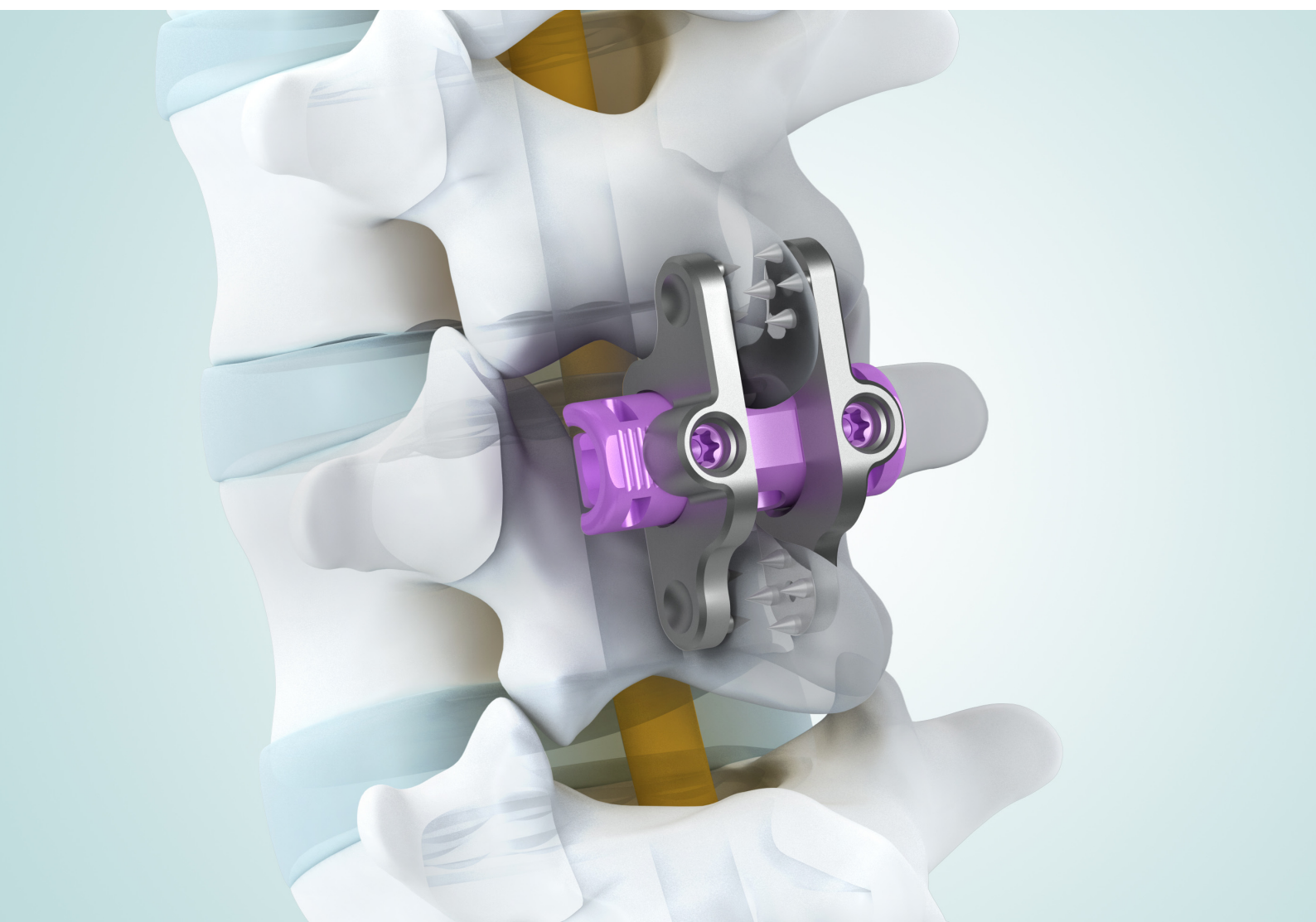
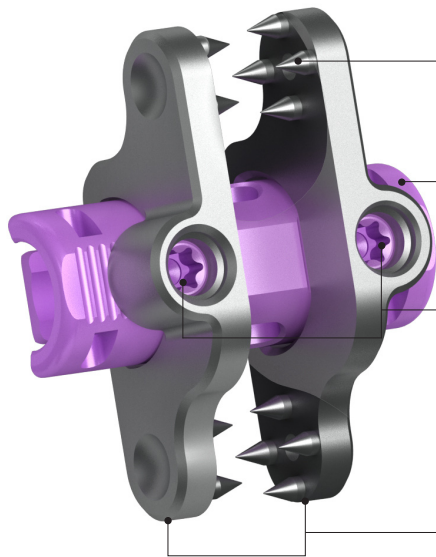


Benefix™

Interspinous Fixation System



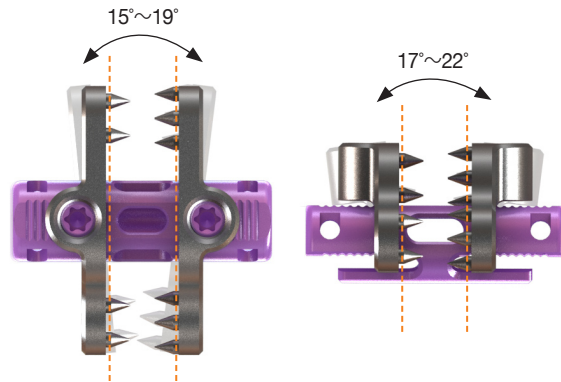


- **Aggressive fixation spikes**
increase stability and security
- **Unique central barrel design**
provides load-sharing support and bone graft containment to facilitate fusion
- **Final fixation**
Final tightening of set screw provides additional force on each plate toward interspinous process to maximize stability and security
- **Telescoping plates**
provide the ability to compressor distract spinous processes

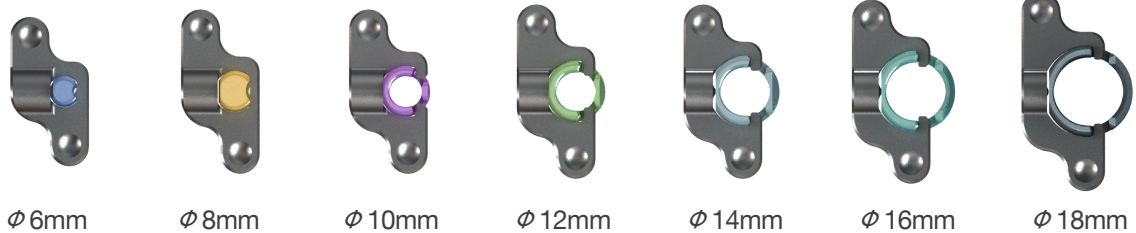
• **Multiple implant lengths and implant capability**

accommodate a variety of patient anatomies and provide excellent fit and optimal fixation

ROM (Range of Motion)		
Barrel Dia.	Frontal(AP) View(α)	Transverse(β)
6mm	19°	22°
8mm	18°	20°
10mm	17°	20°
12mm	17°	20°
14mm	16°	18°
16mm	16°	18°
18mm	15°	17°

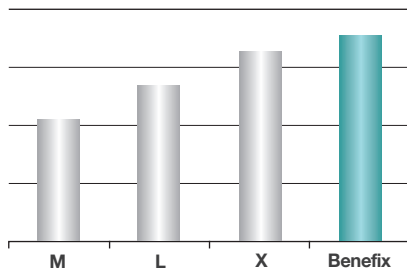


• **Color coded barrel**

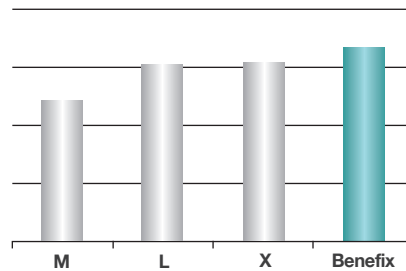


• **Biomechanical Performance**

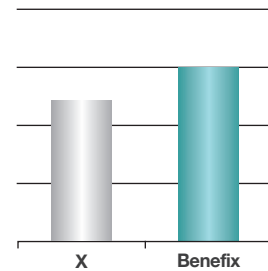
Static Compression Bending Test



Static Torsion Test



Dynamic Compression Test Cycle @41(N)



Note : All the testings were run on Servo-Hydraulic MTS machinery utilizing a modified ASTM F1717 setup and custom test fixtures via ASTM F2624

Preparation and Exposure

Preparing the patient and identifying the surgical access point

1. Position the patient in prone position on the operating table.
2. Identify the spinous processes at the level to be instrumented, using manual palpation and intraoperative imaging.
3. Make a midline incision about 3~5 cm in length to expose the spinous process at the correct level.
4. Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joints. Depending on the surgeon's preferred technique, the supraspinous ligament may be left intact, reflected or removed entirely.

Preparing the implantation site

1. Clear the fusion site of connective and soft tissue, lightly decorticating the bone surface.
When fusing through the spinous processes, a burr, rongeur or rasp can be used to remove the interspinous ligament. The interspinous ligament may optionally be incised / dilated without complete removal.
2. If a decompression procedure is desired, perform a conservative laminotomy, partial facetectomy, foraminotomy or other decompression procedure as needed.

Caution

Do not remove excessive amounts of bone, particularly from the base of the spinous processes and midline lamina. Weakening the posterior arch by aggressive bone removal may increase the risk of intraoperative or postoperative fracture of the adjoining spinous processes or posterior arch.

3. If the facets are hypertrophied and do not allow for proper anterior placement of the implant, the facets can be trimmed. Do not perform a complete facetectomy. Preserving a sufficient portion of the facets to provide biomechanical stability for axial rotation and transverse shear loads is required.

Tissue Dilation

Instrument	
IS5204	Initial Dilator – 4mm
IS5206	Initial Dilator – 6mm
IS6010	Quick Connector Handle

If the interspinous ligament has been left intact, use the **Initial Dilator**, after attached to **Quick Connector Handle** (Fig. 1), to punch a hole through the anterior region of the interspinous ligament. Make sure that the **Initial Dilator** is placed at midpoint between the adjacent spinous processes (Fig. 2).

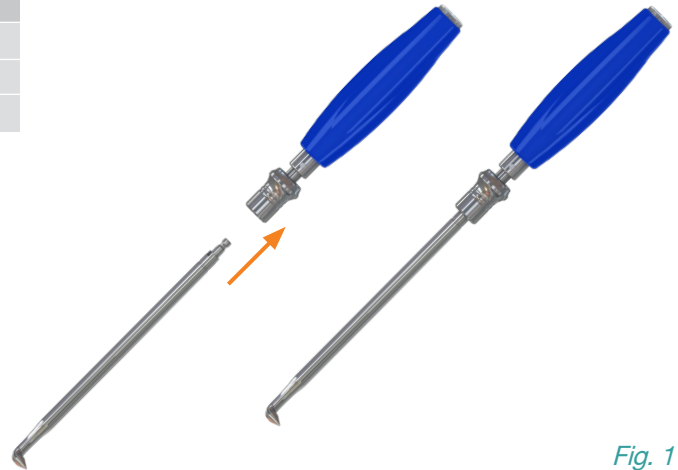


Fig. 1

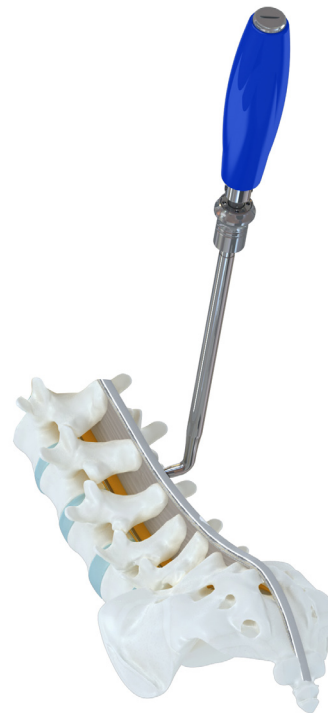


Fig. 2

Distraction and Sizing

Two techniques are available for distraction of the interspinous spaces and measuring the appropriate size of the implants.

Option 1. With Distractor only

Instrument	
IS2010	Distractor

Use the **Distractor** to dilate adjacent spinous processes, with the ratcheting bar up to ensure tactile feedback during distraction (**Fig. 3**).

After dropping down the ratcheting bar in the proper tension, read the scale markings on the ratcheting bar of the **Distractor** to determine appropriate size of implant (**Fig. 4**).

Caution

Do not overdistract spinous processes. Overdistraction could damage the spinous process.

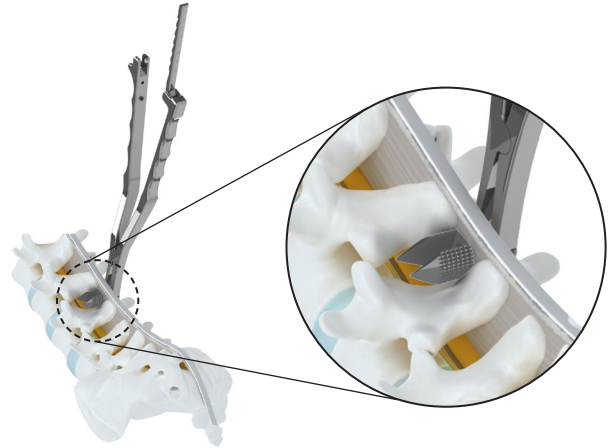


Fig. 3

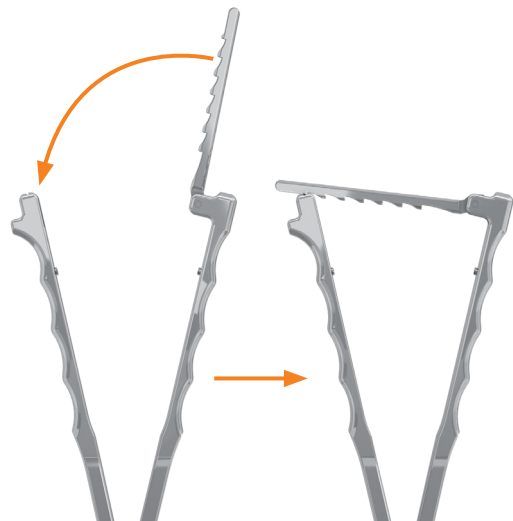


Fig. 4

Option 2. With Dilator and Guide Sleeve

Instrument	
S2010	Distractor
IS5006 ~ IS5018	Dilator, size D6 ~ D18
IS5106 ~ IS5118	Guide Sleeve, size D6 ~ D18
IS6010	Quick Connector Handle

After determining the correct size of **Dilator** by using the **Distractor**, insert the **Dilator** being attached to **Quick Connector Handle** into the interspinous space and rotate the instrument cephalad and caudad to prepare the fusion site (Fig. 5).

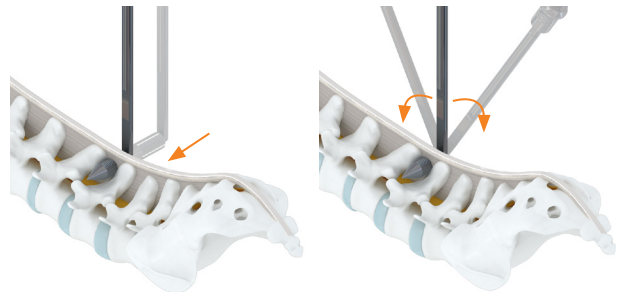


Fig. 5

Remove the **Dilator** from the interspinous space and slide the instrument into the **Guide Sleeve** (Fig. 6). Insert both instruments into the interspinous space, while holding the **Guide Sleeve** in place (Fig. 7).

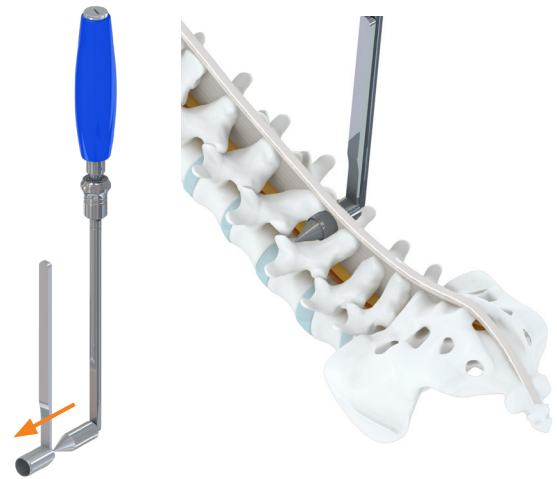


Fig. 6

Fig. 7

Caution

Do not damage the spinous processes.

Remove the **Dilator** only while keeping the **Guide Sleeve** in the interspinous space to create a cannular for easy insertion for the implant (Fig. 8).

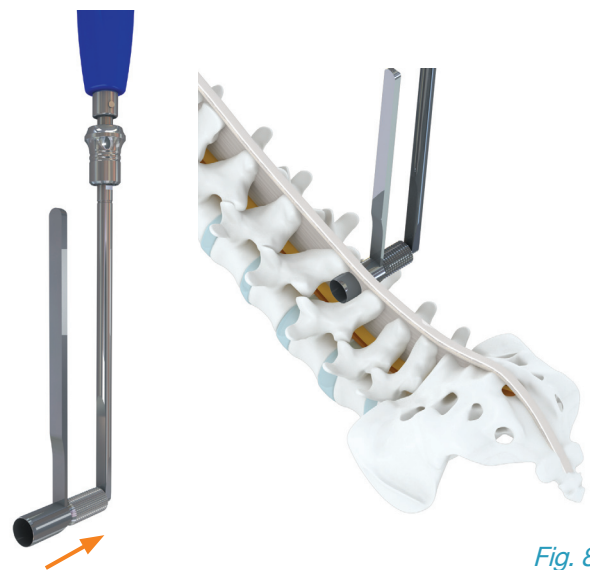


Fig. 8

Implant Attachment

Instrument	
IS1010	Holder for barrel 6~8mm
IS1020	Holder for barrel 10~18mm
IS3010	Set Screw Driver

Insert the barrel to the plate only one side and use the **Set Screw Driver** to loosely tighten the set screw to the top side of the plate (Fig. 9).

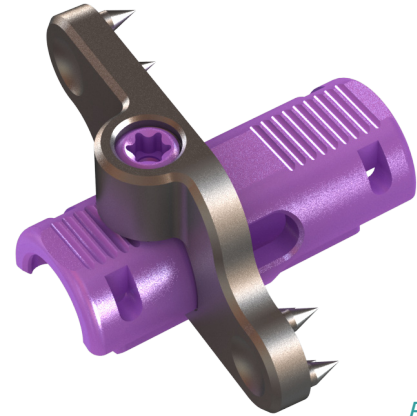


Fig. 9

Attach the barrel to the corresponding holder as follows :

A. Holder for barrel 6~8mm

Align the protruded portion on the **Holder** tip into the divots on the barrel. Gently squeeze the **Holder** until the implant and instrument are fully engaged (Fig. 10).

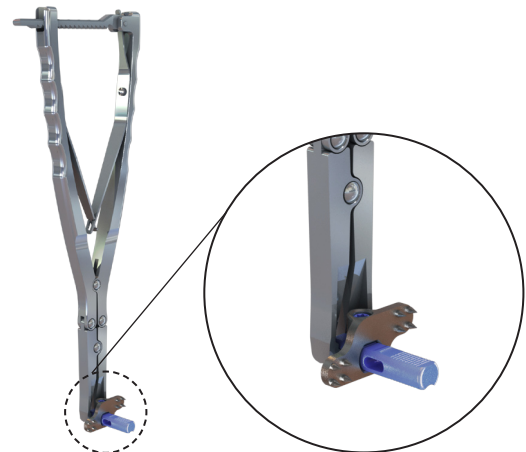


Fig. 10

B. Holder for barrel 10~18mm

Align the pin on the lower shaft tip into the cannula barrel and slide down the upper shaft by squeezing the **Holder** with ratchet down.

Ensure that the pins on the upper shaft tip should be positioned inside the slots on the top aspect of the barrel (Fig. 11).

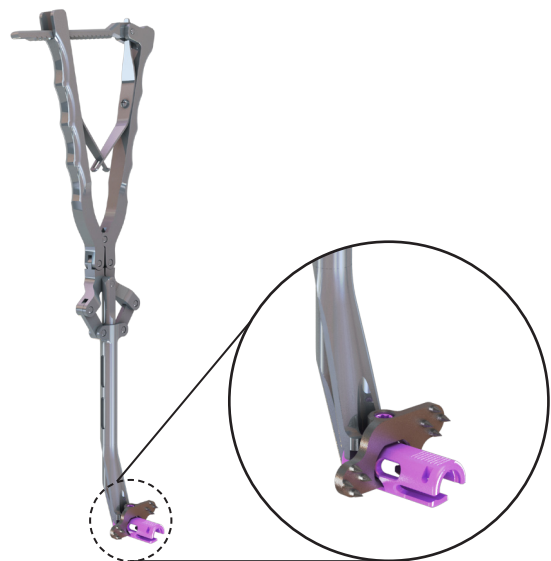


Fig. 11

Implant Insertion

Instrument	
IS1010	Holder for barrel 6~8mm
IS1020	Holder for barrel 10~18mm
IS5106 ~ IS5118	Guide Sleeve, size D6 ~ D18

From the opposite side of the cannula, introduce the barrel with the plate.
Rotate the implant into its final position while simultaneously removing the **Guide Sleeve** from the interspinous space (Fig. 12).

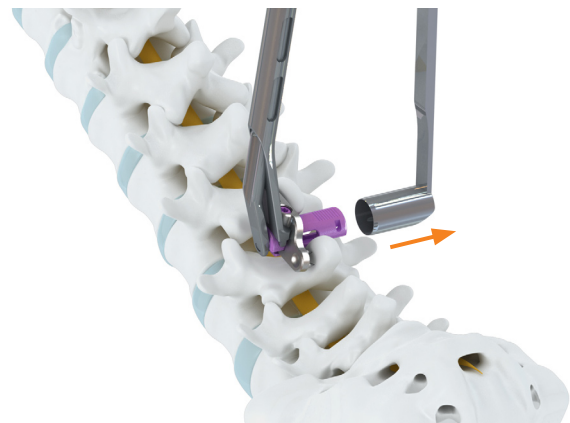
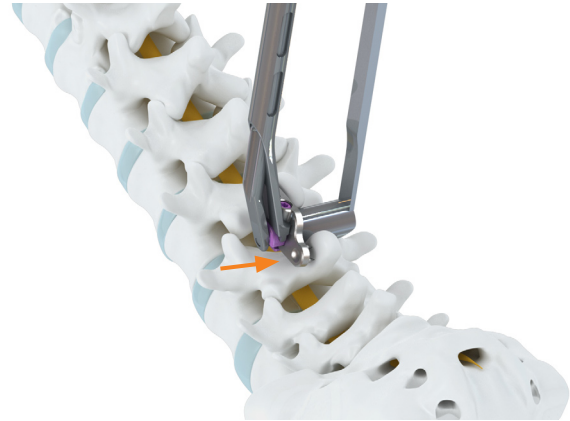


Fig. 12

Final Attachment

Instrument	
IS1030	Plate Holder

Hold the other corresponding plate with the **Plate Holder** by placing the peg side of the holder into the set screw while the curved portion surrounds the set screw housing (Fig. 13).

Caution

It is important to ensure that the set screw has been adequately backed up, flush with the top of the plate for smooth sliding.

Slide the implant over the barrel until it comes in contact with the spinous processes (Fig. 14).

Ensure that the set screws on both plates are in the position such that the plates can slide together.

It is important that the implant is placed as far as anteriorly as possible, and that the plate does not protrude above the lumbodorsal fascia. Confirm placement with fluoroscopy or visual inspection.

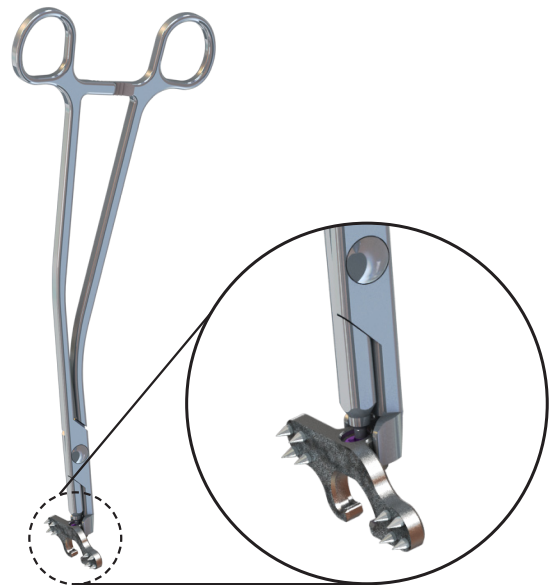


Fig. 13

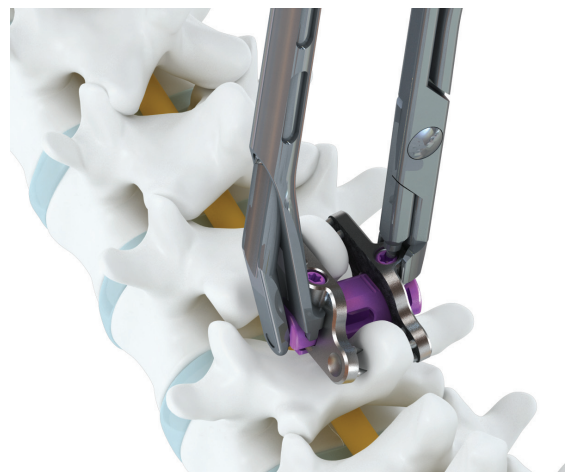


Fig. 14

Compression

Instrument	
IS2020	Compressor

After confirming desired placement, align the hemispherical tips of the **Compressor** into the lateral divots in each plate. Insert the second **Compressor** onto the opposite end of the plate (Fig. 15).

Clamp the plates to the spinous processes by squeezing both Compressors simultaneously or alternate back and forth. Ensure the spikes of the plates are firmly seated into the bone. Confirm that each grip has engaged the spinous processes by gently attempting to move the implant (Fig. 16).

Remove the **Holder** from the plate by releasing the ratcheting engagement. Also, remove the Plate Holder in the same manner.

Caution

Do not remove Holder and Plate Holder before the implant is compressed sufficiently.

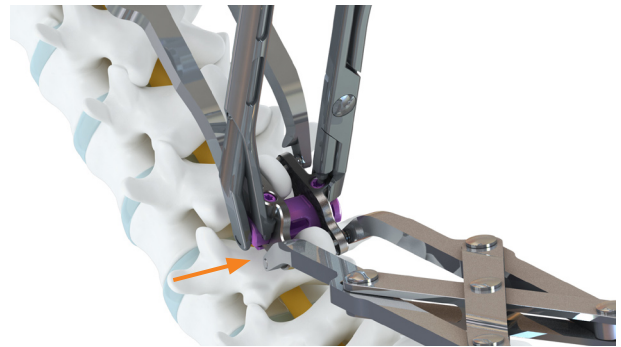


Fig. 15

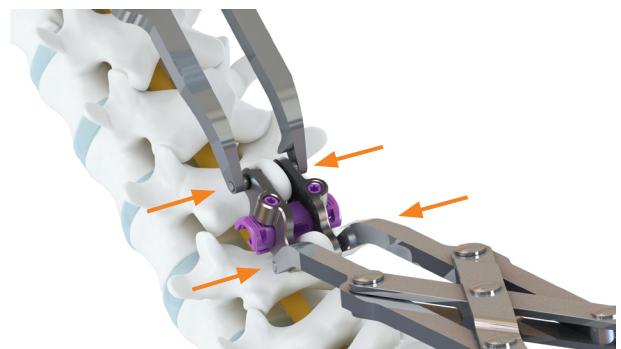


Fig. 16

Final Locking

Instrument	
IS2020	Compressor
IS3010	Set Screw Driver
IS4010	Torque Limiting Driving Handle

Attach the **Set Screw Driver** to the **Torque Limiting Driving Handle** (2 Nm) (Fig. 17).

While maintaining compression on the plates, insert the **Set Screw Driver** into the set screw. Tighten the set screw until the torque handle clicks twice (Fig. 18).

Caution

While inserting the **Set Screw Driver** into the set screw, keep the **Set Screw Driver** aligned to the set screw. Do not twist or angle the **Set Screw Driver** off axis. To ensure that the plates and set screws are fully engaged at the interconnection, visually confirm that the barrel protrudes beyond the lateral surface of plates by at least a plate thickness (3mm).

After removing the **Compressors**, manually and visually inspect the plate to confirm secure fixation (Fig. 19).

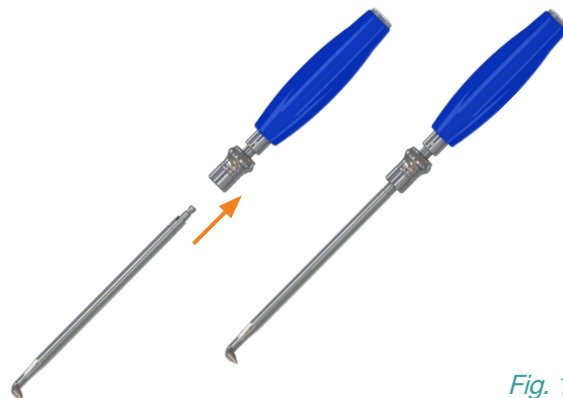


Fig. 17

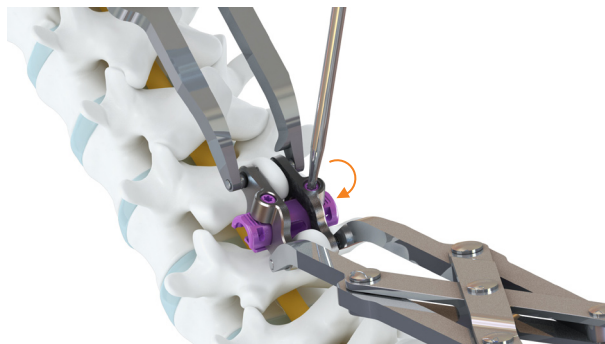


Fig. 18

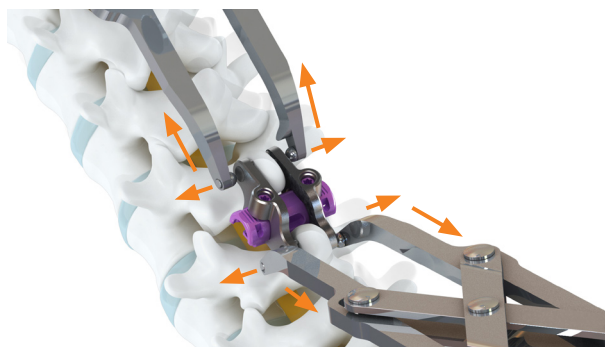


Fig. 19

Implant Removal

Instrument	
IS3010	Set Screw Driver
IS4010	Torque Limiting Driving Handle

Remove any tissue or bone impeding access to the implant.

Use the **Set Screw Driver** to loosen the set screw (Fig. 20).

Attach forceps to implant and remove from the spinous processes (Fig. 21).

Note

Explanted surgical implants must never be reused. Benefix™ Interspinous Fixation system construct can be removed if necessary. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed nonunion of bone will result in excessive and repeated stresses on the implants. These stresses may cause eventual bending, loosening, or breakage of the device(s).

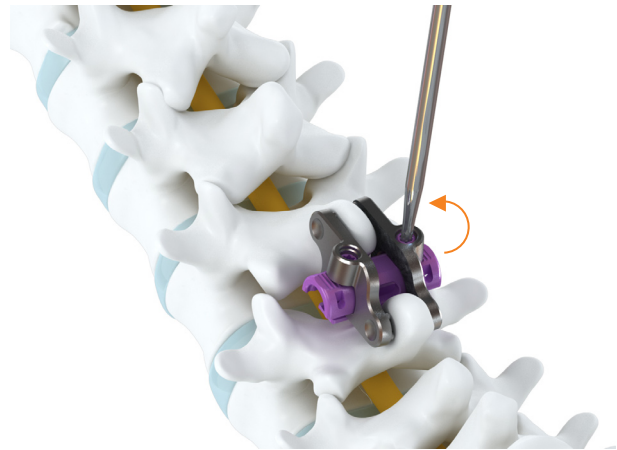


Fig. 20

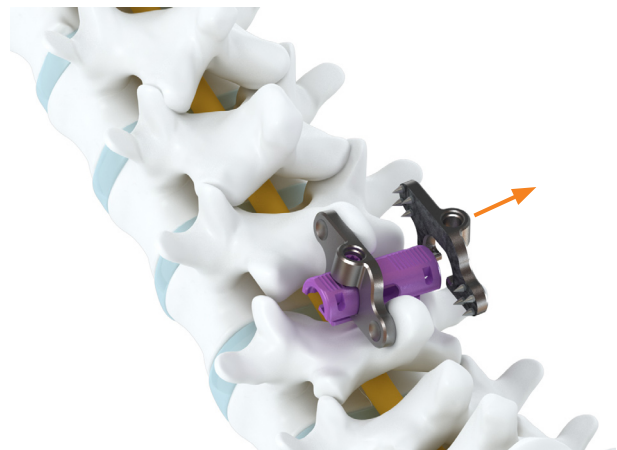









Fig. 21

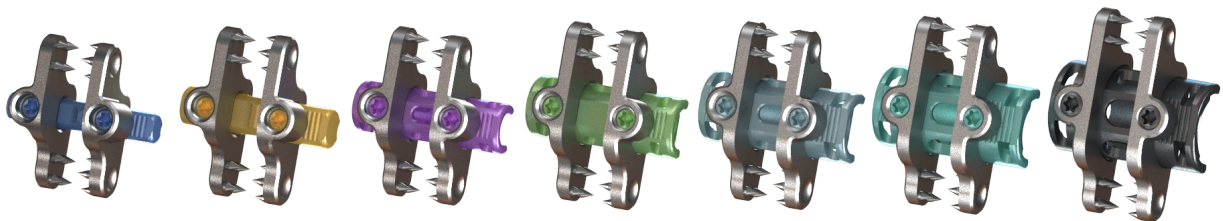
Ordering Information

Implant (Single Use Only)

Cat. No	Barrel size	
IS10627	Ø6 x L27 mm	
IS10632	Ø6 x L32 mm	
IS10637	Ø6 x L37 mm	
IS10827	Ø8 x L27 mm	
IS10832	Ø8 x L32 mm	
IS10837	Ø8 x L37 mm	
IS11027	Ø10 x L27 mm	
IS11032	Ø10 x L32 mm	
IS11037	Ø10 x L37 mm	
IS11227	Ø12 x L27 mm	
IS11232	Ø12 x L32 mm	
IS11237	Ø12 x L37 mm	
IS11427	Ø14 x L27 mm	
IS11432	Ø14 x L32 mm	
IS11437	Ø14 x L37 mm	
IS11627	Ø16 x L27 mm	
IS11632	Ø16 x L32 mm	
IS11637	Ø16 x L37 mm	
IS11827	Ø18 x L27 mm	
IS11832	Ø18 x L32 mm	
IS11837	Ø18 x L37 mm	

Cat. No	Left Plate size
IS20630L	Ø6 x 30 mm
IS20635L	Ø6 x 35 mm
IS20640L	Ø6 x 40 mm
IS20833L	Ø8 x 33 mm
IS21033L	Ø10 x 33 mm
IS21235L	Ø12 x 35 mm
IS21435L	Ø14 x 35 mm
IS21637L	Ø16 x 37 mm
IS21840L	Ø18 x 40 mm

Cat. No	Right Plate size
IS20630R	Ø6 x 30 mm
IS20635R	Ø6 x 35 mm
IS20640R	Ø6 x 40 mm
IS20833R	Ø8 x 33 mm
IS21033R	Ø10 x 33 mm
IS21235R	Ø12 x 35 mm
IS21435R	Ø14 x 35 mm
IS21637R	Ø16 x 37 mm
IS21840R	Ø18 x 40 mm



Instruments

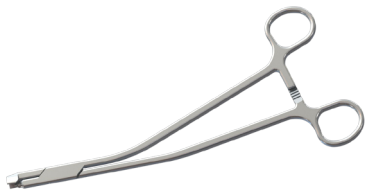
| **IS1010** Holder for Barrel 6~8mm



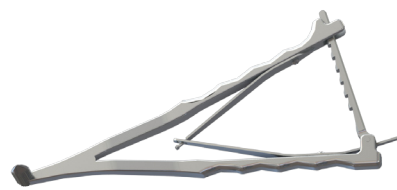
| **IS1020** Holder for Barrel 10~18mm



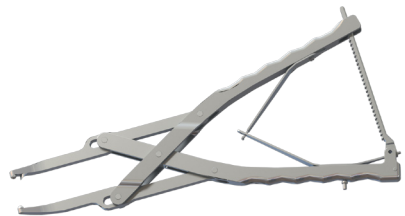
| **IS1030** Plate Holder



| **IS2010** Distractor



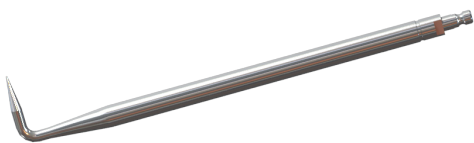
| **IS2020** Compressor



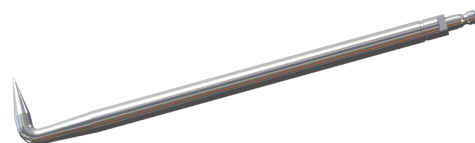
| **IS3010** Set Screw Driver



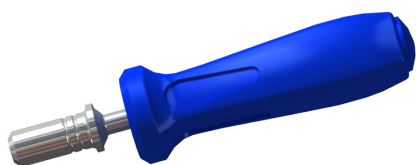
| **IS5204** Initial Dilator – 4mm



| **IS5206** Initial Dilator – 6mm



| **IS4010** Torque Limiting Driving Handle



| **IS6010** Quick Connector Handle



Instruments

| **IS5006** Dilator D6



| **IS5106** Guide Sleeve D6



| **IS5008** Dilator D8



| **IS5108** Guide Sleeve D8



| **IS5010** Dilator D10



| **IS5110** Guide Sleeve D10



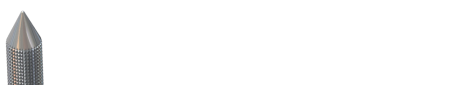
| **IS5012** Dilator D12



| **IS5112** Guide Sleeve D12



| **IS5014** Dilator D14



| **IS5114** Guide Sleeve D14



| **IS5016** Dilator D16



| **IS5116** Guide Sleeve D16



| **IS5018** Dilator D18



| **IS5118** Guide Sleeve D18





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