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Interspinous Fixation System

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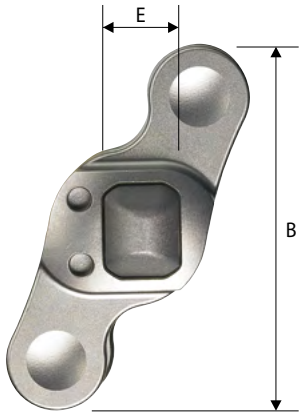
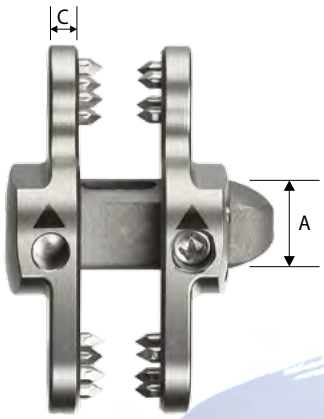
The Huvex Interspinous Fixation System is a single-level, posterior, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1~S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the Huvex Interspinous Fixation System for the purpose of achieving supplemental fusion.

The Huvex Interspinous Fixation System te is an interspinous fusion device designed to provide supplemental fixation in your spine and supports a minimally invasive surgical technique. The Huvex Interspinous Fixation System is available in various sizes to fit specific anatomy.





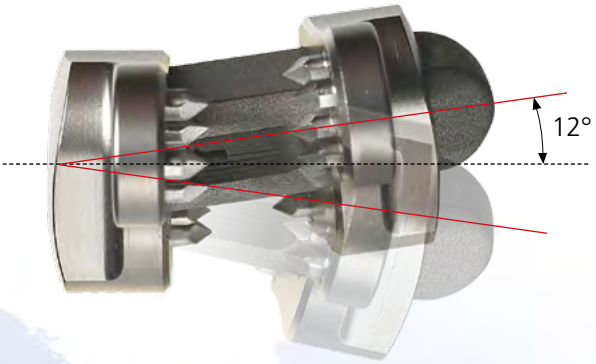
Reference height	Centerbar height(A)	Implant length(B)	Implant thickness(C)	Centerbar length(E)	Part Number
8mm	7.8mm	39mm	3.5mm	7.8mm	SO.IM.0008
10mm	9.8mm	39mm	3.5mm	7.8mm	SO.IM.0010
12mm	11.8mm	43mm	3.5mm	9.8mm	SO.IM.0012
14mm	13.8mm	43mm	3.5mm	9.8mm	SO.IM.0014
16mm	15.8mm	45mm	3.5mm	9.8mm	SO.IM.0016

Description

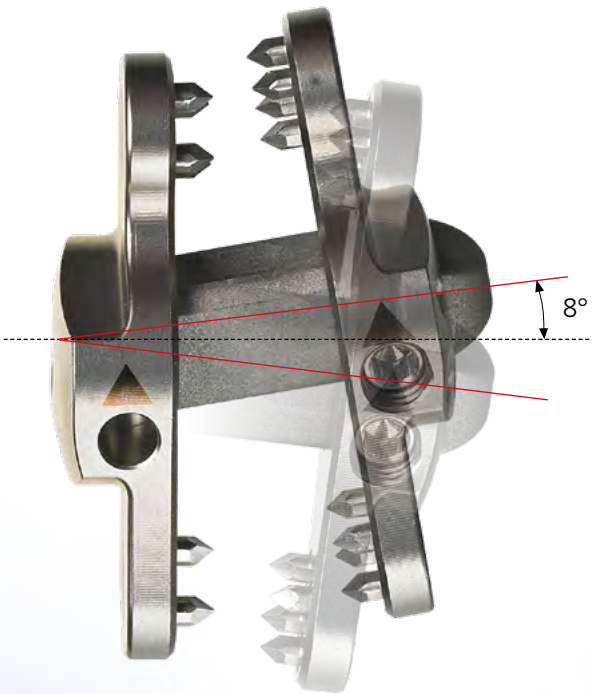
The Huvex Interspinous Fixation System is an internal fixation device for spinal surgery. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patients. The device consists of Ti6Al4V ELI. All implants are intended for single level use only and should not be reused under any circumstances.

Indication for Use

The Huvex Interspinous Fixation System is a single-level, posterior, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1~S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the Huvex Interspinous Fixation System for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Huvex Interspinous Fixation System is intended for use at one level, with autogenous bone graft, and not intended for stand-alone use.



Anterior - Posterior



Cephalad - Caudal

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Surgical Technique

Step 1 : Approach
Step 2 : Perforating
Step 3 : Spinous process Prepare
Step 4 : Trial and bone packing
Step 5 : Insert the implant
Step 6 : Locking set screw

Step 1 : Approach

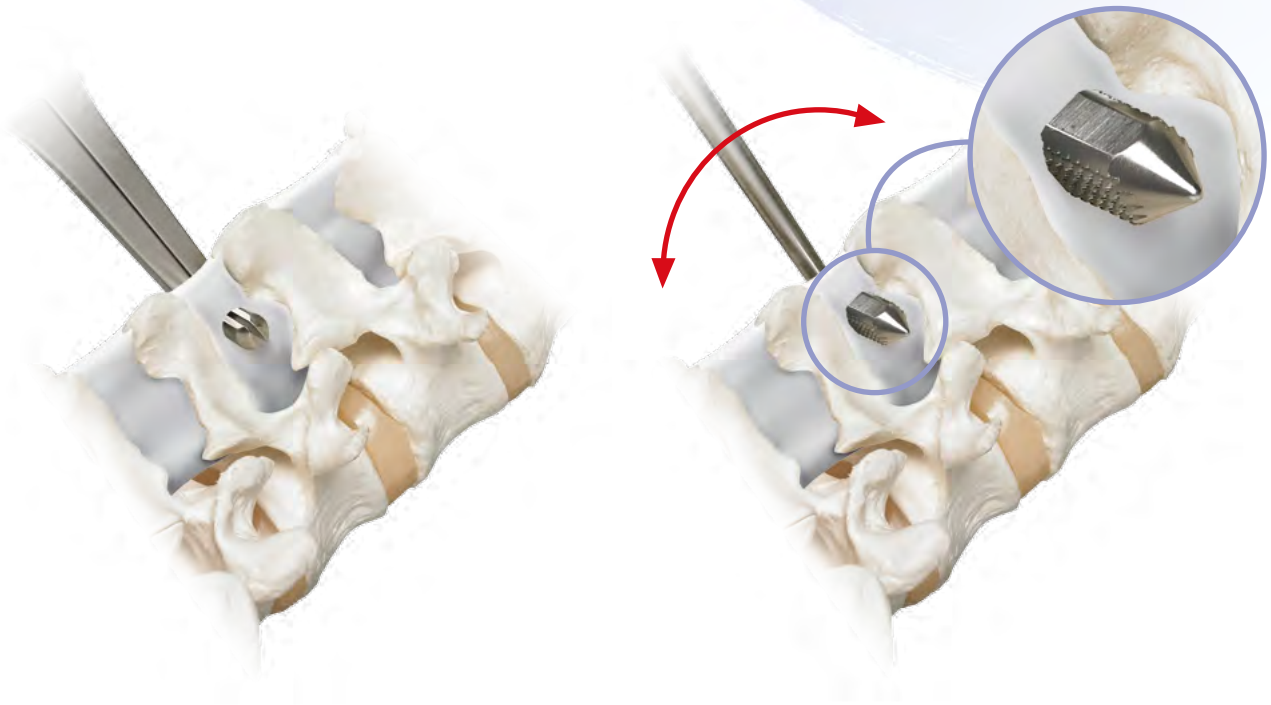
Position the patient in the prone position on the operating table. Make a midline incision about 4~5cm in length to expose the spinous processes at the correct level. Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joint. Depending on the surgeon's preferred technique, the supraspinous ligament may be lleft intact, reflected or removed entirely.

Step 2 : Patient positioning

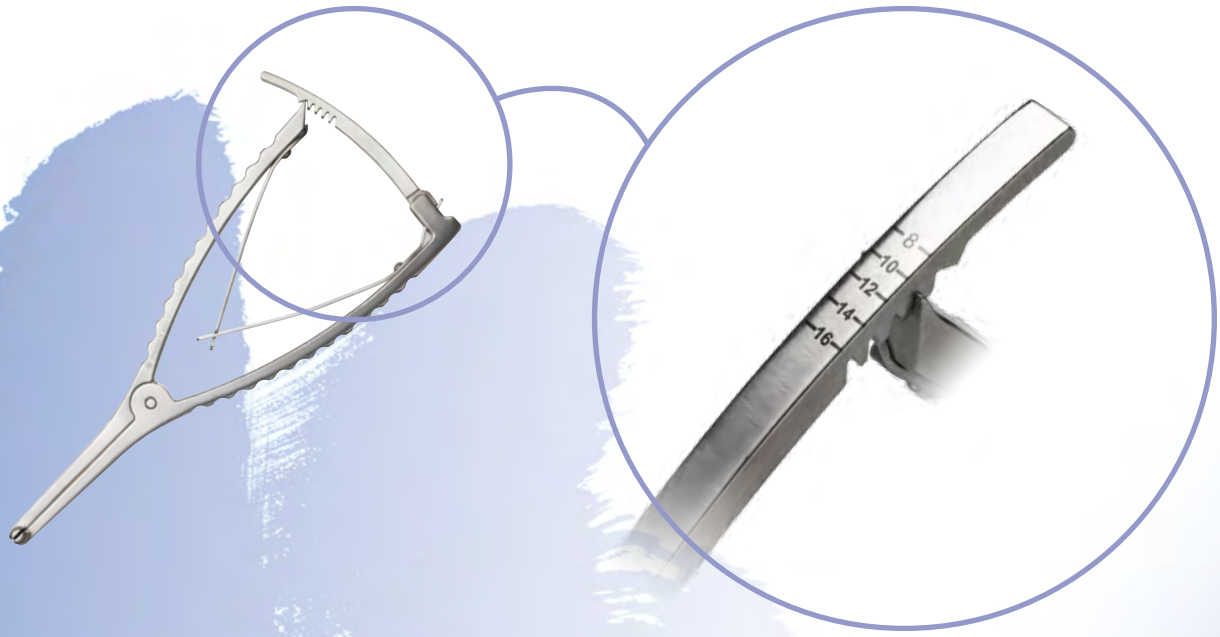
Insert the interspinous ligament Perforator and puncture the interspinous ligament, placing it as far anterior as possible.

Step 3 : Spinous process Prepare

The Spreader insert the tips into the anterior portion of the interspinous space where the spinous process plate will be implanted, near the base of the spinous processes or upon the lamina. Engage the ratchet arm and compress the handles of the Spreader to spread the tips and distract the interspinous space. Do not overdistract spinous processes. Overdistraction could damage the spinous process.



Using the Rasp prepare the fusion site and decorticate the spinous processes.



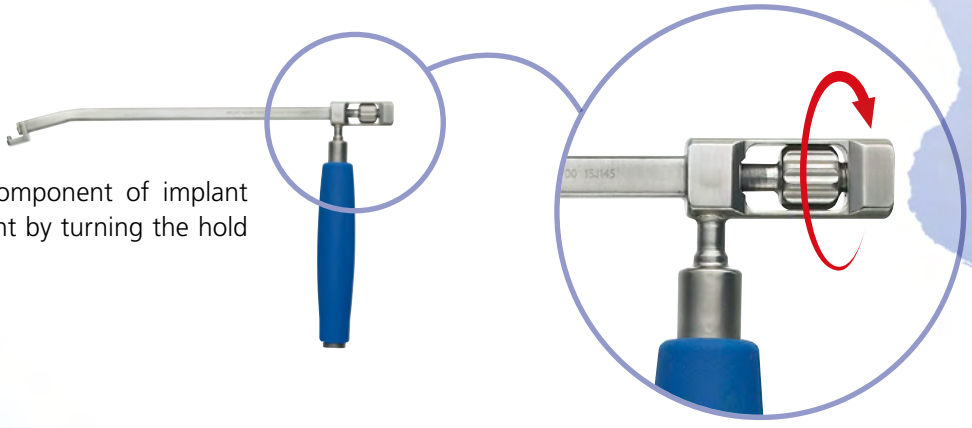
Step 4 : Trial and bone packing

Once the interspinous space is prepared, determine the desired implant size starting with the smallest Trial and increasing sequentially until initial sizing is determined.

Select the indicated implant size. Bone graft is packed into the graft window of the implant prior to insertion.

Step 5 : Insert the implant

Fix the left plate component of implant to implant holder left by turning the hold driver clockwise.



Fix the right plate component of implant to implant holder right by turning the hold driver clockwise.

Insert the implant holder left to inside interspinous space. Using the correctly matched implant holder right upon the left plate.

Step 6 : Locking set screw

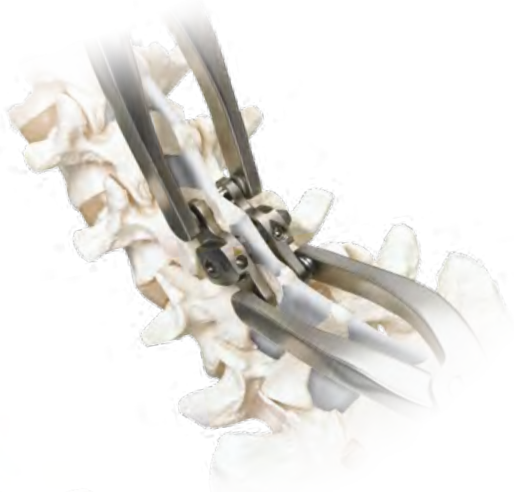
After left plate and right plate are in desired position, align the spherical tips of the Compressors into the round lateral wings in each plate. Prior to applying compression, take a lateral x-ray to confirm proper positioning. Using the Compressors, clamp the plates against the spinous processes, driving the spikes into the bone.

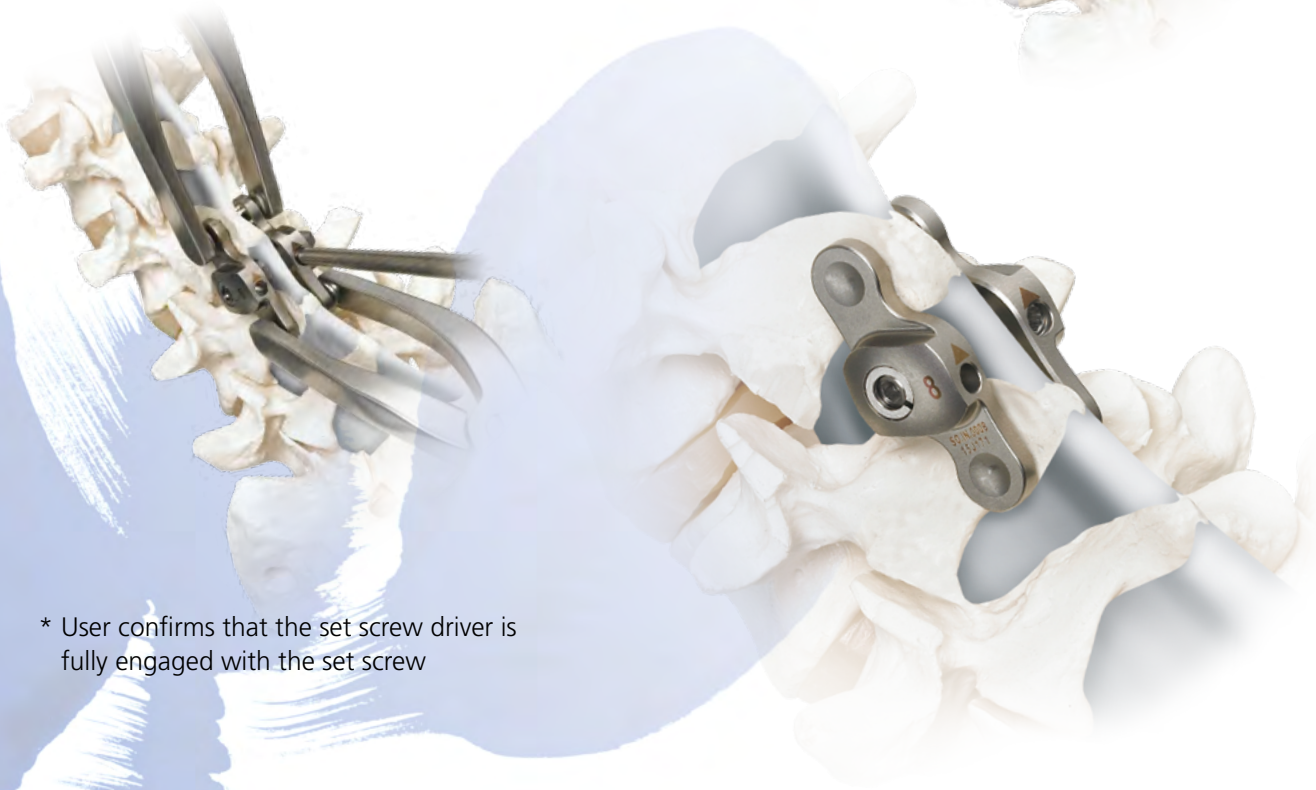
Then, remove Implant holder left and implant holder right from fixing implant.

Squeeze both Compressors simultaneously or alternate back and forth, to ensure the spikes seat properly in both the inferior and superior spinous processes. Visually confirm that the spikes are fully seated in the bone, with good apposition of the plates against the sides of the spinous processes. If the base of the spikes is still visible, apply more compression until the plates are fully seated.

Attach the set screw driver to the torque limiting handle. While maintaining compression on the plate to ensure adequate counter torque, tighten the locking set screw until the torque limiting handle click.

Remove the compressors.





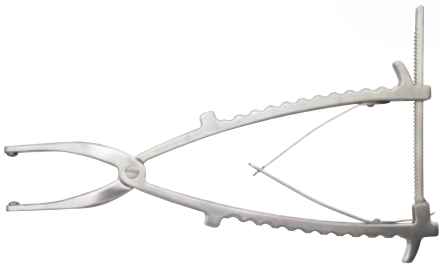
* User confirms that the set screw driver is fully engaged with the set screw

Huvex instrument Set

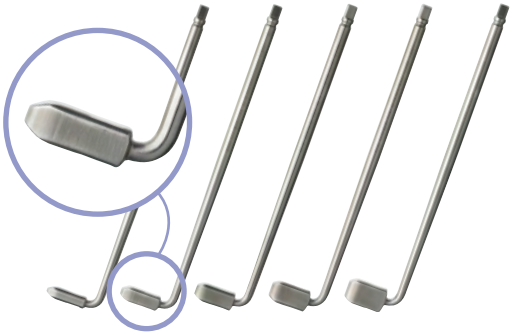
Part number	SO.IN.0001
Device name	Implant holder left
Description	The Instrument used to fix the left plate

Part number	SO.IN.0002
Device name	Implant holder right
Description	The Instrument used to fix the right plate

Part number	SO.IN.0003
Device name	Compressor
Description	The Instrument apply force to the implant until fixing to the spinous process through spikes.



Part number	SO.IN.0009, SO.IN.0010, SO.IN.0011, SO.IN.0012, SO.IN.0013
Device name	Trial Assembled type.
Description	The instrument is used determine the appropriate size implant. Assembled type.
Size	8mm, 10mm, 12mm, 14mm, 16mm.



Part number	SO.IN.0014
Device name	Perforator
Description	The instrument is used punch hole through the anterior region of the interspinous ligament.

Part number	SO.IN.0015
Device name	Set screw driver
Description	The instrument is used Tighten locking the set screw

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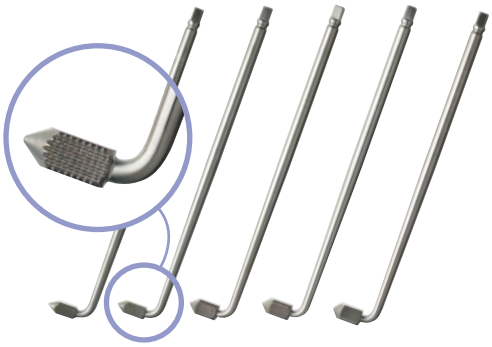
Part number	SO.IN.0016
Device name	Spreader
Description	The instrument is used determine the appropriate size of implant and Between the spinous process extends.

Part number	SO.IN.0023, SO.IN.0024, SO.IN.0025, SO.IN.0026, SO.IN.0027
Device name	RASP assembled type.
Description	Removal of cartilaginous tissue from the endplates to expose bleeding bone. assembled type.
Size	8mm, 10mm, 12mm, 14mm, 16mm

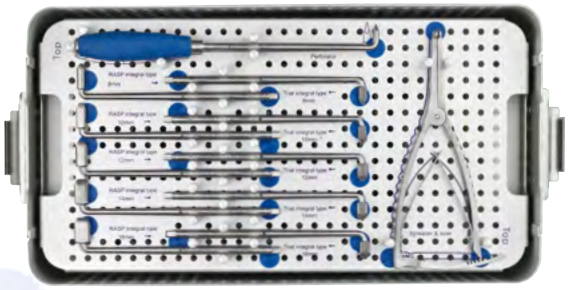


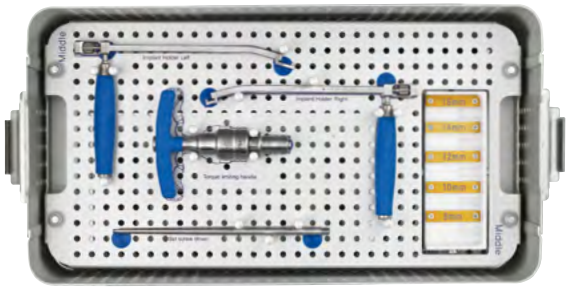
Part number	SO.IN.0028
Device name	Bone packing block
Description	block for fixing the implant.

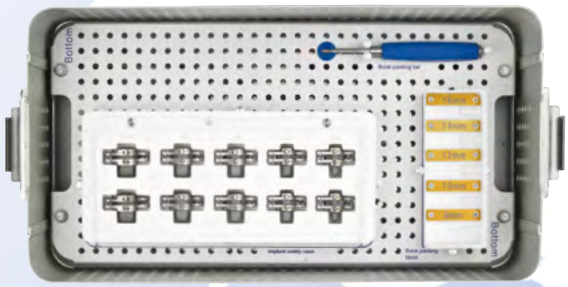
Part number	SO.IN.0029
Device name	Bone packing bar
Description	The instrument is used to insert the bone graft material in implant

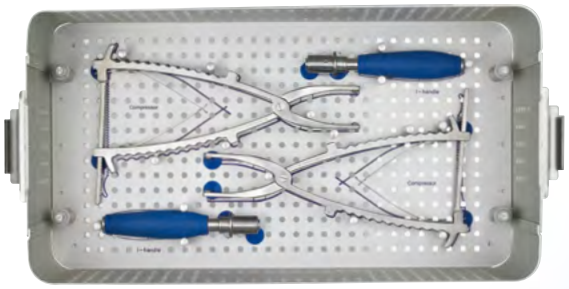
Part number	SO.IN.0030
Device name	Torque limiting handle
Description	The instrument is used in combination with set screw driver.

Part number	SO.IN.0031
Device name	I-Handle
Description	The instrument is used in combination with jacobs shaft.









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Huvex Brochure Rev.00 2018.03