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MEDICAL SERVICES FOR BETTER LIFE

Fixpino

Interspinous Fusion System

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Fixpino

Interspinous Fusion System

Overview

FIXPINO, an Interspinous Implant, is an s-shaped metallic device that is inserted between the spinous processes. It is made of a single machined piece of Ti-6Al-4V ELI titanium alloys (ASTM F 136). The FIXPINO is designed to increase the cross-sectional diameter of the stenotic canal in patients suffering from neurogenic claudication.

The S-shaped spacer fits between the spinous processes and the wings are designed to prevent the implant from moving. Furthermore, the S-shaped spacer can make inserting the implant easy because the S-shape can be compressed.

Device Name

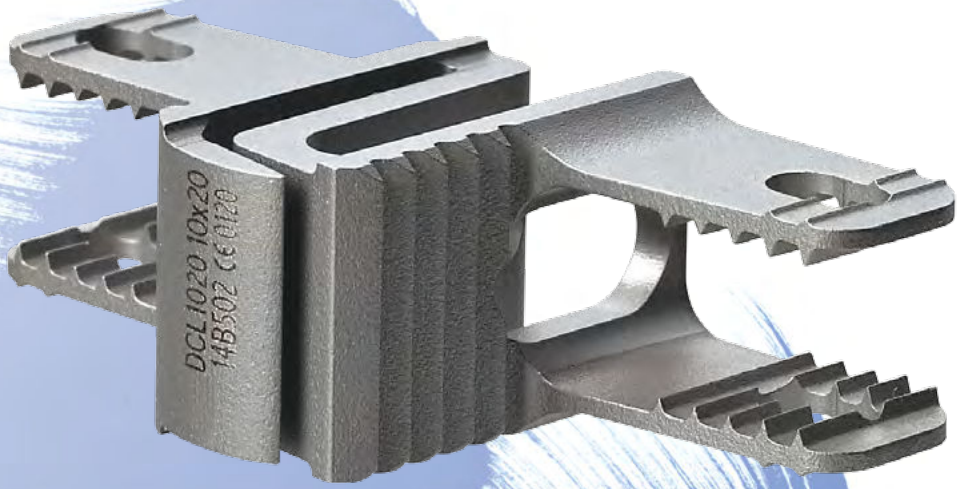
1) Common name : interspinous fixation system
2) Proprietary name : Fixpino

Indication for Use

The Fixpino InterSpinous Fusion System is intended Radiographically confirmed moderate to severe stenosis with neural element compromise resulting in claudication and/or radicular symptoms isolated to 1 or 2 levels, in the region of L1 to S1 with or without concomitant low back pain.

Fixpino

The fixpino interspinous fixation system is designed to insert the cross-sectional diameter of the stenotic canal in patients suffering from neurogenic claudication. The fixpino has S-shaped metallic device that is inserted between the spinous processes. The S-shaped spacer fits between the spinous processes and the wings are designed to prevent the implant from moving. Furthermore, the S-shaped spacer can make inserting the implant easy because the spacer can be compressed.



Fixpino DBM

- Remark : 'Fixpino DBM' must be used with DBM

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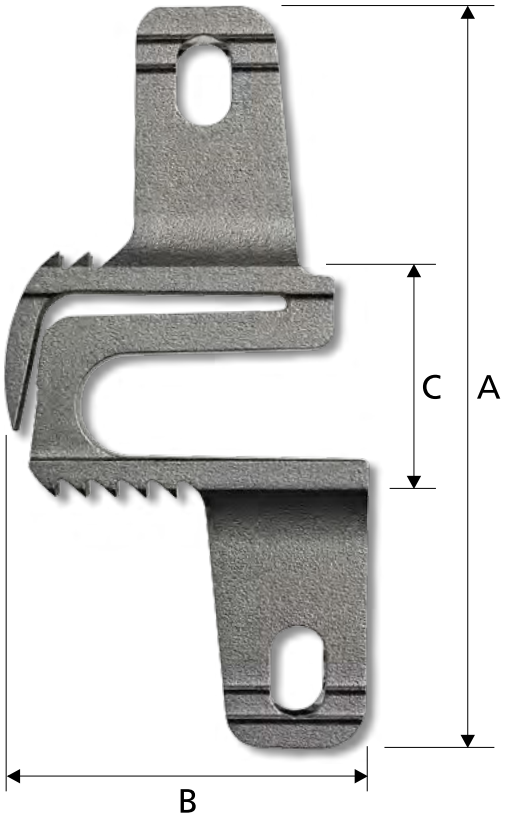

Fixpino Implant

Part number	A (mm)	B (mm)	C (mm)
DLS0820	36.7	20	8.1
DLS1020	38.7	20	10.1
DLS1220	40.7	20	12.1
DLS1420	42.7	20	14.1
DLS1620	44.7	20	16.1
DLS0823	36.7	23	8.1
DLS1023	38.7	23	10.1
DLS1223	40.7	23	12.1
DLS1423	42.7	23	14.1
DLS1623	44.7	23	16.1

Fixpino Instrument

Part number	Description	Size
DLS-IN-08	Impact & Guide	8mm
DLS-IN-10	Impact & Guide	10mm
DLS-IN-12	Impact & Guide	12mm
DLS-IN-14	Impact & Guide	14mm
DLS-IN-16	Impact & Guide	16mm

Part number	DLS-IN-18
Device Name	Wing clamper
Description	Use as clamping opened wing of implant
Material composition	SUS630

Part number	DLS-IN-19
Device Name	Wing opener
Description	Use as opening the wing of implant
Material composition	SUS630

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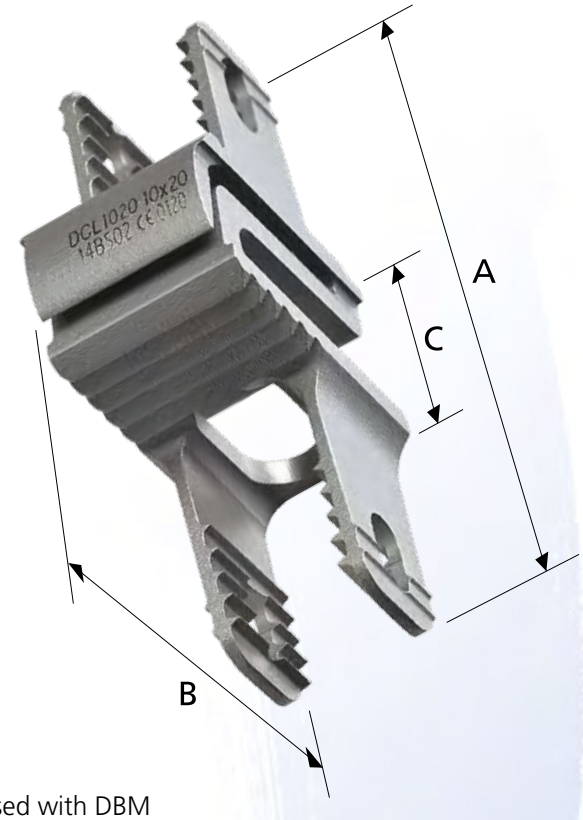

• Remark : 'Fixpino DBM' must be used with DBM

Fixpino DBM Implant

Part number	A (mm)	B (mm)	C (mm)
DCL0820	36.7	20	8.1
DCL1020	38.7	20	10.1
DCL1220	40.7	20	12.1
DCL1420	42.7	20	14.1
DCL1620	44.7	20	16.1
DCL0823	36.7	23	8.1
DCL1023	38.7	23	10.1
DCL1223	40.7	23	12.1
DCL1423	42.7	23	14.1
DCL1623	44.7	23	16.1

Fixpino DBM Instrument

Part number	Description	Size
DCL-IN-0820	Impact & Guide	8mm L20
DCL-IN-1020	Impact & Guide	10mm L20
DCL-IN-1220	Impact & Guide	12mm L20
DCL-IN-1420	Impact & Guide	14mm L20
DCL-IN-1620	Impact & Guide	16mm L20
DCL-IN-0823	Impact & Guide	8mm L23
DCL-IN-1023	Impact & Guide	10mm L23
DCL-IN-1223	Impact & Guide	12mm L23
DCL-IN-1423	Impact & Guide	14mm L23
DCL-IN-1623	Impact & Guide	16mm L23

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Surgical Technique

Step 1 : Lumbar interbody fusion
Step 2 : Patient positioning
Step 3 : Microsurgical decompression
Step 4 : Implant site preparation
Step 5 : implant insertion

Step 1 : Lumbar Interbody fusion

According to the pathology, interbody fusion is performed at the surgeon's discretion. It is important to note that the Fixpino implant is always inserted after implantation fo an intervertebral device.

Step 2 : Patient positioning

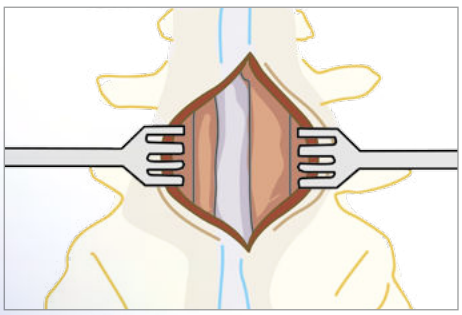
Patient is placed in prone position on surgical frame avoiding hyperlordosis of the spinal segment(s) to be operated upon.

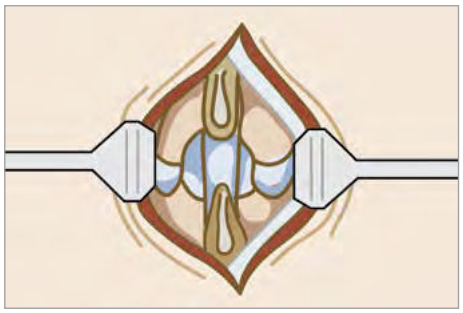
A neutral position or a slight kyphosis may be advantageous for surgical decompression as well as for appropriate interspinous distraction

Paraspinal muscles are stripped off the laminae while preserving the facet capsules. The supraspinous ligament is dissected subperiostally and preserved as a thick cuff and retracted laterally. If possible a small portion of the bony tip can be resected together with the supraspinous ligament. This will aid a faster healing after reconstruction of the ligament.

Note *: Dependent on the pathology a microsurgical unilateral decompression can be performed and then the supraspinous ligament together with the fascia and muscle from the opposite side can be mobilized together. Completion of the microsurgical decompression can then be performed.*

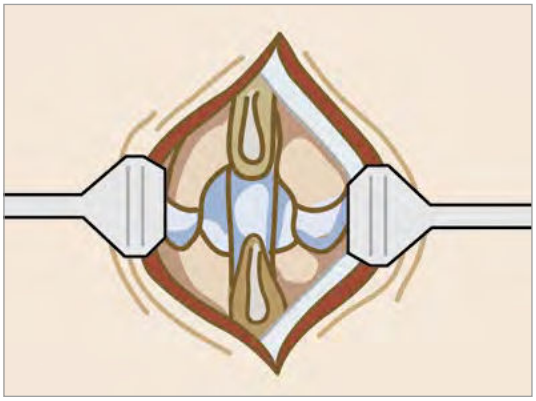
The interspinous ligament is sacrificed and any bony overgrowth of the spinous process that may interfere with insertion is resected.





Step 3 : Microsurgical Decompression

Ligamentum Flavum is resected and microsurgical decompression is performed,
relieving all points of neural compression.



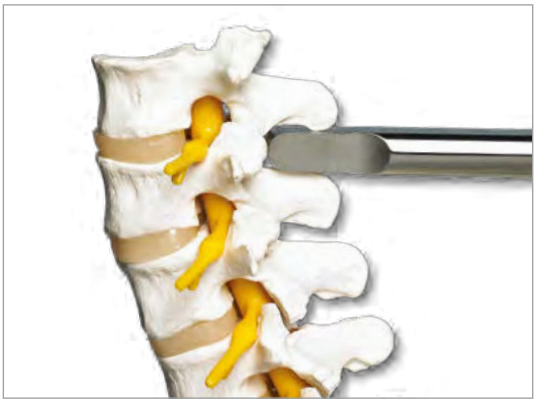
Step 4 : Implant Site Preparation

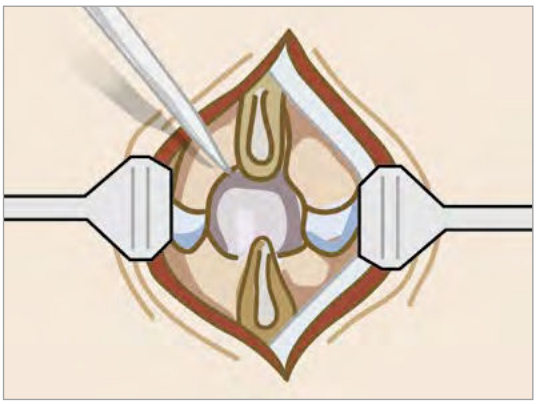
- Determine implant size

Trials are utilized to define appropriate implant size. Trial instrument is placed to evaluate proper contact with spinous process and amount of interspinous distraction.

- Implant site preparation

Some bony resection of the spinous process may be needed to ensure proper contact of the implant. Distraction is considered to be appropriate to prevent any settling of the interspinous distance after successful decompression of the spinal stenosis.





To ensure proper depth of implant insertion a small portion of the laminar surface may need partial resurfacing.

Distraction is considered to be appropriate to prevent any settling of the interspinous distance after successful decompression of the spinal stenosis.

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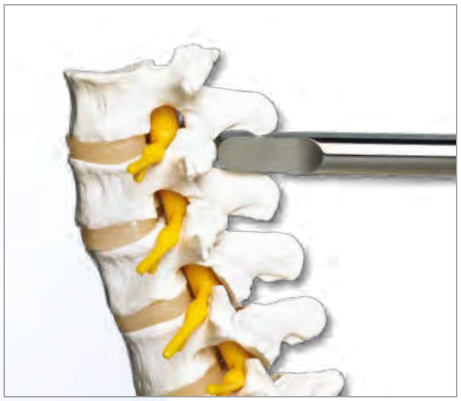
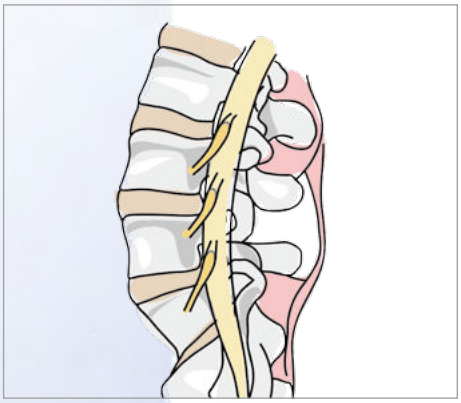
Step 5 : Patient positioning

The wings may need to be opened slightly using wing opener at the mid portion of the wing to ensure appropriate depth of insertion. Implant is introduced via impaction utilizing a mallet.





Proper depth is determined if a beaded tip probe can be passed freely leaving 3-4mm separation from the dura. If the implant is not seated appropriately further resurfacing or slightly more impaction force may be utilized.

If the wings are not having sufficient bony contact after insertion additional stability can be achieved by slightly crimping the wings. Once proper placement has been achieved, it is recommended to securely crimp the wings of the implant using the clamper. The teeth of both wings should be firmly engaged into the cortices of the spinous processes.

In case of FIXPINO DBM used,
we recommend putty type of DBM

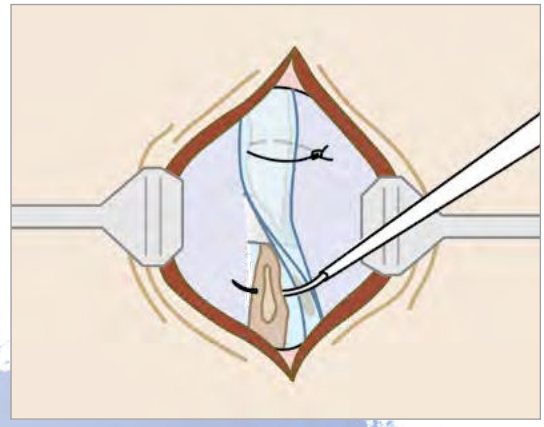
By deeply inserting the Fixpino implant at the level of the facet joints the implant counteracts the majority of posterior column forces.

Note *: In case of Fixpino DBM use, implant in the empty space will be completely filled with DBM*

- Supraspinous Ligament

In case of ligament reconstruction a suture through two bone holes in the spinous process and through the supraspinous ligament is performed. A surgical drain may be placed as per surgeon preference. Paraspinal muscles are reattached to the supraspinous ligament. Skin is closed in the usual manner.

Alternatively the fascia and the supraspinous ligament can be closed in one layer over the spinous processes.



• Removal or revision procedure

The Fixpino implant is intended for permanent implantation and is not intended for removal.

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