



TECHNICAL FILE
(DOCUMENT NO: TD-02.2)

***II. Product Information About
Surgical Technique***

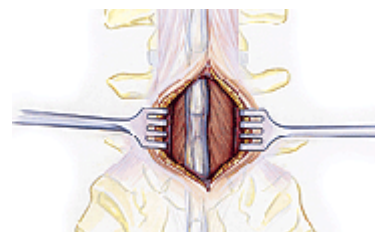
II.4.B.c U DEVICE

1. Preparation

- 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.



- Routine (midline) skin incision is performed. The muscle is sharply dissected lateral to the supraspinous ligament preserving the entire thickness of the supraspinous ligament. Alternatively the supraspinous ligament may be resected depending on surgeon's preference.

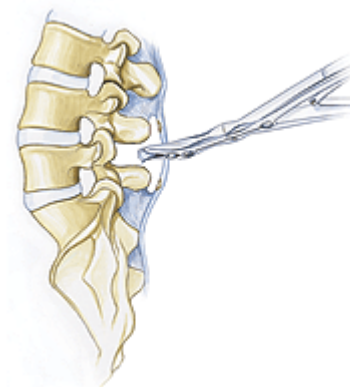


- Paraspinal muscles are stripped off the laminae while preserving the facet capsules. The supraspinous ligament is dissected subperiostally and preserved as a thick cuff and retracted laterally. If possible a small portion of the bony tip can be resected together with the supraspinous ligament. This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

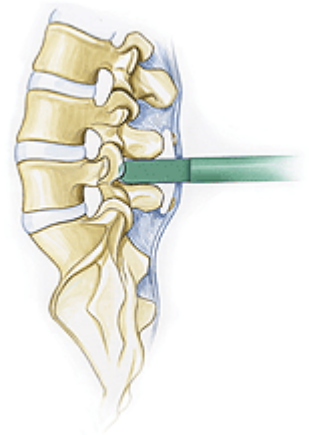


2. Microsurgical Decompression Ligamentum Flavum is resected and microsurgical decompression is performed, relieving all points of neural compression.

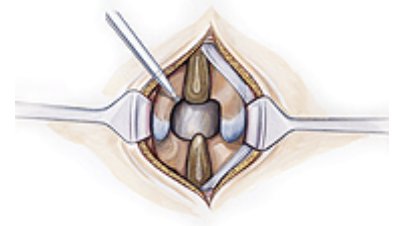


3. Implant Site Preparation

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

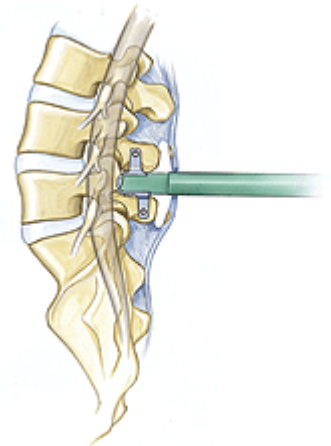


-To ensure proper depth of implant insertion a small portion of the laminar surface may need partial resurfacing.

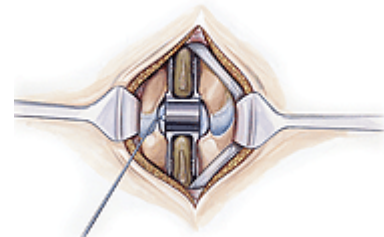


4. Implant Insertion

Implant is introduced via impaction utilizing a mallet. If the wings are not having sufficient bony contact after insertion additional stability can be achieved by slightly crimping the wings.



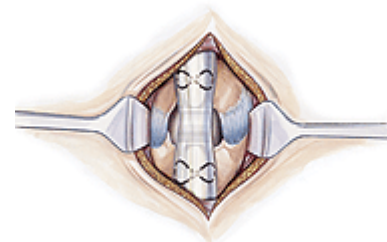
-Proper depth is determined if a beaded tip probe can be passed freely leaving 3-4 mm separation from the dura. If the implant is not seated appropriately further resurfacing or slightly more impaction force may be utilized.



-In case of ligament reconstruction a Figure 8 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.

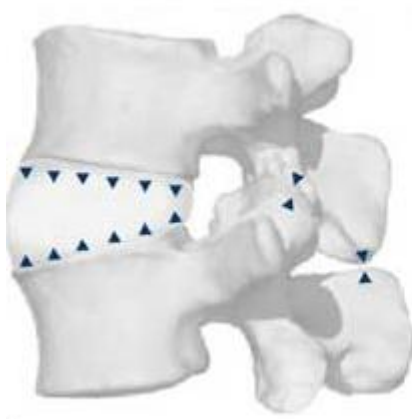
Paraspinal muscles are reattached to the supraspinous ligament. Skin is closed in the usual manner.

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



- Double-Level Implantation

If a two level decompression is mandated the implants must be sequentially placed to the appropriate depth avoiding any overlap (contact) of one pair of wings upon the other.



Before Implantation



After Implantation