

Surgical Technique

U-Spine

about us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 75 countries worldwide.

Our Achievements



Guidelines

This publication sets forth detailed recommended procedures for using Auxein Medical devices and instruments.

It offers guidance that needs to be heeded. However, with any such technical guide, each surgeon must consider the unique needs of each patient and make appropriate adjustments when and as required.

A workshop training under DAIS Academy by Auxein will provide assistance prior to first surgery. It is vital to know that all non-sterile devices must be cleaned and sterilized before use.

Moreover, multi-component instruments must be disassembled for cleaning. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Please NOTE that all the bone screws referenced in this document here are not approved for screw attachment or fixation in the areas not mentioned in this publication.

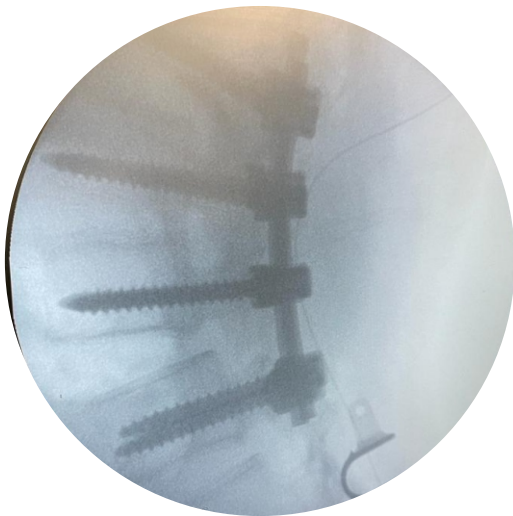
Warning:

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.

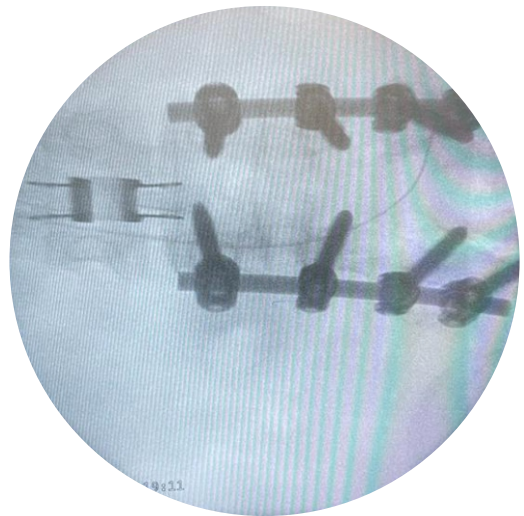


INDICATION

The U-Spine device indicated for use in one or two level lumbar stenosis in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/ buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. The U-Spine is intended to be implanted midline between adjacent lamina of 1 or 2 contiguous lumbar motion segments. U-Spine is performed after decompression of stenosis at the affected level(s).

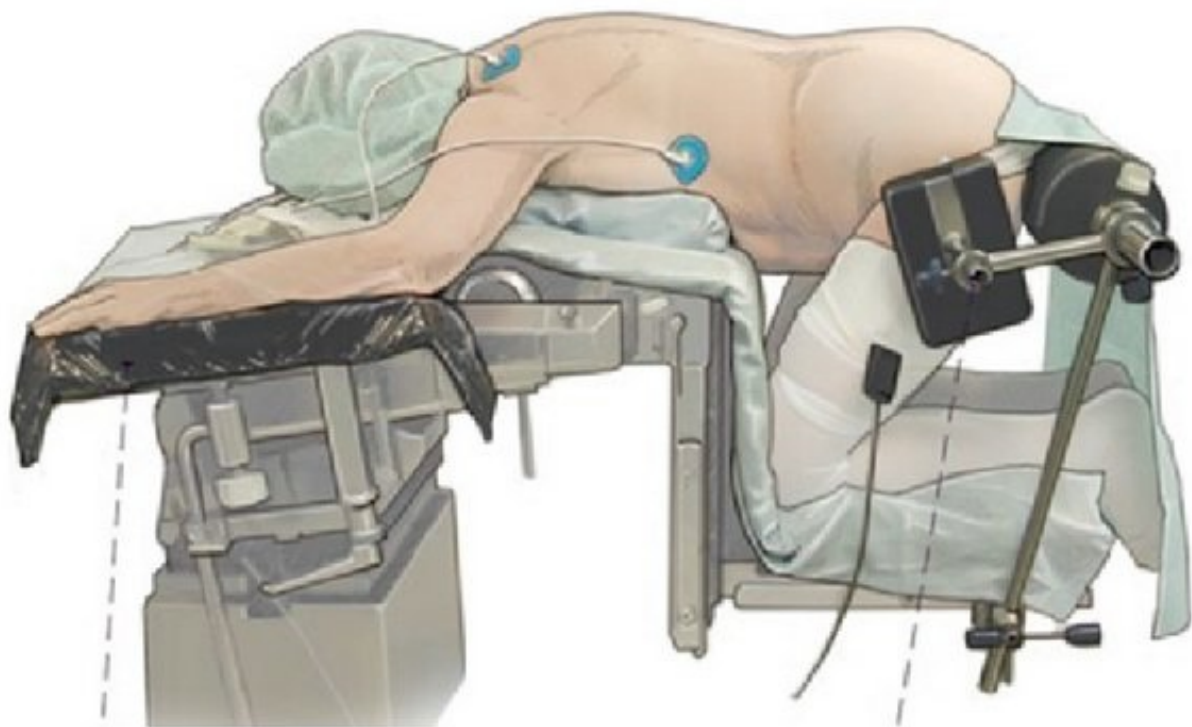


Lateral View



Posterior View

(1) Patient Preparation and Decompression

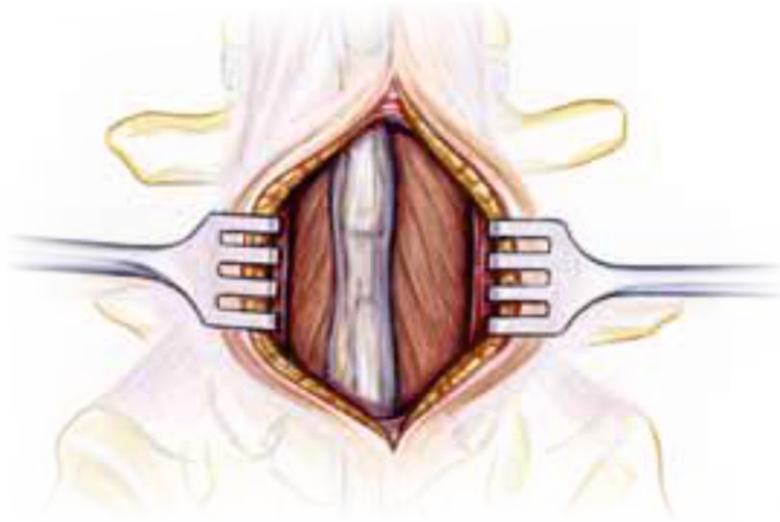


The patient is placed in prone position on a surgical frame avoiding hyperlordosis of the spinal segment(s) to be operated on.

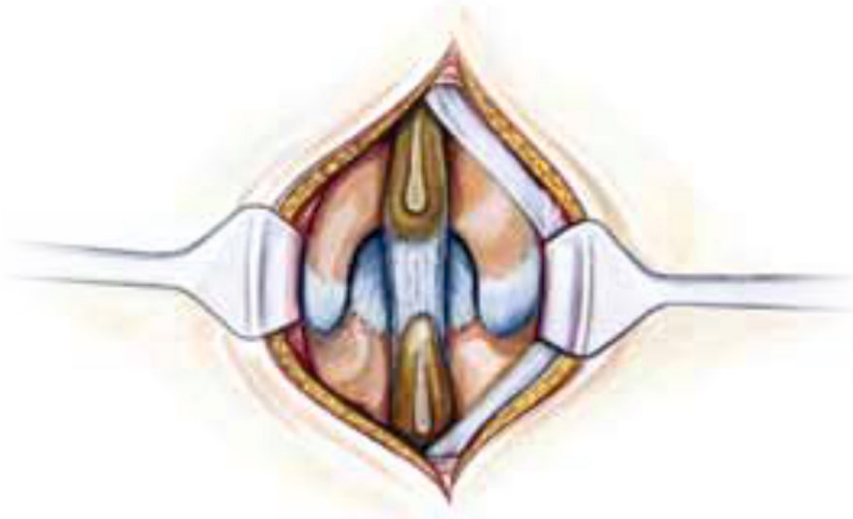
For the surgical decompression as well as for appropriate interspinous distraction, a neutral position or a slight kyphosis may be advantageous.

(2) Opening

Paramedian or midline approach is taken with preservation of the supraspinous ligament.

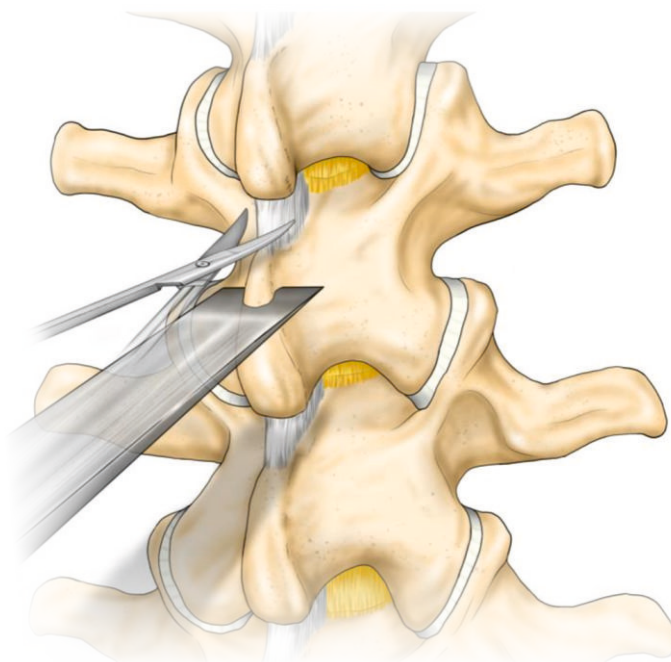


The muscle is sharply dissected lateral to the supraspinous ligament preserving the entire thickness of the supraspinous ligament.

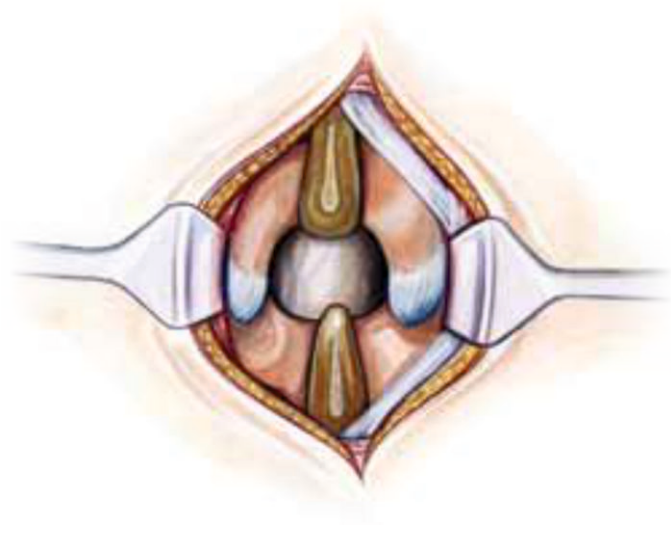


The basic surgical approach entails a midline incision and reflection of the supraspinous ligament. For a minimally invasive approach, this reflection of tissues extends to the base of the spinous process, which affords microsurgical access through the ligamentum flavum into the spinal canal. For an open approach, this reflection of tissues extends to the facet capsules affording total access to the entirety of the posterior elements.

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

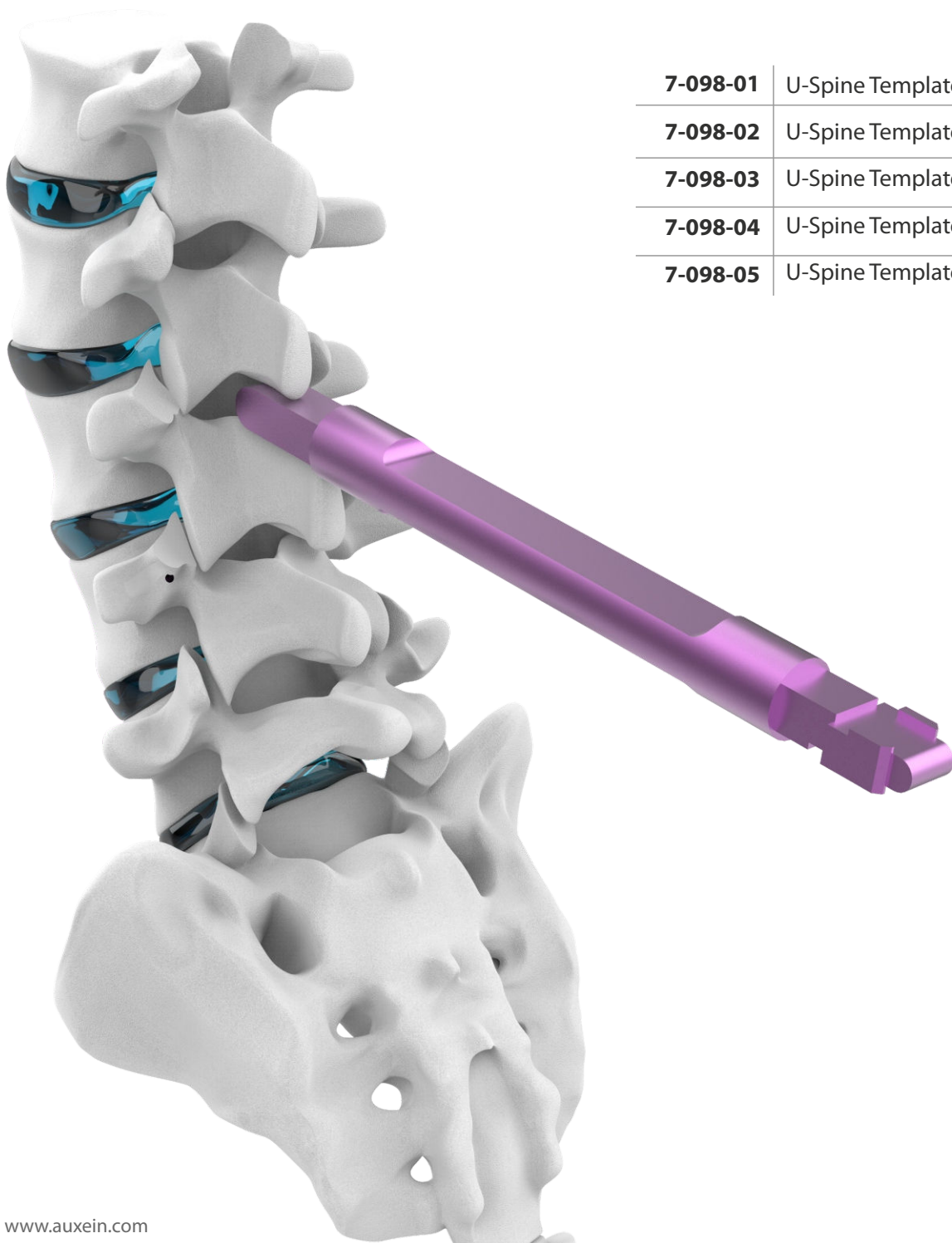


Ligamentum flavum is resected and microsurgical decompression is performed, relieving all points of neural compression.



(3) Size Checking

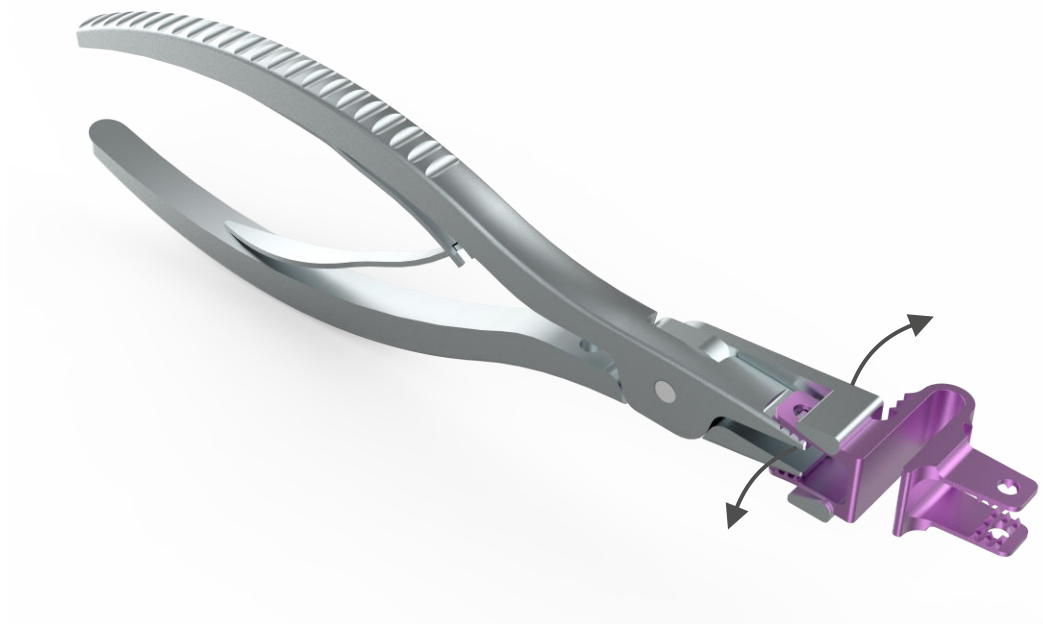
U-Spine Template Inserter are utilized to define the appropriate implant size. The U-Spine Template Inserter instrument is placed to evaluate proper contact with the spinous process and the amount of interspinous distraction. Some bony resection of the spinous process may be needed to ensure proper contact of the implant.



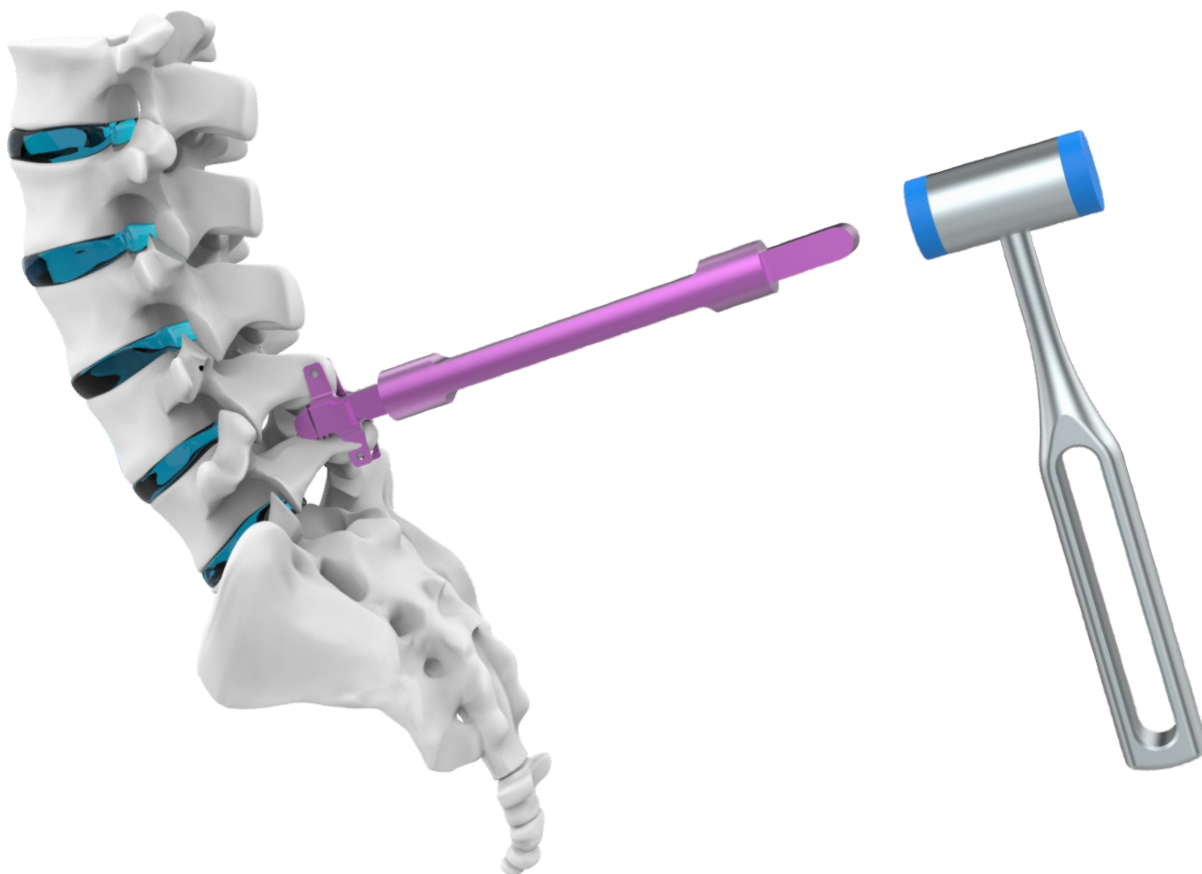
| | |
|-----------------|---------------------------------|
| 7-098-01 | U-Spine Template Inserter, 8mm |
| 7-098-02 | U-Spine Template Inserter, 10mm |
| 7-098-03 | U-Spine Template Inserter, 12mm |
| 7-098-04 | U-Spine Template Inserter, 14mm |
| 7-098-05 | U-Spine Template Inserter, 16mm |

(4) Implant Preparation for Insertion

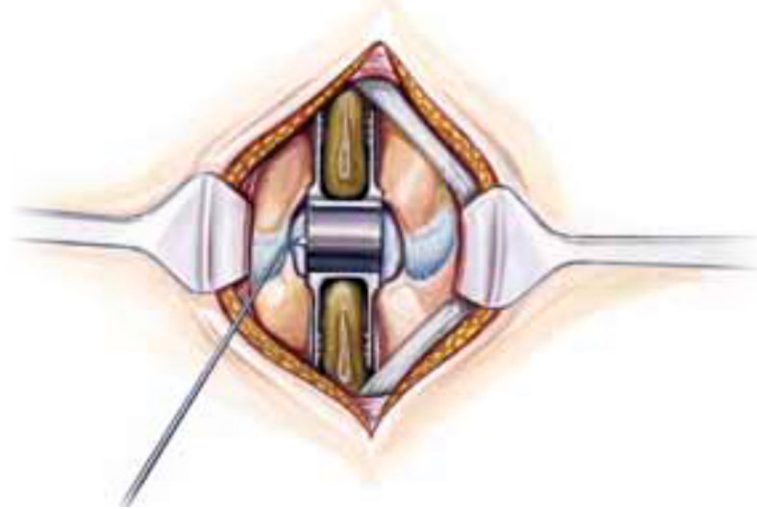
Prior to insertion, the wings may need to be opened slightly using the U-Spine Bending Plier (**7-098-06**) to ensure appropriate depth of insertion.



The implant is introduced via impaction utilizing a U-Spine Mallet (**7-098-09**).



Proper depth is determined if a ball tip probe can be passed freely leaving 1–2mm separation from the dura.



(5) Crimping

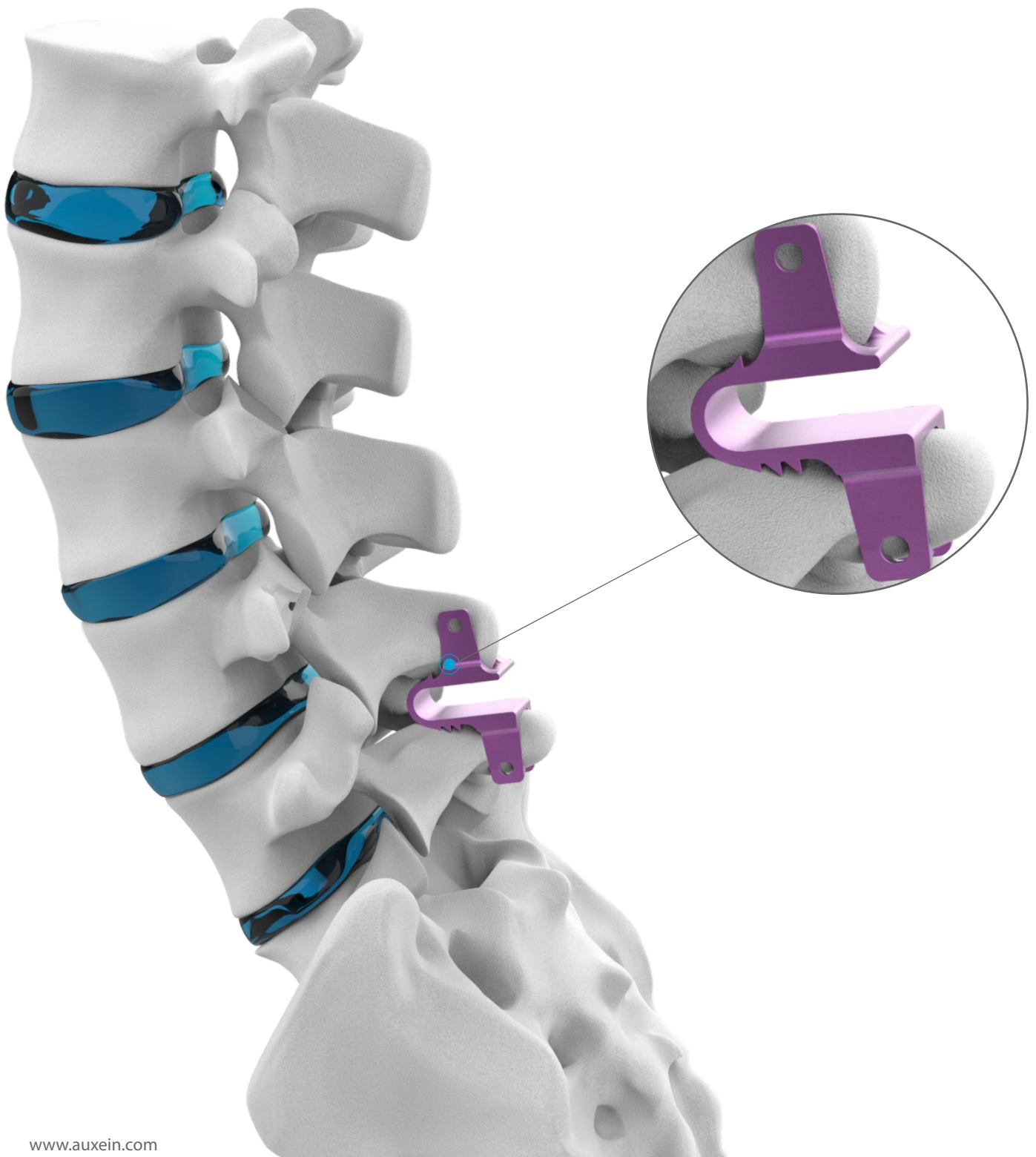
Once proper placement has been achieved, it is recommended to securely crimp the wings of the implant using the U-Spine Crimping Plier (**7-098-08**).



In case of ligament reconstruction, the fascia and the supraspinous ligament can be closed in one layer over the spinous processes. A surgical drain may be placed as per surgeons' preference. Paraspinal muscles are reattached to the supraspinous ligament. Skin is closed in the usual manner.





(6) One Level Implantation

By deeply inserting the **U-Spine** implant at the level of the facet joints, the implant counteracts the majority of posterior column forces (interlaminar positioning).



U-Spine

U-Spine color

| | | | | |
|---|---|---|---|---|
|  |  |  |  |  |
| Pink 8mm | Type II 10mm | Green 12mm | Blue 14mm | Brown 16mm |



Material:






Wrought titanium 6-aluminium 4-vanadium alloy according to ISO 5832-3

The **U-Spine** implant is delivered in sterile packaging.

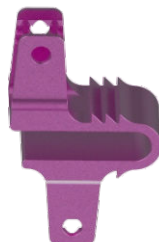
During the course of the clinical trial, the wings were modified slightly for ease of stacking two devices at adjacent levels. The modification was not the result of any clinical problems, safety issues or adverse events, product complaints, or surgeon requests from within or outside the United States. As this modification was minor, it did not affect the mechanical behavior of the device or the anticipated clinical outcome.

U-Spine Implant

U-Spine color

| | | | | |
|---|---|---|---|---|
|  |  |  |  |  |
| Pink 8mm | Type II 10mm | Green 12mm | Blue 14mm | Brown 16mm |

4-073-08TI U-Spine, 8mm



4-073-10TI U-Spine, 10mm



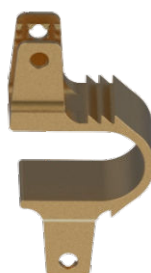
4-073-12TI U-Spine, 12mm



4-073-14TI U-Spine, 14mm



4-073-16TI U-Spine, 16mm

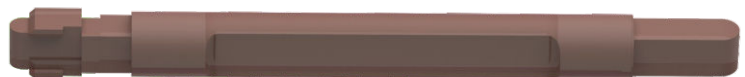


U-Spine Instruments

7-098-01 U-Spine Template Inserter, 8mm



7-098-02 U-Spine Template Inserter, 10mm



7-098-03 U-Spine Template Inserter, 12mm



7-098-04 U-Spine Template Inserter, 14mm

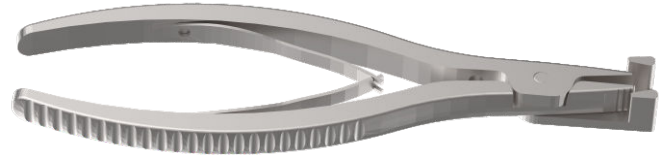


7-098-05 U-Spine Template Inserter, 16mm

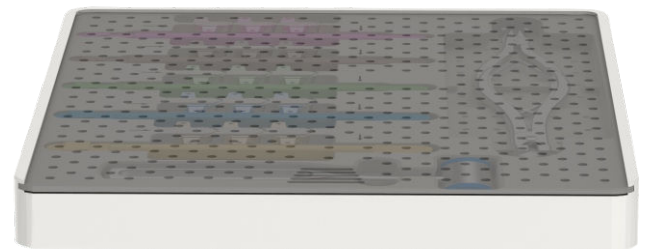


U-Spine Instruments

7-098-06 U-Spine Bending Plier



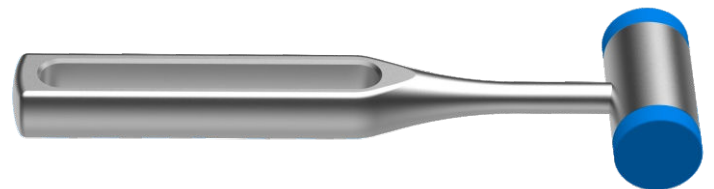
7-098-07 U-Spine Instrument and Implant box with lid



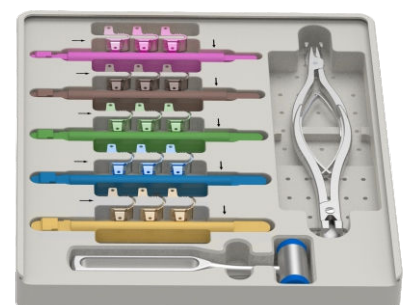
7-098-08 U-Spine Crimping Plier



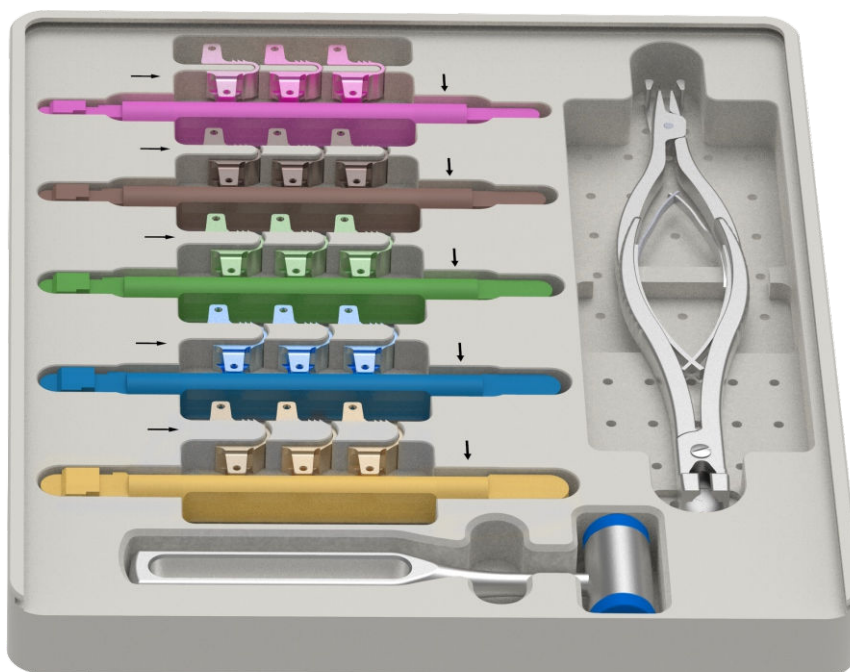
7-098-09 U-Spine Mallet



7-098 U-Spine Instrument and Implant Set



7-098 U-Spine Instrument and Implant Set



| Code | Set Consisting of | Qty. |
|-------------------|---|------|
| 4-073-08TI | U-Spine, 8mm | 3 |
| 4-073-10TI | U-Spine, 10mm | 3 |
| 4-073-12TI | U-Spine, 12mm | 3 |
| 4-073-14TI | U-Spine, 14mm | 3 |
| 4-073-16TI | U-Spine, 16mm | 3 |
| 7-098-01 | U-Spine Template Inserter, 8mm | 1 |
| 7-098-02 | U-Spine Template Inserter, 10mm | 1 |
| 7-098-03 | U-Spine Template Inserter, 12mm | 1 |
| 7-098-04 | U-Spine Template Inserter, 14mm | 1 |
| 7-098-05 | U-Spine Template Inserter, 16mm | 1 |
| 7-098-06 | U-Spine Bending Plier | 1 |
| 7-098-07 | U-Spine Instrument and Implant box with lid | 1 |
| 7-098-08 | U-Spine Crimping Plier | 1 |
| 7-098-09 | U-Spine Mallet | 1 |



USA

Auxein Inc.
1500 Nw 89th Court, Suite 107-108
Doral, Florida 33172
Tel: +1 305 395 6062
E Fax: +1 305 395 6262
Email: USoffice@auxein.com

MEXICO

Auxein México, S.A. de C.V.
Tepic 139 int 801, Colonia Roma Sur,
Alcaldía Cuauhtémoc, CDMX,
México, C.P. 06760
Tel: +521 55 7261 0318
Email: info@auxein.mx

INDIA

Auxein Medical Pvt. Ltd.
Plot No. 168-169-170, Phase-4,
Kundli Industrial Area,
HSIIDC, Sector-57, Sonapat - 131028, Haryana
Tel: +91 99106 43638 | Fax: +91 86077 70197
Email: info@auxein.com