UniWallis™
Posterior Dynamic Stabilization System

Surgical Technique

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Indications/Contraindications

The *UniWallis* Posterior Dynamic Stabilization System treats low-back pain that accompanies degenerative lesions of grade II, III and IV (Pfirrmann MRI classification)\(^1\) in the following indications:

### Indications

- Massive herniated disc in young adults or Recurrent herniated disc or
  Hemiated disc accompanying an L5 sacralization transitional anomaly, treated by discectomy
- Degenerative disc disease at a segment adjacent to fusion
- Degenerative lesions with or without Modic 1
- Lumbar canal stenosis treated by laminotomy (not by complete laminectomy)\(^2\)

### Contraindications

- Grade V degenerative lesions in the MRI classification of Pfirrmann
- Spondylolisthesis
- Osteoporosis
- Nonspecific low back pain
- Modic 2 and Modic 3
- This implant is not recommended for the L5-S1 level
- Local or general infections that may jeopardize the outcome of the operation
- Major local inflammations
- Pregnancy
- Immuno-depressive pathologies
- Bone immaturity
- Severe mental illnesses
- Pathological diseases of the bone metabolism that render the mechanical support to be expected from this type of implant insufficient
- Excessive physical activity

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\(^2\) Important: If the procedure includes enlargement of a stenotic lumbar canal by resection of the upper portion of the laminae, make sure to preserve sufficient spinous process thickness.
UniWallis Instruments

UniWallis sizer instrument
Right band passer
Left band passer
Tension guide

Interspinous distractor
Interspinous ligament remover
Interlaminar distractor
Band forceps

Torque-indicating tensioning tool
Screwdriver
Crimper
Ring passer
Surgical technique

Step 1: Exposure

The patient is placed in the prone position on a padded frame. During the procedure, the lumbar spine should be maintained in a position of physiological lordosis, in which the implant is most beneficial.

After making a midline incision, the surgeon has the choice of retracting the muscles on only one side without detaching the supraspinous ligament (fig. 1) or retracting the muscles on both sides, in which case the supraspinous ligament is detached and retracted along with the muscle on one side permitting direct posterior insertion of the UniWallis Implant.

The edges of the operative wound should be covered with two small drapes under the muscle retractors to avoid any contact between band and skin.

The interspinous ligament is removed using the interspinous ligament remover without damaging the supraspinous ligament (fig. 2).

The junction between the laminae and the spinous process is trimmed (fig. 3) to prepare the area of contact of the spacer against the base of the spinous process. This preparation is key to the final positioning in the interspinous space.
The optimal spacer size is determined using the UniWallis sizer instrument.

The sizer instrument is placed in the interspinous space in the closed position and then opened until contacting the underlying and overlying spinous processes without applying distraction (fig. 4).

When the correct opening of the instrument is attained, the size of implant to be used is indicated on the ratchet of the handle (fig. 5).

Between two sizes of implants, the surgeon should choose the smaller to preserve physiological lordosis. Given the reclining position of the patient during the intervention, strong primary stability of the implant is not necessary.
Step 3: Passage of the band through the spacer

The band is first threaded through the small portion of the UniWallis Spacer (fig. 6) until there is the same length of band on both sides (fig. 7).

It is important not to remove or loosen the locking screw of the UniWallis Spacer.
Step 4: Passage of the band through the interspinous ligaments above and below the spacer

It is recommended to initially use the band passer alone to make a pilot pathway through the interspinous ligament and behind the spinous process as close as possible to the periosteal bone. Then use this instrument to pass the band through the same pathway.

The hole at the tip of the band is placed in the notch of one of the two band passers (fig. 8) to push the band around the spinous process and through the interspinous ligament (fig. 9).

During this initial passage of the band on one side, it is important not to let the other end of the band slip out of the spacer.

When the band tip appears through the ligament (fig. 10), the surgeon pulls it through using the band forceps while removing the band passer with the other hand. One should make sure that the band lies flat against the spinous process without twists.

In similar fashion, the surgeon passes the other end of the band around the second spinous process with the opposing band passer.

Before proceeding to the next step, the two ends of the band should be of equal length.
Step 5: Insertion of the two extremities of the band into the *UniWallis* Spacer

Once the ends of the band have been matched in length, the two extremities are slipped through the corresponding slots on each side of the *UniWallis* Spacer (figs. 11 and 12).
Step 6: Placement of the band tensioner on the implant

The torque-indicating tensioning tool is inserted into the tension guide (fig. 13).

The two extremities of the band are threaded through the eye of the torque-indicating tensioning tool (fig. 14).

For this step, it is important to make sure that the band is not twisted.

The pegs of the assembled tensioner are inserted into the corresponding slots in the UniWallis Spacer (fig. 15).
Step 7: Insertion of the spacer between spinous processes

The UniWallis Spacer should be inserted between the spinous processes using the tensioner (fig. 16).

If necessary, the interspinous distractor can be used to facilitate insertion of the UniWallis Spacer (fig. 17).

It is important to make sure that there is no slack in the band when the implant is being positioned in the interspinous space.

*Note:* There is also an interlaminar distractor to facilitate insertion of the UniWallis Spacer, if necessary.
Step 8: Application of tension to the band

Before using the tensioner, it is important to verify with the band forceps that there is no slack in the band around the two spinous processes (fig. 18). The bands should be taut between the spacer and the tensioner (fig. 19). During this step, it is important to verify that there are no twists in the band.
The surgeon holds the handle of the tension guide in one hand, and tightens the band with the other hand by turning the torque-indicating tensioning tool, while pressing the thumb release of the turn stopper on the tension guide (figs. 20 and 21).

The recommended final tension is attained when the cursor lies within the corresponding zone on the device (figs. 22a and 22b).
If the surgeon wishes to verify the band tension, the tightener must be turned back to unwind the band. The tightening step can then be repeated after pulling out residual slack.

When the desired band tension is attained, the surgeon can release pressure on the stopper to block the tightener thus maintaining the achieved tension (fig. 23).

To maintain this final tension definitively, the locking screw on the UniWallis Spacer is tightened with the screwdriver, which is aligned in the dedicated notch on the tension guide for optimal tightening of the screw (fig. 24).

*Note: For final tightening, turn the screwdriver with only one hand.*
A titanium crimping ring is threaded onto the ring passer, one extremity of the band is gripped with the ring passer, and the ring is slipped onto the band (fig. 25).

The ring is then lightly gripped with the crimper (fig. 26), slid to within one or two millimeters of the UniWallis Spacer, and firmly crushed with the crimper (fig. 27).

With a scalpel, the excess band is cut level with the ring (fig. 28).

When cutting the excess band, the surgeon should cut in an upward direction to eliminate any risk of damaging the implanted band.

This step is repeated for the second extremity of the band.
Two-level implants

The principle of the technique remains the same. It is, however, recommended to place the two UniWallis Spacers in opposing directions (fig. 29) to avoid possible contact between the two spacers. For each UniWallis Spacer, one extremity of the corresponding band is passed around the spinous process (1) and the other extremity is passed to the other side of the middle spinous process for the system of fixation of the other UniWallis Spacer (2).

The bands should be carefully adjusted with the band forceps for optimal use of the tensioner. To apply final tension, the surgeon should tighten the screw in one of the UniWallis Spacers and then apply the tensioner on the second spacer.

The surgeon can also return to the first spacer to readjust the final tension after loosening its screw. The crimping rings are then applied to all the band extremities.

It is also possible to use only one band for the two UniWallis Spacers (fig. 30). In this case, the band is passed through the small part of one of the spacers (1). One extremity of the band is passed around the spinous process at one end (2).

The second extremity is passed along the central spinous process, through both slots of the system of fixation in the second spacer (3), around the third spinous process (4), through the small side of the second spacer (5), and finally into the system of fixation of the first UniWallis Spacer (6). It is important to tighten the two locking screws of the two UniWallis Spacers.

The remaining operative technique is the same starting from Step 6.

Remark: One should limit as much as possible trimming of the central spinous process to avoid any contact between implants.
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