Trabecular Metal™ Technology TM-300 Device

Surgical Technique

The Best Thing Next to Bone™

zimmer | spine

Confidence in your hands®

TM-300 TLIF Device

Developed in conjunction with

Dr. Rune Hedlund
Karolinska Institute
Huddinge University Hospital
Huddinge, Sweden

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Implant Description

The *Trabecular Metal* Fusion Device (TM-300) consists of a single component comprised wholly of porous tantalum. A single implant is used to fuse a single-level. It is crescent-shaped and comes in a variety of heights to match the height of the disc space.

The TM-300 is intended for use in patients with degenerative disc disease at one or two levels from L2 to S1. The patients may also have up to Grade II Spondylolisthesis at the involved level(s). The device is intended for use with bilateral titanium supplemental posterior fixation (e.g. pedicle screws and rods).

Pre-Operative

Pre-operatively, the surgeon must decide which intervertebral levels to fuse. This may be done using a variety of diagnostic techniques such as radiographs, MRI, myelography, discography, patient history and physical examination.

Patient Positioning

The patient is positioned in the 90° kneeling-sitting position on an Andrews frame or similar apparatus. This maintains lumbar lordosis and affects abdominal decompression to reduce epidural and venous pressure. A table should be used that accommodates both lateral and anterior-posterior radiographs.

Exposure

The skin and fascia are incised in the midline at the level(s) to be fused. The paravertebral muscles are retracted laterally, beyond the edge of the facet joints.

Identify Location

To identify the correct disc level(s), needle(s) are inserted into the intervertebral disc(s) as markers, and the location(s) determined by means of fluoroscopy or lateral C-arm radiograph.

Placing Pedicle Screws

At this point, pedicle screws are placed at the identified level(s). The screws may be helpful in maintaining distraction at the identified level(s). The screws should be implanted according to manufacturer's recommendations. Only titanium alloy (ISO 5832-3) systems should be used.

Harvesting Autograft

If it is anticipated that more autograft will be needed than what is obtained via the facetectomy, graft can be harvested from the posterior iliac crest. Standard techniques for harvesting should be used.

Disc Exposure and Decompression

A total facetectomy (Figure 1) is performed to accommodate the implants and instruments and to decompress the lateral recess and the foramen. The bone is retained and morselized to increase the volume of the bone graft available to pack into the disc space after placement of the implant. When necessary, additional decompression is performed.

The dura and nerve roots above and in selected cases below must be identified, mobilized and protected from injury during the preparation of the interdiscal space and insertion of the trials and device. Use of an operating microscope or loupes enhances surgeon visibility related to the disc exposure.

Figure 1

Annulotomy and Discectomy

After identifying the dura and nerve roots above and below, an annulotomy is performed using a scalpel (Figure 2). A window is cut in the annulus, at least 13 mm in width and approximately the height of the disc space.

Caution: Care should be taken to ensure that all exposed blood vessels are properly retracted. Unintended contact with the curettes and rongeurs could result in ruptured blood vessels.

Figure 2

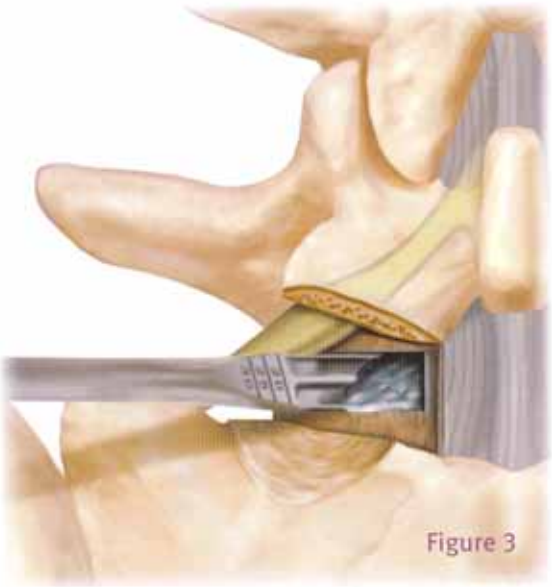

Figure 3

The opening in the posterior elements is then shaped to accommodate the implant, using shavers (Figure 3).

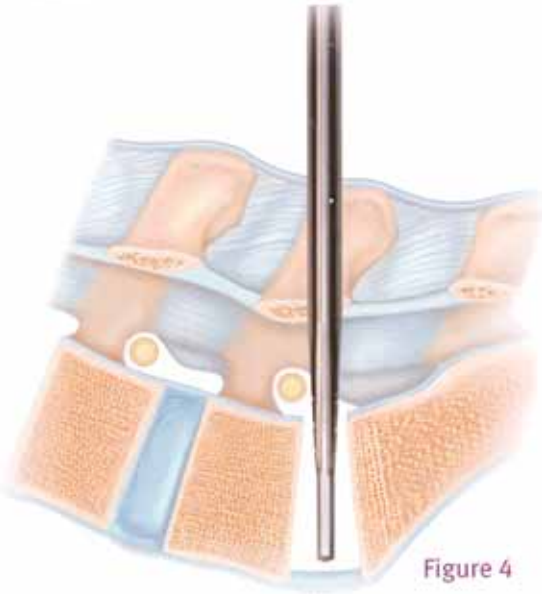

Figure 4

The shaver can also be advanced into the disc space to obtain distraction and remove some disc material (Figures 4 and 5).

Note: The shavers and distractors are contained in the TM-Prep instrument set.

A discectomy is then performed using rongeurs and small curettes. Complete removal of the nuclear material is required.

Caution: Ensure sharpness of curettes and rongeurs prior to use. Dull instruments require excessive force to operate and could result in damage to bone, nerves or other tissue.

Figure 5

Distraction and Endplate Preparation

Distraction is obtained off the pedicle screws, using the appropriate instrument from the pedicle screw set. It may be required to distract bilaterally. After distraction, a variety of curettes and rongeurs are used to remove the cartilage from the endplates. Ring curettes can be especially efficient at scraping the cartilage off of the endplates and then rongeurs used to remove the loose cartilage.

Punctuate bleeding should be obtained, but the endplate should not be removed.

Figure 6

Implant Selection

Once the endplates are prepared, the size of the implant is determined. A trial is inserted into the disc, and the handle rotated laterally while translating the trial anteriorly until the trial is centrally located in the disc space (Figures 6 and 7). Segment stability is assessed. Trial size can be increased until adequate stability is achieved. Care should be taken to position the trial appropriately. C-arm radiographs are necessary to evaluate the position of the trial in the disc space in both A/P and lateral projections. Once appropriate stability is obtained, the trial is removed.

Figure 7

Implant Insertion

The appropriate implant is based on the trial that provided appropriate stability. The appropriate implant is placed on the straight inserter. The straight inserter is used to insert the device into the evacuated disc space (Figure 8). Moderate impaction of the inserter may be required, using a mallet. If excessive force is needed, the implant should be removed and disc space checked for obstructing bone or a narrow transforaminal opening.

Caution: If excessive force is necessary, a change in implant size may be required. Excessive driving force on the implant may deform the *Trabecular Metal* structure.

Figure 9

Once inside the disc space, the implant is advanced far anteriorly and medially. This is accomplished by tapping on the handle while pushing the handle laterally (Figure 9). When the inserter begins to contact the lateral retractors or is restricted by the working space, the straight inserter is disconnected from the implant and removed from the site.

To enable further advancement and rotation of the implant, the angled inserter is then inserted into the disc space and connected to the implant (Figure 10). The implant is again advanced anteriorly across the midline through a combination of lateral rotation of the inserter handle and anterior translation of the assembly (Figure 11). The device should be positioned at the anterior edge of the disc space at the midline, abutting the anterior annulus (Figure 12).

Following final implant insertion, lateral and A/P radiographs may be taken to assure proper implant placement.

As an option, a tamp may also be used. Place the tip of the tamp into the slot of the implant. Using a mallet, advance the implant to the desired position.

Figure 10

Bone Grafting

After implantation of the device, bone graft from the facetectomy and if necessary, from the iliac crest is applied. The bone graft is packed posteriorly behind the device. Additional bone can be placed between the transverse processes to obtain a posterolateral fusion.

Figure 11

Application of Posterior Instrumentation

After implantation of the device, the remaining posterior instrumentation is applied. Compression should be applied to the construct prior to locking the pedicle screws to the rods or plates used. The posterior instrumentation should be implanted according to manufacturer's recommendations.

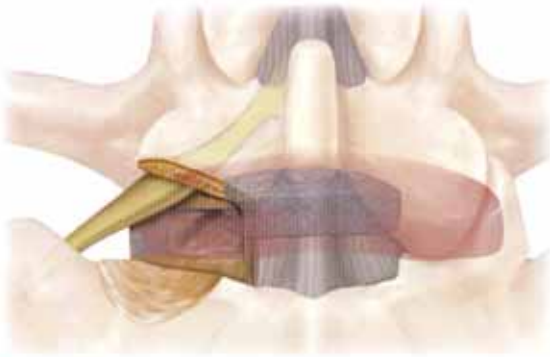

Figure 12

Post-Operative Management

Post-operative regimens may include the following:

1. Bracing at the discretion of the surgeon.
2. Avoidance of repetitive back bending and heavy lifting until advised by their surgeon.
3. Avoidance of non-steroidal anti-flammatory and steroidal drugs for at least 45 days post-operatively.