VySpine™

LumiVy™-P
NanoVy™ Ti
Lumbar IBF System

Surgical Technique

System Overview

Description:

The Vy Spine™ LumiVy™ Lumbar IBF System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The Vy Spine™ LumiVy™ Lumbar IBF device consists of intervertebral spacers of various shapes, sizes, and angulation. Each Vy Spine™ LumiVy™ Lumbar IBF has anti-migration teeth on the superior and inferior surfaces to engage the adjacent vertebral body. The Vy Spine™ LumiVy™ Lumbar IBF System implant components are made of medical grade PEEK-Optima LT1 described by ASTM Standard F-2026 and coated in NanoVy™ Ti, a CP Titanium coating mere nanometers thick. These components also have radiographic markers made of Tantalum embedded in the PEEK material. The Vy Spine™ LumiVy™ Lumbar IBF System may also include bone screws manufactured from Titanium alloy to secure the device to the vertebral body.

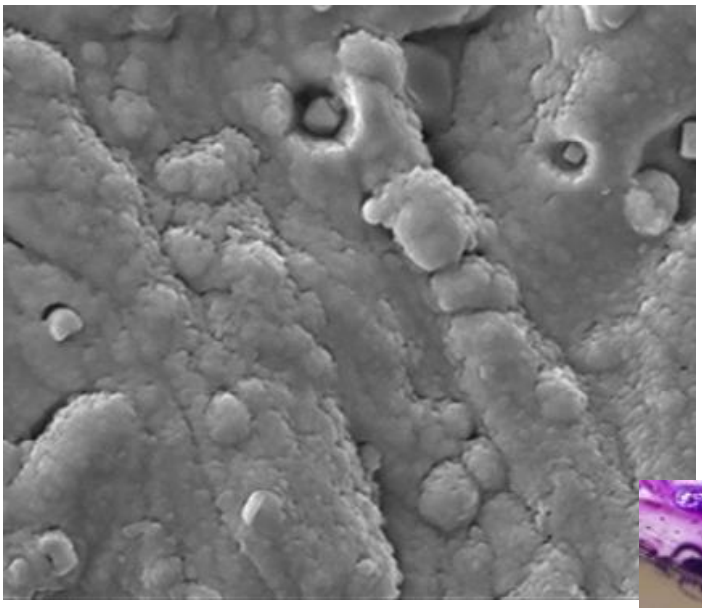
The Vy Spine™ LumiVy™ Lumbar IBF System must be used with additional anterior and/or posterior spinal instrumentation to augment stability.

Do not use implant components from any other manufacturer with Vy Spine™ LumiVy™ Lumbar IBF System components. As with all orthopedic implants, in no case may the implants be re-used.

Sizing Overview

The LumiVy-P Lumbar System is a curved implant, available in numerous sizes, heights, and angles of lordosis. All footprints are offered in heights from 6mm to 21mm, upon special request. Additionally, all sizes and heights are available in lordotic angles of 0°, 6°, 8°, and 10°, upon special request. Available sizes are listed below, with standard sizes in bold:

9 x 22	9 x 25	**9 x 28**	**9 x 30**

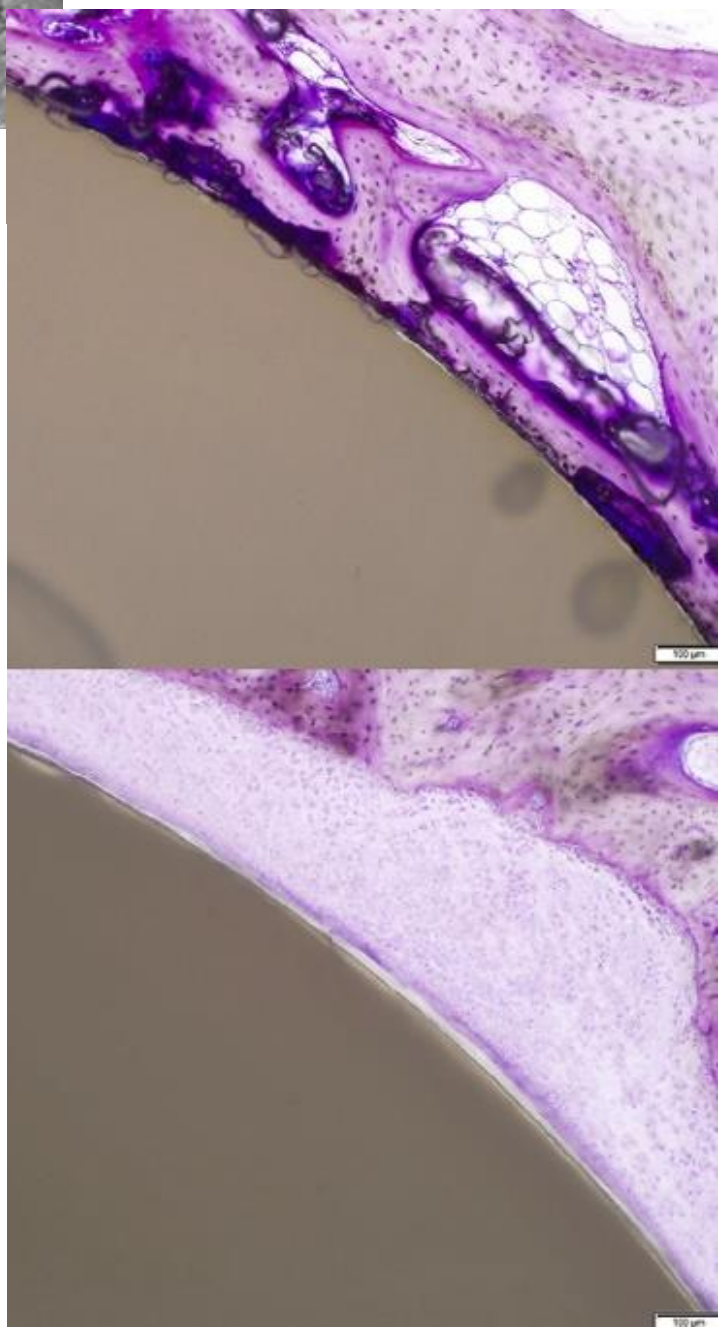


NanoVy™ Ti

NanoVy™ Ti is a nano coating of CP Titanium onto the surface of the LumiVy™ PEEK polymer. The NanoVy™ Ti coating is a mere 0.5microns thick, and intimately follows the contours on the LumiVy™ PEEK part. The NanoVy™ Ti greatly improves the performance of the native PEEK polymer, making for a superior implant.

Better Bony Apposition

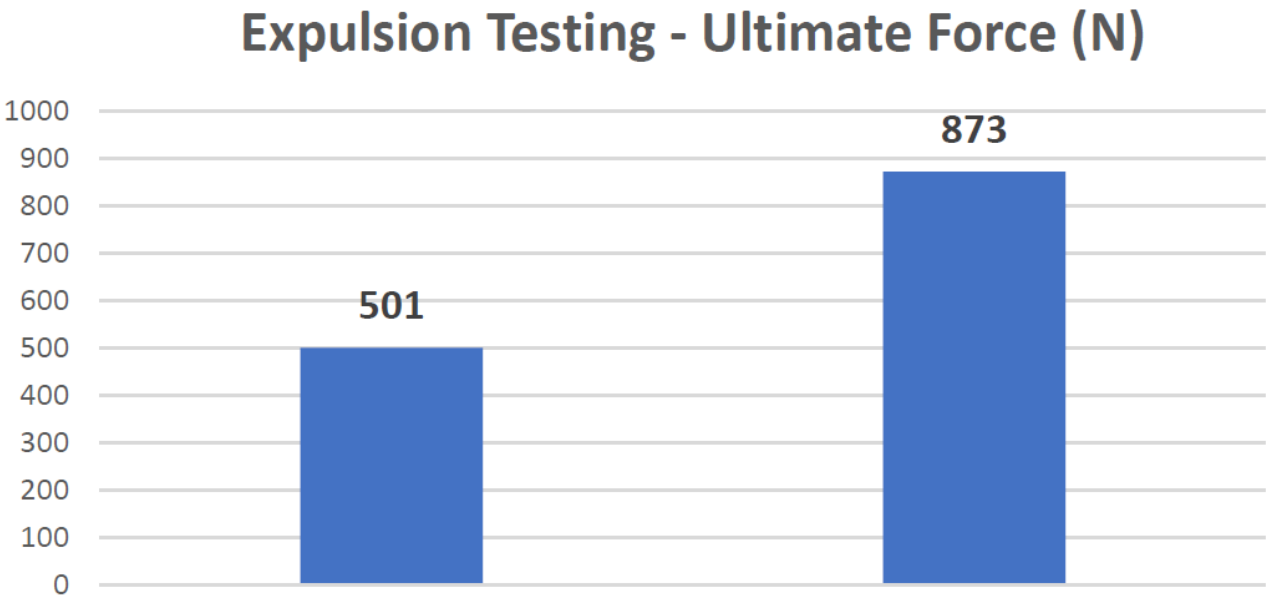
At 4 week, and again at 8 weeks, the PEEK implant with NanoVy™ Ti coating (top picture) demonstrates much better bony apposition in comparison to a native PEEK implant (bottom picture). Additionally, there is a significant reduction in fibrous tissue when comparing the PEEK implant with NanoVy™ Ti coating (top picture) to the native PEEK implant (bottom picture).

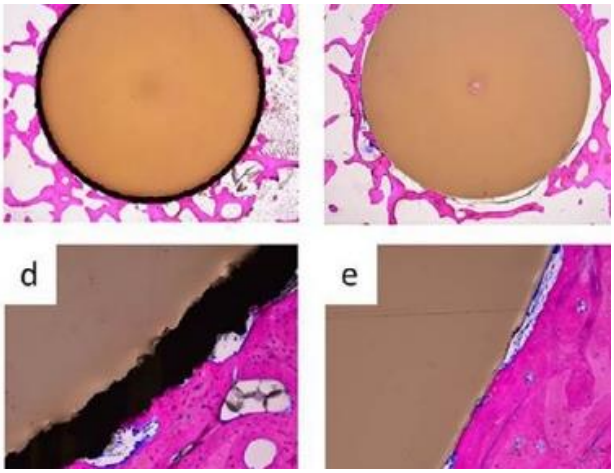


Spine J_18_(2018)_ Walsh B et al, The in vivo response to a novel Ti coatifn compared twith PEEK-evlauation of the periphery and inner surfaces of an implant, p1237, ©2018. (Note Nanometalene is another brand name for NanoVy Ti, data based on in vivo studies).

NanoVy™ Ti offers Superior Initial Fixation

In an expulsion test of NanoVy™ Ti coated implants, the force required to expulse the implant with NanoVy™ Ti coating required 74% more force than the uncoated PEEK implant.



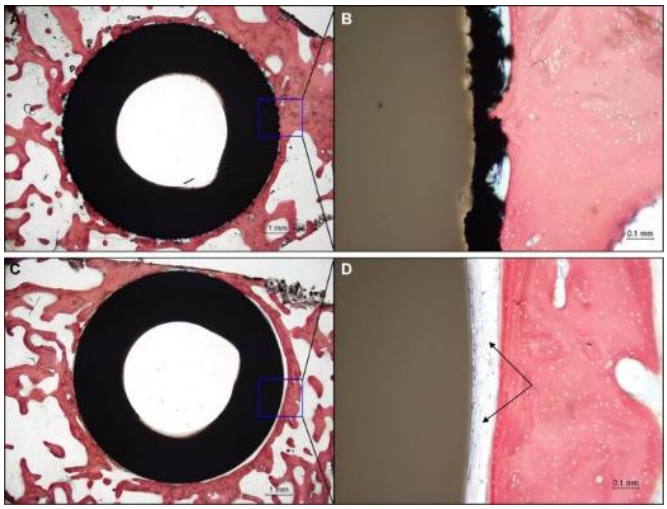


NanoVy™ Ti resists delamination

Unlike other titanium spray or plasma coating, NanoVy™ Ti coatings have demonstrated excellent adherence to the PEEK substrate, exhibiting little to no de-lamination, even during impaction against bony surfaces.

Osseointegration without Compromise

NanoVy™ Ti coated implants have demonstrate significant reduction in fibrous layer associated with uncoated PEEK implants. This is achieved without reducing the radiolucency or altering the modulus of elastic of the PEEK implant.



LumiVy™-P Surgical Technique

Step 1. Affected Disc Removal

The affected disc is exposed through the traditional anterior, anterolateral, lateral, or posterior approach that is appropriate for the affected level. Following standard technique, remove the affected portion of the disc. If desired, any removed healthy portion of the vertebral body may be saved and used for bone graft later in the procedure.

After the excision of the affected portion of the disc, each adjacent vertebral body endplate is prepared by removing all cartilage tissue while conserving subchondral bone to provide optimal compressive/support interface surfaces.

Step 2. Restoration of Anatomy

If the LumiVy™ Lumbar IBF device is being used with an anterior supplemental fixation system, then please refer to that particular system's surgical technique for further information. To distract the defect using an anterior supplemental fixation device, place the screws, bolts, or staples appropriately into the two vertebral bodies adjacent to the defect. Use these structures to distract the defect to the desired height. If an anterior supplemental fixation system is not used to achieve distraction and restoration of the anatomy, a vertebral body spreader may be used. Place the tangs of the spreader on each endplate of the vertebral bodies adjacent to the defect. Use the spreaders to distract the defect to the desired height. Additionally, the device trials (See Step 3) may be used to distract the disc space to the desired height.

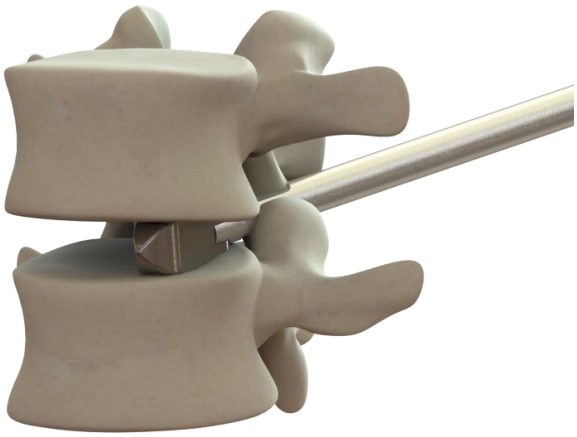
LumiVy™-P Surgical Technique

Step 3. Device Selection

Once the dissection and restoration have been achieved, it is important to ensure that enough of the affected disc has been removed such that the LumiVy™ Lumbar IBF device can be placed into the defect. Trials can be utilized to ensure proper implant selection. The Trial footprint should cover as much of the defect as possible.

Step 4. Attach Inserter

Thread the Inserter onto the LumiVy™ Lumbar IBF device. Ensure that the implant is secure, but take care not to overtighten. The central opening of the device should be filled as much as possible using autogenous bone (except in the case of metastatic tumor). Surgeon discretion should dictate the location and timing of any harvesting procedure.



Step 5. Implant Placement

With the LumiVy™ Lumbar IBF implant attached to the Inserter, place the device into the defect. Check the placement of the LumiVy™ Lumbar IBF using x-ray or fluoroscope to ensure proper placement. The placement of the device should be confirmed, and the position modified if necessary.

Step 6. Remove Instrumentation

Detach the Inserter from LumiVy™ Lumbar IBF implant. Additional graft material may be placed around the device after insertion as well.

Step 7. Supplemental Fixation

If the LumiVy™ Lumbar IBF device is being used with an anterior supplemental fixation system, place the supplemental device at this time. Use the supplemental fixation system to provide compression to the LumiVy™ Lumbar IBF device. Note that any anterior device can migrate in the absence of adequate compression. Please refer to that particular system's surgical technique for further information. Once the anterior supplemental fixation has been properly implanted, the wound should be closed using standard technique.

If the LumiVy™ Lumbar IBF device is being used with a posterior supplemental fixation system, then the anterolateral wound should be closed in standard fashion. Drainage is placed at the surgeon's discretion, and the patient is then repositioned supine. For the placement of the posterior supplemental fixation, please refer to that particular system's surgical technique for further information. Use the supplemental fixation system to provide compression to the LumiVy™ Lumbar IBF device. Note that any anterior device can migrate in the absence of adequate compression. Once the posterior supplemental fixation has been properly implanted, the wound should be closed using standard technique.

Optional. Removal of Device

To remove the LumiVy™ Lumbar IBF device, first the supplemental fixation must be removed. Reasons for removal can be found in the "Possible Adverse Effects" section of the Package Insert. The vertebral bodies adjacent to the LumiVy™ Lumbar IBF device are then distracted using the spreader instrument. Then, reattach the inserter to one of the threaded holes on the LumiVy™ Lumbar IBF construct. Then remove the device from the incision.

LumiVy™-P IBF Ordering Information

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PEEK Optima™ NanoVy™-Ti Implants

Part Number	Product Size
03-P-0922-6-06-PET-R	9x22, 6°, 6mm
03-P-0922-6-07-PET-R	9x22, 6°, 7mm
03-P-0922-6-08-PET-R	9x22, 6°, 8mm
03-P-0922-6-09-PET-R	9x22, 6°, 9mm
03-P-0922-6-10-PET-R	9x22, 6°, 10mm
03-P-0922-6-11-PET-R	9x22, 6°, 11mm
03-P-0922-6-12-PET-R	9x22, 6°, 12mm
03-P-0922-6-13-PET-R	9x22, 6°, 13mm
03-P-0922-6-14-PET-R	9x22, 6°, 14mm
03-P-0922-6-15-PET-R	9x22, 6°, 15mm
03-P-0928-6-06-PET-R	9x28, 6°, 6mm
03-P-0928-6-07-PET-R	9x28, 6°, 7mm
03-P-0928-6-08-PET-R	9x28, 6°, 8mm
03-P-0928-6-09-PET-R	9x28, 6°, 9mm
03-P-0928-6-10-PET-R	9x28, 6°, 10mm
03-P-0928-6-11-PET-R	9x28, 6°, 11mm
03-P-0928-6-12-PET-R	9x28, 6°, 12mm
03-P-0928-6-13-PET-R	9x28, 6°, 13mm
03-P-0928-6-14-PET-R	9x28, 6°, 14mm
03-P-0928-6-15-PET-R	9x28, 6°, 15mm
03-P-0930-6-06-PET-R	9x30, 6°, 6mm
03-P-0930-6-07-PET-R	9x30, 6°, 7mm
03-P-0930-6-08-PET-R	9x30, 6°, 8mm
03-P-0930-6-09-PET-R	9x30, 6°, 9mm
03-P-0930-6-10-PET-R	9x30, 6°, 10mm
03-P-0930-6-11-PET-R	9x30, 6°, 11mm
03-P-0930-6-12-PET-R	9x30, 6°, 12mm
03-P-0930-6-13-PET-R	9x30, 6°, 13mm
03-P-0930-6-14-PET-R	9x30, 6°, 14mm
03-P-0930-6-15-PET-R	9x30, 6°, 15mm

Part Number	Product Size
03-P-0922-10-06-PET-R	9x22, 10°, 6mm
03-P-0922-10-07-PET-R	9x22, 10°, 7mm
03-P-0922-10-08-PET-R	9x22, 10°, 8mm
03-P-0922-10-09-PET-R	9x22, 10°, 9mm
03-P-0922-10-10-PET-R	9x22, 10°, 10mm
03-P-0922-10-11-PET-R	9x22, 10°, 11mm
03-P-0922-10-12-PET-R	9x22, 10°, 12mm
03-P-0922-10-13-PET-R	9x22, 10°, 13mm
03-P-0922-10-14-PET-R	9x22, 10°, 14mm
03-P-0922-10-15-PET-R	9x22, 10°, 15mm
03-P-0928-10-06-PET-R	9x28, 10°, 6mm
03-P-0928-10-07-PET-R	9x28, 10°, 7mm
03-P-0928-10-08-PET-R	9x28, 10°, 8mm
03-P-0928-10-09-PET-R	9x28, 10°, 9mm
03-P-0928-10-10-PET-R	9x28, 10°, 10mm
03-P-0928-10-11-PET-R	9x28, 10°, 11mm
03-P-0928-10-12-PET-R	9x28, 10°, 12mm
03-P-0928-10-13-PET-R	9x28, 10°, 13mm
03-P-0928-10-14-PET-R	9x28, 10°, 14mm
03-P-0928-10-15-PET-R	9x28, 10°, 15mm
03-P-0930-10-06-PET-R	9x30, 10°, 6mm
03-P-0930-10-07-PET-R	9x30, 10°, 7mm
03-P-0930-10-08-PET-R	9x30, 10°, 8mm
03-P-0930-10-09-PET-R	9x30, 10°, 9mm
03-P-0930-10-10-PET-R	9x30, 10°, 10mm
03-P-0930-10-11-PET-R	9x30, 10°, 11mm
03-P-0930-10-12-PET-R	9x30, 10°, 12mm
03-P-0930-10-13-PET-R	9x30, 10°, 13mm
03-P-0930-10-14-PET-R	9x30, 10°, 14mm
03-P-0930-10-15-PET-R	9x30, 10°, 15mm

LumiVy™-P IBF Ordering Information

Instrumentation Options

Part Number	Description	Size
03-INP-001	LumiVy-P Inserter	
03-ITP-0922-6-06	LumiVy™ P Trial	9x22, 6°, 6mm
03-ITP-0922-6-07	LumiVy™ P Trial	9x22, 6°, 7mm
03-ITP-0922-6-08	LumiVy™ P Trial	9x22, 6°, 8mm
03-ITP-0922-6-09	LumiVy™ P Trial	9x22, 6°, 9mm
03-ITP-0922-6-10	LumiVy™ P Trial	9x22, 6°, 10mm
03-ITP-0922-6-11	LumiVy™ P Trial	9x22, 6°, 11mm
03-ITP-0922-6-12	LumiVy™ P Trial	9x22, 6°, 12mm
03-ITP-0922-6-13	LumiVy™ P Trial	9x22, 6°, 13mm
03-ITP-0922-6-14	LumiVy™ P Trial	9x22, 6°, 14mm
03-ITP-0922-6-15	LumiVy™ P Trial	9x22, 6°, 15mm
03-ITP-0928-6-06	LumiVy™ P Trial	9x28, 6°, 6mm
03-ITP-0930-6-06	LumiVy™ P Trial	9x30, 6°, 6mm

Indications:

The Vy Spine™ LumiVy™ Lumbar IBF System, when used as an Intervertebral Body Fusion device, is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. The implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.
The Vy Spine™ LumiVy™ Lumbar IBF System, when used as an Intervertebral Body Fusion device is also intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment.
Additional supplemental fixation is not necessary for the LumiVy™ -AS implants if the integrated screws are implanted.

FOR ADDITIONAL INFORMATION INCLUDING PRECAUTIONS, WARNINGS, CONTRAINDICATIONS, CLEANING AND STERILIZATION, PLEASE REFER TO THE PACKAGE INSERT

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