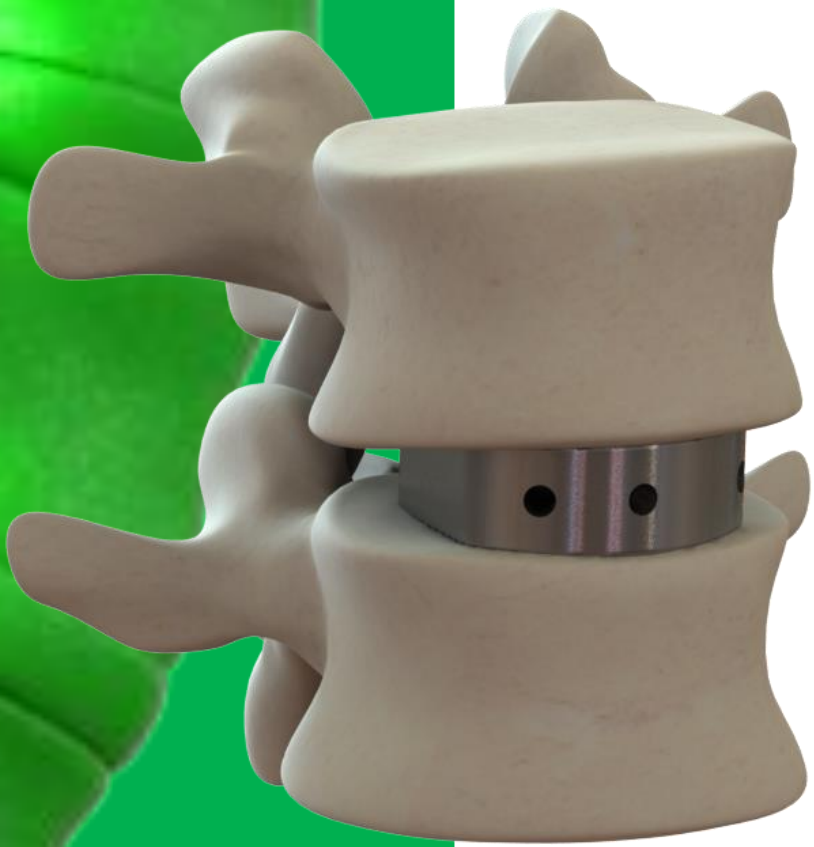
VySpine™

LumiVy™-A
LumiVy™-AS
NanoVy™-Ti
Lumbar IBF System

Surgical Technique



System Overview

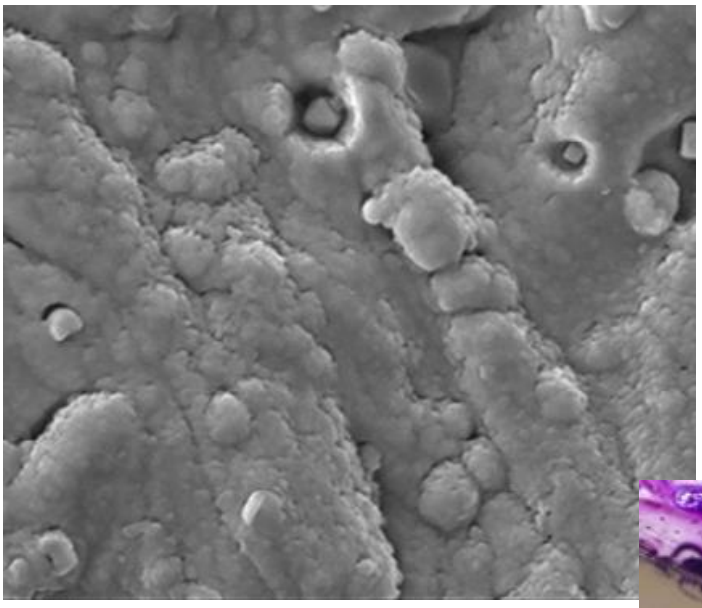
Description:

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.

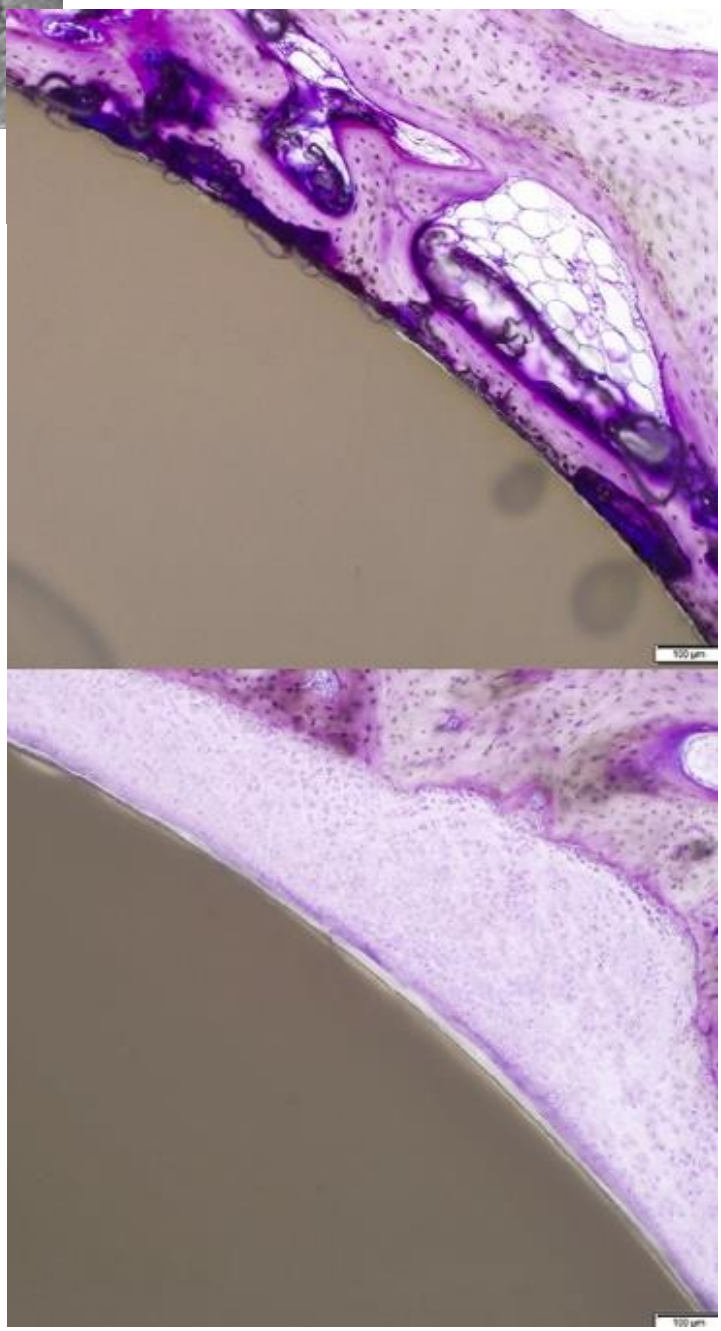


NanoVy™ Ti

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

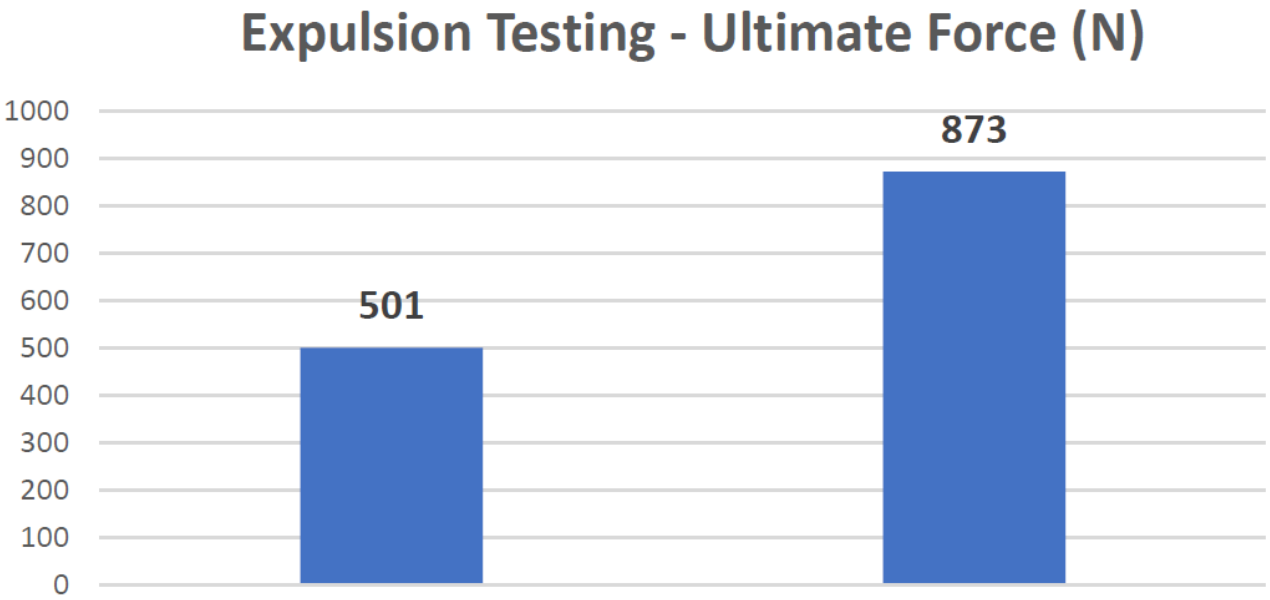
At 4 weeks, and again at 8 weeks, the PEEK implant with NanoVy™ Ti coating (top picture) demonstrates much better bony apposition in comparison to a native PEEK implant (bottom picture). Additionally, there is a significant reduction in fibrous tissue when comparing the PEEK implant with NanoVy™ Ti coating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

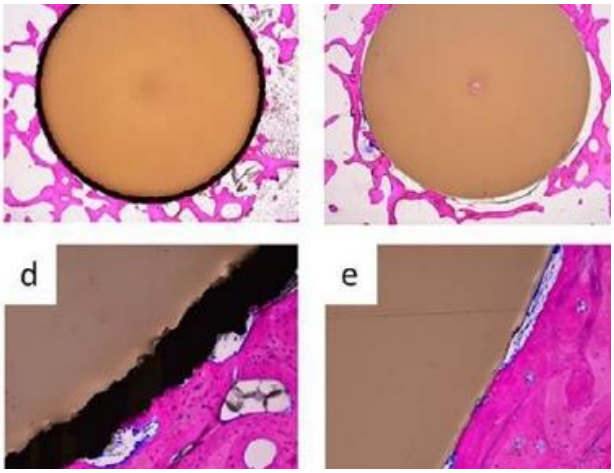


Spine J_18_(2018)_ Walsh B et al, The in vivo response to a novel Ti coatifn compared twith PEEK-evlauation of the periphery and inner surfaces of an implant, p1237, ©2018. (Note Nanometalene is another brand name for NanoVy Ti, data based on in vivo studies).

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.



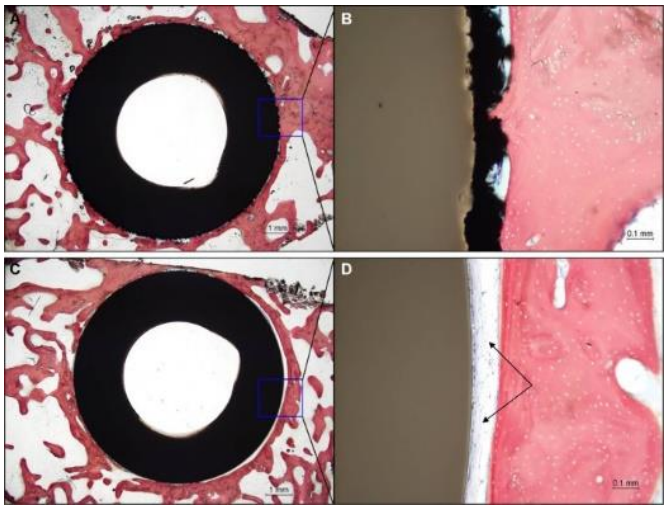


NanoVy™ Ti resists delamination

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 demonstrated 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™-A Surgical Technique

Step 1. Affected Disc Removal

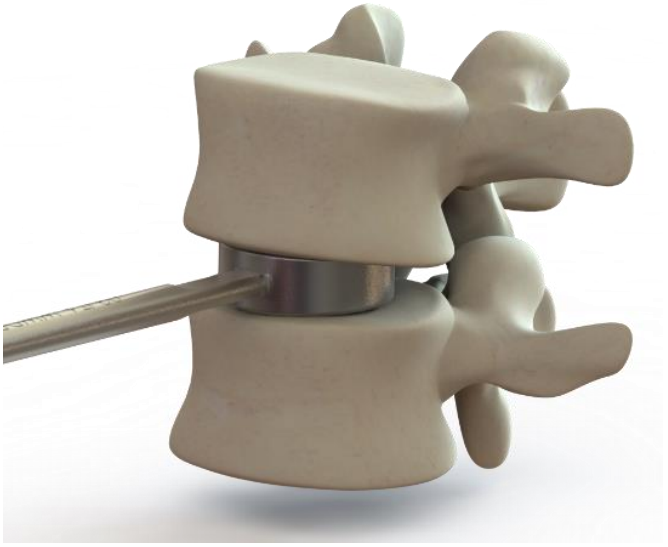
The affected disc is exposed through the traditional anterior, anterolateral, lateral, or posterior approach that is appropriate for the affected level. Following standard technique, remove the affected portion of the disc. If desired, any removed healthy portion of the vertebral body may be saved and 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™-A Surgical Technique

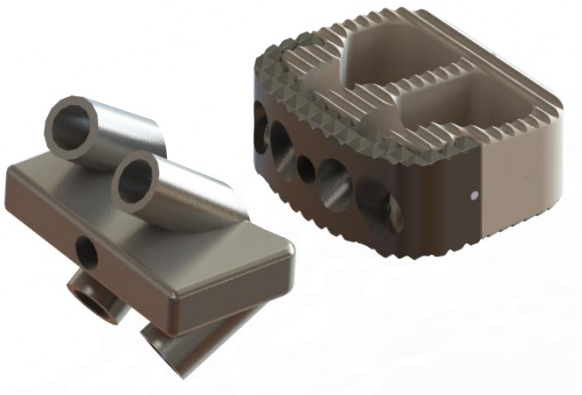


Step 3. Device Selection

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.

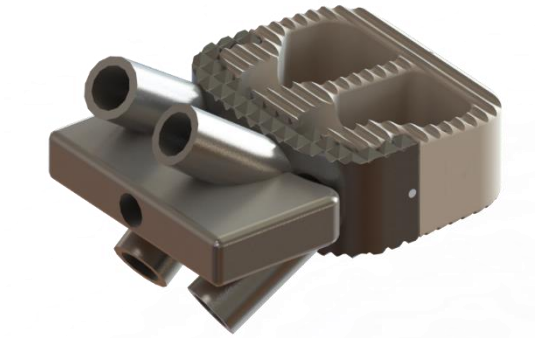


Step 4a. Drill Guide (Only if using LumiVy™ Lumbar IBF-S)

Remove the central threaded shaft from the IBF-S Inserter. Slide the IBF-S onto the appropriate Drill Guide

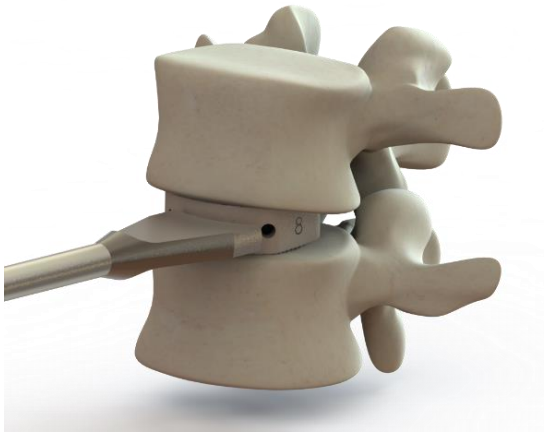
Step 4b. Drill Guide (Only if using LumiVy™ Lumbar IBF-S)

With the Drill Guide secure on the IBF-S Inserter, reattach the central threaded shaft to the IBF-S Inserter, through the Drill Guide.



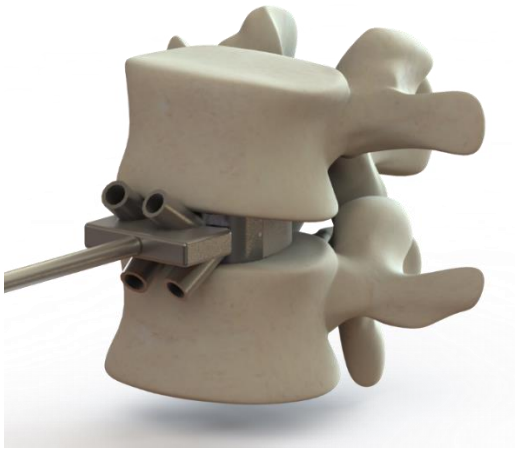
Step 4c. Attach IBF-S Inserter (Only if using LumiVy™ Lumbar IBF-S)

Thread the IBF-S Inserter Drill Guide assembly onto the LumiVy™ Lumbar IBF-S 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.



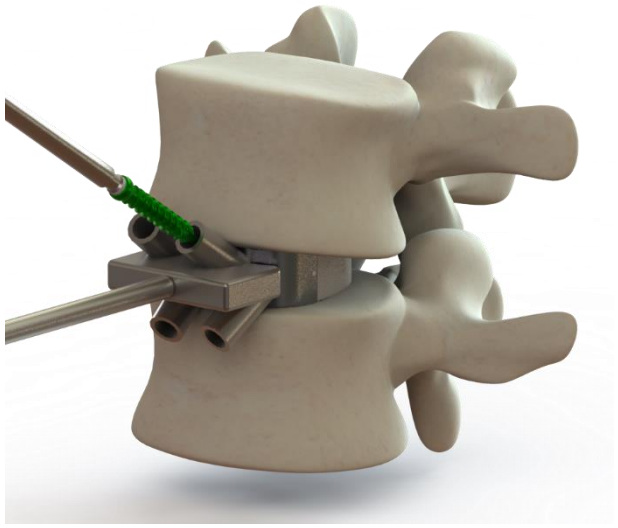
LumiVy™-A Surgical Technique

Step 6. Awl (Only if using LumiVy™ Lumbar IBF-S)

Break the cortical layer of bone using the awl, through the drill guide. Repeat for the other side.

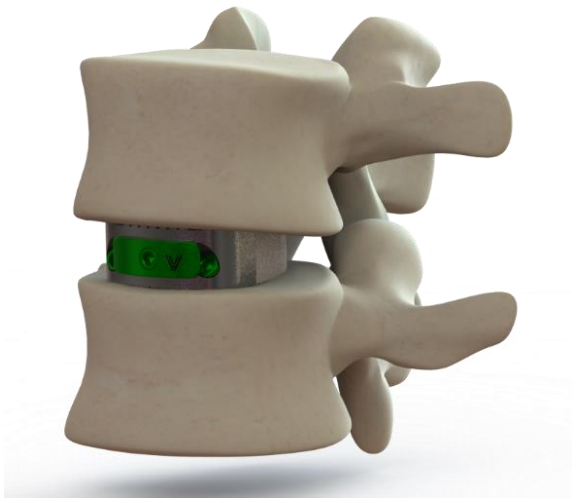
Step 7. Drill (Only if using LumiVy™ Lumbar IBF-S)

Although all of the Screws in the LumiVy™ Lumbar IBF-S system are self-drilling, a drill may be used through the drill guide in order to prepare a pilot for the screw.



Step 8. Insert Screw (Only if using LumiVy™ Lumbar IBF-S)

Place the LumiVy™ Screw onto the Screwdriver, then insert the Screw through the Drill Guide until the Screw is seated fully into the LumiVy™ Lumbar IBF-S implant. The Screw will actually cut into the LumiVy™ Lumbar IBF-S implant to prevent back-out. Repeat steps 6-8 for the second Screw.



Step 9. Place Cover Plate (Only if using LumiVy™ Lumbar IBF-S)

Remove the drill guide from the implant. Place the cover plate onto the screwdriver, insert the cover plate onto the Vy Spine™ LumiVy™ Lumbar IBF implant.

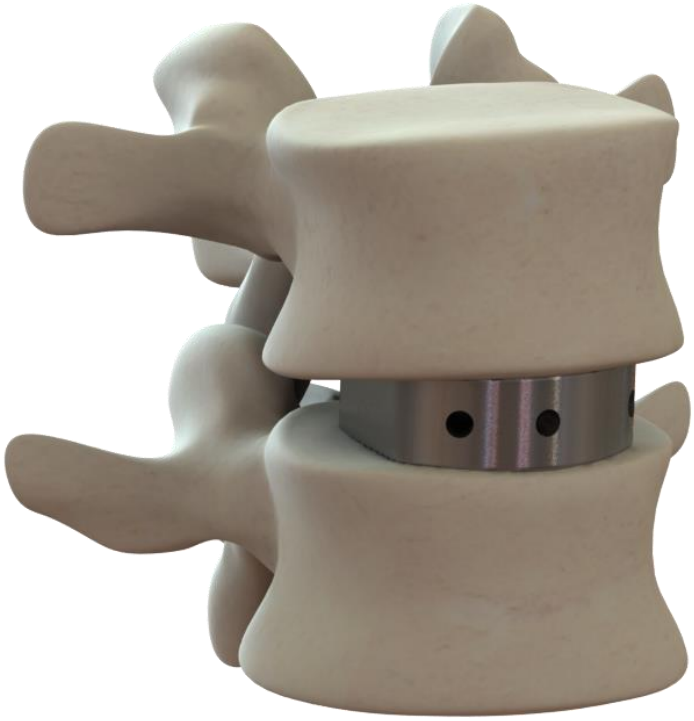
Step 10. Remove Instrumentation

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

Step 11. 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. If the LumiVy™ Lumbar IBF-S was used, first remove the two Screws with the Screw Driver. Then, reattach the inserter to one of the threaded holes on the LumiVy™ Lumbar IBF construct. Then remove the device from the incision.

LumiVy™ IBF Ordering Information

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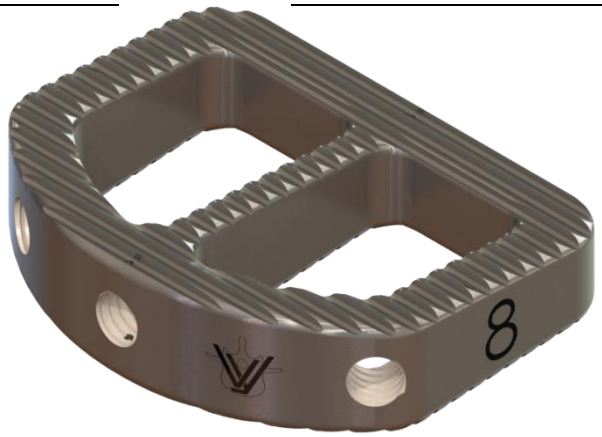
PEEK Optima™ NanoVy™-Ti Implants

Part Number	Product Size
03-A-3024-6-06-PET-R	30x24, 6°, 6mm
03-A-3024-6-07-PET-R	30x24, 6°, 7mm
03-A-3024-6-08-PET-R	30x24, 6°, 8mm
03-A-3024-6-09-PET-R	30x24, 6°, 9mm
03-A-3024-6-10-PET-R	30x24, 6°, 10mm
03-A-3024-6-11-PET-R	30x24, 6°, 11mm
03-A-3024-6-12-PET-R	30x24, 6°, 12mm
03-A-3024-6-13-PET-R	30x24, 6°, 13mm
03-A-3024-6-14-PET-R	30x24, 6°, 14mm
03-A-3024-6-15-PET-R	30x24, 6°, 15mm
03-A-3426-6-06-PET-R	34x26, 6°, 6mm
03-A-3426-6-07-PET-R	34x26, 6°, 7mm
03-A-3426-6-08-PET-R	34x26, 6°, 8mm
03-A-3426-6-09-PET-R	34x26, 6°, 9mm
03-A-3426-6-10-PET-R	34x26, 6°, 10mm
03-A-3426-6-11-PET-R	34x26, 6°, 11mm
03-A-3426-6-12-PET-R	34x26, 6°, 12mm
03-A-3426-6-13-PET-R	34x26, 6°, 13mm
03-A-3426-6-14-PET-R	34x26, 6°, 14mm
03-A-3426-6-15-PET-R	34x26, 6°, 15mm
03-A-3827-6-06-PET-R	38x27, 6°, 6mm
03-A-3827-6-07-PET-R	38x27, 6°, 7mm
03-A-3827-6-08-PET-R	38x27, 6°, 8mm
03-A-3827-6-09-PET-R	38x27, 6°, 9mm
03-A-3827-6-10-PET-R	38x27, 6°, 10mm
03-A-3827-6-11-PET-R	38x27, 6°, 11mm
03-A-3827-6-12-PET-R	38x27, 6°, 12mm
03-A-3827-6-13-PET-R	38x27, 6°, 13mm
03-A-3827-6-14-PET-R	38x27, 6°, 14mm
03-A-3827-6-15-PET-R	38x27, 6°, 15mm

Part Number	Product Size
03-A-3024-10-06-PET-R	30x24, 10°, 6mm
03-A-3024-10-07-PET-R	30x24, 10°, 7mm
03-A-3024-10-08-PET-R	30x24, 10°, 8mm
03-A-3024-10-09-PET-R	30x24, 10°, 9mm
03-A-3024-10-10-PET-R	30x24, 10°, 10mm
03-A-3024-10-11-PET-R	30x24, 10°, 11mm
03-A-3024-10-12-PET-R	30x24, 10°, 12mm
03-A-3024-10-13-PET-R	30x24, 10°, 13mm
03-A-3024-10-14-PET-R	30x24, 10°, 14mm
03-A-3024-10-15-PET-R	30x24, 10°, 15mm
03-A-3426-10-06-PET-R	34x26, 10°, 6mm
03-A-3426-10-07-PET-R	34x26, 10°, 7mm
03-A-3426-10-08-PET-R	34x26, 10°, 8mm
03-A-3426-10-09-PET-R	34x26, 10°, 9mm
03-A-3426-10-10-PET-R	34x26, 10°, 10mm
03-A-3426-10-11-PET-R	34x26, 10°, 11mm
03-A-3426-10-12-PET-R	34x26, 10°, 12mm
03-A-3426-10-13-PET-R	34x26, 10°, 13mm
03-A-3426-10-14-PET-R	34x26, 10°, 14mm
03-A-3426-10-15-PET-R	34x26, 10°, 15mm
03-A-3827-10-06-PET-R	38x27, 10°, 6mm
03-A-3827-10-07-PET-R	38x27, 10°, 7mm
03-A-3827-10-08-PET-R	38x27, 10°, 8mm
03-A-3827-10-09-PET-R	38x27, 10°, 9mm
03-A-3827-10-10-PET-R	38x27, 10°, 10mm
03-A-3827-10-11-PET-R	38x27, 10°, 11mm
03-A-3827-10-12-PET-R	38x27, 10°, 12mm
03-A-3827-10-13-PET-R	38x27, 10°, 13mm
03-A-3827-10-14-PET-R	38x27, 10°, 14mm
03-A-3827-10-15-PET-R	38x27, 10°, 15mm



LumiVy™ IBF-S Ordering Information

PEEK Optima™ NanoVy™-Ti Implants

Part Number	Product Size
03-AS-3024-6-08-PET-R	30x24, 6°, 8mm
03-AS-3024-6-09-PET-R	30x24, 6°, 9mm
03-AS-3024-6-10-PET-R	30x24, 6°, 10mm
03-AS-3024-6-11-PET-R	30x24, 6°, 11mm
03-AS-3024-6-12-PET-R	30x24, 6°, 12mm
03-AS-3024-6-13-PET-R	30x24, 6°, 13mm
03-AS-3024-6-14-PET-R	30x24, 6°, 14mm
03-AS-3024-6-15-PET-R	30x24, 6°, 15mm
03-AS-3426-6-08-PET-R	34x26, 6°, 8mm
03-AS-3426-6-09-PET-R	34x26, 6°, 9mm
03-AS-3426-6-10-PET-R	34x26, 6°, 10mm
03-AS-3426-6-11-PET-R	34x26, 6°, 11mm
03-AS-3426-6-12-PET-R	34x26, 6°, 12mm
03-AS-3426-6-13-PET-R	34x26, 6°, 13mm
03-AS-3426-6-14-PET-R	34x26, 6°, 14mm
03-AS-3426-6-15-PET-R	34x26, 6°, 15mm
03-AS-3827-6-08-PET-R	38x27, 6°, 8mm
03-AS-3827-6-09-PET-R	38x27, 6°, 9mm
03-AS-3827-6-10-PET-R	38x27, 6°, 10mm
03-AS-3827-6-11-PET-R	38x27, 6°, 11mm
03-AS-3827-6-12-PET-R	38x27, 6°, 12mm
03-AS-3827-6-13-PET-R	38x27, 6°, 13mm
03-AS-3827-6-14-PET-R	38x27, 6°, 14mm
03-AS-3827-6-15-PET-R	38x27, 6°, 15mm

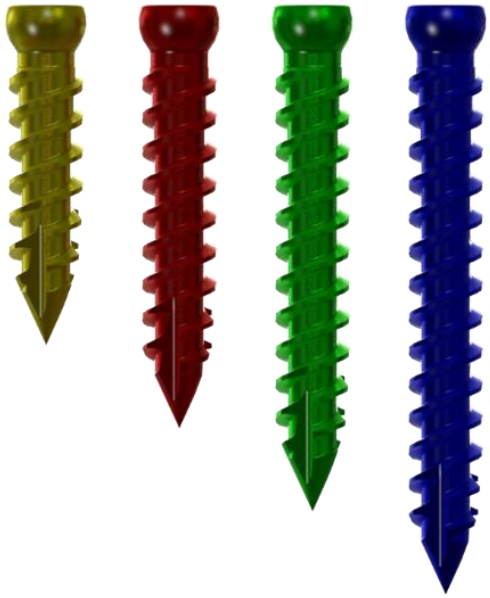
Part Number	Product Size
03-AS-3024-10-08-PET-R	30x24, 10°, 8mm
03-AS-3024-10-09-PET-R	30x24, 10°, 9mm
03-AS-3024-10-10-PET-R	30x24, 10°, 10mm
03-AS-3024-10-11-PET-R	30x24, 10°, 11mm
03-AS-3024-10-12-PET-R	30x24, 10°, 12mm
03-AS-3024-10-13-PET-R	30x24, 10°, 13mm
03-AS-3024-10-14-PET-R	30x24, 10°, 14mm
03-AS-3024-10-15-PET-R	30x24, 10°, 15mm
03-AS-3426-10-08-PET-R	34x26, 10°, 8mm
03-AS-3426-10-09-PET-R	34x26, 10°, 9mm
03-AS-3426-10-10-PET-R	34x26, 10°, 10mm
03-AS-3426-10-11-PET-R	34x26, 10°, 11mm
03-AS-3426-10-12-PET-R	34x26, 10°, 12mm
03-AS-3426-10-13-PET-R	34x26, 10°, 13mm
03-AS-3426-10-14-PET-R	34x26, 10°, 14mm
03-AS-3426-10-15-PET-R	34x26, 10°, 15mm
03-AS-3827-10-08-PET-R	38x27, 10°, 8mm
03-AS-3827-10-09-PET-R	38x27, 10°, 9mm
03-AS-3827-10-10-PET-R	38x27, 10°, 10mm
03-AS-3827-10-11-PET-R	38x27, 10°, 11mm
03-AS-3827-10-12-PET-R	38x27, 10°, 12mm
03-AS-3827-10-13-PET-R	38x27, 10°, 13mm
03-AS-3827-10-14-PET-R	38x27, 10°, 14mm
03-AS-3827-10-15-PET-R	38x27, 10°, 15mm

LumiVy™ IBF-S Ordering Information

Screw Options

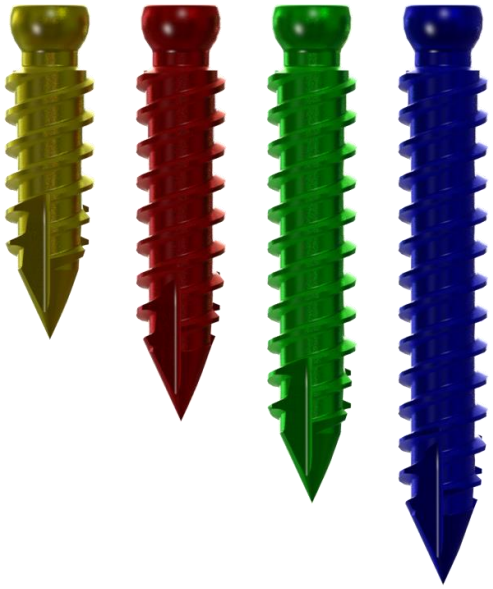
Variable Angle, Self-Drilling Screws

Part Number	Product Size
03-DVS-45-15-TI-N	Ø4.5mm, 15mm
03-DVS-45-20-TI-N	Ø4.5mm, 20mm
03-DVS-45-25-TI-N	Ø4.5mm, 25mm
03-DVS-45-30-TI-N	Ø4.5mm, 30mm



Variable Angle, Self-Drilling Screws

Part Number	Product Size
03-DVS-55-15-TI-N	Ø5.5mm, 15mm
03-DVS-55-20-TI-N	Ø5.5mm, 20mm
03-DVS-55-25-TI-N	Ø5.5mm, 25mm
03-DVS-55-30-TI-N	Ø5.5mm, 30mm



Cover Plate

Part Number	Product Size
03-AP-08-TI-N	8mm
03-AP-10-TI-N	10mm
03-AP-12-TI-N	12mm
03-AP-14-TI-N	14mm

LumiVy™ IBF Ordering Information

Instrumentation Options

Part Number	Description	Size
03-INA-001	LumiVy-A Inserter	
03-ITA-3024-6-06	LumiVy™ A Trial	30x24, 6°, 6mm
03-ITA-3024-6-07	LumiVy™ A Trial	30x24, 6°, 7mm
03-ITA-3024-6-08	LumiVy™ A Trial	30x24, 6°, 8mm
03-ITA-3024-6-09	LumiVy™ A Trial	30x24, 6°, 9mm
03-ITA-3024-6-10	LumiVy™ A Trial	30x24, 6°, 10mm
03-ITA-3024-6-11	LumiVy™ A Trial	30x24, 6°, 11mm
03-ITA-3024-6-12	LumiVy™ A Trial	30x24, 6°, 12mm
03-ITA-3024-6-13	LumiVy™ A Trial	30x24, 6°, 13mm
03-ITA-3024-6-14	LumiVy™ A Trial	30x24, 6°, 14mm
03-ITA-3024-6-15	LumiVy™ A Trial	30x24, 6°, 15mm
03-ITA-3426-6-06	LumiVy™ A Trial	34x26, 6°, 6mm
03-ITA-3827-6-06	LumiVy™ A Trial	38x27, 6°, 6mm

LumiVy™ IBF-S Ordering Information

Instrumentation Options

Part Number	Description	Size
03-ISNA-001	LumiVy-AS Inserter	
03-ISA-001	Awl	
03-ISD-001	Screw Driver	
03-ISD-002	4.0 Drill Bit	
03-ISGA-3024-08	LumiVy™ AS Guide	30x24, 8mm
03-ISGA-3024-09	LumiVy™ AS Guide	30x24, 9mm
03-ISGA-3024-10	LumiVy™ AS Guide	30x24, 10mm
03-ISGA-3024-11	LumiVy™ AS Guide	30x24, 11mm
03-ISGA-3024-12	LumiVy™ AS Guide	30x24, 12mm
03-ISGA-3024-13	LumiVy™ AS Guide	30x24, 13mm
03-ISGA-3024-14	LumiVy™ AS Guide	30x24, 14mm
03-ISGA-3024-15	LumiVy™ AS Guide	30x24, 15mm
03-ISGA-3426-08	LumiVy™ AS Guide	34x26, 8mm
03-ISGA-3426-09	LumiVy™ AS Guide	34x26, 9mm
03-ISGA-3426-10	LumiVy™ AS Guide	34x26, 10mm
03-ISGA-3426-11	LumiVy™ AS Guide	34x26, 11mm
03-ISGA-3426-12	LumiVy™ AS Guide	34x26, 12mm
03-ISGA-3426-13	LumiVy™ AS Guide	34x26, 13mm
03-ISGA-3426-14	LumiVy™ AS Guide	34x26, 14mm
03-ISGA-3426-15	LumiVy™ AS Guide	34x26, 15mm
03-ISGA-3827-08	LumiVy™ AS Guide	38x27, 8mm
03-ISGA-3827-09	LumiVy™ AS Guide	38x27, 9mm
03-ISGA-3827-10	LumiVy™ AS Guide	38x27, 10mm
03-ISGA-3827-11	LumiVy™ AS Guide	38x27, 11mm
03-ISGA-3827-12	LumiVy™ AS Guide	38x27, 12mm
03-ISGA-3827-13	LumiVy™ AS Guide	38x27, 13mm
03-ISGA-3827-14	LumiVy™ AS Guide	38x27, 14mm
03-ISGA-3827-15	LumiVy™ AS Guide	38x27, 15mm

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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