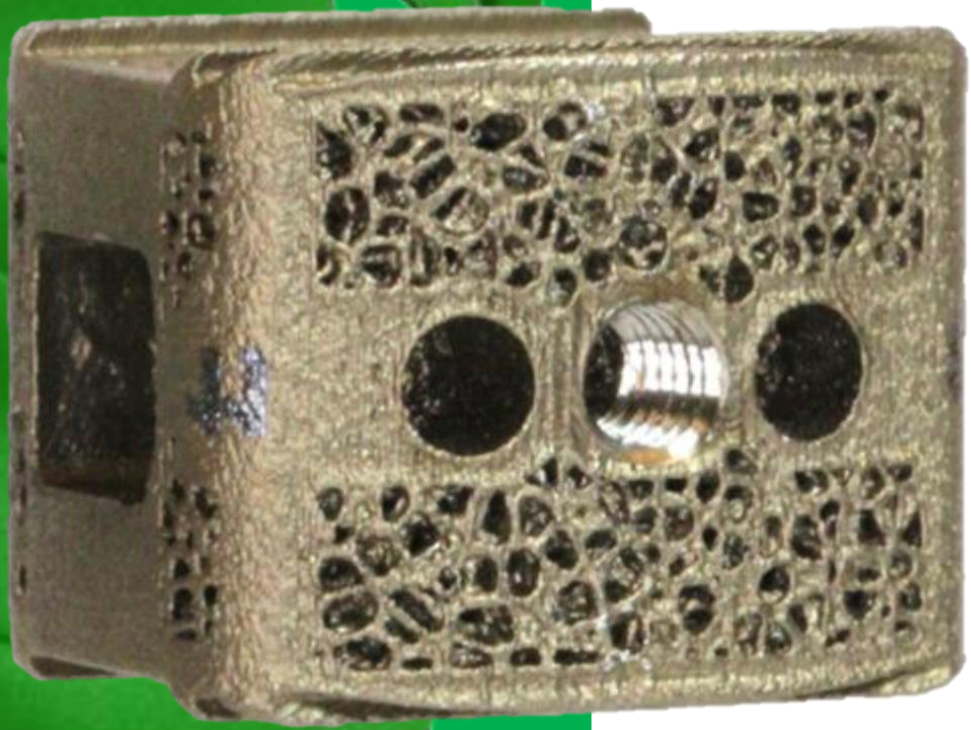
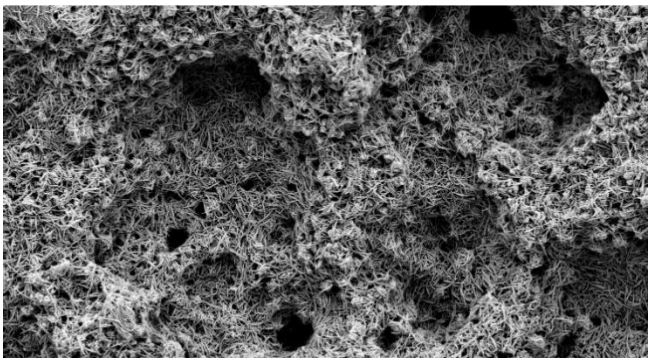
VySpine™

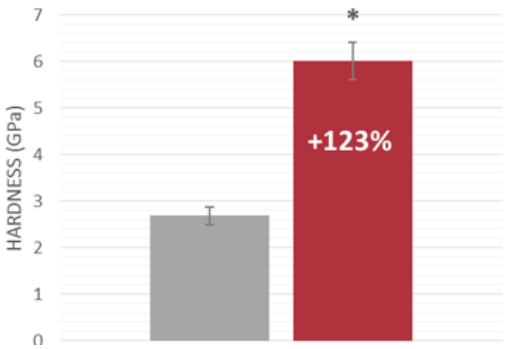
UniVy™
OsteoVy™ Ti
NanoVy™ HA
Cervical IBF System

Surgical Technique



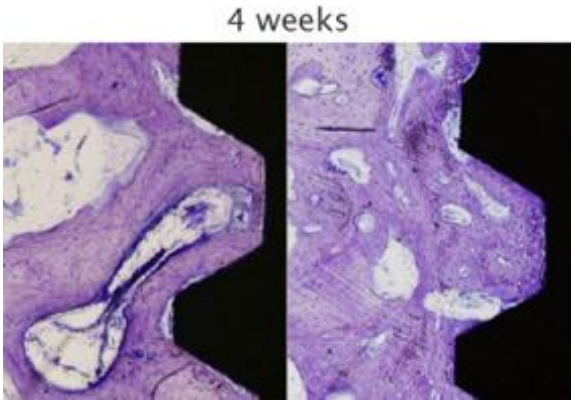
System Overview





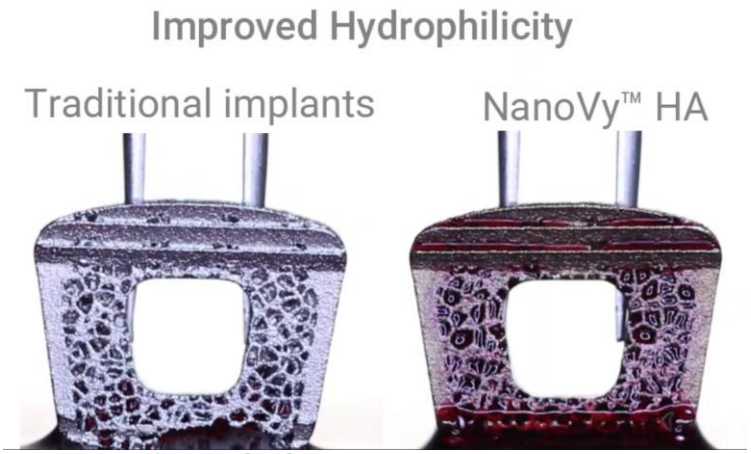
NanoVy™-HA

NanoVy™ HA is a 20 nm thin implant surface modification composed of crystalline hydroxyapatite (HA) particles that through shape, composition, and structure mimic human bone tissue.



Bone Integrity

The new bone tissue quality was significantly enhanced around the titanium implants with NanoVy™ HA by over 120% in comparison to titanium implants without coating. [1]

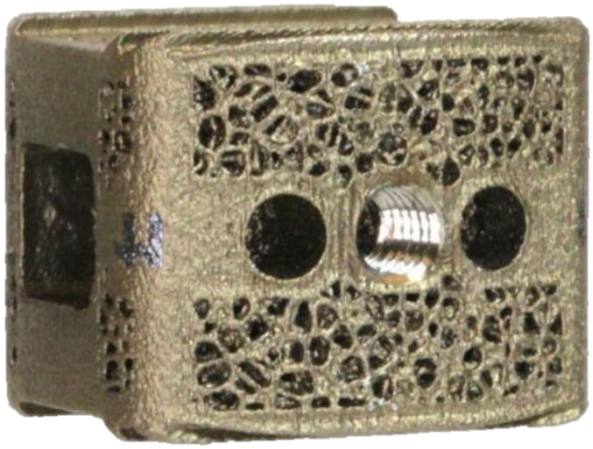


Enhanced Integration

NanoVy™ HA coated titanium implants demonstrate enhanced early bone integration by nearly 37% compared to uncoated titanium implants with the same base surface finish. [2]

Hydrophilicity

NanoVy™ HA coatings enhance the hydrophilicity of titanium implants to help the osseointegration of the implant and the surrounding bone.

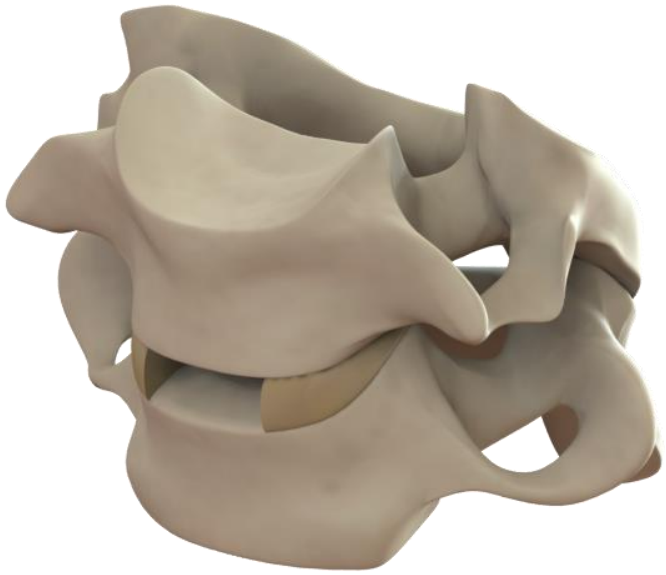


1Jimbo et al. (2012), 'The biological response to three different nanostructures applied on smooth implant surfaces', Clinical Oral Implants Research, vol. 23, no. 6, pp. 706-712 (data is derived from in vivo rabbit studies, these in vivo studies may not be representative of clinical experience)

2 Jimbo et al. (2011), 'Genetic Responses to Nanostructured Calcium-phosphate-coated Implants', Journal of Dental Research, vol. 90, no. 12, pp. 1422-1427 (data is derived from in vivo rabbit studies, these in vivo studies may not be representative of clinical experience)

Step 1. Affected Disc Removal

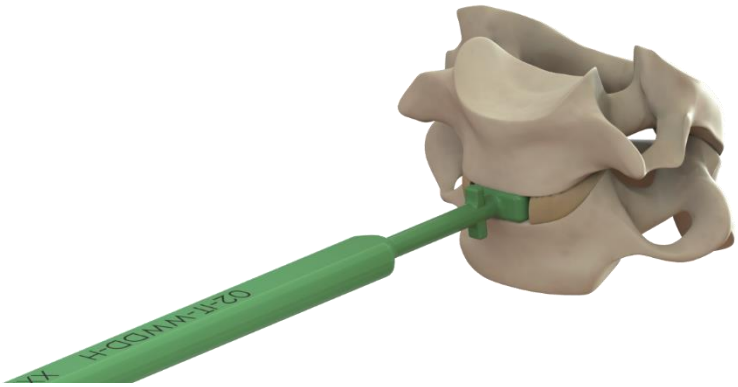
The affected disc is exposed through the traditional anterior, approach that is appropriate for the affected level. Following standard technique, remove the affected portion of the disc. If desired, any removed healthy portion of the vertebral body may be saved and used for bone graft later in the procedure.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

Surgical Technique

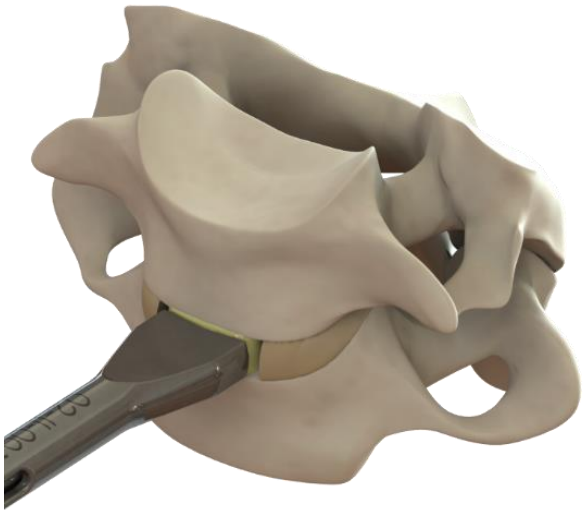


Step 3. Device Selection

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 UniVy™ Cervical IBF device can be placed into the defect. Trials can be utilized to ensure proper implant selection. The Trial footprint should as much of the defect as possible.

Step 4. Attach Inserter

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

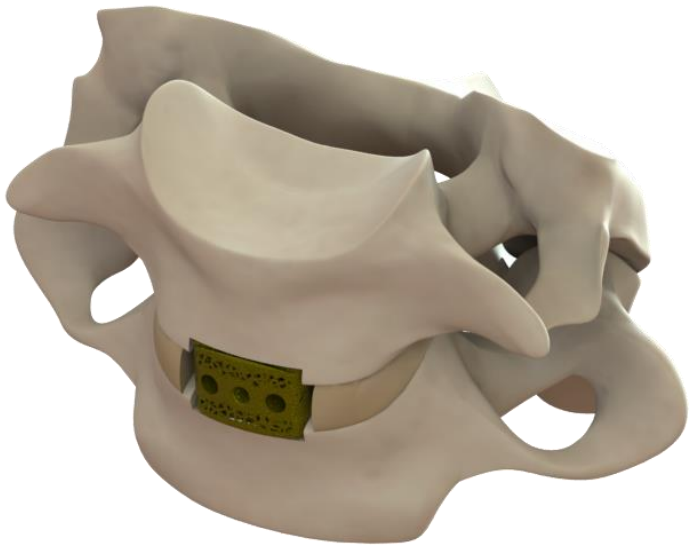
Step 6. Remove Instrumentation

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

Step 7. Supplemental Fixation

If the UniVy™ Cervical 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 UniVy™ Cervical 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 UniVy™ Cervical 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 UniVy™ Cervical 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 UniVy™ Cervical 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 UniVy™ Cervical IBF device are then distracted using the spreader instrument. Then, reattach the inserter to one of the threaded holes on the UniVy™ Cervical IBF construct. Then remove the device from the incision.

UniVy™ IBF Ordering Information

OsteoVy™ Ti NanoVy™ HA Implants

Part Number	Product Size
07-C-1210-0-04-OTH-R	12x10, 0°, 4mm
07-C-1210-0-05-OTH-R	12x10, 0°, 5mm
07-C-1210-0-06-OTH-R	12x10, 0°, 6mm
07-C-1210-0-07-OTH-R	12x10, 0°, 7mm
07-C-1210-0-08-OTH-R	12x10, 0°, 8mm
07-C-1210-0-09-OTH-R	12x10, 0°, 9mm
07-C-1210-0-10-OTH-R	12x10, 0°, 10mm
07-C-1210-0-11-OTH-R	12x10, 0°, 11mm
07-C-1210-7-04-OTH-R	12x10. 7°, 4mm
07-C-1210-7-05-OTH-R	12x10. 7°, 5mm
07-C-1210-7-06-OTH-R	12x10. 7°, 6mm
07-C-1210-7-07-OTH-R	12x10. 7°, 7mm
07-C-1210-7-08-OTH-R	12x10. 7°, 8mm
07-C-1210-7-09-OTH-R	12x10. 7°, 9mm
07-C-1210-7-10-OTH-R	12x10. 7°, 10mm
07-C-1210-7-11-OTH-R	12x10. 7°, 11mm
07-C-1411-0-04-OTH-R	14x11, 0°, 4mm
07-C-1411-0-05-OTH-R	14x11, 0°, 5mm
07-C-1411-0-06-OTH-R	14x11, 0°, 6mm
07-C-1411-0-07-OTH-R	14x11, 0°, 7mm
07-C-1411-0-08-OTH-R	14x11, 0°, 8mm
07-C-1411-0-09-OTH-R	14x11, 0°, 9mm
07-C-1411-0-10-OTH-R	14x11, 0°, 10mm
07-C-1411-0-11-OTH-R	14x11, 0°, 11mm

Part Number	Product Size
07-C-1411-7-04-OTH-R	14x11. 7°, 4mm
07-C-1411-7-05-OTH-R	14x11. 7°, 5mm
07-C-1411-7-06-OTH-R	14x11. 7°, 6mm
07-C-1411-7-07-OTH-R	14x11. 7°, 7mm
07-C-1411-7-08-OTH-R	14x11. 7°, 8mm
07-C-1411-7-09-OTH-R	14x11. 7°, 9mm
07-C-1411-7-10-OTH-R	14x11. 7°, 10mm
07-C-1411-7-11-OTH-R	14x11. 7°, 11mm
07-C-1614-0-04-OTH-R	16x14, 0°, 4mm
07-C-1614-0-05-OTH-R	16x14, 0°, 5mm
07-C-1614-0-06-OTH-R	16x14, 0°, 6mm
07-C-1614-0-07-OTH-R	16x14, 0°, 7mm
07-C-1614-0-08-OTH-R	16x14, 0°, 8mm
07-C-1614-0-09-OTH-R	16x14, 0°, 9mm
07-C-1614-0-10-OTH-R	16x14, 0°, 10mm
07-C-1614-0-11-OTH-R	16x14, 0°, 11mm
07-C-1614-7-04-OTH-R	16x14. 7°, 4mm
07-C-1614-7-05-OTH-R	16x14. 7°, 5mm
07-C-1614-7-06-OTH-R	16x14. 7°, 6mm
07-C-1614-7-07-OTH-R	16x14. 7°, 7mm
07-C-1614-7-08-OTH-R	16x14. 7°, 8mm
07-C-1614-7-09-OTH-R	16x14. 7°, 9mm
07-C-1614-7-10-OTH-R	16x14. 7°, 10mm
07-C-1614-7-11-OTH-R	16x14. 7°, 11mm

UniVy™ IBF Ordering Information

Instrumentation Options

Part Number	Description
02-IN-001	Inserter
02-IR-001	Rasp
02-IT-1210-04	Trial, 12x10, 4mm
02-IT-1210-05	Trial, 12x10, 5mm
02-IT-1210-06	Trial, 12x10, 6mm
02-IT-1210-07	Trial, 12x10, 7mm
02-IT-1210-08	Trial, 12x10, 8mm
02-IT-1210-09	Trial, 12x10, 9mm
02-IT-1210-10	Trial, 12x10, 10mm
02-IT-1210-11	Trial, 12x10, 11mm
02-IT-1411-04	Trial, 14x11, 4mm
02-IT-1411-05	Trial, 14x11, 5mm
02-IT-1411-06	Trial, 14x11, 6mm
02-IT-1411-07	Trial, 14x11, 7mm
02-IT-1411-08	Trial, 14x11, 8mm
02-IT-1411-09	Trial, 14x11, 9mm
02-IT-1411-10	Trial, 14x11, 10mm
02-IT-1411-11	Trial, 14x11, 11mm
02-IT-1614-04	Trial, 16x14, 4mm
02-IT-1614-05	Trial, 16x14, 5mm
02-IT-1614-06	Trial, 16x14, 6mm
02-IT-1614-07	Trial, 16x14, 7mm
02-IT-1614-08	Trial, 16x14, 8mm
02-IT-1614-09	Trial, 16x14, 9mm
02-IT-1614-10	Trial, 16x14, 10mm
02-IT-1614-11	Trial, 16x14, 11mm

Indications:

The UniVy™ OsteoVy™ Cervical IBF System 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. One device may be used per intervertebral space. The implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.
The UniVy™ OsteoVy™ Cervical IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical degenerate disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The UniVy™ OsteoVy™ Cervical IBF System is to be used in patients who have six weeks of non-operative treatment.

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

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