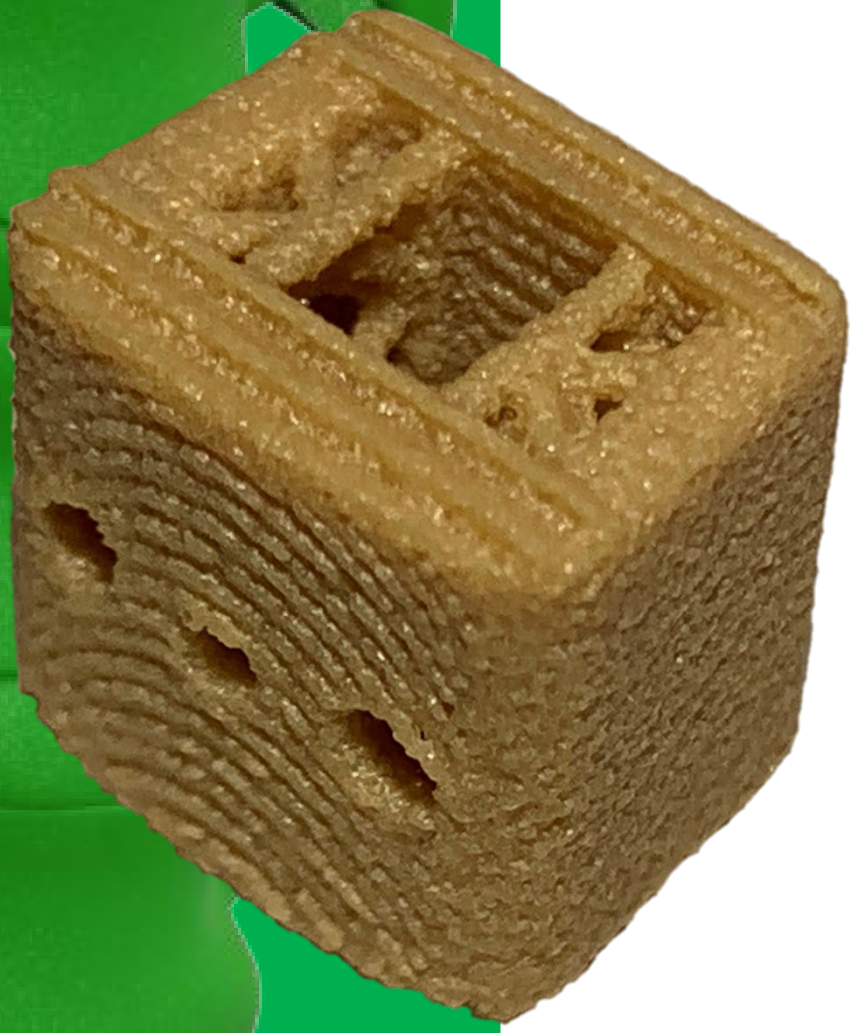
VySpine™

ClariVy™ OsteoVy™ PEKK Cervical IBF System

Surgical Technique



System Overview

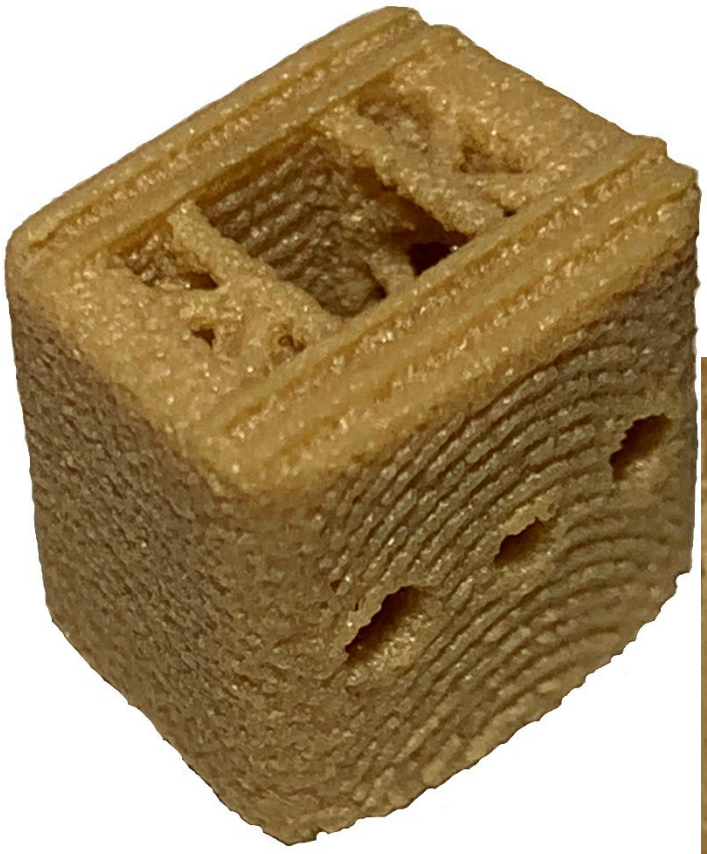
Description:

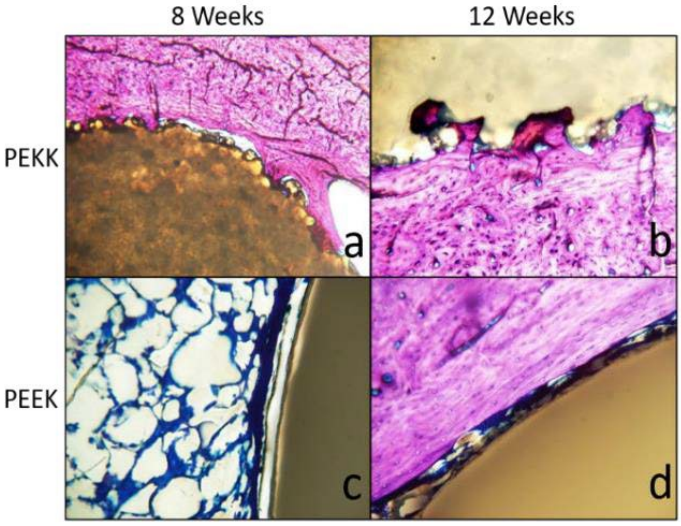
The ClariVy™ OsteoVy™ PEKK Cervical IBF System is intended for use at one level in the Cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

The ClariVy™ OsteoVy™ PEKK Cervical IBF device consists of intervertebral spacers of various shapes, sizes, and angulation. Each ClariVy™ OsteoVy™ PEKK Cervical IBF has anti-migration teeth on the superior and inferior surfaces to engage the adjacent vertebral body. The ClariVy™ OsteoVy™ PEKK Cervical IBF device is made of medical grade OXPEKK IG100 as described by ASTM Standard F-2820. These components also have radiographic markers made of Tantalum embedded in the PEKK material. Additionally, the ClariVy™ OsteoVy™ PEKK Cervical IBF-S System has components made from Titanium Alloy 6Al-4V as described by ASTM Standard F136. The ClariVy™ OsteoVy™ PEKK Cervical IBF has an integrated porous lattice structure.

The ClariVy™ OsteoVy™ PEKK Cervical 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 ClariVy™ OsteoVy™ PEKK Cervical IBF System components. As with all orthopedic implants, in no case may the implants be re-used.





Enhanced Osseointegration

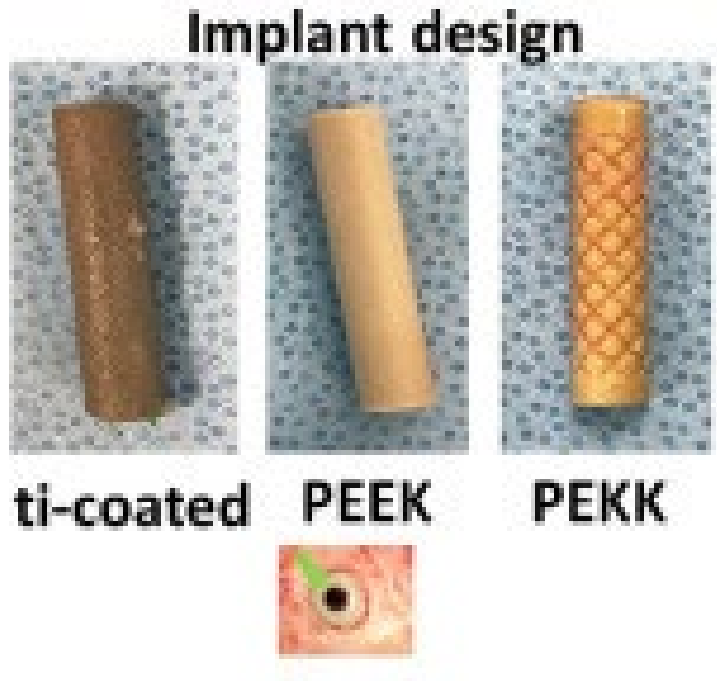
The *in vivo* bone response to OsteoVy™ PEKK compared to machined PEEK in a rabbit femoral model at 8 and 12 weeks demonstrated bone growing onto the surface of a PEKK rod implant and into the peaks and pits of the rough surface. However, fibrous tissue (blue) was noted surrounding a PEEK rod implant

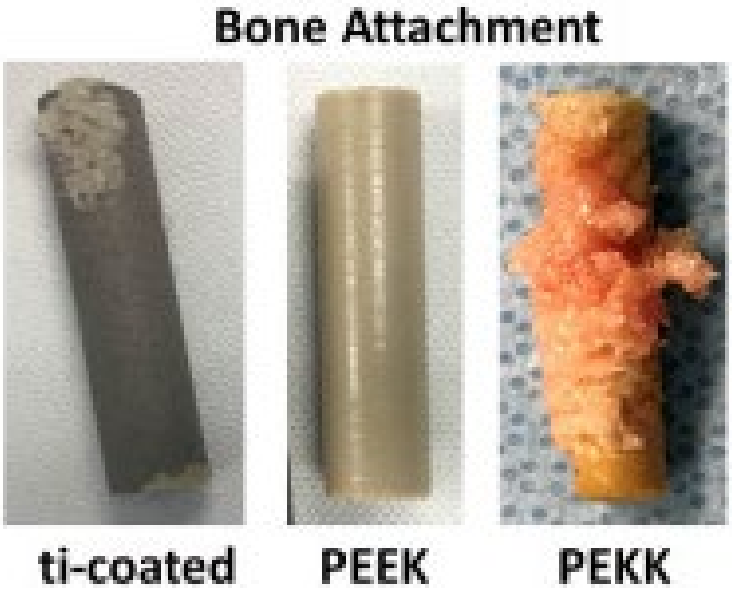
OPM Internal Study with Yale University – 2014. Data on file at OPM. (Note: OsteoFab PEKK is another brand name for OsteoVy™ PEKK)

Better Bony Ongrowth

OsteoVy™ PEKK is manufactured from biocompatible OXPEKK® polymer, which has been evaluated for osseointegration through in-vitro and in-vivo studies utilizing animal models, yielded superior results. PEKK implants demonstrated bone ingrowth, no radiographic interference, no fibrotic tissue membrane formation, significant increase in bony apposition over time, and significantly higher push-out strength compared to standard PEEK. The PEKK implant displayed bone growth characteristics comparable to Ti-coated PEEK with significant improvements in implant integrity and radiographic properties.

Cheng, B., Jaffee, S., Averick, S., Swink, I., Horvath, S., & Zhukauskas, R. (2020). A comparative study of three biomaterials in an ovine bone defect model. The Spine Journal, 20(3), 457-464

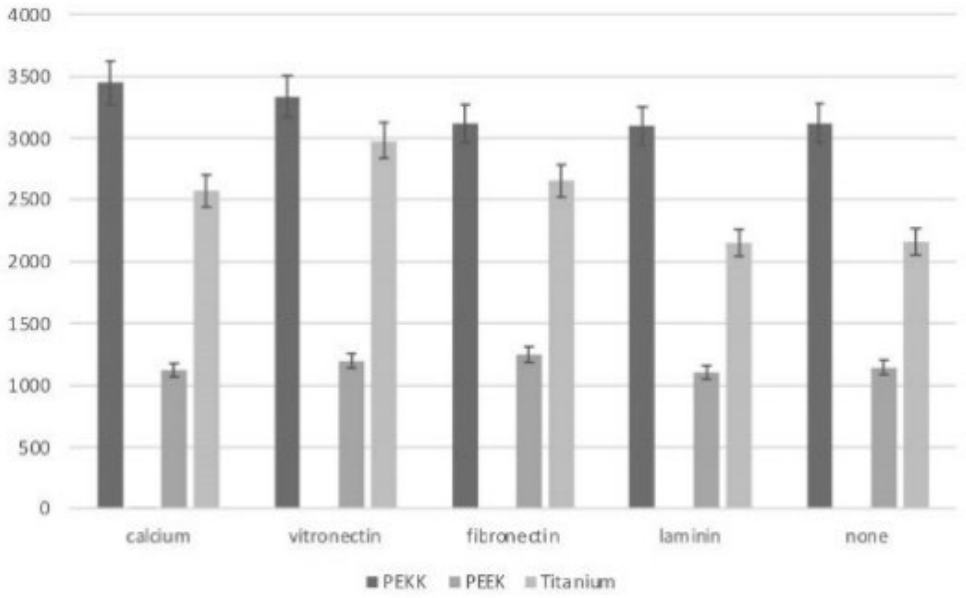




Improved Bone Density

OsteoVy™ PEKK material demonstrated greater osteoblast adhesion, calcium deposition, and select protein absorption. These are the main mechanisms of action which promoted osteoblast density on the implant surface compared to PEEK and Titanium.

OsteoFab® Surface Properties:Bacteria Inhibition and Osteoblast Functions. Presented by Thomas Webster, Ph.D., Northeastern University October 19, 2020.



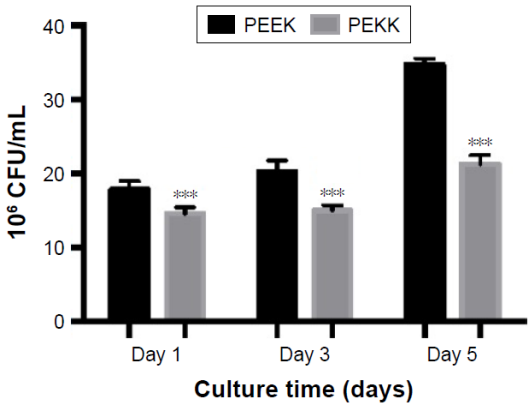


Figure 3 *Staphylococcus epidermidis* on different samples after 1 day, 3 days, and 5 days culture.

Anti-Microbial Properties

Results of *in vitro* study indicated decreased adhesion and growth of P. aeruginosa and S. epidermidis on nanorough PEKK surface compared with conventional PEEK surfaces.

Wang, M., Bhardwaj, G., & Webster, T. (2017). Antibacterial properties of PEKK for orthopedic applications. International Journal Of Nanomedicine, Volume 12, 6471-6476

Hydrophilicity

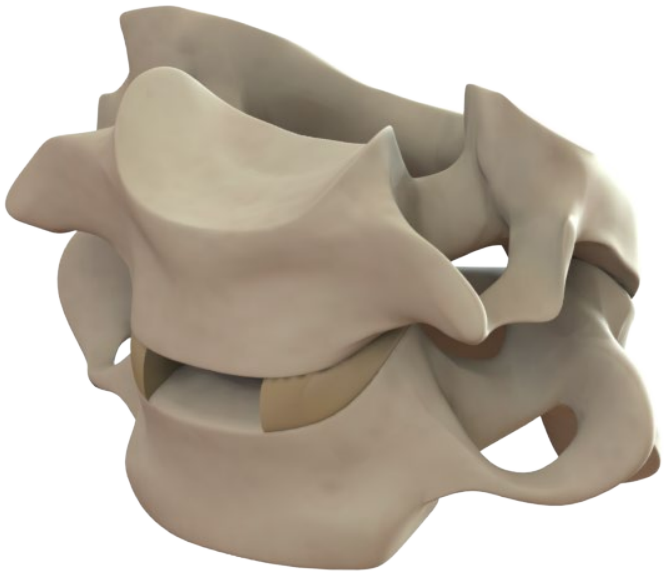
OsteoVy™ PEKK material has demonstrated extraordinary vertical fluid conduction through the rough outer surface.

OPM Internal Study with Yale University – 2014. Data on file at OPM. (Note: OsteoFab PEKK is another brand name for OsteoVy™ PEKK)

ClariVy™ Surgical Technique

Step 1. Affected Disc Removal

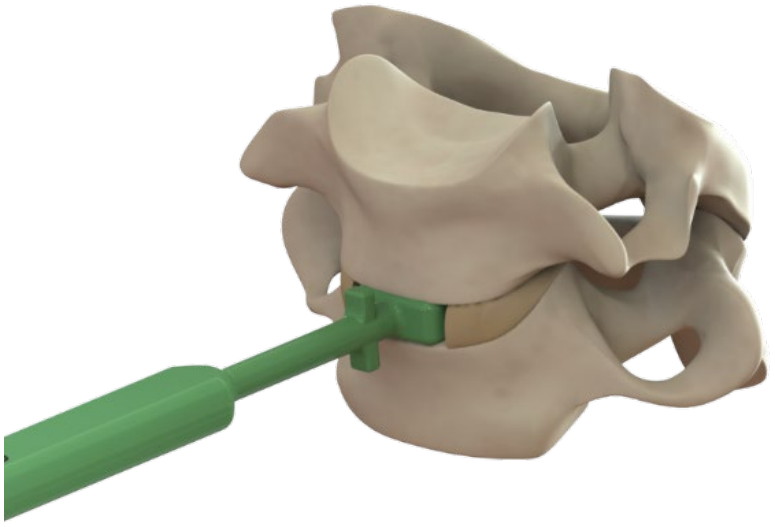
The affected disc is exposed through the traditional anterior approach that is appropriate for the affected level. Following standard technique, remove the affected portion of the disc. If desired, any removed healthy portion of the vertebral body may be saved and used for bone graft later in the procedure.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

ClariVy™ 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 ClariVy™ Cervical 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 ClariVy™ 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.

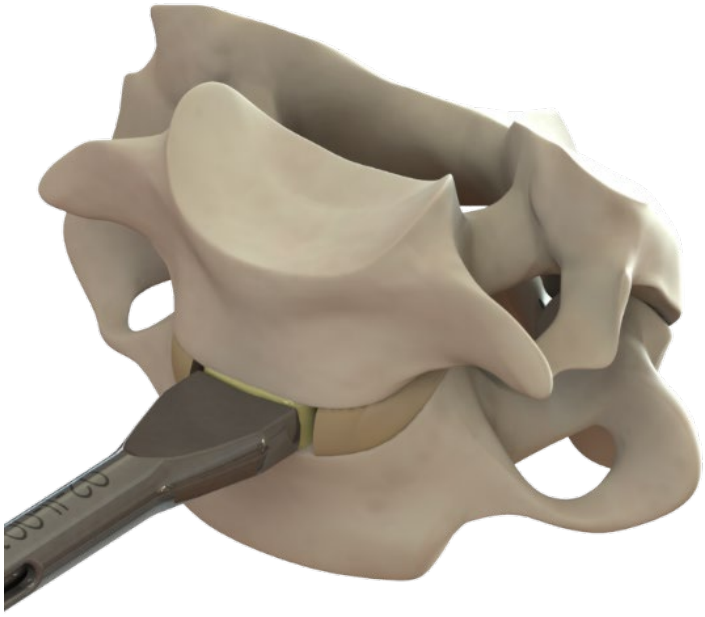
Step 5. Implant Placement

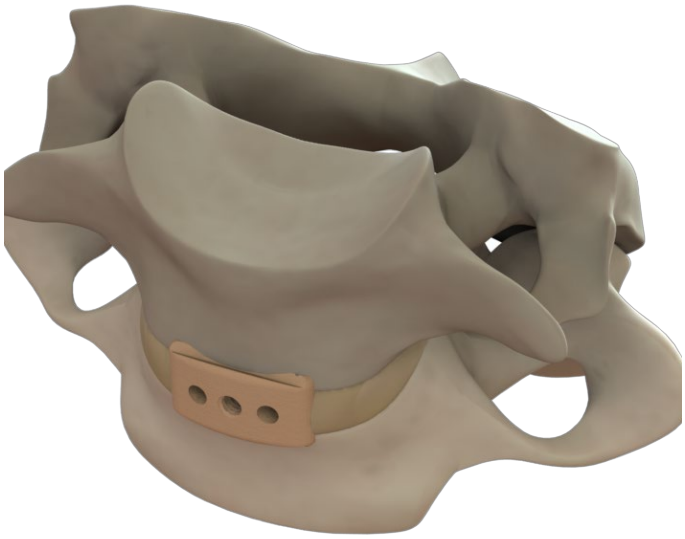
With the ClariVy™ Cervical IBF implant attached to the Inserter, place the device into the defect. Check the placement of the ClariVy™ Cervical IBF using x-ray or fluoroscope to ensure proper placement. The placement of the device should be confirmed, and the position modified if necessary. Detach the Inserter from ClariVy™ Cervical IBF implant. Additional graft material may be placed around the device after insertion as well.

Step 6. Supplemental Fixation

If the ClariVy™ 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 ClariVy™ Cervical IBF device. Once the anterior supplemental fixation has been properly implanted, the wound should be closed using standard technique.

If the ClariVy™ 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 ClariVy™ 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

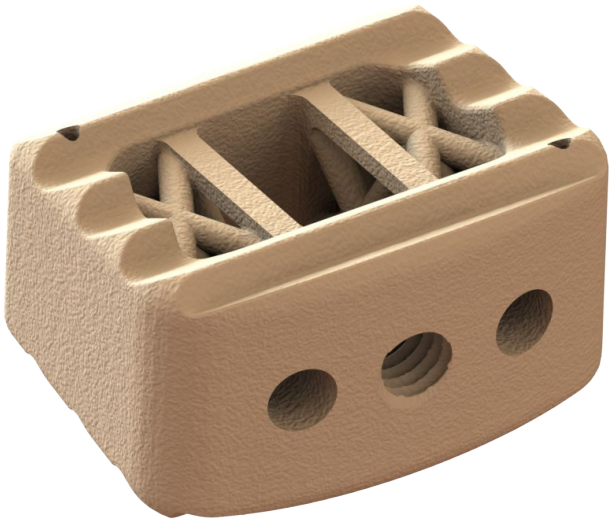
To remove the ClariVy™ Cervical IBF device, first the supplemental fixation must be removed. Reasons for removal can be found in the "Possible Adverse Effects" section of the Package Insert. The vertebral bodies adjacent to the ClariVy™ Cervical IBF device are then distracted using a spreader instrument.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

ClariVy™ IBF Ordering Information

OsteoVy™ PEKK Implants

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

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



ClariVy™ 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 ClariVy™ 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 ClariVy™ 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 Vy Spine™ ClariVy™ 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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Nov 2023