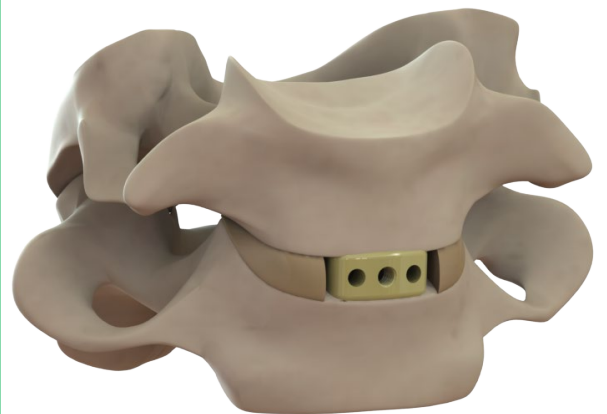


ClariVy™
ClariVy™-S
NanoVy™ Ti
Cervical IBF
System

**Surgical
Technique**



System Overview

Description:

The ClariVy™ 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™ Cervical IBF device consists of intervertebral spacers of various shapes, sizes, and angulation. Each ClariVy™ Cervical IBF has anti-migration teeth on the superior and inferior surfaces to engage the adjacent vertebral body. The ClariVy™ Cervical IBF System implant components are made of medical grade PEEK-Optima LT1 described by ASTM Standard F-2026 and PEEK-Optima HA-Enhanced. The ClariVy™ NanoVy™ Ti Cervical IBF device is made of medical grade PEEK-Optima LT1 described by ASTM Standard F-2026 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. Additionally, the ClariVy™ Cervical IBF-S System has components made from Titanium Alloy 6Al-4V as described by ASTM Standard F136. The ClariVy™ 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 Vy Spine™ ClariVy™ Cervical IBF System components. As with all orthopedic implants, in no case may the implants be re-used.

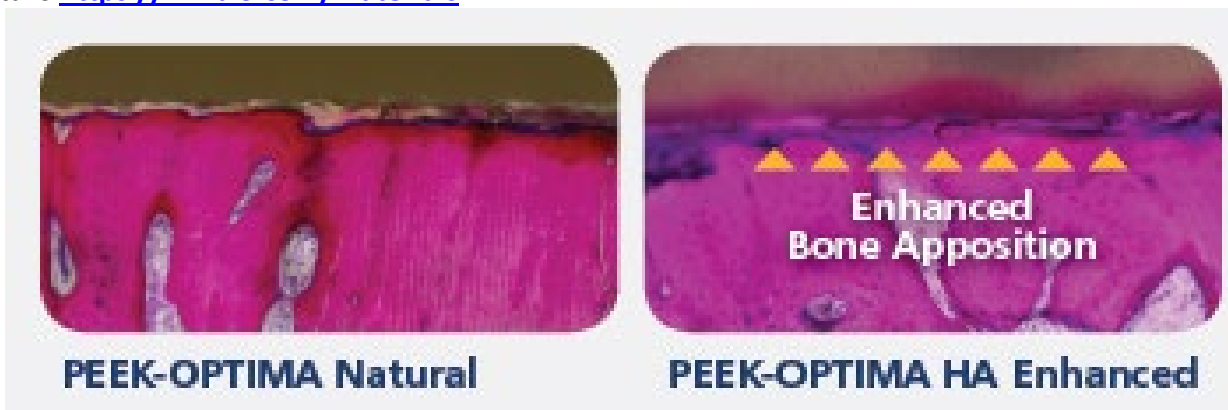


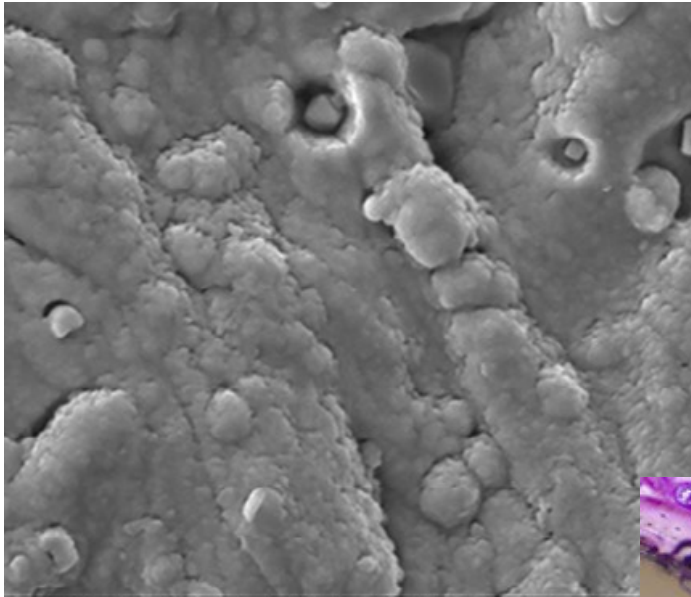
PEEK-OPTIMA™ HA Enhanced is a material enhancement in spinal device technology. Hydroxyapatite (HA), a well-known Osteoconductive material, is fully integrated (not coated) with PEEK-OPTIMA Natural, making it available on all surfaces of a device. This results in a strong, versatile and highly effective biomaterial that offers a superior solution for bone apposition.

The main benefits of PEEK-OPTIMA™ HA Enhanced include all the benefits of PEEK-OPTIMA Natural plus Hydroxyapatite (HA), to encourage bone in-growth.

- HA is integrated, not coated, making it available on all surfaces of a finished device.
- Enhances bone apposition
- Fully integrated HA compound eliminates time and expense of applying a surface coating

PEEK Optima-HA Enhanced is a product of InVibio Biomaterial Solutions. Please visit InVibio website for more details <https://invibio.com/materials>



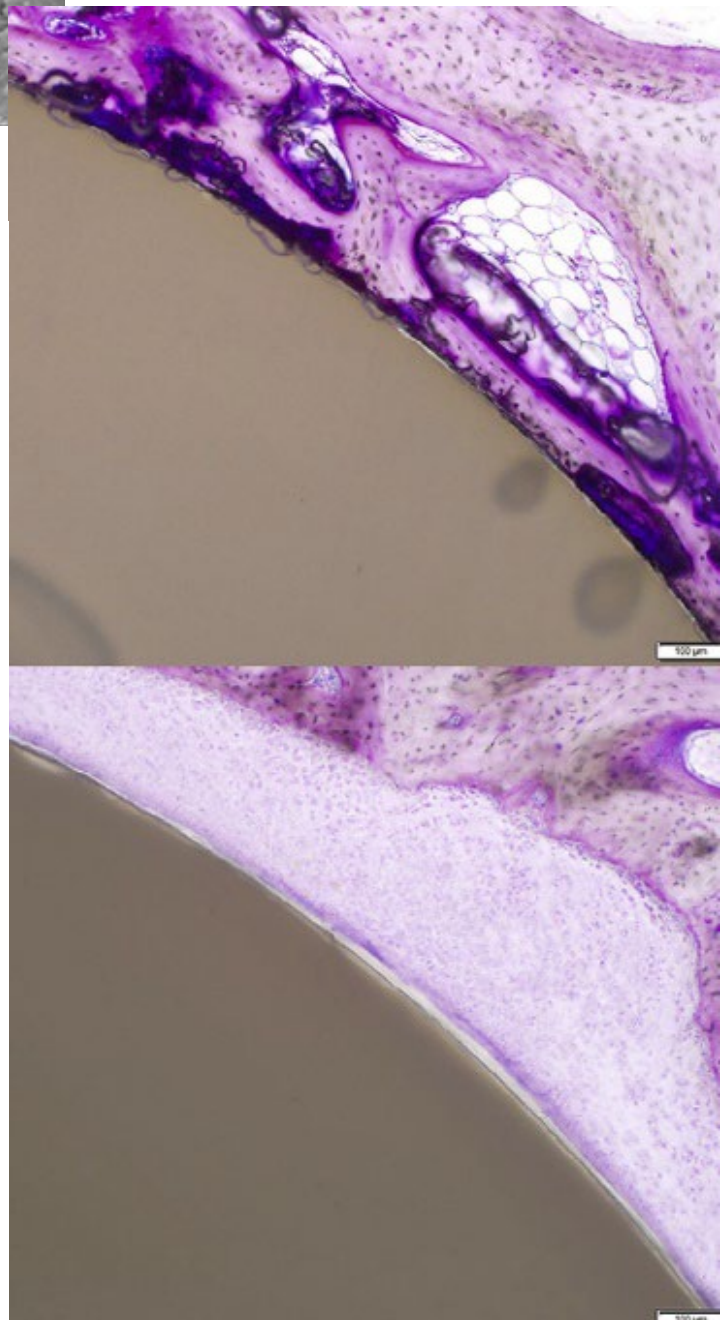


NanoVy™ Ti

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).



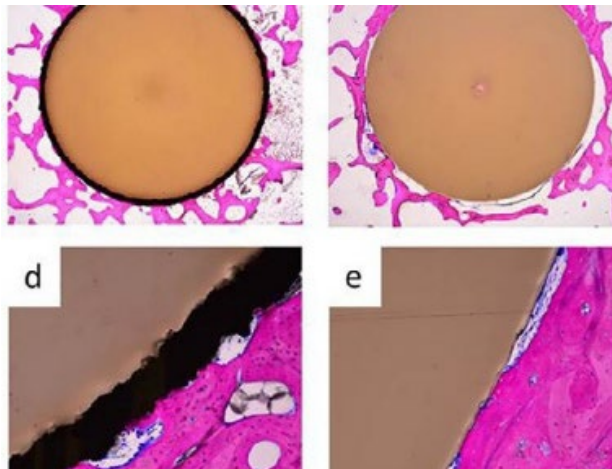
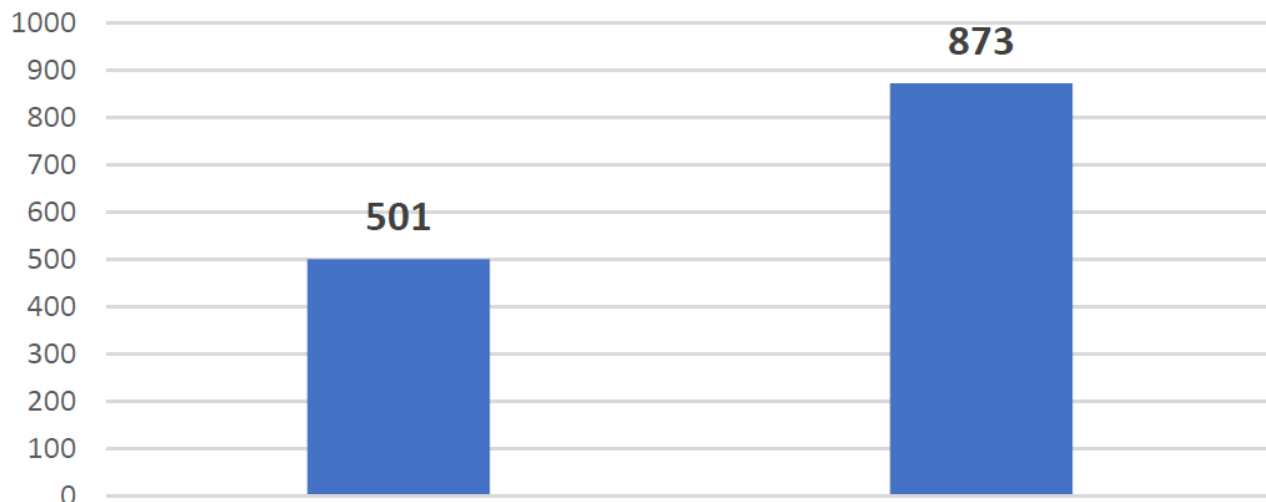
Spine J_18_(2018)_ Walsh B et al, The in vivo response to a novel Ti coating compared with PEEK-evaluation of the periphery and inner surfaces of an implant, p1237, ©2018. (Note Nanometalene is another brand name for NanoVy Ti, data based on in vivo studies).



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.

Expulsion Testing - Ultimate Force (N)

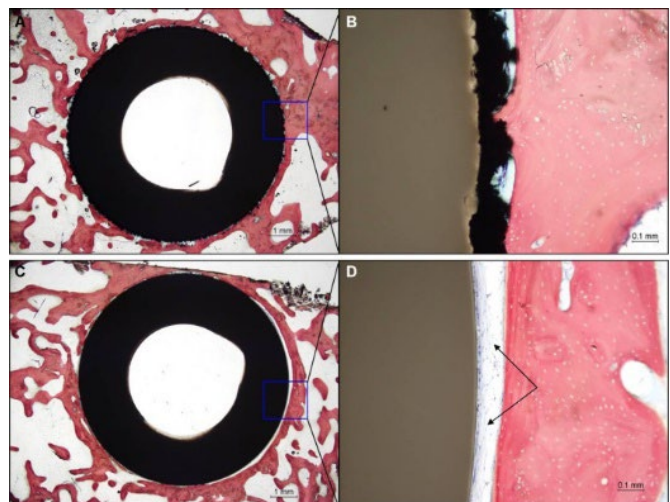


NanoVy™ Ti resists delamination

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.



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.



Step 3. Device Selection

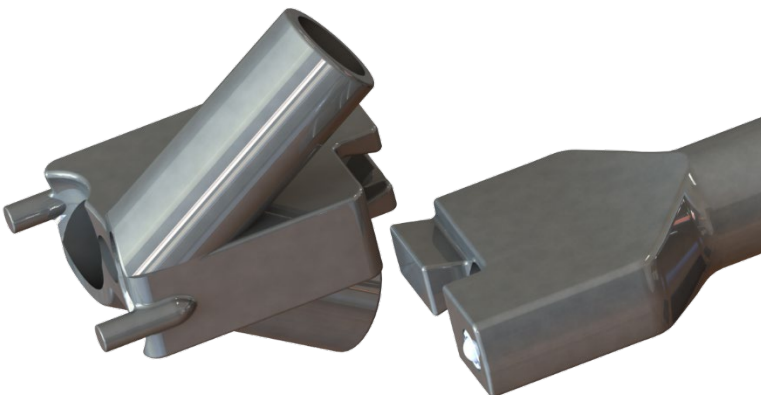
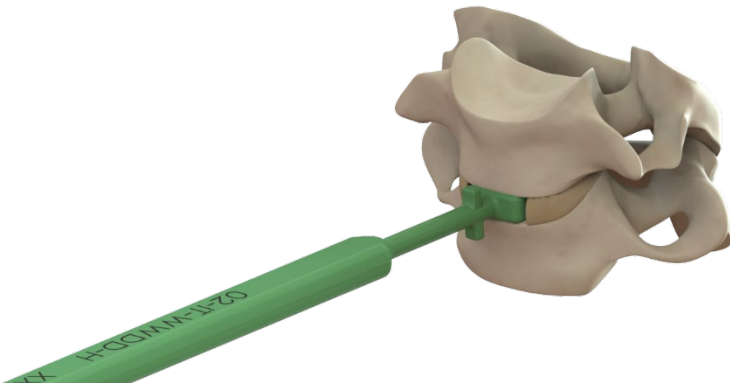
Once the dissection and restoration have been achieved, it is important to ensure that enough of the affected disc has been removed such that the ClariVy™ Cervical IBF device can be placed into the defect. Trials can be utilized to ensure proper implant selection. The Trial footprint should as much of 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 4a. Drill Guide (Only if using ClariVy™ Cervical IBF-S)

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



ClariVy™ Surgical Technique

Step 4b. Drill Guide (Only if using ClariVy™ Cervical IBF-S)

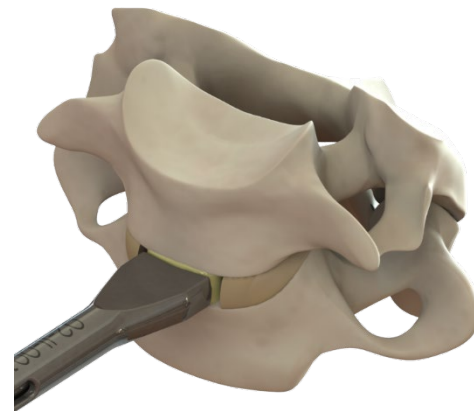
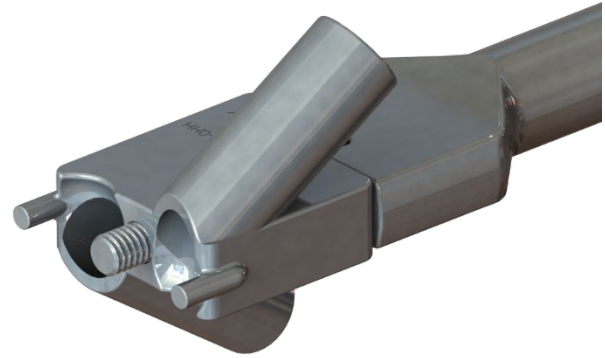
With the Drill Guide secure on the IBF-S Inserter, reattach the central threaded shaft to the IBF-S Inserter, through the Drill Guide.

Step 4c. Attach IBF-S Inserter (Only if using ClariVy™ Cervical IBF-S)

Thread the IBF-S Inserter Drill Guide assembly onto the ClariVy™ Cervical 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.

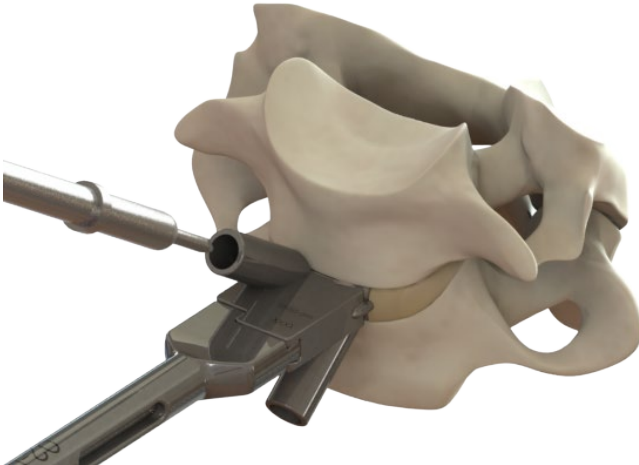
Step 5. Implant Placement

With the 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.

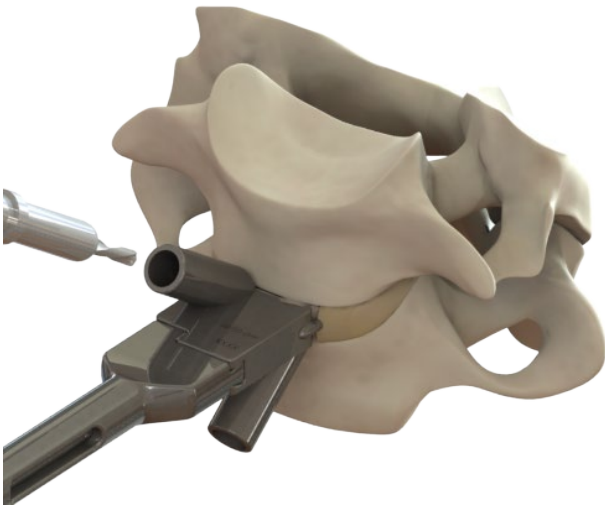


Step 6. Awl (Only if using ClariVy™ Cervical IBF-S)

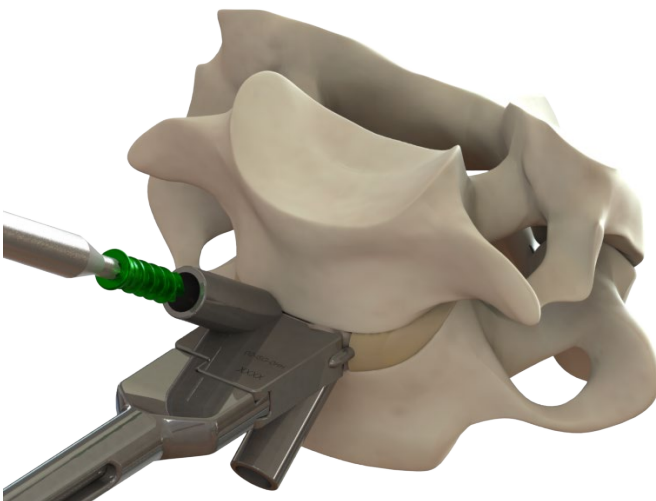
Break the cortical layer of bone using the awl, through the drill guide. Repeat for the other side.

**Step 7. Drill (Only if using ClariVy™ Cervical IBF-S)**

Although all of the Screws in the ClariVy™ Cervical 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 ClariVy™ Cervical IBF-S)**

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



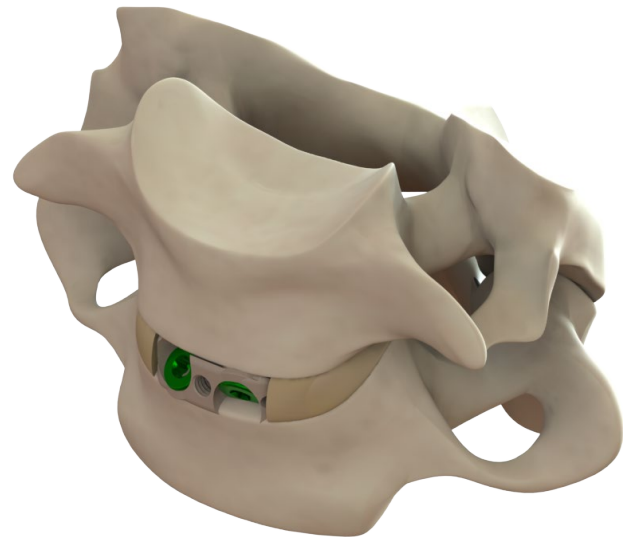
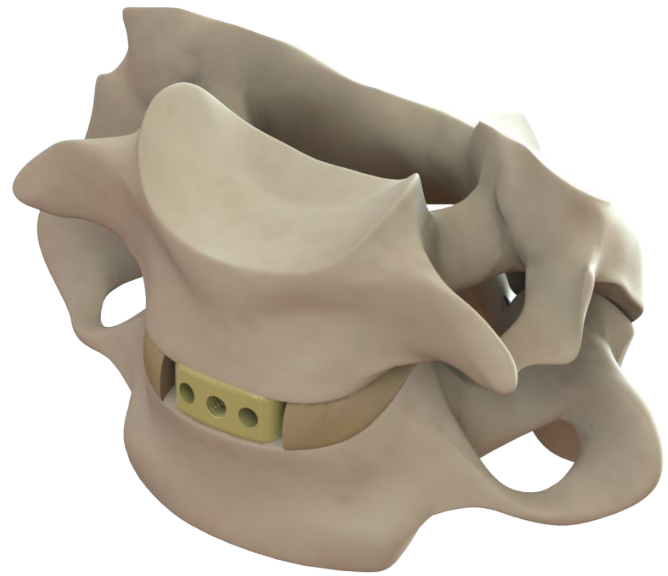
Step 9. Remove Instrumentation

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

Step 10. 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. 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 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 the spreader instrument. If the ClariVy™ Cervical 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 ClariVy™ Cervical IBF construct. Then remove the device from the incision.



ClariVy™ IBF Ordering Information

PEEK Optima™ Implants

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

02-C-1210-7-04-PE-R	12x10, 7°, 4mm
02-C-1210-7-05-PE-R	12x10, 7°, 5mm
02-C-1210-7-06-PE-R	12x10, 7°, 6mm
02-C-1210-7-07-PE-R	12x10, 7°, 7mm
02-C-1210-7-08-PE-R	12x10, 7°, 8mm
02-C-1210-7-09-PE-R	12x10, 7°, 9mm
02-C-1210-7-10-PE-R	12x10, 7°, 10mm
02-C-1210-7-11-PE-R	12x10, 7°, 11mm

02-C-1411-0-04-PE-R	14x11, 0°, 4mm
02-C-1411-0-05-PE-R	14x11, 0°, 5mm
02-C-1411-0-06-PE-R	14x11, 0°, 6mm
02-C-1411-0-07-PE-R	14x11, 0°, 7mm
02-C-1411-0-08-PE-R	14x11, 0°, 8mm
02-C-1411-0-09-PE-R	14x11, 0°, 9mm
02-C-1411-0-10-PE-R	14x11, 0°, 10mm
02-C-1411-0-11-PE-R	14x11, 0°, 11mm

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

02-C-1614-0-04-PE-R	16x14, 0°, 4mm
02-C-1614-0-05-PE-R	16x14, 0°, 5mm
02-C-1614-0-06-PE-R	16x14, 0°, 6mm
02-C-1614-0-07-PE-R	16x14, 0°, 7mm
02-C-1614-0-08-PE-R	16x14, 0°, 8mm
02-C-1614-0-09-PE-R	16x14, 0°, 9mm
02-C-1614-0-10-PE-R	16x14, 0°, 10mm
02-C-1614-0-11-PE-R	16x14, 0°, 11mm

02-C-1614-7-04-PE-R	16x14, 7°, 4mm
02-C-1614-7-05-PE-R	16x14, 7°, 5mm
02-C-1614-7-06-PE-R	16x14, 7°, 6mm
02-C-1614-7-07-PE-R	16x14, 7°, 7mm
02-C-1614-7-08-PE-R	16x14, 7°, 8mm
02-C-1614-7-09-PE-R	16x14, 7°, 9mm
02-C-1614-7-10-PE-R	16x14, 7°, 10mm
02-C-1614-7-11-PE-R	16x14, 7°, 11mm



ClariVy™ IBF Ordering Information

PEEK Optima™ HA Enhanced Implants

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

02-C-1210-7-04-PH-R	12x10, 7°, 4mm
02-C-1210-7-05-PH-R	12x10, 7°, 5mm
02-C-1210-7-06-PH-R	12x10, 7°, 6mm
02-C-1210-7-07-PH-R	12x10, 7°, 7mm
02-C-1210-7-08-PH-R	12x10, 7°, 8mm
02-C-1210-7-09-PH-R	12x10, 7°, 9mm
02-C-1210-7-10-PH-R	12x10, 7°, 10mm
02-C-1210-7-11-PH-R	12x10, 7°, 11mm

02-C-1411-0-04-PH-R	14x11, 0°, 4mm
02-C-1411-0-05-PH-R	14x11, 0°, 5mm
02-C-1411-0-06-PH-R	14x11, 0°, 6mm
02-C-1411-0-07-PH-R	14x11, 0°, 7mm
02-C-1411-0-08-PH-R	14x11, 0°, 8mm
02-C-1411-0-09-PH-R	14x11, 0°, 9mm
02-C-1411-0-10-PH-R	14x11, 0°, 10mm
02-C-1411-0-11-PH-R	14x11, 0°, 11mm

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

02-C-1614-0-04-PH-R	16x14, 0°, 4mm
02-C-1614-0-05-PH-R	16x14, 0°, 5mm
02-C-1614-0-06-PH-R	16x14, 0°, 6mm
02-C-1614-0-07-PH-R	16x14, 0°, 7mm
02-C-1614-0-08-PH-R	16x14, 0°, 8mm
02-C-1614-0-09-PH-R	16x14, 0°, 9mm
02-C-1614-0-10-PH-R	16x14, 0°, 10mm
02-C-1614-0-11-PH-R	16x14, 0°, 11mm

02-C-1614-7-04-PH-R	16x14, 7°, 4mm
02-C-1614-7-05-PH-R	16x14, 7°, 5mm
02-C-1614-7-06-PH-R	16x14, 7°, 6mm
02-C-1614-7-07-PH-R	16x14, 7°, 7mm
02-C-1614-7-08-PH-R	16x14, 7°, 8mm
02-C-1614-7-09-PH-R	16x14, 7°, 9mm
02-C-1614-7-10-PH-R	16x14, 7°, 10mm
02-C-1614-7-11-PH-R	16x14, 7°, 11mm



ClariVy™ IBF Ordering Information

PEEK Optima™ NanoVy™ Ti Implants

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

02-C-1210-7-04-PET-R	12x10. 7°, 4mm
02-C-1210-7-05-PET-R	12x10. 7°, 5mm
02-C-1210-7-06-PET-R	12x10. 7°, 6mm
02-C-1210-7-07-PET-R	12x10. 7°, 7mm
02-C-1210-7-08-PET-R	12x10. 7°, 8mm
02-C-1210-7-09-PET-R	12x10. 7°, 9mm
02-C-1210-7-10-PET-R	12x10. 7°, 10mm
02-C-1210-7-11-PET-R	12x10. 7°, 11mm

02-C-1411-0-04-PET-R	14x11, 0°, 4mm
02-C-1411-0-05-PET-R	14x11, 0°, 5mm
02-C-1411-0-06-PET-R	14x11, 0°, 6mm
02-C-1411-0-07-PET-R	14x11, 0°, 7mm
02-C-1411-0-08-PET-R	14x11, 0°, 8mm
02-C-1411-0-09-PET-R	14x11, 0°, 9mm
02-C-1411-0-10-PET-R	14x11, 0°, 10mm
02-C-1411-0-11-PET-R	14x11, 0°, 11mm

Part Number	Product Size
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02-C-1411-7-05-PET-R	14x11. 7°, 5mm
02-C-1411-7-06-PET-R	14x11. 7°, 6mm
02-C-1411-7-07-PET-R	14x11. 7°, 7mm
02-C-1411-7-08-PET-R	14x11. 7°, 8mm
02-C-1411-7-09-PET-R	14x11. 7°, 9mm
02-C-1411-7-10-PET-R	14x11. 7°, 10mm
02-C-1411-7-11-PET-R	14x11. 7°, 11mm

02-C-1614-0-04-PET-R	16x14, 0°, 4mm
02-C-1614-0-05-PET-R	16x14, 0°, 5mm
02-C-1614-0-06-PET-R	16x14, 0°, 6mm
02-C-1614-0-07-PET-R	16x14, 0°, 7mm
02-C-1614-0-08-PET-R	16x14, 0°, 8mm
02-C-1614-0-09-PET-R	16x14, 0°, 9mm
02-C-1614-0-10-PET-R	16x14, 0°, 10mm
02-C-1614-0-11-PET-R	16x14, 0°, 11mm

02-C-1614-7-04-PET-R	16x14. 7°, 4mm
02-C-1614-7-05-PET-R	16x14. 7°, 5mm
02-C-1614-7-06-PET-R	16x14. 7°, 6mm
02-C-1614-7-07-PET-R	16x14. 7°, 7mm
02-C-1614-7-08-PET-R	16x14. 7°, 8mm
02-C-1614-7-09-PET-R	16x14. 7°, 9mm
02-C-1614-7-10-PET-R	16x14. 7°, 10mm
02-C-1614-7-11-PET-R	16x14. 7°, 11mm



ClariVy™ IBF-S Ordering Information

PEEK Optima™ Implants

Part Number	Product Size
02-CS-1411-0-04-PE-R	14x11, 0°, 4mm
02-CS-1411-0-05-PE-R	14x11, 0°, 5mm
02-CS-1411-0-06-PE-R	14x11, 0°, 6mm
02-CS-1411-0-07-PE-R	14x11, 0°, 7mm
02-CS-1411-0-08-PE-R	14x11, 0°, 8mm
02-CS-1411-0-09-PE-R	14x11, 0°, 9mm
02-CS-1411-0-10-PE-R	14x11, 0°, 10mm
02-CS-1411-0-11-PE-R	14x11, 0°, 11mm
02-CS-1411-7-04-PE-R	14x11. 7°, 4mm
02-CS-1411-7-05-PE-R	14x11. 7°, 5mm
02-CS-1411-7-06-PE-R	14x11. 7°, 6mm
02-CS-1411-7-07-PE-R	14x11. 7°, 7mm
02-CS-1411-7-08-PE-R	14x11. 7°, 8mm
02-CS-1411-7-09-PE-R	14x11. 7°, 9mm
02-CS-1411-7-10-PE-R	14x11. 7°, 10mm
02-CS-1411-7-11-PE-R	14x11. 7°, 11mm

Part Number	Product Size
02-CS-1614-0-04-PE-R	16x14, 0°, 4mm
02-CS-1614-0-05-PE-R	16x14, 0°, 5mm
02-CS-1614-0-06-PE-R	16x14, 0°, 6mm
02-CS-1614-0-07-PE-R	16x14, 0°, 7mm
02-CS-1614-0-08-PE-R	16x14, 0°, 8mm
02-CS-1614-0-09-PE-R	16x14, 0°, 9mm
02-CS-1614-0-10-PE-R	16x14, 0°, 10mm
02-CS-1614-0-11-PE-R	16x14, 0°, 11mm
02-CS-1614-7-04-PE-R	16x14. 7°, 4mm
02-CS-1614-7-05-PE-R	16x14. 7°, 5mm
02-CS-1614-7-06-PE-R	16x14. 7°, 6mm
02-CS-1614-7-07-PE-R	16x14. 7°, 7mm
02-CS-1614-7-08-PE-R	16x14. 7°, 8mm
02-CS-1614-7-09-PE-R	16x14. 7°, 9mm
02-CS-1614-7-10-PE-R	16x14. 7°, 10mm
02-CS-1614-7-11-PE-R	16x14. 7°, 11mm



ClariVy™ IBF-S Ordering Information

PEEK Optima™ HA Enhanced Implants

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

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



ClariVy™ IBF-S Ordering Information

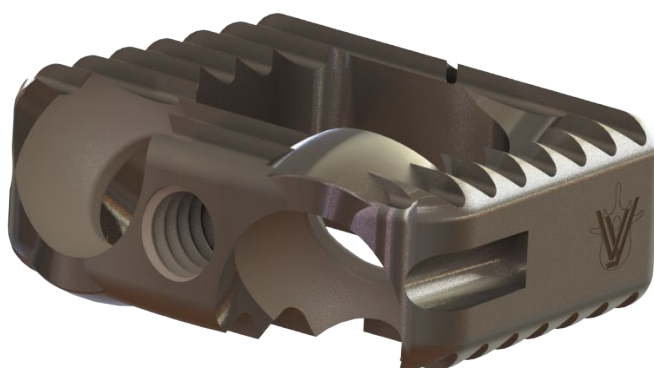
PEEK Optima™ NanoVy™ Ti Implants

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

02-CS-1411-7-04-PET-R	14x11. 7°, 4mm
02-CS-1411-7-05-PET-R	14x11. 7°, 5mm
02-CS-1411-7-06-PET-R	14x11. 7°, 6mm
02-CS-1411-7-07-PET-R	14x11. 7°, 7mm
02-CS-1411-7-08-PET-R	14x11. 7°, 8mm
02-CS-1411-7-09-PET-R	14x11. 7°, 9mm
02-CS-1411-7-10-PET-R	14x11. 7°, 10mm
02-CS-1411-7-11-PET-R	14x11. 7°, 11mm

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

02-CS-1614-7-04-PET-R	16x14. 7°, 4mm
02-CS-1614-7-05-PET-R	16x14. 7°, 5mm
02-CS-1614-7-06-PET-R	16x14. 7°, 6mm
02-CS-1614-7-07-PET-R	16x14. 7°, 7mm
02-CS-1614-7-08-PET-R	16x14. 7°, 8mm
02-CS-1614-7-09-PET-R	16x14. 7°, 9mm
02-CS-1614-7-10-PET-R	16x14. 7°, 10mm
02-CS-1614-7-11-PET-R	16x14. 7°, 11mm



ClariVy™ IBF-HS Ordering Information

PEEK Optima™ Implants

Part Number	Product Size
02-CHS-1411-0-04-PE-R	14x11, 0°, 4mm
02-CHS-1411-0-05-PE-R	14x11, 0°, 5mm
02-CHS-1411-0-06-PE-R	14x11, 0°, 6mm
02-CHS-1411-0-07-PE-R	14x11, 0°, 7mm
02-CHS-1411-0-08-PE-R	14x11, 0°, 8mm
02-CHS-1411-0-09-PE-R	14x11, 0°, 9mm
02-CHS-1411-0-10-PE-R	14x11, 0°, 10mm
02-CHS-1411-0-11-PE-R	14x11, 0°, 11mm
02-CHS-1411-7-04-PE-R	14x11. 7°, 4mm
02-CHS-1411-7-05-PE-R	14x11. 7°, 5mm
02-CHS-1411-7-06-PE-R	14x11. 7°, 6mm
02-CHS-1411-7-07-PE-R	14x11. 7°, 7mm
02-CHS-1411-7-08-PE-R	14x11. 7°, 8mm
02-CHS-1411-7-09-PE-R	14x11. 7°, 9mm
02-CHS-1411-7-10-PE-R	14x11. 7°, 10mm
02-CHS-1411-7-11-PE-R	14x11. 7°, 11mm

Part Number	Product Size
02-CHS-1614-0-04-PE-R	16x14, 0°, 4mm
02-CHS-1614-0-05-PE-R	16x14, 0°, 5mm
02-CHS-1614-0-06-PE-R	16x14, 0°, 6mm
02-CHS-1614-0-07-PE-R	16x14, 0°, 7mm
02-CHS-1614-0-08-PE-R	16x14, 0°, 8mm
02-CHS-1614-0-09-PE-R	16x14, 0°, 9mm
02-CHS-1614-0-10-PE-R	16x14, 0°, 10mm
02-CHS-1614-0-11-PE-R	16x14, 0°, 11mm
02-CHS-1614-7-04-PE-R	16x14. 7°, 4mm
02-CHS-1614-7-05-PE-R	16x14. 7°, 5mm
02-CHS-1614-7-06-PE-R	16x14. 7°, 6mm
02-CHS-1614-7-07-PE-R	16x14. 7°, 7mm
02-CHS-1614-7-08-PE-R	16x14. 7°, 8mm
02-CHS-1614-7-09-PE-R	16x14. 7°, 9mm
02-CHS-1614-7-10-PE-R	16x14. 7°, 10mm
02-CHS-1614-7-11-PE-R	16x14. 7°, 11mm

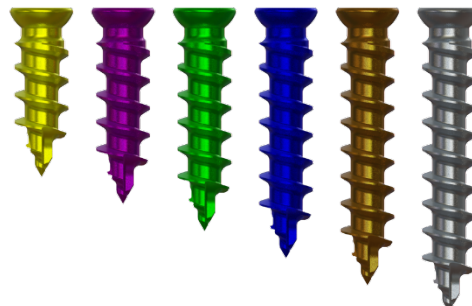


ClariVy™ IBF-S Ordering Information

Screw Options

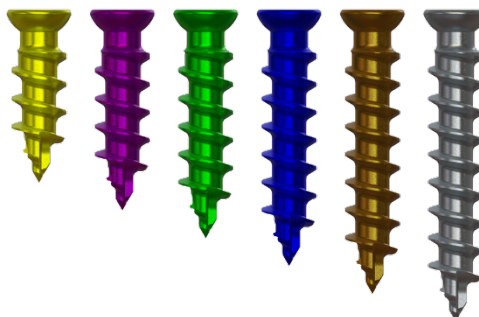
Fixed Angle, Self-Drilling Screws

Part Number	Product Size
02-DF-40-10-TI-N	Ø4.0mm, 10mm
02-DF-40-12-TI-N	Ø4.0mm, 12mm
02-DF-40-14-TI-N	Ø4.0mm, 14mm
02-DF-40-16-TI-N	Ø4.0mm, 16mm
02-DF-40-18-TI-N	Ø4.0mm, 18mm
02-DF-40-20-TI-N	Ø4.0mm, 20mm



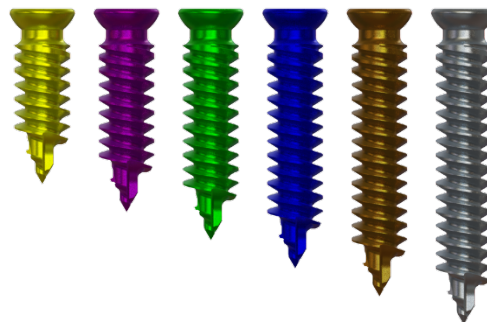
Variable Angle, Self-Drilling Screws

Part Number	Product Size
02-DV-40-10-TI-N	Ø4.0mm, 10mm
02-DV-40-12-TI-N	Ø4.0mm, 12mm
02-DV-40-14-TI-N	Ø4.0mm, 14mm
02-DV-40-16-TI-N	Ø4.0mm, 16mm
02-DV-40-18-TI-N	Ø4.0mm, 18mm
02-DV-40-20-TI-N	Ø4.0mm, 20mm



Fixed Angle, Self-Drilling Rescue Screws

Part Number	Product Size
02-DFR-40-10-TI-N	Ø4.0mm, 10mm
02-DFR-40-12-TI-N	Ø4.0mm, 12mm
02-DFR-40-14-TI-N	Ø4.0mm, 14mm
02-DFR-40-16-TI-N	Ø4.0mm, 16mm
02-DFR-40-18-TI-N	Ø4.0mm, 18mm
02-DFR-40-20-TI-N	Ø4.0mm, 20mm



Variable Angle, Self-Drilling Rescue Screws

Part Number	Product Size
02-DVR-40-10-TI-N	Ø4.0mm, 10mm
02-DVR-40-12-TI-N	Ø4.0mm, 12mm
02-DVR-40-14-TI-N	Ø4.0mm, 14mm
02-DVR-40-16-TI-N	Ø4.0mm, 16mm
02-DVR-40-18-TI-N	Ø4.0mm, 18mm
02-DVR-40-20-TI-N	Ø4.0mm, 20mm

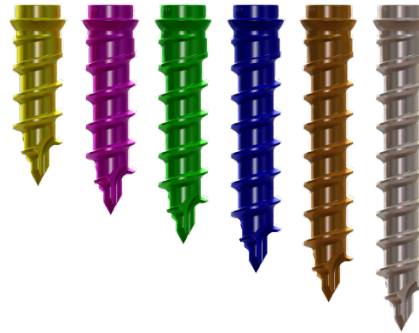


ClariVy™ IBF-HS Ordering Information

Screw Options

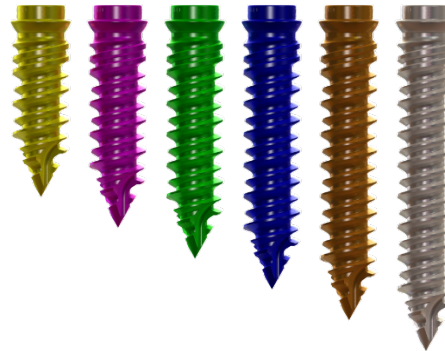
Variable Angle, Self-Drilling Screws

Part Number	Product Size
02-DV-35-10-TI-N	Ø3.5mm, 10mm
02-DV-35-12-TI-N	Ø3.5mm, 12mm
02-DV-35-14-TI-N	Ø3.5mm, 14mm
02-DV-35-16-TI-N	Ø3.5mm, 16mm
02-DV-35-18-TI-N	Ø3.5mm, 18mm
02-DV-35-20-TI-N	Ø3.5mm, 20mm



Variable Angle, Self-Drilling Rescue Screws

Part Number	Product Size
02-DV-37-10-TI-N	Ø3.75mm, 10mm
02-DV-37-12-TI-N	Ø3.75mm, 12mm
02-DV-37-14-TI-N	Ø3.75mm, 14mm
02-DV-37-16-TI-N	Ø3.75mm, 16mm
02-DV-37-18-TI-N	Ø3.75mm, 18mm
02-DV-37-20-TI-N	Ø3.75mm, 20mm



ClariVy™ IBF Ordering Information

Instrumentation Options

Part Number	Description
02-IN-001	Insertter
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



ClariVy™ IBF-S Ordering Information

Instrumentation Options

Part Number	Description
02-ISN-001	IBF-S Inserter
02-ISS-001	IBF-S Screwdriver
02-ISS-002	IBF-S Flex Screwdriver
02-ISD-010	Drill, 10mm
02-ISD-012	Drill, 12mm
02-ISD-014	Drill, 14mm
02-ISD-016	Drill, 16mm
02-ISD-018	Drill, 18mm
02-ISD-020	Drill, 20mm
02-ISD-F10	Flex Drill, 10mm
02-ISD-F12	Flex Drill, 12mm
02-ISD-F14	Flex Drill, 14mm
02-ISD-F16	Flex Drill, 16mm
02-ISD-F18	Flex Drill, 18mm
02-ISD-F20	Flex Drill, 20mm
02-ISG-1411-04	Drill Guide, 14x11, 4mm
02-ISG-1411-05	Drill Guide, 14x11, 5mm
02-ISG-1411-06	Drill Guide, 14x11, 6mm
02-ISG-1411-07	Drill Guide, 14x11, 7mm
02-ISG-1411-08	Drill Guide, 14x11, 8mm
02-ISG-1411-09	Drill Guide, 14x11, 9mm
02-ISG-1411-10	Drill Guide, 14x11, 10mm
02-ISG-1411-11	Drill Guide, 14x11, 11mm
02-ISG-1614-04	Drill Guide, 16x14, 4mm
02-ISG-1614-05	Drill Guide, 16x14, 5mm
02-ISG-1614-06	Drill Guide, 16x14, 6mm
02-ISG-1614-07	Drill Guide, 16x14, 7mm
02-ISG-1614-08	Drill Guide, 16x14, 8mm
02-ISG-1614-09	Drill Guide, 16x14, 9mm
02-ISG-1614-10	Drill Guide, 16x14, 10mm
02-ISG-1614-11	Drill Guide, 16x14, 11mm

ClariVy™ IBF-HS Ordering Information

Instrumentation Options

Part Number	Description
02-ISN-001	IBF-S Inserter
02-ISS-001	IBF-S Screwdriver
02-ISS-002	IBF-S Flex Screwdriver
02-ISA-001	IBF-S Awl
02-ISD-010	Drill, 10mm
02-ISD-012	Drill, 12mm
02-ISD-014	Drill, 14mm
02-ISD-016	Drill, 16mm
02-ISD-018	Drill, 18mm
02-ISD-020	Drill, 20mm
02-ISD-F10	Flex Drill, 10mm
02-ISD-F12	Flex Drill, 12mm
02-ISD-F14	Flex Drill, 14mm
02-ISD-F16	Flex Drill, 16mm
02-ISD-F18	Flex Drill, 18mm
02-ISD-F20	Flex Drill, 20mm
02-ISHG-004	Drill Guide, 4mm
02-ISHG-005	Drill Guide, 5mm
02-ISHG-006	Drill Guide, 6mm
02-ISHG-007	Drill Guide, 7mm
02-ISHG-008	Drill Guide, 8mm
02-ISHG-009	Drill Guide, 9mm
02-ISHG-010	Drill Guide, 10mm
02-ISHG-011	Drill Guide, 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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