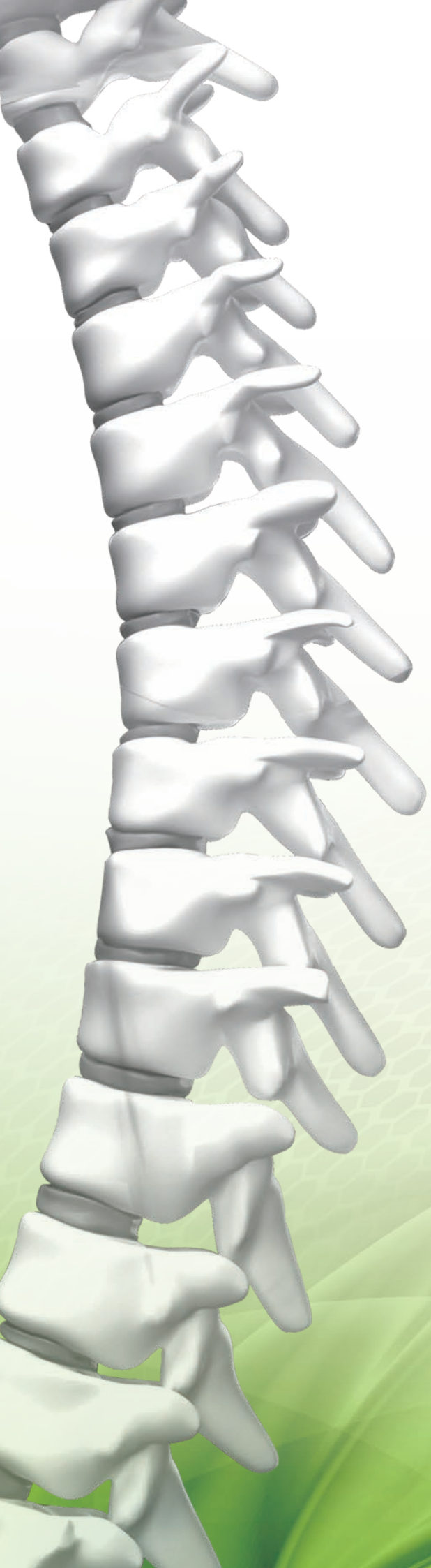
A-SPINE

VIGOR® PEEK Cervical Disc Spacer

Surgical Technique Guide



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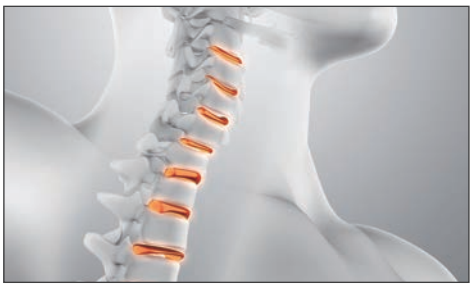
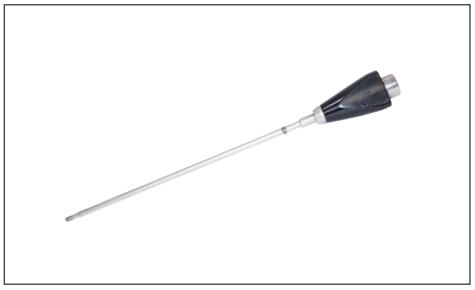
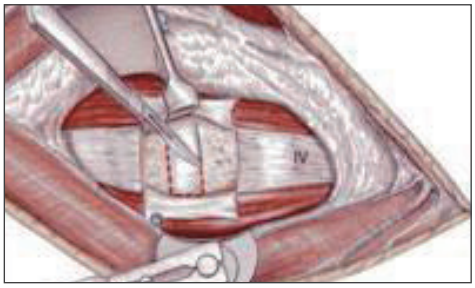
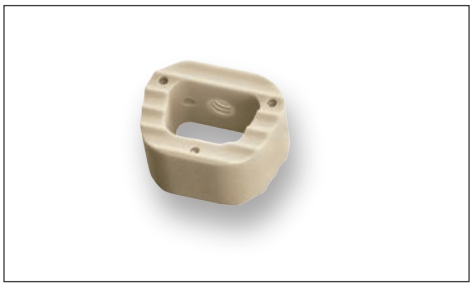








Introduction

The anterior spinal fusion surgical technique have been developed for many years, and numerous types of instruments has been the implantation of intradiscal spacer with capability of enhancing the success of bone graft fusion. The goals of this device are by the design and material of this device, to eliminate or to reduce patient's symptom and promote long term stability of the implant through the successful fusion at the lesion site to the adjacent vertebrae of the cervical spine.

Design Rationale

1. material :
The A-SPINE Vigor® PEEK Cervical Disc Spacer is made of surgical PEEK, Polyetheretherketone, a high performance composite material lighter than Ti alloy.

2. shape :
Two distinctive parts of upper anterior cervical spine (C_2~C_4) are the beak shape-like interior edge of cervical vertebrae; the endplate of inferior body has obvious concavity. In order not to jeopardize the vertebrae cortex and to meet the concave curvature of the inferior end plate, the spacer is designed in trapezoid shape with superior oval build up for promoting spinal stability with increased contact surface area with vertebrae.

Indications

Indications for fusion procedures are for example:

- Degenerative disk disease
- Spondylolisthesis and retrolisthesis grade 1
- Degenerative scoliosis
- Revision operation
- Pseudarthrosis

Contraindications

- Patients with fever or leukocytosis
- Patients with infections associated with the spine (e.g. spondylodiscitis)
- Patients with a history of material allergy or who tend to react to foreign bodies
- Patients whose general medical or psychological condition is unfavorable for- or could be worsened by the procedure; careful consideration is required on the part of the treating physician/surgeon for these patients
- Patients with inadequate bone quality or quantity (e.g. severe osteoporosis, osteopenia, osteomyelitis)
- Pregnancy

Sterilization

The cage had been sterilized by gamma radiation at least 25 kGy dose. It should avoid contaminating while operation process. It is necessary to exchange if the packaging has been broken without reason.

Components

The implant is made of Polyetheretherketone (PEEK) in compliance with ASTM F2026,the marker is made of Tantalum in compliance with ASTM F560 and the spike is made of Titanium alloy (Ti6Al4V) in compliance with ASTM F136 .

Pre-operation Announcements of Anterior Cervical Surgery

Ⓐ Pre-operative Preparation

- CT or MRI is employed to confirm the location of lesion, dimensions of the vertebra(e) to be fused, to determine the lengths of plate & screws to be implanted.
- Operation is performed under endo-tracheal anesthesia.

Ⓑ Patient Position

- The patient is placed in a supine position. (Figure 1)
- Patient's neck is positioned with a rolled-up towel & pad between the scapulae to keep the operated site slightly overextended if desired.
- The head is kept in neutral position and is rotated 15° to 30° to the opposite side.
- Both shoulders were pulled downward with strips of adhesive tape to obtain clear access of radiographic visualization of lower cervical spine.
- Caution: Care should be taken to avoid overstretching the brachial plexus.
- One iliac crest or leg is placed, padded and p repared for autologous bone graft harvesting.

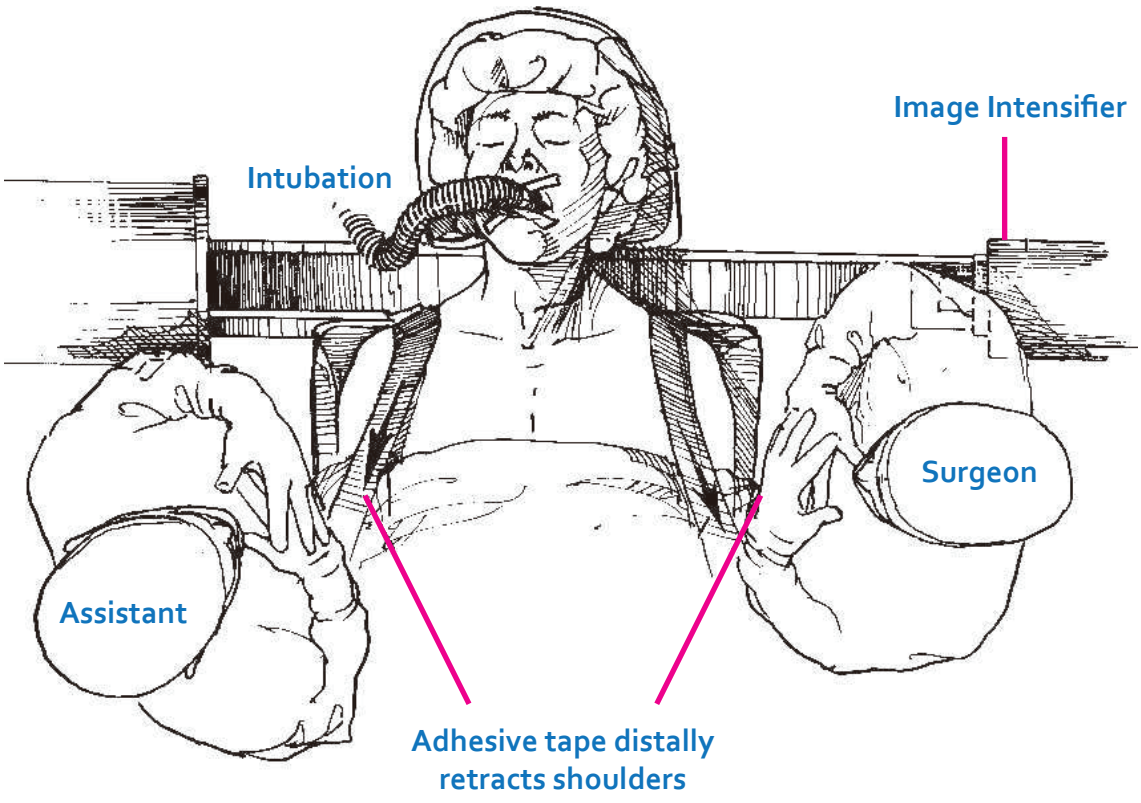


Figure 1

Surgical Procedure

01 Locate & Expose

A transverse incision parallel to the neck fold is indicated to expose one or two segments, while a longitudinal incision anterior to the sternocleidomastoid muscle is preferred for a broad exposure of several segments of the cervical spine. After incision, the platysma muscle is divided by the direction of its' fiber and retracted to both sternocleidomastoid muscle. If the omohyoid muscle runs transversely across the operative field, can be divided by two ligatures and retracted bilaterally.
(Figure 2 and 3)

CAUTION:
Protection of the superior laryngeal nerve should be noted to avoid postoperative hoarseness and speech disorder.

The deep prevertebral fascia is divided from the midline and dissected laterally to the long muscle of the neck, followed by the elevation with rasp on both side on the anterior longitudinal ligament. With a longitudinal resection of ligament, the anterior surface of cervical vertebrae is exposed.
(Figure 4)

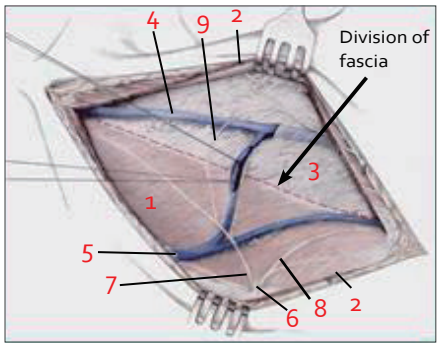


Figure 2

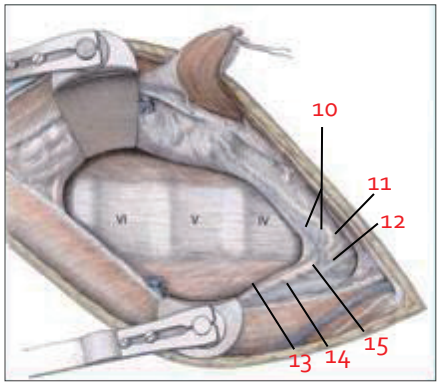


Figure 4

1. Sternocleidomastoid muscle with superficial cervical fascia
2. Platysma muscle, cut
3. Superficial cervical fascia
4. Anterior jugular vein
5. External jugular vein
6. Punctum nervosum
7. Transverse nerve of the neck
8. Great auricular nerve
9. Superficial ansa cervicalis

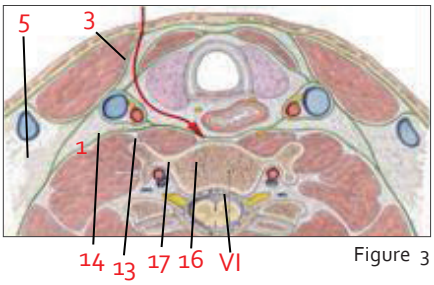


Figure 3

10. Superior thyroid artery & vein
11. Lingual artery
12. External carotid artery
13. Common carotid artery
14. Internal jugular vein
15. Facial vein
16. Prevertebral cervical fascia
17. Long muscle of the neck
IV~VI C4~C6 Cervical vertebrae

02 Discectomy

- The lesioned segment(s) is confirmed with C-arm.
- The longus colli muscle is retracted laterally with a self-retaining retractor while Caspar Distractor is applied longitudinally distracting the upper and lower bodies. The anterior longitudinal ligament and anterior portion of the annulus fibrosus are excised, exposing vertebral body. (Figure 5)
- The upper and lower end plates of the adjacent vertebrae are removed. Large anterior osteophytes are trimmed, yet the original cortical edge is retained. (Figure 6)

- If the end plates are highly sclerotic and avascular, perforation at individual spots with a ball-pointed drill is carried out with an prepared bone bed surface averaged 15mm X 15mm.
- The maximal expansion of the intervertebral space and exact measurement of graft size is conducted with Caspar Distractor.
  (Figure 7)
- The Fixation Pins of the Caspar Distractor are inserted into the vertebraes at the midline of the anterior cortex.

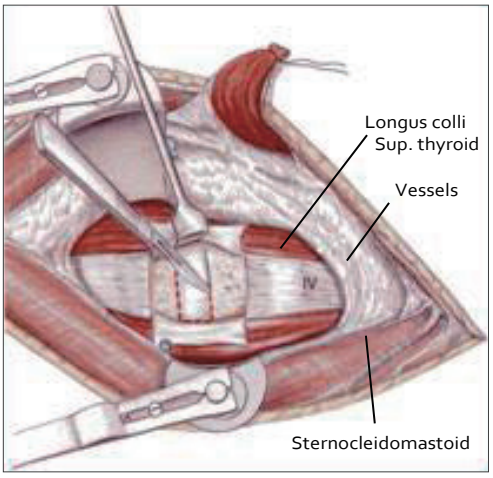


Figure 5

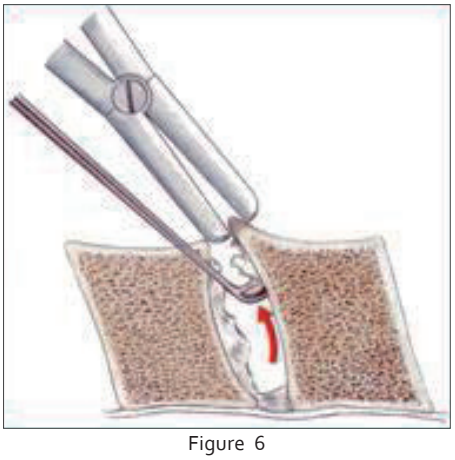


Figure 6

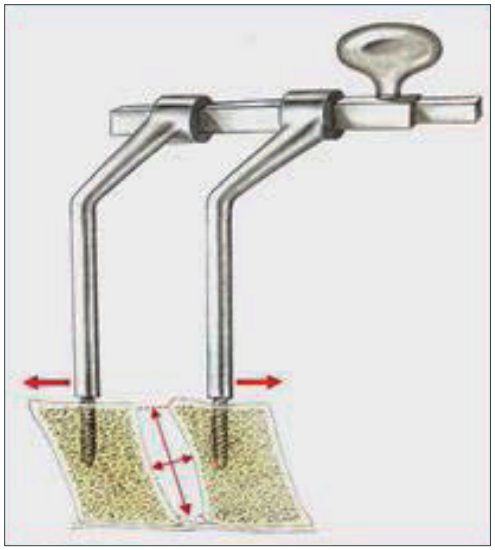
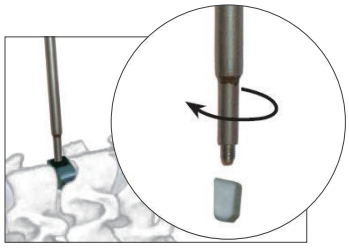
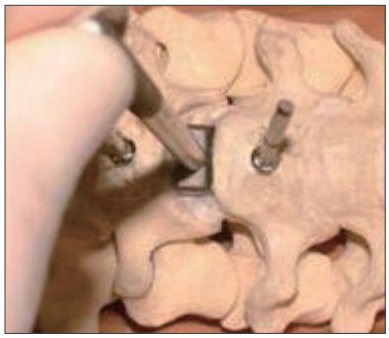


Figure 7





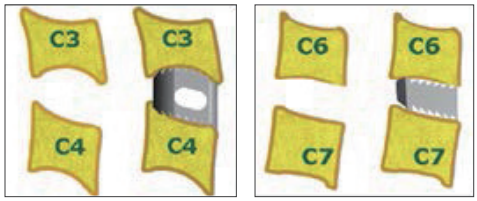


Figure 8

03 Trialing & Implanting

After removing the damaged disc, the ***6mm Implant Driver (218-0806)*** was used to connect the appropriate ***Trial (232-0635~232-0670)*** and insert it into the disc space to determine the implant size.
Released Caspar Retractor to allow the upper and lower vertebral bodies to automatically contract, feel the space tension by pulling the test handle up slightly.
If the Trial pulls out easily, retracting the Caspar Retractor and removed the former Trial.
Repeat these procedures with a larger Trial until it reach the right size. (Figure 8)

CAUTION:
Start with the smallest Trial and select a larger one based on the surgical conditions.

218-0806

6mm Implant Driver

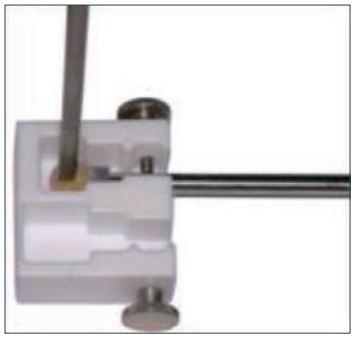


Figure 9

04 Cage Insertron

Use ***Cervical PEEK Insertor (Straight) (232-1702***) to connect appropriate size of implant and turn ***Cervical PEEK Screw Driver (232-1704)*** clockwise for tightening cage.
Put it into ***Bone Graft Template (232-2901)*** and fill bone graft into cage by ***Bone Graft Impactor (218-3301)***.
(Figure 9)

Insert cage to the space and check the position by radiographic imaging.

232-1702

Cervical PEEK Insertor (Straight)

232-1704

Cervical PEEK Screw Driver

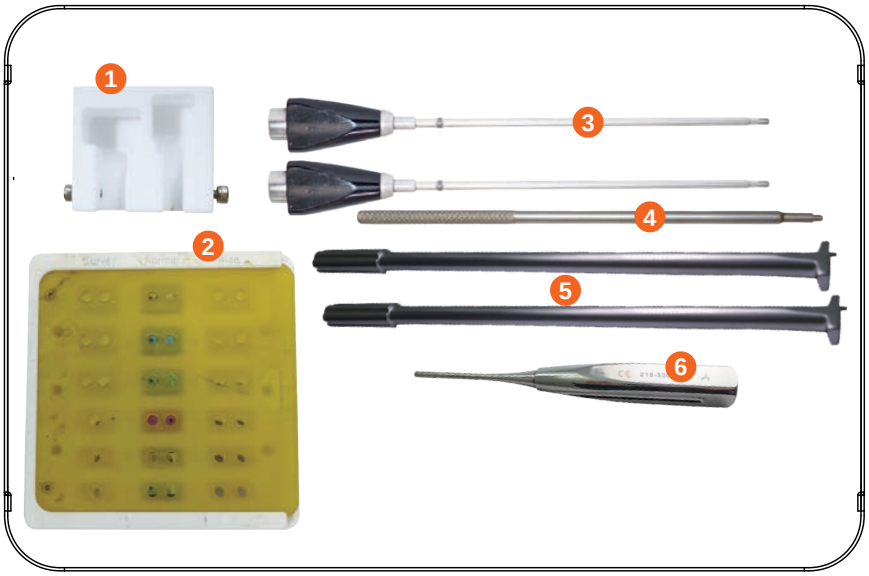
232-2901

Bone Graft Template

218-3301

Bone Graft Impactor

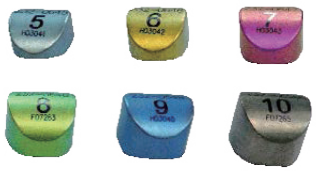
Instrument Set



Instrument Tray

Cat.No.	Description	Q'nty
1 232-2901	Bone Graft Block	1
2 20151-005	Trial Block	1
3 232-1704	Cervical PEEK Screw Driver	2
4 218-0806	6mm Implant Driver	1
5 232-1702	Cervical PEEK Insertor (Straight)	2
6 218-3301	Bone Graft Impactor	1

Instruments

Cat.No.	Description		
232-0635 232-0636 232-0637 232-0638 232-0639 232-0640	PEEK Trial (Wide)	12x15x5mm, 0° 12x15x6mm, 0° 12x15x7mm, 0° 12x15x8mm, 0° 12x15x9mm, 0° 12x15x10mm, 0°	
232-0645 232-0646 232-0647 232-0648 232-0649 232-0650	Trial (Wave)	12x12x5mm, 0° 12x12x6mm, 0° 12x13x7mm, 0° 12x14x8mm, 0° 12x14x9mm, 0° 12x14x10mm, 0°	
232-0665 232-0666 232-0667 232-0668 232-0669 232-0670	Trial (5°)	12x14x5mm	
232-2901	Bone Graft Template		
20151-005	Trial Block		
232-1704	Cervical PEEK Screw Driver		
218-0806	6mm Implant Driver		

Cat.No.	Description	
232-1702	Cervical PEEK Insertor (Straight)	
218-3301	Bone Graft Impactor	
99901-005	Cervical PEEK Case, Metal Lid	
99903-005	Cervical PEEK Case, Plasty Lid	

STERILIZATION:

The instruments are delivered non sterile. Before use needed cleaned and sterilized recommended to be steam sterilized refer to "A-SPINE Reprocessing Manual" following process parameters:
Steam Wrapped Gravity Cycle at 121 °C/250 °F for 30 minutes.
If need more information, the "Intended for Use" and "A-SPINE Reprocessing Manual" can be downloaded from A-SPINE official website: http://www.aspine.com.tw/

Implants

Vigor PEEK Disc Spacer (O)+

Cat.No.	Description
165-65126	Vigor PEEK Disc Spacer (O)+ 0° / H5.0 x L 12 x W15 mm
165-66126	Vigor PEEK Disc Spacer (O)+ 0° / H6.0 x L 12 x W15 mm
165-67126	Vigor PEEK Disc Spacer (O)+ 0° / H7.0 x L 12 x W15 mm
165-68126	Vigor PEEK Disc Spacer (O)+ 0° / H8.0 x L 12 x W15 mm
165-69126	Vigor PEEK Disc Spacer (O)+ 0° / H9.0 x L 12 x W15 mm
165-60126	Vigor PEEK Disc Spacer (O)+ 0° / H10.0 x L 12 x W15 mm

50 Vigor PEEK Disc Spacer (O)+

Cat.No.	Description
165-25126	50 Vigor PEEK Disc Spacer (O)+ 5° / H5.0 x L 12 x W14 mm
165-26126	50 Vigor PEEK Disc Spacer (O)+ 5° / H6.0 x L 12 x W14 mm
165-27126	50 Vigor PEEK Disc Spacer (O)+ 5° / H7.0 x L 12 x W14 mm
165-28126	50 Vigor PEEK Disc Spacer (O)+ 5° / H8.0 x L 12 x W14 mm
165-29126	50 Vigor PEEK Disc Spacer (O)+ 5° / H9.0 x L 12 x W14 mm
165-20126	50 Vigor PEEK Disc Spacer (O)+ 5° / H10.0 x L 12 x W14 mm

Vigor PEEK Disc Spacer (W)

Cat.No.	Description
584-05126	Vigor PEEK Disc Spacer (W) H5.0 x L 12 x W12 mm
584-06126	Vigor PEEK Disc Spacer (W) H6.0 x L 12 x W12 mm
584-07136	Vigor PEEK Disc Spacer (W) H7.0 x L 12 x W12 mm
584-08146	Vigor PEEK Disc Spacer (W) H8.0 x L 12 x W12 mm
584-09146	Vigor PEEK Disc Spacer (W) H9.0 x L 12 x W12 mm
584-10146	Vigor PEEK Disc Spacer (W) H10.0 x L 12 x W12 mm

NOTE

NOTE

A-SPINE

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