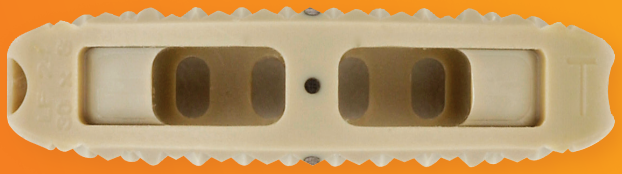
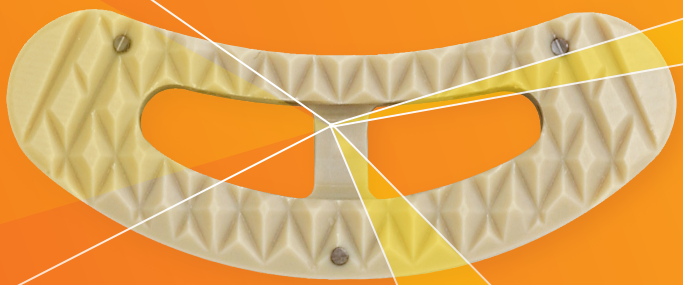
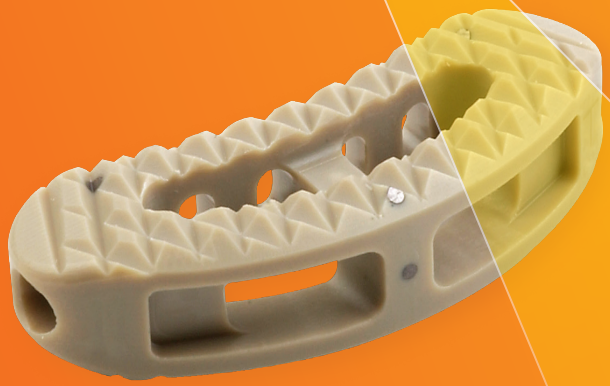
Medtronic

CRESCENT® Spinal System–PEEK







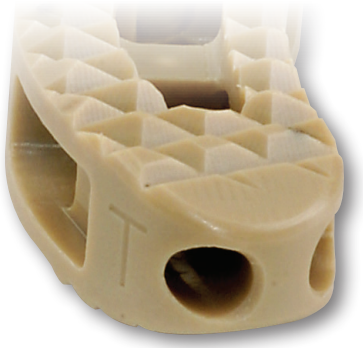
The CRESCENT® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

The spacer is made of a medical grade PEEK (polyetheretherketone) polymer with four tantalum wires embedded for use as radiographic markers. It is available in 25mm, 30mm, and 36mm lengths.

MICHELSON TECHNOLOGY AT WORK

Distinctive Design

- Bulleted nose for insertion.
- Ball tip inserter for inserting, tamping, and final positioning.
- Straight and 15° offset inserter attachment options.
- Teeth for fixation.
- Consistent 10mm AP width for all construct lengths.
- MAST™ compatible instrument set.
- Derotation tools to reposition an over-rotated construct.
- Extraction tools to remove a construct.



15° offset denoted by a "T" on the right side anterior portion of the implant

Radiographic Markers

Lateral

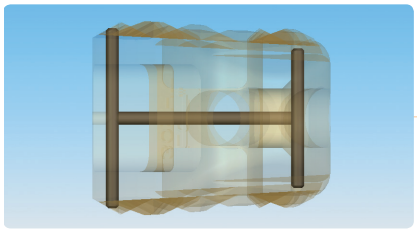


Figure 1L:
Final placement

If you see Figure 1L or 1AP, the implant is in its proper final position

Anterior/Posterior

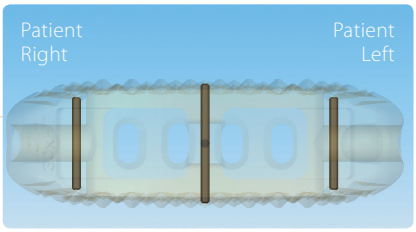


Figure 1AP:
Final placement

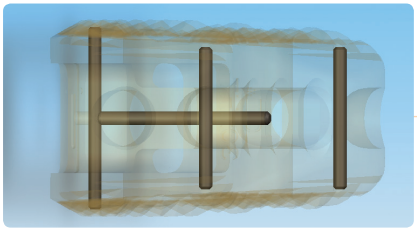


Figure 2L:
Under- or over-rotated implant

If you see Figure 2L or 3L on a lateral view, take an AP view (Figures 2AP or 3AP) to determine whether the implant is under- or over-rotated

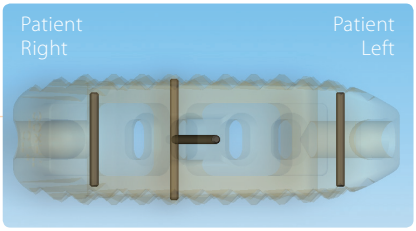


Figure 2AP:
Under-rotated when inserted via patient's right side
Over-rotated when inserted via patient's left side

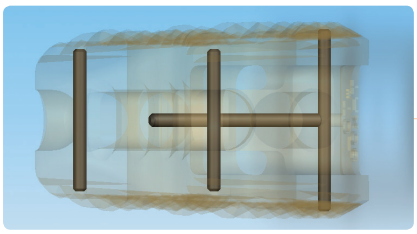


Figure 3L:
Under- or over-rotated implant

If under-rotated, continue to use the Inserter and Tamps to turn the implant. If over-rotated, use the Anterior Pusher to derotate the implant.

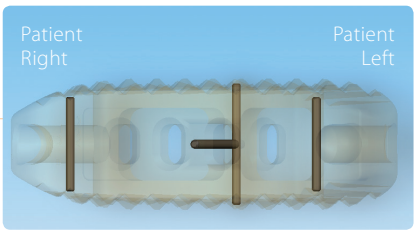
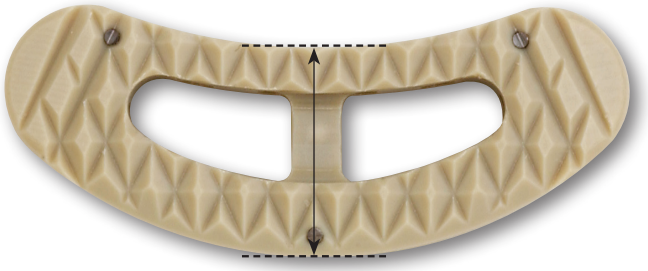


Figure 3AP:
Over-rotated when inserted via patient's right side
Under-rotated when inserted via patient's left side

Internal Volume and Surface Area

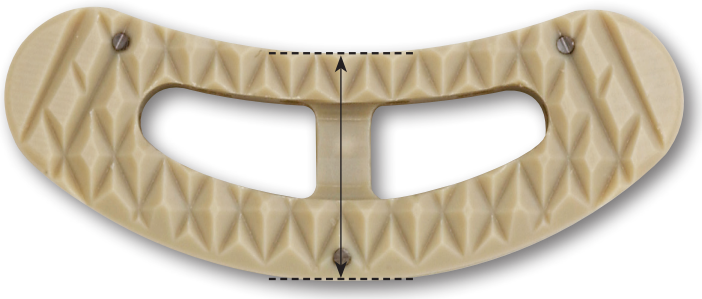
AP width = 10mm



25mm length
Surface area = 133mm²

Part Number	Description	Internal Volume
9392507INT	25mm × 7mm	0.30cc
9392508INT	25mm × 8mm	0.39cc
9392509INT	25mm × 9mm	0.42cc
9392510INT	25mm × 10mm	0.44cc
9392511INT	25mm × 11mm	0.51cc
9392512INT	25mm × 12mm	0.55cc
9392513INT	25mm × 13mm	0.59cc
9392514INT	25mm × 14mm	0.59cc
9392515INT	25mm × 15mm	0.68cc

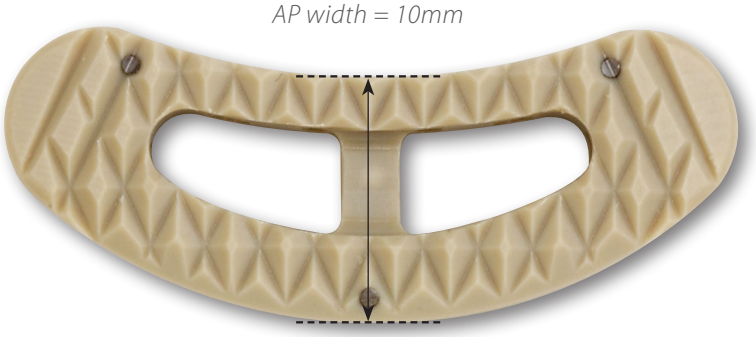
AP width = 10mm



30mm length
Surface area = 156mm²

Part Number	Description	Internal Volume
9393007INT	30mm × 7mm	0.50cc
9393008INT	30mm × 8mm	0.56cc
9393009INT	30mm × 9mm	0.62cc
9393010INT	30mm × 10mm	0.69cc
9393011INT	30mm × 11mm	0.75cc
9393012INT	30mm × 12mm	0.82cc
9393013INT	30mm × 13mm	0.88cc
9393014INT	30mm × 14mm	0.96cc
9393015INT	30mm × 15mm	1.02cc

AP width = 10mm



36mm length
Surface area = 180mm²

Part Number	Description	Internal Volume
9393607INT	36mm × 7mm	0.66cc
9393608INT	36mm × 8mm	0.72cc
9393609INT	36mm × 9mm	0.81cc
9393610INT	36mm × 10mm	0.91cc
9393611INT	36mm × 11mm	0.98cc
9393612INT	36mm × 12mm	1.11cc
9393613INT	36mm × 13mm	1.19cc
9393614INT	36mm × 14mm	1.27cc
9393615INT	36mm × 15mm	1.38cc

Product Ordering Information

Set Type SPS01110
(CRESCENT® Spinal System–PEEK Implants)

Part Number	Description	Quantity
9392507INT	25mm × 7mm	2
9392508INT	25mm × 8mm	2
9392509INT	25mm × 9mm	2
9392510INT	25mm × 10mm	2
9392511INT	25mm × 11mm	2
9392512INT	25mm × 12mm	2
9392513INT	25mm × 13mm	2
9392514INT	25mm × 14mm	2
9392515INT	25mm × 15mm	2
9393007INT	30mm × 7mm	2
9393008INT	30mm × 8mm	2
9393009INT	30mm × 9mm	2
9393010INT	30mm × 10mm	2
9393011INT	30mm × 11mm	2
9393012INT	30mm × 12mm	2
9393013INT	30mm × 13mm	2
9393014INT	30mm × 14mm	2
9393015INT	30mm × 15mm	2
9393610INT	36mm × 10mm	1
9393611INT	36mm × 11mm	1
9393612INT	36mm × 12mm	1
9393613INT	36mm × 13mm	1
43000000	PEEK Suitcase	1

Set Type SPS01110
(CRESCENT® Spinal System– PEEK Implants)

Part Number	Description	Quantity
9393607INT	36mm × 7mm	2
9393608INT	36mm × 8mm	2
9393609INT	36mm × 9mm	2
9393610INT	36mm × 10mm	2
9393611INT	36mm × 11mm	2
9393612INT	36mm × 12mm	2
9393613INT	36mm × 13mm	2
9393614INT	36mm × 14mm	2
9393615INT	36mm × 15mm	2
43000000	PEEK Suitcase	1

Notes

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Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

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Potential risks associated with the device include, but are not limited to:

- Implant migration
- Loss of spinal curvature, correction, height, and/or reduction
- Bone fracture or stress shielding at, above, or below the level of surgery
- Bone graft donor site complication
- Loss of or increase in spinal mobility or function

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