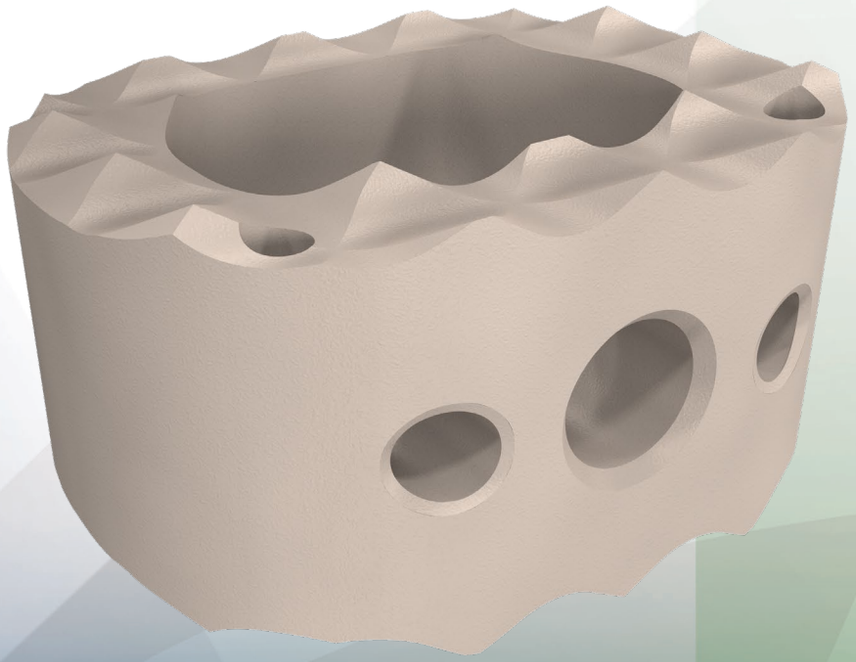
ChoiceSpine™
Propelling Spinal Surgery



STEALTH™ Surgical Technique

PEEK Cervical Spacer

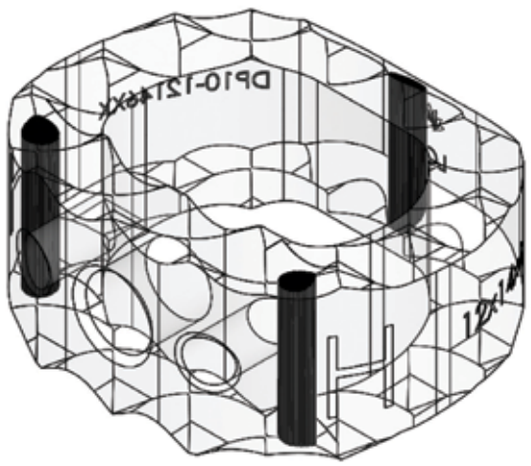
STEALTH Cervical Trial Colors

5	Blue
6	Green
7	Gold
8	Magenta
9	Purple
10	Aqua
11	Seafoam
12	Bronze

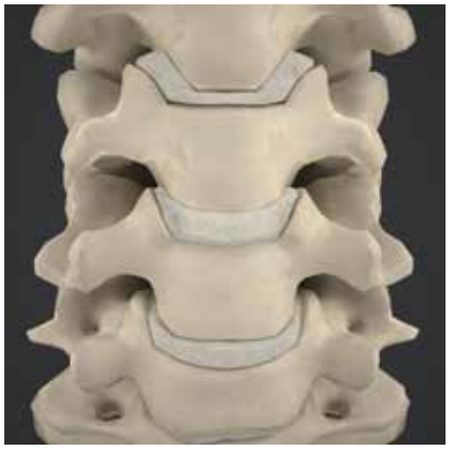
STEALTH Cervical PEEK Implant Configurations

- 12x14mm Parallel PEEK
- 12x14mm Lordotic PEEK
- 14x16mm Parallel PEEK
- 14x16mm Lordotic PEEK

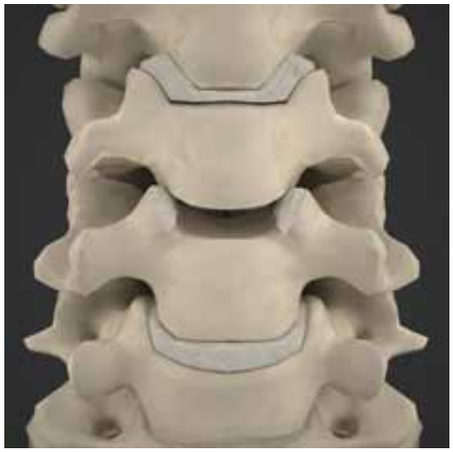
STEALTH Radiographic Pin Locations



Step 1: Approach
The patient is positioned and the appropriate anterior incision is made at the affected level(s) (Fig. 1).



Step 2: Disc Space Access
The affected disc material is carefully removed (Fig. 2).



Step 3: Endplate Preparation
The Rasp and/or other endplate preparation instruments are used to remove the cartilaginous endplate and to prepare the bleeding bone for fusion in the disc space (Fig. 3).

Step 4: Implant Sizing

Select a Trial and sequentially trial until a desired fit within the disc space is achieved (Fig. 4). Refer to the color code on the Trial to choose the corresponding implant (Fig. 5).

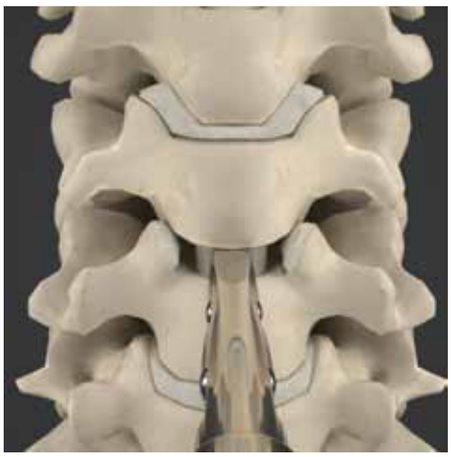
It is important to note that the length of a STEALTH Trial is 2mm longer than the length of the corresponding implant in the AP plane. The Trial length is determined by measuring from the leading edge of the stop on the inserter (AP plane) to the posterior edge of the Trial. This STEALTH Trial design feature is intended to optimize final implant placement within the AP plane of the disc space.

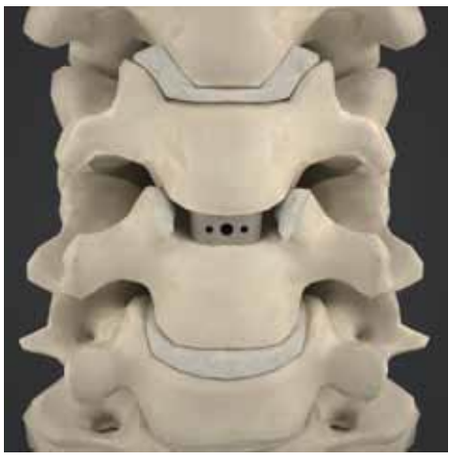
Step 5: Implant Insertion

Slide the Inserter Sleeve onto the Inserter. Once the Inserter Sleeve is fully seated on the Inserter, rotate the Inserter Sleeve so it is retained on the Inserter.

Thread the Implant onto the Inserter until fully seated (Fig. 7). The prongs on the end of the Inserter Sleeve should be captured in the holes next to threaded hole in the center of the implant.

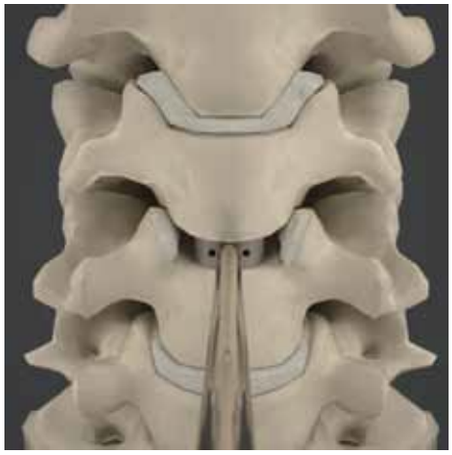
Insert the implant into the disc space to securely seat it in its final position (Fig. 8). Release the Inserter from the implant to verify the placement of the implant (Fig. 9).





Step 5: Implant Insertion (continued)

The Tamp can be used for implant adjustments within the disc space for final placement (Fig. 10). If the implant needs to be removed, thread the Inserter onto the implant until it is fully seated to the wall of the implant. Carefully remove the implant with the Inserter (Fig. 11).



Step 6: Final Construct

Place supplemental fixation as desired (Fig. 12).

Instruments

Product Number	Description	
D070-1214008	12x14x8mm 0° Parallel	
D070-1214609	12x14x9mm 6° Lordodic	
D070-1416011	14x16x11mm 0° Parallel	
D070-1416609	14x16x9mm 6° Lordotic	
D070-0001	Inserter & Sleeve	
D070-0002	Rasp	
D070-0003	Tamp	


ChoiceSpine
STEALTH


ChoiceSpine
STEALTH
CERVICAL FUSION DEVICE
12 x 14 x 6°

Item #	12x14mm Lordotic PEEK	Qty
DP10-1214605	12x14x5mm 6°	3
DP10-1214606	12x14x6mm 6°	3
DP10-1214607	12x14x7mm 6°	3
DP10-1214608	12x14x8mm 6°	3
DP10-1214609	12x14x9mm 6°	3
DP10-1214610	12x14x10mm 6°	1
DP10-1214611	12x14x11mm 6°	1
DP10-1214612	12x14x12mm 6°	1

Item #	12x14mm Parallel PEEK	Qty
DP10-1214005	12x14x5mm 0°	3
DP10-1214006	12x14x6mm 0°	3
DP10-1214007	12x14x7mm 0°	3
DP10-1214008	12x14x8mm 0°	3
DP10-1214009	12x14x9mm 0°	3
DP10-1214010	12x14x10mm 0°	1
DP10-1214011	12x14x11mm 0°	1
DP10-1214012	12x14x12mm 0°	1

Item #	14x16mm Lordotic PEEK	Qty
DP20-1416605	14x16x5mm 6°	3
DP20-1416606	14x16x6mm 6°	3
DP20-1416607	14x16x7mm 6°	3
DP20-1416608	14x16x8mm 6°	3
DP20-1416609	14x16x9mm 6°	3
DP20-1416610	14x16x10mm 6°	1
DP20-1416611	14x16x11mm 6°	1
DP20-1416612	14x16x12mm 6°	1

Item #	14x16mm Parallel PEEK	Qty
DP20-1416005	14x16x5mm 0°	3
DP20-1416006	14x16x6mm 0°	3
DP20-1416007	14x16x7mm 0°	3
DP20-1416008	14x16x8mm 0°	3
DP20-1416009	14x16x9mm 0°	3
DP20-1416010	14x16x10mm 0°	1
DP20-1416011	14x16x11mm 0°	1
DP20-1416012	14x16x12mm 0°	1

Item #	12x14mm Lordotic Trials	Qty
D070-1214605	12x14x5mm 6°	1
D070-1214606	12x14x6mm 6°	1
D070-1214607	12x14x7mm 6°	1
D070-1214608	12x14x8mm 6°	1
D070-1214609	12x14x9mm 6°	1
D070-1214610	12x14x10mm 6°	1
D070-1214611	12x14x11mm 6°	1
D070-1214612	12x14x12mm 6°	1

Item #	12x14mm Parallel Trials	Qty
D070-1214005	12x14x5mm 0°	1
D070-1214006	12x14x6mm 0°	1
D070-1214007	12x14x7mm 0°	1
D070-1214008	12x14x8mm 0°	1
D070-1214009	12x14x9mm 0°	1
D070-1214010	12x14x10mm 0°	1
D070-1214011	12x14x11mm 0°	1
D070-1214012	12x14x12mm 0°	1

Item #	14x16mm Lordotic Trials	Qty
D070-1416605	14x16x5mm 6°	1
D070-1416606	14x16x6mm 6°	1
D070-1416607	14x16x7mm 6°	1
D070-1416608	14x16x8mm 6°	1
D070-1416609	14x16x9mm 6°	1
D070-1416610	14x16x10mm 6°	1
D070-1416611	14x16x11mm 6°	1
D070-1416612	14x16x12mm 6°	1

Item #	14x16mm Parallel Trials	Qty
D070-1416005	14x16x5mm 0°	1
D070-1416006	14x16x6mm 0°	1
D070-1416007	14x16x7mm 0°	1
D070-1416008	14x16x8mm 0°	1
D070-1416009	14x16x9mm 0°	1
D070-1416010	14x16x10mm 0°	1
D070-1416011	14x16x11mm 0°	1
D070-1416012	14x16x12mm 0°	1

Item #	Cases & Caddies	Qty
D090-1000	12x14x0 case	1
D090-1200	12x14x6 case	1
D090-1400	14x16x0 case	1
D090-1600	14x16x6 case	1
D090-1100	12x14x0 caddy	1
D090-1300	12x14x6 caddy	1
D090-1500	14x16x0 caddy	1
D090-1700	14x16x6 caddy	1

Item #	Insertion Tray	Qty
D070-0001	Inserter & Sleeve	2
D070-0002	Rasp	1
D070-0003	Tamp	1

General Description:

The STEALTH™ Cervical Spacer System consists of intervertebral body fusion devices ("interbody spacers") comprised of polyetheretherketone (PEEK-OPTIMA® polymer, Invibio®) with tantalum markers (ASTM F2026 and ASTM F560, respectively). The spacers have a basic oval shape that coincides with the shape of vertebral bodies, a hollow center for placement of bone graft, and angled ridges, or "teeth," on both the superior and inferior surfaces for resisting migration. They are available in an assortment of heights and in multiple angles of lordosis to accommodate different anatomic requirements.

Indications for Use:

The STEALTH Cervical Spacer System is intended for anterior cervical spine intervertebral body fusion at one level from the C2-C3 disc space to the C7-T1 disc for the treatment of degenerative disc disease (DDD) in skeletally mature patients who have had six (6) weeks of non-operative treatment. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is to be used with autogenous bone and/ or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, and supplemental fixation to facilitate fusion.

Contraindications:

Contraindications for the STEALTH Cervical Spacer System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Conditions, such as morbid obesity, which may put excessive stress on the bone and implants
3. Severe osteopenia or osteoporosis may prevent adequate fixation
4. Suspected or documented metal allergy
5. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions
6. Pregnancy

Warnings:

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. A satisfactory outcome is enhanced by the selection of the appropriate device size and angle.
3. The Stealth Cervical Spacer System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Stealth Cervical Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions:

1. The STEALTH Cervical Spacer System should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques as this is a technically demanding procedure.
2. The spacers should not be reused even if they appear in a perfect state. Any spacer that has been used, twisted, bent, implanted and then removed, even if it appears intact, must be discarded.
3. The STEALTH Cervical Spacer System is used to augment the development of a spinal fusion by providing temporary stabilization. The device (spacer) is not intended to be the sole means of spinal support. Supplemental internal fixation must be used. Bone grafting must be part of the spinal fusion procedure. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
4. Refrain from handling the STEALTH Cervical Spacers as much as possible before implantation, and always handle it with the utmost care. STEALTH Cervical Spacers (in their original packaging) must be stored with care in a clean and dry place away from radiation or extreme temperatures. Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.

Notes

ChoiceSpine™
Propelling Spinal Surgery

400 Erin Drive, Knoxville, TN 37919 | O: 865.246.3333 | F: 865.246.3334 | choicespine.com

LIT# Stealth STG | REV02 | 9/19