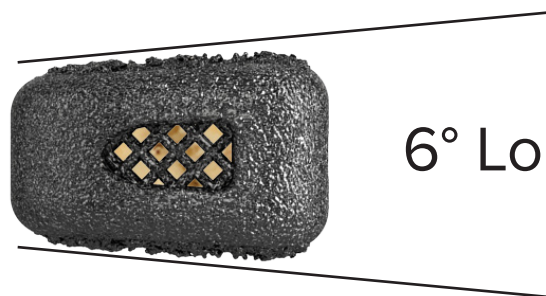
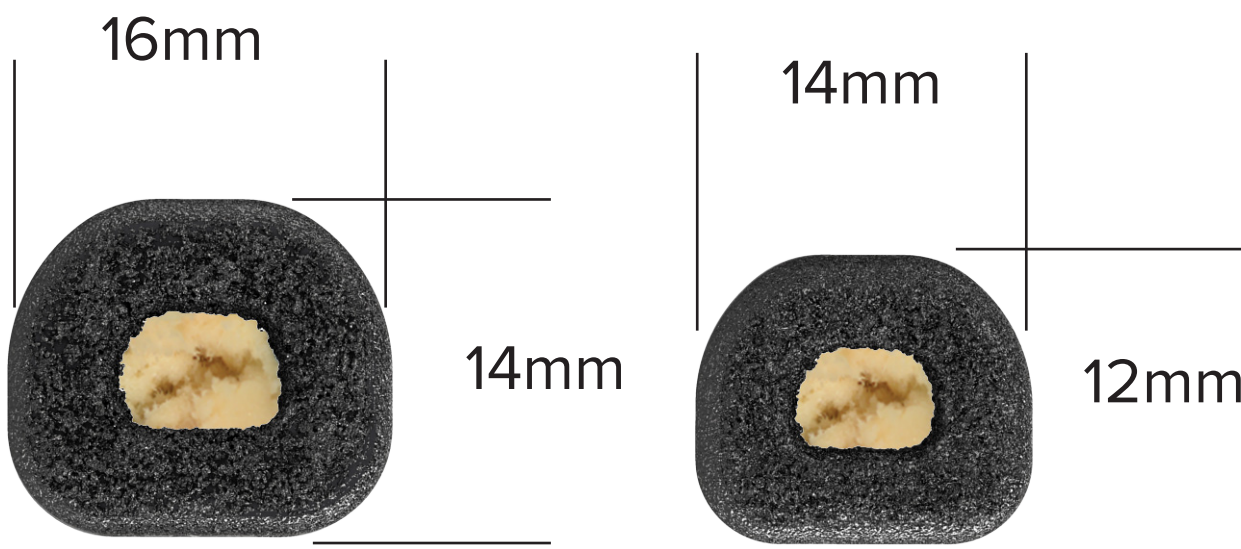




**TIGER SHARK™** C Surgical Technique  
3D Printed Titanium Cervical Spacer System



6° Lordosis



Anterior

### ***TIGER SHARK C Trial Colors***

5	Blue
6	Green
7	Gold
8	Magenta
9	Purple
10	Aqua

## 1 Approach

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

Figure 1



## 2 Disc Space Access

The affected disc material is carefully removed (Fig. 2).

Figure 2



## 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).

Figure 3



#### 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). Trials are measured line-to-line.

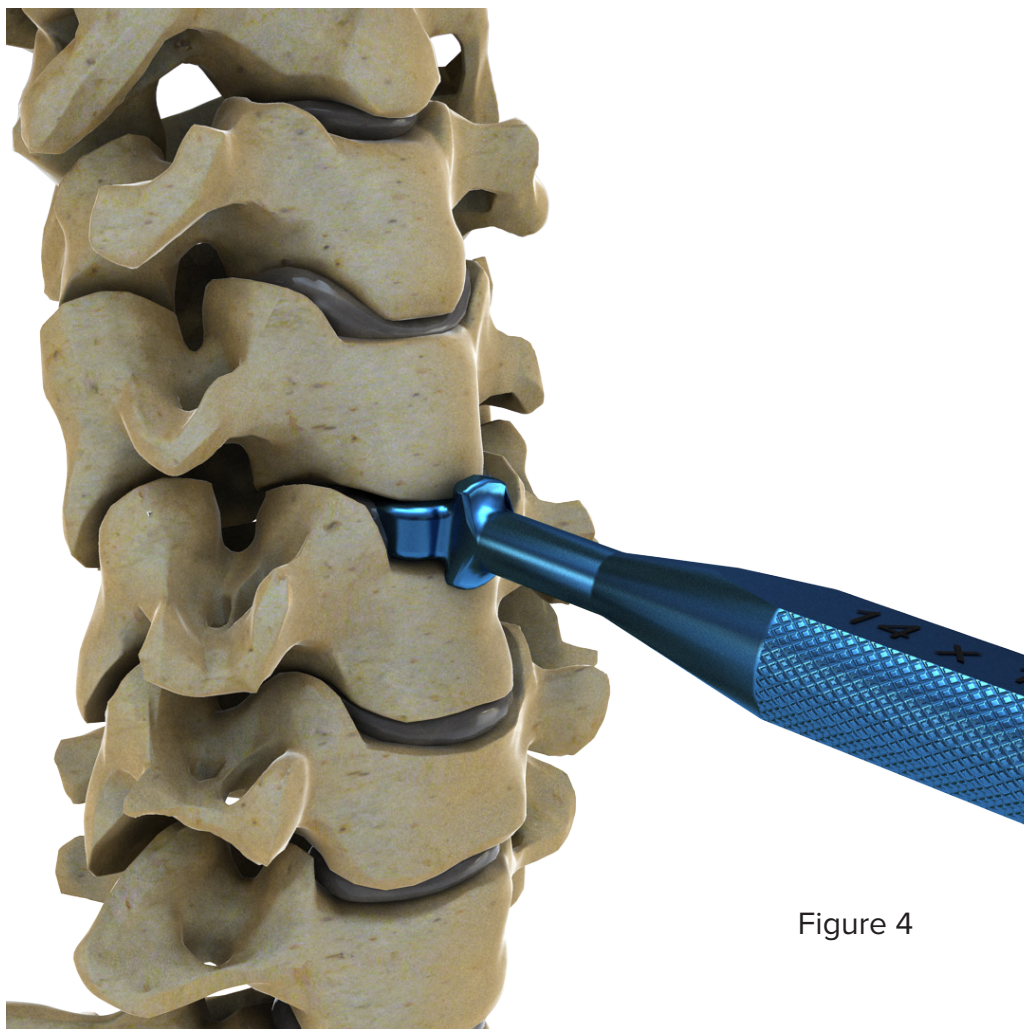


Figure 4



Figure 5

## 5 Implant Sizing

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.



Figure 6

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. Load the implant with chosen bone graft material.

Figure 7



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).



Figure 8



Figure 9

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).

Figure 10



Figure 11



6

### Final Construct

Place supplemental fixation as desired (Fig. 12).

7

### Implant Removal

If it becomes necessary to remove the implant, carefully observe the implant position and the presence of any scar tissue, which can make exposure more challenging compared to the unoperated spine.

To remove the implant, use a standard operating instrument like a kocher to grasp the implant and proceed with removal. Alternatively, the implant inserter can be reattached to the implant with the locking shaft in place as described in Step 5 so that the implant can be removed. If the implant cannot be easily removed, a Cobb elevator or osteotome should be used to loosen the bone to implant interface.










Figure 12



Figure 13



# Instruments

Product Number	Description	
D070-DS614120506	LORDOTIC 6° 14x12 DUAL TRIAL WITH HEIGHTS 5&6	
D070-DS614120708	LORDOTIC 6° 14x12 DUAL TRIAL WITH HEIGHTS 7&8	
D070-DS614120910	LORDOTIC 6° 14x12 DUAL TRIAL WITH HEIGHTS 9&10	
D070-DS616140506	LORDOTIC 6° 16x14 DUAL TRIAL WITH HEIGHTS 5&6	
D070-DS616140708	LORDOTIC 6° 16x14 DUAL TRIAL WITH HEIGHTS 7&8	
D070-DS616140910	LORDOTIC 6° 16x14 DUAL TRIAL WITH HEIGHTS 9&10	
D070-0001	INSERTER & SLEEVE	
D070-0002	RASP	
D070-0003	TAMP	



**General Description:**

The TiGER SHARK Cervical Spacer System consists of intervertebral body fusion devices comprised of titanium alloy (Ti-6Al-4V ELI per ASTM F3001, Class C). The spacers have a basic oval shape that coincides with the shape of vertebral bodies and a hollow center for placement of bone graft. They are available in an assortment of heights and in multiple angles of lordosis to accommodate different anatomic requirements. The devices are manufactured using the Electron Beam Melting (EBM) additive manufacturing method.

**Indications for Use:**

The TiGER SHARK 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 TiGER SHARK Cervical Spacer System is to be used with supplemental fixation and with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft to facilitate fusion.

**Contraindications:**

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

- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Conditions, such as morbid obesity, which may put excessive stress on the bone and implants
- Severe osteopenia or osteoporosis may prevent adequate fixation
- Suspected or documented metal allergy
- 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
- Pregnancy

**Warnings:**

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a

construct.

- A satisfactory outcome is enhanced by the selection of the appropriate device size and angle.
- The TiGER SHARK Cervical Spacer System has not been evaluated for heating, migration, or image artifact in the MR environment.
- Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.

**Cautions:**

- If the packaging of the sterile packed implants is compromised, the sterility of the device will be compromised, and the implant must be discarded.
- If the expiry date on the packaging has been exceeded the implant must be discarded.
- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.
- As with all orthopedic implants, none of the TiGER SHARK Cervical Spacer System implants should ever be reused under any circumstances.







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