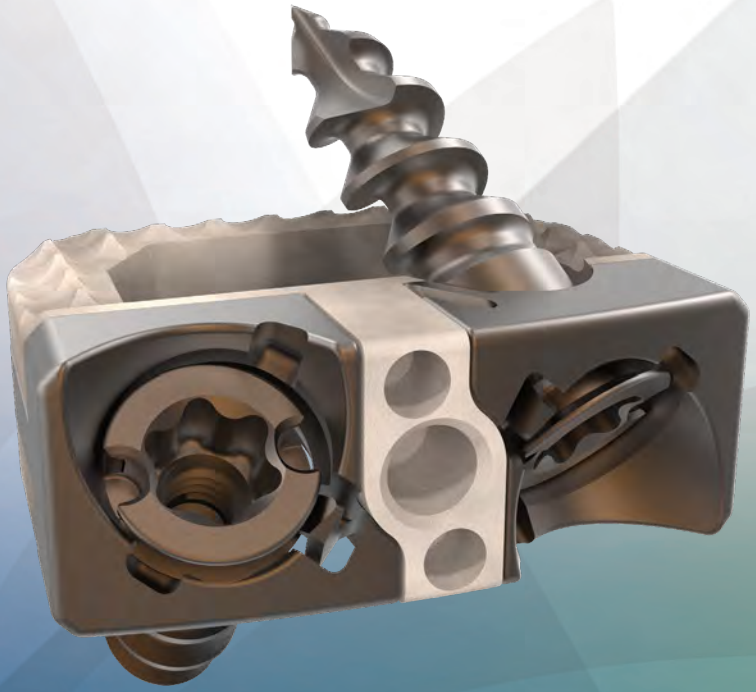
ChoiceSpine™
Propelling Spinal Surgery



TOMCAT™ Surgical Technique

Stand Alone Cervical Spine System

TOMCAT™

CERVICAL SPINAL SYSTEM

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The TOMCAT™ Cervical Spinal System is designed as an effective means of stabilizing the cervical vertebral column as an adjunct to fusion of vertebral bodies.

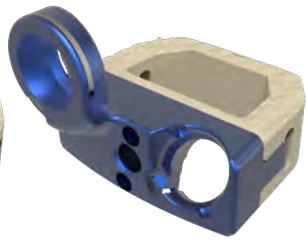
The TOMCAT™ implant is made of PEEK-OPTIMA® HA Enhanced from Invibio and the system will provide an alternative to the traditional plate and screw anterior cervical fusion that involves placement of separate fixation and interbody devices.

Features & Benefits

- Early bone appositions with PEEK-OPTIMA™ HA Enhanced
- Simplified & modular instrumentation
- Self-locking retention mechanisms
- Hybrid device option for difficult screw trajectories

Hybrid

Zero Profile



14x12mm 16x14mm

Standard Heights: 6mm - 10mm
Standard Lordosis: 4°

14x12mm 16x14mm

Standard Heights: 6mm - 10mm
Standard Lordosis: 4°& 8°

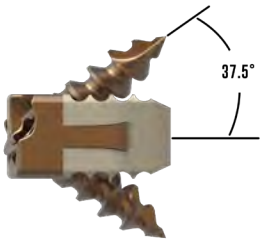
3.5mm Self Drilling Variable Angle Screws	
Length	**Color**
10mm	Magenta
12mm	Bronze
14mm	Dark Blue
16mm	Gold

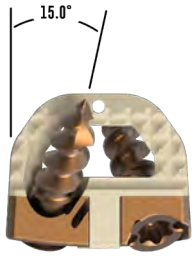
4.0mm Self Drilling Fixed Angle Screws	
Length	**Color**
10mm	Magenta
12mm	Bronze
14mm	Dark Blue
16mm	Gold

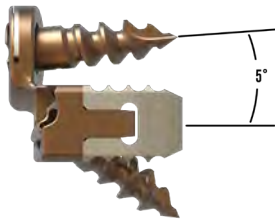
Note: Self tapping screws are avaliable upon request.

Implant Sizing

Select screw color to match interbody. Position the screw at 37.5° cranial/caudal and 15° medial/lateral to achieve fixation where screw is flush with posterior wall of interbody. Alternative screw selection or angulation will result in screw position that either extends or is short of the posterior wall of the interbody.







Zero Profile Implant		
	Cephalad/Caudal	Medial/Lateral
4.0mm Fixed Screws	37.5°	15°
3.5mm Variable Screws	27° - 47°	9^0 - 22^0

Hybrid Implant		
	Cephalad/Caudal	Medial/Lateral
Hybrid Tab	5°	10°

Implant	***Screw Length***		
14 x 12mm	10mm	12mm	14mm
	-2mm 	0mm 	+2mm 

Implant	***Screw Length***		
16mm x 14mm	12mm	14mm	16mm
	-2mm 	0mm 	+2mm 

Step 1: Patient Positioning & Exposure

- Position the patient on a radiolucent operating table in the supine position.
- Place the head in a neutral position.
- Prepare and drape in the conventional manner.
- Create a transverse or oblique incision.
- Gently expose the anterior cervical spine after careful dissection through the various layers.

Step 2: Distraction

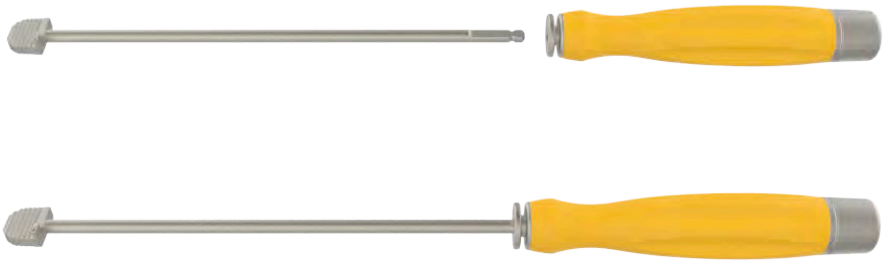
- Distract the disc space using standard methods.
- Restore lordosis & open the neural foramen (Fig. 1).
- Use caution to avoid over-distraction.

Figure 1

Step 3: Discectomy & End-Plate Preparation

- Mark the midline of the intervertebral disc above and below the discectomy site and perform a standard discectomy.
- Attach the appropriate sized rasp to the quick connect axial handle (Fig. 2).
- Use the rasp to prepare the endplates.

NOTE: The offset stop on the rasp allows for traditional midline distraction of the cervical spine & prevents the instrument from advancing beyond the disc space (Fig. 3).



NOTE: Rasps are available in both footprints: 14x12mm & 16x14mm

Figure 2

NOTE: Rasps are 5.2mm & measured from tooth to tooth

Figure 3

Step 4: Implant Sizing

- Trials are undersized by 1mm and are provided to determine the appropriate implant size (Fig. 4).
- Insert the appropriate trial into the quick connect axial handle and carefully insert into the disc space (Fig. 5).
- The trial should pass into the distracted disc space without excessive force.

Color	Depth
Bronze	12mm
Dark Blue	14mm

NOTE: The larger number is height, the smaller number is lordosis.

Figure 4

NOTE: Trials have a color band which corresponds to implant footprint.

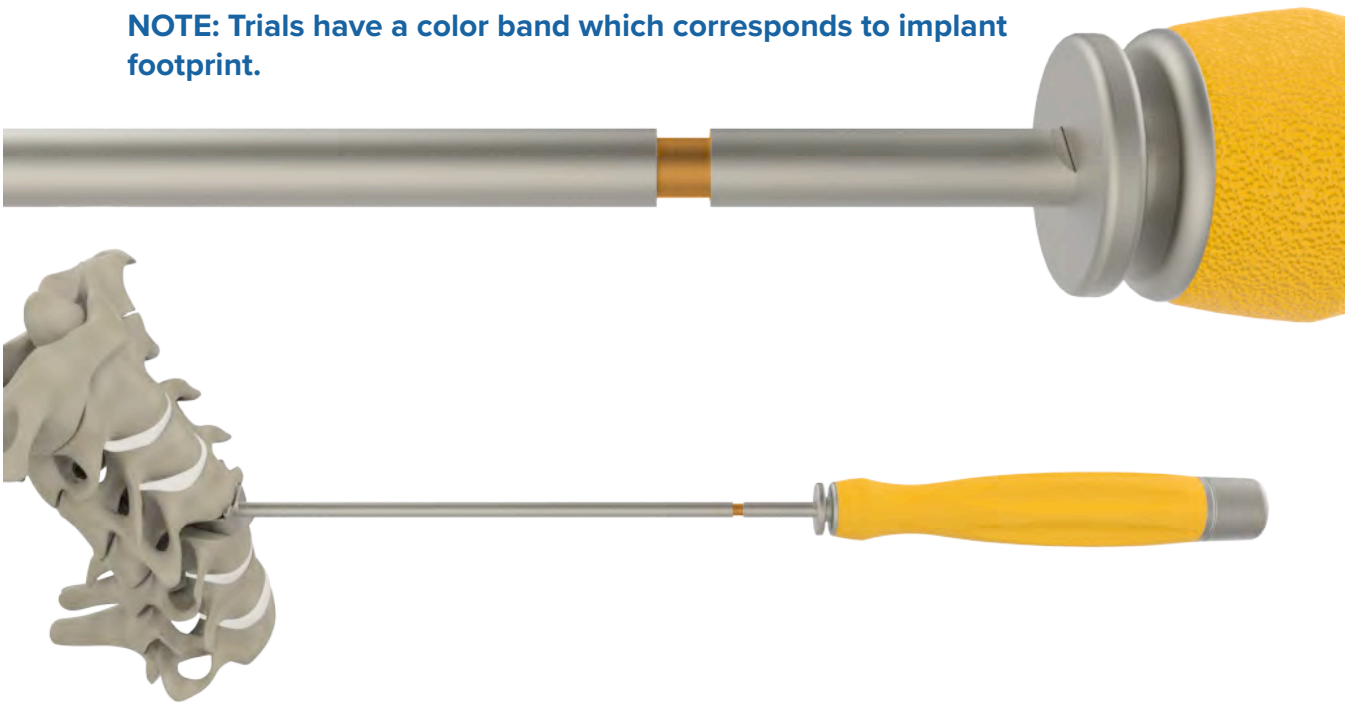


Figure 5

Step 5: Cage Preparation and Insertion

ZERO PROFILE:

- Fill the implant with desired graft material, as determined by the surgeon.
- Attach the appropriate zero profile guide that corresponds to Implant height to the distal tip of the guided inserter shaft (Fig. 6).
- Place the zero profile implant onto the distal end of the zero profile guide (Fig. 7).
- Place the inserter drawrod through the guided inserter shaft and thread the distal tip into the implant until finger tight (Fig. 8).
- Insert the implant into the disc space (Fig. 9).

Figure 6

Figure 7

Figure 8

Figure 9

HYBRID:

- Fill the Implant with desired graft material, as determined by the surgeon.
- Attach the appropriate height hybrid guide that corresponds to Implant height to the distal tip of the guided inserter shaft (Fig. 10).
- Place the hybrid implant onto the distal end of the hybrid guide.
- Place the inserter drawrod through the guided inserter shaft and thread the distal tip into the implant until finger tight.
- Insert the implant into the disc space (Fig. 12).

NOTE: An implant guide is not needed if using the low profile inserter.

NOTE: The guide is held in place by a snap mechanism on the distal tip of the inserter (Fig. 11).

Figure 10

Figure 11

Figure 12

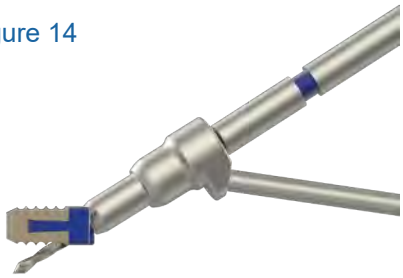
Step 6: Screw Hole Preparation – Awl & Drill

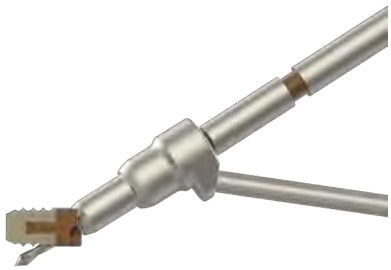
- Use the awl through the zero profile or hybrid guide to penetrate the cortical bone (Fig. 13).
- Select the appropriately sized drill that corresponds with the screw & interbody length.
- Attach the drill to the quick connect axial handle and drill into the vertebral body through the drill guide (Fig. 15).

Figure 13

NOTE: A straight, angled, and spring loaded awl are available based on surgeon preference. Awl penetration depth is 10mm

Figure 14





NOTE: If using a 14x12mm footprint implant (bronze) use the bronze banded drill. If using a 16x14mm footprint implant (blue), use the blue banded drill. This will ensure that the surgeon does not drill past the posterior wall of the implant (Fig. 14)

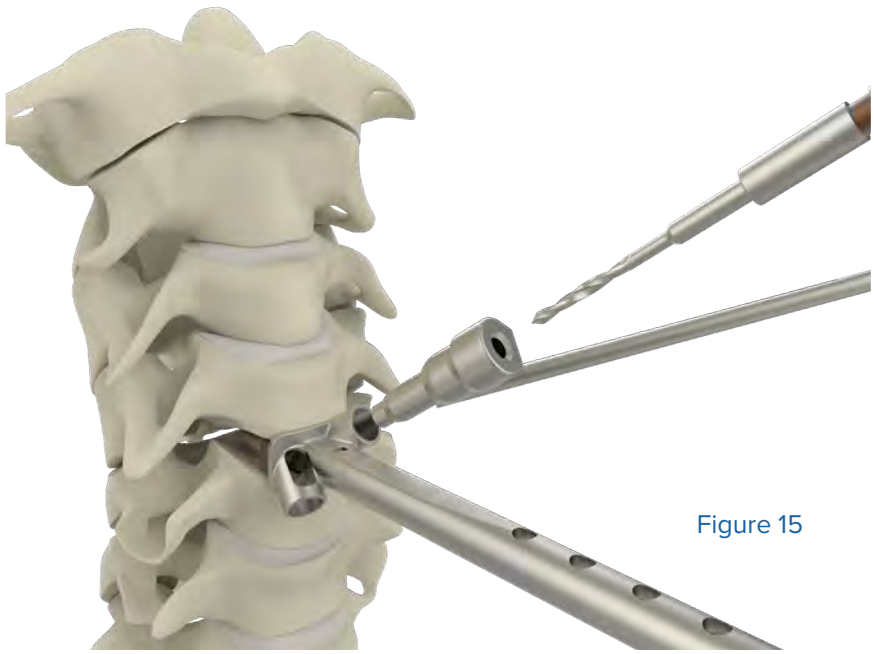


Figure 15

Step 7: Screw Insertion

- Attach the driver to a quick connect axial handle.
- Load the screw onto the driver.
- Place the screw into the prepared screw hole through the zero profile or hybrid guide (Fig. 16).
- Advance the screw until it passes the locking mechanism. The screw is seated once the black band on the driver disappears.
- The screw is in the locked position once the locking strut is in the inner channel of the screw (Fig. 17).
- If using the hybrid implant, advance the screw until the retention clip sits inside of the screw's inner channel.
- Repeat steps for the second screw.

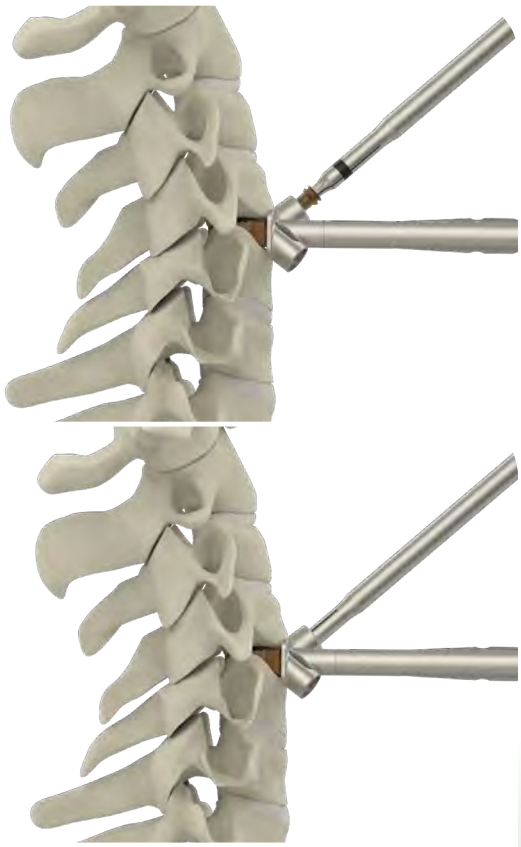


Figure 16

Step 8: Inserter Removal

- Rotate the inserter drawrod counterclockwise to release it from the implant.
- Gently rock the inserter shaft in a medial/lateral motion to release it from the surgical site.

Figure 18

NOTE: A straight, fixed angle, and universal joint driver are available depending on surgeon preference (Fig. 18). All drivers have split tips.

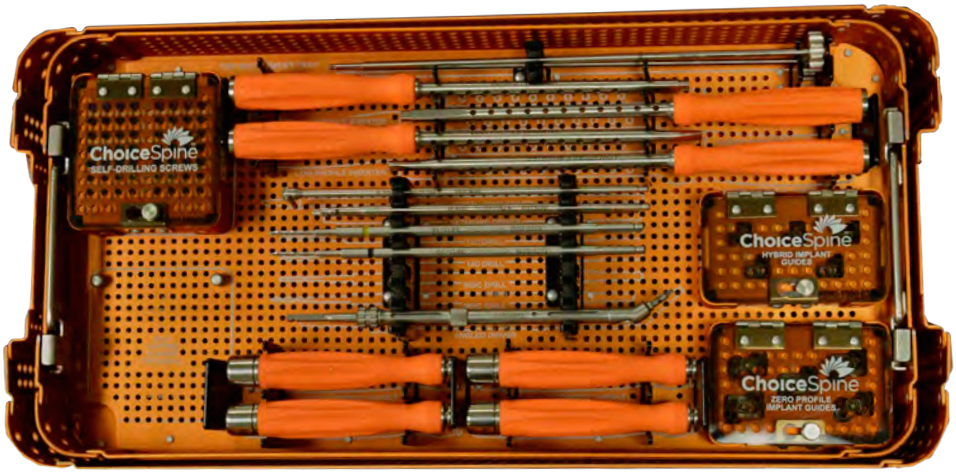
Figure 17

Step 9: Screw Removal

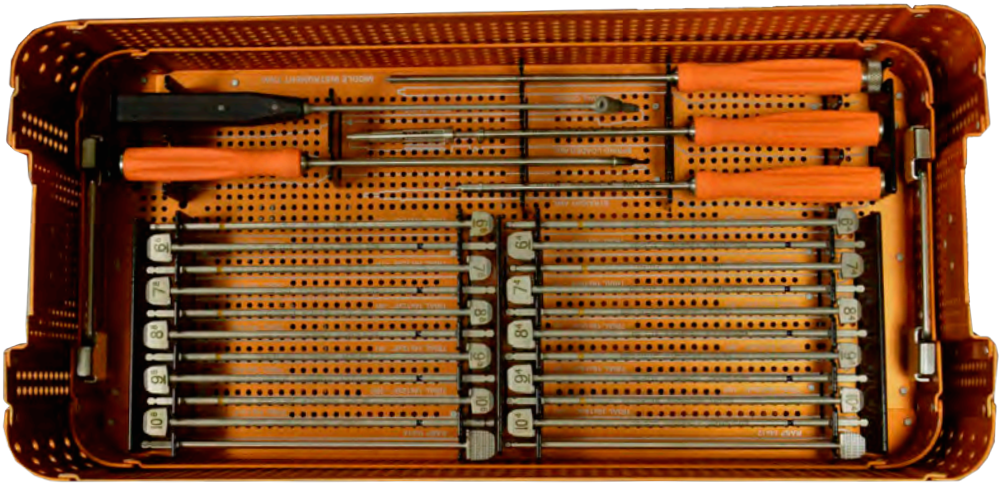
- Insert the removal driver into the screw by aligning its pins with the holes of the Screw head (Fig. 20).
- Thread the drawrod into the screw until finger tight.
- Rotate the removal driver counterclockwise to bypass the locking mechanism and remove the screw.
- Repeat for the other screw.

Figure 20

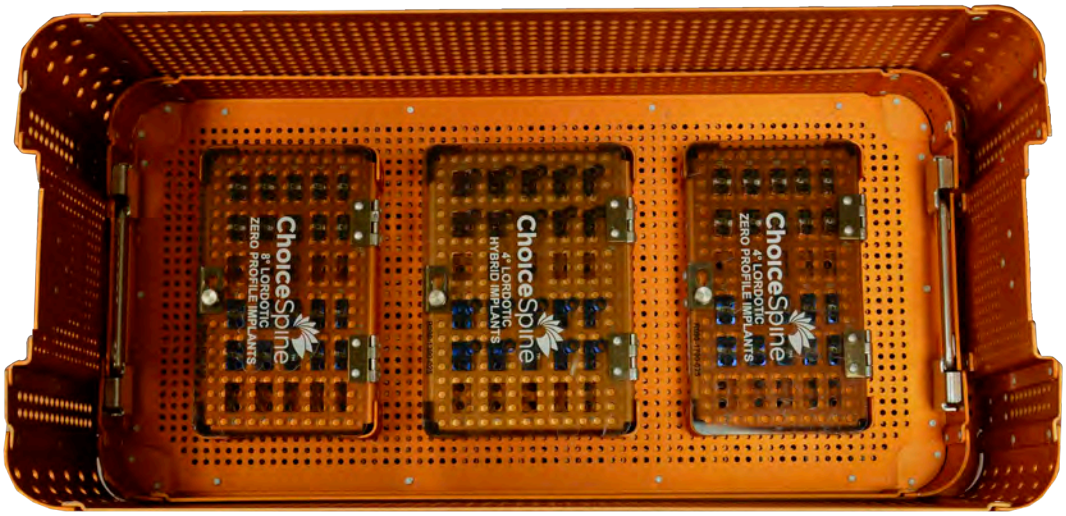
Case Layout



Top Tray



Middle Tray



Bottom Tray

Part Number	Description	QTY
R070-0001	Guided Inserter Shaft	2
R070-0002	Low Profile Inserter	2
R070-0004	Straight Awl	1
R070-0005	Angled Awl	1
R070-0028	Spring Loaded Awl	1
R070-0007	Drill Guide	1
R070-0009	14x12 Rasp	1
R070-0010	16x14 Rasp	1
R070-0012	Fixed Angle Driver	1
R070-0015	Removal Driver	1
R070-0017	Inserter Drawrod	2
R070-0018	Straight Split Driver	2
R070-0019	Universal Joint Driver	1
R070-D012	12D drill	2
R070-D014	14D drill	2
L070-0030	Axial Handle	4
R070-1412406	Trial 14x12x6, 4°	1
R070-1412407	Trial 14x12x7, 4°	1
R070-1412408	Trial 14x12x8, 4°	1
R070-1412409	Trial 14x12x9, 4°	1
R070-1412410	Trial 14x12x10, 4°	1
R070-1412806	Trial 14x12x6, 8°	1
R070-1412807	Trial 14x12x7, 8°	1
R070-1412808	Trial 14x12x8, 8°	1
R070-1412809	Trial 14x12x9, 8°	1
R070-1412810	Trial 14x12x10, 8°	1
R070-1614406	Trial 16x14x6, 4°	1
R070-1614407	Trial 16x14x7, 4°	1
R070-1614408	Trial 16x14x8, 4°	1
R070-1614409	Trial 16x14x9, 4°	1
R070-1614410	Trial 16x14x10, 4°	1
R070-1614806	Trial 16x14x6, 8°	1
R070-1614807	Trial 16x14x7, 8°	1
R070-1614808	Trial 16x14x8, 8°	1
R070-1614809	Trial 16x14x9, 8°	1
R070-1614810	Trial 16x14x10, 8°	1
R070-H006	H-guide, 6	1
R070-H007	H-guide, 7	1
R070-H008	H-guide, 8	1
R070-H009	H-guide, 9	1
R070-H010	H-guide, 10	1
R070-Z106	0P-guide, 6 tabs	1
R070-Z107	0P-guide, 7 tabs	1
R070-Z108	0P-guide, 8 tabs	1
R070-Z009	0P-guide, 9	1
R070-Z010	0P-guide, 10	1

DESCRIPTION

The TOMCAT Cervical Spinal System is an anterior cervical spinal fixation system for an effective means of stabilizing the cervical vertebral column (C2-T1) as an adjunct to fusion of vertebral bodies. The TOMCAT System will provide an alternative to the more common cervical plate and cervical interbody spacer Anterior Cervical Discectomy & Fusion (ACDF) surgical procedure. The TOMCAT Cervical Spinal System is a radiolucent and radiopaque intervertebral body fusion device. The interbody is made from PEEK per ASTM F2026 with titanium alloy (Ti-6Al-4V ELI) per ASTM F136, tantalum radiopaque markers per ASTM F560, and nitinol clips per ASTM F2063. This device accepts titanium (Ti-6Al-4V ELI) bone screws that are available in two diameters and multiple lengths.

The system will be composed of a cervical interbody spacer with a zero profile and a hybrid profile design. The hybrid device is implanted anteriorly by inserting two screws, one screw into the anterior face of vertebral body and the other diagonally though the end plate.

The zero profile device implants are implanted anteriorly and stabilized by two diagonally placed screws.

INDICATIONS FOR USE:

The TOMCAT Cervical Spinal System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients. The interbody is used with bone screws provided and requires no additional supplementary fixation. The interbody is inserted between the vertebral bodies into the disc space at one level from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, to facilitate fusion. The device is implanted by an anterior approach. The TOMCAT implant must be used with the screws included in the TOMCAT system. This device is to be used in patients who have had six weeks of non-operative treatment.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

- Infection, systemic or localized
- Signs of local inflammation
- Morbid obesity
- Fever or leukocytosis
- Mental illness
- Alcoholism or drug abuse
- Pregnancy
- Severe osteopenia
- Suspected or documented sensitivity allergies to the implant materials
- Presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device
- Any condition having inadequate tissue coverage over the operative site
- Any circumstances not described under Indications for Use
- Patients unwilling or unable to follow post-operative instructions
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)

CAUTIONS:

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.
- Do not use components of the TOMCAT Cervical Spinal System with components from any other system.
- As with all orthopedic implants, none of the TOMCAT Cervical Spinal System implants should ever be reused under any circumstances.

WARNINGS:

- Patient compliance to postoperative pre-cautions will greatly affect surgical outcomes.
- The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. All implants should be examined before use and discarded if damaged.

This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur.

The TOMCAT Cervical Spinal System has not been evaluated for safety and compatibility in the MR environment. TOMCAT Cervical Spinal System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the TOMCAT Cervical Spinal System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

ChoiceSpine™
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