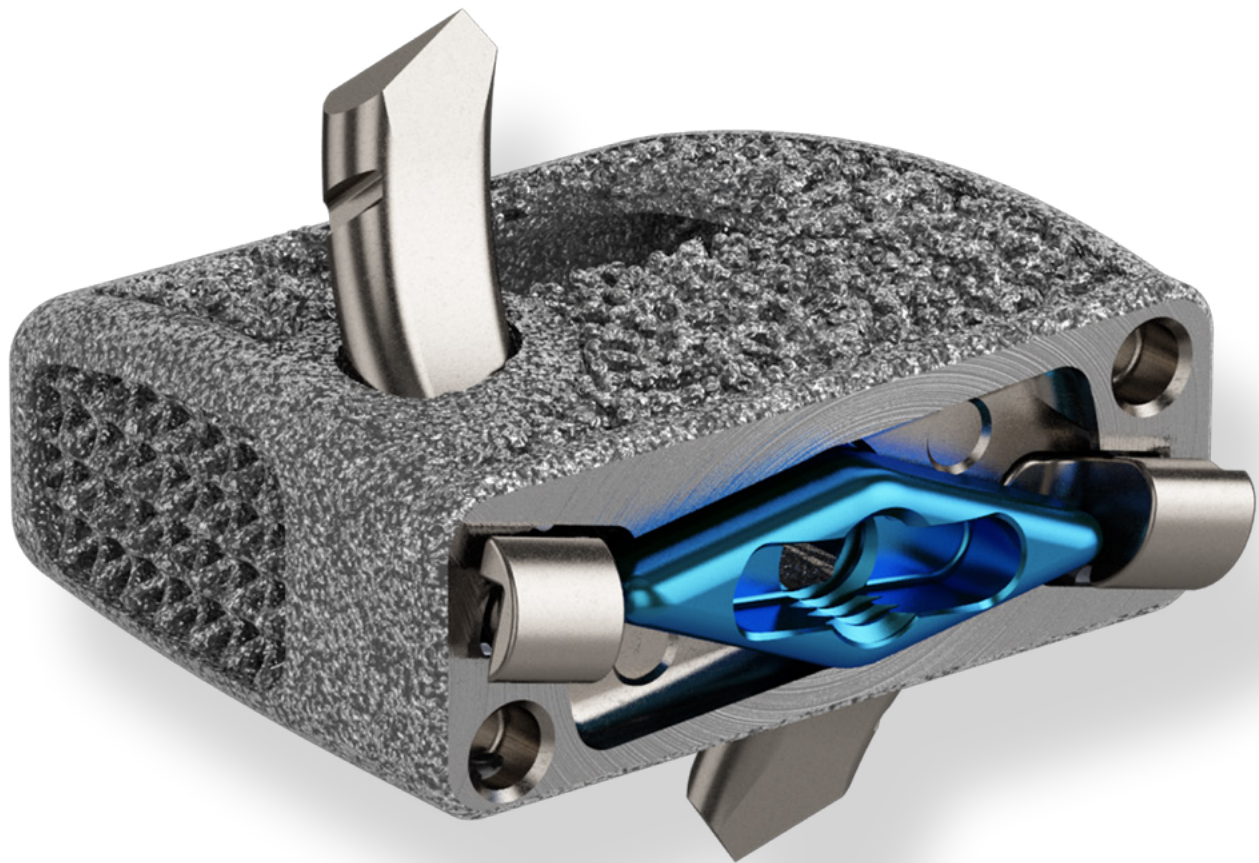


BLACKHAWK[®] TI

Standalone Cervical Spacer System

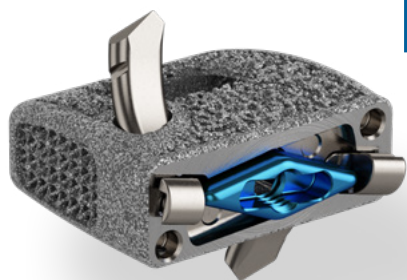




choicespine.com

Table of Contents

Introduction.....	4
System Features.....	4
Surgical Steps	4
Surgical Overview	4
Detailed Operative Technique.....	5
Patient Positioning.....	5
Surgical Approach.....	6
Distraction	6
Discectomy	6
Implant Size Selection	7
Connect Implant to Inserter	9
Anchor Confirmation	11
Implant Insertion.....	12
Deployment of the Integrated Anchors.....	12
Lock Cam Locking Mechanism	14
Implant Removal.....	15
Blackhawk® TI Case Layout.....	16



BLACKHAWK® TI

Standalone Cervical Spacer System



Introduction

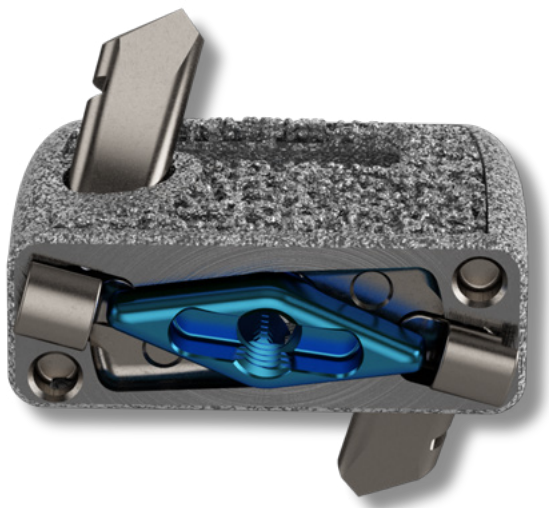
The ChoiceSpine Blackhawk® Ti Standalone Cervical Spacer System is a cervical spacer that has integrated anchors for anterior cervical spinal fusion. The single-step anchor deployment is designed to reduce surgical steps in the operating room. The implant is 3D printed with our proprietary BioBond® technology and is available in two anatomical footprints. Blackhawk Ti features a cam-locking mechanism that provides visual and tactile confirmation of final locking. The Blackhawk Ti System has standalone indication.

System Features

- Footprints Available: 12mm x 14mm and 14mm x 16mm, 6mm-10mm heights, 6 degrees and convex
- Large open graft window for bone graft and visualization under fluoroscopy
- 4.8mm – 5.5mm anchor deployment depth
- Simultaneous, single-step anchor deployment
- Cam-locking mechanism provides visual and tactile confirmation

The Blackhawk® Ti Standalone Cervical Spacer System is designed to provide biomechanical stabilization as an adjunct to fusion. Spinal fixation should only be undertaken after the surgeon has had hands-on training in this method of spinal fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics.

The integrated fixation anchors may not provide adequate stability for all situations. The surgeon should consider the appropriate fixation for each patient and determine if additional supplemental fixation (e.g. an anterior plate, posterior pedicle screws) may be needed.



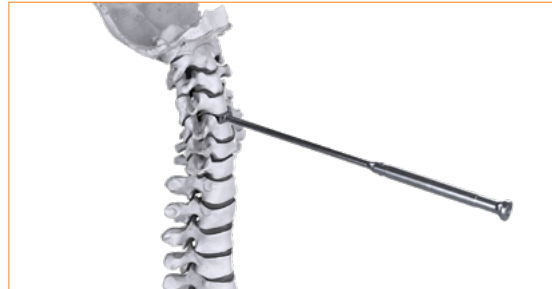
BLACKHAWK® TI

Standalone Cervical Spacer System

Surgical Steps Overview



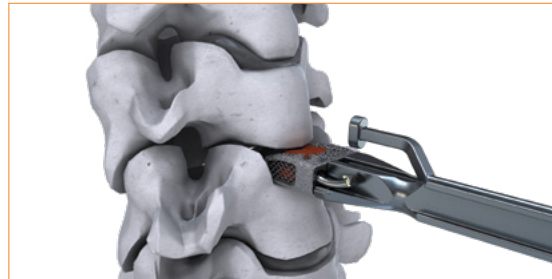
1. Prepare the Disc Space



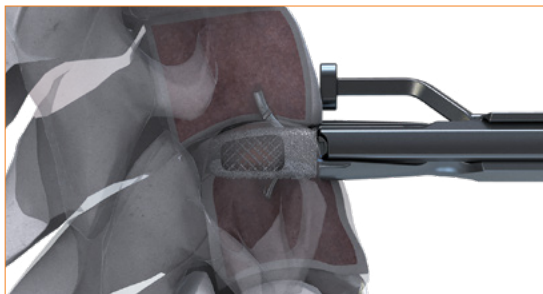
2. Trial Disc Space



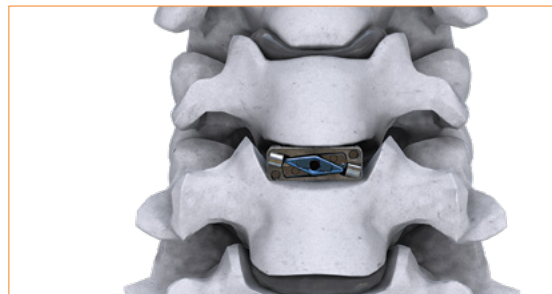
3. Attach Implant to Insertor



4. Position Implant in Disc Space



5. Deploy Anchors



6. Final Locking Confirmation

DETAILED OPERATIVE TECHNIQUE

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 a conventional manner.
- Create a transverse or oblique incision.
- Gently expose the anterior cervical spine after careful dissection through various layers.

Surgical Approach

Identify the affected level radiographically. Using a standard surgical approach, expose the vertebral bodies to be fused. Prepare the fusion site following the appropriate technique for the given indication.

Step 1: Distraction

Surgeon should perform preferred distraction method. If using a caspar distractor, place one distraction pin in the vertebral body superior to the affected level and the other distraction pin in the vertebral body inferior to the affected level. When placing the distraction pins, be aware of the space needed to rest the offset stop on the inserter (See Figure 1 & 2). Place the pin distractor over the pins and open as needed to distract the vertebral bodies, using caution not to over distract the vertebral segment.

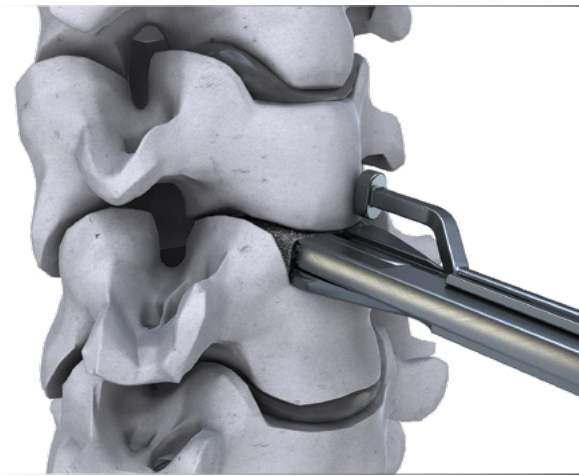


Figure 1: Inserter Depth Stop Reference

NOTE: If using caspar distraction, the caspar pins **MUST** be placed at least 7mm (Cephalad/Caudal) away from the disc space to avoid interference with the anchors.

Step 2: Discectomy

Surgeons should perform preferred discectomy to remove the intervertebral disc and osteophytes as needed. Use the Rasp (05-099-10-0000) to prepare the endplates just enough to create a surface that will encourage vascularization between the endplates and the graft without weakening cortical bone.

CAUTION: Aggressive preparation of the endplate may remove excessive bone and weaken the endplate.

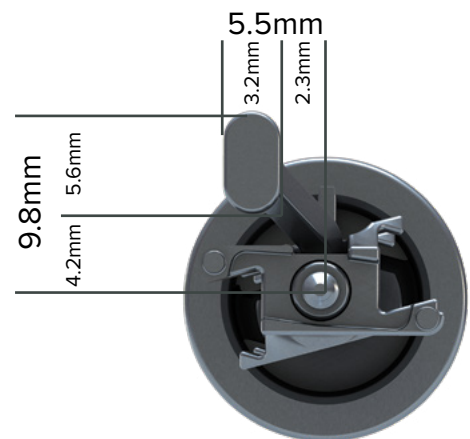


Figure 2: Depth Stop Offset Dimension

Step 3: Implant Size Selection

12L x 14W Footprint			
Configuration	Posterior Height (mm)	Anchor Penetration Depth (mm)	Graft Volume (cc)
6H Lordotic	4.7	5.5	0.47
7H Lordotic	5.7	5.5	0.57
8H Lordotic	6.7	5.5	0.66
9H Lordotic	7.7	5.5	0.76
10H Lordotic	8.7	5.5	0.85
6H Convex	5.0	4.8	0.62
7H Convex	6.0	4.9	0.72
8H Convex	7.0	4.9	0.83
9H Convex	8.0	4.9	0.93
10H Convex	9.0	5.0	1.03

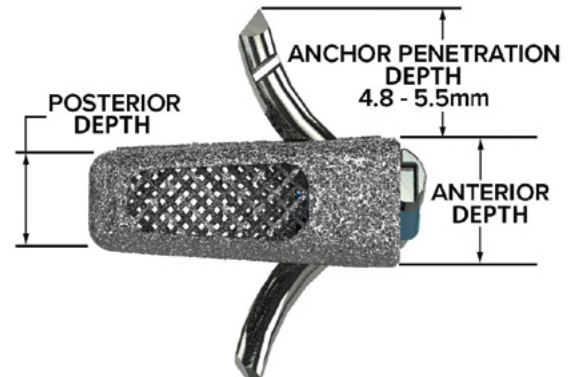


Figure 3a Lateral 6° Lordotic Implant Dimensions

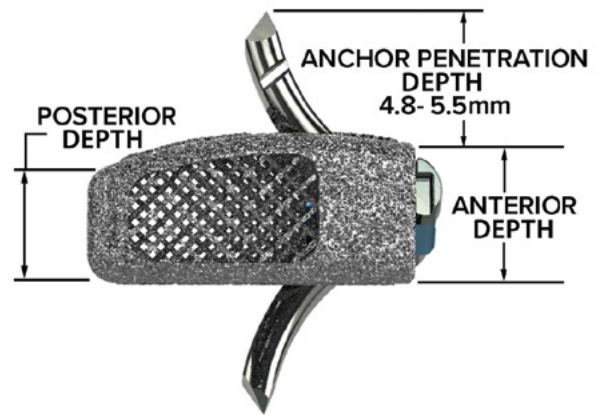


Figure 3b: Lateral Convex Implant Dimensions

14L x 16W Footprint			
Configuration	Posterior Height (mm)	Anchor Penetration Depth (mm)	Graft Volume (cc)
6H Lordotic	4.5	5.5	0.69
7H Lordotic	5.5	5.5	0.83
8H Lordotic	6.5	5.5	0.97
9H Lordotic	7.5	5.5	1.10
10H Lordotic	8.5	5.5	1.24
6H Convex	5.0	4.8	0.89
7H Convex	6.0	4.9	1.05
8H Convex	7.0	4.9	1.20
9H Convex	8.0	4.9	1.35
10H Convex	9.0	5.0	1.50

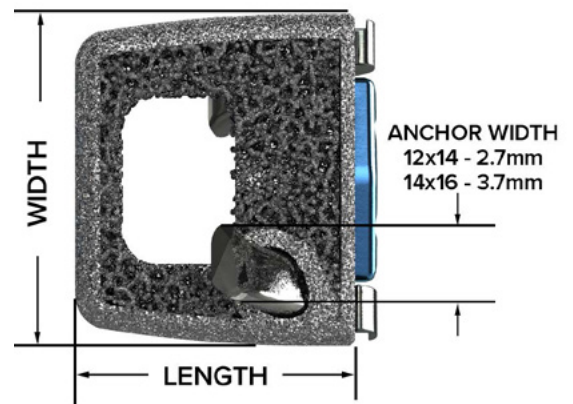


Figure 4: Axial Implant Dimensions

Table 1: Blackhawk Ti Implant Dimensions

NOTE: Convex implants and trials are optional. If needed, contact ChoiceSpine Sales Support Department.

Choose a trial spacer of the appropriate height and footprint. The selection of the trial spacer size is dependent upon the height and depth of the intervertebral space, individual patient anatomy, and disc preparation (Figure 5). Trials are line-to-line with the depth, width, and height matching exact dimensions of the implant.

Once the appropriate implant size has been selected, bone graft can be packed into the implant. See Table 1 for graft volume reference.

Insert the appropriately sized trial into the disc space and check for a secure fit. If necessary, use incrementally larger sizes until a tight fit is obtained. Use radiographic imaging to confirm the implant depth and height as well as endplate coverage (Figure 6). The standard trials come without stops but trials with stops are available upon request. The stops allow for a maximum countersink of 2mm in the disc space.

NOTE: The trials are color coded to indicate footprint and anatomical configuration (Figure 7).



Figure 5: Axial view of trial in disc space



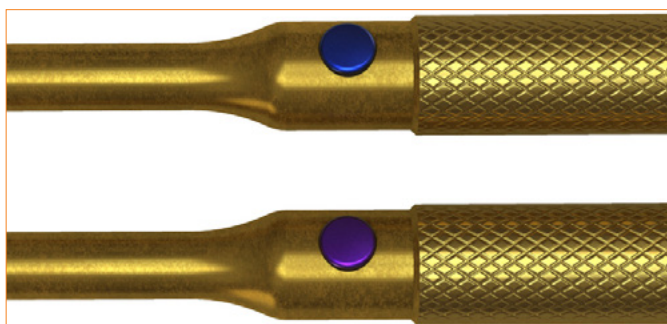
Figure 6: Trial disc space



Silver - 12mm x 14mm Trials



Gold - 14mm x 16mm Trials



Convex* - BLUE

*Optional

Lordotic - PURPLE

Figure 7: Trials

Step 4: Connect Implant to Inserter

Introduce the implant into the disc space using the **Main Core Inserter (T070-0001-A3)** provided in the set. Select the appropriate implant size as determined through trialing. The Inserter is provided disassembled in the set (Figure 8). To assemble the inserter for use, insert the **Inner Shaft Rod (T070-0001-02)** into the **Main Core Inserter (T070-0001-A3)**, then secure using the **T20 hexalobe Draw Rod Driver (T070-0001-07)** in the **Main Core Inserter** housing as shown in Figure 9. Once threaded in, the **Inner Shaft Rod** should slide up and down freely inside the **Main Core Inserter**.

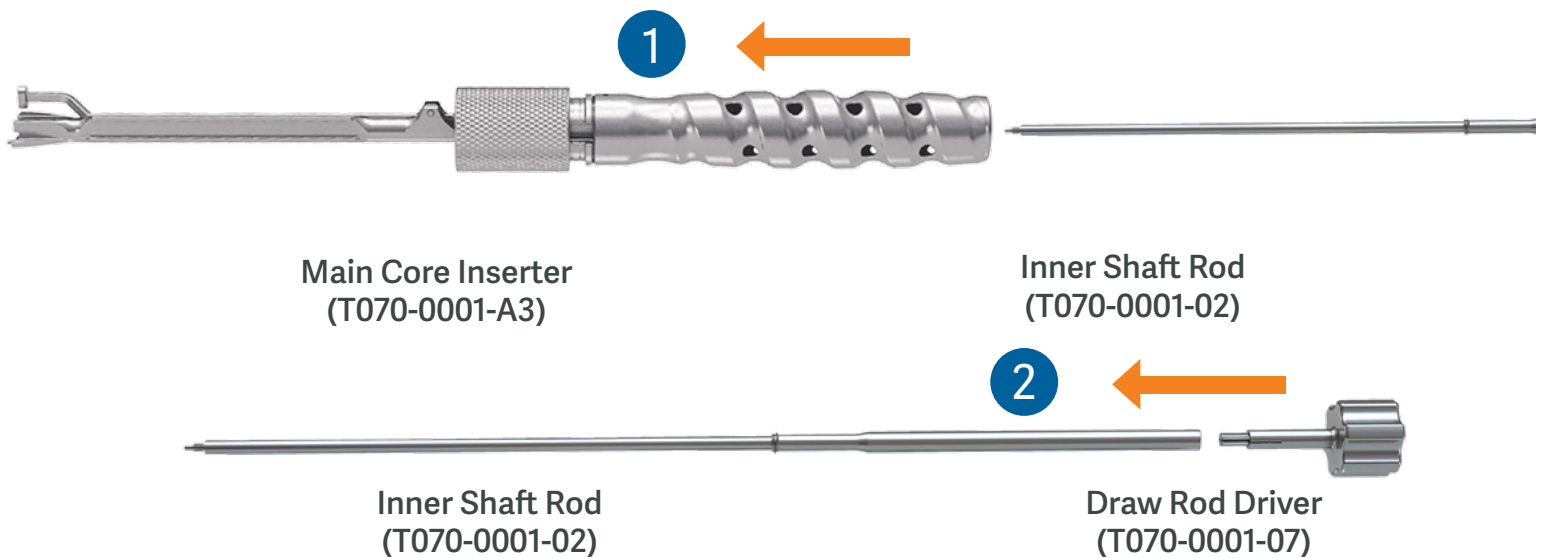


Figure 8: Initial assembly of inserter

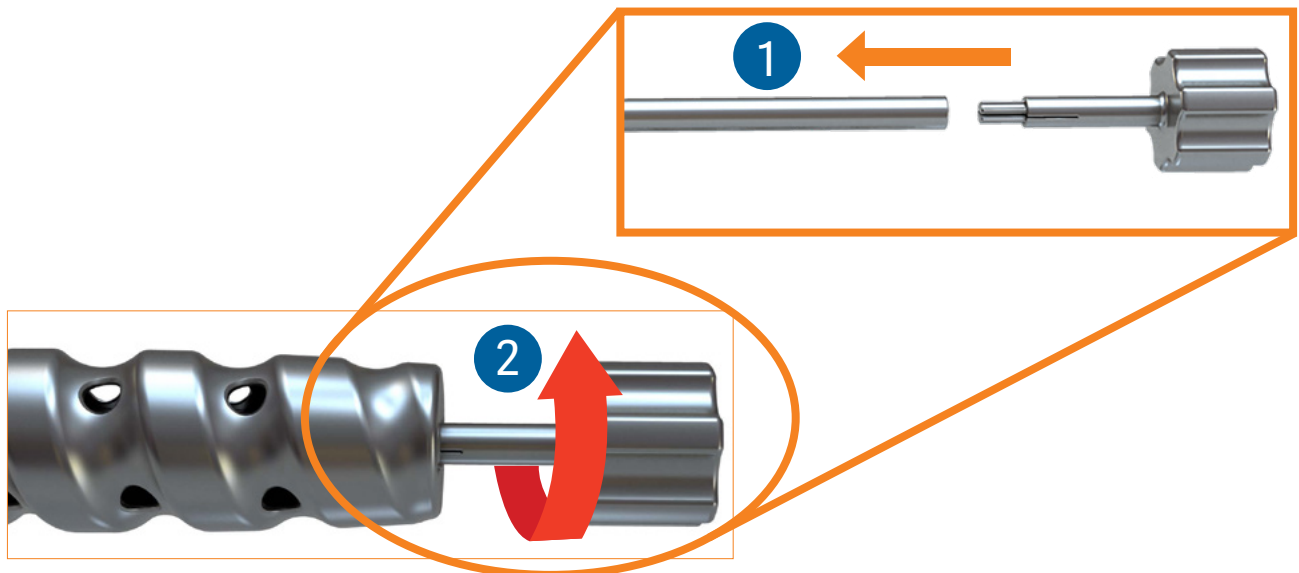


Figure 9: Using Draw Rod Driver (T070-0001-07) to thread Inner Shaft Rod (T070-0001-02) into Main Core Inserter (T070-0001-A3)



Figure 10: Loading Block (T070-0005)

NOTE: It is recommended to load the implant with the depth stop on the yellow epoxy line (2mm subflush) to prevent attachment issues while loading the implant.

Place the selected implant inside the implant Loading Block (T070-0005) (Figure 10). Place the Main Core Inserter (T070-0001-A3) over the implant, ensuring the anchors are resting in the correct location (Figure 11).

Next, use the Draw Rod Driver (T070-0001-07) to thread the Main Core Inserter (T070-0001-A3) to the implant. Thread the Inner Shaft Rod (T070-0001-02) until snug, but do not overtighten. After removing from the Loading Block (T070-0005), check the inserter/implant for a rigid connection.

NOTE: The Deployment Arm (T070-0001-A1) should not be placed at this time to avoid accidental anchor deployment.

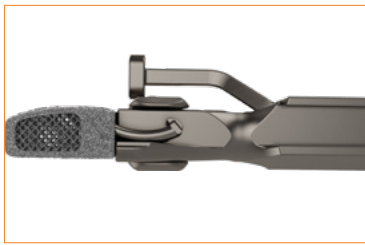


Figure 11: Implant in Loading Block (T070-0005) and Main Core Inserter (T070-0001-A3) correctly aligned to implant

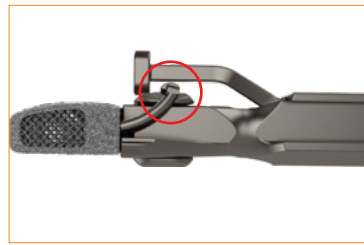
CAUTION: Implant assemblies should be inspected prior to use. Implants with anchors partially deployed and/or protruding out of the implant should be discarded and a new implant should be used.

Step 5: Anchor Confirmation

Before implanting the Blackhawk Ti implant, remove the Protection Sleeve (T070-0019-01) from the Anchor Tool (T070-0019). Guide the distal end of the Anchor Tool over the inserter and implant anchors to assess anchor positioning. Refer to the images below for guidance on correct and incorrect anchor alignment.



Correct Alignment



Incorrect Alignment



Continue to the graft loading and implant insertion steps if the user is able to guide the Anchor Tool over the Inserter and **BOTH** implant anchors without resistance or interference between devices.

If the tool experiences any resistance from the anchors, **DO NOT IMPLANT THE DEVICE**. Malfunctions may occur during blade deployment with this device. Open a new implant and start with **Step 4**. RETURN the potentially defective implant to the ChoiceSpine Sales Support Department.

NOTE: The Anchor Tool is not a calibrated gauge. It is intended to be used as a reference device for anchor positioning.

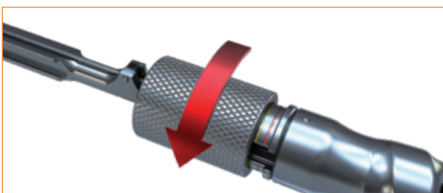
NOTE: **DO NOT DISCARD** the **Protection Sleeve** as the device is used to protect the **Anchor Tool** during handling and transportation. Reassemble the **Protection Sleeve** to the **Anchor Tool** after use.

Adjust the depth stop of the Inserter to the desired countersink depth by rotating the knob clockwise to decrease countersink or counterclockwise to increase the countersink. The depth stop on the inserter can be adjusted from 0mm to 4mm (Figure 12). The Main Core Inserter has colored bands to assist in identifying the countersink depth: 0mm/green, 2mm/yellow, and 4mm/red (Figure 13).

Figure 12: Depth stop adjustment reference



Rotate **CLOCKWISE** to decrease countersink



Rotate **COUNTERCLOCKWISE** to increase countersink



Figure 13

Final View of Implant Correctly Attached to Inserter

NOTE: **DO NOT PLACE** Deployment Arm **AT THIS TIME**



Deployment Arm (T070-0001-A1)

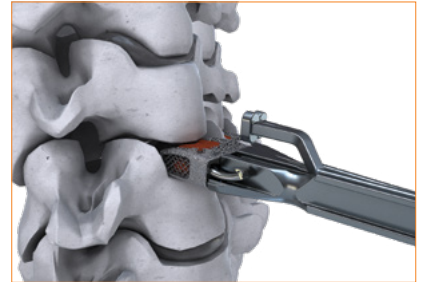
Once the appropriate implant size has been selected and anchor is confirmed, bone graft can be packed into the implant. The Graft Tamp (T070-0006) (Figure 14) can be used to aid in adding graft in the implant.



Figure 14: Graft Tamp (T070-0006)

Step 6: Implant Insertion

Insert the implant into the disc space until the depth stop rests on the anterior surface of the caudal or cephalad vertebral body (Figure 15A & B). If the implant position is too anterior, the position can be adjusted by changing the depth stop. Confirm the final position of the implant under radiographic imaging and remove distraction instruments (if used).



NOTE: If there are osteophytes or anatomy that causes the anterior surface of one vertebral body to be more anterior than the other vertebral body, we recommend that the depth stop be placed on the vertebral body with the more posterior position to facilitate optimal implant placement.

NOTE: Important—Before impaction of anchors verify the main core inserter is firmly attached to the implant to help with blade deployment.

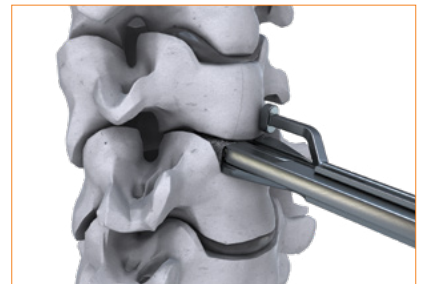


Figure 15A & B: Implant Inserted into Disc Space

Step 7: Deployment of Integrated Anchors

Once seated in the disc space, insert the Deployment Arm (T070-0001-A1) through the Inserter assembly until the Deployment Arm rest on the anchors (Figure 16-17).

Using the Mallet (05-099-30-0000) provided, impact the Deployment Arm (T070-0001-A1) until anchors are fully deployed.

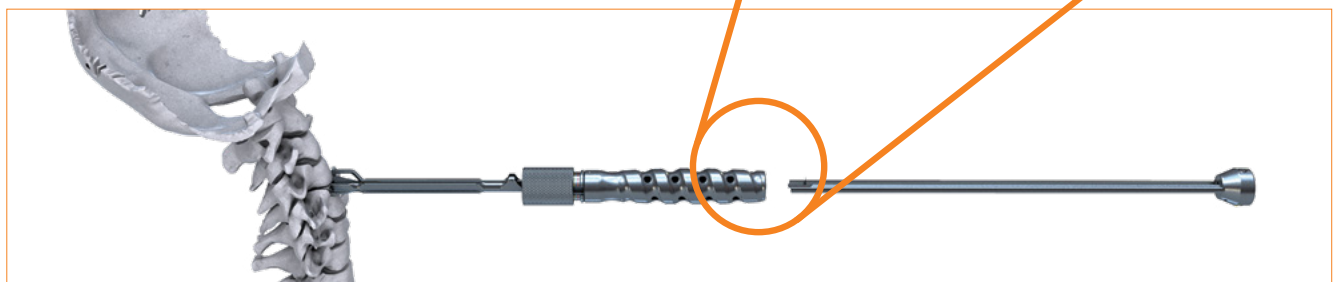


Figure 16: Inserting Deployment Arm (T070-0001-A1) through Inserter assembly

NOTE: The lip of the Deployment Arm should rest over top the anchor as shown in Figure 17A.

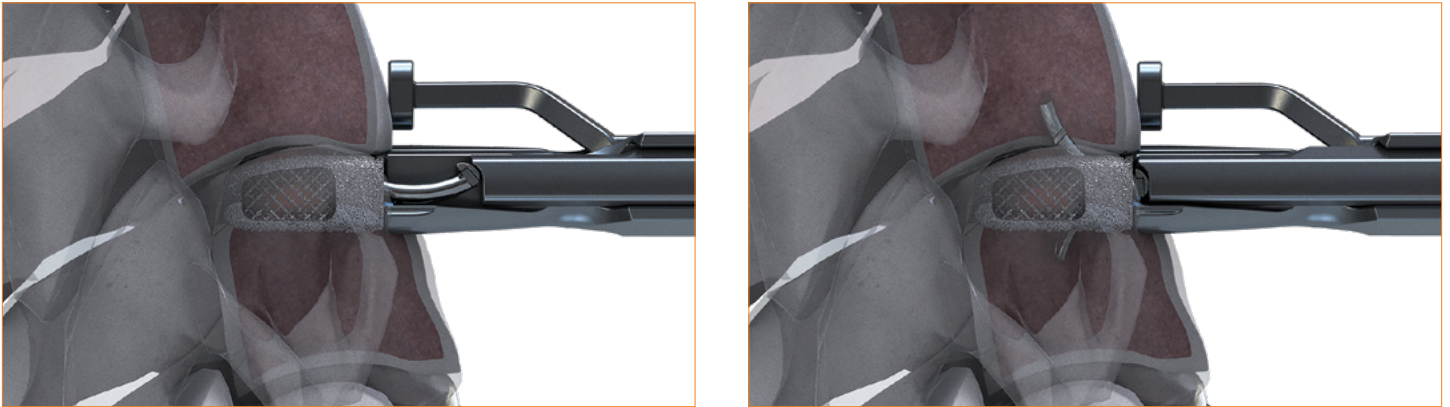
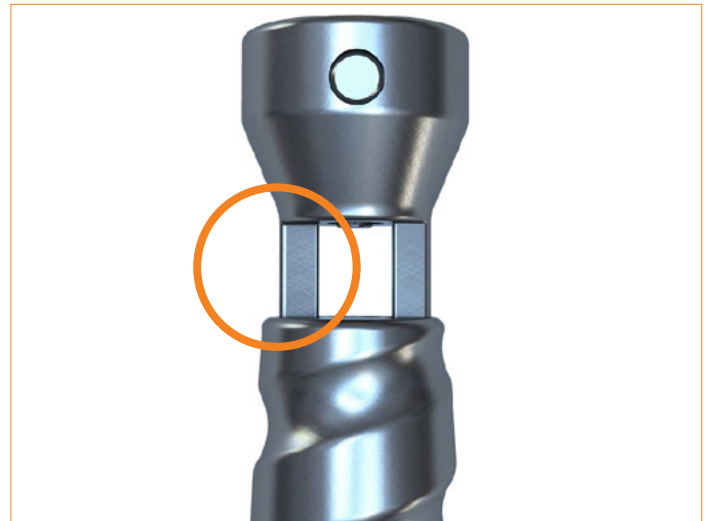


Figure 17A-B: Distal end of Deployment Arm resting correctly on anchors

To confirm the anchors are deployed, confirm the bottom of Deployment Arm is flush with the inserter as shown below (Figures 18 - 19).

DEPLOYED

UNDEPLOYED



Figures 18-19: Deployment indicator views

Single Anchor Impactor

In the event that an anchor needs additional deployment a **Single Anchor Deployment Arm (T070-0017)** is available. Place the **Single Anchor Deployment Arm** through the Inserter assembly until the deployment arm rests on the anchor. Using the Mallet, impact the **Single Anchor Deployment Arm** until the anchor is fully deployed



Step 8: Lock Cam Locking Mechanism

Leaving the Deployment Arm (T070-0001-A1) on the Main Core Inserter (T070-0001-A3), unthread and remove the Inserter from the implant using the Draw Rod Driver (T070-0001-07) (Figure 20). Next, use the Cam Driver (T070-0003) to lock the cam locking mechanism, turning clockwise 25° (Figure 21 and 22).

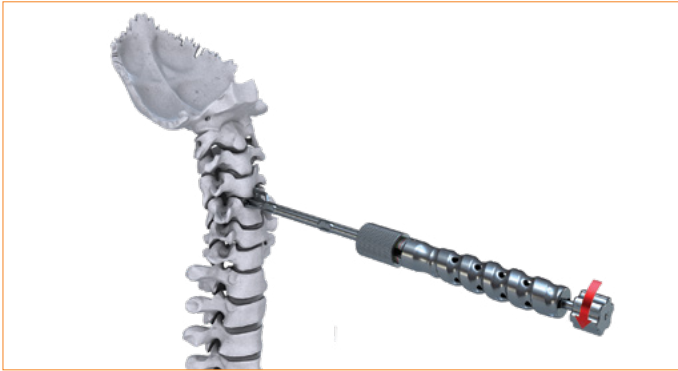


Figure 20: Removing inserter

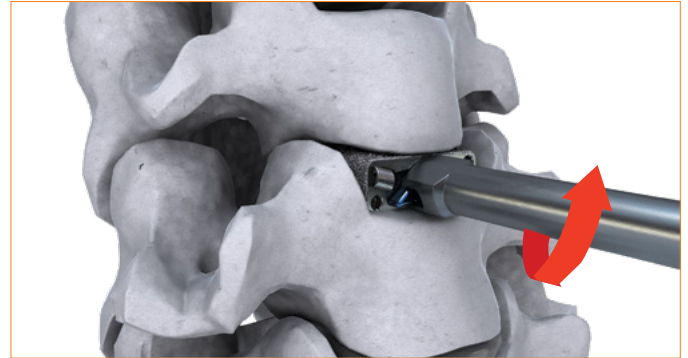


Figure 21: Cam Driver on cam (unlocked)



Figure 22: Locking cam with Cam Driver (T070-0003)

NOTE: The groove machined on the proximal end of the Cam Driver is in-line with the cam position as shown in Figure 23. Figure 22 & 23 show confirmation of the cam lock. View of final locked implant is in Figure 24.

NOTE: If unable to turn the cam to the shown position, the anchors may not be fully deployed. It is recommended that the inserter is reattached and that the Deployment Arm is used to further deploy the anchors.

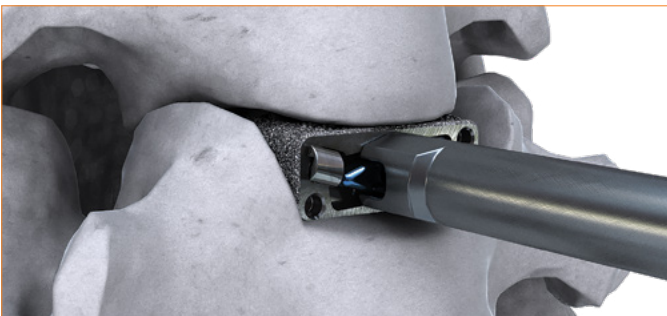


Figure 23: Cam Driver on cam (locked)



Figure 24: Implant with anchors deployed and cam locked

The Blackhawk® Ti System has standalone indication. If the procedure requires supplemental fixation ChoiceSpine's Boomerang®, Ambassador® or Falcon™ Cervical Plate System can be used.

Step 9: Implant Removal

If it becomes necessary to remove the Blackhawk® Ti implant, use the Cam Driver (T070-0003) to unlock the cam (Figures 25-26). Next, use the Anchor Removal Tool (T070-0004) to remove each anchor (Figures 27-28).

NOTE: Each anchor can be fully removed or left in the pre-assembled position for final removal.

NOTE: The anchors should be fully retracted prior to attempting removal of the interbody. It is recommended that anchor retraction is confirmed radiographically prior to removal. If the anchors are still partially deployed, plier-like instruments may be used to assist in retraction. It is recommended that distraction of the disc space is performed during removal situations.

Finally, thread the Inserter onto the implant and remove the device from the disc space (Figure 29).



Figure 25-26: Turning the cam from locked position (left) to unlocked (right)

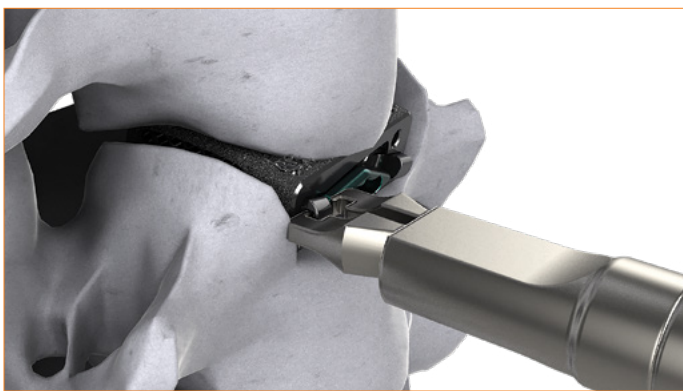


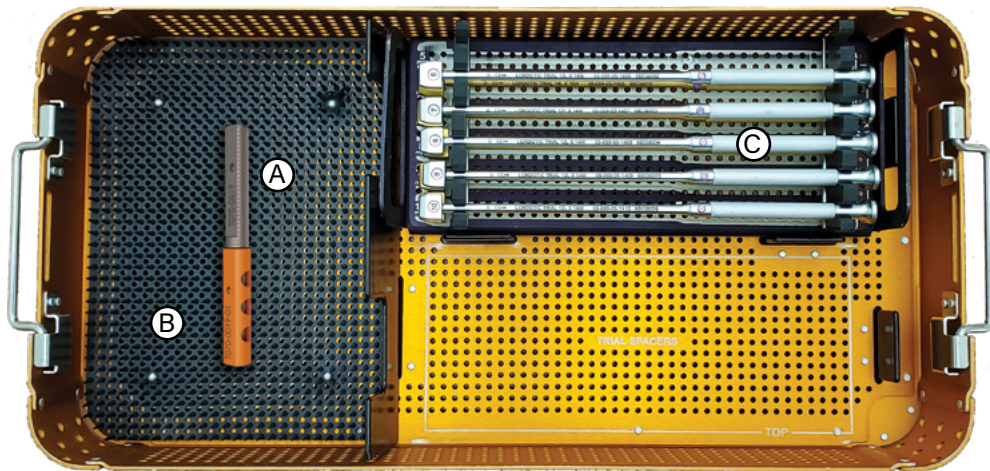
Figure 27-28: Anchor Removal Tool (T070-0004) placed to remove anchor



Figure 29: Inserter reattached to remove implant

Blackhawk® TI Instrument Tray

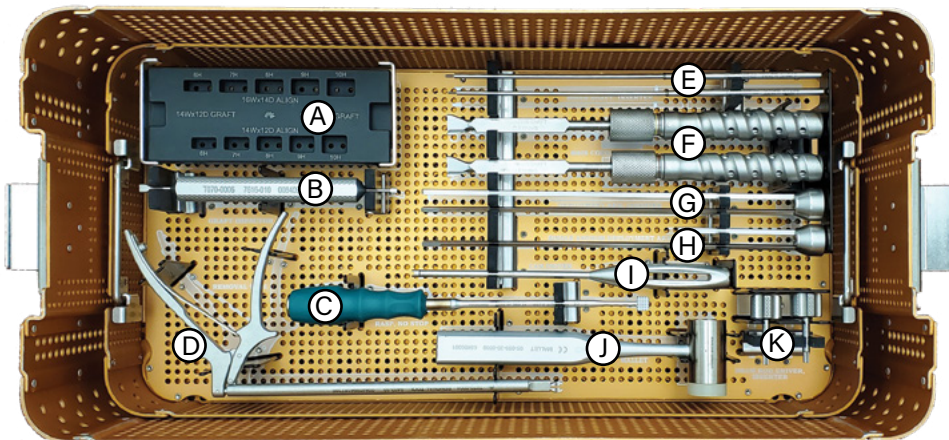
Top Tray



- Ⓐ Anchor Tool T070-0019

Ⓑ Protection Sleeve T070-0019-01
- Ⓒ Trials 14mm X 12mm, 16mm X 14mm, 6mm - 10mm

Bottom Tray



- Ⓐ Loading Block T070-0005

Ⓑ Graft Impactor T070-0006

Ⓒ Rasp, No Stop 05-099-10-0000

Ⓓ Removal Tool T070-0004
- Ⓔ Inner Shaft, Inserters x2 T070-0001-02

Ⓕ Main Core, Inserters x2 T070-0001-A3

Ⓖ Deployment Arm Inserters T070-0001-A1

Ⓗ Single Anchor Impactor T070-0017
- Ⓘ Cam Driver T070-0018

Ⓝ Mallet 05-099-30-0000

Ⓚ Draw Rod Driver, Inserters x2 T070-0001-07



BLACKHAWK[®] TI

Standalone Cervical Spacer System

Spine the Right Way.[™]



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