

TOMCAT™

Standalone Cervical Spinal System





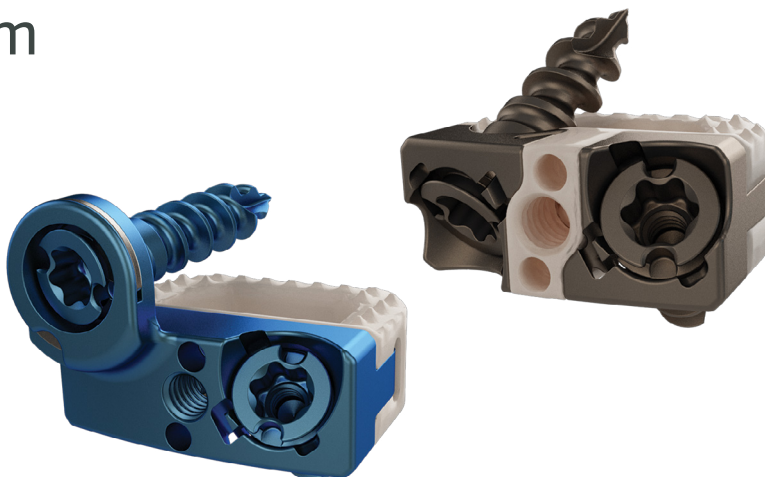
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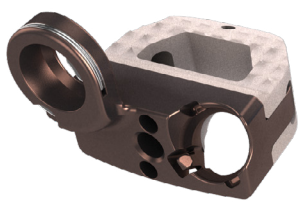
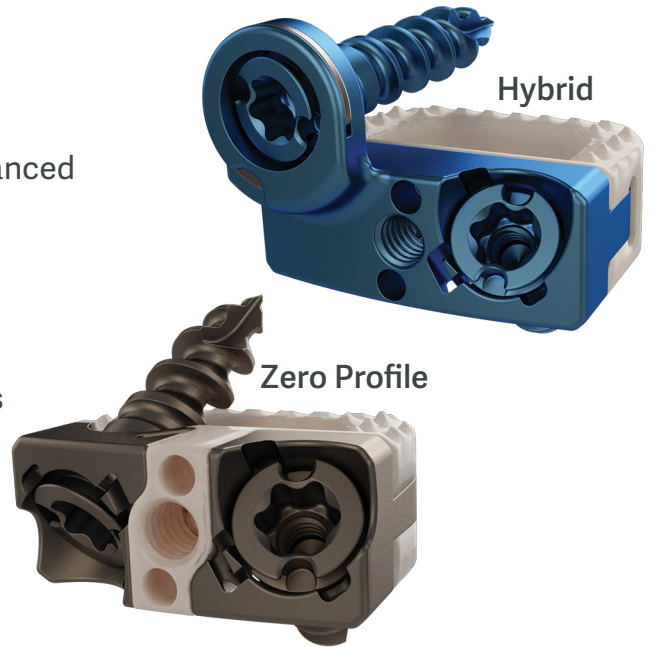


Introduction

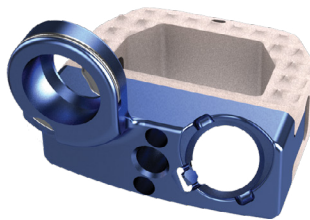
The Tomcat™ Standalone Cervical Spinal System is designed to provide biomechanical stabilization to the cervical vertebral column (C2-T1). The Tomcat™ implant, consisting of PEEK-OPTIMA™ HA enhanced from Invibio®, offers an alternative to traditional anterior cervical fusion using plates and screws.

System Features and Benefits

- Early bone appositions with PEEK-OPTIMA™ HA Enhanced
- Simple instrumentation
- Self-locking retention mechanisms
- Hybrid interbody option for difficult screw trajectories
- Screw diameters: Ø3.5mm and Ø4.0mm



14x12mm



16x14mm

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



14x12mm



16x14mm

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

Ø3.5mm Self Drilling Variable Angle Screws	
Lengths	Color
10mm	Magenta
12mm	Bronze
14mm	Dark Blue
16mm	Gold



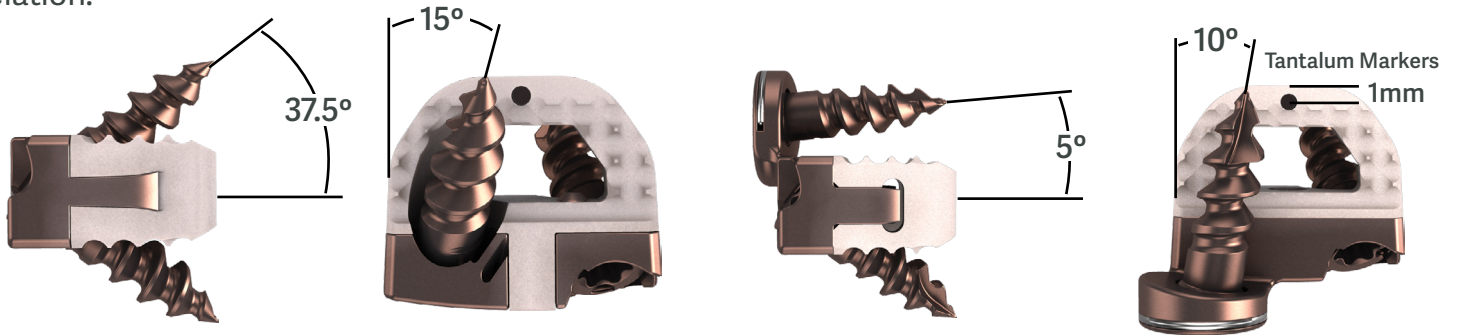
Ø4.0mm Self Drilling Fixed Angle Screws	
Lengths	Color
10mm	Magenta
12mm	Bronze
14mm	Dark Blue
16mm	Gold



NOTE: Self-tapping screws are available upon request.

Implant Sizes

The same color screw and interbody will result in the distal tip of the screw being flush with the posterior wall of the interbody at the neutral screw angles shown below. For example, if the bronze screw is used with the 14x12mm bronze interbody, then the distal screw tip will be flush with the posterior wall of the interbody at 12 mm. See charts below for alternative screw depth to interbody relation.



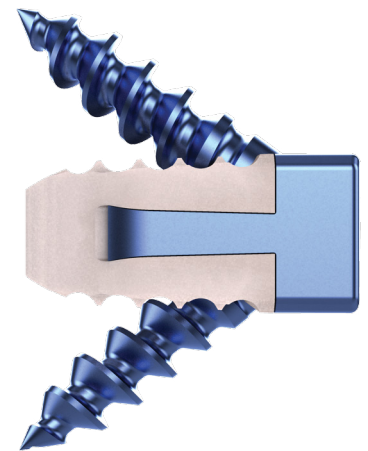
Zero Profile Implant		
	Cephalad/Caudal	Medial/Lateral
4.0mm Fixed Screws	37.5°	15°
3.5mm Variable Screws	27° - 47°	9° - 22°

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

NOTE: Tantalum Markers are 1mm from posterior of implant.

Implant	Screw Length		
14x12mm	10mm	12mm	14mm
	-2mm	0mm	+2mm

Implant	Screw Length		
16x14mm	12mm	14mm	16mm
	-2mm	0mm	+2mm



Step 1: Patient Positioning & Exposure

- Position and prepare the patient.
- Create the appropriate incision at the affected levels and gently expose the cervical spine.

Step 2: Distraction

- Distract the disc space using standard methods.
- Use caution to avoid over-distraction.

Step 3: Discectomy & Endplate Preparation

- Remove the affected disc material by performing a standard discectomy (Figure 1).
- Attach the appropriately sized Rasp (R070-0009; 14x12) or (R070-0010; 16x14) to the Quick Connect Axial Handle (L070-0030) (Figure 2).
- Use the Rasp to prepare the endplates.



Figure 1



Figure 2

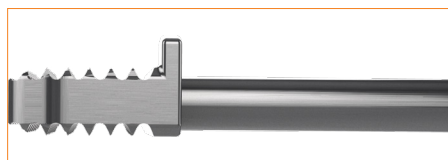


Figure 3

NOTE: Rasps are 5.2mm in height measured from tooth to tooth.

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 (Figure 3).

Step 4: Implant Sizing

- Trials (R070-XXXXXXX) are undersized by 1mm in height and are provided to determine the appropriate implant size (Figure 4).
- Insert the appropriate trial into the **Quick Connect Axial Handle** and carefully insert into the disc space (Figure 5).
- The trial should pass into the distracted disc space without excessive force.

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

Depth	Color
12mm	Bronze
14mm	Dark Blue

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



Figure 4

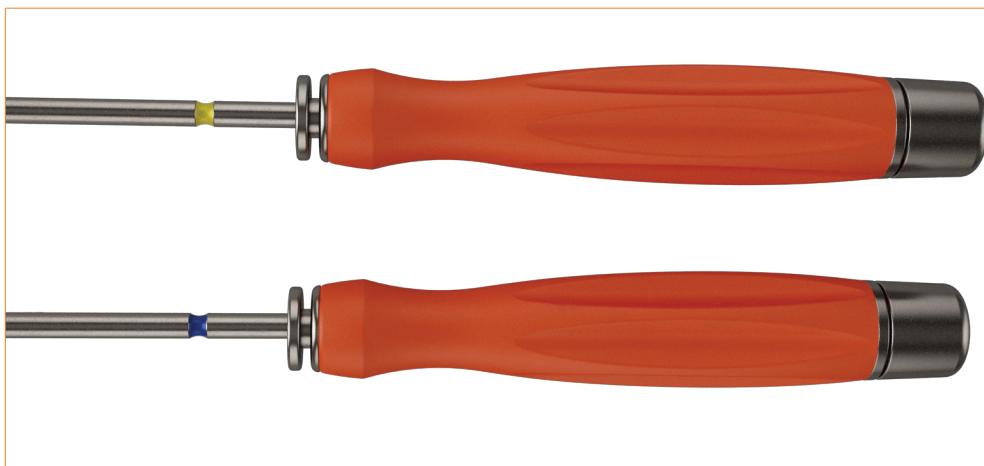


Figure 5

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 (R070-ZXXX) that corresponds to implant height to the distal tip of the Guided Inserter (R070-0001) (Figure 6).
- Place the Zero Profile Implant onto the distal end of the Zero Profile Guide (Figure 7).
- Place the Inserter Drawrod (R070-0017) through the Guided Inserter and thread the distal tip into the implant until finger tight (Figure 8).
- Insert the implant into the disc space (Figure 9).

NOTE: An Implant Guide is not needed if using the Low Profile Inserter (R070-0002). If using the Low Profile Inserter, care must be taken to keep axial alignment with threaded interbody connection.

NOTE: The guide is held in place by a snap mechanism on the distal tip of the inserter (Figure 7).



Figure 6



Figure 7



Figure 8

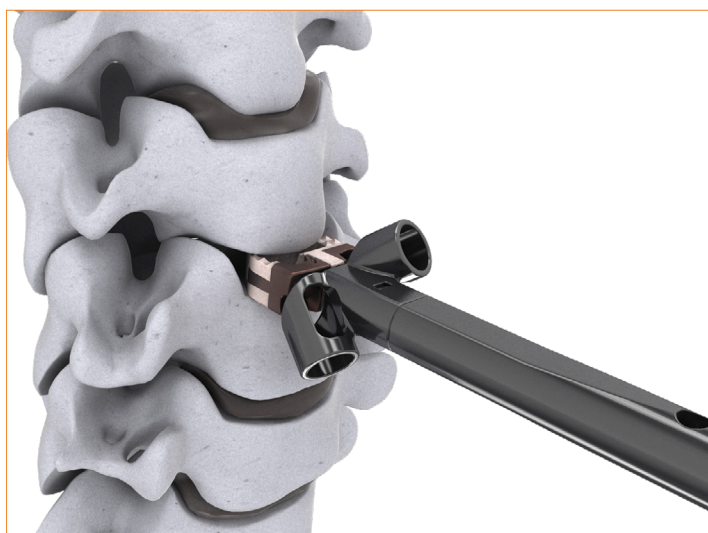


Figure 9

HYBRID PROFILE:

- Fill the implant with desired graft material, as determined by the surgeon.
- Attach the appropriate height Hybrid Guide (R070-HXXX) that corresponds to implant height to the distal tip of the Guided Inserter (R070-0001) (Figure 10).
- Place the Tomcat™ Hybrid implant onto the distal end of the Hybrid Guide.
- Place the Inserter Drawrod (R070-0017) through the Guided Inserter and thread the distal tip into the implant until finger tight.
- Insert the implant into the disc space (Figure 12).

NOTE: An implant guide is not needed if using the Low Profile Inserter (R070-0002). If using the Low Profile Inserter, care must be taken to keep axial alignment with the threaded interbody connection.

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



Figure 10



Figure 11



Figure 12

Step 6: Screw Hole Preparation – Awl & Drill

- Use the Awl (R070-0004, R070-0005, or R070-0006) through the Zero Profile or Hybrid Guide to penetrate the cortical bone (Figure 13).
- Select the appropriately sized Drill (R070-D012 or R070-D014) that corresponds with the screw & interbody length (Figure 14).
- Attach the drill to the Quick Connect Axial Handle (L070-0030) and drill into the vertebral body through the Drill Guide (R070-0007) (Figure 15).



Figure 13

NOTE: A Straight (R070-0004), Angled (R070-0005), and Spring Loaded Awl (R070-0006) are available based on surgeon preference. Awl penetration depth is 10mm.

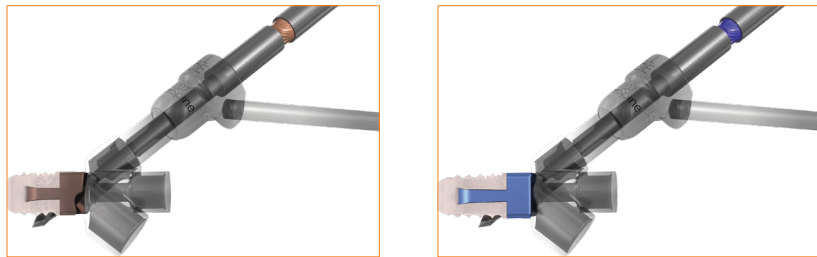


Figure 14

NOTE: If using a 14x12mm footprint implant (bronze) use the Bronze Banded Drill (R070-D012). If using 16x14mm footprint implant (blue), use the Blue Banded Drill (R070-D014). This will ensure that the surgeon does not drill past the posterior wall of the implant (Figure 14).

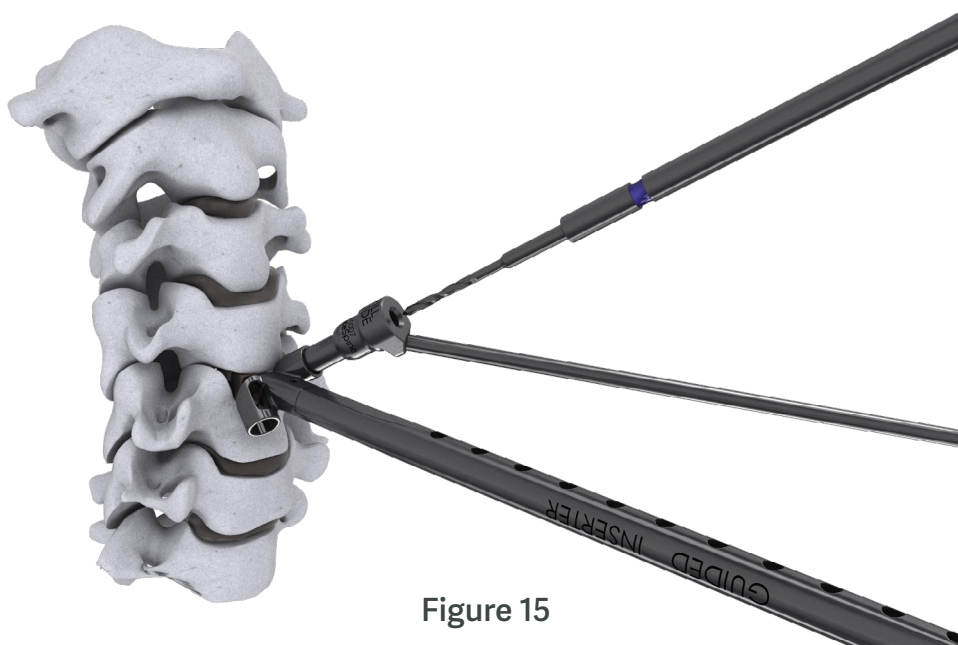


Figure 15

Step 7: Screw Insertion

- Attach the Driver (See driver options below Figure 18) to Axial Handle (L070-0030).
- Load the screw onto the driver.
- Place the screw into the prepared screw hole if using the **Low Profile Inserter** or through the **Zero Profile, Hybrid Guide** if using the **Guided Inserter**.
- Advance the screw until fully seated in the locked position. Confirm this by ensuring the black band on the driver is covered (when using the **Guided Inserter**) or by verifying the locking strut sits inside with the inner channel of the screw (when using the **Low Profile Inserter**; see Figure 17).
- If using the Tomcat™ Hybrid implant, advance the screw until the retention clip sits inside of the screw's inner channel.
- Repeat steps for the second screw.

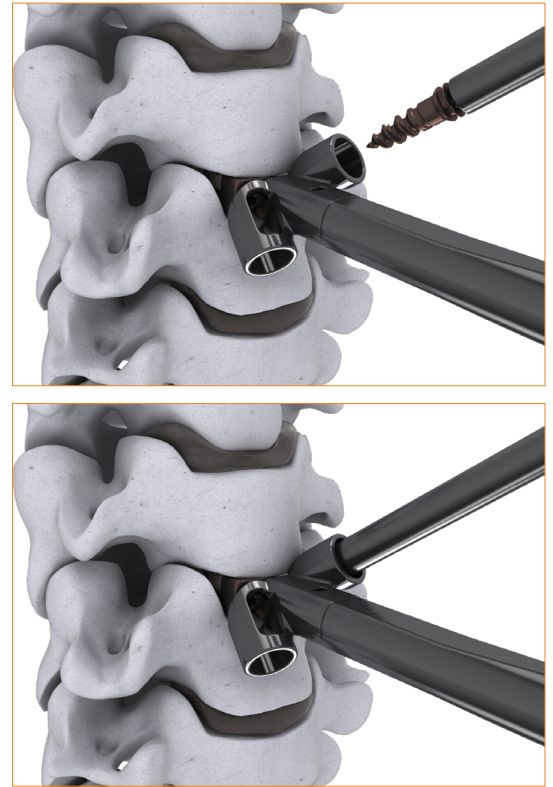


Figure 16

Step 8: Inserter Removal

- Rotate the Inserter Drawrod (R070-0017) counterclockwise to release it from the implant.



Figure 17



Figure 18

NOTE: The Straight Driver (R070-0018), Fixed Angle Driver (R070-0012), and Universal Joint Driver (R070-0019) are available depending on surgeon preference (Figure 18). All drivers have split tips.

Screw Removal

- Insert the Removal Driver (R070-0015) into the screw by aligning its pins with the holes of the screw head (Figure 19).
- Thread the Drawrod (R070-0017) into the screw until finger tight.
- Rotate the Removal Driver (R070-0015) counterclockwise to bypass the locking mechanism and remove the screw (Figure 20).
- Repeat for the other screw.

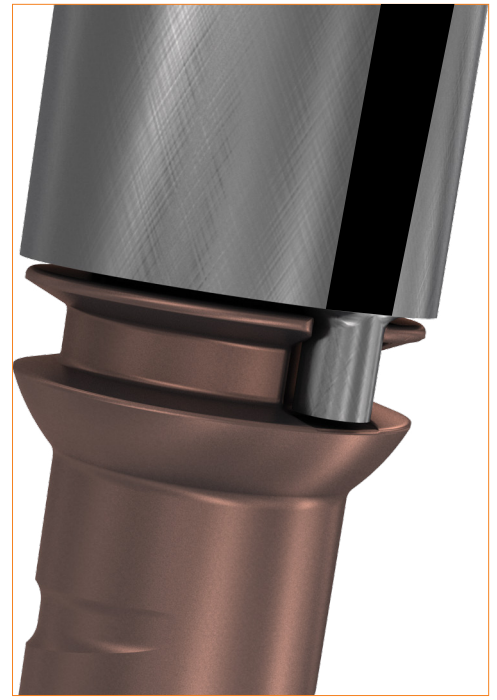


Figure 19

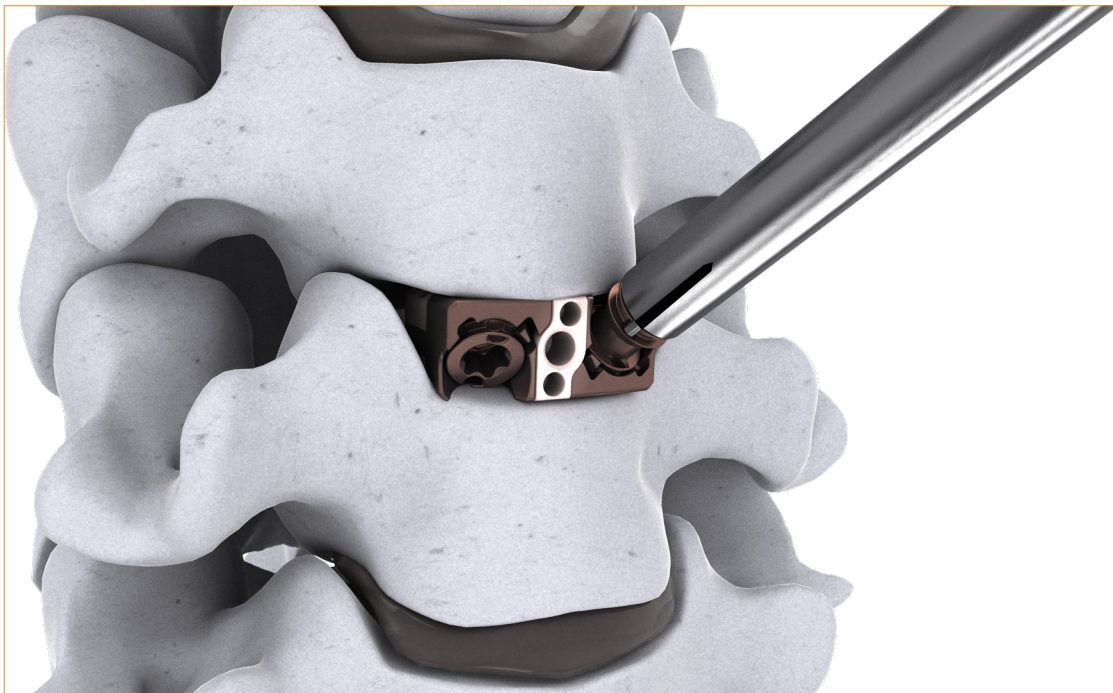
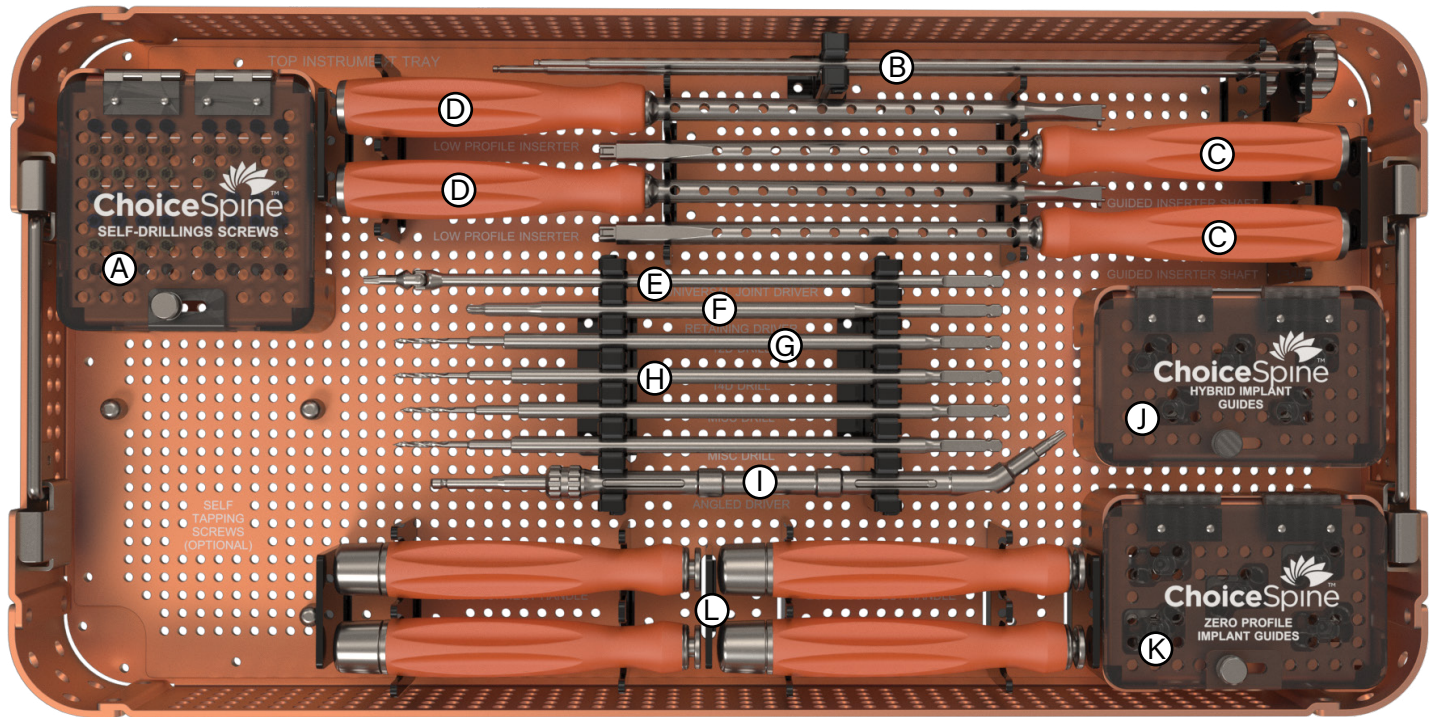


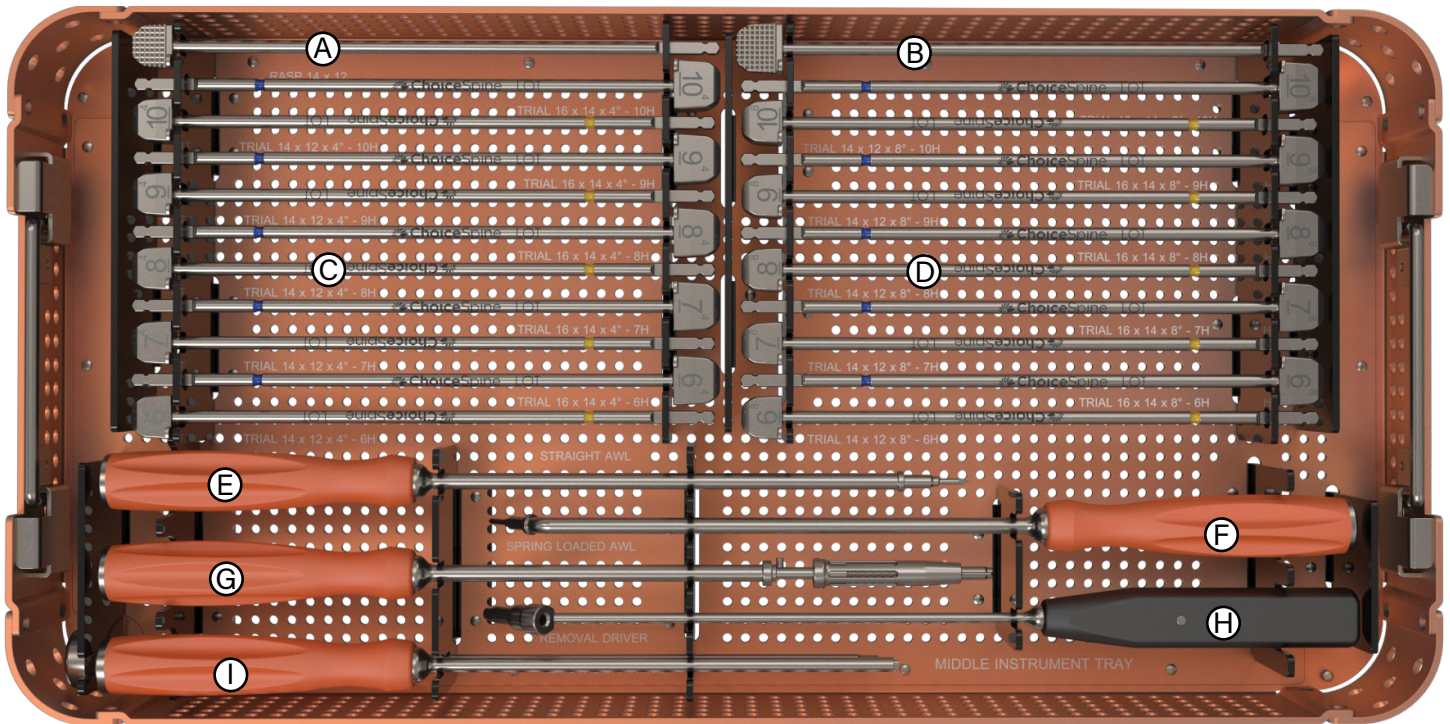
Figure 20

Tomcat™ Top Tray



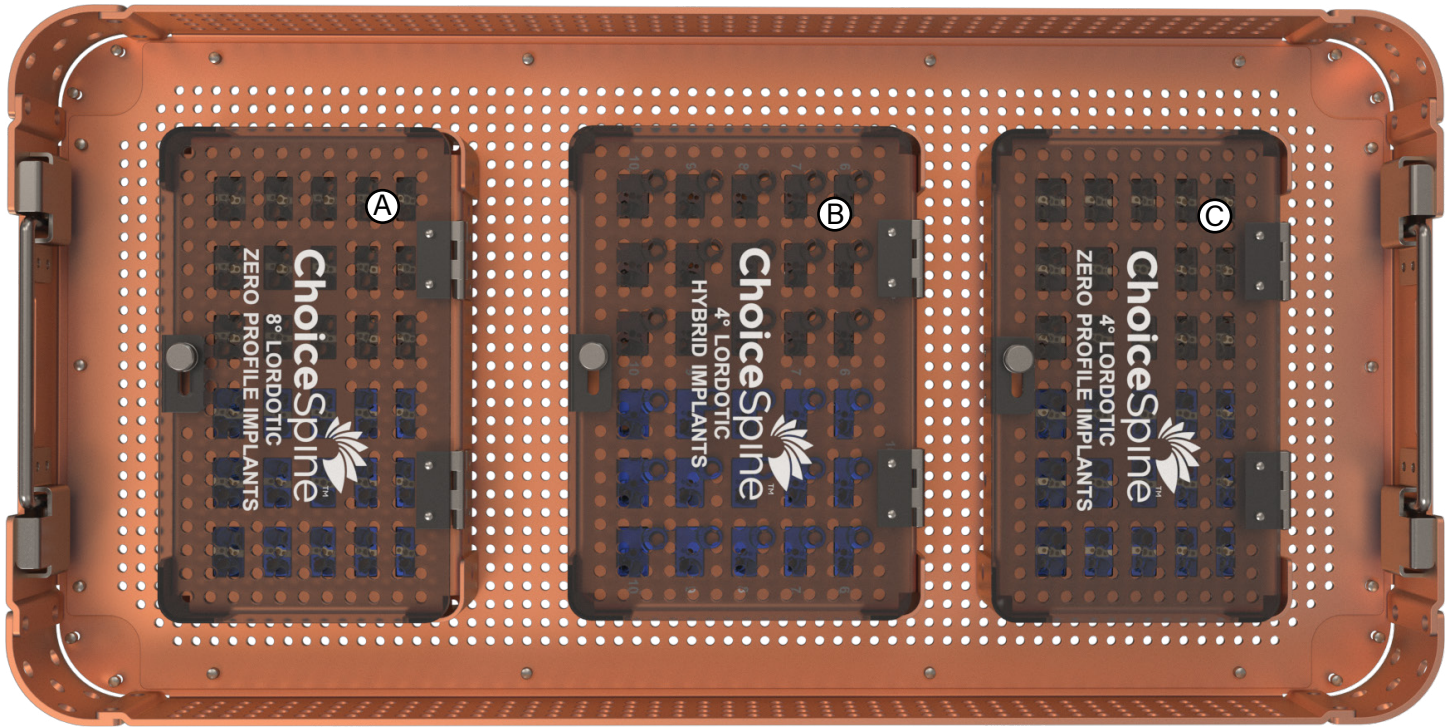
- Ⓐ **Self-Drilling Screws (R090-1900) (Ø3.5 & Ø4.0)**
- Ⓑ **Inserter Drawrod (R070-0017) x2**
- Ⓒ **Guided Inserter (R070-0001) x2**
- Ⓓ **Low Profile Inserter (R070-0002) x2**
- Ⓔ **Universal Joint Driver (R070-0019) x1**
- Ⓕ **Straight Driver (R070-0018) x2**
- Ⓖ **12D Drill (R070-D012) x2**
- Ⓗ **14D Drill (R070-D014) x2**
- Ⓘ **Fixed Angle Driver (R070-0012) x1**
- Ⓙ **Hybrid Guides Caddy (R090-1500)**
- Ⓚ **Zero Profile Guides Caddy (R090-2000)**
- Ⓛ **Axial Handle (L070-0030) x4**

Tomcat™ Middle Tray



- (A) **14x12 Rasp (R070-0009)**
- (B) **16x14 Rasp (R070-0010)**
- (C) **Trials 14x12, 16x14 (6-10mm) 4° (R070-1412406 through R070-1614410)**
- (D) **Trials 14x12, 16x14 (6-10mm) 8° (R070-1412806 through R070-1614810)**
- (E) **Straight Awl (R070-0004)**
- (F) **Angled Awl (R070-0005)**
- (G) **Spring Loaded Awl (R070-0006)**
- (H) **Drill Guide (R070-0007)**
- (I) **Removal Driver (R070-0015)**

Tomcat™ Bottom Tray

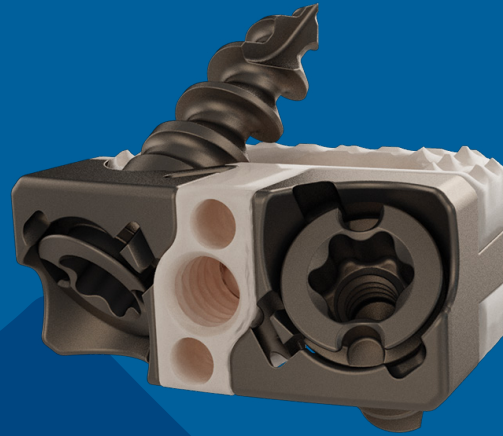
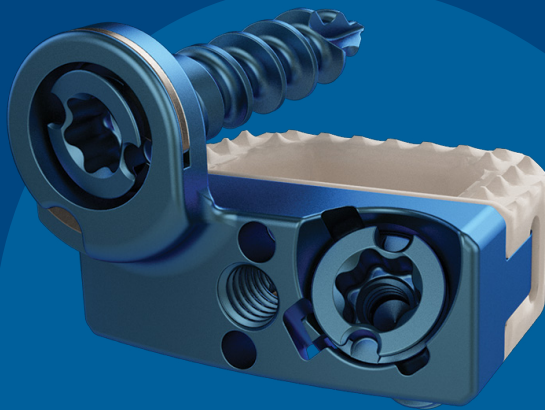


- Ⓐ Zero Profile 8° Caddy (R090-1800)
- Ⓑ Hybrid 4° Caddy (R090-1300)
- Ⓒ Zero Profile 4° Caddy (R090-1700)

Instrument Listing

R070-0001	Guided Inserter	2
R070-0002	Low Profile Inserter	2
R070-0004	Straight Awl	1
R070-0005	Angled Awl	1
R070-0006	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 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	Hybrid Guide, 6	1
R070-H007	Hybrid Guide, 7	1
R070-H008	Hybrid Guide, 8	1
R070-H009	Hybrid Guide, 9	1
R070-H010	Hybrid Guide, 10	1
R070-Z106	Zero Profile Guide, 6	1
R070-Z107	Zero Profile Guide, 7	1
R070-Z108	Zero Profile Guide, 8	1
R070-Z009	Zero Profile Guide, 9	1
R070-Z010	Zero Profile Guide, 10	1



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System

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