

BOOMERANG™

Anterior Cervical Plate System

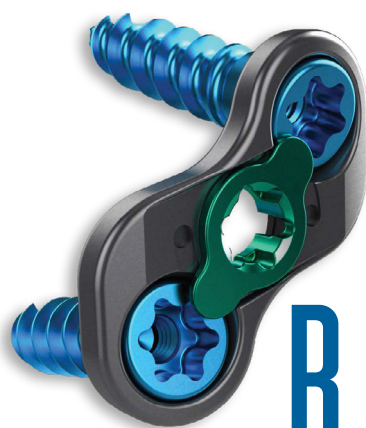




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Introduction

The ChoiceSpine Boomerang™ Anterior Cervical Plate System is a low-profile, two-screw implant that can be inserted simultaneously with our TigerShark™ C 3D Printed Titanium Interbody or Stealth™ PEEK Interbody. Boomerang has an integrated single-step screw locking mechanism for fast insertion and fixation to the anterior cervical spine. In addition, the plate's low-profile offset design allows Boomerang to be used for multiple adjacent levels and is an excellent option for revision surgery.

System Features

- Traditional 510(k) plate clearance for cervical use Boomerang was tested against a traditional plate in compression bending and torsion for strength
- Stackable to accommodate multiple adjacent levels
- Insert together using TigerShark™ C or Stealth™ cervical interbody design to limit steps in the operating room
- Integrated single-step screw locking mechanism allows for visual and tactile confirmation of locking
- 20° maximum cranial/caudal screw angulation
- Easy to use and minimal instrumentation

Implant Sizes

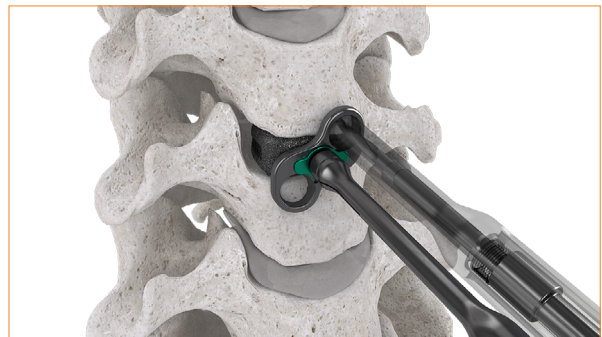
- Plate Sizes (screw-to-screw): 10mm-13mm (1mm increments); Optional sizing: 14mm, 16mm and 18mm
- Overall Plate Size: Plate Size + 7.5mm
- Plate Width: 15mm
- Screw Diameters: ø4.0mm and ø4.5mm
- Screw Lengths: 10mm-16mm (2mm increments)



OPERATIVE TECHNIQUE OVERVIEW



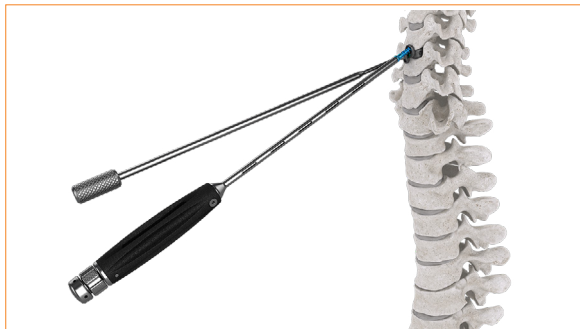
Use Plate Holder to Place Plate



Drill



Attach a Screw to the Screwdriver



Insert the Screws

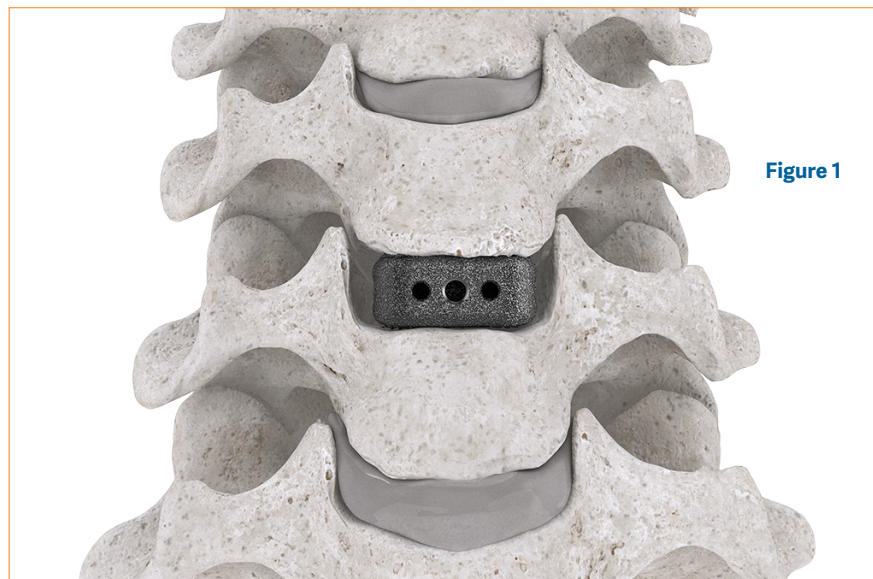


Engage Screw Blocker

DETAILED OPERATIVE TECHNIQUE

Exposure and Sizing Interbody

A transverse incision over the anterior aspect of the neck with a Smith-Robinson or other preferred approach can be used to expose the anterior cervical spine. Fluoroscopy is used to confirm the appropriate disc level has been exposed. Careful removal of anterior osteophytes should be performed to allow the Boomerang plate to sit flush with the anterior cervical spine. The preferred choice of distraction can be employed either via Caspar pin distraction or lamina spreader. Thought should be given to placement of Caspar pins so to not impede implantation of the plate if left in place during graft and plate placement. A thorough discectomy should be performed along the cartilaginous endplate at the operative level. The size of the disc space should be measured with sequential trials until the desired fit is achieved and the matching graft or interbody size can be selected to restore disc space height and lordosis (Figure 1).



After exposure and decompression is completed, the Boomerang Anterior Cervical Plate may be implanted in one of two ways:

1. A plate-only technique, after a cervical graft or interbody has been placed.
2. A combined plate/interbody technique, with an appropriate ChoiceSpine cervical interbody, such as TigerShark™ C or Stealth™.

Plate Selection

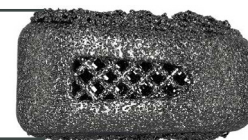
The Boomerang Anterior Cervical Plate is available in screw-to-screw lengths ranging from 10mm to 13mm in 1mm increments. 14mm, 16mm, and 18mm plates are also available if additional anterior coverage is desired.

Determine the appropriate plate length based on the desired position and trajectory of each screw relative to its location to the anterior corners of the cervical graft using the guidelines in the table below:

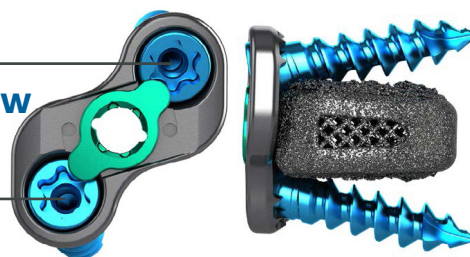
ANTERIOR GRAFT / INTERBODY HEIGHT (mm)	MIN.PLATE LENGTH, SCREW- TO-SCREW(mm)
5	10
6	10
7	11
8	12
9	13
10	14*

*14 is Optional.

**Anterior
Height**



**Screw-to-Screw
Distance**



**Overall Plate Height = Screw-to-Screw
Distance + 7.5mm**

NOTE: The table specifies the minimum recommended plate length that can be used with a given anterior graft height. This ensures the closest possible screw insertion point to the anterior corners of the graft/ vertebral endplates without interference between the screws and graft. A larger plate can be selected for a given graft height, if desired.

WARNING: Do not attempt to bend the Boomerang Anterior Cervical Plate. It is designed such that the screw holes will rest near the anterior corners of the cervical graft/interbody and vertebral endplates. Therefore, contouring

Screw Selection and Preparation Options

The Boomerang Anterior Cervical Plate System has been designed with simplicity in mind and allows for direct screw placement after plate insertion. The system includes Ø4.0mm and Ø4.5mm variable, self-drilling screws in lengths from 10mm to 16mm by 2mm increments. Screw angulation range is shown below:

Cranial-Caudal Screw Angulation Medial-Lateral Screw Angulation



If pre-drilling is preferred, two methods are provided to correspond with the desired technique for plate implantation: 1) Using the Combination Awl/Drill with incorporated Guide Sleeve or 2) Using the Drill Guide and Drill provided as optional. These methods are described with each respective plate insertion technique.

NOTE: Stay within the limits of screw angulation when drilling and inserting screws to ensure the screw blocking mechanism engages properly.

Plate-Only Technique

Step 1a: Plate Placement

After selecting a plate, place it onto the cervical spine using the **Plate Holder (B070-0000)** and center it over the interbody in the disc space (Figure 2). Proper placement can be verified visually by confirming that the screw holes are not obstructed by the interbody. Gentle pressure on or impaction of the plate against anterior column is encouraged as this will help seat the anti-migration teeth on the posterior face of the plate into the cortices of the vertebral bodies to be fixated (Figure 2a).



Figure 2

Figure 2a

CAUTION: Do not use excessive force when impacting the plate and interbody into place. The plate holder retention feature may become wedged in the center hole of the plate, making it difficult to remove the plate holder when it is no longer needed.

Step 2a: Screw Hole Preparation

Use the Plate Holder (B070-0000) and Combination Awl/Drill (B070-0001) with Drill Guide Sleeve (B070-0005) to prepare screw holes. Hold the plate in the desired position over the interbody. Attach the AO Quick Connect Handle (L070-0029) to the Combination Awl/Drill. Insert the instrument into a screw pocket in the BOOMERANG plate and gently apply pressure while rotating the **Combination Awl/Drill** clockwise to penetrate the vertebral body. The slight pressure will facilitate awl/drill penetration and keep the tip of the **Drill Guide Sleeve** seated in the screw pocket, helping to control the desired angulation. When used properly, the **Combination Awl/Drill** will ensure that the limits of screw angulation are not exceeded (e.g. the user will feel the tip of the guide sleeve coming out of the screw pocket when it is over-angulated). The sleeve will retract as the instrument advances into the bone and will come to rest against the shoulder of the awl/drill shaft when it reaches a depth of 10mm. Repeat this step for preparation of the second screw hole. Figures 3 and 4, below demonstrate use of the Plate Holder and Combination Awl/Drill.



Figure 3



Figure 4



Step 3a: Screw Insertion

Remove the **Combination Awl/Drill (B070-0001)** from the surgical site prior to screw insertion. The **Plate Holder** may remain in place, if desired, to maintain plate location while starting screws. Select the appropriate diameter and length of screw and attach it to the **Combination Inserter/Screwdriver (B070-0003-A1 & B070-0003-A2)**, as shown below. Advance the screw until it is fully seated in the plate. Repeat steps for placement of the second screw. Take care to stay within the limits of screw angulation so that the cam-lock can be rotated over a portion of the screw heads and engage the locking features on the face of the plate (Figure 5).

NOTE: Both screws must be inserted in the plate before engaging the cam-lock to cover the screw heads.



NOTE: The outer shaft can also be used by itself to retain the screw by pressing the outershaft into the head of the screw for a press fit.

Insert the Draw Rod (B070-0003-A2) into the Outer Shaft (B070-0003-A1), as shown below



Insert the hexalobe on the **Outer Shaft** into the head of the screw and rotate the knurled knob on the **Draw Rod** to secure the screw to the **Outer Shaft**.



Figure 5

Step 4a: Cam-Locking Mechanism Engagement

The cam-lock should be engaged after placement of both screws. To engage, insert the **Outer Shaft (B070-0003-A1)** of the **Combination Inserter/Screwdriver (B070-0003-A1 & B070-0003-A2)** into the T20 hexalobe at the center of the cam-lock. Gently rotate the cam counterclockwise until engagement of the cam is in the locked position and both felt and seen. The cam does not require aggressive force to turn. Cam-lock engagement is demonstrated in Figures 6 and 7 below:

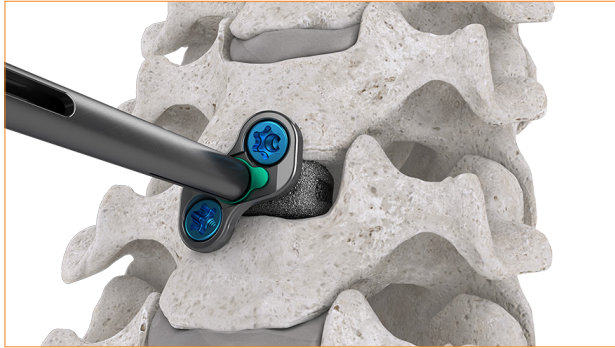


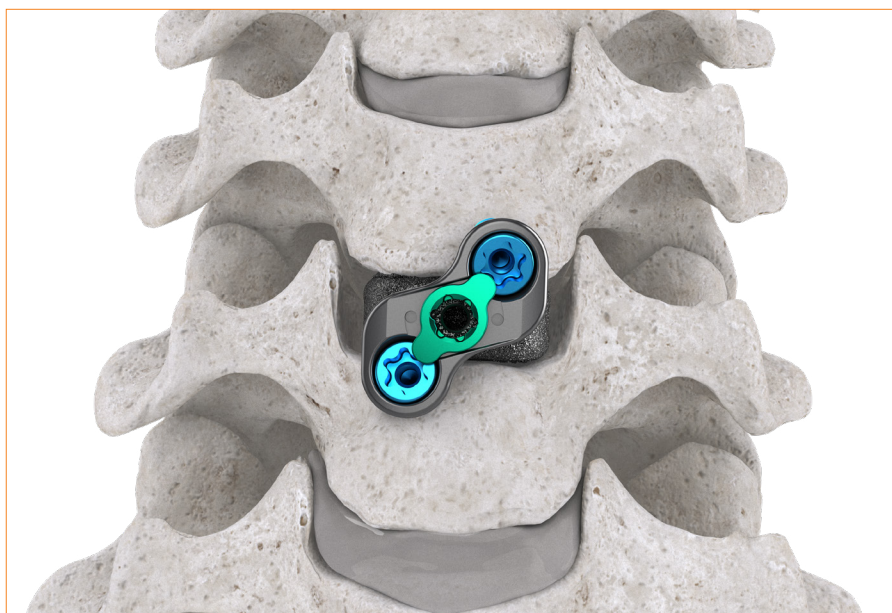
Figure 6 (Unlocked)



Figure 7 (Locked)

WARNING: Rotation of the cam causes permanent deformation of its locking feature that engages the plate, as intended. Do not repeatedly engage/disengage the cam-lock to/from the locked position. The cam-lock may not retain its locked position after repeated engagement/disengagement. The user should verify correct screw placement **BEFORE** engaging the cam-lock. It should be noted that the cam-lock is **NOT** required for securing the screws to the plate. It is a backup mechanism to prevent screws from backing out of the plate and potentially causing local tissue irritation if screws become loose.

WARNING: Each plate length has a predetermined amount of rotation required to rotate the cam-lock and engage it in the locked position. Do not attempt to over-rotate the cam once engagement is felt and seen. Over-rotation may disengage the cam from the locked position and screw heads may not be adequately covered.



Completed Construct

Combined Plate and Interbody Insertion Technique

The Boomerang Combination Inserter/Screwdriver (B070-0003-A1 & B070-0003-A2) is configured to accept both the Boomerang Plate and ChoiceSpine cervical interbody implants having the threaded inserter attachment feature like the ChoiceSpine TigerShark™ C or Stealth™ cervical interbody.

NOTE: This method does NOT permanently or semi-permanently integrate the Boomerang Anterior Cervical Plate to the interbody. Joining the implants is achieved solely through use of the Combination Inserter/Screwdriver instrument. Prepare the disc space and vertebral bodies for implant insertion and determine the appropriate size of interbody per the applicable interbody surgical technique (see Page 7 of this technique).

Step 1b. Coupling the Plate and Interbody

Place the selected interbody, packed with autogenous bone graft, into the appropriately marked space provided in the Boomerang Alignment Block (B070-0004) (Figure 8). Make sure that the interbody is face-up, exposing the threaded insertion feature. Select the appropriate Boomerang Anterior Cervical Plate using the table on page 7 as a guide. Place the Boomerang Plate face-up above the interbody, centering it over the threaded insertion feature (Figure 9).

NOTE: The Alignment Block is configured to accept 14W x 12D and 16W x 14D TigerShark C and Stealth interbodies in 5mm-10mm heights. Each space is clearly marked to indicate where the interbody and the corresponding plate should be placed for example, in the below images 14W x 12D size interbody matches a (6H/10P) 6H (6 Height Interbody) with a 10P (10 Plate).



Figure 8



Figure 9

Two implant coupler options are provided in the Boomerang system:

1. The Standard Coupler (B070-0003-04, Silver): Allows flush pairing of the Boomerang Plate with the Stealth or TigerShark C cervical interbody (Figure 10).
2. The Countersinking Coupler (B070-0009, Gold): Allows for 2.7mm offset between the Boomerang Plate and the anterior face of the cervical interbody (Figure 11).



Figure 10



Figure 11

Select the desired coupler and attach it to the **Outer Shaft** of the **Combination Inserter/Screwdriver** (Figure 12a-b). The split tip in the shaft will retain the **Coupler (B070-0003-04)**. Place the coupler into and through the center hole in the Boomerang Plate and thread it into the interbody until it is finger-tight (13a-b).

NOTE: The Standard Coupler will maintain alignment between the plate and interbody where as the Countersinking Coupler will not, due to the offset between components. The plate can be oriented (i.e. rotated) into the desired position once placed in-situ.

NOTE: Combined plate/cage insertion can be achieved without use of the Inserter Draw Rod.

CAUTION: Finger-tighten the coupler to the interbody to avoid stripping the threads. Excessive torque is not required.



Figure 12a



Figure 12b



Figure 13a

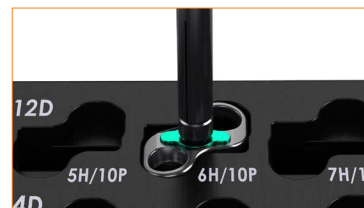


Figure 13b

Step 2b. Plate and Interbody Insertion

The assembled construct is now ready to be placed into the prepared cervical disc space.



Impact the construct into the disc space until the Boomerang Plate is seated flush against the vertebral bodies.

Pull the **Outer Shaft (B070-0003-A1)** of the **Combination Inserter/Screwdriver** from the **Coupler (B070-0003-04 or B070-0009)**, leaving the combined coupler, plate and interbody in place.

NOTE: Adjustments can be made to interbody placement in the countersunk configuration by assembling the **B070-0003-A2 Draw Rod** to the threads in the Countersinking Coupler through the Combination Inserter/Screwdriver Outer Shaft. Once secured, the depth/position of the interbody can be adjusted manually as desired. Remove the Draw Rod and Outer Shaft of the inserter once the desired adjustments are made, leaving the countersinking coupler, plate and interbody in place.

CAUTION: Do not use excessive force when impacting the plate and interbody into place. The plate holder retention feature may become wedged in the center hole of the plate, making it difficult to remove the plate holder when it is no longer needed.

Step 3b: Screw Preparation

Use the Drill Guide (B070-0005) and Drill (B070-D010) to prepare screw holes while performing the combined interbody/plate technique. Insert the tip of the guide into the desired screw pocket in the plate. Attach the AO Quick Connect Handle (L070-0029) to the drill and insert the drill tip into the guide. Maintain slight pressure on the drill guide to keep it seated in the plate when adjusting it to the desired angle for drilling. When used properly, the Drill Guide will ensure that the limits of screw angulation are not exceeded (e.g. the user will feel the tip of the guide coming out of the screw pocket when it is over-angulated). Advance the drill to penetrate the vertebral body. The shoulder of the drill will come to rest against the top of the drill guide when a depth of 10mm is reached. Repeat this step for the second screw hole. Use of these instruments is demonstrated below:



NOTE: The Combination Awl/Drill (B070-0001) can be substituted for optional instruments Drill Guide (B070-0002) and Drill (B070-D010) for the combined interbody/plate technique to simplify screw hole preparation.

Step 4b: Screw Insertion

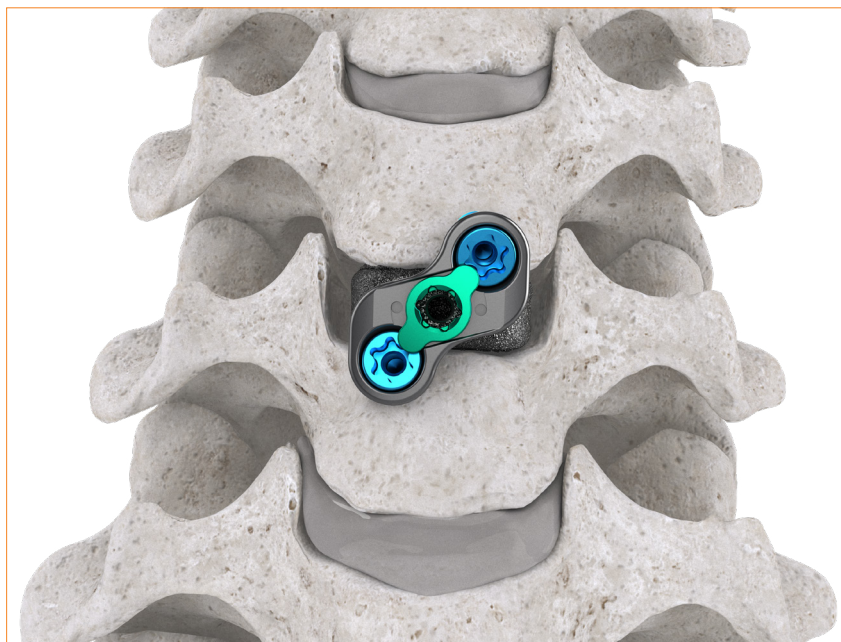
Remove the Drill (B070-D010) and Drill Guide (B070-0002) from the surgical site. Select the appropriate diameter and length of screw and attach it to the Combination Inserter/Screwdriver (B070-0003-A1 & B070-0003-A2) as described in Step 3a. Advance the screw until it is fully seated in the plate. Repeat steps for placement of the second screw. Take care to stay within the limits of screw angulation so that the cam-locking mechanism can be rotated over a portion of the screw heads and engage the locking features on the face of the plate.

NOTE: Both screws must be inserted in the plate before engaging the cam to cover the screw heads.

NOTE: The Combination Inserter/Screwdriver Coupler (B070-0003-04 or B070-0009) **MUST** be removed after screws have been placed and prior to screw blocker engagement. Remove it by inserting the tip of the Combination Inserter/Screwdriver Outer Shaft (B070-0003-A1) back into the Coupler (B070-0003-04) hexalobe and reverse it from interbody. The coupler will be attached to the Combination Inserter/Screwdriver Outer Shaft by way of the split tip design.

Step 5b: Cam-Locking Mechanism Engagement

Cam-lock engagement is performed after screw insertion and coupler removal as described in Step 4a, above.



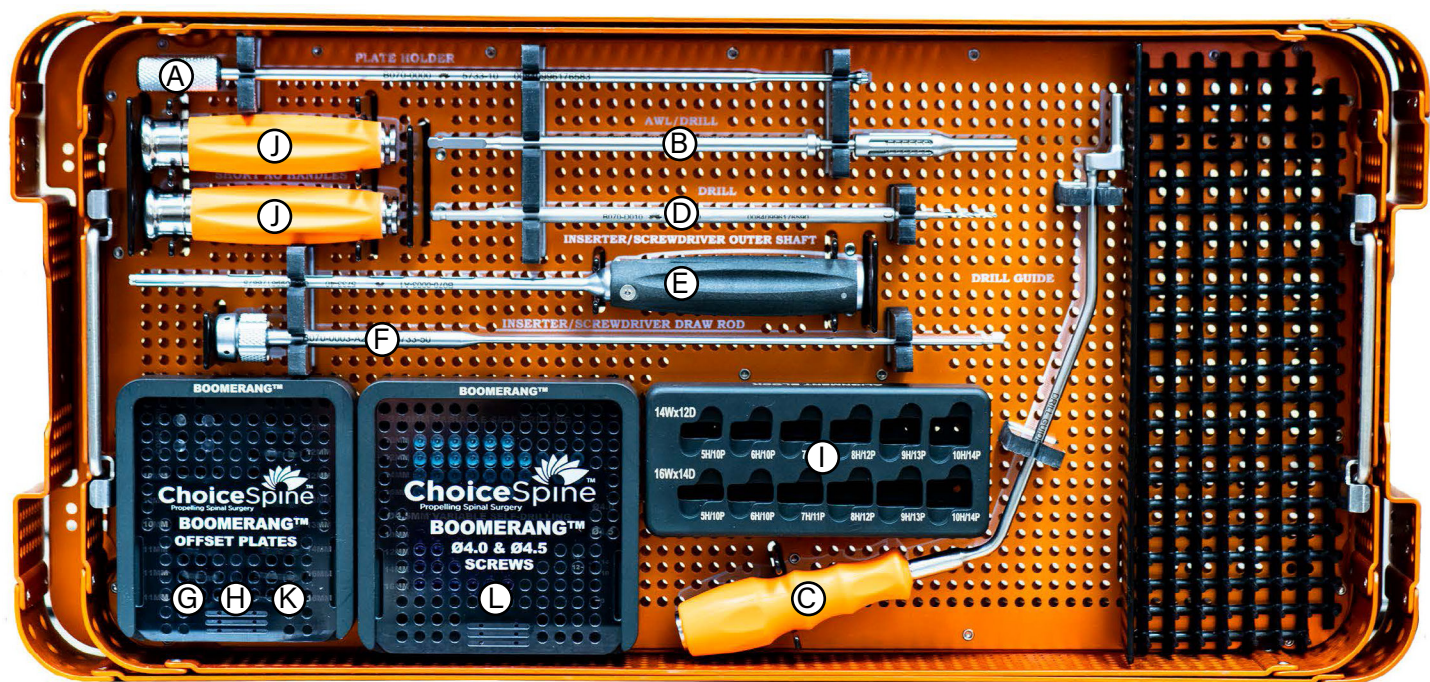
Completed Construct

Screw Removal

Use the **Outer Shaft** of the **Combination Inserter/Screwdriver Outer Shaft (B070-0003-A1)** to rotate the cam to the unlocked position, fully exposing the screw heads for screwdriver access. Insert the **Combination Inserter/Screwdriver Outer Shaft** into the screw head and reverse the screw from the vertebral body and plate. The **Outer Shaft** of the **Combination Inserter/Screwdriver** has a split-tip design that will retain the screw as it exits the vertebral body and plate. Should additional security be desired at the driver/screw interface, the **Combination Inserter/Screwdriver Draw Rod (B070-0003-A2)** can be assembled to the **Outer Shaft** and the threads at the distal tip of the **Draw Rod** can be used to engage and secure the screw before extraction. Refer also to Step 3a for instrument assembly to the screw.



Boomerang™ Instrument Tray



- Ⓐ **Plate Holder B070-0000**
- Ⓑ **Combination Awl/Drill B070-0001**
- Ⓒ **Fixed Handle Drill Guide B070-0005 (OPT)**
- Ⓓ **10mm Drill B070-0010 x 2 (OPT)**
- Ⓔ **Combination Inserter/Driver Outer Shaft B070-0003-A1**
- Ⓕ **Combination Inserter/Driver Draw Rod B070-0003-A2**
- Ⓖ **Combination Inserter/Driver Coupler B070-0003-A4 x 2**
- Ⓗ **Countersink Combination Inserter/Driver Coupler x 2**
- Ⓘ **Alignment Block B070-0004**
- Ⓙ **Short AO Handle L070-0029 x 2**
- Ⓚ **Plate Caddy B090-1110**
- Ⓛ **Screw Caddy B090-1200**

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For Instructions for Use please visit <https://choicospine-eifu.com/>



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