



BOOMERANG™ Surgical Technique
Anterior Cervical Plate System

BOOMERANG™

Introduction

The ChoiceSpine BOOMERANG™ Anterior Cervical Plate System is a versatile system of implants and instruments designed to simplify and improve the efficiency of anterior cervical spine fusion. The BOOMERANG Anterior Cervical Plate features a streamlined two-screw configuration and an integrated single-step screw blocking mechanism for fast insertion and fixation to the anterior cervical spine. The low-profile offset design of the plate permits use at multiple adjacent levels and provides visual confirmation of the cervical graft in the disc space. Streamlined instrumentation facilitates a simplified surgical approach and ensures excellent control during the procedure. The instrumentation also allows the user to simultaneously insert the BOOMERANG plate with a cervical interbody such as TIGER SHARK™ C or STEALTH™, mimicking a stand-alone ACDF concept, eliminating surgical steps and reducing O.R. time.

System Features

- Two-screw design
- Stackable
- Combined insertion with TIGER SHARK™ C or STEALTH™ cervical interbody
- Integrated single-step screw blocking mechanism
- 20° maximum cranial/caudal screw angulation
- Narrow 15mm plate width
- Anti-migration teeth
- Streamlined instrumentation

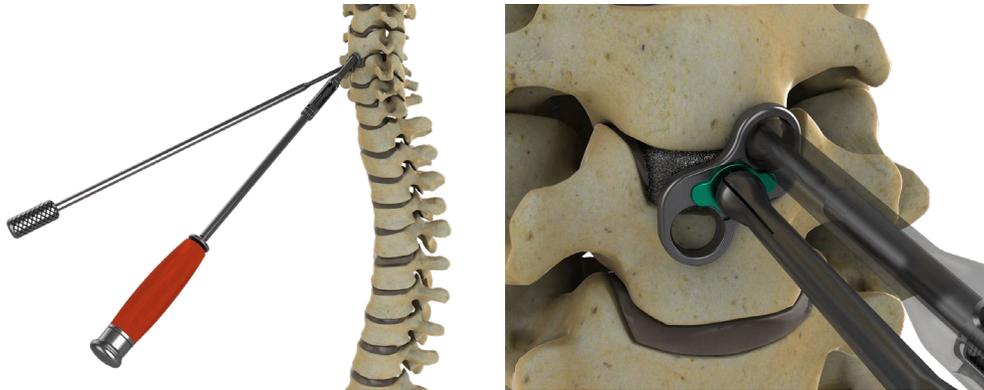
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OPERATIVE TECHNIQUE OVERVIEW



Use Plate Holder to Place Plate



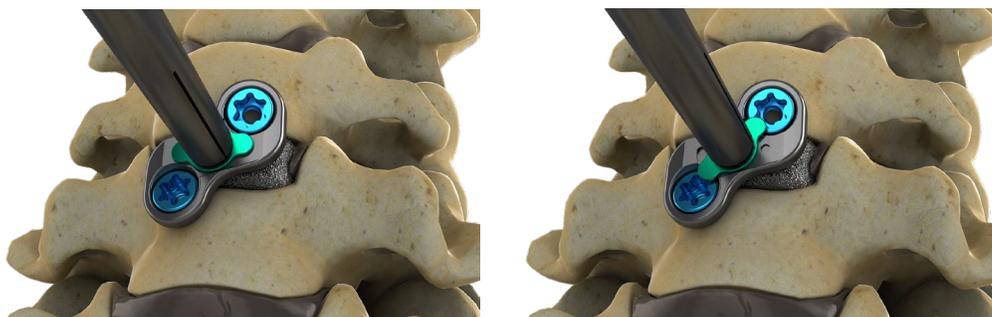
Drill



Attach a Screw to the Screwdriver



Insert the Screws



Engage Screw Blocker

DETAILED OPERATIVE TECHNIQUE

Exposure and Graft/Interbody Trialling

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 as not to impede implantation of the plate if left in place during graft and plate placement. A through discectomy is performed and the cartilaginous endplates are removed at the operative level. Posterior decompression is performed to adequately decompress the spinal canal and/or foramina. The size of the disc space is measured with sequential trials until the desired fit is achieved and the matching graft or interbody size is selected to restore the normal disc space height (Figure 1).



Figure 1

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

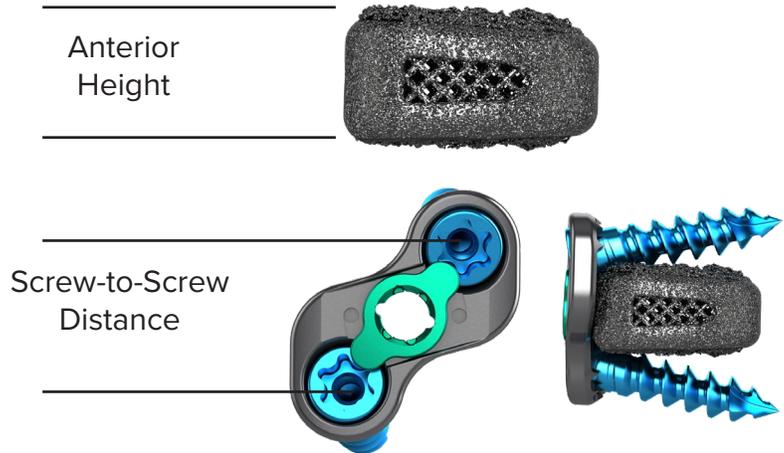
1. A plate-only technique, after a cervical graft or interbody has been placed
2. A combined plate/interbody technique, with an appropriate ChoiceSpine cervical Interbody, such as TIGER SHARK™ C or STEALTH™, by way of instrumentation that is provided.

Plate Selection

The Boomerang Anterior Cervical Plate is available in screw-to-screw lengths ranging from 10mm to 14mm in 1mm increments. 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



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 is not necessary. Bending the plate could cause unknown damage to the plate and possibly render it unusable.

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. The limits of screw angulation are 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. These methods are described with each respective plate insertion technique.

Plate-Only Technique

Step 1a: Plate Placement

After selecting a plate, place it onto the cervical spine using the Plate Holder and center it over the cervical graft in the disc space (Figure 2). Proper placement can be verified visually by confirming that the screw holes are not obstructed by the graft. 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 and Combination Awl/Drill with guide sleeve to prepare screw holes. Hold the plate in the desired position over the graft. Attach the AO Quick Connect Handle to the Combination Awl/Drill. Insert the instrument into a screw lobe 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 guide sleeve seated in the screw lobe, 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 lobe 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

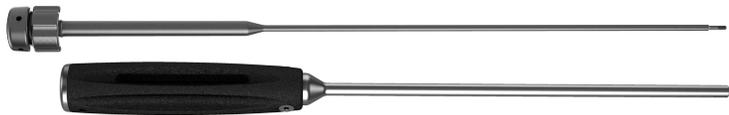


Figure 4

Step 3a: Screw Insertion

Remove the Combination Awl/Drill 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, 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 propeller-shaped screw blocker (“prop”) 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 prop to cover the screw heads.



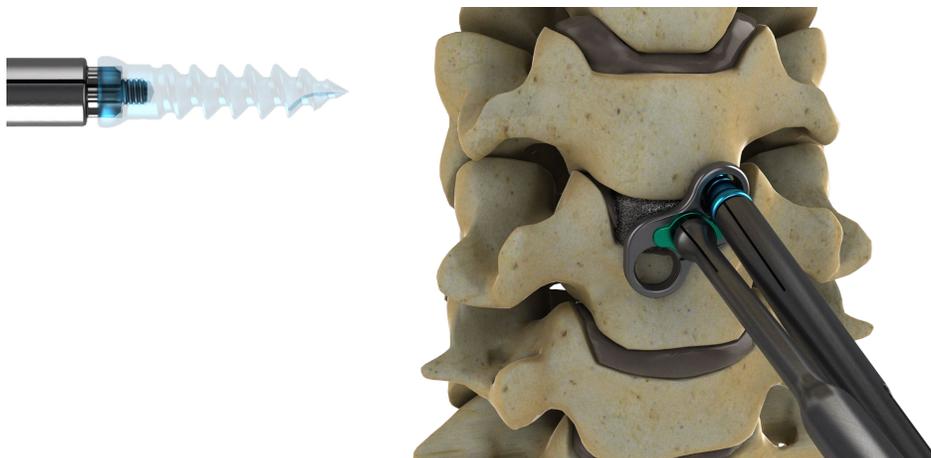
Insert the Draw Rod into the Outer Shaft, as shown below



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: Screw Blocker (Prop) Engagement

The screw blocker should be engaged after placement of both screws. To engage, insert the Outer Shaft of the Combination Inserter/Screwdriver into the T20 hexalobe at the center of the prop. Gently rotate the prop counterclockwise until engagement of the prop in the locked position is both felt and seen. The prop does not require aggressive force to turn. Screw blocker engagement is demonstrated in Figures 6 and 7 below:

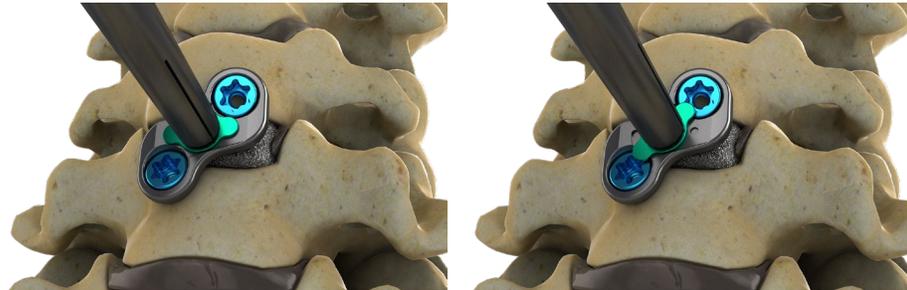


Figure 6
Unlocked

Figure 7
Locked

WARNING: Rotation of the prop causes permanent deformation of its locking feature that engages the plate, as intended. Do not repeatedly engage/disengage the screw blocker to/from the locked position. The screw blocker may not retain its locked position after repeated engagement/disengagement. The user should verify correct screw placement **BEFORE** engaging the screw blocker. It should be noted that the screw blocker 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 screw blocker and engage it in the locked position. Do not attempt to over-rotate the prop once engagement is felt and seen. Over-rotation may disengage the propeller 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 is configured to accept both the Boomerang Plate and ChoiceSpine cervical interbody implants having the threaded inserter attachment feature like the ChoiceSpine TIGER SHARK™ 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 4 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 (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 5 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 14Wx12D and 16Wx14D TIGER SHARK 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.



Figure 8



Figure 9

Attach the Combination Inserter/Screwdriver Coupler to the Outer Shaft of the Combination Inserter/Screwdriver (Figure 10a-b). The split tip in the shaft will retain the Coupler. Place the coupler into and through the center hole in the Boomerang Plate and thread it into the interbody until it is drawn against the back of the plate (Figure 11a-b).

CAUTION: Avoid stripping the Coupler and/or interbody threads by not over-tightening the interbody to the plate.



Figure 10a



Figure 10b



Figure 11a



Figure 11b

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 of the Combination Inserters/Screwdriver from the Coupler, leaving the combined 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 and Drill To prepare screw holes while performing the combined interbody/plate technique. Insert the tip of the guide into the desired screw lobe in the plate. Attach the AO Quick Connect Handle 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 lobe 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 can be substituted for the Drill Guide and Drill for the combined interbody/plate technique to simplify screw hole preparation.

Step 4b: Screw Insertion

Remove the Drill and Drill Guide from the surgical site. Select the appropriate diameter and length of screw and attach it to the Combination Inserter/Screwdriver 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 propeller-shaped screw blocker (“prop”) 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 prop to cover the screw heads.

NOTE: The Combination Inserter/Screwdriver Coupler **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 back into the Coupler 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: Screw Blocker (Prop) Engagement

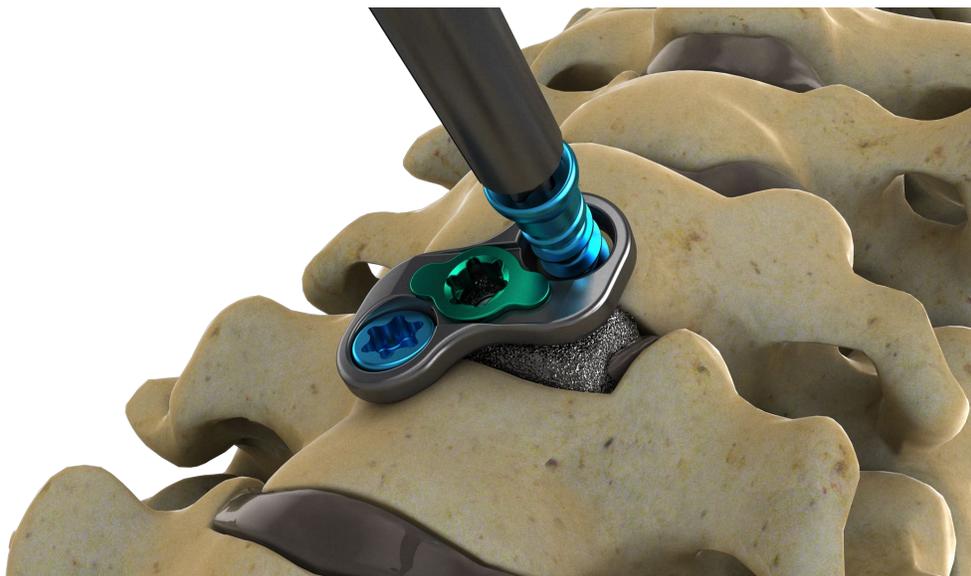
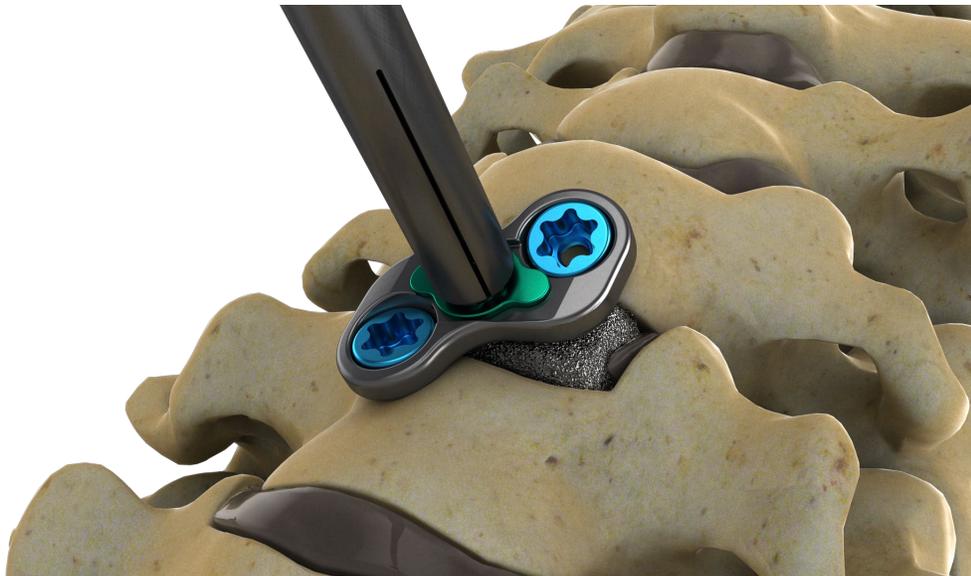
Screw blocker engagement is performed after screw insertion and coupler removal as described in Step 4a, above.



Completed Construct

Screw Removal

Use the Outer Shaft of the Combination Inserter/Screwdriver to rotate the prop 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 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 3 for instrument assembly to the screw.





Boomerang™ Set

Part Number	Description	QTY
1 B070-0000	Plate Holder	1
2 B070-0001	Combination Awl/Drill, AO	1
3 B070-0005	Fixed Handle Drill Guide	1
4 B070-D010	10mm Drill	2
5 B070-0003-A1	Combination Inserter/Driver Outer Shaft	1
6 B070-0003-A2	Combination Inserter/Driver Draw Rod	1
7 B070-0003-04	Combination Inserter/Driver Coupler	4 Inside Plate Caddy
8 B070-0004	Alignment Block	1
9 L070-0029	Short AO Handle	2
10 B090-1100	Plate Caddy	
11 B090-1200	Screw Caddy	

Plates

Part Number	Description	QTY
BT10-0010	Small Offset Plate - 10 mm	3
BT10-0011	Small Offset Plate - 11 mm	3
BT10-0012	Small Offset Plate - 12 mm	3
BT10-0013	Small Offset Plate - 13 mm	2
BT10-0014	Small Offset Plate - 14 mm	1
BT10-0016	Small Offset Plate - 16 mm	1
BT10-0018	Small Offset Plate - 18 mm	1

Screws

Part Number	Description	QTY
BT20-D4010	Variable Self-Drilling Screw, 4.0mm x 10mm	6
BT20-D4012	Variable Self-Drilling Screw, 4.0mm x 12mm	10
BT20-D4014	Variable Self-Drilling Screw, 4.0mm x 14mm	10
BT20-D4016	Variable Self-Drilling Screw, 4.0mm x 16mm	6
BT20-D4510	Variable Self-Drilling Screw, 4.5mm x 10mm	6
BT20-D4512	Variable Self-Drilling Screw, 4.5mm x 12mm	6
BT20-D4514	Variable Self-Drilling Screw, 4.5mm x 14mm	6
BT20-D4516	Variable Self-Drilling Screw, 4.5mm x 16mm	6

General Description:

The ChoiceSpine Boomerang™ Anterior Cervical Plate system is intended for anterior screw fixation to the cervical spine. The system consists of a variety of bone plates and screws made from titanium alloy (T-6Al-4V ELI) per ASTM F136 and a set of instruments made from stainless steels (455, 465 and 17-4) per ASTM A564 and ASTM F899. The system components are provided non-sterile and must be steam sterilized by the user prior to use.

Indications for Use:

The ChoiceSpine Boomerang Anterior Cervical Plate system is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

WARNING: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine

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Contraindications:

Contraindications include, but are not limited to:

- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Signs of local inflammation
- Morbid obesity - Pregnancy
- Grossly distorted anatomy due to congenital abnormalities
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- Rapid joint disease, bone absorption, osteopenia, osteomalacia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation
- Suspected or documented metal allergy or intolerance
Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- 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
- Any time implant utilization would interfere with anatomical structures or expected physiological

performance

- Any case not needing a bone graft and fusion or where fracture healing is not required

Warnings and Precautions:

The ChoiceSpine Boomerang Anterior Cervical Plate System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results. The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance. The ChoiceSpine Boomerang Cervical Plate System is only a temporary implant used for the correction and stabilization of the cervical spine. The system is also used to augment the development of a spinal fusion by providing temporary stabilization. This system is not intended to be the sole means of spinal support. A suitable bone graft/interbody device must be part of the spinal fusion procedure in which The ChoiceSpine Boomerang Anterior Cervical Plate System is used. Use of this product without a bone graft may not be successful. The spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.

Based on fatigue testing results, when using the Boomerang Anterior Cervical Plate, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

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

Additional warnings and precautions should be followed as directed by the surgical technique guide.

Based on fatigue testing results, when using the Boomerang Anterior Cervical Plate, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.



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LIT# Boomerang STG | REV00 | 6/19