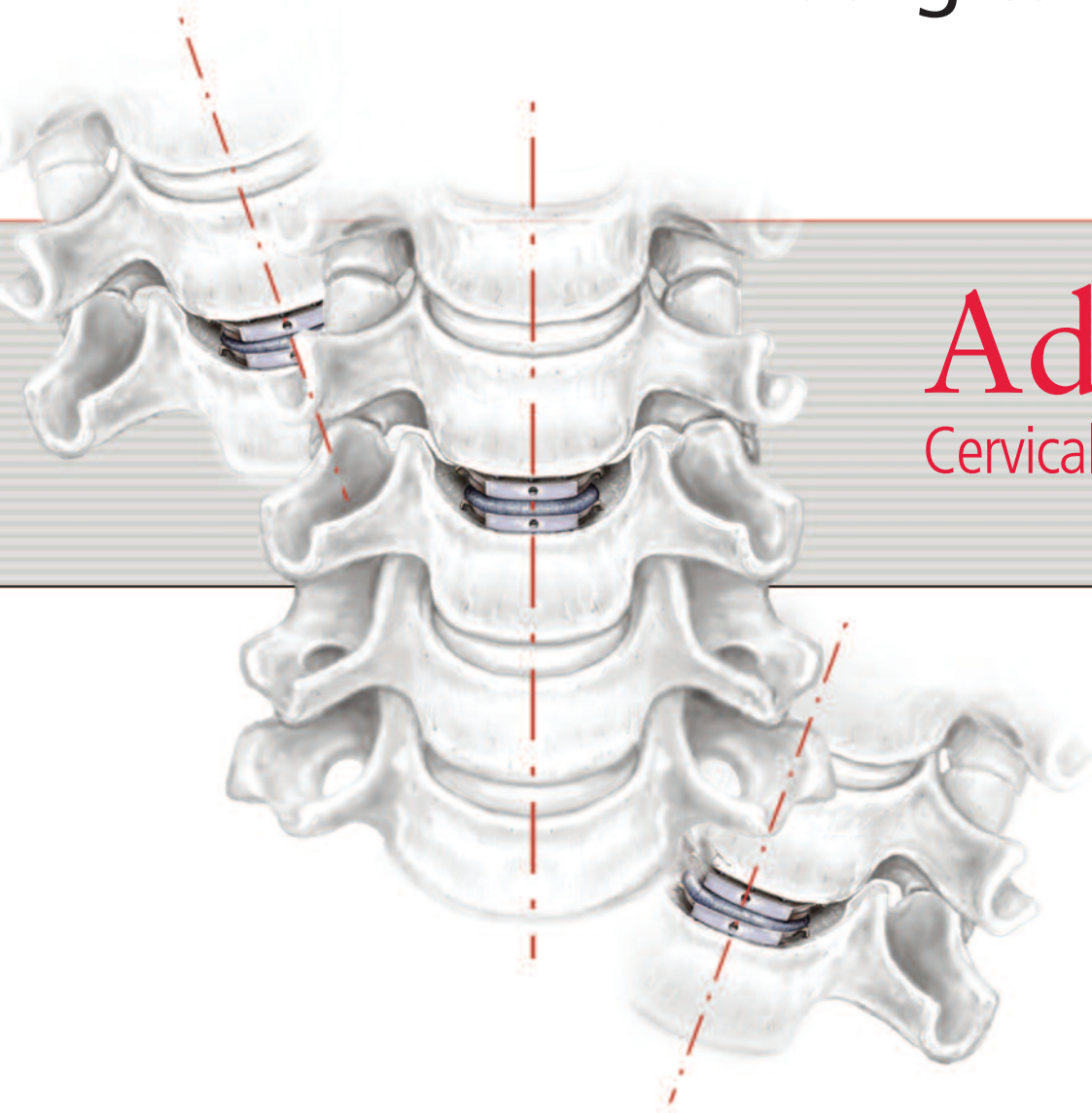


Surgical Technique



AdventTM Cervical Disc System

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 **BLACKSTONE**
M E D I C A L I N C

an Orthofix Company

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Introduction
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Pre-Operative

1.

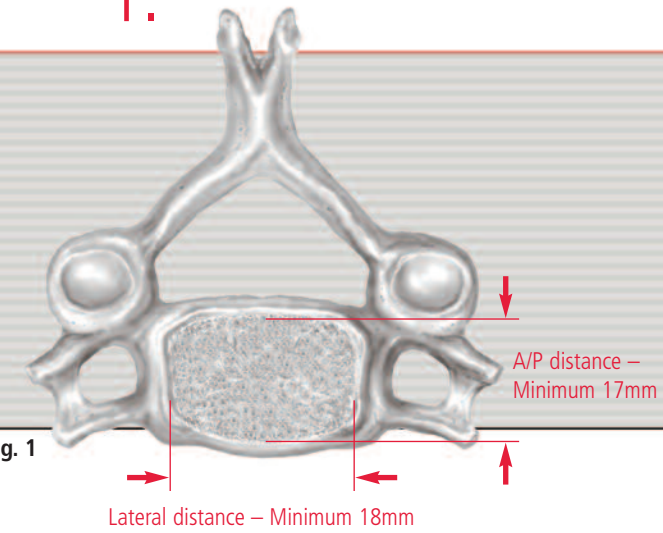


Fig. 1

Step 1

Pre-Operative measurement

Use magnetic resonance imaging (MRI), computer tomography (CT), or X-Ray to determine the smaller of the two endplates at the target disc space.

Do not include any bony structures in the measurement that will be removed later in the procedure.

Measure the A/P and lateral distance for the smaller of the two endplates.

The minimum A/P distance is 17mm and minimum lateral distance is 18mm, (See fig. 1.) If the patient does not meet the minimum footprint requirements, then alternative treatments should be considered.

Note: Verify the magnification factors for MRI, CT and X-Ray when performing preoperative measurements.

2.



Step 2

Patient positioning

The patient is placed in the supine position with all bony prominences padded and the cervical spine in neutral to slight extension.

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3.



Step 3

Exposure

Adequate visualization of the vertebrae and disc space is critical. Use standard techniques to identify the correct disc level.

4.

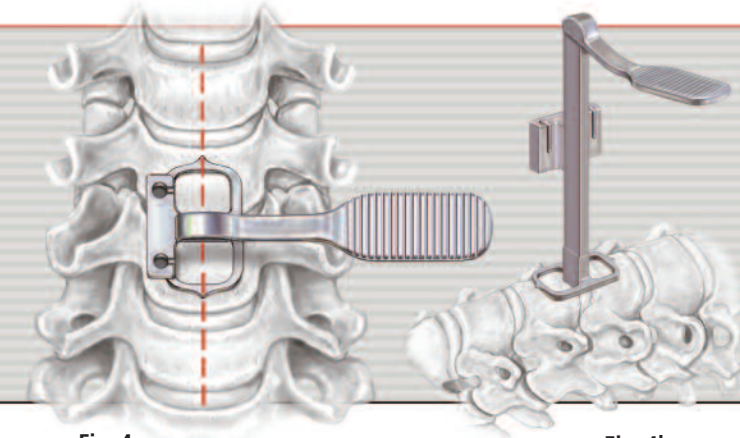


Fig. 4a

Fig. 4b

Step 4

Midline determination

It is very important to accurately place the implant in the midline of the spine.

Place the mid-line marker over the midline of the spine and gently tap it into place, (See fig. 4a and 4b.) Verify placement of the mid-line marker using A/P and lateral fluoroscopy. Adjust the position if necessary using fluoroscopy to verify position.

Note: It may be necessary to perform a partial discectomy to insert the mid-line marker.

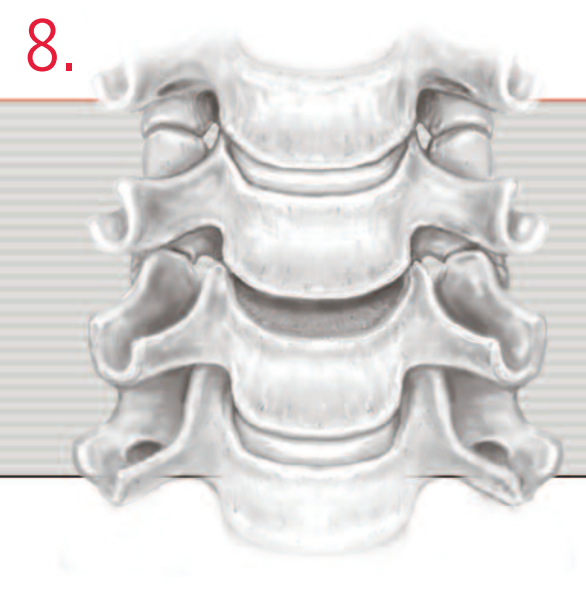
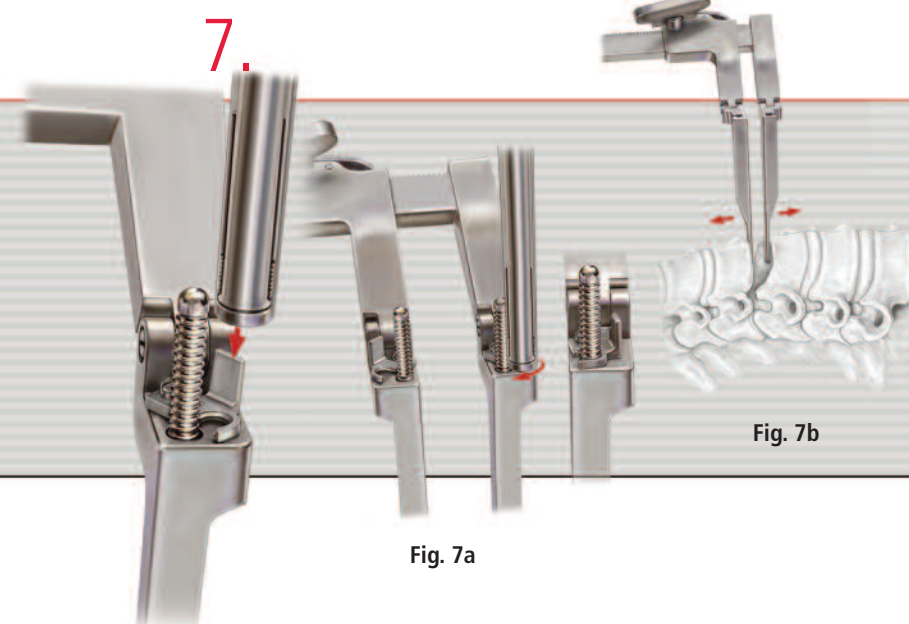
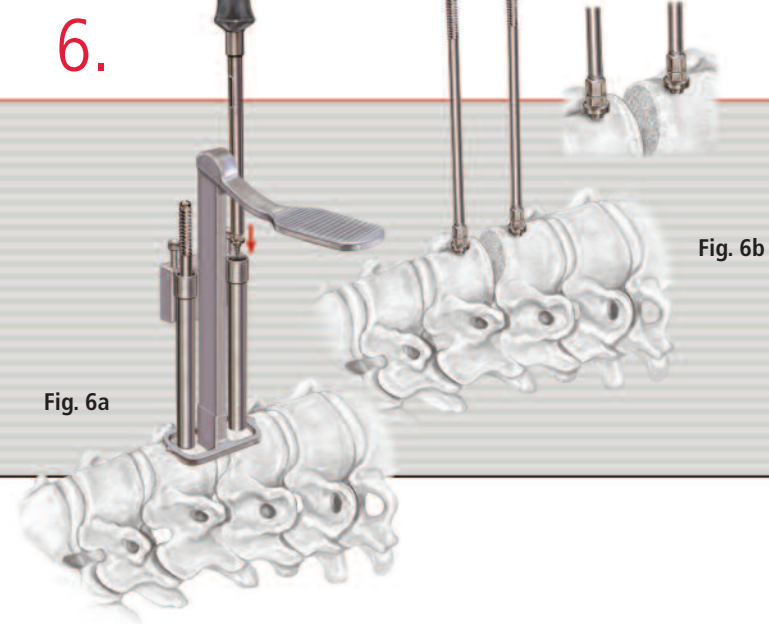
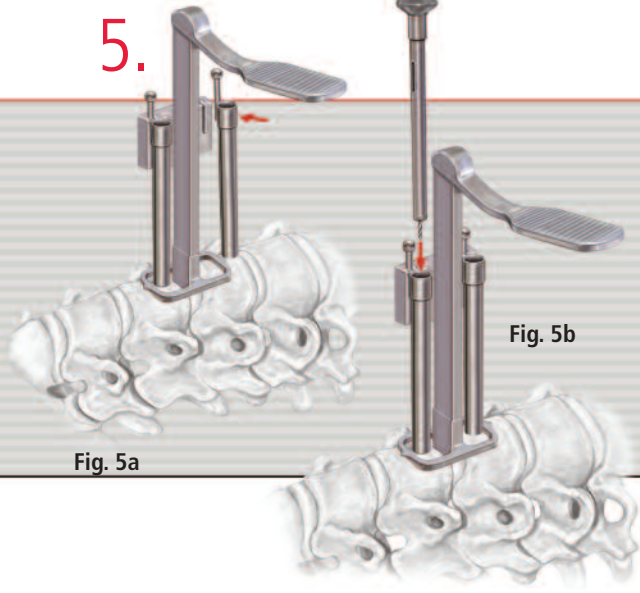
Note: The mid-line marker has spikes to maintain its position at the bony interface. However, it may be necessary to hold the mid-line marker in its vertical position during this and subsequent steps including drilling and placing distraction pins.

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Step 5

Drilling for distraction pins

With the mid-line marker in place, load both drill guides, (See fig. 5a.) Next, insert the drill into the hex driver. Drill a pilot hole in both cephalad and caudal vertebral bodies, (See fig. 5b.)

Note: Make sure to securely hold the mid-line marker so that the midline position is maintained.

Step 6

Placing distraction pins

Attach the appropriate length distraction pin to the hex driver. Next, place distraction pins into both cephalad and caudal vertebral bodies through the drill guides, (See fig. 6a.)

Note: Make sure to securely hold the mid-line marker so that the midline position is maintained.

Remove the drill guides and mid-line marker, (See fig. 6b).

Step 7

Distraction

Attach the pin distractor to the vertebral distraction pins by sliding the pin distractor over the distraction pins. Next, Lock the pin distractor to the vertebral distraction pins using the retaining hex driver, (See fig. 7a).

The disc space is ready for distraction

Note: Avoid over-distraction.

Note: The pin distractors are available in both left and right orientations.

Note: Blade distractors are available for distracting in between the disc space. Blade distractors are available in both left and right orientations

Step 8

Discectomy and decompression

Perform a discectomy at the indicated level and expose the posterior longitudinal ligament. It is important to ensure a complete and thorough decompression. Remove any anterior and posterior osteophytes to achieve decompression.

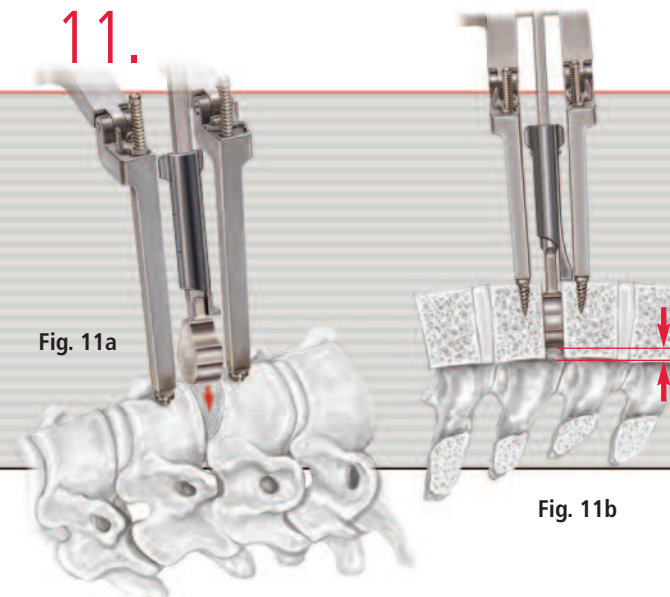
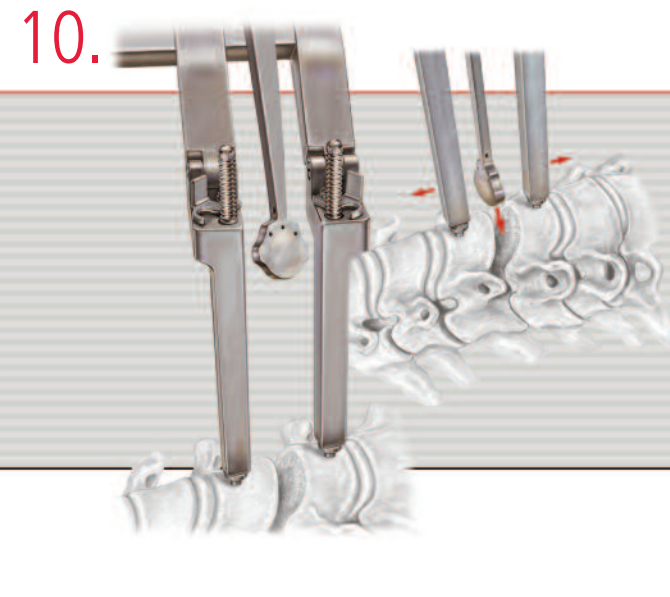
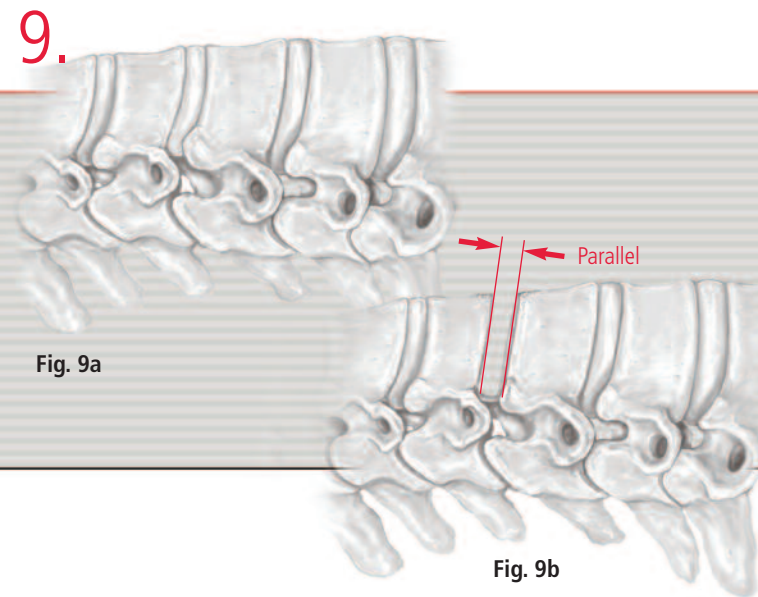
Note: It is recommended to carefully incise the posterior longitudinal ligament.

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Step 9

Endplate preparation

Once the discectomy and decompression is completed, prepare the endplates so they are flat and parallel (See figs. 9a and 9b).

Note: Preserve as much of the cortical bone as possible

Step 10

Footprint selection

There are two requirements for correct implant footprint selection. The implant should be placed within 1-2mm of the posterior vertebral margin. Second, the implant footprint should cover as much endplate surface area as possible.

There are 2 implant footprints and corresponding footprint trials (Medium and Large). Starting with the Medium footprint trial, insert the trial into the disc space. Next, using A/P and lateral fluoroscopy, choose the correct footprint trial paying attention to the 2 requirements for correct implant footprint selection.

Note: The footprint trials are true to the implant footprint. There is a hole in the footprint trial that identifies the anterior margin of the implant which can be seen under fluoroscopy.

Note: The implant should be positioned within the margins of the vertebral bodies.

Step 11

Height selection

Choose the 6mm height trial that corresponds to the footprint determined from step #10. Next, attach the orange (Letter "A") safety stop to the height trial. (See figure 11a).

Insert the trial into the disc space being careful to not use excessive distraction. If the trial is not tall enough, use the next tallest trial.

Use fluoroscopy during the trialing process to determine the correct A/P positioning (1-2mm from the posterior vertebral margin, (See figure 11b).

If the trial is not correctly positioned A/P, choose shorter safety stops (letters "B" – "F") until the correct A/P position is obtained.

Step 12

Medial / Lateral Broaching

Once the implant size has been determined, broaching can be done to remove any remaining bony structures. Use the lateral broach to prepare the lateral portions of the disc space.

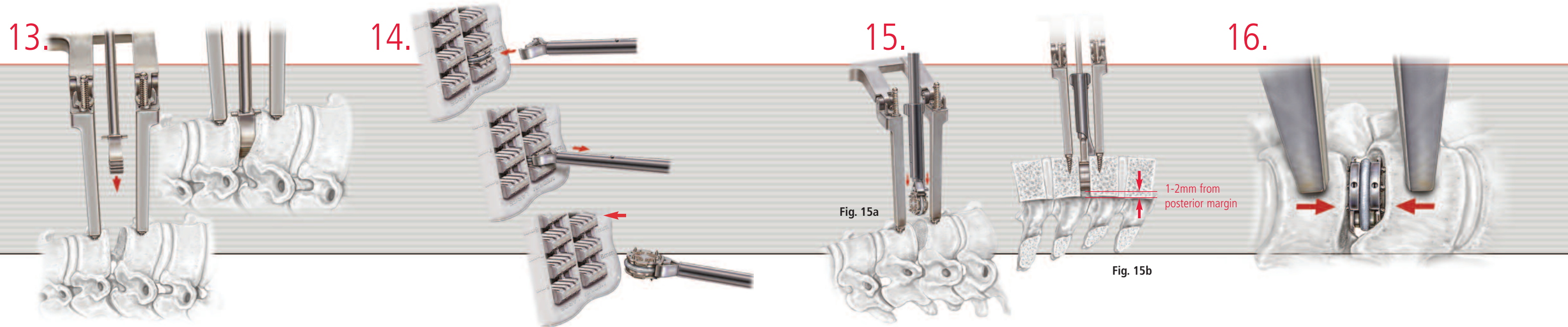
Note: Lateral broaches are available for each disc footprint and height.

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Step 13

Posterior Broaching

Use the posterior broach to prepare the posterior portion of the disc space. Pay close attention to depth when using the posterior broach.

Note: Posterior broaches are available for each disc footprint and height.

Step 14

Holder / inserter attachment

Place the correctly-sized implant, selected as outlined in the previous steps, into the implant alignment caddy. There is a position in the alignment caddy for each footprint and height of implant.

Next, attach the holder/inserter by aligning the pins on the inserter with the holes on the implant. Turn knob on inserter clockwise to actuate the jaws until a snug fit has been achieved.

Remove the implant from the alignment caddy.

Verify the implant attachment by trying to pull the implant from the inserter with your fingers.

15.

Fig. 15a

Step 15

Implant Placement

Attach the safety stop determined in the implant height selection step to the holder / inserter.

Note: The implant has a top and bottom orientation. The orientation is marked on the implant. Make sure the top of the implant is cephalad (toward the head).

Place the implant into the midline of the vertebral space using fluoroscopy. Position the implant 1-2mm from the posterior vertebral margin. (See figs. 15a and 15b.)

Before removing the inserter from the implant, verify implant placement with AIP and lateral fluoroscopy.

16.

1-2mm from posterior margin

Fig. 15b

Step 16

Final position verification

Remove the holder / inserter from the implant by turning the inserter knob counterclockwise.

Next, release the pin distractor to compress the vertebral bodies onto the implant fixation spikes.

Take final AIP and Lateral fluoroscopy images to verify final implant position.

Remove the pin distractor and distraction pins.

Complete the surgery using standard anterior cervical closure procedures.

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Implant Removal

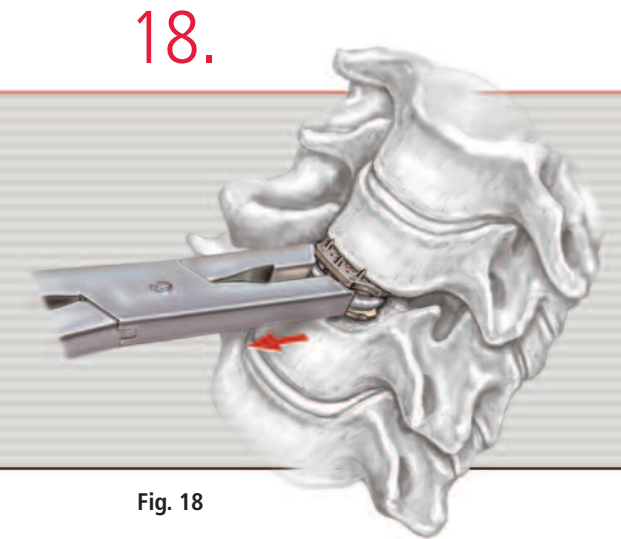
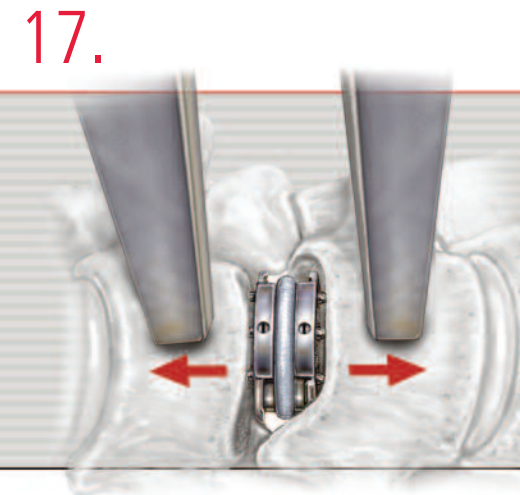


Fig. 18

Step 17

Implant removal preparation

Should it become necessary to remove the implant after implantation, use the following procedure.

Distract the disc space. The pin distractor can be used by re-inserting the distraction pins and attaching the pin distractor.

If the implant does not release from the vertebral body endplates, use an osteotome or similar instrument to release the implant from the vertebral bodies.

Step 18

Removing implant

With the disc space distracted, attach the disc removal instrument to the implant. Gently remove the implant, (see fig. 18.)

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Package Insert

Package insert will be placed here upon approval

Part Numbers



Advent Cervical Disc System

INSTRUMENTS		
15-0001	Advent Instrument Case #1	
15-1001	Holder / Inserter	
15-1002	Blade Distractor, Right	
15-1003	Blade Distractor, Left	
15-1004	Pin Distractor, Right	
15-1005	Pin Distractor, Left	
15-1006	Drill Guide	
15-1007	Drill	
15-1008	Hex Driver	
15-1012	Distraction Pin	12mm
15-1014	Distraction Pin	14mm
15-1016	Distraction Pin	16mm
15-1104	Footprint Trial	Medium
15-1105	Footprint Trial	Large
15-1306	Height Trial	Medium 6mm Tall
15-1307	Height Trial	Medium 7mm Tall
15-1308	Height Trial	Medium 8mm Tall
15-1406	Height Trial	Large 6mm Tall
15-1407	Height Trial	Large 7mm Tall
15-1408	Height Trial	Large 8mm Tall
15-5011	Mid-line Marker	

INSTRUMENTS		
15-0002	Advent Instrument Case #2	
15-1614	Medial / Lateral Broach (Broach one)	14mm Wide x 6mm Tall
15-1616	Medial / Lateral Broach (Broach one)	16mm Wide x 6mm Tall
15-1618	Medial / Lateral Broach (Broach one)	18mm Wide x 6mm Tall
15-1714	Medial / Lateral Broach (Broach one)	14mm Wide x 7mm Tall
15-1716	Medial / Lateral Broach (Broach one)	16mm Wide x 7mm Tall
15-1718	Medial / Lateral Broach (Broach one)	18mm Wide x 7mm Tall
15-2613	Posterior Broach (Broach Two)	13.5mm Long x 6mm Tall
15-2615	Posterior Broach (Broach Two)	15.0mm Long x 6mm Tall
15-2616	Posterior Broach (Broach Two)	16.5mm Long x 6mm Tall
15-2618	Posterior Broach (Broach Two)	18.0mm Long x 6mm Tall
15-2713	Posterior Broach (Broach Two)	13.5mm Long x 7mm Tall
15-2715	Posterior Broach (Broach Two)	15.0mm Long x 7mm Tall
15-2716	Posterior Broach (Broach Two)	16.5mm Long x 7mm Tall
15-2718	Posterior Broach (Broach Two)	18.0mm Long x 7mm Tall
15-5012	Alignment Caddy	
98-1418	Safety Stop – "A" Orange	
98-1419	Safety Stop – "B" Bone	
98-1420	Safety Stop – "C" Blue	
98-1421	Safety Stop – "D" Green	
98-1422	Safety Stop – "E" Yellow	
98-1423	Safety Stop – "F" Grey	
98-0047	Disc Removal Instrument	

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Notes

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IMPLANTS		
85-4006	Advent Cervical Disc	Medium Footprint, 6mm Tall
85-4007	Advent Cervical Disc	Medium Footprint, 7mm Tall
85-4008	Advent Cervical Disc	Medium Footprint, 8mm Tall
85-5006	Advent Cervical Disc	Large Footprint, 6mm Tall
85-5007	Advent Cervical Disc	Large Footprint, 7mm Tall
85-5008	Advent Cervical Disc	Large Footprint, 8mm Tall

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U.S.A.

Blackstone Medical, Inc.
1211 Hamburg Turnpike
Suite 300
Wayne, NJ 07470

Phone: 973.406.2800
Toll free: 888.298.5400
Fax: 973.633.6811 / 973.633.9948

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