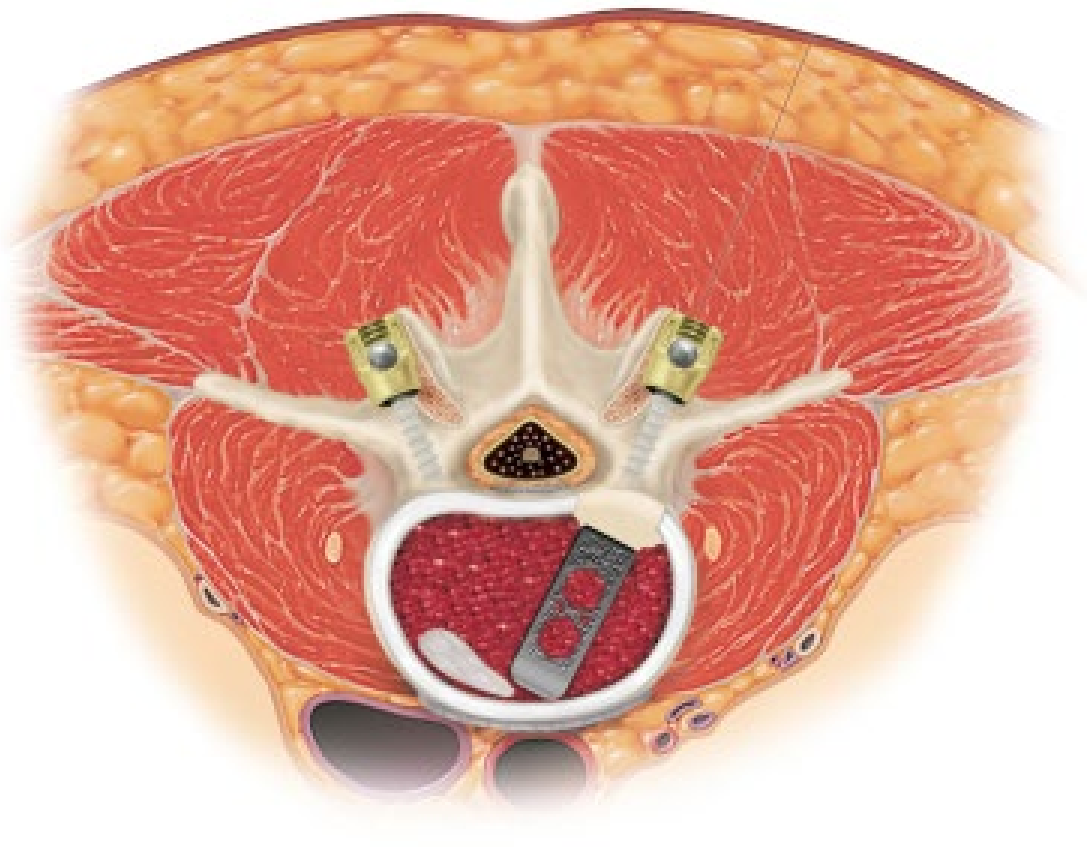
SURGICAL TECHNIQUE

Infuse™ Bone Graft - TLIF



Final expected construct view. Image is representative and is for reference only.

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Introduction

This surgical technique is designed to familiarize healthcare professionals with the surgical procedure for use of Infuse™ Bone Graft in a Transforaminal Lumbar Interbody Fusion (TLIF) procedure.

It is important to review this surgical technique and the associated surgical techniques for the selected intervertebral body fusion device and supplemental posterior fixation system prior to the use of the implants.

Consult instructions for use (IFU) included with the product and/or at this website: medtronic.com/manuals. The IFU contains the complete list of indications, warnings, precautions, and other important medical information.

Infuse™ Bone Graft Preparation

Prepare the Infuse Bone Graft according to the Instructions for preparation provided in the appendix to achieve implant volume of either 1.4 cc (2.10 mg rhBMP-2) or 2.8 cc (4.2mg rhBMP-2) per treated spinal level.

Infuse Bone Graft™ is prepared at the time of surgery. Allow wetted collagen sponges to stand for a minimum of 15 minutes. Use within 2 hours.

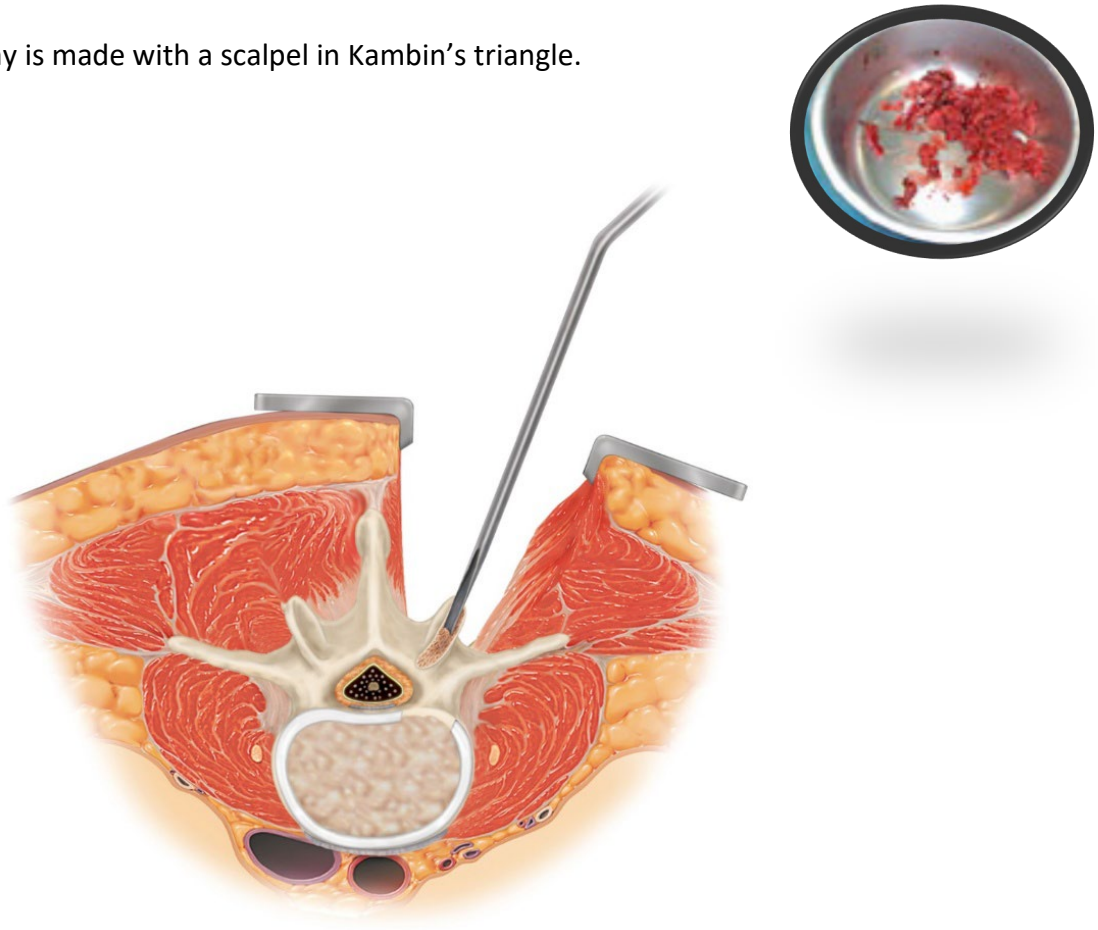
		Infuse™ Bone Graft Kit Description					
	Volume (rhBMP-2 dose)	XX small 0.7 cc (1.05 mg)	X small 1.4 cc (2.1 mg)	Small 2.8 cc (4.2 mg)	Medium 4.2 cc (8.4 mg)	Large 8 cc (12 mg)	Large II 8 cc (12 mg)
		Total number of required kits to achieve dose					
ONE-LEVEL TLIF Procedure	**2.1 mg rhBMP-2 per level**	2 kits	1 kit	1/2 kit	1/4 kit	1/6 kit	1/6 kit
	4.2 mg rhBMP-2 per level	4 kits	2 kits	1 kit	1/2 kit	1/3 kit	1/3 kit
TWO-LEVEL TLIF Procedure	**2.1 mg rhBMP-2 per level**	4 kits	2 kits	1 kit	1/2 kit	1/3 kit	1/3 kit
	4.2 mg rhBMP-2 per level	8 kits	4 kits	2 kits	1 kit	2/3 kit	2/3 kit

Image is representative and is provided for reference only.

Access and Decompression

The main goal of this step is to remove extruded fragments, decompress neural elements, and provide entry into the disc space for distraction, with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.

1. Using the appropriate retractors, gain access to the treated level through either an open or minimally invasive approach.
2. Perform a facetectomy on the ipsilateral side. Remove the ascending and descending articular processes as well as perform any additional necessary bony removal.
3. Collect local bone autograft from facetectomy and decompression for use as graft material later in the procedure.
4. An annulotomy is made with a scalpel in Kambin's triangle.



Images are representative and are provided for reference only.

Disc Space Preparation

Remove anterior, ipsilateral, and contralateral portions of the intervertebral disc to provide adequate space for placement of Infuse™ Bone Graft, autograft, and intervertebral body fusion device.

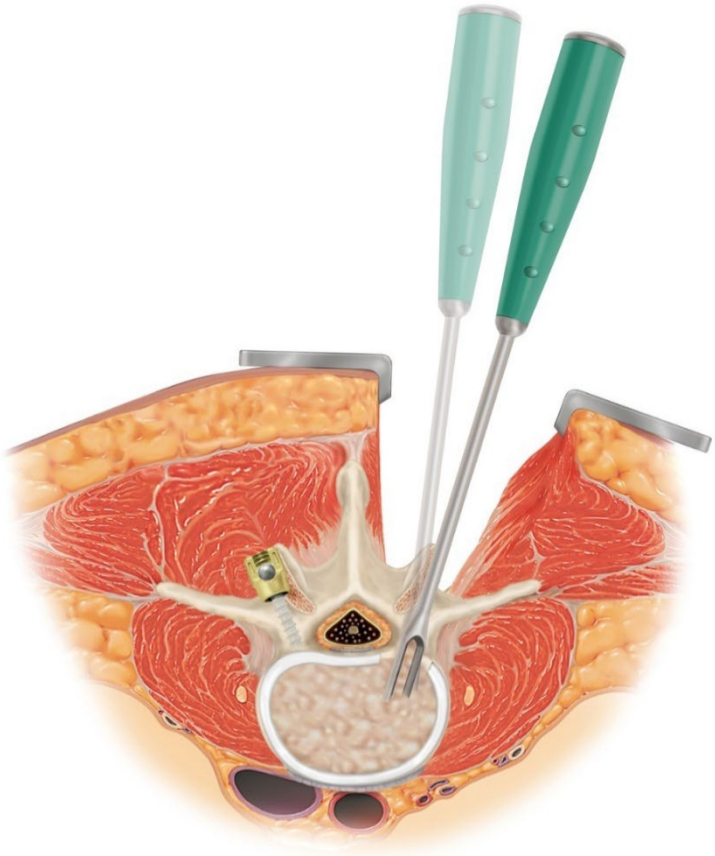
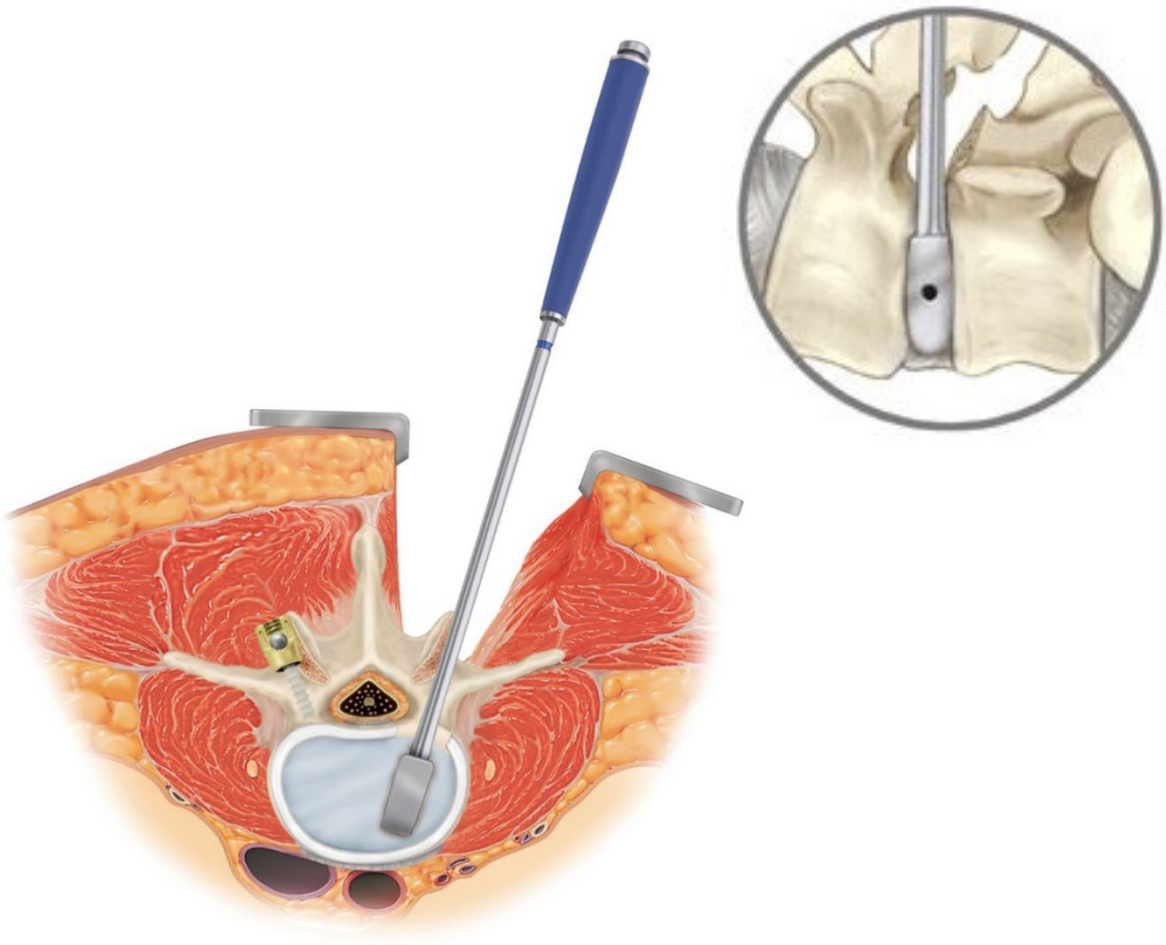


Image is representative and is provided for reference only.

Distraction

The disc space is sequentially distracted until adequate disc space height is obtained and adequate foraminal size restored.

- Insert the distractor with the curved sides touching the end plates.
- Sequentially insert distractors until the desired height is obtained. Other forms of distraction including lamina spreaders may be used as needed.
- Supplemental screw and rod fixation on the contralateral side can be used to maintain distraction during disc space preparation. Provisionally tighten construct if used to maintain distraction.

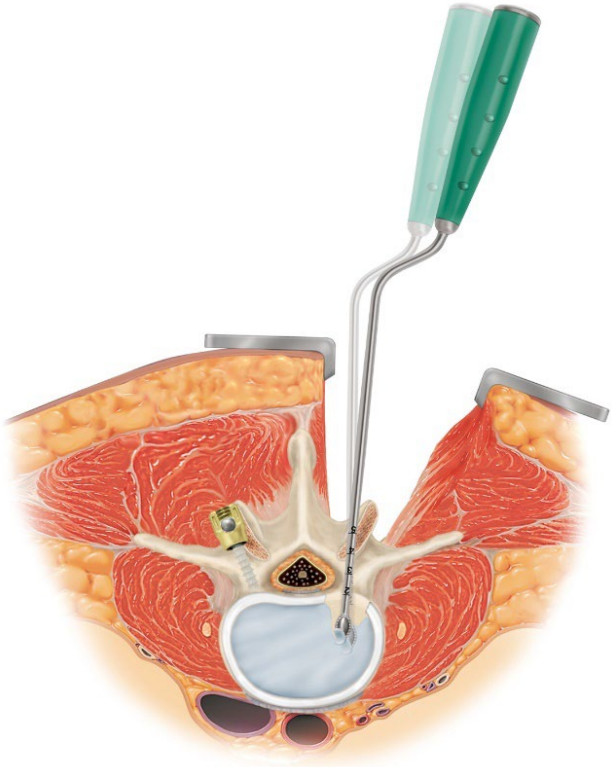


Images are representative and are provided for reference only.

Endplate Preparation

Remove cartilaginous portions of the end plates while preserving the underlying cortical bone.

Use caution when utilizing shavers and/or rotating cutters in preparing the end plates. Ensure punctate bleeding of the cortical endplates is achieved.



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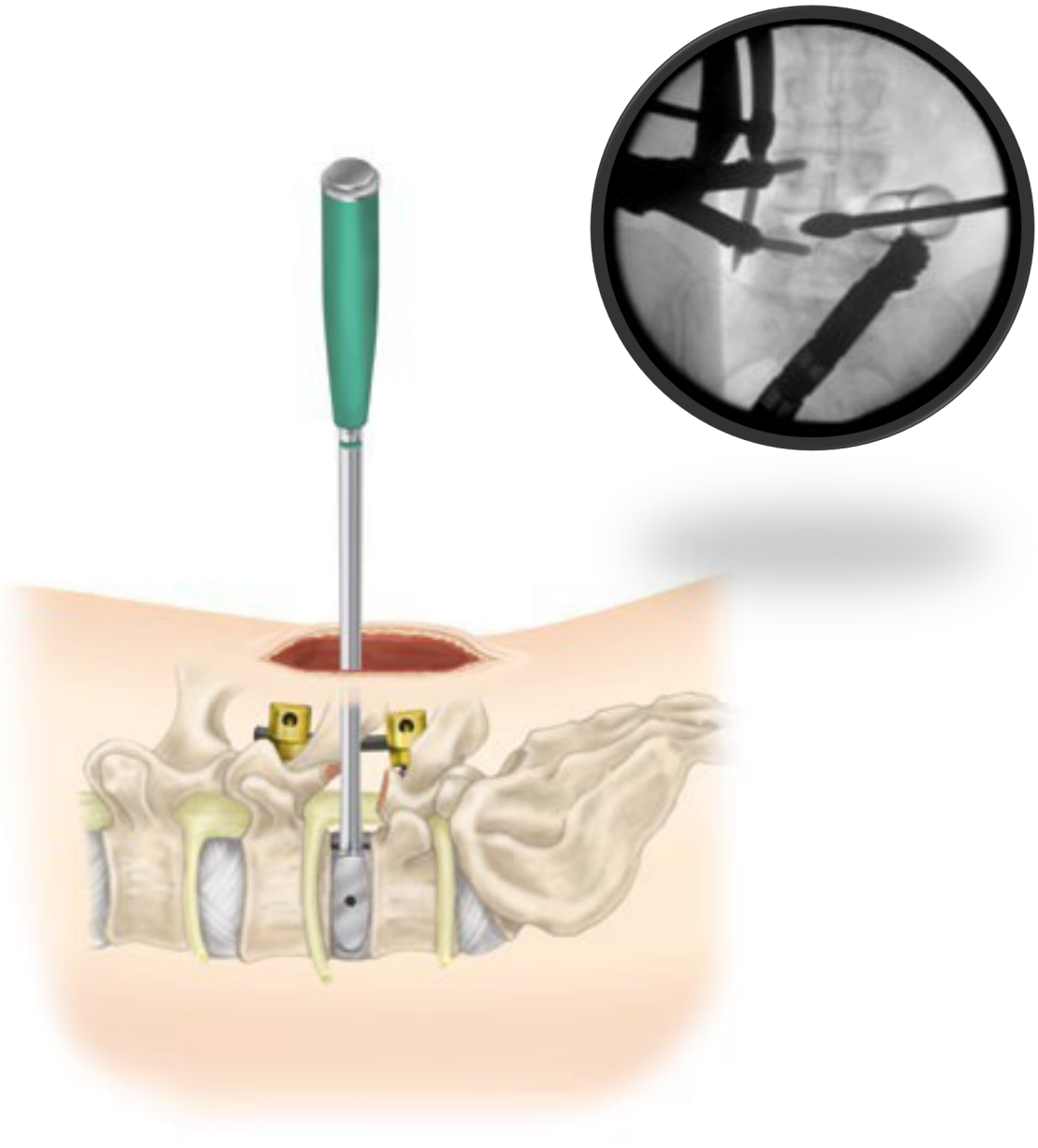
Trialing

Use the appropriate trials for the surgeon's selected intervertebral body fusion device.

For further details on standard trialing and trialing selection, please refer to the surgical technique of selected intervertebral body fusion device.



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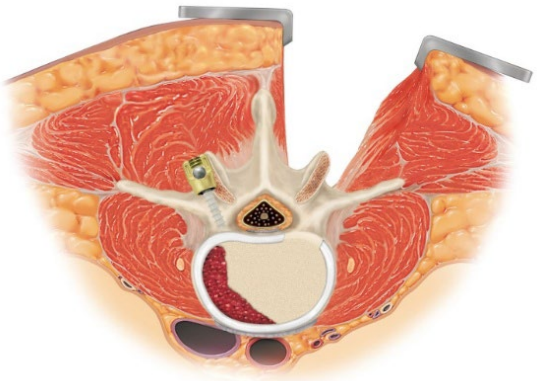
Graft Placement

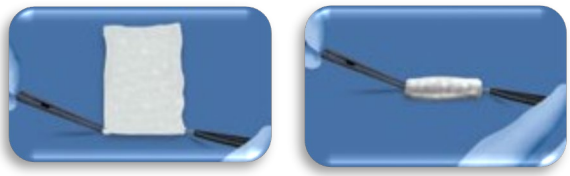


1. **Place autograft**

   Position ~1cc of autograft anterior and contralateral to the intended location of the intervertebral body fusion device.

2. **Place Infuse™ Bone Graft**

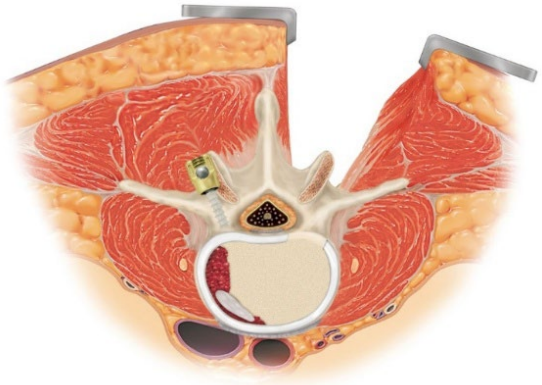
   a. Gently roll one wetted Infuse™ Bone Graft sponge lengthwise. If desired, roll the wetted Infuse™ sponge together with autograft to facilitate delivery.



   b. Place the Infuse™ Bone Graft in the prepared disc space, ensuring it is:
      - In the anterior portion of the disc space, contralateral to the intended interbody device location,
      - In contact with the previously placed autograft,
      - As distant from annulotomy as possible.

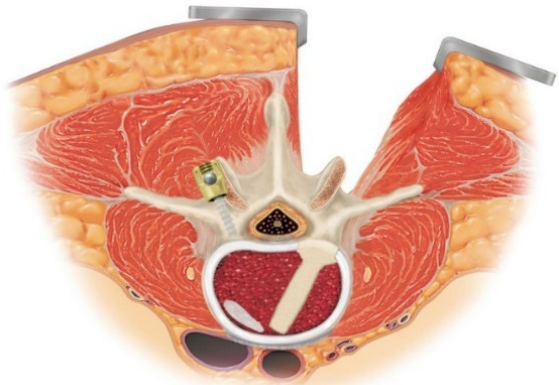
   If using an Infuse™ kit that requires more than one Infuse sponge to achieve an rhBMP-2 dose of 2.1 mg or 4.2 mg per level*, repeat steps 2a and 2b for each additional Infuse™ sponge.

   **Refer to Table on page 4 for guidance on kit preparation to achieve the specified rhBMP-2 dose per level.*



3. **Place additional autograft**

   Surround the Infuse™ Bone Graft with additional autograft to ensure that Infuse™ Bone Graft is localized to the anterior and contralateral portion of the disc space[1]. If additional graft volume is required, autograft may be supplemented with mineralized cancellous allograft.



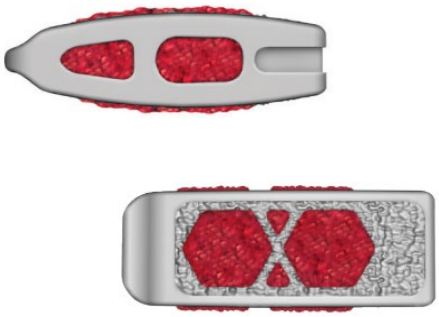
Images are representative and are provided for reference only.

[1]Note: Positioning of Infuse™ Bone Graft as described in this surgical technique, contralateral to the interbody device location, is consistent with the technique prescribed in the pivotal clinical study supporting this indication.

Intervertebral Body Fusion Preparation

Prepare the selected intervertebral body fusion device according to the surgical technique and instructions for use for the device.

Attach the intervertebral body fusion device to its inserter.



Images are representative and are provided for reference only.

Intervertebral Body Fusion Device Implantation

Please refer to the selected intervertebral body fusion device surgical technique and Instructions for Use related to preparation and implantation of the selected device[2].

- Gently impact the intervertebral body fusion device until it is least 3mm below the posterior margin of the annulus. Expandable devices may be post-packed with bone graft following expansion according to the instructions for use for the selected device.

- Following oblique insertion of the interbody fusion device, additional autograft should be placed ipsilateral and contralateral until bone is flush with the posterior margin of the intervertebral body fusion device.

- Ensure the construct is aligned properly. A properly placed construct should be positioned obliquely across the disc space, crossing the midline.

- After hemostasis has been achieved, remove all hemostatic agents or sealants from the operative site. Ensure no sealants remain in the interbody space.

- Irrigate as deemed necessary.

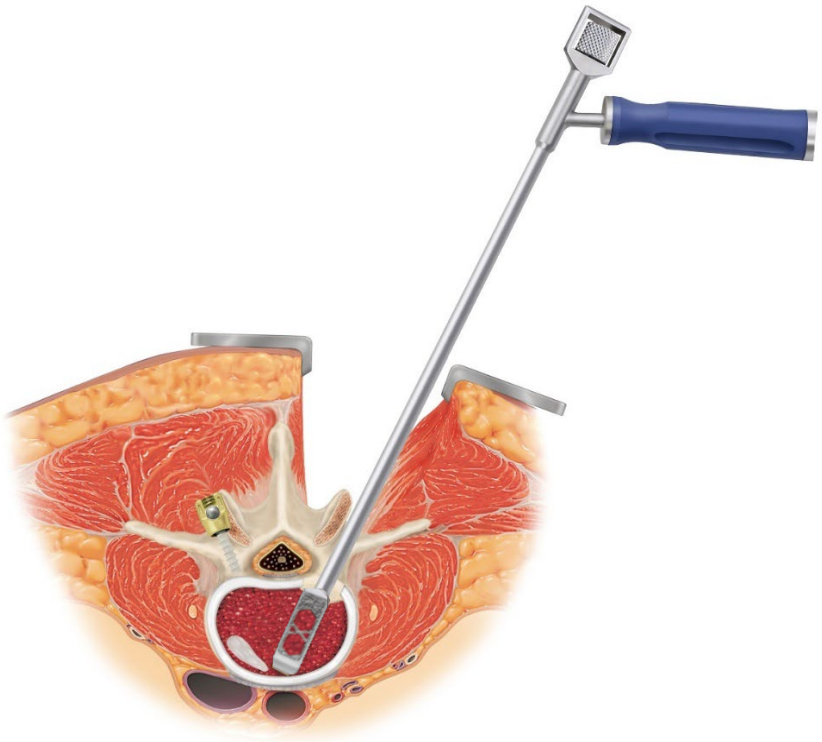
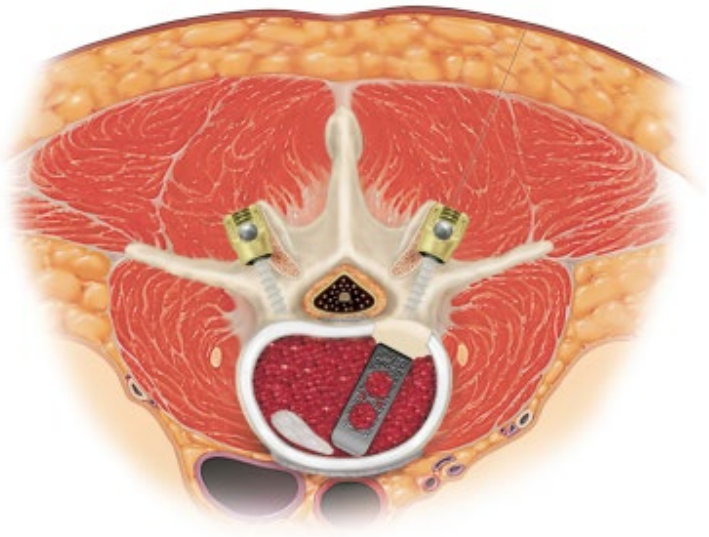


Image is representative and is provided for reference only.

[2]Note: Placement of a single TLIF cage per treated spinal level as described in this surgical technique, is consistent with the technique prescribed in the pivotal clinical study supporting this indication.

Supplemental Fixation

- Compress the metallic screw and rod construct to restore lordosis. The extradural space and foramina are probed to ensure adequate decompression of the neural elements has been achieved.
- Refer to the relevant screw and rod surgical techniques and instructions for use as needed.
- Use irrigation and suction as necessary.
- Use standard procedure to close.



Final expected construct view. Image is representative and is provided for reference only.

Explantation

Should explantation be required, the interbody device may be removed by exposing the posterior surface and removing surrounding bone with a high-speed burr or osteotomes. Please refer to the selected intervertebral body fusion device surgical technique for instructions regarding explanting the device. Remove all residual Infuse™ Bone Graft from the disc space.

Appendix

Preparation of Infuse™ Bone Graft

7510050 XX Small kit (0.7 cc)

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.
Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

In non-sterile field

1. Observing proper sterile technique, open the outer absorbable collagen sponge (ACS) package and place the inner package containing the one ½" × 2" collagen sponge in the sterile field. Open and place one of the two 3 mL syringe/needles in the sterile field.
2. Using one needle and 3 mL syringe/needle, withdraw 0.9 mL of sterile water for injection.
3. Reconstitute the rhBMP-2 with 0.9 mL of sterile water.
4. Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing.

In the sterile field

5. Open the inner ACS package leaving the collagen sponge in the plastic tray.
6. In the sterile field use the 3 mL syringe/needle to withdraw 0.7 mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.
7. Uniformly distribute 0.7 mL of reconstituted rhBMP-2 on the ½" × 2" collagen sponge.

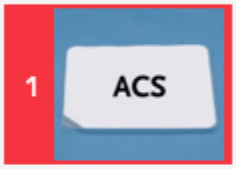
7510100 X Small kit (1.4 cc)

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.
Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

(2) 10 mL vials (2) 1.05mg vials

(1) ACS 1" × 2" (2.5 cm × 5.08 cm) 1.4 cc graft volume

In non-sterile field



Observing proper sterile technique, open the outer absorbable collagen sponge (ACS) package and place the inner package containing the one 1" × 2" collagen sponge in the sterile field. Open and place two 3 mL syringes/needles into the sterile field.

Using one of the two remaining 3 mL syringes/needles withdraw 0.9 mL of sterile water for injection.

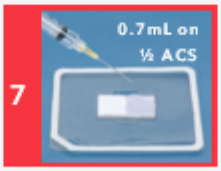
Reconstitute one vial of the rhBMP-2 with 0.9 mL of sterile water.

Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing. Using a second 3 mL syringe/needle repeat steps 2-3 with the remaining vial of sterile water and vial of rhBMP-2.

In the sterile field

Open the inner ACS package leaving the collagen sponge in the plastic tray.

In the sterile field use the 3 mL syringe/needle to withdraw 0.7 mL of reconstituted rhBMP-2 from the first vial held by the person in the non-sterile field.



Uniformly distribute 0.7 mL of reconstituted rhBMP-2 on half of the 1" × 2" collagen sponge.

In the sterile field use the second 3 mL syringe/needle to withdraw 0.7 mL of reconstituted rhBMP-2 from the second vial held by the person in the non-sterile field.

Uniformly distribute 0.7 mL of reconstituted rhBMP-2 on the other half of the 1" × 2" collagen sponge. The total amount of reconstituted rhBMP-2 delivered to the sponge is 1.4 mL.

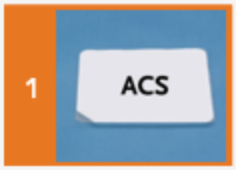
7510200 Small kit (2.8 cc)

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.
Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

(1) 10 mL vial (1) 4.2 mg vial

(2) ACS 1" × 2" (2.54 cm × 5.08 cm) 2.8 cc graft volume

In non-sterile field



Observing proper sterile technique, open the outer ACS package and place the inner package containing the two 1" × 2" collagen sponges in the sterile field. Open and place one of the two 5 mL syringes/needles into the sterile field.

Using the other 5 mL syringe/needle, withdraw 3.2 mL of sterile water for injection.

Reconstitute the rhBMP-2 with 3.2 mL of sterile water.

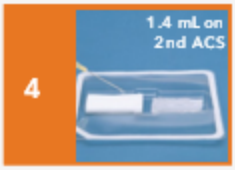
Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing.

In the sterile field

Open the inner ACS package leaving all collagen sponges in the plastic tray.

In the sterile field use the 5 mL syringe/needle to withdraw 1.4 mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

Uniformly distribute 1.4 mL of reconstituted rhBMP-2 on one of the 1" × 2" collagen sponges.



Using the same 5 mL syringe/needle, repeat steps 6 and 7 for the remaining 1" × 2" collagen sponge.

7510400 Medium kit (5.6 cc)

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.
Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

(2) 10 mL vials (2) 4.2 mg vials

(4) ACS 1" × 2" (2.54 cm × 5.08 cm) 5.6 cc graft volume

In non-sterile field

Observing proper sterile technique, open the outer ACS package and place the inner package containing the four 1" × 2" collagen sponges in the sterile field. Open and place two of the four 5 mL syringes/needles into the sterile field.

Using one of the two remaining 5 mL syringes/needles, withdraw 3.2mL of sterile water for injection.

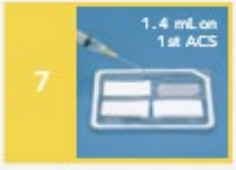
Reconstitute one vial of the rhBMP-2 with 3.2 mL of sterile water.

Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing. Using a second 5mL syringe/needle, repeat steps 2 and 3 with the remaining vial of sterile water and vial of rhBMP-2.

In the sterile field

Open the inner ACS package leaving all collagen sponges in the plastic tray.

In the sterile field use the 5 mL syringe/needle to withdraw 1.4 mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

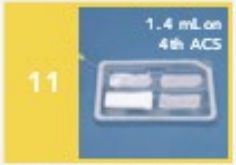


Uniformly distribute 1.4 mL of reconstituted rhBMP-2 on one of the 1" × 2" collagen sponges.

Using the same 5 mL syringe/needle, repeat steps 6 and 7 for the second 1" × 2" collagen sponge.

In the sterile field use the second 5 mL syringe/needle to withdraw 1.4 mL of reconstituted rhBMP-2 from the second vial held by the person in the non-sterile field.

Uniformly distribute 1.4 mL of reconstituted rhBMP-2 on the third 1" × 2" collagen sponge.



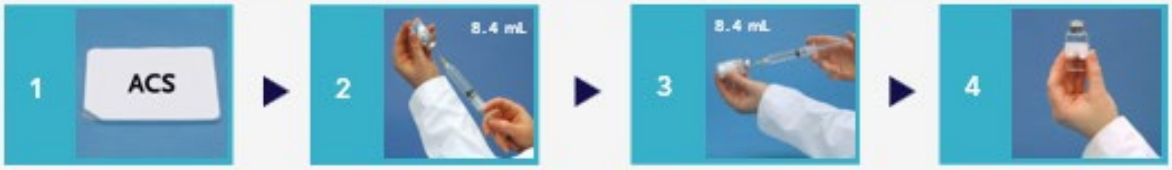
Using the second 5 mL syringe/needle, repeat steps 9 and 10 for the fourth 1" × 2" collagen sponge.

7510600 Large kit (8.0 cc)

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

In non-sterile field



1. Observing proper sterile technique, open the outer ACS package and place the inner package containing the six 1" × 2" collagen sponges in the sterile field. Open and place one of the two 10 mL syringes/needles into the sterile field.
2. Using the other 10 mL syringe/needle, withdraw 8.4 mL of sterile water for injection.
3. Reconstitute the rhBMP-2 with 8.4 mL of sterile water.
4. Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing.

In the sterile field

5. Open the inner ACS package leaving all collagen sponges in the plastic tray.
6. In the sterile field use the 10 mL syringe/needle to withdraw 4.0 mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.
7. Uniformly distribute 4.0 mL of reconstituted rhBMP-2 on three of the 1" × 2" collagen sponges.
8. Using the same 10 mL syringe/needle, repeat steps 6 and 7 for the remaining 1" × 2" collagen sponges.

7510800 Large II kit (8.0 cc)

Note: You will need to prepare a sterile and non-sterile field before beginning product preparation.

Total preparation time: Allow at least 15 minutes for preparation and an additional 15 minutes for protein to bind to collagen sponge.

(1) 10 mL vial

(1) 12 mg vial

(1) ACS 3" × 4" (7.62 cm × 10.16 cm) 8.0 cc graft volume

In non-sterile field

Observing proper sterile technique, open the outer ACS package and place the inner package containing the 3" × 4" collagen sponge in the sterile field. Open and place one of the two 10 mL syringes/needles into the sterile field.

Using the other 10 mL syringe/needle, withdraw 8.4 mL of sterile water for injection.

Reconstitute the rhBMP-2 with 8.4 mL of sterile water.

Gently swirl (do not shake) the rhBMP-2 vial to ensure adequate mixing.

In the sterile field

Open the inner ACS package. Using sterile scissors, cut the 3" x 4" collagen sponge into two 3" x 2" halves. Cut each half into three 1" x 2" pieces for a total of six pieces. Return the cut collagen sponges to the plastic tray.

In the sterile field use the 10 mL syringe/needle to withdraw 4.0 mL of reconstituted rhBMP-2 from the vial held by the person in the non-sterile field.

Uniformly distribute 4.0 mL of reconstituted rhBMP-2 on three of the 1" x 2" collagen sponges.

Using the same 10 mL syringe/needle, repeat steps 6 and 7 for the remaining three 1" x 2" collagen sponges.