Designed to prevent reherniation

Surgeon Technique Manual

BARRICAID®

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1.0 Foundation

1.1. About This Manual

This technique manual is designed to support user training and reference for Intrinsic Therapeutics' "Barricaid," a device for reducing the risk of reherniation after lumbar discectomy in indicated patients, and its accompanying system for reduction of reherniation of intervertebral lumbar discs.

This manual is designed to provide surgeons with preoperative and intraoperative procedural guidance and training for proper clinical treatment using the Barricaid device.

Please refer to the Barricaid Indications For Use for a complete description of indications for use, precautions, warnings, and contraindications for the instrument set up and implant procedure.

1.2. Learning Objectives

This technique manual is designed to assist surgeons in mastering Barricaid implantation. At the completion of your training, you should be able to:

- Identify appropriate surgical candidates for Barricaid implantation.
- Understand annular defect locations and features that are appropriate and inappropriate for Barricaid implantation.
- Identify all Barricaid system components and understand their functions.
- Achieve competence with all Barricaid system measurement and implantation devices.
- Properly set up the surgical theater for the Barricaid implantation procedure, including proper imaging configuration.
- Properly measure intervertebral disc and annular parameters to ensure appropriate Barricaid size and correct implantation.
- Properly perform Barricaid implantation and confirm proper positioning.

NOTE: The Barricaid must not be implanted by anyone who is not fully trained per the Company's certification policy.

2.0 Patient Selection

2.1. Indications

The Barricaid is indicated for reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

2.2. Contraindications

- The Barricaid should not be implanted in patients with active systemic infection or infection at the site of implantation.
- The Barricaid should not be implanted in patients with back or non-radicular leg pain of unknown etiology, scoliosis >10° (rotational or angular), spondylolisthesis >Grade 1, or clinically compromised vertebral bodies in the lumbosacral region due to any traumatic, neoplastic, metabolic, or infectious pathology.
- The Barricaid should not be implanted in patients with allergies/hypersensitivity to the implant's components (polyethylene terephthalate [PET], polytetra-fluoroethylene [PTFE], titanium, platinum, iridium) or the instrument's components (stainless steel, nickel).
- The Barricaid should not be implanted in patients with prior surgery at the index level, other than intradiscal electro-thermal annuloplasty (IDET), percutaneous nucleoplasty, microdiscectomy, hemilaminectomy, or laminotomy.
- The Barricaid should not be implanted in patients with osteoporosis or osteopenia defined as DEXA bone mineral density T-score less than or equal to -2.0.
- The Barricaid should not be implanted in patients who require spinal surgery other than a discectomy (with or without laminotomy) to treat leg/back pain (scar tissue and osteophyte removal is allowed).
- The Barricaid should not be implanted in patients with a preoperative posterior disc height <5 mm or with annular defects outside of these size ranges: between 4-6 mm tall and between 6-10 mm wide.
- The Barricaid should not be implanted in patients with insulin-dependent diabetes, peripheral neuropathy, arterial insufficiency, or a BMI >40.

2.3. Warnings

- The long-term effects of the Barricaid prosthesis have not been established.
- Do not implant the Barricaid prosthesis if the annular defect is taller than 6mm.
- Do not use the 10mm mesh in annular defects wider than 10mm; do not use the 8mm mesh in annular defects wider than 8mm. Failure to observe these defect size limitations may result in worse clinical outcomes and increased patient risk.
- Do not implant the Barricaid prosthesis in patients with posterior disc height of less than 5mm.
- Do not specifically enlarge an annular defect to qualify for the size recommendations to allow for implantation of a Barricaid. If the annular defect does not fit recommended defect measurements after the discectomy, the patient should not be considered a candidate for implantation.
- Do not implant the Barricaid prosthesis in case of extra-foraminal herniations and any defect you cannot completely visualize.
- The potential for intra-operative dural tears increases with higher numbers of prior surgeries at the involved spinal level(s).

- Only implant the Barricaid prosthesis in skeletally mature patients.
- Do not implant the Barricaid prosthesis if the structural integrity of the vertebral body appears damaged, weakened, or compromised in the region targeted for implantation.
- The Barricaid is only indicated for use in the lumbar spine.
- Do not use the Barricaid prosthesis in cervical discs. Use of the device in the thoracic spine has not been evaluated. The Barricaid prosthesis is indicated for a single level between L4 and S1.
- The Barricaid prosthesis, and the Barricaid prosthesis delivery tool (i.e. pusher, delivery sheath, strike-cap and packaging clip), may not be re-sterilized or reused. Re-sterilization or re-use may result in compromised device performance or risk improper sterilization which may cause infection or cross contamination.
- The Barricaid prosthesis cannot be used by any surgeon who has not been properly trained.
- The Barricaid prosthesis will only be delivered under a no train/no use policy.
- Use of the Barricaid prosthesis requires thorough knowledge of spinal anatomy and biomechanics.
- Surgeons must have experience with discectomies to be qualified to use the Barricaid prosthesis.
- The Barricaid prosthesis should be handled with appropriate precautions to maintain sterility.

2.4. Precautions

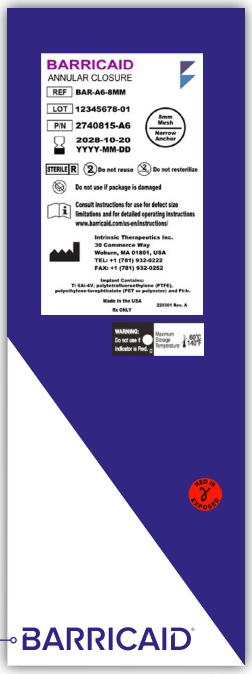
- Herniation at more than one vertebral level.
- Back or leg pain of unknown etiology
- The Barricaid prosthesis has not been studied clinically in patients excluded from the randomized clinical trial including patients who required spinal surgery other than a discectomy (with or without laminotomy) to treat leg/back pain (scar tissue and osteophyte removal is allowed), had sustained pathologic fractures of the vertebra or multiple fractures of the vertebra or hip, cauda equina syndrome or neurogenic bowel/bladder dysfunction, severe arterial insufficiency of the legs or other peripheral vascular disease, significant peripheral neuropathy, active hepatitis, AIDS, or HIV, rheumatoid arthritis or other autoimmune disease, known allergy to titanium, polyethylene or polyester materials, pregnant, active or recent tuberculosis, history of active malignancy, immunologically suppressed and/or having received steroids >1 month over the past year, currently taking anticoagulants other than aspirin, current chemical/alcohol dependency or significant psychosocial disturbance, life expectancy of less than three (3) years, involved in active spinal litigation, incarcerated, or had any contraindication for MRI or CT scan (e.g. claustrophobia, contrast allergy).
- Implant components can break when subjected to the increased loading associated with delayed, or lack of, osteointegration.
- See the surgeon training manual for important instructions related to use of the Barricaid prosthesis.

3.0 Product Description

3.1. Barricaid

The Barricaid is an implantable device designed to help reduce the risk of reherniation through the weakened annulus following discectomy. The Barricaid is available in two anchor widths of 6mm (aka Narrow) and 8mm and two mesh widths of 8mm and 10mm. The desired implant is delivered pre-loaded onto a disposable delivery tool. The delivery tool is comprised of a delivery sheath, a pusher, and a strike-cap. All of these components are disposable and should be discarded following implantation.

There is one sterile barrier: The seal between the Tyvek and PETG blister pack is the sole sterile barrier system for the Barricaid product.



The Barricaid comes in two anchor widths (A8 and A6 (Narrow)) and two mesh widths (8mm and 10mm). Anchor and Mesh widths are indicated here.

Part number, lot number, and expiration date. Please ensure that the product has not expired prior to opening.

Indicates that the product has or has not been exposed to dangerously high temperatures. If the small circle in the sticker turns RED, do not use the product.

Indicates that the product has been sterilized. The sticker MUST be RED for safe use. The implant and packaging are single-use only, and cannot be re-sterlized. Please see the included Instructions for Use for more information.

Turquoise = 8mm anchor width

Purple = Narrow anchor width

Outer Box

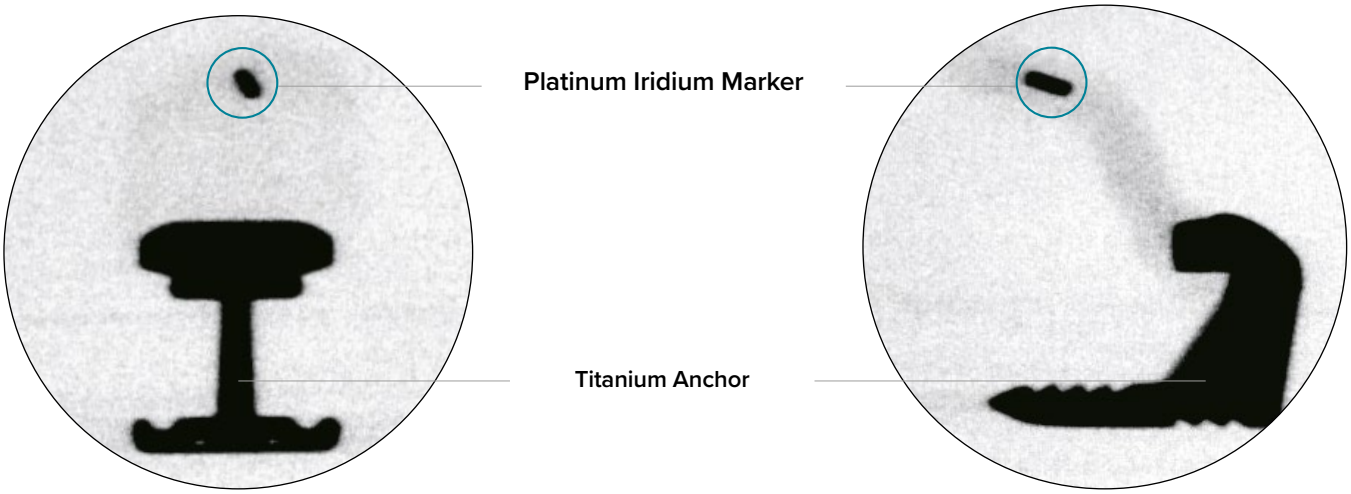
Inner Pouch

IMPORTANT: Remove and dispose of blue packaging clip prior to attempting implantation.

2 **The Barricaid delivery instrument is NOT reusable, and all components (Strike Cap, Pusher, and Delivery Sheath) must be discarded following implantation.**

The Barricaid implant is composed of the following components:

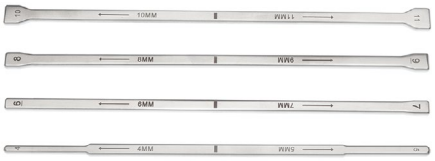
The Barricaid anchors into the vertebral body and is intended to block the annular defect to help prevent extrusion of nucleus and resulting reherniation.



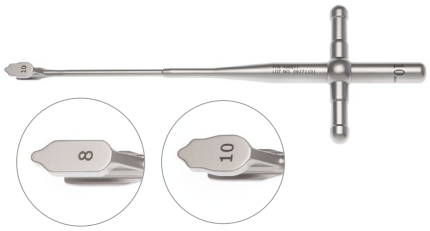
3.2. Barricaid Implantation System

The Barricaid implantation instruments are packaged in an autoclave-ready kit containing the following components required to surgically implant the Barricaid.

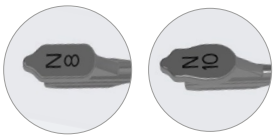
NOTE: Barricaid instrument kits all contain the same instruments, but may come in multiple configurations. Please ask your Barricaid representative for exact layout information. The Removal Tool (also referred to as an "extractor") and Impactor are supplied separately as single-use disposable items.



Defect Measurement Tools
Reusable devices for measuring height and width of annular defect to determine if the Barricaid is indicated.



Alignment Trials
Reusable device for determining adequate size of laminotomy and of annular defect to permit proper implantation. Use the Alignment Trial to determine if there is adequate access to the disc space for the Barricaid.



Note: The Alignment Trials for use with the Narrow anchor have additional labeling of N.

Mallet
Reusable device for advancing the Barricaid into the disc and vertebral body. Use only the mallet included with the Barricaid system.

DO NOT use a heavier mallet or hammer to implant the Barricaid and do not use any tool other than the delivery instrument provided to strike the implant.

Retraction Wedge
Reusable wedge designed to help pull back the Strike Cap following full Barricaid deployment.

3.3. Single Use Disposable Instruments

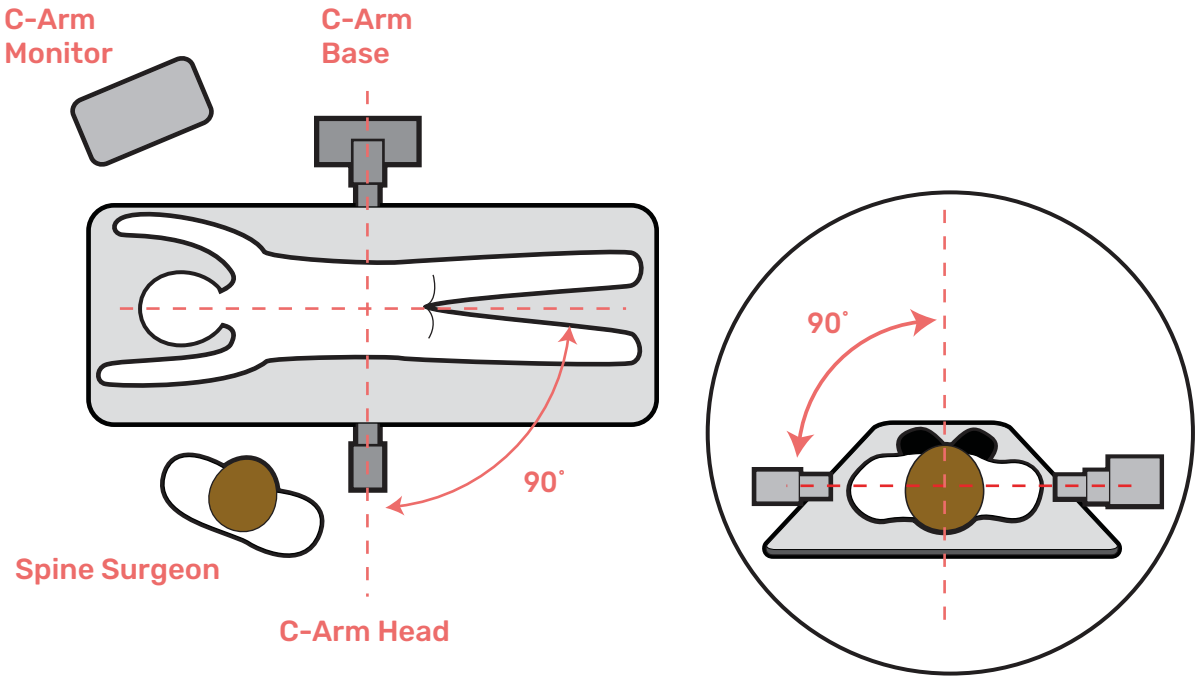
Removal Tool
Single use extractor design to facilitate Barricaid removal.

Impactor
Single use impactor designed to further advance the Barricaid anchor into the vertebral body, if during the implantation the satisfactory depth has not been achieved and Barricaid Delivery Tool has already been removed.

4.0 Operating Room And Fluoroscopy Set Up, Surgical Approach

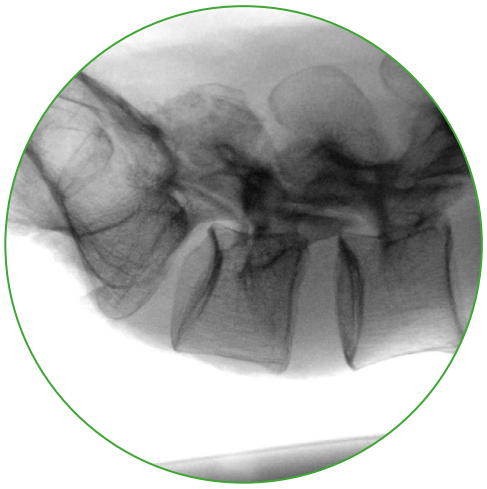
4.1. Fluoroscopy Positioning

Intraoperative imaging using a fluoroscope or X-ray is essential to ensure proper alignment and use of measurement devices and proper alignment and placement of the Barricaid. The Imaging monitor should be arranged to be easily visible to the surgeon during implantation, and the imaging equipment must be arranged to provide a lateral view of the disc.



Important: The target endplate must be clearly visible and in-plane prior to beginning the implantation procedure.

To ensure the view is in-plane, make certain there is no “double shadow” of the vertebral endplates.



In Plane: L5 endplate of L4-L5

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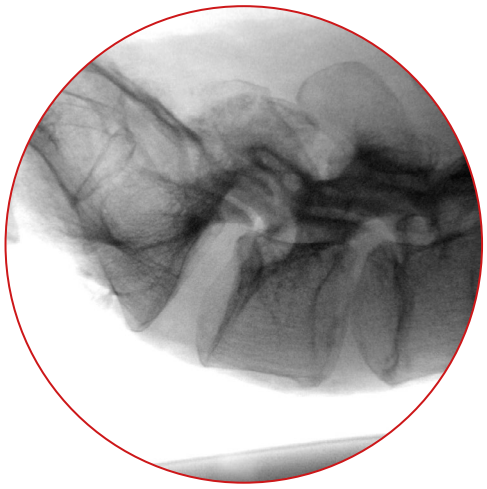
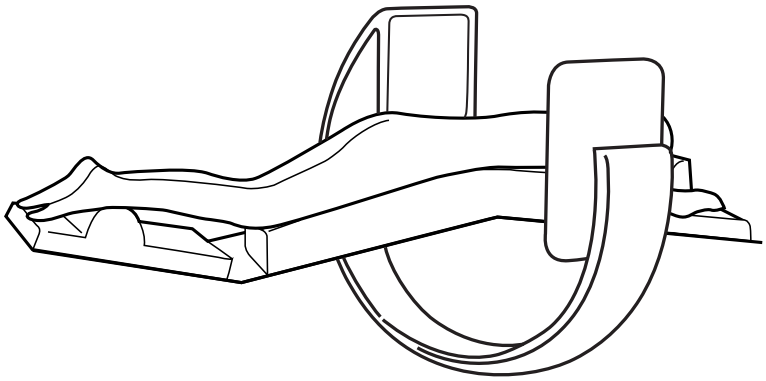


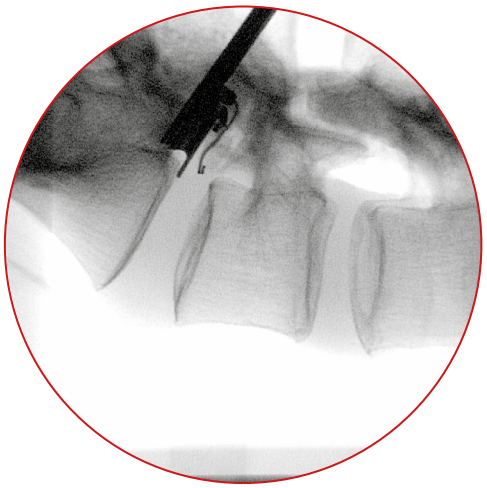
Out of Plane: L4-5

WRONG

Positioning the patient in flexion on the table will improve access to the disc space, and reduce or eliminate the need to resect bone from the lamina (see Section 5.2). It may be easier to use the mallet if the tool (and thus the target endplate) is perpendicular to the floor. In many cases, particularly in L5-S1, this will require a reverse Trendelenburg position (i.e., raising of the head relative to the pelvis and feet).



Typical Surgery Position



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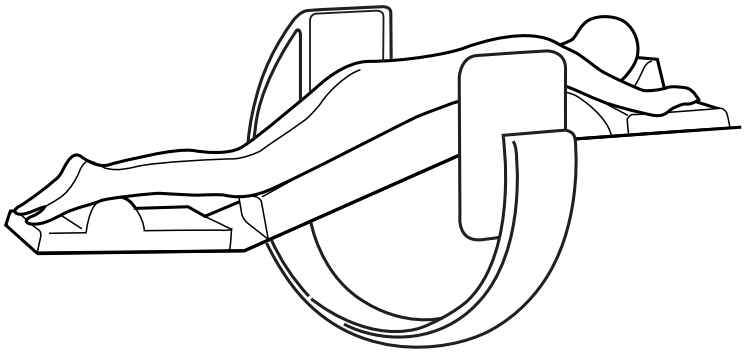
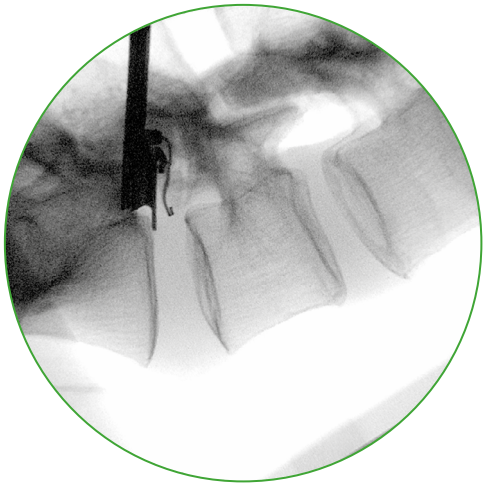


Slight raising of head, to bring disc plane more perpendicular to floor, may make hammering easier.



CORRECT

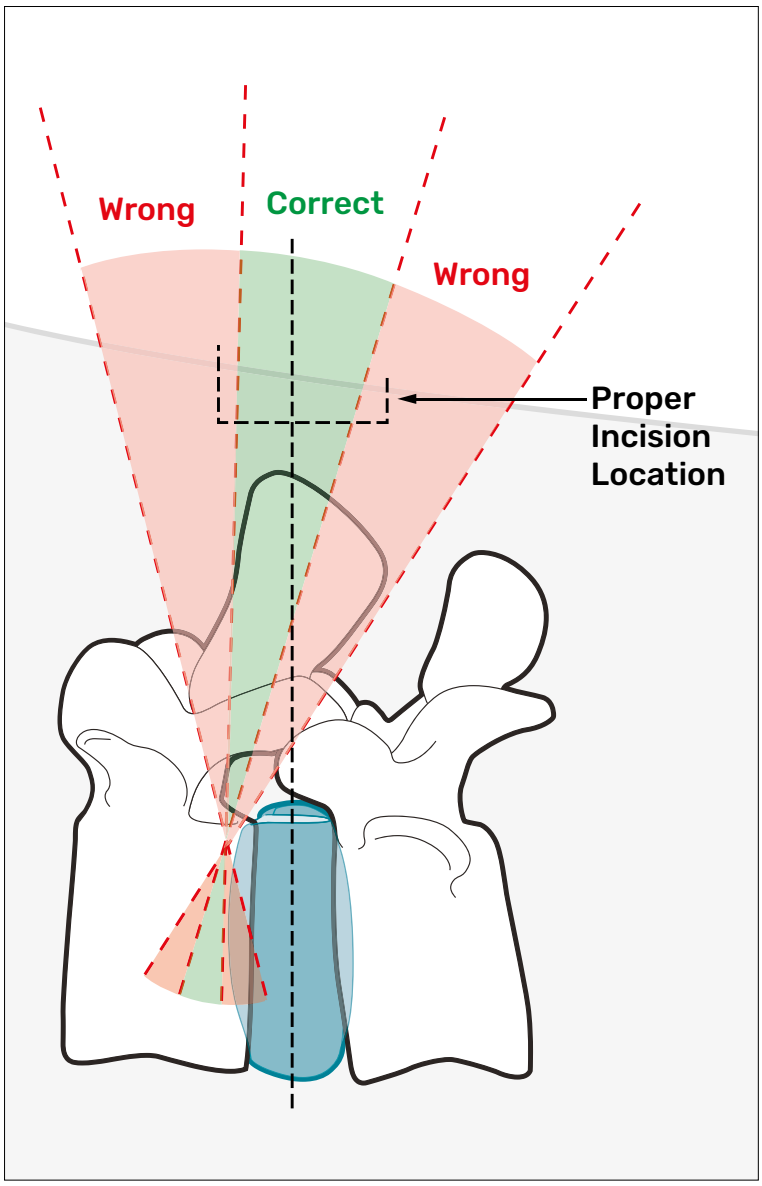
4.2. Angle of Approach

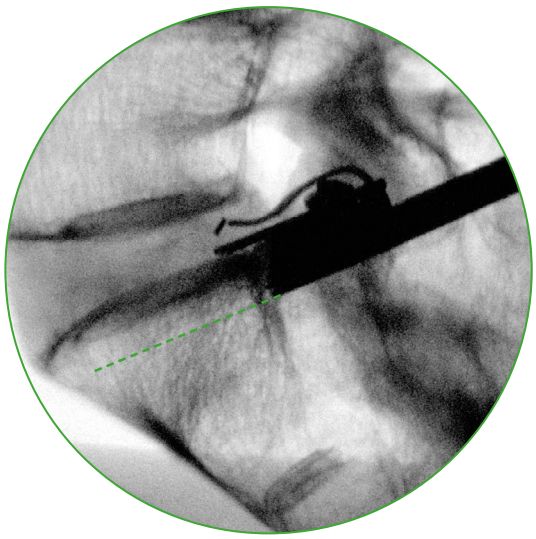
If the Barricaid is implanted at an angle too shallow, it can cause damage to the endplate. When implanting, pay close attention to your angle of approach. Refer to the diagram below for acceptable and unacceptable angles. In this example, an approach to the inferior endplate is shown, although the Barricaid may also be implanted similarly into the superior endplate.

Key Learning Point:

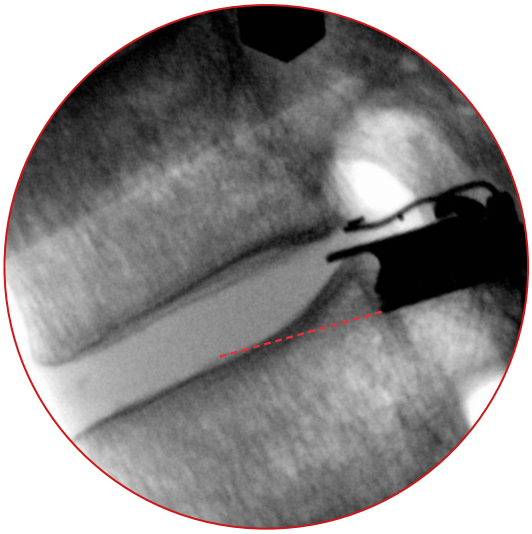
The skin incision should be made such that a line that passes through the middle of the disc also passes through the middle of the incision. Achieving this may mean that the skin incision is a centimeter or two more cranial than with the typical discectomy approach.

NOTE: Review the pre-operative images (including MR or CT) to ensure that there is adequate bone in the region of targeted anchor implantation.





CORRECT: bottom of anchor is parallel to endplate surface



WRONG: Bottom of anchor may penetrate the vertebral endplate.

View from lab specimen

5.0 Defect Measurement, Size Selection and Tool Alignment

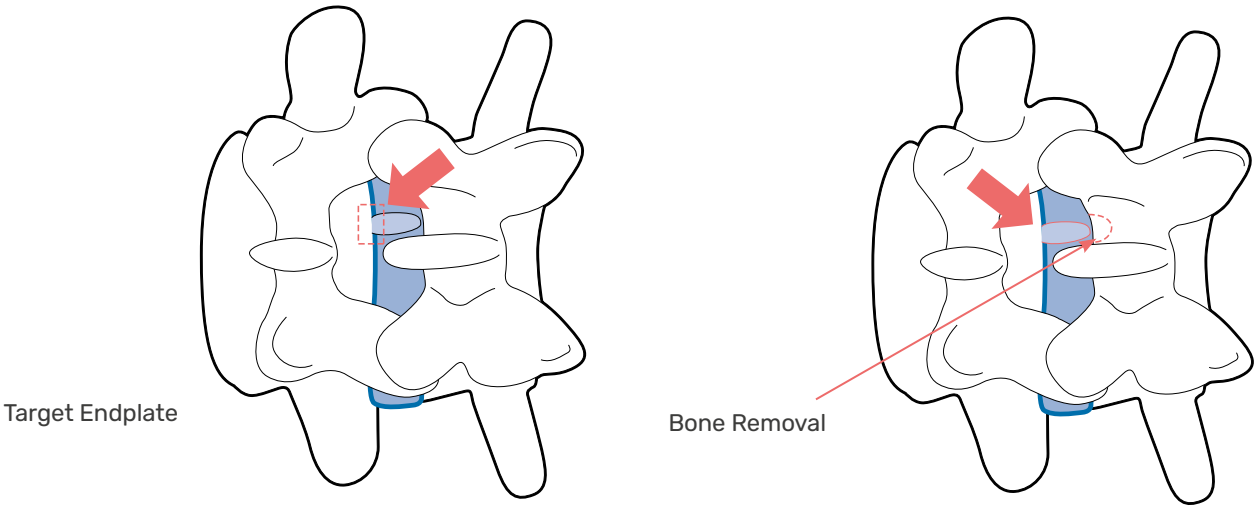
5.1. Annular Defect Location and Size

The Barricaid is intended for closure of large annular defects in the posterior lumbar intervertebral disc.

- An annular defect or weakness must be present to implant the Barricaid. If possible, the Barricaid should be inserted through the pre-existing or naturally occurring defect. Implantation through a surgically created defect is possible.
- Posterior disc height must be at least 5 mm.
- The annular defect should be between 4 and 6 mm tall and 6-10mm wide. The defect should be no wider than the Barricaid size implanted; (e.g., for an 8 mm-wide mesh, the annular defect should be no wider than 8 mm; for a 10 mm-wide mesh, the annular defect should be no wider than 10 mm).
- The annular defect should not be specifically enlarged to allow for implantation of a Barricaid. If the annular defect is less than 6mm wide, the patient should not be considered a candidate for implantation.
- The width of the mesh is marked on both the box and tray labels. Use the Barricaid with the widest mesh that is possible given the access constraints, in order to maximize the protection against reherniation.
- The Barricaid can be implanted into either the inferior or superior vertebral body.
- The incision size and location must allow access to the disc space in line with the intended vertebral body.
- The defect must be confirmed to be a full-thickness defect by inserting a defect measurement tool into the central region of the disc space.

5.2. Creating Access To The Annular Defect

Barricaid implantation requires that you gain adequate access to the implantation site to permit the Barricaid and implantation tools to pass through the ligament and/or laminotomy defect to the intervertebral disc and annulus. Make sure that the initial skin incision is made so that you will have the appropriate angle and approach to the defect and the target vertebral body (see section 4.2). Depending on the location of the annular defect, removal of bone from the lamina may be required to allow adequate access (see diagram below).



5.3. Limited Discectomy - Nucleus Removal

The amount of nucleus removed during the discectomy is of critical importance for patients considered for Barricaid implantation. Some surgeons have been aggressive in removing nucleus material with the goal of preventing reherniation. However, aggressive nucleus removal has been shown to result in significantly higher levels of back pain and worse clinical outcomes than more conservative nucleus removal.[1] A limited discectomy as described by Spengler is recommended when implanting the Barricaid.[2] This technique involves removing any nucleus that has migrated within the annular defect or beyond the annular wall (including sequestered fragments).

Surgeons may or may not have to perform an annulotomy to access and remove the disc herniation. It is best to find the existing annular defect if possible, which may be underneath the posterior longitudinal ligament (PLL). Surgeons are advised not to perform an annulotomy or increase the width of a naturally occurring defect specifically to implant a Barricaid device.

1 Watters W and McGirt M. An evidence-based review of the literature on the consequences of conservative versus aggressive discectomy for the treatment of primary disc herniation with radiculopathy. SpineJ 9:240-57. 2009.
2 Spengler, DM, Lumbar discectomy. Results with limited disc excision and selective foraminotomy, Spine. 1982 Nov- Dec;7(6):604-7

5.4. Measure Annular Defect Size And Select Appropriate Barricaid

Device: Defect Measurement Tools (4 mm – 11mm)

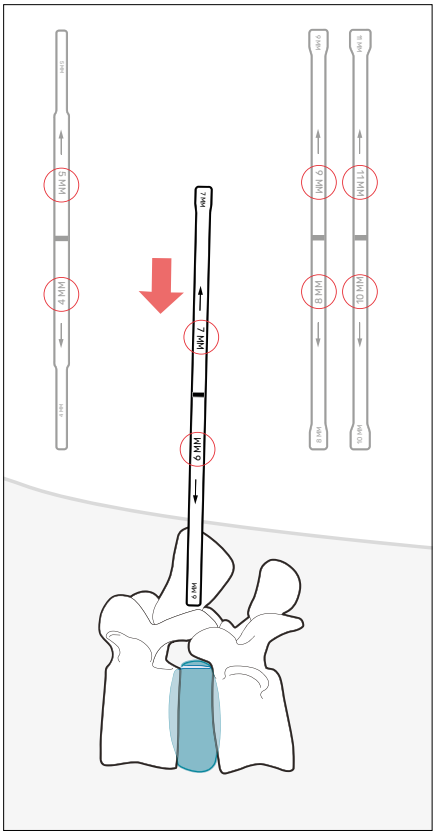
Purpose: To ensure the annular defect is the appropriate size for Barricaid implantation.

Procedure:

1. Measure defect height and width by inserting different sized Defect Measurement Tools into the annular defect, in both orientations.

NOTE: DO NOT rotate the Defect Measurement Tools while inserted in the annular defect.

2. Continue to try larger size tools until a size is reached that fits snugly into the annular defect in each orientation. The Defect Measurement Tool should be able to pass through the defect into the nucleus with very slight resistance. To avoid dilating the annular defect, do not attempt to insert a larger size Defect Measurement Tool when the previous size Defect Measurement Tool fits snugly.
3. Record both measurements.
4. Use the Barricaid with the widest mesh that is possible given the access constraints, in order to maximize the protection against reherniation. Never use a mesh size that is less than the width of the defect. The width of the mesh is marked on both the box and tray labels.



NOTE: If the annular defect is taller than 6 mm, DO NOT implant the Barricaid. Ensure that the annular defect is not wider than the mesh being inserted (e.g., for an 8 mm-wide mesh, the annular defect should be no wider than 8 mm; for a 10 mm-wide mesh, the annular defect should be no wider than 10 mm).

NOTE: The annular defect should not be specifically enlarged to allow for implantation of a Barricaid. If the annular defect is less than 6 mm wide, the patient should NOT be considered a candidate for implantation.

NOTE: DO NOT implant the Barricaid in patients with a posterior disc height <5mm.

NOTE: DO NOT use the 10mm mesh in annular defects wider than 10mm; do not use the 8mm mesh in annular defects wider than 8mm. Failure to observe these defect size limitations may result in worse clinical outcomes and increased patient risk.

SIZING GUIDE

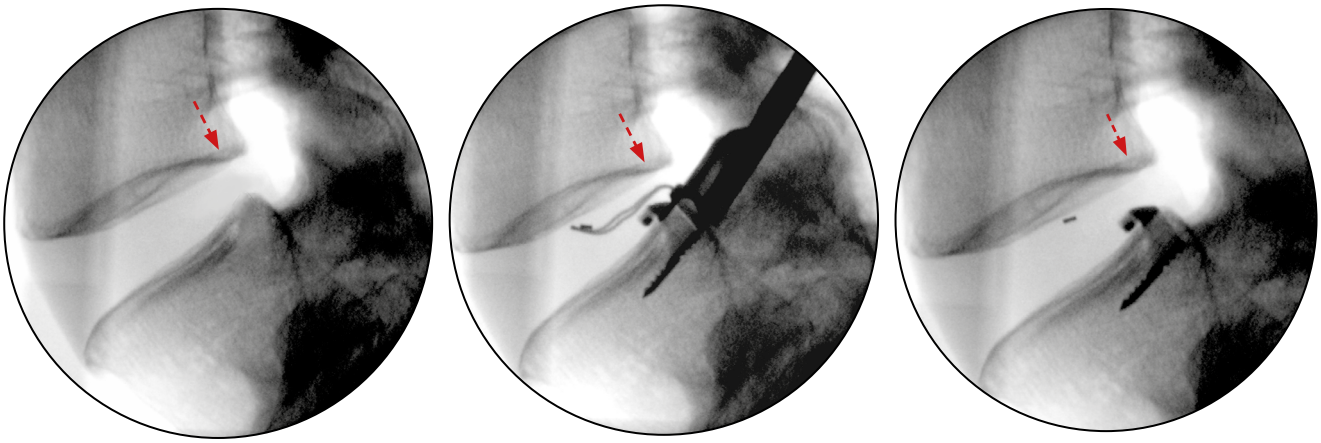
		DEFECT WIDTH			
		<6mm	**6-8 mm**	**9-10 mm**	**>10 mm**
DEFECT HEIGHT	**4-6 mm**	DO NOT IMPLANT	8mm Barricaid or wider	10mm Barricaid	DO NOT IMPLANT
	>6 mm	DO NOT IMPLANT			

Narrow and 8mm Anchor is available in both mesh widths

6.0 Implantation Procedure

6.1. Implantation Depth - Reference Point Check

Prior to implanting, identify a reference point on the non-Implanted endplate beyond which the head of the anchor should pass when implantation is complete. During implantation and before pulling back on the Strike Cap, confirm in a lateral fluoro that the head of the anchor is beyond this point. If not, the delivery sheath may not be fully down against the posterior of the target vertebral body.



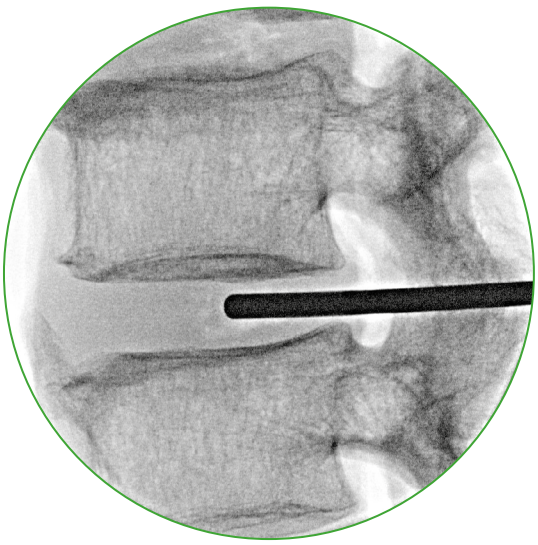
6.2. Confirm Full-Thickness Defect

Device: Defect Measurement Tool (size that matches the width of the annular defect)

Purpose: To confirm that there is a full-thickness defect through the annulus.

Procedure:

1. Successful implantation of the Barricaid requires access to the nuclear space. Confirm in a lateral fluoro that it is possible to enter the nuclear space through the annular defect. This should be done using the Defect Measurement Tool that matches the width of the annular defect. It should be possible to easily advance the tool into the middle of the disc space. Ensure that there is no loose tissue in the defect that may interfere with the mesh advancement.



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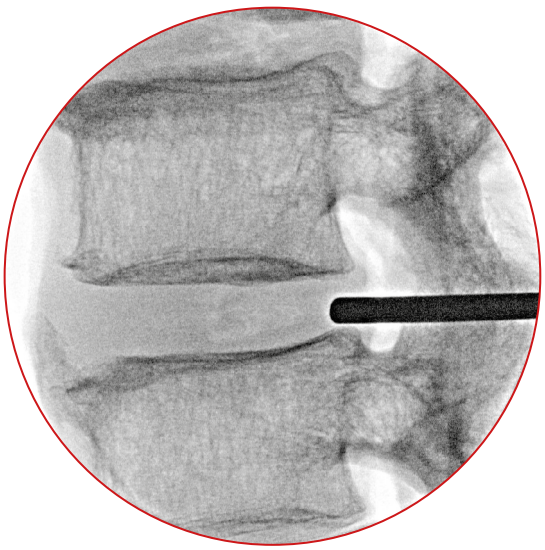


WRONG

6.3. Confirm Access and Angle

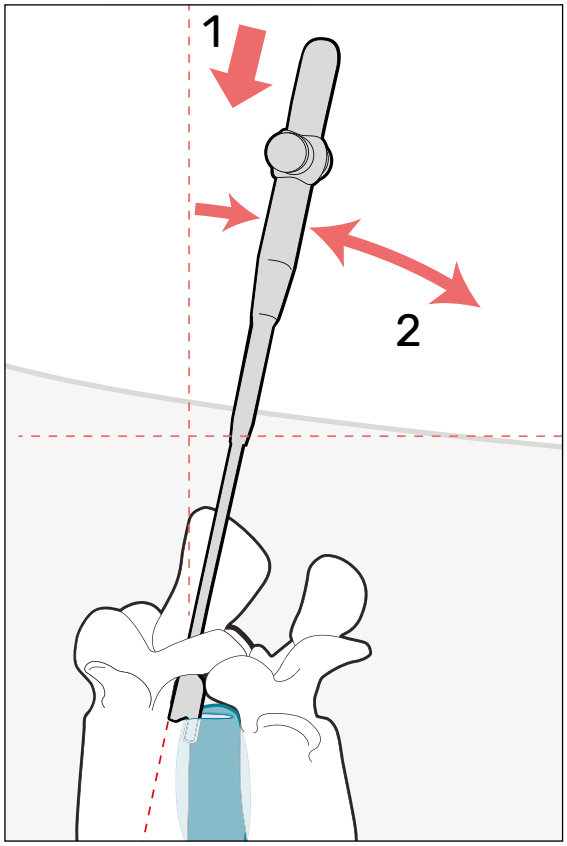
Device: Alignment Trials (8mm and 10mm)

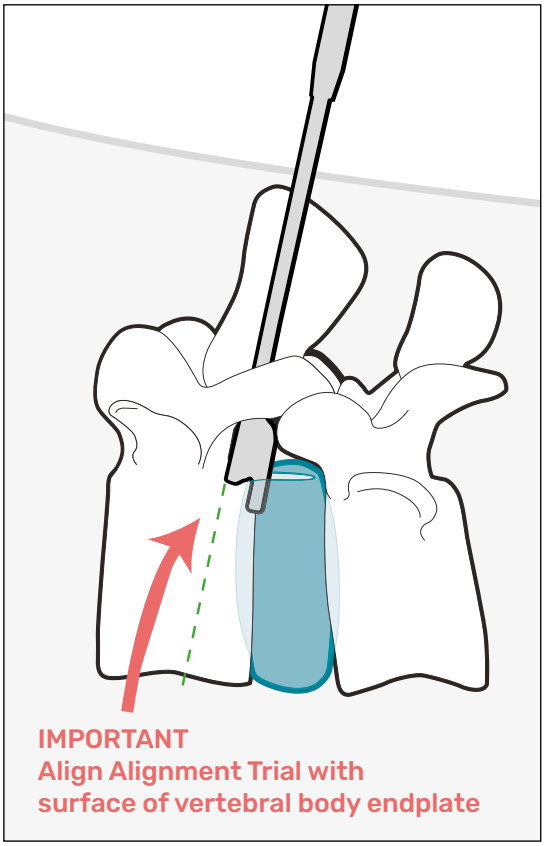
Purpose: To ensure access through the lamina is adequate to allow implantation; to establish the proper angle of approach for implantation; to ensure that there is little or no soft tissue above the target endplate in the region of anchor implantation.

Use the appropriate size Alignment Trial Tool to determine if there is adequate access to the disc space for the implantation of the Barricaid. The Alignment Trial Tool used should match the Barricaid size determined during defect measuring in Step 5.1. (e.g. if you intend to implant an 8 mm Barricaid, use the 8 mm Alignment Trial Tool, 10 mm Barricaid, use the 10 mm Alignment Trial Tool.)

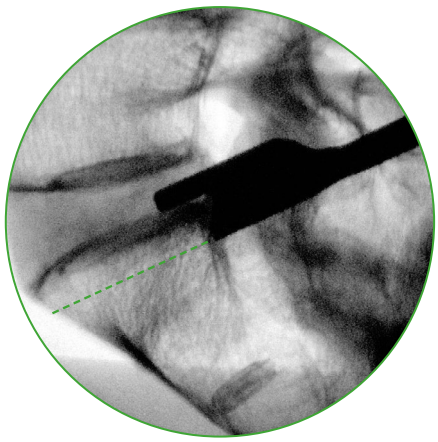
Procedure:

1. Insert the distal end of the Alignment Trial through the annular defect. Keep the endplate guide along the surface of the endplate of the vertebral body to be implanted and ensure the distal end of the Alignment Trial is against the posterior wall of the vertebra. Confirm proper position using fluoro. If access is blocked by the lamina, gradually remove bone from the lamina until access is gained.
2. Angle the Alignment Trial to determine the optimal angle for implantation. Note the angle, which should be replicated during implantation. Obtaining the appropriate angle should require little or no force. If force is required, first ensure the distal tip of the tool is in the annular defect; if necessary, remove additional bone from the lamina or consider the opposite endplate for implantation.

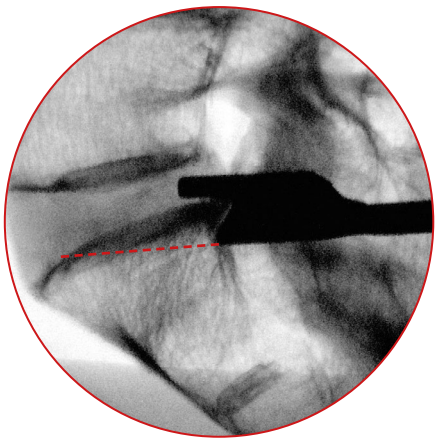




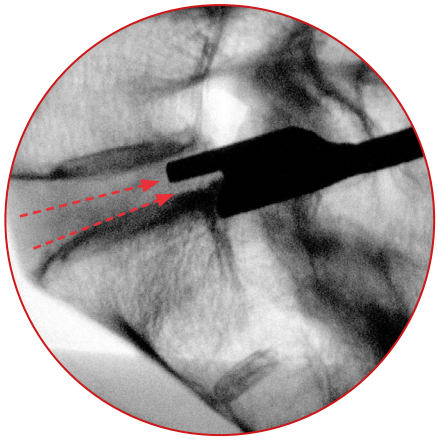
NOTE: The Barricaid can be implanted into either the superior or the inferior endplate depending on location of annular defect or anatomic variables such as nerve root location.



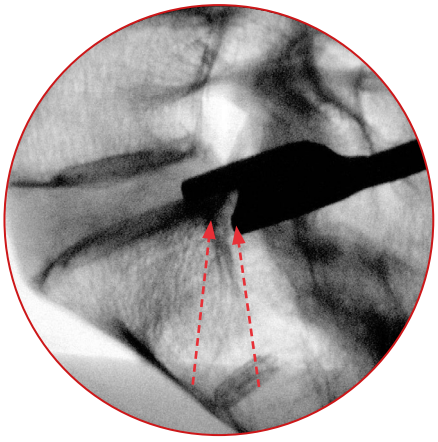
CORRECT



WRONG: Angled off endplate



WRONG: Too high



WRONG: Off posterior of vertebral body

3. Ensure there is little or no soft tissue between the Alignment Trial probe and the target endplate. It may be necessary to trim some soft tissue away from the endplate to achieve proper implantation. If the soft tissue is not trimmed, the trial and implant will be too high off of the implanted endplate.

DO NOT try to achieve the proper angle to the endplate with the Alignment Trial or the Delivery Tool by using the instruments to force the spine into flexion.

This will overload the tool, possibly damaging it, and will put excessive loads onto the bone anchor and mesh, which may cause the following problems:

- Damage or detachment of the Barricaid mesh.
- Excessive resistance to implantation from bending or damaging the Delivery Tool.
- A “backing out” of the Delivery Tool, making deployment depth inaccurate.

Instead, remove bone from the lamina to achieve the proper angle to the endplate without force. If it is not possible to remove adequate bone for alignment with either endplate, the Barricaid should not be implanted.

6.4. Proper Alignment and Placement

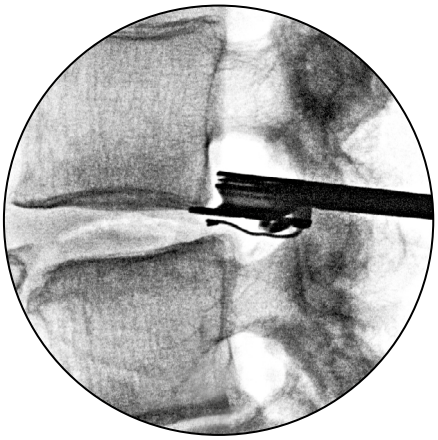
When implanting the Barricaid, proper alignment and placement are critical to ensure correct and full implantation of the device, to prevent damage to the vertebral body, and to ensure the Barricaid mesh is deployed in the correct location to perform its function. Ensure adequate protection of the dura and nerve root to avoid injury during positioning of the implantation tools and throughout the implantation procedure.

Successful implantation requires proper alignment in both axes, as well as proper placement above the endplate of the vertebral body.

Listhesis

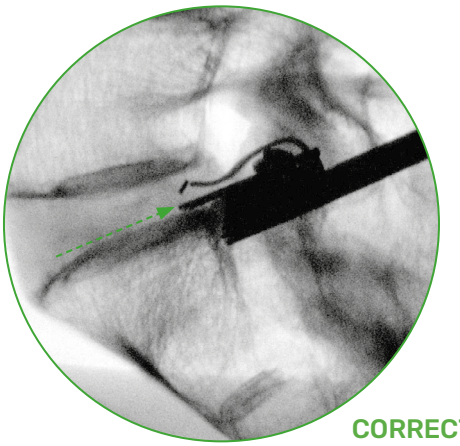
In the case of listhesis or retrolisthesis, implant into the vertebral body that is further anterior.

DO NOT implant if the listhesis is Grade II, i.e. 25% or higher.

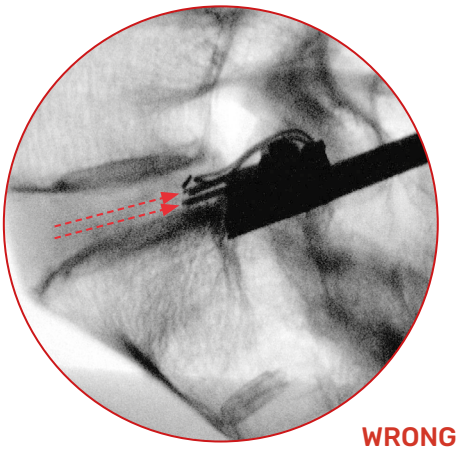


Angle of Rotation

The baseplate (i.e., bottom of the anchor) of the Barricaid should be parallel to the surface of the endplate. When implanting, pay close attention to ensure the Barricaid is not rotated in relation to the endplate. The endplate guides on the Barricaid Delivery Tool enable you to confirm proper orientation under fluoroscopic guidance. If you can see two endplate guides in the fluoroscopic image, the Delivery Tool is not parallel to the endplate. See fluoro below.



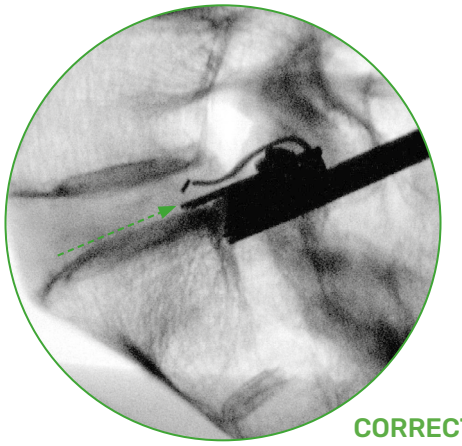
CORRECT



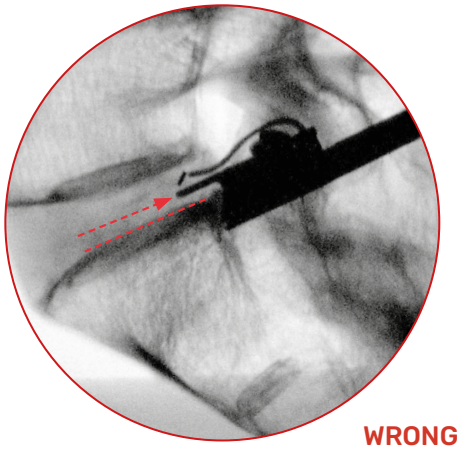
WRONG

Implantation Height

The head of the anchor of the Barricaid should rest on the surface of the endplate. If the head of the anchor is too high, it can contact and damage the opposing endplate. If the head is too low — penetrating the vertebral body below the endplate — it can damage the Barricaid mesh and the endplate being implanted.



CORRECT



WRONG
Too high

NOTE: If any part of the baseplate (i.e., bottom of the anchor) of the Barricaid penetrates the endplate of the target vertebra following placement, it must be removed. Once a Barricaid has been removed, it is not possible to re-implant another Barricaid into the same vertebral body for the same annular defect. Either implant into the opposing vertebral body's endplate or do not implant at all.

If it is necessary to remove the Barricaid Delivery Tool with the Barricaid after it has been inserted into the site but prior to deployment, be sure to grasp the Strike Cap as well as the Delivery Tool when removing. This will assure that the Barricaid is not dislodged from its preloaded position on the Delivery Tool during removal. Be sure to inspect the mesh for damage prior to re-inserting.

6.5. Barricaid Implantation

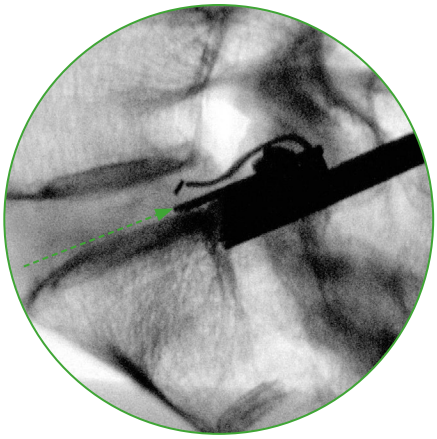
Device: Barricaid Delivery Tool with Barricaid, Mallet

Purpose: To correctly implant the Barricaid

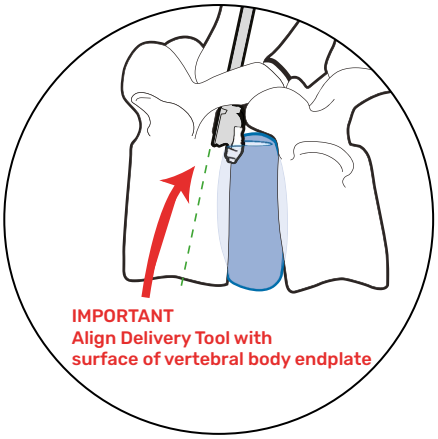
Procedure:

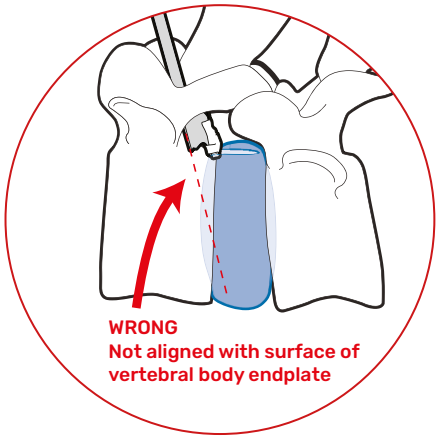
1. It is important to first make sure that the distal tip of the Delivery Tool and the marker within the mesh are in the annular defect. Insert the distal end (including implant) of the Delivery Tool through the annular defect. Keep the endplate guides along the endplate of the vertebral body to be implanted.
2. Angle the Delivery Tool to the correct implantation angle, as determined in Section 6.4. The alignment rod at the proximal end of the Delivery Tool should be parallel to the disc plane to ensure proper rotation. Using fluoro, confirm that the endplate guides are against the endplate and are not rotated, but in plane with each other.

NOTE: The Barricaid can be implanted into either the superior or the inferior endplate.

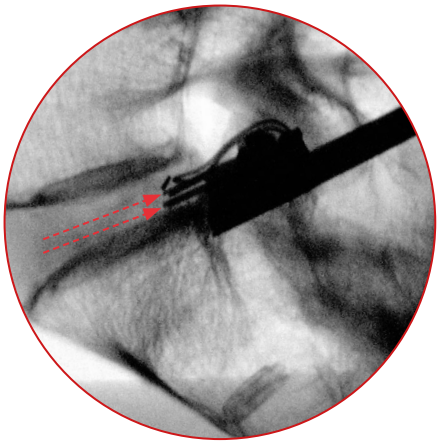


CORRECT

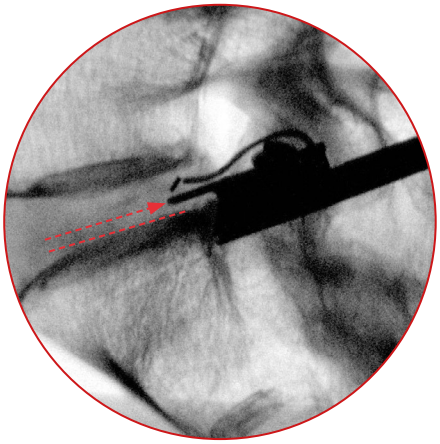




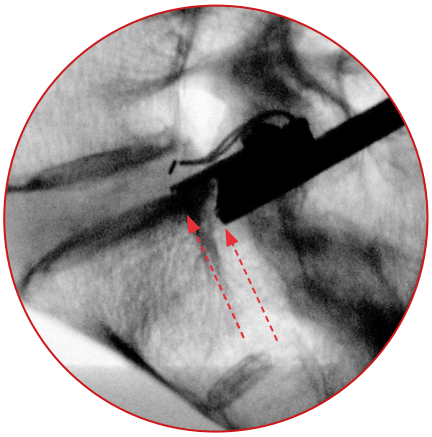
WRONG: Poor alignment



WRONG: Rotated off endplate



WRONG: Too high



WRONG: Off posterior

Key Learning Point:

Trim any residual annular tissue down to the target endplate, to allow proper placement of the anchor against the target endplate.

Correct Angle and Positioning of Instruments in the Defect

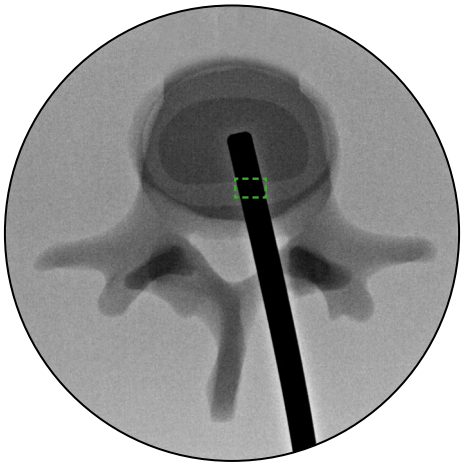
The images below show an axial view of a disc model, with annulus, and a green box to indicate the location of the defect. It is important that the Barricaid be implanted centrally in the defect, to prevent recurrent disc herniation and difficulty in advancing the mesh.

The medial-lateral position of the defect will vary. Once you have located the defect, the instruments should all be similarly positioned and angled to access the defect. In the example below, note in the fourth image that the angle and position have changed, indicating the potential for an incorrectly placed Barricaid.

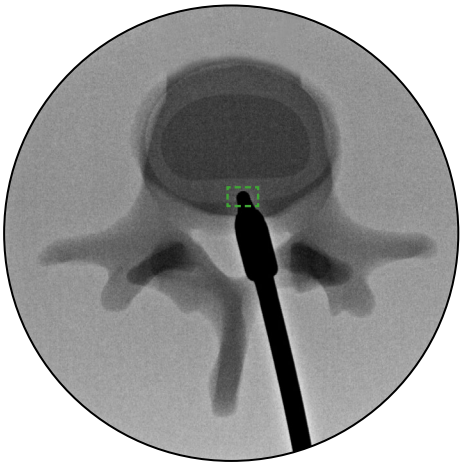
Key Learning Point:

If the Barricaid is not centered within the annular defect, the mesh may be directed into healthy annulus which can block its progress and result in a failed implantation.

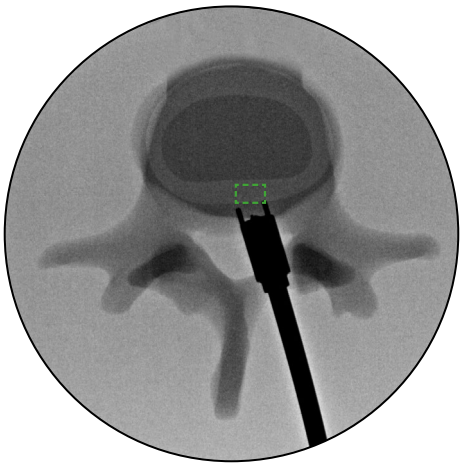
NOTE: The Barricaid should be positioned centered from left to right within the annular defect. Do not implant the Barricaid overly shifted toward either lateral defect edge.



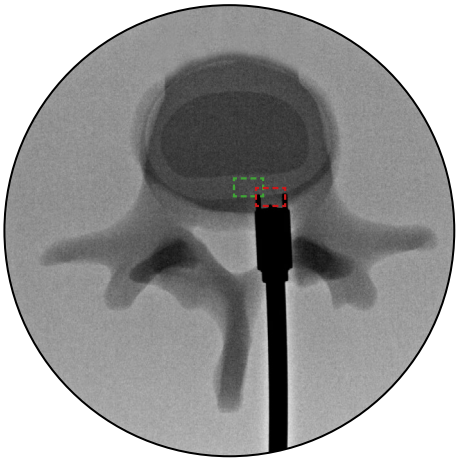
Defect Measuring Tool positioning



Alignment Trial positioning



CORRECT: Delivery Tool positioning



WRONG: Delivery Tool not in defect

Mesh/Guide-Wire Buckling

As you begin to hammer the implant into position, if the mesh does not have a clear path into the nucleus, the mesh/guide-wire may buckle resulting in a failed implantation.

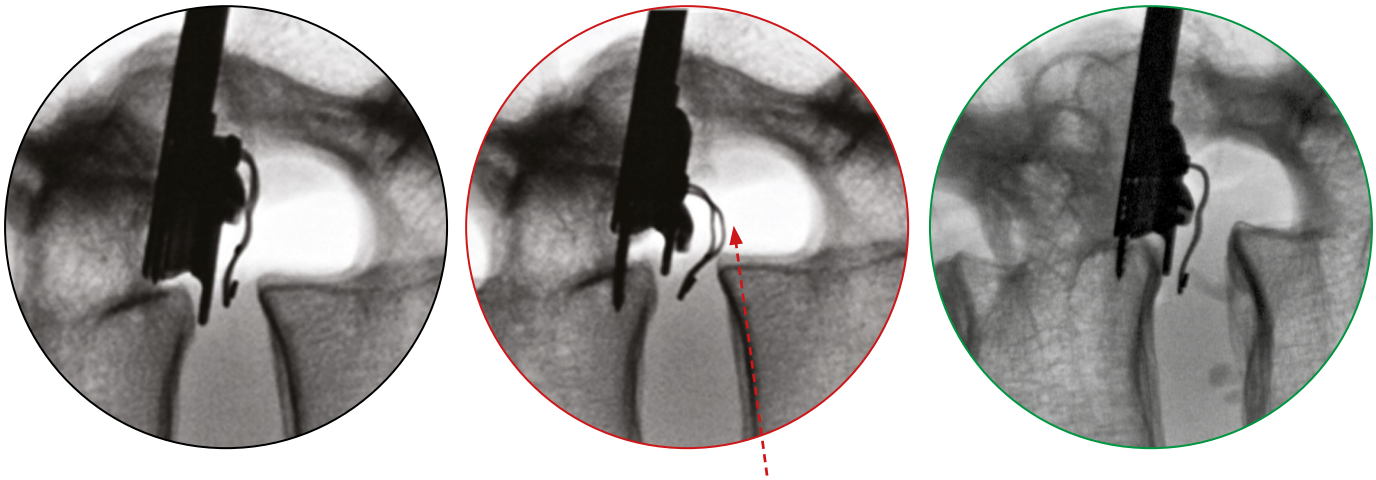
Common causes for mesh/guide-wire buckling are as follows:

- Delivery Tool is missing the defect in the medial-lateral direction (see previous page)
- Delivery Tool is missing the defect in the superior-inferior direction
- Delivery Tool position is not held constant during implantation
- Annular defect is not full thickness (see section 6.2), or soft tissue is blocking the defect
- Avoid these situations to avoid mesh/guide-wire buckling. If buckling is observed, stop implantation. Remove and discard the Implant and Delivery Tool. A second implantation may be attempted.

NOTE: If the anchor penetrated the bone in the first attempt, the implantation must be made into the opposing vertebral body.

Prior to attempting a second implantation, repeat the annular defect measurement (section 5.4). If implanting into a different vertebral body than the first attempt, use the Alignment Trial to confirm access and angle (section 6.3).

3. Maintaining a steady hand position with the distal end of the Barricaid Delivery Tool against the posterior wall of the target vertebra, tap the Strike Cap with the supplied mallet at the proximal end of the Delivery Tool until the deployment depth indicator on the tool indicates the proper depth. Use small, steady forces when tapping the Strike Cap. This will help maintain the proper angle and reduce the risk of damage to the vertebral body from misalignment. Take fluoro shots every few mm, to ensure appropriate progress. When deployed properly, the Barricaid will be countersunk in the bone by 2 mm.



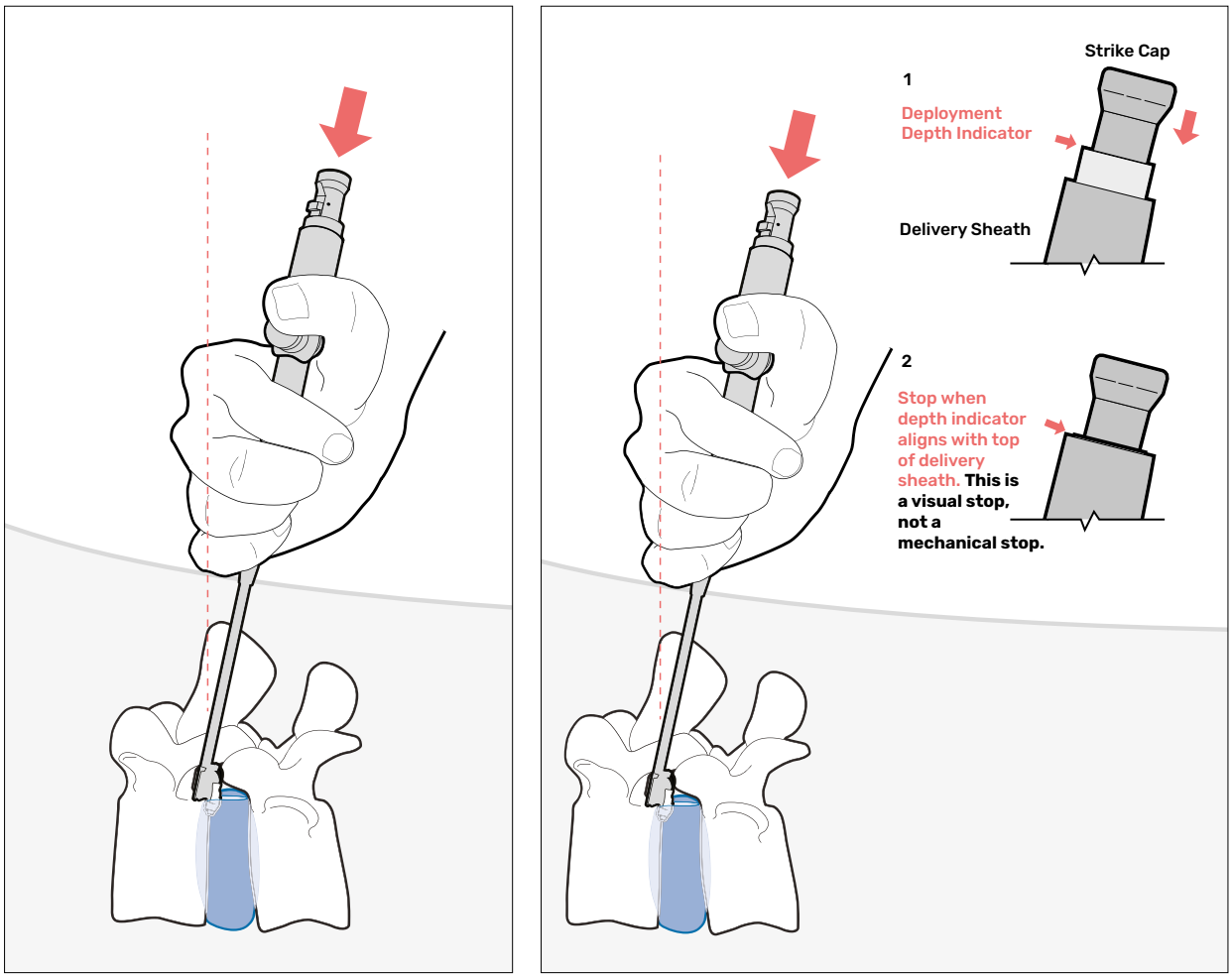
Starting position | **Mesh/Guide-wire buckling** | **Correct implantation**

Key Learning Point:

Take final alignment fluoro with the mallet in hand just before you are ready to strike the Strike Cap.

Barricaid is fully implanted when the Strike Cap lines up with the delivery sheath. **This is a visual stop, not a mechanical stop.**

NOTE: DO NOT tap Strike Cap once this is achieved.



Key Learning Point:

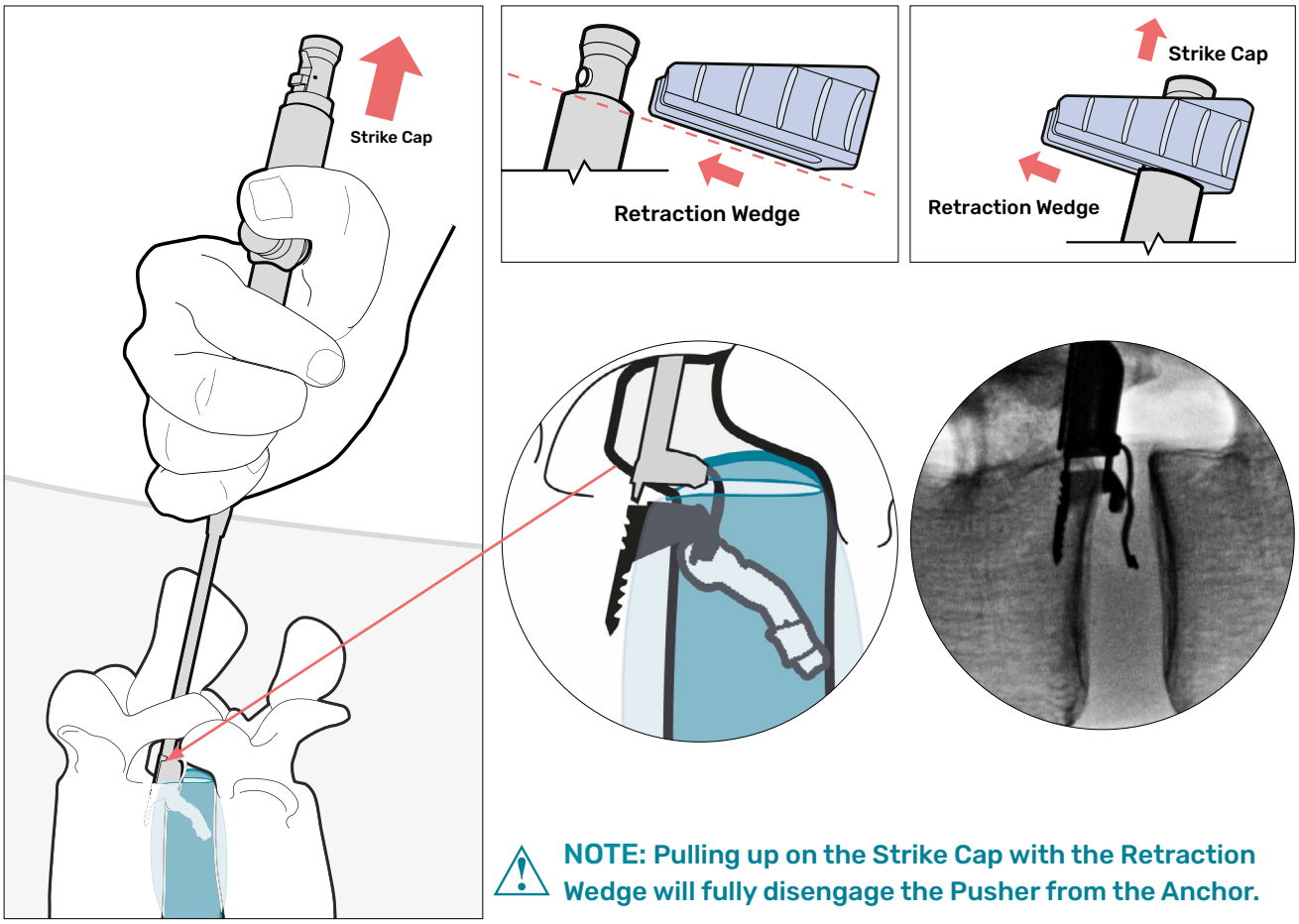
Make sure to maintain a steady hand position during implantation. It may be helpful to maintain correct position by resting your hand on the patient's body. Any movement prior to or during implantation can result in improper alignment of the Barricaid and/or damage to the endplate, instrument or implant.

DO NOT over-hammer the Strike Cap when implanting!
Small, steady tapping force is best to help maintain proper alignment. Once the deployment depth indicator on the Delivery Tool indicates the proper depth has been achieved, DO NOT strike it again. Doing so will continue to advance the anchor; the Strike Cap will not "bottom out" until beyond the recommended advancement.

CAUTION: DO NOT retract the Pusher or withdraw the delivery instrument until the anchor is fully implanted. Full implantation is indicated by the depth indicator on the strike-cap being lined up with the top of the delivery sheath (see previous picture), and should be confirmed with a lateral fluoro/x-ray. Failure to fully implant the anchor may result in the anchor protruding beyond the vertebral body, into the spinal canal.

4. Retract the Pusher component of the Delivery Tool by pulling up on the Strike Cap using the Retraction Wedge. This retracts the nitinol guide-wire from the mesh, and disengages the pins on the end of the Pusher from the anchor (see image below). Be careful not to depress the release button on the Strike Cap at this point.

   Orient the Retraction Wedge as shown in the drawing (with “This Side Up” facing up). Maintaining the orientation of the Delivery Tool, slide the Retraction Wedge along the Strike Cap until the Strike Cap is fully engaged at the end of the slot. For additional disengagement, pry the Retraction Wedge upward like a bottle opener - this will make removal of the Pusher easier, particularly in shorter disc heights. Remove the Retraction Wedge before proceeding.

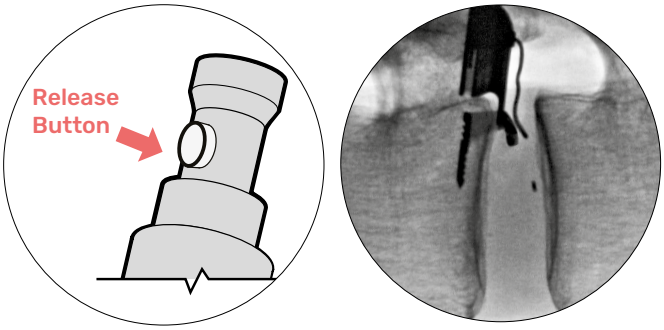


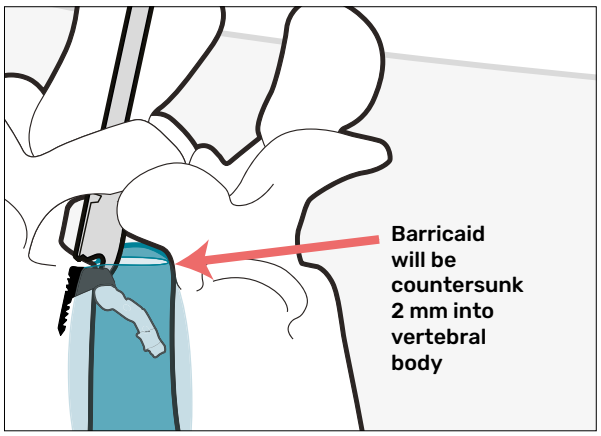
NOTE: Pulling up on the Strike Cap with the Retraction Wedge will fully disengage the Pusher from the Anchor.

CAUTION: Retracting the nitinol guide-wire completely out of the disc space without visualizing and/or controlling the neural elements could result in damage to the neural elements.

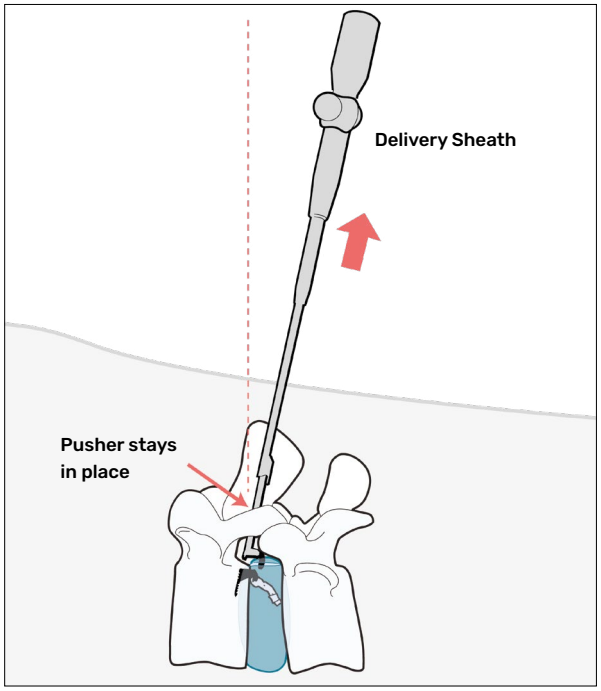
CAUTION: If retracting or removing the pusher is difficult, identify whether the guide-wire is impinged. If it is, rotate the wire away from this impingement and/or remove the impingement to free the guide-wire. Failure to identify and remove this impingement could disturb the implant position.

5. Remove the Strike Cap from the end of the Pusher by depressing the release button on the Strike Cap.

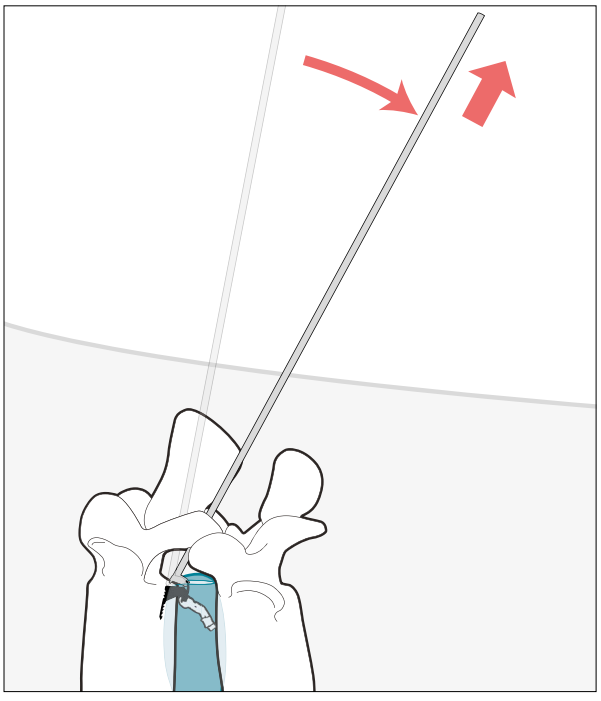




6. Withdraw the Delivery Sheath from the patient.



7. Angle the Pusher Rod away from the implanted vertebral body and pull out. Angling away from the implanted vertebral body will avoid having the Pusher pins re-engage with the anchor.

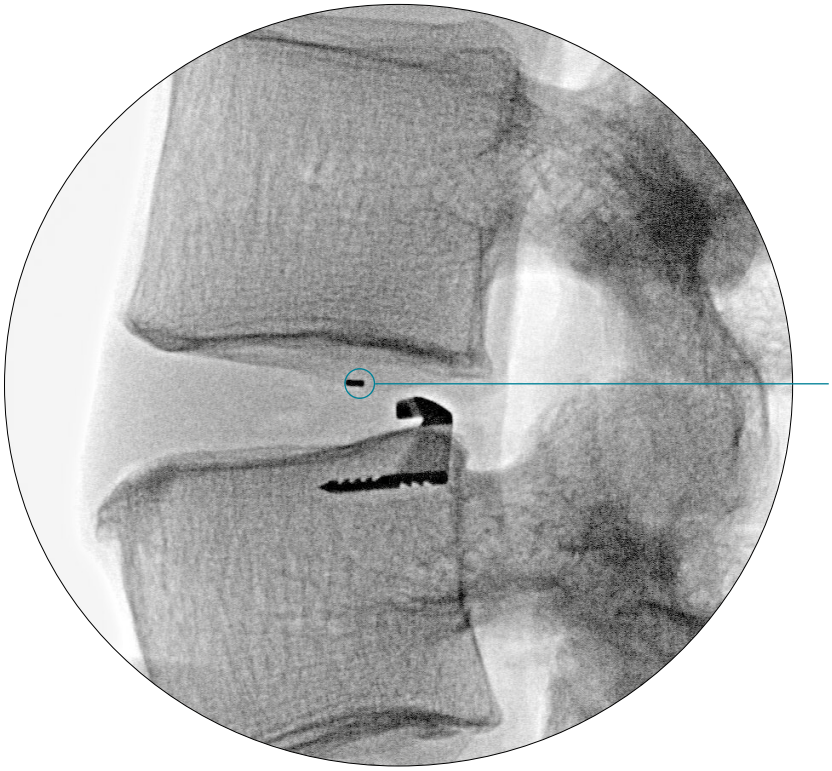


IMPORTANT: Be sure to keep the neural elements under visualization at this step to reduce the risk of neural damage.

8. Take a fluoro to confirm proper position of the Barricaid.
9. Inspect all instruments. If any damage is noted, contact the manufacturer at Quality@barricaid.com, and you will be provided instructions for return and replacement.

IMPORTANT: Dispose of the entire Delivery Tool (Sheath, Pusher, and Strike Cap) following implantation of the Barricaid. DO NOT re-sterilize or re-use any part of the Delivery Tool.

Never strike the implant with any tools other than the Delivery Tool or Impactor provided.

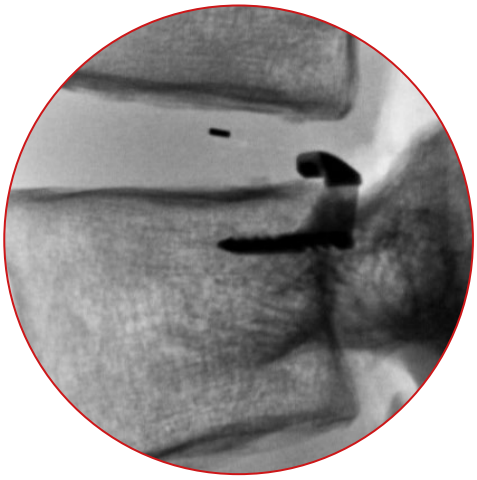


Platinum Iridium Marker – Good Mesh Position

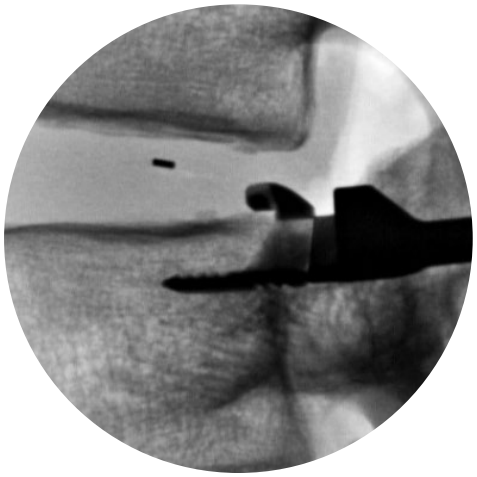
7.0 Impactor (Single-Use Disposable)

NOTE: The Impactor is supplied separately as a single-use disposable tool. The Impactor is packaged in a PETG blister pack sealed with a Tyvek lid. The seal between the Tyvek and PETG blister pack is the sole sterile barrier system for the Impactor.

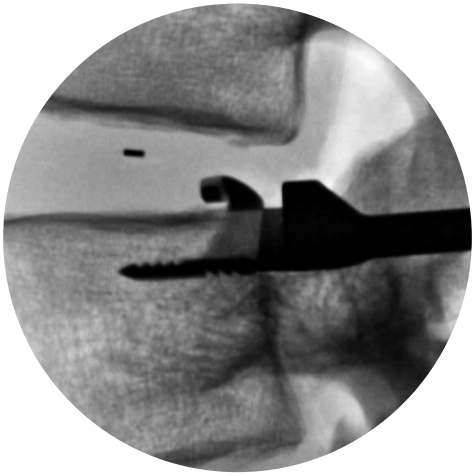
In the event that the Delivery Tool is removed prematurely and the anchor is not implanted completely within the target vertebral body, the Impactor may be used to finish the implantation procedure. The Impactor may be used on the Narrow and 8mm anchor and should only be considered if the anchor is outside the vertebral body by 3mm or less. If more than 3mm of the anchor remains in the spinal canal, a Barricaid extraction is recommended. DO NOT attempt a second implantation into a vertebral body where a Barricaid extraction has taken place.



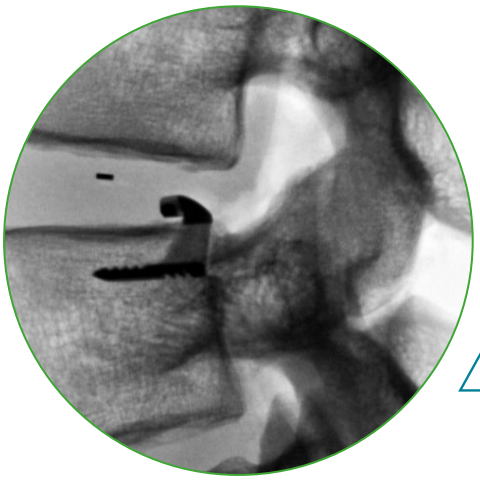
WRONG POSITION



Insert the pins of the Impactor into the two holes in the Barricaid anchor and align the Impactor to be in full contact with the anchor. Note: Additional bone removal of the lamina may be required to allow the Impactor to fit past the lamina.



Using the Mallet, gently tap the back of the Impactor, advancing the anchor deeper into the vertebral body. Continue tapping the Impactor until the depth stop is aligned with the posterior aspect of the opposing vertebral body.



CORRECT POSITION

Verify the final position by confirming that the Barricaid anchor is fully countersunk into the target vertebral body, with no part of the implant in the spinal canal.

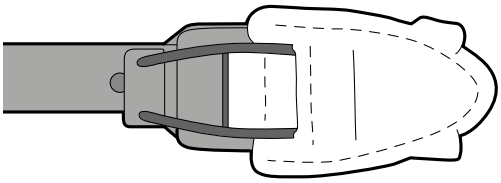
NOTE: Dispose of the Impactor following use. Do not re-use or re-sterilize.

8.0 Re-loading the Device

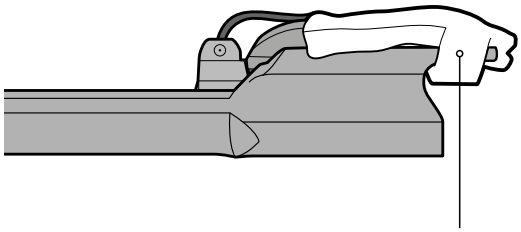
Device: Delivery Tool, Barricaid

Purpose: Prepare the Barricaid Delivery Tool for implantation if the Barricaid has been accidentally or prematurely removed from the Delivery Tool; for example, from unintentional Strike Cap advancement, or during removal from the surgical site. If re-loading is necessary, first inspect the mesh for damage, particularly the attachment loops. If torn or ripped, do not continue - dispose of the implant and use a new one.

You can avoid accidentally unloading the implant by lightly pulling on the Strike Cap when removing or re-positioning the loaded Delivery Tool within the wound. Do not use or re-load any implant that has left the sterile field.



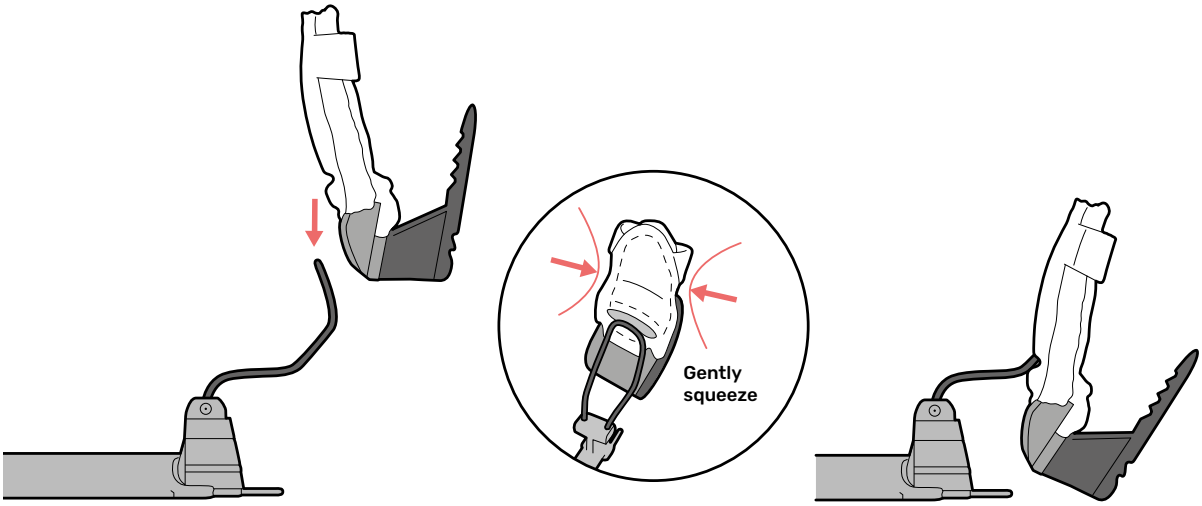
Assembled Top View



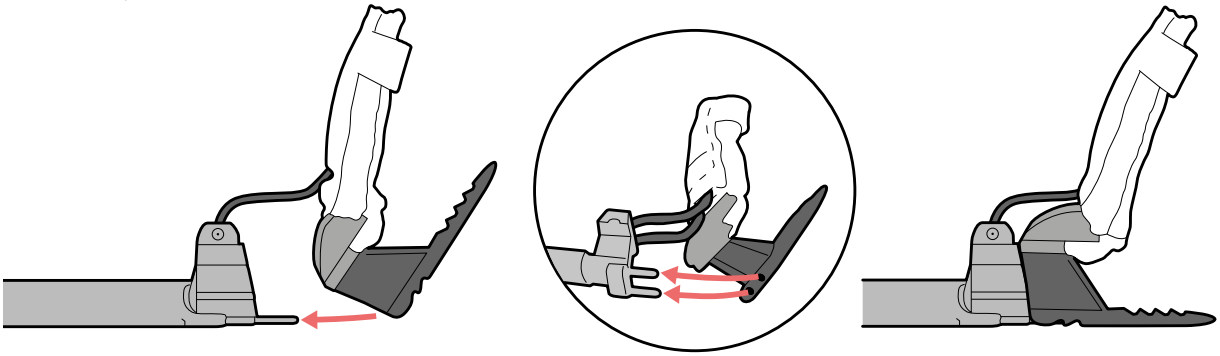
Assembled Side View **Attachment Loops**

Procedure

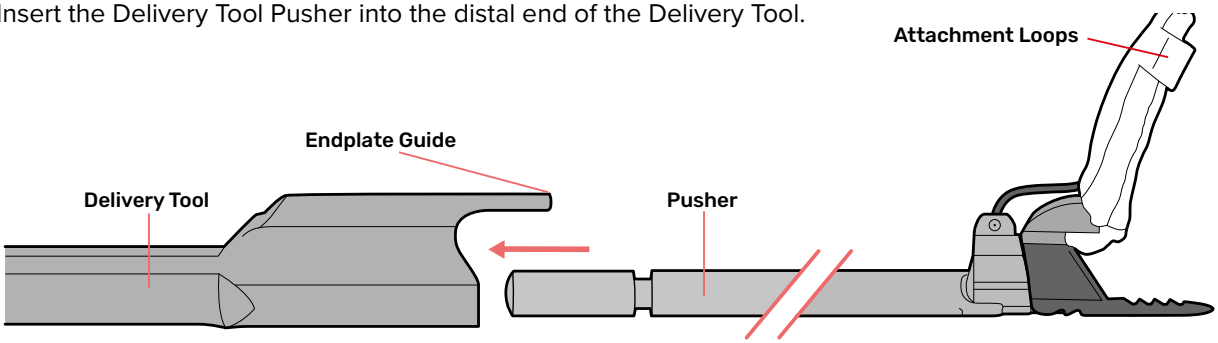
1. If the Barricaid has been removed from the Pusher and Guide-wire, gently squeeze the sides of the Mesh to open the Mesh Pocket. Carefully insert the Nitinol Guide-wire at the end of the Delivery Tool Pusher into the Pocket. It is advised to use a new set of surgical gloves following re-loading the Barricaid.



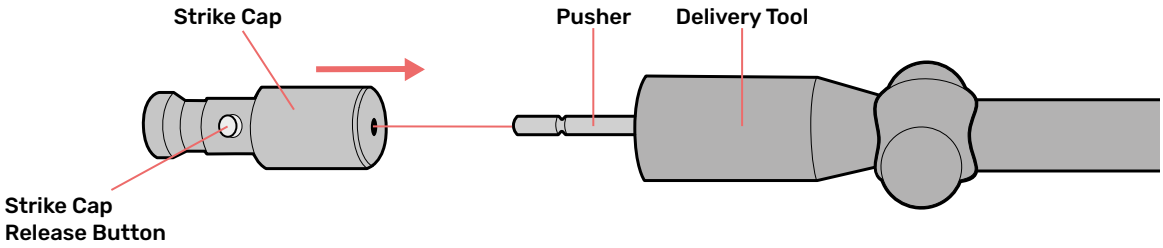
2. Rotating the Barricaid down, insert the Guide Pins on the distal end of the Pusher into the corresponding holes in the Barricaid anchor. Check proper positioning: the Nitinol Guide-wire should hold the mesh in an upright orientation, as shown.



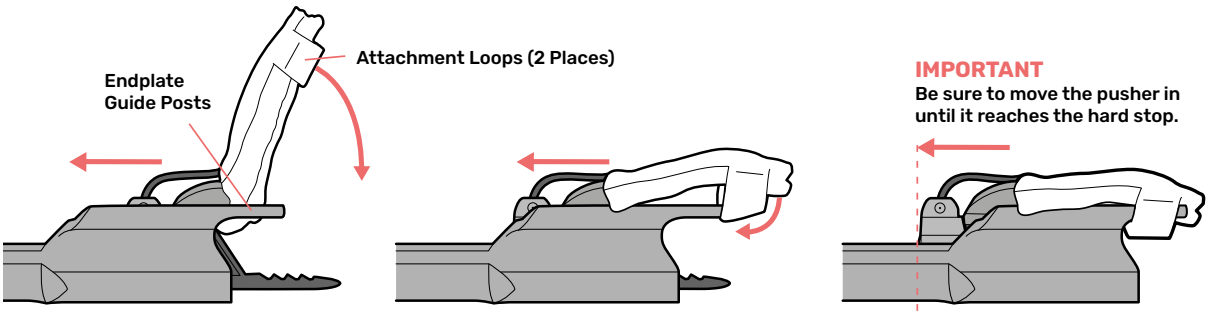
3. Insert the Delivery Tool Pusher into the distal end of the Delivery Tool.



4. Hold the Barricaid firmly in place, depress the release button on the Strike Cap and slide the Strike Cap over the Pusher extending out of the Delivery Tool. Slide the Strike Cap until it stops. Release the button. Gently pull back on the Strike Cap to check that it is locked in place.



5. Align the mesh so as to fit the attachment loops over the two posts of the endplate guide and insert the posts; the implant is pushed onto the applicator.



9.0 Device Removal

9.1. Barricaid Removal

Device: Rongeurs, Barricaid Removal Tool, 3mm Osteotome or High-Speed Burr or Drill

Purpose: To remove (explant) the Barricaid, if necessary.

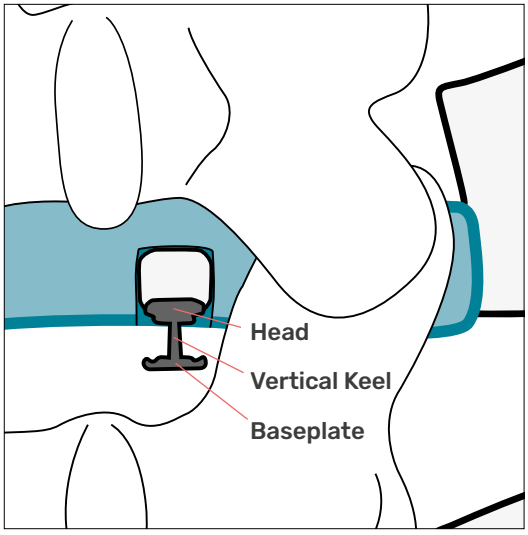
Contact Intrinsic Therapeutics at Quality@barricaid.com when planning Barricaid removal to facilitate device retrieval and complaint handling.

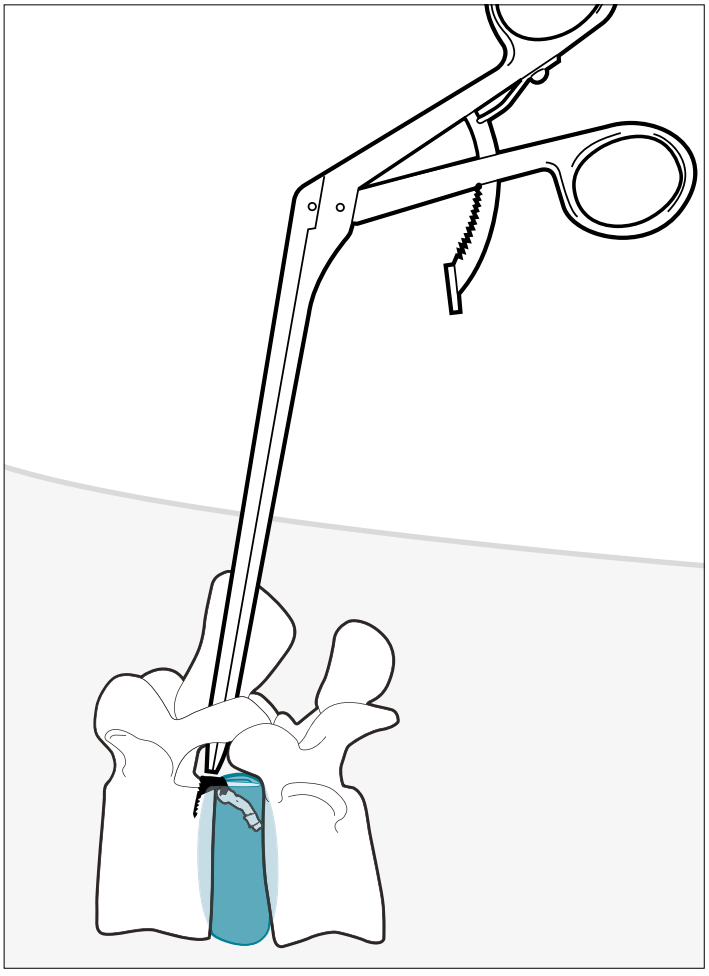
During extraction, be sure to provide protection to the adjacent nerve root and spinal cord using typical nerve root retractors, as needed.

NOTE: The Removal Tool is supplied separately as a single-use disposable tool and may be used with both the Narrow and 8mm Anchors. The Removal Tool is packaged in a PETG blister pack sealed with a Tyvek lid. The seal between the Tyvek and PETG blister pack is the sole sterile barrier system for the Impactor.

Procedure:

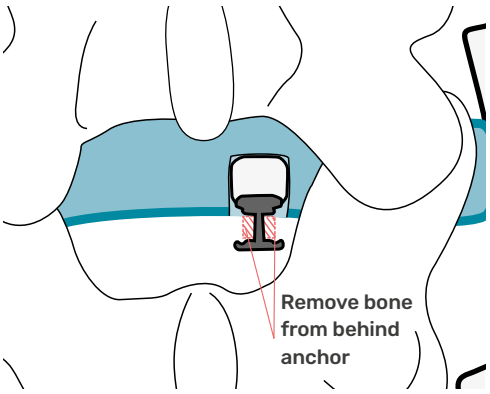
1. If the Barricaid anchor is very loose, protruding into the spinal canal, or has a large gap between the vertebral endplate and the bottom of the head, use a standard forward-opening biter, forceps, or rongeurs to grab the keel of the Barricaid, and gently tug it out of the bone. Start with gentle tugs, and reduce force as the anchor loosens and begins to back out. If not able to remove the Barricaid this way, proceed to Step 2.



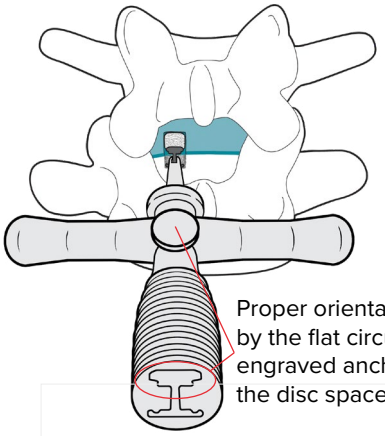


2. Removal of the anchor should be performed according to the following procedure. Care should be taken to retain control and protection of the neural element throughout the procedure.

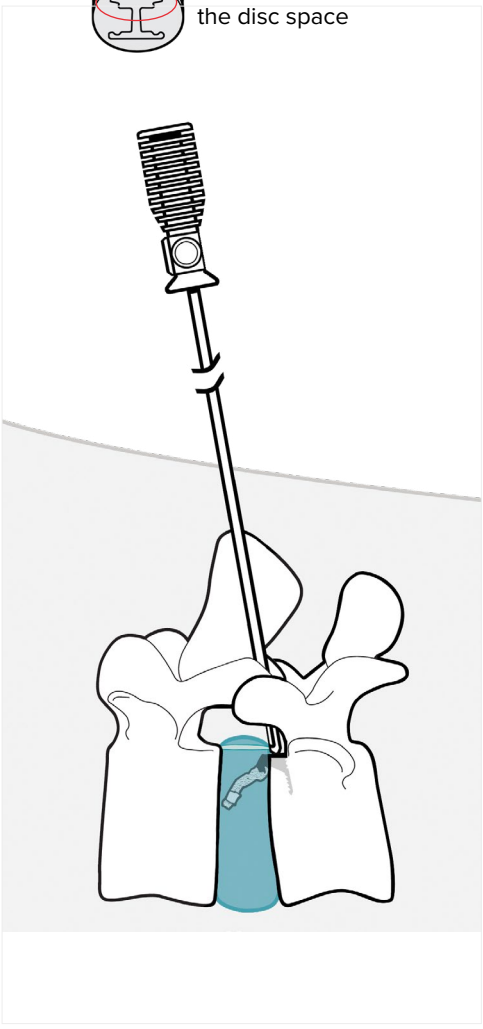
   - Identify and visualize the implant to be removed. Specifically, the anchor keel must be visible. If bone needs to be removed in order to clearly visualize the anchor keel, a small bone chisel or other common surgical tool can be used. If particularly dense bone is present, it is recommended that a chisel is used to remove bone on each side of the keel prior to using the Removal Tool.



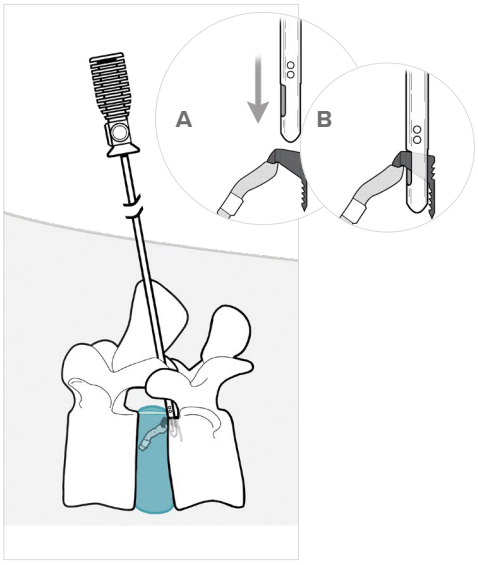
   - Orient the Removal Tool such that the vertical opening can fit over the anchor keel and the shorter slot of the distal end of the tool is facing the anchor head (as opposed to the anchor baseplate). Proper orientation is indicated by the boss (flat circular feature with the company logo) in the center of the T-handle facing the anchor head, or by the silhouette of the anchor on the back of the Removal Tool oriented like the implanted device to be removed.



   - Pass the Removal Tool through the lamina and into position over the anchor keel, ensuring that the tool is centered medial-laterally. Once positioned, use fluoro to confirm that the tool angle is parallel with the baseplate in a sagittal view, and positioned substantially between the anchor's baseplate and head.

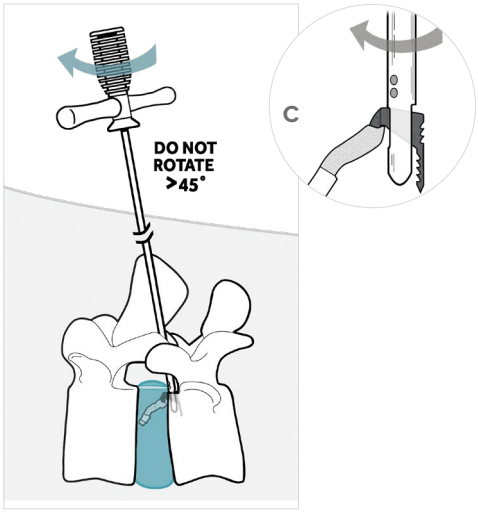


- Slowly tap the tool into the bone. Intermittent fluoro should be used to ensure that the tool is advancing past the anchor keel. The tool should be moving towards the anterior of the vertebral body while the anchor remains stationary. If the anchor is advancing anteriorly into the bone, STOP and reposition the tool. Tap until the proximal end of the slot has reached the anchor keel. Fluoro can be helpful to evaluate the position of the anchor keel relative to the extractor slot. There are two 1.5mm diameter holes in the shaft region of the Removal Tool. The distal-most hole can be used to help visualize the depth on fluoro by its position being flush with the vertebral body posterior surface. The second hole is 2mm proximal from the first hole. A depth reaching the second hole location would be an indicator of excessive depth of the Removal Tool.



- If the tool is removed for repositioning, inspect the Removal Tool for any signs of damage and remove any bone that may be caught within the tubular section. If any damage is observed or if the bone cannot be removed, use a new Removal Tool.

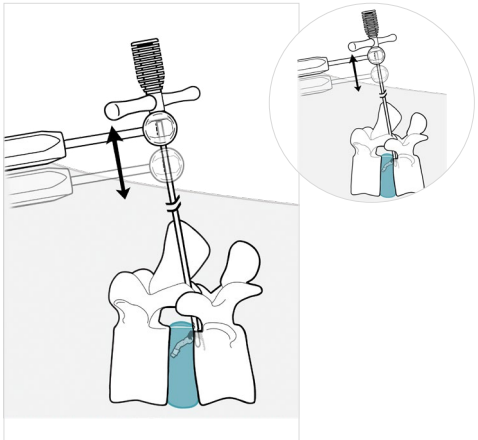
- If splaying of extractor slot is observed, it is recommended that a chisel is used to remove bone on both sides of the keel prior to using the new Removal Tool.



- Turn the tool 45 degrees clockwise. **DO NOT** rotate beyond 45 degrees. The anchor keel should be fully captured by the Removal Tool. If no resistance was felt, the Removal Tool may have been tapped in medial or lateral to the implant. Check to ensure that the Removal Tool is properly positioned over the anchor keel before proceeding.

- Using the slotted mallet, position the slot of the mallet head onto the shaft portion of the Removal Tool axially. Using an axial motion in the proximal direction, apply an upward force on the handle of the Removal Tool. Intermittent fluoro should be used to check that the anchor is advancing posteriorly and that the implant is still captured within the Removal Tool.

- Once the anchor has been advanced out of the vertebral body, remove the tool from the laminar opening and then remove the device from the Removal Tool.



NOTE: Dispose of the Removal Tool following use. Do not re-use or re-sterilize.

9.2. Barricaid Removal: Mesh Only

Procedure:

If the Barricaid mesh is detached or partially detached from an anchor that is firmly implanted, a surgeon may decide to remove only the mesh component. Use a standard scalpel to ensure that the mesh is fully detached from the anchor component, and with forceps, grab the mesh component to gently remove. A surgeon may also use rongeurs to grab and twist the mesh to separate the mesh from the anchor.

Device: Forceps, Scalpel, Rongeur

Purpose: To remove (explant) the Barricaid, if necessary.

⚠ **Contact Intrinsic Therapeutics at Quality@barricaid.com when planning Barricaid removal to facilitate device retrieval and complaint handling.**

⚠ **During extraction, be sure to provide protection to the adjacent nerve root and spinal cord using typical nerve root retractors, as needed.**

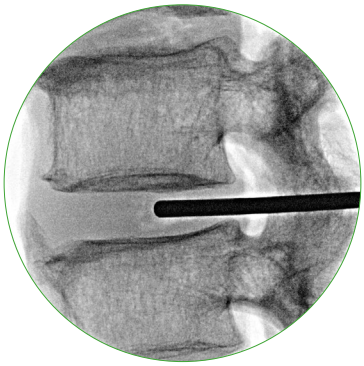
10.0 DO's and DON'T's

NOTE: Once a Barricaid has been removed, it is not possible to re-implant another Barricaid into the same vertebral body for the same annular defect. Either implant into the opposing vertebral body's endplate or do not implant at all.

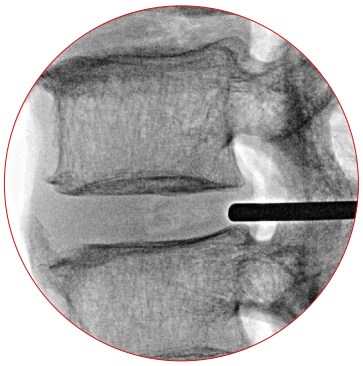
- **DON'T** try to achieve the proper angle to the endplate with the Alignment Trial or the Delivery Tool by using the instruments to force the spine into flexion. This will overload the tool, possibly damaging it, and will put excessive loads onto the bone anchor and mesh, which may cause the following problems:
  - Damage or detachment of the mesh.
  - Excessively high implantation resistance from bending or damaging the Delivery Tool.
  - A "backing out" of the Delivery Tool, making deployment depth inaccurate.

  Instead, remove bone from the lamina to achieve bony access. If it is not possible to remove adequate bone for alignment with either endplate, the Barricaid should not be implanted.

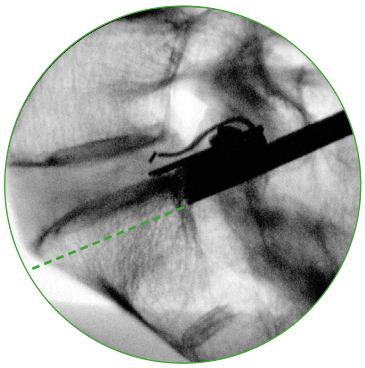
- **DO** confirm there is a full-thickness defect through the annulus. This can be done using the Defect Measurement Tool or other instrument. It should be possible to easily advance a tool into the middle of the disc space. Ensure that there is no loose tissue in the defect that may interfere with mesh advancement.



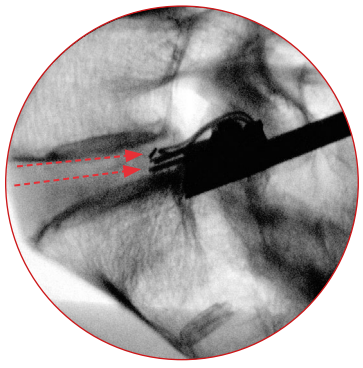
CORRECT



WRONG



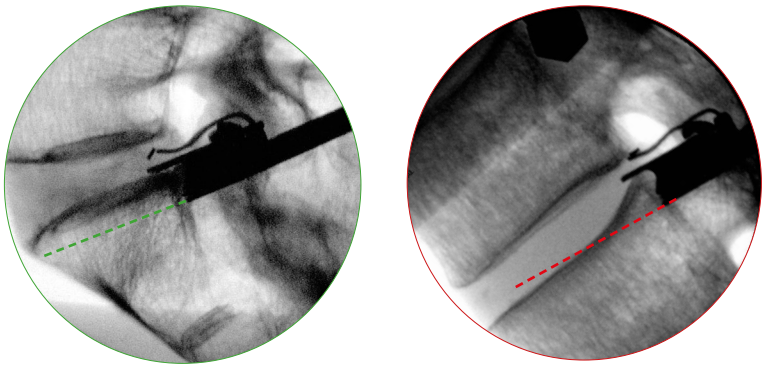
CORRECT



WRONG

- **DO** make sure both endplate guides of the Barricaid Delivery Tool are resting on top of the endplate and are not rotated prior to implanting the Barricaid. This will help ensure proper alignment of the implant. The endplate guides should appear as one using a lateral fluoro view.

- **DO** make sure the Barricaid Delivery Tool is oriented at the correct angle for implantation. An imaginary line from the bottom of the Delivery Tool should extend through the vertebral body below the edge of the lowest point in the endplate. Confirm using fluoro. This will ensure there is adequate bone material to anchor the Barricaid.
- **DON'T** allow the angle of the Delivery Tool to be too shallow. If an imaginary line from the bottom of the Delivery Tool extends above the edge of the lowest point in the bone, the angle of approach is too shallow, creating the risk of chipping or damaging the vertebral body, resulting in a failed implantation.



CORRECT WRONG

- **DON'T** move your hand during the implantation procedure. This could change the angle or "wiggle" the Barricaid as it is driven in, preventing proper anchoring in the bone.
- **DO** use small, steady forces when implanting the Barricaid. This will help maintain the proper angle and reduce the risk of damage to the vertebral body from misalignment.
- **DON'T** over hammer the Strike Cap when implanting the Barricaid. Once the depth indicator on the Barricaid Delivery Tool indicates that the correct depth has been achieved, DO NOT strike the tool again.
- **DON'T** implant a Barricaid in any disc in which the annular defect is wider than the Barricaid device (for an 8 mm-wide mesh, the annular defect should be no wider than 8 mm; for a 10 mm-wide mesh, the annular defect should be no wider than 10 mm).
- **DON'T** attempt to re-sterilize or re-use any component of the Delivery Tool in which the Barricaid is pre-packaged (Delivery Sheath, Pusher, or Strike Cap).
- **DON'T** strike the implant with any tools other than the Delivery Tool or Impactor provided.
- **DON'T** increase the width of a defect during a discectomy procedure specifically to implant a Barricaid device.

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WARNING: This product has labeling limitations. See package insert for additional warnings, precautions and possible adverse effects. **CAUTION:** USA law restricts this device to sale by or on the order of physician. All medical devices have associated risks. Please refer to the package insert and other labeling for a complete list of indications, contraindications, precautions and warnings (www.barricaid.com/us-en/instructions). For further information on Barricaid, contact your Intrinsic representative.

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