OPTIMIZING DISCECTOMY OUTCOMES IN HIGH RISK PATIENTS

Prevent Reherniation. Preserve Disc.

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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 Prosthesis, an endo-prosthesis for anular closure, and its accompanying system for closure of the posterior anulus fibrosus in 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 Prosthesis.

Please refer to the Barricaid Prosthesis IFUs 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 anulotomy locations and features that are appropriate and inappropriate for Barricaid implantation.
- Identify all Barricaid Prosthesis system components and understand their functions.
- Achieve competence with all Barricaid Prosthesis 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 anular parameters to ensure appropriate Barricaid size and correct implantation.
- Properly perform Barricaid implantation and confirm proper positioning.
- Properly perform Barricaid removal, if required.

**NOTE:** The Barricaid prosthesis must not be implanted by anyone who is not fully trained per the Company’s certification policy.
2.0 PATIENT SELECTION

2.1 PATIENT SELECTION

- Skeletally mature patients with disc herniations (primary or recurrent) between L1 and S1 with radiographic confirmation of neural compression using MRI.
- Minimum posterior disc height of 5mm at the index level.
- Intra-operative confirmation of an anular defect that is between 4mm – 6mm in height and between 5mm – 12mm in width.

2.2 WARNINGS

- Do not implant the Barricaid prosthesis in case of spondylolisthesis and/or instability requiring stabilization.
- Do not use the Barricaid prosthesis in anular defects wider than 12mm or taller than 6mm.
- Do not implant the Barricaid prosthesis if subject has clinically compromised vertebral bodies in the lumbosacral region due to any traumatic, neoplastic, metabolic, or infectious pathology.
- Do not implant the Barricaid prosthesis in case of osteoporosis.
- Do not implant the Barricaid prosthesis in case of extra-foraminal herniations and any defect you cannot completely visualize.
3.0 PRODUCT DESCRIPTION

3.1 BARRICAID PROSTHESIS

The Barricaid Prosthesis, an endo-prosthesis for anular closure, is an implantable device designed to help reduce the risk of re-herniation through the weakened anulus following discectomy. The Barricaid Prosthesis is available in three widths of mesh (8 mm, 10 mm and 12 mm), and 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.

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.

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

The Barricaid comes in three mesh widths. Mesh width is indicated here.

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-sterilized. Please see the included Instructions for Use for more information.

Four peel-off stickers are provided for hospital use.

Confirm the inner pouch matches the box label prior to use.
IMPORTANT: Remove and dispose of blue packaging clip prior to attempting implantation.

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:

- Platinum Iridium Marker
- Polymer Mesh
- Titanium Anchor

The Barricaid anchors into the vertebral body and blocks the anular defect to help prevent extrusion of nucleus and resulting re-herniation.
3.2 BARRICAID PROSTHESIS IMPLANTATION SYSTEM

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

**Defect Measurement Tools**

- Reusable devices for measuring height and width of anular defect to determine if the Barricaid is indicated. Reference codes: 4x5mm: 400209, 6x7mm: 400210, 8x9mm: 400211, 10x11mm: 400212 and 12x13mm: 400213)

**Sizing Trial Tools**

- Reusable devices for determining adequate size of laminotomy and of anulotomy to permit proper implantation. Use the Sizing Trial Tools to determine if there is adequate access to the disc space for the Barricaid.
**IMPACTOR**  
(REF. CODE: 400906)  
Reusable 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.

**HAMMER**  
(REF. CODE: 400896)  
Reusable device for advancing the Barricaid into the disc and vertebral body. Use only the hammer included with the Barricaid system.  

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

**BARRICAID REMOVAL TOOL**  
(REF. CODES: 400763, EXTRACTOR WEIGHT: 400766)  
Reusable extractor designed to facilitate Barricaid removal.

**RETRACTION WEDGE**  
(REF. CODE: 400846)  
Reusable wedge designed to help pull back the strike cap following full Barricaid deployment.
4.0 SURGICAL CONSIDERATIONS

4.1 FLUOROSCOPY SET UP

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

OUT OF PLANE: L4-5
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 4.4).

It may be easier to use the hammer 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

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

![Diagram showing correct and incorrect angles for Barricaid implantation]

**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.

4.3 ANULAR DEFECT LOCATION AND SIZE

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

- An anular 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 anular defect should be no taller than 6 mm and should be no wider than the mesh being inserted (e.g., for an 8 mm-wide mesh, the anular defect should be no wider than 8 mm; for a 10 mm-wide mesh, the anular defect should be no wider than 10 mm; for a 12 mm-wide mesh, the anular defect should be no wider than 12 mm). There is no limit to the disc height, only the defect height.

• 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.

**KEY LEARNING POINT:**
When performing the anulotomy, trim any residual anular tissue down to the target endplate, to allow proper placement of the anchor against the target endplate.

4.4 CREATING ACCESS TO THE ANULAR DEFECT

Barricaid implantation requires that you gain adequate access to the implantation site to permit the Barricaid and implantation tools to pass through the lamina to the intervertebral disc and anulus. 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 anular defect, removal of bone from the lamina may be required to allow adequate access (see diagram above).

⚠️ **DO NOT** try to achieve the proper angle to the endplate with the Sizing 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.
4.5 NUCLEUS REMOVAL

The amount of nucleus removed during the discectomy is of critical importance for patients considered for Barricaid implantation. Some surgeons have been fairly aggressive in removing nucleus material with the goal of preventing re-herniation. 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. A limited discectomy as described by Spengler is recommended when implanting the Barricaid.¹

¹Spengler, DM. Lumbar discectomy. Results with limited disc excision and selective foraminotomy, Spine. 1982 Nov-Dec;7(6):604-7

4.6 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.

⚠️ NOTE: Do not implant if the listhesis is Grade II, i.e. 25% or higher.
5.0 DEFECT MEASUREMENT, SIZE SELECTION AND TOOL ALIGNMENT

5.1 MEASURE ANULOTOMY SIZE AND SELECT APPROPRIATE BARRICAID

Device: Defect Measurement Tools (4 mm – 13 mm)

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

Procedure:

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

   **DO NOT** rotate the Defect Measurement Tools while inserted in the anulotomy.

2. Continue to try larger size tools until a size is reached that fits snugly into the anulotomy 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 anulotomy, 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 anular defect is taller than 6 mm, do not implant the Barricaid. Ensure that the anular defect is not wider than the mesh being inserted (e.g., for an 8 mm-wide mesh, the anular defect should be no wider than 8 mm; for a 10 mm-wide mesh, the anular defect should be no wider than 10 mm; for a 12 mm-wide mesh, the anular defect should be no wider than 12 mm).

   **NOTE:** Do not implant the Barricaid in patients with a posterior disc height <5mm.

### SIZING GUIDE

<table>
<thead>
<tr>
<th>DEFECT HEIGHT</th>
<th>DEFECT WIDTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5mm</td>
<td>4-6mm</td>
</tr>
<tr>
<td>5-8mm</td>
<td>8mm Barricaid or wider</td>
</tr>
<tr>
<td>9-10mm</td>
<td>10mm Barricaid or wider</td>
</tr>
<tr>
<td>11-12mm</td>
<td>12mm Barricaid</td>
</tr>
<tr>
<td>&gt;12mm</td>
<td><strong>DO NOT IMPLANT</strong></td>
</tr>
</tbody>
</table>

**DO NOT IMPLANT**
5.2 CONFIRM FULL-THICKNESS DEFECT

Device: Defect Measurement Tool (smallest available)

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

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 anular defect. 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 implantation.

5.3 CONFIRM ACCESS AND ANGLE

Device: Sizing Trial Tools (8 mm, 10 mm, 12 mm)

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 Sizing Trial Tool to determine if there is adequate access to the disc space for the implantation of the Barricaid. The Sizing 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 Sizing Trial Tool, 10 mm Barricaid, use the 10 mm Sizing Trial Tool, etc.)

Procedure:

1. Insert the distal end of the Sizing Trial Tool through the anulotomy. Keep the endplate guide along the surface of the endplate of the vertebral body to be implanted and ensure the distal end of the Sizing Trial Tool 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 Sizing Trial Tool 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, remove additional bone from the lamina or consider the opposite endplate for implantation.
IMPORTANT
Align Sizing Trial Tool with surface of vertebral body endplate

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

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 Sizing Trial Tool 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.
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 fluoror 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.

⚠️ If it is necessary to remove the Barricaid Delivery Tool with the Barricaid Prosthesis 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 pre-loaded position on the Delivery Tool during removal. Be sure to inspect the mesh for damage prior to re-inserting.

ENDPLATE ANGULATION

While positioning the loaded delivery tool, attention should be paid that the projected deployment line (anchor baseplate penetrating under the endplate) is parallel with, and following the target endplate surface line. In other words, endplate angulation should be taken in account and followed, in order to avoid possible endplate penetration, or deep under the endplate positioning (risking anchor head detachment during deployment).

IMPLANTATION HEIGHT

During implantation, the Barricaid anchor head should be targeted to rest on the surface of the endplate itself. If the head of the anchor is positioned too high (too far from the target endplate), it could damage the opposing endplate. If the head is positioned too low (penetrating the vertebral body below the endplate) — it can damage the Barricaid mesh and the endplate during implantation.

⚠️ 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 anular defect. Either implant into the opposing vertebral body’s endplate or do not implant at all.
VERTEBRAL BODY CONTACT

Same as with the sizing trials, the loaded delivery tool must be simultaneously firmly sitting (without any gaps) on the targeted implantation endplate, and also on the posterior vertebral wall of the targeted vertebral body. Failure to achieve and maintain full contacts in both directions prior and during the deployment, can result with incomplete deployment.

DELIVERY TOOL ROTATION ANGLE

The Barricaid baseplate (bottom of the anchor) should be parallel with the target vertebral endplate surface. When implanting, pay close attention to ensure the Barricaid is not rotated in relation to the endplate. The endplate guides (two metal tips that hold the mesh loops) on the Barricaid Delivery Tool, enable you to confirm proper rotation under fluoroscopic guidance. In case that you can see both endplate guides on fluoroscopic image, the Barricaid is not parallel to the endplate (see fluoro to the left below), and will need to be corrected to the position where both endplate guides are parallel with the endplate (as on fluoro to the right below).

NOTE: The Barricaid can be implanted into either the superior or the inferior endplate.
CORRECT ANGLE AND POSITIONING OF INSTRUMENTS IN THE DEFECT.

The images below show an axial view of a disc model, with anulus, 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.

**Correct Measuring Tool positioning**

![Correct Measuring Tool positioning](image1)

**Sizing Trial Tool positioning**

![Sizing Trial Tool positioning](image2)

**Correct: Delivery Tool positioning**

![Correct Delivery Tool positioning](image3)

**Wrong: Delivery Tool not in defect**

![Wrong Delivery Tool positioning](image4)
**MESH BUCKLING**

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

Common causes for mesh buckling are as follows:

1. Delivery tool is missing the defect in the medial-lateral direction (see previous page)
2. Delivery tool is missing the defect in the superior-inferior direction
3. Delivery tool position is not held constant during implantation
4. Anular defect is not full thickness (see section 5.2)

Avoid these situations to avoid mesh buckling.

If mesh 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 anular defect measurement (section 5.1). If implanting into a different vertebral body than the first attempt, use the sizing trial to confirm access and angle (section 5.3).

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**6.2 BARRICAID PROSTHESIS IMPLANTATION**

**Device:** Barricaid Delivery Tool with Barricaid Prosthesis, Hammer

**Purpose:** To correctly implant the Barricaid.

**Procedure:**

1. Insert the distal end (including implant) of the Delivery Tool through the anulotomy. 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 5.3. 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 (see images in the section: DELIVERY TOOL ROTATION ANGLE for reference).
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 hammer 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. When deployed properly, the Barricaid will be countersunk in the bone by 2 mm.

**KEY LEARNING POINT:**
Take final alignment fluoro with Hammer 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.

⚠️ **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 mesh guide 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. 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 mesh guide 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 mesh-guide wire is impinged. If it is, rotate the wire away from this impingement and/or remove the impingement to free the mesh-guide. 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.

⚠️ 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 instrument or impactor provided.
7.0 REUSABLE IMPACTOR

1. 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. Use of the Impactor 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.

2. 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.

3. Using the hammer, 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.

4. 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. Inspect the tip of the impactor to verify that the pins were not bent or damaged during use.
8.0 RE-LOADING THE DEVICE

8.1 RE-LOAD THE BARRICAID

Device: Delivery Tool, Barricaid

Purpose: Prepare the Barricaid Delivery Device for implantation if the Barricaid has been accidentally or prematurely removed from the delivery tool; for example, from unintentional Strike Cap advancement, or removal from wound. If re-loading is necessary, first inspect the mesh for damage, particularly the mesh 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 Device within the wound. Do not use or re-load any implant that has left the sterile field.

Procedure:

1. If the Barricaid has been removed from the Pusher and Mesh Guide, gently squeeze the sides of the Barricaid Mesh to open the Mesh Pocket. Carefully insert the Nitinol Mesh Guide at the end of the Delivery Tool Pusher into the Mesh 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 Mesh Guide 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. Align the mesh so as to fit the mesh loops over the two posts of the endplate guide and insert the posts; the implant is pushed onto the applicator.

5. 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.
9.0 DEVICE REMOVAL

9.1 BARRICAID REMOVAL

Device: Rongeurs, Barricaid Removal Tool, 3mm Osteotome or Milling Machine

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

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

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. Bone removal may be necessary to facilitate extraction of the Barricaid using the Extractor if the head of the Barricaid anchor is close to the endplate. In this case, remove bone to an anterior depth of approximately 10 mm from at least one side of the anchor keel in the region between the anchor baseplate and head. This will allow the Extractor the access to the Barricaid keel necessary for extraction.

Removal of bone is only necessary on the side the extractor will be placed.

3. Orient the tip of the Extractor almost vertically with the opening of the Extractor hook toward the implanted endplate. Insert the Extractor on the side of the Barricaid where bone was removed. Advance the tip of the Extractor into the disc space until the hook opening is slightly anterior to the vertical keel of the Barricaid anchor.

Rotate the Extractor 90° with the hook opening toward the Barricaid anchor, staying against the implanted endplate, until the anchor keel is captured by the Extractor. Adequate capture of the anchor has occurred when the outer edge of the Extractor is even with the outer edge of the anchor head.

If you cannot hook the extractor around the vertical keel of the anchor, use a chisel or osteotome to create additional space. If not able to hook the keel, try again on the opposite side of the Barricaid.

Anchor is captured when edge of Extractor aligns with anchor head.
**WARNING:** The thinnest region of the distal tip of the Extractor is approximately one inch long (25 mm). Never FULLY insert this tip into the anulotomy as you may go so far anterior as to penetrate the anterior anulus.

**If there is insufficient clearance to hook the Barricaid anchor, do not force it.**

If the anchor is hooked but cannot be extracted with hand force, use the Extractor Weight to remove the anchor. Only hammer the Weight against the Extractor rod AWAY from the patient. Lightly hammer the anchor until it begins to loosen, and then use hand-force to remove the anchor the rest of the way.
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 anular 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 Sizing 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 anulus. 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 implantation.

DO make sure the border of the anulotomy is trimmed as close as possible to the endplate of the vertebral body at the intended site of Barricaid implantation.
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.
**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 anular defect is wider than the Barricaid mesh (e.g., for an 8 mm-wide mesh, the anular defect should be no wider than 8 mm; for a 10 mm-wide mesh, the anular defect should be no wider than 10 mm; for a 12 mm-wide mesh, the anular defect should be no wider than 12 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 instrument or impactor provided.
ABOUT INTRINSIC THERAPEUTICS

Intrinsic Therapeutics is dedicated to the science of spinal care with a focused mission: To offer surgeons and patients better options for treating painful disc herniations that cause sciatica and low back pain for millions of people worldwide.

Under the direction and guidance of our experienced management team and scientific advisory board, including renowned neuro and orthopedic surgeons from around the world, Intrinsic Therapeutics has developed the next generation of innovative disc closure solutions designed to improve patient outcomes.