Instructions for Use Barricaid® - Disposable Instruments

DESCRIPTION
The Barricaid Annular Closure Device (ACD) disposable instruments are provided STERILE. The instruments are designed to support insertion or removal of the Barricaid ACD into/from a lumbar intervertebral disc and an adjacent vertebral body. See the IFU for the Barricaid ACD for further information regarding the components, indications and instructions for use of the Barricaid ACD.

All Disposable Instruments are delivered STERILE and are single-use only and should NOT be re-used.

For detailed operating instructions, see the surgical technique available at www.barricaid.com/us-en/instructions/.

Carefully read all directions prior to use. Observe all warnings and cautions.

INTENDED USE

Barricaid ACD Disposable Instruments are intended to support surgical implantation or removal of the Barricaid ACD.

INDICATIONS

The Barricaid is intended to reduce the incidence of reherniation and reoperation following primary limited lumbar discectomy procedures (i.e., excision of herniated intervertebral disc). The Barricaid is indicated for 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 (i.e., between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure at a single level between L4 and S1.

WARNINGS

- The long-term effects of the Barricaid ACD have not been established.
- The Barricaid ACD Disposable Instruments are not intended for use with any devices other than the Barricaid ACD.
- The Barricaid ACD Disposable Instruments have not been tested for use in surgeries where the disc is approached from the anterior, trans-psoas, or far lateral. The Barricaid ACD Disposable Instruments are indicated for lumbar spinal procedures performed using a posterior approach.
- Prior to use, carefully inspect all items for damage. Damage may include (but is not limited to) rust; full or partial fracture of any component; bent guides, tubes or handles; severe discoloration; binding during assembly. If damaged in any way, DO NOT USE.

PRECAUTIONS

- The Barricaid ACD Disposable Instruments cannot be used by any surgeon who has not been properly trained.
- The Barricaid ACD Disposable Instruments will only be supplied under a no-train/no-use policy.
- Use of the Barricaid ACD Disposable Instruments requires thorough knowledge of spinal anatomy and biomechanics.
- Surgeons must have experience with discectomies to be qualified to use the Barricaid ACD Disposable Instruments.
- The Barricaid ACD Disposable Instruments should be handled with appropriate precautions to maintain sterility after being brought into the sterile field.
- Use only the mallet that is provided for implantation and/or removal of the Barricaid ACD.
- See the surgeon training manual for important instructions related to use of the Barricaid ACD Disposable Instruments.
- All of the Barricaid ACD Disposable Instruments are MR-unsafe and are not to be brought into the MRI environment. Refer to the Barricaid ACD instructions for use for information regarding the MR-compatibility of the Barricaid implant.

STERILIZATION AND STORAGE

The Barricaid disposable instruments are sterilized by gamma irradiation and are provided sterile. There is one sterile barrier: The seal between the Tyvek and PETG blister pack is the sole sterile barrier system for the Barricaid disposable instruments. Verification that the product has been exposed to gamma irradiation is verified by the gamma indicator label being red in color. Store in a cool, dry place. Packaging material should be inspected for damage prior to use. If the packaging is damaged (torn, bent, wet, etc.) or if the gamma indicator label is not red, the product must be assumed to be non-sterile and should not be used. In the event of damage to the sterile packaging or inadvertent contamination during surgery, the instrument may not be re-sterilized or re-used. Any damaged packages should be returned to Intrinsic Therapeutics, Inc. at the address listed below.

The Barricaid disposable instruments are provided sterile and may not be re-sterilized under any circumstances.

HOW SUPPLIED

The Barricaid Disposable Instruments are provided sterile, in a single-unit PETG blister pack, sealed with Tyvek. Other tools in the Barricaid Instrument Kit are reusable and are provided non-sterile – see the Barricaid Instrument Kit Instructions for Use for more information.

LIMITED WARRANTY AND DISCLAIMER: Intrinsic Therapeutics products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

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Intrinsic THERAPEUTICS

Made in the U.S.A.

This product may be covered by one or more patents or pending patent applications. See www.barricaid.com/patents/.