Instructions for Use Barricaid® Anular Closure Device Instrument Kit

DESCRIPTION

The Barricaid® Anular Closure Device Instruments are reusable instruments provided NON-STERILE. The instruments are designed to support insertion of the Barricaid into a lumbar intervertebral disc and an adjacent vertebral body. See the IFU for the Barricaid for further information regarding the components, indications and instructions for use of the Barricaid.

All components are delivered NON-STERILE and should be cleaned and sterilized prior to each use, as described below. All components are re-useable.

The Barricaid comes in various size configurations, each pre-loaded into a disposable delivery instrument. All use the same Instruments.

Use the sizing trial tool to determine if there is adequate access to the disc space for the Barricaid prosthesis prior to implantation.

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

INTENDED USE

The Barricaid implantation instruments are intended to surgically implant the Barricaid.

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 anular 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 prosthesis have not been established.
- The Barricaid Instruments are not intended for use with any devices other than the Barricaid.
- The Barricaid Instruments have not been tested for use in surgeries where the disc is approached from the anterior, trans-psoas, or far lateral. The Barricaid Instruments are indicated for lumbar spinal procedures performed using a posterior approach.
- Clean and sterilize before use. See cleaning/sterilization instructions below.
- 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 use. If damaged in any way, DO NOT USE.
- All components of this device are supplied NON-STERILE and are intended to be cleaned and sterilized before each use.
- All of the Barricaid Instruments are re-useable.

PRECAUTIONS

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

STERILIZATION AND CLEANING

CAUTION: Do not reuse the delivery tool (i.e., strike cap, delivery sheath, pusher and packaging clip), which is supplied sterile with the Barricaid prosthesis pre-loaded. All components of the delivery tool itself (strike cap, delivery sheath, pusher and packaging clip) must be discarded following implantation of a Barricaid prosthesis. All other components are re-useable.

Reprocessing should consist of the following three steps, in sequence:

1) Point of use: Implement prompt cleaning steps and/or measures to prevent drying of soil and contaminants in and on the instrument(s).

2) Cleaning: All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Use of hard water should be avoided. Softened tap water may be used for initial rinsing, and for preparation of cleaning agents. Filtered (distilled) water should be used for final rinsing to eliminate mineral deposits on instruments. Use of recommended temperatures is important for optimal performance of cleaning agents.

Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning Intrinsic Therapeutics reusable devices. Alkaline agents with pH≤12 may be used to clean stainless steel and some polymer instruments in countries where required by law or local ordinance. **It is critical that alkaline cleaning agents be completely and thoroughly neutralized and rinsed from devices.**

The following instructions for use are required for the manual/automated cleaning and sterilization for the reusable instrument set:

Manual/Automated Combination**:**

1. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard-to-clean areas.
2. Rinse device with enzymatic detergent. Place the prepared enzymatic detergent in a sonication unit. Completely submerge instrument in enzymatic detergent and sonicate for 15 minutes at 45-50 kHz.
3. Remove the device from the enzymatic detergent and rinse in filtered (distilled) water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes, and other difficult to reach areas.
4. Place device in a suitable washer disinfector basket and select either the machine manufacturer's validated program for cleaning surgical instruments, or set the parameters according to the following steps 5-11.
5. Pre-wash with cold tap water (2X): 4 minutes.
6. Enzymatic detergent wash: 4 minutes.
7. Rinse with cold tap water (2X): 15 seconds.
8. Enzymatic detergent wash with hot tap water: (66-68 °C/150-154 °F): 4 minutes.
9. Rinse with filtered (distilled) hot tap water (2X): 4 minutes.
10. Thermal rinse with hot filtered (distilled) water (83-92 °C/181-198 °F): 5 minutes.
11. Hot Air Dry: (75 °C/167 °F): 15-30 minutes.
12. Visually inspect each instrument after cleaning to ensure it is thoroughly clean and free of organic debris. If organic material is present, the instrument should be cleaned again according to the instructions described above.

3) Sterilization: The Barricaid Instruments are supplied NON-STERILE and must be cleaned and sterilized prior to each use. Only FDA cleared trays and wraps should be utilized for sterilization of the reusable instruments. Place the instruments in the sterilization tray. Steam sterilize per one of the autoclave cycles shown below. Store the instruments in a dry place.

Sterilizer Type	Method	Temperature	Exposure Time	Minimum Drying Time	Minimum Cool Down Time
Pre-Vacuum	Wrapped[1]	132°C (270°F)	4 minutes	30 minutes	15 minutes outside of chamber on wire racks

[1] The tray must be wrapped in an approved (e.g. FDA cleared or ISO 11607 compliant) medical grade sterilization wrap by following the double wrap method or equivalent (ref: AAMI ST79, AORN Guidelines).

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