Intended Use

The DEKOMPRESSOR® is intended for use in aspiration of disc material during percutaneous discectomies. Closely follow all instructions for use.

Physicians using the DEKOMPRESSOR™ should have training and experience with discography and other intradiscal therapies.

Prior to opening, verify that the packaging is not damaged in any way that could compromise the sterility of the probe.

1. Open the header pouch and introduce the tray in a sterile fashion into the sterile field. Grasp the pouch at the opposite end from the opening and allow the tray to slide out of the pouch and on to the sterile tray.

2. Using sterile technique, remove the probe from the tray and inspect for any visible damage. Confirm that the probe threads extend 1 to 2 thread turns beyond the cannula tip. Activate the probe briefly to confirm it is working properly. Remove the introducer cannula from the probe collection chamber by rotating the cannula wings to loosen and carefully remove the cannula from the probe. Flush the introducer cannula with sterile saline. Insert the stylet into the cannula and tighten.

3. After administering local anesthetic along the trajectory necessary to gain extrapedicular disc access, the cannula with stylet can be introduced into the center of the disc. A curved cannula can be purchased to facilitate maneuverability into the disc space.

4. After confirming radiological position in the disc using AP and lateral views, the stylet is removed. Non-ionic contrast with antibiotic should be injected to visualize the nucleus pulposus boundaries. In this fashion, the physician can clearly visualize the nucleus and confine the discectomy accordingly.

The probe tip is then carefully advanced into the introducer cannula. Firmly attach the probe collection chamber to the luer fitting on the cannula. Visually confirm through fluoroscopy that at least one full thread turn of the probe tip extends beyond the cannula tip. If not, gently tighten the cannula to the collection chamber.
The clear cannula hub and collection chamber should be visually monitored for collection of nucleus pulposus material. Approximately 1 cc of tissue has been removed once the tissue becomes visible at the collection chamber entrance. If no material becomes visible in the needle hub within 3 minutes of activation and/or 6 to 8 passes through the nucleus, the probe may be removed from the cannula and inspected for presence of nucleus pulposus tissue along its length. Remove any visible tissue from the probe using the black probe cleaner before re-inserting it into the cannula and continuing the procedure. Use a scalpel blade to clean the probe threads. Be careful not to kink the probe while cleaning.

Discontinue use when any of the following occur:
- The physician believes sufficient material has been removed.
- No material is present in the cannula following 3 minutes of activation.
- A maximum of 10 minutes of operation has expired.
- The collection chamber becomes full.

The probe and introducer cannula may be removed together or the probe may be removed from the introducer cannula first if the physician desires to inject dye into the disc following the procedure. Antibiotic containing dye should be used if not already injected prior to commencing the procedure.

Follow standard procedure for post procedure cleaning of the skin and place a sterile dressing over the exit site.

The clear collection chamber may be removed and sent with appropriate precaution to pathology for examination of the tissue removed.

The probe and introducer cannula should be disposed of in a proper biohazard receptacle. Do not attempt to re-sterilize.
DEKOMPRESSOR®
Percutaneous Discectomy Probe

Ordering Information

DEKOMPRESSOR®
407-230-000 6” Straight 17 Gauge (1.5mm) Dekompressor® Kit
407-231-000 6” Curved 17 Gauge (1.5mm) Dekompressor® Kit
407-260-000 9” Straight 17 Gauge (1.5mm) Dekompressor® Kit
407-278-000 6” Straight 19 Gauge (1.0mm) Dekompressor® Kit
407-265-000 6” Straight 13 Gauge (2.5mm) Dekompressor® Kit
407-266-000 6” Straight 15 Gauge (2.0mm) Dekompressor® Kit

Cannulae (5/pkg)
407-253-000 6” Straight 17 Gauge (1.5mm) Dekompressor® Introducer Cannula
407-254-000 6” Curved 17 Gauge (1.5mm) Dekompressor® Introducer Cannula
407-255-000 6” Straight 17 Gauge (1.5mm) Blunt Dekompressor® Introducer Cannula

Description
The DEKOMPRESSOR® is a single use disposable discectomy probe that passes through and works in conjunction with a 1.0, 1.5, 2.0, 2.5mm introducer cannula to remove intervertebral disc nucleus pulposus material.

Intended Use
The Dekompressor® Percutaneous Discectomy Probe is intended for use in aspiration of disc material during Percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine.

Contraindications
1. Traumatic spinal fracture, infection, tumor, pregnancy, and severe co-existing medical disease are contraindications.
2. The probe is not appropriate for treating patients who present with pain originating from structures other than contained herniated discs. Patients presenting with free fragments, severe bony stenosis, or severely degenerative discs should be excluded.
3. The procedure should be performed under local anesthesia or conscious sedation to allow patient monitoring for signs of segmental spinal nerve irritation. General anesthesia is contraindicated.
4. Patients with severe and rapidly progressing neurological deficits should be excluded.

Special Notes
1. The probe should only be used by physicians who have received training and have previous experience in discography and intradiscal therapies.
2. Special Notes (cont.)
   2. The probe is designed only for use with the introducer cannula provided in the kit.
   3. Never bend or straighten the preferred introducer cannula. Failure to comply may result in patient injury.
   4. The probe and introducer Cannula are single use disposable items provided sterile. DO NOT ATTEMPT TO RE-STERILIZE OR RE-USE.
   5. Disc space infection is a rare but potentially serious complication. The procedure should be performed under sterile technique. Intradiscal and parenteral antibiotics are recommended unless contraindicated. If there is an infection present in the vicinity of the spine, especially near the treatment area, it is mandatory to treat the infection before attempting the procedure.
   6. Placement of the introducer cannula and probe requires direct visualization of a secure approach to the posterolateral disc annulus. Fluoroscopy, or an alternate imaging technology, is essential to the secure conduct of the procedure.

Caution
1. Read all instructions carefully prior to use.
2. For single intervertebral disc access only, do not use on multiple intervertebral levels. Do not immerse in liquids.

Complication
Potential complications include: infections, bleeding, nerve damage, worse pain, failure of technique, paralysis, idiosyncratic reaction, anaphylaxis, & death.

This document is intended solely for the use of healthcare professionals.

The information presented in this brochure is intended to demonstrate the breadth of Stryker product offerings. Always refer to the package insert, product label and/or user instructions before using any Stryker product. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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