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**MR Information**

This device has not been evaluated for safety and compatibility in the MR environment.

This device has not been tested for heating or migration in the MR environment.
Introduction

The CONCORDE™ Clear MIS Discectomy Device is an orthopedic manual hand held surgical instrument for use in performing a discectomy in open and minimally invasive spinal procedures. It is composed of a distal cutting head with serrated cutting edges, a distal guard, and a hollow shaft that connects the cutting head to the handle proximally. The handle is hollow and serves as a reservoir to collect extracted disc tissue. The CONCORDE Clear Device has a port for connecting to a standard suction tube, which is attached to standard hospital wall or pump suction. Different tip angles and working lengths are available to facilitate disc removal and accommodate approaches.
Features and Benefits

Disc Removal & Endplate Preparation with One Tool

- **Variable Cutting Tip Sizes**
  - Available in angles of 15°, 30° & 40° and multiple lengths to accommodate various approaches.
  - Cutting edges shear disc material from the endplates while the suction draws disc material into the tube.

- **Tip Guard**
  Impedes penetration of the anterior annulus and minimizes clogging of the tip.

- **360° Wall Suction Connection**
  Allows for user-friendly instrument movement.

- **Finger-Controlled Suction Valve**
  Places on/off control of suction in surgeon’s control.

- **Transparent Handle to Visualize Collection of Disc Material**
  Provides visualization of collected disc material.

Tip Guard

Variable Cutting Tip Sizes

360° Wall Suction Connection

Finger-Controlled Suction Valve

Transparent Handle to Visualize Collection

Compatible with Standard Hospital Suction
Surgical Technique

Step 1
Setup:

1. Carefully select the correct size of the CONCORDE Clear MIS Discectomy Device for desired working length, both cutter diameter and tip bend angle. Failure to do so could result in tissue damage.

2. Carefully inspect the CONCORDE Clear Device package prior to use for any breach of the sterile barrier or damage to the contents and ensure the device has not expired. Failure to do so could result in patient infection.

3. Connect a standard suction tube to a dedicated suction canister with a standard vacuum source (wall or pump) (Fig. 1). Please follow Standard Hospital/OR protocol and aseptic techniques when attaching the suction tubing.

4. Regulate vacuum pressure to be in the range of 300 mm Hg to 600 mm Hg.

   **Warning:**
   - Use of the device with vacuum levels above 600 mmHg may result in residual suction at device tip while suction control valve is open, increasing the risk of injury to vascular or nervous tissues and related patient injury.

5. Fill a small basin with approximately 300-500 cc of sterile saline.

Step 2
Device Preparation

1. Attach the elbow connector to both the suction tube and device (Fig. 2).

   **Precaution:**
   - Ensure complete connection of device to suction tube, canister, and wall vacuum or pump prior to use.
   - Do not attach device to hospital air-line. Failure to do so could result in patient injury.

2. Verify device suction by inserting the device tip into the basin of sterile saline and activating suction. Cover the Suction Control Valve hole to activate suction at the device tip (Fig. 3).
Step 3

Annulotomy and Initial Disc Dissection

1. Insert a nerve root retractor to protect neural structures. Care should be taken to gently retract and protect the exiting nerve root and lateral part of the central thecal sac. A dissector or nerve root retractor is used to ensure the protection of these neural structures at every step of the procedure (Fig. 4).

2. Perform an annulotomy on the target disc to create a window into the disc space (Fig. 5).

After the annulotomy, a pituitary rongeur is used to initially remove disc tissue in order to clear an initial space for the tip of the CONCORDE Clear Device (Fig. 6).
Step 4

Initial Disc Distraction & Preparation of Disc Space

1. Insert the tip of the CONCORDE Clear Device into the disc space until the laser markings at the distal end of the device tip are fully within the disc space. (Figs. 7 & 8)

   Use a spreader if additional room is needed to safely insert the device.

2. Cover the Suction Control Valve hole to activate suction at the device tip. (Fig. 9)

   **Warnings:**
   
   • Do not insert into, or remove the device from the intervertebral disc with the tip suction ON (suction tubing connected to device with suction control valve closed or finger covering the suction control valve). Failure to comply could result in possible injury to nervous or vascular tissues.

   • The device should never be in direct contact with any vascular or nervous tissues. The tip suction should be OFF when the cutting head is in close proximity to any vascular or nervous tissues. Failure to comply may result in injury to these tissues and related patient injury.

   • Do not use excessive force when using the device. Failure to comply may result in device breakage, malfunction, or patient injury.

**Tips:**

• **Observe depth markers to estimate the position of the device tip within the disc space.**

• **Use fluoroscopy to assist with determining the location of device tip within the disc space.**

• **Confirm vacuum source is ON before performing discectomy**

• **The tip orientation is aligned with the location of the suction control valve.**

**Precautions:**

• Use visual modalities such as fluoroscopy or direct visualization to ensure that the device tip is not accidentally placed outside of the disc space. Failure to do so could result in possible injury to nervous or vascular tissues.
Step 5
Final Disc Preparation & Endplate Clearing

Nucleotomy Step:

a) With the CONCORDE Clear Device tip approximately parallel to the upper or lower endplate, gently push the tip forward with pressure against the endplate or annulus to remove target nucleus.

b) Repeat this in a series of push and pull motions at different axial-plane angles to expand the cavity within the disc space. (Fig. 10)

Tips:

- When using the 15° tip, it is recommended to point the tip both laterally and medially to reach more target tissue. The device should be removed from the disc space before adjusting tip orientation from medial to lateral.
- Fluoroscopy can be used to verify the location of the device within the disc space. Additionally, laser markings along the shaft of the device provides an estimate of the length of the device shaft in the disc space.

Precautions:

- Caution should be taken to avoid the device tip fully penetrating the annulus contralateral to the annulotomy. Failure to do so could result in possible injury to nervous, vascular or soft tissues.
- Use visual modalities such as fluoroscopy or direct visualization to ensure that the device tip is not accidentally placed outside of the disc space. Failure to do so could result in possible injury to nervous or vascular tissues.
- If the device gets clogged with tissue, quickly insert and remove the device in a bowl of sterile saline several times with device suction activated. Alternatively, use the stylet provided in the device package to remove the clog by inserting the stylet into the tip of the device to push clog towards the handle of the device. Caution should be taken to avoid glove contact with the cutter tip. Failure to do so could result in possible injury to the user.
Step 6
Endplate Cartilage Removal Step:

Once the bulk of the nucleus in the target area is removed, apply tip pressure to the endplate and gently scrape the cutting tip in a parallel direction to the endplate where there is remaining cartilage to remove (Fig. 11). Repeat this at various medial to lateral angles to thoroughly remove disc material from the caudal endplate of the superior vertebral body and the rostral endplate of the inferior vertebral body.

Warning:
- Do not repeatedly use device on the vertebral endplates once cartilage has been removed as overuse may cause damage to the endplate bone.

Optional Step

Remove excess tissue and target inner annulus by gently sweeping the device tip against the inner annulus to remove any remaining target tissue (Fig. 12).
**Step 7**

When the discectomy is complete, turn suction off at tip and remove CONCORDE Clear Device from the disc space (Fig. 13).

**Warning:**
- Do not insert into, or remove the device from the intervertebral disc with the tip suction ON (suction tubing connected to device with suction control valve closed or finger covering the suction control valve). Failure to do so could result in possible injury to nervous or vascular tissues.

**Step 8**

Use a Penfield or preferred instrument to confirm that the discectomy and endplate preparation is complete for the reachable target disc area (Fig. 14). If not complete, reinsert the device and complete the discectomy.

**Step 9**

The cap can be removed to access tissue in the handle by gently prying it from the handle (Fig. 15). Once the reservoir has been emptied, the cap can be reattached to the handle and the device can continue to be used.
Step 10
For procedures requiring an additional device, repeat steps 1 through 8 to complete the discectomy including endplate preparation.

Tips:
- The elbow connector can remain attached to the hospital suction and be re-connected to the new device during the same procedure.
- After using device, evacuate sterile saline through device to purge the device so it does not clog if used at a later time during the procedure.
- When using the 30° or 40° tip, it is only recommended to point the tip towards the contralateral side.

Step 11
Dispose of device(s) according to local regulations.
Packaging, Handling, and Sterilization

- The sterile packaging should be inspected for damage and expiration date prior to use. Inspect the package prior to use for any sterile barrier breach or damage to the contents. Do not use if the package is damaged or if you suspect that sterility has been compromised. Do not reuse or re-sterilize the device.

- The device is supplied sterile. It has been sterilized by gamma radiation.

- If packaging or sterile barrier is breached, or there is damage to the contents of the packages, do not use and contact your DePuy Synthes Spine representative.
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<thead>
<tr>
<th>Part Number</th>
<th>Product Description</th>
<th>Description</th>
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<td>163005515</td>
<td>CONCORDE Clear Device</td>
<td>15° × 5 mm</td>
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<td>163005540</td>
<td>CONCORDE Clear Device</td>
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<tr>
<td>163010515</td>
<td>CONCORDE Clear Device, Long</td>
<td>15° × 5 mm</td>
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Indications and Contraindications

**Indications for Use**
The CONCORDE Clear MIS Discectomy Device is indicated for spinal discectomy procedures for the cutting and removal of soft and hard tissue in open and minimally invasive spinal surgeries.

**Contraindications**
Contraindications for the CONCORDE Clear MIS Discectomy Device include but are not limited to patients with:

- Active local or systemic infection
- Allergy to any device materials, including stainless steel
- Discitis
- Irreversible bleeding disorder or coagulopathy
- Pregnancy
- Severe Osteoporosis

**Warnings**
- The device should only be used by physicians with experience and training in spine surgery.
- Do not use excessive force when using the device. Failure to comply may result in device breakage, malfunction, or patient injury.
- Never bend device shaft before or during procedure. Failure to comply may result in device breakage, malfunction, or patient injury.
- Do not insert into, or remove the device from the intervertebral disc with the tip suction ON (suction tubing connected to device with suction control valve closed or finger covering the suction control valve). Failure to do so could result in possible injury to nervous or vascular tissues.
- The device should never be in direct contact with any vascular or nervous tissues. The tip suction should be OFF when the cutting head is in close proximity to any vascular or nervous tissues. Failure to comply may result in injury to these tissues and related patient injury.
- Use of the device with vacuum levels above 600 mmHg may result in residual suction at device tip while suction control valve is open, increasing the risk of injury vascular or nervous tissues and related patient injury.
- Do not repeatedly use device on the vertebral endplates once cartilage has been removed as overuse may cause damage to the endplate bone.
- For single procedure use only. Do not reuse, reprocess or re-sterilize. Failure to comply may result in device breakage, malfunction, the use of a non-sterile or contaminated System, or patient injury.
- The components of the CONCORDE Clear MIS Discectomy Device are designed to be used in combination and function as a single unit. Failure to properly follow instructions may lead to improper functioning of the device and may cause patient injury.

**Precautions**
- Caution should be taken to avoid the device tip fully penetrating the annulus contralateral to the annulotomy. Failure to do so could result in possible injury to nervous, vascular or soft tissues.
- Use visual modalities such as fluoroscopy or direct visualization to ensure that the device tip is not accidentally placed outside of the disc space. Failure to do so could result in possible injury to nervous or vascular tissues.

- When nervous tissue is near the pathway to the disc space, use a nerve root retractor to protect the nervous tissue.
- When removing the sterile device, socket, and stylet from the packaging, be aware that the device, socket, and stylet are separate items within the same packaging.
- Ensure complete connection of device to suction tube, canister, and wall vacuum or pump prior to use.
- If the device gets clogged with tissue, quickly insert and remove the device in a bowl of sterile saline several times with device suction activated. Alternatively, use the stylet provided in the device package to remove the clog by inserting the stylet into the tip of the device to push clog towards the handle of the device. Caution should be taken to avoid glove contact with the cutter tip. Failure to do so could result in possible injury to the user.

**Possible Adverse Effects**
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common may include:

- Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding,iatrogenic vital organ, neural and vascular injury, including spinal cord, dural tear or spinal fluid leak. Functional impairment of the musculoskeletal system, allergy/hyper-sensitivity reactions, ongoing pain; damage to adjacent bones which may interfere fusion; damage to soft tissue, including swelling or abnormal scar formation.

**Magnetic Resonance (MR) Compatibility**
- The CONCORDE Clear MIS Discectomy Device has not been evaluated for safety and compatibility in the MR environment. The device has not been tested for heating or migration in the MR environment.