Elliquence
Innovative Medical Solutions

Disc-FX® System

Quick Reference Guide

Elliquence | DISC-FX

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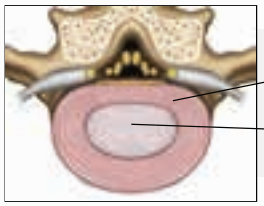
1. Anatomy of a Disc

A. *Annulus Fibrosa* is the fibrous outside portion of an intervertebral disc. This portion circumferentially surrounds the Nucleus Pulposa.

B. *Nucleus Pulposa* is the gelatinous center portion of the disc. It is naturally acidic, and any chemical leakage through a tear in the annulus elicits an inflammatory response to the surrounding area, which in turn is a pain generator.



2. Disc Degeneration

Intervertebral disc degeneration is a natural occurrence that happens over time. Over time, the nucleus pulposa loses its water content and the nucleus begins to lose its disc height. This process is called degenerative disc disease (DDD). It can be seen as a black disc on a T2 MRI due to the lack of water content.

3. Herniations, Bulges, Sequestered, Prolapsed

A contained disc herniation or disc bulge is a condition where the nucleus pulposa is pushing on and has partially gone through the annulus fibrosa deforming the outside portion of the disc. This disc can push into the spinal canal or into the intervertebral foramen where the exiting nerve roots come off of the spinal cord. Symptoms of this condition include but are not limited to-low back pain, weakness; and/or paresthesia (numbness) extending into lower extremities. A sequestered disc, which can be referred to as a prolapsed disc is when the nuclear material has torn through the annulus completely and can migrate into the spinal canal or into the intervertebral foramen.

NOTE: Doctors can use the Disc-FX® System to treat a contained disc herniation or disc bulge. Doctors must choose a more invasive procedure to treat a sequestered or prolapsed disc. The majority of intervertebral disc pathologies are contained disc herniations and disc bulges.

Disc Herniation/Disc Bulge

Non-Contained Disc Herniation

4. Disc FX® System

Step 1. Under fluoroscopic guidance a spinal needle (either 18g or 16g) is inserted into the nucleus pulposa. The end of the needle should be in the proximal 1/3rd of the disc. At this point the doctor can inject dye and contrast into the disc. This is most commonly done in a 6:3:1 ratio (6 parts contrast 3 parts saline, 1 part dye). The most commonly used dye is indigo carmine. The saline is added to dilute the contrast. This will lessen the radiodensity of the contrast making it easier to visualize the instrumentation under fluoroscopy. The contrast will verify proper needle placement. The dye will help differentiate the nuclear material endoscopically.

Insertion of the Needle

Step 2. A guide wire is inserted into the needle and advanced to the nucleus. This should be verified with fluoroscopy.

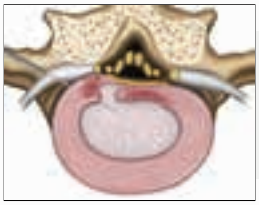
Insertion of the Guidewire

Step 3. A #11 scalpel is used to make an incision (the width of the scalpel on either side of the needle). This will allow for subsequent cannula insertion.

Step 4. The needle is then removed. The doctor should have one hand on the needle and the other hand on the proximal end of the guide wire. The needle should be slowly spun as it is removed to allow for smoother removal. Fluoroscopy should be performed at this point to verify the distal end of the guide wire has remained in the nucleus.

Step 5. The dilator is inserted into the cannula and screwed on tightly. (There are 2 cannulas, one straight and the other beveled. This is doctor preference). The depth stop is slid onto the shaft of the cannula up to the proximal end and tightened. At this point the cannula is inserted over the guide wire and advanced to the annulus. The cannula should be slowly spun and advanced at the same time for easier insertion. This should be done under fluoroscopic guidance.

Insertion of the Dilator



Step 6. With the cannula against the annulus an annulotomy can now be performed. The dilator is removed (taking care not to disturb the position of the guide wire) and the trephine is inserted over the guide wire and advanced to the nucleus. The trephine is slowly spun and advanced at the same time; thereby coring a hole into the annulus. The trephine is then removed and the dilator is reinserted. At this time the cannula can be advanced into the nucleus. The cannula is advanced to the proximal 1/3rd of the nucleus. This is verified by fluoroscopy. The guide wire and dilator can now be removed leaving the cannula as a working portal. The depth stop is brought down to the patient's skin and tightened on the cannula. This will prevent distal movement of the cannula. An endoscope (if being used) can be inserted and advanced into the nucleus at this time to verify proper cannula positioning. Blue nuclear material will be visualized.

Annulotomy

Advance Cannula

Verify Cannula Positioning

Step 7. At this point a 2.7mm grasping forceps is inserted into the cannula and advanced into the nucleus. A manual discectomy is performed. The excised nuclear material can be sent to pathology for verification. Most doctors take a fluoroscopic picture with the forceps open inside of the disc for documentation purposes.

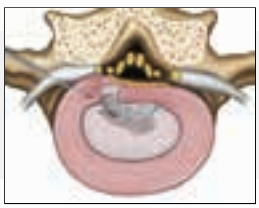
Grasping Forceps

Step 8. The next part of the procedure is nucleus ablation. The doctor will use the Trigger-Flex® radiofrequency probe for this step. The Trigger-Flex® is irrigated with saline using gravity. A pressure cuff can be used over the saline bag to increase the saline pressure going to the probe. IV tubing (sterile on the field) is connected from the saline bag to the Luer fitting on the handle of the Trigger-Flex®. A steady drip of saline should be seen coming out of the distal end of the Trigger-Flex® at a rate of 1-2 drops per second. The probe is inserted into the cannula and advanced into the nucleus. Placement should be verified using fluoroscopy. At the proximal end of the silver shaft of the Trigger-Flex® are 2 laser etchings. These are used to mark placement of the Trigger-Flex® inside the disc and minimize fluoroscopy. Under fluoroscopic guidance align the proximal end of the cannula (plastic purple end) with the center of the 2 laser etchings. The doctor should hold the Trigger-Flex® handle in his dominant hand. The other hand should hold the shaft of the Trigger-Flex® at the laser etchings, using two fingers to prevent the shaft from moving in and out of the cannula. At this point the doctor will squeeze the Trigger-Flex® and verify under fluoroscopy that the distal end is reaching out to the desired position. Squeezing the Trigger-Flex® handle makes the bipolar electrode extend out of the distal end of the shaft and point upward. This allows the silver electrode tip (the area where the RF emits from) to be guided towards a dorsal disc herniation during parts of the procedure. At this point the doctor presses the black pedal labeled Bipolar Turbo. This will activate the RF and a steady beep will come from the Surgi-Max®. The volume can be adjusted by a knob in the back of the machine. The doctor will squeeze the Trigger-Flex® handle continuously for 6 seconds while holding down the pedal. He or she should not slide the Trigger-Flex® in and out in a sawing motion, it should be squeezed and released. This procedure will be repeated 6 times. Once at 12:00, 2:00, 4:00, 6:00, 8:00 and 10:00. Studies have shown this will ablate approximately 1.0 gram of nuclear material.

Nucleus Ablation

Disc-FX® with IV Tubing

Annulus Modulation



Step 9. The final part of the procedure is annular modulation or annuloplasty. In this part of the procedure the bipolar hemo (blue pedal) is used. The Trigger-Flex® is held in the vertical position so the tip will come out and up (dorsally). In this part of the procedure the tip of the Trigger-Flex® is going to be rubbing along the interior portion of the annulus where the disc is herniated or bulging. At the lower bipolar hemo setting the radio frequency will contract the collagen fibers of the annulus and shrink the herniated area. The doctor uses the same technique as in step 9 with the exception of only doing two 6 second sweeps with the Trigger-Flex® in the vertical position.