



enSpire™ FLEX MIS DISCECTOMY SYSTEM

Replaces Manual Instruments with Articulating Power Tool

*Easier, Faster, and More Thorough Discectomy and
Simultaneous Endplate Preparation*

A number of techniques exist for interbody fusion of the lumbar spine, each with its own limitations and advantages. As spine surgery trends toward minimally invasive (MIS) access and techniques, and posterior and lateral approaches increasingly replace ALIFs, the challenges associated with traditional discectomy instrumentation are clearer than ever. The **enSpire™ FLEX MIS Surgical Discectomy System** (Spine View, Inc., Fremont, CA), is a novel, safe, powered technology platform that facilitates a more complete discectomy, including endplate preparation, accelerating tissue removal in both open and MIS procedures, including TLIF, PLIF and Lateral.

The **enSpire™ FLEX MIS Discectomy System** enables the simultaneous cutting and removal of disc material and endplate cartilage, with a unique ability to articulate. The result is a more thorough, more effective radical discectomy, considered a major contributing factor to a successful interbody fusion.

“There’s a real opportunity with this device to make MIS easier and better,” according to John Pelozza, M.D., a Dallas orthopedic surgeon who’s practice specializes in MIS spine procedures, including lumbar fusion. “We find with this instrument we can do a much better endplate preparation, without which the chance of non-union increases.”

Dr. Pelozza explains: “We can fill in the back space, away from the implant, increasing the surface space. The larger the fusion area, the better the healing. We’ve shown intraoperatively with our fluoroscopy that we cover the entire disc space and endplate with this tool. In addition, later on, when we evaluate the fusion with CT scans, we see that the fusion mass is healed with

good fusion mass all the way across the endplate. We did not see this before the use of this tool.”

The **enSpire** system features an expandable wire with integrated cutter to selectively side-cut nucleus and end-plate cartilage, and an impeller mechanism to extract tissue out of the disc space into a proximal, integrated tissue collection chamber. The system articulates at the tip to better reach concave endplate surfaces, the contralateral side of the disc space, and ipsilateral corner.



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After more than 50 procedures using the **enSpire** device, Brad Jones, M.D., an orthopedic surgeon in Redding, CA, reports (1) a drastic reduction in the number of instrument passes; (2) reduction of discectomy time by 50 to 75 percent; and (3) significantly increased local bone graft. He also speaks to the economics associated with the system. “Our BMP usage has gone down dramatically with this. If you can demonstrate that you are saving 10-15 minutes per case per level, that’s a dramatic cost savings for the hospital.”

In “An Operative Case Study using the **enSpire Surgical Discectomy System**,” Dr. Jones

reports on a two level L4-S1 TLIF and decompression in a 52-year-old man. A total of three **enSpire** instrument passes were required after the completion of annulotomy and before graft. Dr. Jones puts this in perspective in a follow-up interview. "Typical is 50 passes for prep, trialing and then insertion of the actual implant. Now, I don't even retract the dura or nerve root one bit."

In the same case study, Dr. Jones notes the volume of interbody graft around the interbody spacer. "This is perhaps the most important parameter studied," he writes, "as the graft volume is a predictor of the amount of disc material removed, and therefore how much actual surface area is available for bone fusion from endplate to endplate." In the interview, he adds: "We can see more graft in the disc space than I have ever seen in my personal experience."

This instrument conforms to the concavity, Dr. Jones explains. "Without it, we're probably leaving a layer of cartilage on the endplate, which isn't conducive to fusion. Since using **enSpire**, I've brought my endplate preparation up to a new level."

Related to **enSpire**'s ease of use, Dr. Jones adds: "The hassle factor is the biggest thing, it's fast, reliable and reproducible."

"It is very difficult to achieve a thorough discectomy with traditional, manual instruments," according to Rajesh Patel, M.D., an orthopedic spinal surgeon who practices in West Virginia. "If we are honest with ourselves, we're looking at probably about 33% at most as being removed." He adds: "The quality of your discectomy is the most

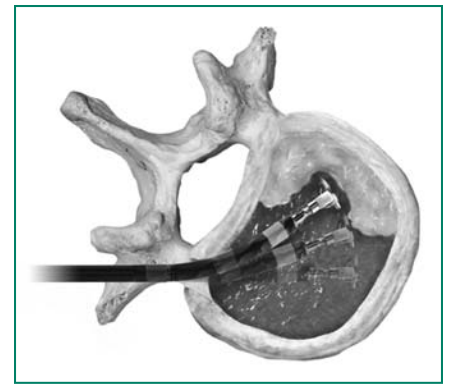
important component of an interbody fusion." Today, Dr. Patel says, "with the **enSpire FLEX**, I do believe I am getting a much more complete discectomy, and much more thorough endplate preparation."

In addition to the limitations of instruments that don't bend, and places they can't reach, "there is always concern about maneuvering around the nerves," says Dr. Patel, whose preference for lumbar fusion is an MIS TLIF approach. "One of the biggest concerns with traditional, manual tools is the number of instrument passes. The instrument is sharp. Passing 50-70 times increases risk of neural injury."

Regarding economics, besides a more expedited discectomy, which provides a significant time savings, Dr. Patel reports that "with the use of the **enSpire FLEX**, I've completely stopped using BMP for MIS TLIF procedures."

A multi-surgeon, comparative cadaveric study to appear in the *Journal of Spinal Disorders and Techniques* was conducted by the Hospital for Special Surgery (New York, NY) and looked at both discectomies performed with the **enSpire** system and with traditional, manual instruments, all using a standard TLIF approach. Three parameters were investigated: (1) percentage of discectomy completed (including endplate preparation); (2) number of instrument passes; and (3) discectomy time.

"We conducted a cadaveric study involving three spine attending surgeons and two clinical spine fellows," explains Matthias Pumberger, M.D., Spine Research Fellow at the Hospital for Special Surgery. "Our results demonstrated an increased discectomy



enSpire™ FLEX performing a TLIF discectomy.

surface area as well as decreased average time and instrument passes of the **enSpire** instrument."

In fact, the attending surgeons in this study had a 47 percent improvement for the discectomy and endplate preparation, compared to discectomies using manual instruments. In addition, a five-fold reduction in instrument passes was noted in the **enSpire** group, which averaged eight, versus 44 in the manual instrument group.

A clinical study is underway to further investigate time differences with the use of the **enSpire** system. The time difference is expected to be far greater when performed clinically, as vital nervous tissue would then need to be navigated with each instrument pass. Significantly reduced time and instrument passes may translate into decreased blood loss, decreased risk of neurological injury and infection, decreased operating room time and physician fatigue. ♦

*For more information about the **enSpire™ FLEX MIS Discectomy System** call Spine View, Inc. at 510-623-1931; email to info@spineview.com, or visit their website at www.spineview.com.*