

## Summary of the Discseel<sup>®</sup> Procedure

The Discseel<sup>®</sup> Procedure provides high safety and efficacy for treating lumbar and cervical disc pathology when compared to other surgical and non-surgical treatments and is being performed more frequently by spine surgeons in the United States, Europe, and Asia.

Because the Discseel<sup>®</sup> Procedure is relatively new, this document provides spine surgeons and other physicians pertinent scientific information to explain how the Discseel<sup>®</sup> Procedure provides patients benefit. Kevin Pauza, MD, and his co-investigators are currently performing several investigations evaluating the Discseel<sup>®</sup> Procedure. He and his co-investigators previously won several NASS Outstanding Study Awards evaluating surgical and non-surgical spine treatments. Their previous research studied the Mobi-C artificial disc and minimally invasive spine technologies.

Published research affirms that disc pathology, including herniations, degeneration, and bulges, occurs because of progressively worsening annulus fibrosus (AF) tears and defects. When the nucleus pulposus (NP) leaks through AF tears, the NP is perceived as a foreign substance, initiating the inflammatory cascade and autoimmune response within discs, on spinal nerves, and dura. Resultant inflammatory constituents and not nerve root compression as once thought, cause the pain and weakness because constituents increase disc and nerve root sensitivity. This explains why MRIs and CTs don't correlate with symptoms.

Fusions cannot address annular tears and leaks, so they cannot reduce pain caused by leaky discs. Furthermore, fusions create detrimental forces on adjacent discs causing "adjacent segment accelerated degeneration." Additionally, surgical discectomy itself causes worsened annular defects, which causes "the same segment accelerated degeneration."

The Discseel<sup>®</sup> Procedure utilizes the FDA-approved Fibrin made by Baxter Pharmaceutical to first seal annular tears, then stimulate disc tissue growth, permanently repairing disc pathology. A randomized, controlled study confirms the ability of Baxter's Fibrin to grow discs and was awarded the NASS Outstanding Paper. Prospective investigations pending publication confirm statistically significant outcomes in all measurements of low back and leg pain, function, mental health, and quality of life. Safety and efficacy profiles of the Discseel<sup>®</sup> Procedure surpass all spine surgery study results.

Fibrin (Baxter Pharmaceutical), and not stem cells or other such biologics, is utilized in the Discseel<sup>®</sup> Procedure because it is an excellent bio-adhesive that remains within annular defects, whereas studies demonstrate that other biologics, such as stem cells, have poor ability to remain within torn and leaky discs. Baxter's FDA-approved Fibrin is

NON SURGICAL  
**DISCSEEL**<sup>®</sup>  
SPINE PROCEDURE

an excellent tissue bio-adhesive with a long history of successfully treating heart, brain, spine, and other tissue and organs.

The Discseel<sup>®</sup> Procedure is not to be confused with stem cells or other treatments not demonstrating efficacy through rigorous studies.