



**SPINAL STABILIZATION
TECHNOLOGIES™**



PATIENT ELIGIBILITY



PerQdisc™ Nucleus Replacement
Clinical Trial

You may be eligible for the
DISCPAIN1 Clinical Trial.
Talk to your doctor to see if
joining this study is right for you.

What is Degenerative Disc Disease?

Degenerative disc disease (DDD) is often linked to aging, but changes in the discs of the spine can start as early as childhood due to both natural body processes and everyday movement. Degenerative disc disease (DDD) happens when the discs in your spine start to break down over time. These discs work like shock absorbers between your bones. They help your spine move and stay flexible.

Often time as we age, some of the special cells inside the discs begin to disappear. However, this can start as early as childhood due to normal, everyday movement. Without these cells, the discs lose water and flexibility, becoming dry, stiff, and less able to support your spine properly.

Common Symptoms of DDD

Symptoms of lumbar degenerative disc disease (DDD) may include:

- Lower Back Pain that can range from mild to severe and is often worse with activities like bending, lifting, or prolonged sitting.
- Pain that radiates to the legs, a condition known as sciatica.
- Stiffness in the lower back, making it harder to bend or move.
- Numbness or tingling resulting from pressure on nerves can cause numbness, tingling, or a “pins and needles” sensation in the legs, feet, or buttocks.
- Weakness is a symptom of more severe cases where nerve pressure results in muscle weakness.

PerQdisc™ Nucleus Replacement (artificial implant) may assist patients with single level discogenic back pain in preserving their motion and alleviating pain. The PerQdisc™ Nucleus Replacement System is not yet FDA-approved and is not currently for sale in the U.S. This device is only available to participants in the clinical trial.

Treatment Options

There are numerous options available to help treat lumbar DDD including: physical therapy, lifestyle modifications, non-steroidal anti-inflammatory medications like ibuprofen, epidural injections, etc. However, when non-surgical treatments have failed, surgery may be considered. Spinal fusion and/or total disc replacement (TDR) are often performed when the disc is severely damaged. The **PerQdisc™ Nucleus Replacement** is different. It aims to restore disc function and alleviate pain potentially preventing progression of DDD.

Could you Qualify for the DISCPAIN1 Trial?

Patients may be eligible if:

- You are between 22-70 years old
- You have low back pain that is caused by degeneration of one of the discs in your lumbar spine (low back) confirmed by MRI
- You have not improved after completing at least 6 months of conservative treatment for your back pain (e.g., physical therapy, medications, injections, ablations, lifestyle changes, etc.)

If you are interested in participating in this study, further screenings and evaluations are required to confirm eligibility.

What is my commitment?

If you qualify for the study, are selected and choose to participate, you will be followed by the research team for up to 60 months (5 years) after your surgery. You will be asked to return to the clinic for 9 follow-up visits during that timeframe for medical evaluations. These visits will occur at approximately 2 weeks, 6 weeks, 3 months, 6 months, 12 months, 24 months, 36 months, 48 months, and 60 months post-surgery. These visits help your doctor and research staff understand how well the device performs over time and identify any possible risks associated with the use of the device or the procedure.

What are the risks?

If you are interested in enrolling in the study, you will be asked to sign an Informed Consent form that outlines all known risks and side effects. The study physician will also review this with you before you decide to participate.

About the PerQdisc™

The PerQdisc is a custom, form-fitting, medical grade silicone-based implant. The PerQdisc does not require screws or rods and is implanted through a small surgical incision on the side of the body via the PerQdisc Implant Delivery Device.



PerQdisc Implant Delivery Device



PerQdisc Implant

The PerQdisc replaces the middle part of the disc while preserving the outside structural part of the disc (disc fibers) and other parts of the spine.

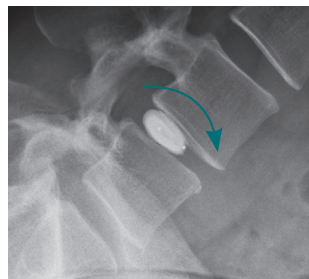
About the Clinical Trial

The DISCPAIN1 Clinical Trial research study is offered to volunteers who suffer from chronic low back pain caused by degenerative disc disease at a single spine level. This study is designed to confirm the safety and effectiveness of the PerQdisc Nucleus Replacement Device (NRD) prior to the U.S. Food and Drug Administration (FDA) determining in a follow up study if the device will become available to the general public as a solution for degenerative disc disease.

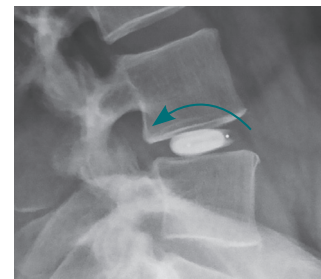
Potential Benefits of the PerQdisc may include but are not limited to:

- **Reduced Pain¹ (back and leg pain if present)**
- **Improved/Restored Disc Function¹**
- **Return to Work/resume daily routines¹**

1. Lumbar Disc Nucleus Replacement for Refractory Back Pain: A Case Report. *Journal of Spine Research and Surgery* 5 (2023): 65-68.



Flexion X-ray with PerQdisc in place.



Extension X-ray with PerQdisc in place.

To learn more about this study, contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT06860867

(Place Referring Physician Information Here)

This brochure is for educational use only. Speak with your doctor about diagnosis and treatment options.



**SPINAL STABILIZATION
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