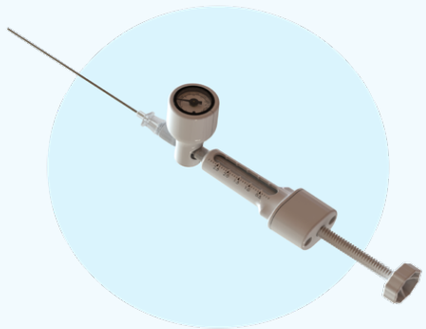
Why Should I Participate?

People participate in research studies for many reasons, including the opportunity to assume a more active role in their healthcare, access to cutting-edge treatments when other therapies have failed, or a desire to contribute to medical research for future patients with the disease. Only you can decide if participating in a research study is right for you.



HYDRAFIL is not approved in the United States. If you and your doctor think that you might benefit from a minimally invasive hydrogel implant to augment the disc nucleus for treatment of chronic low back pain, the only way to potentially receive the **HYDRAFIL** implant at this time is to enroll in the **HYDRAFIL-D Study**.

Next steps: How to Participate

If you have received this brochure, your doctor believes that you may be a candidate for the **HYDRAFIL-D Study**. If you would like to take the next step toward possible participation or if you have more questions, please contact the research staff at your local study center, or you can visit the study website at **www.HYDRAFILStudy.com**.

ReGelTec

HYDRAFIL-D

A Clinical Study for Patients with Degenerative Disc Disease of the Lumbar Spine

Protocol: RGT-2000PS

CONTACT US

For more information on the **HYDRAFIL-D Study** and to see if you might be eligible, contact your local study center or please visit

www.HYDRAFILStudy.com

The **HYDRAFIL-D Study** is sponsored by ReGelTec, Inc.

Caution — Investigational device. Limited by federal (or United States) law to investigational use.

ReGelTec

Do You Suffer from Painful Low Back Degenerative Disc Disease?

Learn More About the HYDRAFIL-D Research Study

Investigating a New Treatment for Patients with Chronic Low Back Pain Caused by Degenerative Disc Disease

HYDRAFIL® - Injectable Gel Implant for Degenerated Discs

Researchers are conducting this study to evaluate the safety and effectiveness of a new investigational spinal implant called **HYDRAFIL** for the treatment of lumbar (low back) degenerative disc disease. **HYDRAFIL** is intended to treat one (1) or two (2) lumbar disc levels.

HYDRAFIL is a hydrated polymer gel (hydrogel) that mimics the natural properties of the nucleus inside an intervertebral disc in the spine. It is designed to be an injectable, soft, space-filling, disc augmentation technology.

- **Permanent implant device -** motion preserving biomechanical properties
- **Minimally invasive procedure -** quick, percutaneous injection administered via a 17-gauge needle
- **Short recovery time -** patients are walking within two hours following injection
- **Early clinical results -** show satisfaction and significant improvements in pain and function

About the Current Research - The HYDRAFIL-D Study

Approximately 225 people will participate in this research study being conducted at multiple clinical sites (i.e., the 'local study centers') located in the United States and Canada.

Participants will receive study-related medical care and treatment from a local spine specialist physician (i.e., the 'local study doctor').

To be eligible to participate, you must meet specific eligibility criteria that include, among others:

- **Be 22 to 85 years of age**
- **Have a diagnosis of lumbar spine (low back) degenerative disc disease (DDD) (as determined by the local study doctor)**
- **Have chronic low back pain due to DDD lasting at least 6 months**
- **No history of lower back surgery**
- **Be willing and able to return for all study related follow-up procedures**

Following the investigational treatment, there are post-treatment study assessments consisting of medical examinations, imaging, and questionnaires that will occur at the local study center. The required study **follow-up visits will be completed at 1 month, 3 months, 6 months, 1 year and 2 years,** following the investigational treatment. Additionally, you may be asked to return annually thereafter for up to 5 years post-treatment.

The complete schedule of screening and follow-up visits and assessments, and types of medical examinations and evaluations, will be explained to you by the research staff at the local study center before you have to commit to participating.

Discuss everything with the local study doctor and research team and **make sure you can commit to all requirements before you agree to participate!**

Preliminary 2-Year OUS Early Feasibility Study Results (N=75)[1]

[1] Data on file at ReGelTec, Inc.

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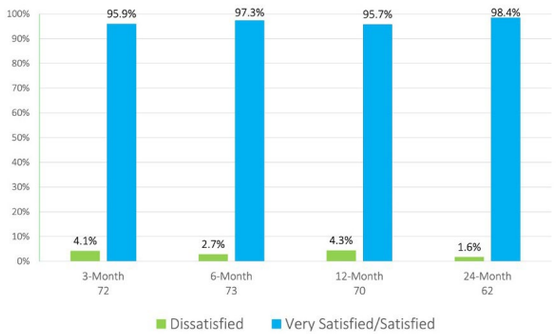
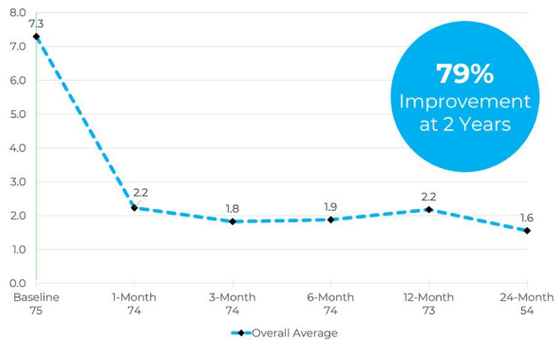
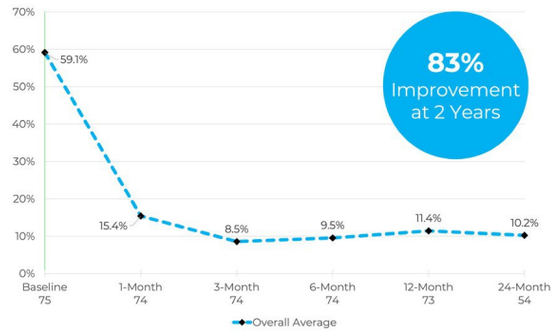


Patient Satisfaction Following Treatment



Low Back Pain Improvement Over Time



Function Improvement Over Time