

About Clinical Research

Clinical studies often compare new treatments with the current standard of care. Many new treatments may help people enjoy healthier and more comfortable lives. Strict government regulations control the conduct of clinical studies to protect the rights and ensure the safety of volunteers.

Ideally, the CarboClear® System will aid spinal fusion and reduce pain in patients, like other approved therapies for DDD. It will also enable improved follow-up by your physician, since the system allows the patient to undergo artifact-free CT and MRI imaging follow-up, should the need arise.

Clinical study participation is voluntary. Make sure your doctor answers all your questions and explains the potential risks and benefits.

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How Can I Participate ?

If you or someone you know is interested in additional information about this trial, please consult with your physician.

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www.carbo-fix.com

CAUTION: The CarboClear® System is an investigational device. Limited by Federal (or United States) law to investigational use.



CarboClear® Clinical Study



**Are you suffering
from low back or leg pain?**

**Unresponsive to non-surgical
management for over 6 month?**

We are seeking participants in a clinical trial to determine the safety and effectiveness of a new treatment for lumbar degenerative disc disease.

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Degenerative Disc Disease (DDD) Treatment

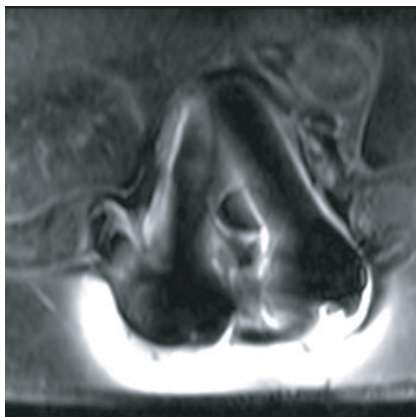
If you suffer from lumbar DDD and require a spinal fusion to relieve your back and/or leg pain, you are not alone. Over 400,000¹ spinal fusion surgeries are performed in the US annually. Current surgical treatment includes metal implants which hold the vertebrae together until new bone grows between them.

The CarboClear® Pedicle Screw System is the first device to replace the metal in these implants with carbon fiber. The expected benefit of carbon fiber implants over metal implants is that the carbon fiber implant will allow accurate imaging of the spine when using MRI or CT post-operatively.

Carbon Fiber Technology in Medicine

Over the past decade, carbon fiber implants have been used clinically in the US and worldwide for orthopedic indications. The benefits of these implants include transparency in x-ray imaging and the ability to perform MRI and CT without disturbance.

This transparency allows for improved follow-up care by the medical team. To date, following a successful multi-center clinical study in Europe, the CarboClear® carbon fiber implants have been used out of the US in over one hundred spinal procedures.



MRI image with metal screws

The CarboClear® Study

The CarboClear® clinical study will evaluate the safety and effectiveness of the CarboClear® System for lumbar DDD patients undergoing one level spinal fusion.

The study is seeking adults with degenerative disc disease who are experiencing significant low back and/or leg pain at selected medical centers in the US. The investigators are top surgeons who specialize in treating disc disease and in spine surgery in general.



MRI image with carbon fiber screws

1. Spine (Phila Pa 1976). 2012 Jan 1;37(1):67-76