If you are one of the millions of Americans that suffer from Degenerative Disc Disease and non-surgical treatments, such as pain medication and physical therapy, fail to alleviate your symptoms, surgical options may be a path for relief. You may be eligible to participate in a research study.

WHAT IS THE ASPIRE TRIAL?

The ASPIRE trial is a new clinical study being conducted at 36 locations throughout the United States. This research study has been designed to determine if the use of P-15L Bone Graft is as good at fusing bones surrounding your damaged disc as using your own bone and possibly donor bone following a spinal fusion surgery. It is believed that fusing the bones will help in relieving your pain and loss of function. Currently, P-15L Bone Graft is only available for use in this trial.

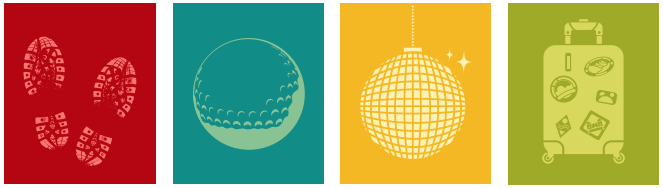
CP-1006

WHEN DID YOU STOP RUNNING ?

GOLFING

DANCING

TRAVELING



WANT TO GET BACK AT IT? ASK YOUR DOCTOR ABOUT THE ASPIRE TRIAL.

A NEW ALTERNATIVE FOR SPINAL FUSION

Degenerative disc disease (DDD) occurs when your discs degenerate (break down) and cause pain. As you age, the discs can lose flexibility, elasticity, and shock absorbing characteristics. When all that happens, the discs change from a supple state that allows fluid movement to a stiff and rigid state that restricts your movement and may cause pain. In order to treat the pain associated with DDD, physicians typically start to treat with exercise, physical therapy, pain medications and more. If those treatments do not provide relief, you may be referred to a surgical procedure, such as a fusion, to relieve the pain.

ASPIRE TO MOVE FREELY

This research study has been designed to determine if the use of P-15L Bone Graft is as good at fusing bones surrounding your damaged disc as using your own bone and possibly donor bone following a spinal fusion surgery. It is believed that fusing the bones will help in relieving your pain and loss of function. P-15L Bone Graft is investigational, which means that it is not approved by the Food and Drug Administration (FDA). Using your own bone or donor bone is considered common practice for spine fusion surgery called the control treatment for this study.

P-15L Bone Graft contains calcium phosphate particles and P-15 in a carrier. Calcium phosphate is a mineral found in your bone. P-15 peptide is a synthetic (man-made) segment of collagen (main component of the tissues in your body) that is responsible for natural cellular attachment and activation. The carrier is a collagen putty made from bovine (cow) tissue that holds these components together. The P-15L Bone Graft triggers your body's natural bone healing response and then it will reabsorb after healing has occurred.

ASPIRE TO PARTICIPATE

There are many factors that will affect whether a person can participate in this study. Some of the criteria to participate include:

- Between 22 and 80 years old at the time of starting the study
- Have disc pain between L2 and S1 at a single level
- Had the pain for at least 6 months without relief from non-operative treatment
- Experiencing leg pain
- Not pregnant or planning to become pregnant
- Planned lumbar fusion at one level

There are more study criteria that can be determined by your study doctor.

About 270 people will take part in this study at 36 hospitals in the United States.

FAQ'S

How long will I be in this research?
Your participation in the study is expected to last for 6 years in total. The first two years follows most doctors' standard of care post-operatively and after that, you will return once a year for four additional years to complete the study visits.

Has P-15 been studied before?
P-15 has been studied in the cervical spine (neck) and was approved by the FDA in 2016. In that study, 319 people were studied and P-15 was found to be superior to autograft (the patient's own bone) at 1 year for the composite endpoint of overall success. To have this product approved for lumbar fusion, Cerapedics (the company Sponsoring the trial) must conduct the study and provide the data for FDA to review and determine if it can be approved.

How will I benefit from the participating?
Although there is no guarantee that you will benefit from participating, the study has been designed to compare P-15L against what is the standard of care for most surgeons. Also, for those who are eligible and choose to participate, their data will help contribute to a future submission to FDA to determine if P-15L is as at least as good as the standard of care.

If you are interested in being considered for the trial or have questions, talk to your doctor or the research team using the contact information listed below:

First Name, Last Name
Hospital Name

Phone: 000-000-0000
Email: first.last@email.com