What is OsteoAdapt SP?

OsteoAdapt SP is an investigational new option for patients with degenerative disc disease. Based on results of preclinical studies, OsteoAdapt may be safer and more effective compared to approved spinal fusion grafts.

During surgery, OsteoAdapt is placed in the spinal fusion cage. OsteoAdapt contains a protein engineered to help bone grow. The protein is called AMP2.

What are the Potential Benefits of OsteoAdapt?

OsteoAdapt is designed to avoid the challenges associated with bone grafts. It is a synthetic material. As a result, it eliminates the risk of disease transmission associated with donor bone grafts, as well as chronic pain that sometimes results from taking a graft from your own body. It also may be more effective in promoting bone growth.

If you would like more information about the OASIS Trial, please visit **www.theradaptive.com/OASIS.**

The OASIS Trial

Evaluating the OsteoAdapt SP Spinal Fusion Implant for Degenerative Disc Disease

Theradaptive

CAUTION: Investigational Device. Limited by Federal law to investigational use.

What is Degenerative Disc Disease?

Degenerative disc disease occurs when discs in your spine break down slowly over time. These discs normally act as cushions between the vertebrae, or bones, in your spine. As you age, the discs can wear down. This causes the bones to rub together and can result in back pain.

What is Spinal Fusion?

Spinal fusion is surgery to connect bones in the spine. Connecting the bones prevents movement, which helps to reduce or eliminate back pain.

During this surgery, the surgeon will remove a portion of the disc between two bones. Then they will insert a spinal fusion cage. The cage is hollow and needs to be filled to enable bone growth necessary for spinal fusion. A bone graft from you or a donor, or a synthetic graft, can be used to fill the cage. Over the next several months, the bones will heal together into one piece.

What is TLIF?

TLIF, or transforaminal lumbar interbody fusion, is a spinal fusion surgery for the lower back.

What is the OASIS Trial?

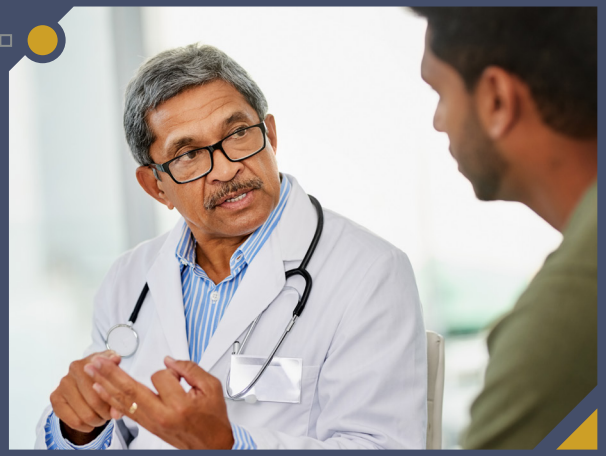
The OASIS Trial is evaluating a new spinal fusion implant called OsteoAdapt SP. The trial is assessing if the implant is safe and how well it works. It will also determine the best dosages of OsteoAdapt SP for future clinical trials.

The OASIS Trial is randomized. This means that participants will receive spinal fusion with OsteoAdapt SP or a standard bone graft. Participants have a 2 to 1 chance of receiving spinal fusion with OsteoAdapt SP.

Who is Eligible?

Up to 80 patients will be enrolled in the trial. You may be eligible if you:

- Need spinal fusion for degenerative disc disease
- Have had at least 6 months of conservative care
- Are between 18 and 80 years of age
- Have a BMI less than 40
- Are a non-smoker
- Do not suffer from another major health condition



What Are Trial Requirements?

Participating in a clinical study such as the OASIS Trial offers you access to treatment and scheduled check-ups as part of the trial plan. This may result in more frequent and detailed evaluations.

You will be evaluated at regular times after surgery: at discharge, 6 weeks and 3, 6, 12 and 24 months. At these check-ups, you will be asked to complete questionnaires, forms, lab testing, X-rays and physical examinations.

The same check-ups are required regardless of which spinal fusion implant you receive in the study. You may receive compensation for study check-ups that are not part of routine spinal fusion care.

Why Participate in the OASIS Trial?

OsteoAdapt is a new treatment for spinal fusion that is only available to patients enrolled in this clinical study. Development of new treatments is impossible without patient participation in clinical trials. Your participation in this trial may provide potential benefits for you and others affected by degenerative disc disease in the future.

Theradaptive