PATIENT INFORMATION

ACADIA®

FACET REPLACEMENT SYSTEM

Life moves us

Outside the US Only

GLOBUS MEDICAL

ACADIA®
Facet Replacement System

Patient Information

This brochure will help you understand more about:

- **General conditions of the spine**
- **Information about surgical treatment**
- **What to expect from surgery**

The decision to receive medical treatment is individualized to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment, or its outcome, as surgical techniques vary and complications can occur. It is important to discuss the viability of this procedure with your physician to decide whether this treatment option is right for you.

This brochure is intended to be an educational resource only and is not meant to be a warranty or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, precautions, clinical results and other important medical information that pertains to this procedure.

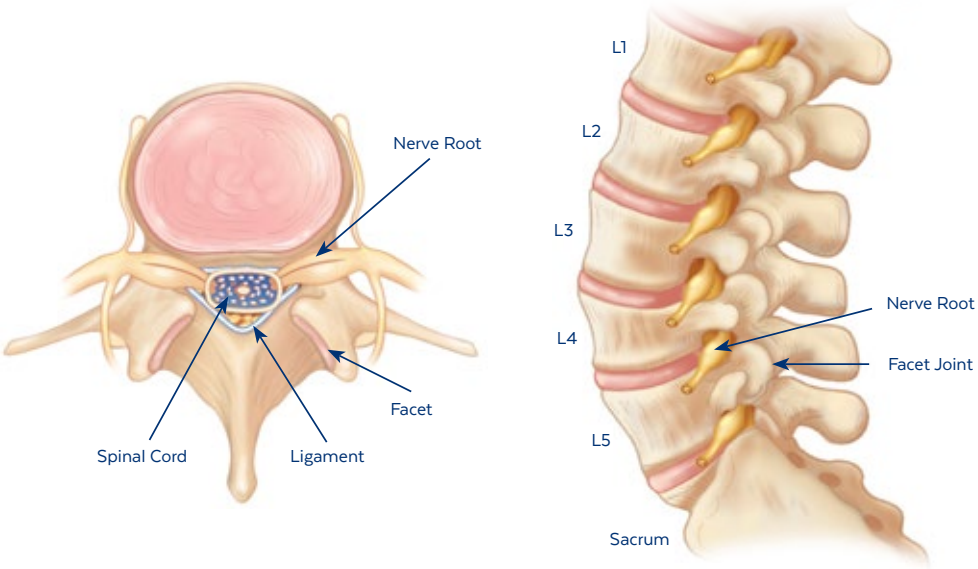
Table of Contents

Lumbar Spinal Stenosis

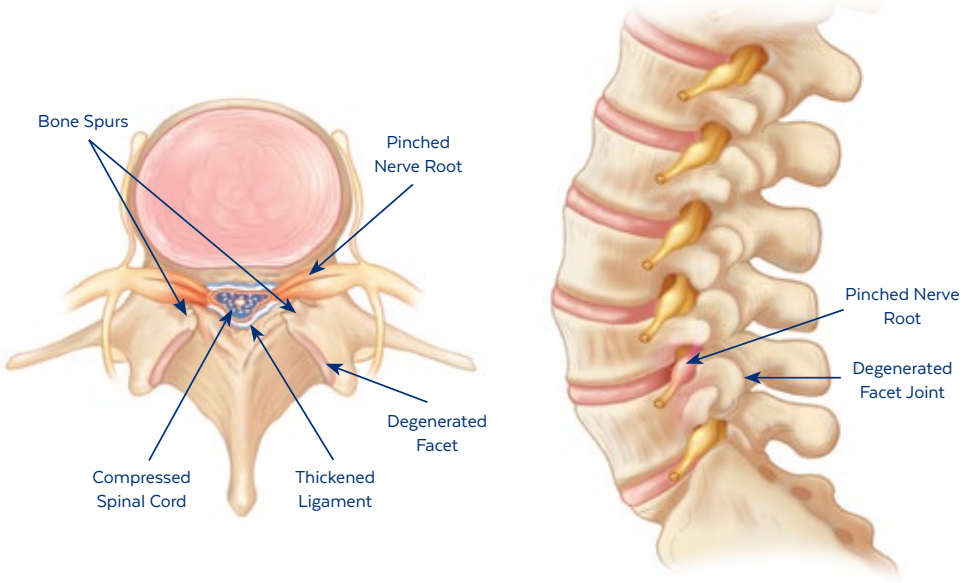
The lumbar spine is made up of five vertebrae (bones) in your lower back, separated by spinal discs (cushions between the vertebrae), and linked by facet joints (flexible areas between bones on the sides of the spine). The vertebrae protect the spinal cord (bundle of nerves) as it runs through the spinal canal (opening in the vertebra that covers and protects the spine cord). The discs help absorb pressure and distribute stress between the vertebrae. The facet joints help make the spine flexible and stable.

As you age, your facet joints may break down and degenerate. When facet joints degenerate, bone spurs (projections) may form around your spine. Sometimes bone spurs form at the edges of the facet joints where nerve roots leave the spinal canal, which narrows the area around the spinal cord. This narrowing is called lumbar spinal stenosis. When bone spurs rub against a nerve root, the nerve can become irritated and inflamed. This may cause pain, numbness, burning, tingling, and weakness in the lower back, buttocks, and legs. These symptoms may be worse when standing or bending backwards and may be relieved when sitting or bending forward.

Non-surgical treatments, such as medications, physical therapy, and injections are usually prescribed first by a doctor. If a patient's symptoms do not go away with non-surgical care, spine surgery may be recommended.



Normal Lumbar Spine



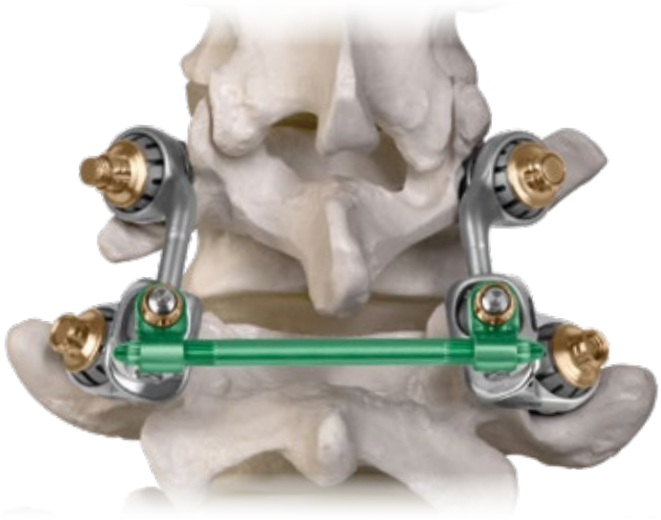
Lumbar Spinal Stenosis

ACADIA® Facet Replacement System

ACADIA® is designed to replace degenerated facets with artificial facets to allow motion. Degenerated facet joints and other structures that are compressing the spinal cord and causing pain or discomfort are removed.

ACADIA® is implanted using a posterior approach (from the back) to the lumbar spine. Specialized tools are used to place the implants, including the articulating (moving together) parts. The goal of this surgery is to align and secure the implants in a position that mimics how these joints align in a natural spine.

After surgery, the system is designed to move and slide to allow motion.

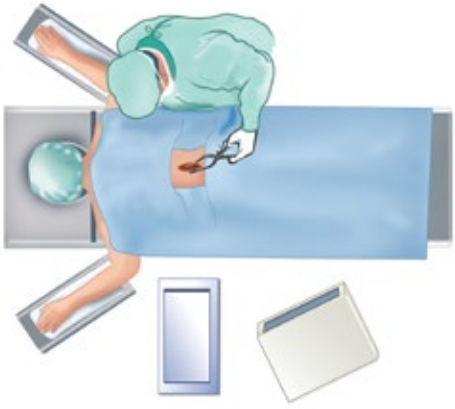


ACADIA® Facet Replacement System

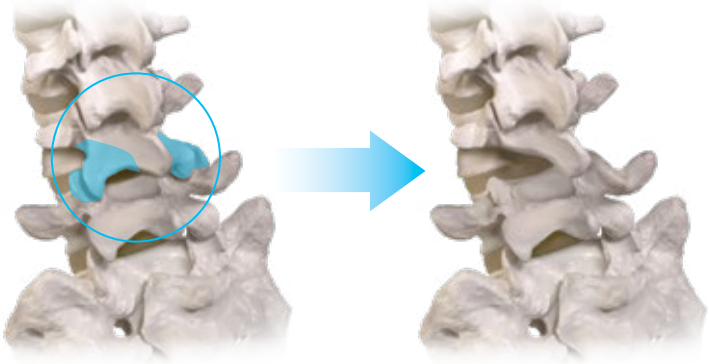
ACADIA® implants are composed of polyetheretherketone (PEEK), titanium alloys, cobalt chromium alloy, commercially pure titanium, and/or hydroxyapatite. These materials are biocompatible and have a history of clinical use. If you have an allergy to any of these materials, please consult with your physician.

Surgical Treatment: ACADIA®

Surgery is performed from a posterior approach with decompression.



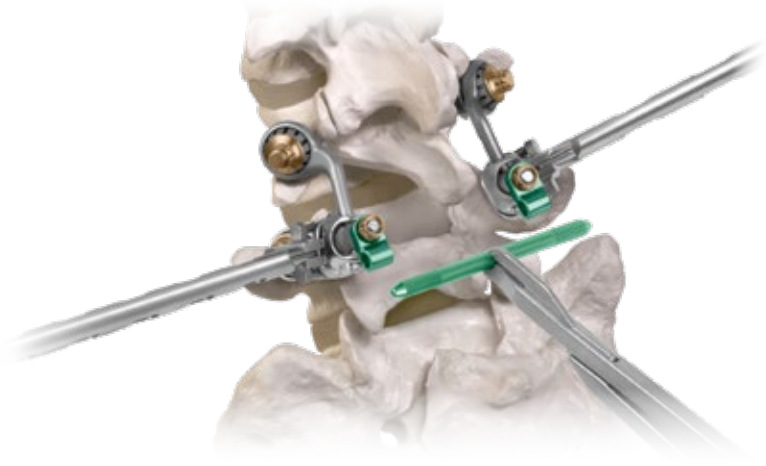
Posterior Approach



Decompression

After decompression, the ACADIA® implants are inserted.

Surgical Treatment: ACADIA® (Cont'd)



ACADIA® Implants Inserted

Final Implants

Frequently Asked Questions

How is treatment with the facet replacement different from spinal fusion (joining of bones)?

The primary difference between facet replacement and fusion is that ACADIA® is designed to allow motion. Fusion is intended to prevent motion by permanently fusing two or more vertebrae together.

What should I expect with my recovery?

Many patients notice improvement of some or all of their symptoms, and pain may diminish a few weeks after surgery. However, recovery time varies among patients.

Typically, it is the surgeon's goal for the patient to eventually return to their preoperative activities. A positive attitude, reasonable expectations, and compliance with your doctor's post-surgery instructions may all contribute to a satisfactory outcome.

How long will my implant last?

The expected lifetime of these devices is difficult to determine but it is not indefinite. While these devices are made of synthetic materials and are designed to survive the life of the patient, there are many factors which may affect the device lifetime. Therefore, these devices cannot be expected to indefinitely withstand the applied loads of the spine.

Can I have an MRI after the devices are implanted?

ACADIA® implants have not been evaluated for safety and compatibility in the MR environment, and have not been tested for heating or migration in the MR environment.

Contraindications and Adverse Effects

You may be contraindicated (not suitable) for this device if you have an infection, a congenital abnormality, a primary diagnosis of discogenic back pain, scoliosis, certain allergies, greater than grade I spondylolisthesis or retrolisthesis at the involved level, spinal stenosis at 3 or more levels, spondylolisthesis at other areas in the spine, had previous spinal fusion or trauma to the lumbar spine, are obese, pregnant, mentally ill, diabetic, immunocompromised, suffer from rheumatoid arthritis, systemic diseases, metabolic bone disease, osteoporosis, or cancer .

As with any surgical procedure, complications or adverse effects may occur following the placement of this device. These can include but are not limited to early or late implant bending, breakage, failure, loosening, movement/migration, bone fracture, chronic pain, abnormal sensations, and allergic reaction to implant material .

Other adverse effects that may be associated with any non-fusion spinal surgical procedure include pain, secondary surgery, bleeding, infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, cardiovascular system compromise, joint inflammation, respiratory problems, reactions to anesthesia, impotence, sexual dysfunction, paralysis, and death .

If you experience any of the above adverse effects, please contact a health professional. This list does not include all possible contraindications and adverse effects. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.

If you experience a serious adverse effect with your implant, please report the incident to your local health authority and to Globus Medical. Some health authorities are listed below for convenience.

Region	Authority	Website
All	Globus Medical	https://www.globusmedical.com/international/about/contact/
Australia	Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	https://www.medsafe.govt.nz/
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
Other	Report to your local health authority per local guidelines	

About Globus Medical: Globus Medical, Inc. is a leading musculoskeletal implant company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders.

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
globusmedical.com/international

Customer Service:
Phone: 1-866-GLOBUS1 (or 1-866-456-2871)
Fax: 1-866-GLOBUS3 (or 1-866-456-2873)

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