

You and your surgeon will continue to work together during your recovery. Before you leave the hospital, your surgeon may schedule follow-up visits with you so he or she can evaluate your progress.

What are the possible complications?

As with any surgery, spinal surgery is not without risk. Complications, such as infection, blood loss, bowel or bladder problems, are some of the potential adverse risks. Please consult your physician for a complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information, if necessary.

Talk to your Doctor

While this brochure is meant to provide you with information you need to make an informed decision about your treatment options, it is not intended to replace professional medical care or provide medical advice.

If you have any questions or need additional information about DIAM spinal stabilization system, please call or see your doctor who is the only one qualified to diagnose and treat your back. As with any surgical procedure, you should find a surgeon who is experienced in performing the specific surgery that you are considering.

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DIAM

Spinal Stabilization System

Patient Information Brochure



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DIAM Spinal Stabilization System

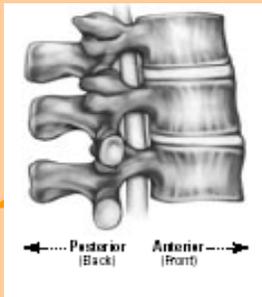
This patient information brochure is designed to help you make an informed decision about treatment for your back and related problems. Your doctor has recommended surgery to relieve your pain and related problems. As part of the surgical procedure your doctor has also recommended using the DIAM spinal stabilization system to support motion in your spine.

How does the spine work?

The Spine is a column of bony vertebrae, which supports your body, allows movement, and protects the spinal cord. The functional spine unit comprises of the intervertebral disc, facet joints as well as associated bony processes with muscular and ligament attachment.

Each intervertebral disc allows for shock absorption and flexibility and works with the spines joints, muscles and ligaments for movement.

Nerves branching from the spinal cord pass through openings in the vertebrae to other parts of your body. Several of these nerves form the sciatic nerve, which runs down your leg.



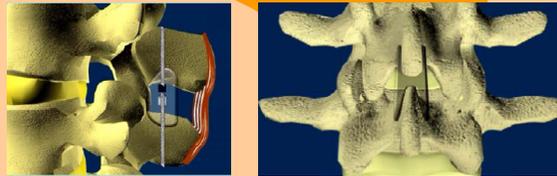
What causes back pain?

As discs lose their water content because of disease or age, they lose their height. As a result, the vertebrae become closer, causing the nerve openings in the spine to become narrower. When a disc ruptures in the lumbar spine, it puts pressure on one or more nerve roots or on the spinal cord, causing pain and other symptoms in the back and legs.

Many people with disc degeneration respond to a non-surgical approach that includes physical therapy and exercises to strengthen the back and abdominal muscles, anti-inflammatory medication, and the avoidance of repetitive jarring activities. If this approach does not work, surgery may be needed.

What is the DIAM Spinal stabilization system?

The DIAM Spinal stabilization system was designed to aid in the treatment of degenerative disc disease. The DIAM acts as a spacer which when placed between two spinous process restores the natural height of the disc, taking the pressure off the intervertebral disc and associated structures, and allows the nerve to exit freely from the spinal cord while maintaining normal movement of the spine. The device is made of a hardened silicone covered with a polyethylene sock and has two ligatures, which allow it to be secured in place between the two spinous processes.



What are the advantages of the DIAM spinal stabilization system?

Following standard surgery where a part of the intervertebral disc is removed (discectomy), the rest of the disc can degenerate further potentially requiring fusion surgery at a later date. In fusion surgery the surgeon uses a bone graft to join, or fuse, two or more vertebrae together. Once the bone and spinal bone grow together, the two vertebrae function as one unit, stabilizing that part of the spine. With the disc space restored to its original height, pressure on nerves is usually relieved.

The DIAM spinal stabilization system negates the need for fusion in some patients and can act as an alternative for fusion in some patients. The device is designed to assist in allowing normal motion in the spine. In addition, the device may help to protect the spine from mechanical stress that can cause further degeneration of discs near the level of surgery.

Who can benefit from surgery?

You may benefit from the DIAM spinal stabilization system if;

- Your doctor has confirmed by your history and x-ray studies that you have degenerative disc disease in your lower back
- You have narrowing of a vertebral opening due to loss of disc height, or
- You have back and/or leg pain that has not responded to non-surgical treatment.

How is the surgery performed?

The DIAM spinal stabilization system surgery takes only a short time added onto the standard procedure of discectomy. Your surgeon will access your spine through an opening in your back, remove portions of the degenerated disc, measure the required height and then position the DIAM to maintain function of your spine.

There are alternative treatments to this surgery, both surgical and non-surgical. You should discuss these options with your doctor before making your decision.

What is the recovery process?

Immediately after surgery, you will be moved to the recovery room where you will remain for a few hours while your recovery from the anaesthesia is monitored. After you awaken fully, you will be taken to your hospital room. You may have a drainage tube in your wound and your doctor may prescribe medicines to control pain and nausea.

Ask your doctor about your hospital stay and your specific recovery plan following surgery. It is important to follow your doctor's instructions carefully to recover from surgery as quickly as possible and increase your chances of a successful outcome.

After surgery your surgeon may refer you to a physical therapist who will teach you exercises to improve your strength and mobility. The goal of physical therapy is to help you become active as soon as possible, using safe body movements that protect your back.