DIAM™

SPINAL STABILIZATION SYSTEM

Patient Labeling

Caution: Federal Law restricts this device to sale by or on the order of a physician.

This brochure will provide you with information about the DIAM™ Spinal Stabilization System, a new treatment for moderate low back pain from lumbar degenerative disc disease.

Your doctor will answer any questions you have regarding lumbar degenerative disc disease and the DIAM™ Spinal Stabilization System as a treatment for you.

COMPANION SPINE

Changing spine care for good.

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DIAM™ SPINAL STABILIZATION SYSTEM

DIAM™ Spinal Stabilization System is a dynamic stabilization device that can be used to treat primary low back pain (greater than leg pain) which may result from degenerative disc disease (Figure 1).

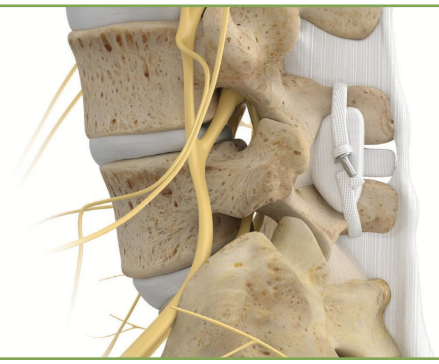

Figure 1: DIAM™ Spinal Stabilization System Shown Implanted in the Spine Viewed from the Side

The core of the DIAM™ Spinal Stabilization System is made of stiff silicone (Figure 2). The silicone is covered with an outer mesh made of polyester. Two cables, also made from polyester, are used to attach the DIAM™ Spinal Stabilization System to the spinous process bones at the rear of the spine (Figure 1). Two titanium crimps (clips) are used to secure the cable loops.

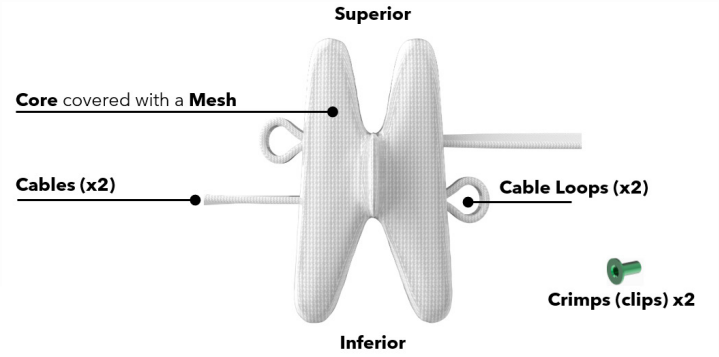

Figure 2: Parts of the DIAM™ Spinal Stabilization System

You have been experiencing back pain without adequate relief from your degenerative disc disease symptoms after at least 6 months of non-surgical care, such as, but not limited to, prescribed medications, physical therapy, and spinal injections. Your doctor has reviewed your medical history, X-rays, and other tests, and has recommended discussing the option of surgery with the DIAM™ Spinal Stabilization System to help relieve your back pain. This brochure can help assist in your choice on how to treat your pain.

DIAM™ Spinal Stabilization System – A Breakthrough Device

The DIAM™ Spinal Stabilization System helps **relieve moderate to severe low back pain** while **preserving natural motion, stabilizing and preserving your anatomy**. Many patients feel significant **improvement within six weeks, with lasting benefits for years**.

On October 5, 2021, the U.S. Food and Drug Administration (FDA) granted the DIAM™ Spinal Stabilization System Breakthrough Device Designation. This designation is granted to devices that meet certain criteria prior to their evaluation for market clearance or approval. In the FDA's words: "We are pleased to inform you that your device and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device."

Indications for Use

The DIAM™ Spinal Stabilization System is indicated for skeletally mature patients that have moderate to severe primary low back pain (greater than leg pain) secondary to lumbar degenerative disc disease (DDD), at a single level from L2-L5 with current episode refractory to at least 6 months non-operative care.

Symptomatic disc disease is confirmed by patient history, physical examination, and radiographic evaluation with one or more of the following factors:

- Greater than 2mm of decreased disc height (average <disc height) compared to the adjacent level
- Scarring/thickening of the ligamentum flavum, annulus fibrosus, or facet joint capsule
- Non-extruded herniated nucleus pulposus

The DIAM™ Spinal Stabilization System is implanted via a minimally invasive posterior approach.

CLINICAL SUMMARY

A clinical trial was conducted in the United States to evaluate subjects with degenerative disc disease treated with the DIAM™ Spinal Stabilization System. Two years after implantation, patients in the study group treated with the DIAM™ Spinal Stabilization System experienced the following:

- 77.0% (97/126) of patients experienced clinically meaningful improvement in back pain related disability (evaluated using the Oswestry Disability Index).
- 83.2 % (104/125) of patients experienced a clinically meaningful improvement in back pain intensity (evaluated using the Numerical Rating Scale).
- 93.1% (134/144) of patients reported no treatment-related Serious Adverse Events
- 94.4% (136/144) of patients had no additional surgical intervention.

WHAT IS DEGENERATIVE DISC DISEASE?

Disc degeneration, most often age related, is the gradual breakdown, or degeneration, of an intervertebral disc.

Healthy intervertebral discs act as padding between the spine's vertebrae (bones that make up the spinal column) and cushion the stress when the spine moves or bears weight. The healthy intervertebral disc is made up of two layers, the soft, jelly-like core (nucleus pulposus) and the firm, tough outer layer (annulus fibrosus).

The degenerative breakdown of the intervertebral disc results in loss of fluid in the disc, making it harder for it to absorb shocks, reduced height of the disc, and loss of mechanical integrity between the bones in the spine. You can see a comparison of a normal spine versus one suffering from degenerated discs in Figure 3.

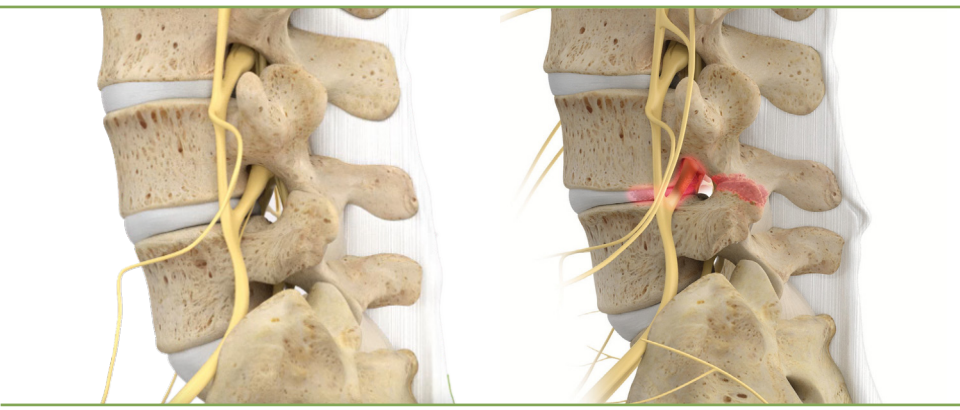

Figure 3: Side View of Normal Spine (left) and Spine Suffering From Degenerative Discs (right)

HOW DO I KNOW IF I HAVE DEGENERATIVE DISC DISEASE AND IF I AM A GOOD CANDIDATE FOR DIAM™ SPINAL STABILIZATION SYSTEM?

If you suffer from degenerative disc disease you may feel various symptoms. These symptoms may include:

- Ongoing low back pain that is worse than any leg pain.
- Pain caused by wear and tear in one spinal disc in the lower back (between the 2nd and 5th lumbar vertebrae).
- Current pain episode having lasted for at least 6 months and not improving with non-surgical treatments (such as physical therapy, medications, injections, or rest).

Before diagnosing degenerative disc disease, your doctor will first rule out other conditions that may cause similar symptoms. To do this, your doctor will:

- Ask you to describe your symptoms, how they have changed over time, and what treatments you have already tried (such as medications, physical therapy, or injections).
- Perform a physical exam and may order imaging tests such as an MRI or X-ray.

These tests help confirm if your pain is caused by degenerative disc disease. Results may show one or more of the following:

- The disc has become thinner compared to nearby discs.
- There is scar tissue or thickening in the tissues around the disc or joints.
- There is a disc bulge or herniation that has not fully broken through the outer layer.

WHO SHOULD NOT RECEIVE THE DIAM™ SPINAL STABILIZATION SYSTEM?

The DIAM™ Spinal Stabilization System is designed to help many people with lower-back problems, but it isn't the right choice for everyone. Your safety comes first, so this device should **not** be used if any of the following apply to you:

- **Allergies:** You are allergic to any of the materials in the device (silicone, PET fabric, or titanium).
- **Spinal Conditions That Affect Stability:** Your spine is too unstable for the device to remain secure—for example, if one backbone has slipped too far forward or backward.
- **Severely Collapsed Disc:** The disc at the affected level has lost more than two-thirds of its normal height.
- **Spine Shape or Alignment Issues:** You have scoliosis (a curve greater than 10 degrees), a flat-back posture, or a forward-curved spine at the treatment level.
- **Major Structural Problems in the Spine:** You have birth-related spine abnormalities, a spinal tumor, or signs of past or recent injury in the area to be treated.
- **Previous Surgery at the Same Level:** The DIAM™ Spinal Stabilization System cannot be placed at a level that has already been operated on.
- **Serious Nerve Compression:** You have symptoms of cauda equina syndrome, such as loss of bladder or bowel control.
- **Multiple Disc Issues:** You need treatment at more than one disc level in the lower back.

- **Large Disc Herniation:** Part of your disc has broken off and moved into the spinal canal.
- **Significant Bone Overgrowth or Joint Enlargement:** You have large bone spurs or severe joint changes around the vertebrae.
- **Weak or Fragile Bones:** You have osteoporosis (a bone density test showing a T-score of –2.5 or lower).
- **Pregnancy:** This procedure is not recommended during pregnancy.
- **Infection:** You have an active infection anywhere in your body or at the planned surgical site.
- **Severe Obesity:** Your body mass index (BMI) is greater than 40.

WHAT ARE THE WARNINGS AND PRECAUTIONS ASSOCIATED WITH THE DIAM™ SPINAL STABILIZATION SYSTEM?

- **Only trained doctors should use the DIAM™ Spinal Stabilization System**. It's meant for surgeons who know the procedure, the tools, and the possible risks. Using it without proper training can lead to serious problems.
- **The DIAM™ Spinal Stabilization System is not for everyone**. The device hasn't been proven safe or effective for:
  - People under 22 years old
  - People over 60 years old
  - Patients who are still growing (skeletally immature)
- **Extra caution for certain spine conditions.** If the bones in your spine are very close together (a condition called Baastrup sign), there's a higher chance of breaking a bone during surgery. Surgeons should adjust the spine slowly and carefully.
- **The DIAM™ Spinal Stabilization System is for single-use only**. This device is for one patient only. It should never be reused or cleaned for another surgery. Reusing it could make it weak or contaminated, which could cause serious harm, illness, or even death.
- **Keep the supraspinous ligament intact.** The supraspinous ligament should be carefully preserved during surgery to avoid overstressing the bone-implant interface.

- **The safety and effectiveness of the DIAM™ Stabilization System has not been established in patients with the following conditions:**
  - More than one spinal level requiring surgical intervention.
  - More than one surgical procedure at any combination of lumbar levels.
  - Prior surgery at any lumbar vertebral level with instrumentation.
  - Prior surgery at an adjacent lumbar vertebral level without instrumentation.
  - History of Paget's disease, osteomalacia, or other metabolic bone disease.
  - History of an autoimmune disease.
  - Psychiatric or cognitive impairment.
  - Current or recent history of illicit drug or alcohol abuse, or dependence as defined as the continued use of alcohol despite the development of social, legal, or health problems

HOW DO I PREPARE FOR SURGERY?

You and your doctor may choose for you to have surgery with the DIAM™ Spinal Stabilization System. If so, there are several things you can do to help you have the best possible results for your surgery. Your doctor will give you specific instructions prior to your surgery that you should follow. You can also increase your chances of a successful outcome by eating well-balanced nutritious meals before your surgery. Poor nutrition can reduce the body's ability to heal.

WHAT HAPPENS DURING SURGERY?

The DIAM™ Spinal Stabilization System surgery is performed with the patient lying on his or her stomach. An incision about two (2) inches long is made along the back of the spine. Then an instrument called a retractor is used to retract, or pull back, the muscle and tissue so that the surgeon can view the spine. The surgeon will prepare the area for the implant by removing only the necessary soft tissue and bone. A series of templates are then used to select the appropriate-sized DIAM™ Spinal Stabilization System. The surgeon will then implant the device between two spinous processes. The spinous process is the portion of the vertebrae that protrudes from the back of the spinal column. They create the "bumps" that you can feel along the middle of the back.

Two polyester cables allow the surgeon to fasten the DIAM™ Spinal Stabilization System to the spinous processes to stabilize the vertebrae and help maintain position of the device. The operation is completed when the surgeon closes the incision.

WHEN SHOULD I CALL MY DOCTOR?

Ask your doctor about 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. Recovering from back pain and surgery is an ongoing process. How fast you recover depends on the type of surgery you had, your commitment to working closely with your physical therapist, and moving and exercising correctly, as recommended by your surgeon.

In most cases, immediately after surgery, your heart and lung function will continue to be monitored, a drainage tube may have been left in your wound, and your doctor may prescribe medicines to control pain and nausea.

A nurse will show you how to care for your wound before you are sent home, and your doctor will discuss a program to gradually increase your activity. You may be required to wear a back brace after surgery and you may be told to avoid repetitive bending, lifting, twisting, and athletic activities while you recover. You may also be cautioned to avoid vibrations, such as those you might experience when driving a car, for a period of time after your surgery. Your doctor will schedule office visits to check on how you are doing and see if anything else needs to be done.

Contact your doctor immediately if:

- you get a fever,
- the wound starts leaking fluids,
- you have trouble swallowing or breathing,
- you have trouble urinating, or
- you have new or increased back or leg pain or numbness.

After surgery, your surgeon may refer you to a physical therapist who will teach you exercises to improve your strength and increase your mobility.

The goal of physical therapy is to help you become active as soon as possible, using safe body movements that protect your spine. This often includes abdominal strengthening exercises.

WHAT ARE THE POTENTIAL RISKS ASSOCIATED WITH SURGERY USING THE DIAM™ SPINAL STABILIZATION SYSTEM?

As with any surgery, surgical treatment of lumbar spine disorders is not without risk. A variety of complications related to the surgery or the use of DIAM™ Spinal Stabilization System may occur. Potential adverse effects (i.e., complications associated with the use of DIAM™ Spinal Stabilization System were identified from DIAM™ Spinal Stabilization System clinical trials in and outside of the United States, approved device labeling from other lumbar spinal devices, and published scientific literature appear in the package insert of the device. The Adverse Effects are subdivided into four categories: (1) those commonly associated with any surgical procedure; (2) those associated with lumbar spinal surgery procedures using a posterior approach; (3) those associated with the DIAM™ Spinal Stabilization System; and (4) adverse events related to the DIAM™ Spinal Stabilization System or procedure which were observed in the US clinical study. These risks may occur singly or in combination and may be severe and/or negatively impact patient outcomes. The list below is not a full list of risks. There may be other risks with treatment using DIAM™ Spinal Stabilization System.

There is the possibility that this surgery may not be effective in relieving your symptoms. It is possible your symptoms could worsen. If this happens, you may require additional surgery. You should discuss these risks and any concerns with your doctor before deciding to have surgery with the DIAM™ Spinal Stabilization System. A complete list of risks is provided in the package insert for the device, which your doctor has received. Please ask your doctor for more information about any additional risks that could be related to your planned surgery.

Risks Associated with Any Surgery:

All surgeries—no matter where they are performed—carry some degree of risk. These complications are not common, but they are possible. They include:

- **Reactions to anesthesia,** ranging from mild allergic responses to severe reactions.
- **Low red blood cell levels (anemia)**.
- **Significant bleeding,** which may require a blood transfusion; rarely, a reaction to the transfusion may occur.
- **Heart problems**, including heart attack.
- **Blood clots**, which can travel to the lungs and cause serious breathing issues.
- **Inflammation of veins** (phlebitis).
- **Injury to blood vessels** during surgery.
- **Serious infections in the bloodstream** (septicemia).
- **Stroke**, caused by disrupted blood flow to the brain.
- **Lung complications**, such as collapsed lung, pneumonia, fluid in the lungs, or difficulty breathing.
- **False aneurysm**, a swelling near a blood vessel caused by injury.
- **Infections** at the wound, in nearby tissues, or throughout the body, sometimes causing fever or abscess formation.
- **Problems with the incision**, such as the wound reopening, tissue death, or noticeable scarring.

- **Digestive issues,** including constipation, blocked bowels, nausea, or vomiting.
- **Urinary or reproductive system problems**, such as difficulty urinating, incontinence, or urinary tract infections.
- **Nerve-related issues**, including nerve injury, weakness, seizures, confusion, or chronic nerve pain.
- **Numbness** in certain areas of the body.
- **Pregnancy-related complications**, including miscarriage or birth defects.
- **Pain at or around the surgical site.**
- **In rare cases, death.**

Risks Associated with Lumbar Spine Surgery:

Lower-back surgery involves working around sensitive nerves, bones, and soft tissues. While the goal is to relieve symptoms and improve function, complications can occur. These may include:

- **Risks to Nerves and Spinal Tissues**
  - **Tears in the protective covering of the spinal cord (dura)**, which may cause spinal fluid leakage.
  - **Inflammation of spinal nerves** (arachnoiditis), which can lead to long-lasting pain.
  - **Nerve injury**, which may result in pain, weakness, numbness, tingling, changes in reflexes, or—rarely—partial or complete paralysis.
  - **Difficulty walking or problems with balance.**
  - **Cerebrospinal fluid leaks**
  - **Cerebrospinal fistulas**- abnormal fluid pathways.
  - **Chronic nerve pain syndromes**, such as Reflex Sympathetic Dystrophy (RSD).

- **Pain Symptoms**
  - New or worsening pain in the back or legs.
- **Injury to Surrounding Structures**
  - Damage to nearby nerves, blood vessels, muscles, or other tissues.
- **Muscle or Nerve Weakness**
  - Reduced muscle strength or decreased nerve function.
- **Bleeding or Tissue Changes**
  - Bleeding around the spinal cord, fluid buildup, or the formation of scar tissue.
- **Surgery at the Wrong Level**
  - In rare instances, surgery may be performed at a different spinal level than intended.
- **Bone Reactions**
  - Breakdown or loss of bone near the surgery site (osteolysis).
- **Loss of Bowel or Bladder Control**
  - Rare but serious nerve-related complications affecting bowel or bladder function.
- **Bone Fractures**
  - Fractures of the vertebrae or nearby bony structures during or after surgery.
- **Muscle and Tissue Discomfort**
  - Pain or soreness in muscles or soft tissues following surgery.
- **New Disc Problems Nearby**
  - Development of disc degeneration at levels adjacent to the treated area.
- **Scar Tissue**
  - Scar formation that may irritate or compress nearby nerves.
- **Spinal Instability**
  - The spine may become unstable, sometimes requiring additional treatment.

- **Post-surgical spondylolisthesis (vertebral slippage)**
  - Forward slippage of one vertebra over another
- **Retrolisthesis**
  - Backward slippage
- **Narrowing of the Spinal Canal**
  - Spinal stenosis, which can place pressure on the nerves.
- **Progressive Wear-and-Tear**
  - Ongoing age- or stress-related changes in the spine (spondylosis).
- **Bone or Soft Tissue Infection**
  - Infection in a vertebra or in the surrounding tissues.
- **Scar Tissue Around Nerves**
  - Excessive scarring (perineural fibrosis) that may affect nerve function.
- **Pain from Implants**
  - Discomfort related to any hardware used during the procedure.
- **Pain from the Surgical Approach**
  - Pain caused by moving or cutting muscles, ligaments, and tissues during surgery.
- **Changes in Spinal Alignment**
  - Loss of natural spinal curve, spinal height, or proper alignment, sometimes requiring further surgery.
- **Bone–Implant Reactions**
  - Poor bone response to an implant, leading to irritation or abnormal bone changes.
- **Instrument Issues**
  - Surgical tools may break or malfunction during the procedure, potentially causing injury to nearby tissues.

Risks Associated with Lumbar Spine Implants, including the DIAM™ Spinal Stabilization System:

Implants placed in the lower back are designed to help reduce pain and improve stability. However, as with any implanted device, complications can occur. These may include:

- **Material Sensitivity**
  - You may have an allergic reaction or sensitivity to the materials in the implant (PET fabric, silicone, or titanium).
- **Limited Benefit**
  - The implant or the surgery may not relieve symptoms or improve function as expected.
- **Pain or Discomfort**
  - You may feel pain or discomfort where the implant is placed.
- **Implant Position Issues**
  - The implant may be placed at a slightly incorrect angle or position, which could affect how well it works.
- **Sizing Challenges**
  - The implant may not fit your anatomy perfectly, leading to issues with size or placement.
- **Technical Difficulties During Surgery**
  - Occasionally, surgical tools or parts of the system may not work as expected, potentially lengthening the operation.
- **Placement Difficulties**
  - Your anatomy or surgical complexities may make the implant harder to position correctly.
- **Small Bone Fractures**
  - The bony area where the implant sits (spinous process) may fracture.
- **Bone Thinning or Bone Loss**
  - The bone near the implant may thin or weaken over time.

- **Bone Density Changes**
  - Reduced bone density may occur due to changes in how the implant transfers stress to surrounding bone.
- **Wear Debris**
  - Small particles from the implant may form over time and irritate nearby muscles, nerves, or soft tissues.
- **Reactions to Implant Materials**
  - The body may react to implant materials or debris, which can include inflammation or immune-related responses.
- **Deep Infection**
  - Infection can occur in the tissues around the implant.
- **Scar Tissue Formation**
  - Scar tissue may develop around the implant, potentially affecting comfort or nerve function.
- **Wrong-Level Placement**
  - The implant could be placed at the incorrect spinal level, though this is rare.
- **Implant Movement**
  - The implant may shift or move from its original position, reducing its effectiveness or causing irritation to nearby bones or nerves.
- **Need for Additional Surgery**
  - Further procedures may be needed to adjust, remove, or replace the implant.
- **Implant Wear or Breakage**
  - Over time, the implant may loosen, deform, break, or come apart, possibly requiring another operation

Risks Associated with the DIAM™ Spinal Stabilization System or Procedure Observed in the Clinical Study:

A clinical trial was conducted in the United States to evaluate patients with degenerative disc disease treated with the DIAM™ Spinal Stabilization System. In this study 182 subjects were implanted with the DIAM™ Spinal Stabilization System in the study group of the clinical trial. From the time of surgery and out to 2 years afterwards, study participants experienced problems that could be related to the patient's health, the surgical procedure, and the DIAM™ Spinal Stabilization System.

The following is a listing of adverse events (and associated rates) reported in the investigational subjects during the FDA study that were determined to be related to the DIAM™ Spinal Stabilization System implant itself and/or the procedure to implant the DIAM™ Spinal Stabilization System.

- Overall, 56 adverse events occurred in 52 patients (28.6%) that were determined to be likely related to the DIAM™ Spinal Stabilization System and/or the surgical procedure used to implant the device.
- Fourteen patients (7.7%) experienced superficial incision infection
- Eleven patients (6%) experienced incision related adverse events including pain on the incision site, delayed wound healing, erythema, bruising hematoma or rash
- Nine patients (4.9%) experienced prolonged postoperative conditions such as post-operative low back pain, tightness in chest, fever, ENT issue, tachycardia, low potassium or hyperglycemia

- Eight patients (4.4%) experienced a spinal event at the level at which the DIAM™ Spinal Stabilization System was implanted such as disc herniation/stenosis/ slip, spinous process fracture, spinous process bony erosion, hip and leg pain or low back pain with or without leg pain.
- Four patients (2.2%) experienced radiculopathy/ sciatica without back pain such as an event related to pinched or compressed nerve
- Three patients (1.6%) experienced back and/or leg pain (from back conditions)
- One patient (0.5%) experienced lower extremity pain
- One patient (0.5%) experienced a spinal event at a different level where the DIAM™ Spinal Stabilization System was implanted such a degradation of adjacent level
- One patient (0.5%) experienced a worsening pain and increased back pain
- One patient (0.5%) experienced an accidental injury / muscle strain
- One patient (0.5%) experienced a gastrointestinal disorder such as abdominal pain
- One patient (0.5%) experienced a respiratory issue
- One patient (0.5%) experienced a skin disorder

There were a total of 13 secondary surgeries in 12 (6.6%) patients treated with the DIAM™ Spinal Stabilization System in the first two years after treatment.

DIAM™ SPINAL STABILIZATION SYSTEM CLINICAL STUDY

A clinical study that was conducted at 23 sites in the United States showed that the DIAM™ Spinal Stabilization System is reasonably safe and effective for the treatment of moderate lumbar degenerative disc disease. The DIAM™ Spinal Stabilization System patients were compared to a group of patients who were treated with non-surgical care treatments. There were 182 subjects who were randomly assigned and treated with DIAM™ Spinal Stabilization System. Safety data are presented on these subjects. Demonstration of the effectiveness of the DIAM™ Spinal Stabilization System relied primarily on a subset of 144 DIAM™ Spinal Stabilization System patients who presented with back pain greater than leg pain prior to treatment.

Two years after surgery, 94.4% (136/144) of DIAM™ Spinal Stabilization System patients had no secondary surgical intervention. Further, two years after treatment a total of 77.0% (97/126) DIAM™ Spinal Stabilization System patients experienced clinically meaningful improvements in back pain related disability. (evaluated with Oswestry Disability Index) and 93.1% (134/144) of DIAM™ Spinal Stabilization System patients reported no treatment-related Serious Adverse Events

Two years after treatment, 83.2% (104/125) of DIAM™ Spinal Stabilization System patients experienced clinically meaningful improvements in back pain intensity (evaluated per Numerical Rating Scale).

For more detailed information about these studies and their outcomes, talk to your doctor.

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WHERE CAN I FIND OUT MORE INFORMATION?

If you have any questions about the DIAM™ Spinal Stabilization System, you may ask your doctor. For additional information, you may contact Companion Spine at custormerservice@companionspine.com.

You may also find additional information at www.companion-spine.com.

Changing spine care for good.

Date of publication of the current version of the Patient Labeling by Companion Spine: 2025-12-10
Edition (version) of the Patient Labeling: CS001E0013_2

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