

Dynesys[®] Dynamic Stabilization System:

An alternative to spinal fusion for the treatment of leg pain.



zimmer | spine
Confidence in your hands[®]

GLOSSARY

Adverse Effect: Negative consequence of medication or therapy.

Alignment: Proper Position.

Allergies: Sensitivities to foreign substances.

Anatomy: Parts of the body.

Anesthetic: A drug that eliminates or reduces pain.

Bladder: The organ in the body that collects and empties urine.

Bone Grafting Material: Substances used to promote bone growth.

Clinical Trial: A research study to determine the safety and/or effectiveness of a medical procedure.

Contraindication: A reason not to use a medical treatment.

Degenerative: A breakdown of tissue over time.

Disc: A fluid-filled jelly-like cushion between the vertebrae of the spine.

Disc Degeneration: The deterioration of a disc (Drying, thinning, wearing).

Dural Tear: A tear in the spinal cord lining.

Dynamic: The ability to bend or move.

Dynesys® Dynamic Stabilization System: A device attached in surgery to stabilize the spine without fusion.

Foraminal Stenosis: A narrowing of the bony window through which the spinal nerves pass.

Fracture: A break in a bone.

Fusion: The joining or healing of bones.

Hematoma: Collection of blood near an implant site.

Herniated Disc: A bulge or break (sometimes called a “ruptured disc”) in the outer portion of a disc.

Ileus: Blockage of the bowel (intestine).

Implant: An object placed in the body as part of a medical treatment.

Incision: A cut made during surgery.

Indication: A valid reason to use a medical treatment.

Infection: Invasion of germs in the body.

Invasive: Involving entry into the body (like surgery).

Osteomalacia: A softening of bone.

Osteoporosis: A condition causing bones to become fragile.

Pneumonia: An infection of the lung.

Polyethylene: A soft, yet durable plastic material.

Polyurethane: A clear, tough and durable plastic material.

Pulmonary Embolism: Blockage of an artery in the lungs.

Radicular Symptoms: Sensations such as pain in the arms or legs. Sensations may also include muscle weakness, numbness and tingling.

Retrolisthesis: A term which refers to a vertebra which has moved backwards relative to the vertebra below.

Scoliosis: An abnormal curvature of the spine.

Spinal Fusion Surgery: A surgical treatment to stabilize the vertebrae or other bones of the spine until they can grow together.

Spine: The bony column from the base of the skull to the tailbone.

Spondylolisthesis: Abnormal or excessive movement of the vertebrae (commonly known as a “slipped disc”), which may cause pain in the lower back or leg.

Stabilization: A reduction or control of abnormal or excessive movement.

Stabilize: To reduce or control abnormal or excessive movement.

Stenosis: A narrowed space in the spine that presses on a nerve.

Stroke: Death of brain cells caused by inadequate oxygen to the brain.

Titanium Alloy: A metal material containing a mixture of titanium and other chemical elements.

Urinary Tract: The organs of the body that produce and release urine.

Vertebra: One of thirty-three bones that form the spine.

Vertebral Segment: The location of one specific vertebra on the spine.

Wound Dehiscence: The splitting or reopening of a wound.

DYNESYS®

THE DYNAMIC STABILIZATION SYSTEM FOR THE SPINE



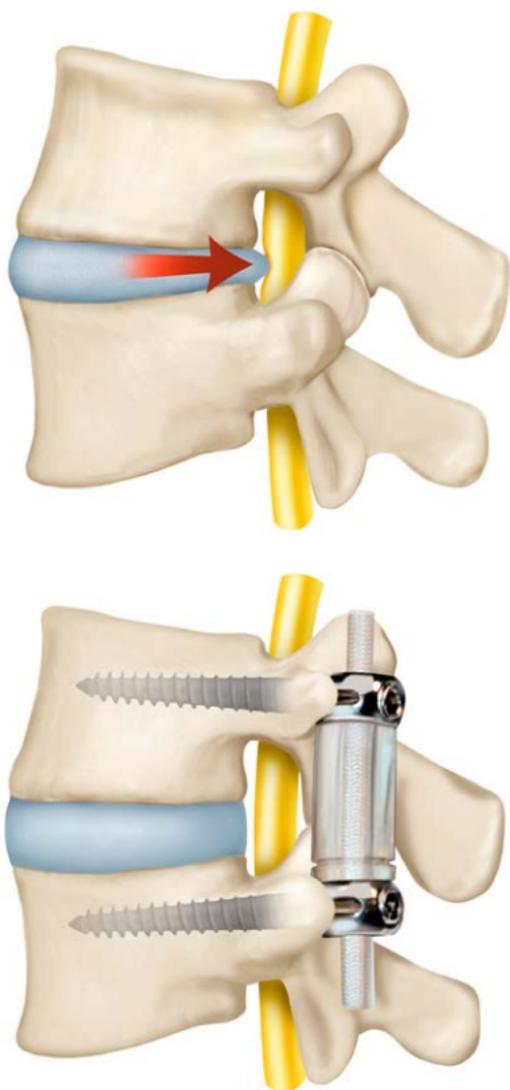
Your doctor may recommend the *Dynesys* Dynamic Stabilization System to treat your radicular symptoms (leg pain, muscle weakness and sensation abnormalities). Your doctor's recommendation will be based on the findings of your examination. Treatment with the *Dynesys* System may help you return to normal daily activities with less pain. Speak to your doctor to learn more about your condition and how the *Dynesys* System might help you.

This brochure is designed to help you understand more about the *Dynesys* System. A Glossary of Terms has been included to help you understand some of the medical terms. You should discuss all options with your doctor before making a treatment decision.

WHAT IS THE DYNESYS DYNAMIC STABILIZATION SYSTEM?

The *Dynesys* System is a device used to treat radicular symptoms caused by common conditions of the spine. These conditions include spinal stenosis, and spondylolisthesis.

The *Dynesys* System consists of titanium alloy screws and spacers made of flexible plastic tubing (polyurethane) that surrounds a nylon-like cord (polyethylene).



HOW IS THE DYNESYS SYSTEM DIFFERENT THAN TRADITIONAL SYSTEMS?

Traditional spinal fusion surgery has been the main surgical choice for many years. Traditional spinal fusion generally includes removal of the affected discs and fusion of the vertebrae using rigid rods, screws and bone grafting material. The result is stopping any motion in the area. The *Dynesys* System uses flexible materials to preserve and stabilize the parts of the spine without fusion.

WHAT HAPPENS DURING SURGERY?

The surgery involves placing the device through an incision in the back. The *Dynesys* System is attached to both sides of the affected vertebrae. The push-pull relationship between the spacers and the cord helps to stabilize the vertebrae. This lessens unwanted motion in the spine without the need for fusion.

Cord:

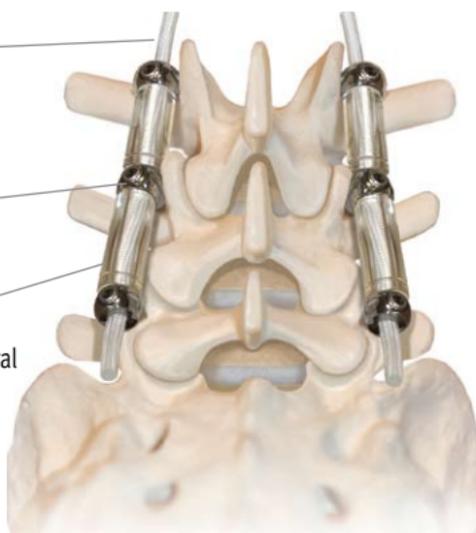
Limits bending movements

Pedicle Screw:

Anchors the *Dynesys* Device in the pedicles

Spacer:

Holds the segments in a more natural anatomical position



HOW IS THE DYNESYS SYSTEM USED (GENERAL INDICATIONS FOR USE)?

The *Dynesys* System is used to treat patients with radicular symptoms when caused by:

- Forward or backward movement (slipping) of one vertebrae on another (spondylolisthesis or retrolisthesis)
- Narrowing of the spinal canals (stenosis)

These patients must have fully developed bones. Placement of the *Dynesys* System works by providing stability at one or two levels of the lower spine.

WHEN SHOULD THE DYNESYS SYSTEM NOT BE USED (CONTRAINDICATIONS)?

Your doctor may decide that the *Dynesys* System is not appropriate if:

- Most of your pain is caused by a diseased disc
- You have a curve of the spine (scoliosis) of greater than 10 degrees
- You have known allergies to titanium alloy or to polymers (plastics)
- You have fractures (breaks) in the affected vertebrae
- You have noticeable bone loss or a severe decrease in bone mass (advanced osteoporosis)
- You are pregnant

WHAT WARNINGS APPLY TO THIS DEVICE?

Warnings for the *Dynesys* System will be considered in two groups:

1. Before Surgery, the *Dynesys* System should not be used in people having known allergies to its contents.
2. After Surgery, patients should carefully follow the treatment plan of the doctor. This includes any activity restrictions that are recommended.

WHAT ARE THE RISKS, BENEFITS AND PRECAUTIONS?

The *Dynesys* System was created to give spine surgeons another choice for treating conditions of the lower spine. The *Dynesys* System should only be used if all other options have been considered (this is true for any spine system). While there can be no guarantee of success, the benefits of the *Dynesys* System may include:

- Pain relief
- Return to normal daily activities
- Stabilization of affected vertebrae without fusion
- Sparing much of the anatomy of the spine
- Potential for a less invasive procedure

It is expected that the risks, complications, and precautions of the *Dynesys* System will be similar to those of other spinal systems. The following is a list of complications that could occur during or after surgery. These complications may require more medical attention and possible removal of the system.

Complications may include:

- Metal and plastic allergic reactions are rare, but have been reported. Tell your doctor if you have any allergy symptoms.
- Any implant is subject to unavoidable wear and aging. Wear, aging, and loosening can lead to the need for another operation.
- A broken implant is rare, but has been reported. It is important to follow medical instructions to avoid possibly breaking your implant.
- Infection can occur after any type of surgery. Preventing or managing infection is important to the success of the surgery. Tell your doctor if any symptoms of infection occur. These may include localized pain, redness near the surgical site, increased temperature near the surgical site, or increased overall body temperature. Infection usually requires treatment and can lead to failure of the implant or the need for removal.

HAS THIS DEVICE UNDERGONE CLINICAL STUDIES?

A study consisting of 367 patients was conducted in the United States. The *Dynesys* System was compared to a standard screw and rod system with fusion. This was done to determine the safety and effectiveness of the *Dynesys* System.

At 2 years after surgery:

- 87% of the patients who received the *Dynesys* System without fusion experienced a significant reduction in leg pain. 73% of the patients that received the standard rod and screw system with fusion experienced a significant reduction in leg pain.
- 76% of the patients who received the *Dynesys* System without fusion had a significant increase in their daily functioning. 70% of patients that received the standard rod and screw system with fusion had a significant increase in their daily functioning.
- 8% of the patients who received the *Dynesys* System without fusion reported increased radicular symptoms. 16% of patients that received the standard rod and screw system with fusion reported increased radicular symptoms.
- 9% of the patients who received the *Dynesys* System without fusion required additional surgery. 11% of the patients who received the standard rod and screw system with fusion required additional surgery.
- 0.4% of the patients who received the *Dynesys* System without fusion had a major complication. 0.9% of the patients who received the standard rod and screw system with fusion had a major complication.

WHAT COMPLICATIONS MIGHT OCCUR DURING SURGERY OR LATER (ADVERSE EFFECTS)?

Complications occurring in this study of the *Dynesys* System were similar to those reported in other rod and screw systems on the market. The following is a list of complications reported in the 253 patients who received the *Dynesys* System:

<u>Complication</u>	<u>% Reported</u>
Allergic reaction	2%
Anesthetic complication	0.4%
Bladder complication	1.2%
Disc herniation	1.6%
Tear in spinal cord lining (dural tear)	9.9%
Heart attack	0.4%
Collection of blood near the implant site (hematoma)	0.4%
Blockage of the bowel (ileus)	2.4%
Implant movement (migration)	0.4%
Increased spine instability	0.4%
Infection at implant site	1.6%
Urinary tract infection	1.2%
Pneumonia	1.2%
Blockage of an artery in the lungs (pulmonary embolism)	0.8%
Stroke	0.4%
Wound dehiscence (splitting open)	1.2%
Back pain	18.6%
Leg pain	12.3%
Foraminal stenosis	0.4%
Hip pain	0.4%
Urinary problems	0.8%
Disc degeneration	2.4%
Central stenosis (narrowing of the spinal canal)	0.8%
Back and leg pain	18.6%
Vertebral fracture	1.6%
Screw failure	1.6%
Screw misplacement	0.8%

*There are risks associated with any surgery. Please consult with your doctor regarding potential surgical complications.

WHAT MIGHT INCREASE THE RISK OF FAILURE?

- Patients who are unable or unwilling to follow instructions given by medical professionals
- Noticeable bone loss or a severe decrease in bone mass (osteoporosis)
- Softening of the bones (osteomalacia)
- Metal and plastic allergies
- Infection

WHAT IS MY ROLE AS A PATIENT?

There will be limits in your activity after surgery. You may be instructed to limit your activity for a period of time. This might include limiting how much you can lift and carry. Your doctor may also ask you to wear a back brace for a period of time. You will gradually increase your activity level over a period of weeks as instructed by your doctor.

Please read and obey any instructions given to you by your doctor or health care professional.

WHEN SHOULD I CONTACT MY DOCTOR?

When any of the following occur *or* as your doctor instructs:

- Redness, swelling, or drainage from the incision
- Any unexplained fever (temperature over 100 degrees Fahrenheit or 38 degrees Centigrade)
- Chills that last more than a day
- Severe pain that is not relieved by pain medication
- A feeling that “something isn’t right”
- Any shortness of breath
- Any chest pressure
- Increased numbness, tingling, or muscle weakness

WHAT OTHER TREATMENT CHOICES DO I HAVE?

Treatment choices depend on your situation. The use of other products or nonsurgical treatments may be options. Nonsurgical options may include reduced activity or the use of pain medications. Other choices may include medical treatments that do not involve the use of an implant.

WHAT ABOUT MY SPINAL IMPLANT AND AIRPORT SECURITY?

Any metal implant may be detected by electronic security devices at airports. Implant identification (ID) cards are not required, but may speed the inspection process. Ask your doctor if you qualify for an implant ID card.

Disclaimer

Information presented in this brochure is of a general nature and has been thoroughly researched and prepared closely with medical professionals, physical therapists and afflicted individuals. The information provided herein may not be applicable to all patients and cannot substitute the advices that you need to obtain from your doctor with regard to the special circumstances which may apply to your particular cases, together with the associated risks and limitations.

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