Seeking Patients for Back Pain Study

DIAM™ Spinal Stabilization System
vs.
Conservative Care Therapies

Wayne Cheng, MD

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Medtronic

listen. respond. deliver.

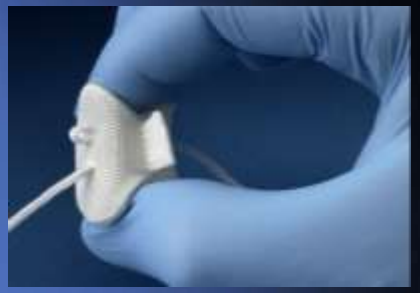
What is the DIAM™ Spinal Stabilization System?

- A viscoelastic interspinous spacer
- Surgically placed between the spinous processes of the affected spinal level
- Designed to stabilize movement in flexion and extension

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Where is the DIAM™ Device being used?

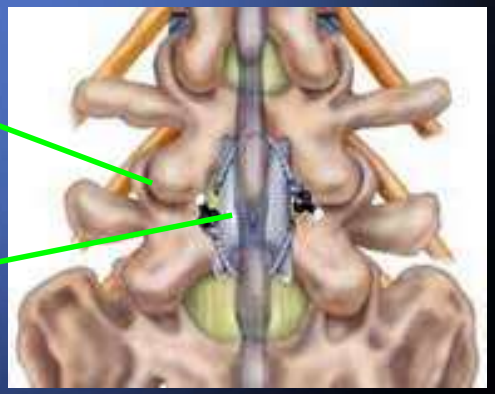
- First implanted in France in 1997
- Has been used for 10 years outside the United States
- Not yet approved for use in the U.S.
- Currently in three multicenter, randomized clinical trials studying:
  - Degenerative disc disease associated with mostly back pain (U.S.)
  - Stenosis associated with mostly leg pain (U.S.)
  - Herniated disc associated with long history of low back pain (Europe)



Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Design Goals of Interspinous Spacers

- Stabilize movement in spinal flexion and extension (backward and forward bending)
- Reduce pressure on the posterior disc
- Restore proper alignment at the affected spinal level and offloads the facets



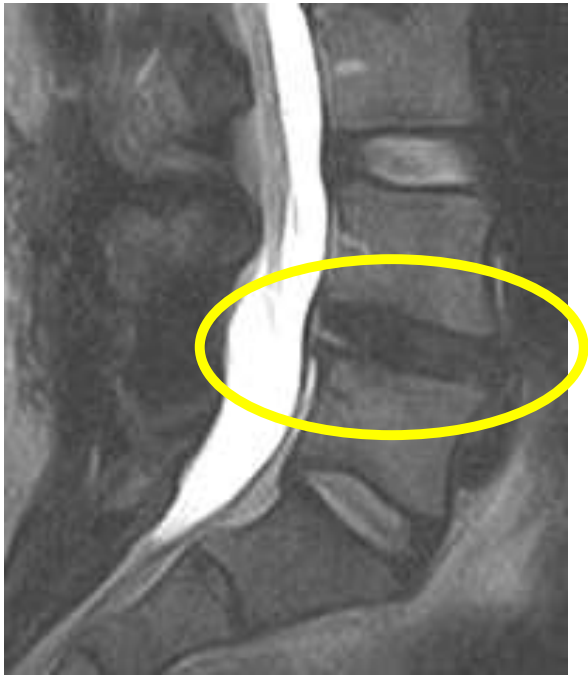
Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Medtronic

listen. respond. deliver.

Potential DIAM™ Device Study Patient

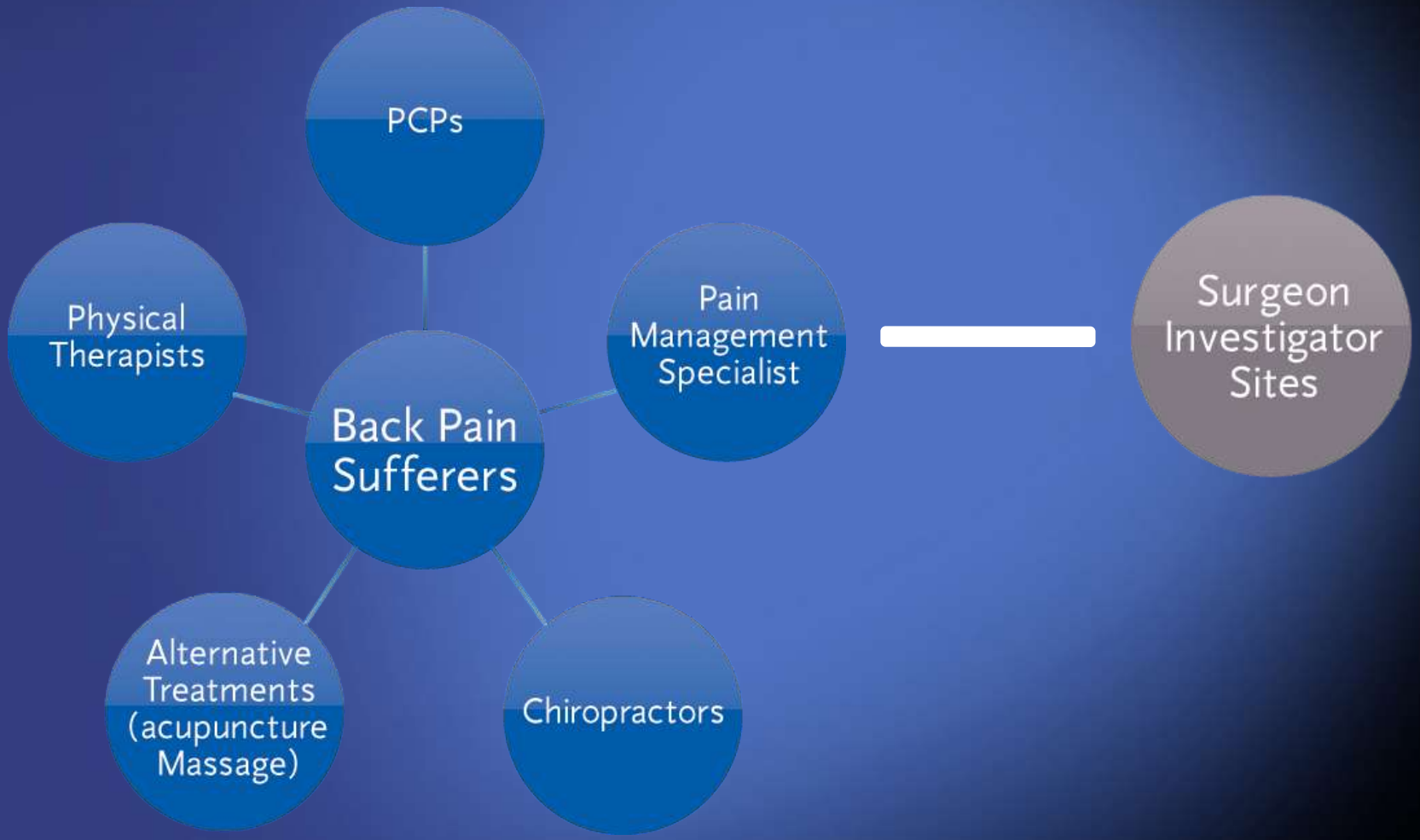
- Back Pain with or without leg pain
- Symptomatic – this episode < one year
- Single-level DDD – radiographic evidence of dark disc or facet arthropathy
- Single level between L2-L5
- No gross instability



Source: Dr. Jean Taylor

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Current physician referral pattern



Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Why should I refer one of my patients?

- Concerns / Questions
  - I'm giving up my patient!
  - What about lost revenue?
  - Can I still be involved in their care?
- Answer: Your patient gets:
  - All indicated conservative care treatments, and their current pain doctor can administer them
  - Crossover to DIAM™ Device if they fail conservative treatment in control group and still meet the inclusion criteria
  - Fusion option if they do not meet DIAM™ Device criteria

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Study Design

Patient meets the criteria for the study

Patient agrees to participate and is enrolled

Patient is randomly selected to receive one of the two treatment options

DIAM™ DEVICE GROUP 204 Pts	**CONTROL GROUP 102 Pts**
SURGERY	CONSERVATIVE CARE

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Medtronic

listen. respond. deliver.

Conservative Care Treatment

Medication

Active Physical Therapy

Patient Education

Injections

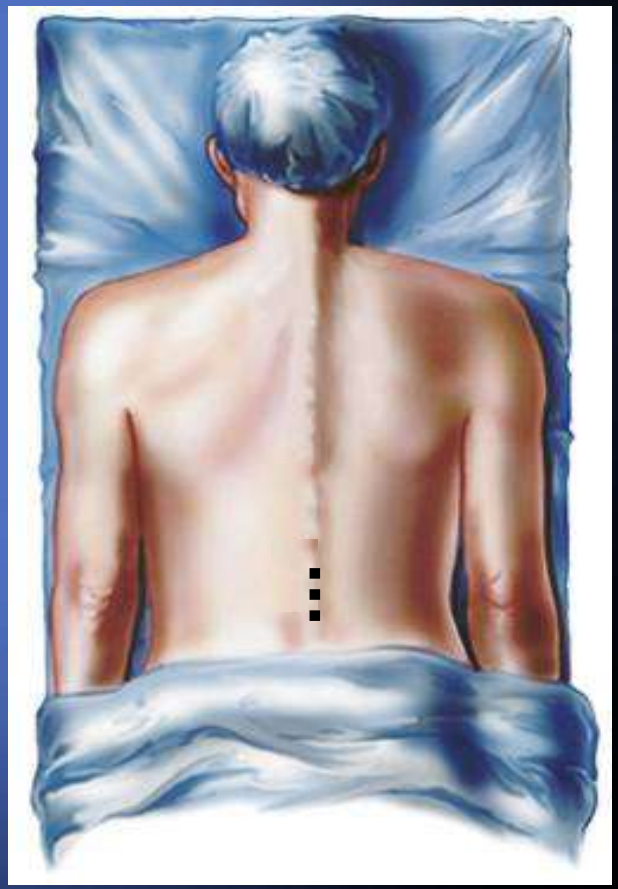
Control patients receive a six-month regimen consisting of a combination of the four treatment options described above. If after six months the patient is no better, they have the ability to cross over to the surgical treatment option.

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Investigational Group

The DIAM™ Spinal Stabilization System Procedure

- The procedure is performed under general anesthesia
- The patient is positioned prone, or face down
- A small incision is made to provide access to the affected level of the lumbar spine

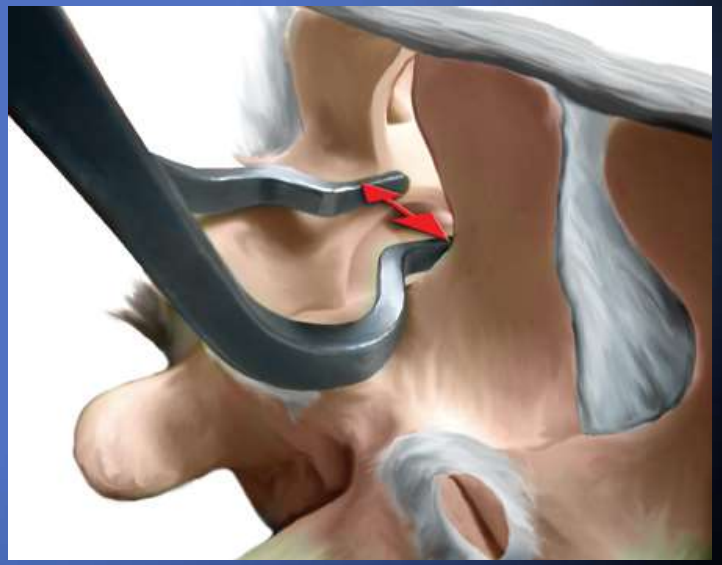


Caution: Investigational device, limited by Federal (or United States) law to investigational use.

The Procedure

Approach and Distraction

- Surgical instruments are used to gain access to the space between the spinous processes at the affected level
- The space is opened and stretched to re-establish normal distance between the spinous processes

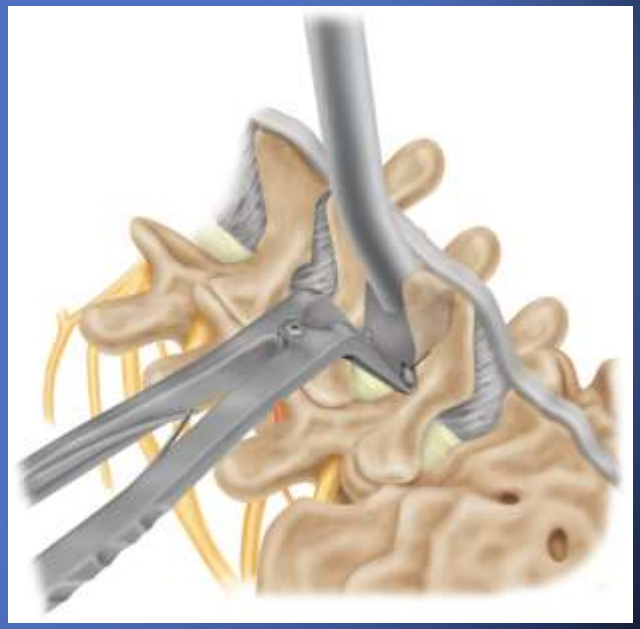


Caution: Investigational device, limited by Federal (or United States) law to investigational use.

The Procedure

Measuring for Device Size

- Measurement trials are used to select the proper DIAM™ Device size



Caution: Investigational device, limited by Federal (or United States) law to investigational use.

The Procedure

Placement of the DIAM Device

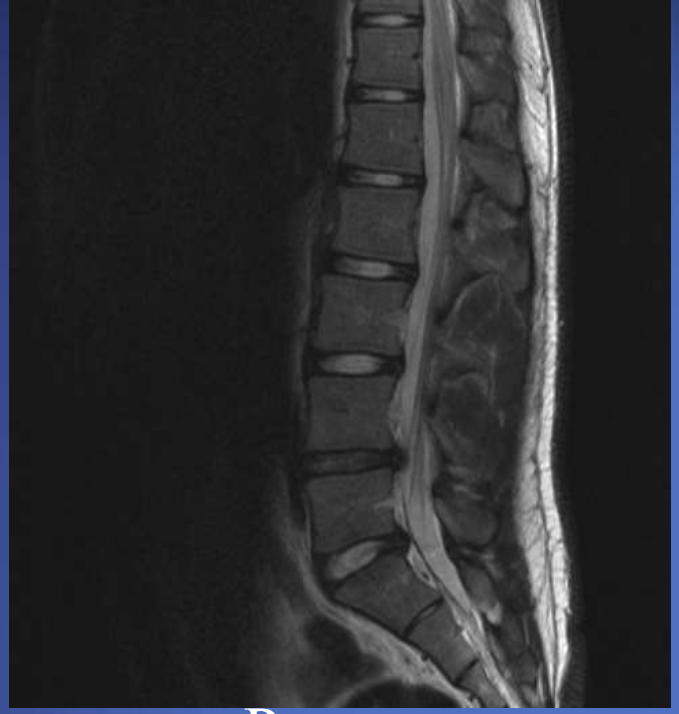
- The DIAM™ Device is placed in the space between the spinous processes

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

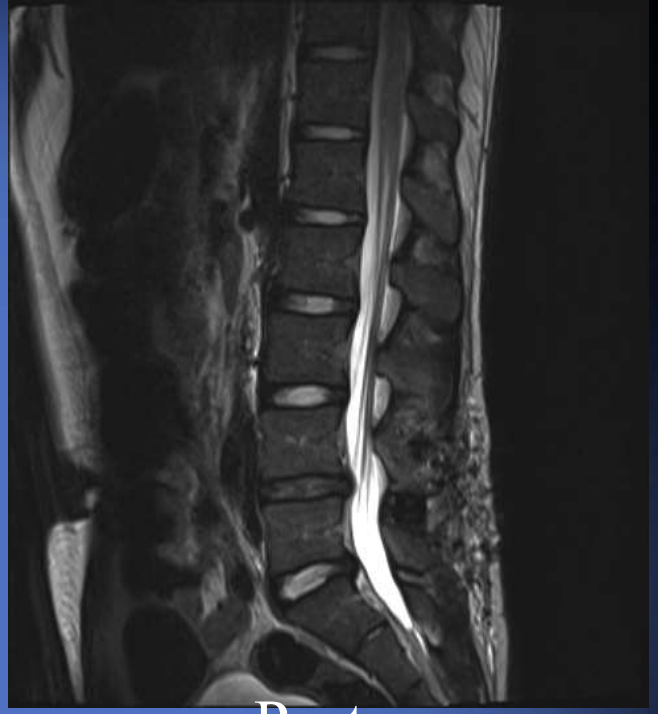
Finishing the Procedure

- The DIAM™ Device is secured to the adjacent spinous processes by means of the tethers
- The incision is closed
- The hospital stay is usually one to two days

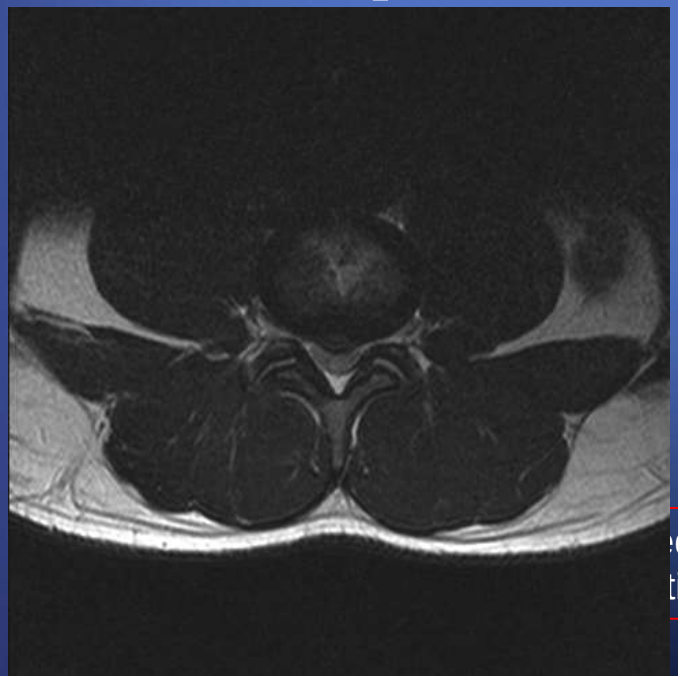
Caution: Investigational device, limited by Federal (or United States) law to investigational use.

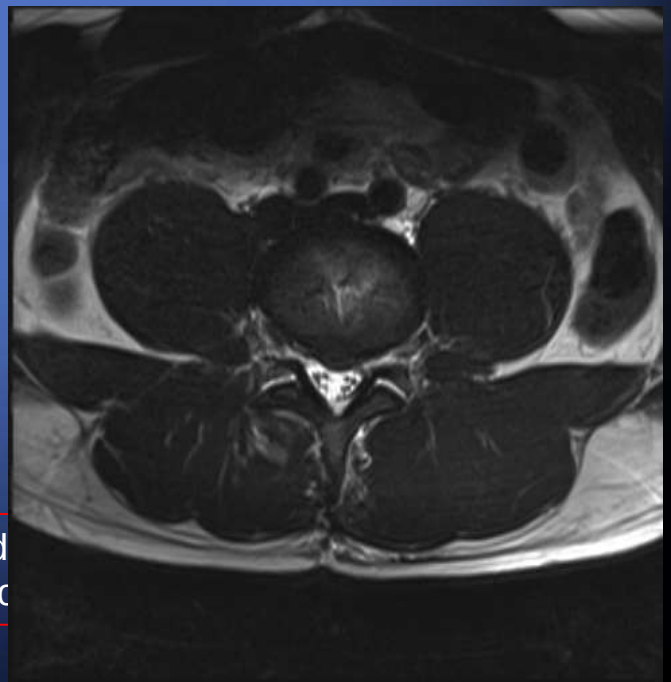


Pre op



Post op





Medtronic

I think I have a potential patient; what now?

- Contact our office
- Liz. will schedule an office visit
- If the patient qualifies, they will be randomized to receive the investigational device (DIAM™ Device) or conservative care

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

THANK YOU

Caution: Investigational device, limited by Federal (or United States) law to investigational use.

Medtronic

listen. respond. deliver.