

## X STOP® Fact Sheet

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X STOP® is a new, less invasive treatment for a common back disorder called spinal stenosis. The X STOP® IPD (Interspinous Process Distraction) is a small device that corrects the root cause of spinal stenosis — the pinching and pressing of nerves.

FDA trials have proven that for many spinal stenosis patients, the insertion of the X STOP® IPD is safe and effective in treating spinal stenosis. It is less costly than traditional surgeries, relieves symptoms effectively, and does not require the hospitalization of major surgery. The X STOP® usually allows a patient to be back on their feet the same day as surgery, unlike previous surgical treatments. This fact sheet will answer some of the basic questions you might have about the disorder and this new treatment.



## **1. What is spinal stenosis? What causes it?**

The spine is a column of 24 bones called vertebrae, which join together like links in a chain, extending from the skull to the hips. Between each vertebrae are discs of soft tissue that act as cushions. The spine provides support for the head and body, and also encloses and protects a cylinder of nerve tissues inside a tunnel called the spinal canal.

As we age, the ligaments and bone that surround the spinal canal can thicken, which narrows the spinal canal itself. This crowds the spinal cord and nerve roots, creating pinching and constriction, which results in pain and numbness in the back and legs. The condition of narrowing is called spinal stenosis.

Spinal stenosis is occasionally the result of genetics, but more often is simply a by-product of aging and “wear and tear” on the vertebrae and ligaments. It is estimated that 400,000 Americans are affected each year by spinal stenosis.

## **2. What are the symptoms of spinal stenosis?**

Symptoms vary, but the most common signs of spinal stenosis include:

- Dull or aching back pain that spreads to the legs
- Numbness and “pins and needles” in the legs, calves or buttocks
- Weakness or a loss of balance
- Decreased endurance for physical activities

Typically, the symptoms increase after walking for a predictable distance or standing for a certain period of time. The pain and numbness can be relieved by sitting, bending forward, lying down or putting the foot on a raised rest.

When spinal stenosis is suspected, the diagnosis is confirmed through a series of techniques that may include an extensive patient history and physical examination, and tests such as X-ray, MRI, CAT or Myelogram (a dye injection that highlights the spinal cord and nerves on X-ray film.)

## **3. What are the traditional non-surgical treatment options?**

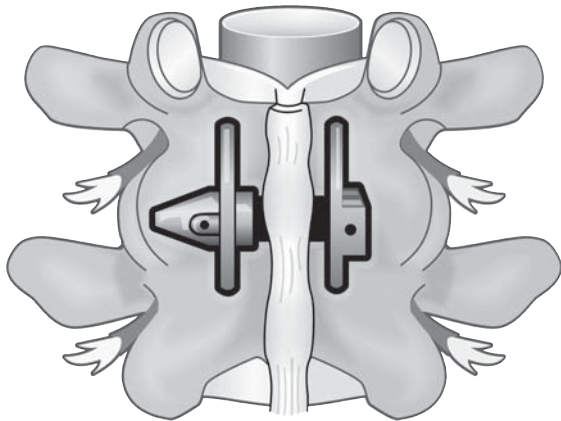
Treating spinal stenosis without surgery is almost always the first course of action. Such treatments include:

- Medications such as non-steroidal anti-inflammatory drugs (NSAIDs) to reduce swelling, and analgesics to relieve pain.
- Corticosteroid injections (epidural steroids) which reduce swelling and treat acute pain radiating to the hips or legs.
- Rest or restricted activity
- Physical therapy and/or prescribed exercises to help stabilize the spine and increase flexibility.

#### 4. What are traditional surgical treatments?

Traditional surgery to address spinal stenosis involves a major procedure under general anesthesia. There are four approaches:

- **Decompression:** Decompressive laminectomy, also called “unroofing” the spine, involves the removal of various parts of the vertebrae, attached ligaments and enlarged facets and bulging disc material.
- **Laminotomy:** A small portion of the lamina (surface) is removed to relieve pressure on the nerve roots.
- **Faraminotomy:** The opening where the nerve roots exit the spinal canal is enlarged to increase space for the nerves.
- **Medial Facetectomy:** Part of the facet is removed to increase space for the nerves.



#### 5. What is surgical treatment with IDP (Interspinous Process Distraction)?

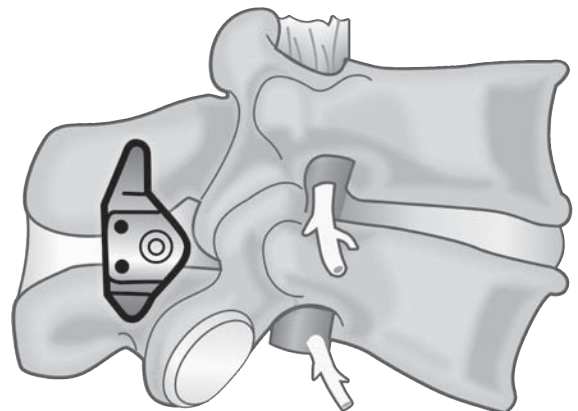
##### Who qualifies?

The IPD device (X STOP®) is inserted between vertebrae under local anesthesia. The device holds the vertebrae in a position that relieves pressure on the nerve canal (distraction.) There is no removal of bone or tissue and the device does not fuse to any bone structures. These factors make the procedure fully reversible and there are no limitations placed on future surgical or non-surgical treatment options.

The IPD treatment is only appropriate for patients with one or two vertebrae involved in their spinal stenosis, as a maximum of two devices can be inserted into the spinal column.

#### 6. What is the X STOP®?

The X STOP® is a small “thumb” of titanium, attached to a mount, which fits to a vertebrae in the lower back. It is not fixed to the bones, and does not fuse, but is instead held in place by tab-like “wings.” The X STOP® acts as a wedge to lift the bone and hold the nerve tunnels open, freeing the nerve from constriction and reducing the pain and numbness associated with spinal stenosis.





**7. What are the benefits of IPD?**

IPD is a simpler, minimally invasive procedure that can be performed on an outpatient basis. Recovery is quicker and typically no hospitalization is required. It is less costly than traditional surgery, and equally effective in most patients.

**8. How is IPD performed?**

Most IPD surgery patients will not require hospitalization, and the procedure can be performed in either the operating room or a special procedures room at the hospital. It is done under local anesthesia with the patient lying on his or her side. During the 45 to 90 minutes the procedure takes, the patient is awake and able to communicate with the surgeon. For most patients, there is little, if any, pain or discomfort.

**9. Who is not recommended for IPD?**

As previously mentioned, IPD is only appropriate for patients with one or two vertebrae involved in their spinal stenosis. Only two X STOPS® can be used in the spinal column. Other factors may also play into the decision on treatment, and Dr. Nowacek can explain all treatment options.

**10. When did the treatment receive FDA approval?**

The FDA approved use of the X STOP® in the United States in November, 2005. The device has been previously available in Europe and Japan, and about 4,000 X STOP® devices have been implanted around the world.

