

TREATMENT OF SPINAL CANAL STENOSIS



PATIENT INFORMATION BOOKLET

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Dear Patient,

This brochure is intended to inform you of a treatment option for narrowing of the spinal canal, often called spinal canal stenosis, or just stenosis, and usually found in the region of the lower lumbar spine. We hope the Booklet will help inform you in more depth about this procedure, and enable you to make an informed decision on whether you believe it is for you, and why your Surgeon has recommended it for you.

The information given here is general in nature, and we therefore strongly advise each patient to talk to one's family doctor to obtain more detailed information as well as individual advice.



"G" Device - Interlaminar Implant

Dynamic stabilization with the "G" Device implant in the treatment of narrow lumbar spinal canal: The Device helps to support and stabilise the immediate area after decompression Surgery or it can just be used as a spinal support to assist in maintaining the normal extension of the spine, and help to alleviate pressure on exiting nerve roots.

The advantages of the "G" Device over other similar devices is that it can be Implanted at L5/S1. It is shorter with a curved base to allow this particular level to be dealt with, and this design feature allows it to be implanted lower in the interspinous space, making it generally more stable and more secure and allowing for more defined distraction. In addition as you can see, the device has clearly defined "teeth" to give it this increased stability in situ.



THE SPINE

Stabilisation

One of the principal tasks of the spine is to stabilise the head and upper body, which enables us to walk upright. The main burden for this support falls on the vertebrae to supply this central support. Their structure gives them particularly good resilience and resistance against fractures possibly caused by serious external forces applied for whatever reason. For example when jumping, climbing, skiing or even walking. The soft tissues associated with the spine (muscles, ligaments, tendons) and the joints; contribute to dynamic stability or limiting the impact of twisting forces at any one single point.

Mechanical Protective Function

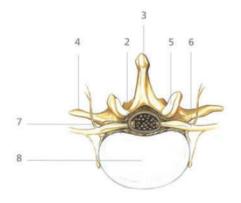
The lumbar spine is composed of five vertebrae. A vertebra consists of a vertebral body, a vertebral arch along with its facet joints, and transverse processes. The vertebral body and vertebral arch form a channel through which the exiting spinal nerves run and are protected from external impact. This channel is called the FORAMEN.

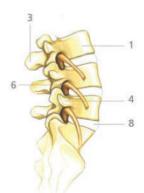


Shock Absorption and Mobility

The vertebral discs, or "Shock absorbers", are inbetween the vertebral bodies to buffer the force of an impact. Along with the facet joints, they enable the body to flex during turning, stretching and bending movements. The vertebral disc consists of an outer fibrous ring and a central cushion called the Nucleus Pulposus. The use of a "G" Device, often in conjunction with decompression, is to try to regain support in the area of the disc, and to attempt to take the strain off localised soft tissues and to open the exiting nerve root canal to relieve pressure, and thus reduce or remove pain.

- 1 Vertebral body
- 2 Vertebral arch
- 3 Spinous process
- 4 Transverse process
- 5 Facet joint
- 6 Nerve root
- 7 Spinal canal
- 8 Intervertebral disc





SPINAL CANAL STENOSIS

Lumbar Spinal Canal Stenosis

The spinal cord runs through the vertebral, or spinal canal and the spinal nerves exit from there. In the case of hereditary or degenerative narrowing of the lumbar spinal canal, the foramen, or space enclosed by the vertebral arch is often considerably reduced. Spinal nerves and emerging nerve roots become subject to pressure, causing sciatica, which manifests itself in radicular or leg pain.

Symptoms

Symptoms manifest themselves in different ways, depending on the site and extent of the foraminal stenosis. They include pain, abnormal sensations, and occasionally drop foot along with total leg numbness in extreme circumstances. One of the characteristics of lumbar spinal stenosis is a noticeably shortened stride due to the onset of symptoms. Sometimes such severe discomfort from stenosis occurs during walking, which radiates pain to the buttocks and the legs, and this pain can be so debilitating as to force the person to stop, and stand still. Often it is possible to take only a few steps. The discomfort is relieved by bending forward, sitting down, or lying down since the movements widen the spinal canal. So, for example, cycling is often no problem at all. But if you bend your spine downwards, you create additional narrowing of the canal and the pain will actually increase.



Cause

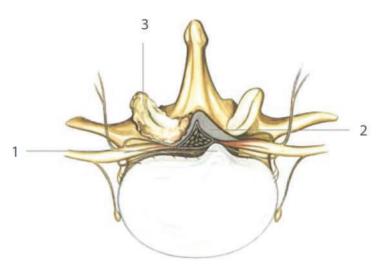
There are many possible causes that may give rise to spinal canal stenosis. It often happens that several factors come together to promote wear and tear (degenerative changes), for example:

- 1. Degenerative changes give rise to bony spurs and bony outgrowths on the vertebrae. These osteophytes or spikes of bone can extend in the direction of the spinal canal and occlude or put pressure on it.
- 2. Degenerative changes in the spinal ligaments such as the posterior longitudinal ligament over a lifetime lead to thickening of these ligaments. The foraminal space inside the vertebral arch can also be narrowed in this way.
- 3. If spinal osteoarthritis occurs, the facet joints can enlarge to the extent that they project into the spinal canal.
- 4. A disc herniation or disc protrusion reduces the diameter of the spinal canal. These changes often occur together and cause spinal canal narrowing. It is possible that permanent nerve injury may occur due to the constant pressure exerted on the nerves by the narrowed spinal canal.

Healthy Spinal Canal



Narrowed Spinal Canal



- 1 Disc protrusion
- 2 Yellow ligament thickening
- 3 Facet joint osteoarthritis/osteophytes



Treatment

"Decompression surgery" releases pressure on irritated and inflamed nerves. The extent of the required operation depends on any particular conditions encountered in each patient. The vertebral arch or foramen, bony spurs, thickened ligaments and joints, and herniated or prolapsed disc tissue can be systematically pared away at one or more adjacent spinal segments. Prevention of recurrence of spinal canal stenosis requires decompression of the affected areas of the spinal column and sufficient stabilization to maintain flexibility. Hence the "G" Device.

A small operation with a big result – this is a well recognised treatment for stabilization of the spinal column with the "G" Device – but there have already been thousands of successful procedures. The "G" Device offers a procedure which is much less invasive and simple for both Patient and Surgeon, and which can offer greatly improved function and pain relief in both the short and long term. Every Patient is different.

The "G" Device implant was designed for functional dynamic stabilization of the spinal column after decompression surgery.



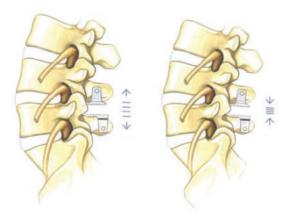
The "G" Device implant focuses on three important factors:

1. Stabilization

The result of a decompression operation results in a possible loss of stability in the spinal column, dependant upon the level of decompression required, and because a level of the bony structures and spurs must be removed to achieve relief of the exiting nerve roots. This loss can be compensated for through the insertion of a "G" Device implant, and it also ensures that the proper height of the segment will be maintained. The vertebral joint is effectively decompressed and nerves which were previously irritated are now protected.

2. Maintenance of Mobility

In addition to stabilization, maintenance of function (or mobility) is also very important to prevent the advance of the degenerative process into the adjacent spinal segments. The "G" Device implant allows itself to be compressed if you bend backwards and in this way it is functionally dynamic.



3. Less-invasive Treatment

The "G" Device implantation procedure is performed in a less-invasive manner whilst also permitting the surgeon to maintain precision and accuracy. The "G" Device implant is made of a very resilient titanium alloy; the implant material has excellent biocompatibility and has been implanted safely for many years.



THE OPERATION

Decompression

The operation requires general anaesthesia. First, the exact location of the spinal canal stenosis is determined by x-ray and the skin incision is defined. Next, the skin is incised and the muscles of the back are retracted to either side, allowing the spinal canal to be cleared of osteophytes and bony spurs. The next step involves decompression of the irritated and inflamed nerve fibres. This involves the surgeon removing and paring away all bone, joint, ligament or disc segments that are narrowing the spinal canal.

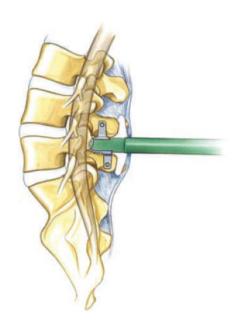
Implant Selection

Once the spinal canal is cleared and the exiting nerves are decompressed, the surgeon chooses the appropriate implant for insertion. He measures the distance between the spinous processes with a trial implant and determines the correct size of implant needed.



Implant Insertion

The "G" Device implant is inserted between the adjacent spinous processes providing a level of distraction, support and relief. The "G" Device, although similar to several other devices currently available, has many advantages over them. The Device is slightly shorter and the tip angled upwards to enable deeper Implantation at any level, but also offers the ability to safely Implant at the L5/S1 Junction, which many other devices fail to achieve.



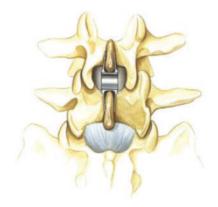
Final situation after implantation

View from the side



Final situation after implantation

View from above



Once decompression of the irritated and inflamed nerve fibres is complete, the "G" Device implant will permanently stabilize the spinal column.

Maintenance of the function is now ensured.



What happens after the operation?

Although the pain in one's back and at the wound site after surgery can be uncomfortable, there are many pain remedies available that will usually relieve the discomfort, and your anaesthetist will advise you accordingly. The implant is immediately ready to bear weight and also stabilizes the spinal column. You will usually be able to stand immediately after the operation. During the first weeks after surgery you should generally avoid severe stress on the spine through heavy lifting, twisting and/or leaning backwards. This will speed up the healing process for the implant.





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