



## Welcome to the Inion Spine Patient Education Site:

Surgical procedures and surgery can be a frightening prospect for many patients and this is why we hope to offer a good insight into the type of injury, some possible solutions and how Inion® implants and technologies can help.

It is always extremely important for you to find out as many details as possible about your problem, the available methods of treatment for that condition, and any particular surgical method your physician may recommend for you.

### The Spine:

To best understand your surgery, it is important that you learn as much about the spine as you can. The spinal column surrounds and protects your spinal cord. Your spinal column is made up of 24 vertebrae (bones), plus the sacrum and the tailbone (coccyx). Each vertebra is separated by shock-absorbing discs. These discs give your spine flexibility to move and bend. Nerves branch out from your spinal cord and pass through openings in these vertebrae to other parts of your body.

Your neck is part of a long flexible column, known as the spinal column or backbone, which extends through most of your body. The cervical spine (neck region) consists of seven bones (C1-C7 vertebrae), which are separated from one another by intervertebral discs. These discs allow the spine to move freely and act as shock absorbers during activity.

Attached to the back of each vertebral body is an arch of bone that forms a continuous hollow longitudinal space, which runs the whole length of your back. This space, called the spinal canal, is the area through which the spinal cord and nerve bundles pass. The spinal cord lies in cerebrospinal fluid (CSF) and is surrounded by three protective layers called the meninges (dura, arachnoid, and pia mater).

At each vertebral level, a pair of spinal nerves exit through small openings called foramina (one to the left and one to the right). These nerves serve the muscles, skin and tissues of the body and thus provide sensation and movement to all parts of the body. The delicate spinal cord and nerves are further supported by strong muscles and ligaments that are attached to the vertebrae.





### **Cervical disc disease**

You may have been referred to a neurosurgeon because of pain in your neck or shoulder, or tingling and numbness in your arms. You may also have experienced some weakness in your arms or hands.

Neck pain may be caused by disc degeneration, narrowing of the spinal canal, arthritis, and, in rare cases, cancer or meningitis. For serious neck problems, a primary care physician and often a specialist, such as a neurosurgeon, should be consulted to make an accurate diagnosis and prescribe treatment.

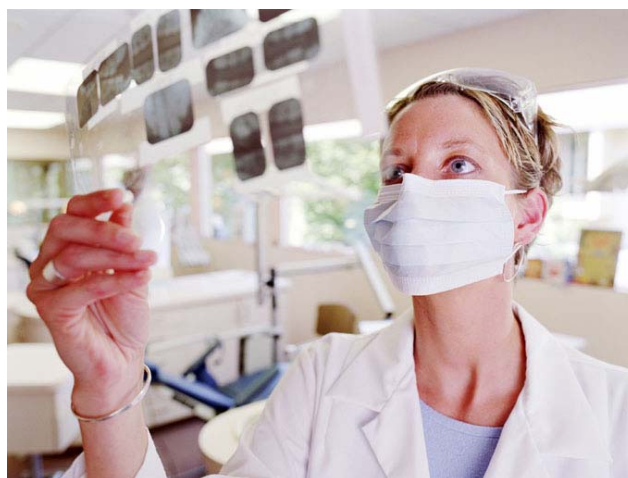
### **You should consult a neurosurgeon for neck pain if:**

It occurs after an injury or blow to the head;

- Fever or headache accompanies the neck pain
- Stiff neck prevents you from touching your chin to your chest
- Pain shoots down one arm
- There is tingling, numbness or weakness in your arms or hands
- Neck symptoms associated with leg weakness or loss of coordination in arms or legs.
- Your pain does not respond to over-the-counter pain medication
- Pain does not improve after a week

Age, injury, poor posture, or diseases such as arthritis can lead to degeneration of the bones or joints of the cervical spine, causing disc herniation ( bulge) or bone spurs to form. Sudden severe injury to the neck may also contribute to disc herniation, whiplash, blood vessel destruction, vertebral injury, and, in extreme cases, permanent paralysis. Herniated discs or bone spurs may cause a narrowing of the spinal canal or the small openings through which spinal nerve roots exit.

Pressure on the spinal cord in the cervical region can be a very serious problem because virtually all of the nerves to the rest of the body have to pass through the neck to reach their final destination (arms, chest, abdomen, legs).





## **What is Cervical Spine Surgery?**

The goal of cervical spine surgery is to relieve pain, numbness, tingling and weakness, restore nerve function and stop or prevent abnormal motion in the spine. Your surgeon does this by removing a disc or a bone and fusing the vertebrae together with a bone graft either in front of or behind the spine. The bone graft may be one of two types: an autograft (bone taken from your body) or an allograft (bone from a donor bank). Sometimes metal plates, screws or wires are also used to further stabilize the spine. These techniques are called instrumentation. When the vertebrae have been surgically stabilized, abnormal motion is stopped and function is restored to the spinal nerves.

## **What are the Reasons for Cervical Spine Surgery?**

Cervical spine surgery may be indicated for a variety of cervical spine problems. Generally, surgery may be performed for degenerative disorders, trauma or instability. These conditions may produce pressure on the spinal cord or on the nerves coming from the spine.

## **What Conditions are Treated with Cervical Spine Surgery?**

### **Degenerative Disease**

In degenerative disease the discs or cushion pads between your vertebrae shrink, causing wearing of the disc, which may lead to disc herniation( bulge). You may also have arthritic areas in your spine. This degeneration can cause pain, numbness, tingling and weakness from the pressure on the spinal nerves.

### **Cervical Deformity**

Patients with a deformity in their cervical spine, such as hyperlordosis(swan neck ) deformity, may benefit from surgery to straighten and stabilize the spine. Injury Since the neck is so flexible it is vulnerable to injury, some injuries can cause a fracture and or dislocation of the cervical vertebra. In a severe injury the spinal cord may also be damaged. Patients with a fracture, especially with spinal cord damage, undergo surgery to relieve pressure on the spinal cord and stabilize the spine.

## **Anterior cervical spinal fusion surgery:**

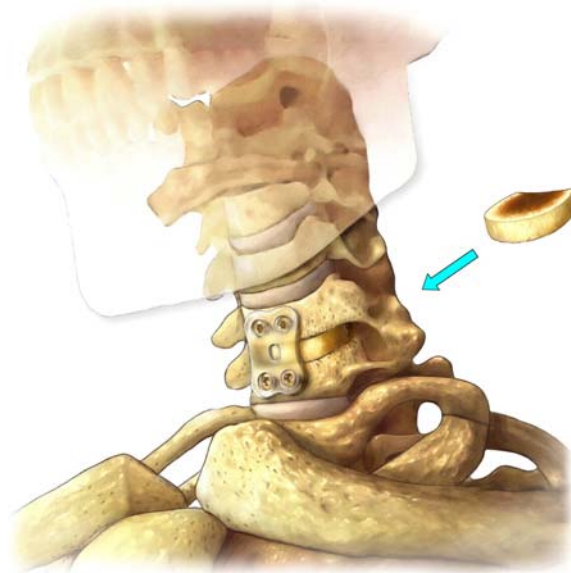
### **Understanding cervical spinal fusion:**

Anterior cervical spinal fusion surgeries are commonly done in conjunction with an anterior cervical discectomy( removal of disc).

For many patients, cervical spinal fusion surgery (fusing one vertebrae to another) is often done to eliminate movement of a vertebral segment. Decreasing the movement at the level of a painful segment should decrease the pain at that segment. Fusion also serves to maintain adequate space for the decompressed spinal cord and/or nerve roots. The fusion may also prevent the spine from falling into a collapsed deformity this is known as kyphosis.

Additionally, anterior cervical spinal fusions are also done to treat cervical instability due to:

- Trauma (fractures or dislocations)
- Tumor
- Infection



## **Bone grafts for spinal fusion surgery**

To achieve a spinal fusion, a bone graft is used to promote two bones growing together into one. The patient's own bone will grow into and around the bone graft and incorporate the graft bone as its own. This process creates one continuous bone surface and eliminates movement at the fused joint. A small piece of bone is commonly used to fuse a disc space, and a longer bone graft is used to bridge across multiple disc spaces if necessary.

### **1. Autograft bone for spinal fusion**

Autograft bone (patient's own bone) is harvested from the iliac crest (hip). This technique has been the gold standard since the 1950's.

The principal disadvantage with using autograft bone is that another incision needs to be made over the hip to harvest the bone graft.

Possible complications associated with taking out bone graft include:

- Graft site chronic pain (which happens 10% to 25% of the time)
- Infection
- Bleeding

### **2. Allograft bone for spinal fusion**

Allograft bone (donor bone from a cadaver) eliminates the need to harvest the patient's own bone. Basically, the donor graft acts as a bone scaffolding onto which the patient's own bone grows and eventually replaces over years. There are no living cells in the bone graft, so there is little chance of a graft 'rejection' like with an organ transplant.

### **Potential risks and complications of a spinal fusion surgery include:**

The principal risk from a spine fusion is that the graft does not heal. In general, allograft bone does not heal quite as well as autograft bone, but both achieve good results when used in the anterior cervical spine.



### 3. Implants for spinal fusion:

The use of biodegradable implants in spine surgery is being adopted by many surgeons as they demonstrate sufficient strength for use in spinal stabilization applications. Biomechanical studies have for example demonstrated their ability to immobilize a cervical segment to enable spinal fusion.

Biodegradable technology offers many distinct advantages over conventional metallic devices that are currently being used in spine surgery. Firstly, these implants allow optimal postoperative radiographic evaluation because of their radiolucency. Biodegradable implants also offer advantages with "progression of fusion" in respect to fusion healing due to their unique biomechanical properties. With a modulus of elasticity closer to that of human bone and with its gradual resorptive properties, biodegradable implants gradually diminish the stress shielding effect seen with stiff metal implant systems. In anterior cervical plating, for example, the flexibility and lower rigidity of biodegradable implants offer the advantage of stabilizing the motion segments while allowing for some load sharing with the graft positioned in the intervertebral space. In addition, as the plate degrades over time and bony fusion progresses, more load is transferred to the graft, potentially enhancing the fusion result.

#### **Inion S -1 Cervical Spine System: Indications approved only for use in Europe**

The Inion S-1 is a biodegradable single level fusion system for anterior cervical spinal fusions. The Inion cervical plate is intended for use in single level Anterior Cervical Discectomy and Fusion procedures as a means to maintain the relative position of block bone allografts or autografts. This device is not intended to be used in other areas of spine, and not for load bearing indications.





### What are the Inion® S-1 implants made of?

The products are made of highly pure polymers selected for their strength, toughness, malleability and biodegradation properties. Bioresorbable polymers are a special class of plastic materials that allow the material to serve a function, and then gradually break down and be eliminated from the body through entirely natural processes.

By tailoring the polymer selections, manufacturing processes and product designs, each implant has optimal strength, flexibility, malleability and biodegradation profiles to meet the specific surgical requirements.

These materials have changed surgery because the surgeon does not have to remove the hardware. When you use a nonbiodegradable material, sometimes patients complain of pain from the friction between the implant and body's tissue.

The polymers in the Inion Optima™ materials are: L-Lactide, D,L-lactide

### What is Inion Optima™?

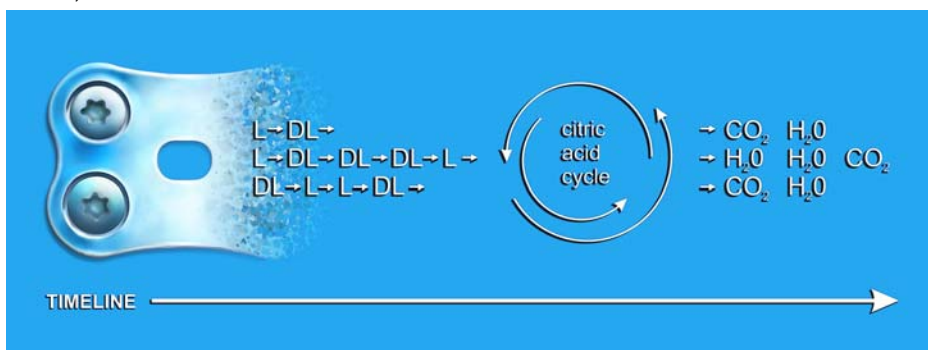
Inion Optima™ materials are made by the blending of rigid, highly pure polymers and elastic polymers. The result of blending the polymers is a unique family of materials called Inion Optima™ that possess extraordinary combinations of strength, toughness (malleability) and biodegradation ability.

### What are biodegradable implants?

Medical implants that are biodegradable break down gradually by a series of natural processes in the body over a period of time. Biodegradable materials are also known as (bio)resorbable, and (bio)absorbable. These implants are metabolized by the body into carbon dioxide and water which is then exhaled and excreted.

### What eventually happens to the implant?

The implants degrade by hydrolysis and over a period of time are metabolized into carbon dioxide and water, which is then exhaled and excreted.

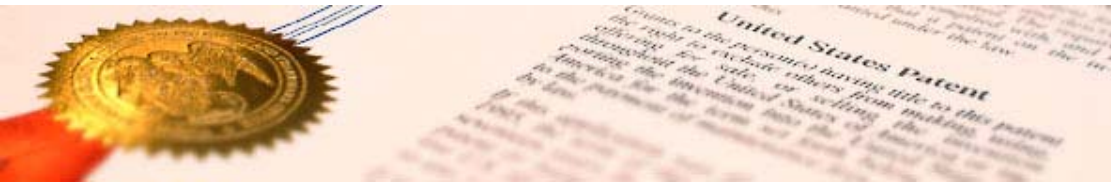


### I have heard that biodegradables can leave crystals that can cause problems after biodegradation?

Inion Optima™ materials are both safe and biocompatible with the human body. They are completely or substantially amorphous, meaning that they do not leave any crystals after biodegradation – the ideal for biodegradable implants.

### What are the advantages of biodegradable implants over metal implants?

Bioresorbable implants have many advantages over metal implants, including:  
No need for the surgeon to reoperated to remove implants



## Material safety

- Inion Optima™ is a family of biomaterials that are made by blending rigid and elastic polymer components. The resulting polymer blends possess an extraordinary combination of strength, toughness (malleability) and degradation profile.
- The implants retain most of their initial strength up to 16 weeks and gradually lose their strength thereafter; and bioresorption takes place within two to four years.
- Strength, elasticity and initial strength retention are tailored for this specific application using polymer blends that possess a combination of strength, toughness and degradation profile
- The polymer components have FDA clearance and have a long history of use in surgical and pharmaceutical applications
- Safe and biocompatible material - no risk of metal allergic reactions
- Minimised risk of stress risers (normally associated with implant removal)
- As with all biodegradable implants, they biologically resorb over time, allowing the load to transfer to the bone after primary bone healing and eventually completely disappear through safe biological resorption.
- Biodegradable polymers are a special class of plastic materials that allow the material to serve a function and then gradually break down, metabolise and be eliminated from the body.
- The screw is fixed to the plate when it is fully inserted

## Questions & Answers

- **Q: Why use a biodegradable implant?**
- A: There are occasions when metal implants have to be removed, e.g. due to palpability, patient sensitivity, imaging interference or infection etc. In addition metal can be too stiff for optimal healing in some surgical applications. Patients, when given a choice, usually voice a preference for a biodegradable implant rather than for one that remains permanently in their body or for enduring a second removal procedure.
- **Q: May the implant interfere with swallowing when you eat?**
- A: The Inion S-1 plate is no more bulky than most of the standard titanium plates used and therefore bear no bigger risk to interfere with swallowing.



- **Q: May the surgery to place the degradable plate lead to soft tissue swelling?**
- A: The surgical technique with our plate is just the same as with standard titanium plates. Thus, no additional risk is encountered.
  
- **Q: Can the screws loosen and cause irritation to the patient and other complications?**
- A: Inion's plating system has a restricted screw back out and the screws show good integration with bone. Also, there is no metallic debris which could lead to adverse reactions
  
- **Q: May material degradation cause local inflammation to the soft tissue.**
- A: "the customised recipe allows for gentle dissolution with almost no foreign body reaction, certainly no more than with titanium plates"  
(Prof. K. Wood, Mass. General Hospital)
  
- **Q: Are the implants Radiopaque?**
- A: Not entirely. The implants are not radiopaque, however, the screw holes can be seen in post operative X-rays.
  
- **Q: Can you use Inion implants in patients who are lactose intolerant?**
- A: Lactose is a natural sugar found in most mammalian milk. The chemical structure of lactose is very different from that of lactic acid which is a natural metabolite of carbohydrate metabolism. One would not expect any interaction at all from lactic acid on lactose intolerant people.