Ortho Space

InSpace™

New solution for rotator cuff injury

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This leaflet is intended to provide you with information on the InSpace™ balloon which is a new solution for Rotator Cuff injury.

Background

The rotator cuff is a group of four tendons that connects the upper shoulder muscles to the bones.

Rotator cuff tear is a common shoulder problem that might be a result of a sudden single traumatic event or develop gradually. When rotator cuff tendons or muscles tear, you may experience limited range of motion when lifting and moving the arm as well as significant pain associated with shoulder motion. The pain is also very common at night, often radiating down the arm.

A complete rotator cuff tear will not heal spontaneously. Complete ruptures usually require surgery, however, some massive tears and /or poor tendon and muscle quality will not allow such repair.

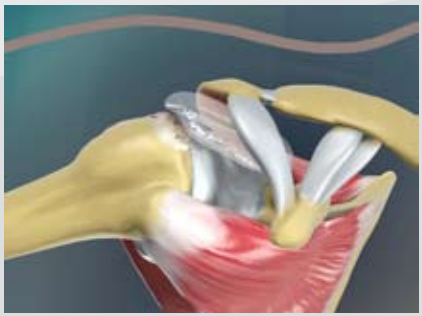
InSpace™ balloon

The InSpace™ balloon is made of a widely used polymer in the medical industry. The polymer is biodegradable, which means that following implantation it will gradually dissolve until complete absorption within one year.

The InSpace™ Balloon is intended to decrease pain associated with ruptured tendons following a rotator cuff tear. The InSpace™ balloon has been approved by the European authorities since July 2010.

Surgery

The surgical procedure of InSpace™ balloon insertion is similar to other routine rotator cuff surgeries, conducted in an operating theater, under general or regional anesthesia using an arthroscopic approach.



Warning and precautions

The potential risks that are present for any shoulder arthroscopic surgery apply to this procedure as well. The most common side effect is of this type of surgery include, but are not limited to: swelling, pain, nerve injury, infection, restriction of movements and discomfort.

As an implant, it is possible that the InSpace™ balloon may cause tissue reaction and/or sensitivity reaction to the device. There is also a possibility that the device will displace from the original implantation site. If this occurs, the surgeon will decide whether to deflate the device using a needle, remove the device in an arthroscopic procedure or leave it where it is until complete absorption in the body. These events are unlikely to happen and occur in less than 5% of the treated patients. The InSpace™ balloon should not be implanted if you suffer from one the following conditions:

- Active or latent infection or of signs of tissue necrosis in your shoulder.
- Known allergy to the balloon polymer (poly lactide co epsilon caprolactone).
- Any blood coagulation disorder, compromised immune system, sever/unstable chronic disease such as heart failure, cirrhosis, chronic renal failure or any other condition that would compromise implantation procedure healing should be carefully considered by the surgeon.

Summary

It is anticipated that the implantation of InSpace™ balloon may reduce your pain and help you in restoring your functional shoulder motion. Following the surgery you will be asked to avoid quick sudden movements, repetitive movements, any weight lifting and force or power demanding activities. In addition, you will be asked to follow a physical therapy plan as recommended by your surgeon until satisfactory shoulder function is achieved.

For any further information please be advised by your physician.

Disclaimer

The above information is not medical information and should not replace consultation with a medical doctor on your shoulder treatment. The InSpace™ balloon should be used only in accordance with and subjected to the detailed documentation provided together with such device.