What is expected of me in this clinical research study?

The clinical research study requires six (6) post-operative visits to the clinic over a period of 24 months (2 years). You will have a shoulder assessment and you will be asked to complete quality of life questionnaires. At no additional cost, you will be required to have one (1) MRI of your shoulder at 12 months (1 year). You may also be required to have three (3) Ultrasound tests during the first three (3) months of the clinical research study.

Do I have to participate in research?

No. Research participation is strictly voluntary. Your decision to participate, or not, will not affect your health care treatment.

About the Sponsor

Ortho-Space Ltd. is a medical device company that manufactures the investigational device, InSpace™.

The InSpace system was CE (Conformité Européenne, 2011) marked in July 2010 and is available for use throughout Europe. Since its approval, more than three (3) thousand (3000) InSpace devices have been implanted into patients with a similar shoulder problem as you.

For more information please contact:

Surgeon Name: Laith Jazrawi, MD & Robert Meislin, MD

Clinical Research Staff: Ariel Aponte & Cara Fontaine

Phone: 212-460-0176 | 212-598-6673

Email: ariel.aponte@nyumc.org | cara.fontaine@nyumc.org

Clinical Research Study Registered at: www.clinicaltrials.gov

ORTHO-SPACE Ltd.

Web: www.orthospace.co.il

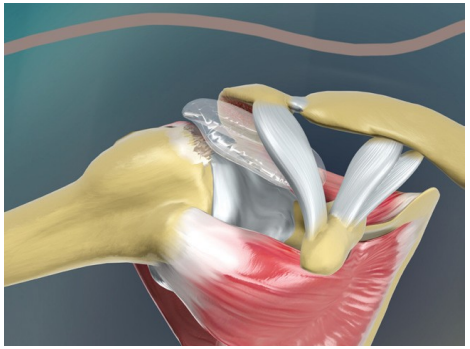
CLPR15021551_rev 01

ROTATOR CUFF

CLINICAL RESEARCH STUDY

ORTHOSPACE

Approved For Period: 7/28/2015 - 7/27/2016



InSpace™ Investigational Device Information

Investigational devices have not been approved by the U.S. Food and Drug Administration (FDA) for commercial use, but have been approved for use in a clinical research study.

The InSpace device is a balloon shaped implant made from a polymer, which is widely used material in the medical industry. The material is biodegradable meaning that following surgery it will gradually dissolve until it is completely absorbed at approximately one year following the implantation. During this time, the device is intended to support your shoulder healing allowing frictionless gliding between the shoulder bones which may improve shoulder muscle activity.

What is this clinical research study about?

Your doctor is conducting a clinical research study to evaluate a new investigational device for arthroscopic treatment of massive rotator cuff tears in the shoulder.

If you choose to take part and qualify for the clinical research study, you will be randomly assigned (like flipping a coin). You will have a 50% chance of receiving the investigational device. You will not know which treatment you receive until the clinical research study is completed.

What are the costs of this clinical research study?

If you have health insurance, there will be no extra costs to you beyond the care you would normally receive to treat your condition. The MRI and Ultrasounds required by the clinical research study will be paid for by the sponsor.

To qualify for this clinical research study, you must:

Be 40 years of age or over and in general good health

Experiencing persisting shoulder pain for at least four (4) months which failed non-operative treatments such as:

- Physical therapy
- Activity modification
- Rest (sling)
- Anti-inflammatory medication

Have had an MRI within 9 months that confirms a full thickness rotator cuff tear

Fulfil all study criteria as assessed by your surgeon and be willing to return for all follow-up visits

What are the risks?

The risks of this clinical research study are the same as those expected in any standard arthroscopic shoulder surgery. There are additional risks that may be associated with the investigational device. Speak with your doctor to understand the risks