Intervention Name:
InSpace™ Device

Title:

A prospective, single blinded, multi-center, randomized, controlled, pivotal study to assess the safety and effectiveness of the InSpace™ device for treatment of full thickness Massive Rotator Cuff Tears

NCT02493660

ICP (Informed Consent Procedure)
26 March 2018

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13.0 APPENDICES

13.1 Appendix A: Sample Core Informed Consent Form

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: A prospective, single blinded, multi-center, randomized, controlled, pivotal study to assess the safety and effectiveness of the InSpace™ device for treatment of full thickness Massive Rotator Cuff Tears

Protocol Number: IS- CL-04

Version: **1.0**

Date: _____

Investigator: _____

Study Sponsor: Ortho-Space Ltd.

Introduction: Before agreeing to participate in this clinical research study, it is important that you read and understand this research consent form. This form provides all the information we think you will need to know in order to decide whether you wish to participate in the study. If you have any questions after you read through this form, ask your questions to a doctor or study personnel. You should not sign this form until you are sure you understand everything on this form. You may also wish to discuss your participation in this study with your family doctor, a family member, or a close friend.

It is important that you answer any questions, to the best of your ability, which your study doctor may ask with respect to your health history and any medications you may be taking. This is done in order to prevent any unnecessary harm to you should you decide to participate in this study.

Purpose of the Study: You have been diagnosed with a full thickness massive tear of your rotator cuff (the group of connective tissues in the shoulder) which requires surgical treatment because your condition has not improved with conservative treatment.

This clinical research study will evaluate a new device, InSpace device (the investigational device), for use in treatment for a full thickness massive rotator cuff tear. The study is being conducted to see whether the InSpace device is safe and effective as a surgical treatment for subjects with shoulder problems such as yours.

This study will involve 184 patients, who will participate in this study at up to 20 medical centers across North America. Information will be collected on the participants, all of whom need a shoulder procedure like you. Arthroscopic surgery will be used for all participants. During this type of surgery, 2-3 small incisions are made around the shoulder instead of a single large incision.

Pharmacoeconomic data such as the bills relating to your surgical procedure (i.e., operating room time, length of stay, medications, research center visits, rehabilitation and other related procedural costs) will be collected at the follow-up visits, if applicable. In addition, procedural and diagnostic codes, and reimbursement information may be collected.

Investigational Device Description: The InSpace device is an investigational device manufactured by Ortho-Space Ltd.

Investigational devices have not been approved by the U.S. Food and Drug Administration (FDA) or the Canadian Health Protections Branch (HPB) for commercial use, but have been approved for use in a clinical study.

The InSpace system was CE (*Conformité Européenne,* 2011) marked in July 2010 and is available for distribution throughout Europe. Since its approval, approximately two thousand (2000) InSpace s have been implanted into patients with a similar shoulder problem as you.

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.

Description of the Study: If you choose to participate in this study you will be evaluated to determine if you are a good candidate for the study. You will undergo routine tests and procedures for rotator cuff surgery, including magnetic resonance imaging (MRI) and a physical examination. MRI is a tool that uses a magnetic field and radio waves rather than x-rays to allow the physician to see multiple images from different angles to evaluate potential problems or things in the head and body that are not normal. A physician can use these detailed, clear images to see and diagnose a wide range of conditions. Because of the use of this diagnostic tool, if you have had any medical products made from metal implanted into your body, you may not be eligible for this study. Additionally, if you have been diagnosed with claustrophobia you will not be able to participate in the study. You and your doctor will talk about any implants you have received and whether or not you may participate in the study because of them.

In addition to your normal and standard care, you will be asked study questions prior to your surgery about your medical history and your shoulder to be treated. You will also be asked to answer study questionnaires about the pain, disability and function of your shoulder, your general health and about any medications you are currently taking (prescription or over-the-counter). The questionnaires will require about 20 minutes of your time to complete.

If you are a woman that is able to bear children, you may be asked to take a pregnancy test prior to surgery. Your surgeon will explain the pre-surgical and surgical procedures to you in greater detail and answer any questions you have.

Once you have been evaluated, you will be scheduled for surgery. You will then be randomized to receive either the investigational treatment (InSpace device) or the control treatment (Partial Repair). This will be determined by a random process (like flipping a coin). For this study you will be randomized at 1:1 ratio, which means that you have approximately a 50% (1 in 2) chance of receiving the investigational treatment and a 50% (1 in 2) chance of receiving control treatment. You will not be made aware of which treatment you have received until the study is completed.

The choice of anesthesia for this surgical procedure will be up to the discretion of your surgeon. Several small incisions will be made on your shoulder and the surgical procedure will be performed. The tendons in your shoulder will be examined. If you are randomized to receive the investigational device, the InSpace device will be placed in your shoulder. If you are randomized to receive the standard surgical procedure, the tendon ends will be secured with suture anchors. The surgical site for both treatments will be closed with tape/sutures/staples and bandaged.

If, during the surgery, your surgeon determines that your rotator cuff tear does not meet the requirements for the study (i.e., the tear is too small), or it cannot be treated using the surgical procedure defined in the study protocol, he/she will decide not to enroll you in the clinical study. If you are not enrolled, you will not have a chance to receive the investigational device, and will not be asked to undergo additional study visits. In this case, you will be treated according to standard practice for your condition.

Following the shoulder surgery, your shoulder will be immobilized and you may be fitted with a sling. Physical therapy will be prescribed at the discretion of your surgeon. These are the same procedures used for any shoulder surgery.

If you are enrolled in the study, you will be asked to visit the research center for scheduled appointments during the 24 months following your surgery. You will be asked to return for follow-up at 10 days after surgery, 6 weeks, 3 months, 6 months, 12 months, and 24 months after surgery. You will have an assessment of the treated shoulder at each visit. At all follow-up visits, you will be asked study questions about your progress, including the use of medications, and given the study questionnaires at specific visits. You will be free to decline answering any questions that you do not feel comfortable answering. You will undergo an MRI at 12 months. You may also undergo an MRI at 6 weeks after surgery.

Potential Harms (Injury, Discomforts, or Inconvenience):
As with any shoulder surgery involving anesthesia there are potential risks and complications, including dizziness, fainting, difficulty breathing, wound infection, wound drainage, swelling, localized pain, bleeding, bruising, surgical wound opening, nerve pain or injury which could result in dysfunction or the loss of the affected arm, tendon injury, loss of sensation in the skin and muscle around your surgical site, inflammation of the tissues that surround the rotator cuff joint, a frozen rotator cuff (inability to freely move the shoulder joint) and delayed wound healing. Risks of deep

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vein thrombosis (blood clot) and pulmonary embolism (a blood clot that has traveled to the lung) could result in stroke, heart damage or death.
The potential medical risks associated with implantation of the InSpace device in the shoulder are unknown, but are expected to include the risks listed above for standard shoulder surgery. There may be a risk of prolonged surgical time due to device breakage or malfunction. Local tissue response to the implant or significant device displacement (movement from initial placement) may also occur, in this case your doctor will decide whether to remove the device by surgery or leave in place till it has completely dissolved.

Your surgeon is experienced in this type of surgery, but the results of this surgery cannot be guaranteed. It is possible that the surgery will not reduce the pain or disability felt before surgery. In addition, the pain or disability may be worse after the surgery. There is some element of this risk in all surgeries, whether or not you receive the investigational device. If the treatment fails, standard surgical and non-surgical options will be discussed and planned with your surgeon.

The Food & Drug Administration (USA) has indicated that for clinical diagnosis an 'insignificant' risk is associated with human MRI exposure at the intensities used in this project. Current Canadian guidelines follow the USA guidelines. Although very rare, injury and deaths have occurred in MRI units from unsecured metal objects being drawn at high speeds into the magnet or from internal body metal fragments of which the subject was unaware or had not informed MRI staff. To minimize this latter possibility it is essential that you complete a screening questionnaire. Other remote but potential risks involve tissue burns and temporary hearing loss from the loud noise inside the magnet. The latter can be avoided with ear headphone protection that also allows continuous communication between the subject and staff during the study.

If you choose to take part in this study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the study, that might cause you to change your mind about continuing in the study.

Women as Research Subjects: If you are pregnant you cannot be in this study. If a woman is pregnant or nursing a child when she has medication associated with surgery there may be risks to the unborn baby or nursing child. If you are planning to become pregnant during the study you will not be allowed to participate in the study. Participating women who become pregnant during the study should tell their study doctor and research personnel. They will continue to be followed as per the study protocol.

Potential Benefits: You may not benefit directly from participating in this study. The known benefits of full thickness massive rotator cuff tear surgery may include reduction in pain and a potential for increase in function. If you choose to participate in the study, your shoulder may or may not heal more quickly. The information collected in this study to determine the safety and effectiveness of this new investigational device may benefit future subjects undergoing shoulder surgery.

Treatment Options: If you choose not to participate in this study, there are other treatments available to you. These include physical therapy, surgical debridement of the joint, or replacement of the shoulder joint. Similar risks may apply to those alternative procedures as they involve relatively similar surgical techniques, and some of these procedures may involve additional risks and

precautions due to the nature of these procedures. Your surgeon will have additional information on each of these alternative treatments.

Confidentiality and Privacy: All persons associated with this study, including study Investigators, coordinators, nurses and delegates (hereby referred to as "study personnel") and the study sponsor (Ortho-Space Ltd.) are committed to respecting your privacy. No other persons will have access to your personal health information or other identifying personal information without your consent, unless required by law.

The study information collected will be part of what is called your "personal health information," and is identifying information about you that relates to your health or the provision of health care services to you. If your personal health information cannot be collected and used by the Investigator or disclosed to Ortho-Space Ltd., then the study objectives cannot be achieved. Your personal health information may include diagnostic and treatment information, such as:

- MRI
- Specific medical history
- Information contained in your hospital medical record

Any personal health information collected, or other information related to you will be coded by study numbers to ensure that persons outside of the study will not be able to identify you. The study personnel are in control of the study code key, which is needed to connect your personal health information to you. The following guidelines are used to maintain confidentially:

- All information that identifies you, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study personnel will be able to access.
- Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices.

It is important to understand that despite these protections being in place, there continues to be the risk of unintentional release of information. The study personnel will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will be accidentally released is small.

By signing this consent form, you are authorizing access to your medical records by the study personnel, authorized representatives (i.e., study monitor or auditor) of the sponsoring company, the Institutional Review Board (IRB), Research Ethics Board (REB) and by government regulatory authorities such as the US Food and Drug Administration (FDA), the Department of Health and Human Services, and/or Health Canada (HC). Such access will be used only for the purpose of verifying the authenticity and accuracy of the information collected for the study, without violating your confidentiality to the extent permitted by applicable laws and regulations.

Federal and Provincial Data Protection regulations, including the Health Insurance Portability and Accountability Act (HIPPA) and Personal Information Protection and Electronic Documents Act (PIPEDA 2000) protect your personal information. They also give you the right to control the use of your personal information (including personal health information) and require your written permission for this personal information to be collected, used, or disclosed for the purposes of this study, as described in this consent form. You have the right to review and copy your personal information collected in this study. However, if you decide to be in this study or choose to withdraw

from it, your right to look at or copy your personal information related to this study will be delayed until after the research is completed.
Photographs may be taken of your shoulder before, during, and after the surgery, however, your identity will not be revealed.

A description of this research study will be available on http://www.ClinicalTrials.gov, as required by US Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

By FDA regulations, the study sites and the sponsor will keep your study records for at least 2 years from the conclusion of the study. Your study records will then be destroyed in a secure manner once the retention period has elapsed.

By Health Canada regulations, the study investigators and sponsor will keep your study records for 25 years from the conclusion of the study. Your study records will then be destroyed in a secure manner once the retention period has elapsed.

Study Results: The results of this study may be presented at conferences, seminars, or other public forums, and published in journals, but at no time will you be identified. No information will be used in these presentations that would disclose your identity as a study subject. The analyzed data may also be used to plan for future clinical studies or to prepare reports or marketing applications to regulatory agencies.

Voluntary Participation: Your participation in this research is VOLUNTARY. If you choose not to participate, you and your family will continue to have access to customary care at _____.
By agreeing to participate in this study, you are agreeing to return for follow-up visits until the study is completed. However, your participation in this study is conditional upon signing this consent form and authorization to disclose personal health information. If you do not sign this form, you cannot participate in the study.

Cost: All costs that are part of your usual medical care, such as your surgery and physical therapy will be charged to your insurance company if you have such coverage. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this study. If you have no health insurance, you will be held responsible for paying all costs of the study.

Costs which are not associated with standard treatment, such as costs of MRI required specifically for this research study, will be paid for by the sponsor.

While you are in the study, you may still need to get regular medical care. You will still have to pay for the costs of your regular medical care that are not a part of this study. To find out more about costs, you can ask the study doctor or study personnel.

Study Withdrawal: If you choose to participate in this study, you have the right to withdraw from the study at any time. This will have no effect in regard to your care, or your family's care, at

_____. Your surgeon will continue to provide standard care and will advise you of any new information related to the study that may be important to your health or well-being.
The sponsor, the study doctor, FDA, HC, or the IRB/REB may withdraw you from the study without your consent under the following circumstances:

1) to protect your health and safety,
2) failure to comply with study procedures, or
3) the study is terminated for any reason.

If you withdraw from the study, the data collected for you up to that time will be used to maintain the integrity of the study, but no more data on you will be collected. You will also be asked to return for a final visit for safety concerns and standard clinical care.

Compensation for Injury: If you experience an injury or illness during the course of the study you should seek medical treatment from a physician or treatment center of your choice, and promptly notify your surgeon. Participation in the study does not affect your legal rights. If you suffer a physical injury as a direct result of the administration of the study device or study procedures, you will receive medical care in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor relieve the investigator, sponsors, and involved institution from their legal and professional responsibility.

If you are physically injured due to the implanted study device you will be reimbursed for reasonable medical expenses. The expenses will be for the treatment of that injury, which are not covered by your own insurance or health care provider associated with a shoulder repair procedure. No other compensation will be available from Ortho-Space Ltd., if injuries occur that are associated with the shoulder surgery.

Reimbursements: You will be compensated $60 (per visit) for Visits 1, 3, 4, 5, 6, and $100 (per visit) for Visits 7, and 8 that you complete. This will total $500 over the course of the study and is to compensate you for your time and any travel expenses associated with your participation in this study.

Source of Funding for the Study: Funding for this study will be provided by the sponsor (Ortho-Space Ltd.).

Research Ethics Board Contact: If you have any questions regarding your rights as a research participant in this study, you may contact the chair of the IRB/REB,
_____, at (_____) _____-_____.

Consent: This consent form is only part of the process of informed consent. It should give you the basic idea of what the research study is about and what your participation will involve. It is not consent for surgery. You will be asked to sign a separate consent form for surgery. Your continued participation should be as informed as this initial consent so you should feel free to ask for clarification or new information throughout your participation in the study.

CONSENT SIGNATURE PAGE

A prospective, single blinded, multi-center, randomized, controlled, pivotal study to assess the safety and effectiveness of the InSpace™ device for treatment of full thickness Massive Rotator Cuff Tears

• I have read this explanation about this study and this study has been explained to me to my satisfaction and I have been given sufficient time to read and understand the above information.

• I have had the opportunity to ask questions about this study and have them answered and I know that I may ask now, or in the future, any questions that I have about the study or the research procedures.

• I understand that I have not waived my legal rights nor released the study doctors, or involved institutions, from their legal and professional duties.

• I have been informed of the alternatives to participation I this study, including the right to withdraw without compromising the quality of medical care at this study site for me and for other members of my family.

• I have been informed of the potential risks, harms, and discomforts have been explained to me, and I also understand the potential benefits of participating in the research study.

• I have been assured that those records relating to me, and my care, will be kept confidential and that no information will be released or printed that would disclose personal identity without my permission unless required by law.

• I understand that by signing this form I am giving permission for the FDA, HC, Sponsor and its representatives, and study personnel to have access to my medical records.

• I hereby freely and voluntarily consent to participate in this study, and I will be given a signed copy of this consent form.

_____
Name of Subject (please print)

_____ _____
Signature of Subject Date

_____
Name/Status of Individual obtaining Consent (please print)

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_____	_____
Signature of Individual obtaining Consent	Date

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