Informed Consent Document

TITLE:	A Randomized, Post-market Study Evaluating Dermal Allograft Augmentation of Large and Massive Rotator Cuff Tears
PROTOCOL NO.:	AIRR-0094 WCG IRB Protocol #20232513
SPONSOR:	Arthrex, Inc.
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

INTRODUCTION
You are being invited to take part in a medical research study. Before you decide to take part in this study, you should read this document. This document, called an informed consent document, explains the study. Please ask as many questions as needed so that you can decide if you want to be in the study.

You are being asked to take part in this study because you are scheduled to undergo rotator cuff repair surgery and are a candidate for dermal allograft augmentation.

WHY IS THIS STUDY BEING DONE?
Rotator cuff injuries are a common clinical problem and often require treatment. Massive rotator cuff tears may account for approximately 30% of surgically repaired rotator cuff tears.

Specifically, we want to assess the healing of the rotator cuff repair based on MRI in patients that participate in the study. This Interventional study will compare the outcomes of patients comparing two groups:

Group 1 will consist of patients having rotator cuff repair with the addition of dermal allograft Augmentation (DAA).

Group 2 will consist of patients having rotator cuff repair *without* the addition of dermal allograft augmentation (control).

All devices, FiberStitch RC, PushLock or SwiveLock anchors and FiberTape sutures. used in this study are cleared by the U.S. Food and Drug Administration.

Dermal allograft augmentation (DAA) has been shown to improve healing postoperatively. The Dermal allograft product is also registered and listed with the U.S. Food and Drug Administration.

WHO CAN BE IN THIS STUDY?
Eligible patients who are undergoing rotator cuff surgery, and who meet the study inclusion/exclusion criteria are given the option to consider joining this study.

HOW MANY PEOPLE ARE EXPECTED TO TAKE PART IN THIS STUDY?
About 120 participants, male and female, ages 30 to 75 years of age will be enrolled in this research study.

WHAT WILL YOUR PARTICIPATION IN THIS RESEACH INVOLVE?
If you choose to consent to participate in this research study, your involvement will last for approximately two years. Information will be collected from your medical chart at the clinic. This will include demographic information, age, gender, race, and past, current and future medical information related to your rotator cuff problem. Information from surveys you complete will also be collected.

You will be randomly assigned (by chance) to receive a dermal allograft augmentation during your scheduled rotator cuff repair. You have a 50 / 50 or 1:1 chance of being assigned to either study arm. If you are eligible and you decide to consent to participate in this study, you will receive your surgery, per standard of care. After your surgery, you will come in for a series of study visits where your study doctor will assess how you are healing through the following patient assessment tools.

Specifically, you will take the following surveys at some or all of the study visits:

- American Shoulder and Elbow Surgeons Score (ASES)
- Single Assessment Numeric Evaluation score (SANE)
- Visual Analog Scale (VAS) for pain
- Veterans RAND Health Survey (VR-12)

Completion of ALL these surveys is projected to take approximately 30 minutes or less.

An additional MRI may be done outside of your doctor's standard of care schedule.

****ALL SITES:** The following risk information from [START] through [END] cannot be altered without submission of supporting documentation and/or Sponsor approval of changes. Submitted changes without appropriate documentation will be reverted during Board review.

[START] **WHAT ARE THE POSSIBLE RISKS OF YOUR PARTICIPATION?**
Potential risks from the surgery are equivalent to standard surgery and will be discussed with the patient as normal standard of care.

Potential risks related to the DAA include possible allergic or host reaction to the graft. However, these risks are minimal as it is provided sterile according to device grade standards. However, in a research study all the risks cannot be predicted and there may be some unknown risks.

Treatment risks are standard procedure risks that are discussed as part of orthopedic care. These include:

- Infections, both deep and superficial
- Allergies or other reactions to device materials
- Temporary or permanent nerve damage as a result of pressure or hematoma.

- Loosening of the implant or tissue reaction to implant
- Dislocation, subluxation, or inadequate scope of movement as a result of failure to achieve optimum positioning of the implant.
- Bone fractures as a result of one-sided overload or weakened bone structure.
- Allergic reaction to allograft or residual allograft processing reagents

The treatment may be obtained outside of the study and is considered standard of care. Any changes that may affect your participation in this study will be communicated to you by the study staff or doctor.
[END]

STUDY PROCEDURES RISKS

An AP radiograph will be used instead to determine bone mineral density and this test will expose you to radiation, a DXA scan is optional for this study.

MRI risks
If you have implants containing metal, it can cause problems with an MRI scan. The magnets used can interfere with pacemakers or cause implanted metal to shift in your body. Be sure to tell your doctor if you have any metal implants in your body.

In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the MRI. Temporary hearing loss has been reported from this loud noise. You may be asked to wear ear protection. At some time during the test, you may be asked to hold your breath for a while, which can be uncomfortable.

General anesthesia
The common side effects of general anesthesia include nausea and vomiting, dry mouth, sore throat or hoarseness, chills, confusion, dizziness, muscle aches, itching and difficulty urinating. Serious, life threatening side effects such as heart rhythm disturbances, strokes or accidents causing brain damage can occur.

CONFIDENTIALITY
In an effort to preserve confidentiality, both the study doctor and the study sponsor have taken precautions to protect the data collected for this research. We will attempt to preserve the confidentiality of your information by assigning a special research code number to your information stored in the online system. Your email or phone number address will be stored encrypted in the online system. Information linking the research code number to your name and other personal identifiers will be stored in a separate secure location at the study site.

WHAT OTHER OPTIONS ARE THERE?
An alternative is not to participate in this research study. You can receive the same treatment and surgery whether or not you decide to participate in this study.

HOW LONG WILL YOU BE IN THE STUDY?
You will be involved in this study for approximately two years. You can stop participating at any time. Your decision to withdraw from the study will not affect in any way your medical care and/or benefits.

POSSIBLE BENEFITS OF THE STUDY

There may not be a direct benefit to you. Information learned from the study may be of future benefit to other people undergoing this treatment. The benefit of participation in the study is furthering scientific knowledge of products currently on the market. There may not be a direct benefit to participation in this study. Future patients undergoing rotator cuff repair using a dermal allograft augmentation may benefit from the knowledge gained from this research.

COMPENSATION
[Site-Specific Payment Language]

COSTS
You and/or your insurance company will pay for the normal cost of all treatments, tests, office visits and imaging that are part of your routine medical care. Any procedure related solely to the study that would not otherwise be necessary will be covered by the sponsor.

RESEARCH RELATED INJURY
If you have serious adverse effects or are injured as a result of participating in this study, the study doctor will provide any necessary medical treatment to help you recover as quickly as possible. Your insurance will be billed for the medical treatment and you may be billed for the costs your insurance does not cover. No other form of compensation is being offered.

If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

WHO WILL KNOW ABOUT YOUR PARTICIPATION IN THIS RESEARCH STUDY?
The following people will have access to your study records:

- Study Doctor
- Study Coordinator/Staff
- Sponsor Company
- The United States Food and Drug Administration (FDA)
- Institutional Review Board (IRB)
- Other State or Federal Regulatory Agencies

Any information about you will be kept as confidential as possible. Confidentiality cannot be totally guaranteed. If information from this study is published or presented at scientific meetings, your name and other identifiers will not be used. This information will be collected from your study site records, hospital records, and if applicable and permitted by you, private physician records.

WHOM TO CONTACT
You may contact the research team at the phone number(s) listed in this document.

- for answers to questions, concerns, or complaints about this research study,
- to report a research related injury, or
- for information about study procedures.

If you need medical attention, please go to the nearest emergency room.

You may contact IRB if you:

- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights as a research participant.

WCG IRB
855-818-2289
researchquestions@wcgirb.com

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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.

IS YOUR PARTICIPATION IN THE STUDY VOLUNTARY?
Your participation in this research registry is voluntary. Whether or not you provide your permission for participation in this research registry will have no effect on your current or future medical care at this site, or your current or future relationship with your health care provider.

If you wish to leave this study, please call the study doctor or study staff at the telephone number listed on the first page of this consent document to schedule study exit procedures. You have the right to leave this study at any time.

Your part in this study may be stopped at any time without your permission. The following people can stop your participation and/or the study itself:

- Study Doctor
- Sponsor Company or designee(s)
- Institutional Review Board (IRB)
- The United States Food and Drug Administration (FDA)

If you do not follow the study procedures, you may be taken out of the study. If you withdraw from the study, no new data about you will be collected for study purposes. All data that have already been collected for study purposes will be shared with the study sponsor.

VOLUNTARY AGREEMENT TO BE IN THE STUDY

Participation in this study is voluntary and refusal to participate will not involve any penalty or loss of benefits. You may discontinue participation of the study at any time for any reason without penalty or loss of benefits. All of the above has been explained to me and all of my current questions have been answered. I have had ample time to consider participation and was told that I may ask questions about any aspect of my participation in the research study at any time A copy of this consent form signed and dated by me and the individual obtaining consent will be given to me.

By signing below, I agree to participate in this research study.

_____

Printed Name of Participant

_____

Signature of Participant Date

By signing below, I acknowledge that the consent process has been conducted.

By signing this form, the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, will be provided to the participant.

_____

Printed Name of Person Explaining Informed Consent Document

_____

Signature of Person Explaining Informed Consent Document Date

You will be given a signed and dated copy of this informed consent document to keep.

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

_____ _____

Signature of Subject **Date**