Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Investigation of a New Skin Closure Device, Dermabond PRINEO, for Total Shoulder Arthroplasty: A Randomized, Controlled Trial

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. This is a research study to find out whether wound closure (the process of closing the surgical wound after your procedure is complete) with Dermabond PRINEO Skin Closure System (PRINEO) will be faster and improve wound healing compared to standard closing methods after total shoulder replacement. The PRINEO system involves using running stitches to close your wound, and then taping over the sutures with a sticky film that holds the wound closed.

If you agree to participate, you will be randomly selected into one of two possible groups. Your surgical wound will be closed either with the current standard of care used by your surgeon, or with PRINEO. Researchers will collect basic information from your medical records, including your age, weight, and smoking history. You will not know which group you are in until your first follow up visit after surgery. The length of surgery and closure time during your operation will also be recorded. The state of your wound healing will be checked by your surgeon in the clinic at standard follow-up visits after surgery, at 2 weeks, 6 weeks and 3 months. The total duration of participation will start from the day you consent for the study until your three month post-operative visit.

You will experience no more than the usual risks of surgery from participating in this study. There is a very small chance (between 0% to 1.8%) of getting skin allergies from PRINEO, but these cases have not increased risk of infection. Previous studies show that PRINEO lead to similar or improved wound appearance and infection rates for some other surgeries. Your participation in this study can help us better understand which methods of closing wounds are best for shoulder replacement surgeries. If you don't want to participant, you can choose to receive the standard wound closure treatment your surgeon currently uses.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you are planned to receive a total shoulder replacement. All patients who are scheduled to have a shoulder replacement procedure by Dr. Richard Friedman or Dr. Josef Eichinger are eligible for inclusion in this study.

The PRINEO closure system is approved for use by the FDA. The closure system uses the Dermabond PRINEO (which is similar to clear tape stuck over your wound) placed over running stitches, rather than stitches alone or with metal staples.

The study is sponsored by Ethicon, Inc. (Johnson & Johnson), the maker of the PRINEO closure system. The investigator in charge of this study is Josef Eichinger, MD. The study is being done only at the Medical University of South Carolina (MUSC). Eighty-eight people will take part in this study. MUSC, the study team and the Principal Investigator will be paid to conduct the study. Dr. Friedman works as a consultant for Johnson & Johnson, but not for the product under study in this investigation. You may request any details concerning this compensation from the Principal Investigator.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. After signing consent you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are Group A (PRINEO system) and Group B (control group with the surgeon's current standard of care). You will not be made aware of which group you are in until your first follow up visit.
2. Group A will receive the PRINEO skin closure system during their operation. Group B will receive the control closure system (either metal staples or sutures) during their operation. The time taken to close the wound will be recorded during your surgery, regardless of which group you are assigned to.
3. At six weeks and three months after surgery, you will return to the clinic for a standard post-operative check-up by your physician. These two visits are standard of care for shoulder replacement surgeries, so you will not have to come into clinic more than you would if you were not in the study. Your physician will inspect your healing wound. In addition to the typical post-operative evaluation, the surgeon will complete two additional research assessments to see how well your wound is recovering. This process should not increase your clinic visit by more than 10 minutes. Photos of the wound will also be taken during your visit for research purposes will be given a unique code and will not contain your name. If you have unique, identifying tattoos near your shoulder, we will avoid the tattoo while photographing if possible, or edit the photos to 'blur' out your tattoos before storage.
4. If any wound healing complications occur after your surgery, it will be recorded from your medical records and treated per standard of care by your surgeon.
5. We will review your medical record to gather basic information about your health, including your age, height, weight, race/ethnicity and gender. We will also record your diabetes status, smoking history and alcohol consumption.

You can choose to withdraw from the study at any point and stop participating in this data collection. No additional information will be collected from you after you withdraw. However, information already collected will remain in our database. You will not lose any benefits or rights that you are otherwise entitled to. You may discontinue participation at any time without penalty by letting your surgeon or other members of the research staff know in person, over the phone, or

over email. You can contact Dr. Eichinger at the following number: (843) 876-0111, or over email at eichinge@musc.edu.

C. DURATION

Participation in the study will take about 4 visits over a period of 4 months after surgery. Your first visit, the pre-operative visit when you sign the consent form, may be extended by up to 10 minutes to a total of 20 minutes. Your second visit will be your surgical procedure, which may be extended by 5 minutes. The last two visits are post-surgery follow ups that will require up to 10 minutes each.

D. RISKS AND DISCOMFORTS

There is a risk to randomization, meaning that you might be randomized to a treatment that is less effective than the others.

There are also different risks associated with being assigned to the treatment group. Adverse events occurring in approximately 0-1.8% of subjects who used PRINEO include:
Rashes or skin allergies at site of contact (contact dermatitis).

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. There might be unknown risks associated with the treatment that could arise during the study.

E. MEDICAL RECORDS

If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

F. BENEFITS

The potential benefit to you is that the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed.

If you are in the group that receives the PRINEO closure system, and it is successful in improving the speed of wound healing, the appearance of your scar, or reduce the chance of surgical site infection compared to current standard therapy, you may benefit from participating in the study. However, this cannot be guaranteed. Future patients will potentially benefit from the knowledge gained from this study.

G. COSTS

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. It is possible that your insurance company will refuse to pay for the costs associated with study participation, in which case you will be held financially responsible. Please ask Dr. Josef Eichinger if you would like to know more about which tests and studies are being done solely for research purposes.

The sponsor (Ethicon, Inc., Johnson & Johnson) will not pay for the treatment of any injuries incurred through participation in this study or failures of the study compound, and you or your insurance will be responsible for any treatment costs. Some insurance companies will not cover costs when the injuries are associated with participation in a research study. Signing this consent will not remove any of your legal rights.

H. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

I. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

J. DISCLOSURE OF RESULTS

You will not be automatically notified of any incidental clinical findings during the study.

K. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;

- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. SIGNIFICANT NEW FINDINGS

Participants will not be automatically informed about significant new findings on the study. However, if you have questions about progress of the study, you can reach out to your surgeon or a member of the study team to ask for updates.

N. CLINICAL TRIALS.GOV

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.
Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Josef Eichinger at (843) 876-0111. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____
Signature of Person Obtaining Consent Date

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." W**e collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your

health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for

copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a

signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES
MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES
If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE
We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE
This Notice went into effect on April 14, 2003.Revised September 2013.