VA Consent Document

DESCRIPTION OF RESEARCH BY INVESTIGATOR

BACKGROUND
You are being asked to be in a research study. Before you decide, it is important to understand why the research is being done and what it will involve. Please read the information carefully. Discuss it with friends and relatives if you wish. Ask the researchers if there is anything that is not clear or if you would like more information. Take time to decide whether or not to participate. If you decide you would like to be in this research study (also called a "clinical trial") after learning about it, you will sign at the bottom of this form.

What is an Early Feasibility Study? What is the purpose of this study?
You are being asked to be part of an early feasibility research study. This study is under the direction of Sarina Sinclair, PhD, and her research team. Some of the funding is from the Department of Veterans Affairs. The purpose of this study is to determine the safety and function of a new implant for prosthesis attachment after above the knee amputation.

- An early feasibility study is a small clinical study. This is the first time this implant has been used in humans. The information from this study might help us change the design of the implant. This study is going to help us learn more about the safety and function of the implant in humans.
- The FDA has not approved this implant yet. The FDA has granted Dr. Sinclair permission to investigate it in 10 people. DJO Surgical is manufacturing the implant.
- This new implant is intended to replace your current socket-docking system.
- There may be unknown risks with participation in an early feasibility study. There is little data available on the risk of using this implant. Because it is so new, there is also little experience with the implant.

What is the implant being studied? Why is it being studied?
The implant is the Percutaneous Osseointegrated Prosthesis (POP) implant (Figure 1). The POP is meant to restore lost function for above the knee amputees. Currently, attaching your prosthetic leg uses socket technology. A custom designed socket is fitted over your leg after the amputation. A prosthetic leg is then attached to the end of the socket. Socket patients have problems like skin breakdown due to sweating, discomfort, phantom limb pain, insecure sockets, and frequent re-fitting due to weight loss/gain. These challenges make it hard for some amputees to wear their prosthetic limb for more than a few hours a day.

- The POP is an implantable metal orthopedic implant, like implants used in hip and knee replacements.
- Percutaneous means that the implant crosses from the inside of the body to the outside. It goes through the skin.
- Osseointegrated (OI) means that the POP implant is fixed into the bone. It will be fixed to the remaining part of the bone in your stump. This is similar to how parts of hip replacement implants attach to bone.
- The use of OI technology for amputees has been done in other countries for twenty (20) years but has not been tested in an FDA-authorized trial in the United States.

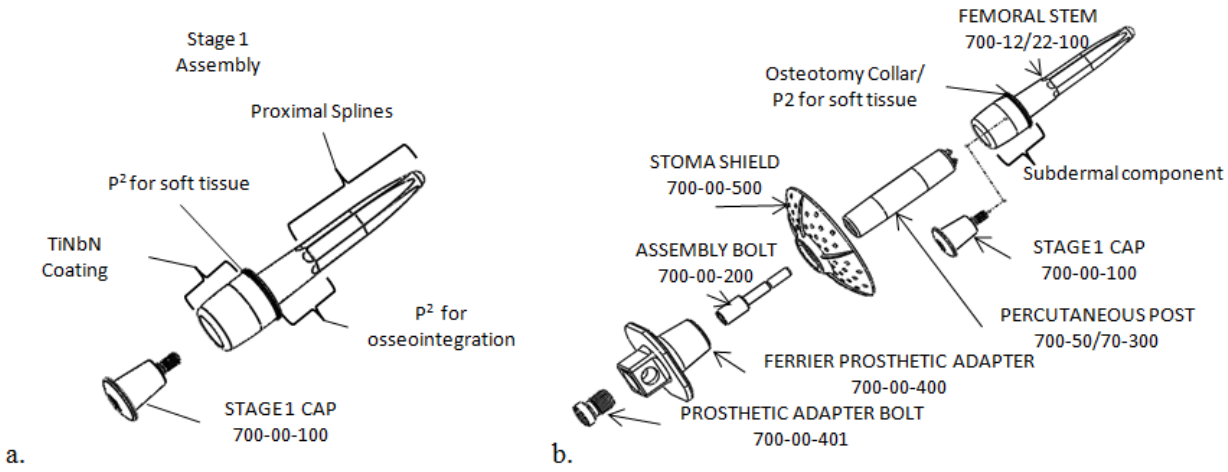

Figure 1a Demonstrates the two major components of the Stage One implant: the Femoral Stem endoprosthesis and Stage One Cap. The unitized osseointegrated endoprosthesis consists of four regions: the proximal splined stem, the porous coated region (P^2) intramedullary region, the P^2 coated osteotomy collar, and titanium-niobium nitride (TiNbN) coated subdermal component. Figure 2b: During the Stage Two procedure the 2cm soft tissue punch is made and the Stage One Cap is removed. This allows for the attachment of the Stage Two percutaneous post and connector device adapter to be bolted to the osseointegrated endoprosthesis implanted during Stage One. The stoma shield is placed external of the body and is used to maintain gauze near the stoma during wound healing.

CONFLICT OF INTEREST

An investigator(s) has a proprietary interest in the test implant because they are an inventor(s) on a intellectual property patent for the device. The investigators on a patent for this device are: Drs. Erik Kubiak, Jayant Agarwal and James Peter Beck. A Conflict of Interest Management Plan has been established for the investigator(s) and can be provided to you.

STUDY PROCEDURES

This study has five stages. Your participation will last about 18 months.

a) Pre-Op
b) Stage 1 Surgery
c) Post Stage 1 Rehabilitation (approximately 4-6 weeks)
d) Stage 2 Surgery
e) Post Stage 2 Rehabilitation and follow-up (approximately 52 weeks)

The standard-of-care for a traditional prosthetic implant does not involve a two-stage surgery. It also does not involve so many follow-up visits and tests.

a) Pre-op

The Pre-op study session will begin approximately two weeks prior to your visit to Salt Lake City, Utah. At this time you will be mailed a Step Watch activity monitor and be asked to wear it attached to your prosthetic limb during waking hours. Instructions will be included in the mailed package. All expenses for your trip to Salt Lake City, Utah will be covered by the study. You will meet with the surgeons, doctors, rehabilitation specialists, social worker and psychologist to complete all pre-operative procedures to include if needed:

- Ask detailed questions about your medical history.
- Perform a routine physical examination.
- Draw blood for a drug screen, clinical lab tests, and (if female) a pregnancy test.
- Collect urine for lab tests, including testing for nicotine use.
- Have you participate in function and kinematics testing. You will walk on a treadmill while wearing a mask to measure your breathing. We will record your regular stride while walking for six minutes, while standing on one leg, and while moving as quickly as you can through cones set in various shapes.
- Anterior/Posterior and Lateral X-rays of residual limb (outside standard clinical care).
- Take DEXA images of your remaining limb. A DEXA is a type of x-ray used to measure bone strength. During this test, X-ray pictures of your body will measure how much fat and muscle are present. You will lie flat on a table and a machine will take pictures of different areas of your body.
- Physical therapy evaluation.
- Answer questions about your experience with your prosthetic, your mood, and your pain.
- Take skin swabs to look at the "good" and "bad" bacteria on your skin
- Answer questions about your personal health habits
- Take photographs of the amputated limb before and after surgery.

b) Stage 1 Surgery

After pre-op procedures are completed you will then have Stage 1 of a two-stage surgical procedure. Stage 1 surgery will be the implantation of the part of the implant that will fix into your bone ('stem'). After the surgery, you will be treated the same as a patient who has had an above-knee amputation. X-rays, skin swabs, blood draws, and questions about your personal health habits will be collected while you are in recovery. You will be discharged from the hospital approximately 4 to 5 days after surgery after a physical exam.

c) Stage 1 Rehabilitation

Before you are discharged from the hospital, we will make sure you can do some basic tasks, like transferring yourself from the wheelchair to the bed, activities of daily living, and cleaning and taking care of the wound. On day 3, we will collect skin swabs, blood draw, and ask you questions about your personal health habits. You will also need to follow directions for a physical therapy program at home. This could include aerobic, flexibility, and strength exercises. Your physical therapy program will be customized for you. You will agree not to wear your prosthetic limb after surgery. You will also agree not to stand without support after the surgery. You will be discharged to return home for up to 6 weeks before you come back for the next stage of surgery.

d) Stage 2 Surgery

You will return to Salt Lake City, Utah. All expenses for this trip will be covered by the study. You will return to the Veterans Affairs Salt Lake City Health Care System (VASLCHCS). At this visit, we will do the following:

- Perform a routine physical examination, including checking your incision for any signs of problems with healing.
- Draw blood for clinical lab tests, and (if female) a pregnancy test.
- Collect urine for lab tests, including testing for nicotine use.
- Take standard X-ray and DEXA images of your remaining limb. A DEXA is a type of x-ray used to measure bone strength. During this test, X-ray pictures of your body will measure how much fat

and muscle are present. You will lie flat on a table and a machine will take pictures of different areas of your body.
- Arrange for you to meet with a psychologist or social worker to talk about your experiences in the study.
- Take photographs of the implanted limb.
- Take skin swabs to look at the "good" and "bad" bacteria on your skin
- Answer questions about your personal health habits
- Ask detailed questions about any undesirable medical problems, signs, symptoms, or other concerns you have had since the Stage 1 surgery.

The part of the implant that will be outside of your bone will be implanted during Stage 2 (the 'post'). This part of *the surgery will involve removing enough tissue necessary to implant the post that will stick out through your skin.* After the surgery, you will be treated the same as a patient who has had an above-knee amputation. X-rays, skin swabs, blood draw, and questions about your personal health habits will be collected while you are in recovery. You will be discharged from the hospital up to 2 weeks after surgery.

During those 2 weeks, you will only be able to stand and transfer on an immobile prosthetic leg until cleared by our medical team. You will not be allowed to walk, but will be allowed to put as much weight as you are able to without pain while under supervision. After the medical team clears you to walk, a research study prosthetist will work with you. A prosthetist is someone who makes sure a prosthetic fits and is aligned correctly. The prosthetist will work to fit and align your prosthetic limb. The same prosthetic knee and foot components that you used with your pre-operative prosthesis will be used. Once fitting and proper alignment of the limb is done, you will be enrolled in your physical therapy rehabilitation program. *On day 7, we will collect skin swabs, blood draw, and ask you questions about your personal health habits.*

e) Stage 2 Rehabilitation

You will have a minimum number of nine (9) supervised physical therapy sessions after the Stage 2 procedure at the VASLCHCS. More sessions will be available to you to reach your specific goals. You will have at least two sessions on balance training, two sessions on walking status training, two sessions on stair training, two sessions on return-to-work activity (work, golf, low impact sports, etc), and one session of a home program where we will make sure you can complete your therapy at home before you will be cleared to return home.

f) Follow-up

You will need to return to Salt Lake City six more times after you are discharged from the hospital so we can collect follow-up data. All expenses for these trips will be covered by the study. Those visits will happen at the following time points after Stage 2 Surgery:
- 2 weeks/Prior to discharge)
- 6 weeks
- 3 months
- 6 months
- 9 months
- 12 months

Each visit will have slightly different tests, but the tests will always take two days or less.

Week 2:
- Conduct a routine physical examination, including checking the implant site.

- Draw blood for clinical lab tests.
- Physical therapy evaluation.
- Photograph the implanted limb.
- Take skin swabs to look at the “good” and “bad” bacteria on your skin
- Answer questions about your personal health habits
- Ask detailed questions about any undesirable medical problems, signs, symptoms, or other concerns you have had.

Week 6:

- Conduct a routine physical examination, including checking the implant site.
- Arrange for you to meet with a psychologist or social worker to talk about your experiences in the study.
- Draw blood for clinical lab tests.
- Have you participate in function and kinematics testing. You will walk on a treadmill while wearing a mask to measure your breathing. We will record your regular stride while walking for six minutes, while standing on one leg, and while moving as quickly as you can through cones set in various shapes.
- Collect X-rays and CT scans
- Physical therapy evaluation.
- Usage measurement using the Stepwatch
- Answer questions about your experience with your prosthetic, your mood, and your pain.
- Photograph the implanted limb.
- Take skin swabs to look at the “good” and “bad” bacteria on your skin
- Answer questions about your personal health habits
- Ask detailed questions about any undesirable medical problems, signs, symptoms, or other concerns you have had

Month 3:

- Conduct a routine physical examination, including checking the implant site.
- Arrange for you to meet with a psychologist or social worker to talk about your experiences in the study.
- Have you participate in function and kinematics testing. You will walk on a treadmill while wearing a mask to measure your breathing. We will record your regular stride while walking for six minutes, while standing on one leg, and while moving as quickly as you can through cones set in various shapes.
- Collect X-rays and DEXA scans.
- Physical therapy evaluation
- Usage measurement using the Stepwatch.
- Answer questions about your experience with your prosthetic, your mood, and your pain.
- Photograph the implanted limb.
- Draw blood for clinical lab tests
- Take skin swabs to look at the “good” and “bad” bacteria on your skin
- Answer questions about your personal health habits
- Ask detailed questions about any undesirable medical problems, signs, symptoms, or other concerns you have had.

Month 6:

- Conduct a routine physical examination, including checking the implant site.
- Arrange for you to meet with a psychologist or social worker to talk about your experiences in the study
- Have you participate in function and kinematics testing. You will walk on a treadmill while wearing a mask to measure your breathing. We will record your regular stride while walking for six minutes, while standing on one leg, and while moving as quickly as you can through cones set in various shapes.
- Collect X-rays, DEXA, and CT scans (12 month only).
- Physical therapy evaluation.
- Usage measurement using the Stepwatch.
- Answer questions about your experience with your prosthetic, your mood, and your pain.
- Photograph the implanted limb.
- Draw blood for clinical lab tests
- Take skin swabs to look at the "good" and "bad" bacteria on your skin
- Answer questions about your personal health habits
- Ask detailed questions about any undesirable medical problems, signs, symptoms, or other concerns you have had.

Month 9:

- Draw blood for clinical lab tests
- Take skin swabs to look at the "good" and "bad" bacteria on your skin
- Answer questions about your personal health habits
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Month 12:

- Conduct a routine physical examination, including checking the implant site.
- Arrange for you to meet with a psychologist or social worker to talk about your experiences in the study
- Have you participate in function and kinematics testing. You will walk on a treadmill while wearing a mask to measure your breathing. We will record your regular stride while walking for six minutes, while standing on one leg, and while moving as quickly as you can through cones set in various shapes.
- Collect X-rays, DEXA, and CT scans (12 month only).
- Physical therapy evaluation.
- Usage measurement using the Stepwatch.
- Answer questions about your experience with your prosthetic, your mood, and your pain.
- Photograph the implanted limb.
- Draw blood for clinical lab tests
- Take skin swabs to look at the "good" and "bad" bacteria on your skin
- Answer questions about your personal health habits
- Ask detailed questions about any undesirable medical problems, signs, symptoms, or other concerns you have had.

RISKS

Not all risks associated with the use of the study implant are currently known. There may not be information to fully predict how often the risks may occur and how much of a problem they may be. Risks, discomforts or side effects we are aware of that you may experience for each procedure include:

- **General Risks of research:**

- There is always a chance that the information you provide could be used by people who are not authorized. We will use a combination of numbers and your initials instead of your name to identify you in study records. All medical records are protected as required by national regulations for handling research and medical data. No personal identification (such as your name, date of birth or social security number) will be used in any reports or publications.

- **Risks of Study Procedures**
  - Typical risks include typical complications from blood draws (e.g., bruising, discomfort) and the rehabilitation tests (e.g., falls, fatigue, discomfort). These risks are no different than the risks of routine medical procedures.
  - Radiation exposure. This research study involves X-rays, DEXA scans, and CT scans. These scans are not standard of care. You are having them only because you are in this study. You will be exposed to radiation. The risk from this radiation exposure is small. It is similar to other every day risks. To put this risk in perspective, everyone receives a small amount of unavoidable radiation every day. Some of this radiation comes from space while some comes from radiation that is naturally occurring in water, soil, rocks and minerals found in plants and animals. The excess radiation that you will be exposed to in this research study is equivalent to about 339 days of natural background radiation. This does not include any radiation exposure that you may receive from other types of tests.
- **Risks of Surgery:**
  - General risks of surgery include the risk of infection, heart attack or stroke, blood loss, blood clot (DVT), pain, and death.
  - Risks in this procedure are similar to those associated with joint replacements. They can include the risks listed above and implant loosening, impingement (muscles or tissue near joints getting “pinched” by the bones), osteolysis (loss of bone around the implant), metal sensitivity, leg length difference, nerve palsy (usually a temporary weakness or inability to move parts of the body), and embolic disease potential (clots that break off in one part of the body and block blood flow in another part).
  - Other risks with this specific implant include: Soft tissue infection, periprosthetic fracture (fractures around the implant), and inability to wear a conventional socket prosthesis due to complications.
- **Risks of POP Device:**
  - A risk analysis of the POP device has been conducted in compliance with the FDA Guidance (21 CFR 820/ISO 14971). All anticipated risks have been mitigated through appropriate POP device design control and confirmed by nonclinical bench and/or laboratory testing. The results of the analysis indicate that all potential device-related hazards have been reduced to an acceptable level. The POP device materials have been shown to be biocompatible and acceptable for human use.
  - The risks identified prior to this study include all of the standard risks of major surgical procedures. These risks include:
    a. Risks of anesthesia (provided to subjects as part of the surgical informed consent process)
    b. Infection
    c. Pain
    d. Cardiovascular complications, including deep vein thrombosis, heart attack, or stroke
    e. Death
  - Additional, device specific risks include pain, infection, discomfort, revision, altered gait, and dissatisfaction with the device. Specific routes that may lead to each of these risks

and the mitigation strategies for each are listed in the table below:

Device Failure Modes and Mitigation Strategies	
Potential Route for Risk	**Mitigation Strategies**
Failure to achieve the biobarrier between soft tissue and the device	Monitoring of skin grade, antibiotics, daily hygiene, x-rays, clinical laboratory testing, surgical intervention or revision.
Soft tissue abrasion (impact to residual limb pinching soft tissue against implant)	Monitoring of skin grade, patient instruction surgeon mitigation strategy, daily hygiene
Stoma too tight-preventing wound healing	Monitoring of skin grade, surgeon mitigation strategy, daily hygiene, self-report usage measures
Stoma too loose preventing wound healing	Monitoring of skin grade, surgeon mitigation strategy, daily hygiene, self-report usage measures
Bacterial or chemical contamination of the stoma	Monitoring of skin grade, surgeon mitigation strategy, daily hygiene, self-report usage measures
Exceeds expected loading capacity/fatigue damage to system joints	Device design – including low plasticity burnishing to increase taper locking strength and reduce fretting and use of locking assembly screw and secondary assembly of connection device to post, physical examinations, kinematic assessments, physical therapy assessments, functional assessment tools
Pain or discomfort during device use or when at rest	Device design, including easy to use connector device with a low profile from stoma emergence, Self-report usage measures, kinematic assessments, physical therapy evaluations
Difficult to don and doff	Device design, including using a sacrificial connector device attached to distal end of post, connection to off-the-shelf class 1 prosthetic device, self-report usage measures, timed don/doff assessment

Unfortunately, we cannot predict all risks with a new implant. We also cannot predict how common some of these possible risks are. We have designed the study to make it as low-risk for you as we can. Some of those strategies are listed below.

- **Design strategies:** Engineers and doctors have designed the implant to limit the risk of infection.
- **Surgical strategies:** We are using a two stage surgical procedure should help minimize risk of infection. The surgeons will use conventional surgical antibiotic treatment and vented surgical instruments.
- **Therapy strategies:** You are encouraged to start walking early after surgery, will have close supervision of physical therapy activities, and a standardized minimal rehabilitation protocol. The six-week wait period before the stage 2 surgery is designed to help prevent loss of bone around the implant (osteolysis) and loosening.

The clinical study protocol has been established to ensure that your risks will be minimized. Specific processes put into place include:

- Ensuring that investigators meet specific criteria for selection as an investigator

- Selecting a Good Clinical Practices (GCP) experienced study center and study staff (including investigators) aware of the need to protect a subjects rights, safety, and welfare as well as confidentiality of subject information
- Clearly defining inclusion and exclusion criteria that are written to eliminate subjects thought to be a medical "high risk" for the procedure
- Observing standard hospital procedures in the care of subjects for non- clinical study protocol defined treatments
- Ensuring comprehensive and consistent subject follow-up by frequent monitoring visits to investigational sites to avoid unnoticed safety events or delayed event reporting.
- Emphasizing device use and pre and post-procedure management in the initial physician training program and continuing this process throughout the treatment phase of the clinical study.
- Monitoring by an external data safety monitoring board throughout the study

UNFORESEEABLE RISKS
In addition to the risks listed above, you may experience a previously unknown risk or side effect.

REPRODUCTIVE RISKS
It is possible that if the treatment is given to a pregnant woman, follow-up radiation could harm the unborn child. Pregnant women must not take part in this study, nor should women who plan to become pregnant during the study. Women who are at risk of pregnancy will be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. If you could become pregnant, you must use an effective contraceptive during the course of this study. Acceptable methods of birth control include abstinence and hormonal birth control. If you become pregnant while taking part in the study, you must immediately tell your research doctor. Options will be discussed with you at that time. Whether or not you remain on study treatment, we will follow the outcome of your pregnancy and we will continue to follow you according to the study plan.

BENEFITS
We designed this study to improve the quality of life for amputees by improving prosthetic limb attachment. We hope that this study will help you personally but we cannot guarantee any result.

The POP implant has the potential to improve care for amputees by reducing complications from traditional systems. Even if there is limited or no personal benefit to you as the study subject, future amputee patients may benefit from the information you provide during this study.

ALTERNATIVE PROCEDURES
This study is completely voluntary. You may choose not to participate in this study without changes to your regular prosthetic care. The alternative to being in this study is to continue using your current prosthetic.

CONFIDENTIALITY
We will keep all research records that identify you private to the extent allowed by law. Records about you will be kept in locked filing cabinets and on computers protected with passwords and encryption, etc. Only people who work with this study or are performing their job duties for the VA Salt Lake City Health Care System (VASLCHCS) will be allowed access to your information.

Representatives from the Veteran's Administration, the Food and Drug Administration (FDA), and DJO Surgical (the implant manufacturer) may inspect and/or copy your records. We will do everything we can to keep your records private, but cannot guarantee this. We will also have independent reviewers look at

safety information during the study. They will not have access to your name, but they will be able to look at all the study records.

Results of the study may be published. Your name and other identifying information will be kept private.

A Department of Veterans Affairs Checklist for Reviewing Information Protection in Research will be used as a reference by the Investigator(s) to document the plan for privacy, confidentiality and security of VA data and information

Photographs and Multimedia Recordings to be Collected:

- Photographs your residual limb will be taken over the course of the study.
- A video will record all gait analysis during the course of the study. Your face may be recorded but all attempts will be made to record you from the neck down.
- Video of your performing functional assessments may be recorded. Your face may be recorded but all attempts will be made to record you from the neck down.
- No compensation will be offered to you for allowing yourself to be recorded for research purposes
- All members of the study team will have access to the recording(s), which will contain no identifiers
- Recordings will be stored on a password-protected computer in the VASLCHSC Building 2 Room 2D32B. Recording(s) will be kept until journal publication of the study is complete.
- Multimedia images/recordings will be disclosed outside of the VA

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact Sarina Sinclair, PhD at (801) 582-1565 ext. 4330. If you think you may have been injured from being in this study, please call Dr. Sinclair. She can be reached at (801) 585-1565 ext. 4330 Monday-Friday 9:00 am-5:00 pm. After these hours and on weekends, you can call the VA Hospital operator at 801-587-1565 and ask for the orthopaedic resident on-call.

INSTITUTIONAL REVIEW BOARD

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

MEDICAL TREATMENT OR COMPENSATION FOR INJURY

The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

VOLUNTARY PARTICIPATION

It is up to you to decide to be in the study or not. If you decide to be in the study, you can still quit at any time and without giving a reason. Deciding not to be in the study or withdrawing yourself from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff. It will not decrease the standard of care that you receive as a patient.

If you want to stop being in this study, please let Dr. Sinclair know. You can find out what should be done about your routine care outside of the study. If you withdraw between Stage 1 and Stage 2 surgeries, you will still need a surgery to remove the implant from Stage 1. This may affect your ability to go back to using your old prosthesis. If you withdraw after Stage 2, you will still be able to have care through the VA system. You will not be under the care of the research doctors at the VA Salt Lake City Health Care System.

RIGHT OF INVESTIGATOR TO WITHDRAW

The investigator can withdraw you without your approval.

- This can be done for safety reasons. The research team will decide if adverse reactions that develop during the study make it unsafe for you to continue to participate. If new information becomes available that makes the researcher believe the study is no longer safe for you, the research team might withdraw you from the study.
- This can be done for compliance reasons. If you are unable or unwilling to follow study rules or attend the study visits when they must be scheduled, the researcher can remove you from the study. If you become involved in another clinical study, you can be removed from this study.
- This can be done for a combination of reasons. If you attempt to modify the implant – for example, tightening or altering connections without approval from a researcher – you can be removed from this study. This could be a safety issue, a compliance issue, or both.

CONSEQUENCES OF SUBJECT WITHDRAWAL

If you withdraw from the study or are removed, you may not return to the VA Salt Lake City Health Care System for regular study visits. You may need to return for a final visit in order to ensure that you exit the study safely.

If there are problems with the implant that require surgery to correct or if you have not had Stage 2 surgery, you will return to VA Salt Lake City Health Care System for surgery to correct the problem and/or remove the implant. We will pay for this travel. This could result in a shorter limb than when you entered the study. This will also mean that you need a new conventional prosthetic. This will be covered under regular VA care, so you will use the resources of the VA system you regularly use, not necessarily the VA Salt Lake City Health Care System.

If you experience a research related injury that does not require surgery and you withdraw or are withdrawn from the study, the researchers will determine the best course of action based on your individual situation. If you need to come to the VA Salt Lake City Health Care System, your travel expenses will be paid. If not, this will be covered under regular VA care, so you will use the resources of the VA system you regularly use.

As the study goes on, we will always share new information with you that will help you decide if you want to stay in the study.

COSTS TO PARTICIPANTS AND COMPENSATION

We will pay for your travel to and lodging while in Salt Lake City, Utah for research purposes. Veteran participants are not required to pay for care and services (treatment) received as subjects in VA research projects. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. You will be given the federal per diem rate for expenses while in Salt Lake City, Utah for the study.

NEW INFORMATION
Sometimes during the course of a research project, new information becomes available. If this happens, the researcher will tell you about it and discuss with you whether you want to continue in the study.

If you decide to drop out at that time, your research doctor will make arrangements for your medical care to continue. If you decide to stay in the study, you may be asked to sign an updated consent form that contains the new information.

NUMBER OF PARTICIPANTS
We expect to enroll ten (10) participants at the VA Salt Lake City Health Care System (VASLCHCS).

TISSUE COLLECTION AND USE
Some of the tissue (bone, skin) and blood samples that you provide in this study will be used up during the initial tests performed for this study. Some of the samples will be stored for future evaluation regarding the POP implant. One question that is likely to be investigated will be how the bacteria present on your residual limb changes over time. Because this study is an early feasibility study, we do not know every possible question that might come up during the research on the POP implant and your surgery to receive this implant. If we later discover a research question about the implant or your health in terms of the implant that we can answer by using your sample, we would like to be able to go back and use it. Your sample will only be used to answer research questions that arise regarding the device in question. If we keep your tissue for later research on the implant, the sample and your clinical data will be assigned a code that does not contain your name, initials, SSN, date of birth, or other unique identifiers. Your sample will be coded so that your name is not on the sample and will be stored in a locked freezer at the VASLCHCS. Dr. Sarina Sinclair and the VASLCHCS will keep your name in a separate place so that we can link your sample back to you later if we need to.

Tissue or blood samples obtained from you in this research may help in the development of a commercial product by the University of Utah, DJO Surgical or its research partners. There are no plans to provide financial compensation to you should this occur.

If you withdraw from the study, your samples will be removed from storage and destroyed. You will need to contact Sarina Sinclair, PhD at (801) 582-1565 ext. 4330.

CONSENT

I confirm that I have read this consent document and have had the opportunity to ask questions. I will be given a signed copy of the consent form to keep. I agree to participate in this research study as you have explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of Person Obtaining Consent	_____ Signature of Person Obtaining Consent	_____ Date