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Orthopaedics

Triathlon PSR Outcomes Study

CLINICAL PROTOCOL

A prospective, post-market, multi-center evaluation of the clinical outcomes of the Triathlon Total Knee System using the Triathlon PSR Tibial Insert

Sponsor:	*Stryker Orthopaedics* *325 Corporate Drive* *Mahwah, NJ 07430* *201-831-5000*
Study Product:	*Triathlon PSR Tibial Insert*
Protocol Number:	*103*
510(k) Clearance Number:	*190402*

Version 1.1

Date: 13-Apr-2021

CONFIDENTIAL

Appendix C

Model Informed Patient Consent

Informed Patient Consent

I. Study Title: A prospective, post-market, multi-center evaluation of the clinical outcomes of the Triathlon PS Total Knee System using the Triathlon PSR Tibial Insert

II. Description of the Study

You have been asked to be in this research study because your doctor believes you need surgery to replace your knee joint. About 250 people from up to 8 different hospitals will be in this study.

The reason this study is being done is to see how successful a knee replacement is using parts called the Triathlon PS Total Knee System and the Triathlon PSR Tibial Insert. Some of these parts will be put in using bone cement. The study will be able to tell how the knee replacement parts are performing by comparing the score from one of your questionnaires with a reference score obtained from subjects who received the Triathlon PS Total Knee System and the Triathlon PS Tibial Insert (ClinicalTrials.gov Identifier: NCT00957021).

This study is being done by Stryker Orthopaedics (the maker of the knee replacement, also called the Sponsor) and your doctor.

Your doctor and his staff will ask you some questions during this visit. Based on the requirements of the study, you may or may not be chosen to be in the study.

Fitting all of these requirements does not mean you will be in the study. The doctor also has to examine you to make sure the study is right for you. The staff at the doctor's office will tell you everything about the study. Then you can decide if you want to be in the study or not.

Your participation in the study will last for 10 years following your study surgery. Your doctor will examine you before surgery and during surgery. You will have surgery and your doctor will tell us the details of your surgery. During the visit before surgery you will need to fill out forms about your health. Your doctor will also collect other information and x-rays that would be collected at a normal visit.

He will then examine you for the study after your surgery. During your visits to the doctor after surgery, your doctor will figure out how your knee is performing and take x-rays. These x-rays are the same kind you would have if you were not in the study.

At your visits to the doctor after surgery, your doctor will ask you to fill out questionnaire forms. These forms will be about your health. These visits will follow the evaluation schedule below:

Evaluation	Before Surgery	6 Weeks	1 Year	2 Year	3 Year	4 Year	5 Year	Annually 6 Years - 9 Years	10 Years
Inclusion/ Exclusion	X								
Demographics & Medical History	X								
Surgical Details									
2011 Knee Society Score	X	X	X	X			X		X
Forgotten Joint Score				X					
SF-36	X	X	X	X	X	X	X		X
EQ-5D	X	X	X	X	X	X	X	X	X
Radiographs: AP/ML/Merchant View	X	X	X	X			X		X
Follow-up Questionnaire					X	X		X	

2011KSS: The 2011 KSS is a standardized instrument with both patient-reported outcomes and surgeon completed sections that evaluate function, satisfaction, expectations and range of motion.
SF-36: The SF-36 is a standardized 36 item patient reported outcome questionnaire that evaluates general health and well-being.
FJS: The FJS is a 12-item questionnaire assessing a patient's ability to forget his/her artificial joint in everyday life.
EQ-5D: The EQ-5D is a standardized instrument for use as a measure of health outcome.
Follow-up Questionnaire: The Follow-up Questionnaire is a short patient questionnaire intended to provide information on patient satisfaction, pain, study device survivorship and AEs
AP View: Radiographic view of the knee containing the femoral component, medial and lateral femoral epicondyles, tibial component, and polyethylene insert.
ML View: Radiographic view of the knee containing the patella, patellar component, and overlapping posterior condyles of the femoral and tibial component.
Merchant View: Radiograph view of the knee containing the articular surface of the patella and femur.

III. Condition and Care after Surgery

Your doctor will tell you what to do to get better after your surgery. Like with any surgery, your body takes time to heal. That amount of time will be related to the surgery and your health. While you are healing, you may experience pain because of the surgery. This pain might last a few months after the surgery.

Your doctor will tell you to use crutches, a walker, or a cane after your surgery. This will take some weight off of your knee. This can help your knee replacement last longer. You must follow your doctor's orders on using a cane, crutches, or walker.

The goal of this surgery is to lessen pain and improve your knee performance. You will need to see your doctor at the scheduled follow-up visits after your surgery for an evaluation of your knee replacement.

IV. Possible Risks

This study looks at how your knee replacement is performing. The Food and Drug Administration (FDA) already allows this knee replacement to be sold in the United States. There are no extra risks for you because you are in this study, just the normal risks of knee replacement surgery. You may need to spend a little more time in the doctor's office to fill out paperwork. If the doctors and scientists find out any new information during this study that might make you change your mind about being in the study, you will get that new information.

There are some risks in knee surgery. These might be: moderate to severe pain; breaking the knee replacement parts or the surrounding bones; movement of parts of the replacement inside your body; parts of the replacement sinking; parts of the replacement moving out of their normal position; allergies to the metal parts of the replacement; removal of one or more of the parts; loosening and infection; rubbing of parts of the replacement which might lead to losing part of the bone; disorders of the nerves involving your legs; damage to the nerves; abnormal building up of bone; changes in movement of your blood related to your heart, blood and lymph vessels; problems with urinating; problems with your stomach or intestines; problems with blood vessels like blood clots; lung problems like pneumonia; a clogged blood vessel; or a heart attack.

V. Potential Benefits

You might not benefit personally from being in the study, but the results might help out others that have knee replacement surgery in the future.

VI. Other Types of Treatment

You have talked about other possible treatments with your doctor. These treatments might be: conservative treatment that is not surgery or no treatment at all.

You can say no to being a part of this study. This will not change any part of your knee surgery. Your doctor can tell you detailed facts about this treatment and the benefits of other types of treatment you can have. You should feel free to talk with your doctor about other options.

VII. Making Financial Information Known

Your doctor and/or the hospital can be paid money from the company that made the knee replacement. This money would be to pay for the cost of doing the study or for other reasons. If you want to know more about this you can ask your doctor or his staff.

VIII. Privacy

If you say yes to being a part of this study, your medical records and identity will be kept private. They will be kept private based on the law. The records will not be given to anyone unless you give written permission.

If you sign this consent form, you allow Sponsor employees to see your medical records. You also allow people who look at how safe and effective medical products are to see your records. These people also make sure that medical treatment and research studies are safe. Your name and identity will not be in those records.

IX. Cost to Be in the Study

Your procedure is a routine primary knee surgery and should be covered by your insurance carrier.

Additionally, you will be offered a stipend in the form of a debit card for various follow-up visits held in your doctor's office. You must complete all of the applicable questionnaires and evaluations in order to receive the stipend per visit. You can learn more about the program from your study doctor and his staff.

X. Device Retrieval Analysis Study

If [Investigators' Names] finds it medically necessary to perform a knee revision because of device failure, Stryker Orthopaedics (the Sponsor) has a procedure to test the parts.

I understand that the Sponsor makes the implant and runs the study. I understand that the Sponsor will ask my doctor to send any removed knee replacement parts to them. My doctor will send them to the Product Surveillance department at Stryker Orthopaedics. They will test these parts, and this can be a part of being in the study.

I allow my doctor to give the Sponsor any knee implant parts that have been removed. I also allow my doctor to give the Sponsor other information. This other information is my birth date, sex, and details about my knee surgery. Then the Sponsor can test the knee replacement parts that have been taken out.

My doctor will get the results of this testing. I understand that I will not get these parts back. I also understand that I will not get the results of any tests that are done on those parts.

I understand that nobody outside of the Sponsor will see my removed knee replacement parts.

I understand that I can I decide I do not want to let these knee replacement parts be analyzed anymore. I can also decide I do not want my identity information to be used anymore. I understand that I will need to say this in writing. I understand that any information from before this decision is still allowed to be used.

Records about me will be kept private. I can choose whether I want to allow my knee replacement parts to be studied if they are taken out. I understand I am allowed to say no to having my knee replacement parts studied. I also understand that I can stop being in the study whenever I want. If I choose to stop being in the study, my doctor will not change my care or treatment.

I have signed below and have read and understood what is written above. I allow for information about my identity to be released. My signature shows that I have had a chance to ask questions about this removed knee replacement parts study. My doctor has answered these questions. I have been given a copy of the consent form.

Please check one of the boxes below:
☐ I agree to allow the Sponsor to study any knee replacement parts removed from me.

☐ I do not want to allow the Sponsor to study any knee replacement parts removed from me.

_____ _____

Signature of Subject/Legal Representative Date

XI. Clinical Trial Website Posting

A description of this clinical trial will be on the website http://www.ClinicalTrials.gov. The U.S. law says it has to be posted on that website. This Web site will not have any information that can tell other people who you are. The Web site will show some of the results, or maybe even less than that. You can search this Web site whenever you want.

XII. Payment and Medical Treatment Related to Injury

The Sponsor will not give you any money if you have a medical problem related to surgery. Stryker Orthopaedics will not give you free medical treatment. If you have a medical problem related to your surgery you should call [Investigators' Names] as soon as you can at [Phone Number].

[Institution Name] will not give any money back or free treatment to you either. [Investigators' Names] should tell you about what the hospital does if you have a complication. By signing this consent form you are not getting rid of any of your rights. Your doctor is still responsible if he does something wrong.

XIII. Access to Data and Privacy

By being part of this study, you are letting your doctor and his staff give the Sponsor information about your health. You also allow people who look at how safe and effective medical products are, to see your records. These people also make sure that medical treatment and research studies are safe. This is required by the law. This health information includes all information from the study. It may also include other health information in your medical records. Some of this health information might be from before you joined the study.

The Sponsor will only collect information that they need for the study. They will make sure that the information they get does not have your name or address on it. They will make sure that no one else will see information about your identity.

The Sponsor will use information about your health to do the study. They will use the results of the study to evaluate the performance of the knee replacement parts. They will also use the results to improve the parts that they make. They might also use the information to design new parts.

This permission to use your information does not have an ending date. You can take back this permission to release your health information at any time. You can do this by telling your doctor in writing. If you say you do not want to be in the study anymore it will not change the work that has already been done in the study.

You have to sign this consent form to be in the study. This form also lets your health information be seen by those groups mentioned before. If you take back this consent

you cannot be in the study anymore. At the end of the study, information about your identity cannot be used anymore.

XIIV. People to Contact

If you have any questions you can call [IRB Name] IRB at [IRB Phone Number]. If you want to know your rights as part of the study, you can also ask the IRB. You should contact Dr. [Investigators' Names] as soon as you can at [Phone Number] if you have an injury that is related to the study.

XV. Being in the Study

Being part of this study is your choice. If you do not choose to be in the study you will not lose any benefits that you are supposed to have. You can decide you do not want to be in the study anymore and will not lose the benefits you are supposed to have.

By signing and dating this form below, you are saying you have read and looked over all sections of this Informed Consent Form. You are also saying someone has answered all of your questions. You are also saying that you voluntarily consent to be in this research study. If you do not sign this form, you will not be allowed to be in the research study.

_____
Printed name of Subject/Legal Representative

_____ _____
Signature of Subject/Legal Representative Date Signed

_____ _____
Signature of Person conducting the consent process Date Signed

_____ _____
Signature of Investigator Date Signed

A signed and dated copy of this consent form must be given to the patient.