Model Informed Patient Consent

04/28/2008

Triathlon TS Outcomes Study

A prospective, post-market, multi-center study of the outcomes of the Triathlon Total Stabilizer (TS) Total Knee System

ClinicalTrials.gov Identifier: *NCT00958789*

Informed Patient Consent Form

1. **Study Title:** Post-market Study of the Stryker Orthopaedics Triathlon® TS Total Knee System

2. **Description of the Study**

You have been asked to take part in this research study because your physician has determined that you need surgery to replace your artificial knee joint. A total of approximately 181 subjects from 7 - 12 different clinics will be participating in this study.

The purpose of this study is to evaluate a knee implant called the Triathlon® TS Total Knee System used when a previous knee replacement surgery has failed. The Triathlon® TS Total Knee System includes femoral components (attached to your thigh bone), distal and posterior femoral augments (helps attach femoral components to your bone, if needed), fluted and cemented stems (when more length and stability are required), stem extenders (to add more length to a stem) and offset adapters (to change where the stem can be placed). When mated with the Triathlon® TS Universal Tibial Baseplate (attached to your shin bone), tibial inserts (the plastic piece that attaches to the baseplate) and tibial augments (helps attach tibial components to your bone, if needed), the parts provide a stable, balanced total knee replacement.

We (Stryker Orthopaedics, implant manufacturer and sponsor of this study, and your physician) are doing this study to find out if Stryker Orthopaedics Triathlon® TS Total Knee System is at least as good as other revision knee systems that are currently being sold.

You will be asked some questions during this visit and based on the study specific criteria, you may or may not be selected to participate in the study.

If selected, your participation in the study will last 5 years. You will be evaluated for this study during a preoperative visit, during surgery, as well as 6 weeks, 6 months, 1, 2 and 5 years postoperatively.

During the preoperative visit you will be asked to complete four (4) general health assessment questionnaires in addition to the standard information and x-rays that your doctor will collect during your office visit.

You will undergo surgery and your doctor will also provide us with the details of your surgery.

During your 6-week, 1, 2 and 5-year follow-up visits, your doctor will assess the function of your knee and take three (3) x-rays. This set of x-rays is the standard of care following knee surgery and would be performed in the same manner if you were not involved in the study. Your doctor will inform you where the x-rays will be done. In addition, your doctor will ask you to fill out the four (4) general health assessment questionnaires at your 1, 2 and 5-year visits.

At your 6-month time point, a follow-up visit is not required, but you will be asked again to complete the four (4) general health assessment questionnaires. The questionnaires may be mailed to you if you do not return to the office.

3. Postoperative Condition and Care

Your doctor will give you specific instructions regarding your care and rehabilitation after your surgery. As with any surgery, your body takes time to heal. That amount of time will be related to the extent of the surgical procedure and your general physical condition. During this period of healing, you may experience postoperative pain, perhaps lasting for several months after the operation.

You will be told to use walking aids (crutches, walker or cane) for a period of time after your surgery. The use of these walking aids will lessen pressure and weight loads on your knee, which is thought to increase the chances for a stable implant. You have been informed that you must follow your physician's orders, including those regarding the use of walking aids.

The goal of this surgery is to lessen pain and increase your knee function. You will need to see your physician at 6 weeks, 1, 2 and 5 years after your surgery for evaluation of your artificial knee joint.

4. Foreseeable Risks and Discomforts

This study involves the routine assessment of a revision knee replacement procedure. The FDA has cleared the device used in this study for sale in the United States. There are no additional risks associated with participating in this study over and above that of the revision knee surgery. You may need to spend a little more time in the doctor's office to fill out paperwork. If at any time new information is developed during this research study which may affect your willingness to participate, the information will be provided to you.

There are, however, standard risks associated with knee surgery. These include but are not limited to: moderate to severe pain; infection; dislocation (to move out of normal position) of the femoral [thigh]; tibial [shin] or patellar [knee cap] prosthesis (artificial knee); fatigue fracture (breakage) of the components; wear (rubbing) of the components which could lead to bone loss; loosening and infection; sensitivity to metal components (femoral [thigh] and tibial [shin]); revision (removal) of one or more of the components; peripheral neuropathies (any disorder of the nerves involving your legs); nerve damage; circulatory compromise (changes in circulation related to your heart, blood and lymph vessels, to varying degrees) and abnormal bone formation; genitourinary disorders (related to urination); gastrointestinal disorders (related to the stomach and intestines); vascular disorders (related to blood vessels: including thrombus [blood clot]); bronchopulmonary disorders (related to the bronchi tubes and lungs, such as pneumonia); emboli (plugged vessel); myocardial infarction (heart attack) or death.

5. Potential Benefits

While there is no guarantee that you will personally benefit from inclusion in this study, information gathered in this study may benefit others undergoing knee revision surgery in the future.

You will have incentives to return for follow-up visits through a patient retention program. Patients enrolled into the study are encouraged to complete all of their required follow-up visits. You will earn points for completing each follow-up visit within the windows outlined in the protocol and without any protocol deviations. You will then have the opportunity to redeem your points for a gift selected from a specific listing, or save them and work toward a higher-level gift. As the follow-up visits increase in number, the point values associated with the visits will also increase. The monetary value of the gifts is modest and should not influence your decision to participate in the study.

Number of Visits Completed	Award Level	Points
1 visit	A	100 points
2 visits	B	200 points
3 visits	C	300 points
4 visits	D	400 points
5 visits	E	500 points

6. Alternative Treatment

You have discussed alternative treatments with your surgeon, which include but are not limited to: conservative non-surgical treatment, resection arthroplasty (bone sectioning), knee arthrodesis (knee fusion) or no treatment at all.

You may decline to participate in this study. This will not change any procedures associated with your knee surgery. Your physician can provide detailed information about this treatment and the benefits of various treatment options available to you. You should feel free to discuss your alternatives with your physician.

7. Confidentiality

If you consent to participate in this study, your medical records and identity will be kept confidential to the extent permitted by law and will not be released without your written permission. By signing this consent form, you agree to allow representatives from the study sponsor to review your medical records. Some of this information will be provided to the study sponsor and its agents and contractors, and as required by law, review boards and other people who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research. Your name and identity will not be revealed in those reports.

8. Cost to participate in this study

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

9. Device Retrieval Analysis Study

The sponsor of this study is conducting an analysis of retrieved devices in the event that a study component that you have implanted by your physician is removed during the course

of the investigation. In the event the device ever requires removal, and with your permission, the sponsor has asked your physician to send your retrieved component to the sponsor for evaluation as part of your participation in the study. Your retrieved study component and your individually identifiable information will not be released to outside parties. The device will not be returned to you, nor will you receive directly the results of any tests, analysis or evaluations on the returned device.

10. Clinical Trial Website Posting

Information about this study will be posted on the following website: www.clinicaltrials.gov. This website provides general information including, but not limited to, the number of patients enrolled in the study, the primary and secondary objectives/outcomes, and overall demographics (items such as average age, height and weight) of the study group. In no way will specific patient information be posted on this website.

11. Injury Related Compensation and Medical Treatment

Stryker Orthopaedics will not provide compensation or free medical treatment if you suffer any medical complications related to the surgery. (Investigator's name) should be contacted immediately at (Investigator's phone number) if such a complication occurs. No monetary compensation or free medical treatment will be made available by (Name of Hospital). (Investigator's name) should inform you of the hospital's policy in such matters. Signing this consent in no way waives your legal rights or releases the investigator, the sponsor, the institution or its agents from liability or negligence.

12. Access to Data and Confidentiality

By participating in this study, you are also authorizing your physician and his/her staff to provide your health information to the sponsor, its agents and contractors, and as required by law, review boards and other people who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research. This health information includes all information collected during the research and health information in your medical records that is relevant to the research.

The sponsor will only collect that information which is necessary to support the objectives of the research, and will take precautions to ensure that data received has your identifying information (name, address, etc.) removed as much as possible. In the case that some identified information is received, the sponsor will ensure that any identifying information will not be reported. Use of your health information, once received by the sponsor, is no longer covered by national privacy laws.

The sponsor will use your health information to conduct the study, as well as for additional purposes such as overseeing and improving the performance of its devices, proposals for developing new medical products or procedures and other business purposes.

This permission does not have an ending date, but you may take back this permission to release your health information at any time by notifying your physician in writing. Understand that doing so will have no effect on actions taken before that time. This consent, authorizing that your health information may be provided to those indicated, must be signed in order for you to participate in this research study. If this consent is revoked

you can no longer participate in this research study. In any case, your authorization to release individually identifiable information will expire at the end of this study.

13. Contact Persons

If you have any questions about this study or about your rights as a research subject, please contact (provide name and phone number). If you have a research-related injury, you should immediately contact (provide name and phone number).

14. Participation

Your participation in this study is strictly voluntary. Refusal to participate in the study will not result in any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

By signing and dating the form below, you are indicating that you have read and reviewed all sections of this Informed Consent Form, you have had all your questions answered and you voluntarily consent to participate in this research study.

_____
Printed name of Subject/Legal Representative

_____ _____
Signature of Subject/Legal Representative Date Signed

(additional signatures that may be required):

_____ _____
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.