# Triathlon II Acetabular Shell Revision Study

*October 9, 2019*

*NCT04317586*

## Model Informed Patient Consent

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I. **Study Title:** A prospective, post-market, multi-center evaluation of the clinical outcomes of the Trident II Acetabular Shell in a revision indication

II. **Description of the Study and Your Participation in the Study**

You are being asked to take part in this research study because you are having revision surgery to replace your failed hip joint. A total of approximately 347 subjects from up to 15 different clinics will be participating in this study.

The purpose of this study is to evaluate the success rate of cementless revision hip replacement with the Trident II acetabular shell as compared to other cementless acetabular shells, through absence of revision at 5 years postoperative. This research study is being conducted by Stryker Orthopaedics (Sponsor and Implant manufacturer) and your doctor.

Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. Your doctor and his staff will ask you some questions during your preoperative visit to determine whether you are eligible to participate in the study. If you meet the study requirements, and if your doctor determines that the study is right for you, you will have the option of participating in the study. Your doctor can answer any questions you might have about the study before you decide to participate. Your participation in this study is voluntary. You can tell your doctor you do not want to be a part of the study. If selected, your participation in the study will last 10 years. You will be evaluated for this study during a preoperative visit and during surgery. Postoperatively, you will be evaluated at 6 weeks, and then on an annual basis from 1 through 10 years. Some of these visits will be in the office, and others can be completed through the mail.

During the preoperative visit you will be asked to complete 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, 5, 7, and 10-year follow-up visits, your doctor will assess the function of your hip and take two x-rays. This set of x-rays is part of the standard care following hip surgery, and would be performed in the same manner if you were not involved in the study. During your 3-6 month visit, only a set of x-rays are requested. Your doctor will inform you where the x-rays will be done. In addition, your doctor will ask you to fill out the general health assessment questionnaires either in the office during your follow-up visit, or via mail when you are not required to go to the office.

The forms that are completed, and a description of the forms at each visit are summarized below:

| Evaluation | Pre-op X-rays (-1 yr) eCRFs (-4 mos) | Intra op | 6 week (+2 wks) | 3-6 mos (+2wks) | 1 year (+2 mos) | 2 year (+2 mos) | 3 year (+3 mos) | 4 year (+4 mos) | 5 year (+4 mos) | 6 year (+4 mos) | 7 year (+4 mos) | 8 year (+4 mos) | 9 year (+4 mos) | 10 year (+4 mos) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Inclusion/ Exclusion | X | | | | | | | | | | | | | |
| Demographics | X | | | | | | | | | | | | | |
| Previous Implant Information | | X | | | | | | | | | | | | |
| Surgical Details | | X | | | | | | | | | | | | |
| HHS | X | | X | | X | X | | | X | | X | | | X |
| Postoperative Events | | | X | | X | X | | | X | | X | | | X |
| VR-12 | X | | X | | X | X | X | X | X | | X | | | X |
| LEAS | X | | X | | X | X | X | X | X | | X | | | X |
| EQ-5D | X | | X | | X | X | X | X | X | | X | | | X |
| Radiographs: Low AP Pelvis, Lateral | X | | X | X | X | X | | | X | | X | | | X |
| Follow-up Questionnaire* | | | X | X | X | X | X | X | X | X | X | X | X | X |

- HHS: The HHS is an assessment that measures function, pain, deformity and motion.
- VR-12: The VR-12 is a self-administered patient evaluation that evaluates general health and well-being.
- Postoperative Events: The Postoperative Events form is a questionnaire completed by the Investigator intended to provide information on the patient's health status since the last follow-up visit.
- LEAS: The LEAS is a self-administered patient evaluation designed to reflect patient activity.
- EQ-50: The EQ-50 is a standardized instrument for use as a measure of health outcome.
- Follow-up Questionnaire: The Follow-up Questionnaire is a questionnaire intended to provide information on patient satisfaction, pain, and survivorship.* Only administered when the patient is not present to complete the HHS.
- Low AP Pelvis: Standard radiographic view of the pelvis containing bilateral hips and demonstrating the iliac bone, sacrum, pubis, ischium, femoral heads and necks, and greater or lesser trochanters.
- Lateral: Standard radiographic view of the hip joint (can be the Lauenstein lateral, frog leg lateral or cross-table lateral) demonstrating complete visualization of the hip joint and femoral neck.

## III. 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 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 hip, 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 hip function. You will need to see your physician at 6 weeks, 1, 2, 5, 7, and 10 years after surgery for evaluation of your artificial hip joint.

## IV. Possible Risks and Discomforts

This study involves the routine assessment of a primary hip replacement procedure. The Food and Drug Administration (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 primary hip 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 standard risks associated with hip surgery. These include but are not limited to: moderate to severe pain; damage to soft tissue or ligaments of the hip; crack/fracture (breakage) of femoral (thigh) or acetabular (pelvic) bones or components; migration (movement) of components; subsidence (sinking) of components; dislocation (to move out of normal position) of components; sensitivity to metal components (femoral [thigh] and acetabular [pelvic]); revision (removal) of one or more of the components; loosening and infection; wear (rubbing) of the components which could lead to bone loss; peripheral neuropathies (any disorder of the nerves involving your legs); nerve damage; abnormal bone formation; circulatory compromise (changes in circulation related to your heart, blood and lymph vessels, to varying degrees); 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. Adverse effects may require reoperation, revision and or amputation of the limb. Metal sensitivities have been reported following joint replacement. Use of MRI imaging may be prohibited. Microscopic particles may shed from the device over time and it is not clearly understood what the long-term effects from these particles may be.

Your privacy is very important and your surgeon and Sponsor will take precautions to protect your privacy, but cannot guarantee that your identity will never become known. It is possible that there could be security breaches of the computer systems used to store your medical information. There may also be other privacy risks that we have not foreseen.

Talk to your doctor if you have any questions about the risks of hip replacement surgery, or about any risks associated with participating in this study.

There may be risks from participating in this study that are unknown.

## V. Potential Benefits

You might not receive any benefits from being in the study but the results might help out others that have primary hip surgery in the future.

## VI. Other Types of Treatment

You have discussed alternative treatments with your doctor which include but are not limited to: conservative non-surgical treatment, cemented total hip replacement utilizing commercially available components, hip fusion or no treatment at all.

You may decline to participate in this study. This will not change any procedures associated with your hip surgery. Your doctor 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 doctor.

## VII. Making Financial Information Known

Your doctor and/or the research institution may receive compensation from the Sponsor, which is the company that made the implant device to cover the time and/or expenses associated with this Study or for other services. This money will be used to pay for the cost of doing the study or for other reasons. If you require any further information please consult your doctor or his staff about this issue.

## VIII. Confidentiality

Once you sign this consent form, you allow your doctor, his or her staff and the hospital to give information about your health to the Sponsor, and you allow the Sponsor to see and use your health information and other information collected during, or in connection with, the study, as described in this consent.

Other people or groups that may see information about your health and other information collected in this study include:

- Sponsor affiliates
- The investigator who conducts this study and his or her research staff.
- Government bodies, such as the FDA, that may inspect all records relating to the study.
- People who ensure that medical treatment and research studies are safe, such as the institutional review board that reviews the study.

Some of the persons and groups listed above may not be required by law to protect your health information to the same extent as your doctor and the hospital. Once your health information has been released, it may be redisclosed or used for other purposes.

You have the right to refuse to sign this consent form, but if you do not sign it, you will not be able to participate in this study. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.

This permission to release and use your health information does not have an end date. You can take back this permission at any time by telling your doctor in writing. If you take back this permission you cannot be in the study anymore. If you take back this permission, it will not change the work that has already been done in the study, and the Sponsor may keep and use information that has already been collected.

By signing this consent form, you give the Sponsor permission to store your data in one or more password-protected databases accessible only by Sponsor and use such data for the purposes described in this consent form. Such databases may be located at an international Stryker or a third-party location, and may be accessible to Stryker personnel worldwide. As also described herein, in the course of administering this study, Sponsor personnel will see a copy of your signed consent with your personal information to verify you agreed to participate in this study, but such copies will not be generally accessible and will not be maintained in Sponsor's records.

**IX. Cost to Participate in Study**

Your procedure is a routine primary hip surgery and should be covered by your insurance carrier. Additionally you will be offered a stipend for various follow-up visits. You will be paid in the form of a $___ debit card at the completion of various study visits throughout the end of the study.

**X. Device Retrieval Analysis Study**

I understand that the Stryker Orthopaedics Trident II Revision Outcomes Study has a protocol for the analysis of retrieved devices in the event that any study component(s) that I have had implanted by Dr. <Investigator's Name> are removed during the course of the investigation.

I understand that Stryker Orthopaedics Corporation (implant manufacturer and Sponsor), requests my Physician to send my retrieved study component(s) to the Product Surveillance department at Stryker Orthopaedics for evaluation as part of my participation in the study.

I hereby authorize my Physician and his staff to provide my retrieved study component(s), name, birth date, and any and all information about my hip surgery to Stryker Orthopaedics for the purposes of evaluating my retrieved device(s) and reporting the results of the analysis to my Physician and Stryker Orthopaedics Corporation.

My Physician will be provided with the results of this analysis. I understand that the device(s) will not be returned to me, nor will I receive the results of any tests, analysis, or evaluations on the returned device(s).

I understand that, except for sending my retrieved study component(s) to Stryker Orthopaedics, my retrieved study component(s) will not be released to outside parties.

I understand that, except for providing my individually identifiable information to the Physician who performed my surgery and Stryker Orthopaedics, my individually identifiable data will not be released to outside parties. I also understand that I may inspect or copy the information by requesting said information from my Physician.

I understand that I may revoke this authorization for release of my retrieved study component(s) and individually identifiable information at any time by notifying my Physician in writing, but I understand that doing so will have no effect on actions taken before the receipt of my revocation.

I will have confidentiality in all records kept about me. My agreement to participate in this implant retrieval analysis study is completely voluntary. I understand that I have the right to not participate and the right to withdraw from the study at any time of my choosing and that this will in no way compromise my care, delay my treatment, or affect any future medical care.

I, the undersigned, have read and understood the above and agree to participate in the implant retrieval analysis study, and I hereby consent to the release of my retrieved study component(s) and my individually identifiable information under the conditions stated above. My signature indicates that I have had the opportunity to ask questions about the device retrieval study, have had my questions answered to my satisfaction and that I have received a copy of the consent form.

_____ _____

Signature of Subject/Legal Representative Date

## XI. Clinical Trial Website Posting

**A** description of this clinical trial will be available onhttp://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.

## XII. 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.

## XIII. Use of Data Collected as Part of the Study

The Sponsor will use the information collected during the study for the purposes described in this consent, and for any future anticipated or unanticipated scientific uses as the Sponsor or other third parties may deem appropriate. The information collected is necessary to support the objectives of the research.

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.

## XIIV. Contact Information

During the study, if you experience any medical problems, suffer an injury, or have questions, concerns or complaints about the study, please contact the study doctor at <names and phone numbers>. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in a research study being conducted by the <name>.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should contact <IRB Information>.

## XV. New Findings

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

## XVI. Voluntary Participation/ Withdrawal

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, your images and data may remain in storage and use, as described in this consent for an indefinite period of time.
You may withdraw consent up until your images and data are de-identified. If you withdraw your consent before de-identification, Sponsor will no longer disseminate your data and images, but your data and images already collected and used may remain part of the Sponsor's database and may not be removed in order to ensure the scientific validity of the Study. After your images and data are de-identified you will not be able to withdraw consent for your images and data to be retrieved or not further disseminated, stored, or used.

The study doctor or sponsor can stop your participation at any time without your consent for the following reasons: if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if it is discovered that you do not meet the study requirements, if the study is canceled, or for administrative reasons including competitive enrollment - the target number of subjects has entered the study

Being part of this study is your choice. If you decline to participate in the study, it will not prejudice your care. By signing and dating this form below, you are saying you have carefully read all the sections of this Informed Consent Form. You are also saying someone has answered all of your questions and that you voluntarily consent to be in this research study. If you do not sign this form, you will not be able to take part in the research study.

_____
Printed name of Subject/Legal Representative

| | |
|---|---|
| Signature of SubjecULegal 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.