Participant Informed Consent Form

Prospective Data Acquisition from Mako Total Knee Arthroplasty Procedures
Perth, Australia Mako TKA Data Acquisition Project 2.0

This information sheet explains the research project and describes what will be involved should you decide to participate. Please read the information carefully and ask Dr Clark or Dr Collopy any questions you might have.

1. What is the purpose of the project?

This project is being conducted by Stryker Orthopaedics (an implant manufacturer and the Sponsor of this project) and your surgeon. The purpose of this project is to collect data which will allow Stryker Orthopaedics to enhance its ability to design, develop, and manufacture high quality medical devices.

2. Why have I been asked to participate?

You have been asked to take part in this project because you will undergo a robotic-assisted Total Knee Replacement performed by Dr Clark or Dr Collopy. Patients who received/will receive a Total Knee Replacement implanted with the assistance of Mako at St John of God Hospital will be invited to participate in this project.

3. What is the information being collected?

As part of standard clinical practice for this procedure, an image of your joint (i.e. a CT scan) will be obtained from which a pre-operative surgical plan will be created. Should you agree to participate in this project, a de-identified version of your CT, x-rays, intraoperative data, robotic session file, demographics and outcomes will be archived in the Stryker Research and Development database for future research, training and medical education by Stryker and to develop products, equipment and software to help patients in the future.

4. Do I have to participate?

Participation in this project is voluntary, and it is up to you to decide if you want to take part. Your surgeon can answer any questions you might have about the project before you decide to participate. If you do not wish to participate in this project and you wish to replace your knee joint with a Mako robotic arm assisted procedure, your surgeon will perform your surgery according to their standard clinical practice. Your surgeon 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 surgeon about other options and/or inform your surgeon if you do not want to partake in this project.

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 project. Your health care outside of this project, payment for

your health care, and your health care benefits will not be affected if you choose not to sign this form.

If you do decide to participate you will be asked to sign a consent form, and will be given a copy of this document for your own records. You are free to withdraw from the project at any time and do not need to provide a reason for doing so. If you decide not to take part, or withdraw from the project, your decision will not affect the relationship or treatment you receive from Dr Clark or Dr Collopy.

If you choose to withdraw from the project, any of your data that has already been collected prior to the withdrawal of consent will be used and retained by the Sponsor. There are no penalties for withdrawing.

5. What will happen to me if I participate?

Your project participation begins once you sign this consent form. You will undergo a pre-operative CT scan and robotic-assisted Total Knee Replacement surgery. Once you have completed the surgery, you will continue with the standard follow up care provided by your surgeon. Please check with Dr Clark or Dr Collopy if you are unsure of what this involves. You will not be required to return to the surgeon for any tests or visits beyond what would normally be required for follow-up care of knee replacement patients.

If you choose to participate in this project, a de-identified version of your pre-operative CT , x-rays, intraoperative data, robotic session file, demographics and outcomes will be archived in the Stryker Research and Development database for future research, training and medical education by Stryker.

6. What do I have to do?

There are no lifestyle or dietary restrictions regarding this project. If you sign the consent form below, you will still follow the normal standard of care as described by Dr Clark or Dr Collopy. Participating in this project will not cost you any extra money.

7. What will happen to the information being collected during the project?

If you participate in this project, your medical records and identity will be protected as required by law and as explained in this consent (see Question 13). The Sponsor will use the de-identified version of your pre-operative CT, x-rays, intraoperative data, robotic session file, demographics and outcomes collected as part of standard practice for your surgery to complete this project. The Sponsor will use the information collected during this project for the purposes described in this consent, and for any future anticipated or unanticipated scientific uses as the Sponsor may deem appropriate.

The pre-operative image of your knee and the pre-operative plan may be added to a database of many other knee images and plans that the Sponsor may use to help design

new (or refine the designs of existing) products, instruments and software in the future, such as knee replacement parts. The Sponsor may also use this information for development and training of new and existing products, instruments and software, such as knee replacement parts, as well as service and process improvement, government regulatory approvals, and publications.

8. What are the possible side effects or risks of participating?

There are no side effects related to this project. In general, there are no additional risks for you because of participation in this project, as there will be no changes from standard clinical practice for this procedure. Your surgeon should have already informed you of risks/side-effects associated with knee replacement surgery, but to summarize, you may experience

none, some or all the effects listed below to varying degrees during/ following your surgery, irrespective of whether you are involved in this research study:

- Pain and symptoms of non-inflammatory degenerative joint disease may persist to a lesser or greater degree than before surgery.
- Your ability to use your knee may be worse compared to before surgery.
- Deep vein thrombosis (DVT) – a blood clot in the veins of your legs which can cause pain and swelling (occurs in approximately 26% of patients). Rarely (less than 2% of patients), parts of the clot may break off and go to the lungs which can be fatal.
- Some blood loss occurs during surgery – you may need extra blood given to you if you lose a large volume of blood.
- Infection in the joint or at the wound site which may require antibiotics or further surgery (occurs in approximately 1% of patients). Bone fracture (occurs in less than 1% of patients).
- Redness and scarring at the wound site.
- Damage to nerves and blood vessels (rare).

Other medical complications of surgery can occur, especially if you already have a pre-existing condition. Such complications include heart attack, stroke, kidney failure, pneumonia, bladder infection, or allergic reaction to medication

See Question 13 for more information regarding the possible risks related to your personal information. Talk to your surgeon if you have any questions about the risks of robotic-arm assisted knee replacement surgery, or about any risks associated with participating in this project.

9. What are the possible benefits of participating?

You might not receive any benefits from participating in this project but the results might help others that have joint replacement surgery in the future.

10. What are my alternative treatment options?

You have discussed alternative treatments with your surgeon which include but are not limited to: conservative non-surgical treatment, robotic-arm assisted total knee replacement surgery, total knee replacement surgery without the assistance of the arm, or no treatment at all.

11. What are the financial disclosures of this project?

Your surgeon and/or the hospital where your robotic-arm assisted surgery occurs can be paid money from the Sponsor, which is the company that made the knee replacement and the robotic arm. This money will be used to pay for the cost of doing the project or for other reasons. If you want to know more about this, you can ask your surgeon or their staff.

12. What if new information becomes available?

Sometimes during the course of a project, new information becomes available about the technique being studied. If new information does become available, Dr Clark or Dr Collopy will discuss this with you.

13. Will my participation in this project be kept confidential?

If you participate in this Project, your medical records and identity will be kept confidential as required by law and as explained in this consent. In Australia these privacy laws and regulations comprise the Privacy Act 1988 (Cth) and the Australian Privacy Principles.

Once you sign this consent form, you allow your surgeon, their staff (including the study co-ordinator) and the hospital to give information about your health, medical records or the procedure (including CT scan, pre-operative plan, x-rays, intraoperative data, robotic session file, demographics and outcomes) (Personal Information) to the Sponsor, and you allow the Sponsor to see and use this Personal Information and other information collected during, or in connection with, the Project. Other people or groups that may see this Personal Information collected in this Project include:

- The investigator (being the surgeon) who conducts this study and their research staff.
- Government bodies or agencies, such as the United States Food and Drug Administration (FDA) or the Australian Therapeutic Goods Administration (TGA), that may inspect all records relating to the Project.
- People who ensure that medical treatment and research studies are safe, such as the Ethics Committee that reviews the Project.
- Related entities of the Sponsor, including those operating outside Australia. To the extent your Personal Information is transferred outside Australia, it will be done so in accordance with relevant local and international data protection (privacy) laws.

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 surgeon and the hospital. Once your health

information has been released, it may be re-disclosed or used for other purposes.

By signing this consent form, you also allow the Sponsor (or its related entities) to de-identify and/or store or your de-identified Personal Information in a Research and Development database operated by or on behalf of Stryker for future research, product development, training and medical education by or on behalf of the Sponsor. The data will be labelled with a unique code in place of your name, and will be stored in a password-protected database. Whilst you do not own your Personal Information, you have a right of access to your Personal Information upon your written request.

This Project currently does not meet the definition of an "applicable clinical trial" for ClinicalTrials.gov registration, as the study is not a prospective study of health outcomes. If the definition changes throughout the course of the Project and the Project meets the definition of an "applicable clinical trial", 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.

14. What are the costs involved to participate in this project?

The cost of your treatment and surgery is not affected by participation in this product and costs will be determined by your surgeon with your out of pocket expense dependant on your insurer. You will not be paid for participating in this project.

15. What will happen to the results of the project?

If you give us your permission by signing the consent document, we may discuss/publish the results in Orthopaedic journals and oral presentations at national and international conferences. In any publication, information will be provided in such a way that you cannot be identified.

16. Who is organising and funding the project?

Stryker Orthopaedics is funding this project and Stryker Australia Pty Ltd is coordinating the project locally. Dr Clark and Dr Collopy will receive payments for expenses specifically related to the project, including payment for research assistant time.

This project is conducted in accordance to the *National Statement on Ethical Conduct in Human Research* (2007, updated May 2015) produced by the National Health and Medical Research Council of Australia. This guideline has been developed to protect the interests of people who agree to participate in human research studies.

17. What if something goes wrong?

The Sponsor will not provide compensation, reimbursement, or free medical treatment if

you suffer an injury or other medical complications as a result of your medical treatment, including your participation in this project. The principal investigator, Dr Clark, should be contacted immediately at **(08) 6489 1700** if such injury or complication occurs. They have informed you of the hospital's policy and their policy on such matters. Your insurer may or may not cover such injuries or complications, however, by signing this consent form, you are not waiving any legal rights that you would otherwise have.

18. Who has reviewed the project?

The St John of God Human Research and Ethics Committee (HREC) has given ethical approval for the conduct of this project. If you have any concerns or complaints, you can contact the Executive Officer of the Committee on **(08) 9382 6940** on a confidential basis. Your concerns will be drawn to the attention of the Committee that is monitoring the project.

19. Who should I contact for more information?

Contact the principal investigator, Dr Clark, as soon as you can on **(08) 6489 1700** if you have an injury that is related to the study. You can also call Dr Clark if you want to know your rights as part of the study or if you have any questions.

Consent

- *Being part of this study is your choice. If you decline to participate in the study, it will not prejudice your care.*
- *By signing this form, you agree that Stryker Orthopaedics and its affiliates (including its parent and sister companies and subsidiaries, successors and assigns) will be the sole owners of any and all intellectual property, including inventions, discoveries, materials, works of authorship (including computer software) and copyrighted materials, that is created, conceived, discovered or reduced to practice during or as a result of this project. There are no plans to share with you any compensation that is earned through the use of these materials.*
- *By signing and dating this form below, you are saying you have carefully read all the sections of this Informed Consent Form (dated 26-Feb-2018, version 1.0) and wish to participate in the project. You are also saying someone has answered all of your questions and that you voluntarily consent to be in this project. If you do not sign this form, you will not be able to take part in this project.*

_____

Name of Participant/Legal Representative (Printed)

_____ _____

Signature of Participant/Legal Representative **Date Signed**

I, the undersigned have discussed the nature and purpose of the study and the possible risks and benefits of participation with the participant and/or legally authorised representative. I believe that the participant and/or their representative has been fully informed, using language which is understandable and appropriate, and has understood this explanation.

_____ _____

Signature of Investigator **Date Signed**

Withdrawal of Consent

*I hereby **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal will not make any difference to my medical care or my relationship with my surgeon or other clinic staff.*

_____

Name of Participant/Legal Representative (Printed)

_____ _____

Signature of Participant/Legal Representative **Date Signed**

This Withdrawal of Consent should be forwarded to:

Dr Gavin Clark/Dr Dermot Collopy
Perth Hip & Knee
Suite 1/1 Wexford Street
Subiaco WA 6008

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