Participant Information and Consent Form

Extension Study Participants
A follow-up, longitudinal study of the clinical and radiographic outcomes of participants that receive a Triathlon Custom Fit Knee® using Stryker ShapeMatch® Technology.

Investigator: Mr Gavin Clark, Orthopaedic Surgeon, Perth Hip and Knee

You are being invited to participate in a continuation of this research study, as you previously took part in a clinical trial where you had a Total Knee Replacement using ShapeMatch™ cutting guides. This information sheet explains the study and describes what will be involved should you decide to participate. Please read the information carefully and ask any questions you might have. You may also wish to discuss the study with a relative or friend or your GP.

Background and aim of the trial
This study will follow patients who had a Total Knee Replacement and participated in the ShapeMatch™ clinical trial, which was investigating the effectiveness and safety of the ShapeMatch™ cutting guides.

The aims of this trial are to look at the way your knee functions. We want to know the way you bend, move and use your knee now you have had surgery. We also want to know how your knee implant affects your pain levels and quality of life. The x-rays of your knee and full leg that are taken for the study will also be looked at, and if you have had any problems with your knee since surgery.

What participation in the study will involve
As this study continues to follow the progress of your previous ShapeMatch Total Knee Replacement, you will not receive any medical device by participating. If you decide to participate in this study you will be required to attend the clinic for 1 study follow-up visit at 5 years.

At your 5 year visit you will be asked to complete five questionnaires about your knee awareness, pain levels, knee symptoms and stiffness, and your daily activities at each clinic visit. It will take about 15-20 minutes to complete the questionnaires.

You will also be required to have x-rays of your knee and your full leg.

At the clinic visit your knee will be looked at by a medical professional. The total visit should take 20-30 minutes.

Potential side effects from X-rays?
This Research Study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.02 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal.

What are the possible benefits?

This study aims to collect further data on the Stryker Triathlon Knee using ShapeMatch™ cutting guides. While there is no intended direct benefit to you, it could possibly help other patients in the future have Total Knee Replacement surgery with better results.

How will your privacy and confidentiality will be maintained
The information gathered about you by Dr Clark will be held and treated in strict confidence. Your study records will be coded with a Study ID number and your initials only. This coded information is made available to the study sponsor, Stryker Australia Pty Ltd, who monitors original medical records for verification of data. All study records will be coded with your Study ID number and initials through the sponsor to government regulatory bodies in Australia and overseas.

Anyone involved in the study that has access to your personal information, including Dr Clark, the hospital staff and the research study sponsor, is bound by the traditional standards of confidentiality and will adhere to the legislation in Australia's Privacy Act 1988. The Ethics Committee has obtained assurances from the sponsor that the 'Information Privacy Principles' laid down in the Act will be met, and they will oblige the investigator and other hospital staff to ensure strict privacy standards are met.

Australia's Privacy Act does not apply overseas but there are equivalent binding legislations in force in the USA, the European Union and elsewhere which will all be upheld.

Whilst it is intended that the results of this study will be published in a medical journal or at industry conferences at no point will the author, reader, presenter or audience be able to identify individual patients.

What if something goes wrong?
In the event that you suffer an adverse event or a medical accident that arises from your participation in the study, you will be offered all full and necessary treatment by St John of God Hospital.

The Ethics Committee has approved this study on the basis that:

- the risk of an adverse event is small; or
- the risk of an adverse event is acceptable in terms of the usual risk you face as a result of your current illness; or
- the benefits of the new treatment being tested are greater and more likely than the risk of an adverse event

In addition to this treatment, the sponsors of the study have agreed to payment of **no-fault compensation** under the guidelines proposed by the Medicines Australia (see www.medicinesaustralia.com.au/public/formind.pdf or obtain a copy of the guidelines from your study doctor). The provision of compensation under this scheme does not compromise your rights to seek compensation under common law.

Cost of participation in the trial
You will not be paid for your participation in this research, but you will be reimbursed for any reasonable costs (e.g. parking or local taxi ride) that you incur for any visits related specifically to your participation.

Voluntary participation and withdrawal
Participation in this study is entirely voluntary. You do not have to participate if you do not want to. Your decision to participate or not participate will in no way affect your current or future care at St. John of God Hospital.

You are also free to withdraw from the study at any time without reason or justification. If you decide not to participate in this study, your current and future care at St. John of God Hospital will not be affected.

Could this research project be stopped unexpectedly?

This research project may be stopped for a number of reasons. These may include:

- Unacceptable side effects;
- The treatment being shown not to work;
- The treatment being shown to work and not need further testing; and
- Decisions made in the commercial interests of the sponsor or by local health authorities.

Contacts for further information
Further information may be obtained by contacting the Principal Investigator **Mr Gavin Clark**. Contact details will be given by your surgeon at your initial visit.
This study has been approved by the St. John of God Ethics Committee. If you have any concerns about the conduct of the study or your rights as a research participant, please contact Gorette De Jesus, on (08) 9382 6940. If after reading this sheet you are interested in enrolling in the trial you should now sign the CONSENT FORM attached. Thank you for considering participating in this study.

Consent Form

Extension Study Participants
A follow-up, longitudinal study of the clinical and radiographic outcomes of participants that receive a Triathlon Custom Fit Knee® using Stryker ShapeMatch® Technology.

1. I confirm that I have read and understand the Participant Information and Consent Form dated **6-September-16, version 1.0** for the above study and have had the opportunity to ask questions and all of these have been answered in a way I understand.
2. I understand that my participation is voluntary. I may refuse to take part in this study and I am free to withdraw from the study at any time, without my medical care or legal rights being affected. There is no penalty. My decisions do not affect my continuing medical care including my relationship with my doctor or other clinical staff.
3. I understand that sections of any of my medical record may be looked at by responsible individuals from Stryker Australia Pty Ltd or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I agree that my images (whether CT or otherwise) may be used by Stryker or surgeons involved in the study for the purposes of surgical planning and further research during and post this study.
5. I agree that my de-identified data related to this research study may be used by Stryker or surgeons involved in the study for the purposes of further research during and post this study.
6. I agree to take part in the above study.

Name of Participant (Printed)	**Signature of Participant**	**Date**
_____	_____	_____

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 his/her representative has been fully informed, using language which is understandable and appropriate, and has understood this explanation.

Principal Investigators Name (Printed)	**Signature**	**Date**
_____	_____	_____

Revocation 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 doctor or other clinic staff.

Name of Participant (Printed)	**Signature**	**Date**
_____	_____	_____