Participant Information and Consent Form

A prospective, randomised controlled trial evaluating Total Knee Replacement with the Stryker Triathlon Primary Total Knee System, compared to Bicompartmental Knee Replacement with Restoris MCK Multicompartmental Knee System performed using Stryker's Robotic-arm assisted surgery system, Mako

Investigator: Dr Gavin Clark, Orthopaedic Surgeon, Perth Hip and Knee, and St. John of God Hospital
Investigator: Dr Dermot Collopy, Orthopaedic Surgeon, Perth Hip and Knee, and St. John of God Hospital

You have been invited to participate in this clinical research study because you are being reviewed to have Bi-Compartmental Knee Replacement Surgery due to non-inflammatory degenerative joint disease with Dr Clark or Dr Collopy. This information sheet explains the study 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 may have. You may also wish to discuss the study with a relative, friend or your GP.

If you do not wish to be involved in this study, then the next patient Dr Clark or Dr Collopy see who may be a candidate for Bicompartmental Knee Replacement will be invited to participate.

Background and Aim of the Research Study

This study is comparing the use of the Restoris® MCK Multicompartmental Knee System to the Triathlon Total Knee System used in the treatment of non-inflammatory degenerative joint disease such as osteoarthritis of the knee.

The Restoris® MCK Multicompartmental Knee System and Triathlon Total Knee System are approved on the Australian Register of Therapeutic Goods for use in Australia.

The Restoris® MCK Multicompartmental Knee System has been designed for patients that do not require a total knee replacement. This means that only part of your knee needs replacement, and is called bi-compartmental knee replacement. The Restoris® MCK Multicompartmental Knee System has been designed for your surgeon to use with new robotic surgery, which is a new area for knee research. The Triathlon Primary Total Knee System can also be used with robotic surgery. Robotic surgery used for knee replacement can potentially improve surgical accuracy, operating room efficiency, improve patient outcomes and result in shorter hospital time.

The aim of this study is to compare the Restoris® MCK Multicompartmental Knee System to the Triathlon Total Knee System which is currently widely used for total knee replacement.

No comparison has previously been measured between Restoris® MCK Multicompartmental Knee System and the Triathlon Total Knee System, so the outcomes of the study will help doctors understand the differences in patient results between the two groups.

What will participation in the study involve?

If you choose to participate in this study, Dr Collopy or Dr Clark will ask you to sign the study consent form. Once you provide your consent you will referred for a CT Arthrogram. Dr Clark or Dr Collopy will review this CT Arthrogram scan to make sure you meet the study requirements. If you meet the requirements, you will be enrolled into the study and randomly allocated to either Group 1 or Group 2. The study will enrol 70 patients' total, with 35 patients in group 1, and 35 patients in group 2.

If you are allocated to group 1, you will receive a Bi-compartmental Knee Replacement with the Restoris® MCK Multicompartmental Knee System. If you are allocated to group 2, you will receive a Total Knee Replacement with the Triathlon Total Knee System. Both surgeries will be performed using robotic technology.

The total participation duration for all patients will be about 2 years.

Pre-Surgery:
Participants in both groups will first be asked to come to Dr Collopy or Dr Clark's clinic where a record of your name, date of birth, gender, information about your knee and other medical history will be taken. At this visit, all patients will have a knee x-ray as normal routine care. If you have recently had a knee x-ray prior to the visit, your doctor may decide to use this x-ray and you will not require a new knee x-ray. You will also be asked to complete 4 questionnaires which should take no more than 30 minutes:

1) The Oxford Knee Score will evaluate the levels of function of your knee
2) The Euro-Qol (EQ-5D) questionnaire will measure your mobility, pain and levels of anxiety or depression associated with your knee condition
3) The VAS pain score will ask you to indicate your pain level on a scale from none to extreme pain
4) The Knee Society is completed by a medical professional and yourself. It will assess your knee function, such as your range of motion, alignment and stability.

Surgery:
Group 1: Your surgery will be performed by Dr Clark or Dr Collopy. The surgery will involve your surgeon making incisions in your skin and the underlying tissues. Using state of the art instruments and robotic technology he will remove the unhealthy parts of your knee bones to make way for your new prosthesis. This group will receive a Bi-compartmental Knee Replacement with the Restoris® MCK Multicompartmental Knee.

Group 2: Your surgery will be performed by Dr Clark or Dr Collopy. The surgery will involve your surgeon making incisions in your skin and the underlying tissues. Using state of the art instruments and robotic technology he will remove the unhealthy parts of your knee bones to make way for your new prosthesis. This group will receive a Total Knee Replacement with the Triathlon Total Knee System.

Post-Surgery:
Immediately following surgery, before leaving the hospital, all patients will need to have knee x-rays which are routine care.

All patients will need to attend the clinic or be contacted by phone or mail 6 weeks post-surgery, to complete the Oxford Knee Score questionnaire and answer a few questions on your knee.

All patients will also need to attend the clinic for three follow-up visits post-surgery at 3 months, 12 months and 24 months. At these follow-up visits you will be asked to answer the same questionnaires you completed before surgery, along with a new questionnaire 'The Forgotten Joint Score', which will

evaluate how aware you are of your knee joint. All patients will also repeat the knee x-rays to monitor your knee. Please see the table below which gives details on each study visit.

		Study Visits					
	Pre-Surgery	Surgery	Less than 5 days after surgery	6 weeks later	3 months later	12 months later	24 months later
Informed Consent	x	Knee surgery occurs					
Clinical exam	x				x	x	x
Questionnaires	x			x	x	x	x
CT Arthrogram	x						
X-rays	x		x		x	x	x

Potential side effects and risks

Any surgery comes with potential side effects or risks. Your doctor or surgeon should already have informed you of those associated with knee replacement surgery, but to summarize, you may experience none, some or all of the effects listed below to varying degrees during your 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

Possible side effects from x-rays:

This study involves exposure to a small amount of radiation which occurs from having an x-ray taken. The effective dose from this study is approximately 0.2 mSv.

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 0.2 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 of participation in this study?

Whilst there are no guarantees of lesser or greater outcomes based on your participation in the study,

possible benefits may include:

- Less pain and discomfort
- Increased movement
- Increased ability to perform daily activities

In addition, this study may also assist doctors in determine what is a better prosthesis to use for knee replacement surgery, which may help improve the outcomes and results for future patient.

What happens when the research is completed?

Once you have completed this study 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.

How will your privacy and confidentiality be handled?

The information gathered about you by Dr Clark and Dr Collopy 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 or Dr Collopy, 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 as a result of 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. You will need to pay for all standard of care x-rays that would occur as part of a normal knee replacement. These costs will be discussed with you at the first study visit. You will not be charged for any additional costs that are not part of routine care, and included as part of the study.

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. You should ask your doctor about alternative treatments for your knee. 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 study be stopped unexpectedly?

This research study may be stopped for any or all of the following reasons:

- 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

If new information becomes available that may be relevant to your willingness to participate in this study, you will be informed immediately by Dr Clark or Dr Collopy.

What will happen to the results of the study?

If you give us your permission by signing the consent document, we plan to 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. Please let your doctor know if you would like to be provided with a copy of the study results.

Contacts for further information

Further information may be obtained by contacting the Principal Investigators **Dr Gavin Clark** or **Dr Dermot Collopy.** 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

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1. I confirm that I have read and understand the Participant Information and Consent Form dated**22 February 2018, version 7.0** 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**
_____	_____	_____