Study Title: Total Knee Replacement With Tourniquet Or Irrigation-Coupled Bipolar Device

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Consent and Authorization to Participate in a Research Study

KEY INFORMATION FOR COMPARISON OF SHORT-DURATION TOURNIQUET TOTAL KNEE ARTHROPLASTY (TKA) WITH THE AQUAMANTYS®:

We are asking you to choose whether or not to volunteer for a research study comparing short-duration tourniquet total knee replacement with the Aquamantys bipolar sealer versus being treated with standard of care which usually involves using a tourniquet throughout your entire knee replacement surgery. The Aquamantys bipolar sealer is a device used during surgery to help reduce bleeding in the joint. The system uses radiofrequency energy and sterile saline (salt water) to close small blood vessels in the knee to help reduce bleeding. We are giving you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to compare quadriceps muscle strength, pain, opioid consumption and patient function during the first three months after short-stay total knee replacement between patients treated with short-duration tourniquet knee replacement with the Aquamantys® bipolar sealer versus those treated with the standard of care (tourniquet used throughout the case and no Aquamantys®).

By doing this study, we hope to learn if short duration tourniquet knee replacement with the Aquamantys® bipolar sealer is more effective than standard of care (tourniquet used throughout the case and no Aquamantys®). Your participation in this research will last about 12 months.

The purpose of this research is to gather information on the safety and effectiveness of FDA approved Aquamantys Bipolar sealer compared with standard of care treatment (tourniquet used throughout the case and no Aquamantys®.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might want to volunteer to participate in this study if you need to have Total Knee Replacement. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might not want to participate in this study if you are undergoing repeat knee replacement, called revision arthroplasty. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

There are no alternative treatments to this study other than not participating in this study. You may receive either short or long duration tourniquet use without being in the study as both methods of surgery are currently utilized. For a complete description of alternate treatment/procedures, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Stephen Duncan, M.D. of the University of Kentucky, Department of Orthopedic Surgery and Sports Medicine. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 859-323-5533

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You will be excluded from participating in this study if you are undergoing repeat knee replacement (called revision arthroplasty), are planning on having both knees replaced on the same day, or are having a partial knee replacement. You will also be excluded if you have other health conditions or social limitations that do not allow you to be discharged to home on either the same day that you have your knee replaced or on the day after your surgery.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at Orthopaedic Surgery & Sports Medicine, UK Good Samaritan Medical Office Building 125 E Maxwell St., Suite 201, Lexington, Kentucky, 40508. There will be 4 visits (preop, 2, 6 and 12 week postop). Each of those visits will take about 20-30 minutes. The total amount of time you will be asked to volunteer for this study is 2 hours over the next 3 months.

WHAT WILL YOU BE ASKED TO DO?

If you are participating in this study, you have elected to undergo total knee replacement which is also called Total Knee Arthroplasty or TKA. If you decide to participate, you will be randomly selected to be placed in one of two groups: the study group or the control group. This is a blinded study, so neither you nor the researchers performing the post-op assessments will be aware of which group you have been assigned to.

The TKA procedure will last about 75 minutes and include three follow up visits. The visits will occur approximately 2, 6 and 12 weeks after the procedure. The following tests will be performed during the follow-up visits:

Isometric Quadriceps Strength Testing: You will be asked to sit in a seated position and a stabilizing strap will be placed around the bottom of your leg and attached to a hand-held dynamometer. The hand-held dynamometer is a device that records how much force your quadriceps (muscle on the front of your thigh) can produce. You will be asked to slowly kick your foot as hard as you can into the dynamometer pad placed in front of the leg. One practice trial followed by 3 actual trials will be performed. You will receive a 30-second rest in between each trial and a 1-minute rest in between legs for each test to prevent fatigue.

Five Times Sit-to-Stand Test: The five-repetition sit-to-stand is used to measure mobility and function in older adults. You will be positioned in a standard 16" office chair with your arms at your sides and back located against the back of the chair. You will be instructed to "Please stand up straight as quickly as you can 5 times, without stopping in between. Keep your arms folded across your chest. I'll be timing you with a stopwatch. Ready, begin." The test is timed using a stopwatch and the timer is stopped when you achieve a standing position on the 5th trial. To make the test as safe as possible, we will use a four-legged chair that does not have wheels, and the chair will be placed so it backs against a wall to prevent the chair from moving during the test. While you will be asked to complete the test without using the chair's armrests, the armrests are available for balance should you need assistance. If at any visit you cannot complete one practice repetition of sit to stand without using the armrests, we will not ask you to participate in the test at that visit.

Patient-Reported Outcomes: You will be asked to complete a series of four questionnaires at each study visit. You will be asked to complete the Knee injury and Osteoarthritis Outcome Score, Joint Replacement (KOOS JR) questionnaire to assess the condition of your knee, Veterans Rand-12 (VR-12) to assess physical and mental health and a Visual Analogue Scale (VAS) to assess your pain and confidence in your knee. In addition, a study-specific questionnaire will be used to assess whether you are able to walk without an assistive device like a walker or cane and to determine how you go up and down stairs (one-step at a time, requires the use of a handrail, etc.).

The following table outlines the study visits and what procedures are performed during each visit

Study Flow Chart

All tests and procedures being performed in this study are listed in the table below and are coded to define what is considered standard of care (NR) and what is considered research (R)

	Screening	TKA Procedure	Post-Operative Follow-up		
	Visit 1 (Pre-op)	Day 0	Visit 2 (week 2 +/- 4 days)	Visit 3 (week 6 +/- 1 week)	Visit 4 (week 12 +/- 2 weeks)
Informed Consent	R				
Medical History	NR	NR	NR	NR	NR
Medication History	NR	NR	NR	NR	NR
Aquamantys® bipolar sealer		NR			
Isometric quadriceps testing			R	R	R
Sit-to-stand test				R	R
KOOS, JR questionnaire	R		R	R	R
VR-12 questionnaire	R		R	R	R
VAS pain scale	R		R	R	R
Functional questionnaire	R		R	R	R

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Aquamantys Bipolar Sealer: Delicate body structures could be damaged by hot saline run-off. We will use proper suctioning and other protective measures during surgery to reduce this risk.
Isometric Quadriceps Strength and Sit-to-Stand Testing: The possible risks for participation in this study are minimal. You may injure your leg during the performance of the functional testing; however, all precautions will be taken to prevent this. All functional testing will be carried out by a trained member of the research team. It is also possible that you may experience muscle soreness following the strength and functional testing. However, this soreness will not be significantly greater than that which you may experience in response to starting a new exercise during physical therapy. If the functional testing is deemed unsafe for you to complete you will not complete the testing at that session.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study. However, this study may help doctors better understand different techniques used during knee replacement surgery that may help others in the future.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

There are no alternative treatments to this study other than not participating in this study. If you decide not to participate in the study, you may still receive either short-or long-duration tourniquet use as Dr. Duncan currently utilizes both methods.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

The following costs will be paid for by the study:

- Quadriceps strength testing
- Sit-to-stand test
- KOOS JR Questionnaire
- VR-12 questionnaire
- VAS pain scale
- Functional questionnaire

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will not reveal your name or other identifying private information. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is.

You should know that in some cases we may have to show your information to other people. For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, if you report information about a child being abused; or if you pose a danger to yourself or someone else.

The study information collected from the participation in the study will be entered into a secure computer system called REDCap.

Data will be stored in full compliance with institutional and governmental regulations regarding privacy and security. To protect your privacy and maintain confidentiality, no identifiers (e.g., name, social security number, date of birth) will be directly linked to the data. Your initials will be collected in the Electronic Data Capture system, and will be listed at the top of each of the visit electronic case report forms as an additional source of verification for study staff that they are entering data in the correct subject's form. The collection of initials is meant to assist in avoiding data entry errors that may result from confusion of subject ID numbers. These initials will solely be used by each specific site and will not be used in any way to re-identify the individual for whom data were collected centrally.

All participant data collected through the case report forms will be stored in the secure Electronic Data Capture system, which is encrypted and restricts access to individuals with proper credentials. Protected health information (PHI) will be encrypted and kept confidential. Though case report forms will be completed electronically, hard copy documents with participant identifiers will be stored in locked, secure areas to protect participant data.

Officials of the Food & Drug Administration, UK Institutional Review Board, Medtronic and the Center for Clinical and Translational Science may look at or copy pertinent portions of the participant records.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Stephen Duncan, M.D. at (859)-323 5533 immediately. If you are hurt or become sick after normal business hours or on the weekend or holiday, please call 859-323-5321. Stephen Duncan M.D. will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility or be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances).

A co-payment/deductible/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive up to $50.00 for taking part in this study. Payment will be prorated and you will receive $12.50 for each of the four study visits. Payment will be received in the form of a check 3-4 months after your surgery.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by Stephen Duncan, M.D. to determine if it is in your best interest to contact you.

Do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

☐ Yes ☐ No _____Initials

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to one time per year.

Do you give your permission to be contacted in the future by Dr. Duncan or his research staff regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 70 people to do so at the University of Kentucky.

There may be other people on the research team assisting at different times during the study.

Medtronic, the company that makes the Aquamantys device, is providing financial support and/or material for this study.

The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

AUTHORIZATION TO USE OR DISCLOSE YOUR INDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information (name, initials, gender, race, age, study number, mailing address, email address, and home/work/cell phone numbers and pager number)
- Dates including date of birth, hospital admissions discharges, dates of medical events, study visits.
- Information obtained during this research about
  - Physical exams
  - Radiographs
  - Questionnaires
- Records about the study device
- Past and present medical records as they relate to your enrollment and participation in this study
- Records about your study visits
- Results from study questionnaires

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK Hospital
- Food and Drug Administration
- Center for Clinical and Translational Science (CCTS)
- Medtronic and it's agents

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky;
- Current or future payments to the University of Kentucky;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- Send a written letter to: Stephen Duncan, M.D. to inform him of your decision.

  Orthopaedic Surgery & Sports Medicine
  UK Good Samaritan Medical Office Building
  125 E Maxwell St., Suite 201
  Lexington, KY 40536-0284

- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

You will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you may have the right to access the information.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ _____ **Signature of research subject** *or, if applicable,* **Date** * _____ **Printed name of research subject**
_____ _____ Printed name of [authorized] person obtaining informed consent Date _____ Signature of Principal Investigator or Sub/Co-Investigator