Wake Forest™
School of Medicine

A randomized controlled trial to compare single portal versus two portal knee arthroscopy techniques in patients with meniscal injuries and articular cartilage pathology

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Department of Orthopaedic Surgery

APPENDIX

SUPPLEMENT TO INFORMED CONSENT FORM

Introduction

This supplement to the consent form is to inform you about some recent changes to the above study. In the original consent form that you signed for this study, we stated that we would follow you for up to 1 year after your arthroscopic knee surgery. The study sponsor, Stryker Inc., has decided to stop the study you had originally agreed to participate in. The study sponsor no longer wants to fund or support the continuation of the study. We would like to know how your study knee is doing now and we wish to follow-up with you as a final step of your study participation.

What is Involved?

If you agree, we are offering a final close-out clinical examination visit of your study knee if you would like to return. This research visit would be at no-charge to you or your insurance company. It would consist of a brief knee exam by a member of the study team and we will measure how well you can bend and straighten your knee (your range of motion). We would also like you to answer a short survey about your knee function and pain. This survey is the same questionnaire you would have completed during the study at your regular study follow-up visits. We anticipate this visit will take approximately 15-20 minutes. We still offer patient compensation of $10 for completion of this final study visit.

If you are having any other issues with your study knee, with your knee on the other side, or any other orthopaedic problems or issues and you would like to see an orthopaedic surgeon, we will be happy to schedule an appointment for you as a regular clinical visit. However, you and/or your insurance company will be charged for this appointment.

If you choose not to return to the clinic for the knee exam, we would still like you to complete the final brief survey about your knee function and pain. This survey may be completed either on the telephone or by email through an electronic survey. You can decide which way is more

convenient for you. If you decline to participate in this final knee exam and/or survey, we will note your decision and not contact you any further about this study.

You will be transferred to clinical management of your study knee and we will be glad to follow you as part of standard clinical care by one of our orthopaedic surgeons in the future.

What Are the Risks and Benefits?

Although you yourself may not benefit from taking part in this study, other individuals who undergo a knee arthroscopy surgery may benefit from the information that is learned from this study. Your answers to the questions will remain confidential. Your answers and answers from other patients will be combined to find out how patients that have had a similar type of knee surgery after treatment. We are not aware of any serious adverse events or unanticipated risks to patients during the course of the study.

What are Your Rights as a Study Participant?

If you agree to participate, we will ask you to sign this supplement to the informed consent form. Your confidentiality will be maintained and none of your results will be identified to you as an individual. You may choose to participate in this final study visit or you may decide not to participate. The decision to participate is entirely your choice. If there are questions that you are asked that you do not want to answer, you may skip them and not answer them. Whether or not you decide to take part in the study will not affect your current or future care by anyone at Wake Forest Baptist Health.

Who Should You Call if You Have Questions?

If you have questions about this research study, you can call the Chairman of the Institutional Review Board of Wake Forest School of Medicine at [redacted] or the principal investigator of this study who is Dr. John Hubbard at ([redacted]

You will receive a copy of this signed supplement to the informed consent form.

I acknowledge that I have read and understand this supplement document for the study.

Patient's Printed Name: _____

Patient Signature: _____

Date: _____ Time:_____ am pm

Person Obtaining Consent:_____

Date: _____ Time:_____ am pm