

UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH
The Department of Radiological Sciences

TITLE OF STUDY
Bioflo Clinical Study

Lay Title: Efficacy of Bioflo DuraMax Dialysis Catheter in Routine Dialysis in
Comparison with Palindrome Catheter

INTRODUCTION

Dr. Edward Lee, MD at the University of California, Los Angeles is conducting a research study.

Dr. Lee will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask Dr. Lee for more information before deciding to participate.

Dr. Lee is asking you to be in this study because he is conducting a clinical study to evaluate the clinical efficacy of Bioflo dialysis catheter in routine dialysis. This consent form provides information on the procedures and risks involved in the clinical study. Please read this form carefully so that you can decide if you want to take part in the study.

Why is this study being done?

The purpose of this research study is to collect more data about the safety and effectiveness of Bioflo Duramax dialysis catheter and to compare the catheter thrombosis rate and catheter exchange rate of Bioflo Duramax catheter vs. Palindrome catheter.

This study is being funded by Angiodynamics Inc.

How many people will take part in this study?

60 people will take part in this study at UCLA.

What will happen if I take part in this research study?

Before you begin the study:

Before you begin the study, Dr. Lee will need to determine if you are eligible to participate. If you choose to take part in this study, you will be asked to sign this consent form before any study procedures can be done.

During the study:

If you agree to be in the study, you will be randomized based on randomized software to either the **Bioflo dialysis catheter group** or **Palindrome dialysis catheter group**.

Details regarding the two groups of the study are described below:

1. Both Bioflo and Palindrome dialysis catheters are FDA approved and widely used worldwide.
2. There is no difference in expected functions of both catheters as a long term tunneled dialysis catheter.
3. The Bioflo catheter is made of a newer synthetic material with clot resistance.

4. Both groups will undergo a standard minimally invasive, image-guided, sterile interventional procedure for placement of the catheter.

Follow-up Appointments (All Patients)

Each patient will complete a 3 month follow up telephone visit. Some patients will also be contacted at the 6 month follow up time point if additional data needs to be collected.

At each follow up visit, Dr. Lee and his research team will be collecting information only related to the catheter and the use of the catheter. We will obtain your written permission to collect any medical records associated with the use of the catheter from the dialysis center which you are being treated. Details of the data to be collected at each time are listed in the table below:

	Screening visit	Insertion of the catheter	3 Month Follow-Up Telephone Call and Collection of Medical Records	6 Month Follow-Up Telephone Call and Collection of Medical Records
Demographic information	X			
Clinical information	X		X	X
Procedure information	X			
Procedure		X		
Hemodialysis information			X	X
Frequency of tPA thrombolysis			X	X
Frequency of catheter exchange			X	X
Other complication			X	X

How long will I be in the research study?

You will be in the study for a maximum of 6 months.

Are there any potential risks or discomforts that I can expect from this study?

The possible risks and/or discomforts associated with the insertion and use of the catheters include bleeding from the insertion site (less than 10%), infection (uncommon), catheter malfunction (less than 10%), catheter thrombosis or blood clot (less than 10%), vessel damage (rare), and pain/discomfort around the catheter insertion site and vessel entrance site (uncommon). These risks and discomforts are not any more than performing other procedures in general.

Are there any potential benefits if I participate?

Possible benefits to me:

There will be no direct benefit to you from participating in this study.

Possible benefits to others or society:

The information collected in this study will help physicians and researchers learn more about the BioFlo DuraMax catheter. Other patients requiring the use of these catheters in the future may benefit due to the knowledge gathered from this research study.

What other choices do I have if I don't want to participate?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, you may choose to continue to get regular care from your own doctor. Talk with the study doctor, or your family doctor, about your treatment choices.

Will I be paid for participating?

You will not receive any payment for your participation in this research study.

There will be no additional cost to you or your health plan as a result of your participation in this study. Items and services described in this consent form would have occurred regardless of your participation in this study or, if research-related, will be provided to you at no cost.

Will information about me and my participation be kept confidential?

Your privacy is important. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:

All information gathered in this study will be kept private. Your identity as a participant in this study will be kept as confidential as possible within the law.

The research team, authorized UCLA personnel or the study sponsor may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

How information about you will be stored:

The information collected and analyzed by the researcher, sponsor or its representatives should not include your name or personal data that would allow you to be identified. You will only be identified in the study under a study-specific code. If the results of this study are published your identity will remain confidential.

How long information from the study will be kept:

All source documents, records and reports related to data provided to this study will be retained in accordance with applicable federal guidelines for at least three (3) years following the closure of the study.

What are my rights if I take part in this study?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

• The research team:

If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

Dr. Edward Lee at 310-267-8771

- **UCLA Office of the Human Research Protection Program (OHRPP):**

If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, please call the OHRPP at (310) 825-7122 or write to:

UCLA Office of the Human Research Protection Program
11000 Kinross Avenue, Suite 211, Box 951694
Los Angeles, CA 90095-1694

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell Dr. Lee if you believe that you have been injured because of taking part in this study. You can inform him in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor [Angiodynamics], or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep.

SIGNATURE OF STUDY PARTICIPANT

Name of Participant

Signature of Participant

Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent

Contact Number

Signature of Person Obtaining Consent

Date