

FOR CCI USE ONLY		
Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations, New Procedures and New Forms of Therapy:		
Administrator: _____	Date: _____	

Protocol	Number: _____	Expiration
Date: _____		

INFORMED CONSENT

- Subject's name: _____
- Title of Research Protocol: **Cutting Balloon Registry**
- Principal Investigator's Name: Roger J. Laham, MD
- Co-Investigators: Donald Baim, Richard Kuntz, David Cohen, Joseph Carrozza
- Protocol Number:

D1. PURPOSE OF STUDY:

You will be undergoing an angioplasty procedure to open a narrowing (lesion) in the coronary artery. The device commonly used in this procedure is a balloon-tipped catheter. The balloon expands and pushes on the lesion. By pushing on the lesion material, the material spreads around inside the vessel and cracks in the lesion may occur. Lesions are formed from different materials (cholesterol, calcium, fibrous tissue) and are of different shapes and sizes. When performing an angioplasty procedure, it make take increasing balloon pressures or multiple inflations to open the narrowing. Higher pressure may crack the lesion, but this can also cause more damage to the vessel wall (barotrauma). The more damage that occurs to the vessel wall, the more likely it is that the lesion can reform (restenosis).

This study will be using a new type of balloon catheter that works similarly to standard balloon catheters. This new catheter is called the Cutting Balloon and has 3 or 4 micro-blades mounted on the balloon surface. As the Cutting Balloon inflates, the tiny blades first cut the surface of the lesion, which may allow the balloon to enlarge the narrowed section of the artery with less pressure. By exerting less pressure, it may also reduce the likelihood of restenosis. The Cutting Balloon is an investigational device and is not commercially available in the U.S.

D2. SUBJECT SELECTION:

You are being asked to participate in this investigational device study to collect additional information about the Cutting Balloon. The purpose of this registry study is to provide a physician with the option to use the Cutting Balloon catheter for those patients the physician believes would benefit from this device. Twenty hospitals in the U.S. will participate to enroll 200 patients over the next several months.

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D3. PROCEDURE:

Preparation for the angioplasty procedure will be per your doctor's routine. An ECG will be taken before and after the procedure. Blood will be drawn (approximately 1 teaspoon for each test) once before and 3 times after the procedure to check on the heart muscle condition.

Diagnostic coronary arteriography will be performed to determine suitability of the target lesion(s) for treatment with the Cutting Balloon. The Cutting Balloon will be sized not to exceed 1.1:1 to the reference vessel diameter. Preparation and use of the device will be according to the Cutting Balloon Instructions for Use (Appendix 2). It is intended that the Cutting Balloon will be the first interventional device used in the procedure. If it is determined that pre-dilatation must be performed prior to the Cutting Balloon, the diameter of the angioplasty catheter should be small (<2.0 mm), to minimize the likelihood of complications.

After positioning the balloon across the lesion, the Cutting Balloon will be slowly inflated to no more than 8 atmospheres (atms), watching for the typical lesion "waist" in the balloon to go away. Lesions can be treated with multiple inflations. And, if lesions are longer than the Cutting Balloon, tandem inflations can be performed.

Use of adjunctive devices such as stenting or other will be determined by the physician.

D4. RISKS AND DISCOMFORTS:

Risks incurred from this study are not anticipated to be any different from those involving other conventional balloon angioplasty catheters. The following lists the potential risks as a result of the balloon angioplasty procedure, but are not limited to: disruption of the inner layer of the vessel wall (arterial dissection), vessel spasm, perforation of the vessel, dislodgement of particles from the plaque that move downstream with the blood flow through the vessel (distal embolization), blood clots that form in the vessel (thrombosis), total occlusion of the vessel, chest pain (angina), a heart attack (acute myocardial infarction), life-threatening irregular heart rhythm (ventricular fibrillation) or death, a collection of blood under the skin usually around the arterial puncture site in the groin (hematoma), the creation of a pathway for blood flow between the artery and the vein in the groin (arteriovenous fistula formation) or infection at the groin insertion site, reaction to x-ray dye (contrast media), or even death. During the Cutting Balloon procedure, the micro-blades may unfavorably change the lesion and lead to a serious event. The Cutting Balloon may also fail to function due to fracture, leaks, or damage caused by improper handling. There may be unknown risks which can occur.

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D5. BENEFITS:

The potential benefit from participating in this study is the possibility of a lower restenosis rate. This may occur if the Cutting Balloon can open the clogged artery with less pressure, causing less damage to the wall of the artery.

D6. ALTERNATIVE PROCEDURES:

Alternative methods of treatment available would include the use of another coronary interventional device (such as a balloon catheter, a stent, an atherectomy device, etc.).

You may refuse to participate or, at any time, withdraw consent for participation in this study. Your decision to stop will not influence present or future care at this hospital.

D7. COST/PAYMENT:

There will be no special costs to you if you participate. Costs associated with this interventional procedure will be the same as with standard balloon angioplasty. The hospitalization and other diagnostic and therapeutic procedures necessary for your care are unchanged. The costs will be the responsibility of you or your third-party payor (such as an insurance company).

D8. CONFIDENTIALITY:

The information gathered during this study will be kept confidential (not given out). Treatment results, laboratory tests and cineangiograms (X-rays pictures taken during the procedure) may be published in appropriate medical literature. However, your identity will be kept confidential. In addition, the study sponsor, Interventional Technologies, Inc. or the U.S. Food and Drug Administration, may request access to the medical records and the study data for audit purposes.

I understand that I have a right to privacy and that the investigators on this study will take all reasonable measures to protect the confidentiality of my records. My name and any other information which might identify me will not appear in any presentation or publication resulting from this study. My name and any other information which might identify me will not be available to any person or group other than the investigators of this study and the Committee on Clinical Investigations of the Beth Israel Deaconess Medical Center which oversees all studies.

Date submitted to Committee: _____

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CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page(s) of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Chairman of the Medical Center's Committee on Clinical Investigations at (617) 667-4272

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that I may be contacted by the Beth Israel Deaconess Medical Center's Committee on Clinical Investigations during or after my participation in this study as part of its efforts to monitor the experience of subjects in clinical investigations.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

WITNESS

DATE

STUDY SUBJECT

DATE

PARENT OR LEGAL GUARDIAN

DATE

(If subject is a minor, or subject is unable to give consent)

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

PRINT INVESTIGATOR'S NAME

SIGNATURE OF INVESTIGATOR (or designee) DATE

For any questions regarding the rights of a research subject, or information regarding treatment of research-related injuries, please contact Nan Clark, Manager, Research Administration, (617) 667-3743

