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**MINNEAPOLIS HEART INSTITUTE FOUNDATION/ABBOTT
NORTHWESTERN HOSPITAL**

Study Title:	WATCHMAN™ Left Atrial Appendage Filter System Pilot Study Investigation
Primary Investigator:	Michael Mooney, MD 920 East Twenty-Eighth Street, Suite 300 Minneapolis, MN 55407
Study Sponsor:	Atritech, Inc. (Minneapolis, Minnesota)

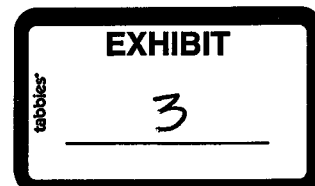
INTRODUCTION

People who volunteer to participate in an experiment (also called a research study or clinical trial) need to understand what is expected of them and why the research is being done. As you think about whether or not to volunteer, it is important that you know that you have rights in place to help protect you. These rights, listed below, will be further explained as you read this informed consent document.

If you are asked to participate in a research study, you have the right to:

- be told the purpose and details of the research study,
- have the drugs or devices (tools or pieces of equipment) used in the research study described;
- have the procedures of the research study and what is expected of you explained,
- have the risks, dangers, and discomforts of the research study described,
- have the benefits and advantages of the research study described,
- be told of other drugs, devices or procedures (and their risks and benefits) that may be helpful to you,
- be told of medical treatment available to you should you be injured because of the research study,
- have a chance to ask questions about the research study,
- quit the research study at any time without it affecting your future treatment,
- have enough time to decide whether or not to take part in this research study and to make that decision without feeling forced or required to participate, and
- be given a copy of this signed and dated informed consent form.

The investigators do not have financial interest in the study company.



What you should know about this research study:

You have been given this consent form so that you may read about the purpose, possible benefits, and risks of participating in this research study. The main goal of research is to gain knowledge that may help you and future patients. We cannot promise this research will benefit you. As with any treatment, this research can have side effects that can be minor or serious. You have the right to refuse to participate or agree to participate and change your mind later. Whatever you decide, it will not affect your normal care.

Please read this consent form carefully. You may agree to participate by signing page 6. Ask questions before you make a decision to participate. If there are any words you do not understand, please ask your physician or their staff to explain the information that is not clear.

Why am I being asked to participate?

Your doctor has invited you to participate in a research study because you have a heart condition in which the upper chambers of your heart beat too fast. This condition, also known as atrial fibrillation, can cause blood clots to form in an area of your heart called the left atrial appendage. Everyone has a left atrial appendage, and it looks like a pouch on the top of your heart. If a clot forms, it can increase your chances of having a stroke or other related problems.

This research study will involve the participation of 50 patients enrolled at up to five hospitals in the United States.

What would not allow me to participate in this study?

There are certain conditions that would not allow you to participate in this study. These conditions are described as entrance criteria and will be reviewed with you prior to your participation. Your doctor will speak with you and review your medical history to determine if you are an appropriate candidate for this research.

What is being studied and what is the purpose of the study?

The investigational device undergoing testing in this study is a new type of device called a Left Atrial Appendage Filter. An investigational device is one that has not yet been approved by the Food and Drug Administration (FDA), but is allowed by the FDA to be studied. In this study, the WATCHMAN™ Left Atrial Appendage Filter System will be used. The WATCHMAN™ is manufactured by Atritech, Inc, a medical device company in Minneapolis, Minnesota. The WATCHMAN™ is made of materials that are common to many medical devices. The WATCHMAN™ is available in many different sizes so the appropriate size will be available for you.

Because you have atrial fibrillation, it is believed that if the pouch in your heart called the left atrial appendage is closed, then blood clots would not be able to form in that area which could possibly cause you harm. The WATCHMAN™ is specifically designed to be permanently implanted in the left atrial appendage of your heart.

The goals of this initial pilot study are to determine whether the WATCHMAN™ device can be safely implanted and to assess the safety of the device over the early follow-up period.

The only experimental part of this research study is the use of the WATCHMAN™ device. The methods used during the procedure are well known and other methods have been used previously to close the left atrial appendage.

The safety and performance of the WATCHMAN Left Atrial Appendage Filter System has been under investigation in a clinical trial in Europe since August 2002. The purpose of the study has been to evaluate the safety of the WATCHMAN device. To date, there have been no reports noted during the follow-up examinations of stroke, systemic embolism (blood clots traveling to other parts of the body other than the brain) or major bleeding events in patients who received a WATCHMAN device. A total number of 16 patients received a WATCHMAN device from August 2002 through February 2003.

In February 2003, the study was temporarily suspended by Atritech, Inc. due to two occurrences of device embolization (movement) to the aorta from its original implanted position. Successful removal of the WATCHMAN device occurred in both patients. Additional safety features have been incorporated into the WATCHMAN device, and procedural steps have been added to ensure that the risk of device movement has been significantly reduced.

The European clinical study resumed patient enrollment July 2003 and as of September 12, 2003, a total of seven additional patients have successfully received the WATCHMAN device.

What are the procedures and how long will this study last?

If you decide to participate in this clinical study, you will first be asked to sign and date this consent form. Then you will have a physical exam and a test to determine if it is safe to go ahead and implant the WATCHMAN™. The test is a standard procedure that allows your doctor to visualize your heart by means of an instrument that goes down your throat. This test is called a transesophageal echo (TEE). It may cause some discomfort in your throat and chest for a brief period of time. If the TEE test confirms you are a proper candidate for the procedure, you then will undergo a cardiac catheterization procedure to have the WATCHMAN™ implanted in the left atrial appendage of your heart.

In addition, if you are not already taking blood thinning medication, you will be required to begin a blood thinning medication called warfarin (or Coumadin) the day prior to your WATCHMAN™ procedure. If you are currently taking warfarin, your medication will be adjusted prior to your procedure. You will also be required to begin taking one aspirin per day, if not already on aspirin, starting the day before the procedure.

Using standard techniques, your doctor will guide the WATCHMAN™ into your heart through a flexible tube inserted through a vein in your groin. Once your doctor is in the correct position, s/he will take pictures of your heart in order to take appropriate measurements of your left atrial appendage. These measurements will determine which size WATCHMAN™ device to use. After the WATCHMAN™ is put into place, additional measurements and pictures will be taken to make sure the device is in the correct position. Once your doctor is satisfied, s/he will release the device to leave it permanently implanted in your heart.

With this type of procedure, you will need to stay in the hospital overnight and recovery will take about 24 hours.

After you have the WATCHMAN implanted in your heart, you will be required to return for follow-up exams so your doctor can check the status of the device. For the purposes of this research, it is very important that you return for each exam. Your doctor will schedule follow-up exams at 45 days, six months and 1 year after the implant procedure. At the 45-day and 6 month exams, your doctor will again complete an x-ray of your chest and perform the same TEE test as mentioned above to visualize your heart so as to check your WATCHMAN. The TEE test is not required for the study at the one-year visit or any annual visit thereafter.

In addition, you will be required to have a small amount of blood drawn a few times during the first 45 days after your procedure to monitor your blood thinning medication in order to make corrections to your medication if it is needed. You may also have additional tests or procedures if your doctor feels it is necessary. While the protocol requires your involvement for a minimum of 1 year, you may be asked to continue to come back for doctor visits at annual intervals until enough information on the WATCHMAN™ device has been collected in order to receive the necessary regulatory approvals. This study could last 3 years.

What are the possible benefits of participating in this study?

The possible benefits of receiving the WATCHMAN device include:

- minimizing the possibility of having a stroke or related complication due to a blood clot that may form in the left atrial appendage of your heart,
- eliminating the need to use blood thinning medications for life and
- contributing to the advancement of medicine.

There is no guarantee that you will receive any medical benefits from participating in this study.

What are the possible risks and discomforts of participating in this study?

There are certain risks associated with the use of the WATCHMAN device. These risks include those typically related to any surgical procedure, those typically related to similar types of procedures performed in the heart, and those that are unique to the use of the WATCHMAN device.

The risks typically related to any surgical procedure include: blood clots or air bubbles to the lungs or other parts of the body, heart attack, stroke, anesthetic problems, bleeding problems, infection and death.

The risks typically related to similar types of procedures performed in the heart include: blood collecting in the sack around your heart, cardiac tamponade (pressure on your heart from fluid accumulation around your heart), an accidental hole punctured in your heart, irregular heart beats, hematoma or seroma (collection of blood under your skin), and allergic reaction to contrast dye.

The risks associated with implanting the WATCHMAN device include: misplacement of the device, movement of the device in your heart or embolization into the aorta, the inability to place the device in the correct position or unable to remove the device if necessary, device fracture, allergic reaction to the implant materials, calcification of the implanted device, hypertrophic scarring or thrombosed veins, pain from improperly sized and/or placed device, serous fluid accumulation, the potential of death, bleeding, infection, blood clot formation on the device, damage to the heart, blood vessels or heart valves, additional surgery if the device is not placed in the correct position.

Additionally, from the test to visualize your heart (TEE), you could experience some bleeding in your esophagus (your food tube) and, in rare instances, your esophagus may get torn.

After you receive the WATCHMAN device, you will be required to stop warfarin (Coumadin) therapy at 45 days following your procedure; therefore, at that time, you may be at an increased risk of stroke. Warfarin is the proven standard of care for reducing the risk of stroke in atrial fibrillation. The WATCHMAN device is designed to be used instead of warfarin. This device is unproven and requires that warfarin not be used. Thus, the absence of warfarin may represent a risk, especially if the device is not effective in preventing stroke.

Inconveniences include but are not limited to: the inconveniences of recovery from the procedure, required follow-up examinations including the tests mentioned above, and following your doctors recommendations for recovery. You and your doctor should discuss in detail all of the possible risks involved with participating in this study. Then you can decide whether the WATCHMAN device is appropriate for you.

What are the risks to pregnant women?

Due to the required x-rays during the study, this research may represent risk to an unborn child. Therefore, if you are a woman of childbearing potential, you will be given a pregnancy test prior to participating. If you are pregnant, you will not be allowed to participate in this research.

Are there any unforeseen risks?

Due to the investigational nature of this study, there may be other potential risks that are not currently known. It is important that you report any reactions to your doctor. Study personnel will monitor you for problems that you may experience.

Will I be informed of any new findings?

You will be provided with any significant information that develops during the course of the study which may affect your willingness to continue with your participation.

Are alternative treatments or procedures available?

It is not necessary for you to be enrolled in this study to protect you from stroke or related complications from blood clots. Alternative ways that doctors can protect patients like you against stroke or related complications due to blood clots are medicines that thin your blood. One of the more common blood thinning medications is effective, but may cause undesirable side effects, such as bleeding, and it requires you to have your blood drawn frequently to monitor your dosage. With use of this device, you will be required to be on a blood thinning medication for only 45 days. There may be other medicines or procedures that would also work to protect you against stroke and related complications, and your doctor can explain these and tell you whether any of these alternatives would be acceptable for you. You cannot receive the WATCHMAN device without participating in this study.

Will my medical records be kept private?

The information gathered during your participation in this study will be submitted to Atritech, Inc., who is the manufacturer of the WATCHMAN device and study sponsor. Appropriate representatives of the Food and Drug Administration (FDA), an agency of the U.S. Government, may wish to inspect the records of this study at any time as part of their responsibility to monitor these types of research studies. By signing this consent form, you give permission for copies of your medical records, x-rays, test results and some billing and cost data to be available to research personnel involved with this study, including those from Atritech, Inc., any contract organization used by Atritech, Inc., and to the FDA if necessary.

All information will be handled and stored in a confidential manner, such that your identity is not disclosed to anyone outside of the study physician's and sponsor's research personnel, or as necessary, the FDA.

The results of this study will be submitted to the FDA and may be used for scientific publication, but your identity will not be disclosed.

What are the costs of participating?

The WATCHMAN device will be provided to you at no cost by Atritech, Inc. Atritech, Inc. will not pay for the costs of the WATCHMAN implantation procedure and follow-up care. Those costs will be the responsibility of you and whoever normally covers your medical care. The usual costs connected with your cardiac catheterization procedure will normally be covered by your health insurance. Costs, which are associated with examinations especially for this clinical study, will be covered through an established contract between Atritech and your hospital.

Will I be paid for participating in the study?

Patients will not be compensated for participating in this research.

Will I be compensated if I get sick or hurt?

If physical injury results from your participation in this study, medical treatment will be available just as if an injury had occurred during any other standard medical treatment. However, Atritech, Inc. does not intend to offer any payments for injuries or hospitalizations that may occur as a result of your participation in this study. Costs for such treatment is the responsibility of you and whoever normally covers your medical care. You should immediately report any injury resulting from participation in this study to the **Dr. Michael Mooney's Office** at the following phone number **612-863-3900**.

Can I leave the study after I received treatment?

Your participation in this study is voluntary. You are free to refuse participation in this study or to withdraw your participation at any time before or after surgery by simply informing your physician of this decision. A refusal or withdrawal of participation will not affect the continuity of your care, nor a cordial physician/patient relationship. Your doctor also has the right to end his or her participation in this study.

What if I have questions or problems?

You are free to ask questions before or at any time during your participation in the

WATCHMAN™ study.

The person to contact at any time you have questions or concerns about the study or any result of the procedures is **Holly MacDonald, RN** at **Abbott Northwestern** and the phone number to call is **612-863-6051**.

If you have questions regarding your rights as a research participant you may contact the **Institutional Review Board (IRB)** at **612-863-5213**. The IRB is the committee that approves research at the hospital.

You will receive a copy of this consent agreement so you can refer to this information in the future.

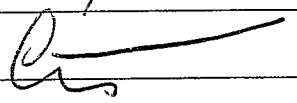
Consent of the Patient

You are making a decision whether or not to participate in this study. Your signature indicates that you have read and understood the information provided above, have had all your questions answered by the study physician, and have decided to participate.

By signing this form, you also authorize the release of your medical records to the sponsor, research personnel and the FDA.

Patient Information

Full Name (PRINT): CHRISTOPHER T. DAHL Date/Time 2/10/04

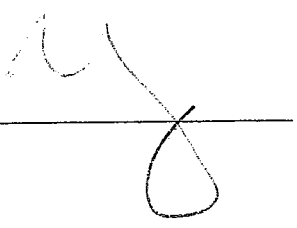
Signature: 

Legally Authorized Representative Information:

The person being considered for this study is unable to consent for himself/herself. I have been asked to give my permission to include my relative in this study. I know of no reason why he/she would refuse were it possible to do so now.

Legally authorized representative: _____ Date/Time _____

Relationship to Patient: _____

Investigator Signature:  Date/Time 2/10/2004