Why CryoCath?

the answer in here >

CRYOCATH®

stop arrhythmias cold

> Why choose cryoablation?

With over 250,000 procedures performed each year, ablation is one of the most common treatments for arrhythmias. While the majority of patients that are treated with heat-based (RF) ablation have successful outcomes, there are risks associated with RF ablation like irreversible damage to critical heart structures, blood clots and pain. More serious side effects can include stroke, and, in extreme cases, death. Cryoablation uses cold energy to produce the same effect as heat-based ablation — it destroys the tiny heart cells that are causing the arrhythmia. While cryoablation is effective, it has certain advantages that differentiate it from RF ablation:

1 less discomfort

Cold is one of nature's anesthetics; accordingly, cryoablation results in little or no discomfort or pain during the procedure.

2 greater stability

When cold temperatures are applied, cryocatheters stick to the tissue they touch, much like a tongue on cold metal. This is an advantage because ablation is performed in a beating heart where there is constant movement. By sticking to the exact spot to be ablated, the electrophysiologist can avoid any accidental slips of the catheter tip, thereby preventing accidental damage to critical structures nearby.

3 ability to confirm target ablation site

Cryoablation allows the electrophysiologist to slightly freeze tissue to test whether it is responsible for conducting an arrhythmia. Heat-based therapies don't allow that — once the tissue is burned, it stays burned. By contrast, cryoablation allows the electrophysiologist to re-warm frozen tissue (that is not responsible for the arrhythmia) and restore its normal electrical function.

4 minimizes the risk of damaging critical structures

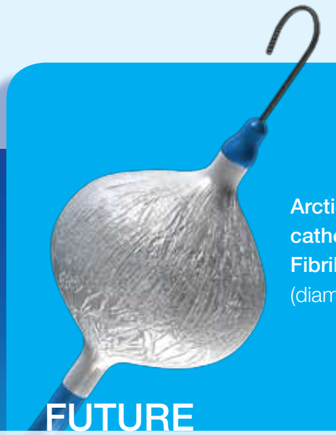
Treating arrhythmias with ablation involves working very close to critical structures, for example, the heart's natural pacemakers, the esophagus or coronary arteries. Damage to critical structures can result in the permanent interruption of normal electrical conduction in the heart and require the placement of an artificial pacemaker in the patient — an outcome everyone absolutely wants to avoid. With cryoablation — which freezes tissue instead of burning it — the risk of damage to these critical structures is minimized.

5 minimizes the risk of perforation

Perforation — for example, to the atrial wall — is a dangerous risk that can lead to serious complications. Thanks to its ability to preserve tissue integrity, there is minimal risk of perforation with cryoablation.

6 minimizes the risk of clot formation

Heat burns and chars the ablated tissue. This tissue disruption can result in clot formation called thrombus in medical terms. The thrombus can dislodge and migrate into a blood vessel which can lead to stroke. With cryoablation, this risk is minimized.



Arctic Front® balloon catheter to treat Atrial Fibrillation (AFib)
(diameter 23 or 28mm)

FIRST

First in man
In 1998, CryoCath was the first company to treat a patient with a percutaneous cryoablation catheter.

First in Europe
In 2001, CryoCath became the first company with commercially available percutaneous cryoablation products.

First in the U.S.
In 2003, CryoCath became the first company to have a percutaneous cryoablation product approved for commercial use by the FDA.

FOREMOST

4 product portfolio. Building on our first product, today CryoCath has three focal catheters approved around the world. We provide physicians with an optimal choice to better serve patients by offering multiple French (7 & 9F) and tip sizes (4, 6 & 8mm) with various reaches.

>50 global representatives and clinical specialists providing physicians with the support they need to ensure the optimal usage of CryoCath's products, resulting in the best possible outcomes for the patients.

>450 centers world-wide use our products everyday, including **>250** in the U.S.

>40,000 patients have been successfully treated using CryoCath's catheters.

FUTURE

One out of every two arrhythmias is AFib. That is more than 160,000 new cases of disease diagnosed each year in the U.S. Yet, there is still no perfect solution to meet this pervasive unmet need.

Treating AFib is the future of cardiac ablation.

CryoCath is that future.

In fact, we are already leading the charge. We are approved in the EU with a steadily growing installed base; at last count, our innovative Arctic Front product to treat AFib has treated more than 1,000 patients. As the subject of an FDA pivotal IDE clinical trial (STOP AF) in over 20 centers, it won't be long until Arctic Front is available in the United States.

"We use cryo so often now, that there is rarely a case in which we don't utilize cryo! Success has been similar with radiofrequency (RF), but RF does not come with the peace of mind that you get with cryo."

Source: EP Lab Digest, August 2007 by Dr. Dan Dan,
Co-Director of Cardiovascular Reasearch, Fuqua Heart Center, Atlanta, Georgia

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The 7F Freezor® Cardiac CryoAblation Catheter and CCT.2 CryoAblation Console System and related accessories are indicated for the cryoablation of the conducting tissues of the heart in the treatment of patients with atrioventricular nodal reentrant tachycardia (AVNRT). Please consult the Instructions for Use for all relevant Contraindications, Warnings and Precautions.

Freezor® *Xtra* and Freezor® *MAX* are approved as PMA supplements of 7F Freezor catheter for the indication of minimally invasive cardiac surgery procedures, including surgical treatment of cardiac arrhythmias.

Proposed Indication: The CryoCath Arctic Front® Cardiac Cryoablation catheter system, including the FlexCath™ Steerable Sheath, and the Freezor *MAX* Cardiac CryoAblation catheter, are indicated for the treatment of patients with paroxysmal atrial fibrillation to reduce the subsequent occurrence of symptomatic atrial fibrillation.

Investigation Device Exemption (IDE) Study ongoing and is not available for sale in the United States.

Freezor®, Freezor® *Xtra*, and Freezor® *MAX* Cardiac CryoAblation Catheters are intended for use in the treatment of cardiac arrhythmias.

The Arctic Front Cardiac CryoAblation Catheter is intended for the treatment of patients suffering from paroxysmal atrial fibrillation (PAF). Adjunct devices (Freezor *MAX*) can be used with Arctic Front in the treatment of PAF.

M051 Rev-0