

cool stuff ...

... for your heart

cryotechnology for treatment of cardiac arrhythmias



AFreeze develops cryotechnology for therapy of atrial fibrillation which is the most common type of cardiac arrhythmia. The focus of AFreeze is to cure atrial fibrillation by shock freezing tissue in the atria of the heart via a catheter.

The brand

What is AFreeze?

The company was founded in 2005. Our vision is to establish a comprehensive portfolio of products to treat cardiac arrhythmias by cryoablation.

Afreeze is a medical technology centre, development and clinical application of medical devices. We can also provide our broad network of expertise with various clinical specialists to other companies.



Well organized and motivated specialists are needed to realize visions based on research. AFreeze is a start-up company founded by Florian Hintringer MD, cardiologist, and by Gerald Fischer PhD in 2005. The company is based on the research these two scientists

The partnership

Who stands behind AFreeze?

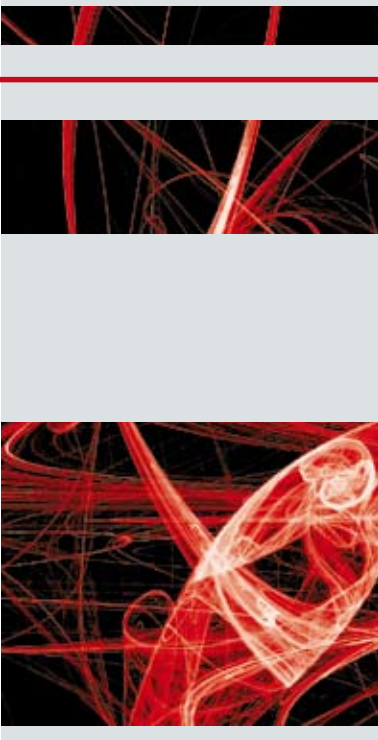
performed for many years at the Medical University in Innsbruck (MUI) and the University for Health Sciences, Medical Informatics and Technology (UMIT) in Hall, both in Tyrol, Austria. Excellent teamwork in the field of medical and technical research has resulted in designing a cryoablation system, which has already been validated through animal testing.



Florian Hintringer, cardiologist at MUI, is in charge of clinical research. Trained in Austria and at St. George's Hospital in London, UK, he has been director of the unit to treat cardiac arrhythmias at MUI since 1997.



Gerald Fischer has been responsible for research and development since the company started. There has been continuous cooperation with Florian Hintringer in basic and clinical research at MUI since 2000. In addition, he has directed a working group for biomedical modelling at the UMIT since 2002.

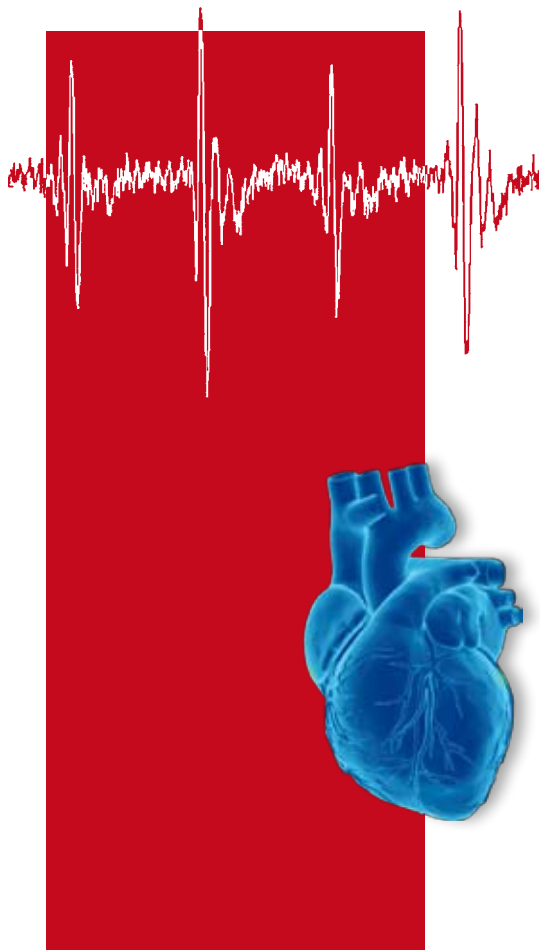


Atrial fibrillation is a very common disease. In the first world countries alone approximately 14 million people suffer from atrial fibrillation.

According to Germany's hospital statistics (DRG-Statistik), 1.1 million people (this figure corresponds to 1.4% of the German population) were affected by atrial flutter and atrial fibrillation in 2006. Atrial fibrillation affects mainly older people (5% < 60 years old, 10% < 70 years old). Due to ongoing demographic changes, the number of people affected by atrial fibrillation is expected to rise to 2.5 million within the next 40 years in Germany alone.

Atrial fibrillation


The most common type of cardiac arrhythmia.



Besides heart attacks, atrial fibrillation is the most common reason for strokes in Germany. Atrial fibrillation causes 15% of all strokes, which corresponds to 40,000 cases per year.

Currently available drugs are often ineffective. The maze procedure is a surgical technique and the most effective (therapeutic) method. However, it requires open heart surgery.

For more than 15 years catheter ablation has provided a minimally invasive treatment of various cardiac arrhythmias and therefore has gained enormous significance in the past years. However, the results of catheter ablation for atrial fibrillation are still not satisfactory.



For catheter ablation of atrial fibrillation different strategies are applied: Segmental ostial catheter ablation (SOCA) and wide area catheter ablation (WACA). Both kinds of treatment are complex and therefore only available at very experienced clinics.

SOCA: *Fibres of atrial myocardium stretch into the pulmonary veins draining into the left atrium. Fast firing electrical foci may be located in this area initiating (triggering) atrial fibrillation. Isolating the orifice of the pulmonary veins by means of catheter ablation is intended to prevent initiation of atrial fibrillation. The isolation is then validated by specific diagnostic catheters. In the past few years, new catheters applying radio-frequency current, ultrasound or freezing the tissue (cryoablation) have been introduced in order to simplify and to increase the efficiency of the ablation procedure. However, this concept of treatment only eliminates the trigger for atrial fibrillation but leaves other mechanisms of atrial fibrillation unaddressed.*

Catheter ablation of atrial fibrillation

Medical and technical challenges.

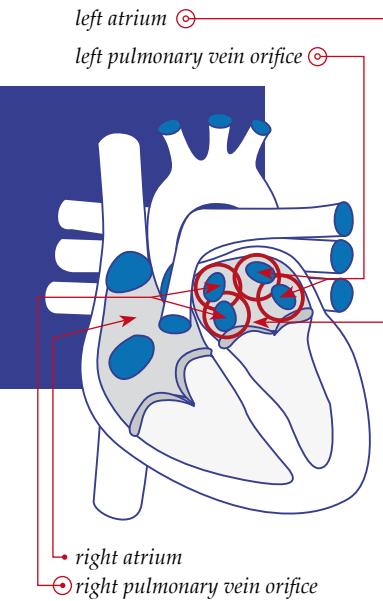
WACA: *This technique aims at generating long lines of necrosis in order to isolate the pulmonary vein orifices and to separate the atrial myocardium into small, electrically isolated segments, thus preventing the spread of atrial fibrillation once it has started. However, generating these long linear lesions without leaving any gaps is difficult and time consuming, and it is almost impossible to validate the continuity of the lines in detail.*

The new technology of AFreeze provides a simple tool to create long linear lesions quickly and reliably.

CoolLoop

CoolLoop is a cryoablation catheter which is protected by patents in Europe and the USA.

This catheter allows generating long lines of necrosis similar to the surgical maze procedure. It is possible to mimic the highly effective but invasive surgical method via a simple puncture in the groin. The stretched catheter (passive position) is introduced into the left atrium where it is fixed in one of the pulmonary veins. In the following step the CoolLoop is formed into a loop (active position) and is pressed towards the wall of the left atrium.

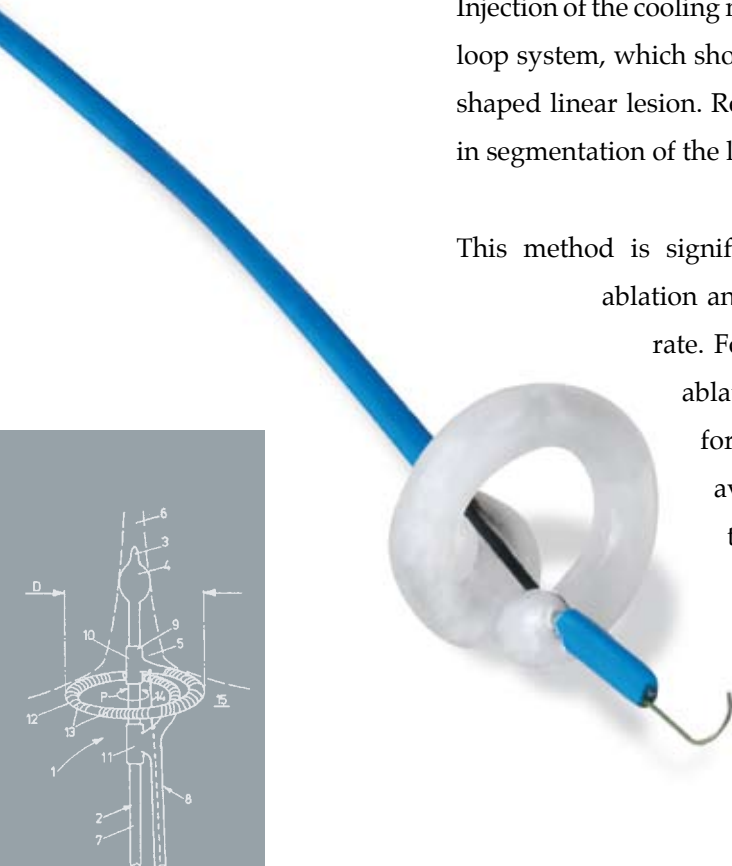


CoolLoop

An innovative technology expanding the market for catheter ablation of atrial fibrillation.

Injection of the cooling medium (dinitrogen monoxide) into a closed loop system, which shock freezes the tissue, results in a long bow-shaped linear lesion. Repeating this procedure on all veins results in segmentation of the left atrium.

This method is significantly easier than conventional catheter ablation and shows a considerable rise in the success rate. For this reason it is very likely that catheter ablation of atrial fibrillation, currently reserved for highly specialized hospitals, will be available in smaller clinics as well. Besides that it could become an option for a greater number of patients, offering a higher chance for permanent cure of atrial fibrillation.



Statistics display the number of ablations in some European states as an indicator for the current market potential.

The European Heart Rhythm Association published data in the „EHRA White Book 2008“ about the status of cardiac electrophysiology in member states of the European Society of Cardiology. The total number of ablations in the countries listed is 125,000. The total number of ablations for atrial fibrillation per year is 26,000 cases which on average is 21% of all ablations.

Country	Number ablations per year	Number specialty hospitals	Ablation per hospital	Number ablations AF	Percentage AF
Denmark	2550	6	425	1400	55%
Italy	17.977	81	222	5341	30%
Switzerland	3123	18	174	829	27%
EU total	125.000			26.000	21%

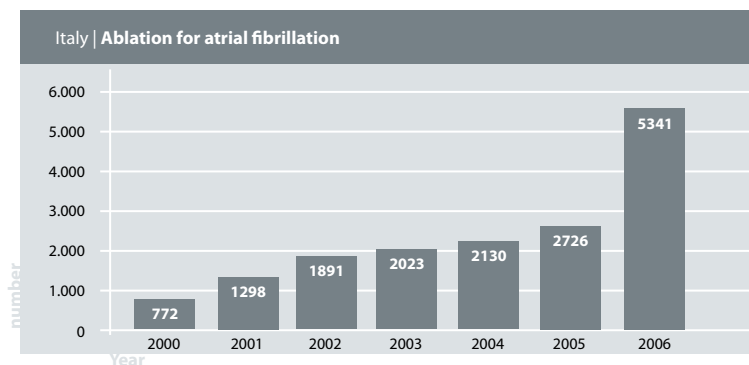
The numbers from Switzerland and Italy illustrate the dynamic growth of the market for catheter ablation for atrial fibrillation.

The market potential

In Europe - EHRA White Book

The number of catheter ablations in Switzerland is constantly increasing. From 2002 to 2007 the number of ablations for atrial fibrillation rapidly grew from 64 to 829 per year which is an increase of more than tenfold (Source: European Heart Rhythm Association).

In 2007 the Associazione Italiana Arithmologia e Cardiosstimolazione published data about the number of ablations with radiofrequency. In 2002 the number was 9583 and increased in the following four years to 17,977. In 2002 the number of catheter ablations in the left atrium was 1,981 (21%) and increased to 5341 (30%) in 2006.



AFreeze expects the market for ablations to treat atrial fibrillation to double again within the next years. The market launch of the CoolLoop is scheduled for 2010, resulting not only in simplifying the intervention but in reducing cost of treatment. This should raise market demand for catheter ablation significantly.

Patents and Patent applications:

- EP 1.356.779 Hintringer F, Geistert W
cardiac tissue ablation device for the creation
of a circular lesion in an infundibulum
- US 6.979.331 Hintringer F, Geistert W
ablation device for cardiac tissue, in particular for
a circular lesion around a vessel orifice in the heart
- EP 08.016.125 Fischer G, Hintringer F, Goll M
cooling system for a catheter
- US 12/210052 Fischer G, Hintringer F, Goll M
cooling system for a catheter
- US 61/035.847 Hintringer F, Fischer G, Goll M
handle for an ablation system
- US 61/035.865 Hintringer F, Fischer G
ablation system



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