Atrial Fibrillation Therapy Fact Sheet

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What is atrial fibrillation?

AF currently affects more than 6 million Europeans[1]

AF decreases the heart's pumping efficiency by 30%[2]

AF causes the blood to pool in the left atrial appendage

Atrial fibrillation (AF) is the most common type of arrhythmia, a problem with the rate or rhythm of the heartbeat. During an arrhythmia, the heart can beat too fast, too slow, or with an irregular rhythm. AF occurs if rapid, disorganised electrical signals cause the heart's two upper chambers, the atria, to fibrillate[3].

In atrial fibrillation, the heart does not contract as strongly as it should. This can cause blood to pool in the heart and form clots. When the blood clots dislodge, they may move through the aorta to the brain, where they can become trapped in a narrow brain artery, blocking the blood flow and causing a stroke. Research suggests that over 90 percent of blood clots responsible for stroke in patients with AF originate in a pouch on the left upper chamber of the heart called left atrial appendage (LAA)[4].

Atrial fibrillation may be brief, with transient symptoms and it is possible to have an AF episode that resolves on its own. However, AF may be persistent and require treatment. In this circumstance, medications or other treatments cannot restore a normal heart rhythm.

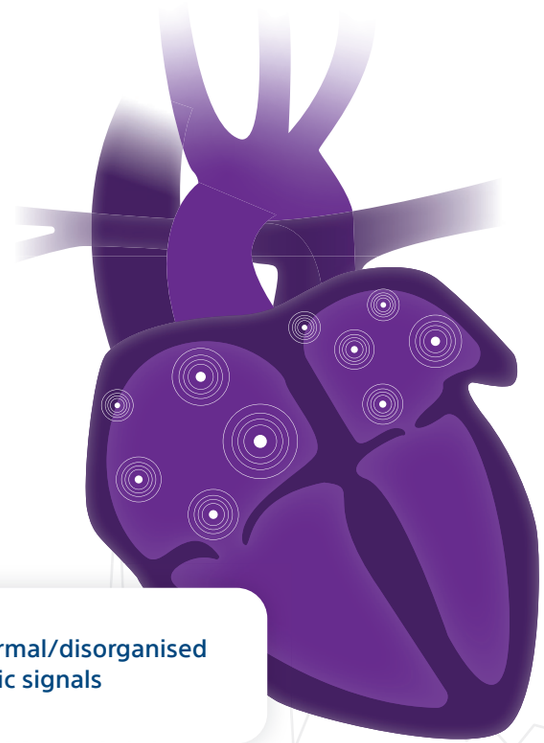
Risk factors for AF include[5]:

- Haemodynamic stress *(i.e. heart failure or hypertension)*
- Atrial ischemia
- Inflammation
- Non-cardiovascular respiratory causes
- Alcohol and drug use
- Endocrine disorders *(i.e. diabetes)*
- Neurologic disorders
- Genetic factors/advancing age

1.Guidelines for the management of atrial fibrillation. The task force for the management of atrial fibrillation of the European Society of Cardiology(ESC).Eur. Heart J 2010 ; 31 : 2369-2449. 2. Harvard Health Publications. Atrial Fibrillation: Common, serious, treatable. November 1, 2011. 3. National Lung Blood and Heart Institute, National Institutes of Health (NIH), July 1, 2011. 4. Randall J. Lee, MD, PhD; Krzysztof Bartus, MD; Steven J. Yakubov, MD, Catheter-Based Left Atrial Appendage (LAA) Ligation for the Prevention of Embolic Events Arising From the LAA: Initial Experience in a Canine Model, Circ Cardiovasc Interv 2010;3;224-229. 5. Medscape: http://emedicine.medscape.com/article/151066-overview#aw2aab6b2b3aa (Accessed: November 3, 2015 – 12:53 am).

Symptoms

- Heart palpitations
- Chest pains
- Dizziness
- Fainting
- Shortness of breath
- Lowered ability to exercise
- Feeling tired



Abnormal/disorganised electric signals

Prevalence and death rates

Atrial fibrillation affects approximately 1.5 to 2 percent of the general population worldwide[6]. Over six million Europeans suffer from this arrhythmia, and its prevalence is estimated to at least double over the next 50 years as the population ages.

Global burden of atrial fibrillation

Atrial fibrillation is an increasing burden on the global healthcare system because of the numbers of patients affected, the impact of stroke, and the cost of both inpatient and outpatient therapy[7]. Atrial fibrillation is associated with significant economic costs from the perspective of statutory health insurance, with the largest part of costs attributable to inpatient stays and drug usage. According to studies, direct-cost estimates ranged from $2,000 to $14,200 per patient-year in the USA and from €450 to €3,000 in Europe[8].

6. *Camm JA et al.* 2012 focused update of the ESC Guidelines for the management of atrial fibrillation, European Heart Journal 2012, 33:2719–2747. 7. Mayo Clinic: http://www.mayoclinic.org/documents/mc5234-23-pdf/doc-20079137 (Accessed: November 3, 2015 – 12:59 am). 8. The cost of illness of atrial fibrillation: a systematic review of the recent literature cost of illness of atrial fibrillation: a systematic review of the recent literature | EP Europace | Oxford Academic (oup.com).

Treatment modalities: focus on atrial fibrillation ablation

Electrophysiology, a cardiological discipline dedicated to the study, diagnosis and treatment of cardiac rhythm disorders, underwent its first revolution some 30 years ago with the use of radiofrequency energy, which allowed the development of interventional treatment of most cardiac rhythm abnormalities, and then, some 15 years ago, of cryotherapy, which emerged as a particularly effective and attractive alternative to radiofrequency.

Ablation is a minimally invasive procedure used to correct certain heart rhythm abnormalities such as AF. During an ablation procedure a thin, flexible tube called a catheter is guided with X-ray or dedicated systems that represent the interior of the heart in 3D, to the interior of the heart from the patient's groin. Traditionally, the tip of an ablation catheter generates extreme temperatures – hot (using radiofrequency) or cold (using cryotherapy) – to eliminate the targeted heart tissue associated with irregular heartbeats.

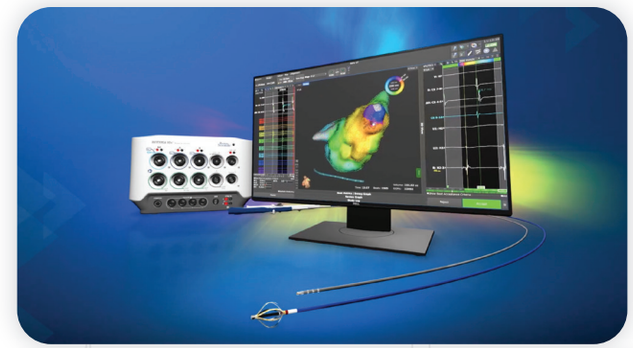
Today, most forms of cardiac ablation to treat arrhythmias are thermal, including both radiofrequency and cryoablation. The tissue-selective FARAPULSE™ Pulsed Field Ablation (PFA) System has pioneered the Pulsed Field Ablation energy source for cardiac ablation, including pulmonary vein isolation to treat AF. Leading with safety, the FARAPULSE PFA System makes durable cardiac lesions in seconds while sparing non-target tissue and has already treated over 12,000 patients and counting.

Radiofrequency

Radiofrequency (RF) catheter ablation has emerged as an important therapeutic option in patients with drug-resistant atrial fibrillation (AF), with a success rate of ≈75-80% in European medical institutions[9].

Radiofrequency ablation can be performed as a minimally invasive cardiac catheterisation procedure.

How it works? For years, physicians guided their ablation catheters with X-ray. However and because of the risks associated to the continuous and long exposure to fluoroscopy, the industry developed mapping systems, such as RHYTHMIA HDx™, that represented the inner part of the heart in 3D and allowed to understand the precise location of the arrhythmia source for a more efficient therapy delivery.
The procedure takes two to four hours, and the patient can go home the same day.



Watch a video about radiofrequency treatment

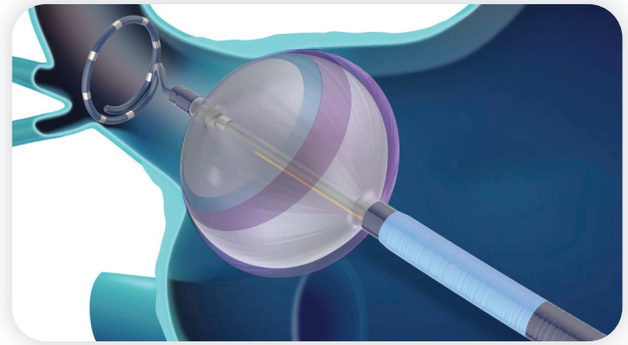
9. Kuck *et al.* N Engl J Med 2016; 374:2235-2245 DOI: 10.1056/NEJMoa1602014.

Cryotherapy

Most patients are treated with heat-based ablation using radiofrequency (RF) catheters, but this procedure has some risk of complications. Cryoablation helps physicians avoid these risks by using cold instead of heat to disable abnormal heart tissue. Unlike heat-based ablation, cryoablation allows physicians to cool tissue to make sure it is the area causing an irregularity. If it is not, the site's normal electrical function can be restored simply by allowing the tissue to thaw and re-warm.

Cryoballoon ablation is a well-studied solution comprising an important part of the clinical armamentarium in AF ablation. In regards to utilisation of the therapy, cryoablation standardises a treatment entry point for a more predictable patient journey.

How it works? The physician inserts the balloon catheter into a blood vessel, usually in the upper leg, and then threads it through the body until it reaches the heart. This narrow tube has an inflatable balloon on one end that engages the pulmonary vein. Using advanced imaging techniques, the doctor is able to guide the catheter to the heart.

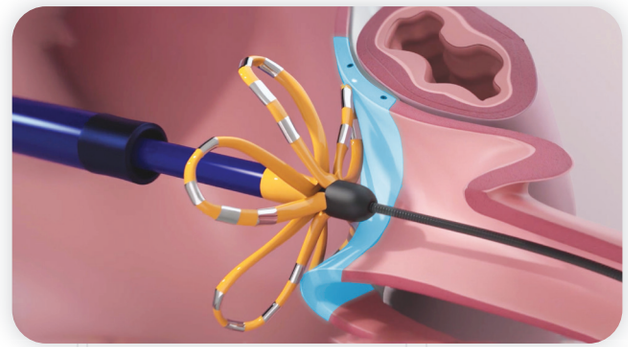


Watch a video about the POLARx™ FIT expandable cryoballoon ablation catheter

Pulsed field ablation (PFA)

Boston Scientific's PFA System, however, relies on non-thermal electric fields that are tissue-selective. PFA selectively ablates heart tissue without affecting other critical surrounding structures such as the oesophagus or major nerves – an unfortunate potential risk of standard thermal ablation. Based on European clinical trials, these electric fields have proven very effective in durably 'silencing' abnormal heart signals, while reducing the risk of damage to other nearby tissues.

Boston Scientific is pioneering tissue-selective ablation through the development and commercialisation of its FARAPULSE™ PFA System, which received CE Mark approval in January 2021 and is commercially available across Europe.



Learn more about the FARAPULSE PFA System

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