

Glossary of Terms:

Atrial fibrillation, stroke and left atrial appendage closure

❖ **Arrhythmia**

Heartbeats which are too slow, too rapid, irregular or too early.

❖ **Atria**

The plural of atrium. The atria are the two smaller, upper chambers of the human heart.

❖ **Atrial Fibrillation (AF)**

The most common sustained cardiac rhythm disorder; occurs when the upper chambers (atria) of the heart beat irregularly. As a result, the atria do not empty adequately and blood does not flow properly, potentially allowing blood clots to form, which can break loose and travel to the brain, resulting in a stroke.¹ Patients with AF are at a five-fold increased risk of stroke.^{2,3}

❖ **Cardiac arrhythmia**

Medical conditions with an abnormal heart beat.

❖ **Cardiomyopathy**

Disease of the heart muscle (the myocardium). Stems from the following Greek roots: cardio = heart; mys = muscle; pathos = disease.

❖ **Catheter**

A thin, flexible tube which is, for example, placed in a vein to provide a pathway for giving drugs, nutrients, fluids, blood products or devices.

❖ **CHADS₂ score, CHA₂DS₂-VAsc score**

Simple clinical prediction rules for estimating the risk of stroke in patients with atrial fibrillation (AF), which are used to determine whether or not treatment is required with anticoagulation therapy or antiplatelet therapy. The higher the score, the greater the risk of stroke is.

❖ **Clinical endpoint**

Overall outcome that the protocol is designed to evaluate. Common endpoints of clinical trials are, for example, disease progression, stroke or death.

❖ **Contraindication**

A specific circumstance when the use of certain treatments could be harmful.

❖ **Double-blind study**

A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy), so that results are thought to be objective, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome.

❖ **Echocardiography**

A diagnostic test which uses ultrasound waves to make images of the heart chambers, valves and surrounding structures. It can measure cardiac output and is a sensitive test for thrombi in or liquid accumulations around the heart. It can also be used to detect abnormal anatomy or infections of the heart valves. In addition, it can be used to assess the size of the left atrial appendage.

❖ **Efficacy**

The maximum ability of a drug or treatment to produce the desired effect or result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed.

❖ **Electrocardiogram (ECG)**

A simple, non-invasive procedure that records the electrical activity of the heart by placing electrodes on the chest and which is used to detect abnormal rhythms, coronary blood flow and heart muscle damage.

❖ **Electrophysiology**

The biomedical field dealing with the study of electric activity in the body. Electrophysiology includes the study of the production of electrical activity and the effects of that electrical activity on the heart.

❖ **Embolism**

Obstruction of a blood vessel by a foreign substance or a blood clot which migrates from one part of the body (through circulation) to another, lodges in a vessel and blocks the flow of blood.

❖ **Endothelialisation**

The formation of endothelial tissue, which is tissue of or pertaining to the endothelium (a thin layer of flat epithelial cells that lines in the heart, serous cavities, lymph and blood vessels). When endothelialisation takes place, it means that the healing process after the device implant is complete.

❖ **Esophagus**

The tube which connects the pharynx (throat) with the stomach. It lies between the trachea (windpipe) and the spine and is about 25 centimetres long. It also is the part of the body in which the transesophageal echocardiogram (TEE)ⁱ is able to visualise the heart and its structures, especially the left atrium.

❖ **Fibrillation**

Incoordinate twitching of the heart muscle fibres.

❖ **Fluoroscopy**

An x-ray procedure that makes it possible to see internal organs in motion. Fluoroscopy is commonly used during cardiac procedures to visualise the heart.

ⁱ Also referred to as TOE.

❖ Haemorrhagic stroke

A stroke caused by rupture of a blood vessel or an abnormal vascular structure which leads to bleeding inside of the brain. Haemorrhagic stroke is a potential side effect of oral anticoagulants.

❖ Heart attack

The death of heart muscle due to the loss of blood supply. The loss of blood supply is usually caused by a complete blockage of a coronary artery, one of the arteries that supplies blood to the heart muscle. Death of the heart muscle, in turn, may cause chest pain and electrical instability of the heart muscle tissue.

❖ International Normalised Ratio (INR)

A system for assessing the clotting tendency of blood in patients receiving anticoagulant therapy with vitamin K antagonists (VKAs), such as warfarin.

❖ Ischaemic stroke

A stroke which is caused by an interruption of the blood supply due to a blockage (e.g. a blood clot or embolism).⁴

❖ Left Atrial Appendage (LAA)

A pouch-like extension located in the upper left chamber of the human heart. The LAA is about the size of a thumb and has a narrow opening (ostium) into the left atrium. It is known to be the main source of blood clots being formed in patients with AF, which is why closing it off can reduce the risk of stroke.

❖ Left atrium

The upper left chamber of the heart. The left atrium receives oxygenated blood from the lungs and pumps it down into the left lower chamber (left ventricle) which pumps it out under high pressure through the aorta to the body.

❖ Oral anticoagulant drugs (OACs, e.g. Marcumar, Warfarin, Coumadin) and new oral anticoagulant drugs (NOACs)

Medicinal drugs commonly referred to as “blood thinners”, which prevent and treat potentially deadly blood clots, that could cause a stroke or a heart attack.

More recent generation of OACs are usually referred to as new or novel oral anticoagulants (NOACs). NOACs such as Apixaban (Eliquis™), Edoxaban (Lixiana™), Dabigatran (Pradaxa™) and Rivaroxaban (Xarelto™) inhibit the building of blood clots. Not all patients tolerate them. However, there is no need for INR controls like with OACs. NOACs showed non-inferiority or even superiority vs. warfarin in randomised trials.^{5,6,7}

❖ Palpitations

Unpleasant sensations of irregular and/or forceful beating of the heart, which can result from abnormal heart rhythms (arrhythmias).

❖ Paroxysmal AF

An intermittent form of atrial fibrillation characterised by a sudden onset and abrupt cessation of this rhythm.

❖ Patient-Years

The concept of patient-years is used in many clinical studies and statistical assessments of risk. To obtain the number, researchers multiply the number of patients enrolled in a given study by the number of years of follow up. To statistically assess the risk of a given event, the number of times where the adverse event happened is then divided by that number (“events per patient years”).

For example, if ten patients participated in a study on heart attacks for 15 years (i.e., 150 patient-years (10 x 15)), and three of them had heart attacks, there would be one heart attack for every 50 patient-years in the study. While it is important to look at individual data in any study, looking at things in these terms can reveal trends.

❖ Randomised trial

A study in which participants are randomly (i.e. by chance) assigned to one of two or more treatment arms of a clinical trial. Occasionally placebos are utilised.

❖ Right atrium

The right upper chamber of the heart which receives deoxygenated blood from the body through the vena cava and pumps it into the lower right chamber (right ventricle) of the heart which then pumps it under low pressure into the lungs via the pulmonary artery to be oxygenated. The trans-septal access into the left atrium and LAA is performed through the right atrium.

❖ Standards of care

Treatment regimen or medical management based on state-of-the-art participant care.

❖ Stroke

A stroke is the sudden or rapidly developing loss of brain cells due to a lack of oxygen. Strokes are caused by a lack of blood supply to the brain due to a blockage or haemorrhage and can cause severely restricted movement paralysis, loss of speech or vision, and death.

❖ Systemic embolism

A clot which blocks the blood flow in an artery somewhere in the human body.

❖ Transesophageal echocardiogram (TEE)ⁱⁱ

A diagnostic test with very accurate imaging capabilities which uses ultrasound waves to make images of the heart chambers, valves and surrounding structures and which is done through the esophagus. It is used, among others, to detect blood clots in the left atrium and is therefore useful in guiding cardioversion in patients with atrial fibrillation who are prone to form such clots. Transesophageal

ⁱⁱ Also referred to as TOE.

echocardiogram is also used to assess the optimal size and guide placement of the Watchman LAA closure Device.

❖ **Transient ischaemic attack (TIA)**

A change in the blood supply to the brain which results in transient neurologic dysfunction, which is associated with seriously increased risk of following stroke.

❖ **Thromboprophylaxis**

Measures including pharmacological agents which prevent blood clotting.

❖ **Thrombus**

A blood clot (blood that has been converted from a liquid to a solid state).

❖ **Valvular & non-valvular AF**

Valvular AF occurs in patients who have evidence or history of e.g. rheumatic mitral valve disease or a prosthetic valve. Patients with valvular AF have a 17-fold increased risk of suffering a stroke.⁸ In contrast, the term non-valvular AF applies to all other forms of AF and thus occurs in patients who do not have rheumatic mitral valve disease, a prosthetic heart valve or mitral valve repair.

❖ **Warfarin**

An oral anticoagulant drug (brand names: Coumadin[®], Panwarfin[®], Sofarin[®]) which is used to prevent the blood from clotting and to treat existing blood clots.⁹ It is also used to reduce the risk of clots causing stroke or heart attack. Warfarin works by slowing the activation of clotting factors and requires frequent blood testing to ensure the correct therapeutic range (INR monitoring).

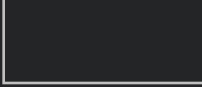
Media Contacts

For further information contact the
EMEA Corporate Communications
Team

EMEA.MediaRelations@bsci.com

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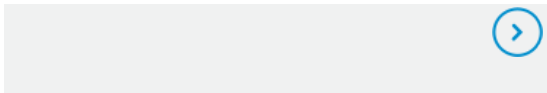
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