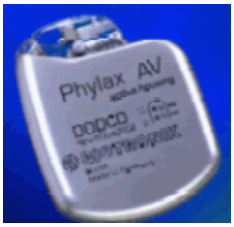
New Device Approvals

Phylax AV Implantable Cardioverter Defibrillator System with Program Software



This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	Phylax AV Implantable Cardioverter Defibrillator System & Program Software
Manufacturer:	BIOTRONIK GmbH & Co
Address:	Woermannkehre 1, Berlin, Germany
Approval Date:	September 29, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p000009a.pdf

What is it? A dual chamber Implantable Cardioverter Defibrillator (ICD) with programmer software

How does it work? The ICD is an implantable electronic device built inside a metal (titanium) shell that is placed under the skin in the shoulder area. The ICD is connected to standard ICD leads (wires) that have been inserted through a vein into the heart. Inside the ICD are a battery and a small computer that monitors heart function. The ICD continuously monitors heart rhythms through the implanted leads and responds when it detects an abnormal rhythm, such as a ventricular tachyarrhythmia, which causes the heart to beat too fast and/or irregularly. The ICD's response can give low energy electrical stimulation or pulses that control pacing of the heart or high energy defibrillation shocks that will be felt by the patient. This response by the ICD is therapy delivered to the heart in order to return the heart to a normal rhythm. The ICD also provides therapy when the heart rhythm is too slow (bradycardia), in either one or two of the heart's chambers (atrium and/or ventricle).

When is it used? The Phylax AV is used for patients who are at high risk of sudden death due to abnormal rhythms in the ventricle and have experienced one or more of the following situations:

- survival of at least one episode of cardiac arrest with a loss of consciousness due to a ventricular tachyarrhythmia
- recurrent, poorly tolerated abnormally fast beating of the ventricular chamber of the heart (ventricular tachycardia or VT)

What will it accomplish? When patients receive therapy (electric stimulus) from the Phylax AV ICD, their abnormal heart rhythm will be converted back to a normal heart rhythm.

When should it not be used? The Phylax AV should not be used for patients whose ventricular tachyarrhythmias may have temporary or reversible causes or when their ventricular arrhythmias are not treatable with electrical therapy. The ICD should not be used for patients who have a unipolar or single

lead pacemaker, or for patients whose only disorders are slow heart rates (bradyarrhythmia) or atrial arrhythmias. In addition, patients with long-term refractory atrial tachyarrhythmias who require both atrial and ventricular (dual chamber) pacing, are not candidates for the Phylax AV.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p000009.html

Other: http://www.americanheart.org