New Device Approvals

NAVI-STAR® Diagnostic/Ablation Deflectable Tip Catheter

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:	NAVI-STAR® Diagnostic/Ablation Deflectable Tip Catheter
Manufacturer:	Biosense Webster, Inc
Address:	3333 Diamond Canyon Rd., Diamond Bar, CA 91765
Approval Date:	June 15, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p990025a.pdf

What is it? The NAVI-STAR® catheter is a steerable thin flexible catheter (tube) containing multiple electrodes. This catheter can provide information about the location of the electrical impulse conduction path (called electrophysiological mapping) responsible for heart muscle contraction. The catheter also can transmit RF (radiofrequency) current through an electrode at the catheter tip for the purpose of ablation (destruction) of a small segment of heart muscle responsible for abnormal impulse conduction. When used with the CARTO® system and REF-STAR® reference device, a real-time 3-dimentional image of the heart chamber can be made. For ablation, the catheter can be used with a compatible commercially available RF generator and dispersive pad which carries energy from the patient's body back to the RF generator.

How does it work? The NAVI-STAR® catheter is available with different temperature sensing devices embedded in the electrode located at the tip of the catheter. In addition, a magnetic field location sensor is embedded in the catheter tip that transmits location information to the CARTO system. This allows RF thermal (heat) energy to be delivered to a specific location to produce a lesion that interrupts the defective electrical conduction pathway in the heart's wall.

When is it used? The device and related accessory devices are indicated for catheter-based atrial (upper heart chamber) and ventricular (lower heart chamber) cardiac mapping, and for cardiac ablation procedures.

What will it accomplish? The NAVI-STAR® catheter and related accessory devices are designed to enable a physician to locate sites in the heart that can cause or support, abnormal heart rhythms by mapping the electrical signals of the heart. This system can then deliver RF energy in the form of heat to specific areas of the heart muscle in order to destroy tissue that can cause or support abnormal heart rhythms.

When should it not be used? This device should not be used in patients with active systemic infection; a blood clot in the left atrium; or myxoma (a tumor of connective tissue); or an interatrial baffle or patch. In patients with aortic valve replacement, the NAVI-STAR® catheter should not be inserted through the aorta to the heart or through the heart's dividing walls.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p990025.html **Other:** http://www.americanheart.org