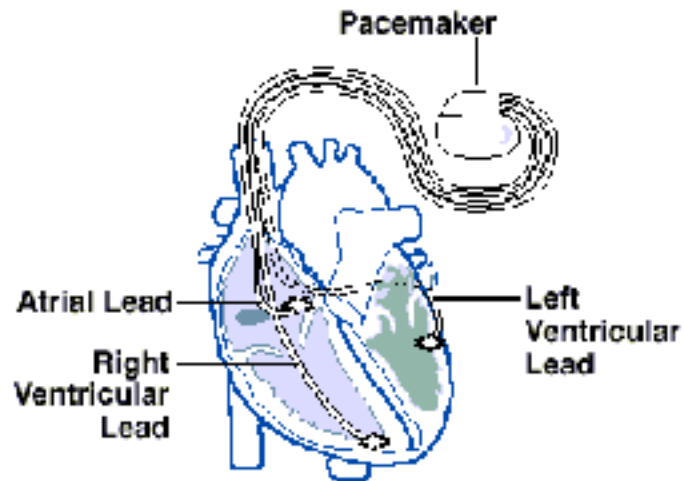




New Device Approvals

Medtronic® InSync® Biventricular Pacing System including the InSync® Model 8040 Pulse Generator, Attain™ LV Model 2187 and Attain™ CS Model 2188 Leads - P010015



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 and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

- Product Name:** Medtronic® InSync® Biventricular Cardiac Pacing System includes the InSync® Model 8040 Pulse Generator and leads (Attain™ LV Model 2187 and CS Model 2188).
- Manufacturer:** Medtronic, Inc
- Address:** 710 Medtronic Parkway, Minneapolis, MN 55432
- Approval Date:** August 28, 2001
- Approval Letter:** <http://www.fda.gov/cdrh/pdf/p010015a.pdf>

What is it? The InSync® System is used to help treat congestive heart failure, a condition where the heart can not adequately pump blood around the body. It does this by providing specially timed electrical impulses to simultaneously stimulate the heart's lower chambers (right and left ventricles). The system consists of a pulse generator (containing a battery and electronic circuitry) connected to three leads (insulated wires) that deliver electrical impulses to stimulate the heart. One lead is placed in an upper heart chamber (right atrium) and the two other leads are placed in each of the ventricles.

How does it work? In some heart-failure patients, the right and left sides of the heart may not contract together, at the same time. The InSync system sends electrical impulses to the heart to promote simultaneous contraction of both ventricles.

When is it used? ? It should only be used in patients who:

- have moderate to severe symptoms of congestive heart failure;
- have an electrical disturbance in the heart that causes the ventricles not to contract at the same time;
- and are not likely to improve with additional drug therapy.

What will it accomplish? This therapy may relieve some of the symptoms associated with heart failure that include shortness of breath or fatigue during exertion.

When should it not be used? It should not be used in patients whose congestive heart failure is reversible.

Additional information: Summary of Safety and Effectiveness is available at:

<http://www.fda.gov/cdrh/pdf/p010015.html>

FDA Talk Paper at: <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01100.html>

(Updated 08/28/2001)