



New Device Approvals

Medtronic® IsoMed® Constant Flow Infusion System

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® IsoMed® Constant Flow Infusion System
Manufacturer: Medtronic Inc.
Address: 800 53rd Avenue Northeast, Minneapolis, Minnesota 55421
Approval Date: July 21, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990034a.pdf>

What is it? IsoMed® Constant Flow Infusion System consists of a pump and a thin hollow tube (catheter) that is surgically implanted in a patient's abdomen. This infusion system stores and delivers a constant flow of fluids and medication to a specific body site.

How does it work? IsoMed® Constant Flow Infusion System uses a small pump that is surgically placed under the skin of the abdomen. Medication is delivered through a small catheter that is also surgically placed. The pump contains a medication reservoir which is a space inside the pump that holds the medication. The pump stores and automatically delivers a controlled amount of medication through the catheter to the targeted body organ. To treat chronic pain, the catheter is placed within the sheath around the spinal cord where it is most effective. In the case of chemotherapy, the catheter is placed in a blood vessel to deliver the medication to a specific body organ.

When is it used? An infusion system is typically used when more traditional therapies are considered ineffective or inappropriate. In the case of chronic pain, an infusion system is used when oral, intravenous, or topical medications fail to provide effective pain relief or cause uncomfortable side effects. For chemotherapy, an infusion system is commonly used when delivering the medication to a specific site or organ is more effective or causes fewer uncomfortable side effects than delivering the medication systemically (to the entire body).

What will it accomplish? The use of an infusion system allows a physician to target sites within the body for more effective delivery of a medication.

When should it not be used? An infusion system is not recommended when infection or wide-spread disease is present, or when a patient's body size or weight is too small to accommodate the size of the pump.

Additional information: Summary of safety and effectiveness data and labeling:
<http://www.fda.gov/cdrh/pdf/p990034.html>