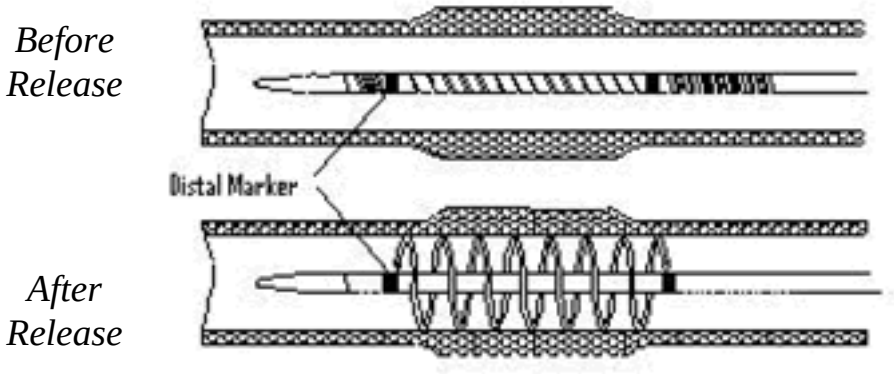
IntraCoil® Self-Expanding Peripheral Stent - P000033

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:	IntraCoil® Self-Expanding Peripheral Stent
Manufacturer:	Sulzer IntraTherapeutics Inc.
Address:	651 Campus Drive, St. Paul, MN 55112
Approval Date:	April 3, 2002
Approval Letter:	http://www.fda.gov/cdrh/pdf/P000033a.pdf

What is it and when is it used? The IntraCoil® Self-Expanding Peripheral Stent (IntraCoil® Stent) is a flexible coil-shaped metallic device that is used in the femoral and popliteal arteries in the leg to hold open areas that were blocked by atherosclerotic disease. Blocked arteries can cause leg pain by preventing adequate blood flow from reaching the lower leg and foot.



How does it work? The IntraCoil® Stent is mounted on the end of a long flexible tube (delivery catheter) and held in place by a mechanism that can release the coil. The delivery catheter and IntraCoil® Stent are inserted in the femoral artery through a puncture in the leg and advanced through the artery to the blocked section of the femoral and/or popliteal artery. The IntraCoil® Stent is released from the delivery catheter after it is correctly positioned within the blocked area of the artery. The IntraCoil® Stent self-

expands within the artery, opening the blocked area and thereby improving the flow of blood. The delivery catheter is removed from the patient, leaving the IntraCoil® Stent within the patient's artery.

What will it accomplish? When the IntraCoil® Stent is released within the blocked area of the artery, it self-expands, which opens the blocked area and allows more blood to flow to the lower leg and foot.

When should it not be used? The IntraCoil® Stent should not be used in patients whose blockages cannot first be penetrated with a guide wire or a balloon dilatation catheter. The guide wire and balloon dilatation catheter assist with the implantation of the IntraCoil® Stent by providing a pathway to the blocked area and a large enough opening in the blocked area to insert the IntraCoil® Stent.

Additional information: Summary of Safety and Effectiveness is available at:Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/P000033.html

Other:

- Society of Cardiovascular & Interventional Radiology, PVD: http://www.scvir.org/patient/pibs/pvdout.htm
- American Heart Association, PVD: http://www.americanheart.org/presenter.jhtml?identifier=4692

Updated June 28, 2002