WALLSTENT® Venous Endoprosthesis with Unistep™ Plus Delivery System - P980033

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:	WALLSTENT® Venous Endoprosthesis with Unistep™ Plus Delivery System
Manufacturer:	Boston Scientific Corporation
Address:	One Boston Scientific Place, Natick, MA 01760
Approval Date:	November 16, 2001
Approval Letter:	http://www.fda.gov/cdrh/pdf/p980033a.pdf

What is it? The WALLSTENT Venous Endoprosthesis (WALLSTENT) is an implantable stent, an expandable, tube-like scaffold that is mounted on a flexible wire called the Unistep™ Plus Delivery Catheter. It is used in hemodialysis patients who have a blockage in a major vein near the heart called a central vein. This blockage could lead to failure of the graft that allows the patient to be connected to the dialysis equipment. The WALLSTENT is threaded into the narrowed portion of the vein, where it expands and holds open the vein's inner walls. The larger opening allows an increased flow of blood through the vein.

How does it work? The Unistep Plus delivery catheter with the mounted WALLSTENT is inserted into a vein in the arm and navigated through the vein to the narrowed portion of the central vein. The WALLSTENT is released by retracting the outer tube that had been confining the WALLSTENT on the delivery catheter. The delivery catheter is then removed leaving the WALLSTENT within the patient's central vein.

When is it used? The WALLSTENT is used in patients who are on long-term hemodialysis and have a narrowed opening in a central vein, which was not successfully opened in an earlier procedure called venous angioplasty. The WA LLSTENT is implanted as a scaffold to further expand and support the walls of the central vein.

What will it accomplish? The WALLSTENT should benefit patients on long-term hemodialysis who have a narrowed segment in their central vein that slows the flow of blood. This restricted blood flow can lead to blockage and failure of the patient's hemodialysis access graft.

When should it not be used? The WALLSTENT should not be used in patients who have bleeding disorders that are not responsive to Vitamin K or blood-product therapy.

Additional information: Summary of Safety and Effectiveness is available at:
http://www.fda.gov/cdrh/pdf/p980033.html

Other:

- National Institutes of Health (NIH) information on dialysis: http://medlineplus.nlm.nih.gov/medlineplus/kidneyfailureanddialysis.html
- NIH MedlinePlus information on stent types: http://medlineplus.nlm.nih.gov/medlineplus/ency/article/002303.htm
- Federal Register WallStent approval notice: http://www.FDA.gov/ohrms/dockets/98fr/021100f.pdf

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