



New Device Approvals

PALMAZ® Balloon-Expandable Stent for Renal Arteries - P890017/S10

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: PALMAZ® Balloon-Expandable Stent for Renal Arteries
Manufacturer: Cordis Corporation
Address: 14201 N.W. 60th Avenue, Miami Lakes, Florida 22014
Approval Date: July 10, 2002
Approval Letter: <http://www.fda.gov/cdrh/pdf/P890017/S10a.pdf>

What is it and when is it used? The PALMAZ® Balloon-Expandable Stent for Renal Arteries (PALMAZ® Stent) is a stainless steel, expandable, wire-mesh tube, mounted over a balloon on the end of a long thin flexible tube called a delivery catheter (Powerflex® Plus delivery catheter). The PALMAZ® Stent is used in patients who have a narrowing in an artery caused by the deposition of a fatty material (atherosclerotic plaque) in a section of the renal artery (blood vessel leading to the kidney), which was not successfully opened in an earlier procedure called balloon angioplasty. This narrowing could restrict blood flow to the kidneys; complete blockage of blood flow can lead to the loss of kidney function.

How does it work? The PALMAZ® Stent, mounted on the delivery catheter, is inserted into a blood vessel in the groin (the femoral artery) and is advanced to the narrowed section of the renal artery. When the PALMAZ Stent is correctly positioned within the renal artery, the balloon is inflated, causing the stent to expand. Expansion of the stent pushes the plaque aside, opening the narrowed section of the artery, restoring normal blood flow to the kidney. The balloon on the delivery catheter is deflated and the delivery catheter is removed from the patient. The PALMAZ® Stent remains permanently implanted within the renal artery, acting as a scaffold to support the newly opened section.

What will it accomplish? Expansion of the PALMAZ® Stent within the narrowed section of the renal artery opens the narrowing, allowing more blood flow to the kidney. If the narrowing is not treated, a person can develop high blood pressure (the kidney's response to decreased blood flow) and if the narrowing is severe, loss of kidney function may occur over time.

When should it not be used? The PALMAZ® Stent should not be used in patients with bleeding disorders or in patients who have transplanted kidneys or kidneys that have had bypass surgery.

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

<http://www.fda.gov/cdrh/pdf/P890017S010.html>

Other:

National Institutes of Health, National Library of Medicine:

- Drawing of renal artery; explains insertion of catheter-similar to balloon insertion: <http://www.nlm.nih.gov/medlineplus/ency/imagepage/9818.htm>
- Renal artery stenosis with drawings of kidney: <http://www.nlm.nih.gov/medlineplus/ency/article/001273.htm#visualFile>
- Acute renal occlusion: <http://www.nlm.nih.gov/medlineplus/ency/article/001272.htm#visualFile>
- Description of X-ray with contrast: <http://www.nlm.nih.gov/medlineplus/ency/article/003781.htm>

(Updated 08/08/2002)