

Long-term performance of closed cell design self-expanding stainless steel stents in the treatment of Cockett's Syndrome

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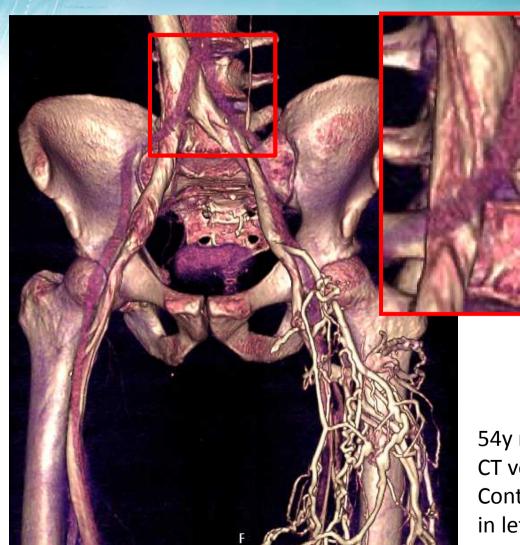
Disclosure

Speaker name:

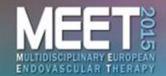
Luís Loureiro

I do not have any potential conflict of interest





54y male PTS CT venous angiogram Contrast-dye injected in left foot



Methods

- Review clinical and imaging records of first 10 stents implanted in the left iliac veins at our center
- Venous claudication and/or non-healing ulcer despite compression stockings



Cook Medical Launches World's First Stent Engineered Specifically for Use in the Iliofemoral Veins

SEPTEMBER 9TH, 2011

Tags: cook medical job loss medical device excise tax

Munich, Germany – Cook Medical, a world leader in minimally invasive medical technologies, has launched the world's first-ever stent designed and approved specifically to treat symptomatic illiofemoral venous outflow obstruction. The Zilver Vena Venous Self-Expanding Stent has received CE Mark approval and is now available to physicians across Europe.



Ms. Sherry L. Sparrow Regulatory Affairs Manager Boston Scientific Scimed, Inc. One Scimed Place Maple Grove, MN 55311-1566 Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Re: P980033

WALLSTENT® Venous Endoprosthesis with Unistep™ Plus RP Delivery System

NOV 1 6 2001

(10 mm Venous Endoprosthesis)

WALLSTENT® Venous Endoprosthesis with Unistep™ Plus Delivery System

(12 mm - 16 mm Venous Endoprostheses)

Filed: August 3, 1998

Amended: October 8 and November 27, 1998, March 25 and October 5, 1999, January 3

and 10, and June 29, 2000 and November 16, 2001

WALLSTENT Venous Endoprosthesis is indicated for:

- Improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract.
- The vessels that can be treated with the WALLSTENT Venous Endoprosthesis are the innominate and subclavian veins, ranging from 8mm to 15mm in diameter

http://www.accessdata.fda.gov/cdrh docs/pdf/p980033a.pdf

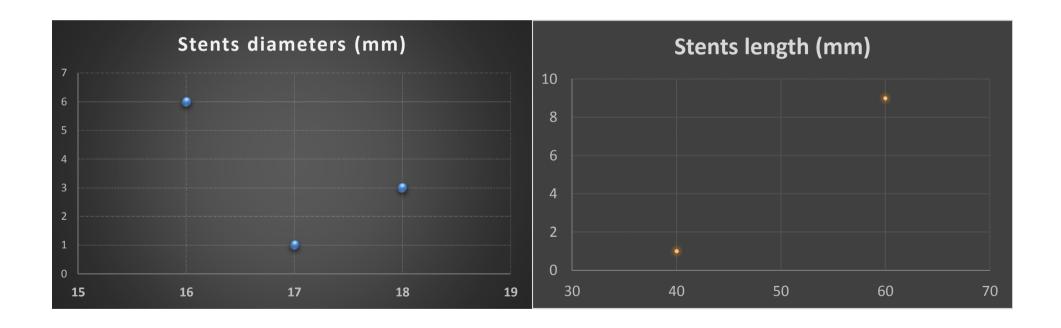
https://www.bostonscientific.com/en-US/products/stents--vascular/wallstent-endoprosthesis/wallstent-endoprosthesis-prescriptive-information.html



Results

- 7 patients (6 women)
- mean 40,5years-old (25-72)
- Treated from 2004 to 2007
- 1 stent five patients
- 2 stents one patient
- 3 stents one patient
 - (2 primary treatment, 3rd in re-intervention)





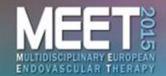


Results

- 3 months anticoagulation
- Life-long aspirin
- Life-long compression stockings
- 3 months, after yearly
 - X-Ray
 - Venous Doppler Enhanced Ultrassound



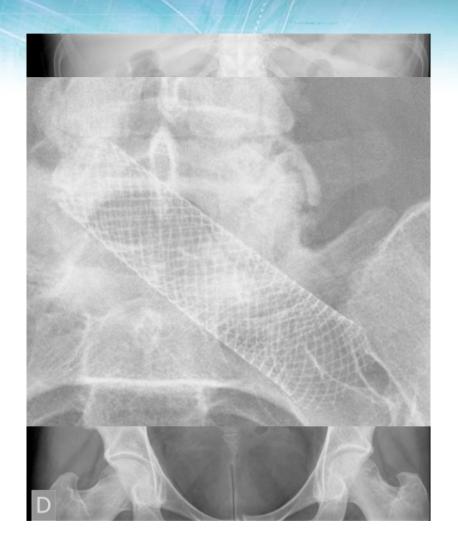


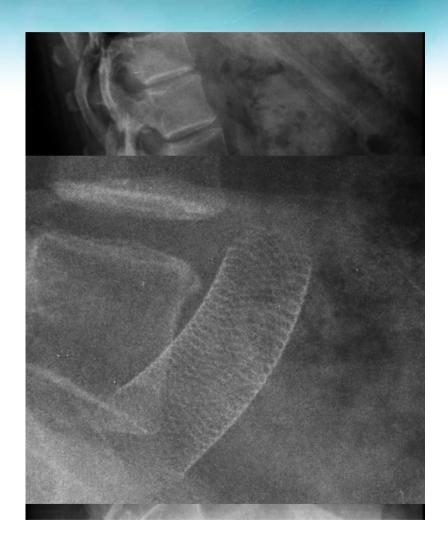


Results

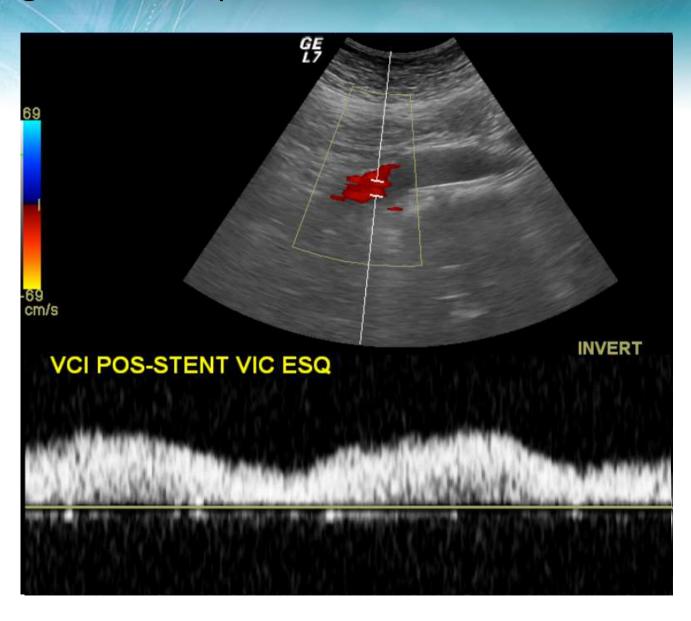
- Follow-up
 - Mean 107 months (88-148)
 - Primary patency rate at 1 year: 86%
 - Primary assisted patency rate at 8 years:100%
 - Stent fracture: 0%
 - Mortality: 0%

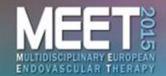


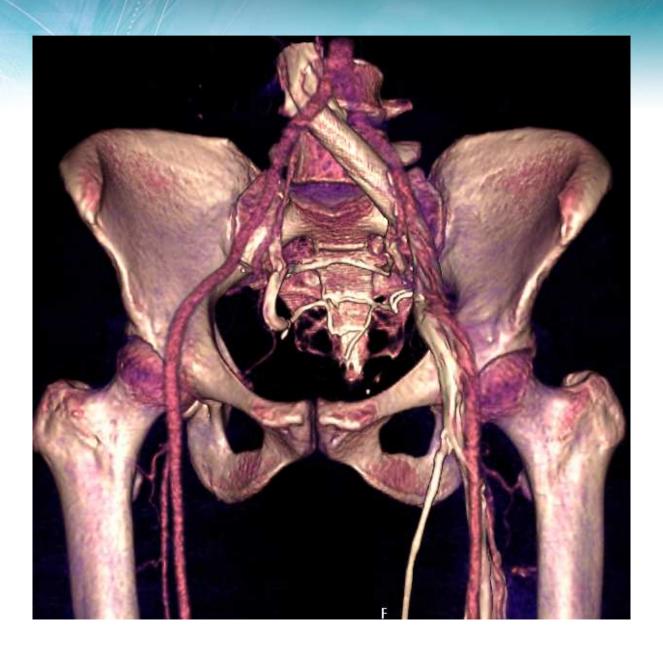




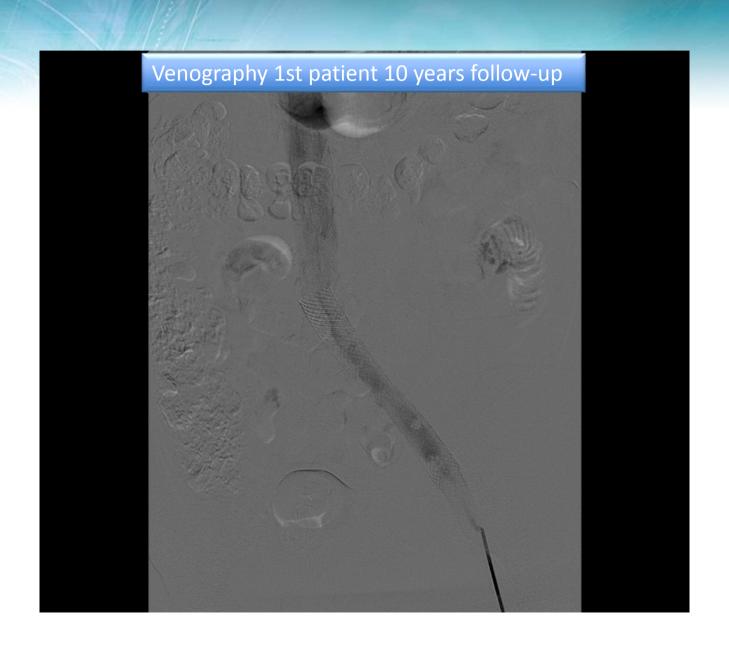














 The Wallstent ™ Endoprosthesis was never approved in the European Community for the treatment of iliac veins obstruction.

 Nevertheless, our center experience shows that the device performs flawlessly in this sector.



