**CONTRAINDICATIONS:**

- In pediatric patients
- In total non-thrombotic chronic iliac artery ostium into the aorta as this may result in thrombus formation.
- A stent cannot be repositioned or removed after the deployment threshold has been exceeded.
- Patients who experience the complication of arterial perforation during the angioplasty procedure preceding possible stent implantation.
- Patients with bleeding disorders unresponsive to vitamin K or blood product therapy.
- The WALLSTENT™ Endoprosthesis is contraindicated for use in the treatment of patients with active inflammation or infection at the intended stent site, post thrombolytic therapy.

**INDICATIONS FOR USE/INTENDED USE:**

- **Central Venous Occlusion:**
  - The WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic are indicated for use in the treatment of central venous occlusion (CVO) and stenosis associated with the presence of unfavorable lesion morphology such as:
    - An inadequate angiographic and/or hemodynamic result as defined by a 30% or greater residual stenosis after PTA, or a stenosis with a mean pressure gradient between the proximal and distal segments of the vessel equal to or greater than 10 mm Hg.
    - A 5 mm Hg or greater mean transtenotic pressure gradient post PTA.
    - Flow limiting dissections post PTA longer than the initial lesion length.

**ADVERSE EVENTS:**

- Hyperbilirubinemia secondary to bile duct puncture – 1%
- Hepatic Lobe Infarction – 1%
- Biliary Stricture – 1%
- Duodenal or jejunal perforation – 1%
- Pancreatitis – 1%
- Duodenal or jejunal obstruction – 1%
- Stent migration – 1%
- Stent misplacement – 1%
- Stent fracture – 1%
- Limb ischemia – 1%
- Pulmonary embolus – 1%
- Thrombotic or bleeding complications associated with the WALLSTENT™ Endoprosthesis are stent misplacement, stent migration, or vein perforation.

**STENT PLACEMENT PRECAUTIONS:**

- Do not advance a partially (≥ 50% for a vein > 10 mm in diameter, a tear which interrupts the integrity of the intima or lumen, abrupt lesion site recoil, or intimal flaps.
- Flow limiting dissections post PTA longer than the initial lesion length. The WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic may include the usual contraindications associated with the use of a fully-covered or partially-covered stent, such as abnormalities of the arterial or venous wall, significant atheroma, acute aneurysmal or traumatic injury, and the presence of aortic aneurysm or occlusion.

**COMPLICATIONS:**

- Complications associated with the WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic include:
  - Thrombotic or bleeding complications associated with the use of a fully-covered or partially-covered stent, such as abnormalities of the arterial or venous wall, significant atheroma, acute aneurysmal or traumatic injury, and the presence of aortic aneurysm or occlusion.
  - Thrombotic or bleeding complications associated with the use of the WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic include:
    - Thrombotic or bleeding complications associated with the use of a fully-covered or partially-covered stent, such as abnormalities of the arterial or venous wall, significant atheroma, acute aneurysmal or traumatic injury, and the presence of aortic aneurysm or occlusion.
    - Thrombotic or bleeding complications associated with the use of a fully-covered or partially-covered stent, such as abnormalities of the arterial or venous wall, significant atheroma, acute aneurysmal or traumatic injury, and the presence of aortic aneurysm or occlusion.
    - Thrombotic or bleeding complications associated with the use of a fully-covered or partially-covered stent, such as abnormalities of the arterial or venous wall, significant atheroma, acute aneurysmal or traumatic injury, and the presence of aortic aneurysm or occlusion.
    - Thrombotic or bleeding complications associated with the use of a fully-covered or partially-covered stent, such as abnormalities of the arterial or venous wall, significant atheroma, acute aneurysmal or traumatic injury, and the presence of aortic aneurysm or occlusion.

**TIPS INDICATIONS FOR ENDOPROSTHESIS USE:**

- The WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Venous are indicated for Improving central venous luminal diameter following unsuccessful angioplasty in patients on chronic hemodialysis with stenosis of the venous outflow tract. Unsuccessful angioplasty is defined as residual stenosis ≥ 50% for a vein > 10 mm in diameter, a tear which interrupts the integrity of the intima or lumen, abrupt lesion site recoil, or intimal flaps.

**OPERATOR’S INSTRUCTIONS:**

- Care should be taken during stent deployment to avoid stent placement beyond the iliac bifurcation. Further dilation, placement of additional stents, or other procedures should be performed if necessary.
- Patients should be observed for 24 hours after stent placement at the discretion of the attending physician.
- The WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic may include the usual contraindications associated with the use of a fully-covered or partially-covered stent, such as abnormalities of the arterial or venous wall, significant atheroma, acute aneurysmal or traumatic injury, and the presence of aortic aneurysm or occlusion.

**CONTRAINDICATIONS:**

- The WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic are contraindicated for use in patients:
  - With hereditary or acquired diseases that could result in stent failure such as: malignant neoplasms, atheromatous disease, and severe vascular collagen disorders.
  - With a history of prior thromboembolic events, systemic lupus erythematosus, or prior stent deployment.
  - With the presence of arteriosclerotic plaques or aneurysms in the target site.
  - With infection at the intended stent site.
  - With the presence of unfavorable lesion morphology such as:
    - An inadequate angiographic and/or hemodynamic result as defined by a 30% or greater residual stenosis after PTA, or a stenosis with a mean pressure gradient between the proximal and distal segments of the vessel equal to or greater than 10 mm Hg.
    - A 5 mm Hg or greater mean transtenotic pressure gradient post PTA.
    - Flow limiting dissections post PTA longer than the initial lesion length. The WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic may include the usual contraindications associated with the use of a fully-covered or partially-covered stent, such as abnormalities of the arterial or venous wall, significant atheroma, acute aneurysmal or traumatic injury, and the presence of aortic aneurysm or occlusion.

**INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE EVENTS, AND OPERATOR’S INSTRUCTIONS.**

- The use of antiplatelet, anticoagulation therapy, or thrombolytic drugs are contraindicated or who exhibit coagulopathy
- Care should be taken during stent deployment to avoid stent placement beyond the iliac bifurcation. Further dilation, placement of additional stents, or other procedures should be performed if necessary.
- The WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic are contraindicated for use in patients:
  - With hereditary or acquired diseases that could result in stent failure such as: malignant neoplasms, atheromatous disease, and severe vascular collagen disorders.
  - With a history of prior thromboembolic events, systemic lupus erythematosus, or prior stent deployment.
  - With the presence of arteriosclerotic plaques or aneurysms in the target site.
  - With infection at the intended stent site.
  - With the presence of unfavorable lesion morphology such as:
    - An inadequate angiographic and/or hemodynamic result as defined by a 30% or greater residual stenosis after PTA, or a stenosis with a mean pressure gradient between the proximal and distal segments of the vessel equal to or greater than 10 mm Hg.
    - A 5 mm Hg or greater mean transtenotic pressure gradient post PTA.
    - Flow limiting dissections post PTA longer than the initial lesion length. The WALLSTENT™ Endoprosthesis and WALLSTENT™ Endoprosthesis Transhepatic may include the usual contraindications associated with the use of a fully-covered or partially-covered stent, such as abnormalities of the arterial or venous wall, significant atheroma, acute aneurysmal or traumatic injury, and the presence of aortic aneurysm or occlusion.

**CAUTION:**

- Stenting across major bifurcations may result in the formation of side branches that could impede blood flow. Further dilation, placement of additional stents, or other procedures should be performed if necessary.
**Approximate implanted stent length. Refer to DFU sizing chart for more information.**

**Diameters from 5 mm to 24 mm**

**Closed-Cell Design**
- Intended to provide increased scaffolding for optimal lesion coverage and a smooth inner lumen

**Compression Resistance**
- Braided construction and Eligily™ Material designed to provide excellent compression resistance

**Conformability**
- Excellent adaption to anatomical contours designed to provide exceptional stent-to-wall apposition

**Flexibility**
- Highly flexible stent designed to smoothly cross lesions

---

**WALLSTENT™ Endoprosthesis**

**Product Information for WALLSTENT™ Endoprosthesis with the UNISTEP™ Plus Delivery System**

<table>
<thead>
<tr>
<th>Product Information</th>
<th>WALLSTENT™ Endoprosthesis with the UNISTEP™ Plus Delivery System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compression Resistance</strong></td>
<td></td>
</tr>
<tr>
<td>Braided construction and Eligily™ Material designed to provide excellent compression resistance</td>
<td></td>
</tr>
<tr>
<td><strong>Closed-Cell Design</strong></td>
<td></td>
</tr>
<tr>
<td>Intended to provide increased scaffolding for optimal lesion coverage and a smooth inner lumen</td>
<td></td>
</tr>
<tr>
<td><strong>Conformability</strong></td>
<td></td>
</tr>
<tr>
<td>Excellent adaption to anatomical contours designed to provide exceptional stent-to-wall apposition</td>
<td></td>
</tr>
<tr>
<td><strong>Flexibility</strong></td>
<td></td>
</tr>
<tr>
<td>Highly flexible stent designed to smoothly cross lesions</td>
<td></td>
</tr>
</tbody>
</table>

---

**Key**
- Traction balloon
- Triangular Inspiraplot: Portosystemic Shunt (TIPS)
- Angioplasty: Bilary
- Elie
- Versus

---

**Reconstranability**
- Designed for ease of placement, the WALLSTENT Endoprosthesis allows reconstranability with the stent deployed up to the limit marker band

---

**Visibility**
- Exclusive HALO™ Technology and platinum core provides excellent fluoroscopic visibility intended to facilitate precise positioning

---

*Available sizes vary per indication. See product information table for specific size availability.

**Approximate implanted stent length. Refer to DFU sizing chart for more information.
WALLSTENT™ Endoprosthesis

PROVEN SOLUTIONS, DEPENDABLE CHOICE

WALLSTENT™ Endoprosthesis

Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operators Instructions.

Peripheral Interventions

300 Boston Street

Woburn, MA 01801-3234

www.bostonscientific.com

To order product or for more information

contact customer service at 1.800.372.1001.

© 2015 Boston Scientific Corporation
or its affiliates. All rights reserved.

P-49693-6B 7/1/2015

WALLSTENT™ Endoprosthesis

Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operators Instructions.

Peripheral Interventions

300 Boston Street

Woburn, MA 01801-3234

www.bostonscientific.com

To order product or for more information

contact customer service at 1.800.372.1001.

© 2015 Boston Scientific Corporation
or its affiliates. All rights reserved.

P-49693-6B 7/1/2015

WALLSTENT™ Endoprosthesis

Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operators Instructions.

Peripheral Interventions

300 Boston Street

Woburn, MA 01801-3234

www.bostonscientific.com

To order product or for more information

contact customer service at 1.800.372.1001.

© 2015 Boston Scientific Corporation
or its affiliates. All rights reserved.

P-49693-6B 7/1/2015

WALLSTENT™ Endoprosthesis

Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operators Instructions.