Assurant Cobalt® Iliac
BALLOON EXPANDABLE STENT SYSTEM

With Modular Cobalt Chromium Technology
CONFORMABILITY

THE ASSURANT COBALT ILIAC STENT, WITH ITS UNIQUE COBALT CHROMIUM MODULAR DESIGN, PROVIDES EXCELLENT CONFORMABILITY WITHOUT SACRIFICING RADIAL STRENGTH.¹

• Greater conformability
• Excellent radial strength

Modular design for providing radial strength with conformability.

6F SHEATH COMPATIBILITY

BY COMBINING ITS UNIQUE COBALT CHROMIUM MODULAR DESIGN WITH OUR PATENTED SECURE TECHNOLOGY, ASSURANT COBALT ILIAC ACHIEVES 6F SHEATH COMPATIBILITY FOR EVERY STENT SIZE.²

Sheath Compatibility Matrix

<table>
<thead>
<tr>
<th>Diameter (mm)</th>
<th>Assurant Cobalt® Iliac</th>
<th>Express® LD</th>
<th>Omnilink Elite®</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>6F</td>
<td>6F</td>
<td>6F</td>
</tr>
<tr>
<td>7</td>
<td>7F</td>
<td>7F</td>
<td>7F</td>
</tr>
</tbody>
</table>

Lower Crossing Profile design makes the stent extremely trackable.³

Sheath Compatibility for every stent size

Small Conistent Cell Size is designed to conform to the vessel wall.

³Bench data on file at Medtronic, Inc., compares the Assurant Cobalt Iliac stent with the Boston Scientific Express® LD stent and Abbott Omnilink Elite® stent. Bench test results may not be indicative of clinical performance.

¹Bench data on file at Medtronic, Inc., compares the Assurant Cobalt Iliac stent with the Boston Scientific Express® LD stent and Abbott Omnilink Elite® stent. Bench test results may not be indicative of clinical performance.

²Medtronic, Inc., compares the Assurant Cobalt Iliac stent with the Boston Scientific Express® LD stent and Abbott Omnilink Elite® stent. Bench test results may not be indicative of clinical performance.

³Medtronic, Inc., compares the Assurant Cobalt Iliac stent with the Boston Scientific Express® LD stent and Abbott Omnilink Elite® stent. Bench test results may not be indicative of clinical performance.
CLINICAL RESULTS

ACTIVE US CLINICAL TRIAL — 9-MONTH FOLLOW-UP

CLINICAL RESULTS

**Primary Endpoint**
- Major adverse events at 9 months

**Secondary Endpoints**
- Primary Acuity, Acute Success, Clinical Success, ABI, and Walking Capacity at 9 months

**Number of Subjects**
- 123 subjects with symptomatic PAD

**Baseline Characteristics**

<table>
<thead>
<tr>
<th>Lesions (Baseline)</th>
<th>MLD (mm)</th>
<th>2.39 ± 1.17</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Stenosis (most severe)</td>
<td>68.74 ± 14.22</td>
<td></td>
</tr>
<tr>
<td>Mean lesion length (mm)</td>
<td>29.43 ± 14.66</td>
<td></td>
</tr>
</tbody>
</table>

**Lesions (Procedural)**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Direct Stenting (%)</th>
<th>46.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions (Baseline)</td>
<td>Post Proc. Diameter Stenosis (% ± SD)</td>
<td>14.61 ± 6.99</td>
</tr>
<tr>
<td>Lesions (Procedural)</td>
<td>Post Procedure MLD (mm ± SD)</td>
<td>6.58 ± 1.16</td>
</tr>
</tbody>
</table>

**Primary Endpoint Shows Low MAE Rates**

- Major Adverse Event (MAE) rates include target lesion revascularization (TLR), target vessel revascularization (TVR), target lesion failure, and death, including both device-related and procedure-related. During the ACTIVE Trial, one of 123 subjects received a TVR/TLR (0.8%). No death or target limb loss occurred in the study, thus the composite 9-month MAE is 0.8%.

**Secondary Endpoints Show 99.3% Primary Patency**

1. In the ACTIVE study, Primary Patency is reported as 100%. It is defined as the blood flow through the treated vessel segment into the distal vasculature (e.g., the common femoral artery and/or the deep femoral artery) as evidenced by duplex ultrasound scan at 30 days and at intervals for all subjects enrolled with available Doppler scans. Primary patency as defined in this study is independent of interval revascularization (e.g., repeat stenting or surgical bypass) and procedure-related. During the ACTIVE Trial, one of 123 subjects received a TVR/TLR (0.8%). No death or target limb loss occurred in the study, thus the composite 9-month MAE is 0.8%.

2. TLR success defined as angiographic evidence of <30% final residual stenosis of the target lesion using only the assigned device.

3. Procedure success defined as angiographic evidence of <30% final residual stenosis of the target lesion after stent placement and no occurrence of a procedure-related Major Adverse Event (MAE) prior to hospital discharge (for subjects with more than one lesion stented the worse case is counted).

4. Clinical success defined as the improvement of Fontaine classification by at least one stage above the pretreatment (pre-procedural) clinical value.

5. All values are mean (n).

**Improvement in Clinical Status, ABI and Walking Capacity**

**Walking Assessment (%)**

- **Baseline**
  - Walking distance: 34.6 (126)
  - Walking speed: 22.9 (72.6)

- **9 months**
  - Walking distance: 73.0 (131)
  - Walking speed: 53.6 (110)

- **P value (Baseline vs 9-month)** < 0.001

**Walking Assessment, (%)**

- **Baseline**: Walking distance 34.6 (126)
- **9 months**: Walking distance 73.0 (131)

**ABI**

- **Baseline**: 0.6 (0.6)
- **9 months**: 0.0 (0.0)

**P value**: (Baseline vs 9-month) < 0.001

**Cumulative Frequency Distribution**

- **P value (Baseline vs 9-month)** < 0.001

**Improvement in ABI**

- **Baseline**: 0.6 (0.6)
- **9 months**: 0.0 (0.0)

- **P value**: (Baseline vs 9-month) < 0.001

**Walking Impairment Questionnaire (WIQ) scores range from 0% (unable to perform due to severe claudication) to 100% (no impairment).**

- All values are mean (n).

**Clinical Impact**

- The walking impairment questionnaire scores range from 0% (unable to perform due to severe claudication) to 100% (no impairment).

- *P value (Baseline vs 9-month) < 0.001*
**Indications:** The Assurant Cobalt Iliac Balloon-Expandable Stent System is indicated for improving iliac segment diameter in patients with a non-stenotic lesion in the iliac artery or in those with restenosis following previous iliac balloon angioplasty. The system is designed for use in iliac arteries with reference vessel diameters between 6mm and 16mm and lesion lengths up to 4mm. The stent is intended as a permanent implant.

**Contraindications:** There are no known contraindications.

**Warnings and Precautions:** The Assurant Cobalt Iliac Balloon-Expandable Stent System is provided sterile for single use only. Do not reuse, reprocess, or repackage this product. Reuse, reprocessing, or reprocessing may compromise the mechanical/structural integrity of the device, complicate the reprocessing and design characteristics of the device, and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not modify the packaging or labeling in any way that may lead to the use of an incorrect or expired product, which could result in patient injury or death. Do not use the device beyond the pack- age expiration date. Allowing the system to come into contact with chlorine-based products, especially those with high levels of available chlorine, may result in degradation. Administration of appropriate antiplatelet therapy prior to the procedure is recom men ded. The system must not be used for multiple patient treatments. When multiple patients are required and placement may result in overlap of the stent’s distal landing zone, the stent should be further compressed to avoid the potential for dislodgment. Use only appropriate balloon inflation media. Do not use air or gas to inflate the balloon as it may cause uneven expansion and stent deployment difficulties. Subsequence sessions may require repeat dilation of the arterial segment containing the stent. The long-term outcomes following repeat dilation of embolized iliac stents are unknown at present.

**Caution:** Read all of the instructions carefully in the Instructions for Use. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient. Use of the Assurant Cobalt Iliac Balloon-Expandable Stent System requires advanced fluoro-angiographic technical skills. Additional technical guidance but does not alleviate the need for adequate training prior to use of the device. Some placement should only be performed at hospitals where emergency surgery can be performed. Do not use the device on patients with an estimated body mass index (BMI) greater than 35. The stent should not be used in the absence of adequate access, or in case of overt obesity, which may result in insufficient treatment of the vessel. The stent should not be used with a mounted stent. The stent cannot be repositioned once deployed. Prior to completion of the procedure, utilize fluoroscopy to ensure proper deployment. The stent must be properly deployed. The stent cannot be repositioned if deployed. Prior to completion of the procedure, continue high resolution fluoroscopy to verify that the stent has not been damaged or dislodged during positioning. The Assurant Cobalt Iliac Balloon-Expandable Stent System is designed for single use. The stent must not be removed from the delivery system. The Assurant Cobalt Iliac Balloon-Expandable Stent System is designed for use in a single vessel. Special care must be taken not to handle or in any way disrupt the stent position on the delivery system balloon. Removing the stent from its delivery system or even manipulating the stent itself, including the mounted stent may cause dislodgement, damage to the stent, and stent embolization. Once deployment is initiated, the stent cannot be removed. Prior to completion of the procedure, utilize fluoroscopy to ensure proper positioning of the deployed stent. If the target lesion is not completely stented, use additional Assurant Cobalt Iliac stents as necessary to adequately treat the lesion. Use caution when crossing the stented area with any iliac equipment to avoid dislodgment of the stent. Judicious selection of patients is necessary since the use of this device carries the associated risk of radicular thrombosis, vascular complications, and bleeding events. The Assurant Cobalt Iliac Balloon-Expandable Stent System does not provide for distal contrast injections or pressures measurements through the guidewire lumen. Stent retrieval methods (use of additional wires, snare, or forceps) may result in additional trauma to the vascular access site. Complications may include, but are not limited to, embolization, hemorrhage, or pseudoaneurysms. MRI Safety and Compatibility: The Assurant Cobalt Iliac stent was determined to be MRI conditional. It can be imaged safely in both 1.5T & 3.0T MRI systems under certain conditions as described in the product instructions for use. For additional information regarding MR conditions of use, please refer to the product instructions for use. Advanced Events: Potential adverse events include but are not limited to in any particular order: acute myocardial infarction, allergic reaction, aneurysm, pseudoaneurysm, dissections, perforation, embolization, complications, death, embolization and/or implantation of a component of the system, embolization, emergent or urgent surgery, stroke, hematoma or hemorrhagic event, hypertension or hypotension, infections, ischemia, pain, pseudoaneurysm or hemorrhage, stent fracture, stent thrombosis, stroke (CVA or TIA), emboli, vessel occlusion, vascular thrombosis or occlusion at puncture site, treatment site, or remote site, vessel spasm, worsening claudication or rest pain. Please refer to product instructions for use for more information regarding adverse events.

**Caution:** Federal law [510(k)] restricts this device for sale by or on order of a physician. FDA approved by PMA110011.

Assurant Cobalt Iliac balloon-expandable stent system is a registered trademark of Medtronic, Inc. Trademarks are the property of their respective owners.
### Order Information

**Assurant Cobalt Iliac Product Code**

**ASC 6 20 SV**

- **Catheter Working Length (SV = 80cm, LV = 130cm)**
- **Stent Length (mm)**
- **Stent Diameter (mm)**
- **Product Code**

<table>
<thead>
<tr>
<th>Stent Diameter (mm)</th>
<th>Minimum Sheath Size (F)</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>6</td>
<td>ASC620SV</td>
<td>ASC630LV</td>
<td>ASC640SV</td>
<td>ASC660SV</td>
</tr>
<tr>
<td>7</td>
<td>6</td>
<td>ASC720SV</td>
<td>ASC730LV</td>
<td>ASC740SV</td>
<td>ASC760SV</td>
</tr>
<tr>
<td>8</td>
<td>6</td>
<td>ASC820SV</td>
<td>ASC830LV</td>
<td>ASC840SV</td>
<td>ASC860SV</td>
</tr>
<tr>
<td>9</td>
<td>6</td>
<td>-</td>
<td>-</td>
<td>ASC930SV</td>
<td>ASC950SV</td>
</tr>
<tr>
<td>10</td>
<td>6</td>
<td>-</td>
<td>-</td>
<td>ASC1030SV</td>
<td>ASC1050SV</td>
</tr>
</tbody>
</table>

**Order Information**

- **Assurant Cobalt Iliac Compliance**
  - **Deployment Configurations**
    - **Nominal Diameter (mm)**
      - **20**
      - **30**
      - **40**
      - **60**
  - **Assurant Cobalt Iliac Compliance**
    - **Pressure (kPa, atm)**
      - **6**
      - **7**
      - **8**
      - **9**
      - **10**

**Data on file at Medtronic, Inc.**

---

**www.medtronic.com**

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
USA

Product Services Support Center
Tel: 888.283.7868
Fax: 800.838.3103

CardioVascular LifeLine
Customer Support
Tel: 877.526.7890
Tel: 763.526.7890