Integrity BMS—A Revolution in Stent Engineering

The Integrity stent is a single strand of cobalt chromium alloy shaped into a continuous sinusoid—setting a new standard in coronary stent innovation

- Continuous range of motion—continuous bending results from the stent’s single-wire design and the fusion pattern that follows the wire’s pitch
- Optimal deliverability—The MicroTrac delivery system features an integrated tip design, softer Fulcrum® balloon, low-profile exchange joint and swaged marker bands

The Integrity stent’s unique design allows for continual flex, which is not possible in laser-cut stents

Integrity

Multi-link Vision®

constrained by u-joint design
Superior Deliverability vs. Multi-link Vision and VeriFlex (Liberté®)¹

Improved Deliverability with a Continuous Range of Motion

Deliverability in a 3D Model: 3.5-mm BMS

<table>
<thead>
<tr>
<th>Device</th>
<th>Average Peak Force (g/f)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrity</td>
<td>41</td>
</tr>
<tr>
<td>Multi-link Vision</td>
<td>77</td>
</tr>
<tr>
<td>VeriFlex (Liberté)</td>
<td>74</td>
</tr>
</tbody>
</table>

Lower Is Better

Impressive Structural Performance²

Excellent Radial Strength (3.5-mm BMS)

<table>
<thead>
<tr>
<th>Device</th>
<th>Ultimate Crush Pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrity</td>
<td>1096</td>
</tr>
<tr>
<td>Multi-link Vision</td>
<td>946</td>
</tr>
<tr>
<td>VeriFlex (Liberté)</td>
<td>1095</td>
</tr>
</tbody>
</table>

Higher Is Better

Maximum clinically relevant pressure 80–160 mmHg³

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¹Bench test data vs. Abbott Multi-link Vision and Boston Scientific VeriFlex (Liberté) coronary stents on file at Medtronic, Inc. Bench test data may not be indicative of clinical performance.
²Data on file at Medtronic, Inc.
Integrity Product Code
rs.cstechsupport@medtronic.com
representative or e-mail

For technical questions, please contact your local sales representative or e-mail rs.cstechsupport@medtronic.com

Integrity Ordering Information

Integrity Compliance

<table>
<thead>
<tr>
<th>Pressure (atm)</th>
<th>Stent Diameter Deployed Stent I.D. (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.25°F</td>
</tr>
<tr>
<td>6</td>
<td>2.15</td>
</tr>
<tr>
<td>7</td>
<td>2.20</td>
</tr>
<tr>
<td>8</td>
<td>2.20</td>
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<tr>
<td>9</td>
<td>2.25</td>
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<td>10</td>
<td>2.30</td>
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<td>18</td>
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<tr>
<td>19</td>
<td>2.65</td>
</tr>
<tr>
<td>20</td>
<td>2.75</td>
</tr>
</tbody>
</table>

Nominal pressure
Rated burst pressure°F

Do not postulate the 2.25–2.75-mm stents to greater than 3.50 mm. Do not postulate the 3.00–4.00-mm stents to greater than 4.75 mm.

Indications for Use

The Integrity Coronary Stent Systems are indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de novo or restenotic lesions with reference vessel diameters of 2.25–4.00 mm and ≤10 mm in length using direct stenting or predilatation.

Contraindications

- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of a stent or stent delivery system

Warnings/Precautions

The long-term effects of stents and the risks associated with lifelong carrying of these implants are unknown. This lack of knowledge should be considered in making a risk/benefit assessment for the patient prior to implantation.

The Integrity Coronary Stent Systems are provided sterile, for one procedure only. Do not resterilize. Use the “Use By” date noted on the package.

- Only physicians who have received appropriate training should perform implantation of the stent. Use of an Integrity Coronary Stent System requires advanced coronary angioplasty technical skills. The instructions will give technical guidance, but do not obviate the need for formal training in the use of the device.

- Patients allergic to cobalt alloy may suffer an allergic reaction to this implant.

- Do not remove the stent from the stent delivery system; the stent cannot be removed and placed on another balloon catheter for deployment.

- Do not try to straighten a kinked shaft or hypotube. Straightening a kinked metal shaft may result in breakage of the shaft. If the device is kinked, it should not be used.

- Significant amounts of air in the balloon may cause uneven expansion of the stent and difficulty in deployment of the stent. Do not pre-inflate balloon prior to stent deployment. Use balloon preparation technique described within this instructional material.

- The Integrity Coronary Stent Systems do not provide for distal dye injections or pressure measurements through the guidewire lumen.

- Expansion of the stent should not be undertaken if the stent is not appropriately positioned in the vessel. If the position of the stent is not optimal, it should not be expanded.

- Incomplete deployment of the stent (i.e., stent not fully expanded) may cause procedural complications resulting in patient injury.

- Advance an Integrity Coronary Stent System through a previously stented segment may cause procedural complications resulting in patient injury.

- Placement of the stent has the potential to compromise sidebranch patency.

- Administer appropriate anticoagulants/antiplatelet and coronary artery vasodilator therapy according to current medical guidelines and manufacturer’s instructions.

- Caution must be taken when using ancillary equipment, such as an intravascular ultrasound catheter, to avoid dislodgement or deformation of the stent.

- When multiple stents are required, stent materials should be of similar composition.

- Placement of multiple stents of different materials in contact with each other may increase the potential for corrosion. Data obtained from in vitro corrosion tests using a cobalt alloy stent (Medtronic Integrity Coronary Stent) in combination with a stainless steel alloy stent (Boston Scientific Liberix® Coronary Stent) do not suggest an increased risk of in vivo corrosion.

- When using two wires, care should be taken when introducing, torquing and removing one or both guidewires to avoid entanglement. It is recommended that one guidewire be completely withdrawn from the patient before removing any additional equipment.

- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.

- Judicious selection of patients is necessary since the use of this device carries the associated risk of subacute thrombosis, vascular complications and/or bleeding events. Administration of appropriate anticoagulation, anticoagulant and coronary vasodilator therapy is critical to successful stent implantation and follow-up.

- Subsequent restenosis may require repeat dilation of the arterial segment containing the stent. The long-term outcome following an initial dilation of endoluminalized coronary stents is unknown at present.

Potential Adverse Events

The following complications may be associated with the use of coronary stenting devices or PTCA:

- Acute myocardial infarction
- Allergic reaction to contrast medium/stent material/solutions
- Arrhythmias (including ventricular fibrillation and ventricular tachycardia)
- Arteriovenous fistula
- Bleeding complications
- Cardiac tamponade
- Cerebrovascular accidents/stroke
- Death
- Dissection of coronary artery
- Drug reactions
- Embolization (air, stent, tissue or thrombotic)
- Emergency coronary artery bypass graft surgery (CABG)
- Endocarditis
- Failure to deliver the stent
- Stent deformation, collapse or fracture
- Hematoma
- Hypotension
- Hypertension
- Infection
- Injury of the coronary artery
- Inadequate angiographic results
- Myocardial ischemia/infection
- Occlusion
- Occlusion of coronary artery or stented segment
- Pericardial tamponade
- Perivascular tamponade
- Peripheral ischemia
- Peripheral nerve injury
- Pyrogenic reaction
- Restenosis of the dilated artery or stented segment
- Restenosis
- Subsequent restenosis
- Total occlusion of coronary artery
- Transfusion
- Unstable angina
- Vascular thrombosis
- Venous dissection
- Perforation

Please reference appropriate product Code for Use for a more detailed list of indications, warnings, precautions and potential adverse events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Integrity Product Code
INT30018 UX/W
Over-the-Wire (W)
Rapid Exchange (UX)
Length
Product Code

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