True Dilatation™
Balloon Valvuloplasty Catheter

Truly Reliable
RAUTURE RESISTANT

**truly**

**FAST INFLATION & DEFLATION**

Designed to minimize rapid pacing times, the *True Dilatation*™ Balloon Catheter inflates and deflates up to 2 times faster than competitors’ balloons during aortic valvuloplasty.

<table>
<thead>
<tr>
<th>Company</th>
<th>Product</th>
<th>Balloon Size</th>
<th>Inflation* (Average seconds)</th>
<th>Deflation* (Average seconds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bard</td>
<td><em>True Dilatation</em>™</td>
<td>22 mm x 4.5 cm</td>
<td>1.9</td>
<td>3.7</td>
</tr>
<tr>
<td>B. Braun</td>
<td>Z-Med™ II</td>
<td>22 mm x 4 cm</td>
<td>3.8</td>
<td>6.0</td>
</tr>
</tbody>
</table>

*N=10. Bench data on file. Results may not necessarily be indicative of clinical performance. Different tests may yield different results.

**truly**

**RUPTURE RESISTANT**

Engineered to avoid catastrophic failures

Highly resistant to ruptures, punctures, and tears*

Fiber Based Technology

*Bench data on file. Results may not necessarily be indicative of clinical performance. Different tests may yield different results.
Limits the maximum balloon diameter within the labeled size

Offers diameter control with an average balloon growth of 0.6%*

Designed to deliver precision and speed, the True Dilatation™ Balloon Catheter enables accurate, controlled, and reliable aortic valve dilatations.

*22 mm x 4.5 cm True Dilatation™ Catheter - N=10; 22 mm x 4 cm Z-Med™ II Catheter - N=10. Bench data on file. Results may not necessarily be indicative of clinical performance. Different tests may yield different results.
True Dilatation™
Balloon Valvuloplasty Catheter

Truly TIGHT RE-WRAP

Consistent, tight re-wrap

Low withdrawal profile after dilatation

Ordering Information

<table>
<thead>
<tr>
<th>Recommended Guidewire .035&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter (mm)</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>20</td>
</tr>
<tr>
<td>22</td>
</tr>
<tr>
<td>24</td>
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<tr>
<td>26</td>
</tr>
</tbody>
</table>

Instructions for Use

Description

The True Dilatation™ Balloon Valvuloplasty Catheter is an over-the-wire co-axial catheter with a balloon fixed at the tip. The catheter is 110 cm long and has two lumens: one lumen is used to inflate and deflate the balloon and the other permits the use of a guidewire to position the catheter. The balloon inflation luer-lock hub (straight) connects to a syringe inflation device to deliver radiopaque contrast media for inflation. The guidewire luer-lock hub (angled) connects to the guidewire lumen. The balloon is non-compliant and is designed to reach a known diameter and length when inflated within the specified pressure range. Two radiopaque marker bands are provided for fluoroscopic positioning of the device across the aortic valve. These bands are positioned at the proximal and distal balloon shoulders. Balloon catheter dimensions, balloon nominal pressure, maximum inflation pressure, recommended introducer size, and recommended guidewire size are indicated on the package label.

Packaging

Stirte: Sterilized with ethylene oxide gas. Do not use if package is open or damaged.

Storage

Store in a cool, dry place.

This device is available by prescription use only.

Indications

The True Dilatation™ Balloon Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Contraindications

The True Dilatation™ Balloon Valvuloplasty Catheter is contraindicated for use in patients with annular dimensions < 18 mm.

Potential Complications / Adverse Events

In the very unlikely event of balloon burst or rupture, balloon could be more difficult to remove through the sheath and could require introducer sheath removal. Potential complications include, but are not limited to: tissue perforation, conduct system injury, thrombo-embolic events, hematoma, cardiovascular injury, arrhythmia development, annular or valvular tearing or trauma, restenosis development, inflammation, infection.

Warnings & Precautions

- Do not exceed maximum inflation pressure indicated on label. Excess inflation pressure can cause balloon rupture and the inability to withdraw catheter through introducer sheath.
- Do not attempt to clear catheter if flow through catheter becomes restricted. Do not attempt to clear catheter if flow through catheter becomes restricted.
- Do not remove guidewire from catheter during procedure.
- Do not advance or retract device with balloon inflated. Always confirm that balloon has been completely deflated and is under syringe vacuum force prior to releasing.
- Do not exceed maximum inflation pressure indicated on label. Excess inflation pressure can cause balloon rupture and the inability to withdraw catheter through introducer sheath.
- Withdrawing balloon through introducer sheath may damage balloon.
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- Use sterile radiopaque solutions (liquid only) to inflate balloon. Fully de-air fluids before use. Do not use air or gas to inflate balloon.
- Do not advance or retract device with balloon inflated. Always confirm that balloon has been completely deflated and is under syringe vacuum force prior to removing.
- If inflating balloon in patient to improve re-folding, ensure balloon is positioned so that it can be inflated safely.
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Please consult package insert for more detailed safety information and instructions for use.

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