THE PHYSIOLOGIC CHOICE

SimuForm™ Annuloplasty Ring
HYBRID SHAPE

The SimuForm ring provides semi-rigid posterior remodeling while offering a flexible anterior portion to accommodate motion.

The mitral valve annulus changes shape in the cardiac cycle. SimuForm rings do not have a fixed saddle shape, and also change shape in systole and diastole.

SimuForm rings are available in a full size range of 24–40 mm.
Saddle Shaped in Systole

- Flexible anterior portion which accommodates natural motion
- The saddle has been shown to increase leaflet coaptation and curvature,\textsuperscript{1-3} reduce annular forces,\textsuperscript{3,4} and reduce leaflet and chordal stresses\textsuperscript{4-6}

Planar “O” Shaped in Diastole

SimuForm rings are not fixed into a saddle shape — flatten to an “O” shape to accommodate diastolic filling dynamics.
ACCESSORY ENHANCEMENTS

Low-profile Open Holder
Place sutures along the entire semi-rigid ring while fully accessing anatomy.

Clearly Marked Cut Towers
Easily identify the two cut towers on the holder, which enables quick release of the ring.
Stable Handle-to-holder Connection

Allows for low-force, single-cut release, and remains securely attached during suturing.

Visual Chordal Reference Line

Provides visual reference of annular plane when performing chordal repair.
### SIMUFORM RING PRODUCT INFORMATION

<table>
<thead>
<tr>
<th>Size (mm)</th>
<th>Product Codes</th>
<th>“A” (mm)</th>
<th>“B” (mm)</th>
<th>Orifice Area (mm²)</th>
<th>Stiffener Assembly Inner Diameter (mm)</th>
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**A:** Inner Ring Diameter  
**B:** Outer Ring Diameter  
**C:** Inner Stiffener Diameter

[Diagram showing the dimensions of the SIMUFORM ring with labels A, B, and C.]
### SIMUFORM RING ORDERING INFORMATION

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<th>Order Number</th>
<th>Components &amp; Accessories</th>
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<tbody>
<tr>
<td>T7800P</td>
<td>SimuForm Accessory Tray</td>
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<tr>
<td>7800PS</td>
<td>Set of 9 SimuForm Polysulfone Sizers</td>
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<td>7686 7686L</td>
<td>Annuloplasty Handles in Assorted Lengths</td>
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<td>7686XL</td>
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**Brief Statement**

**SimuForm™ Semi-Rigid Annuloplasty Ring**

**Indications:** The SimuForm semi-rigid annuloplasty rings are for use in patients undergoing surgery for diseased or damaged mitral valves. The SimuForm semi-rigid annuloplasty ring provides support for the mitral annulus and restricts expansion of the annulus.

**Contraindications:** Severe, generalized, or localized bacterial endocarditis, heavily calcified valves, greatly dilated annulus (not reducible by standard techniques), severe valvular dysfunction (not correctable by standard techniques), valvular retraction with severely reduced mobility, congenital malformations with lack of valvular tissue.

**Warnings/Precautions/Adverse Events:** Only surgeons who have received appropriate training in valve repair, including ring implant and sizing techniques, should use this device. Adverse events can include: uncorrected or recurrent regurgitation, stenosis, ring dehiscence, hemolysis (even with mild regurgitation), low cardiac output, heart block, systolic anterior motion (SAM) and left ventricular outflow tract obstruction (LVOTO), damage to coronary arteries, endocarditis, thrombosis, thromboembolism, anticoagulant-related hemorrhage, ring fracture, leaflet perforation, bleeding diathesis.

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

For a complete listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

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**References**