The Blom-Singer® FISTULA PROSTHESIS
INSERTION & REMOVAL (I&R) CATHETER

- Material > Semi-rigid thermoplastic
- For insertion and removal with these sizes only, 25mm and 38mm prosthesis
- 8 Fr. catheter diameter gradually increasing to 11 Fr. in the keyhole end
- Designed for non-surgical insertion of the fistula prostheses in the OFFICE or O.R.
- Sterile, 3 year shelf life
- Single use, disposable

ORDERING INFORMATION
Call InHealth Technologies Customer Service, 800.477.5969, and provide the REF number(s) below.

<table>
<thead>
<tr>
<th>SIZE</th>
<th>REF NUMBER</th>
<th>FLANGE DIAMETER</th>
<th>OVERLAP of FLANGE to FISTULA DIAMETER</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMALL I&amp;R Catheter provided</td>
<td>FM1003</td>
<td>25mm</td>
<td>8-10mm</td>
</tr>
<tr>
<td>MEDIUM I&amp;R Catheter provided</td>
<td>FM1004</td>
<td>38mm</td>
<td>8-10mm</td>
</tr>
<tr>
<td>LARGE</td>
<td>FM1005</td>
<td>50mm</td>
<td>12.5mm</td>
</tr>
<tr>
<td>CATHETER</td>
<td>FM1010</td>
<td>Blom-Singer® Fistula Prosthesis Insertion and Removal Catheter *</td>
<td></td>
</tr>
</tbody>
</table>

* Fistula Prosthesis Insertion and Removal Catheter available separately

Blom-Singer®
Federal (USA) law restricts this device to sale by or on the order of a physician.
* US and foreign patents pending
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Introducing the Blom-Singer®
ADJUSTABLE BI-FLANGED FISTULA PROSTHESIS
For the management of hypopharyngeal fistulae

MANAGEMENT OF THE HYPOPHARYNGEAL FISTULA – QUALITY OF LIFE
• Enhances maintenance of a dry fistula tract depending on size of fistula and condition of tissue
• May reduce leakage of saliva, food and drink
• NPO Instructions may be alleviated
• Possible avoidance/reduction of enteral/parenteral nutrition
• Potential for Post-laryngectomy speech with TEP

PROMOTES COST SAVINGS
• Insertion & Removal Catheter (I&R) provided
• Can be placed in OFFICE or O.R. (Choice in Anesthesia protocol/necessity)
• Anesthesia and facility cost may be reduced

WHAT IS INCLUDED IN THE OFFERING?
• Insertion & Removal Catheter (I&R) provided with the 25mm and 38mm Prosthesis
• The 50mm Adjustable Bi-Flanged Fistula Prosthesis does not require the I&R Catheter

IS IT STERILE?
Yes.

SHELF LIFE?
3 years from date of manufacture.

CAN THIS DEVICE BE REPROCESSED FOR MULTI-PATIENT USE?
No, Single patient use only.

FISTULA PROSTHESIS PLACEMENT & FUNCTION
Leakage may be controlled by the fit of the flanges against the open fistula

MATERIALS

FLANGES
• Soft, flexible
• Medical grade silicone
• Translucent to allow Fistula tract visualization

BEADED STEM
• Medical grade silicone, radiopaque
• Elastomeric (stretchable)
• Locking loop prevents flange movement

Designed by Eric D. Blom Ph.D.