If resistance is felt upon removal, then the balloon catheter should be removed together as a unit, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and guidewire as a unit and withdrawing both together, using a gentle twisting motion combined with traction.

Before removing catheter, it is very important that the balloon is completely deflated. Proper functioning of the catheter depends on its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching or forceful wiping of the catheter.

Potential Complications Include, But Are Not Limited To:

- Potential complications related to the introduction of the catheter into the body include, but are not limited to, the following: infection, air embolism and hematoma formation.
- Potential balloon separation following balloon rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces.

Inspection and Preparation:

1. Insert guidewire through the distal tip until guidewire extends proximal port.
2. Remove balloon protector. Inspect the catheter for damage prior to insertion.
3. Perform dilatations using either a 50/50 or a 75/25 solution of saline and contrast medium, respectively.
4. Inflate the balloon to the specified pressure gauge half-filled with the contrast solution to the balloon port of the catheter.
5. Purge the catheter through lumen thoroughly, observing for leaks.
6. To check inflation/deflation times, use a stopwatch. Repeat the procedure several times to verify the inflation/deflation time.
7. Point inflation device with pressure gauge nozzle downward, aspirate until all air is removed from the balloon, and bubbles no longer appear in the contrast solution.
8. Turn the stopcock off to maintain the vacuum in the balloon.
9. Remove guidewire.

Insertion: Vascular:

1. Direct torque guidewire through the esophageal stricture using fluoroscopic guidance.
2. In most patients, the balloon should meet with minimal resistance to insertion. Do not advance the catheter unless the guide wire is felt in place.
3. Insert the balloon catheter into the esophagus using short, deliberate, 2-3cm movements over the appropriate guidewire for the size catheter being used (see references).
4. Position the balloon in the appropriate location with the radiopaque marker bands on either side of the stricture.
5. Referencing to the balloon-sizing chart, inflate the balloon with contrast medium until the desired diameter is achieved or the RBP is reached, whichever comes first. DO NOT EXCEED the RBP.
6. Do not remove the guidewire from the catheter at any time during the procedure.

**IMPACT**™ Esophageal Balloon Sizing Chart

<table>
<thead>
<tr>
<th>Applied Pressure</th>
<th>16.0 mm</th>
<th>18.0 mm</th>
<th>20.0 mm</th>
<th>22.0 mm</th>
<th>25.0 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 ATM</td>
<td>14.72</td>
<td>16.61</td>
<td>18.65</td>
<td>20.71</td>
<td>22.78</td>
</tr>
<tr>
<td>2.0 ATM</td>
<td>15.05</td>
<td>17.01</td>
<td>18.98</td>
<td>21.52</td>
<td>24.36</td>
</tr>
<tr>
<td>3.0 ATM</td>
<td>15.44</td>
<td>17.49</td>
<td>19.29</td>
<td>22.19</td>
<td>25.21</td>
</tr>
<tr>
<td>4.0 ATM</td>
<td>15.84</td>
<td>17.97</td>
<td>19.93</td>
<td>22.79</td>
<td>26.93</td>
</tr>
<tr>
<td>5.0 ATM</td>
<td>16.24</td>
<td>18.38</td>
<td>20.46</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.0 ATM</td>
<td>16.55</td>
<td>18.73</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.0 ATM</td>
<td>16.86</td>
<td>19.09</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.0 ATM</td>
<td>17.17</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For all balloon catheters, an inflation device with pressure gauge should be used.

The under-lined figures represent the balloon diameter at nominal pressure.

The figures in bold face represent the balloon diameter at rated Burst Pressure.

The maximum balloon size is ± 10% at the nominal pressure.

Deflation & Withdrawal:

1. Deflate the balloon by drawing a vacuum with an inflation device with pressure gauge. Note: The greater the vacuum applied and held during withdrawal, the lower the deflated balloon profile.
2. Grasp an inflation device with pressure gauge half-filled with the contrast solution to the balloon port of the catheter. AVOID AIR INTRODUCTION INTO THE SYSTEM.
3. Do not remove the guidewire from the catheter at any time during the procedure.
4. Before removing catheter, it is very important that the balloon is completely deflated.
5. Perform dilatations using either a 50/50 or a 75/25 solution of contrast medium.
6. Do not remove the guidewire from the catheter at any time during the procedure.

Warning:

B. Braun Interventional Systems Inc. catheters are placed in the extremely hostile environment of the human body. Catheters fail to function for a variety of causes including, but not limited to, medical complications or failure of catheters by breakage. In addition, despite the exercise of all due care in design, component selection, manufacture and testing prior to sale, catheters may be easily damaged by forced insertion, during, or after insertion by improper handling or other intervening acts. Consequently, no representation or warranty is made that failure or cessation of function of catheters will not occur or that the body will not react adversely to the placement of catheters or that medical complications will not follow the use of catheters. B. Braun Interventional Systems Inc. cannot warrant or guarantee B. Braun Interventional Systems Inc. accessories because the structure of the accessories may be damaged by improper handling before or during use. Therefore, no representations or warranties are made concerning them.

References:


IMPACT is a trademark of B. Braun Interventional Systems Inc.
Instructions For Use

Eosophageal Balloon Dilatation

Contents of unopened, undamaged package are: STERILE • NONPYROGENIC

Sterile in unopened and undamaged package if the word “gas-check” on the sterility indicator strip has changed from red to green.

Non-sterile if the package has been opened or damaged or the word “gas-check” on the sterility indicator strip is not green.

Disposal of device is interdepartmental. Do not reuse or resterilize. Sterilized with Ethylene Oxide.

Indications:

Eosophageal Balloon Dilatation (Cleared for balloon Diame ters 16mm, 18mm, 20mm, 22mm, and 25mm). Indicated for use in adult and adolescent patients to dilate esophageal strictures due to: esophageal surgery, primary gastroesophageal reflux therapy.

Catheter Description:
The B. Braun Interventional Systems Inc. Catheter is a co-axial design catheter with a balloon mounted on its distal tip. The lum en labeled with the balloon size is utilized for balloon inflation while the through lum en allows the catheter to track over a guidewire before the balloon is inflated. Radiopaque bands define the catheter, guidewire, and sheath as a unit and length at a specific pressure. The balloon diameter is ± 10% at the nominal pressure. The Rated Burst Pressure (RBP) is different for each balloon size. Check the package label of each catheter for the RBP. It is important that the balloon not be inflated beyond its RBP.

Potential Complications Include:

But Are Not Limited To:

• Potential balloon separations related to the introduction of the catheter into the body include, but are not limited to, the following: infection, air embolism and hematoma formation.

• Potential balloon separation following balloon rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces.

• Complications related to the RBP are not limited to: clot formation and embolism, nerve damage, vascular perforation requiring surgical repair, damage to the vascular intima, atheroembolic material, accidental perforation and internal infusion or death. For specifics, refer to: Fellows, K. et al.: Acute Complications of Catheter Therapy for Congenital Heart Disease, Amer Journ of Cardiol, 60;679(1987).

NOTE: There have been infrequent reports of larger diameter bal lons bursting circumferentially, possibly due to a combination of tight focal strictures in patients. In any instance of balloon rupture while in use, it is recommended that a sheath be placed over the ruptured balloon prior to withdrawal through the entry site.

Deflation and Withdrawal:

1. Deflate the balloon by drawing a vacuum with an inflation device with pressure gauge. Note: The greater the vacuum applied and held during withdrawal, the lower the deflated balloon profile.

2. Gently withdraw the catheter. As the balloon exits the vessel, use a smooth, gentle, steady motion. If resistance is felt upon removal of the balloon, guidewire and sheath should be removed as a unit under fluoroscopic guidance, particularly if balloon rupture or leakage is known. This is accomplished by firmly grasping the balloon catheter, guidewire, and sheath as a unit and withdrawing while keeping the balloon profile.

3. Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.

Precautions:

• Dilatation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.

• Guidewires are delicate instruments. Care should be exercised while handling to help prevent the possibility of breakage. The sealed catheter container should be inspected prior to opening. If the seal is broken, or the container has been damaged or wet, sterility cannot be assured.

• Careful attention must be paid to the maintenance of tight catheter connections and aspiration before proceeding to avoid air introduction into the system.

• Under no circumstances should any portion of the catheter system be advanced against resistance. The cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem.

2. Advance the catheter across the lesion with fluoroscopic guidance using accepted percutaneous transluminal angioplasty control techniques (see references). In most patients, the balloon should meet with minimal resistance to insertion. Do not advance the catheter unless the guidewire is in place.

3. Refering to the balloon-sizing chart, inflate the balloon with contrast medium until the desired diameter is achieved or the RBP is reached, whichever comes first. Do NOT EXCEED THE RBP.

4. Do not remove the guidewire from the catheter at any time during the procedure.

Deflation and Withdrawal:

1. Deflate the balloon by drawing a vacuum with an inflation device with pressure gauge. Note: The greater the vacuum applied and held during withdrawal, the lower the deflated balloon profile.

2. Gently withdraw the catheter. As the balloon exits the vessel, use a smooth, gentle, steady motion. If resistance is felt upon removal of the balloon, guidewire and sheath should be removed as a unit under fluoroscopic guidance, particularly if balloon rupture or leakage is known. This is accomplished by firmly grasping the balloon catheter, guidewire, and sheath as a unit and withdrawing while keeping the balloon profile.

3. Apply pressure to the insertion site according to standard practice or hospital protocol for percutaneous vascular procedures.

Among the adverse reactions associated with PTA include, but are not limited to: infection, air embolism and hematoma formation. Potential balloon separation following balloon rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces. Complications related to the RBP are not limited to: clot formation and embolism, nerve damage, vascular perforation requiring surgical repair, damage to the vascular intima, atheroembolic material, accidental perforation and internal infusion or death. For specifics, refer to: Fellows, K. et al.: Acute Complications of Catheter Therapy for Congenital Heart Disease, Amer Journ of Cardiol, 60;679(1987).

NOTE: There have been infrequent reports of larger diameter balloons bursting circumferentially, possibly due to a combination of tight focal strictures in patients. In any instance of balloon rupture while in use, it is recommended that a sheath be placed over the ruptured balloon prior to withdrawal through the entry site. Note: the pressure can be cut by cutting off the proximal end of the catheter and slipping an appropriately sized sheath over the catheter into the entry site. For specific technique, refer to: Tegtmeier, R. M.D. in: “Removing the Stuck, Ruptured Angioplasty Balloon Catheter.” Radiology, Vol u me 139, 231-232, April 1981.

Guidewires are delicate instruments. Care should be exercised while handling to help prevent the possibility of breakage. The sealed catheter container should be inspected prior to opening. If the seal is broken, or the container has been damaged or wet, sterility cannot be assured.

D iode inflations may be accom plished by firm ly grasping the balloon catheter, sheath and guidewire as a unit and withdr aw ing them together, using gentle twisting motion combined with traction.

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