Introduction and Objective

The dilation of narrowed urinary tracts using high pressure balloon dilation catheters has become a commonplace practice among urologists. An anatomical or disease related narrowing of the urinary tract such as stricture, benign prostatic hyperplasia or UPJ obstruction, can often require the use of a balloon dilation catheter.

In order for a successful dilation procedure to occur, a balloon dilation catheter must be easily introduced. Ease of insertion is a very important aspect of balloon catheter design, as surgeons wish to minimize any further trauma to the urinary tract. There are design aspects of the balloons that contribute to the ease of insertion, such as balloon profile, column strength, and catheter lubricity. All of these components contribute to the overall force required to successfully insert the balloon dilation catheter.

The objective of the following testing was to determine the balloon profile, column strength, and catheter lubricity of an X-Force™ U30 Balloon Dilation Catheter and compare it to another commercially available balloon dilation catheter.

Methodology

Balloon Profile:
Guidewires (0.038") were inserted through the guidewire lumen of the balloon dilation catheters. These pre-inflated balloon catheters were then passed through a 6-7Fr. Decimal Gage and the smallest diameter for which the balloon would pass was recorded.

Column Strength:
The distal tip of the balloon catheter was placed into the upper jaws of an Instron® Universal Materials Testing Machine, and the other end of the 14 inch distal section was placed in the lower jaws. The Instron machine was then activated to displace by 0.75inch at a speed of 10in/min. The force required for displacement was recorded.

Shaft Lubricity:
Shaft lubricity was determined by testing the Coefficient of Friction (COF) of the catheter shaft. This was achieved by pulling a known weight along the surface of the catheter shaft. The amount of force required to move the shaft was measured. The COF was calculated by determining the ratio of the force to move the catheter shaft divided by the weight of the catheter shaft (the lower the COF, the more lubricious the catheter shaft).

The balloons used in these tests were:
15 x Bard® X-Force™ Ureteral Balloon Dilation Catheter - 5mm x 10cm
15 x Boston Scientific® UroMax Ultra™ Ureteral Balloon Dilation Catheter - 5mm x 10cm

Results

<table>
<thead>
<tr>
<th>Balloon Profile:</th>
<th>X-Force™ U30 Balloon</th>
<th>UroMax Ultra™ Balloon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Inflation Profile (in)</td>
<td>Pre-Inflation Profile (in)</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>0.085</td>
<td>0.085</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>Median</td>
<td>0.085</td>
<td>0.085</td>
</tr>
<tr>
<td>Minimum</td>
<td>0.084</td>
<td>0.083</td>
</tr>
<tr>
<td>Maximum</td>
<td>0.087</td>
<td>0.089</td>
</tr>
</tbody>
</table>

Statistical analysis was performed using a Mann-Whitney test to compare the median Balloon Profile of the X-Force™ U30 balloon to the UroMax Ultra™ balloon (p-value: 0.572).
Balloon profile, column strength and shaft lubricity each influence the ease of insertion for balloon dilation catheters. In the testing above, it was found that the balloon profile of the X-Force™ U30 balloon was comparable to the UroMax Ultra™ balloon. The column strength of the X-Force™ U30 balloon was 107% greater than the UroMax Ultra™ balloon and the X-Force™ U30 balloon catheter shaft was 34% more lubricious than the UroMax Ultra™ balloon.

### References


*Study performed by C.R. Bard, Inc., Data on File
Please consult product labels and inserts for any indications, contraindications, hazards, warnings, cautions and directions for use.

Bard is a registered trademark of C.R. Bard, Inc. or an affiliate. X-Force is a trademark of C.R. Bard, Inc. or an affiliate. UroMax Ultra is a trademark of Boston Scientific Corporation. Instron is a registered trademark of Instron Corporation.

Copyright (c) 2005 C.R. Bard, Inc. All Rights Reserved. 0511-05 R12/05 THP P12/05