INTRODUCTION AND OBJECTIVE:

Ease of insertion is an important characteristic physicians consider when evaluating a new ureteral stent. Factors influencing ease of insertion are multi-faceted. The stent makeup and the insertion process can impact the ‘ease’ at which the stent is inserted. Common significant stent characteristics include the stent durometer (hardness), coating and dimensional aspects such as taper of the tip. Aspects of the insertion technique include interaction between the stent and the guidewire and the interaction between the stent and the ureter anatomy.

The purpose of this study is to evaluate and quantify the ‘ease of insertion’ of ureteral stents in an in-vitro pig ureter environment.

METHOD:

Equipment

16 pig ureters
16 Bard® InLay Optima® stent sets with guidewire and push catheter
16 InLay® stent sets with guidewire and push catheter
16 Microvasive® Percuflex® Plus stent sets with guidewire and push catheter
Large Pan with Styrofoam® mat
Chattilion Force Gauge

Test Methodology

The pig ureter model is set up as follows:

1. A large pan with a Styrofoam® mat is filled with water.
2. A small pig ureter is tacked down to the Styrofoam® mat.
3. Guidewire is inserted into the distal end of the ureter and advanced until it appears at the proximal end. The guidewire is then tacked down to the Styrofoam® mat.
4. The InLay Optima® stent is back-loaded onto the guidewire and advanced.
5. A push catheter is back-loaded onto the guidewire and advanced until it is flush with the stent.
6. A force gauge (Chattilion) is attached to the push catheter.
7. The push catheter/Chattilion fixture is advanced until the stent is 2 inches outside of the proximal end of the ureter.
8. The maximum force used during the insertion is displayed and recorded (in lbs. of force).
9. Steps 1-9 are repeated using the InLay stent and Percuflex Plus® stent

This procedure is repeated using the remaining 15 pig ureters. To reduce bias associated with stretching of the pig ureter, the sequence of the ureteral stents is rotated. Following is an example of the rotation sequence.

| Order of Insertion |
|---------------------|-------------------|-------------------|
| Pig Ureter #1       | InLay Optima® stent | InLay® stent      | Microvasive® Percuflex® Plus stent |
| Pig Ureter #2       | InLay® stent       | Microvasive® Percuflex® Plus stent | InLay Optima® stent |
| Pig Ureter #3       | Microvasive® Percuflex® Plus stent | InLay Optima® stent | InLay® stent |
| …to Pig Ureter #16  | “                  | “                  | “                  |

…to Pig Ureter #16
RESULTS:

The results are as follows:

<table>
<thead>
<tr>
<th></th>
<th>InLay Optima® stent</th>
<th>InLay® stent</th>
<th>Microvasive® Percuflex® Plus stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>16</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>AVG (lbs)</td>
<td>0.156</td>
<td>0.157</td>
<td>0.230</td>
</tr>
<tr>
<td>StDev</td>
<td>0.0299</td>
<td>0.0420</td>
<td>0.0606</td>
</tr>
<tr>
<td>Min</td>
<td>0.110</td>
<td>0.088</td>
<td>0.126</td>
</tr>
<tr>
<td>Max</td>
<td>0.207</td>
<td>0.250</td>
<td>0.331</td>
</tr>
</tbody>
</table>

CONCLUSION:

The InLay Optima® stent is comparable to the InLay® stent in ease of insertion and 32% easier to place (in-vitro model only) than Microvasive’s Percuflex® Plus stent.

REFERENCES:

1. Stenting the Urinary System
   Daniel Yachia
   Mosby Year Book, Inc, St Louis MO, 1998 pg. 11, 105

*Study performed by C. R. Bard, Inc.

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, cautions and directions for use.