Shockwave Medical Lithoplasty® Catheter

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Lithoplasty® Technology

*Lesion modification using lithotripsy in a balloon*

- Designed to normalize vessel wall compliance prior to controlled, low pressure dilatation
- Effective lesion expansion with minimized impact to healthy tissue
- Familiar Balloon-based endovascular technique
- “Front-line” balloon strategy (.014” compatible)

*Tissue-selective:*
- Hard on hard tissue,
- Soft on soft tissue

*Lithotripsy waves travel outside balloon*

*Designed to disrupt both superficial, deep calcium*

**LINC 2016:** For use outside the U.S. only.
Shockwave Medical Lithoplasty®
Catheter
Taped Case

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Case # 1 - LKH Klinikum Graz

• 81 yr-old, male
  – History of intermittent, lifestyle limiting claudication
  – Bi-lateral peripheral disease previously treated
  – Hypertension
  – Ex-smoker
  – Hyper-lipidemia
  – No history of Coronary or Cerebrovascular disease
Lithoplasty® System

Generator

Lithoplasty® Catheter

Connector Cable

- .014” Guidewire Compatible
- 110 cm Working Length

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Length</th>
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</thead>
<tbody>
<tr>
<td>3.5 mm</td>
<td>60 mm</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>60 mm</td>
</tr>
<tr>
<td>4.5 mm</td>
<td>60 mm</td>
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<td>6.5 mm</td>
<td>60 mm</td>
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<tr>
<td>7.0 mm</td>
<td>60 mm</td>
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</tbody>
</table>
5.5mm RVD treatment zone of total occlusion

4.5mm RVD treatment zone of sub-total occlusion

~ 21 cm
Lithoplasty® System Preparation

• Turn on Generator
• Attach Connector Cable to Generator
• Prepare Lithoplasty® Catheter using standard balloon prep techniques
• Advance Catheter to treatment site
• Attach Connector Cable to Catheter
### Lithoplasty® System Treatment Sequence

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
<th>Balloon Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Position catheter at site of lesion and inflate catheter with 50/50 contrast saline mix</td>
<td>4 Atm</td>
</tr>
<tr>
<td>2</td>
<td>Press Connector Cable button and deliver 30 pulsatile mechanical waves through the balloon</td>
<td>4 Atm</td>
</tr>
<tr>
<td>3</td>
<td>Inflate Lithoplasty balloon to RVD</td>
<td>6 Atm</td>
</tr>
<tr>
<td>4</td>
<td>Deflate and repeat steps 1-3</td>
<td>N/A</td>
</tr>
<tr>
<td>5</td>
<td>As needed, reposition to another treatment area. Proceed with steps 1-4. (up to 6 cycles in total per catheter)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
5.5mm RVD treatment zone of total occlusion

4.5mm RVD treatment zone of sub-total occlusion

≥ 1cm treatment overlap zone

~ 21 cm
Diagnostic Angiogram

Final Angiogram (No stents or other devices used)
Shockwave Medical Lithoplasty® Catheter

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