expands your treatment options.

**Designed for multiple Indications**

The Peripheral Cutting Balloon™ device is designed for multiple indications:

- **Hemodialysis Access Management (HAM):**
  - The PCB scores then dilates fibrotic venous lesions common to hemodialysis access interventions.
  - Dr Mc Bride “2 years experience with the new Peripheral Cutting Balloon™ for stenoses of native fistulas” CIRSE 2004 abstract
  - Dr Singer-Jordan et al. “Cutting Balloon™ angioplasty for primary treatment of common to hemodialysis access interventions. The PCB scores then dilate fibrotic venous lesions common to hemodialysis access interventions.”

- **Superficial Femoral Artery:**
  - The PCB opens ostial focal lesions at low pressure.
  - Dr Rabbi et al “Early Results with infrainguinal Cutting Balloon™ Angioplasty” Heart 94:722-726 (1996)

- **Lower Extremity Occlusive Disease (LEOD):**
  - The PCB provides effective dilation with less pressure.
  - Pr Dr Peregrin “Results of a Peripheral Cutting Balloon™ Prospective Multicenter Data available on request

<table>
<thead>
<tr>
<th>Product Matrix:</th>
<th>Peripheral Cutting Balloon™</th>
<th>Over The Wire System</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 cm Balloon Length</td>
<td>M001 BP 35510 B0 5.00 mm x 1.0 cm x 50 cm 4 4.2F 7F</td>
<td>M001 BPM1 30015B0</td>
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<tr>
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<td>2.0 cm Balloon Length</td>
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<td>3.0 cm Balloon Length</td>
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</table>

**Rated Burst Pressure:** 10 ATM

**Peripheral Cutting Balloon™**

Microsurgical Dilatation Device

**Ordering Information**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Minimum</th>
<th>Shelf</th>
<th>Recommended Introducer Sheath</th>
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<td>M001 BP 50510</td>
<td>Peripheral Cutting Balloon™ Product Matrix: 1.0 cm Balloon Length Over The Wire System</td>
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<td>Peripheral Cutting Balloon™ Product Matrix: 5.0 cm Balloon Length Over The Wire System</td>
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</tbody>
</table>

**Precise Action. Reduced Trauma.**

[Permalink to: Cascade of Nonintimal Hyperplasia Inside]
Microsurgical dilatation for reduced vessel trauma

The Peripheral Cutting Balloon™

The Peripheral Cutting Balloon™ device features an innovative mechanism of action that reduces hoop stress and trauma. The Peripheral Cutting Balloon™ provides you added treatment flexibility when you need it most.

Innovative Mechanism of Action

The Peripheral Cutting Balloon™ device has an innovative mechanism of action, referred to as atherotomy, which utilizes atherotomes mounted on the surface of a non-compliant balloon to:

- Score, then dilate the lesion
- Disrupt the elastic and fibrotic continuity of the lesion
- Allow for gentle and controlled dilatation

Reduces Hoop Stress and Trauma

Atherotomy reduces hoop stress by making small, precisely controlled incisions. Balloon dilatation and neointima proliferation cause a vascular inflammation reaction. Decrease of trauma, limitation of inflammation should decrease restenosis rate.

The Peripheral Cutting Balloon™

- Reduces neointima
- Induces less perivascular injury
- Induces less vessel elastic recoil

Provides Greater Treatment Flexibility

The Peripheral Cutting Balloon™ device provides added treatment flexibility by enabling physicians to use the device:

- As a stand-alone treatment
- Or in conjunction with other treatment options

Flexible over the Wire system available for 0.014” wire platform. Monorail™ system available for 0.018” wire platform.

Shown to be safe and effective*

Cutting Balloon™ Angioplasty (CBA) has been shown to be safe and effective when compared to conventional angioplasty:

- Clinical trials show a reduction in biochemical markers of injury suggesting lower immune response
- IVUS evaluations show CBA to dilate the vessel at lower pressure and increase greater luminal diameters
- Increased luminal diameters with CBA suggests greater plaque compression rather than vessel intact restenosis rates
- Biochemical markers suggest lower wall expansion

Cutting Balloon™ Angioplasty (CBA) has been shown to be safe and effective:

- Clinical trials show a reduction in biochemical markers of injury suggesting lower immune response
- IVUS evaluations show CBA to dilate the vessel at lower pressure and increase greater luminal diameters

Designed for safety and ease of use*

The Cutting Balloon™ device is engineered to be safe and easy to use:

- Folding design protects healthy tissue when tracking
- Manufactured with a ready-to-penetrating and clean the lesion
- MDX coating reduces resistance
- Tapered tip makes it easy to penetrate
- Folding design protects healthy tissue

** Data on file

* pictures courtesy of Dr W. Higashiura - Department of Radiology - Nara Medical University Japan

Hara et al, 2002)