Barostimulation for the Treatment of Refractive Hypertension

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1. MobiusHD™ is a **passive implant** designed to reshape the carotid sinus, delivered using standard percutaneous techniques and angiographic visualization

2. MobiusHD™ is designed to exert just enough radial force on the vessel to reshape it in the diastolic phase, and prevent migration in the systolic phase

3. Reshaping the vessel **increases the differential strain, and therefore the stretch**, measured by the baroreceptors **with every pulsatile wave**, **concentrated within the windows of the device**
<table>
<thead>
<tr>
<th>Size</th>
<th>Indicated Vessel Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>5 – 7 mm</td>
</tr>
<tr>
<td>B</td>
<td>6.25 – 9 mm</td>
</tr>
<tr>
<td>C</td>
<td>8 – 11.75 mm</td>
</tr>
</tbody>
</table>

USA: Caution: Investigational device. Limited by United States law to investigational use. Europe: For clinical trial use only
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- Monorail 6 Fr catheter with recapture capability at partial deployment to allow for repositioning
- 8F guide catheter / 6F sheath
- 0.014” guidewire
- Compatible with distal embolic protection, if required

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Design
Monorail 5.5fr with recapture capability at partial deployment to allow for repositioning)

Current available sizes
- Size A – 5.0-7.0 mm
- Size B – 6.25-9.00 mm
- Size C – 8.25-11 mm
The CALM-FIM Clinical Studies

Controlling and Lowering Blood Pressure with the MobiusHD – A Prospective Multicenter Safety Study

Enrolment completed in US and EU studies
### Key Inclusion

- Office BP $\geq 160$ mmHg
- $\geq 3$ anti-hypertensive medications, at least one of which must be a diuretic
- 18 – 80 years

### Key Exclusion

- BMI $\geq 40$ or arm circumference $>46$ cm
- GFR $<45$ ml / min
- Known or suspected baroreflex failure or autonomic neuropathy
- Treatable resistant hypertension, or hypertension secondary to identifiable and treatable cause, except sleep apnea
- Taking imidazoline receptor antagonist / central sympathetic treatment (e.g., Clonidine)
- Enrolled in concurrent clinical trial or planned surgery in next 6 months

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The MobiusHD Platform
Treatment
HTN and (HF)
Delivery Catheter Compatibility With Ancillary Devices:
Guidewire Compatibility: 0.014”
Guide Catheter/Sheath Compatibility: 8 Fr Guide Catheter / 6 Fr Sheath
Embolic Protection Systems: 0.014”
Actuation of Delivery Catheter

Sheathed

Partially Deployed

Deployed
### Implant

<table>
<thead>
<tr>
<th>Implant</th>
<th>Overall Length (mm)</th>
<th>Diagonal (mm)*</th>
<th>Reference Vessel Sizes (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size A</td>
<td>17.0</td>
<td>9.6</td>
<td>5.0 – 7.0</td>
</tr>
<tr>
<td>Size B</td>
<td>19.3</td>
<td>11.0</td>
<td>6.25 – 9.0</td>
</tr>
<tr>
<td>Size C</td>
<td>17.85</td>
<td>13.7</td>
<td>8.25 – 11.75</td>
</tr>
</tbody>
</table>

**SIZE B ILLUSTRATION**  
(Nominal dimensions in mm)

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*Nominal dimensions in mm*
CONTROLLING AND LOWERING BLOOD PRESSURE WITH THE MOBIUSHD
Mean Change in Office BP and 24 Hr ABPM in CALM FIM Subjects
Clinical Conclusions from CALM-FIM Study

- Effective: Change in mean 24hr systolic ABP (sABP) measured from Baseline reduction of BP 20 points at 180 days average for all patients
- Drug load was reduced by 15% at 180 days
- 23% of Patients (N=9) had a prior unsuccessful RDN procedure 8 of the patients responded to the MobiusHD treatment at the same level of RDN Naive patients
- 38 patients have met the 6 month safety endpoint
- 1 Publication on Mechanism filed in Circulation Research
- Results of EU patients will be submitted for publication in a week.