The GPX Embolic Device does not have marketing clearance or approval in any market.
Disclosure

Speaker name:

Pr Romaric LOFFROY

I have the following potential conflicts of interest to report:

☑ Consulting: Medtronic, Balt, Guerbet, GEM
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest

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Background

• This feasibility clinical trial examined the use of the GPX Embolic Device in distal applications within the peripheral vasculature
• GPX is a novel aqueous-based embolic agent that solidifies in situ through ionic bonds, forming the GPX Embolic Device
• Designed for use with standard microcatheters
• Preparation: Resuspend tantalum by pushing opposing syringe plungers back and forth at least 25 times within 60 seconds
Materials & Methods

- Prospective, multi-center, single-arm, open label, non-randomized, feasibility study evaluating the use of the device for distal applications in the peripheral vasculature

- Performed in 2 hospitals in New Zealand with Andrew Holden MD as PI

- Enrollment consisted of 17 subjects with diverse distal embolization needs

- Primary Endpoints:
  - Technical success (complete occlusion of target region at time of procedure)
  - Incidence of Device-Related Serious Adverse Events (SAEs)

- Follow-up was performed at 30 days, with imaging included if dictated by standard of care

- For each case, operators were asked to score several dimensions of their experience with the GPX Embolic Device including acceptability of preparation, delivery, and visibility

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Results

- Technical success was achieved in all cases with target regions fully occluded at the first angiogram (taken immediately after delivery).
- Excellent distal penetration into vessel beds was observed in all cases.
- GPX exhibited good visibility during and after delivery with operators reporting excellent controllability during injection.
- 15/17 patients (88.2%) were free from device related SAEs.
  - 2 bone tumor patients experienced intraprocedural pain during delivery.

### Demographics

<table>
<thead>
<tr>
<th>Sex</th>
<th>Male</th>
<th>Female</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>8 (47%)</td>
<td>9 (53%)</td>
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<table>
<thead>
<tr>
<th>Age</th>
<th>Mean</th>
<th>Median</th>
<th>Range</th>
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<tbody>
<tr>
<td></td>
<td>54.3</td>
<td>58</td>
<td>22-85</td>
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<table>
<thead>
<tr>
<th>Type of Embolization</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal Angiomyolipoma (AML)</td>
<td>7</td>
</tr>
<tr>
<td>Primary Renal Cell Carcinoma (RCC)</td>
<td>2</td>
</tr>
<tr>
<td>Secondary RCC (Impacting Femur)</td>
<td>2</td>
</tr>
<tr>
<td>Portal Vein</td>
<td>4</td>
</tr>
<tr>
<td>Pelvic Tumor</td>
<td>1</td>
</tr>
<tr>
<td>Polycystic Kidney</td>
<td>1</td>
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</tbody>
</table>

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Results

- At the 30-day follow-up, patients reported good outcomes, and sites remained fully occluded with stable positioning of the embolic device in each case where imaging was available.
- GPX was found to be very acceptable across all usability dimensions studied. Average acceptability scores:
  - Ease of preparation: 4.8/5
  - Ease of delivery: 4.7/5
  - Ease of visibility: 4.6/5
Renal Angiomyolipoma Embolization

Pre-Embolization DSA

Post-Embolization DSA

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Renal Angiomyolipoma Embolization

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Pelvic Tumor Embolization

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Portal Vein Embolization

Initial Angiogram

Segment 8 Final Embolization

Post-Embolization DSA

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Portal Vein Embolization

X100 H&E Vein containing black embolization material, luminal necrosis and foreign body giant cell reaction. The vein is surrounded by a marked fibroinflammatory response.

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Renal Angiomyolipoma Embolization

5 Days Post-Intervention

6 Months Post-Intervention

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Renal Angiomyolipoma Embolization

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6 Months Post-Intervention

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Conclusion

- GPX Embolic Device may provide safe and effective embolization for arterial or venous applications where distal penetration is desired
- 100% technical success with no instances of recanalization or migration observed
- Adverse event rate was comparable to other feasibility trials in the space
- Operators gave the GPX Embolic Device high scores for simple preparation, good radiographic visibility, and favorable control during delivery