Results of a Real-World User Evaluation of the Oscar Peripheral Multifunctional Catheter
**Objective**: Collect acute clinical performance data and customer satisfaction ratings.

**Participating Physicians**

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<thead>
<tr>
<th>Physician</th>
<th>Specialty</th>
<th>Location</th>
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<tbody>
<tr>
<td>Dr. Beasley / Dr. Yates</td>
<td>IR</td>
<td>Coral Cables, FL</td>
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<td>Dr. Brannan</td>
<td>IR</td>
<td>Mesa, AZ</td>
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<td>Dr. Chopra</td>
<td>IR</td>
<td>Chicago, IL</td>
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<td>Dr. Fakorede</td>
<td>IC</td>
<td>Cleveland, MS</td>
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<td>Dr. Gujja</td>
<td>IC</td>
<td>Long Island, NY</td>
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<tr>
<td>Dr. LeSar / Dr. Harris</td>
<td>VS</td>
<td>Chattanooga, TN</td>
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<tr>
<td>Dr. Mustapha</td>
<td>IC</td>
<td>Grand Rapids, MI</td>
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<td>Dr. Peña</td>
<td>IR</td>
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<td>Dr. Raja</td>
<td>IC</td>
<td>El Paso, TX</td>
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<td>Dr. Sastry</td>
<td>IC</td>
<td>Murphy, NC</td>
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<tr>
<td>Dr. Schneider</td>
<td>VS</td>
<td>San Francisco, CA</td>
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<tr>
<td>Dr. Walker / Dr. Nair</td>
<td>IC</td>
<td>Houma, LA</td>
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**Participating States**

*The real-world user evaluation assessed Oscar’s acceptance in the US market and is referred to as Evaluation of Market Acceptance (EMA).*
Oscar: US Real-World User Evaluation*

Total of 78 Cases Completed

- **Oscar** was evaluated in 135 lesions at 12 different centers by 15 physicians across several specialties.
- Data collected on 78 cases
- Total of 91 **Oscar** Kits were used

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<tr>
<th>Kit Split</th>
<th>4F: 51 kits</th>
<th>6F: 40 kits</th>
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Baseline Disease

- **80%** Critical Limb Ischemia
- **74%** Severe/Moderate Calcification
- **53%** Chronic Total Occlusions
- **53%** >130mm lesion length

*The real-world user evaluation assessed Oscar’s acceptance in the US market and is referred to as Evaluation of Market Acceptance (EMA),
Oscar: Success Despite Complex Disease

Acceptance Criteria

- Grading of Specific Tasks: Excellent = 5, Good = 4, Average = 3, Rather Poor = 2, and Poor = 1
- At least 85% of Oscar devices are used successfully to dilate lesions
- At least 65% of Oscar devices are used successfully to support access into and cross the lesion

Results: Oscar Support Catheter with Dilator

- 98% Performance Success
- 90% Crossing Success

4.7 Performance Rating

Results: Oscar Support Catheter with PTA Balloon

- 100% Performance Success
- 95% PTA Technical Success

4.7 Performance Rating

1. PMS 000-015-457 2. As part of this real-world user evaluation. For the intended use of Oscar, please refer to the IFU
Oscar: Crossing Success

71 of 135 total treated lesions were CTOs
- 86% (61/71) of occlusions were successfully crossed with Oscar
  - In 84% (51/61) of these cases, crossing was successful with a standard guidewire--no need for CTO wire escalation
  - Not having to exchange to a CTO wire may save procedural time and costs.

1. PMS 000-015-457; Note: Not rated or N/A evaluations (5/91) were not included in the calculations. For subgroup analyses at least 10 ratings of total (86) were needed and at least 3 physicians needed to have given a rating.
Oscar Results: Market Evaluation

Majority of physicians rated Oscar better or much better than their usual device.

**Oscar Support Catheter with Dilator**

- **Much Better** and Better crossing performance than usual device: 75%

**Crossing Performance**

The overall crossing performance of the Oscar Support Catheter with the Dilator compared to their usual crossing device was rated **75% much better and better**.

**Oscar Support Catheter with PTA Balloon**

- **Much Better** and Better PTA balloon performance than usual device: 74%

**PTA Balloon Performance**

The overall PTA Balloon performance of the Oscar Support Catheter with the PTA Balloon compared to their usual crossing device was rated **74% much better and better**.
Oscar Results: Procedural Efficiency Improvement

Physicians were provided with the following 5 procedural efficiency parameters and asked whether use of Oscar resulted in improvement:

- **Procedural time**: 75% improvement
- **Number of device exchanges**: 73% improvement
- ** Injected contrast media**: 72% reduction
- **Fluoroscopy time**: 52% reduction
- **Used guidewires**: 38% reduction
- **None**: 8% reduction

1. PMS 000-015-457; Note: Not rated or N/A evaluations (5/91) were not included in the calculations. For subgroup analyses at least 10 ratings of total (86) were needed and at least 3 physicians needed to have given a rating.
Conclusion

• **Oscar** underwent a real-world user evaluation after receiving FDA approval with 78 cases performed by 15 physicians in the US.

• Despite high disease complexity (80% CLTI, 74% severe/moderate calcification, 53% CTOs, 53% >130 mm lesion length), **Oscar** demonstrated overall excellent acute clinical performance success.

• **Oscar** demonstrated improvement in procedural efficiency due to reduction of procedural time, device exchanges, contrast media injection, fluoroscopy time and number of guidewires used.