CODMAN NEURO ORBIT GALAXY®
DETACHABLE COIL SYSTEM

A Neurovascular coil comparison focusing on conformability, shape consistency and packing density.

OCTOBER 2014
DSUS/COD/0514/0069(1)
Discussion Summary

- Traditionally coils have been labeled and sized to fit per the open space intended for embolization.
- ORBIT GALAXY Coil has a proprietary coil shape creation process and this helps deliver a microcoil with excellent conformability and softness for optimal embolizations.
- Alternative coil shapes do not exhibit the same consistent shape properties when using a spherical inspection cavity as the ORBIT GALAXY Coil.
Aneurysm volume and Coil volume

Traditionally coils have been sized to fit within the open space identified for embolization.

Websites such as Angiocalc.com and Angiosuite.com educate on this relationship and were used to calculate coil volume.

\[ V = \frac{4}{3} \pi r^3 \]

### Coils and Volume

<table>
<thead>
<tr>
<th>Coil Size</th>
<th>Coil Type</th>
<th>Coil Volume (mm^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1x2</td>
<td>Target 360 Ultra (Nano)</td>
<td>1.01</td>
</tr>
<tr>
<td>2x1.5</td>
<td>ORBIT GALAXY XTRASOFT® Coil</td>
<td>1.09</td>
</tr>
<tr>
<td>1x3</td>
<td>Target 360 Ultra (Nano)</td>
<td>1.52</td>
</tr>
<tr>
<td>2x2</td>
<td>ORBIT GALAXY XTRASOFT® Coil</td>
<td>1.45</td>
</tr>
<tr>
<td>6x20</td>
<td>Target 360 Soft</td>
<td>10.13</td>
</tr>
<tr>
<td>6x20</td>
<td>ORBIT GALAXY Complex Coil</td>
<td>14.59</td>
</tr>
</tbody>
</table>

### Aneurysm Volume

<table>
<thead>
<tr>
<th>Aneurysm size</th>
<th>Aneurysm Volume mm^3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 mm</td>
<td>0.52</td>
</tr>
<tr>
<td>2.0 mm</td>
<td>4.18</td>
</tr>
<tr>
<td>6.0 mm</td>
<td>113.1</td>
</tr>
</tbody>
</table>
Coil Label Comparison
(coil graphics taken from currently marketed product cartons)

ORBIT GALAXY XTRASOFT Coil

Labels secondary diameter (labeled diameter)

ORBIT GALAXY Complex Fill Coil

Labels secondary diameter (labeled diameter) and distal most loop

Target® Ultra 360 Nano Coil

Labels distal loop diameter as secondary diameter

Target Ultra 360 Coil

Labels secondary diameter (labeled diameter) and distal loop
FRAMING COILS
Coils compared with 6mm inspection cavity

6 mm inspection cavity

- The ORBIT GALAXY Coil proprietary shape creation process helps deliver consistently unique conformability providing excellent framing capabilities.

- Coil choices such as the Target 360 Soft coil exhibit less shape consistency in the same spherical inspection cavity.

NOTE: Microcoil Data on file at Codman Neuro

CODMAN NEURO
DePuy Synthes
COMPANIES OF
Johnson & Johnson
**ORBIT GALAXY Coil exhibits consistency & conformability**

<table>
<thead>
<tr>
<th>As labeled</th>
<th>As measured</th>
<th>In 6 mm cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="ORBIT GALAXY Coil 6x20" /> 6mm</td>
<td><img src="image" alt="Outer shape 9.29 mm" /></td>
<td><img src="image" alt="Outer shape 9.29 mm" /></td>
</tr>
<tr>
<td><img src="image" alt="ORBIT GALAXY Coil 6x20" /> 9.56 mm</td>
<td><img src="image" alt="Outer shape 8.78 mm" /></td>
<td><img src="image" alt="Outer shape 8.78 mm" /></td>
</tr>
<tr>
<td><img src="image" alt="ORBIT GALAXY Coil 6x20" /> 8.78 mm</td>
<td><img src="image" alt="Outer shape 9.56 mm" /></td>
<td><img src="image" alt="Outer shape 9.56 mm" /></td>
</tr>
</tbody>
</table>

ORBIT GALAXY Coil 6x20 provides a complex shape with an open core for excellent conformability in a consistent shape configuration.

NOTE: Inner circle ‘as measured’ indicates the coil labeled diameter.

NOTE: Microcoil Data on file at Codman Neuro

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Target 360 Soft Coil exhibits less shape consistency in a 6mm inspection cavity and loops in the middle of its’ structure.

NOTE: Inner circle ‘as measured’ indicates the coil labeled diameter.

NOTE: Microcoil Data on file at Codman Neuro
ORBIT GALAXY Coil offers shape consistency with 44% more packing density providing excellent framing capabilities when compared with Target 360 Soft 10 Coils

- 6mm ORBIT GALAXY Coil demonstrates good conformability in 6 mm inspection cavity
- Target 360 Soft 6x20 Coil exhibits less shape consistency in 6mm inspection cavity

As a 12 system coil, an ORBIT GALAXY XTRASOFT Coil will deliver more platinum per cm than smaller system coils like .010” Target 360 Soft Coils

- A 6mm x 20cm ORBIT GALAXY Complex Fill Coil in a 6mm spherical aneurysm (113.1 mm$^3$) provides 44% more volume than a 6mm x 20cm Target 360 Soft coil (14.59 mm$^3$ vs 10.13 mm$^3$)

NOTE: Microcoil Data on file at Codman Neuro

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FINISH COILS
Coils compared with 2mm inspection cavity

- ORBIT GALAXY Coils proprietary shape creation process helps deliver consistently unique conformability and softness.
- This results in a coil able to conform to the dimensions of an individual aneurysm.
- Coil choices such as the Target Ultra Nano coil are made differently and exhibit less shape consistency in a 2mm inspection cavity.

NOTE: Microcoil Data on file at Codman Neuro
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**XTRASOFT Coil 2x2 exhibits good conformability**

<table>
<thead>
<tr>
<th>As labeled</th>
<th>As measured</th>
<th>In 2 mm cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /> 2mm</td>
<td><img src="image2.png" alt="Image" /> Outer shape 2.75 mm</td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td><img src="image4.png" alt="Image" /></td>
<td><img src="image5.png" alt="Image" /> Outer shape 3.05 mm</td>
<td><img src="image6.png" alt="Image" /></td>
</tr>
<tr>
<td><img src="image7.png" alt="Image" /></td>
<td><img src="image8.png" alt="Image" /> Outer shape 3.01 mm</td>
<td><img src="image9.png" alt="Image" /></td>
</tr>
</tbody>
</table>

**NOTE:** Inner circle ‘as measured’ indicates the coil labeled diameter.  

**NOTE:** Microcoil Data on file at *Codman Neuro*

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<table>
<thead>
<tr>
<th>As labeled</th>
<th>As measured</th>
<th>In 2 mm cavity</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Diagram" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
</tbody>
</table>

The 1mm Target Ultra Nano Coil exhibits less shape consistency in a 2mm inspection cavity:
- Initial most distal loop measures close to 1mm

NOTE: Inner circle ‘as measured’ indicates the coil labeled diameter.

NOTE: Microcoil Data on file at Codman Neuro

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ORBIT GALAXY XTRASOFT Coil offers Softness and Conformability with 44% more packing density per cm

- ORBIT GALAXY Coil demonstrates good softness and conformability in 2mm inspection cavity
- Target Ultra Nano Coil exhibits less shape consistency in 2mm inspection cavity

- As a 12 system coil, an ORBIT GALAXY XTRASOFT Coil will deliver more platinum per cm than smaller system coils like .010” Target Ultra Nano coils
- Each 1cm of ORBIT GALAXY XTRASOFT Coil in a 2mm spherical aneurysm (4.19mm$^3$ volume) provides 44% more packing volume than each 1cm of Target Ultra coil (.73mm$^3$ vs .505mm$^3$)

NOTE: Microcoil Data on file at Codman Neuro

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1. Our random complex coils are shaped using a proprietary, multi-dimensional spherical cavity.

2. The primary coil wind is inserted into the spherical cavity where it conforms to the shape randomly within the surface of the cavity.

3. Making a coil in this manner delivers a spherical 3D shape with an open core, with loops that randomly distribute around the periphery of a cavity.

4. No two coils processed in this manner have the same coil loop configuration, although they will have the same coil outer diameter.

5. The result is a microcoil with high coil conformability and delivery softness helping achieve optimal embolizations.
Discussion Summary

• Traditionally coils have been labeled and sized to fit per the open space intended for embolization.

• ORBIT GALAXY Coils are labeled per their overall outer diameter for the entire coil shape

• Target Ultra 360 Nano Coils are labeled per their distal loop as its secondary outer diameter

• ORBIT GALAXY Coil has a proprietary shape creation process and this helps deliver a microcoil with excellent conformability, shape consistency and softness for optimal embolizations

• Alternative coil shapes such as Target Ultra Nano and Target 360 Soft coils do not exhibit the same consistent shape properties as an ORBIT GALAXY Coil using a 2mm and 6mm inspection cavity
ORBIT GALAXY Complex Fill Coil Indications:
• The Fill ORBIT GALAXY Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms, other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae, and is intended for arterial and venous embolizations in the peripheral vasculature.

ORBIT GALAXY XTRASOFT Coil Indications:
• The ORBIT GALAXY XTRASOFT Microcoil Delivery System is intended for endovascular embolization of intracranial aneurysms.

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