Nit-Occlud® PDA – Choosing the right size for your patient
Coil System for PDA Closure

Important tips & handling features

**Always Flush**
For preparation, flush to remove air from the system completely. During procedure, flush thoroughly to avoid agglutination.

**Temperature Effect**
The pfm Nit-Occlud® PDA coils are especially developed to configure correctly under body temperature.

Correct handling
Hold the handle with one hand and move the delivery system gently forward while holding it between 2 fingers of the other hand. This movement closes the gap between coil and delivery system and should be done under fluoroscopic control. Once the gap is closed the coil can be pulled smoothly into the implantation catheter.

**WARNING!** If a strong resistance is encountered while pulling the delivery system into the catheter, do not pull the system with excessive force because you risk a premature release of the coil.

**Before Retrieval Close the Gap**
Close the gap between delivery system and coil before you retrieve the coil into the implantation catheter.

Gap open
Gap closed

**Correct Configuration**
The coil has a preferred configuration when deployed from the delivery catheter. If the coil does not deploy correctly due to the diameter of the aorta, recapture the coil, then redploy in the correct configuration.

**Preferred Configuration**
The Nit-Occlud® PDA coil adapts to various ductus types and sizes. To secure the implant in the ductus, strong distal windings avoid »pull through« back into the pulmonary artery. To avoid embolization into the aorta, proximal windings are anchoring the device on the pulmonary side.

**Knowledge**
Scan the QR code or follow the link and see how the implant works *
http://www.pfmmedical.com/clip-pda

* Not all devices shown in the video are approved in all markets.

**Indications for Use:** The Nit-Occlud® PDA coil is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of small to moderate size patent ductus arteriosus with a minimum angiographic diameter less than 4mm.

**WARNING!** Refer to the Nit-Occlud® PDA Instructions for Use for relevant warnings, precautions, complications and contraindications. This device has been designed for single use only.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

**D1 = Narrowest diameter**
**D2 = Aortic Ampulla diameter**
**L3 = PDA length**

The distal coil diameter should be at least 3 to 4 mm larger than D1.
The distal coil diameter should be no more than 2 mm larger than D2.
Length of the configured coil Lc should be not longer than L3.

**Ordering Information**

<table>
<thead>
<tr>
<th>Coiltype</th>
<th>REF</th>
<th>Distal x Prox. Coil</th>
<th>Coil Length</th>
<th>Implantation Catheter Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flex</td>
<td>14504V2</td>
<td>4 x 4 mm</td>
<td>3.5 mm</td>
<td>4 F</td>
</tr>
<tr>
<td>Flex</td>
<td>14505V2</td>
<td>5 x 4 mm</td>
<td>3.5 mm</td>
<td>4 F</td>
</tr>
<tr>
<td>Flex</td>
<td>14506V2</td>
<td>6 x 5 mm</td>
<td>3.5 mm</td>
<td>4 F</td>
</tr>
<tr>
<td>Medium</td>
<td>14507V2</td>
<td>7 x 6 mm</td>
<td>4.5 mm</td>
<td>5 F</td>
</tr>
<tr>
<td>Medium</td>
<td>14509V2</td>
<td>9 x 6 mm</td>
<td>5.0 mm</td>
<td>5 F</td>
</tr>
<tr>
<td>Medium</td>
<td>14511V2</td>
<td>11 x 6 mm</td>
<td>6.0 mm</td>
<td>5 F</td>
</tr>
</tbody>
</table>

**Perform an aortogram to measure the size of the PDA and to determine the aortic and pulmonary pressure. For measurements of PDA dimensions, keep to the following rules:**

1) Measure D1 in (mm): Minimal (narrowest) diameter of the duct
2) Measure D2 in (mm): Diameter of the aortic ampulla of the duct
3) Measure the PDA length between D1 and D2 in (mm)

The coil needs to be big enough to grab and anchor into the side walls of the defect.

**Contact**

Distributed by:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018 USA
Tel: 877-VENA CAV (836-2228) (USA)
Fax: 610-489-1334
www.bisusa.org
CV2051-2/16

Manufacturer:
pfm medical ag
Wankelstraße 60
50966 Köln, Germany
T +49 (0)2236 9641-0
F +49 (0)2236 9641-20

www.pfmmedical.com