Nit-Occlud® PDA
Coil System for PDA Closure

Designed For the Safe and Atraumatic Occlusion of the Congenital Heart Defect PDA (Patent Ductus Arteriosus)
The Nit-Occlud® PDA coil system is designed for the safe and atraumatic occlusion of the congenital heart defect PDA (Patent Ductus Arteriosus). Two different coil types and a broad variety of sizes make the unique spiral shaped occlusion device an ideal choice for the closure of small to medium sized PDA types.

**Benefits**

**Customized**
The Nit-Occlud® PDA types Flex and Medium vary in size and flexibility to match individual PDA morphologies and sizes.

**Highly flexible and adaptive**
The degree of stiffness decreases from the distal to the proximal windings, allowing the coil to adapt to the anatomy of various PDA types.

**Safe closure**
The delivery system facilitates optimal device positioning. Tight and compact windings ensure efficient occlusion.

**Ease of use**
The application system is designed for ease of use. It is inserted by means of a 4-5F implantation catheter. The coil is repositionable and retrievable prior to release.

**Details**

- Pre-mounted coil system
- 4F or 5F delivery catheter
- Strong distal windings avoid »pull through«
- Proximal windings anchor the device on the pulmonary side
- Repositionable and retrievable prior to release
- Radiopaque
- MR conditional

**Function**

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 anchor the device on the pulmonary side.

**In Use**

Descending aortography at the straight lateral projection. Baseline angiography (left) shows type A ductus arteriosus with moderate left to right shunt. After implantation of Nit-Occlud PDA coil, angiography (right) demonstrates a satisfactory position of Nit-Occlud PDA coil within the ductus arteriosus, resulting in no residual shunt.

Coil Selection

A lateral aortogram should be performed to measure the dimensions of the PDA. According to the measurements, the ductus type and the following recommendations, a coil should be selected as follows:

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 Distal Coil Diameter should be at least 3 to 4mm larger than D1.
The Distal Coil Diameter should be no more than 2mm larger than D2.

Ordering Information

Nit-Occlud® PDA

<table>
<thead>
<tr>
<th>Coilt Type</th>
<th>Reference Number</th>
<th>Distal x Prox. Coil Diameter</th>
<th>Coil Length</th>
<th>Implantation Catheter</th>
<th>Catheter Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flex</td>
<td>145044V2</td>
<td>4 x 4mm</td>
<td>3.5mm</td>
<td>4F</td>
<td>85cm</td>
</tr>
<tr>
<td>Flex</td>
<td>145054V2</td>
<td>5 x 4mm</td>
<td>3.5mm</td>
<td>4F</td>
<td>85cm</td>
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<tr>
<td>Flex</td>
<td>145065V2</td>
<td>6 x 5mm</td>
<td>3.5mm</td>
<td>4F</td>
<td>85cm</td>
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<tr>
<td>Medium</td>
<td>145076V2</td>
<td>7 x 6mm</td>
<td>4.5mm</td>
<td>5F</td>
<td>85cm</td>
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<tr>
<td>Medium</td>
<td>145096V2</td>
<td>9 x 6mm</td>
<td>5.0mm</td>
<td>5F</td>
<td>85cm</td>
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<tr>
<td>Medium</td>
<td>145116V2</td>
<td>11 x 6mm</td>
<td>6.0mm</td>
<td>5F</td>
<td>85cm</td>
</tr>
</tbody>
</table>

Includes: Implant, delivery system, implantation catheter.
### Clinical Evidence

**Nit-Occlud® PDA outcomes from the pivotal, continuing access and post approval studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Technical success at implantation</th>
<th>Clinical closure at 12 months</th>
<th>Echocardiographic closure at 12 months</th>
<th>Mortality at 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pivotal and continuing access studies</td>
<td>97.2% (347/357)</td>
<td>98.1% (308/314)</td>
<td>96.8% (299/309)</td>
<td>0% (0/314)</td>
</tr>
<tr>
<td>Post approval study (PAS)</td>
<td>97.8% (180/184)</td>
<td>100% (152/152)</td>
<td>93.4%* (142/152)</td>
<td>0% (0/153)</td>
</tr>
<tr>
<td>Combined pivotal, continuing access and PAS</td>
<td>97.4% (527/541)</td>
<td>98.5% (460/467)</td>
<td>95.9% (418/436)</td>
<td>0% (0/467)</td>
</tr>
</tbody>
</table>

*Note, after 12 months, 98.7% (150/152) had trivial or no residual shunt by echocardiography.


### 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.

**Nit-Occlud Brief Statement:**

Do not implant the Nit-Occlud PDA into patients who have endocarditis, endarteritis, active infection, pulmonary hypertension (calculated PVR greater than 5 Wood Units), thrombus in a blood vessel through which access to the PDA must be obtained, thrombus in the vicinity of the implantation site at the time of the implantation or patients with a body weight < 11 lbs. (5kg). An angiogram must be performed prior to implantation for measuring length and diameter of the PDA. Only the pfm medical implantation delivery catheter should be used to implant the device. Administration of 50 units of heparin per kg bodyweight should be injected after femoral sheaths are placed. Antibiotics should be given before (1 dose) and after implantation (2 doses) to prevent infection during the implant procedure. Do not implant the Nit-Occlud coil through heart valves or ventilricular chambers. Contrast media should not be injected through the implantation catheter. The catheter must not be connected to high pressure injectors. Patients may have an allergic response to this device due to small amounts of nickel that has been shown to be released from the device in very small amounts. If the patient experiences allergic symptoms, such as difficulty in breathing or swelling of the face or throat, he/she should be instructed to seek medical assistance immediately. Antibiotic prophylaxis should be performed to prevent infective endocarditis during first 6 months after coil implantation. Potential Adverse Events: Air embolism, Allergic reaction to drug/contrast, Aneurysm, Arteriovenous fistula, Bacterial endocarditis, Blood loss requiring transfusion, Chest pain, Damage to the tricuspid or pulmonary valves, Death, Embolization of the occluder, Endarteritis, Failure of the occluder to occlude, Hypertension, Hypotension or shock, Infection, Myocardial infarct, Occluder fracture or damage, Perforation of the heart or blood vessel, Post procedure fever, Pulmonary embolism, Pulmonary hypertension, Pulmonary valves, Stenosis of the left pulmonary artery or descending thoracic aorta, Stroke/TIA, Thromboembolism (cerebral or pulmonary), Valvular Regurgitation, Sudden death at the site of groin puncture (loss of pulse, hematoma etc.) Reference the Nit-Occlud® PDA Instructions for Use for a complete listing of indications, contraindications, warnings and precautions. www.bisusa.org

### Multi-Snare®

**Dual-Plane Retrieval System**

Designed to grasp objects quickly and safely from any angle

<table>
<thead>
<tr>
<th>Item</th>
<th>Reference Number</th>
<th>Nominal Diameter</th>
<th>Variable Diameter</th>
<th>Snare Length</th>
<th>Recommended Introducer</th>
<th>Introducer Length</th>
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<tbody>
<tr>
<td>Multi-Snare Micro Set</td>
<td>PFM-147302</td>
<td>2mm</td>
<td>2-3mm</td>
<td>175cm</td>
<td>3F</td>
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<tr>
<td>Multi-Snare Micro Set</td>
<td>PFM-147304</td>
<td>4mm</td>
<td>4-6mm</td>
<td>175cm</td>
<td>3F</td>
<td>150cm</td>
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<td>Multi-Snare Set</td>
<td>PFM-147305</td>
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<td>5-8mm</td>
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<td>4F</td>
<td>105cm</td>
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<tr>
<td>Multi-Snare Set</td>
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<td>10-15mm</td>
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<td>105cm</td>
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<tr>
<td>Multi-Snare Set</td>
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<td>15-20mm</td>
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<td>105cm</td>
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<td>Multi-Snare Set</td>
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<td>20-30mm</td>
<td>125cm</td>
<td>6F</td>
<td>105cm</td>
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<td>30-40mm</td>
<td>125cm</td>
<td>6F</td>
<td>105cm</td>
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</table>

Includes: Snare, snare catheter, insertion aid, torque.

The Multi-Snare® is indicated for:
- Retrieval and manipulation of foreign objects from the vascular system and hollow viscera
- Assistance in creating loops where cross-over technique is applied
- Repositioning of indwelling venous catheters
- Assistance in performing venipuncture to obtain access to central vein

Refer to the Multi-Snare® Instructions for Use for relevant warnings, precautions, complications and contraindications. This device has been designed for single use only.

**Rx only**

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