pfmmedical

Interventional Systems
B BRAUN
SHARING EXPERTISE

Nit-Occlud® PDA

Coil System for PDA Closure

Designed For the Safe and Atraumatic Occlusion of the Congenital Heart Defect PDA (Patent Ductus Arteriosus)

Nit-Occlud® PDA

Coil System for PDA Closure

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.

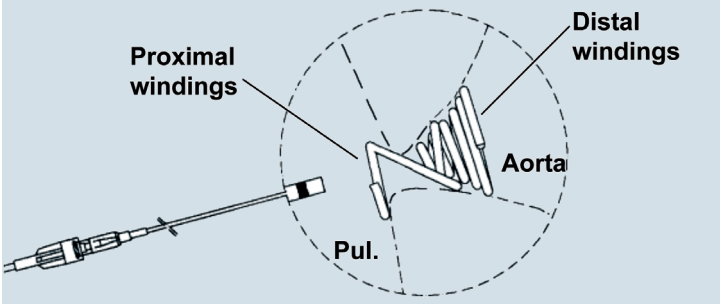
Ease of use

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

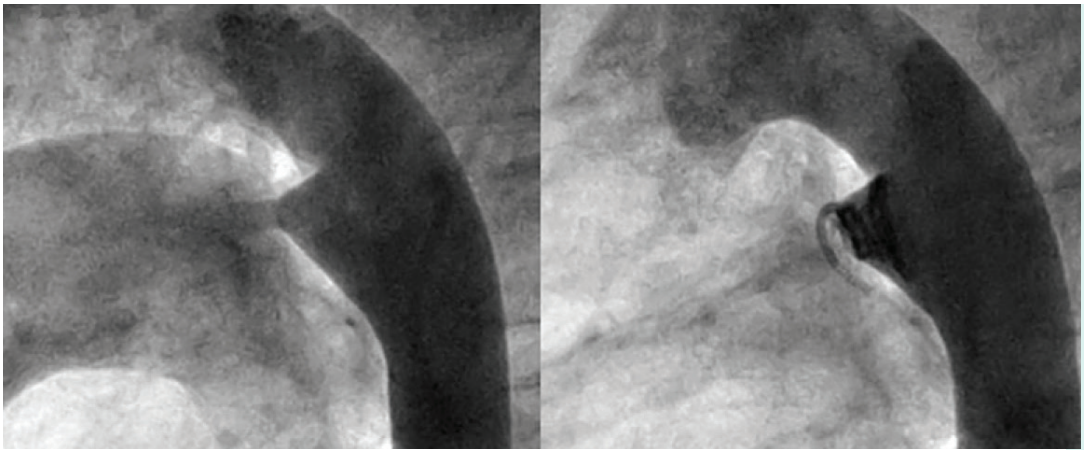
- Pre-mounted coil system
- 4F or 5F delivery catheter
- Strong distal windings avoid »pull through«
- Proximal windings anchor the device on the pulmonary side
- Repositionable and retrievable prior to release
- Radiopaque
- MR conditional

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

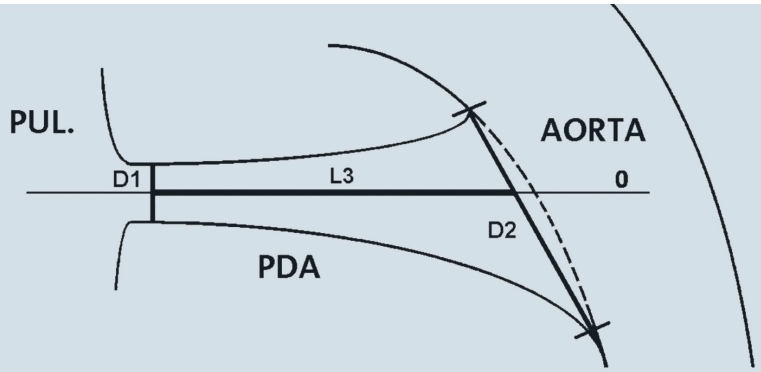


Descending aortography at the straight lateral projection. Baseline angiography (left) shows type A ductus arteriosus with moderate left to right shunt. After implantation of Nit-Occlud PDA coil, angiography (right) demonstrates a satisfactory position of Nit-Occlud PDA coil within the ductus arteriosus,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

Reference: Kobayashi D, Salem MM, Forbes TJ, et al. Results of the combined U.S. multicenter post approval study of the Nit-Occlud PDA device for percutaneous closure of patent ductus arteriosus. Catheter CardiovascInterv. 2018; 1-7. https://doi.org/10.1002/ccd.27995

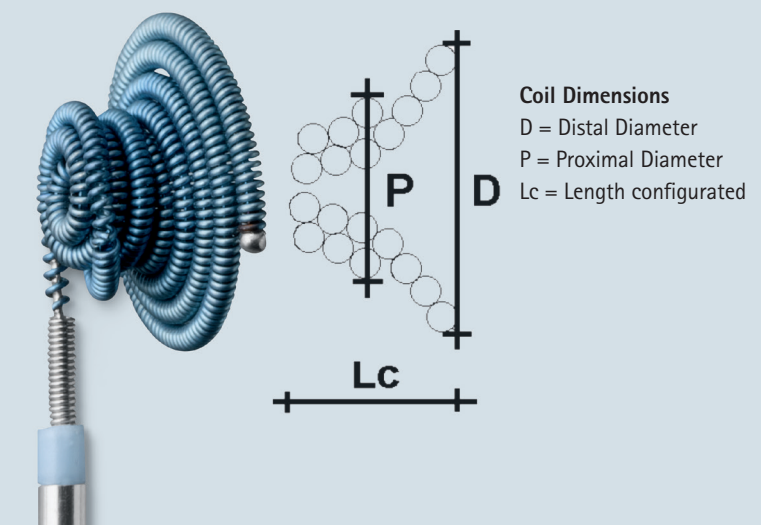
Coil Selection

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:



D1 = Narrowest diameter, D2 = Aortic ampulla diameter, L3 = PDA length.

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).

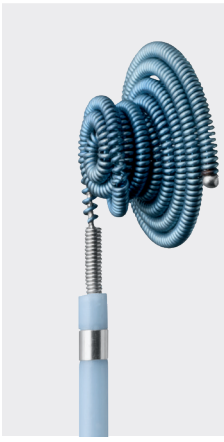


D1	D2	Distal x Prox. Coil Diameter (mm)
1mm	≤3mm	4 x 4
1mm	4mm	5 x 4
1mm	≥5mm	6 x 5
2mm	≤5mm	6 x 5
2mm	6-7mm	7 x 6
2mm	≥8mm	9 x 6
3mm	≤7mm	7 x 6
3mm	8-9mm	9 x 6
3mm	≥9mm	9 x 6 or 11 x 6
<4mm	9mm	11 x 6
<4mm	10-11mm	11 x 6
<4mm	≥12mm	11 x 6

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



Coil Type	Reference Number	Distal x Prox. Coil Diameter	Coil Length	Implantation Catheter	Catheter Length
Flex	145044V2	4 x 4mm	3.5mm	4F	85cm
Flex	145054V2	5 x 4mm	3.5mm	4F	85cm
Flex	145065V2	6 x 5mm	3.5mm	4F	85cm
Medium	145076V2	7 x 6mm	4.5mm	5F	85cm
Medium	145096V2	9 x 6mm	5.0mm	5F	85cm
Medium	145116V2	11 x 6mm	6.0mm	5F	85cm

Includes: Implant, delivery system, implantation catheter.

Clinical Evidence

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

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

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

Reference: Kobayashi D, Salem MM, Forbes TJ, et al. Results of the combined U.S. multicenter post approval study of the Nit-Occlud PDA device for percutaneous closure of patent ductus arteriosus. Catheter CardiovascInterv. 2018; 1-7. https://doi.org/10.1002/ccd.27995

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 PDA in an MR environment. Do not pull the Nit-Occlud coil through heart valves or ventricular 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, Apnea, Arrhythmia requiring medical treatment or pacing, Arteriovenous fistula, Bacterial endocarditis, Blood loss requiring transfusion, Chest pain, Damage to the tricuspid or pulmonary valves, Death, Embolization of the occluder, requiring percutaneous or surgical intervention, Endarteritis, False aneurysm of the femoral artery, Fever, Headache/ Migraine, Heart failure, Hemolysis after implantation of the occluder, Hypertension, Hypotension or shock, Infection, Myocardial infarction, Occluder fracture or damage, Perforation of the heart or blood vessels, Stenosis of the left pulmonary artery or descending thoracic aorta, Stroke/TIA, Thromboembolism (cerebral or pulmonary), Valvular Regurgitation, Vessel damage 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

Item	Reference Number	Nominal Diameter	Variable Diameter	Snare Length	Recommended Introducer	Introducer Length
Multi-Snare Micro Set	PFM-147302	2mm	2-3mm	175cm	3F	150cm
Multi-Snare Micro Set	PFM-147304	4mm	4-6mm	175cm	3F	150cm
Multi-Snare Set	PFM-147305	5mm	5-8mm	125cm	4F	105cm
Multi-Snare Set	PFM-147310	10mm	10-15mm	125cm	4F	105cm
Multi-Snare Set	PFM-147315	15mm	15-20mm	125cm	5F	105cm
Multi-Snare Set	PFM-147320	20mm	20-30mm	125cm	6F	105cm
Multi-Snare Set	PFM-147330	30mm	30-40mm	125cm	6F	105cm

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

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.

~~LATEX~~ Not made with natural rubber latex

~~DEHP~~ Not made with DEHP

~~PVC~~ Not made with PVC

Rx only

CV-2008 Rev. 6/20

Distributed by:
B. Braun Interventional Systems Inc. | Part of the B. Braun Group of Companies
Bethlehem, PA 18018 | USA | Tel 877-836-2228 | Fax 610-849-1334 | www.bisusa.org