

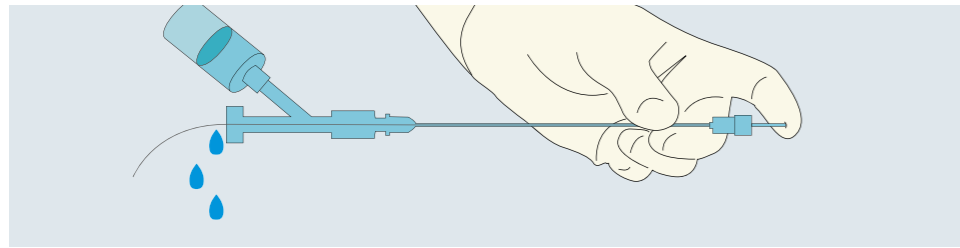
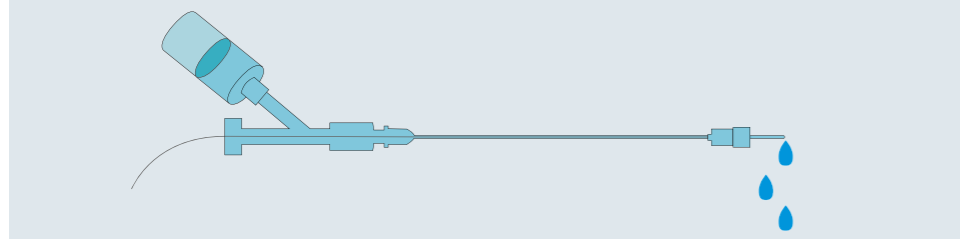
# Nit-Occlud® PDA – Choosing the right size for your patient

## Coil System for PDA Closure

### Important tips & handling features

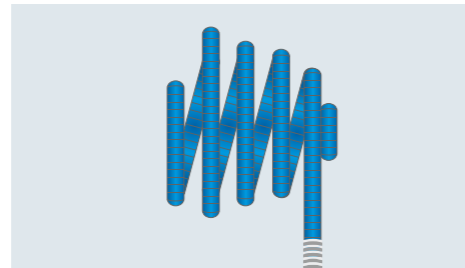
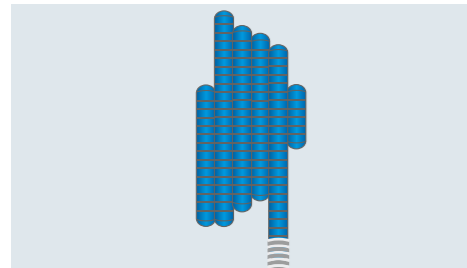
#### Always Flush

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.



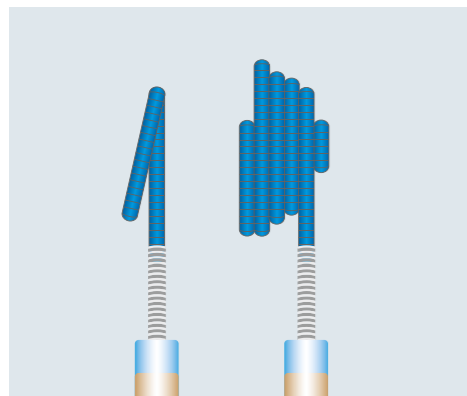
Configuration at: 98.8°F (37°C)

Configuration at: 50°F (10°C)

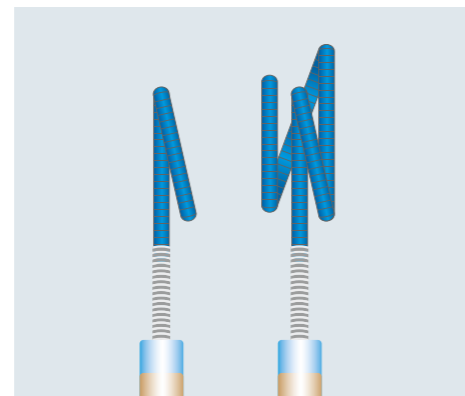
Dry testing at room temperature may cause a misconfiguration.

#### Preferred 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 redeploy in the correct configuration.



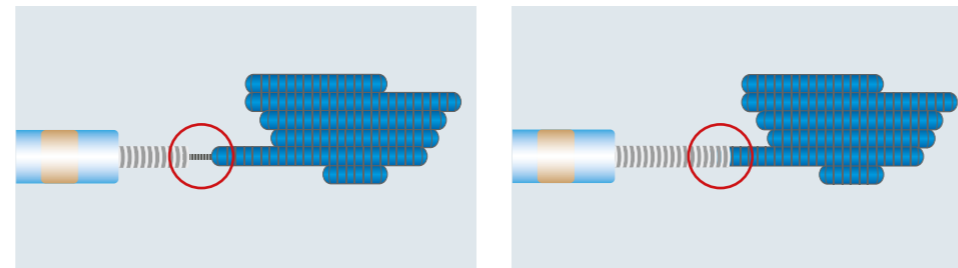
Correct configuration (pref.)



Twisted configuration (non-pref.)

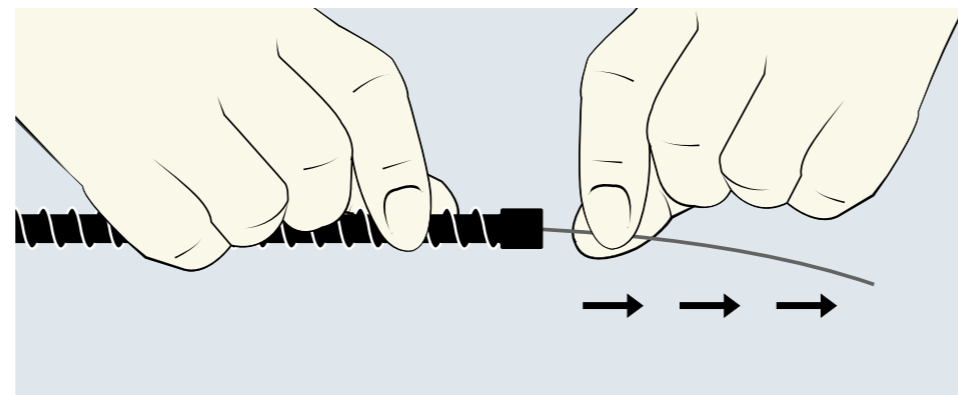
#### Before Retrieval Close the Gap

Close the gap between delivery system and coil before you retrieve the coil into the implantation catheter.



Gap open

Gap closed



#### Correct 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.

#### 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.

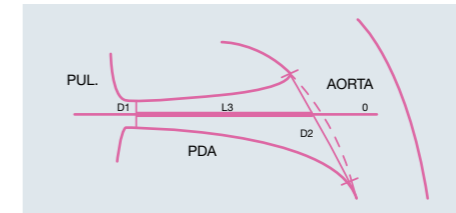
**Indications for Use:** The Nit-Occlud® PDA coil is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of small to moderate size patent ductus arteriosus with a minimum angiographic diameter less than 4mm.

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.

#### Nit-Occlud® Coil Selection

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:

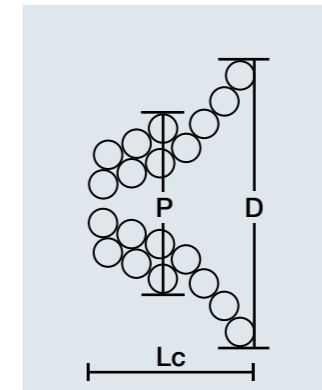


- 1) Measure D1 in (mm): Minimal (narrowest) diameter of the duct
- 2) Measure D2 in (mm): Diameter of the aortic ampulla of the duct
- 3) Measure the PDA length between D1 and D2 in (mm)

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

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

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.



D = Distal diameter  
P = Proximal diameter  
Lc = Length configured

D1	D2	Device (distal coil diameter)
1 mm	≤ 3 mm	4 x 4
1 mm	4 mm	5 x 4
1 mm	≥ 5 mm	6 x 5
2 mm	≤ 5 mm	6 x 5
2 mm	6-7 mm	7 x 6
2 mm	≥ 8 mm	9 x 6
3 mm	≤ 7 mm	7 x 6
3 mm	8-9 mm	9 x 6
3 mm	≥ 9 mm	9 x 6 or 11 x 6
< 4 mm	9 mm	11 x 6
< 4 mm	10-11 mm	11 x 6
< 4 mm	≥ 12 mm	11 x 6

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

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

#### Contact

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