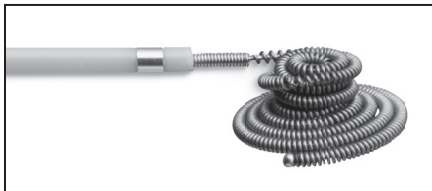


Refer to the Nit-Occlud® PDA Instructions for Use for relevant warnings, precautions, complications and contraindications.
This device has been designed for single use only.

Nit-Occlud®

Coil System for PDA Closure

IMPLANTATION POCKET GUIDE



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.



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STEP 1: PREPARATION

- Unpack the Nit-Occlud® system consisting of coil with disposable handle and implantation catheter under sterile conditions.

Warning:

Do not pull on the delivery system. If the coil is withdrawn into the Y connector, there is a danger that the system can no longer be loaded. Check all screw connections. Some screw joints may have been loosened by the sterilization process.

- Flush the system carefully through the side access of the Y connector with heparinized saline solution, and ensure that there is no air remaining anywhere in the system.
- Check the coil position inside the transparent transportation sheath. The coil should be inside the sheath. When it is in this position, it is essential not to pull on the delivery system. If the coil is not positioned inside the transportation sheath, or shows visible signs of damage, it must be replaced with a new coil.

STEP 2: COIL INTRODUCTION

- Using a soft guide wire, advance the implantation catheter from the right femoral vein through the right heart, across the PDA into the descending thoracic aorta.
- Remove the guide wire and flush the catheter with a heparinized saline solution.
- Attach the luer lock connector of the transportation sheath to the implantation catheter.
- Open the hemostatic valve of the Y connector. The coil is now free for advancement.

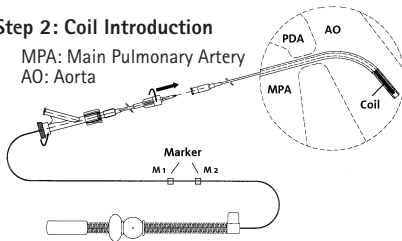
Warning:

Do not pull on the delivery system in this position!

- Advance the coil into the implantation catheter.

Step 2: Coil Introduction

MPA: Main Pulmonary Artery
AO: Aorta



STEP 3: COIL CONFIGURATION

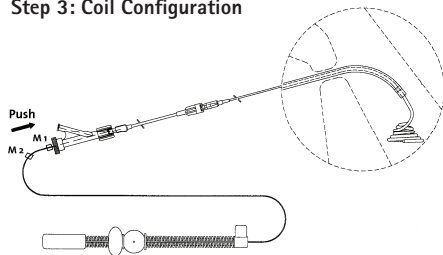
- Under fluoroscopic control advance the coil carefully through the implantation catheter into the aorta. This is done by moving the delivery system forward while arresting the implantation catheter.

Warning:

Ensure that the pigtail aortography catheter does not become entangled with the loops of the coil.

- Advance the coil until the first marker M1 is positioned close to the Y connector. At this position, all but one loop is configured outside the implantation catheter.

Step 3: Coil Configuration



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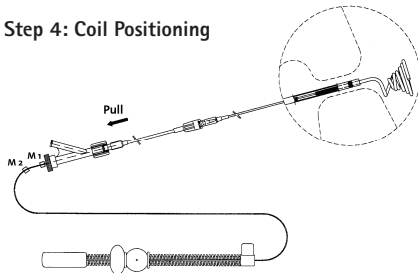
STEP 4: COIL POSITIONING

- Retract the entire system (implantation catheter, delivery system) under fluoroscopic control until the configured coil is positioned in the ampulla of the ductus (close hemostatic valve of Y connector or fix implantation catheter against delivery system).

Note:

For longer ductus types, coil configuration inside the ductus ampulla is recommended. Here, 2-3 windings of the coil must first be configured in the aorta. Then the entire system is pulled into the ductus ampulla for further configuration of the coil.

Step 4: Coil Positioning

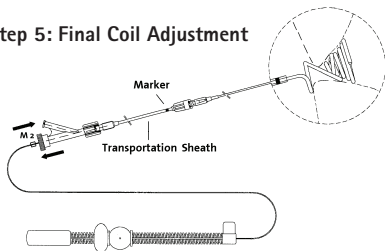


5

STEP 5: FINAL COIL ADJUSTMENT

- Open the hemostatic valve of the Y connector.
- Configure the last 1 or 2 loops on the pulmonary side of the ductus by simultaneously pulling back the implantation catheter (with your left hand) and pushing the delivery system (with your right hand). Advance the delivery system until the second marker M2 is close to the Y connector. At this position the coil is outside the catheter.
- Perform an aortogram to confirm that the coil is in the correct position.

Step 5: Final Coil Adjustment



Note:

If the position or size of the coil is not satisfactory, it should be repositioned or exchanged at this point.

Repositioning:

- To reposition the coil, pull it back into the implantation catheter by pulling the delivery system.

Warning:

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

- To do so, hold the handle with one hand and move the delivery system gently forward while holding it between 2 fingers of the same 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 very hard because you risk a premature release of the coil.

- To reposition the implantation catheter, the coil should be pulled back into the transportation sheath, carefully and under visual control, until the tip of the coil is in line with the marker at the distal end of transportation sheath. Fix the coil position by closing the Y connector.

Warning:

If the coil is pulled back too far, there is the risk that it may not be possible to reload into the delivery system.

- Then flush the implantation catheter with heparinized saline solution and repeat the procedure from Step 2.

STEP 6: COIL RELEASE

- When the coil is properly positioned, it should be released. The rotation screw should lie directly against the pusher ball. If there is any gap between the two, it must be closed.

Warning: Final release should only be performed if the coil is properly positioned in the PDA. Otherwise, the coil must either be retrieved and repositioned or replaced by an appropriate substitute. Before the coil is finally released, proper position of the coil should be confirmed by angiography.

- Remove the safety clip from the handle.
- Turn the rotation screw under fluoroscopy clockwise until the coil is released. Note that depending on the coil type between 8-15 rotations are needed to release the coil. You will feel an increase in resistance immediately prior to release.
- Remove the delivery system and implantation catheter.
- Perform a final aortogram about 10 minutes later to document position of the coil and PDA occlusion.
- Remove the aortography catheter.

Warning:

Ensure that the catheter does not touch the coil.

Step 6: Coil Release

