VSD Occlusion System
Nit-Oclud® Lê VSD

pfm medical’s unique Nitinol coil design developed for the transcatheter occlusion of Ventricular Septal Defect (VSD).

The patented coil design with polyester fibres for accelerated occlusion is intended for the closure of perimembranous and muscular VSDs.

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Unique flexible coil design for the closure of Ventricular Septal Defects (VSD). Closure of perimembranous (aneurysmatic) and muscular VSDs. In all 350 cases\textsuperscript{1,2} no permanent heart (AV) block was reported.

**Benefits**

*Patented coil design with polyester fibres*
The coil design with securely attached polyester fibres results in a rapid, effective and safe VSD occlusion.

*Outstanding adaptation properties*
Nit-Occlud\textsuperscript{®} Lê VSD adapts perfectly to the anatomy of perimembranous VSDs (especially in those with aneurysmatic formation) as well as muscular VSDs.

**Safety for the patient’s benefit**
Due to its flexible design, no permanent AV-Blocks occurred in more than 350\textsuperscript{1,2} reported cases.

**Portfolio**

- **Multi-Snare\textsuperscript{®} VSD-Loop Set**
  VSD Implantation Accessory

- **Nit-Occlud\textsuperscript{®} PDA-R**
PDA Occlusion Device (plug type)

- **Nit-Occlud\textsuperscript{®} PDA**
PDA Occlusion Device (coil type)

- **Nit-Occlud\textsuperscript{®} PFO**
PFO Occlusion Device (umbrella type)

**Details**

- Flexible and adaptive design
- pre-mounted in 5F and 6F delivery catheter
- used along with a 6F and 7F long sheath
- Radiopaque
- MR conditional
- Single-use
- Repositionable prior to release

**Use**

**Case 1: Perimembranous VSD**
Patient: male, 10 years old
VSD size: $\varnothing$ RV 4 mm, $\varnothing$ LV 9 mm
Distance to aortic valve: 3 mm
Selected coil: 10 × 6 mm
Clinical outcome: closed
no AV-Block or other arrhythmias

**Case 2: Perimembranous VSD**
Patient: female, 7 years old
VSD size: $\varnothing$ RV 6 mm, $\varnothing$ LV 13 mm
Distance to aortic valve: 4 mm
Selected coil: 14 × 8 mm
Clinical outcome: closed
no AV-Block or other arrhythmias

**Case 2: Muscular VSD**
Patient: male, 25 years old
VSD size: $\varnothing$ RV 6 mm, $\varnothing$ LV 15 mm
Distance to aortic valve: 6 mm
Selected coil: 14 × 8 mm
Clinical outcome: closed
no AV-Block or other arrhythmias

**Trials and registries:**

1. "International Multicentre Clinical Device Investigation on Safety and Effectiveness of the Nit-Occlud\textsuperscript{®} Lê VSD Spiral Coil System for VSD Occlusion" (clinicaltrials.gov identifier NCT00390702).
2. "The Nit-Occlud\textsuperscript{®} Lê VSD Registry", publication in preparation
The principal concept of Nit-Occlud® Lê VSD is to tamponade the VSD passageway. For that purpose, the implant has a double coil layer at its proximal portion, one inside the other, to fill the VSD with sufficient material.

During deployment, the inner layer is configured first (Fig. A). To increase the amount of occluding material inside the defect, reversed windings of the outer layer are added onto the inner windings (Fig. B).

As opposed to rigid double-umbrella designs of other technologies, VSD coil occlusion has been proven to be more gentle to the cardiac anatomy: In more than 350 Nit-Occlud® Lê VSD implantations¹ ² no permanent heart block has been reported.

**Range of Use**
For the interventional occlusion of ventricular septal defects using catheter techniques. VSD with perimembranous (aneurysmatic) and muscular location can be treated with Nit-Occlud® Lê VSD.

**Configurations**
The Nit-Occlud® Lê VSD is available in the sizes 8 × 6, 10 × 6, 12 × 6, 14 × 8, and 16 × 8 mm corresponding to the distal and proximal diameters respectively. The 14 × 8 mm and 16 × 8 mm devices have an increased axial stiffness, which improves the adaptation to the septum and the fixation of the coil in larger defects.

**Handling**

**Device Selection**
A coil with a distal diameter (D) of at least twice the minimal diameter of the VSD on the right ventricular side and equal to, or 1-2 mm greater than, the diameter of the VSD at the left ventricular opening is appropriate and should be selected.
Ordering Information

Nit-Occlud® Lê VSD
Permanent coil for the closure of perimembranous and muscular ventricular septal defects (VSD).
- Content: coil, delivery system, implantation catheter

<table>
<thead>
<tr>
<th>REF</th>
<th>Distal Coil diameter (D)</th>
<th>Proximal Coil diameter (P)</th>
<th>Recommended long sheath</th>
<th>Implantation catheter length</th>
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<td>6 F</td>
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<td>6 F</td>
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Multi-Snare® VSD-Loop Set
Specially designed to support the implantation of Nit-Occlud® Lê VSD.
- Content: snare, guide wire, 2 clips

<table>
<thead>
<tr>
<th>REF</th>
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<th>Recommended long sheath</th>
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<tr>
<td>147015</td>
<td>15 mm (15–20)</td>
<td>5 F</td>
<td>145 cm</td>
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Contact
Should you have any questions our Customer Service & Sales Support team is happy to advise you.

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