pfmmedical
Quality and Experience

Made in Germany

VSD Occlusion System
Nit-Occlud® Lê VSD

pfm medical's unique Nitinol coil design developed for the transcatheter occlusion of Ventricular Septal Defects (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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NEW

Nit-Occlud® Lê VSD

- New universal handle
- New pusher
- New Packaging

Nit-Occlud® Lê VSD unique flexible coil design for the closure of Ventricular Septal Defects (VSD). Closure of perimembranous (aneurysmatic) and muscular VSDs. In all 350 cases [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® 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 [1,2] reported cases.

Broad range of different sizes
Nit-Occlud® Lê VSD is available in diameters 8, 10, 12, 14 and 16 mm (largest distal winding), making the implant suitable for closing VSDs of various shapes and sizes.

Small Delivery Sheaths
Nit-Occlud® Lê VSD can be deployed through small implantation sheaths of 6F and 7F.

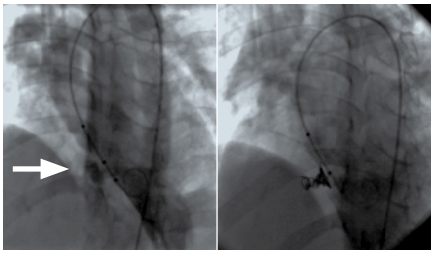
Details

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

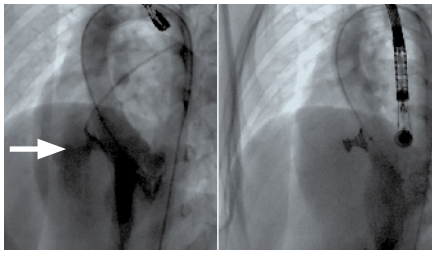
Portfolio

- **Nit-Occlud® Implantation Sheath**
  VSD Implantation Accessory
- **Multi-Snare® VSD-Loop Set**
  VSD Implantation Accessory
- **Nit-Occlud® PDA**
  PDA Occlusion Device (coil type)

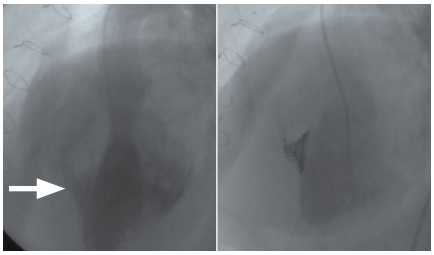
Use



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



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



Case 2: Muscular VSD
Patient: male, 25 years old
VSD size: ⌀ RV 6 mm, ⌀ LV 15 mm
Selected coil: 14 x 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® Lê VSD Spiral Coil System for VSD Occlusion" (clinicatrials.gov identifier NCT00390702).
[2] "The Nit-Occlud® Lê VSD Registry", publication in preparation

Knowledge

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 implantations[1,2] no permanent heart block has been reported.

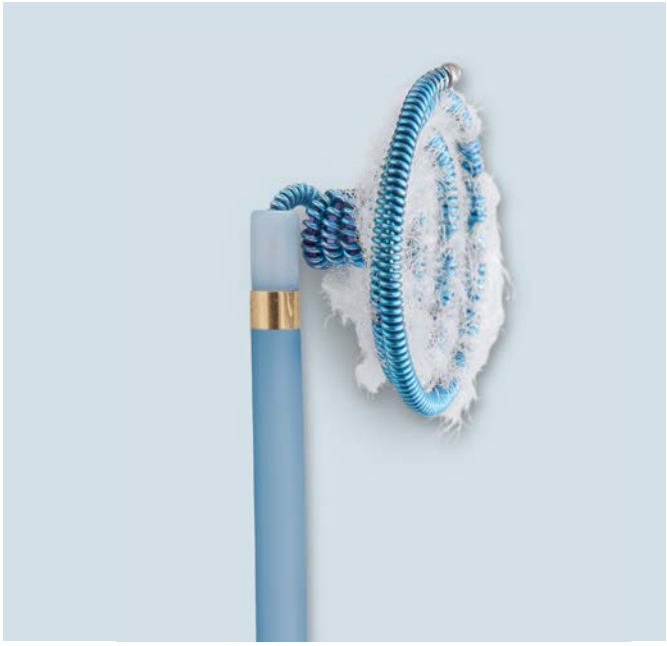


Fig. A

Fig. B

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.

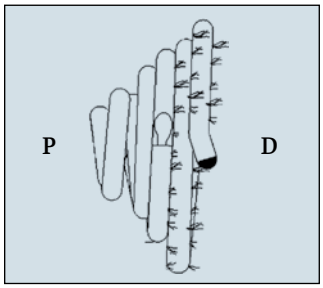
Configurations

The Nit-Occlud® Lê VSD is available in the sizes 8 x 6, 10 x 6, 12 x 6, 12 x 8, 14 x 8, and 16 x 8 mm corresponding to the distal and proximal diameters respectively.
The 14 x 8 mm and 16 x 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.



P = proximal
D = distal

Scan the QR code or follow the link and see how the implant works

http://www.pfmmedical.com/clip-vsd

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*

REF	Distal Coil Diameter (D)	Proximal Coil Diameter (P)	Recommended Implantation Sheath	Implantation Catheter Length
149086V1	8 mm	6 mm	6 F	105 cm
149106V1	10 mm	6 mm	6 F	105 cm
149126V1	12 mm	6 mm	6 F	105 cm
149128V1	12 mm	8 mm	7 F	105 cm
149148V1	14 mm	8 mm	7 F	105 cm
149168V1	16 mm	8 mm	7 F	105 cm

Multi-Snare® VSD-Loop Set

Specially designed to support the implantation of **Nit-Occlud® Lê VSD.**

- *Content: snare, snare catheter, guide wire, 2 clips*

REF	Diameter loop	Catheter Length	Snare Catheter
147015	15 mm (15-20)	145 cm	5 F

The set features a 260 cm hydrophilic-coated crossover wire (0.035 inch with 60° angled tip), and 2 metal clips.

Contact

Should you have any questions our Customer Solutions Team will be glad to assist you.

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Certified according to
DIN EN ISO 13485

Products are subject to alterations
Nit-Occlud®: registered trademark in Germany

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