Vet-PDA Occluder™

en Instructions for use 5

www.evomedvc.com

Explanation of the symbols on label and packaging

REF	Reference Number
LOT	Lot Number
SN	Serial Number
	Attention - note the following information
	Read carefully Instructions for Use
	Protec from direct sunlight
	Expiry Date
	Store in a dry place
	For single use only
	Do not resterilise
STERILE EO	Sterilized by Ethylene Oxide

	Do not use if packaging is damaged
	Manufacturer
	Sin látex
	Sin dietilhexilftalato(DEHP)

Veterinary Instructions for Use Vet-PDA Occluder™ Implantable device to close a patent ductus arteriosus

Product Description

The implantable device is made of a seamless nitinol wire (Figs. 1 to 3) and features a unique configuration to secure the implant in the ductal ampulla.

Fig. 01: Dista view

Fig. 02: Side view

Fig. 03: Proximal view

The elasticity of the Vet-PDA Occluder™ allows it to adapt to a wide range of duct morphologies.

The implantable device is attached to a controlled-release system (Figs. 4 and 5, Table 1).

El Vet-PDA Occluder™ is an implantable, invasive veterinary device that comes into direct contact with the circulatory system. It is implanted using a minimally invasive technique called cardiac catheterization.

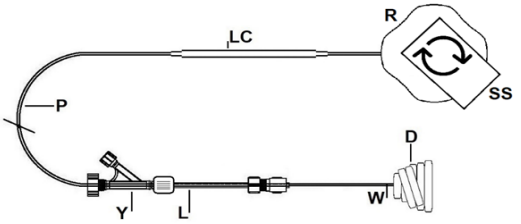

Fig. 04: Complete system

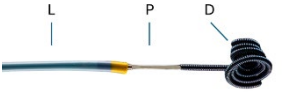

Fig. 05: Side view

Letra	Descripción
D	Device
W	Guide Wire
L	Transporting Cateter “Loader”
Y	Key "Y"
P	Pusher
LC	Loading catheter
R	Release System
SS	Security Seal

Table 01

Overview

Implantation of the device by cardiac catheterization should be performed exclusively by a trained veterinarian. It is recommended that you read these instructions carefully and take into consideration the characteristics detailed on the label.

Product Identification

Each product label contains tear-off labels that allow the product to be accurately identified.

Preserve product information; remove the sticker and attach it to the patient' s medical record.

Indication

The Vet-PDA Occluder™ is an implantable device developed for transcatheter closure of the patent ductus arteriosus (PDA) in defects that are anatomically compatible with the morphology of the device.

Contraindications

Pathological or physical conditions that prevent the implantation of a Vet-PDA Occluder™ such as:

1. Associated cardiomyopathy
2. Immunological or oncological diseases
3. Active infections
4. Febrile syndrome of unknown origin
5. Hematological diseases
6. Allergy to device components (nickel)
7. Endocarditis
8. Allergy to contrast dye used in catheterization.
9. Thrombosis anywhere along the catheter placement pathway
10. Patients with veins that are too small or with abnormal connections that do not allow safe or direct access to the right heart.

Possible Complications

- Embolization of the Vet-PDA Occluder™
- Blockage of the aorta or pulmonary arteries
- Hemolysis
- Weak peripheral pulse or absent
- Vascular perforation
- Haemorrhage
- Bruising at the puncture site
- Adms
- Fever
- Endocarditis
- Death

Precautions

- **Use the Vet-PDA Occluder™ only to occlude patent ductus arteriosus. Do not use this device for other pathologies.**
- **Check that the device conforms to the angiographic dimensions of the defect.**
- **Make sure the implantation catheter is the correct one for your chosen device.**
- **If it is necessary to use a very small device in a patient weighing more than 1.5 kg, it is recommended to use a stabilizing sheath because contraction of the right ventricle can cause instability in the implantation sheath.**
- **Make sure the implantation catheter is appropriate for the weight of the patient. patient to avoid vascular damage.**
- **To avoid the risk of air embolization, all catheters should be carefully purged.**
- **Keep your system straight during the procedure. Avoid accidentally tampering with the guide wire: Do not tamper with the Y-connector seal or torque device until you are sure it is time to release the device.**

- Avoid excessive manipulation of the device, procedures or insufficient heparinization of the patient.
- If the implant becomes embolized, attempt a capture by minimal intervention. Learn about trapping techniques and purchase the necessary equipment (e.g. loop catheters, forceps, long sheath).
- Each device has been packaged in a controlled medium, and sterilized with ethylene oxide; supplied pyrogen-free. The device is single-use only. It is recommended to store the product in a dry place protected from extreme humidity. Products should not be exposed to direct sunlight.
- Do not use the product if the container is damaged, opened, wet, has become undamaged.

  past the expiration date or a system component is corrupted. In any of these cases, contact the manufacturer or distributor.
- Do not reuse the device, do not reprocess it, do not sterilize it again.

  Reuse, reprocessing, or re-sterilization of single-use products may lead to inadequate performance or loss of functionality.
- Reuse of single-use products may cause exposure to pathogens such as viruses, bacteria, fungi or prions.
- Residues of veterinary products and their components may constitute a biohazard.

Patient Medication

Broad-spectrum antibiotics may be given for antibacterial prophylaxis; One dose before and one to two doses after implantation is recommended or proceed as established at your center. Antibiotic prophylaxis for 7 to 10 days is recommended.

Duct Measurement Parameters

Perform an aortogram in lateral projection:

A Measure the minimum diameter (A) of the duct.

B Measure the diameter of the aortic ampulla (B).

C Measure the length (C) between the lung opening and the aortic opening. (Fig. 6)

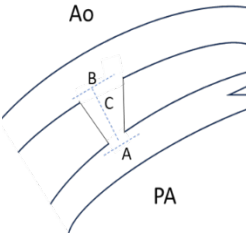

Fig. 06

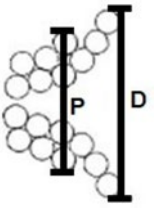

Fig. 07

	Description
PA	Pulmonary Artery
Ao	Aorta
A	Minimum Diameter
B	Blister Diameter
C	Conduit Length

Tabla 02

Choice of device

Based on the measurements, duct type, and recommendations below, the appropriate Vet-PDA Occluder™ device type should be selected:

• The length of defect C must be equal to or greater than the length shown in the table.

• The distal diameter of the spiral device D must be at least 3 mm larger than the minimum diameter A.

• Diameter D must also be the maximum size that diameter B can accommodate.

Reference Number	Diameter (mm) D	Diameter (mm) P	Defect Diameter (mm) A	Min. defect lenght (mm) B
VETPDA000404	4	4	< 2	> 4.0
VETPDA000504	5	4	< 2	> 5.0
VETPDA000605	6	5	< 2	> 6.0
VETPDA000706	7	6	< 3	> 7.0

Tabla 03

Description of the implantation technique

- The recommended implantation catheter should be placed through the defect from the intravenous line and in the usual manner.
- Visually check the entire system and visually check if all components are in place.
- Assemble the transport catheter (L) with the Y(Y) key.
- Retract the pusher (P) until the device (D) is completely inside the transport catheter (L), preferably in a heparinized solution.
- Purge the entire system with a heparinized solution (1 IU/mL), according to the usual technique. It is recommended to aspirate the heparinized solution at least once to remove air bubbles.
- Connect the Transport Catheter (L) to the Implantation and Push Catheter slowly push the pusher (P) until the device (D) reaches the end of the implantation catheter.

- Check the position of the implantation catheter and implant using fluoroscopy.
- Slowly push the pusher (P) to unfold the distal turns of the device in the aorta (Fig. 09).

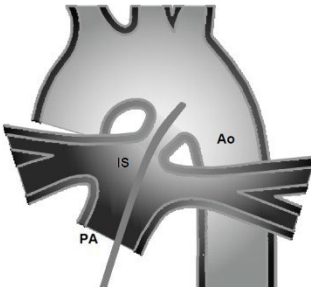

Fig 08

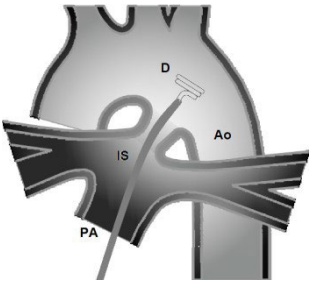

Fig 09

- Pulling the implantation catheter, gently arrange the distal turns of the device against the aortic ampulla.
- Slowly advance the pusher (P) and slowly retract the implantation catheter (IS). At this point you can see the final configuration of the Vet-PDA Occluder™ (D) (Fig. 12)

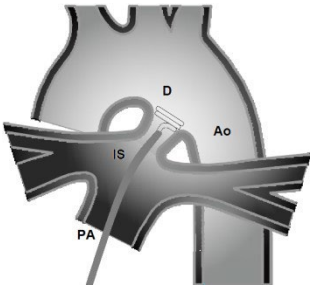

Fig 10

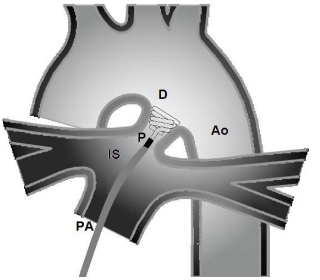

Fig 11

NOTE: Check that at least one turn of the device (D) is positioned on the lung side.

1. Slowly retract the implantation catheter to allow the release of the device (D).
2. Physically stabilize the device.
3. Perform scopy to see if the deployment was successful.
4. Perform intraoperative ultrasound for assessment of flow and position (residual flow until release is possible).

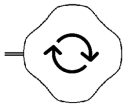

Fig. 12

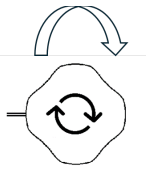

Fig. 13

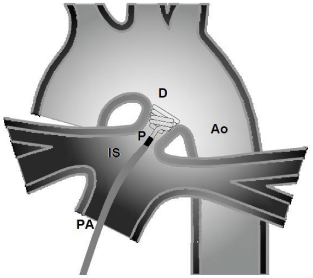

Fig.14

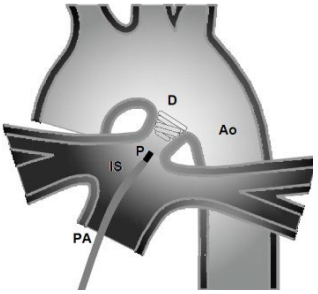

Fig. 15

- Remove or cut the security seal (SS) from the release system composed of two rotating pieces (R).
- With one hand hold the release system firmly (R) and with the other hand turn the steering valve clockwise until you can see the release of the device (D). Fig. 12 – 15.

1. NOTE: Make sure the pusher (P) is as extended as possible when releasing the device (D).

Patient Tips

- It is important to consider possible patient allergies, especially to contrast media.
- It is advisable to inform the tutor orally and in writing about the intervention and its possible complications.
- It is recommended that the patient maintain rest for 24 hours after implantation and relative rest for the following 90 days.
- Clinical and echocardiographic follow-up is recommended after 24 hours, 30 days, and 3 months.

Problem Solving

In the event that the device (D) exits the Y Key (Y) of the Loader Conveyor Catheter (L) when pulling the pusher (P), insert the device (D) through the Loading Catheter (LC). Fig. 16-17.

Insert the Loading Catheter (LC) into the Y-Key (Y) of the Loader (L) until you feel resistance. Fig. 18.

Push the thin catheter from the loading catheter (LC) and push the pusher (P) until the device is inside the loader (L) and follow the procedure by repeating the purge Fig. 19.

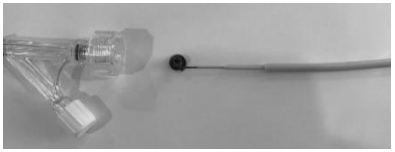

Fig. 16

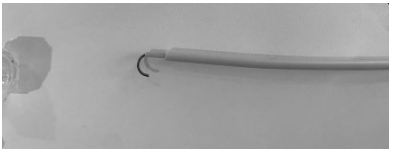

Fig. 17

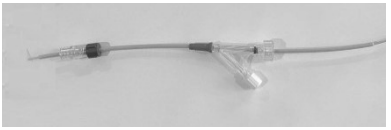

Fig.18

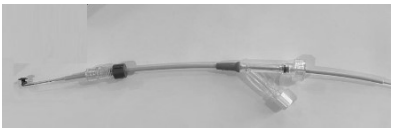

Fig. 19

Way of Disposal

The veterinary products and accessories used could pose a biohazard. For this reason, products and their accessories must be handled and disposed of in accordance with recognized veterinary procedures, applicable legal and local regulations.

Notes

EVOMED, S.L.U.
Ctra. Torrejón-Ajalvir K. 5,200
28864 Ajalvir (Madrid) SPAIN
Tel: +34 91 884 42 20
info@evomedvc.com

www.evomedvc.com