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Lifetech SCIENTIFIC

HeartR™

PDA Occluder

Instructions for Use

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Contents

1 Device Description

- The HeartR™ PDA Occluder is a percutaneous transcatheter occluding device for the non-surgical closure of patent ductus arteriosus defects. The device consists of a knitted nitinol wire mesh, which has been heat set to expand to a T-shape. The disc on the aorta side is designed to hold the plug at the orifice of the ductus arteriosus, while the waist expands to fill and occlude it. A PTFE membrane is sewn inside the disc with nylon thread on the aorta side, and two PTFE membranes are sewn inside the waist to help blocking the abnormal blood flow from the aorta into the pulmonary artery.
- The HeartR™ PDA Occluder must be used in combination with the SteerEase™ Introducer. The introducer contains a coil reinforced sheath, a dilator, a loader, a haemostatic valve and a delivery cable. The introducer is used to advance the HeartR™ PDA Occluder to the proper position. The SteerEase™ Introducer (Refer to Figure 1) is comprised of:
  - ✧ Sheath: The sheath is used to advance the device to its desired position.
  - ✧ Hemostatic valve: The haemostatic valve at the proximal end of the sheath minimizes bleeding. The sideport with the flexible extension tube and stopcock are used to flush the system.
  - ✧ Dilator: The dilator is used to ease penetration of the tissues and the vessel wall
  - ✧ Loader: The loader is used to introduce occluder with the attached delivery cable into the sheath.
  - ✧ Delivery cable: The delivery cable is used to advance the occluder through the sheath, hold it in position while the sheath is pulled back to deploy the occluder and to retrieve it, if either the size, the position or the expansion of the occluder are deemed to be unsatisfactory.
  - ✧ Plastic vise: The plastic vise screwed top the proximal end of the delivery cable is used to facilitate direction control and serve as “handle” for disconnecting (unscrewing) the delivery cable from the device.

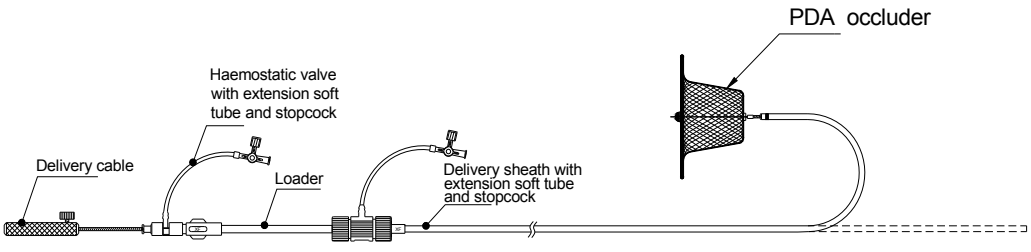


Figure 1 The HeartR™ PDA Occluder and SteerEase™ Introducer

2 Indications and Usage

- The HeartR™ PDA Occluder is a percutaneous, transcatheter device, intended for the non-surgical closure of patent ductus arteriosus (PDA).

- Indications:
  - ✧ Patient has PDA or PDA accompanied with other mild cardiac disease.
  - ✧ Patients weighing more than 6 kg, and 6 months old and above.
  - ✧ The narrowest portion of the PDA is 2 mm or larger.

3 Contraindications:

- ✧ Patients have PDA which is needed for survival of patient due to other cardiac anomalies.
- ✧ Patients weighing less than 6 kg, or less than 6 months old.
- ✧ Presence of thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the defect is gained.
- ✧ Active endocarditic or other infections producing bacterium.
- ✧ Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate sheath size.
- ✧ Patients with pulmonary hypertension with pulmonary vascular resistance over 8 woods units or 0.4 Rp/Rs.

4 Warnings:

- ✧ The device should be removed if more than 3 mm extend into the pulmonary artery, or if more than half of the left pulmonary artery lumen is obstructed by the device.
- ✧ Patient allergic to nickel may suffer an allergic reaction to the device.
- ✧ The HeartR^{TM} PDA Occluder and SteerEase^{TM} Introducer should only be used by those physicians trained in transcatheter defect closure techniques.
- ✧ Physicians must be prepared to deal with emergency situations which require removal of embolized devices that result in a critical hemodynamic compromise. This includes the availability of an onsite surgeon.
- ✧ Embolized devices must be removed. Embolized devices should not be withdrawn unless they have been adequately collapsed within a sheath.
- ✧ The HeartR^{TM} PDA Occluder and SteerEase^{TM} Introducer are for single use only. Do not reuse or resterilize. Structural integrity and/or function may be impaired or be lost through cleaning,

resterilization, or reuse and may cause adverse patient reactions. Lifetech will not be responsible for any direct or consequential damages or expenses resulting from reuse of any of the components in the HeartR™ PDA Occluder and SteerEase™ Introducer.

- ✧ Do not use if the sterile barrier has been compromised in any way.
- ✧ Do not release the HeartR™ PDA Occluder from the delivery cable if the device does not conform to its original configuration or if the device position is unstable. Withdraw the device into the sheath and redeploy it. If still unsatisfactory, withdraw the device completely and replace it with a new device.
- ✧ Double check the connection safety before loading the device into the loader.
- ✧ Retrieve the device when it is hard to release the device from the delivery cable.

5 Precautions:

- ✧ Both the HeartR™ PDA Occluder and the SteerEase™ Introducer are for single use only, and the sterilization expiry period is two years. Do not reuse or resterillze them.
- ✧ Post-procedure
  - Patients should take appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at the discretion of the physician
  - Lung perfusion scan should be completed if the flow through is greater than 3 m/s, or if the Z-score is -2 for the left pulmonary artery diameter.
- ✧ MR conditional

  A patient with an implanted HeartR™ PDA Occluder can be scanned safely immediately after placement of the device under the following conditions:
  - Static magnetic field of 3 T or less.
  - Spatial gradient magnetic field of 720 G/cm or less.
  - Maximum MR system-reported, whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

Remark: MRI image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

- ✧ Use in specific populations
  - Pregnancy – Care should be taken to minimize the radiation exposure to the fetus and the

mother.

- Nursing Mothers – Although appropriate biocompatibility testing has been conducted for this implant device, there has been no quantitative assessment of the presence of leachables in breast milk.

6 Potential Adverse Events

- Placement of the HeartR™ PDA Occluder involves using standard interventional cardiac catheterization techniques. The following adverse events (listed in alphabetical order) might be expected from interventional cardiac catheterization techniques.

✧ Allergic reaction
✧ Arrhythmias
✧ Cardiac temponade
✧ Thrombus formation
✧ Septal tearing
✧ Device migration
✧ Injury to the nerve or vessel well
✧ Cardiac perforation
✧ Incomplete sealing of the defect
✧ Infection
✧ Pulmonary artery dissection
✧ Fever

7 Product Features

- The HeartR™ PDA Occluder and the SteerEase™ Introducer are packaged separately. The occluder and the introducer are available with specifications in the following table (Figure 2 & Table 1).

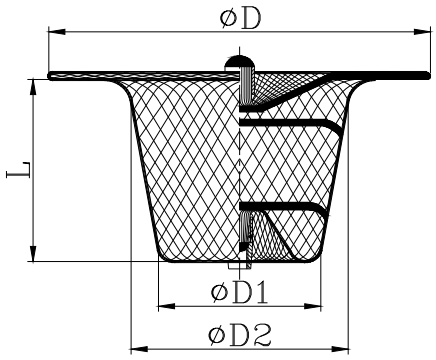


Figure 2 Structure of the HeartR™ PDA Occluder

Table 1 List of available HeartR™ PDA occluders and recommended introducers

unit: mm

Occluder specification	ΦD	ΦD1	ΦD2	L	Recommended sheath size
XJFD0406	10	4	6	7	SFP5F-6F
XJFD0608	12	6	8	7	SFP6F-7F
XJFD0810	14	8	10	7	SFP7F
XJFD1012	16	10	12	7	SFP8F

XJFD1214	20	12	14	7	SFP8F-9F
XJFD1416	22	14	16	8	SFP8F-9F
XJFD1618	24	16	18	8	SFP9F-10F
XJFD1820	26	18	20	9	SFP10F-12F
XJFD2022	28	20	22	9	SFP12F
XJFD2224	30	22	24	10	SFP12F-14F

8 Directions for Use

- Perform a right heart catheterization in a routine way.
- Size the defect and select the correct occluder size
- Select a HeartR^{TM} PDA Occluder based on the smallest diameter measured in the PDA. It is recommended to select a device of which the smaller end is at least 2 mm larger than the narrowest portion of the PDA.
- Introduce a 0.038-inch J-tipped exchange guidewire. Advance the introducer sheath with dilator over the exchange wire via the pulmonary artery into the aorta and position the sheath in the descending aorta while removing the dilator.
- Pass the delivery cable through the loader and screw the PDA occluder clockwise onto the tip of the delivery cable.
- Immerse the device and the loader in saline solution and pull the HeartR^{TM} PDA Occluder into the loader.

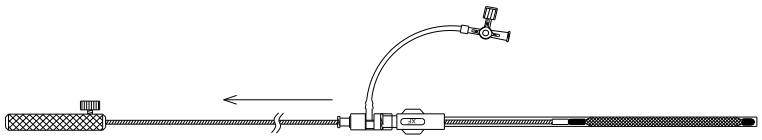


Figure 3 Illustration of loading the device into a loader

- Introduce the loader into the delivery sheath and without rotation, and advance the device into the descending aorta.
- Deploy the retention skirt only and pull firmly against the orifice of the PDA. This can be observed under fluoroscopy, or it can be clearly felt as a tugging sensation in synchrony with the aortic pulsation. The position of the device is confirmed with repeated angiograms in the aorta using the pigtail catheter. The device can be adjusted until the retention skirt is well seated at the orifice. Retract the delivery sheath and deploy the cylindrical portion of the device securely in the patent ductus arteriosus while applying slight tension.

- Perform an aortography to verify the correct position of the device.

WARNING:

Remove the device if over 3 mm extends into the pulmonary artery, or if more than half of the left pulmonary artery lumen is obstructed by the device. In questionable cases, perform transthoracic echocardiography before releasing the device with Doppler measurement of the left pulmonary artery flow velocity. The device should be removed if left pulmonary artery flow velocity is greater than 3.0 m/s (or greater than 75% of the LPA velocity before cardiac catheterization).

- If its position is not satisfactory, recapture the device into the sheath by pulling it back on the delivery cable.

Note:

Do not release the device from the delivery cable if the device does not conform to its original configuration or if device position is unstable. Withdraw the device into the sheath and redeploy. If still unsatisfactory, withdraw the device completely and replace it with a new device.

- Detach the device by rotating the cable counterclockwise as indicated by the arrow on the vise. Repeat aortography.

9 Post-procedure

- All patients should be kept overnight for observation.
- Antibiotic therapy.
- Reexamination by echocardiography, ECG and chest X-ray at 24 hours, 1, 3, 6 and 12 months respectively, after the procedure.

10 Expiry Date

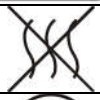
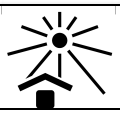
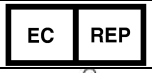
- Both the HeartR™ PDA Occluder and the SteerEase™ Introducer are sterilized by ethylene oxide. The production date and expiry date are marked on the label. DO NOT use the overdue product.

11 Package and Label

- The HeartR™ PDA Occluder is supplied sterile. The HeartR™ PDA Occluder and the SteerEase™ Introducer are packaged separately.
- The HeartR™ PDA Occluder is packaged and protected in a PETG tray sealed with dialyzing paper, and then the product is sealed with another dialyzing pouch, on where a label and a sterilization indicator are attached. The product is sterilized and put in a box with IFU, patient card, customer feedback form, and certificate of compliance. An outer label is attached on the box.

- All the components of the SteerEase™ Introducer are fixed and protected with scale boards, then sealed in two dialyzing pouches, where a label and a sterilization indicator are attached. The product is sterilized and put in a box with IFU, customer feedback form, and certificate of compliance. The primary label is attached on the box.

The symbols used are as the following:

	Date of manufacture
	Manufacturer
	Use by
	Serial number
	Batch code
	Sterilized using ethylene oxide
	Non-pyrogenic
	Do not reuse
	Consult Instructions For Use
	Keep away from the sunlight
	Keep dry
	Catalogue number
	Do not use if package is damaged
	Do not resterilize
	Authorised representative in the European Community
	Store at room temperature
	MR Conditional

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