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Pressure/Volume Catheter

Disclosure of risks

CD Leycom conductance catheters are designed and manufactured using biocompatible materials well sterilized and free from pyrogens. However, care should be taken in all patients for a suspected reaction indicating pyrogenicity or allergic reactions.

WARNINGS and precautions

1. The Inca PV Loop System cannot be used as vital functions monitor.
2. Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.
3. Sterile, Single use: Do not reuse, reprocess, or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to life- threatening injury.
4. Do not use past the shelf-life stated on the catheter packaging.
5. Do not use if packaging is damaged. The catheter pouch should be inspected by the physician on integrity prior to usage.
6. Do not bend the catheter part inside the sterile pouch.
7. Practitioners must be aware of complications associated with this procedure including myocardial perforation, aortic regurgitation, cardiac arrhythmia and cardiac fibrillation and other dysrhythmias, air embolism, thrombi and bacteremia.
8. Care should be exercised when passing catheter in patients with left bundle-branch block because right bundle-branch block induced by traumatic catheter passage could result in complete heart block and asystole.
9. Practitioner must be aware of clinical conditions that may limit use of catheter guide lumens, such as: bacteraemia or sepsis, coagulopathies, permanent venous implants (e.g. vena cava filters), intra-arterial or intra-ventricular thrombus.
10. The catheter should be inspected prior insertion by the physician on integrity of the distal end and its pigtail.
11. Patients should receive anticoagulation when the catheter will be applied for left heart measurements.
12. The catheter should not be inserted in patients undergoing magnetic resonance imaging.
13. To lessen potential for myocardial perforation and mal-positioning, pass catheter under fluoroscopic or ECHO guidance by preference via a catheter exchange procedure.
14. The pressure calibration should be completed and confirmed by the measurement device prior to catheter insertion.
15. A guidewire should be used to straighten the pigtail prior to removal of the catheter.
16. No modification of this equipment is allowed
17. CD Leycom conductance catheters must be used for measurements exclusively as part of the Inca PV Loop system.
18. The CD Leycom conductance catheters must NOT be used for patients with a body weight of less than 7 kg.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Description

The CD Leycom® Pressure/Volume Measuring Catheter is a radiopaque vascular catheter with a pressure sensor and 12 electrodes for volume measurements mounted in the distal end. All CD Leycom conductance catheters are for single use and are sterilized using ethylene oxide.

Indications for use

The CD Leycom conductance catheters are designed for short-term continuous measurement of ventricular blood pressure and volume to allow real-time assessment of cardiovascular function. Refer to the CFL-M User Manuals for a detailed description of the need for pressure and volume measurements in the clinical setting.

Contra-indications

No direct contraindications.

Relative contra indications to cardiac catheterization include: coagulopathy, critical heart failure, fever, systemic infection, transient ischemic attack and uncontrollable arrhythmia or hypotension

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Recommended procedure

Use sterile technique

The CD Leycom conductance catheters can be delivered via various venous and arterial access sites, such that the catheters will be delivered to one of the cardiac ventricles. These approaches with warnings and precautions are detailed in the literature. The instructions below provide a general guide fc use. Physicians may wish to alter procedural details i accordance with their clinical judgement.

Catheter preparation

1. Remove the catheter from the package and withdraw the protective sleeve.
2. Flush catheter lumens (if applicable).
3. Immerse the pressure sensor for approximately 10 seconds in a sterile saline solution.
4. Leave the pressure sensor untouched and connect the catheter to the CFL-M pressure module interface. The measurement interface may request confirmation for calibration or may start calibration immediately.
5. The pressure calibration takes about 20 seconds; the interface will indicate when calibration has been approved. Recalibrate pressure sensor when necessary only when pressure sensor is exposed to atmospheric pressure and recently wetted by saline solution.
6. Insert an appropriately sized guide wire (diameter less than or equal to 0.025 Inch) into the catheter i applicable. Note: some resistance may be felt when the guide wire passes the sensor and straightens the tip o the catheter. This will not damage the catheter.
7. Introduce the catheter into the blood vessel using a vascular entry technique of choice.
8. After catheter has been inserted using fluoroscop advance the catheter into the ventricle. For catheters wi a lumen, place the guide wire across the valves first ar then pass the catheter over the guide wire.
9. Position the tip (pigtail) of the catheter in the apex of the ventricle. For catheters with a lumen, remove the guide wire or pull it back towards the proximal end of the catheter.
10. Review the User Manual for the CFL-M for pressure anc volume recording signals using this catheter.

Catheter removal

1. Prior removal of the catheter from the ventricle it is advise to re-insert the guidewire to straighten the pigtail to avo damages to cardiac valves (aortic valves or tricuspid valve
2. Make a recording during the catheter retrieval, it will allow to determine the pressure gradient across the valves.
3. Record the Inca signals when the pressure sensor is leaving the blood vessels, this allows to determine an eventual pressure off set.
4. The immediate pressure value at the moment (within 8 r seconds) the pressure sensor is out of the vessel indicate such an eventual pressure off set, which can be us for correction of previously measured pressure recording

General precautions

Store catheter in a cool, dark, dry place. Do not use open or damaged packages. Use prior to the "Use Before" date indicated on the package label. Do not resterilize.
Exposure to temperatures exceeding 40°C may damage the catheter.
Before using a catheter, always check the expiration date on the catheter package and the sterilization mark on the inner pouch.
Discard CD Leycom Pressure/Volume Measuring Catheters and accessories after one procedure. Accordingly, CD Leycom will not be responsible for any direct or consequential damages or expenses resulting from reuse of CD Leycom catheters.
Do not alter the catheter or any other kit/set component during insertion, use or removal.
Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
Heavy load above catheter packaging or overtight stacking during storage may result in compromised sterility or physical damage to catheters.

Environmental

The catheters are intended to be used in the professional healthcare facility environment.
Prior to use, the catheter should be stored in a dedicated hospital sterile storage area.

Disposal of catheters

At the end-of-life catheters are considered hazardous medical waste and should be disposed of via dedicated hospital procedures for hazardous materials.
The unused catheters past their shelf-life are considered small electronics waste and should be discarded via standard route for small electronic disposal.

Explanation of symbols

	Manufacturer symbol		Do not re-use
STERILE EO	Sterilized using ethylene oxide		Do not resterilize
	Temperature limits		Date of manufacture
	Consult instructions for use		Do not use if package is damaged
LOT	Batch code		Use-by date

Rx only — CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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13 Sep 2023

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