LEYCOM® Catheter
User manual V008
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The Pressur/Volume catheter, Leycom Catheter® is manufactured, marketed and supported by:

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TRADEMARKS

LEYCOM® Catheter® is a registered trademark of CD Leycom, a registered tradename of CardioDynamics BV

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

The Inca PV Loop System cannot be used as vital functions monitor

Prior to use read all package insert warnings, precautions, and instructions. Failure to do may result in severe patient injury or death

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

Do not use past the shelf-life stated on the catheter packaging

Do not use if packaging is damaged. The catheter pouch should be inspected by the physician on integrity prior to usage

Do not bend the catheter part inside the sterile pouch.

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.

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.

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.

The catheter should be inspected prior insertion by the physician on integrity of the distal end and its pigtail.

Patients should receive anticoagulation when the catheter will be applied for left heart measurements.

The catheter should not be inserted in patients undergoing magnetic resonance imaging.

To lessen potential for myocardial perforation and mal-positioning, pass catheter under fluoroscopic or ECHO guidance by preference via a catheter exchange procedure.

Standard grounding procedures must be followed if electrosurgical instruments are used.

The pressure calibration should be completed and confirmed by the measurement device prior to catheter insertion.

A guidewire should be used to straighten the pigtail prior to removal of the catheter

No modification of this equipment is allowed

CD Leycom conductance catheters must be used for measurements exclusively as part of the Inca PV Loop system

Symbols on conductance catheters packaging

	Manufacturer symbol. The name and address of the manufacturer are noted near this symbol.		Do not re-use Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Sterilized using ethylene oxide		Do not resterilize Indicates a medical device that is not to be resterilized
	Temperature limits Indicates the temperature limits to which the medical device can be safely exposed.		Date of manufacture Indicates the date when the medical device was manufactured.
	Consult instructions for use Read the instructions in this operations manual carefully before using the catheter, and read the safety instructions before setting up or using this device.		Do not use if package is damaged Indicates a medical device that should not be used if the package has been damaged or opened.
	Batch code		Use-by date Indicates the date after which the medical device is not to be used.

CE 0344	CE marked device. 0344: Registered Notified Body: DEKRA, The Netherlands

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1. Conductance Catheter

1.1 Indications for use

The conductance catheters are intended for use with the CD Leycom CFL-M devices during catheterization laboratory procedure where the quantitative assessment of ventricular function is desired. The CD Leycom conductance catheters are designed for short-term continuous measurement of blood pressure and volume. Refer to the CFL-M User Manuals for a detailed description of the need for pressure and volume measurements in the clinical setting.

1.1.1 Intended Use(s)

The CD Leycom **Pressure-Volume Measuring Catheter** is intended for short-time continuous measurements of intraventricular blood pressure and volume, for real-time cardiac function analysis.

The CD Leycom **Pressure Measuring Catheter** is intended for short-time continuous measurements of intravascular and intra-cardiac blood pressure, for derivation of high-fidelity pressure waveforms, and for injection of radiopaque media in ventricular angiography.

1.1.2 Intended users

The user must be a health care professional with the relevant medical background, skills and training to work with the catheter. A clinician trained in placing cardiac catheters, would be able to sufficiently position the catheter.

1.1.3 Essential performance

The conductance catheter does not have an essential performance as defined by IEC 60601-1 international standard.

1.1.4 Contra-indications

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

1.1.5 Intended patient population

The intended patient population for catheterization are adults.

1.1.6 Clinical benefits

The clear and peer reviewed routine clinical and clinical research capabilities of CD Leycom's intra-ventricular pressure-volume analysis technique outweighs the apparently small chance on a clinical complication by using this analysis technique. The numerous publications showing new insights in cardiac diseases and its therapeutics, which could hardly be achieved by other techniques, testifies of added value of using this technique for the cardiac patients

1.2 Catheter description

All CD Leycom conductance catheters are for single use and are sterilized using ethylene oxide.

The CD Leycom conductance catheter is a radiopaque vascular catheter with a pressure sensor and 12 electrodes for volume measurements mounted at the distal end.

1.2.1 Materials contacting the patient

The components of the conductance catheters contacting the patients are:

- Tubing (tested biocompatible)
- Stainless steel electrodes
- Standard catheter adhesives (tested biocompatible)

1.3 Catheter types

Catheters are available in various Fr. sizes. All CD Leycom catheters are CE marked for human use.

All catheters have 12 electrodes to measure pressure, volume and ECG. The types available are:

CD Leycom Standard Pressure/Volume Dyssynchrony Catheters				
Model	Size	Spacing	Pressure sensor	Pigtail/ lumen
CA-41063-PN	4 Fr	6 mm	between 5 and 6	Yes / No
CA-41103-PN	4 Fr	10 mm	between 5 and 6	Yes / No
CA-71083-PL	7 Fr	8 mm	between 5 and 6	Yes / Yes
CA-71103-PL	7 Fr	10 mm	between 5 and 6	Yes / Yes
CA-71103-PL	7 Fr	12 mm	between 5 and 6	Yes / Yes

CD Leycom provides two single-channel pressure catheters. These catheters can be used to measure the aorta, venous and arterial pressure.

CD Leycom Standard Pressure/Volume Dyssynchrony Catheters				
Model	Size	Spacing	Pressure sensor	Pigtail/ lumen
CA-61000-PL	6 Fr	n.a.	At distal tip	Yes / Yes
CA-61000-PLB	6 Fr	n.a.	At distal tip	Yes / Yes

For more information regarding catheters please visit: www.cdleycom.com

1.4 Inca PV Loop System description

Inca PV Loop System (IPVLS) consists of:

- CFL-M, model Inca
- Conductance catheter
- Conduct NT software installed on the dedicated computer

An intra-ventricular catheter with an array of conductance electrodes and a high fidelity solid-state pressure sensor is placed in the ventricle over a guide wire. The catheter is connected to the CFL-M acquiring real-time pressure and volume data from up to 7 segments (volume slices perpendicular to the long-axis) in the ventricle.

From the data, time varying changes in intra-ventricular pressure and volume can be monitored on-line on a connected PC running specific software (Conduct NT). Common indices of cardiac performance (SV, Ees, PRSW, +dP/dt, -dP/dt, Tau, etc) are shown, as well as indices of ventricular mechanical dyssynchrony derived from the volume slices.

For the operating instructions of the CFL-M and Conduct NT, the user should refer to the respective Instruction for Use.

2. Recommended procedure

2.1 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 for use. Physicians may wish to alter procedural details in accordance with their clinical judgement.

2.2 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 if applicable. Note: some resistance may be felt when the guide wire passes the sensor and straightens the tip of 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 fluoroscopy, advance the catheter into the ventricle. For catheters with a lumen, place the guide wire across the valves first and 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 and volume recording signals using this catheter.

2.3 Catheter removal

1. Prior removal of the catheter from the ventricle it is advised to re-insert the guidewire to straighten the pigtail to avoid damages to cardiac valves (aortic valves or tricuspid valves)
2. Make a recording during the catheter retrieval, it will allow to determine the pressure gradient over 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 milli seconds) the pressure sensor is out of the vessel will indicate such an eventual pressure off set, which can be used for correction of previously measured pressure recordings.

3. Technical details

3.1 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.

NOTICE Any serious incident that has occurred in relation to the conductance catheter should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

3.1.1 Environment

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.

3.1.2 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.

3.2 Standards and safety

The catheters meet the following safety standards:

EN 60601-1:2006 / A1:2013	Medical electrical equipment - Part 1: General requirements for basic safet and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 60601-2-34:2014	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 14155:2011 / AC:2011	Clinical investigation of medical devices for human subjects – Good clinical practice
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
ISO 15223-1:2016, Cor. 2017-03	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 10555-1:2013	Intravascular catheters - Sterile, single-use intravascular catheters - Part 1 General requirements
EN 10555-3:2013	Intravascular catheters – Sterile and single-use catheters – Part 3: Central venous catheters
EN ISO 10993-1:2009 / AC 2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008 / AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilizatio residuals
ISO 80369-7:2016	Small bore connectors for liquids and gases in healthcare applications – Pa 7: Connectors for intravascular or hypodermic applications
ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 868-7:2009	Packaging for terminally sterilized medical devices. Adhesive coated paper for low temperature sterilization processes. Requirements and test metho
EN ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirement for development, validation and routine control of a sterilization process fo medical devices