INSTRUCTIONS FOR USE
LithiX™ Hertz Contact Intravascular Lithotripsy Catheter

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CE 2265

ENGLISH

Caution:
Federal (USA) Law restricts this device to sale by or on the order of a physician.
For export only – not for sale in the USA

General Information:

- This device should only be used by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA).
- The Summary of Safety and Clinical Performance (SSCP) for this device is available for digital download in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI. The URL to Eudamed is: https://ec.europa.eu/tools/eudamed. The Basic UDI-DI for the LithiX Hertz Contact Intravascular Lithotripsy Catheter is: 081750801LithiXY7
- Any medical waste generated by the device procedure should be safely disposed of according to hospital policy.

1.0 DEVICE DESCRIPTION

The LithiX Hertz Contact Intravascular Lithotripsy Catheter (LithiX HC-IVL) is a proprietary mechanical lithotripsy catheter delivered through the coronary arterial system to access and treat calcified stenoses anticipated to be resistant to full balloon dilation and uniform stent expansion. The LithiX device consists of multiple rows of stainless-steel hemispheres distributed across the surface of a specialty balloon which are intended to atraumatically fragment calcium via the Hertz Contact Stress method of lithotripsy. The LithiX intravascular lithotripsy device disrupts calcium via discrete contact stress points within the target lesion, allowing dilatation of the coronary artery stenosis under low balloon pressure. Additionally, the hemispheres offer the potential to prevent catheter slippage and geographical miss and hold the device in place as it expands during inflation. The hemispheres are distributed along the working length of the balloon and can also serve as markers to aid in visualization of full balloon expansion during treatment, as well as be referenced for accurate vessel sizing, morphology, and location of calcium.

The product compliance table lists the outer diameter of the balloon surface at each pressure. The lithotripsy hemispheres rise approximately 0.25 mm above the surface of the balloon. There are two radiopaque markers located underneath the balloon to aid in fluoroscopic visualization and to facilitate accurate positioning. Additionally, there are two proximal delivery system shaft markers (90 cm and 100 cm from the distal tip) that indicate the relative position of the catheter to the end of a brachial or femoral guiding catheter tip. The distal portion of the catheter including the balloon and hemispheres is coated with a hydrophilic coating to enhance deliverability to the target location.

Key device characteristics are listed in the following table.

Table 1: LithiX HC-IVL Characteristics

Characteristic	LithiX HC-IVL
Available Balloon Nominal Diameters	1.5, 2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5 mm
Available Balloon Nominal Length(s)	14 mm
Catheter Working Length	140 cm
Catheter Design	Rapid Exchange
Balloon Inflation Pressure*	Nominal: 5 atm (1.5, 2.0, 2.5, 2.75, 3.0, 3.25, 3.5 mm diameters); 3 atm (2.25 mm diameter) Rated Burst Pressure: 12 atm
Guiding Catheter Compatibility	6 French (≥ 0.071" ID)

* See product label and enclosed card for product balloon compliance information.

Clinical Benefit:
The clinical benefit of treating lesions with moderate to severe calcification with the LithiX HC-IVL is reduction in the occurrence of restenosis of the treated vessel due to inadequate stent expansion. The LithiX HC-IVL provides for this benefit through Hertz Contact lithotripsy of calcified lesions resulting in calcium fragmentation thereby promoting proper stent expansion and apposition due to the calcium fracture. To quantify the benefit resulting from proper stent expansion after LithiX treatment, the primary patient-relevant clinical outcome parameter is residual stenosis < 50% after stenting with no evidence of in-hospital MACE. A secondary clinical measure is acute gain (after stenting).

The measurable and patient-relevant outcomes and quantitative clinical data from the PINNACLE I trial are summarized in the following table. In the PINNACLE I trial, 60 patients were treated with the LithiX HC-IVL.

Table 2: PINNACLE I Residual Stenosis and Acute Gain

	Outcome	Objective	Result
Residual Stenosis < 50% with no In-Hospital MACE[a] (N=60)[b]	98.3% (59/60)[c] (91.1% to 100.0% CI[d])	80%	Greater than 80% of patients had residual stenosis < 50% with no in-hospital MACE through discharge.
Acute Gain (after stenting) (L=63)[e]	1.60 ± 0.48 mm	Increase in luminal diameter post stenting	A positive acute gain (after stenting) was observed.

[a] MACE = Major Adverse Cardiac Event defined as the composite of cardiovascular death, myocardial infarction, and target vessel revascularization
[b] Patients treated
[c] All patients had residual stenosis < 50%, one (1) patient experienced a myocardial infarction prior to discharge.
[d] Clopper-Pearson's exact 95% confidence interval
[e] Lesions Treated

2.0 HOW SUPPLIED

Sterile: This device is sterilized with electron beam radiation and is non-pyrogenic. **Do not use the device if the package is opened or damaged.**

Contents: One LithiX Hertz Contact Intravascular Lithotripsy Catheter
One Flushing Needle
One Instructions for Use Document
One Compliance Chart
One Oxygen Absorber

Storage: Store at ≤ 25°C.

3.0 INTENDED PURPOSE, INDICATIONS FOR USE, AND INTENDED PATIENT POPULATION

3.1 Intended Purpose

The LithiX Hertz Contact Intravascular Lithotripsy Catheter is intended to treat calcified stenoses by calcium fragmentation.

3.2 Indications for Use

The LithiX Hertz Contact Intravascular Lithotripsy Catheter is indicated for calcium fragmentation of moderate to severely calcified, stenotic de novo coronary artery lesions prior to stenting.

3.3 Intended Patient Population

The intended patient population for the LithiX Hertz Contact Intravascular Lithotripsy Catheter in patients with moderate to severely calcified, stenotic de novo coronary artery lesions.

LIMITATIONS

The safety and efficacy of the LithiX HC-IVL has not been evaluated in patients with:

- Unresolved thrombus at the lesion site.
- Coronary artery spasm of the target vessel in the absence of a significant stenosis.

4.0 CONTRAINDICATIONS

The LithiX Hertz Contact Intravascular Lithotripsy Catheter is contraindicated for use in:

- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon
- Patients with coronary artery spasm in the absence of significant stenosis
- Post dilatation of expanded stent
- Carotid or cerebrovascular arteries

5.0 WARNINGS AND PRECAUTIONS

WARNINGS

- Do not deliver the LithiX HC-IVL through the side cell of a previously placed stent as the balloon could become entangled in the stent.
- Over sizing increases the risk of dissection. To reduce the potential for vessel damage, the inflated diameter of the balloon should not exceed the diameter of the reference vessel.
- The LithiX HC-IVL is not intended for treatment of in-stent restenosis.
- Treatment in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible procedural hemodynamic support, as this patient population carries special risk.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the rated burst pressure (RBP) indicated on the package. Use of a pressure monitoring device is recommended to prevent over pressurization.

- The procedure should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed on site (or at a nearby facility) in the event of a potentially injurious or life-threatening complication.
- To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Consideration should be given to the risks and benefits of use in patients with history of severe reaction to contrast agents.
- Ensure the hemostatic valve is sufficiently open prior to insertion or removal of the LithiX HC-IVL. A hemostatic valve that is too tight may result in hemisphere dislodgement.

PRECAUTIONS

- Intended for single use only. Reuse, reprocess or resterilization of the device may result in loss of device integrity and/or contamination which may result in patient injury, illness, or death.
- Use the catheter prior to the "Use By" date specified on the package.
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- During the procedure, appropriate anticoagulant therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.
- If fluoroscopic guidance indicates that the LithiX HC-IVL has advanced beyond the end of the guide wire, withdraw the catheter and reload the wire before advancing again.
- Do not attempt to reposition a partially deployed balloon. Attempted repositioning of a partially deployed balloon may result in severe vessel damage.
- Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the catheter system.
- If difficulty is experienced during balloon inflation, do not continue; remove the device and do not attempt to reuse it. Select another device.
- Do not use a guiding catheter or guide extension catheter with an inner diameter less than 0.071" or 1.8 mm.
- Do not use a guidewire with a diameter greater than 0.014 in (0.36 mm).
- Infusion of any medium other than a flush of heparinized normal saline through the guidewire lumen may compromise device performance.
- Prior to use, carefully inspect the device for kinks, bends, or other damage. Do not use if damage is noted or if the device is inadvertently contaminated.
- Carefully slide the protective sheath off the balloon and remove the stylet from the guidewire lumen.
- Immediately before insertion of the LithiX HC-IVL into the guiding catheter, wet the balloon with a sterile saline solution in order to activate the hydrophilic coating.
- After removal from the guiding catheter, the LithiX HC-IVL should not be reinserted.

6.0 POTENTIAL INCIDENTS AND SERIOUS INCIDENTS

Potential incidents, serious incidents and undesirable side effects (in alphabetical order) are consistent with standard catheter-based cardiac interventions and include:

- Abrupt closure
- Access site complications
- Acute myocardial infarction/ischemia

- Angina or unstable angina
- Arrhythmias, including ventricular fibrillation
- Arteriovenous fistula
- Cardiac tamponade/pericardial effusion
- Cardiogenic shock
- Cerebrovascular accident/stroke
- Coronary aneurysm
- Coronary artery bypass graft surgery
- Coronary artery spasm
- Coronary vessel dissection, perforation, rupture, or injury, possibly requiring surgical repair or intervention
- Death
- Drug reactions, including allergic reaction to contrast medium
- Embolism
- Emergency or non-emergency coronary artery bypass surgery
- Emergency or non-emergency percutaneous coronary intervention
- Hemodynamic compromise
- Hemorrhage or hematoma
- Hypo/hypertension
- Infection
- Minor vessel trauma
- Myocardial ischemia
- Pyrogenic reaction
- Renal failure/insufficiency
- Respiratory insufficiency
- Restenosis of the treated coronary artery leading to revascularization
- Side branch occlusion
- Slow flow/no reflow
- Thrombosis
- Total occlusion of the coronary artery

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (Elixir Medical Corporation) and the competent authority of the Member State or other applicable health authority, in which the user and/or patient is established. Manufacturer contact information is included on the final page of this Instructions for Use.

Potential adverse events and reporting of serious adverse events should be discussed with patients.

7.0 CLINICIAN USE INFORMATION

7.1 Materials Required

The following materials (not supplied or manufactured by Elixir Medical Corporation) are required for use with the LithiX HC-IVL

- Appropriate guiding catheter(s)
    - Guiding catheter must have a minimum ID of 6F or 0.071”
- Appropriate guidewire
    - Guidewire must have a maximum OD of 0.014 inch (0.36 mm)
    - Guidewire must have a minimum length of 175 cm
- 2-3 syringes (20 cc)
- Heparinized normal sterile saline
- Rotating hemostatic valve
- 60% contrast diluted 1:1 with normal saline
- Inflation device
- Three-way stopcock
- Torque device
- Guide wire introducer

Only commercially approved (e.g., CE marked) devices meeting the specifications listed above should be used with the LithiX HC-IVL.

7.2 Packaging Removal

7.2.1 Carefully inspect the packaging pouch for damage. **Do not use if the package has been damaged or opened.**
7.2.2 Peel open the pouch using aseptic technique to reveal the sterile device.
7.2.3 Pass or drop the sterile device into the sterile field using aseptic technique.

7.3 Inspection Prior to Use

7.3.1 Carefully remove the device with sheath from the hoop. Be careful not to catch the edge of the sheath on the sidearm of the hoop, which may inadvertently unsheathe and expose the balloon.
7.3.2 Prior to use, carefully inspect the device for kinks, bends, or other damage. Do not use if damage is noted or if the device is inadvertently contaminated.

7.4 Preparation for Use

7.4.1 Prepare the guiding catheter, guidewire, and inflation device according to the manufacturer’s instructions.
7.4.2 Carefully slide the protective sheath off the balloon and remove the stylet from the guidewire lumen.
7.4.3 Flush the LithiX device with heparinized saline using the flushing needle.

Caution: **Avoid manipulation of the balloon during flushing of the guidewire lumen.**

7.4.4 Fill a 20 cc syringe with 5 cc of contrast/heparinized normal saline mixture (1:1).
7.4.5 Attach to the proximal hub of the LithiX device and apply negative pressure for 10 seconds.
7.4.6 With the syringe tip pointing downwards, slowly release pressure to neutral.
7.4.7 Attach a prepared inflation device to the hub of the LithiX device, leave on neutral pressure.

Caution: Do not apply negative pressure on inflation device during delivery of the LithiX device to the lesion site.

7.5 Instructions for Use

7.5.1 Prepare the vascular access site according to standard practice.

7.5.2 Insert a guidewire through the hemostatic valve following the manufacturer's instructions.

7.5.3 Advance the guidewire carefully into and through the guiding catheter. When complete, withdraw the guidewire introducer, if used.

7.5.4 Attach a torque device to the guidewire, if desired. Under fluoroscopy, proceed with accepted PTCA techniques to advance the guidewire to and across the lesion.

7.5.5 Wet the balloon of the LithiX device with a sterile saline solution to activate the hydrophilic coating.

7.5.6 Confirm the LithiX device is deflated. Backload the distal tip of the device onto the guidewire ensuring that the guidewire exits the catheter at the notch located distal to the balloon.

Note: When backloading the device onto the guidewire, the catheter should be supported, ensuring that the guidewire does not wrap around the balloon.

7.5.7 Advance the LithiX device over the guidewire until it approaches the hemostatic valve.

7.5.8 Open the hemostatic valve. Insert the catheter while maintaining guidewire position and tighten the hemostatic valve. To facilitate insertion, the balloon must be fully deflated to negative pressure.

7.5.9 Tighten the hemostatic valve to create a seal around the LithiX device without inhibiting movement of the device. This will allow continuous recording of proximal coronary artery pressure.

Note: It is important the hemostatic valve be closed tightly enough to prevent blood leakage around the LithiX device shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon or restricts guidewire movement.

7.5.10 Advance the LithiX device over the guidewire and into the stenosis. Continue under fluoroscopy and use the radiopaque marker band(s) to position the usable (dilating) section of the balloon within the stenosis.

Note: When using the device on long lesion segments (those lesions in which the targeted length of treatment exceeds the length of the LithiX balloon), the distal portion of the target lesion should be treated first. Then, dilatation of the proximal lesion segment may be performed.

7.5.11 Under fluoroscopy, slowly inflate the LithiX lithotripsy device by 1 atmosphere every 1-2 seconds until the desired inflated surface diameter is achieved. The inflated diameter for the final LithiX treatment should equal the reference vessel diameter (refer to the LithiX compliance chart provided on the product label and the compliance card). **Do not exceed the Rated Burst Pressure printed on the package label.**

Note: The diameters listed in the compliance table are the diameters of the <u>surface</u> of the <u>balloon</u>. The balloon hemispheres extend approximately 0.25 mm <u>beyond</u> the balloon surface and are placed around the balloon diameter.

7.5.12 The radiopaque hemispheres of the LithiX device can aid in visualization of full balloon expansion, and can also be referenced for accurate vessel sizing, morphology, and location of calcium. Perform repeat dilatation if needed.

7.5.13 Apply negative pressure to the inflation device and confirm the balloon is fully deflated.

7.5.14 Withdraw the deflated LithiX device and guidewire into the guiding catheter. Using a technique of choice, remove the LithiX device, guidewire, and guiding catheter from the vasculature.

7.6 Catheter Exchange Procedure

The LithiX device has been specifically designed for rapid, single operator catheter exchanges. To perform a catheter exchange, execute the following steps:

7.6.1 Loosen the hemostatic valve.

7.6.2 Hold the guidewire and hemostatic valve in one hand, while grasping the LithiX device shaft in the opposite hand.

7.6.3 Maintain guidewire position in the coronary artery by holding the wire stationary and begin pulling the LithiX device out of the guiding catheter while monitoring the wire position under fluoroscopy.

7.6.4 Withdraw the fully deflated LithiX device until the guidewire lumen is reached. Carefully pull back the flexible, distal portion of the LithiX device out of the rotating hemostatic valve while maintaining the guidewire position across the lesion.

Note: If significant resistance is felt, remove the LithiX device, guidewire, and guiding catheter together from the vasculature.

7.6.5 Slide the distal tip of the LithiX device out of the hemostatic valve and tighten the valve onto the guidewire to hold it securely in place.

7.6.6 Prepare the next LithiX device to be used, as previously described in the Preparation for Use section.

7.6.7 Backload another LithiX device onto the guidewire as previously described under the Instructions for Use Section and continue the procedure accordingly.

8.0 PACKAGING INFORMATION

A package contains one LithiX HC-IVL and one flushing needle. An Instructions for Use document is included in the package.

The LithiX HC-IVL is supplied sterile using electron beam radiation and non-pyrogenic in unopened, undamaged packages.

Intended for single use only. Do not reuse, reprocess or resterilize.

Store at ≤ 25°C. Use by the "Use by" Date noted on the package.

CAUTION: DO NOT USE IF THERE IS ANY DAMAGE TO THE PACKAGE

9.0 PATENTS

U.S. and foreign patents pending

10.0 DISCLAIMER OF WARRANTY

THERE IS NO EXPRESS OR IMPLIED WARRANTY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ELIXIR MEDICAL SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND ELIXIR MEDICAL TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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	Manufacturer		Upper limit of temperature
	Authorized representative in the European Community		Do not re-use
	Date of manufacture		Consult instructions for use or consult electromic instructions for use
	Use-by date		Caution
	Batch code		Non-pyrogenic
	Catalogue number		Medical Device
	Importer		Unique device identifier
	Sterilized using irradiation		CE marking
	Do not resterilize		Rapid exchange
	Do not use if package is damaged		Guiding catheter
	Single sterile barrier system		

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