Intravascular Lithotripsy (IVL) Connector Cable

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Intravascular Lithotripsy (IVL) Connector Cable

Instructions for Use (IFU)

For use with Shockwave Medical IVL Generator and IVL Catheters

Contents: IVL Connector Cable (1)

How Supplied
The Shockwave Medical IVL Connector Cable is provided non-sterile and reusable. The IVL Connector Cable is intended for use with a sterile sleeve (not supplied). Carefully inspect all packaging for damage or defects prior to use.

Intended Use
The IVL Connector Cable is intended for use with the Shockwave Medical IVL Generator and IVL Catheters.

Device Description
The IVL Connector Cable is a remote actuator that connects the IVL Generator to the IVL Catheter and is used to activate lithotripsy energy within the balloon.

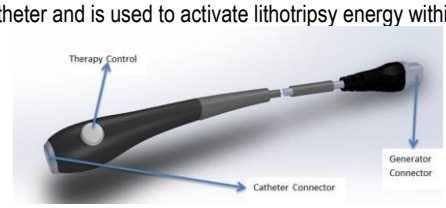

Figure 1: IVL Connector Cable

Warnings
1. DO NOT sterilize the IVL Connector Cable as this can potentially result in compromised device performance.
2. Inspect product and packaging prior to use. Do not use the device if it or the packaging has been damaged.
3. Always insert the IVL Connector Cable into a Sterile Sleeve before connecting the sterile IVL Catheter.
4. Care should be taken to secure the IVL Connector Cable to prevent unintentional movement during treatment. Failure to comply could result in injury to the patient.
5. The IVL Generator delivers low energy, short duration, high voltage pulses to the IVL Catheter through the IVL Connector Cable. The system is designed not to deliver pulses unless an IVL Catheter is mated with the IVL Connector Cable Catheter Connector. *It is important not to allow the contacts or internal surfaces of unmated connectors to be contaminated with fluids. Do not allow any connector to become contaminated by or immersed in fluids. Failure to observe these precautions may damage the IVL Connector Cables or IVL Catheters.*
6. The IVL Connector Cable contains ferromagnetic materials and should not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device.
7. Precaution should be taken when handling device after exposure to patient blood. Used product is potentially biohazardous and should be cleaned and disinfected as described below or in accordance with hospital protocol.
8. Inspect the IVL Connector Cable to confirm that there are no damaged, split or cracked materials and electrical contacts are free of extraneous matter.

Precautions
1. For preparation, operation, warnings and precautions, and maintenance of the IVL Connector Cable please refer to the IVL Generator Operator's Manual.
2. Do not immerse any portion of the IVL Connector Cable in water or other fluids.
3. Do not clean with solvents or flammable agents as this might cause harm to the equipment and/or the user.
4. If the IVL Connector Cable is damaged, remove and use a new IVL Connector Cable.
5. Store the IVL Connector Cable in a dry place with temperature between -20°C and 65°C. Storage of the device in extreme conditions may affect device performance and lead to patient injury.
6. Use only parts and accessories specified in the *IVL Generator and Connector Cable Operator Manual*. Using a connector cable not specified for use may result in increased emissions and/or decreased immunity from electromagnetic or radio frequency interference (RFI) which could affect the performance of this product or of equipment in close proximity.
7. Allow the IVL Connector Cable to adjust to room temperature and humidity conditions for at least twenty four hours before use. Operating the equipment outside of these environmental conditions (10° – 35°C) may cause equipment malfunction or damage.

Caution: Refer to *IVL Generator and Connector Cable Operator's Manual* for preparation, operation, warnings and precautions, and maintenance of this device.

Cleaning the IVL Connector Cable

Dirt and extraneous matter may be removed from the IVL Connector Cable using a soft cotton cloth or a lint free wipe. If needed, use only isopropyl alcohol sparingly as a cleaning agent.

Do not allow any fluids to penetrate the exterior surfaces of the device. Allow equipment to dry thoroughly before testing or use.

Clean connector areas carefully. Do not attempt to clean interior surfaces of connectors or connector contacts. In the event an IVL Connector Cable has become contaminated or malfunctions, remove this cable from use and contact Shockwave Medical for a replacement.

Shockwave Medical recommends replacement of IVL Connector Cables every three years to reduce the possibility of failure during patient use. In the event IVL Connector Cable connectors have become contaminated or the IVL Connector Cable malfunctions, remove this cable from use and contact Shockwave Medical for a replacement.

Return of Devices

If any portion of the Shockwave Medical IVL System fails prior to or during a procedure, discontinue use and notify Shockwave Medical at complaints@shockwavemedical.com. The device should be placed in a biohazard container with a Returned Material Authorization (RMA) number assigned by Shockwave Medical.

Patents: www.shockwavemedical.com/patents

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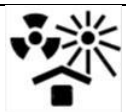
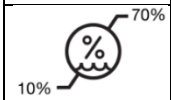
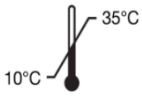
Symbol	Definition
	Caution, read instructions for use. Refer to this IFU and the Operator's Manual for the Shockwave Medical Generator for additional information
	Manufacturer
	Date of manufacture
	Waste from Electrical and Electronic Equipment Directive The IVL Generator and IVL Connector Cable should not be disposed of in the normal waste stream and should be sent to separate collection facilities for recovery and recycling.
	Keep dry
	Authorized Representative in the European Community
	Protect from heat and radioactive sources
	Batch code
	Catalogue number
	Consult instructions for use

Symbol	Definition
	Contains 1 unit (Contents: 1)
	Non-sterile
	Humidity Limitation
	Temperature limitation
	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.
	Conformité Européenne
PAT	Patents. Refer to www.shockwavemedical.com/patents
IVL	Intravascular Lithotripsy
	Indicates a carrier that contains Unique Device Identifier information.
	An indication that the device is a medical device.

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