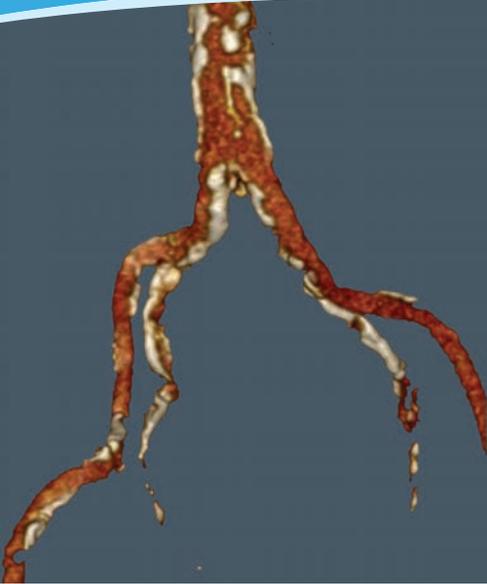


## Expand Transfemoral TAVR

- Calcified iliac arteries increase the risk of serious complications during TAVR<sup>1</sup>
- Transfemoral TAVR has lower morbidity & mortality vs. alternative access options<sup>2,3</sup>
- IVL safely fractures calcium, facilitating transfemoral delivery of large devices



### IVL-Enabled 14Fr TAVR

- Heavily calcified iliacs in a patient with aortic valve stenosis
- 7.0 x 60mm Shockwave IVL used to modify iliac, allowing for introduction of 14Fr introducer
- Successful introduction and delivery of Medtronic EvolutR 29mm TAVR

*Case Courtesy of Prof. Carlo Di Mario*



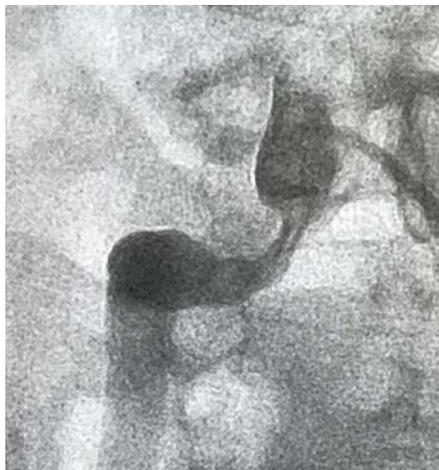
Pre-Intervention



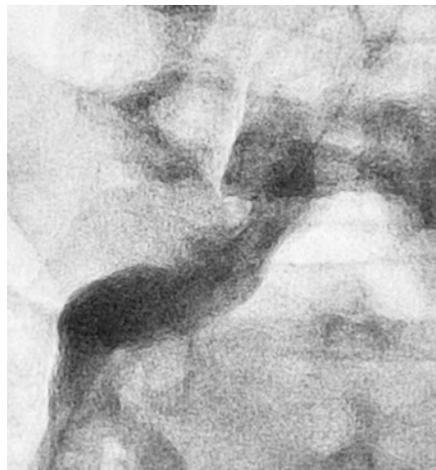
Pre- & Post-IVL



Pre-TAVR



Pre-Intervention



Post-IVL

### IVL-Enabled 18Fr TAVR

- Heavily calcified common iliac artery precluding transfemoral TAVR access
- 7.0 x 60mm Shockwave IVL used to modify iliac to allow for delivery and deployment of 18Fr Edwards TAVR device

*Case Courtesy of Dr. James Stewart*

1. Choudry MA and Sardar MR. Vascular complications of transcatheter aortic valve replacement: A concise literature review. World J Cardiol 2017; Vol. 9(7): 574-582  
 2. Doshi R, Shah P, Meraj PM. In-hospital outcomes comparison of transfemoral vs TAVR replacement in propensity-matched cohorts with severe aortic stenosis. Clin Cardiol. 2018;41(3):326-332.  
 3. Greenbaum AB, Babaliaros VC, Chen MY, et al. Transcaval access and closure for transcatheter aortic valve replacement: A prospective investigation. J Am Coll Cardiol 2017; 69(5):511-521.

# Unique IVL Mechanism of Action



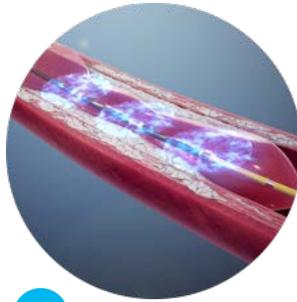
1

The IVL catheter is delivered across a calcified lesion and the integrated balloon is expanded to 4atm to provide good vessel wall apposition, facilitating **efficient energy transfer**



2

An electrical discharge from the emitters vaporizes the fluid within the balloon, creating a rapidly expanding & collapsing bubble that generates **sonic pressure waves**



3

The waves create a **localized field effect** that travels through soft vascular tissue, selectively **cracking intimal and medial calcium** within the vessel wall



4

After calcium modification, the integrated balloon may subsequently be used to **dilate the lesion at low pressure** in order to **maximize luminal gain**

## IVL Catheter Specifications

Larger diameters IVL catheters are capable of modifying calcium in iliac arteries to facilitate delivery of large bore access devices

CATALOG #	DIAMETER (mm)	LENGTH (mm)	GUIDEWIRE COMPATIBILITY (IN)	SHEATH COMPATIBILITY	WORKING LENGTH	PULSES (MAX)
M5IVL3560	3.5	60	0.014	6F	110	300
M5IVL4060	4.0	60	0.014	6F	110	300
M5IVL4560	4.5	60	0.014	6F	110	300
M5IVL5060	5.0	60	0.014	6F	110	300
M5IVL5560	5.5	60	0.014	6F	110	300
M5IVL6060	6.0	60	0.014	6F	110	300
M5IVL6560	6.5	60	0.014	7F	110	300
M5IVL7060	7.0	60	0.014	7F	110	300

Discover how you can treat calcium more effectively with the Peripheral Intravascular Lithotripsy (IVL) System.

Visit [Shockwavemedical.com](http://Shockwavemedical.com) or call 877-77-LITHO (877-775-4846) for more information.

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

**Indications for Use**—The Shockwave Medical Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

**Contraindications**—Do not use if unable to pass 0.014 guidewire across the lesion—Not intended for treatment of in-stent restenosis or in coronary, carotid, or cerebrovascular arteries.

**Warnings**—Only to be used by physicians who are familiar with interventional vascular procedures—Physicians must be trained prior to use of the device—

Use the generator in accordance with recommended settings as stated in the Operator's Manual.

**Precautions**—use only the recommended balloon inflation medium—Appropriate anticoagulant therapy should be administered by the physician—

Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology.

Adverse effects—Possible adverse effects consistent with standard angioplasty include—Access site complications –Allergy to contrast or blood thinner—

Arterial bypass surgery—Bleeding complications—Death—Fracture of guidewire or device—Hypertension/Hypotension—Infection/sepsis—Placement of a stent—renal failure—Shock/pulmonary edema—target vessel stenosis or occlusion—Vascular complications. Risks unique to the device and its use—Allergy to catheter material(s)—Device malfunction or failure—Excess heat at target site.

**Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events.**

[www.shockwavemedical.com](http://www.shockwavemedical.com)