



ELCA CASE REVIEW SERIES

Case Number Three: Laser treatment of a SVG with ISR*



*ELCA is indicated for: Restenosis in 316L stainless steel stents prior to brachytherapy

Coronary Artery Disease – Present

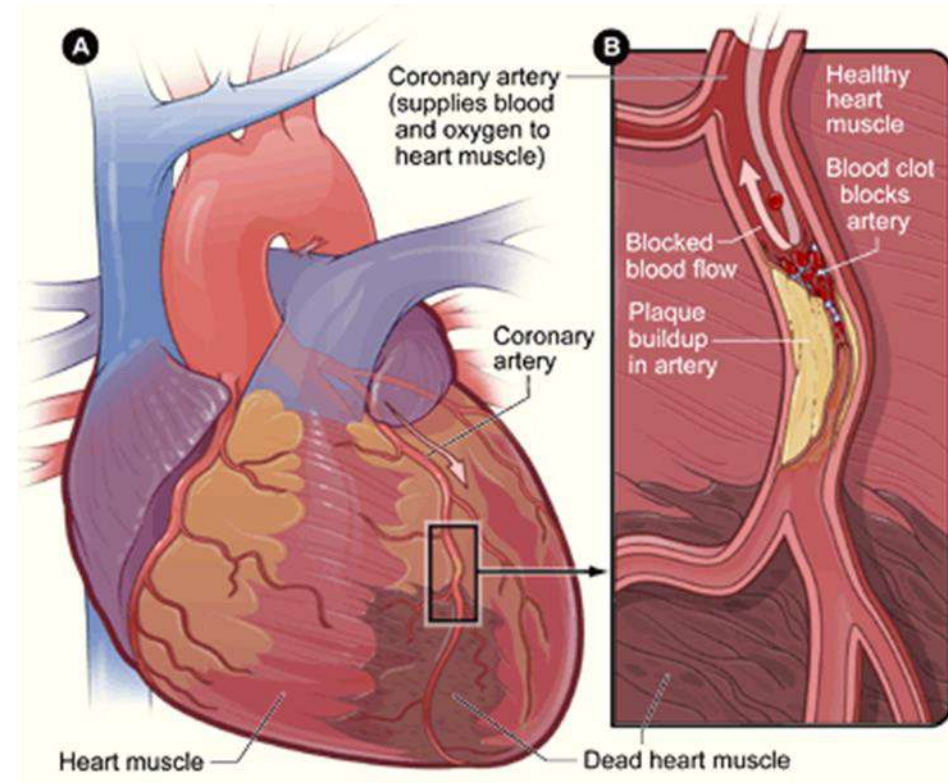
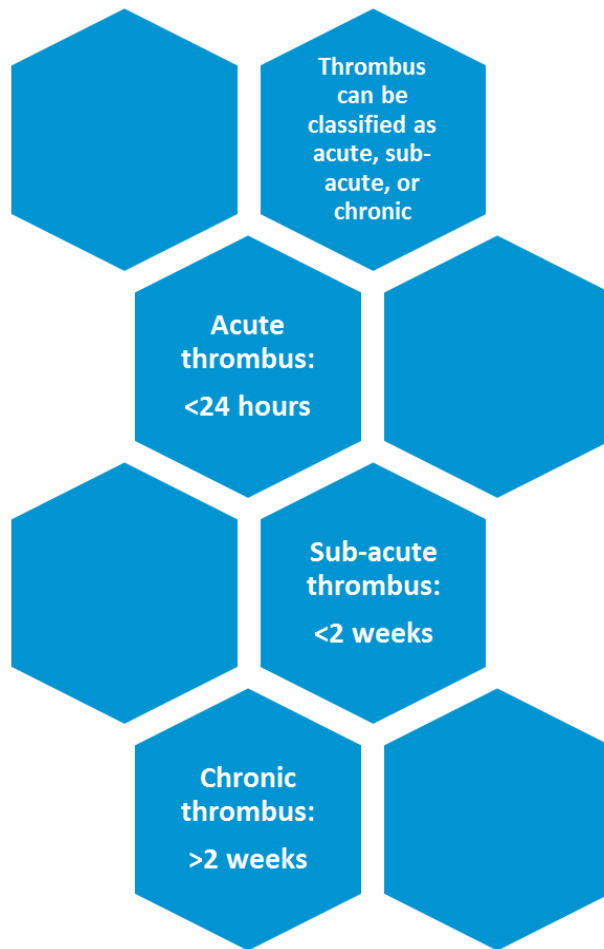
 <p>TREATMENT OPTIONS</p>	<p>500 MILLION ARE AT RISK</p>	 <p>JOIN THE MOVEMENT FOR BETTER TREATMENT OF CAD</p>	 <p>SUCCESSFUL IN THE MOST CHALLENGING CAD CASES</p>
<p>\$190 BILLION SPENT/YEAR ON CAD COSTS</p>	 <p>LASER ATHERECTOMY HELPS PATIENTS RETURN TO MORE ACTIVE LIFESTYLES</p>	 <p>INVENTING & DELIVERING TECHNOLOGY</p>	<p>1/2 MILLION U.S. DEATHS ATTRIBUTED TO CAD/YEAR</p> 

SPNC - Specialized Coronary Solutions

Spectranetics offers a comprehensive portfolio of solutions to ***cross, prep and treat*** compromised vessels.

Segment	Cross	Prep	Treat
In-Stent Restenosis	Quick-Cross	AngioSculpt PTCA, QuickCat Extraction Catheter ELCA Coronary Laser	DES, AngioSculpt PTCA, ELCA Coronary Laser
Fibro-Calcific Lesions	Quick-Cross	AngioSculpt PTCA, QuickCat Extraction Catheter ELCA Coronary Laser	DES
Ostial Lesions	Quick-Cross	AngioSculpt PTCA, ELCA Coronary Laser	DES, AngioSculpt PTCA
CTO's Crossable by a Guidewire	ELCA Coronary Laser	AngioSculpt PTCA, ELCA Coronary Laser	DES
Long Diffuse Lesions	Quick-Cross	AngioSculpt PTCA, QuickCat Extraction Catheter ELCA Coronary Laser	DES

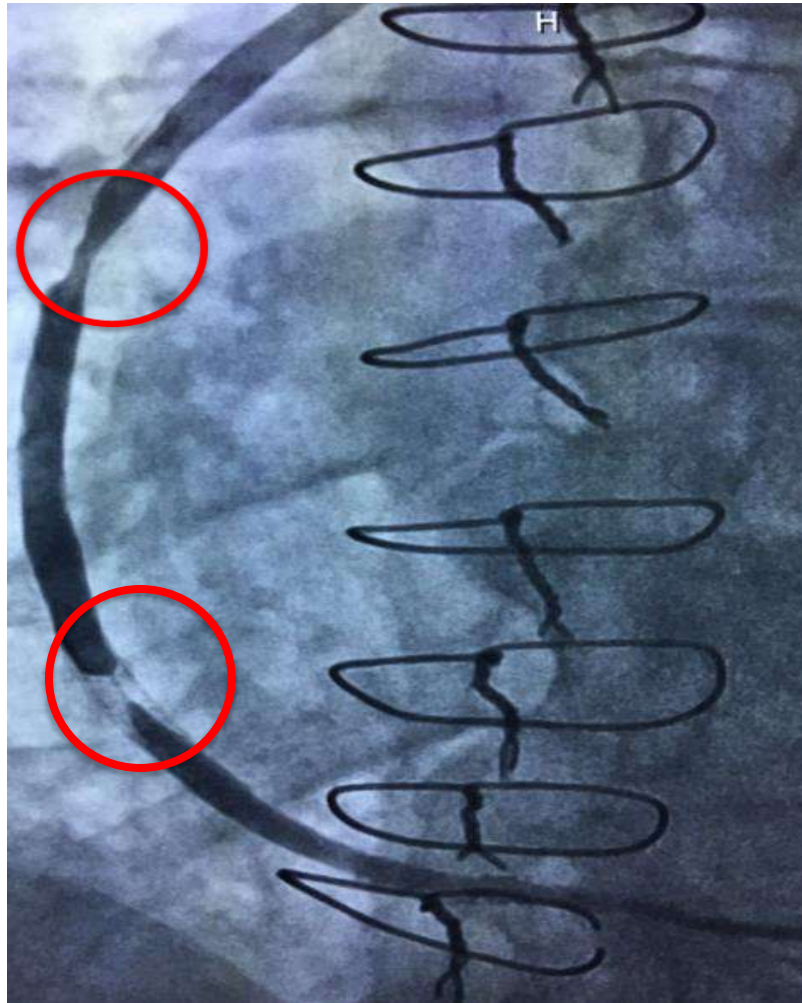
Thrombus Classification in Coronary Arteries and SVGs



Garcia, LD; Carrozza, JP. Mechanical Thrombectomy in Coronary Artery and Saphenous Vein Graft Interventions: A Review and Case Studies. J Invasive Cardiol. 2004; 16 (Suppl 5). 53-57
MEET 2005 Presentation: The Adjunctive Role in Peripheral Arterial Fibrinolysis.
Physician survey on file at Spectranetics

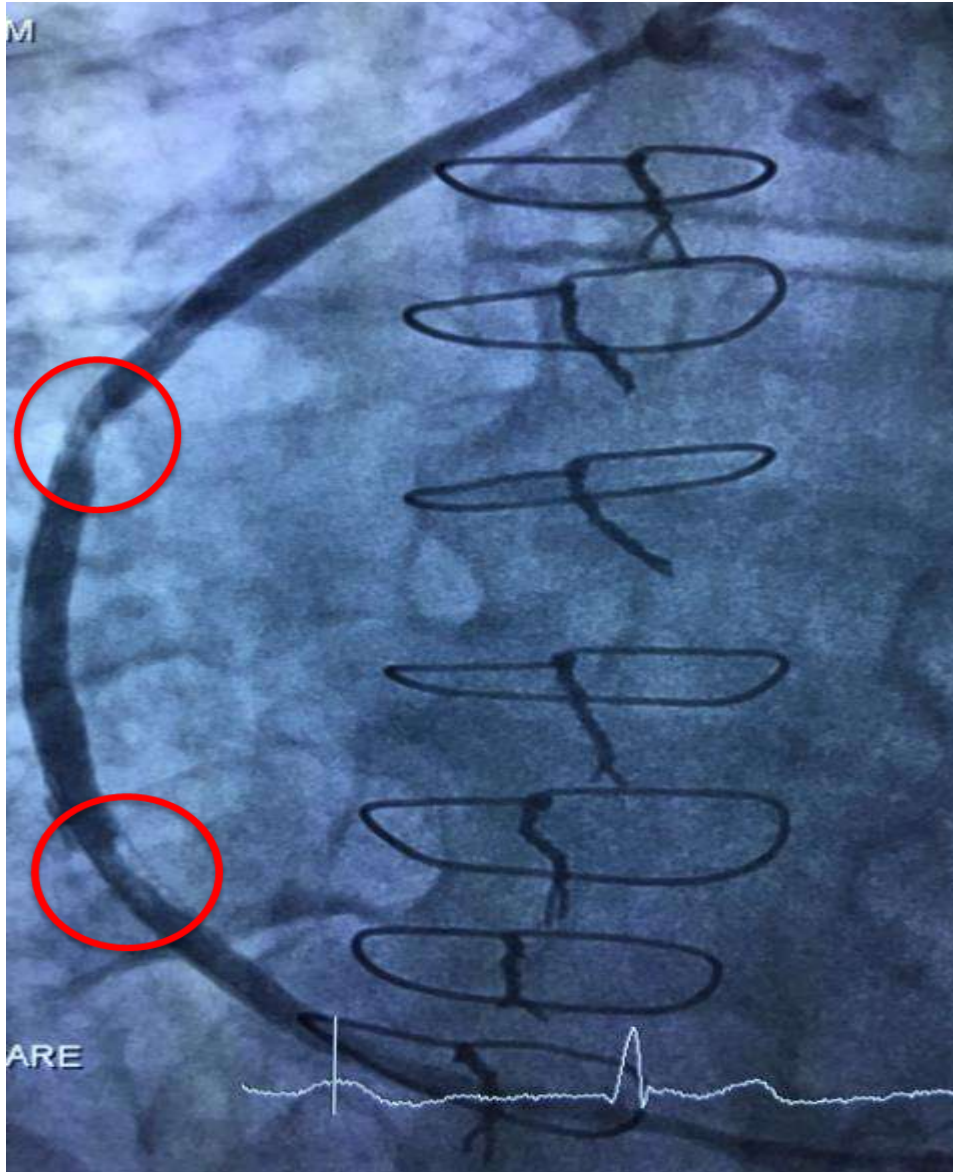
 **Spectranetics**[®]
Always Reaching Farther

Case Number Three – SVG with ISR



- SVG with ISR, two Drug Eluting Stents
- Treatment options?
- ELCA?
- Settings?

Case Number Three – SVG with ISR



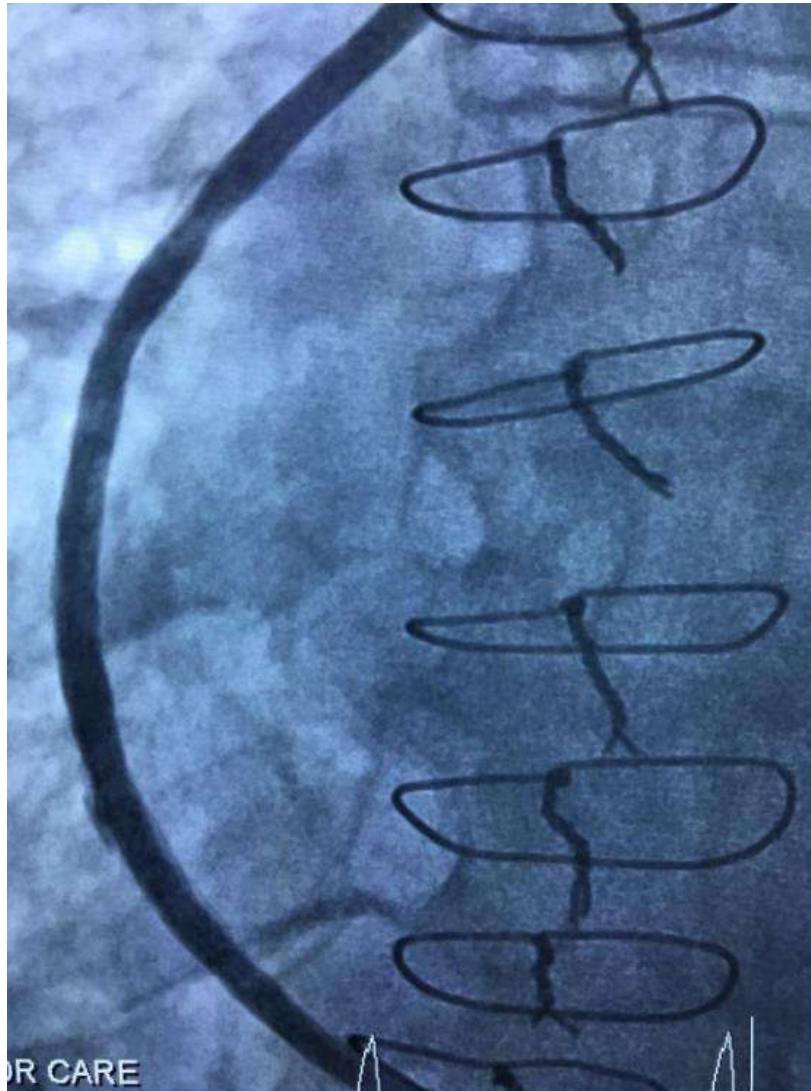
Treatment

- 1.4mm ELCA
- Two Passes
- 60/40

Post Laser

- 3.5mm x 15mm AS

Case Number Three – SVG with ISR



- Final Angiogram
- Post Laser and Angiosculpt

Excimer Laser ISR Data:

Study	# ELCA Patients/Centers	Effectiveness	Safety
Mehran Study	107 ISR lesions, 54 with ELCA + PTCA vs. 53 with PTCA alone	Greater luminal gain Larger IVUS determined cross sectional area	0% laser complications Less frequent TVR vs PTA (p = 0.08)
Dahm and Kuon Study	Eccentric ELCA in 39 patients with ISR	99.8% procedural success	0% MACE 12.8% Clinical TLR
LARS Study	66 ISR patients	89% procedural success	4.5% perforation 11% dissection 1.5% embolism 0% procedural mortality
WRIST Trial	100 ISR patients	100% procedural success	6% procedural complications

Important Safety Information

ELCA™ Indications

The Laser Catheters are intended for use either as a stand-alone modality or in conjunction with Percutaneous Transluminal Coronary Balloon Angioplasty (PTCA) in patients who are acceptable candidates for coronary artery bypass graft (CABG) surgery. The following Indications for Use, Contraindications and Warnings have been established through multicenter clinical trials. The Spectranetics CVX-300® Excimer Laser System and the multifiber laser catheter models are safe and effective for the following indications:

- Occluded saphenous vein bypass grafts.
- Ostial lesions.
- Long lesions—(greater than 20mm in length).
- Moderately calcified stenoses.
- Total occlusions traversable by a guidewire.
- Lesions which previously failed balloon angioplasty.
- Restenosis in 316L stainless steel stents, prior to the administration of intravascular brachytherapy.

These lesions must be traversable by a guidewire and composed of atherosclerotic plaque and/or calcified material. The lesions should be well defined by angiography.

Contraindications

- Lesion is in an unprotected left main artery.
- Lesion is beyond acute bends or is in a location within the coronary anatomy where the catheter cannot traverse.
- Guidewire cannot be passed through the lesion.
- Lesion is located within a bifurcation.
- Patient is not an acceptable candidate for bypass graft surgery.

See complete IFU for more information before attempting use of ELCA.

Warnings

Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training. A clinical investigation of the Spectranetics CVX-300® Excimer Laser System did not demonstrate safety and effectiveness in lesions amenable to routine PTCA or those lesions not mentioned in the Indications for Use, above. The effect of adjunctive balloon angioplasty on restenosis, as opposed to laser alone, has not been studied. The use of the CVX-300® Excimer Laser System is restricted to physicians who are trained in the use of the product.

Precautions

This device has been sterilized using Ethylene Oxide and is supplied STERILE. The device is designated and intended for SINGLE USE ONLY and must not be resterilized and/or reused. Store in a cool, dry place. Protect from direct sunlight and high temperatures (greater than 60°C or 140°F). During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be administered per the institution's PTCA protocol for a period of time to be determined by the physician after the procedure. Percutaneous Excimer Laser Coronary Atherectomy (ELCA) should be performed only at hospitals where emergency coronary bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. The results of clinical investigation indicated that patients with the following conditions are at a higher risk for experiencing acute complications:

- Patients with diabetes.
- Patients with a history of smoking.
- Lesions with tortuous vessels.