Lead Management Utilizing Spectranetics Laser Technology:
Procedure Steps and Considerations

ACTION	PROCEDURE STEPS	CONSIDERATIONS
1. **PRE-CASE PLANNING**	1. Pre-op Imaging a. AP and lateral chest X-ray b. Venogram (upgrades, reimplants) c. TEE (pre-op baseline, intra-op)	Pre-op imaging critical to verify type, quantity, and position of leads, anatomical considerations, etc. Venogram may be helpful in upgrade/reimplant scenarios. Use of TEE intra-op may be considered
	2. Patient Characteristics and Comorbidities a. Gender b. BMI c. Diabetes d. Renal insufficiency e. Prior sternotomy vs. virgin chest	Patient characteristics and comorbidities may affect procedural complexity. Patients with a BMI < 25 are at greater risk of procedural MAE. Diabetics are associated with heavier fibrosis, renal patients are associated with calcification. Both comorbidities are associated with increased infection risk. Prior sternotomy affects many aspects of the procedure; saw type/blade, fem-fem bypass option, pericardial tamponade risk, etc.
	3. CIED System a. Type of leads b. Number of leads c. Implant duration	Thorough knowledge of all indwelling hardware is critical. Single- vs. dual-coil ICD leads, backfilled vs. non-backfilled coils, insulation type, fixation type, age of leads, presence of capped/abandoned leads, left- vs. right-sided system, etc.
	4. Protocols and Preparation a. CTS partnership b. Anesthesia support c. Adherence to perioperative protocols d. Rescue cart/rescue plan	Procedural and room preparation should be consistent with established best practices and peer based recommendations.
2. **LASER PREP**	1. Prior to patient being roomed: a. Power up laser - 5 minute warm-up b. Calibrate laser using Reference Catheter	Verifying that the laser is functioning properly is important. This should be done prior to the patient being roomed/anesthetized, in the event of a serious problem preventing the case from proceeding.
	2. Position laser appropriately for procedural needs	Always position CVX-300 laser and foot pedal in a manner most conducive to efficient procedural time, sterility, and full range of operator motion.
	3. Connect and position foot pedal	
	4. Verify adequate quantity of safety glasses on hand	
	5. Post laser safety signage as appropriate	Laser safety first and foremost.

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3. **PATIENT PREP**	1. Prep patient for full sternotomy	Patient preparation should be consistent with established best practices and peer-based recommendations.
	2. Large-bore venous access in the groin	
	3. A-line BP (consider femoral; radial/brachial options)	
	4. General vs. IV sedation - considerations	
	5. Temporary pacing as needed	
	6. External defibrillation as needed	
	7. Four units of blood typed and cross-matched in room	
	8. Wire placed for Bridge and prep kit utilized for deployment readiness	
4. **POCKET PREP**	1. Utilize fluoroscopy to verify angle of lead entry into implant vein	Angle of lead entry to implant vein may affect incision location/aspect; strive for a location that will lend itself to a straight, coaxial alignment of laser sheath to lead along the plane of venous entry. Location of venous entry site may also be a factor in the extraction; medial vs. axillary, etc.
	2. Make pocket incision	
	3. Remove CIED from pocket	
	4. Disconnect leads from device header	
	5. Thoroughly dissect tissue to expose leads deep in the pocket	
	6. Debride/disrupt pocket capsule as appropriate	
	7. Inspect pocket for signs of infection, presence of calcification, etc.	
5. **LEAD PREP**	1. Attempt to retract helix of active fixation leads (with stylet inserted)	As a rule of thumb, consider prepping ALL leads you intend to extract before extracting any leads. Consider placing a standard stylet in any leads you intend to retain. When cutting the terminal pin, consider making a proximal cut to preserve as much lead length as possible.
	2. Cut terminal pin of leads using Lead Cutter	

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	3. Remove suture sleeve(s) and all suture material on leads	
	4. Remove portion of outer insulation to expose inner coil (and cables if ICD lead)	Certain lead types may have characteristics that affect lead prep considerations.
	5. Use LLD Accessory Kit Coil Expander to restore lumen patency as necessary	
	6. Use LLD Accessory Kit sizing pins to determine correct LLD size	
	7. Use LLD Clearing Stylet as necessary to clear/dilate length of lumen	
6. **ESTABLISH TRACTION**	1. While observing under fluoroscopy, advance LLD to distal tip of lead	The single most important aspect of safe, predictable and responsible lead extraction is traction. Sufficient traction on the lead, thus creating the "rail" that allows the extraction tool to track appropriately, is absolutely critical.
	2. Lock LLD and perform "tug test," applying gentle traction to the lead while observing under fluoroscopy	
	3. Tie off outer insulation with suture a. Consider 0 Ethibond b. Consider series of single half-hitches	Consider options if LLD fails to advance to distal tip of lead. Harnessing cables (if ICD lead) with suture, additional suture ties around outer insulation, half-hitch technique, sterile mineral oil, etc.
	4. On ICD leads, consider suture tie off of cables to enhance traction platform	Certain lead types may have characteristics that affect the lead extraction procedure in general and the means of establishing traction in particular.
	5. Tie suture(s) to LLD or utilize other method of control as appropriate	
7. **PREPARE TOOLS**	1. Select appropriately sized laser sheath a. Sizing guide b. Operator preference	Selection of laser sheath size may be affected by several case-specific variables. SPNC offers a sizing guide as a reference. Operator experience and preference are the determining factors.
	2. If outer sheath use is preferred, select appropriately sized VisiSheath (if available)	Decision to use outer sheath may also be affected by several case-specific variables. Many operators use an outer sheath on most if not all cases; other operators use them sparingly, if ever. It is important for each operator to apply the tools in a manner most comfortable for their own hands.
	a. Diameter and length (three options of each)	
	3. Plug in laser sheath to CVX-300 and calibrate	

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	4. Flush laser sheath with saline	
	5. Dampen outer surface of laser sheath to activate lubricious coating	A comprehensive Lead Management program should be prepared to apply the full range of tools and techniques applicable to the case contingencies at hand.
	6. If outer sheath use, flush/dampen also	
8. **COMMENCE EXTRACTION**	1. Key principles of proper technique throughout the procedure include:	Be particularly mindful of the "rail" from the innominate/SVC, through mid-SVC, and well clear of SVC/RA junction. Maintain sturdy traction on lead at all times when tip of laser sheath is in that part of the anatomy.
	a. RAIL - proper tension on the lead is critical	
	b. Bevel orientation - tip away from lateral SVC wall	
	c. Coaxial alignment of laser sheath to lead	Visual verification of bevel orientation for laser sheath and outer sheath (if used) is critically important.
	d. Establish baseline hemodynamics/imaging	
	e. 1mm/sec advancement rate is optimum	Deciding what to do when the laser sheath fails to advance is a complex decision affected by many variables specific to each case, the operator, and the program.
	f. Failure to advance after 2-3 laser trains = STOP	
	2. When laser fails to advance, assess potential causes and appropriate countermeasures specific to the anatomical zone in question	
	3. Make decision based on that assessment - options include: a. Add outer sheath b. Upsize laser sheath c. Alternate leads (lead on lead binding) d. Tightrail e. Abandon lead extraction procedure	
9. **COMPLETE EXTRACTION**	1. Applying appropriate tools and technique, advance laser sheath to approximately 1cm from distal electrode of lead	The passive traction/countertraction technique is applied to minimize the risk of the laser sheath going past the distal electrode and perforating the heart.
	2. Deactivate laser (place in "Standby" mode)	
	3. Secure laser sheath manually to render it	Utilizing the laser sheath and/or outer sheath to obtain wire access is

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	immobile	particularly useful in an occlusion scenario.
	4. Apply steady traction/countertraction technique to free lead tip from heart	
	5. Position laser sheath in a "neutral" position, aligned with IVC within the heart.	
	6. Remove lead through laser sheath, if possible	
	7. If appropriate, utilize laser sheath to obtain access for reimplant (as a conduit for wire)	
	8. Slowly withdraw laser sheath to innominate/SVC and pause	
	9. Observe fluoroscopy and hemodynamics noting changes from baseline	
	10. Slowly withdraw laser sheath from vein and maintain hemostasis	
	11. Reimplant if appropriate	
	12. Close and execute post-op orders	
10. **RESCUE PLANNING**	1. As a complement to the perioperative protocols, a robust, stress-tested rescue plan is critical to a safe, predictable and responsible Lead Management program	Time to surgical intervention is a key predictor of patient mortality.
	2. Full engagement and partnership with CTS is critical	
	3. SPNC offers extensive support and facilitation of peer-based recommendations through its Complication Prevention and Management (CP&M) program	