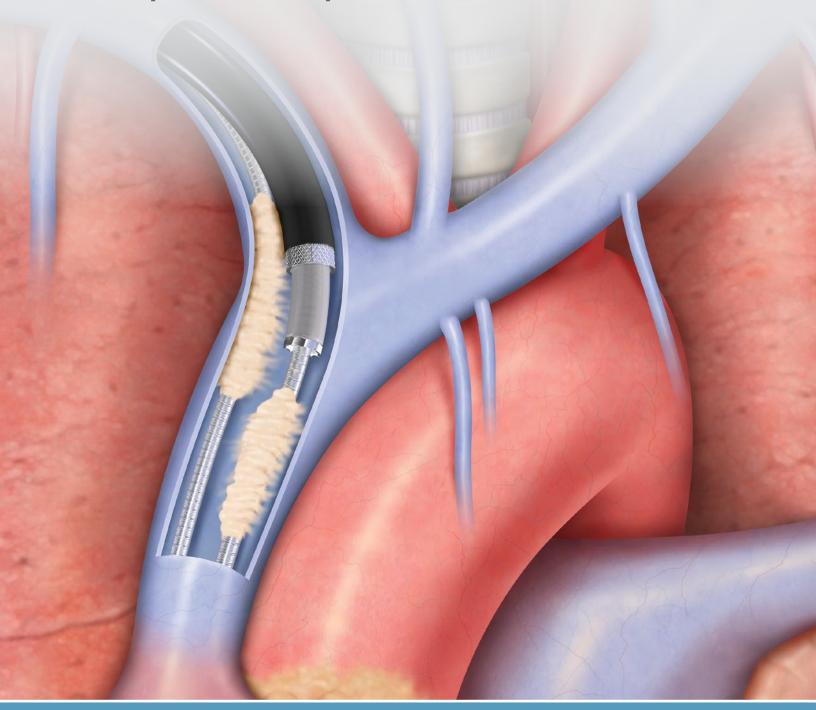
Safe, effective, and efficient for TLE.1



ROTATIONAL TLE SYSTEM



Evolution® RL rotational TLE system

Developing lead extraction devices that provide physicians excellent safety profiles is the focus of our work. Rotational transvenous lead extraction (TLE) is safe, effective, and efficient when using the Evolution RL as a first choice.¹

A **2019** retrospective by Diaz, et al., compiled and analyzed over 50,000 lead extraction procedures and determined that lead extraction with laser sheaths appears to be associated with a higher risk of mortality.²

A **2020** retrospective study (PROMET) by Starck, et al., was the largest study with rotational devices as the primary extraction device. Laser use was nearly abandoned in the first half of the study, and the authors concluded "the low incidence of injury to the SVC demonstrated in the PROMET study constitutes a major advance in TLE."³

In **2021**, the prospective RELEASE study by Sharma, et al., found high clinical success and efficient extraction times per lead despite a median indwell time of 7.4 years.¹

o isolated extrapericardial SVC injuries^{1,3}

minutes median extraction time per lead¹

7.2
times lower mortality rate
than laser sheaths²

Evolution® RL

CONTROLLED-ROTATION DILATOR SHEATH SET

Designed to provide physicians with the most control and user feedback during lead extraction procedures.

- 98.4% of leads with an implant duration of >10 years were removed with complete success.6
- Clinical success rates were >99%.4,5,6

Control

- The amount of sheath rotation is directly proportional to the length of the trigger pull unlike powered devices, which have a preset energy that is triggered upon activation.
- You can control both the direction and speed of rotation.

Bidirectional extraction

• The Evolution device actively extracts leads while rotating in either direction.

Balanced flexibility and stability

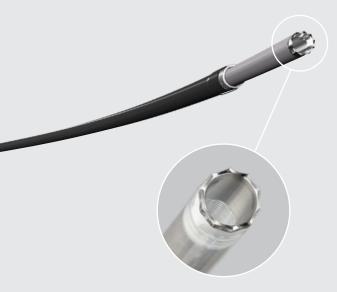
- The Evolution device gives you the flexibility to maneuver through challenging anatomy.⁴
- Benefit from stability when engaging with dense and calcified adhesions.^{5,6}

Decagon tip

- The ten-sided tip is designed to peel the leads away from scar tissue.
- The device disrupts tissue directly in contact with the tip, without forward extending blades.

No lead wrap or damage

 Studies have shown no occurrences of lead wrap or damage to companion leads.^{5,6,7}



Evolution Shortie RL

CONTROLLED-ROTATION DILATOR SHEATH SET

Access every lead

The Evolution Shortie RL is built specifically for vessel entry into the subclavian veins. The Shortie RL combines all the control features of the Evolution RL with a shorter, stiffer sheath and an enhanced tip to facilitate entry through dense scar tissue and calcification.



SteadySheath[®]

EVOLUTION® TISSUE STABILIZATION SHEATH

More visibility, better control

SteadySheath offers a textured radiopaque tip, providing better visibility for the distal tip of the outer sheath. When used while encountering a binding site, the textured tip provides additional support by holding tissue in place while the inner sheath (Evolution RL/Evolution Shortie RL) rotates and frees the lead.



- 1. Sharma S, Lee BK, Garg A, et al. Performance and outcomes of transvenous rotational lead extraction: results from a prospective, monitored, international clinical study. *Heart Rhythm O2*. 2021;2(2):113–121.
- 2. Diaz CL, Guo X, Whitman IR, et al. Reported mortality with rotating sheaths vs laser sheaths for transvenous lead extraction. Europace. 2019;21(11):1703–1709.
- 3. Starck CT, Gonzalez E, Al-Razzo O, et al. Results of the patient-related outcomes of mechanical lead extraction techniques (PROMET) study: a multicentre retrospective study on advanced mechanical lead extraction techniques. *Europace*. 2020;22(7):1103-1110.
- 4. Sharma S, Ekeruo IA, Nand NP, et al. Safety and efficacy of transvenous lead extraction utilizing the Evolution mechanical lead extraction system: a single-center experience. *JACC Clin Electrophysiol*. 2018;4(2):212-220.
- 5. Migliore F, Testolina M, Sagone A, et al. Multicentre experience with the Evolution RL mechanical sheath for lead extraction using a stepwise approach: safety, effectiveness and outcome. *Pacing Clin Electrophysiol*. 2019;42(7):989–997.
- 6. Mazzone P, Migliore F, Bertaglia E, et al. Safety and efficacy of the new bidirectional rotational Evolution mechanical lead extraction sheath: results from a multicentre Italian registry. *Europace*. 2018;20(5):829–834.
- 7. Starck CT, Steffel J, Caliskan E, et al. Clinical performance of a new bidirectional rotational mechanical lead extraction sheath. Europace. 2016;18(2):253–256.



Order Number	Reference Part Number	Inner Sheath ID Fr	Outer Sheath OD Fr	Inner Sheath length cm	
Evolution RL					
G23737	LR-EVN-9.0-RL	9.0	17.2	40.6	
G23746	LR-EVN-11.0-RL	11.0	19.4	40.6	
G23747	LR-EVN-13.0-RL	13.0	21.3	40.6	

Evolution RL is compatible with the following:		Compatible Sheath Fr	SteadySheath ID Fr	SteadySheath OD Fr	Length cm
SteadySheath Evolution Tissue Stabilization Sheath					
G25082	LR-TSS-9.0	9.0	14.2	17.2	36.5
G25083	LR-TSS-11.0	11.0	16.2	19.4	36.5
G25084	LR-TSS-13.0	13.0	18.1	21.3	36.5

Evolution Shortie RL		Inner Sheath ID Fr	Outer Sheath OD Fr	Inner Sheath length cm	
G23748	LR-EVN-SH-9.0-RL	9.0	17.2	13.6	
G23749	LR-EVN-SH-11.0-RL	11.0	19.4	13.6	

Evolution Shortie RL is compatible with the following:		Compatible Sheath Fr	SteadySheath ID Fr	SteadySheath OD Fr	Length cm
SteadySheath E	volution Shortie Tissue Stabilization Sheaths				
G31908	LR-TSS-SH-9.0	9.0	14.2	17.2	11.2
G31923	LR-TSS-SH-11.0	11.0	16.2	19.4	11.2

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Distribution for details.

Customer Service

EU Website: cookmedical.eu EDI: cookmedical.eu/edi

Distributors: +353 61239240, ssc.distributors@cookmedical.com

Austria: +43 179567121, oe.orders@cookmedical.com Belgium: +32 27001702, be.orders@cookmedical.com Denmark: +45 38487607, da.orders@cookmedical.com Finland: +358 972519996, fi.orders@cookmedical.com France: +33 171230269, fr.orders@cookmedical.com Germany: +49 6950072804, de.orders@cookmedical.com Iceland: +354 8007315, is.orders@cookmedical.com Ireland: +353 61239252, ie.orders@cookmedical.com Italy: +39 0269682853, it.orders@cookmedical.com Netherlands: +31 202013367, nl.orders@cookmedical.com Norway: +47 23162968, no.orders@cookmedical.com Spain: +34 912702691, es.orders@cookmedical.com

Sweden: +46 858769468, se.orders@cookmedical.com Switzerland - French: +41 448009609, fr.orders@cookmedical.com Switzerland - Italian: +41 448009609, it.orders@cookmedical.com Switzerland - German: +41 448009609, de.orders@cookmedical.com United Kingdom: +44 2073654183, uk.orders@cookmedical.com

USA Website: cookmedical.com

EDI: cookmedical.com/edi.do

Americas: Phone: +1 812.339.2235, 800.457.4500, Fax: 800.554.8335

E-mail: customersupport@cookmedical.com

Australia: Phone: +61 734346000, 1800777222, Fax: +61 734346001, 1800077283

E-mail: cau.custserv@cookmedical.com





LM-8.5X11