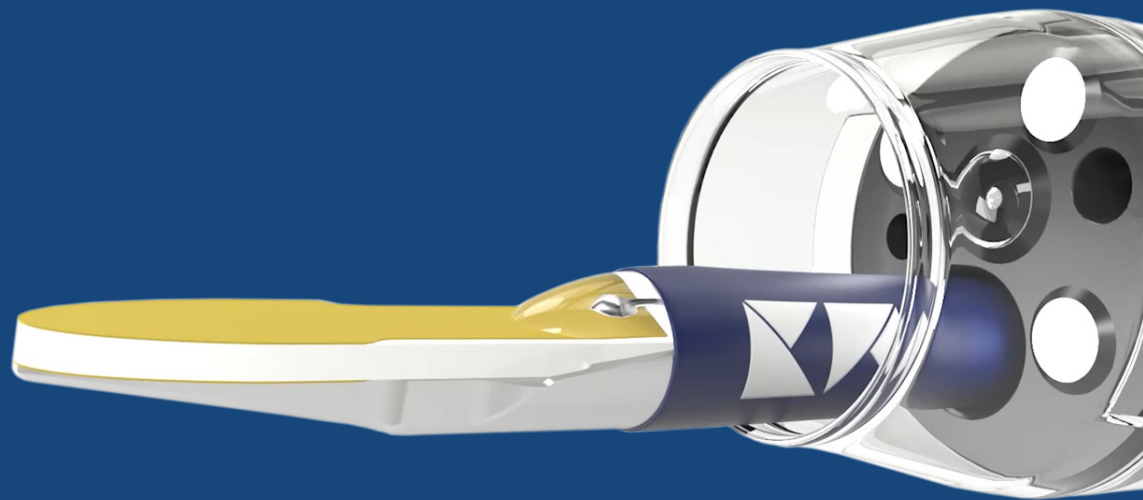




Speedboat™
Inject

The first multi-modal device with advanced bipolar RF adaptive technology for cutting and **super high frequency microwave for coagulation**

Speedboat Submucosal Dissection (SSD)



Anything is Possible
with the Right Approach



CROMA Advanced Energy Platform

The CROMA Energy Platform precisely controls **Advanced bipolar RF** and **Microwave** energy to enable a suite of flexible, miniature endoscopic devices to deliver:

- Unrivaled **usability and safety**¹⁻⁶
- **Optimal tissue effect**¹⁻⁶
- **Improved clinical and economic outcomes**⁶
- **Expanded capabilities** in therapeutic endoscopy



The Power Behind SSD

Our innovative Kamaptive™ Technology combines multiple energy sources within our CROMA Energy Platform to optimise without compromise and provide unrivalled capability to Therapeutic Endoscopy.

Utilizing CROMA and Speedboat Inject, Speedboat Submucosal Dissection is a novel solution that takes endoscopic resection to new levels, bringing the control and precision of Advanced Energy to the endoscopy suite for the first time.

Performing an SSD with Speedboat Inject combines the benefits of advanced bipolar RF and super high frequency microwave energy, enabling the ability to dissect, resect, coagulate and inject in a single device.



Advanced bipolar RF

enables a smooth cut with clean margins and minimal bleeding¹

- Closed-loop technology and proprietary waveform
- Lower voltage than standard monopolar
- Focused energy, adapted based on tissue response



Microwave

enables precise, on-demand reproducible effects for both ablations and hemostasis¹

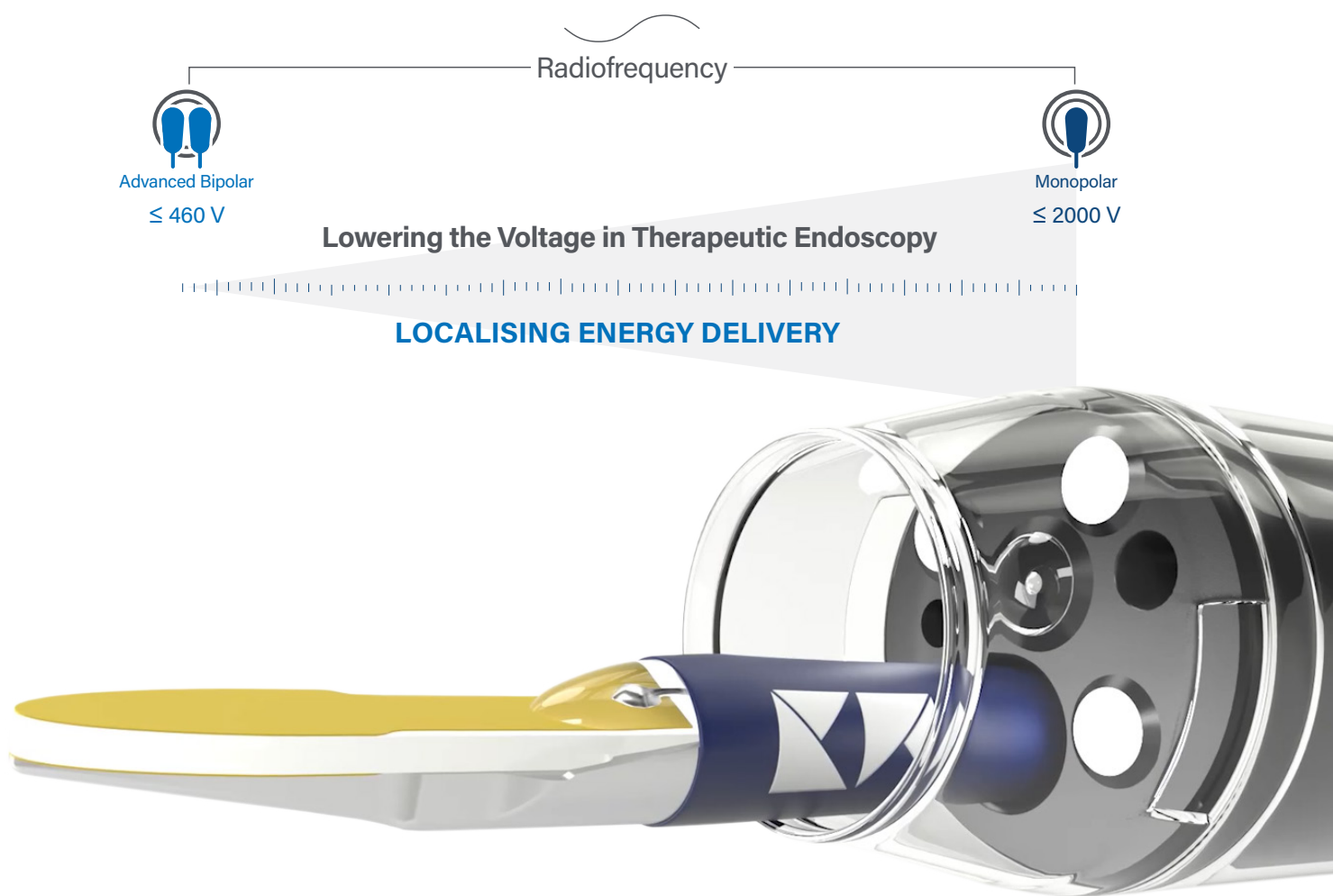
- Super high frequency (5.8 GHz)
- Better control of the thermal energy and depth of penetration

The First Advanced Bipolar RF Multi-Modal Cutting Device for Therapeutic Endoscopy



Safe, precise, contact cut with clean margins to provide high quality histology samples and help healing rates.

- ✓ Blade design
- ✓ Focused energy, <460 V
- ✓ Adaptive waveform to adjust for tissue impedance



Safety & usability – multi-modal design

Multi-functional instrument allows for unrivalled protection of muscle layer¹ without the need to change devices during procedure.

- ✓ Electromagnetic wave
- ✓ Controlled depth
- ✓ Homogenous energy delivery



SSD: A Deeper Dissection

Speedboat Inject is the first Advanced Energy multi-modal instrument designed for flexible endoscopy that can deliver both advanced bipolar RF and microwave energy from a single device.

Microwave Energy for Coagulation

Microwave Energy for Safety and Control

Energy is delivered as an electromagnetic wave instead of an electrical current, which creates a homogenous energy field at the treatment site. The energy penetrates tissue regardless of resistive changes, and reduces heat sink effect while controlling temperature and thermal damage.¹

5.8 GHz Super High Frequency (SHF) for control

Super high frequency allows for a controlled depth of penetration with optimal power delivery to achieve the desired clinical effect.¹

Speedboat Microwave Technology and Control

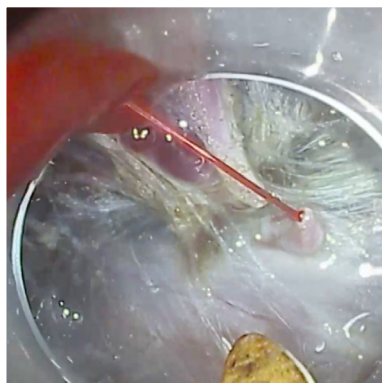
Microwave patented 5.8 GHz technology for instant delivery of coagulation with controlled spread and depth of penetration to prevent or stop bleeding immediately without changing devices.¹ Microwave technology offers multiple advantages over current alternative techniques.¹



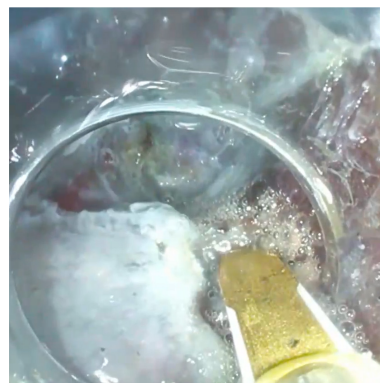
Pre-coagulation



Active bleeding



Active bleeding



Large vessels

Multiple applications

Advanced Bipolar RF for Dissection

Speedboat Advanced Bipolar RF Technology

Advanced bipolar RF adaptive technology differs from monopolar technology in that the tissue effect, and therefore current flow, takes place between two electrodes that are located close together at the tip of the instrument without the need for a return pad.

Delivery of focused, adaptive energy combined with the protective hull structure, for a smooth and precise cut, where it's needed, whilst minimising risk of muscle bed injury.

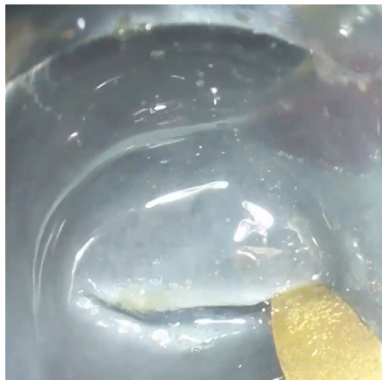
Utilising advanced bipolar RF energy for dissection, the technology is designed a precise cut when in contact with tissue, safely and automatically, with clean margins to improve healing rates and provide high quality histology samples.

Blade Design with Focused Energy

Fixed distance with a short, focused pathway for targeted energy delivery enabling a voltage <460 V.

Adaptive closed-loop technology & proprietary waveform

Adjusts voltage/current based on tissue impedance automatically to maintain power density for a smooth, high quality and precise cut.



Cut with minimal bleed



Cut close to vessels,
cut close to the muscle

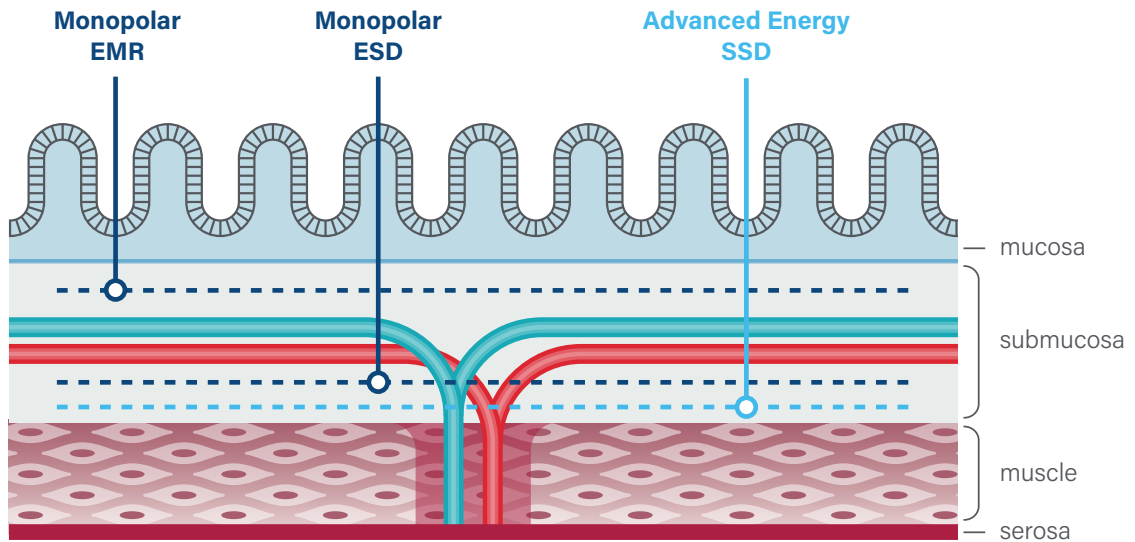


Cut fibrotic tissue



Uncharred margins
and muscle 'bed'

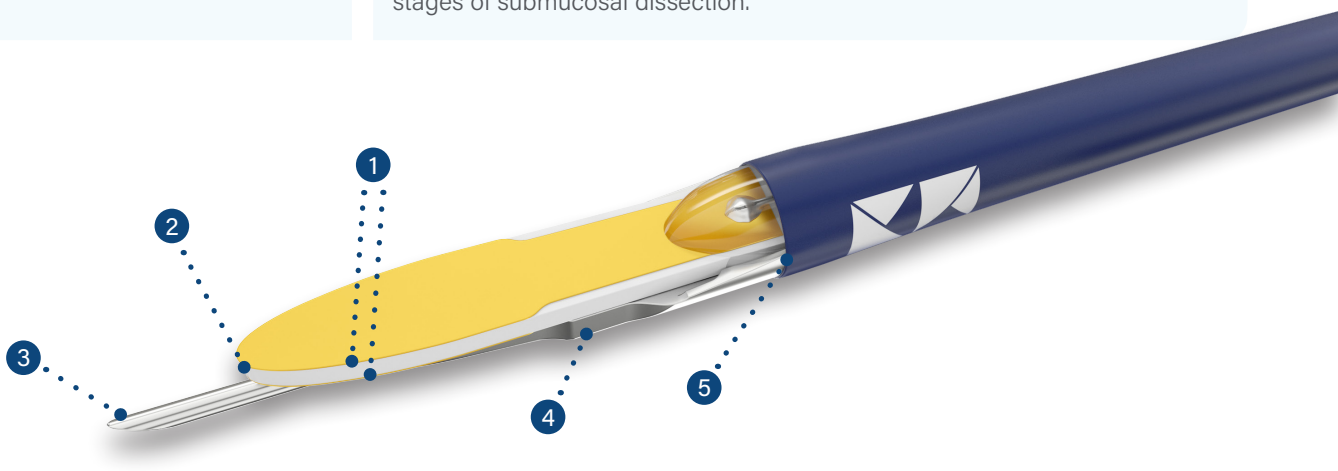
End with a clean resection



Speedboat Inject: Features & Benefits

Speedboat Inject is the first Advanced Energy multi-modal instrument designed for flexible endoscopy that can deliver both advanced bipolar RF and microwave energy from a single device.

Feature	Benefit
<p>1 Advanced bipolar RF blade with adaptive technology</p>	<p>Blade design controls the depth of penetration and provides a focused pathway of energy delivery at lower voltage <460 V.</p> <p>Adaptive waveform automatically adjusts parameters to tissues and balances coagulation during cutting to minimise bleeding.</p>
<p>2 5.8 GHz super high frequency microwave with on-demand controlled coagulation</p>	<p>Microwave energy distributes heat evenly across the treatment area, coagulating the area and constricting the source of bleeds.</p> <p>5.8 GHz enables controlled depth of penetration not impacted by tissue resistance, designed to minimize the risk of perforations and charring.¹</p>
<p>3 Integrated injection needle</p>	<p>On-demand submucosal lift using a 26-gauge extendable needle, eliminating unnecessary instrument exchanges.</p>
<p>4 Protective hull, designed for safety</p>	<p>Protects the muscle bed from unwanted thermal injury by maintaining a consistent distance from the energy source, allowing cutting close to the muscle bed.</p>
<p>5 1:1 rotational feel, enabling predictable rotation for precise control</p>	<p>Torque Rotation Technology™ for accurate control, ensures the tip can be positioned to match the contour of the muscle bed at all stages of submucosal dissection.</p>





Specifications

Specification	Speedboat Inject 10Fr	Speedboat Inject 8Fr
Product Reference	7-RS2-001	7-RS2-003
Min. Channel Size	3.7mm	3.2mm
Catheter Size	3.2mm/10Fr	2.65mm/8Fr
Working Length	2.3m	
Needle Gauge	0.45mm OD (26 Gauge)	
Syringe Size	5 ml, 10 ml	
Advanced Bipolar RF (Cut)	25 -35 Watts	
Super High Frequency Microwave (Coag)	06 – 10 Watts	

Visit: www.creomedical.com for more information

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3. A new approach to endoscopic submucosal tunneling dissection: the “Speedboat-RS2” device. Zacharias P. Tsiamoulos et al. published in Endoscopy. <https://www.thieme-connect.de/products/ejournals/html/10.1055/a-0875-3352>
4. Endoscopic submucosal tunneling dissection: use of a novel bipolar radiofrequency and microwave-powered device for colorectal endoscopic submucosal dissection. Thomas R. McCarty, Hiroyuki Aihara. Published in Video GIE, official video journal of the American Society of Gastrointestinal Endoscopy. [https://www.videogie.org/article/S2468-4481\(20\)30090-4/fulltext](https://www.videogie.org/article/S2468-4481(20)30090-4/fulltext)
5. Tsiamoulos et al. First results using Speedboat Tunneling technique in colorectal submucosal dissection – clinical outcomes and procedure time prediction models. Poster presented at UEG 2020. <https://ueg.eu/library/first-results-using-speedboat-tunneling-technique-in-colorectal-submucosal-dissection-clinical-outcomes-and-procedure-time-prediction-models/240928>
6. Cost-effectiveness analysis of Speedboat submucosal dissection in the management of large non-pedunculated colorectal polyps, based on 50 patients. Authors: Amir Ansaripour, Mehdi Javanbakht, Adam Reynolds, Zacharias Tsiamoulos. Data on file.

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