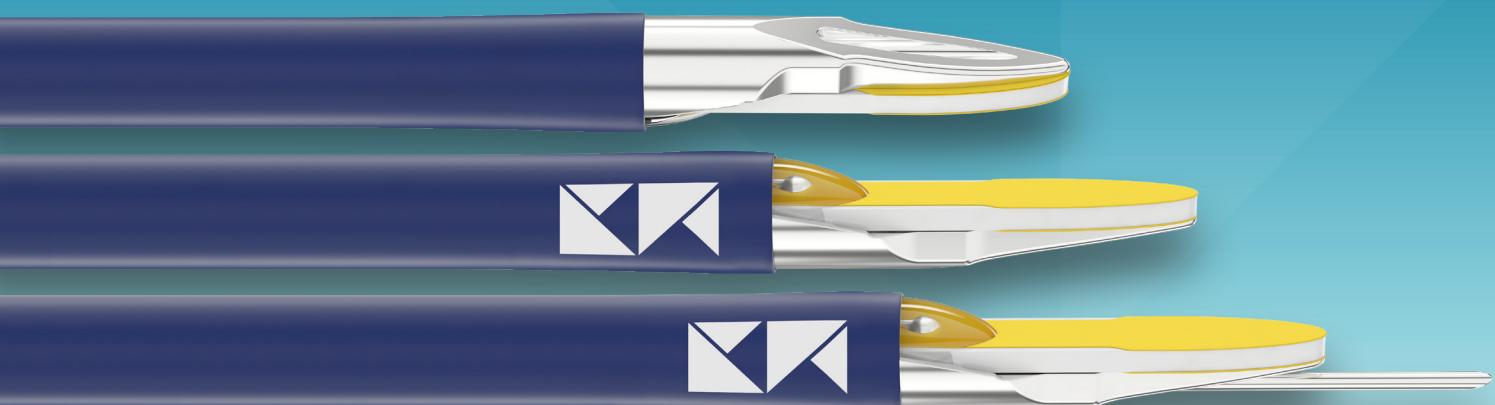




# Speedboat<sup>™</sup> Inject

**The First Multi-Modal Device with Advanced  
Bipolar RF Adaptive Technology for Cutting and  
Super High Frequency Microwave for Coagulation**

## Speedboat<sup>™</sup> Submucosal Dissection (SSD)



# Introducing Speedboat Submucosal Dissection (SSD)

## Introduction

Traditionally electrosurgery is used for therapeutic treatments in open, laparoscopic and endoscopic settings to cut, coagulate, dissect and ablate. Several energy modalities are used, including monopolar and bipolar RF, microwave, laser and ultrasound – each with their own advantages and disadvantages.

For endoscopic resection of tissue, polyps and lesions; channel size and length of endoscopes have traditionally limited use to mainly monopolar and a few bipolar RF devices performed using either Endoscopic Mucosal Resection (EMR) or Endoscopic Submucosal Dissection (ESD) techniques.

## The Power Behind SSD

Our innovative Kamaptive™ Technology combines multiple energy sources within our CROMA Energy Platform to optimize without compromise and provide unrivaled 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.

Using Speedboat Inject to perform SSD 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.

## Addressing Today's Clinical Challenges

Speedboat Inject is a multi-modal device that leverages the benefits of multiple technologies combined with a safety profile designed to increase protection of the muscle layer and provide the highest levels of safety, efficacy and usability for endoscopic resection.

Speedboat Submucosal Dissection addresses the challenges of current technology and devices, which include: lack of precision, lack of hemostatic capability, the need to exchange instruments during procedure (interrupting the procedural flow) and limitations on the size of lesion that can be removed.

SSD also offers a solution to the challenges posed by the complex learning curve and high procedure volumes needed to become proficient in ESD. Our comprehensive training program is designed to shorten the learning curve without compromising safety.

## CROMA Advanced Energy Platform



### Advanced Bipolar RF

enables a smooth cut with clean margins and minimal bleeding

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



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**<sup>3-9</sup>
- **optimal tissue effect**<sup>3-9</sup>
- **improved clinical and economic outcomes**<sup>9</sup>
- **expanded capabilities** in therapeutic endoscopy

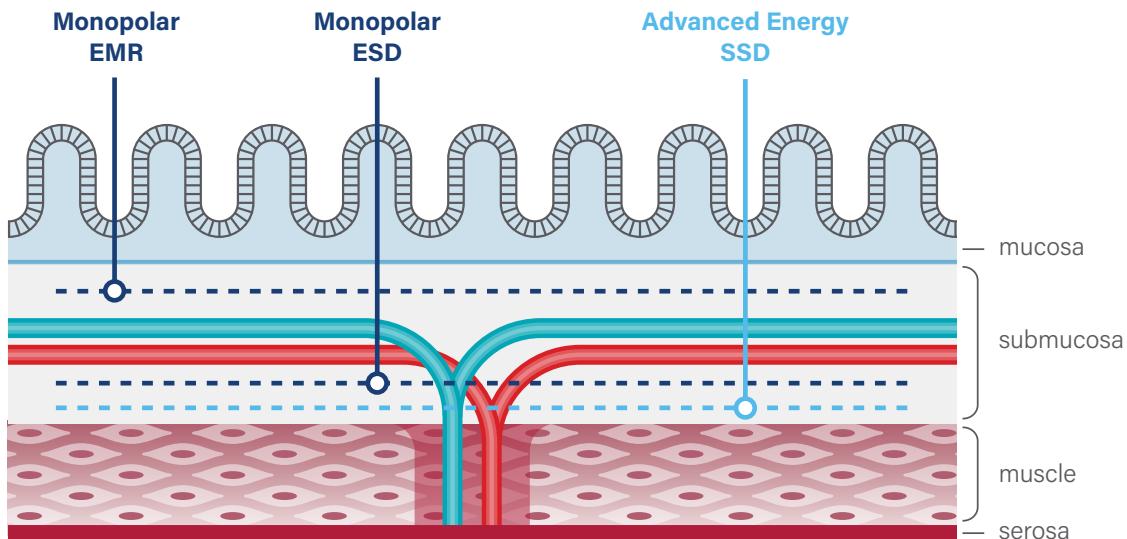


### Microwave

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

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

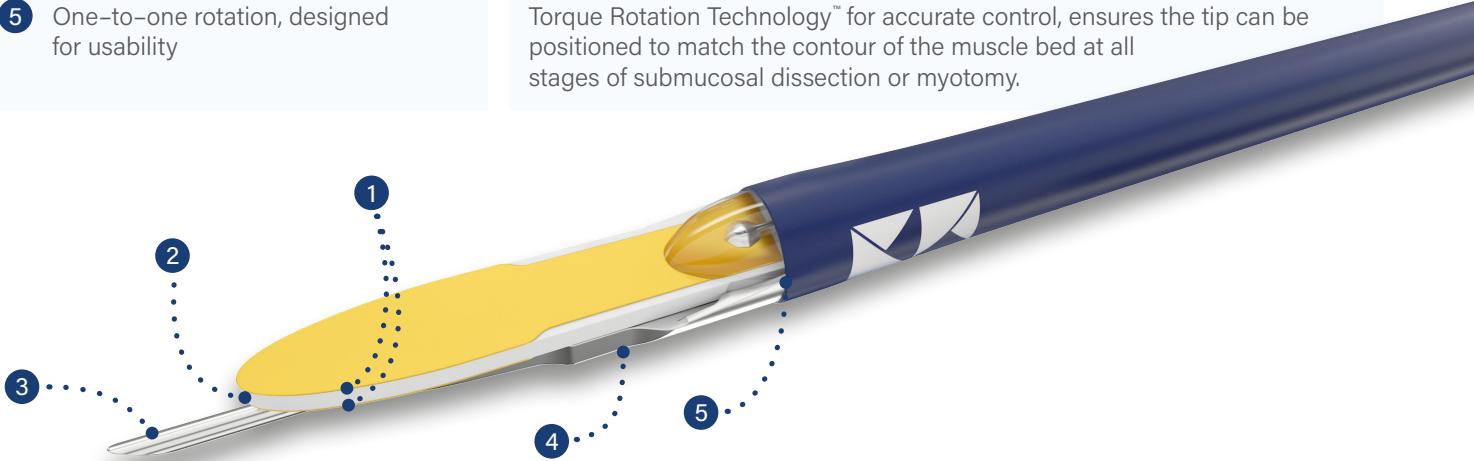
## SSD, A Deeper Dissection



## Speedboat Inject Features & Benefits

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

Feature	Benefit
1 Advanced bipolar RF blade with adaptive technology	Blade design controls the depth of penetration and provides a focused pathway of energy delivery of <460 V. Adaptive waveform automatically adjusts parameters to tissues and balances coagulation during cutting to minimize bleeding.
2 5.8 GHz super high frequency microwave with on-demand controlled coagulation	Microwave energy distributes heat evenly across the treatment area, coagulating the area and constricting the source of bleeds. 5.8 GHz enables controlled depth of penetration not impacted by tissue resistance, preventing the risk of perforations and minimizing charring.
3 Integrated injection needle	On-demand submucosal lift using a 26-gauge extendable needle, eliminating unnecessary instrument exchanges.
4 Protective hull, designed for safety	Protects the muscle bed from unwanted thermal injury by maintaining a consistent distance from the energy source, allowing cutting close to the muscle bed.
5 One-to-one rotation, designed for usability	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 or myotomy.



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

Utilizing advanced bipolar RF energy for dissection, the technology is designed to offer precise, contact cut 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, to maintain power density for a smooth, high quality and precise cut, without user interaction.

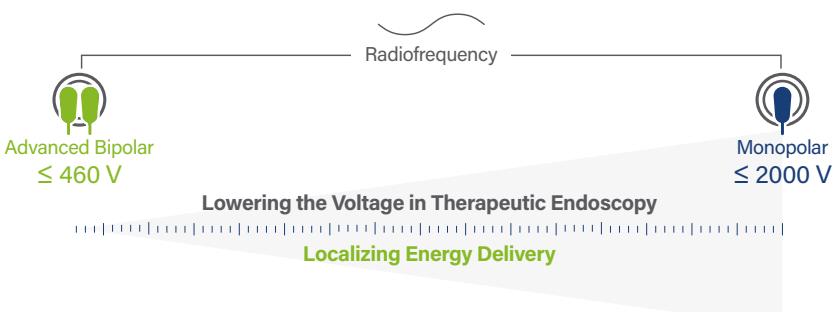
## The First Advanced Bipolar RF Multi-Modal Cutting Device for Therapeutic Endoscopy



### Cutting – Advanced Bipolar RF Blade with Adaptive Technology

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

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



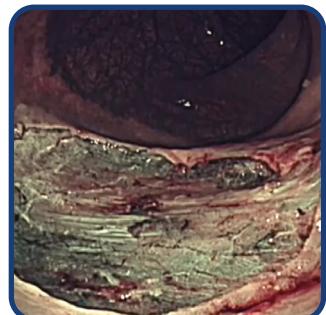
Cut with minimal bleed



Cut close to vessels,  
cut close to the muscle



Cut fibrotic tissue



Uncharred margins  
and muscle 'bed'

**End with a clean resection**



### Safety & Usability – Multi-modality Design

**Multi-functional instrument allows for unrivaled protection of muscle layer** without the need to change devices during procedure.

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

# Microwave Energy for Coagulation

## 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. Microwave technology offers multiple advantages over current alternative techniques.

## Microwave Energy for Safety and Control

Energy is delivered as an electromagnetic wave instead of an electrical current, which creates a homogeneous 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.

## 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.

## The First Microwave Coagulation Device for Therapeutic Endoscopy



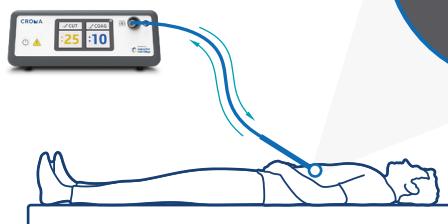
### Coagulation – 5.8 GHz Microwave Energy

**Safe, precise, on-demand coagulation** to both prevent and stop bleeding.

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

Tissue effect controlled by:

- Instrument design
- Time of application ( $\leq 10$  seconds)
- Frequency of microwave



Pre-coagulation



Active Bleeding



Large Vessels

## Multiple applications



### Speedboat Inject Advantages

1. Smooth cut AND highly effective coagulation
2. Minimal thermal damage, only what is intended
3. Protect the muscle layer for a deeper submucosal dissection
4. Minimize device exchanges

# Health Economics & Clinical Impact

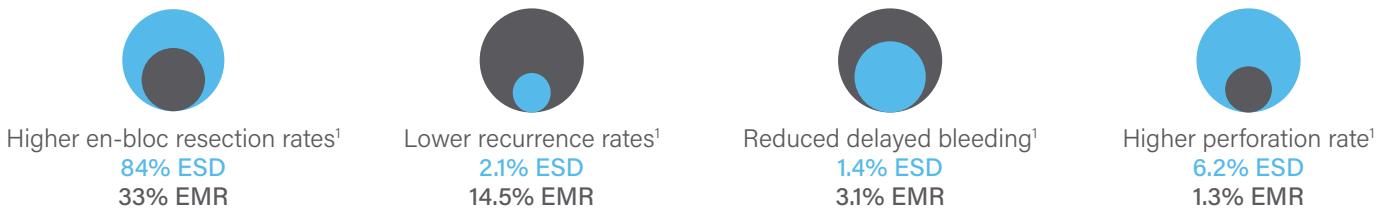
## Health Economics Impact: ESD vs. EMR and Laparoscopy

The submucosal dissection of large mucosal and submucosal lesions has been shown in clinical studies to offer advantages compared to Endoscopic Mucosal Resection<sup>1</sup>, including lower recurrence rates, quicker recovery and reduced hospital stays respectively.

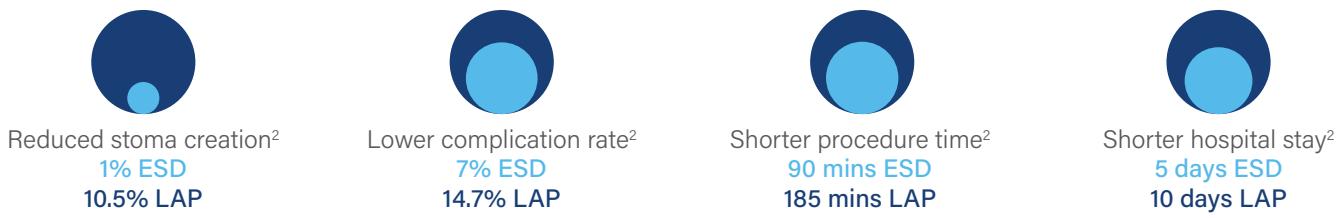
The potential reduction in costs realized with ESD compared to EMR, in the treatment of lesions >1 cm, may be attributed to better histology and lower recurrence rates, reduced delayed bleeding and perforations<sup>1</sup>. ESD also offers significant cost benefits over laparoscopy (LAP), reducing the incidence of stomas, and minimizing complication rates and hospital stays<sup>2</sup>.

The improved outcomes of ESD vs EMR and advantages over laparoscopy allow physicians to refer a larger proportion of patients for treatment in endoscopy with ESD.

### ESD vs. EMR



### ESD vs. LAP



## SSD Clinical Efficacy

Speedboat Submucosal Dissection (SSD), driven by the CROMA Advanced Energy Generator has been clinically shown to remove targeted tissue, while simultaneously offering surgical precision, saving procedure time, and eliminating the need for procedural device exchange both in porcine models<sup>1</sup> and in human trials<sup>3-7</sup>.

A study presented by Tsiamoulos *et al.*<sup>8</sup> reported that 64 patients underwent ESD with Speedboat Inject. En-bloc resection was performed in 83% (53/64) of patients and 77% (49/64) of resections were curative. The average (median) operating time was 90 mins (range 15 – 270 mins) and the average lesion size resected was 4 cm (range 1 – 12 cm). 5.6% (5/53) of cases completed en-bloc showed mild muscle injury, however no further intervention was required. The authors concluded that Speedboat Inject is a safe and optimal device for submucosal tunneling.

**77%** of Speedboat Inject resections were curative

**90 mins** average operating time

**4 cm** average lesion size resected

## SSD Health Economic Data

An independent Health Economic model<sup>9</sup> developed by clinicians and health economists, "Cost-effectiveness analysis of Speedboat Submucosal Dissection in the management of large non-pedunculated colorectal polyps", illustrates substantial savings to the NHS when using SSD versus the alternative EMR and Laparoscopic Colorectal Surgery (LCS) methods.

With approximately 177,000 polyp of colon procedures performed annually in the UK, these savings have the potential to save the NHS millions per annum.

Savings per procedure using SSD

- **SSD vs LCS: £10,878**
- **SSD vs (LCS + EMR): £4,294**

Potential savings for total procedures per annum using SSD

- **SSD vs LCS: £1.9 Billion**
- **SSD vs (LCS + EMR): £800 Million**

# Our Commitment to You Through Education & Training

## Working in Partnership with Healthcare Professionals

Our dedication to improve patient outcomes using Advanced Energy includes substantial investment to educate, train, develop and continuously support healthcare professionals through their learning journey.

## Why Join the Creo Speedboat Educational Programme?

- Personalized approach to your training journey
- Training provided by a Health Care Professional Expert (HCPE) in their field
- Small group courses to ensure training delivery reflects your prior experience and skills
- Immersive integrated experiential & didactic learning
- Access to one-to-one mentorship
- Extensive support provided to wider clinical team, inclusive of those assisting with procedures
- Become part of a user community to exchange ideas and enhance your learning journey



“This is a brilliant course for aspiring SSD practitioners to learn the concept, usability and safety of the device, I can't wait to introduce it into my practice! ”

“I have attended a number of practical skills courses — this was the best. ”

“The right amount of hands-on training with expert faculty available. ”

## Speedboat Inject Specifications

The CROMA Electrosurgical System including Speedboat RS2 Surgical Accessory is intended for use in the cutting of soft tissue using radiofrequency current, the coagulation (hemostasis, cauterization) of soft tissue using microwave energy, and the delivery and injection of solutions for endoscopic surgical procedures within the gastrointestinal tract.

Product code	7-RS2-001
Operating frequency & maximum input voltage	Cut: 400 KHz, 460 V peak Coag: 5,800 MHz, 75 V peak
Working length	2.3 m
Endoscope working channel diameter	3.7 mm or more
Needle gauge	0.45 mm OD (26 gauge)
Syringe size	5 ml, 10 ml
Sterile, single use	Yes
Shelf life from the date of manufacture	12 months. Expiration date is stated on the instrument packaging label.
Electrosurgical recommended settings	Cut: 25 - 35 Watts Coag: 06 - 10 Watts
Compatible with	CROMA Advanced Energy Generator 7-EMR-050 Interface cable 7-RS2-210

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Creo Medical Inc.  
100 Reserve Road  
Suite B400  
Danbury  
CT 06810

UScustomerservice@creomedical.com