

# *A seatbelt approach to safety in colorectal surgery*

*Gastrointestinal Surgical Sealants*



# Driving towards improvements in patient safety...

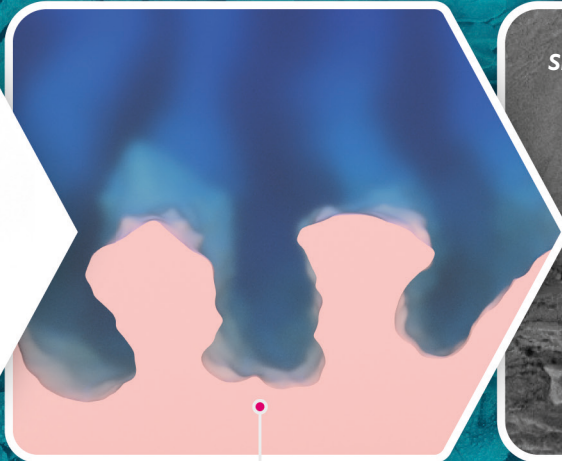
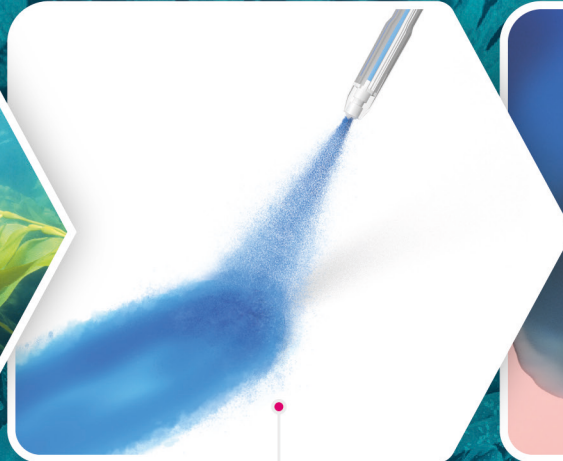
- **SEAL-G is a surgical sealing innovation** designed to provide additional layers of safety for the patient
- **Unique alginate technology** delivers strong and flexible anastomotic sealing to support and naturally protect the anastomosis
- **SEAL-G is ideal to complement the meticulous surgical technique** and additional precautions that you already take to reduce risk and impact of anastomotic leakage
- **SEAL-G provides a seatbelt that is designed to reduce leakage** and delivers peace of mind for you and the patient

8.6% anastomotic leak rate in colorectal surgery<sup>1</sup>

14 day length of stay increase<sup>2</sup>

22% reduction in 5yr survival<sup>3</sup>





SEAL-G sealant

Porcine serosa

- **Developed from nature-inspired Alginate** a safe and well understood marine polymer used in a range of advanced biomedical applications

- **Quickly and easily delivered** with optimised application systems for every anastomosis

- **Unique alginate bonding mechanism** enables strong and flexible anastomotic sealing by penetrating the tissue microstructure

- **Support & protection delivered to the patient** is demonstrated by SEM imaging of sealant-tissue interface in porcine pre-clinical model

***...by harnessing the natural power of the sea***



## Strong Sealing

- ✔ Powerful sealing and tissue bonding
- ✔ Flexible expansion and contraction during peristalsis
- ✔ Durable support during the critical post-operative period



## Natural protection

- ✔ Nature-inspired Alginate technology
- ✔ 100% free of human or animal components
- ✔ Fully resorbable with no toxic degradation by-products



## Easy Reinforcement

- ✔ Full sealing strength achieved within 60 seconds
- ✔ Right tool for every application with complete device family
- ✔ Room temperature storage and rapid preparation



*A seatbelt approach to safety  
in colorectal surgery*

## **SEAL-G<sup>®</sup> MIST System**

**SURGICAL SEALANT KIT**

*Minimally invasive / hybrid access device  
Spray application technique*

## **SEAL-G<sup>®</sup>**

**SURGICAL SEALANT KIT**

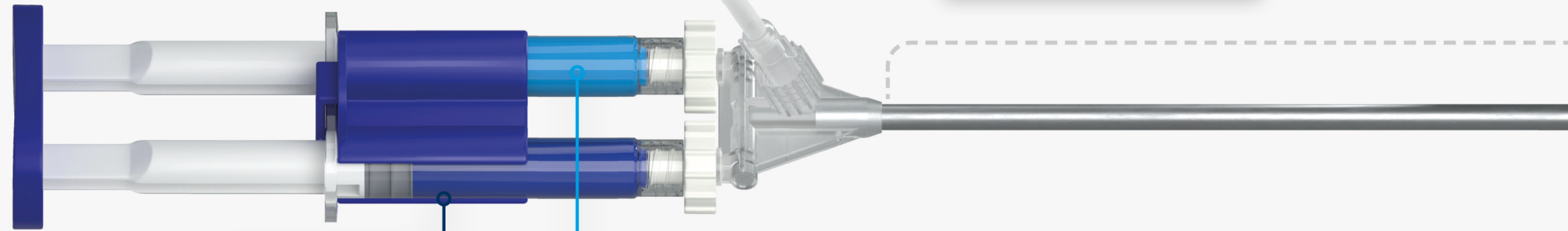
*Open access device  
Spread application technique*

*SEAL-G devices are used to seal & protect the  
serosal surface of the sutured / stapled anastomosis*

*Indicated for protection of gastrointestinal anastomoses*



Protect  
with



CO2 gas driven spray application

Alginate + Acetate  
(Trigger)

Alginate + Calcium Carbonate  
(Cross Linker)

4ml

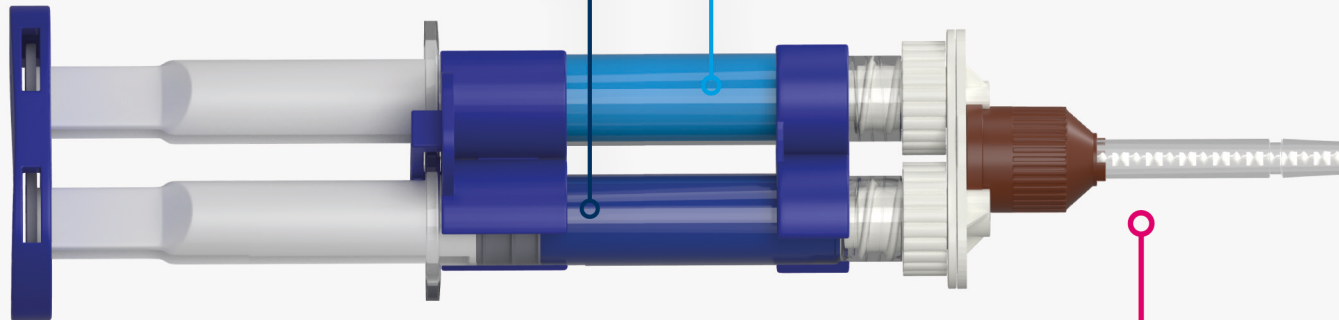
SEALANT  
VOLUME

1hr

WORKING  
TIME

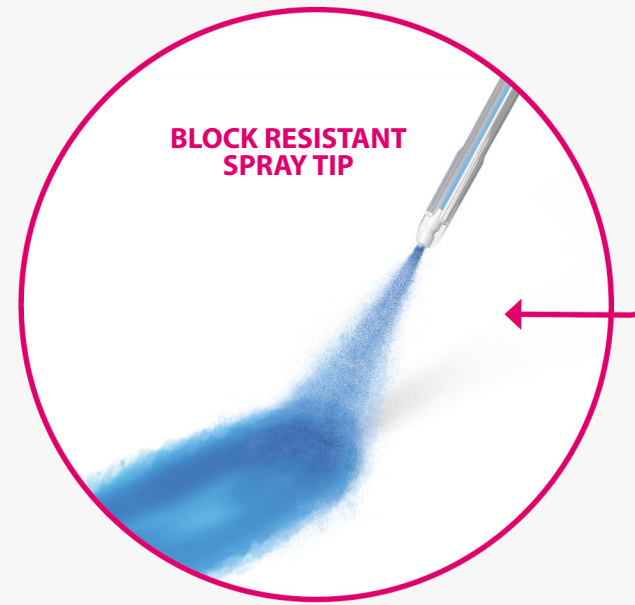
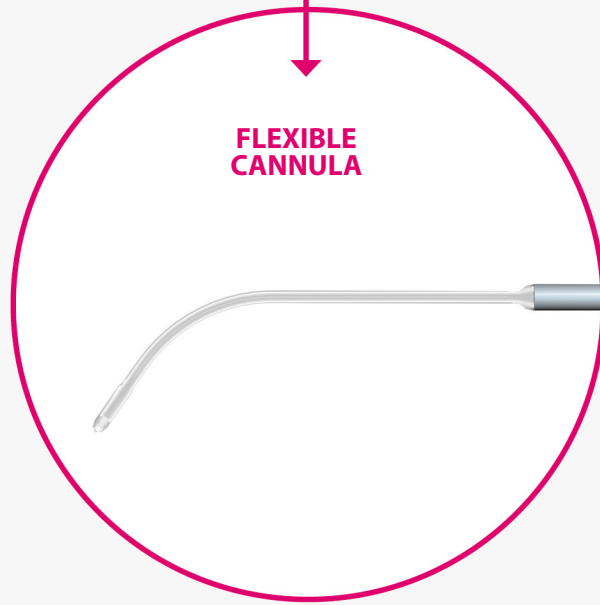
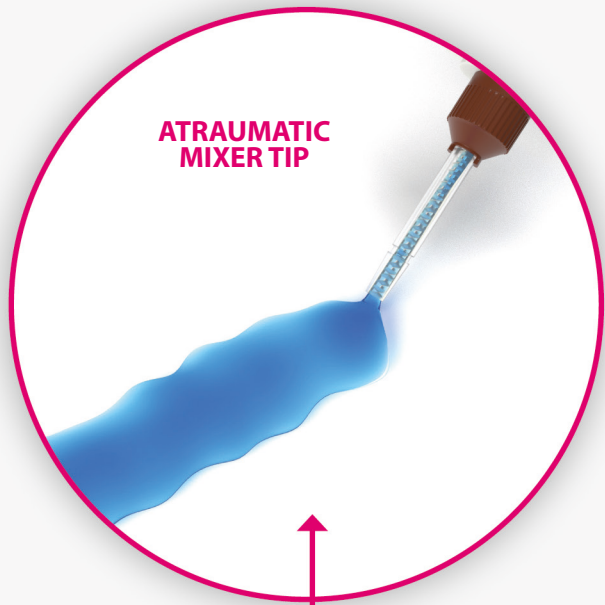


SECONDS  
TO CURE



**SEAL-G**<sup>®</sup>  
SURGICAL SEALANT KIT

400mm & 200mm Cannula lengths available





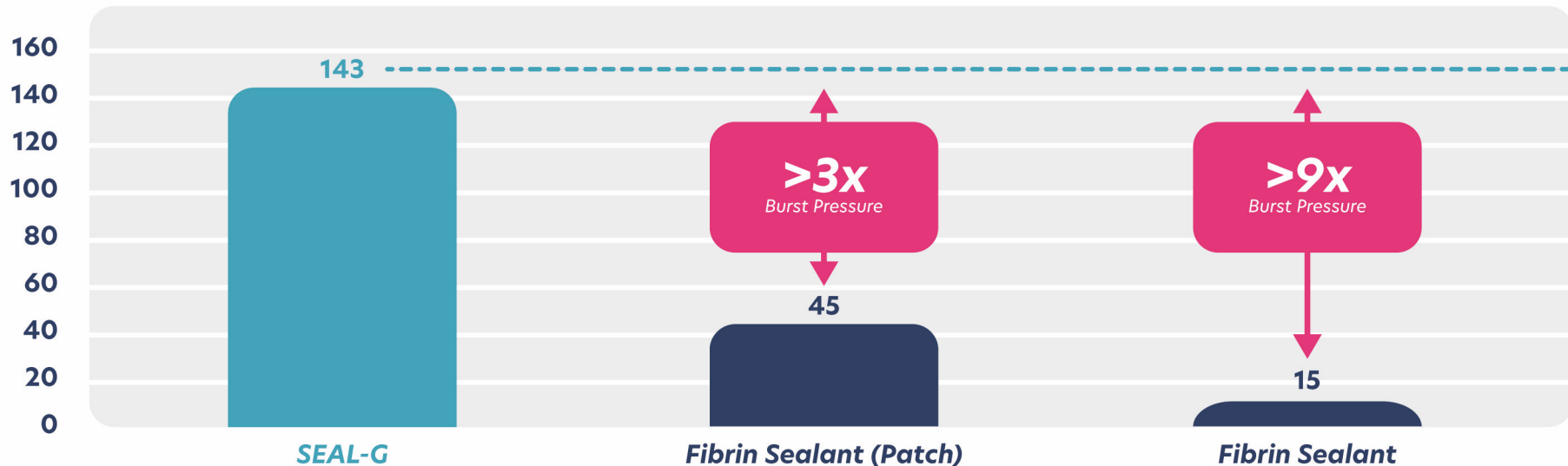
## SEAL-G offers high strength anastomotic sealing & protection

**In-vitro burst test strength testing reflects 2 important metrics:**

- Cohesive Strength: the strength of the bonds between sealant polymers
- Adhesive Strength: the strength of the bond between the sealant and a tissue substrate

**SEAL-G demonstrates both of these in vitro, with significantly better peak performance of SEAL-G vs. commercially available comparators.**

### Average burst pressure of sealants used in colorectal applications (mmHg)



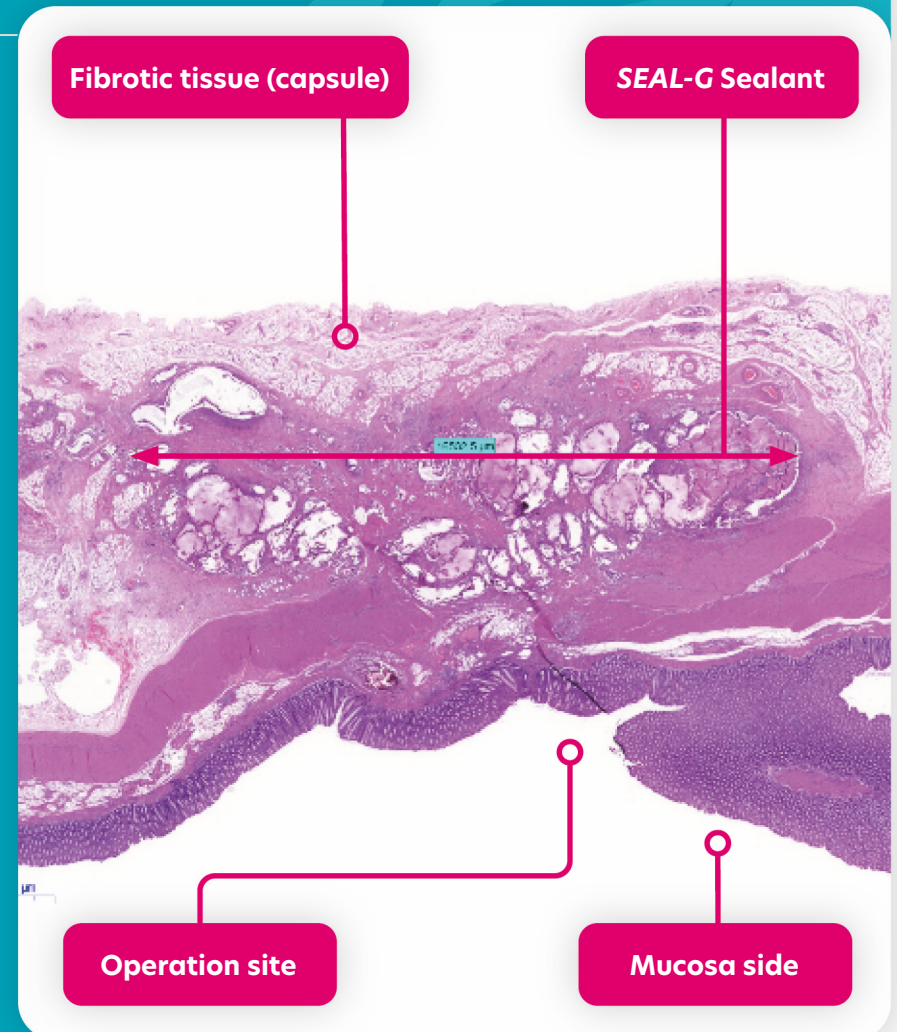
Testing performed per ASTM F 2392-04 (Standard Test Method for Burst Pressure Strength of Surgical Sealants), measured in mmHg. Testing was performed on porcine intestinal serosa.





## Durable anastomotic reinforcement and protection throughout critical post-op window

- **SEAL-G** has been investigated in a range of pre-clinical models to support safety and efficacy feasibility during product development.
- Histological analysis of **SEAL-G** reinforced anastomoses from these models demonstrates that at 14 days post-op **SEAL-G** sealant and surrounding fibrotic tissue completely encapsulate the anastomotic site.
- This ensures that a protective layer surrounds the anastomosis throughout the critical post-operative healing window and that **SEAL-G** supports prevention of anastomotic leakage and healing.
- At 3 months post-implantation, **SEAL-G** is >50% biodegraded. This process takes place as phagocytes biodegrade the **SEAL-G** sealant and replace with fibrotic tissues. Sealant degradation advances simultaneously with the tissue healing response, ensuring that the anastomosis is supported with an additional layer of sealant and fibrotic tissue at all times, preventing leakage.



## Indications for Use:

- **SEAL-G & SEAL-G MIST System Surgical Sealants** are intended for use as an adjunct to standard closure techniques for reinforcement and protection of gastrointestinal anastomoses.

## Contraindications:

- **SEAL-G & SEAL-G MIST System Surgical Sealants** should not be used in place of standard closure techniques (staples, sutures or mechanical closure).
- **SEAL-G** should not be injected into the blood stream.
- Do not spray **SEAL-G MIST** directly over or into open blood vessels, to avoid possible gas embolism.
- Do not use in case of known hypersensitivity to Indigo Carmine dye (FD&C 2/ E132).

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**For complete indications, contraindications, warnings, precautions, and adverse reactions, please refer to full package insert.**

1. The 2017 European Society of Coloproctology (ESCP) international snapshot audit of left colon, sigmoid and rectal resections - Executive Summary. *Colorectal Dis.* 20, 13-14 (2018).
2. Glasbey, J. C. et al. The impact of stapling technique and surgeon specialism on anastomotic failure after right-sided colorectal resection: an international multicentre, prospective audit. *Color. Dis.* 20, 1028-1040 (2018).
3. Stormark, K. et al. Anastomotic leak after surgery for colon cancer and effect on long-term survival. *Color. Dis.* 22, 1108-1118 (2020).

## Ordering information

Part Number	Description	Size	Qty per box
72014037	<b>SEAL-G</b> Surgical Sealant	4ml	1
72014040	<b>SEAL-G MIST</b> System Surgical Sealant Kit (400mm)	4ml	1
72014043	<b>SEAL-G MIST</b> System Surgical Sealant Kit (200mm)	4ml	1



## Contact Us



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