

ORISE™ Gel

**Boston
Scientific**
Advancing science for life™

ORISE Gel

- Pre-filled
- Pre-dyed
- Viscous gel
- Designed for easy injection
- Non toxic, food grade, biocompatible materials

Product
Overview

Endoscopic
Mucosal
Resection
(EMR)

En Bloc
Resection/
ESD

Viscosity
& Injection
Force

Convenience

Indications

Comparison
to Elevation

Ordering
Information

Resources

Product Overview

1

READY TO USE

Pre-filled, pre-dyed 10ml syringe kitted with delivery system 23ga Interject™ Injection Therapy Needle Catheter

2

VISCOUS SOLUTION

Designed to provide a submucosal fluid cushion

3

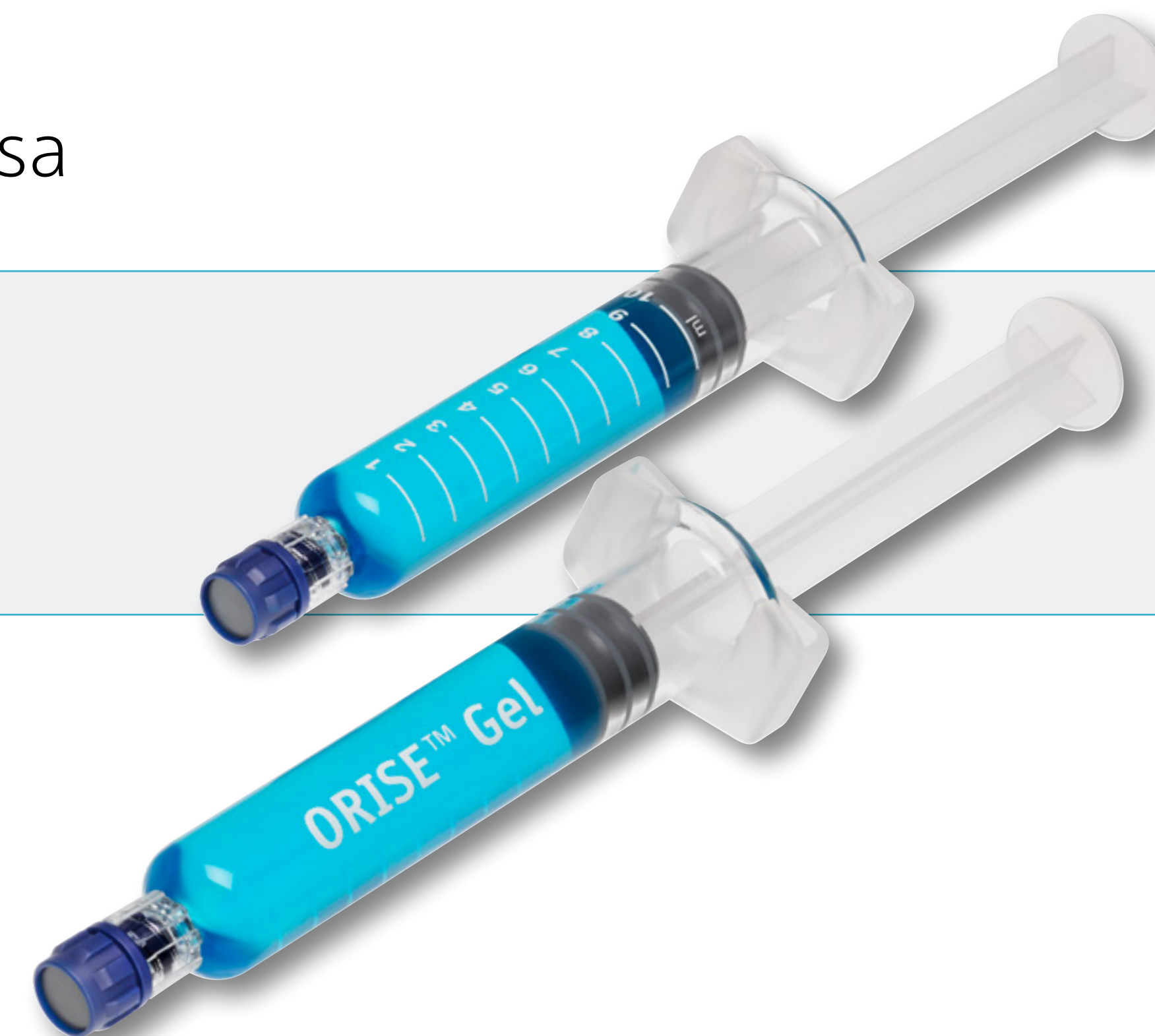
DESIGNED TO HELP REDUCE PROCEDURAL RISK

Provides clear differentiation between muscle and submucosa

4

INDICATED FOR ENDOSCOPIC PROCEDURES

510K K180068



ORISE™ Gel

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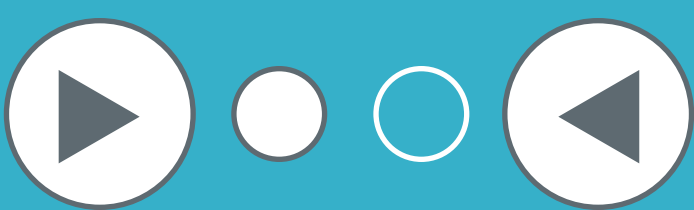
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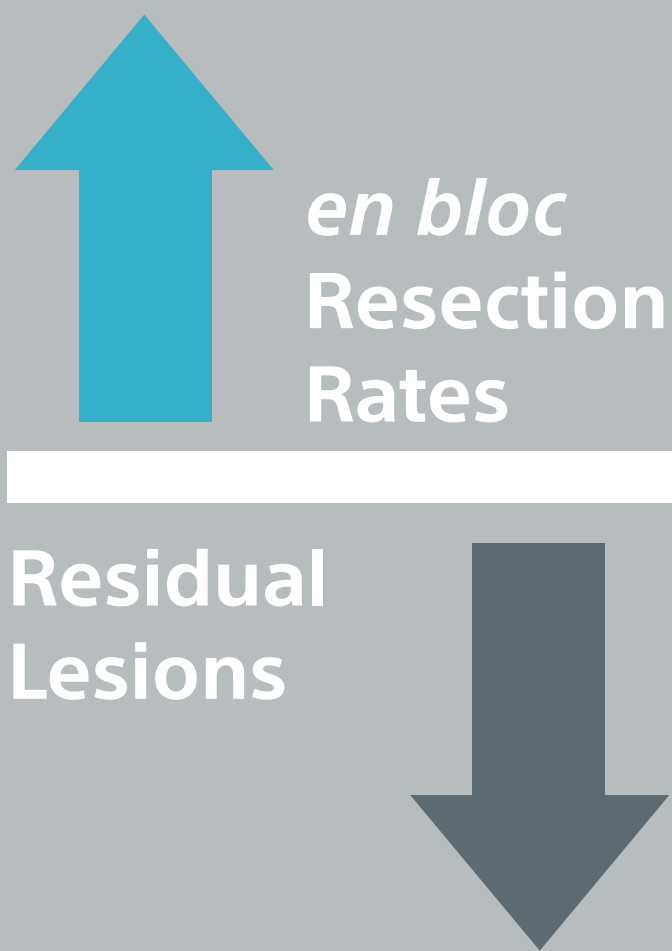
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Endoscopic Mucosal Resection (EMR)



Viscous Solution in Complex Polypectomy



Results of a systematic review and meta-analysis demonstrate an **increase in *en bloc* resection rates** along with **low rates of residual lesions with the use of viscous solutions**, compared to normal saline as the agent for submucosal injection prior to EMR*

Endoscopists should consider using viscous solutions for EMR.

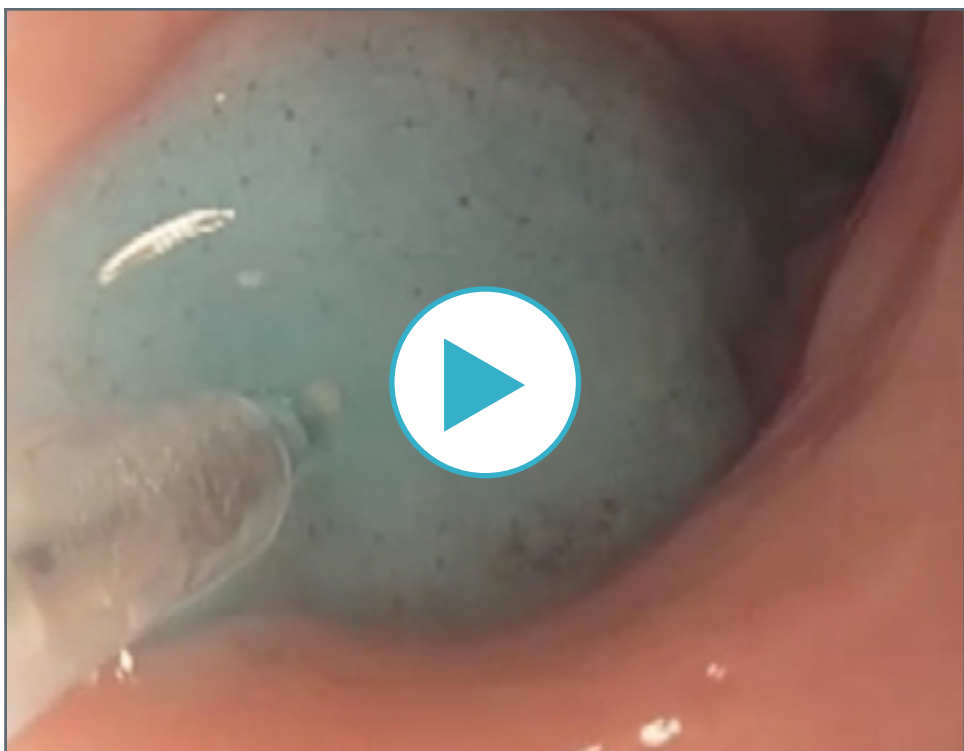
CLICK / TAP TO VIEW



Dynamic Injection Using Viscous Solution Presented by Douglas Rex, MD

- Viscous solution provides a mound that is concentrated underneath the lesion and has a dome shape
- A more viscous fluid provides longer duration of the mound

CLICK / TAP TO VIEW

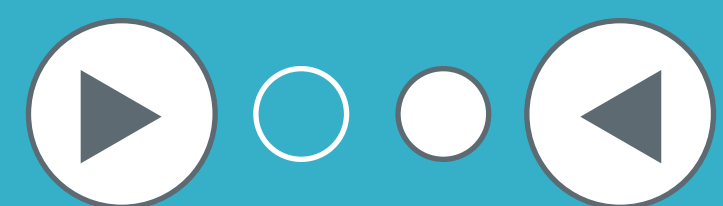


ORISE Gel – *in vivo* EMR

Video owned by Boston Scientific.

*Yandrapu et. Al., Normal Saline Versus Other Viscous Solutions for Submucosal Injection During Endoscopic Mucosal Resection (EMR) of Colorectal Polyps: a Systematic Review and Meta-Analysis. Gastrointestinal Endoscopy, Volume 81, Issue 5, Supplement, Page AB372, 2015

Endoscopic Mucosal Resection (EMR)



Designed to Reduce Procedural Risk – In EMR

Contrast agent in viscous solutions serves multiple purposes:

- 1 **For flat, conventional adenomas and serrated lesions**, contrast provides delineation of lesion edges through resection
- 2 **Contrast agent stains the submucosa blue**, and thereby facilitates identification of muscle injury.*
- 3 **May aid in the recognition of muscle injury** ("target sign") to avoid missed perforation diagnosis

The contrast agent chosen for ORISE Gel is a food grade blue dye.



*Muscle injury is characterized by appearance of white parallel bands in the resection defect and by a circle or ring of white tissue on the cut surface of the EMR specimen

Source Rex. 12 Tips for EMR in the Colon. Gastroendoneews.com 2017

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En Bloc Resection / ESD

Viscous Solution in *En Bloc* Resection (EBR) / Endoscopic Submucosal Dissection (ESD)

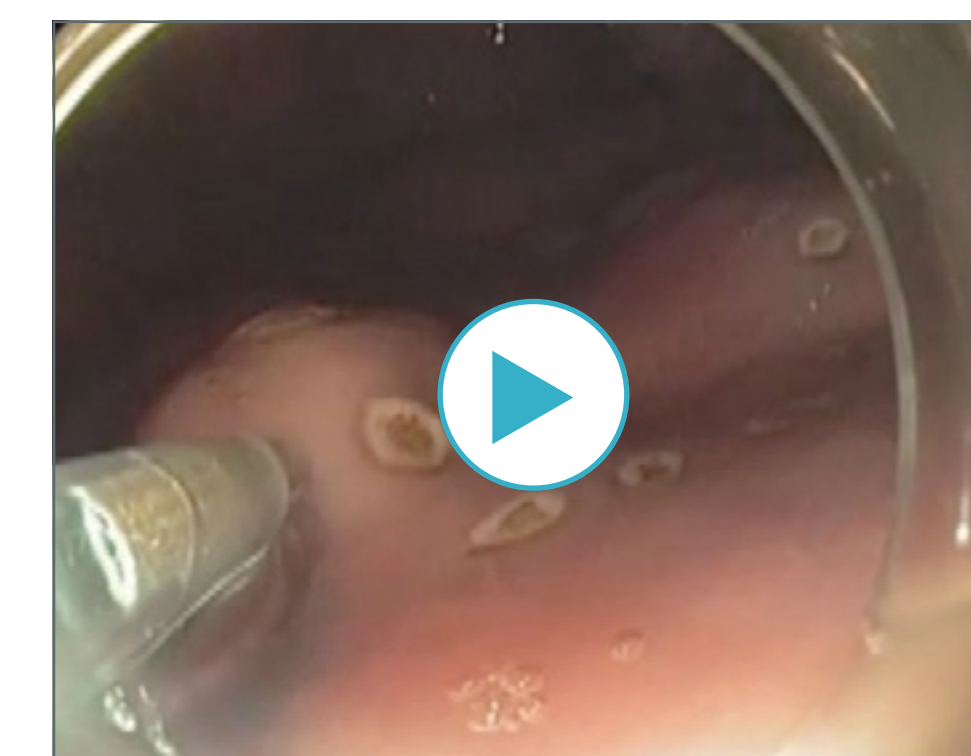
Creating A Submucosal Fluid Cushion



LIFTING ABILITY / VISCOUS SOLUTION*

- 1 **Saline dissipates quickly** when injected into the submucosal layer, resulting in rapid disappearance of the mucosal elevation
- 2 **It is necessary to create a prominent and long-lasting mucosal elevation.** The duration of lesion lifting is crucial for successful results
- 3 **The higher the viscosity,** the longer the submucosal fluid cushion lasts

CLICK / TAP TO VIEW



ORISE Gel -
in vivo ESD

Video owned by Boston Scientific.

*Dynamic Injection Using Viscous Solution, presented by Douglas Rex, MD.

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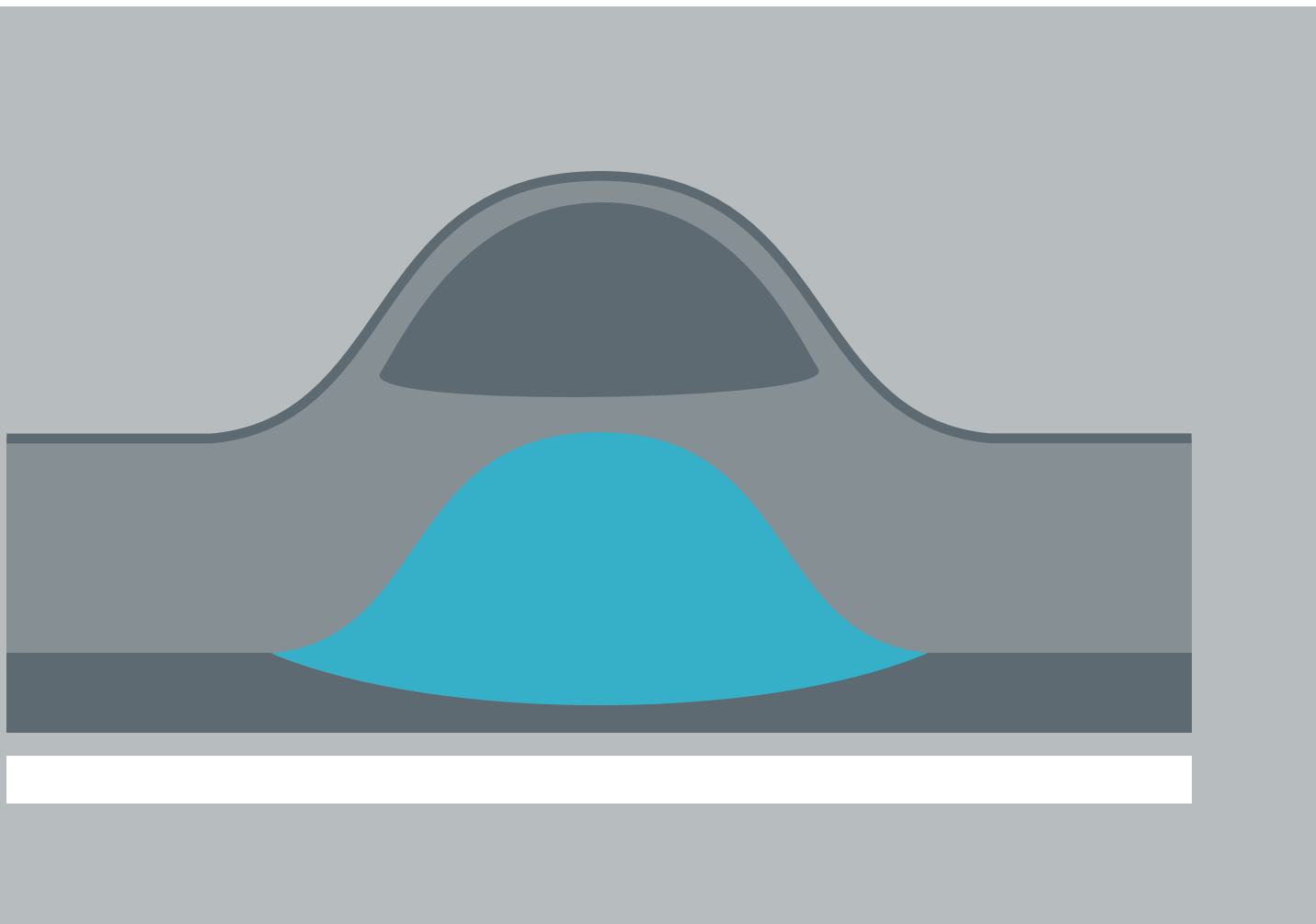
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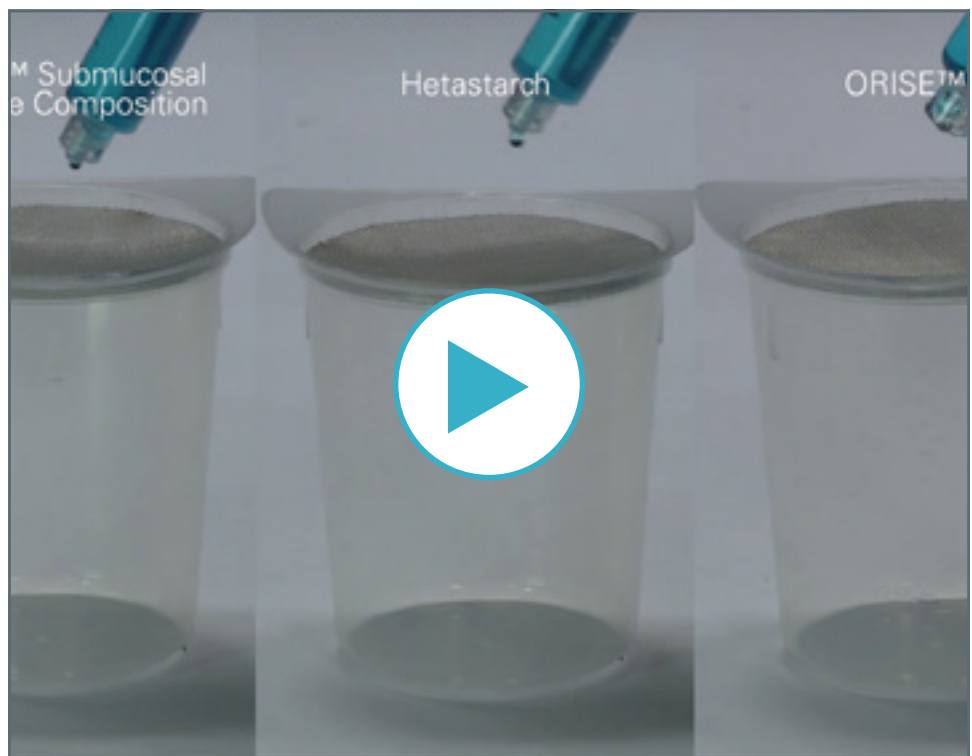
Viscosity & Injection Force

Benefits of a Viscous Solution

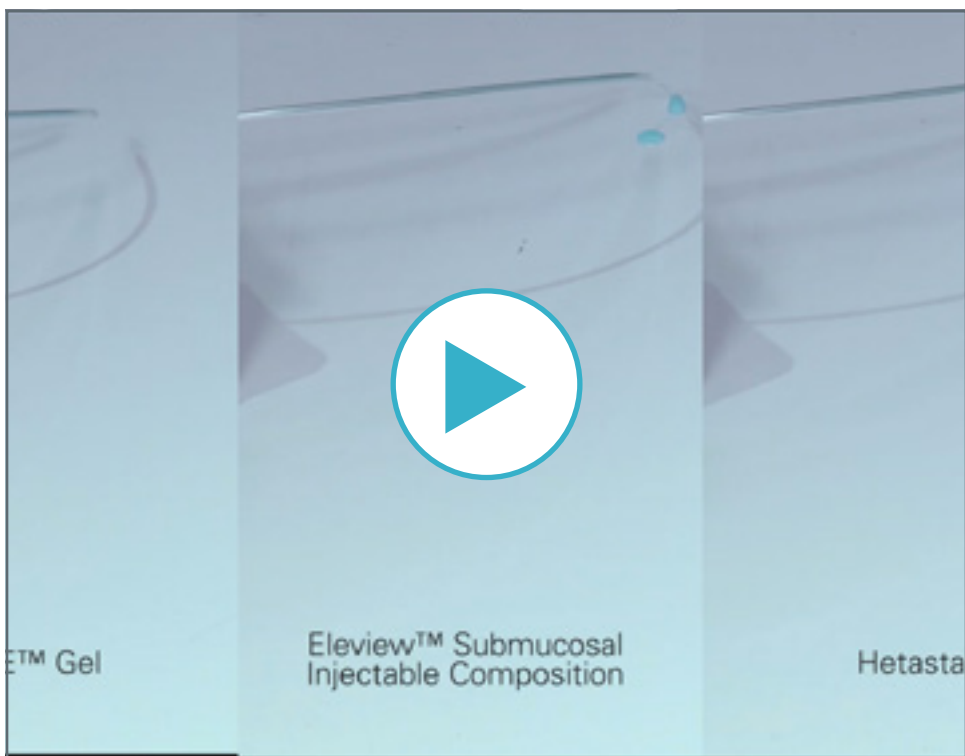


- A viscous solution may help to create a prominent, well-localized submucosal mound that does not spread laterally or dissipate
- Saline may spread beyond lesion borders and dissipate quickly

CLICK / TAP TO VIEW



ORISE Gel
Cup Group



ORISE Gel
Whiteboard Group

SELECT

ORISE GEL IS A VISCOUS SOLUTION WITH LOW INJECTION FORCE

- Designed to push easily through a **23 gauge Interject™ Injection Therapy Needle Catheter** when shearing force is applied
- Additionally, the **23 gauge Interject Needle** has a larger inner catheter diameter than Carr Locke Needle*
- 30 minutes after initial injection, ORISE™ Gel demonstrates 32% better height maintenance† than Eleview™ Injection*



**INJECTION FORCE
COMPARISON DATA CHART**



INTERJECT 23 GAUGE NEEDLE

*Measurements taken by Boston Scientific. Data on file. Actual values may differ. Bench test results may not necessarily be indicative of clinical performance. The testing was performed by or on behalf of BSC.

†Height maintenance is defined as the average change in height of submucosal injections after 30 minutes in ex-vivo study. Sample sizes of ex-vivo study n=45 (15 per solution: ORISE Gel, Eleview Injection, and Saline).

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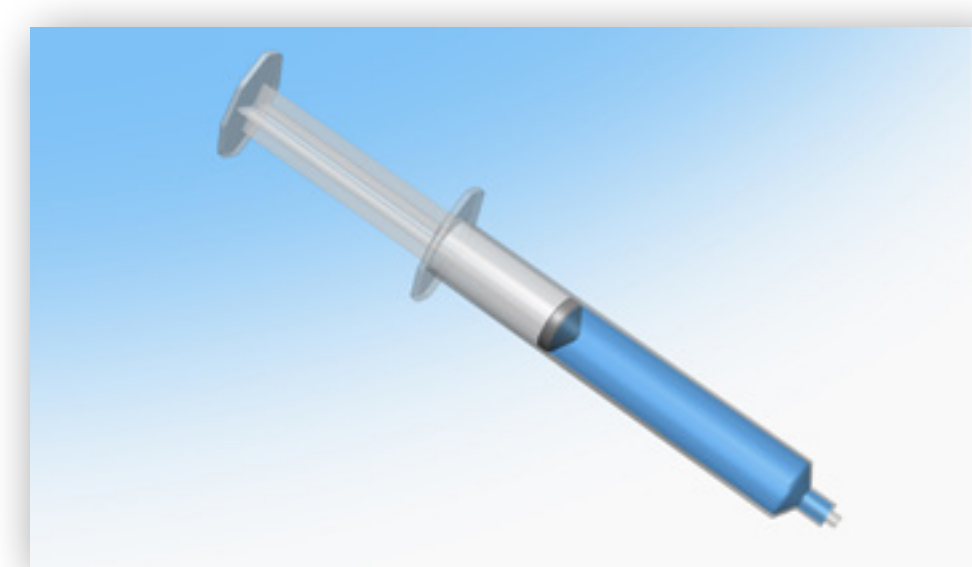
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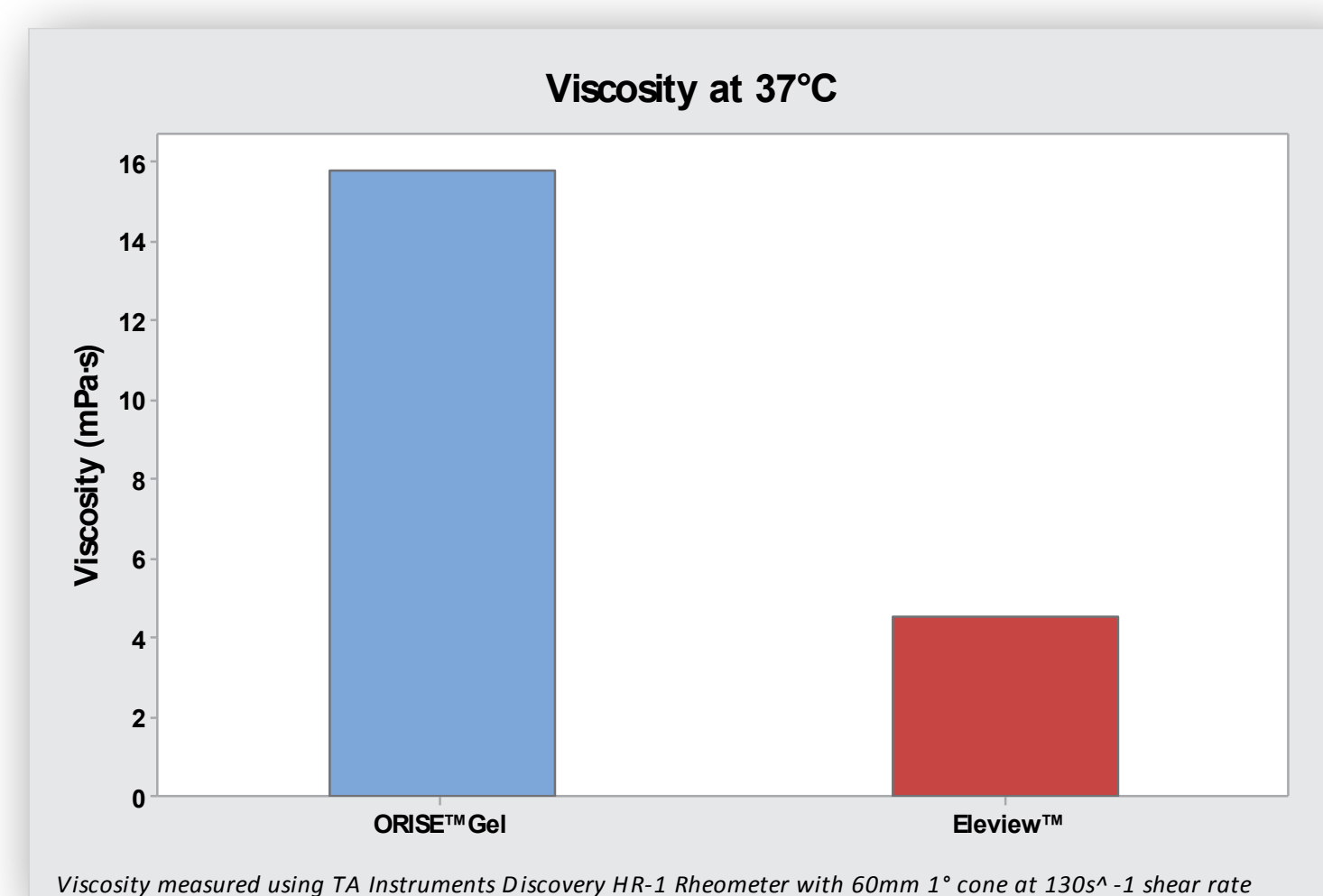
Injection Force and Viscosity



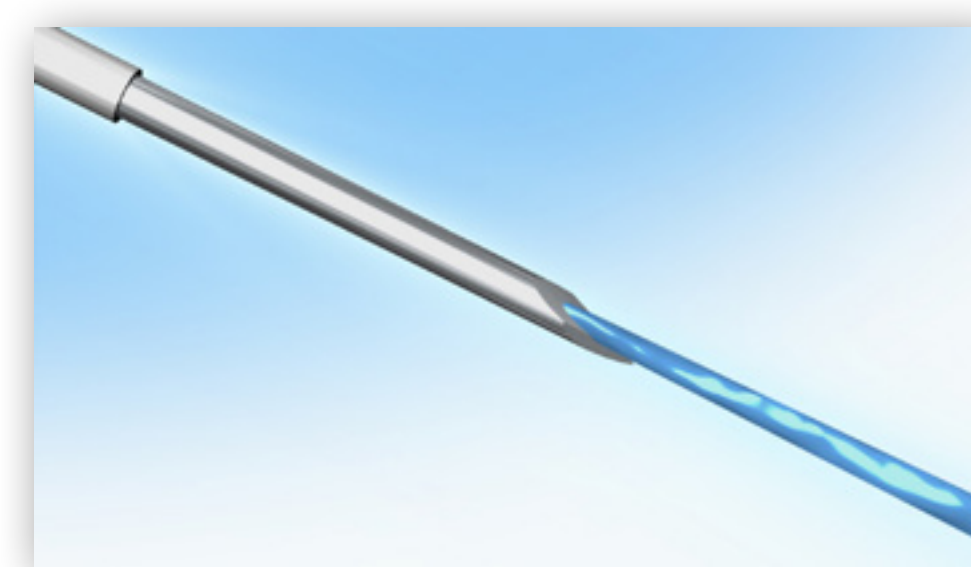
ORISE™ Gel is 3 times more viscous than Eleview™ Injection, but the force required to push through the syringe is similar to Eleview Injection.*



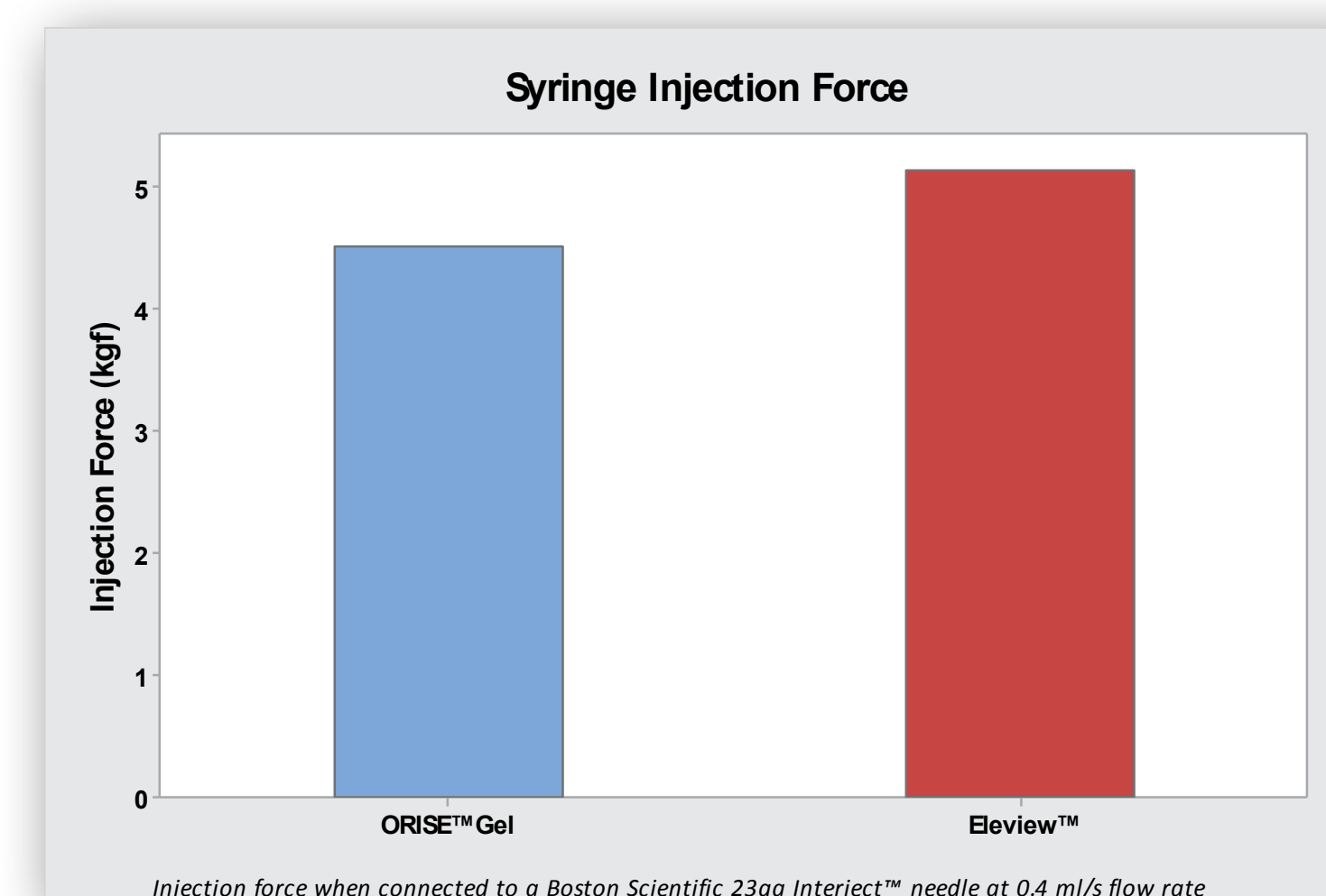
ORISE Gel viscosity, at rest in the pre-filled syringe, is significantly higher than Eleview Injection.*



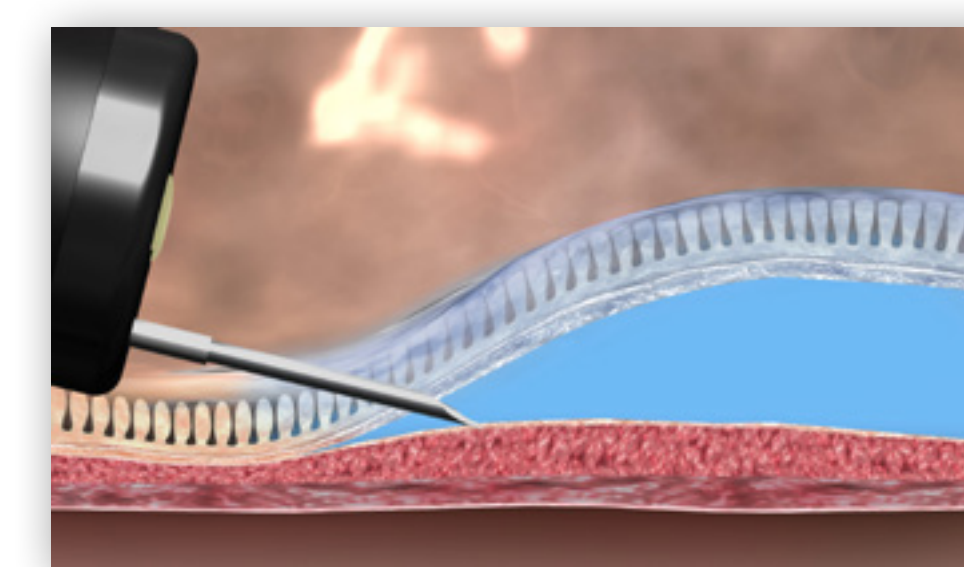
More Viscous...



ORISE Gel has a pseudo-plastic property, meaning its viscosity decreases under “shearing force” of being pushed through the syringe catheter and needle. It turns into a fluid gel.*



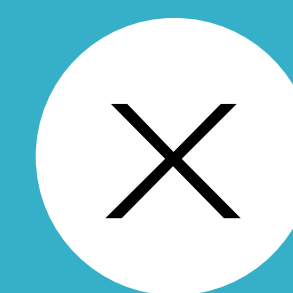
Lower Force Needed to Push through Syringe...



Back at rest within the tissue, the solution reconstitutes to a more viscous state.*

*The testing was performed by or on behalf of BSC. Data on file. Bench Test results may not necessarily be indicative of clinical performance.

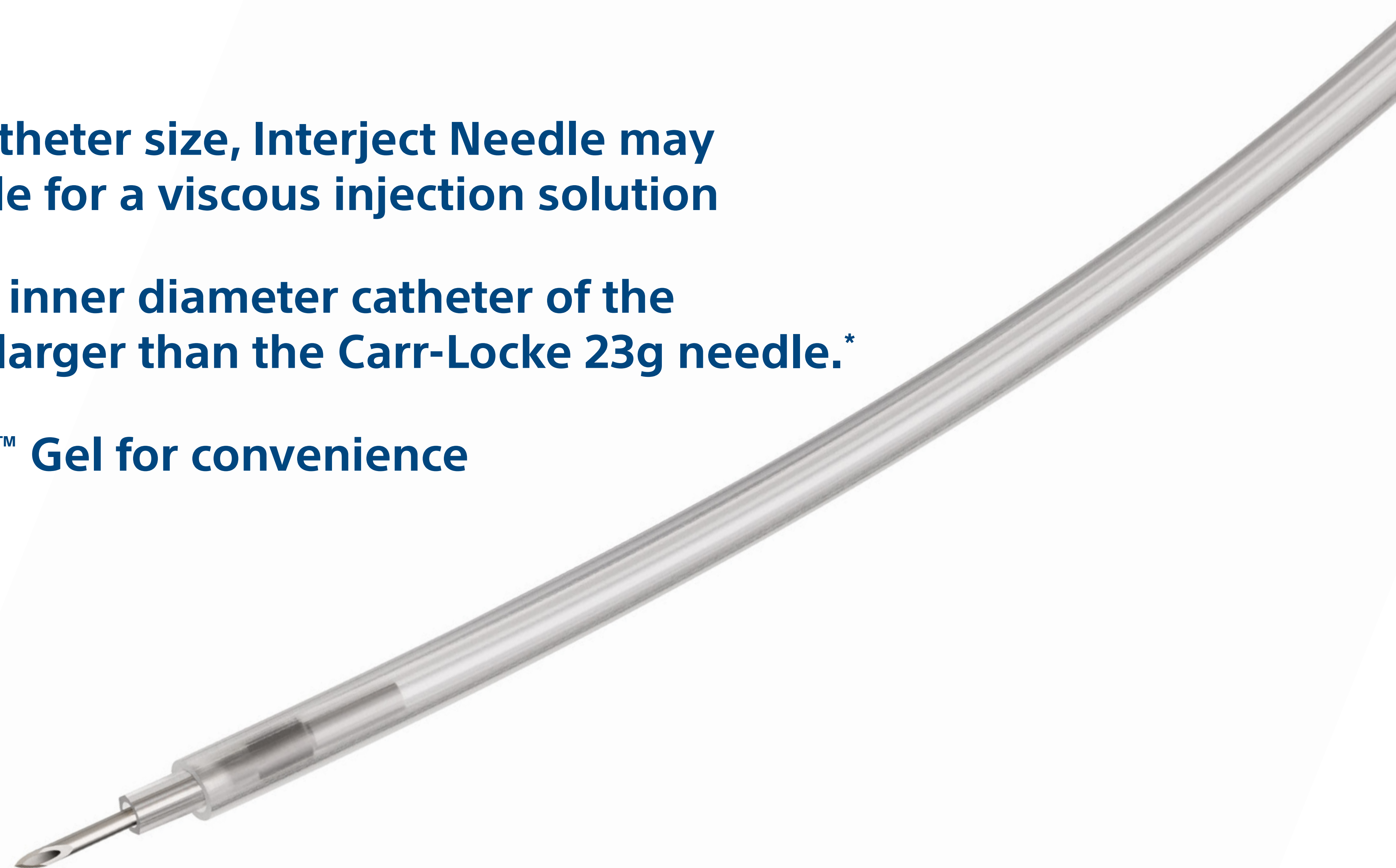
Interject™ Injection Therapy Needle Catheter Specifications



Due to its large inner diameter catheter size, Interject Needle may be a more ideal endoscopic needle for a viscous injection solution

While measuring the devices, the inner diameter catheter of the Interject Needle was found to be larger than the Carr-Locke 23g needle.*

Interject comes kitted with ORISE™ Gel for convenience

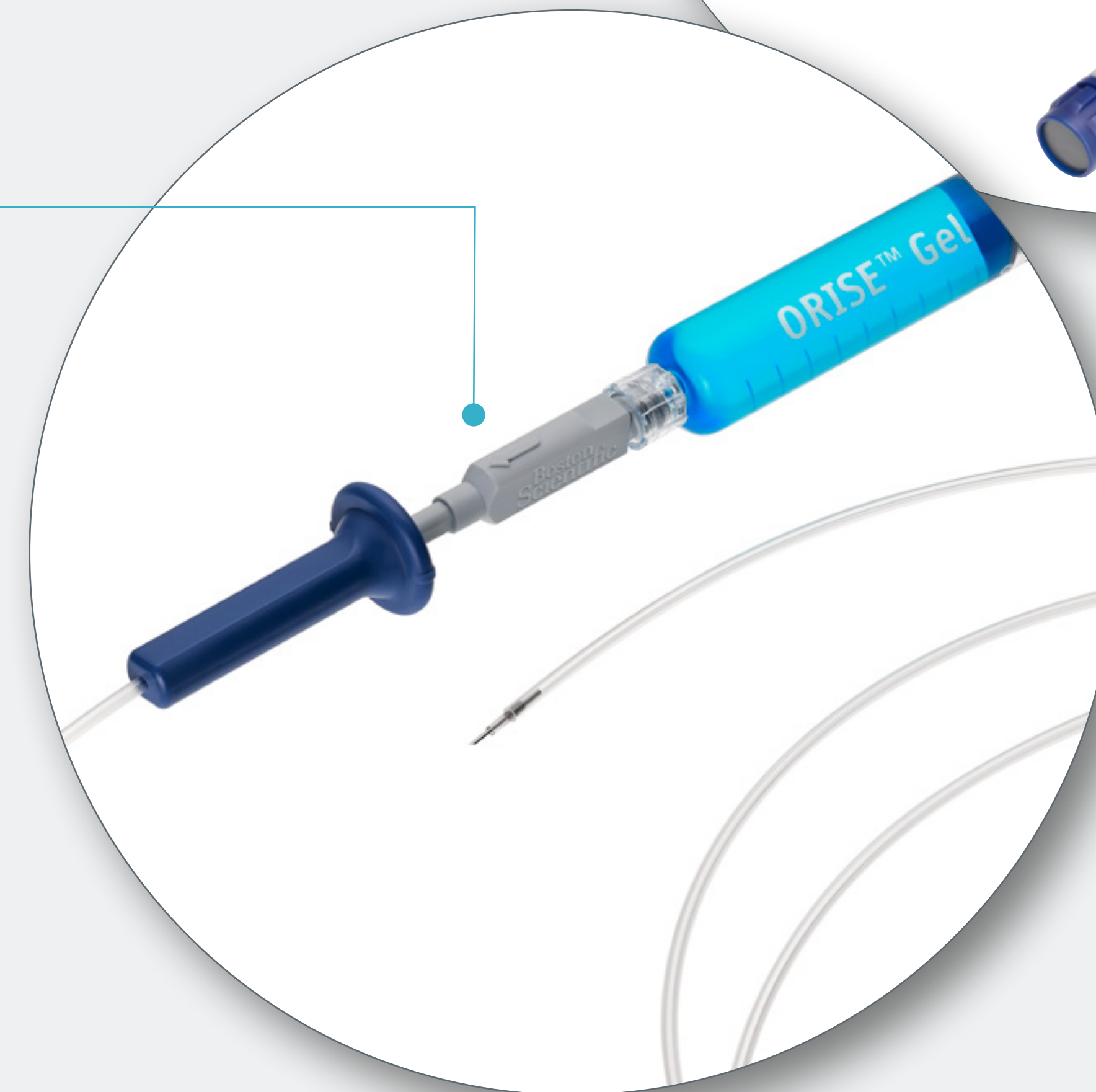
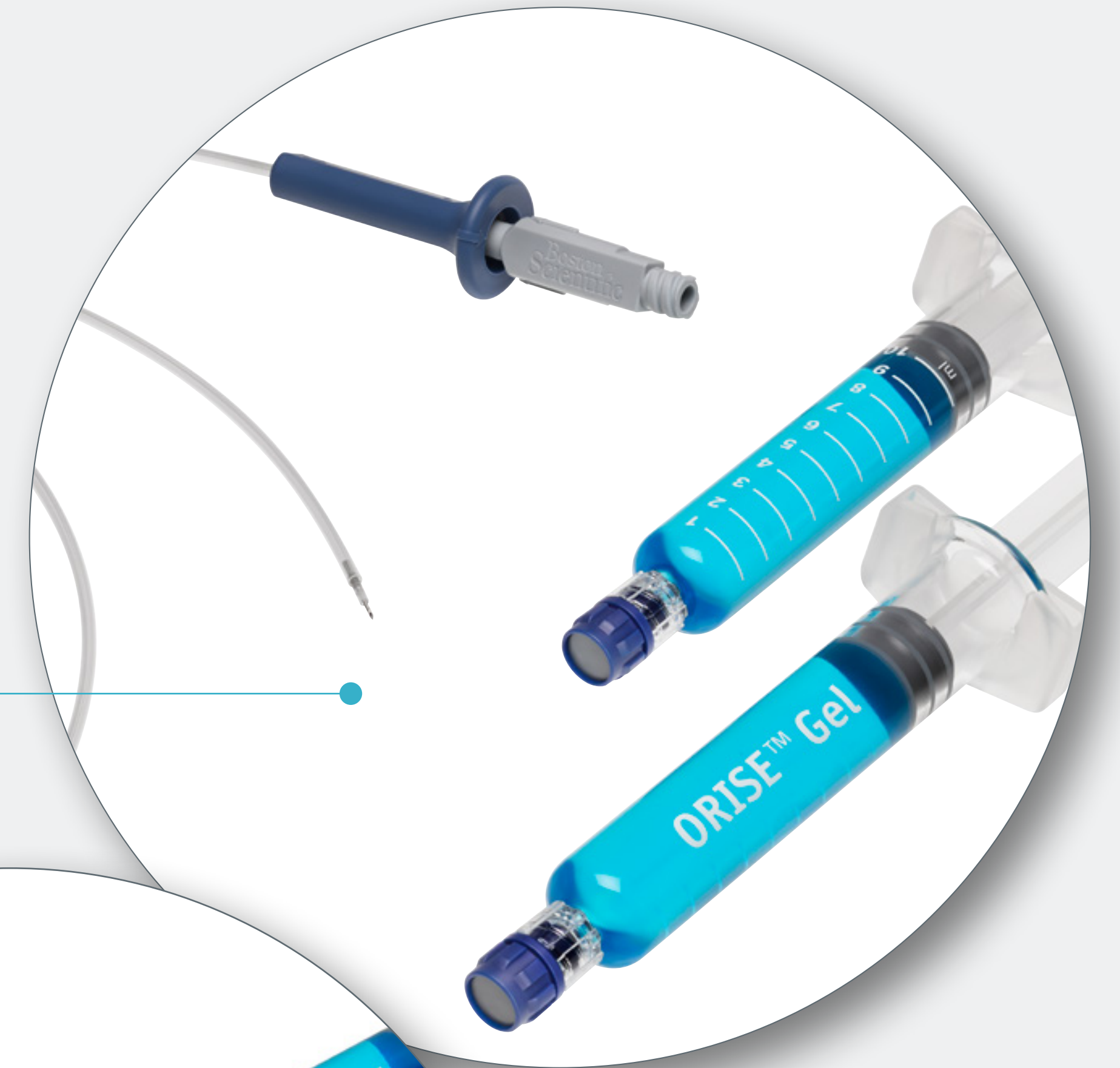


*Measurements taken by Boston Scientific. Data on file. Actual values may differ.

Convenience

Product Overview

- PRE-DYED GEL
- PRE-FILLED 10ML SYRINGE
- PACKAGED WITH 23 GAUGE INTERJECT™ INJECTION THERAPY NEEDLE CATHETER
- NO EXTRA SET UP REQUIRED. SIMPLY ATTACH SYRINGE TO INTERJECT™ NEEDLE'S LUER CONNECTION



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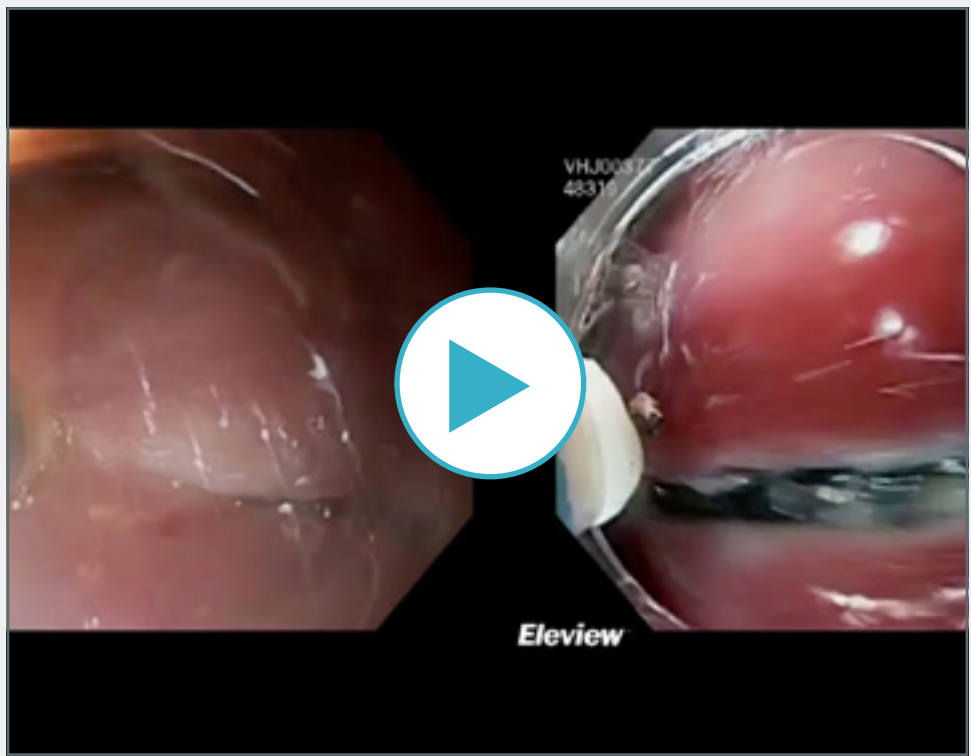
510K K180068

This device is intended for use in gastrointestinal endoscopic procedures. It will be used for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or other suitable endoscopic device.

Comparison to Eleview™ Injection

ORISE Gel	Eleview*
Contains a food grade blue dye	Contains methylene blue
10 ml pre-filled syringe, no extra steps required	10 mL ampule, no syringe included
Packaged in a kit with an Interject™ Injection Therapy Needle Catheter	Requires separate needle purchase
Contains no emulsifier	Contains the emulsifier Polyoxyl-15-hydroxystearate. Emulsifiers may increase the lifetime of bubbles.***

CLICK / TAP TO VIEW

An endoscopic video frame showing a surgical site. A blue play button icon is overlaid in the center. The word 'Eleview' is visible in the bottom right corner of the video frame.

ORISE Gel vs Eleview

Endoscopic Submucosal Dissection, *in vivo* porcine. ORISE Gel and Eleview Injection were used with an Olympus Dual Knife, by the same physician on equal size resections.**

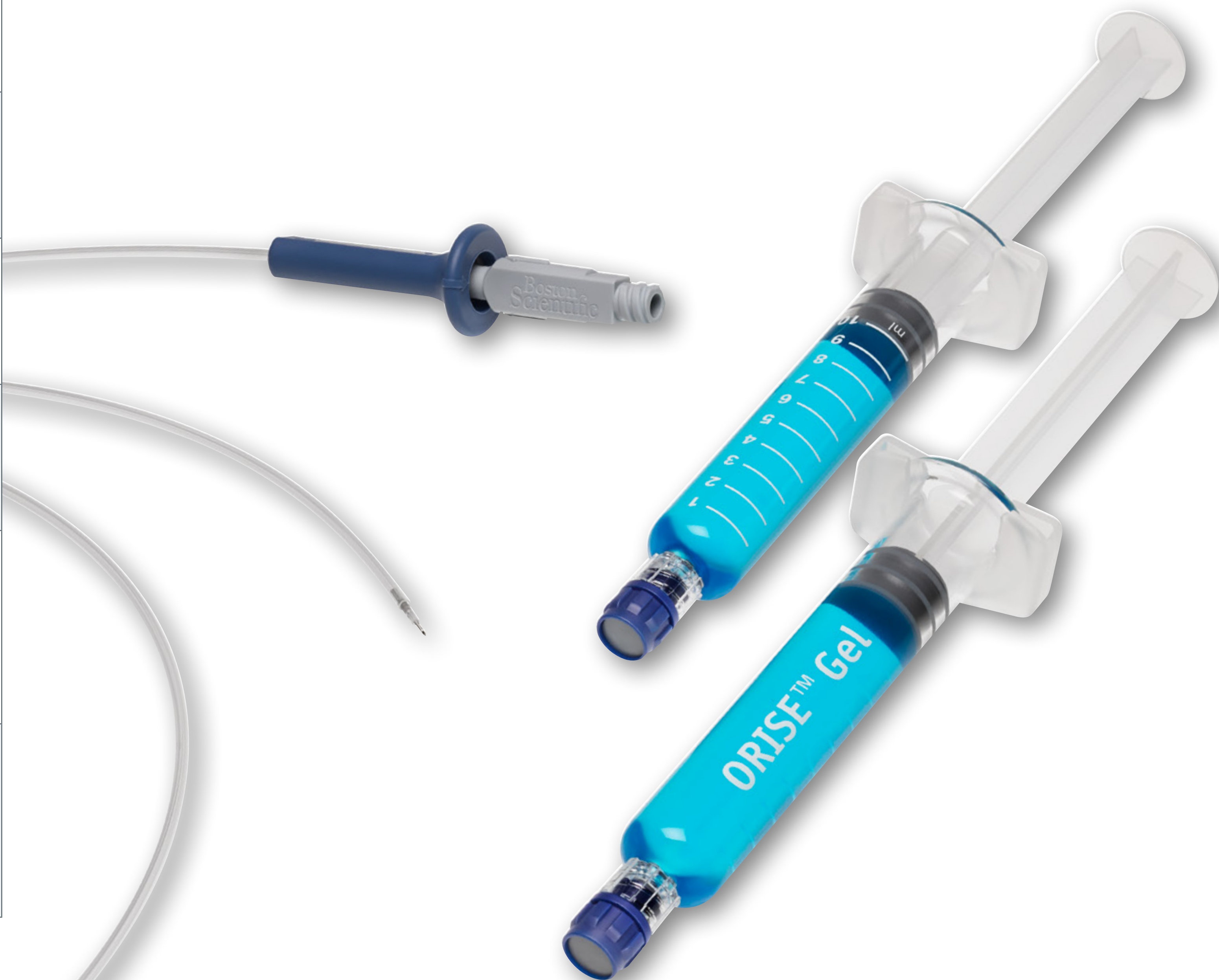
*<https://eleviewus.com>
**Measurement taken by Boston Scientific. Data on file. Actual value may differ.
***Bergensstahl B. (2008) Physicochemical Aspects of an Emulsifier Functionality. In: Hasenhuettl G.L., Hartel R.W. (eds) Food Emulsifiers and Their Applications. Springer, New York, NY

Ordering Information



ORISE™ Gel Ordering Information

ORISE Gel		
Order Number	Description	Packaging
M00519221	ORISE Gel Syringe Single Pack	Box 10
M00519231	ORISE Gel Syringe Single Pack with Interject Needle 23 ga Clear	Box 10
M00519201	ORISE Gel Syringe Twin Pack (two 10mL Syringes per tray)	Box 10
M00519210	ORISE Gel Syringe Twin Pack Kit with Interject Needle 23ga Clear (two 10mL Syringes per Kit)	Box 1
M00519211	ORISE Gel Syringe Twin Pack Kit with Interject Needle 23ga Clear (two 10mL Syringes per Kit)	Box 10



Ordering Information



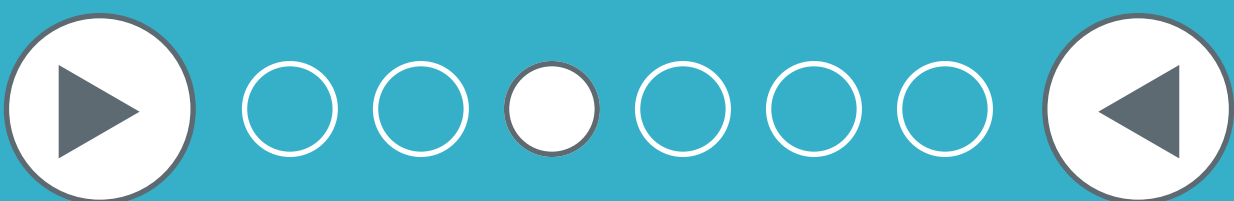
Other Devices for ESD Procedures

ORISE™ Tissue Retractor System							
Order Number	Anatomy	Reference	Diameter (mm)	Cage Length (cm)	Working Length (cm)	# of Channels	Scope Compatibility (mm)
M00519510	Left Colon	OTR-60	26	8	60	3	≤11.7mm outer diameter

ORISE Instrument Guides						
Order Number	Anatomy	Reference	Working Length (cm)	Tip Angles (degrees)	Tip Color	Instrument Compatibility (mm)
M00519520	Left Colon	OTR-90B	81	90	Blue	2.8
M00519530	Left Colon	OTR-90G	81	90	Gray	2.8
M00519540	Left Colon	OTR-60B	81	60	Blue	2.8
M00519550	Left Colon	OTR-45B	81	45	Blue	2.8

Rescue™ Retrieval Devices					
Order Number	Description	Jaw Opening (mm)	Sheath O.D. (mm)	Working Length (cm)	Packaging
DGC-383-5	Rescue Rat Tooth / Alligator Grasping Forceps	8	2.4	230	Box 5
DGR-277-5	Rescue Rat Tooth / Grasping Forceps	4.5	1.8	180	Box 5

Ordering Information



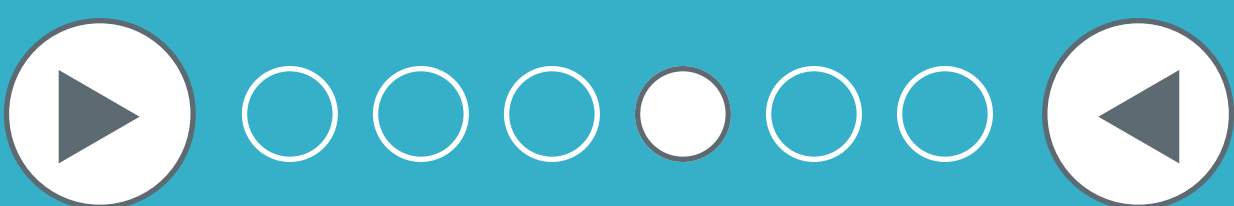
Other Devices for EMR Procedures

Captivator COLD Single-use Snare						
Order Number	Description	Loop Width (mm)	Sheath OD (mm)	Working Length (cm)	Min. Working Channel (mm)	Packaging
M00561101	10mm Rounded – Stiff	10mm	2.4	240	2.8	Box 10


Single-Use Snares Rotatable Snares* ⓧ							
Order Number	GTIN	Description	Loop Width (mm)	Sheath O.D. (mm)	Minimum Working Channel (mm)	Working Length (cm)	Packaging
M00561821	08714729283980	Small Oval – Medium Stiff	13	2.4	2.8	240	Box 10
M00561831	08714729283997	Medium Oval – Medium Stiff	20	2.4	2.8	240	Box 10

*With Star Catheter™ Technology.

Ordering Information



Other Devices for EMR Procedures


Captivator II Single-Use Snares 							
Order Number	GTIN	Description	Loop Width (mm)	Sheath O.D. (mm)	Minimum Working Channel (mm)	Working Length (cm)	Packaging
M00561221	08714729855903	10mm Rounded – Stiff	10	2.4	2.8	240	Box 10
M00561222	08714729861300	10mm Rounded – Stiff	10	2.4	2.8	240	Box 20
M00561223	08714729861317	10mm Rounded – Stiff	10	2.4	2.8	240	Box 40
M00561231	08714729855910	15mm Rounded – Stiff	15	2.4	2.8	240	Box 10
M00561232	08714729861331	15mm Rounded – Stiff	15	2.4	2.8	240	Box 20
M00561233	08714729861348	15mm Rounded – Stiff	15	2.4	2.8	240	Box 40
M00561241	08714729855927	20mm Rounded – Stiff	20	2.4	2.8	240	Box 10
M00561242	08714729861362	20mm Rounded – Stiff	20	2.4	2.8	240	Box 20
M00561243	08714729861379	20mm Rounded – Stiff	20	2.4	2.8	240	Box 40
M00561191	08714729855934	25mm Rounded – Stiff	25	2.4	2.8	240	Box 10
M00561192	08714729861270	25mm Rounded – Stiff	25	2.4	2.8	240	Box 20
M00561193	08714729861287	25mm Rounded – Stiff	25	2.4	2.8	240	Box 40
M00561291	08714729645801	Extra Large Rounded – Stiff	33	2.4	2.8	240	Box 10

Ordering Information



Other Devices for EMR Procedures



Resolution 360™ Clip* 					
Order Number	GTIN	Working Length (cm)	Minimum Working Channel (mm)	Clip Opening (mm)	Packaging
M00521240	08714729875666	155	2.8	11	Each
M00521241	08714729875673	155	2.8	11	Box 10
M00521242	08714729875680	155	2.8	11	Box 20
M00521230	08714729875628	235	2.8	11	Each
M00521231	08714729875635	235	2.8	11	Box 10
M00521232	08714729875642	235	2.8	11	Box 20
M00521233	08714729875659	235	2.8	11	Box 40


*Product with this symbol may be used in Magnetic Resonance environment according to the conditions described in Directions for Use.

Ordering Information



Other Devices for EMR Procedures



Resolution™ Clip 					
Order Number	GTIN	Working Length (cm)	Minimum Working Channel (mm)	Clip Opening (mm)	Packaging
M00522600	08714729504764	155	2.8	11	Each
M00522601	08714729504771	155	2.8	11	Box 10
M00522602	08714729504788	155	2.8	11	Box 20
M00522610	08714729504795	235	2.8	11	Each
M00522611	08714729504801	235	2.8	11	Box 10
M00522612	08714729504818	235	2.8	11	Box 20

¹Product with this symbol may be used in Magnetic Resonance environment according to the conditions described in Directions for Use.

Resources

CLICK / TAP TO VIEW

ORISE™ Gel

Submucosal Lifting Agent

Boston Scientific

Advancing science for life™

Frequently Asked Questions:

What is ORISE Gel?

ORISE Gel:

- Is a **pre-filled, pre-dyed viscous** gel solution
- Is composed of **non-toxic, biocompatible** materials
- Is made with a **food-grade, non-vital dye**, and **polysaccharide-based thickening agent**

Convenience & Performance

- Ready To Use** – Pre-filled, pre-dyed 10mL syringe kitted with delivery system (23ga Interject™ Injection Therapy Needle Catheter)
- Designed to Help Reduce Procedural Risk** – Helps to visualize margins of the target lesion and provides clear differentiation of the muscle layer
- Indicated For Endoscopic Procedures** – 510K K180068
- Ergonomic Injection Force** – designed for ease of pushability

What is ORISE Gel indicated for?

ORISE Gel is designed to be used for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or other endoscopic device.

Is ORISE Gel considered a pharmaceutical?

No. ORISE Gel is a medical device.

How does ORISE Gel Work?

ORISE Gel is designed to create a submucosal fluid cushion, elevating the mucosal layer and the tissue to be excised from the submucosal and the muscular layer, thereby facilitating safe resection or dissection.

What is used to inject ORISE Gel?

ORISE Gel 10mL prefilled luer lock syringes are compatible with Boston Scientific 23ga Interject Injection Therapy Needle Catheter.

How much ORISE Gel should be injected?

The amount to be administered is determined based on the size and type of the lesion to be removed. Inject enough ORISE Gel to form a submucosal cushion of adequate height and shape for the lesion to be removed. (Per the DFL, no more than 10 syringes should be administered in a single procedure.)

How long does the submucosal cushion last?

The duration of the lift will be dependent on patient vasculature and lesion type and will vary from patient to patient. Amount of injection will vary and will be at the discretion of the physician.*

— Continued on next page

FAQ

ORISE™ Gel

Submucosal Lifting Agent

Boston Scientific

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Convenience & Performance

- Ready To Use** – Pre-filled, pre-dyed 10 mL syringe kitted with delivery system (23 ga Interject™ Injection Therapy Needle Catheter)
- Designed to Help Reduce Procedural Risk** – Provides clear differentiation of the muscle layer
- Indicated For Endoscopic Procedures** – 510(k) Number: K180068

Product Codes and Pricing

Order Number	Description	Unit	Hospital Price
M00519201	ORISE Gel Syringe Twin Pack (two 10mL syringes per tray)	Box 10	
M00519210	ORISE Gel Syringe Twin Pack Kit with Interject Needle 23 ga Clear (two 10mL syringes per kit)	Box 1	
M00519211	ORISE Gel Syringe Twin Pack Kit with Interject Needle 23 ga Clear (two 10mL syringes per kit)	Box 10	

Coding

Procedures	CPT™ Code*	Code Descriptions
Endoscopic Mucosal Resection (EMR)	43211	Esophagoscopy, flexible, transoral; with endoscopic mucosal resection
	43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
	44403	Colonoscopy through stoma; with endoscopic mucosal resection
	45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection
	45390	Colonoscopy, flexible; with endoscopic mucosal resection
Gastrointestinal Endoscopic Injection & Snare Polypectomy Procedures	43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance report with CPT Code 43217
	43217	Esophagoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
	43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance report with CPT Code 43251
	43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
	45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance report with CPT Code 45338
	45338	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
	44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance report with CPT Code 44394
	44394	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
	45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance report with CPT Code 45385
	45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique

Coding continues

VAT

ORISE™ Gel

Submucosal Lifting Agent

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Physician Preference and Limited Launch Evaluation

General Information:

Procedure Date: (mm/dd/yyyy)

Tech Name:

Institution:

UPN Used:

Physician:

☐ M00519201 ☐ M00519210 ☐ M00519211

BSC Rep:

Lot Number:

Usual Injection Solution Used For This Type of Procedure:

☐ Saline ☐ Eleview™ ☐ Hetastarch (Hespan/Voluver) ☐ Other

Usual Contrast Agent Mixed Into Injection Solution (if applicable):

☐ Methylene Blue ☐ Indigo Carmine

Today's Procedure:

Needle Used:

☐ 23 ga Interject™ Injection Therapy Needle Catheter

Anatomy:

☐ Esophageal ☐ Gastric ☐ Colonic ☐ Rectal

Procedure:

☐ Snare Polypectomy ☐ EMR ☐ ESD

Lesion Type / Description:

Lesion Size:

☐ <1cm ☐ 1-2cm ☐ 2-4cm ☐ >4cm

Pieces to Complete Resection:

The number of pieces required to complete the resection

Physician Preference and Limited Launch Evaluation

ORISE™ Gel

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