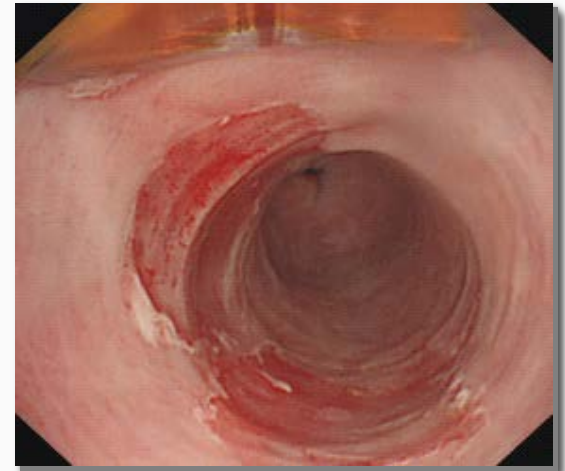
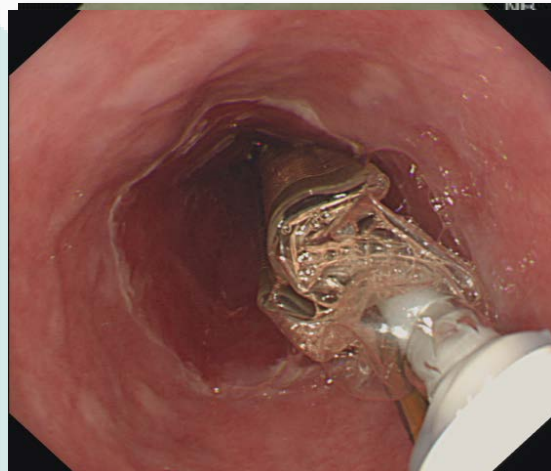
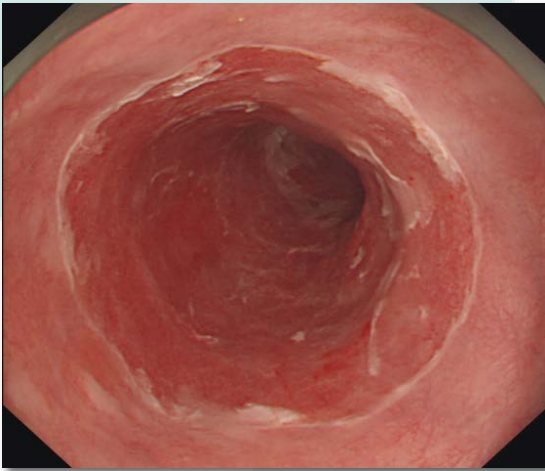


Technical aspects of Barrx TM360 and Barrx TM 90/ultra: Simple regimen and new devices

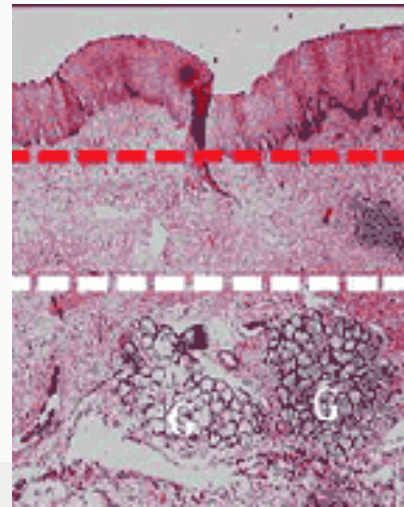
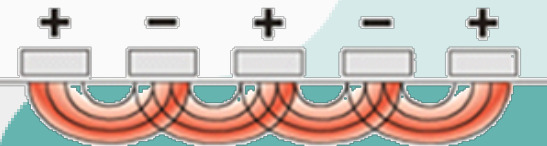


Barrx TM Ablation System

Technical background

Barrx TMFLEX generator delivers radiofrequency energy, resulting in uniform, controlled ablation (~500 microns deep), due to:

- Automated RF energy delivery;
- Fixed amount RF energy density;
- Fixed power;
- Bipolar electrode array.

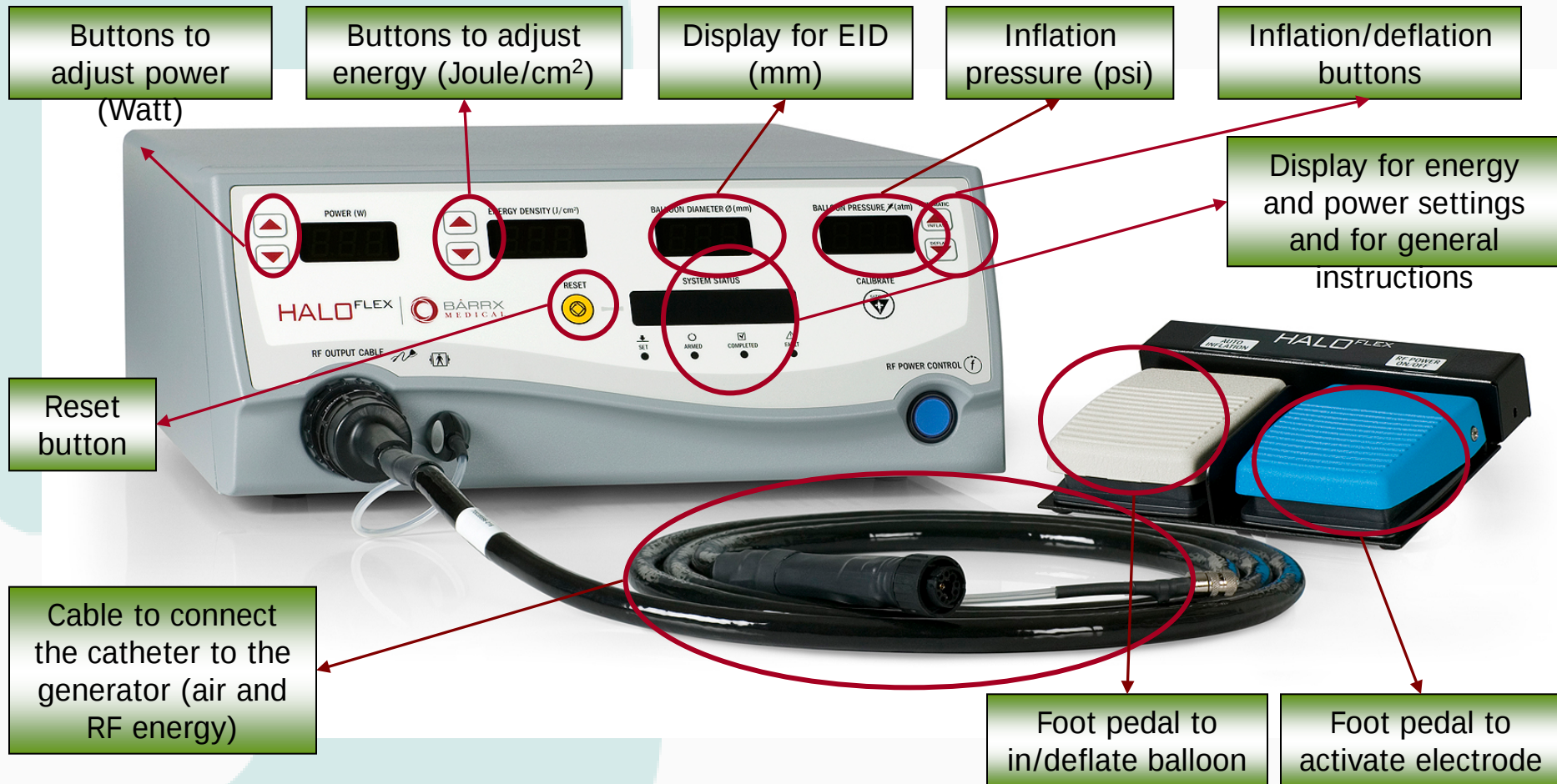


← Target mucosa

← Ablation depth
← Muscularis mucosae

Barrx™ Ablation System

RFA Barrx™ FLEX generator

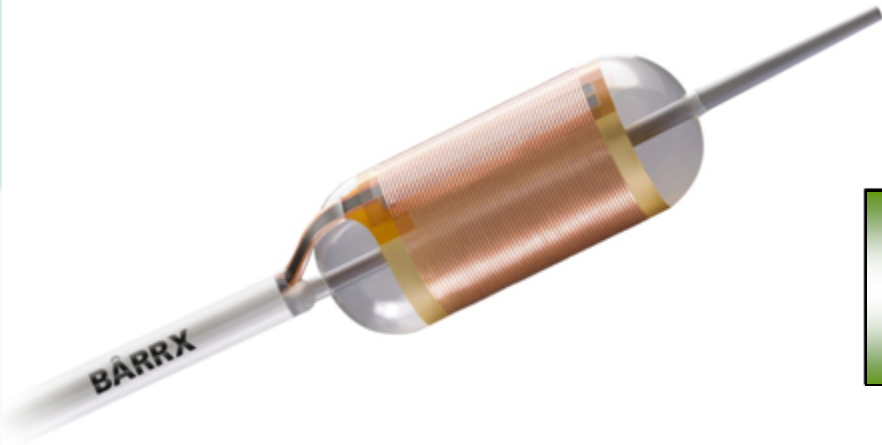


Barrx™ Ablation System

Barrx™360 sizing & ablation catheter



Non-compliant 4cm long balloon catheter, for sizing of esophageal inner diameter.

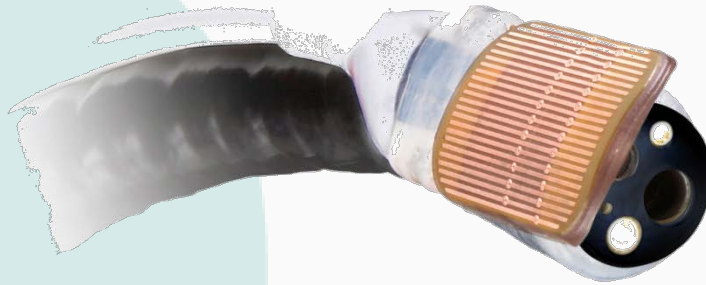


Balloon catheter, encircled by 60 electrode rings that alternate in polarity, over a length of 3-cm.

Barrx™ Ablation System

Barrx™90 ablation catheter

- Bipolar electrode array (20 mm x 13 mm) on an articulated platform, allowing left-right and front-back movement;
- Can be fitted on any endoscope (with diameters ranging from 8.6 mm to 12.8 mm) using a clear flexible strap.



Circumferential ablation using the Barrx TM FLEX System

Indications for Barrx™360 treatment

- The Barrx™360 system is generally used for primary RFA.
- The Barrx™360 system can ablate the esophagus circumferentially.

Indications for Barrx™360 ablation:

- Circumferential BE >2 cm;

1) Select appropriate catheter size

Available catheter sizes: 18 - 22 – 25 – 28 – 31 mm

Recommended size:

- Based on the smallest measured diameter, select a catheter with a diameter closest to the smallest EID,
e.g. EID 26mm: catheter 25mm, or EID 23mm: catheter 22mm.
- In case of prior ER, or pre-existing stenosis, select a catheter one size smaller than recommended to avoid complications,
e.g. EID 32mm: not a 31mm but a 28mm catheter.
 - *Always select a catheter closest to the smallest EID, in case of prior ER take an additional step down.*

2) Circumferential ablation using the “standard regimen”

- Settings: power 300 Watt, energy 12 J/cm² ;
- Treatment regimen: *‘1x-clean-1x’*.
- Cleaning is performed by:
 - Pushing coagulum off the ablation zone using a soft distal attachment cap;
 - If necessary, forceful rinsing with water through a spraying catheter, using a pressure pistol, may be used to remove residual coagulum;
 - Cleaning the electrode surface with a wet gauze, in a circular motion following the direction of the electrodes.

Cleaning

3) Cleaning procedure using the cap

4) Cleaning by forceful water spraying

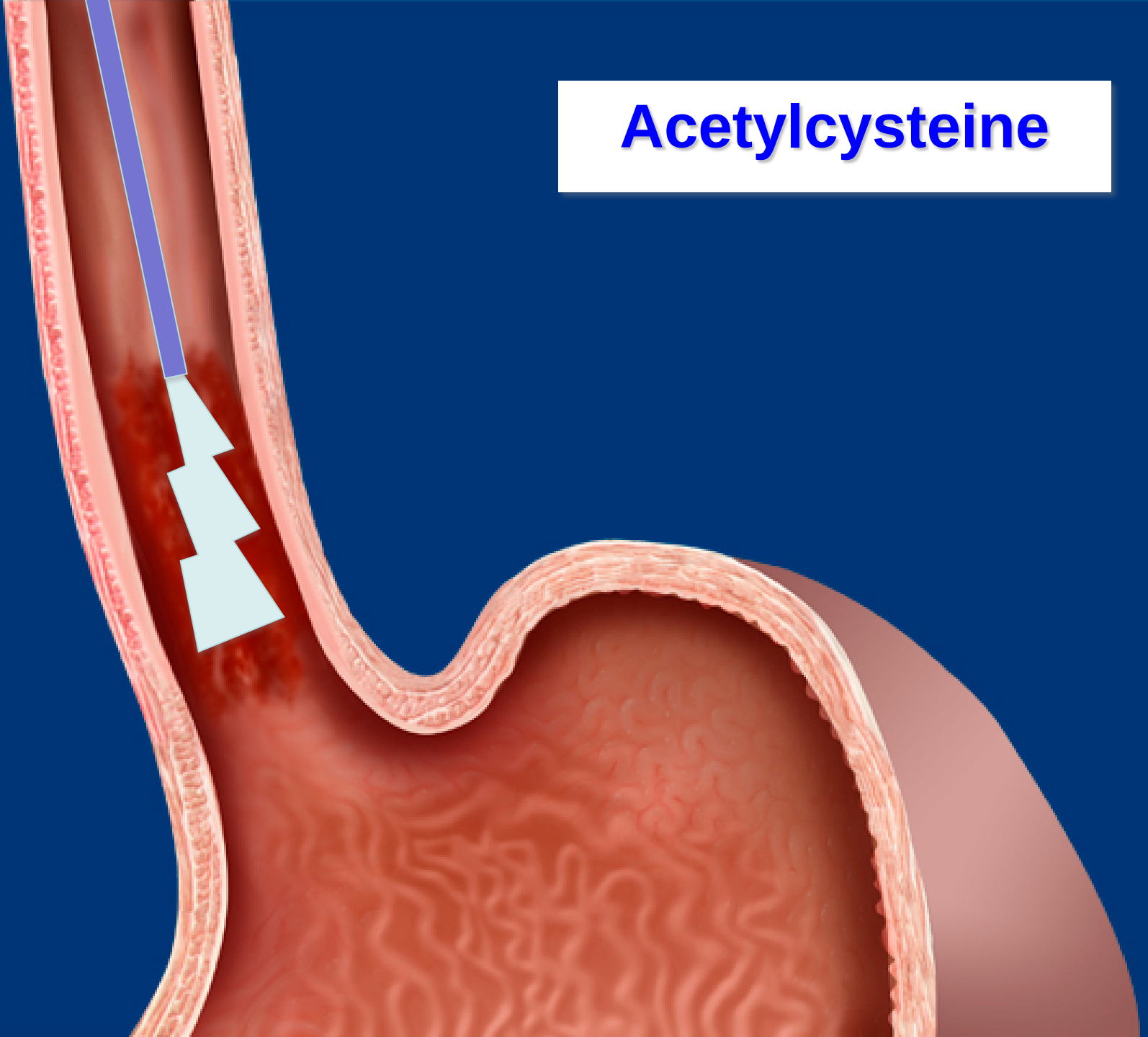
5) “Simplifying” the circumferential ablation regimen

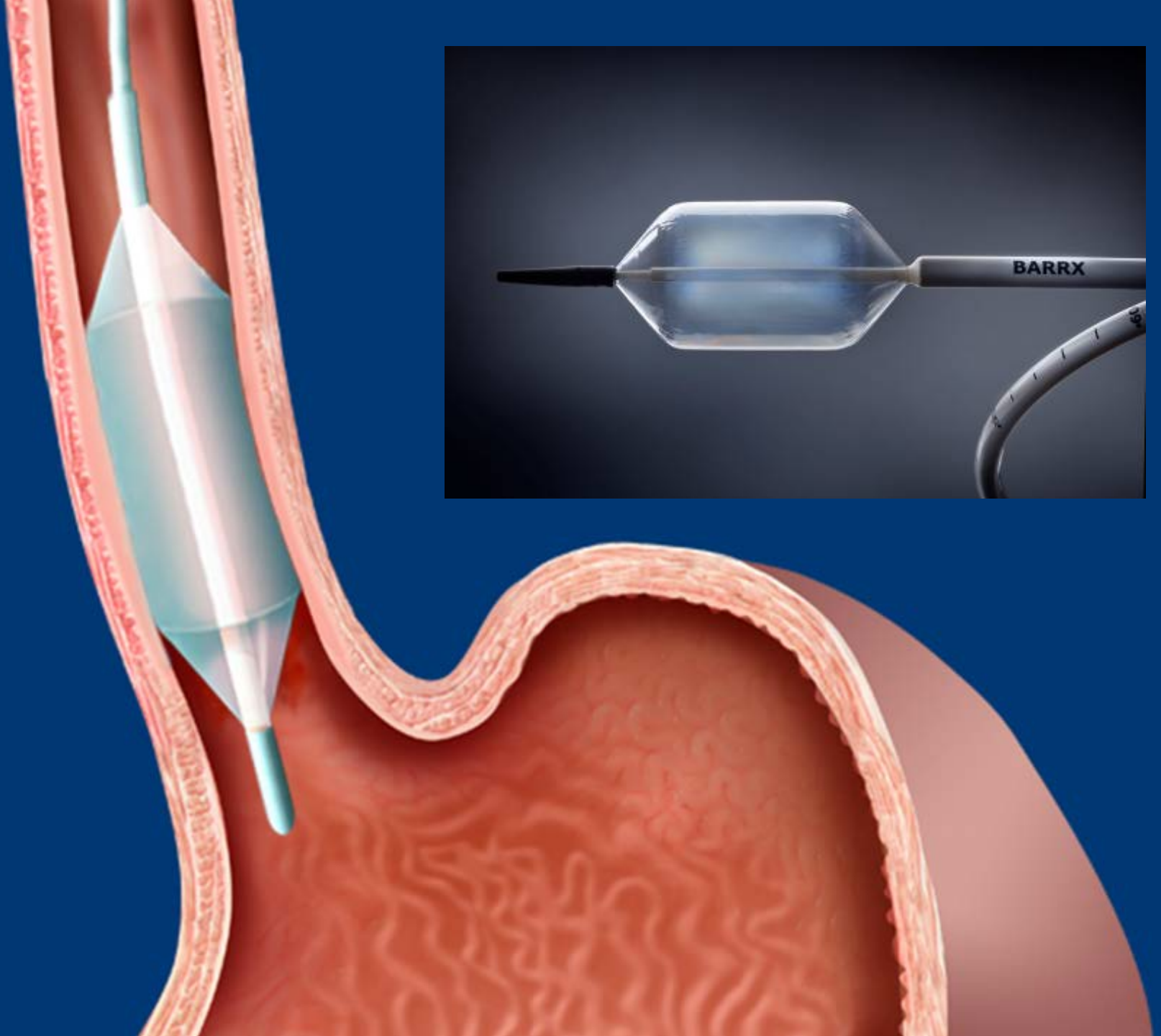
- The currently used regimen for circumferential RFA is complicated due to several introductions and a cleaning step;
- A simplified regimen may make the RFA procedure faster, easier while maintaining safety and efficacy.

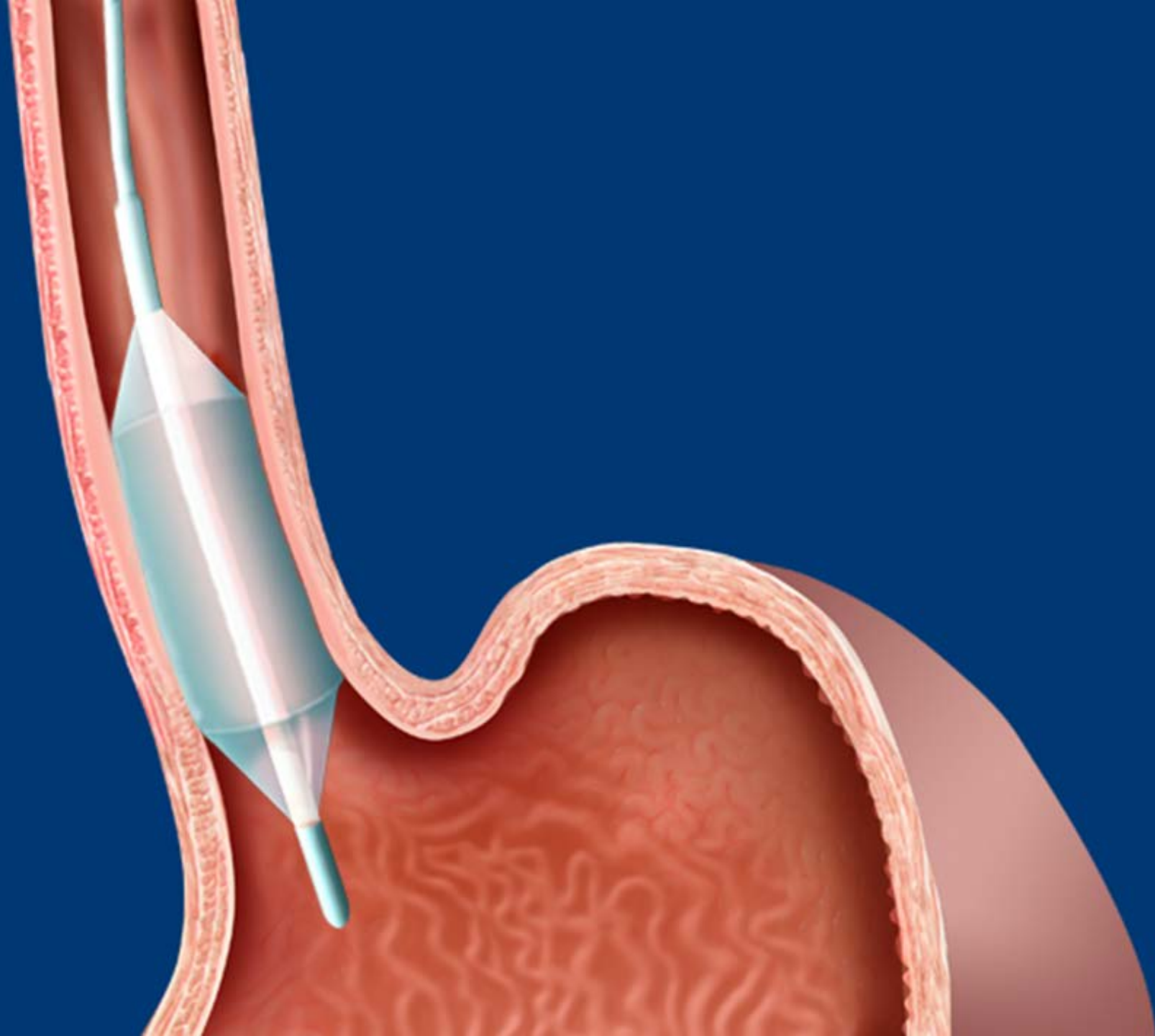
Aim: To compare the safety and efficacy of three different ablation regimens for circumferential balloon-based RFA.

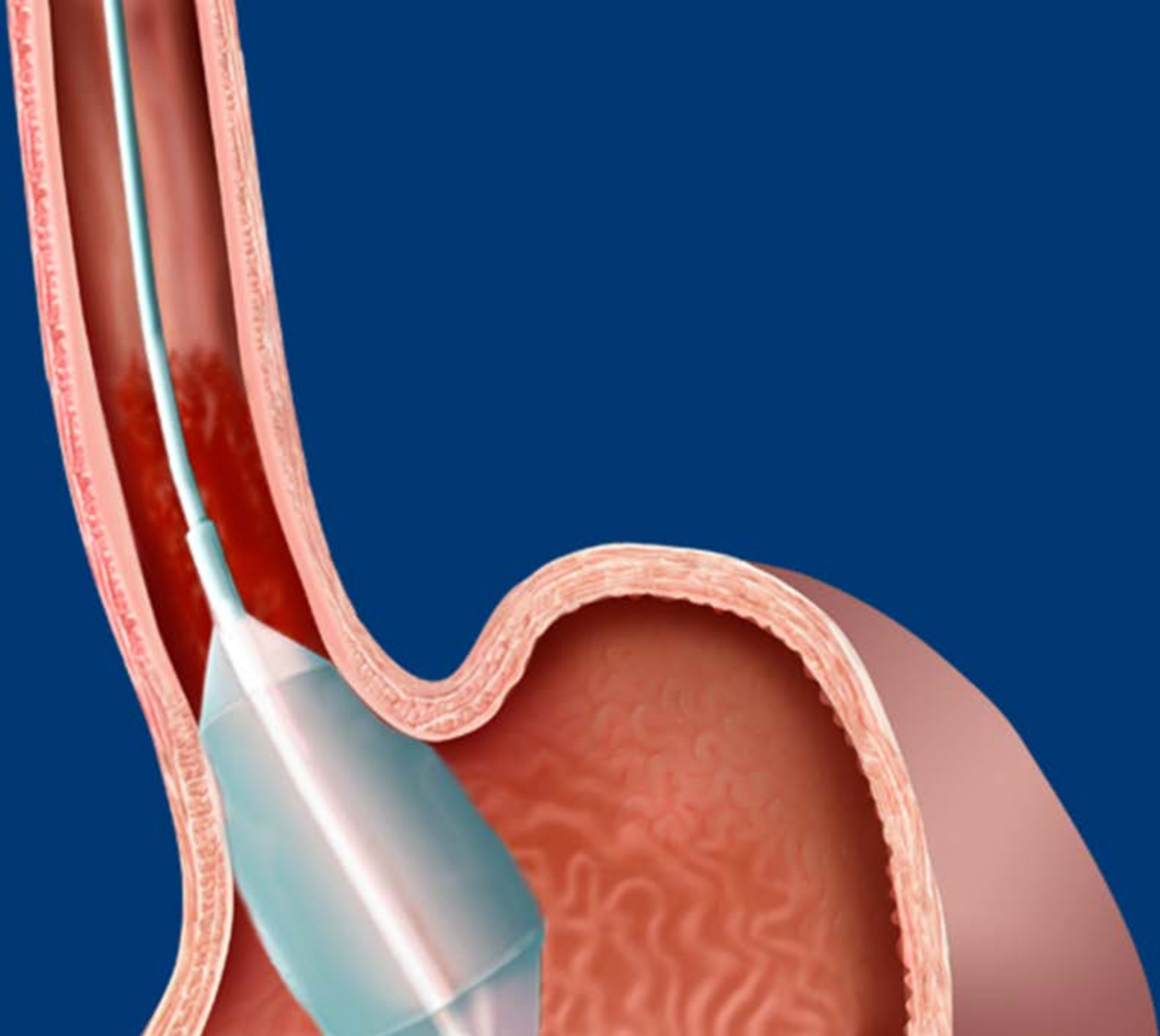
Van Vilsteren et al, Clin Gastroenterol Hepatol 2013

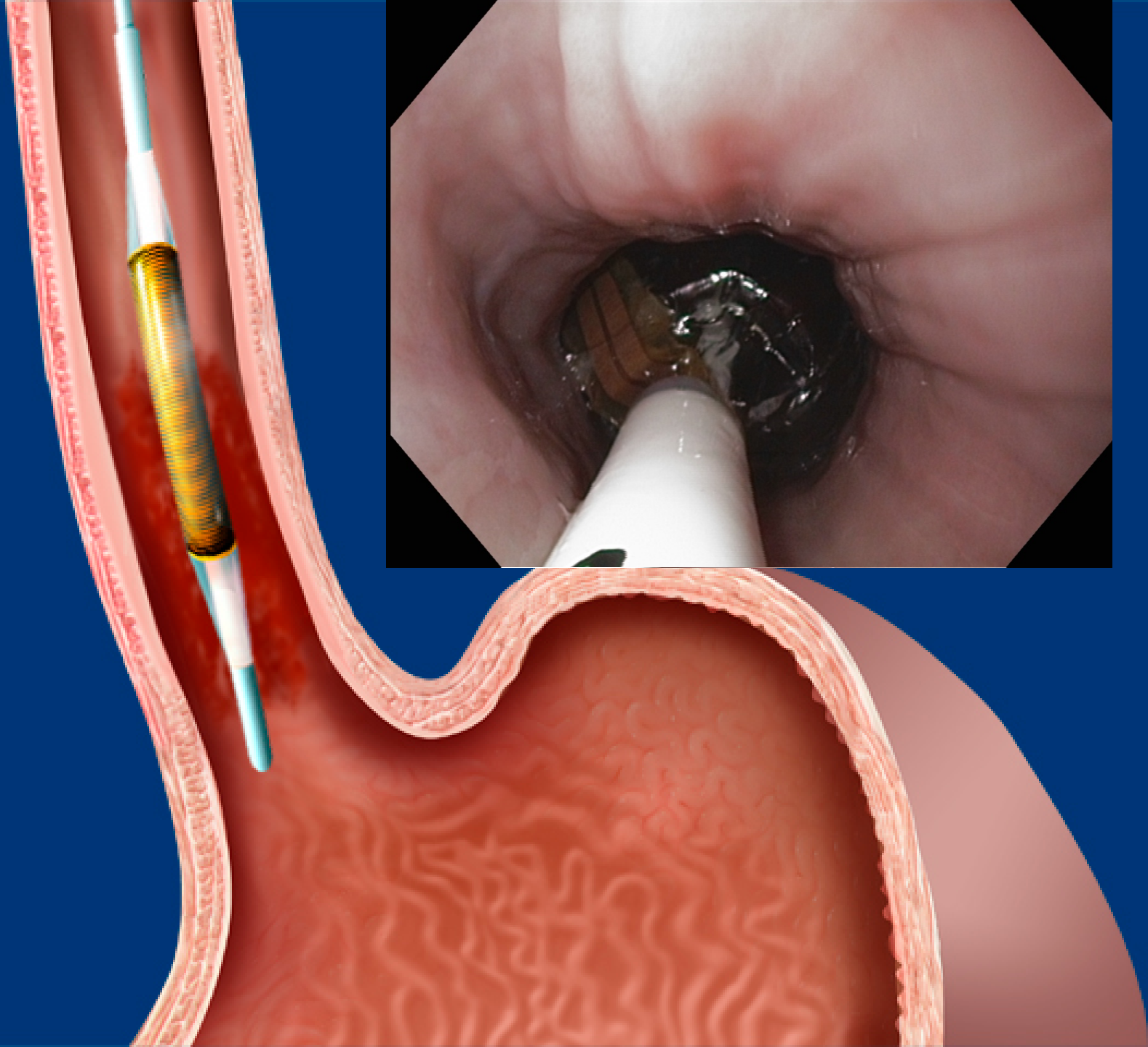
Acetylcysteine

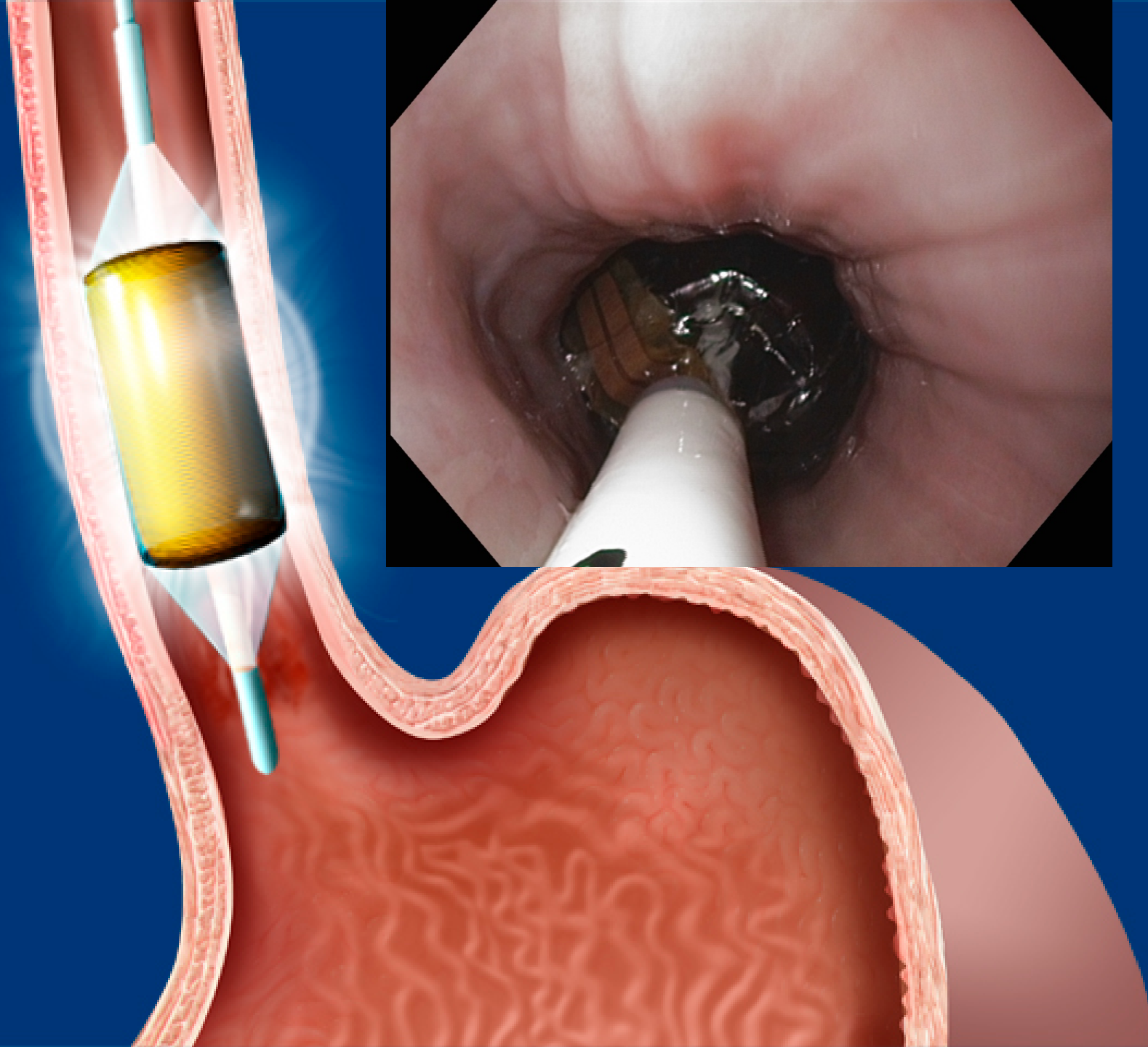


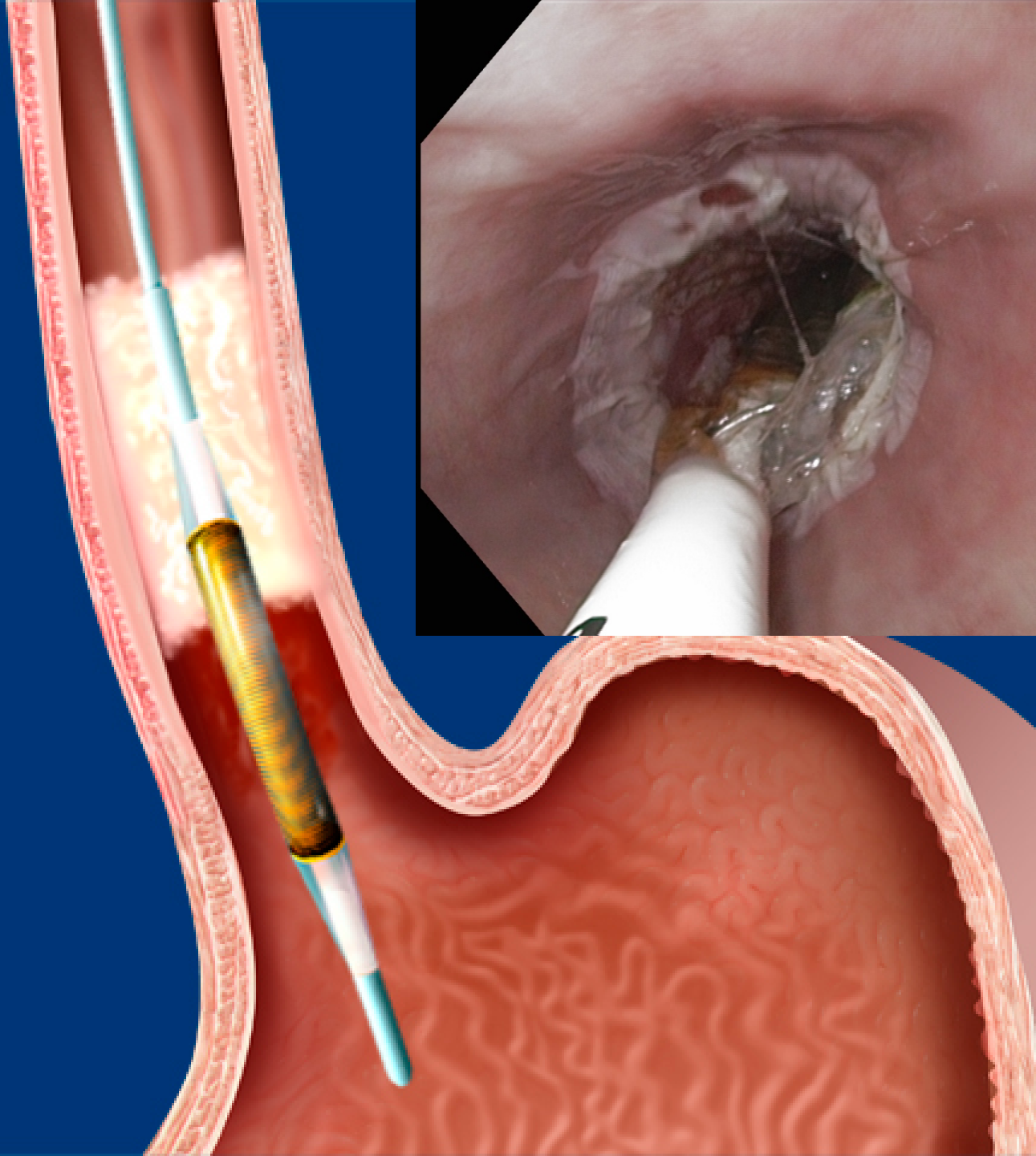


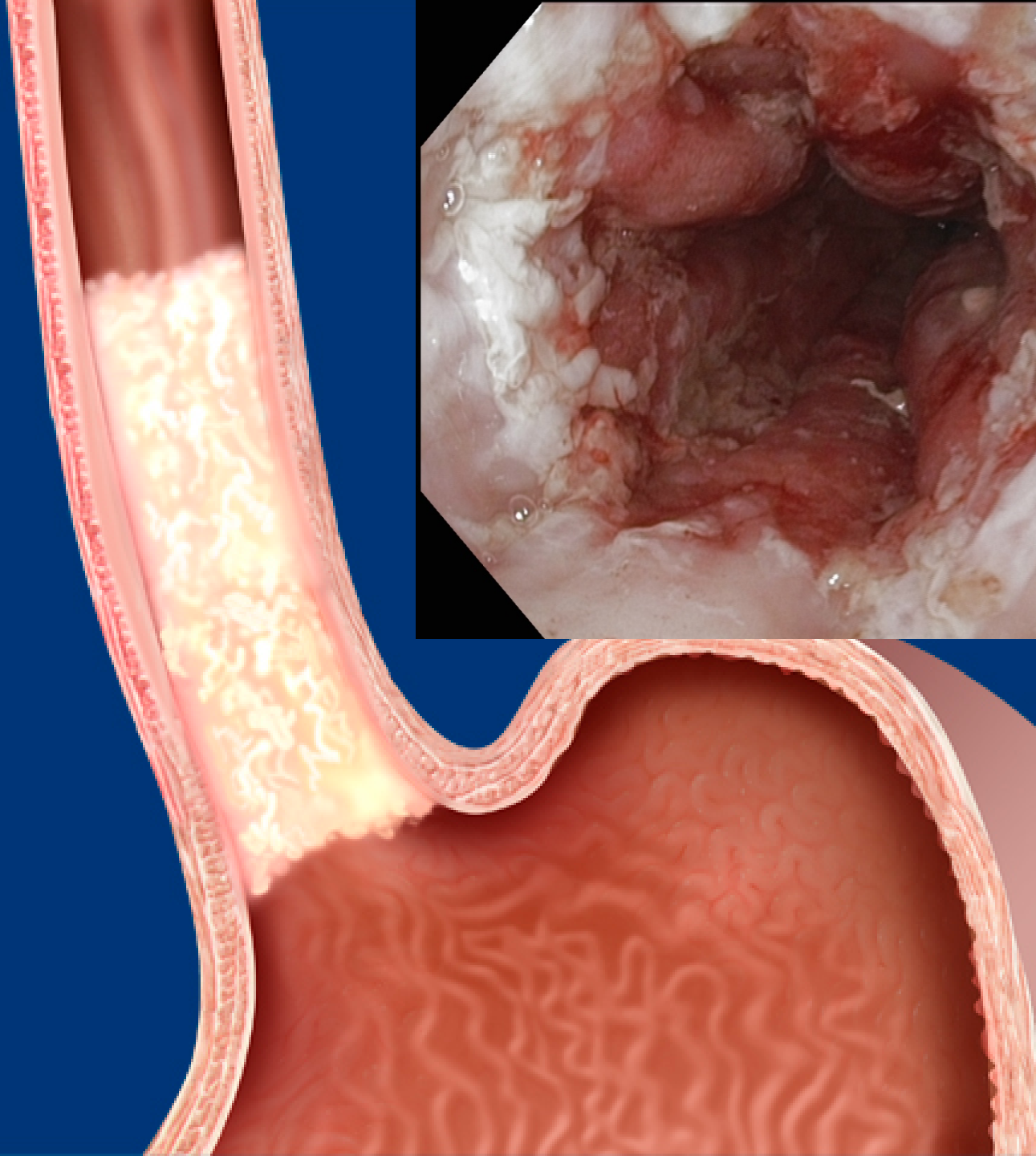


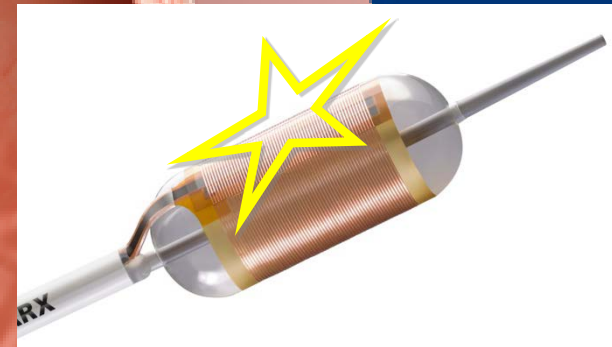
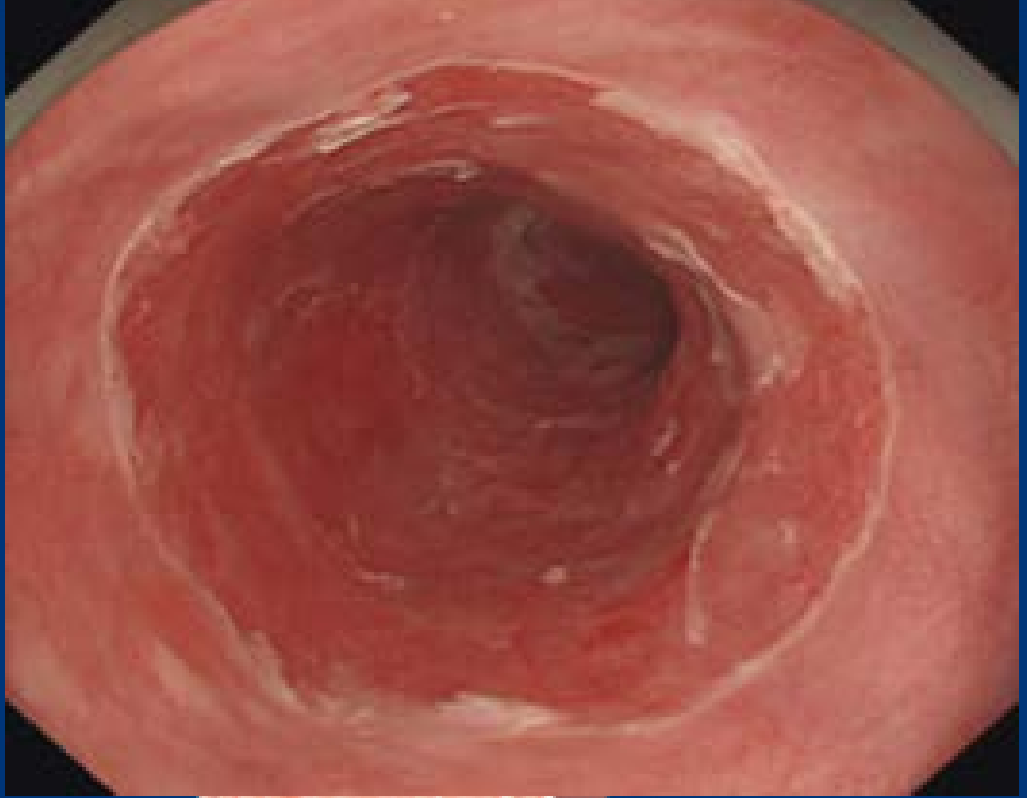
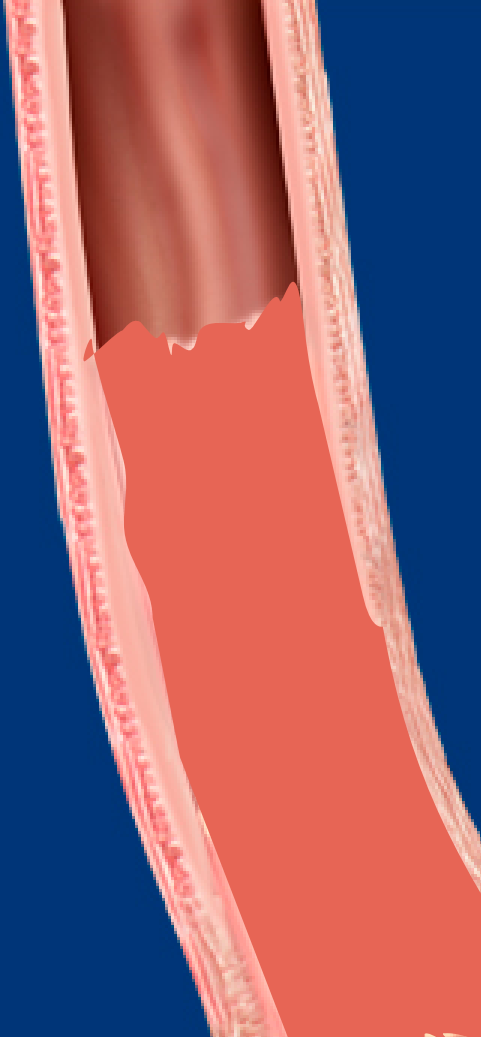


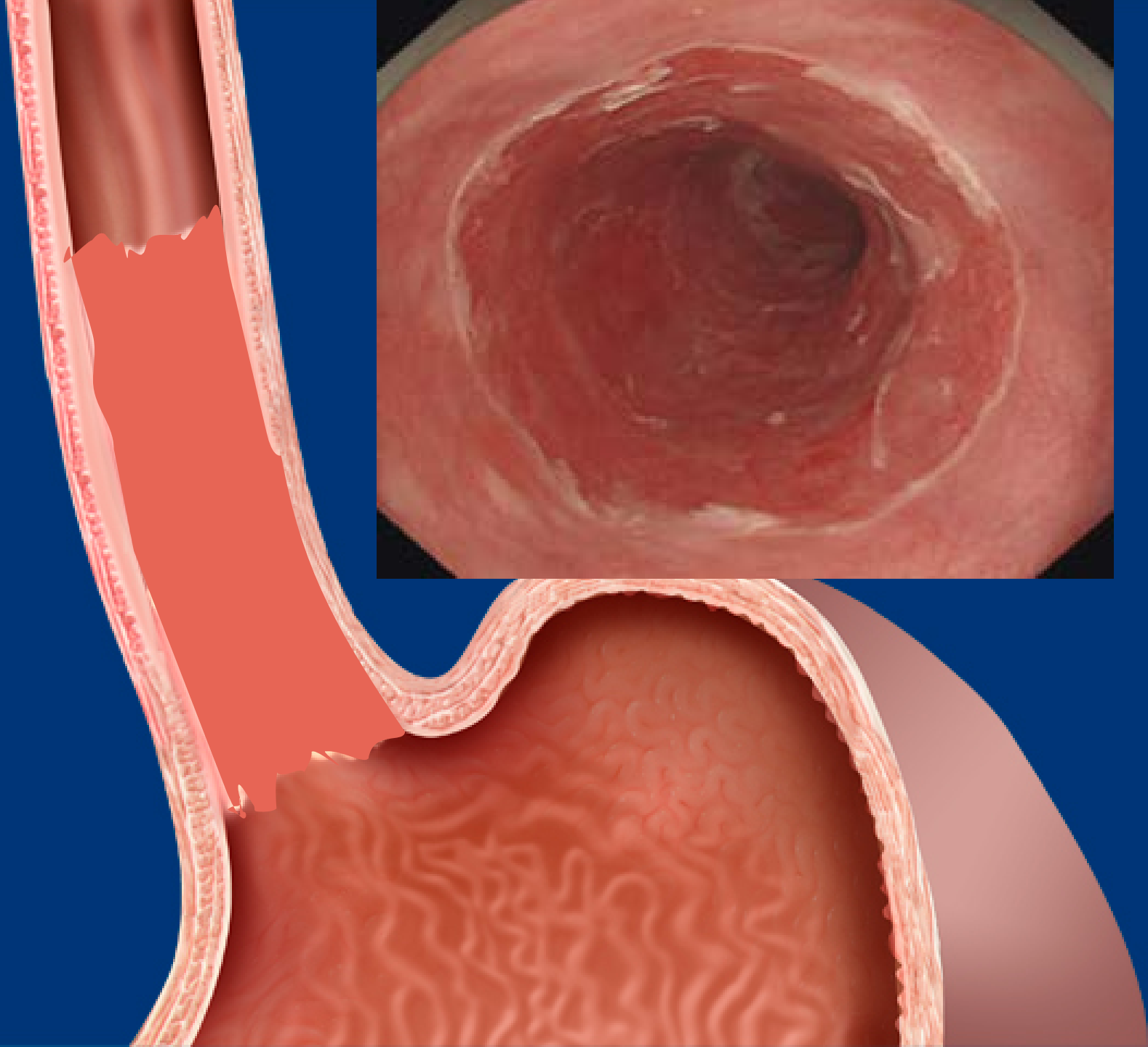


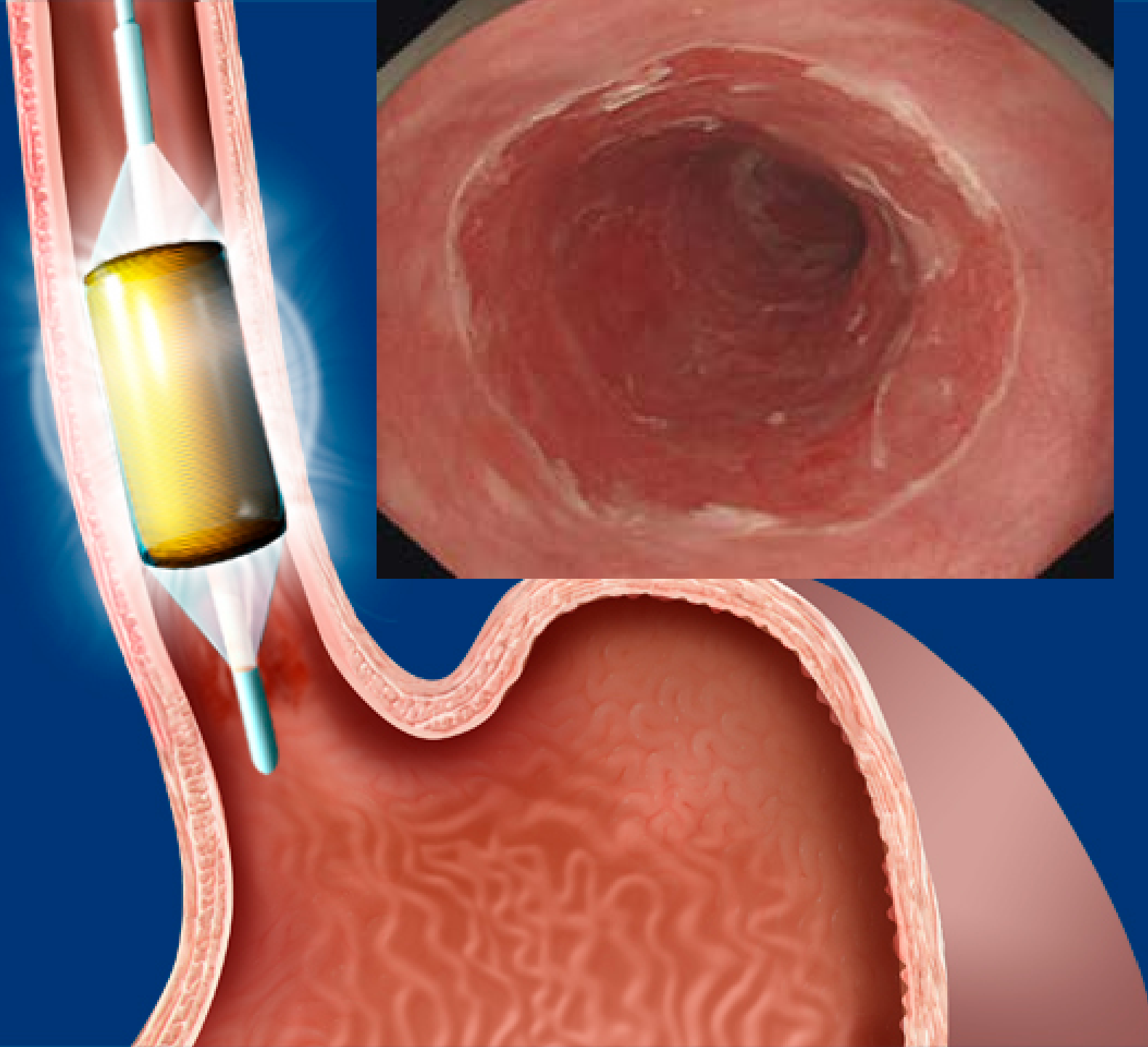


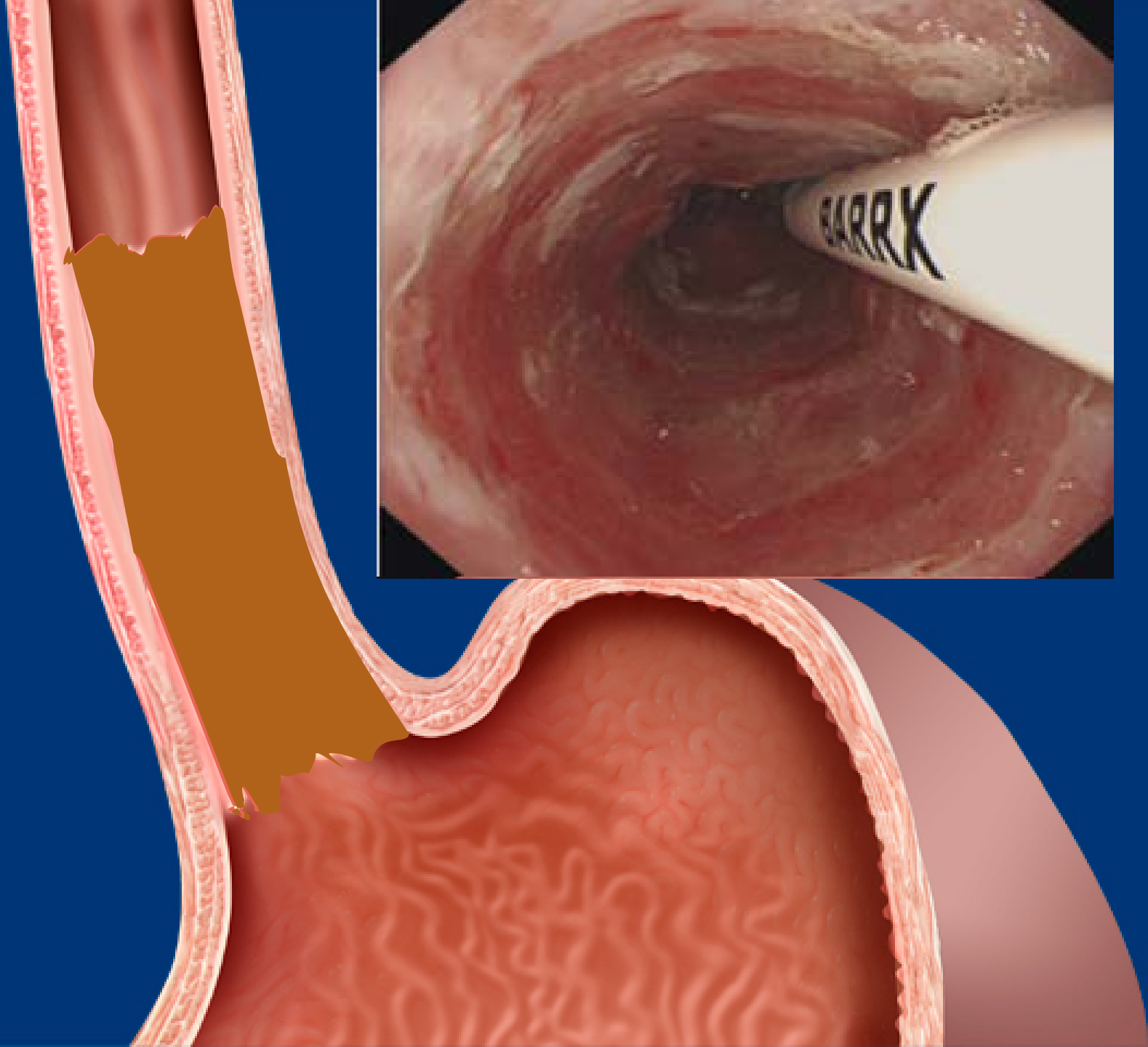












5) “Simplifying” the circumferential ablation regimen

Ablation regimen	Standard	Simple-with-cleaning	Simple-no-cleaning
Spraying with acetylcysteine prior to ablation	Yes	No	No
Cleaning of the debris from the ablation balloon outside of the patient after the first ablation pass	Yes	No	No
Cleaning of the debris from the ablation zone after the first ablation pass	Yes (distal attachment cap, high pressure pistol, spray catheter)	Yes (distal attachment cap)	No
Minimum number of introductions of endoscope and balloon catheters	7	4	4

Van Vilsteren et al, Clin Gastroenterol Hepatol 2013

5) “Simplifying” the circumferential ablation regimen

	‘Standard’ (n=19)	‘Simple- with- cleaning’ (n=19)	‘Simple-no- cleaning’ (n=18)	p- value
BE regression at 3 months	83%	78%	88%	0.14
Procedure time	20 min	13 min	5 min	<0.01

Van Vilsteren et al, Clin Gastroenterol Hepatol 2013

5) “Simplifying” the circumferential ablation regimen

	‘Standard’ (n=19)	‘Simple-with-cleaning’ (n=19)	‘Simple-no-cleaning’ (n=18)	p-value
CR-neoplasia	100% (19/19)	95% (18/19)	100% (18/18)	0.87
CR-IM	90% (17/19)	84% (16/19)	89% (16/18)	0.37
RFA sessions (IQR)	3 (2-3)	3 (2-4)	3 (2-3)	0.72
Complications during c-RFA	1	0	1	0.60

- 2 minor lacerations

Van Vilsteren et al, Clin Gastroenterol Hepatol 2013

6) Circumferential ablation using the “simple- no clean - regimen”

- Settings: power 300 Watt, energy 12 J/cm² ;
- Treatment regimen: *‘1x-no clean-1x’*.

Indications:

The uncomplicated Barrett’s esophagus without

- Scarring
- Stenosis

Focal ablation using the BarrxTMFLEX System

Indications for Barrx TM⁹⁰ treatment

- The BarrxTM90 device is usually used for secondary RFA of residual BE mucosa after initial circumferential ablation using the BarrxTM360 system;
- The BarrxTM90 system may also be used for primary RFA.

Indications for BarrxTM90 ablation:

- Circumferential BE <2 cm;
- Circular treatment Z-line (at least once);
- Small tongues;
- Diffuse islands.

1) Inspection of the esophagus prior to Barrx™90

- Inspect the esophagus for:
 - Presence of a Zenker's diverticulum;
 - Visible abnormalities;
 - Residual Barrett isles or tongues.
- Clean esophageal wall by:
 - spraying with acetylcysteine (1 %), and
 - flushing with plain water.

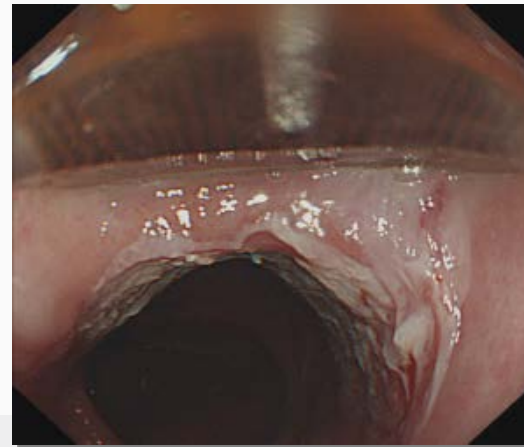
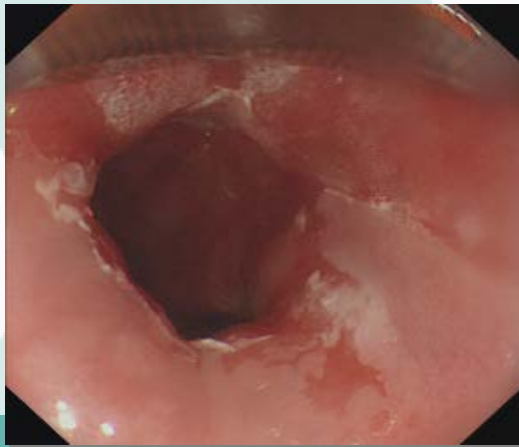
2) Focal ablation using the “standard regimen” (I)

- Check settings: power 104 watt/cm², energy 15 J/cm²;
- Treatment regimen: *‘2x-clean-2x’*.



2) Focal ablation using the “standard regimen” (II)

- Position the target areas of BE at the 12 o'clock position;
- Bring the electrode into contact with the esophageal wall, and angulate the endoscope upwards to improve contact between the electrode and the mucosa;
 - the cap should tilt down in the endoscopic field as on the right:

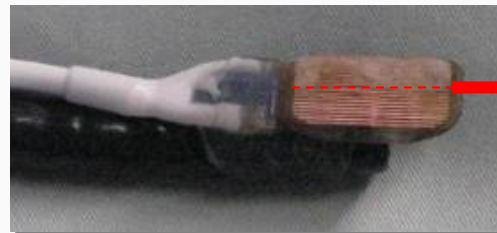


3) Cleaning procedure (I)

- Suction debris from the ablation zones through the suctioning channel of the endoscope;
- Use the distal rim of the electrode to carefully push off coagulum from the ablation zones (longitudinal movements);
- Pay attention when cleaning at the level of the gastric folds, which may be damaged by the lateral rims of the catheter;
- Forceful spraying of water through the spraying catheter can be used to blast off residual debris, which may be very useful at the level of the gastric folds.

3) Cleaning procedure (II)

Clean the electrode surface with a wet gauze:



After cleaning
the lower half
of the
electrode

4) BarrxTM90 ablation of the Z-line (I)

When the BarrxTM90 electrode is introduced to ablate residual islands or tongues of BE mucosa, ablation of the Z-line in the same session is recommended, because:

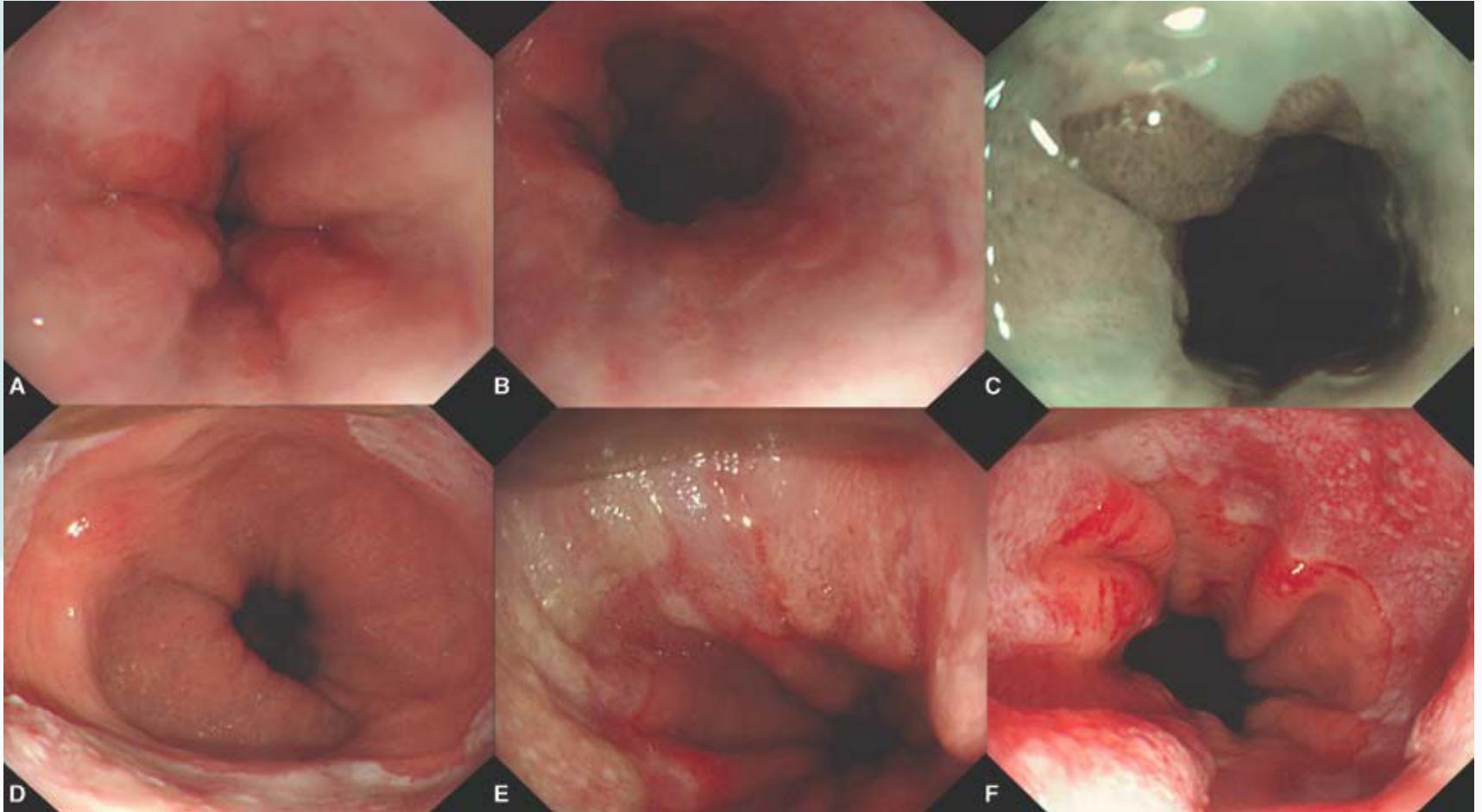
- Contact BarrxTM360 balloon with upper gastric folds not sufficient
- Endoscopic inspection unreliable for presence of BE at gastric junction
- Sampling error of random biopsies for IM in this area

4) Barrx TM⁹⁰ ablation of the Z-line (II)

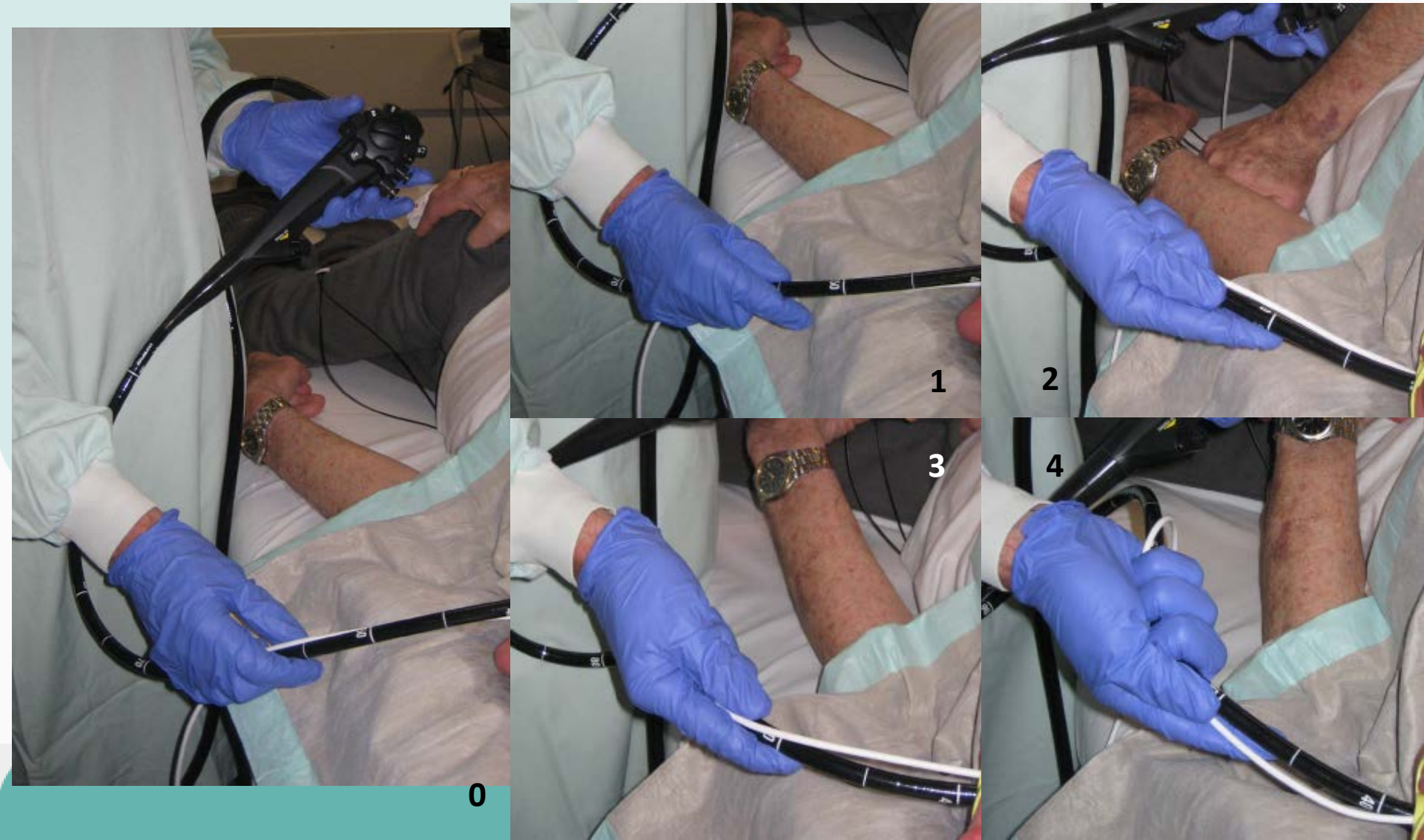
Circumferential ablation of the Z-line using the Barrx TM⁹⁰ System is challenging:

- Ensure that the Z-line is straddled by the Barrx TM⁹⁰ catheter;
- Ablating while keeping the endoscope at the same insertion depth;
- Turn the endoscope step-by-step to circumferentially ablate the Z-line.

4) Barrx TM⁹⁰ ablation of the Z-line (III)



4) Barrx™90 ablation of the Z-line (IV)



5) “Simplifying” the focal ablation regimen

- The currently used ablation protocol for focal RFA is impractical;
- Consists of 2 introductions of the electrode and a cleaning step;
- Sometimes it may be difficult to introduce the BarrxTM90-electrode;
- Removal of the BarrxTM90 electrode may be difficult due to relative narrowing of the esophagus or EUS.

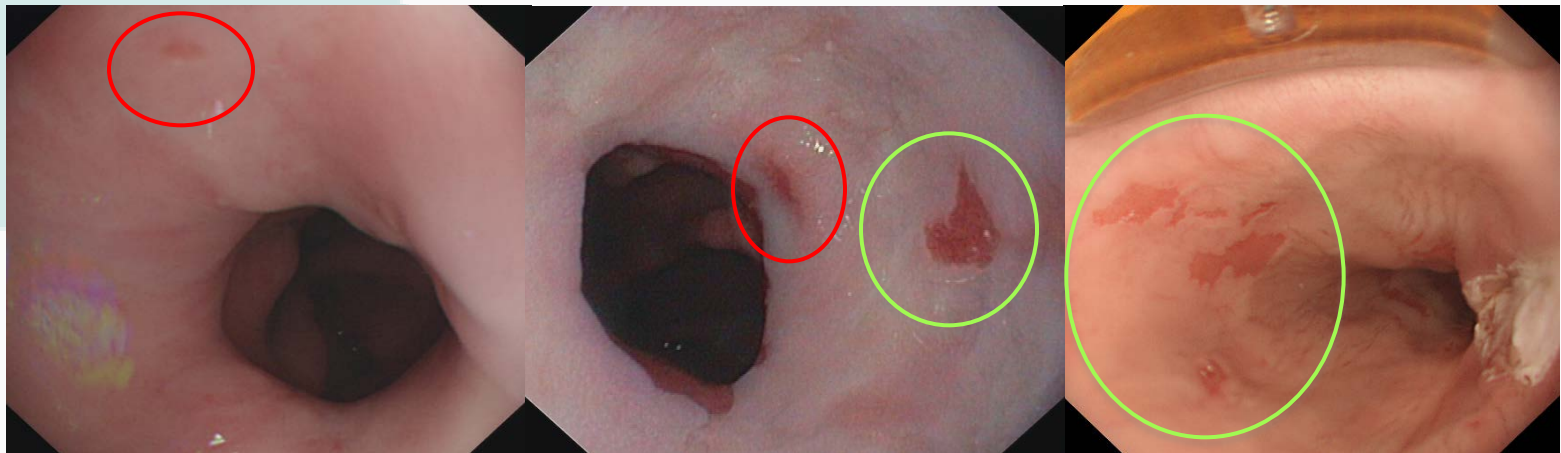


Van Vilsteren et al, Gastrointestinal Endoscoc 2013

5) “Simplifying” the focal ablation regimen

Patient selection for the study:

- Consecutive patients scheduled for focal RFA ($\leq$ HGD)
- ≥ 2 BE islands > 2 mm and distance > 20 mm and > 10 mm Z-line;
- Or groups of BE islands $<$ two BarrxTM90 electrodes.

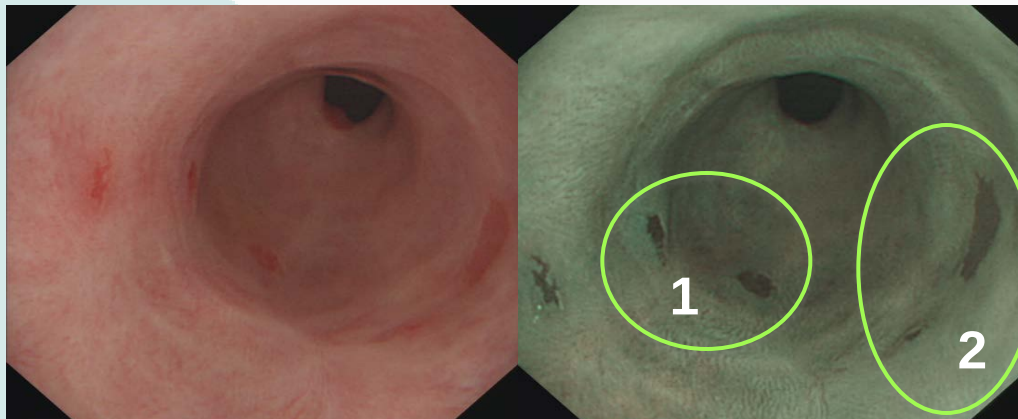


Van Vilsteren et al, Gastrointestinal Endosoc 2013

5) “Simplifying” the focal ablation regimen

Randomization protocol

- Eligible BE areas were numbered from distal to proximal;
- Area 1 was randomized and treated first and Area 2 was automatically allocated to other regimen;
- Forming pairs to rule out interpatient variation, max two pairs per patient;



5) “Simplifying” the focal ablation regimen

- Standard regimen:
 - 2x15J – clean – 2x15J
 - Two introductions of endoscope and Barrx™90-electrode
- Simple regimen:
 - 3x15J – no clean
 - Single introduction

Van Vilsteren et al, Gastrointestinal Endosoc 2013

5) “Simplifying” the focal ablation regimen

	Overall (n=45)	Standard (n=45)	Simplified (n=45)	p-value
Single island : multiple BE islands per area	54:36	26:19	28:17	0.77
Islands per BE area in case of multiple islands (median, range)	2 (2-10)	2 (2-5)	2 (2-10)	0.79
Size of single BE islands (median, IQR)	10 mm (6-15)	10 mm (5-16)	10 mm (7-10)	0.60

Van Vilsteren et al, Gastrointestinal Endosoc 2013

5) “Simplifying” the focal ablation regimen

	Standard (2x2x15 J/cm ² with cleaning) (n=45)	Simplified (3x15 J/cm ² without cleaning) (n=45)
Complete regression at 2 months	67% (30/45)	73% (33/45)
Surface regression overall	100%	100%
Surface regression not removed	78% (50-90)	80.0% (50-90)

- 2 stenoses after 2nd focal RFA -> dilatation

Van Vilsteren et al, Gastrointestinal Endosoc 2013

6) Focal ablation using the “simple regimen”

3x15J is non-inferior for smaller BE areas (< 2 Barrx™90 applications) when compared to the standard regimen (**2x15J-clean-2x15J**).

Potential indications

- Small residual islands
- In patients with a relative stenosis of the esophagus

However.....

- The “simple” regimen may induce stenosis when applied on larger surface areas
- We are still reluctant to advise 3x15J...

New developments

Barrx™ Ablation System

New developments



Barrx™ 90ultra flex



Barrx™ 60

Indications for Barrx TM⁹⁰ ultra flex treatment

- The BarrxTM 90 Ultra Flex device is less well evaluated in terms of energy setting and safety.
- The BarrxTM 90 Ultra Flex device may be used at 3x12J or 2x15J-clean-2x15J.

Indications for BarrxTM 90 ultraflex ablation:

- Large tongues
- Short segment BE

Indications for Barrx TM⁶⁰ treatment

- The BarrxTM 60 device may be used at 3x12J or 2x15J-clean-2x15J.

Indications for BarrxTM 60 ablation:

- Small islands in the presence of a stenosis

Barrx™ Ablation System

Through-the-scope device

- The TTS device may be used at 2x15J-clean-2x15J.
- Offers a simplified and more time-efficient procedure.
- Projected launch: Europe – May, USA – August.

