Medtronic

Field Safety Notice

Use of the Barrx™ 360 Express RFA Balloon Catheter, Model 64082
Instructions for Use Outlines Important Procedural Steps

February 2018

Medtronic reference: FA802

Attention: Gastroenterologists, General Surgeons, GI or Surgical Nurses, and other users of the 360 Express catheters

As a leading healthcare company, Medtronic considers it our responsibility to provide our customers with information related to the safe and effective use of our products. We have become aware of two situations where use of the Barrx™ 360 express RFA balloon catheter in a manner which is inconsistent with the instructions for use (abnormal use), resulted in adverse events, including three esophageal perforations (first abnormal use situation – detailed in Appendix A), and a 15% esophageal stricture rate (second abnormal use situation – detailed in Appendix B). This notification serves to reinforce the information contained in the Instructions for Use (attached).

Actions you should take for these two situations:

- When using the Barrx™ 360 express RFA balloon catheter, position and move the balloon catheter under direct endoscopic visualization. During withdrawal, observe the balloon and electrode for any interaction with the esophageal tissue so as to ensure atraumatic removal. Do not advance or retract the catheter if excessive resistance is met. Observe the other instructions and warnings mentioned in the IFU and in Appendix A.
- When using the Barrx™ 360 express RFA balloon catheter, *do not omit* the esophageal and catheter cleaning step between the two esophageal ablations. Observe the other instructions and warnings mentioned in the IFU and in Appendix B.
- When using the Barrx™ 360 express RFA balloon catheter, please follow *all* the instructions for use to reduce the likelihood of complications.
- Please ensure those using the Barrx™ 360 express RFA balloon catheter are familiar with the instructions for use and the recommended procedural steps outlined in the IFU.
- If your facility has distributed Barrx™ 360 express RFA balloon catheters to other persons or facilities, please promptly forward a copy of this notification to those recipients.
- Please complete the Acknowledgement Form.

If you have questions about this information, Medtronic personnel will be available to assist you and your staff. Please contact your local Medtronic representative for more information.

Medtronic is committed to ensuring unsurpassed product quality, reliability, and patient safety. Please do not hesitate to contact me with any questions.

Sincerely,

LOCAL SIGNATURE

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Appendix A: First abnormal use situation

There have been three cases of esophageal perforation when a combination of steps/warnings in the Barrx™ 360 express RFA balloon catheter IFU are not followed. These include: 1) removal without direct endoscopic visualization; 2) during withdrawal, the catheter is not observed for interaction with the esophageal tissue; 3) the device is advanced or retracted despite excessive resistance; and/or 4) the device is not rotated in the clockwise direction to reduce the device diameter.

You received a copy of the IFU brochure with each Barrx™ 360 express RFA balloon catheter, Model 64082, delivered to your facility. This communication, which includes a copy of the IFU, is to draw specific attention to the section of the IFU that instructs the user on appropriate insertion, withdrawal, and maneuvering of the device.

Related warnings and instructions from the IFU include:

- *Always position or move the balloon catheter under direct endoscopic visualization*
- *Do not advance or retract the catheter if excessive resistance is met*
- *Prior to repositioning or removal, ensure complete deflation of the balloon*

> *Instruction #8. Apply a small amount of gel lubrication to the shaft of the balloon catheter (do not apply gel to the electrode or balloon) and introduce the balloon catheter over the guidewire so that it is ~1 cm proximal to the TIM* or 1 cm proximal to the most proximal unstained lesion (aligned with the proximal tattoo) in esophageal squamous cell neoplasia *by catheter shaft measurements. During introduction, rotation of the device in a clockwise direction may reduce the device diameter and aid in introduction. Hyperextension of the neck may also assist in device introduction.*
>
> ***Precaution***
> *Rotation of the device in a counterclockwise direction may increase the device diameter and lead to insertion difficulties.*
>
> *Instruction #19 After confirming that the entire length of Barrett's esophagus or esophageal squamous cell neoplasia is treated, position the endoscope immediately proximal to the balloon catheter electrode and balloon and ensure that the balloon and electrode are completely collapsed. Disconnect the catheter from the output cable, and then withdraw the endoscope and balloon catheter and guidewire together as a unit. Rotation of the device in a clockwise direction may reduce the device diameter and aid in removal. Hyperextension of the neck may also assist in device removal.*
>
> *Instruction #20. ...during device removal, axial displacement of the electrode may occur. This displacement can be corrected by manually adjusting the electrode prior to cleaning.*
>
> ***Warning***
> *During withdrawal, observe the balloon and electrode for any interaction with the esophageal tissue so as to ensure atraumatic removal.*

Appendix B: Second abnormal use situation

A study and clinical use information suggests that an esophageal stricture rate of approximately 15% is seen when a modified procedure is used. This modified procedure omits cleaning of the esophageal lumen and catheter between the two sets of radiofrequency ablation using the Barrx™ 360 express RFA balloon catheter. An internal investigation showed that the overall stricture rate for the Barrx™ 360 express RFA balloon catheter is not higher than expected, and this abnormal use is the issue in these cases.

You received a copy of the IFU brochure with each Barrx™ 360 express RFA balloon catheter, Model 64082, delivered to your facility. This communication, which includes a copy of the IFU, is to draw specific attention to the section of the IFU that instructs the user on cleaning of the esophagus and device between ablations.

Instruction #20. For Barrett's esophagus: Reattach the balloon catheter to the output cable. Inflate the balloon and clean the electrode surface in a circumferential direction with a clean, moist 4"x 4" pad in the direction of the electrode bars, then deflate and prepare for reintroduction.

Instruction #21. For Barrett's esophagus: Prior to the second set of ablations, it is recommended that the treatment zone be cleaned utilizing the Barrx™ RFA cleaning cap or other soft distal endoscope-attachment device. Insert the distal end of the endoscope into the proximal end of the Barrx™ RFA cleaning cap and then advance the endoscope into the cap until the tip of the endoscope is aligned with the distal ridge line inside the cap. The longest extent of the beveled edge should be positioned at the 12 o'clock position in the endoscopic view. Water may be used to lubricate the endoscope and cap to facilitate placement, but do not use alcohol or gel lubrication. Verify the Barrx™ RFA cleaning cap is securely attached to the endoscope before use.

Instruction #22. For Barrett's esophagus: Reintroduce the endoscope and inspect the treatment zone for completeness of treatment. Using the endoscope with irrigation and the Barrx™ RFA cleaning cap, remove the coagulum from the coagulation zone. Irrigate with plain water. Evacuate all irrigation and air from the stomach and esophagus.

Reinsert the guidewire. Remove the endoscope.

Warning

Failure to clean the balloon catheter electrode and the lumen of treated esophagus after the first treatment pass may result in areas of under treatment and/or over treatment, and could reduce effectiveness and increase risk of complications.

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Acknowledgement Form

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Acknowledgement and Receipt Form—Response is required

Please complete this form in its entirety.

Date: _____

Name of Person Completing this form: _____

Title:_____

Direct Phone #:_____

Email:_____

Account Name:_____

Account Number:_____

Account Address:_____

City: _____State: _____Zip Code:_____

I have read and understand the instructions provided and acknowledge receipt of the Medical Device Field Safety Notice regarding the Barrx™ 360 express RFA balloon catheter by signing below.

I also agree to further distribute and communicate this important information within my facility as required.

_____ _____ _____

Name: (print) Signature: Date:

If you have any questions regarding this Medical Device Field Safety Notice, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO: NordicRA@Covidien.com