



URGENT: ROTH NET POLYP RETRIEVER RECALL

Dear Valued Customer:

US Endoscopy is implementing a voluntary recall of Roth Net Polyp Retriever, item number 00711151; lot numbers 1613898, 1616337, 1616733, 1616734, and 1616735. Our records indicate that your facility purchased product from the affected lots.

Description of the product – The disposable Roth Net retrieval device product line is used in the endoscopic retrieval of foreign body, food bolus, and excised tissue such as polyps.

Description of the problem – US Endoscopy has identified that the expiration date is incorrect on the outer packing label for Roth Net device lots 1613898, 1616337, 1616733, 1616734, and 1616735. The expiration date printed is earlier than the actual expiration date. The performance of the product is not impacted. It is important to note that all individually labeled Roth Net devices contained within the outer shipping package reference the correct expiration date.

User action requested – Our records indicate that you have received product from the affected lots.

1. Quarantine and destroy the affected Roth Net devices in your inventory.
2. Contact US Endoscopy Customer Service at 1-800-769-8226 to obtain no cost replacement product.
3. Complete and return the attached Response Card.

We apologize for any inconvenience this matter may cause you, and as always, US Endoscopy is dedicated to support our products and valued Customers. If you have questions regarding this matter, please contact Cindy Perpar, 1-440-358-6051, or US Endoscopy Customer Service at 1-800-769-8226.

Sincerely,

Coletta Cohara
Director, Quality and Regulatory Compliance
US Endoscopy

ROTH NET POLYP RETRIEVER RECALL – RESPONSE CARD

Recall Regarding: **US Endoscopy Roth Net Polyp Retriever**

Model Number: **00711151**

Lot Numbers: **1613898, 1616337, 1616733, 1616734, 1616735**

We acknowledge the receipt of this recall notification and understand its content.

Next, complete a) or b) below:

a) We have no stock of the listed lot number.

b) We do have stock of the listed lot number and have destroyed the product.

Product	Lot Number Affected	Quantity Received	Quantity Used	Quantity Destroyed

US Endoscopy requests that you:

1. Quarantine the affected Roth Net Polyp Retriever devices in your stock.
2. Destroy each affected device by opening the device package, cutting the device catheter with a scissors, and then discarding the device and package.
3. Complete this Response Card and return to the attention of US Endoscopy Customer Service, via fax 1-440-639-4495 or email orders@usendoscopy.com .

If you have any questions, please contact Cindy Perpar at 1-440-358-6051.

Customer Name (please print) Title Signature and date

Facility Name Address Phone Number

PLEASE RETAIN A COPY FOR YOUR RECORDS