



Cantel Medical Division
Medivators, Inc.
3150 Pollok Drive
Conroe, TX 77303
www.cantelmedical.com

Subject: Urgent Medical Device Recall Notification
Date: 8 October 2019

Product Affected:

Product Name	Part Numbers	Lot Numbers
ENDO SMARTCAP™ Tubing	100145, 100622, 100650, 100651, 100145-CO2, 100145C02EXTU, 100145CO2U, 100145U, BMP-C145, BMP- C145CO2, BMP- C145CO2EXT, CPK- 100222-0002	426399, 426401, 426407, 426431, 426432, 426433, 427098, 427116, 427117, 427118, 427119, 427129, 427130, 427131, 427132, 427154, 427416, 427505, 427516, 427819, 427865, 428107, 428110, 428282, 428284, , 428576, 428806, 428819, 428821, 428823, 429694, 429695, 429884, 430069 430357, 430358, 430566, 430568, 431254, 431455, 431602, 431603, 431611, 431833, 431834, 431972, 431973, 431985, 432106, 432108, 432728, 432919, 432920, 432921, 432922, 433115, 433116, 1000028736

Dear Medivators Customer:

This letter is to inform you of a voluntary recall of specific lots of ENDO SMARTCAP™ Tubing due to a manufacturing anomaly. This anomaly may present itself during endoscopic procedures as inadequate insufflation, presence of air bubbles inside the ENDO SMARTCAP Tubing, insufficient water to rinse the endoscope lens or water leaking from the air/water valve. The specific lots impacted by this recall were manufactured between July 26, 2019 and September 19, 2019.

Through October 4th, 2019, Medivators is aware of twenty-five (25) reported instances that may be related to this anomaly. No reports of patient harm have been received.

Our records indicate your facility received ENDO SMARTCAP Tubing from one or more of the lots that may exhibit this situation. As a result, Medivators requests that you take the following actions:

1. Quarantine and discontinue use of product from the identified lots.
2. Contact Medivators Customer Service at 1-800-444-4729 or custserv@medivators.com with any questions and to receive a return material authorization (RMA) to return any unused product. For replacement product, please contact your Sales Representative or Medivators Customer Service.
3. Please return the enclosed Acknowledgment Form via email to Sadie Martin at smartin@medivators.com.
4. If this product was further distributed, notify your customers of the recall.

We sincerely regret any inconvenience this situation may have caused. Medivators remains committed to safeguarding patients and will continue to ensure we meet your needs and the needs of your patients.

Sincerely,



Eric J. Moore
Vice President, Quality

ENDO SMARTCAP™ is a trademark of Medivators Inc.