Urgent Field Safety Corrective Action

Impacted Adapter Set Models	Incompatible Endoscopes
13890.33	EC-3830TFK, EC-3830TL, EC-3830TM, EC-3830TMK, EC-3830TLK, EG-3830T, EG-3831T, EC-3832TL, EC-3840TF, EC-3840TLK, EC-3840TM, EC-3840TFK, EC-3840TL, EG-3840TK, EG-3840T, EG-3840TK
13890.34	EC-3880TLK, EG-3880TK
13890.63	BF-20D
13890.40	FNL-15RP3, FNL-7RP3, FNL-7RP3, FNL-10RP3, FNL-10RBS
13890.67	CHF-BP30
13893.45	EG-3270UK
13894.03	CHF-P20Q
13890.83#001	TGF-UC180J

31 May 2021

Dear Valued Customer:

This letter is to inform you of a labeling update affecting specific models of Adapter Set used with the Innova E-Series Automated Endoscope Reprocessor (AER).

Explanation of the Issue

Cantel has become aware of discrepancies in the INNOVA Adapter Set Instructions for Use where an adapter set is recommended for use in reprocessing specific endoscope models, however the adapter set does not have the appropriate connections to be compatible with all the listed endoscope models. This could lead to endoscopes being inadequately reprocessed and increased risk of patient infection when the endoscopes are used on subsequent patients. To date, no patient harm has been reported. Our investigation has determined that the impacted Adapter Set models are not compatible with the endoscope models listed in the table above.

Actions to be taken by the end user:
Our records indicate your facility has purchased one or more of the affected Adapter Sets. As a result, Cantel requests that you take the following actions:

1. Discontinue use of the listed Innova Adapter Sets when reprocessing the affected endoscope models listed in the table above. Adapter Sets may continue to be used to reprocess endoscope models listed in the updated INNOVA Adapter Set Instructions for Use provided with this communication.
2. Please return the enclosed Acknowledgement Form as soon as possible via email to Saurav Dubey at saurav.dubey@cantel.com as soon as possible, however not later than within 5 days after receipt. Please note that the collection of such Forms is a regulatory requirement.
3. Contact Laura Prohaszka at Laura.Prohaszka@cantel.com for questions related to this communication.

4. If this product was further distributed, notify your customers of this FCA.

The INNOVA Adapter Set Instructions for Use have been updated to ensure the accuracy of recommended Adapter Sets for the reprocessing of specific endoscope models.

Cantel will notify all applicable regulatory agencies about this matter and they might monitor and follow up on the Acknowledgment Forms completed and provided by you.

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

For the avoidance of doubt, please note that the above-mentioned Adapter Sets can be used with any endoscope other than those listed in the table above.

Sincerely,

[redacted]

Senior Vice President, Quality and Regulatory

CANTEL

INNOVA Adapter Set Field Safety Corrective Action Acknowledgement Form

Please acknowledge receipt of this notification by checking one box and completing the facility information below.

☐ The facility listed below acknowledges the Notification and has not been reprocessing impacted endoscope models with the listed Adapter Sets.

☐ The facility listed below has been reprocessing impacted endoscope models with the listed Adapter Sets, acknowledges this Notification, and therefore will discontinue use of the Adapter Sets when reprocessing the impacted endoscope models.

Facility Information:

Facility Representative Name (Please Print): _____

Signature: _____

Name of Facility: _____

Address: _____

Telephone Number: _____

Email: _____

Please email response forms to Saurav Dubey at saurav.dubey@cantel.com as soon as possible, however not later than 5 days following receipt.