Custom Ultrasonics Inc.

URGENT:
MEDICAL DEVICE RECALL
All System 83 Plus, System 83 Plus 2 and System 83 Plus 9 Automated Endoscope Reprocessors (AER)

May 6, 2016

The purpose of this letter is to advise you that Custom Ultrasonics, Inc. (CUI) System 83 Plus AERs should not be used for cleaning and/or high-level disinfection of duodenoscopes until further notice. This recall is for all System 83 Plus, System 83 Plus 2 and System 83 Plus 9 Automated Endoscope Reprocessors (AER), intended for cleaning and high level disinfection of endoscopes.

Reason for the Recall:

Custom Ultrasonics, Inc. (CUI) has been working with FDA to address concerns with the System 83 Plus Automated Endoscope Reprocessors (AER), as described in the agency's Safety Communications and recall orders dated November 13, 2015, and January 29, 2016. The System 83 Plus AERs will remain in use in the field for reprocessing certain endoscopes.

Risk to Health:

AERs are intended to adequately wash and disinfect endoscopes to mitigate the risk of patient infection. Inadequate validation and instructions for use could result in an increased risk of infection transmission.

Actions to be taken by the User:

Effective Immediately, Custom Ultrasonics AERs should not be used for cleaning and/or high-level disinfection of duodenoscopes.

Custom Ultrasonics will be providing customers with a label to affix in a prominent location on the System 83 Plus AER's on or before June 3, 2016 stating the following;

WARNING: This device is not indicated for reprocessing of duodenoscopes. Do not reprocess any duodenoscopes in this device until further notice. For alternative reprocessing options, please contact the duodenoscope manufacturer.

Custom Ultrasonics will provide a technical bulletin with immediate instructions to reflect that the device should not be used for cleaning and/or high-level disinfection of any duodenoscopes until further written notice. To obtain an electronic copy of the technical bulletin see Custom Ultrasonics website at: customultrasonics.com (Registration is required to obtain access).

The U.S. Food and Drug Administration are aware of and has agreed to this corrective action. This warning does not affect using the System 83 Plus on endoscopes other than duodenoscopes.

Product Information:

Product Information Table					
Product Names	Manufacturer's Model Number	Serial Number	Manufacturing/Distribution Dates	Additional details	Quantity
System 83 Plus	System 83 Plus 2 System 83 Plus 9	All Serial Numbers	All Manufacturing/Distribution Dates	n/a	2439

Additional Action by Custom Ultrasonics:

Custom Ultrasonics is working to complete validation of the cleaning and high-level disinfection process for duodenoscopes and update any instructions accordingly. An update to this notice and instructions will be provided after completion and approval by the FDA.

Custom Ultrasonics, Inc. regrets any inconvenience related to this matter. Please contact CUI for any inquiries.

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Custom Ultrasonics Inc.

URGENT CUSTOM ULTRASONCIS SAFETY NOTIFICATION CORRECTIVE ACTION

ACKNOWLEDGEMENT FORM

Affected Product(s): All System 83 Plus, System 83 Plus 2 and System 83 Plus 9 Automated Endoscope Reprocessor (AER) All Serial Numbers

Your facility will receive a label no later than June 3, 2016 to be affixed in a prominent location on your System 83 Plus device. Once you receive your label, we request you complete and return this acknowledgment form to Custom Ultrasonics, Inc. By returning this form, you are acknowledging receipt of both the written customer and user notification and warning label described in the medical device safety notification corrective action.

Date

_____

Facility Name

_____

Facility Address (physical location of device)

_____

City, State and Postal Code

_____

List of all System 83 Plus 2 or 83 Plus 9 Device Models and Serial Numbers

_____

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Authorized by: (Name, Title and Department) Signature:

_____

Contact, Phone and Email

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Contact Information: Please contact Custom Ultrasonics, Inc. Monday through Friday, 8:00 AM to 5:00PM EST or email us at recall@customultrasonics.com

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm form available to fax or mail), or
- Call FDA 1-800-FDA-1088

Please email this acknowledgement form after receiving your device labels to recall@customultrasonics.com