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QA Release:

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Technical Bulletin

Re: Reprocessing the Olympus MAJ-855 irrigation tubing

At this time Custom Ultrasonics Inc. contraindicates using the System 83™ Plus Washer-Disinfector to reprocess the Olympus MAJ-855 irrigation tubing, and accompanying one-way valve which connects an irrigation pump to the auxiliary water jet channel. The water in this pump is used to irrigate and cleanse the colon during colonoscopy. While the System 83™ Plus's recirculating fluid pump is adequate to flush this long tubing (MAJ-855) with large volumes of detergents and disinfectants (with this restrictive valve in place), the System 83™ Plus's air compressor does not produce a sufficient "cracking" pressure to remove these respective fluids after each reprocessing phase as required to prevent, for example, dilution of the disinfectant and contamination of the patient with reprocessing fluids during colonoscopic irrigation.

Custom Ultrasonics Inc. recommends that GI endoscopy staff members:

- (a) Contact its customer service department (215-364-1477) as required to ensure their medical facility is using the correct color-coded channel adapter (hook-up tubing) to reprocess the colonoscope's auxiliary water jet channel using the System 83 Plus;
- (b) Manually reprocess the Olympus MAJ-855 irrigation tubing in strict accordance with Olympus's operating and reprocessing instructions; and
- (c) Ensure that during the procedure the correct green valve/adaptor (double-winged, one-way flow) is connected to the end of the Olympus MAJ-855 irrigation tubing. Connection of the incorrect valve/adaptor (single-winged, two-way flow; MH-974) to the end of this irrigation tubing can result in back-flow, infectious contamination of the irrigation pump during colonoscopy, and patient-to-patient disease transmission.

This bulletin which is available online at CustomUltrasonics.com refers only to the current design of Olympus's MAJ-855 irrigation tubing. Should the design of this irrigation tubing and valve be modified by Olympus in the future, this bulletin could be subject to revision.

Please let us know if you have any questions.

The Marketing Department
Custom Ultrasonics, Inc.

REVISION	DCO NUMBER	DESCRIPTION OF CHANGE	ORIG.	QA RELEASE	DATE
A	211	New Document	X	Signature on File	5/13/09
B	008	Per Frank Weber's request we added a paragraph stating the following: While the System 83™ Plus's recirculating fluid pump is adequate to flush this long tubing (MAJ-855) with large volumes of detergents and disinfectants (with this restrictive valve in place), the System 83™ Plus's air compressor does not produce a sufficient "cracking" pressure to remove these respective fluids after each reprocessing phase as required to prevent, for example, dilution of the disinfectant and contamination of the patient with reprocessing fluids during colonoscopic irrigation.	-		