Position Statement Related to Reprocessing of Third Party Repaired Endoscopes in MEDIVATORS branded Automated Endoscope Reprocessors (AER’s)

Dear Healthcare Professional,

The purpose of this position statement is to provide important information regarding the reprocessing of third party repaired endoscopes.

Medivators commits a huge amount of resources to the validation of medical devices so that they can be successfully reprocessed in our range of AER’s. This validation includes the design of hookups that allow connection to the endoscope and AER as well as flow studies and microbiological testing to ensure patient safe medical devices.

This testing is conducted on new endoscopes provided by the OEM (Original Equipment Manufacturer) or on models that have been maintained and/or repaired by OEM facilities. This testing methodology ensures consistency in the data that is generated and ensures that customer’s equipment is reprocessed using validated hookups and programs.

It is imperative that customers are diligent in ensuring that their inventory of endoscopes are maintained and repaired to OEM specifications. We have been informed that some materials that are utilized in third party repairs are not of the same specification as the OEM parts. It has also been brought to our attention that certain parts of endoscopes have been substituted with parts from a different model rendering connection to the validated hookup impossible. Under these circumstances, Medivators cannot assume responsibility for inappropriate or incomplete disinfection due to the incorrect repair of the endoscope by a third party repair facility.

It would be impossible for Medivators to validate each and every repaired model from all third party repair companies globally, and therefore can only warrant high-level disinfection of endoscope models that have been maintained and repaired to OEM specifications.

If you have any questions related to this letter, please contact Medivators Technical Service Department on 1-800-444-4729.