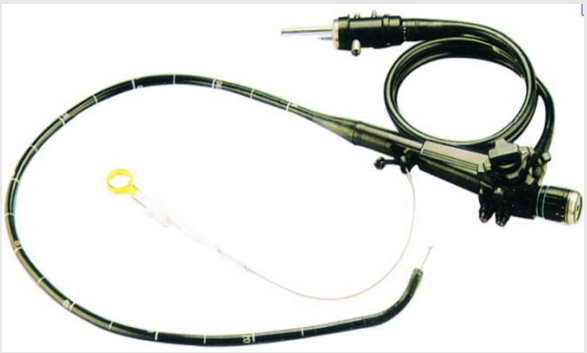
Cambridge Polymer Group
Medical Device Cleanliness

On June 9-8, 2011, the FDA hosted a workshop to discuss issues involved in the re-processing of medical devices, such as endoscopes, suction tubes, and orthoscopic shavers.

How Clean is Clean Enough?

The purpose of the workshop was to establish what guidance documents should be established to ensure that reusable devices are being properly cleaned and disinfected/sterilized to ensure patient safety, as well as to consider other issues involving device cleanliness.

Although the discussion was more focused towards re-usable devices, single use devices were also considered, both disposable and implantable. Representatives from hospitals, regulatory, reprocessors, OEMs, and testing labs discussed the state of instructions for use, cleaning testing and validation, and the risks associated with poor cleaning. Cambridge Polymer Group presented the work performed at ASTM on standards targeted towards improving medical device cleanliness, and participated in a panel discussion of what future standards will be required.



At Cambridge Polymer Group, we assist clients by establishing test methods to assess the cleanliness level of their devices, and help to identify residues on their devices. With increasing scrutiny from regulatory agencies, well-cleaned medical devices and implants has never been more important. Contact us to find out how we can help you test your samples.

Cambridge Polymer Group, Inc. is an ISO 9001:2008 certified contract research laboratory specializing in polymeric materials. We provide routine analytical testing on materials, custom test design, failure analysis, consultation, instrumentation, custom polymer and hydrogel formulation, and out-sourced research.

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