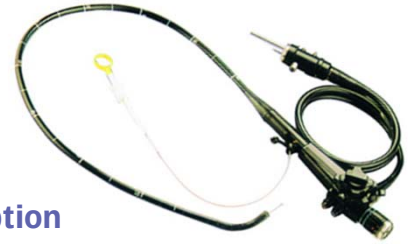
Cambridge Polymer Group

How Clean is Clean Enough?

Summary

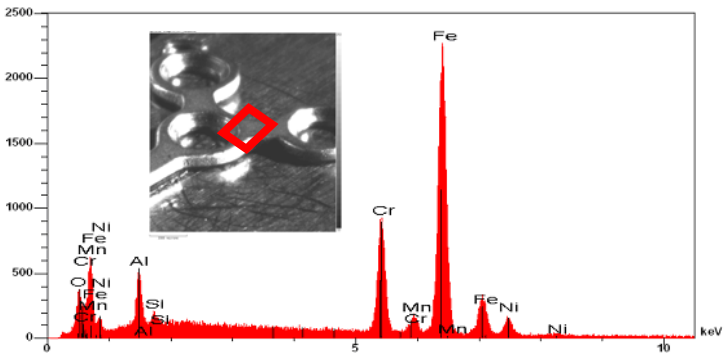
Cleaning assessment and validation of medical devices has received increased scrutiny from the medical device industry and regulatory agencies in the past 10 years. Cambridge Polymer Group provides testing services on cleanliness of medical devices, for both quantification and identification of residues. Additionally, CPG provides guidance on how to establish residue limits and procedures for validating clean lines and test methods.



Description

Since 2000, Cambridge Polymer Group has been active in design and practicing test methods for assessing cleaning efficacy in the medical device industry. We lead an ASTM task group on device cleanliness, and have organized several workshops and symposiums on the subject, and regularly lecture on the subject.

We provide testing analysis on both single use and re-usable devices, and can analyze for manufacturing residues (polishing compounds, lubricants) as well as cleaning compounds (surfactants, buffers).



Key Points

- Residue limits
- Presentations on cleaning assessment
- Cleanliness testing
- Test method validation

Analysis

CPG employs several analytical tools to analyze residues on medical devices, for both *in situ* characterization as well as removal-analysis procedures. Some techniques employed include:

- Fourier transform infrared spectroscopy
- Gas chromatography/mass spectroscopy
- X-ray photoelectron spectroscopy
- Total organic carbon
- Scanning electron microscopy/energy dispersive spectroscopy

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