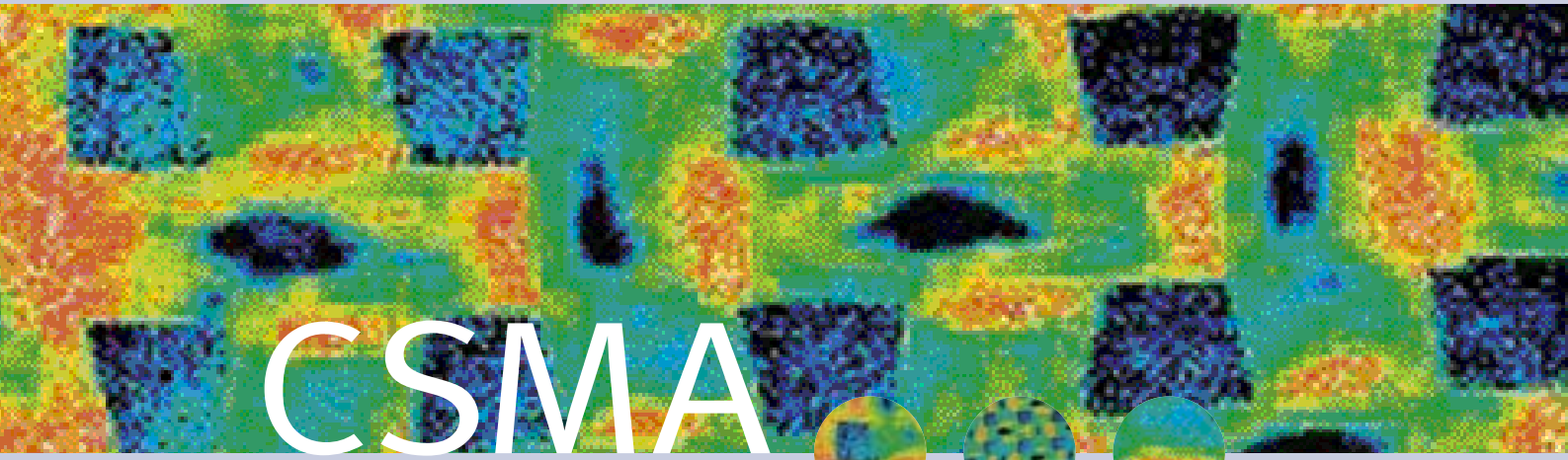
TOTAL SOLUTIONS FOR THE MEDICAL DEVICE INDUSTRY



CSMA

Surfaces of medical devices are of critical importance as they control many clinical properties including the immediate response from the biological host. Medical device developments have benefited greatly from advances in surface analytical tools such as Secondary Ion Mass Spectrometry (Imaging SIMS / ToF SIMS) and X-ray Photoelectron Spectroscopy (XPS). Consequently, the medical device industry is using surface analysis techniques on a day to day basis in the testing sequence for both regular manufacturing QC protocols and in new product development.

Over the last 15 years CSMA Ltd. has built up its own unique level of expertise in the application of surface analysis to medical device technology. This document illustrates how surface analysis can benefit the medical device developer and manufacturer and to illustrate the application of CSMA's specially developed methods, examples of the effects of sterilisation, coating treatments on medical devices are presented here.

BENEFITS TO CUSTOMER

XPS and Imaging SIMS / ToF SIMS have been used to provide this information on medical devices, including catheters, blood contact devices including filters and vascular grafts, contact and intra-ocular lenses. Some of the benefits from surface analyses include:

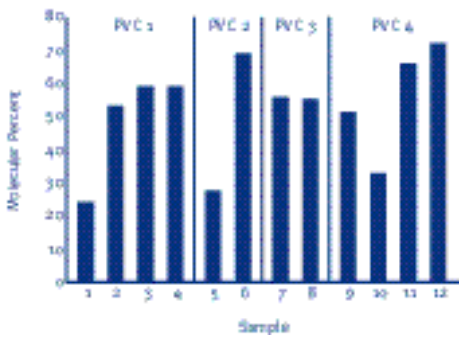
- coating conformation and integrity determination;
- contamination analysis and quantification;
- monitoring molecular diffusion and protein and cell adsorption;
- auditing medical device production.

CASE STUDY ONE

Effects of Sterilisation on Medical Tubing

A series of plasticised PVC tubing samples for blood contact applications were treated in a matrix experiment using different sterilisation procedures, prior to surface analysis of their inner lumens. The aim of this study was to determine the chemical compositions of the inner tubing walls (i.e. blood contact surfaces), in order to identify the changes introduced by the sterilisation processes. The graph (right) shows the variation in the surface coverage of the plasticisers, DEHA and DEHP, on the twelve inner PVC surfaces from different sources after different sterilisation procedures.

Plasticiser Surface Concentration on PVC



These results are initial plasticiser concentrations before blood contact. During renal dialysis procedures, approximately 60mg of DEHP are transferred into the blood of the patient per dialysis session from the PVC tubing. DEHP is rapidly metabolised but there is incomplete information on the final metabolites and whether they accumulate in specific organs. There is likely to be a lower accumulation of aromatic metabolite from DEHA than DEHP, due to the difference in the structures of the original plasticisers. Alternative plasticisers for medical grade plastics are regularly investigated by XPS and SIMS for surface migration under standard sterilisation processes.

CASE STUDY TWO

Medical Sensors

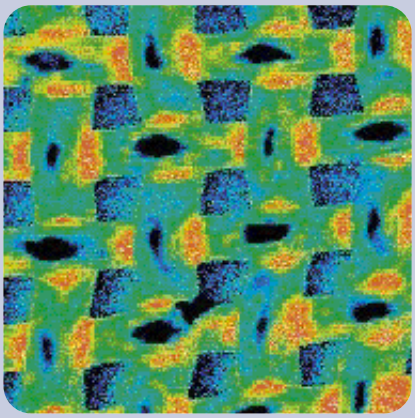
Monitoring patient condition via blood diagnostic sensors has major importance for improving healthcare especially for intensive care patients including premature babies. The critical performance parameter of these devices is the wettability of blood over the catalytic / enzyme activator surface with greater blood contact resulting in better sensitivity and reproducibility.

To disperse blood efficiently, conventional sensor design generally uses a coated woven polymer mesh to overlay the active layer. However the mesh surface is susceptible to contamination and coating failure leading to errors in readings.

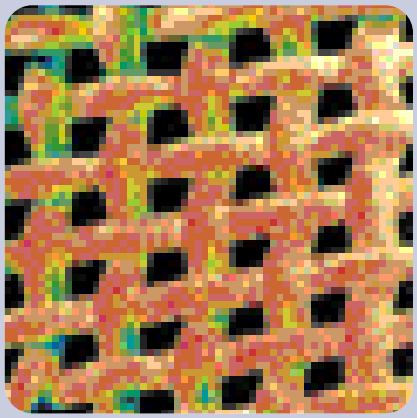
New coating systems have been evaluated by CSMA using plasma pre-treatment followed by coating with a fluoro-carbon terminated poly(butylene oxide-sulphonamide). Imaging SIMS has been used to determine the coating character and coverage in an informative imaging presentation.

SIMS Images of ions F^-, (from the coating), O^-,(principally from the oxidised polymer mesh) and C_2H^- (from the polymer substrate) were mapped. The distribution of O^- and C_2H^- ions confirmed a uniform plasma oxidation process. Ion ratio maps of F^-/C_2H^- eliminated topographic effects and indicated a more uniform coating distribution after plasma oxidation:

Fluorinated Coating: Un-oxidised Mesh



Fluorinated Coating: Oxidised Mesh



Imaging SIMS provides a direct indication of the uptake level and coating uniformity on the different meshes. Plasma oxidation is likely to result in stronger ionic bonding between polymer and coating resulting in greater durability against abrasion.

CSMA provides a complete surface analysis service to industry to accommodate every level of demand:

- rapid turnaround analysis (24 hours)
- problem solving and failure analysis
- litigation and expert witnesses
- training courses
- reverse engineering and competitor analysis
- materials and product development
- patent registration / infringement

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