The International Debate on Protein Residue Removal Research Project University Hospital of Wales HSDU

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Over the last two decades, the Department of Health commissioned three National Research Teams (Southampton, London and Edinburgh) with a brief to investigate if protein residuals is a concern on reprocessed re-usable surgical instruments through a washer disinfector. All three research teams developed a system to measure residual proteins on surgical instruments and all came to the same conclusion, that protein residuals were indeed present on processed instruments, in particular prion protein which has been proven to be extremely difficult to remove with current wash processes and chemistries.

On completion of the research, the Advisory Committee on Dangerous Pathogens (ACDP) Guidance was updated, which in turn pre-empted the update to HTM / WHTM 01-01. The updates recommended additional measures to combat residual proteins on surgical instruments.

These were alternative detection systems for monitoring protein residuals on instruments (in-situ protein detection), reducing the time from patient to washer disinfector for high risk instruments, if there is a delay in reprocessing (preferably with the 6 hour time frame) systems must be place to keep instruments moist and finally protein based fully quantifiable process challenge devices should be considered as they come to market.

Prions are easier to remove if they have not dried on the surface of the instrument, To enable efficient prion removal, theatre and SSD staff should ensure that medical devices are transported to the SSD for cleaning and reprocessing as soon as practically possible. Decontamination Manager Mark Campbell was approached by Aseptium to review the new protein based PCD following presenting at the CSC in Cardiff in 2018. The newly developed PCD fully meets the recommendations identified in the updated HTM 01-01 and a trial was agreed to monitor washer disinfector processes when challenged with a protein based material.

It should be noted that at the time of this initial research, no standard or guidance was available for the manufacture of such PCD's. The PCD's were in development stage, therefore the results are for research purposes only.

The PCD is a stainless steel token (SAE 316), impregnated with 1000mcg of brain homogenate assay (ovine). The token replicates surgical instruments with residual protein residue present. In addition to the tokens, the system comes with a holder, which takes four tokens, with each position on the holder presenting the washer with different challenges. These are: face up, face down, box joint and cannulated instruments.



Background