

09. August 2004

<http://inpharma.com/>

Prion decontamination a reality, says STERIS

A US company (STERIS) has achieved a significant breakthrough in aseptic processing with the development of a method for inactivating prions, the tiny, protein particles that cause diseases such as CJD disease in humans.

The technology is expected to find its first use in the decontamination of surgical instruments, but could also find applications in decontaminating equipment used in the manufacture of medicines, particularly those based on blood or tissue derived components.

The news is significant, given that a report in *The Lancet* (7 August issue) has detailed the second case of a person contracting CJD (Creutzfeldt-Jakob disease) - the human form of a group of diseases known as the transmissible spongiform encephalopathies - from a blood transfusion. The TSEs are debilitating illnesses affecting humans and animals that are characterised by progressive neurodegeneration and death.

STERIS, in cooperation with leading independent prion researchers, has found that several of its proprietary cleaning and sterilisation technologies can be used to inactivate prions. Until now, it has not been possible to inactivate prions without damaging contaminated surfaces.

Although predominantly a disease of the central nervous system, CJD and its related variant vCJD have become a cause for major concern because the prion particles that cause them are distributed widely in tissues around the body, including blood.

In order to create a commercial prion-killing disinfectant, STERIS has launched a new consumable product in its healthcare segment, and is re-introducing an established consumable product in its Life Sciences segment to address prion concerns in both of its major industries.

STERIS' Healthcare business has introduced a new product in the UK, in the form of a cleansing solution designed to be added to the washing-disinfecting cycle of washers that decontaminate surgical instruments after use, and will be sold under the brand name Hamo 100 PID (Prion Inactivation Detergent).

Meanwhile, the Life Sciences business unit is re-introducing a cleaning solution currently on the market that, as part of this research, has been proven to be effective against prions. The product, CIP 100, is a leading solution used to clean pharmaceutical and biotechnology production equipment. The company said it is also in the process of exploring additional commercialisation opportunities for this and other tested technologies. Research on the effectiveness of the disinfectant has also been published in the 7 August edition of *The Lancet*.

In the process of its work with prions, STERIS also helped develop standardised testing and validation protocols that were used to confirm the validity of the test results. These validation protocols are being made available to test the effectiveness of various decontamination methods against prions.

Examples of TSEs in animals include scrapie and bovine spongiform encephalopathies (BSE), which is commonly known as Mad Cow Disease.