

## Commentary by the Quality Task Group of the German Society of Sterile Supply (DGSV) on the topic of the «Hygiene Scandal»

The DGSV Quality Task Group feels the need to issue a commentary on the media portrayals of «Hygiene and instruments in German hospitals» as reported since summer 2010.

While the members of the DGSV Quality Task Group are unable to comment on the concrete situation of medical device reprocessing in individual cases, as an acknowledged group of experts it is optimally equipped to take a stance on the general scenario of medical device reprocessing in Germany.

Overall, it must be stated that the legal regulations governing cleaning, disinfection, inspection, maintenance, packing, sterilisation as well as the final release of instruments (medical devices) as conducted according to the state of the art in science and technology can be viewed as being appropriate and to a large extent adequate. There are myriad requirements in place to assure hygiene (infection control). The criteria determining high quality medical device reprocessing are continually updated and improved through a broad variety of activities and the publications of various specialist societies, including the DGSV Quality Task Group. The working practices of many Central Sterile Supply Departments (CSSDs) are exemplary, as borne out time and again by the spot checks conducted by the competent supervisory bodies in recent years.

We therefore are of the opinion that there is no need at this stage to tighten the 'hygiene regulations', but rather to make some changes to the concrete situation in reprocessing departments in hospitals, medical practitioners' offices and other establishments entrusted with medical device reprocessing.

Above all this includes, we believe, the formulation of a specific professional job description for this activity.

Since its foundation in November 1996, the German Society of Sterile Supply has been the only body to organise, and thus considerably improve, reprocessing practices through the compilation of a general training curriculum and accreditation of the now more than 50 training centres throughout Germany. In the meantime thousands of staff members have participated in the DGSV specialist training courses and gained demonstrable knowledge of medical device reprocessing. The training courses have been, and continue to be, regularly updated by the DGSV Education Committee and brought into line with new requirements for medical device reprocessing. Since 1999 the Quality Task Group has been regularly publishing in the journal *Central Service* advice on how to meet the requirements for medical device reprocessing.

The DGSV Quality Task Group members also interpret the temporary closures of CSSDs as a sign that the scope of the specialist training courses conducted throughout Germany is still insufficient. For several years now the DGSV board of directors, in particular, have called for the introduction of concrete activities and for accredited training for medical device reprocessing personnel. However, there is little support in political circles to invest in highly qualified personnel to meet the demands made by the increasingly more complex arsenal of surgical instruments. At a time when the healthcare sector is facing exorbitant costs, it is difficult to get the backing from decision-makers in politics, medicine and society on the whole for the creation of a professional job description. The DGSV Quality Task Group believes that it is only through having better qualified staff that this demanding task can, and should, be accomplished in the future.

Therefore the problem is not due to a lack of hygiene regulations as reported in the media, but to the manifold reasons for being often unwilling or unable to invest in the education/training of personnel and in the structural and technical facilities required in medical device reprocessing departments. But often these are urgently needed so that these departments are optimally equipped to meet the requirements (clean/sterile instruments) for patient convalescence.

Pursuant to the German Medical Devices Act and the German Medical Operator Ordinance, the risks posed to patients, users and third parties must be limited to an unavoidable residual risk. That calls for better training of reprocessing personnel, also through the formulation of a professional job description.

In the long term it will not be possible for staff who have received at most only between two and eight weeks of training to reprocess technically intricate and highly valuable instruments.

The Quality Task Group, like all other DGSV committees, will continue to actively contribute towards enhancing the quality of reprocessing and training for reprocessing staff.

We appeal to the staff and management of CSSDs and other departments where medical devices are reprocessed to apply the expertise they have gained from the training courses and to update and supplement their knowledge through participation in continuing professional development events.

In the forthcoming edition of *Central Service* we shall be publishing the next in our series of recommendations aimed at supporting medical device reprocessing staff in their everyday working lives.

*DGSV Quality Task Group, February 2011*