

To whom it may concern

RE: Aesculap AdTec Needleholders

Please note that the AdTec needleholder should be machine washed in a thermo washer disinfectant compatible to HTM 2030 recommendations and should be subjected to a cleaning phase of 75 degrees Celsius and a disinfecting phase of between 90 to 95 degrees Celsius.

Chemistries used in this phase should be of a pH between 7.0 to 11.0. Please note, extended exposure to higher pH levels will result in damage to the surface of this device.

Sterilisation should follow HTM 2010 recommendations and the AdTec needleholder can be sterilised between 134 to 137 degrees Celsius for a minimum holding time of three minutes to comply with the UK regulations.

Aesculap develops and produces medical devices according to the European medical Device Directive (MDD 93/42/EEC). Our compliance with these regulations is demonstrated by displaying all of our devices with the CE mark, and all products and processes are strictly validated in accordance with MDD 93/44/EEC.

Amongst other things, MDD 93/44/EEC validates cleaning and reprocessing of medical devices, and Aesculap has proven effective reprocessing, with an internal process for every reusable medical device, including the AdTec Needleholder.

The AdTec needleholder incorporates a complex overload mechanism in the handle, to ensure absolute security, and optimal functionality. The instrument is not a take apart design, but is provided with a flush port. The flush port lumen should be flushed immediately after use, ideally in theatre. The lumen should be flushed once more, as part of any pre cleaning process or attached to the washer disinfectant manifold, as part of the decontamination process.

If reprocessed in line with the above specifications and HTM recommendations, as validated, you can be assured that the AdTec needleholder will be fully decontaminated and sterile.

Please do not hesitate in contacting me directly should you require any additional information.

Kind Regards

Yours sincerely



Alan Barr
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Aesculap Endoscopy Technology