

Date

Ref. FSCA-PE-16-001

MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

Use of alcohol during reprocessing

To: <Customer address>

PENTAX Medical wants to re-emphasise the use of alcohol during reprocessing is being seen critical with regards to the fixative characteristics of alcohol on proteins and organic contaminants. Even though this is already commonly known and has been published via several Guidelines issued by expert-groups we wish to bring this to your attention again.

PLEASE NOTE, we are aware there are countries where the use of alcohol is still recommended. If this is the case in your country, please follow strictly national / regional regulations / guidelines as appropriate.

Please ensure that all potential users in your facility are made aware of this notification.

Issue:

Amendment of current reprocessing Instructions for Use (IFU) with the following warning:

During pre-cleaning, never wipe the insertion tube with alcohol or disinfecting solution. These solutions may fix organic contaminants and proteinaceous debris to the instrument and have an adverse effect on endoscope functionality and proper reprocessing.

It is important to completely dry the endoscope channels in order to prevent bacterial colonization and/or infections associated with waterborne microorganisms. In some countries a final alcohol rinse followed by forced air is recommended. However, in case this is not in accordance with your national / regional regulations or guidelines, sterile filtrated water (0.2 µm) must be used as the rinse water and completely dry the endoscope channels.

Affected products:

All PENTAX Medical Endoscopes

Instruction

1. Please advise your staff of this addendum to the Instructions for Use (IFU)
2. Please put this addendum to the reprocessing IFUs in your premises accordingly.

Contact Information:

<Describe how the customer – consignee can contact the local PENTAX Medical organisation / distributor with any question. Contact name with phone number, email address>

We sincerely regret any inconvenience caused by this action and appreciate your immediate attention to this matter.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any question regarding this action, please feel free to contact your local office of PENTAX Medical.

Sincerely,

PENTAX Europe GmbH

