

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
Leader RA EMEA, Safety Officer for Medical Devices

Dr. Stephan Lunau

Product Category : Endoscopes,

Model Number	MDD Class	Rule	GMDN	GMDN term	
FS-34V	II a	5	15057	Flexible fibreoptic sigmoidoscope	
EB-1990i	II a	5	17662	Flexible video bronchoscope	
EB-1170K	II a	5	17662	Flexible video bronchoscope	
EB-1570K	II a	5	17662	Flexible video bronchoscope	
EB-1572K	II a	5	17662	Flexible video bronchoscope	
EB-1575K	II a	5	17662	Flexible video bronchoscope	
EB-1970K	II a	5	17662	Flexible video bronchoscope	
EB-1970TK	II a	5	17662	Flexible video bronchoscope	
EB-1972K	II a	5	17662	Flexible video bronchoscope	
EB-1975K	II a	5	17662	Flexible video bronchoscope	
EB15-J10	II a	5	17662	Flexible video bronchoscope	
EB19-J10	II a	5	17662	Flexible video bronchoscope	
EG16-K10	II a	5	17663	Flexible video gastroscope	
EG27-i10	II a	5	17663	Flexible video gastroscope	
EG29-i10	II a	5	17663	Flexible video gastroscope	
EG-2790i	II a	5	17663	Flexible video gastroscope	
EG-2990i	II a	5	17663	Flexible video gastroscope	
EG-2990Zi	II a	5	17663	Flexible video gastroscope	
EG-1690K	II a	5	17663	Flexible video gastroscope	
EG-1870K	II a	5	17663	Flexible video gastroscope	
EG-2490K	II a	5	17663	Flexible video gastroscope	
EG-2790K	II a	5	17663	Flexible video gastroscope	
EG-2990K	II a	5	17663	Flexible video gastroscope	
EG-3490K	II a	5	17663	Flexible video gastroscope	
EG-3890TK	II a	5	17663	Flexible video gastroscope	
EG-290Kp	II a	5	17663	Flexible video gastroscope	
ES-3870K	II a	5	17663	Flexible video gastroscope	
FCP- 9P	II a	5	34939	Flexible fibreoptic choledochoscope	
FC-38FV	II a	5	34966	Flexible fibreoptic colonoscope	
FC-38LV	II a	5	34966	Flexible fibreoptic colonoscope	
FD-34V2	II a	5	34966	Flexible fibreoptic colonoscope	
FG-16V	II a	5	35088	Flexible fibreoptic gastroscope	
FG-24V	II a	5	35088	Flexible fibreoptic gastroscope	
FG-29V	II a	5	35088	Flexible fibreoptic gastroscope	
FB-15BS	II a	5	35461	Flexible fibreoptic bronchoscope	
FB-15RBS	II a	5	35461	Flexible fibreoptic bronchoscope	
FB-18BS	II a	5	35461	Flexible fibreoptic bronchoscope	
FB-18RBS	II a	5	35461	Flexible fibreoptic bronchoscope	
FB- 8V	II a	5	35461	Flexible fibreoptic bronchoscope	
FB-10V	II a	5	35461	Flexible fibreoptic bronchoscope	
FB-15V	II a	5	35461	Flexible fibreoptic bronchoscope	
FB-18V	II a	5	35461	Flexible fibreoptic bronchoscope	
FB-19TV	II a	5	35461	Flexible fibreoptic bronchoscope	
VNL-1570STK	II a	5	35462	Flexible video laryngoscope	
VNL-1590STi	II a	5	35462	Flexible video laryngoscope	
VNL-1070STK	II a	5	35462	Flexible video laryngoscope	
VNL-1190STK	II a	5	35462	Flexible video laryngoscope	
FCY-15RBS	II a	5	35980	Flexible fibreoptic cystoscope	

ED34-i10T	II a	5	36112	Flexible video duodenoscope	
ED-3490TK	II a	5	36112	Flexible video duodenoscope	
EC34- i 10F	II a	5	36117	Flexible video colonoscope	
EC34- i 10L	II a	5	36117	Flexible video colonoscope	
EC34- i 10M	II a	5	36117	Flexible video colonoscope	
EC38- i 10F	II a	5	36117	Flexible video colonoscope	
EC38- i 10F2	II a	5	36117	Flexible video colonoscope	
EC38- i 10L	II a	5	36117	Flexible video colonoscope	
EC38- i 10M	II a	5	36117	Flexible video colonoscope	
EC38- i 10M2	II a	5	36117	Flexible video colonoscope	
EC38-i10NF	II a	5	36117	Flexible video colonoscope	
EC38-i10NL	II a	5	36117	Flexible video colonoscope	
EC-2990Fi	II a	5	36117	Flexible video colonoscope	
EC-2990Li	II a	5	36117	Flexible video colonoscope	
EC-2990Mi	II a	5	36117	Flexible video colonoscope	
EC-3490Fi	II a	5	36117	Flexible video colonoscope	
EC-3490Li	II a	5	36117	Flexible video colonoscope	
EC-3490Mi	II a	5	36117	Flexible video colonoscope	
EC-3890Fi	II a	5	36117	Flexible video colonoscope	
EC-3890Fi2	II a	5	36117	Flexible video colonoscope	
EC-3890Li	II a	5	36117	Flexible video colonoscope	
EC-3890Mi	II a	5	36117	Flexible video colonoscope	
EC-3890Mi2	II a	5	36117	Flexible video colonoscope	
EC-3490TFi	II a	5	36117	Flexible video colonoscope	
EC-3490TLi	II a	5	36117	Flexible video colonoscope	
EC-3490TMi	II a	5	36117	Flexible video colonoscope	
EC-3890FZi	II a	5	36117	Flexible video colonoscope	
EC-3890LZi	II a	5	36117	Flexible video colonoscope	
EC-3890MZi	II a	5	36117	Flexible video colonoscope	
EC-3490FK	II a	5	36117	Flexible video colonoscope	
EC-3490LK	II a	5	36117	Flexible video colonoscope	
EC-3490MK	II a	5	36117	Flexible video colonoscope	
EC-3890FK	II a	5	36117	Flexible video colonoscope	
EC-3890FK2	II a	5	36117	Flexible video colonoscope	
EC-3890LK	II a	5	36117	Flexible video colonoscope	
EC-3890MK	II a	5	36117	Flexible video colonoscope	
EC-3890MK2	II a	5	36117	Flexible video colonoscope	
EC-3890TFK	II a	5	36117	Flexible video colonoscope	
EC-3890TLK	II a	5	36117	Flexible video colonoscope	
EC-380FK2p	II a	5	36117	Flexible video colonoscope	
EC-380FKp	II a	5	36117	Flexible video colonoscope	
EC-380LKp	II a	5	36117	Flexible video colonoscope	
EC-380MK2p	II a	5	36117	Flexible video colonoscope	
VSB-2990i	II a	5	36299	Flexible video enteroscope	
FI- 7BS	II a	5	36706	Flexible fiberoptic intubation laryngoscope	
FI- 7RBS	II a	5	36706	Flexible fiberoptic intubation laryngoscope	
FI- 9BS	II a	5	36706	Flexible fiberoptic intubation laryngoscope	
FI- 9RBS	II a	5	36706	Flexible fiberoptic intubation laryngoscope	
FI-10BS	II a	5	36706	Flexible fiberoptic intubation laryngoscope	
FI-10RBS	II a	5	36706	Flexible fiberoptic intubation laryngoscope	

FI-13BS	II a	5	36706	Flexible fibreoptic intubation laryngoscope	
FI-13RBS	II a	5	36706	Flexible fibreoptic intubation laryngoscope	
FI-16BS	II a	5	36706	Flexible fibreoptic intubation laryngoscope	
FI-16RBS	II a	5	36706	Flexible fibreoptic intubation laryngoscope	
EG-3270UK	II a	5	36951	Flexible ultrasonic gastroduodenoscope	
EG-3670URK	II a	5	36951	Flexible ultrasonic gastroduodenoscope	
EG-3870UTK	II a	5	36951	Flexible ultrasonic gastroduodenoscope	
FUR- 9RBS	II a	5	37111	Flexible fibreoptic ureterorendoscope	
EE-1580K	II a	5	38666	Flexible video oesophagoscope	
FNL-10RBS	II a	5	44715	Flexible fibreoptic nasopharyngolaryngoscope	
FNL- 7RP3	II a	5	44715	Flexible fibreoptic nasopharyngolaryngoscope	
FNL-10RP3	II a	5	44715	Flexible fibreoptic nasopharyngolaryngoscope	
FNL-15RP3	II a	5	44715	Flexible fibreoptic nasopharyngolaryngoscope	
EB-1970UK	II a	5	44921	Flexible ultrasonic bronchoscope	
ECY-1570K	II a	5	44925	Flexible video cystoscope	
ECY-1575K	II a	5	44925	Flexible video cystoscope	
FHY-10RBS	II a	5	44956	Flexible video hysteroscope	
FHY-15RBS	II a	5	44956	Flexible video hysteroscope	
VNL8-J10	II a	5	45067	Flexible video rhinolaryngoscope	
VNL11-J10	II a	5	45067	Flexible video rhinolaryngoscope	
VNL15-J10	II a	5	45067	Flexible video rhinolaryngoscope	
VNL9-CP	I	5	45067	Flexible video rhinolaryngoscope	