Urgent Safety Communication

Urgent FSN's of PENTAX Medical Duodenoscope several models Manufactured by PENTAX Europe GmbH

Device/ Product Name:	PENTAX Medical ED-3490TK Duodenoscope and inspection of all PENTAX Duodenscopes
Lot numbers/Serials:	Duodenoscope models: ED-3490TK, FD-34V2, ED-3270K, ED-3430, ED-3430TK, ED-3670TK, ED-3230, ED-3230K, ED-3430K, ED-3430T, ED-3630T... Duodenoscope ED-3490TK Duodenoscope ED34-i10T Please check attachment for details
Manufacturer:	PENTAX Europe GmbH
Problem:	Saudi FDA would like to bring your attention that **PENTAX Europe GmbH** is issuing an **Urgent FSN's** to inform you that during manufacturing of duodenoscopes (including the above mention duodenoscope models of similar design), silicone adhesive is applied to the distal tip prior to affixing the distal cap. During use, in some instances, cracks or gaps may form in the adhesive that may be vulnerable to fluid ingress and soiling. Please read the manufacturer' FSN below.
Recommendation/Actions:	- PENTAX reminds its users of the importance of using the duodenoscopes according to their current intended use. The reprocessing Instructions for Use remain the same. Healthcare facilities must ensure that all reprocessing personnel ("users") are knowledgeable and thoroughly trained on the current Instructions for Use for manual reprocessing of these devices. Meticulous cleaning of the

	elevator recesses and attention to following all reprocessing instructions are required. - As already described in all our current IFU, PENTAX recommends that you immediately remove from use any duodenoscope that shows visible signs of wear or physical damage. Continuing to use devices with integrity issues (i.e. holes, cracks, kinks and scratches) can contribute to persistent device contamination and subsequent patient infection. - PENTAX will contact your facility to schedule inspections of your duodenoscope inventory and heightened vigilance will be applied to the integrity of the distal cap during these inspections. If ho have these products Make sure to contact your distributor to complete the corrective action. - PENTAX will contact your facility to arrange the return of the ED-3490TK and ED34-i10T for the forceps elevator mechanism, O-rings and distal end cap upgrades. Loaner devices will be supplied to customers as needed.
Devices/Products photo:	

Authorized Representative Details	**Company name:**	**Medical supplies & Services Co.Ltd - Mediserv**
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For further information, please **see the FSN below or Click Here.**

Healthcare Professionals should report any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

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Sincerely,
NCMDR Team