
Urgent Field Safety Notice

Olympus KeyMed OFP-2 Flushing Pump Accessory – MAJ-1606 Instrument Channel Adaptor
FSCA-identifier: FSCA – 2015-001 – MAJ-1606
Type of action: Field Safety Corrective Action

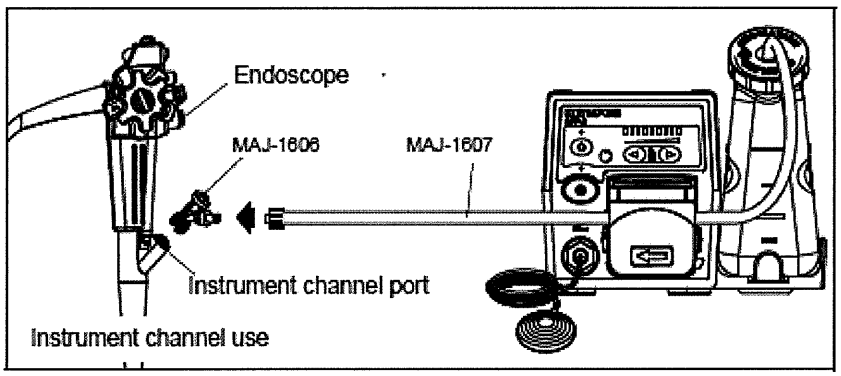
Date: 01 September 2015
Attention: Healthcare Practioner

Details on affected devices:

MAJ-1606 Instrument Channel Adaptor

K10016091 (pack of 10): Lot 20115441, 20116536
K10007072 (pack of 100): Lot 20115441, 20116536
NB. Please note that other lots are not affected

The Olympus flushing pump OFP-2 and its accessories are intended for use during endoscopic procedures to wash blood, faeces and other organic matter from the gastric and colonic mucosa site being visualised, diagnosed, treated and to aid in the filling areas of the gastrointestinal tract with water in order to aid examinations performed with trans-endoscopic ultrasound probes. The MAJ-1606 is a single use adaptor which is supplied sterile and is designed for use with the Olympus MAJ-1607 instrument channel water tube or a standard luer fitting syringe, to facilitate the delivery of sterile water through the instrument channel of an Olympus gastrointestinal/colono/ultrasound endoscopes and allow a sheathed Olympus EndoTherapy instrument or Olympus Ultrasound probe to be inserted



Description of the problem:

The packaging for the MAJ-1606 is formed from two materials. Small puncture marks (not easily visible by eye) have been found on the top packaging of the MAJ-1606. This was caused by variations in the packaging process.
The device is used in a non-sterile clinical environment to wash blood, faeces and other organic matter from the gastric and colonic mucosa site being visualised, diagnosed, treated and to aid in the filling areas of the gastrointestinal tract with water in order to aid examinations performed with trans-endoscopic ultrasound probes sites. A sample of devices with small puncture marks in the packaging have been sent to the HIRL (Hospital Infection Research Laboratory) for bioburden testing. This testing concluded that no bacterial contamination was detected from any of the adaptors sampled. This issue has been identified from within Olympus. There have been no reports of patient injury

Advise on action to be taken by the user:

The Health Care Practioner should:
Use the LOT number printed on the device packaging to identify the affected devices
Quarratine the affected devices
Complete the attached reply form and contact your local Olympus representative for credit or replacement.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. (If appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

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The undersigned confirms that this notice has been notified the appropriate Regulatory Agency

[redacted]

Regulatory Affairs Manager