

**MEDICAL DEVICE FIELD SAFETY CORRECTION**

2017-01-10

To: [contact@sindor.com](mailto:contact@sindor.com)

RE: **Instructions for use of OF-B113 and OE-B5**

Dear Valued Customer,

PENTAX Medical has become aware of a product issue associated with the Luer connector of water jet irrigation tube OF-B113 that may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

**Safety issue:**

The Luer connector of water jet irrigation tube OF-B113 gets deformed and/or damaged while in use due to age-related degradation and impacts. Use of a deformed or damaged Luer connector in irrigation tube OF-B113 and/or in injection tube OE-B5 may cause water leakage or tube disconnection causing that endoscope reprocessing cannot be properly executed.

**Affected Product details:**

All endoscopes in use with OF-B113 and/or OE-B5

**WARNING**

Check that there is not any damage on the Luer connector prior to use OF-B113 or OE-B5.

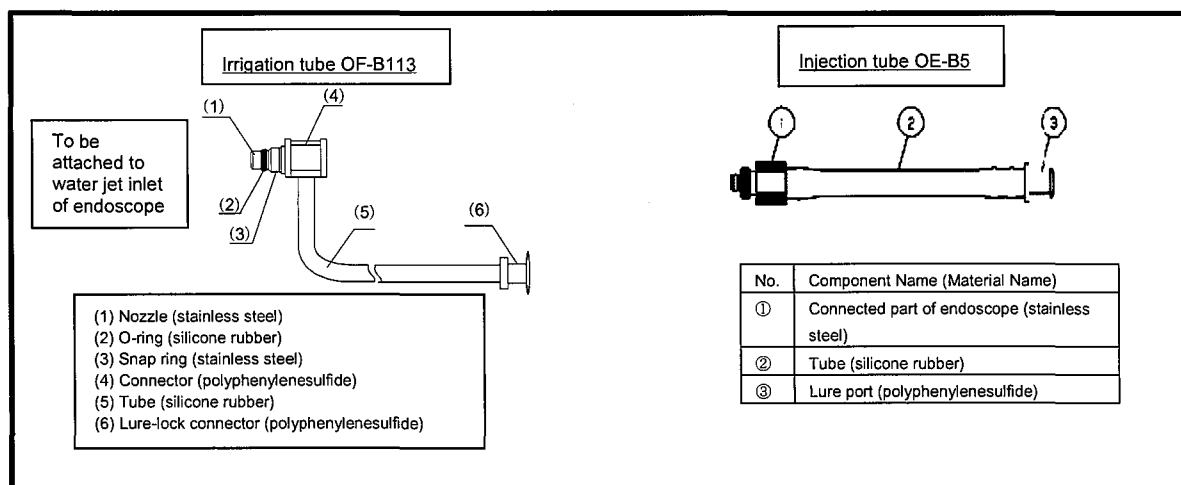
When OF-B113 or OE-B5 is connected with locking type of Luer connector, ensure that the luer connectors are properly locked. If there is damage of the Luer connector of OF-B113 or OE-B5 and/or luer connection is not properly locked, do NOT use the OF-B113 or OE-B5.

The use of damaged Luer connector may result in ineffectiveness endoscope reprocessing due to water leakage from the connected part or tube disconnection, posing a risk of cross-contamination.

**Safety Instructions:**

Although no incidents have been reported, make sure to follow the directions below thoroughly for pre-use inspection.

1. Make sure to conduct pre-use inspection to the lure connector for abnormalities.
2. Make sure no breakage, crack, damage on the plastic parts before use.
3. Make sure that the lure-lock is properly locked when connecting the lure-lock connector.
4. Do not use the endoscope with defect or damaged lure connector, or the endoscope whose lure connector will not be properly locked.
5. If you found any damages and abnormalities, please do not use it and replace with brand new OF-B113 and OE-B5



#### Contact information:

Please feel free to contact at:

Tel: 6507 9266

Fax: 6271 1691

Email: [vigilanceAsia@pentaxmedical.com](mailto:vigilanceAsia@pentaxmedical.com)

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.

Thank you,

