

October 27, 2017

QIL 150-014

**URGENT FIELD SAFETY NOTIFICATION
IMPORTANT FIELD SAFETY INFORMATION FOR THE SIF-Y0019 and ST-Y0008
Olympus Small intestinal videoscope SIF-Y0019 and Single use Spiral tube ST-Y0008**

ATTENTION: Endoscopy Department

Dear Health Care Professional,

Olympus has become aware of an issue that requires your attention. This letter pertains to the Olympus Small intestinal videoscope SIF-Y0019 and Single use Spiral tube ST-Y0008. The Small intestinal videoscope SIF-Y0019 is indicated for use within the upper digestive tract (including the esophagus, stomach, duodenum, and small intestine) by oral insertion or the lower digestive tract (including the anus, rectum, sigmoid colon, colon, ileocecal valve, and small intestine) by anal insertion. Our records indicate that an affected SIF-Y0019 is located at your facility.

Olympus has received a complaint that the spiral tube ST-Y0008 connected on the insertion portion of the SMALL INTESTINAL VIDEOSCOPE SIF-Y0019 was unintentionally detached from the SIF-Y0019 during Spiral endoscopy. In an effort to mitigate a potential risk to patient health, OLYMPUS is undertaking this action to update the instruction manual and provide users with a method for reducing the risk of unintentional detachment. For more detail, please find the updated instructions for the Operation Manual enclosed in Annex 1: "3.9 Attachment of the single use Spiral tube (ST-Y0008) and inspection of the rotation function" and updated instructions for the Reprocessing Manual, enclosed in Annex 2: "5. 3 Precleaning the endoscope and accessories."

Olympus requires you to take the following action:

- Immediately begin to follow the new instructions of the updated Operation - and Reprocessing Manual. Olympus will be working on a change to the device design to address this potential risk, and will provide you with additional information at a future date.
- Please note that you have received this information on the enclosed Reply Form.
- Return the completed Reply Form via e-mail to FSCA@olympus-europa.com latest by 10.11.2017.

In addition, please transfer this notice to all affected departments on which this action has an impact.

The [local / national Competent Authority] is aware of this action.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at (040) 23773-3258 Monday - Friday or by e-mail at tomomichi.onoe@olympus-europa.com for any additional information on this matter.

Sincerely,
Olympus Europa

OLYMPUS URGENT FIELD SAFETY NOTIFICATION REPLY FORM

Affected Model:

Olympus Small intestinal videoscope SIF-Y0019 and Single use Spiral tube ST-Y0008

By submitting this reply form I acknowledge that I have received the Urgent Field Safety Notification for the SIF-Y0019 and ST-Y0008 referenced above.

I understand that I need to attach the enclosed **Annex 1**: "3.9 Attachment of the single use Spiral tube (ST-Y0008) and inspection of the rotation function)" to all the available Operation Manuals.

I will also attach the enclosed **Annex 2** "5. 3 Precleaning the endoscope and accessories." to all available of Reprocessing Manuals.

Furthermore I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact.

Serialnumber available: _____

Facility: (Please do not abbreviate)

Address:

City:

State: _____

Postal Code: _____

Name (Print):

Name (Signature):

Your Phone Number: _____

Please return this completed reply form via e-mail to Olympus Regulatory Affairs Department at FSCA@olympus-europa.com.

Annex 1: Modified SIF-Y0019 OPERATION MANUAL “3.9 Attachment of the single use Spiral tube (ST-Y0008) and inspection of the rotation function”

The sentences written in ***bold italic*** in red show the changes related to prevent the detachment of the spiral tube in the section “***Attachment of the single use Spiral tube (ST-Y0008)***”

Attachment of the single use Spiral tube (ST-Y0008)

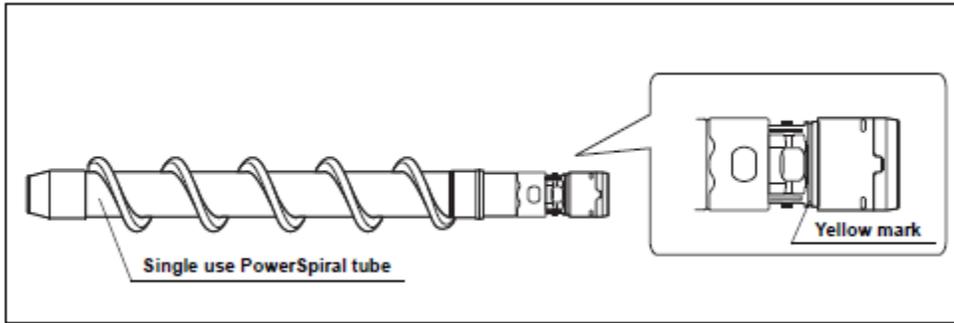
WARNING

- ***Apply medical tape of at least 1 cm width over the release button prior to clinical use in order to reduce the risk of inadvertent release of the Spiral tube during use. Prior to applying the medical tape, thoroughly remove the lubricant on the connector of the single use Spiral tube with clean lint-free cloths. Confirm that the corner of the medical tape is not peeled or protruded from the both ends of the connector. If not fixed securely, the medical tape or the single use Spiral tube may detach and fall into the body cavity during use or the single use Spiral tube could not rotate smoothly.***
- ***Do not use a medical tape that has already been used once. Reusing a medical tape may cause patient or operator infection.***
- ***When the single use Spiral tube is not attached to the endoscope properly, the single use Spiral tube may fall into the body cavity during use.***

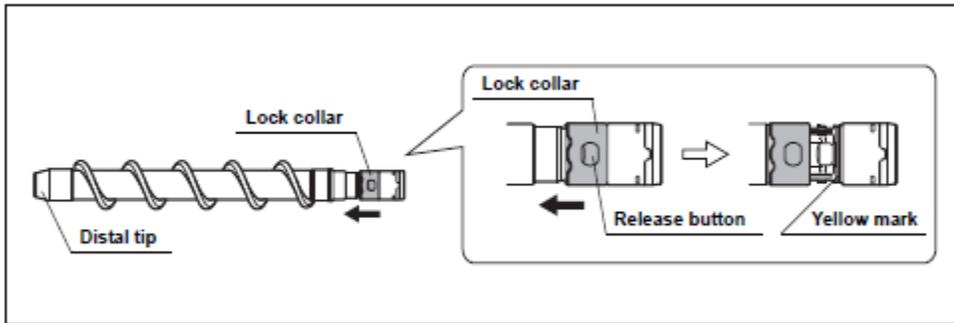
CAUTION

- Before inserting, confirm that the lock collar of the single use Spiral tube is moved toward the distal tip until it stops. While inserting, if the lock collar of the single use Spiral tube is not positioned as specified, the endoscope and the single use Spiral tube may be damaged.
- Thoroughly apply a medical use water-soluble lubricant over the rotation part and entire insertion section distal to the rotation part. Otherwise, equipment damage may result.
- Align the ridges on the rotation part with the hollows on the single use Spiral tube. Otherwise, equipment damage can result.
- Do not grip the connector strongly when sliding the lock collar. The connector maybe damaged.
- ***When the tip of the medical tape peels or protrudes from the tip of the connector, the medical tape or the single use Spiral tube can fall into the body cavity during use or the single use Spiral tube could not rotate smoothly.***

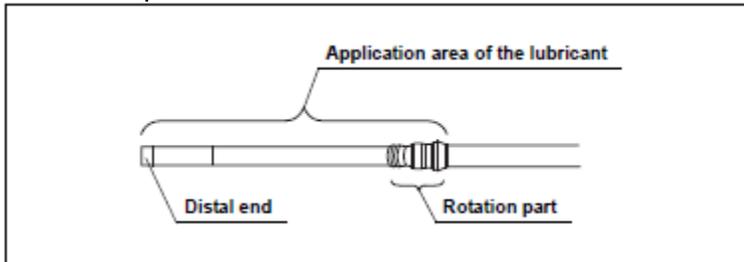
- 1** Inspect the external surfaces and the internal surfaces of the single use Spiral tube for any irregularities such as cracks, dents, bulges, edges, scratches, abnormal stickiness, protruding objects, transformation, adhesion of foreign materials, sagging, and missing parts.
- 2** Run your fingers over the entire external surfaces of the single use Spiral tube. Confirm that there are no irregularities such as cracks, dents, bulges, edges, scratches, abnormal stickiness, protruding objects, transformation, adhesion of foreign materials, sagging, and missing parts.
- 3** Confirm that the yellow mark of the single use Spiral tube is visible.



4 If the yellow mark is not visible, while pressing the release button of the lock collar, slide the lock collar toward the distal tip until it stops.

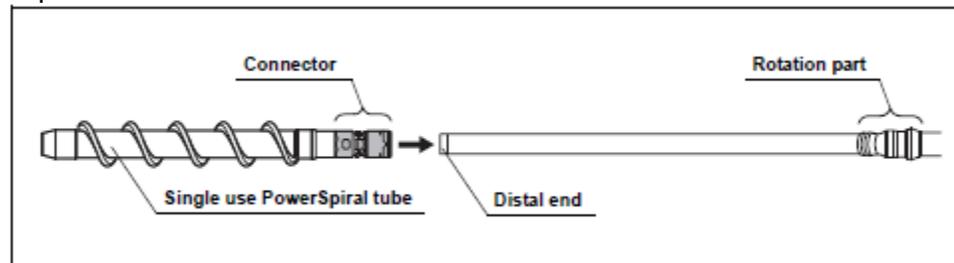


5 Thoroughly apply a medical use water-soluble lubricant on the endoscope from the rotation part to the distal end.

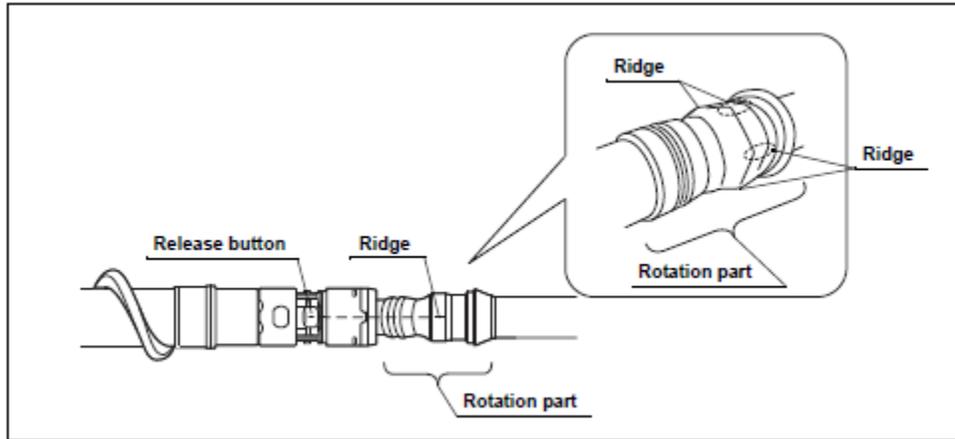


6 Straighten the endoscope from the distal end through the rotation part.

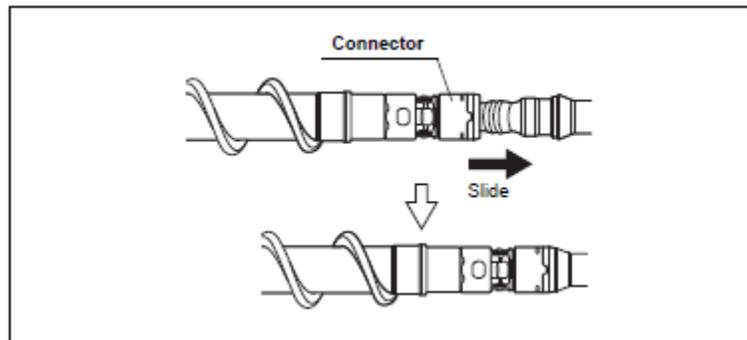
7 Place the connector of the single use Spiral tube over the distal end of the endoscope and carefully slide the single use Spiral tube until the connector is close to the rotation part.



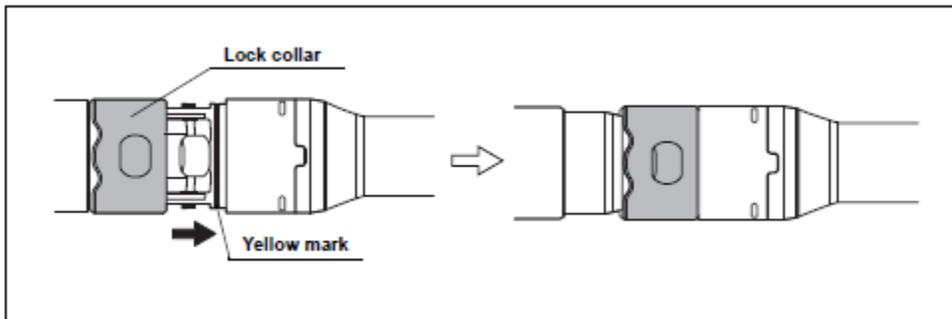
8 Align the release button on the single use Spiral tube with one ridge on the rotation part.



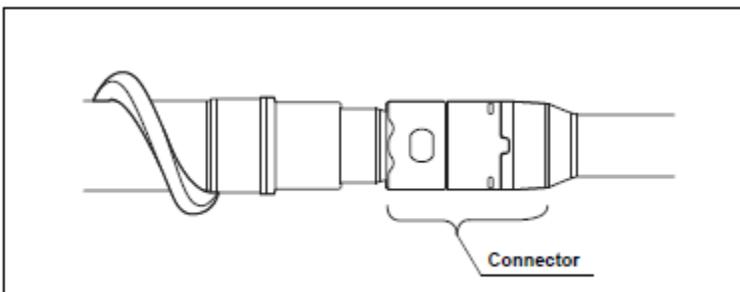
9 Carefully slide the single use Spiral tube until the connector of the single use Spiral tube stops.



10 Slide the lock collar of the single use Spiral tube until the yellow mark becomes not visible.



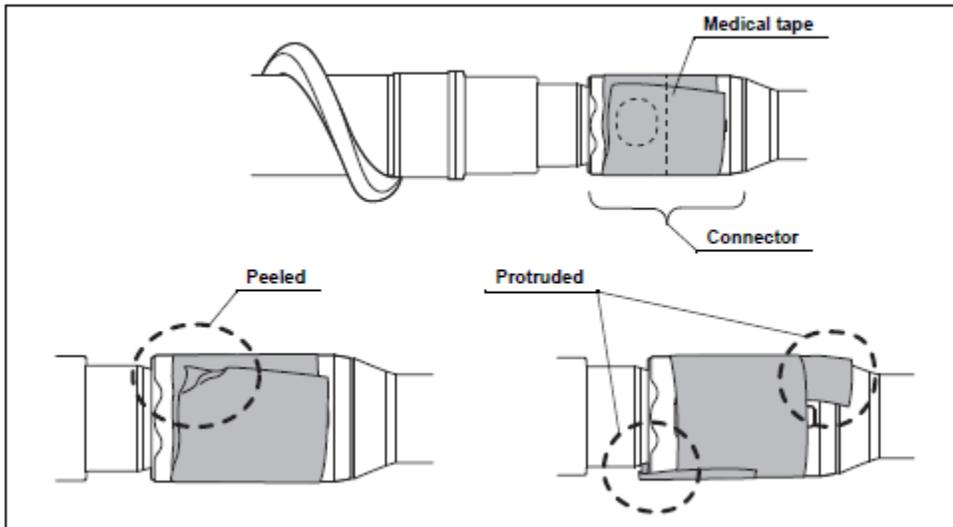
11 Thoroughly remove the lubricant on the connector of the single use Spiral tube with clean lint-free cloths.



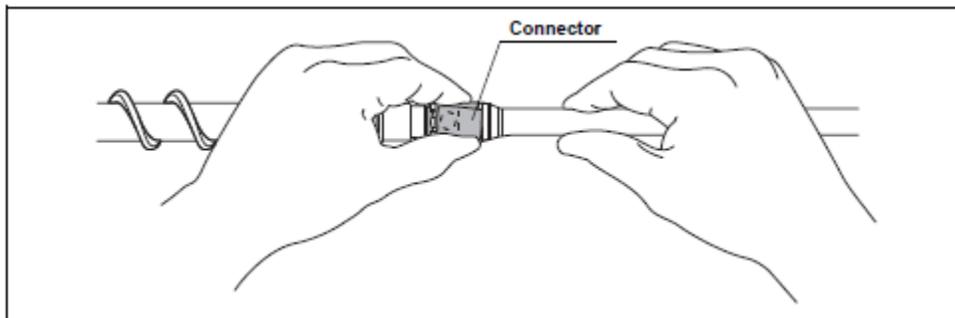
12 Change the gloves to new ones.

13 Apply medical tape of at least 1 cm width over the release button. Confirm that

the corner of the medical tape is not peeled or protruded from the both ends of the connector.



14 *Hold the connector and gently pull the endoscope to make sure that the single use Spiral tube is attached to the endoscope properly.*



NOTE

When holding the connector, do not press the release button over the medical tape. Otherwise, the single use Spiral tube may be detached from the endoscope.

Annex 2:Modified SIF-Y0019 REPROCESSING MANUAL “5.3 Precleaning the endoscope and accessories”

The sentence written in ***bold italic*** in red shows the change related to prevent the detachment of the spiral tube in the section “***5.3 Precleaning the endoscope and accessories***”.

Preparation

Immediately after the patient procedure, with the endoscope still connected to the equipment (i.e., the light source, video system center, and suction pump) used in the patient procedure, perform the following precleaning steps at the patient bed side.

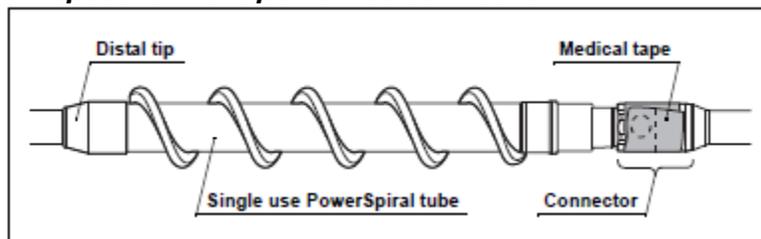
WARNING

- Always remove the single use Spiral tube from the endoscope before Reprocessing the endoscope. Otherwise, the endoscope may not be fully reprocessed.
- Do not reprocess and reuse the single use Spiral tube and mouthpiece. A reprocessed single use Spiral tube may be damaged and a damaged part of the tube may drop into the patient body. It may damage the body cavity.
- Do not remove the single use Spiral tube from the endoscope quickly. This may spray patient blood or mucus, posing an infection control risk or damaging the endoscope.
- Before removing the single use Spiral tube from the endoscope, confirm that the lock collar of the single use Spiral tube is moved toward the distal tip of the single use Spiral tube until it stops. While removing the single use Spiral tube, if the lock collar of the single use Spiral tube is not positioned as specified, the endoscope may be damaged.
- Do not firmly grasp the connector of the single use Spiral tube while pulling out the single use Spiral tube. The connector could be transformed or broken and may damage the endoscope.

NOTE

If the distal attachment has been attached to the endoscope, remove it before removing the single use Spiral tube.

- 1** Turn the video system center, light source, and Spiral tube control unit OFF.
- 2** When using the endoscope position detecting unit (UPD-3), turn it OFF.
- 3** ***Remove the medical tape on the connector of the single use Spiral tube.***
Dispose of the tape as medical waste.



- 4** Straighten the endoscope from the distal end through the connector of the single use Spiral tube.
- 5** While pressing the release button of the lock collar, slide the lock collar toward the distal tip until it stops.
- 6** Hold the connector of the single use Spiral tube and remove it from the endoscope carefully.
- 7** Dispose of the single use Spiral tube.
- 8** Prepare a clean 500 ml container of the water as described in Section 3.2, “Water (for reprocessing)”.