



March 26, 2015

**URGENT SAFETY NOTIFICATION
IMPORTANT UPDATED LABELING INFORMATION:
NEW REPROCESSING INSTRUCTIONS FOR THE OLYMPUS TJF-Q180V
DUODENOSCOPE**

ATTENTION: Endoscopy Department, Risk Management and Reprocessing Units

Dear Health Care Professional:

Olympus America Inc. (OAI) is writing to inform you that we are issuing validated, new reprocessing procedures for the Olympus TJF-Q180V duodenoscope ("TJF-Q180V"), consisting of revised manual cleaning and high level disinfection procedures.

These new reprocessing procedures should be implemented as soon as possible. The new cleaning procedure requires the use of a small bristle cleaning brush (MAJ-1888) which Olympus anticipates shipping no later than May 8, 2015. Until your facility has received the brushes, you should continue to clean the TJF-Q180V duodenoscope in accordance with the original cleaning instructions.

In addition to the new cleaning brush referenced above, the new TJF-Q180V reprocessing procedures requires additional recess flushing and forceps elevator raising/lowering steps during precleaning and manual cleaning, manual disinfection, endoscope rinsing and alcohol flushing. These new TJF-Q180V flushing steps for precleaning and manual disinfection are provided in the Attachment to this Safety Notification. Updated Reprocessing Manuals containing these instructions will be distributed by Olympus.

Please note the key differences in the new reprocessing procedure:

Precleaning:

- During immersion, raise and lower the elevator three times

Manual Cleaning:

- Additional brushing of the forceps elevator recess area
 - The revised cleaning procedure requires brushing of the forceps elevator recess with two different-sized brushes. In addition to the brush that is currently used to clean the elevator recess area, the MAJ-1888 brush (or any Olympus MAJ-1888 equivalent) will be provided for further cleaning

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of this area. Olympus anticipates shipping the MAJ-1888 brushes no later than May 8, 2015.

- Additional flushing of forceps elevator recess area
- Additional raising/lowering the forceps elevator

Manual High Level Disinfection:

- Additional manual flushing steps and increased flushing volume of each endoscope channel, as well as the elevator recess area
- Additional raising/lowering the forceps elevator

Please take the actions indicated below to implement the reprocessing changes.

Immediate Actions:

- Implement the new precleaning and high level disinfection procedure. This procedure does not require additional equipment for implementation.
- Ensure that all personnel involved in the reprocessing are completely knowledgeable and thoroughly trained on the new reprocessing instructions.
- Please indicate on the enclosed questionnaire that you have received this notification. Fax the completed form to (484) 896-7128.

Follow-up Actions:

- The new cleaning procedure involves the use of a new, smaller bristle brush, model MAJ-1888. Continue using the existing procedure with current brushes for manual cleaning of the TJF-Q180V until the new brush is available.
- New brushes (MAJ-1888) or any Olympus MAJ-1888 equivalent and the updated TJF-Q180V Reprocessing Manual will be shipped to your facility no later than May 8, 2015.

Implement the new cleaning instructions, once you have received the new brush

The U.S. Food and Drug Administration has reviewed these procedures and is aware of this corrective action.

If you require additional information about the new flushing steps and new reprocessing procedures, you can obtain additional information as follows:

- You can contact our Technical Assistance Center (TAC) at 1-800-848-9024, option 1 Monday - Friday between 7AM EST - 8 PM EST. The TAC department can assist you in answering questions on the new TJF-Q180V reprocessing procedures and new flushing steps.
- OAI has dedicated field personnel, called Endoscopy Support Specialists (ESSs), who visit customer sites to assess and observe customer reprocessing methods and to provide reprocessing training and education. If you would like an ESS to visit your facility to review and train on the new TJF-Q180V reprocessing procedures and new flushing steps, please request a site visit by calling our TAC department at 1-800-848-9024, option 1.

Olympus regrets any inconvenience and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at (484) 896-5688 or by e-mail at laura.storms@olympus.com for any additional information on this matter.

Sincerely,

A handwritten signature in blue ink that reads "Laura Storms" followed by a circular flourish containing the initials "JS".

Laura Storms
V.P., Regulatory/Clinical Affairs & Quality Assurance

NEW: Supplemental Flushing Instructions for EVIS EXERA II DUODENOVideoscope OLYMPUS TJF TYPE Q180V REPROCESSING MANUAL (GE8415 09)

Note: The following underlined steps are new flushing instructions that do not appear in the latest released EVIS EXERA II DUODENOVideoscope OLYMPUS TJF TYPE Q180V REPROCESSING MANUAL (GE8415 09). These are only excerpts and do not represent the complete reprocessing instructions. Please refer to the REPROCESSING MANUAL in addition to these instructions when reprocessing these devices.

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5.2 Precleaning the endoscope and accessories

Page 44:

Aspirate water

3. Lower the forceps elevator by turning the elevator control lever, immerse the distal end of the insertion section in the water. Depress the suction valve (MH-443) on the endoscope and aspirate the water through the endoscope for 30 seconds.
4. While continuing the immersion and the aspiration, raise and lower the forceps elevator three times, by turning the elevator control lever.
5. Remove the distal end from the water. Depress the suction valve and aspirate air for 10 seconds.
6. Turn the suction pump OFF.

5.5 Manually disinfecting the endoscope and accessories

Flush all channels and around the forceps elevator with disinfectant solution

1. Confirm that the suction port of the injection tube (MH-946) is immersed in the disinfectant solution.
2. Attach a clean 30 ml syringe to the suction channel port of the injection tube and forcefully flush the suction channel with 180 ml of the disinfectant solution – i.e., by pumping the syringe at least six times. Confirm that no air bubbles exit the distal end of the endoscope's insertion section during the sixth flush. If air bubbles still exit, flush the channel with the disinfectant solution until no air bubbles exit. (See Figure 5.32).

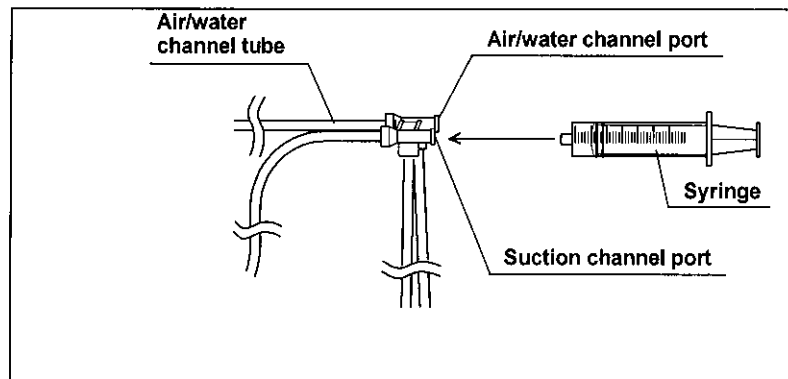


Figure 5.32

3. Move the syringe to the air/water channel port of the injection tube and forcefully flush the air/water channel with 180 ml of the disinfectant solution. Confirm that no air bubbles exit the distal end during the sixth flush. If air bubbles still exit, flush the channel with the disinfectant solution until no air bubbles exit. (See Figure 5.33)
4. Remove the biopsy valve cap of the channel plug (MH-946) from the instrument channel port of the endoscope, leaving the channel plug attached to the air/water and suction cylinders of the endoscope. Forcefully flush the instrument channel with 180ml of the disinfectant solution, using the 30ml syringe - i.e., fill the syringe with the disinfectant solution without air, put the distal end of the syringe in the instrument channel port in the disinfectant solution, and forcefully flush at least six times, minimizing disinfectant solution leakage from the port. Confirm that no air bubbles exit the distal end of the endoscope's insertion section during the sixth flush. If air bubbles still exit, flush the channel with the disinfectant solution until no air bubbles exit.
5. With the forceps elevator raised, insert the tip of the 30 ml syringe into the interior of the forceps elevator recess in the disinfectant solution, and flush the interior of the recess with 60 ml of the disinfectant solution.

**NEW: Supplemental Flushing Instructions for EVIS EXERA II DUODENOVideoscope
OLYMPUS TJF TYPE Q180V REPROCESSING MANUAL (GE8415 09)**

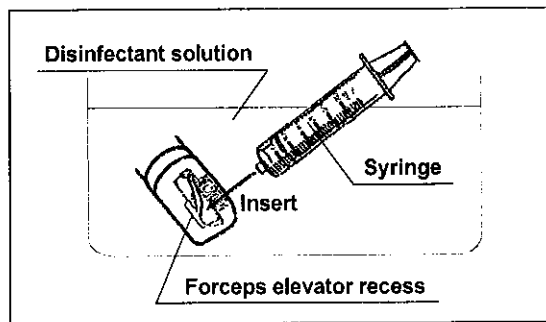


Figure 5.33

NOTE

When using a luer-lock type syringe, the tip of the syringe may not fit into the interior of the forceps elevator recess. In this case, hold the tip of the syringe over the interior of the recess while the syringe contacts the surface of the endoscope.

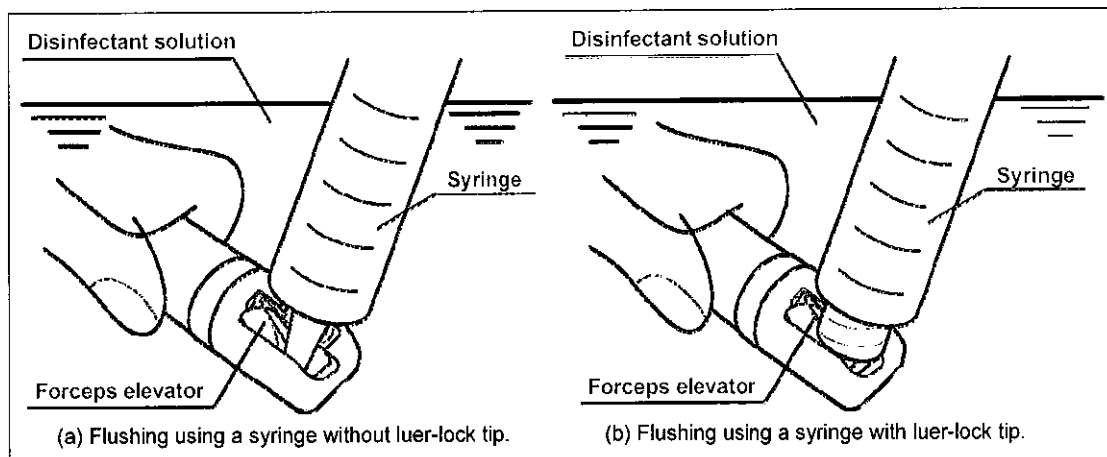


Figure 5.33.2

6. Lower the forceps elevator by turning the elevator control lever. Insert the tip of the 30 ml syringe into the interior the forceps elevator recess in the disinfectant solution, and flush the interior of the recess with 60 ml of the disinfectant solution.

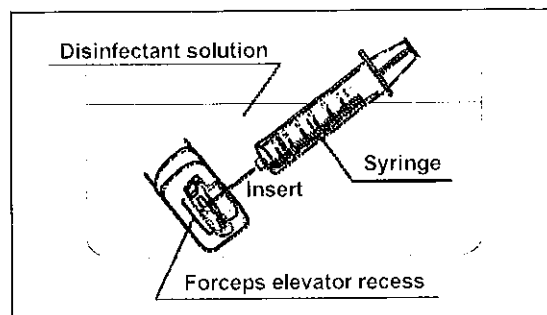


Figure 5.33.3

**NEW: Supplemental Flushing Instructions for EVIS EXERA II DUODENOVideoscope
OLYMPUS TJF TYPE Q180V REPROCESSING MANUAL (GE8415 09)**

NOTE

When using a luer-lock type syringe, the tip of the syringe may not fit into the interior of the forceps elevator recess. In this case, hold the tip of the syringe over the interior of the recess while the syringe contacts the surface of the endoscope.

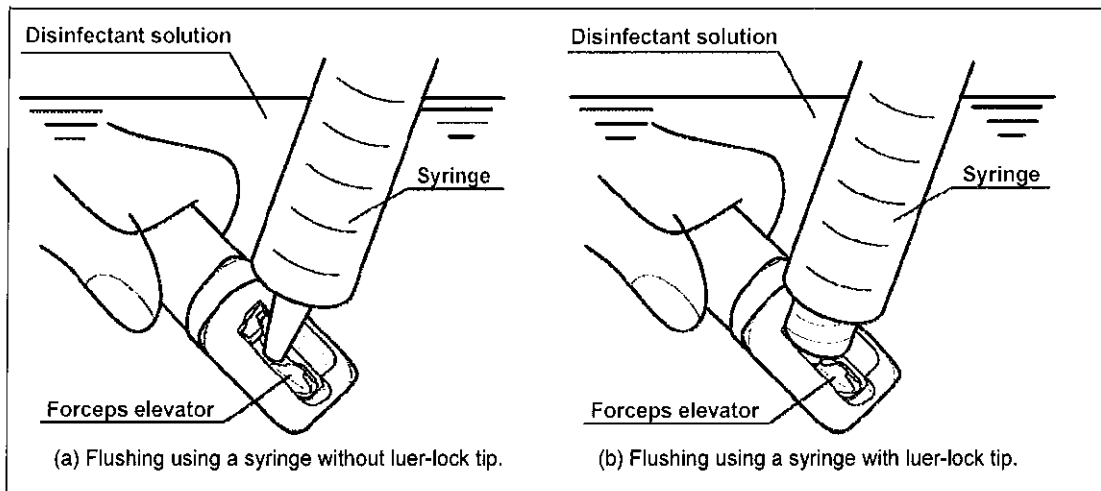


Figure 5.33.4

7. Turn the elevator control lever to raise and lower the forceps elevator three times, keeping the distal end of the endoscope immersed in the disinfectant solution.
8. Forcefully flush the instrument channel with 90ml of the disinfectant solution, using the 30ml syringe - i.e., fill the syringe with the disinfectant solution without air, put the distal end of the syringe in the instrument channel port in the disinfectant solution, and forcefully flush at least three times, minimizing disinfectant solution leakage from the port. Confirm that no air bubbles exit the distal end of the endoscope's insertion section during the third flush. If air bubbles still exit, flush the channel with the disinfectant solution until no air bubbles exit.
9. Repeat the step 5.-8. above.

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5.6 Rinsing the endoscope and accessories following disinfection

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Rinse the endoscope and accessories

1. Fill a sterile large basin with the rinse water referred to in Section 3.5.
2. Immerse the endoscope with attached accessories in the rinse water. Detach the channel plug (MH-944) and injection tube (MH-946) from the endoscope.
3. Wipe all external surfaces of the endoscope and accessories, using a sterile, lint-free cloth.
4. Attach the channel plug and the injection tube to the endoscope. Immerse the suction port of the injection tube in the rinse water. (See Figures 5.27, 5.28, and 5.34)
5. Attach a sterile 30 ml syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of the rinse water – i.e., pump the syringe at least three times. (See Figure 5.31)
6. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 90 ml of the rinse water. (See Figure 5.30)
7. Raise the forceps elevator by turning the elevator control lever. Insert the tip of the 30 ml syringe into the interior of the forceps elevator recess in the rinse water, and flush the interior of the recess with 30 ml of the rinse water.

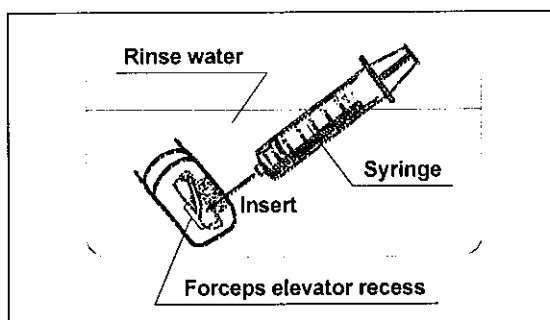


Figure 5.35.1

NOTE

When using a luer-lock type syringe, the tip of the syringe may not fit into the interior of the forceps elevator recess. In this case, hold the tip of the syringe over the interior of the recess while the syringe contacts the surface of the endoscope.

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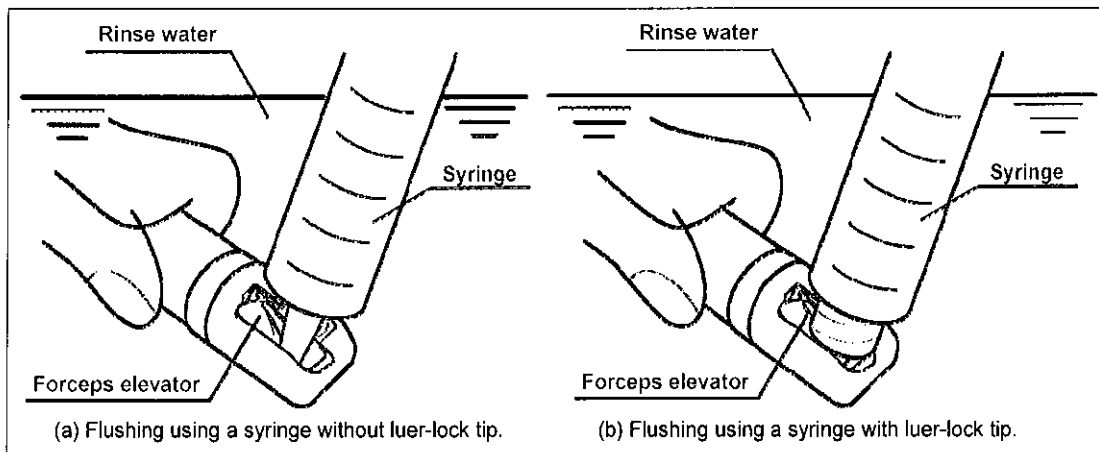


Figure 5.35.2

8. Lower the forceps elevator by turning the elevator control lever. Insert the tip of the 30 ml syringe into the interior the forceps elevator recess in the rinse water, and flush the interior of the recess with 30 ml of the rinse water.

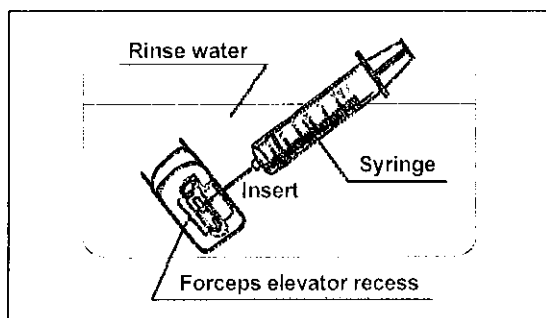


Figure 5.35.3

NOTE

When using a luer-lock type syringe, the tip of the syringe may not fit into the interior of the forceps elevator recess. In this case, hold the tip of the syringe over the interior of the recess while the syringe contacts the surface of the endoscope.

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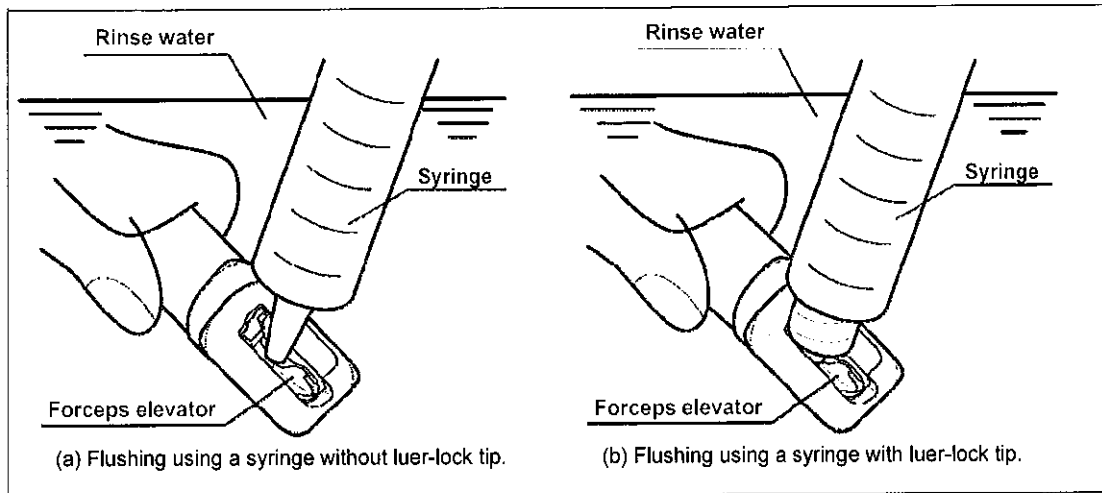


Figure 5.35.4

9. Turn the elevator control lever to raise and lower the forceps elevator three times, keeping the distal end of the endoscope immersed in the rinse water.
10. Repeat the step 1.-9. above for the necessary number of times, following the rinsing method described in the disinfectant solution manual.
11. By turning the elevator control lever, put the forceps elevator in intermediate position of the range of movement.
12. Remove the endoscope with attached accessories from the rinse water and place them in a sterile basin.
13. Cover the distal end and the control section of the endoscope with a sterile, lint-free cloth(s) to prevent splashing from the channel openings.
14. Attach the syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of air. (See Figure 5.38)
15. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 90 ml of air. (See Figure 5.37)
16. Remove the cloth(s) from the endoscope.
17. Detach only the injection tube from the endoscope.
18. Attach a sterile suction tube from the suction pump to the suction connector on the endoscope connector. Turn the suction pump ON and aspirate air for at least 15 seconds. Air will flow through the instrument channel and the suction channel of the endoscope.

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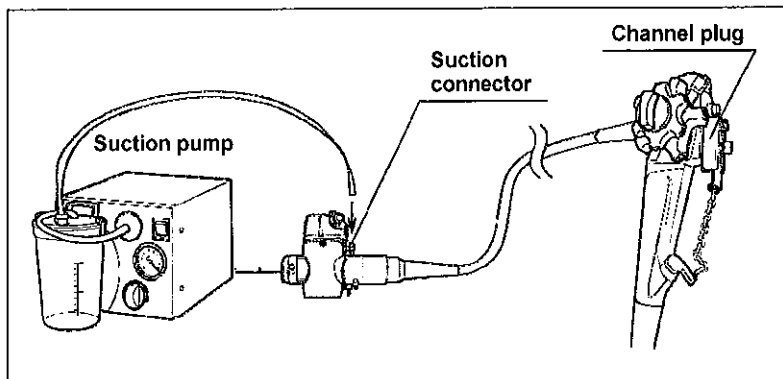


Figure 5.35.5

19. While continuing the aspiration, raise and lower the forceps elevator three times, by turning the elevator control lever.
20. Turn the suction pump OFF.
21. Detach the suction tube and the channel plug from the endoscope.
22. Thoroughly dry the external surfaces of the endoscope, the channel plug, and the injection tube, by wiping with a sterile, lint-free cloth(s).
23. Thoroughly dry the inside of the suction cylinder, the air/water cylinder, the instrument channel port of the endoscope, and forceps elevator recess, using a sterile cotton swab(s).

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Alcohol flush

6. Raise the forceps elevator by turning the elevator control lever. Insert the tip of the 30 ml syringe into the interior of the forceps elevator recess, and flush the interior of the recess with 30 ml of alcohol.

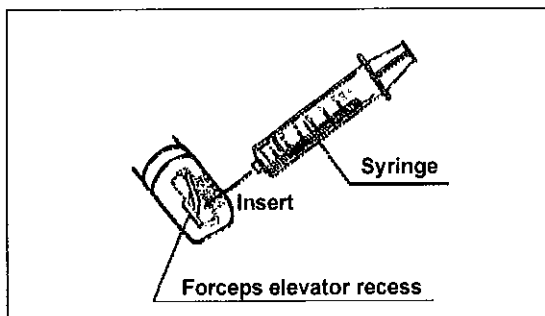


Figure 5.35.6

NOTE

When using a luer-lock type syringe, the tip of the syringe may not fit into the interior of the forceps elevator recess. In this case, hold the tip of the syringe over the interior of the recess while the syringe contacts the surface of the endoscope.

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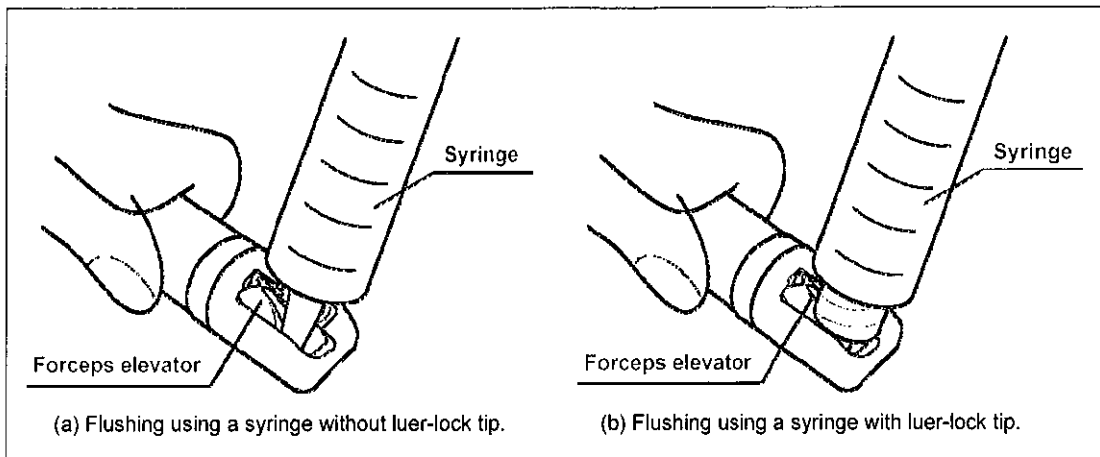


Figure 5.35.7

7. Lower the forceps elevator by turning the elevator control lever. Insert the tip of the 30 ml syringe into the interior the forceps elevator recess, and flush the interior of the recess with 30 ml of the alcohol.

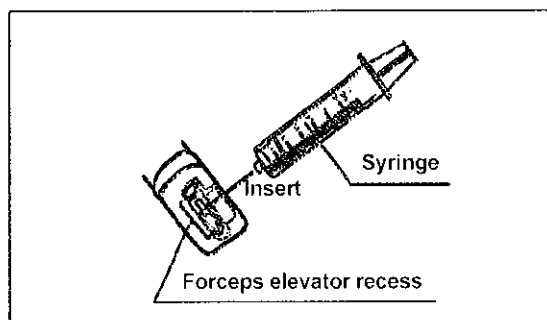


Figure 5.35.8

NOTE

When using a luer-lock type syringe, the tip of the syringe may not fit into the interior of the forceps elevator recess. In this case, hold the tip of the syringe over the interior of the recess while the syringe contacts the surface of the endoscope.

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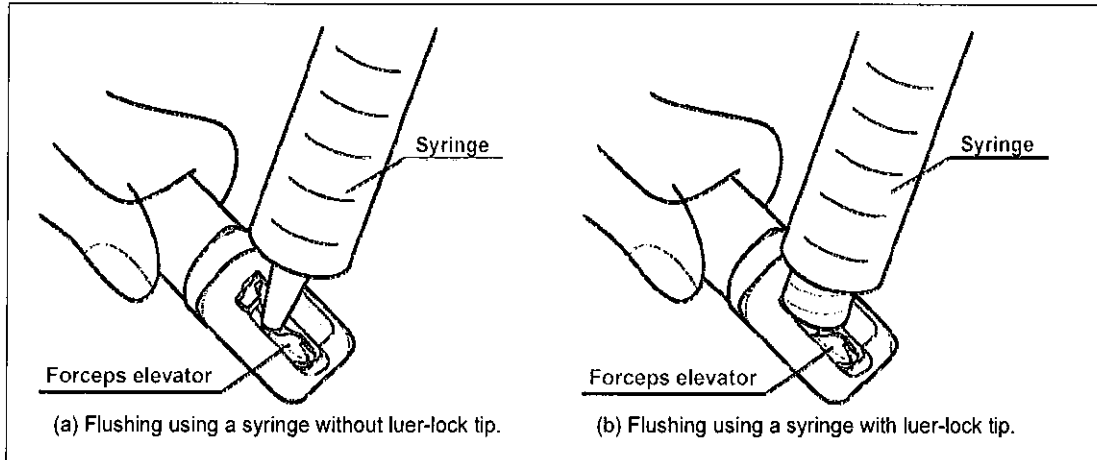


Figure 5.35.9

8. Turn the elevator control lever to raise and lower the forceps elevator three times.
9. Remove the suction port of the injection tube from the alcohol.
10. Attach the syringe to the suction channel port of the injection tube and flush the suction channel with 90 ml of air. (See Figure 5.38)
11. Move the syringe to the air/water channel port of the injection tube and flush the air/water channel with 90 ml of air. (See Figure 5.37)
12. Remove the cloth(s) from the endoscope.
13. Detach the channel plug and the injection tube from the endoscope.
14. Thoroughly dry the external surfaces of the endoscope, the channel plug, and the injection tube, by wiping with a sterile, lint-free cloth(s).
15. Thoroughly dry the inside of the suction cylinder, the air/water cylinder, the instrument channel port of the endoscope, and the forceps elevator recess, using a sterile cotton swab(s)