

OLYMPUS

Field Safety Information

Dear Customer,

For many years you have used the Olympus ETD 2/ ETD2plus or miniETD Washer / Disinfectors (WD) for reprocessing of your flexible endoscopes. These machines were manufactured by Miele in close cooperation with Olympus.

We have become aware of an issue that requires your attention. It is about the following adapters (delivered later than 2007) to be used with ETD2 / ETD2 plus / miniETD:

- ETD2 Adapter XMB-109

Art. No 024451

- EUS-XMB-109 Adapter ETD2 / E480

Art. No 024419

Background:

Recently we had been informed about a single defective connecting tube (XMB-109). The adapter is used for the connection of the jet channel, the elevator channel or the balloon channel at certain endoscope series to the irrigation system of the ETD2 / ETD2plus / miniETD WD. The inside of the connector to the WD irrigation system was blocked. For that reason there might not have been adequate cleaning and disinfection inside this connected endoscope channel.

It was only a single case of a blocked adapter we have been made aware of. Despite the implemented quality checks in manufacturing, this defective adapter appeared in the market. Therefore we cannot safely exclude that other defective adapters may exist.

Your Support:

For patient safety reasons we would like you to preventively check the above mentioned adapters in your facilities. You can identify the adapters by the laser print (see annex 1 to this letter).

The patency of the adapters shall be checked according to the procedure outlined in annex 2 to this letter. In case you identify a blocked adapter, do not use this adapter anymore and inform immediately your local Olympus service representative. The service will inform you about further action.

We regret the inconveniences of implementing these measures and appreciate your cooperation. In case of any questions, please do not hesitate to contact your local Olympus partner who will be ready to support you or make the necessary arrangements.

Please return the completed reply form to

Yours sincerely,

OLYMPUS

Reply Form

[Dept/Attn]
[Street No.]

[ZIP City]

[Date]
[Ref No.]
[EXT-xxx]

Olympus ETD2 / ETD2 Plus / mini ETD: Blocked adapter XMB-109 and EUS-XMB-109

Dear Sirs,

Herewith we confirm the receipt of your customer letter. We have understood and will follow the recommendations given by the manufacturer.

Name _____

Hospital _____

Department _____

Street _____

Postal Code/ City _____

Date Signature

Annex 1: Adapter identification



Figure 1: The adapter XMB-109 can be identified by the laser imprint.



Figure 1: The adapter EUS-XMB-109 can be identified by the laser imprint as shown above.

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Annex 2: Test procedure on adapter patency



Figure 1: Disconnect the adapter from ETD2 / mini ETD. Perform the test outside of ETD machine by using a syringe.



Figure 2: Test all adapters with the laser imprint XMB-109. Test the complete adapter. Do not dismantle the adapters.



Figure 3: Test all adapters with the laser imprint EUS-XMB. Test the complete adapter. Do not dismantle the adapters.



Figure 4: Connect the syringe via a silicone tube to the adapter, while applying the same flow direction as in the ETD machine.



Figure 5: Remove the piston of the syringe and fill in 50 ml of water



Figure 6: Water will flow through the adapter. By gravity 50 ml will flow out within a maximum of 60 seconds. If no water flows through the adapter, inform Olympus