

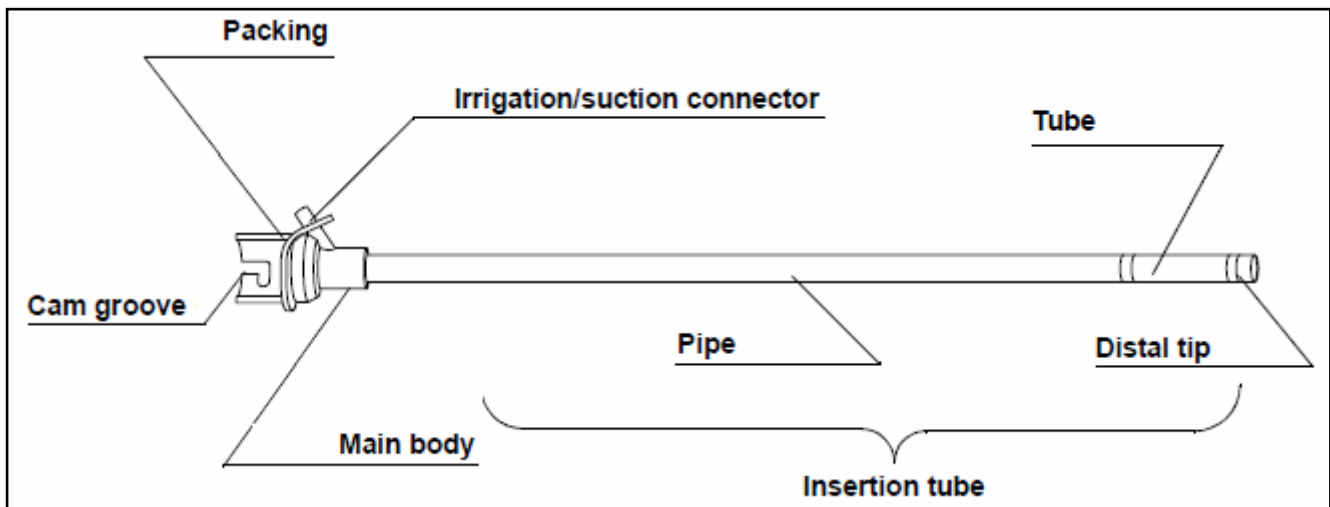
June xx, 2010

- - - -IMPORTANT SAFETY NOTICE- - - -

Dear Olympus customer,

Olympus is notifying you of important information on Lens Cleaning Sheath (for Olympus LTF type VH) MAJ-1537.

We were reported that the distal tip of the lens cleaning sheath attached to the LTF-VH (Laparo-Thoraco Videoscope) fell into patient body in some medical institutions. This notice is to notify you of proper use of the sheath to prevent the distal tip from falling off.



Cause of the distal tip's falling off

The distal tip of the lens cleaning sheath is connected to the sheath pipe, via a thin and flexible tube.

When an endoscope to which the lens cleaning sheath is attached, is withdrawn from a trocar, the distal edge of the trocar causes the distal tip of the sheath to fall off.

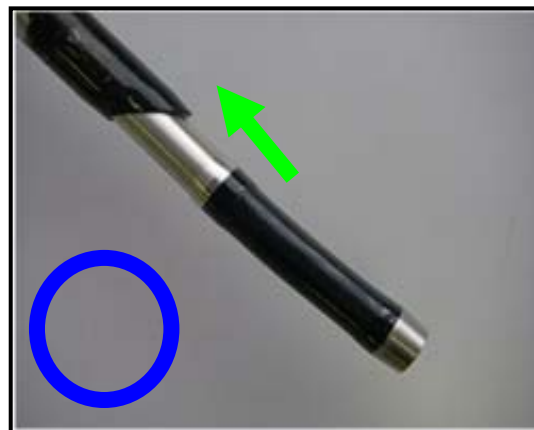
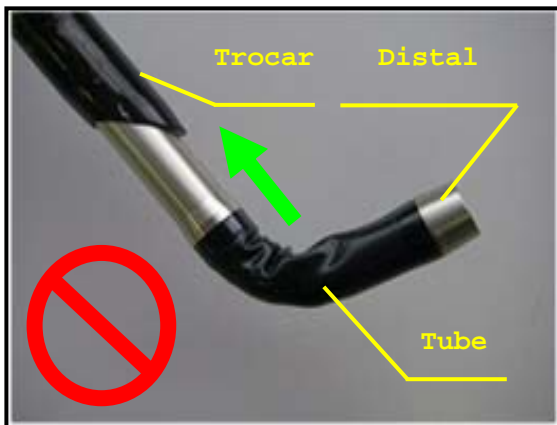
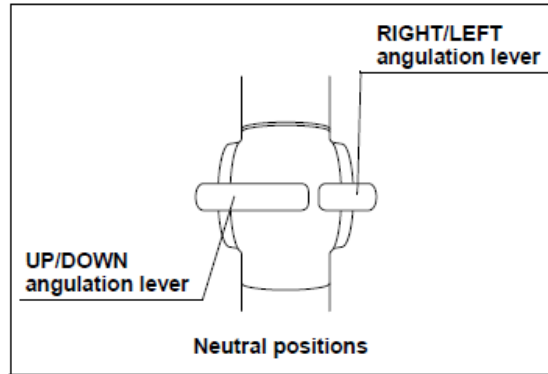
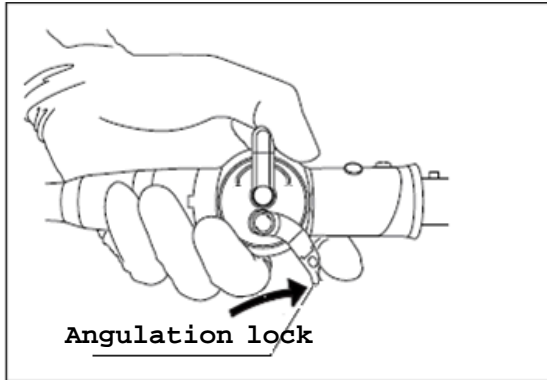
- a) When the endoscope to which the lens cleaning sheath is attached, is withdrawn from the trocar, without turning the angulation locks of the endoscope to its free position nor straightening the bending section of the endoscope, the distal end of the trocar cuts the tube of the sheath. Repetition of such withdrawal causes the cut to be bigger, resulting in the tube cut off and the distal tip's falling off.
- b) If a trocar with too small inner diameter is used, upon withdrawal of the endoscope with the lens cleaning sheath from the trocar, the distal tip of the sheath can not be pulled into the trocar, and distal tip falls off.
- c) Use of the lens cleaning sheath with any irregularity such as cuts on its tube causes the distal tip to fall off.



Distal tip

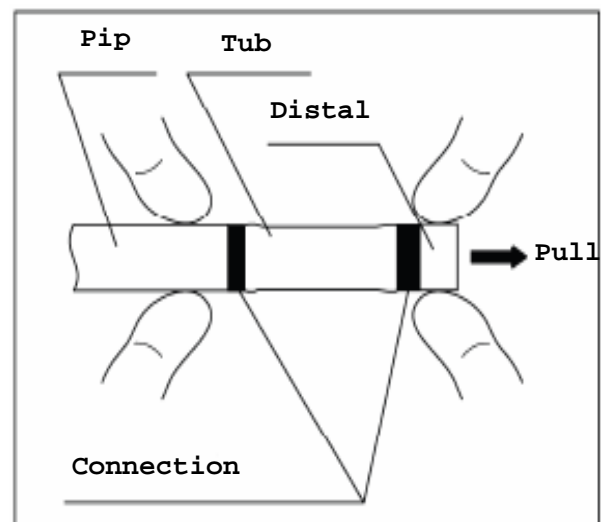
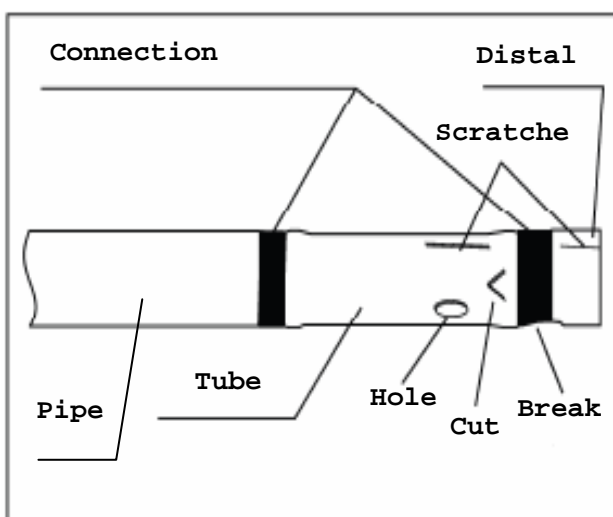
How to prevent distal tip's falling off

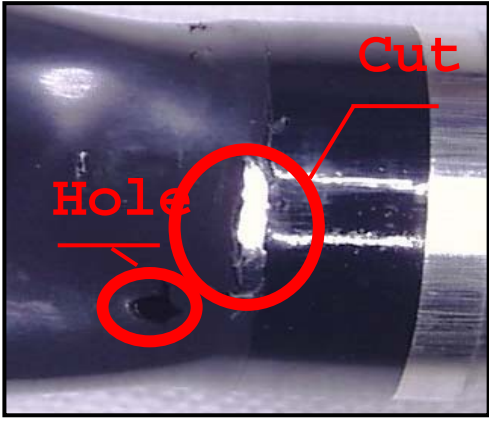
a) When the endoscope to which the lens cleaning sheath is attached, is withdrawn from a trocar, turn the angulation locks to its free position, take your fingers off the angulation lever of the endoscope, straighten its bending section, and withdraw the endoscope slowly and deliberately. When using a trocar with a valve, keep the valve open during withdrawal.



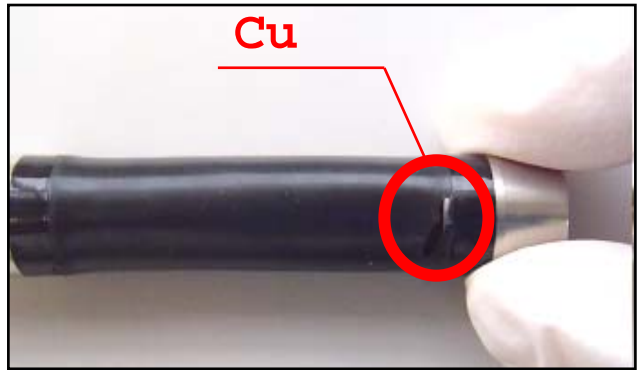
b) The outer diameter of the sheath's insertion tube is 12.2 mm. Before each patient procedure, confirm that the endoscope to which the sheath is attached, can be smoothly inserted/withdrawn into/out of the trocar(s) which is/are going to be used for the patient procedure.

c) Before each patient procedure, confirm that there are no irregularities such as cuts on the tube of the sheath. Dispose of the sheath with any irregularities.

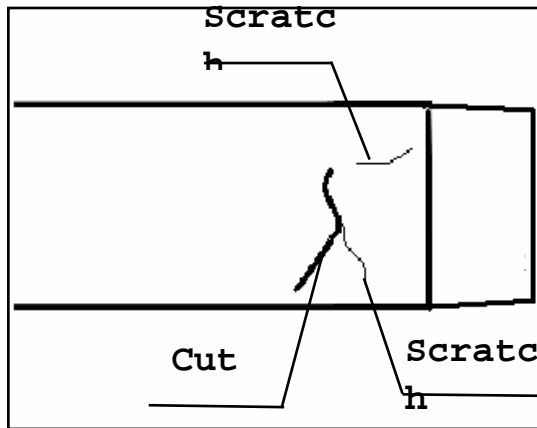




Cut Sample 1



Cut Sample 2: Cuts can be easily detected by pulling.



Cut Sample 3

REPLY FORM

Olympus Subsidiary/Distributor

[Dept/Attn]

[Street No.]

[ZIP City]

Date

Quality Information Letter concerning Models: **Lens Cleaning Sheath for LTV-VH**

Dear Sirs and Madams

We herewith confirm the receipt of your Quality Information Letter. We will share this information with the relevant departments.

Date: _____

Name _____

Hospital _____

Department _____

Street _____

Postal Code/ City _____