Addendum to the Instructions for Use (IFU)

EG-3630U, PENTAX Ultrasound Video Gastroscope (IFU Part Number Z258)
EG-3830UT, PENTAX Ultrasound Video Gastroscope (IFU Part Number Z258)
EG-3870UTK, PENTAX Ultrasound Video Gastroscope (IFU Part Number Z845)
FG-36UX, PENTAX Ultrasound Fiber Gastroscope (IFU Part Number Z166)

3-1. Precise Accessory Control
(For EG-3630U, EG-3830UT, EG-3870UTK, and FG-36UX)

The combination of endoscopic forward oblique optics, linear array ultrasound imaging and a distal elevator mechanism gives users the ultimate control for precise accessory applications. This unique capability allows users to maintain a view (both endoscopic and sonographic) for pinpoint guidance of accessories such as an aspiration needle. Once the accessory exits the distal instrument channel opening, the accessory can be guided by the elevator control knob, located on the proximal control section of the endoscope.

NOTE:
Should resistance in passing the accessory be encountered at the distal portion of the scope, gently pull back the accessory, reduce the angle of the elevator, then re-advance the accessory.

CAUTION:
If the elevator is not deflected at all, the accessory may not be seen in the field of view since these instrument have a forward oblique optic;

<table>
<thead>
<tr>
<th>Model</th>
<th>Forward Oblique Optic °</th>
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<tbody>
<tr>
<td>EG-3630U</td>
<td>60°</td>
</tr>
<tr>
<td>EG-3830UT</td>
<td>50°</td>
</tr>
<tr>
<td>EG-3870UTK</td>
<td>45°</td>
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<tr>
<td>FG-36UX</td>
<td>50°</td>
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</tbody>
</table>

It is recommended that the elevator be slightly deflected so that the accessory exits the distal scope tip and advanced only under full view.

WARNING:
For ALL types of endoscopic accessory instruments, always maintain a endoscopic view and sonographic view of the accessory during advancement, use and withdrawal of the device Otherwise it could result in patient injury such as perforation.
NOTE (for EG-3830UT and EG-3870UTK only):
Since these PENTAX video endoscopes in this instructions for use contain a single channel (within the insertion tube) serving as a common channel for delivery of air or water as well as suction capability, it is recommended that water delivery should NOT be attempted WHILE an endoscopic accessory instrument is inserted into the instrument/working channel. Under the conditions described above, it is possible for fluid or water to leak from the inlet seal/channel inlet port area. This is due to the fact that the accessory device occupies the vast majority of channel volume leaving very little open space between accessory and channel for flow of water. If one insists on activating water delivery while an accessory device is in the channel, caution must be exercised as this expelled fluid may contain patient material. As always for endoscopic procedures, personal protective equipment should be worn and additional protection such as covering the channel inlet with gauze or similar means should be used to prevent potential exposure to expelled fluids.

1) Raise the elevator mechanism.

![Figure 3.5](image)

**Figure 3.5**

2) Insert the accessory

![Figure 3.6](image)

**Figure 3.6** With the rubber inlet seal (for example, the forceps)

![Figure 3.7](image)

**Figure 3.7** Without the rubber inlet seal (for example, FNA needle)
NOTE: Figure 3.6 [and 3.10] shows a rubber inlet seal. Some accessories require the use of a lure-lock adaptor in place of a rubber inlet seal. Refer to the accessory manufacturer’s Instructions for Use to determine if a lure-lock adaptor is required.

NOTE: When the tip of the accessory is first passed through the inlet seal, a temporary resistance will be encountered. Hold the shaft tightly at about 50mm from the tip of the accessory and push it through.

NOTE: During insertion, if the accessory is found hard to advance further due to resistance, decrease the angulation of the bending section to a level suitable for smooth insertion and insert the accessory again.

NOTE: Be certain to hold the forceps handle in such a way to ensure that the jaws of the forceps are in a fully closed position during insertion.

CAUTION: NEVER apply excessive pressure when introducing any accessory since the instrument channel may be damaged. Malfunction of the endoscope as well as costly repairs may result.

3) Insert accessory until it reaches the elevator.

![Figure 3.8](image1)

4) The elevator mechanism shall be lowered to allow accessory advancement.

![Figure 3.9](image2)
5) When the tip of accessory extends about 10mm from the distal of the endoscope, the accessory appears in both the endoscopic view and the sonographic view (See Figure 3.10, 3.11).

**NOTE:**
Figure 3.6 [and 3.10] shows a rubber inlet seal. Some accessories require the use of a lure-lock adaptor in place of a rubber inlet seal. Refer to the accessory manufacturer’s Instructions for Use to determine if a lure-lock adaptor is required.

**WARNING:**
For ALL types of endoscopic accessory instruments, always maintain endoscopic view and sonographic view of the accessory during advancement, use and withdrawal of the device. Otherwise it could result in patient injury such as perforation.
**WARNING:**

If the accessory doesn’t appear in endoscopic view and sonographic view when the accessory is advanced over 15mm, it may be necessary to repeat the procedure from step 1). Otherwise it could result in patient injury such as perforation.

**WARNING:**

Some kinds of accessories can get derailed from the elevator while moving the bending section and/or the elevator (see Figure 3.12). If the accessory has got derailed from the elevator, it is possible that the accessory does not appear in the endoscopic view and sonographic view.

Therefore, for ALL types of endoscopic accessory instruments, it is mandatory to always maintain the endoscopic view and the sonographic view of the accessory during advancement, use, and withdrawal. Otherwise it could result in patient injury such as perforation.

![Figure 3.12](image)

- (1) Derailed position of the Accessory
- (2) The tip of the endoscope

6) The elevator may now be maneuvered as needed to bring the accessory into a view and to aid in the application of the accessory (See Figure 3.8).

**CAUTION:**

If the accessory does not move in the endoscopic view when operating the elevator, it may be necessary to repeat from step 1).

If the accessory in the endoscopic view is not moved in spite of repeating the procedure from step 1), please contact your local PENTAX service facility.

7) When a portion of the tip of the accessory becomes visible in the viewing field, carefully advance the accessory onto the target area.

8) **(When the forceps are used)** Open the forceps cups and advance the forceps against the target area. Carefully squeeze the forceps handle close the cups and obtain a specimen within the cups. Always maintain a endoscopic view of accessory during advancement.

9) Withdraw the accessory slowly.
NOTE:
Because of the effect accessories used in the instrument channel of the endoscope can have on the performance of the endoscope itself, it is strongly recommended that only PENTAX accessories be used with PENTAX endoscopes. If a unique or highly specialized accessory is available from another source, the accessory manufacturer should be consulted to confirm compatibility with PENTAX endoscope before use.

CAUTION:
When withdrawing the forceps from the endoscope, one must close the cup of the forceps. Otherwise the endoscope could be damaged.

WARNING:
Accessories which ENTER STERILE TISSUE or THE VASCULAR SYSTEM must be sterile. Accessories intended for use in the biliary tract should be sterilized before patient use.