### Standard Set List

This package includes the following items:
- Gas/Water Feeding Valve
- Instructions for Use (IFU)

### 1. Intended Use

PENTAX Upper/Lower G.I. Endoscopes are provided with Air/Water Feeding Valve. As an alternative, the optionally available Gas/Water Feeding Valve may be used in place of the standard Air/Water Feeding Valve to deliver a non-flammable gas for insufflation.

<table>
<thead>
<tr>
<th>Valve</th>
<th>Compatible Endoscope</th>
</tr>
</thead>
<tbody>
<tr>
<td>OF-B130</td>
<td>V/W Series 30(K)/40(K)/Kp Series</td>
</tr>
<tr>
<td>OF-B194</td>
<td>-</td>
</tr>
</tbody>
</table>

NEVER use these valves for any purpose other than that for which they have been designed.

### 2. Appearance

#### Replacement O-ring

<table>
<thead>
<tr>
<th>Model</th>
<th>O-ring</th>
</tr>
</thead>
<tbody>
<tr>
<td>OF-B130</td>
<td>PENTAX O-ring set</td>
</tr>
<tr>
<td>OF-B194</td>
<td>PENTAX O-ring set</td>
</tr>
</tbody>
</table>

#### Silicone oil

- PENTAX Silicone Oil OF-Z11

### 3. Preparation and Inspection for Use

**WARNING:**
- For safety use, always ensure to wear proper protective equipment prior to Preparation & Inspection. Failure to do so could create a risk of cross contamination to the end users due to the potential for back-flow of patient fluids out of the valve.
- The valve(s) must be reprocessed prior to every use. Failure to do so could create risk of cross contamination to the patients.
- Preparation & Inspection process must be performed. Failure to do so could cause continuous gas flow or excessive gas insufflation and result in the potential patient injury such as pneumatic perforation or gas (air) embolism.
- Worn and damaged valve(s), as well as those with ANY abnormalities in its operation or function should be replaced with new valve(s) that has been reprocessed.

These valves are packed non-sterile. These valves must be reprocessed prior to use according to the Instruction for Use (Reprocessing). Preparation & Inspection process must be performed according to the following procedure:

1. **3-1. Inspection of Gas/Water Feeding Valve**
   1) Wear protective equipment such as gloves, gowns, face masks, etc.
   2) Check the entire surface of the valve for abnormal conditions such as bend, clog, attachment of foreign matter, crack or looseness of the button. Also check the O-rings for any cut, chip, worn, missing parts of O-rings.
   3) If any abnormalities or outward signs of damage on the O-rings are observed, replace the O-rings using the Pentax O-ring set identified in section 2. Appearance, of this IFU. After the replacement of O-rings, the valve MUST BE reprocessed prior to use.
   4) If any abnormalities or outward signs of damage on the valve(s) are being observed, do not use the instrument and replace the valve with a new one. The valve(s) MUST BE reprocessed before the replacement.
   5) Hold the valve itself in your hands and check if the button of the valve can be depressed smoothly and check that the valve does not get stuck as it is pressed down.

2. **3-2. Preparation for Inspection of Function**
   1) Apply silicone oil lubricant (PENTAX OF-Z11) onto each O-ring according to the following procedure.
      a) Place a small amount of oil on one’s sterile gloved forefinger and gently swirl between thumb and forefinger.
      b) Place the valves with O-ring in-between thumb and forefinger and gently rotate the valve so that the oil is evenly applied to the outer edges of each O-ring.
      c) Make sure the oil is applied to all O-rings and wipe off all excess by lint-free gauze.
   2) Attach the valve to the Air/Water cylinder of endoscope by gently pushing the valve into the cylinder until the click is felt.
   3) Attach Gas Adapter OF-G11 to the Air/Water Port of endoscope. For more detail, refer to Instruction for Use of Gas Adapter.
   4) Attach a gas cylinder whose pressure and flow rate are adjustable to Gas Adapter.
   5) Attach Water Bottle Assembly filled with sterile water to the video processor or light source, and connect A/W Connector of Water Bottle Assembly to Gas Adapter. For more detail, refer to the Instruction for Use of Water Bottle Assembly.

**WARNING:**
Always ensure to use PENTAX OF-Z11 silicone oil lubricant. Use of silicone oil lubricant other than PENTAX OF-Z11, or not using it at all will impact the functionality. It may cause uncontrolled, continuous gas flow or excessive gas insufflations resulting in a patient injury such as pneumatic perforation or gas (air) embolism.

- a) Place a small amount of oil on one’s sterile gloved forefinger and gently swirl between thumb and forefinger.
- b) Place the valves with O-ring in-between thumb and forefinger and gently rotate the valve so that the oil is evenly applied to the outer edges of each O-ring.
- c) Make sure the oil is applied to all O-rings and wipe off all excess by lint-free gauze.

**NOTE:**
Do NOT apply excess oil. Doing so will lead to inadvertent migration of the oil inside channels or other areas not intended to be lubricated.
### 3-3. Inspection of Gas/Water Feeding Function

1) Place the endoscope distal end in sterile water and check that no gas bubbles exit the nozzle at the endoscope distal end.

2) Depress the first stage of the valve (shown as “Gas Feeding” in the figure) and check that gas flow freely from the nozzle at the endoscope distal end.

3) After taking the endoscope distal end out of sterile water, fully depress the second stage of the valve (shown as “Water Feeding” in the figure) and check that water flow in a steady stream from the nozzle at the endoscope distal end.

4) Release the valve and check that the valve freely returns to its OFF (natural) position, and the water flow is stopped.

5) While the valve is released, immerse the endoscope distal end in sterile water and check that no gas bubble comes out from the nozzle; and the gas feeding can be stopped immediately.

### 4. Direction for Use

#### WARNING:
- Adequately control the amount of gas being fed by observing inflation of the organs (upper/lower GIs). Excessive gas feeding may result in serious health hazards such as organ injury and gas (air) embolism. When excessive gas feeding is suspected, attempt suctioning the gas remaining inside the patient body.
- Should abnormalities in gas/water feeding valve during the procedure occur, immediately stop gas/water feeding (stop the gas/water feeding system, and close the gas cylinder valve).

#### NOTE:
To avoid discontinuation of the endoscopic procedure, have an extra (spare) valve that has been reprocessed available.

- When depressing the first stage of the valve, gas flows from the nozzle at the endoscope distal end.
- When depressing the second stage of the valve, water flows from the nozzle at the endoscope distal end.
- When the valve is released, gas and water flows stop.

#### WARNING:
When disposing of the instrument, follow the state or regional regulations for appropriate disposal. Failure to do so may result in an infection(s) caused by blood and mucosal fluid.