UroSeal™ endoscopic valves
Reorder No. 00913401, 00913402, 00913403, 00913404

UroSeal™ adjustable endoscopic valve
Reorder No. 00913410

INSTRUCTIONS FOR USE
This device is not made with natural rubber latex.

Intended Use:
The biopsy valve is used to cover the opening to the biopsy/suction channel of an endoscope. It provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure and provides access for irrigation.

Five (5) different Urology biopsy valves are available. 00913401, 00913402, 00913403, and 00913404, 00913410.

Warnings and Precautions:
- The Urology biopsy valve part #00913401, 00913402, 00913403, 00913404 and 00913410 selected by the clinician must accommodate the size of the instrument to be introduced through the valve. Selection is determined in accordance for use with the size of the hole in the selected valve. (see below)
  - 00913401 - .025in./ 0.6mm
  - 00913402 - .045in./1.15mm
  - 00913403 - .065in./1.65mm
  - 00913404 – slit opening (variable)
  - 00913410 – 0 – 2.5mm (0 -7.5fr.) (adjustable)
- Do not use these devices if there is any apparent shipping or handling damage.
- US Urology did not design these devices to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the devices to ensure patient and/or user safety.
- These disposable medical devices are not intended for reuse. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, resterilizes, and/or reuses these disposable medical devices must bear full responsibility for their safety and effectiveness.
- Exposure to body fluids may occur during connection or disconnection of these devices; adherence to body substance isolation protocols is the responsibility of the user.
- Device has been designed to work optimally with luer connector geometry. Other geometry's may not have optimal performance characteristics.

Directions for use:
1. Open the biopsy valve onto the sterile field using sterile technique. Inspect the biopsy valve for obvious damage. Should there be evidence of damage or if the unit is not functioning properly, **DO NOT USE THIS PRODUCT**.
2. Securely place the biopsy valve onto the biopsy channel opening of cystoscope.
3. Check to make sure the biopsy valve is secure.
4. Prior to removal of device, actuate shut-off on scope to minimize fluid leakage.

Product Disposal:
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Issued Date:  March 2012

Warning:
An issued or revision date for these instructions is included for the user’s information. In the event that two years have elapsed between this date and product use, the user should contact US Endoscopy to determine if additional information is available.

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Made in the U.S.A.
## Explanation of symbols used on Labels and Instructions for Use

<table>
<thead>
<tr>
<th>Symbol/Phrase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use By</strong></td>
<td>Sterilized by Ethylene Oxide</td>
</tr>
<tr>
<td><strong>Contents</strong></td>
<td>Non-Sterile</td>
</tr>
<tr>
<td><strong>Reference</strong></td>
<td>Single Use Only</td>
</tr>
<tr>
<td><strong>Lot</strong></td>
<td>Do Not Re-Sterilize</td>
</tr>
<tr>
<td><strong>Date of Manufacture</strong></td>
<td>Latex Free</td>
</tr>
<tr>
<td><strong>Length</strong></td>
<td>Read instructions prior to using this product</td>
</tr>
<tr>
<td><strong>Authorized Representative in the European Community</strong></td>
<td>For use with Olympus active cord</td>
</tr>
<tr>
<td><strong>Store at controlled room temperature</strong></td>
<td>For use with Microvasive active cord</td>
</tr>
<tr>
<td><strong>I.D.</strong></td>
<td>O.D.</td>
</tr>
<tr>
<td><strong>Discard within 24 hours after opening package</strong></td>
<td>Product contains Phthalates</td>
</tr>
<tr>
<td><strong>Do not use if packaging or product damage is evident. For sterile products only, contents are sterile if package is unopened and undamaged.</strong></td>
<td>Rx Only U.S.A.</td>
</tr>
<tr>
<td><strong>Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.</strong></td>
<td></td>
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</tbody>
</table>

- **STERILE EO**
- **NON-Sterile**
- **Latex Free**
- **Rx Only (U.S.A.)**