

Double Header™ - channel and control head combo	Reorder No. 00913301
Small Wonder® - cleaning brush	Reorder No. 00913302
Cleaning Brush - control head	Reorder No. 00913303
Gemini™ - double ended – channel	Reorder No. 00913304
Gemini™ - double ended 10mm – Semi-Rigid channel	Reorder No. 00913305
Small Wonder® - Double Ended - cleaning brush	Reorder No. 00913306
Small Wonder® - Plus	Reorder No. 00913328

INSTRUCTIONS FOR USE



a division of **us endoscopy**

5976 Heisley Road
Mentor, OH 44060

phone 440 / 639.4494

fax 440 / 639.4495

customer service 800 / 769.8226

www.usendoscopy.com

This device is not made with natural rubber latex.

- **Product #00913301, #00913304** – Use only in channels 2.0mm and larger and in control head valve and luer port openings
- **Product #00913303** – Use only in control head valve openings
- **Product #00913302, #00913306** – Use only in channels between 1.0mm and 2.0mm
- **Product #00913305** – Use only in channels from 22 Fr.(7.3mm) up to 27 Fr.(9.0mm)
- **Product #00913328**– (Two brush combo pack) Use only in channels between 1.0mm and 2.0mm and in control head valve openings

Intended Use:

Based on the product number, the cleaning brush(es) are used for endoscope accessory/suction channel, or control head cleaning. The intended use of these cleaning brushes is as follows:

- The channel cleaning brush is a nylon flexible brush attached to a flexible plastic sheath designed to safely remove debris from flexible and rigid endoscopes and accessories /devices.
- The control head cleaning brush is used to safely remove debris from the valve and luer port openings and dials of the control head of flexible and rigid endoscopes and accessories/devices.
- The Small Wonder[®] cleaning brush is designed to safely remove debris from channels between 1.0mm and 2.0mm, such as the working channels of flexible and rigid endoscopes and accessories/devices.
- The Small Wonder[®] - Micro cleaning brushes are designed to safely remove debris in rigid channel devices.

Warnings and Precautions:

- The cleaning brush should never be used as a cytology brush.
- Original Equipment Manufacturer's guidelines regarding the care and cleaning of individual endoscope channels must be reviewed prior to the use of any cleaning brush.
- Dispose of the cleaning brush after initial use. The mechanical attachment of the brush(es) to the plastic sheath cannot be guaranteed to be reliable or secure following initial use.
- If sharp bends in the plastic sheath or wire cable are observed during insertion of the brush, the brush should be disposed of to avoid causing damage to the endoscope's operating channels.
- **Never transfer** a used cleaning brush from one endoscope to another endoscope, since cross-contamination could occur and result in patient complications. Disposable cleaning brushes are designed to safely remove debris, some of which can be retained in the bristle structure.
- These products are intended for single patient use only. US Endoscopy does not take responsibility for the safety and effectiveness of this disposable medical device following reuse, reprocessing, remanufacturing, and/or resterilization by any institution, practitioner, or third party.

Contraindications:

- If the channel(s) are known to be occluded or resistance is met in attempting to pass the brush through the endoscope, **do not force** the cleaning brush through the endoscope, as this may result in damage to the channel.
- Do not use a specific cleaning brush in a specific channel if use is not recommended by the endoscope's Original Equipment Manufacturer.
- Do not use Small Wonder[®] - Micro cleaning brushes in flexible endoscopes

Directions for use:

1. Prior to clinical use, familiarize yourself with the device and read all the Instructions for Use.
2. Inspect the package for shipping or handling damage. If damage is evident, do not use this device.
3. Channel cleaning brush:
 - a) Using the cleaning media of choice, advance the cleaning brush through the **entire length of the endoscope before reversing direction**. Reversing direction inside the endoscope could cause the brush to expand, which could potentially damage the endoscope.
 - b) Using the cleaning media of choice, pass the channel cleaning brush through the valve stem openings.
4. Control head cleaning brush:
 - a) Remove valve(s) from the control head of the endoscope. Using the cleaning media of choice, use the brush to gently cleanse the valve and luer port openings. Avoid twisting or torquing the brush handle. The brush handle will prevent the brush from being pushed too deeply into the valve openings.
 - b) Using the cleaning media of choice, clean control head and control head dials.



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: November 2014













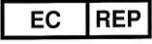
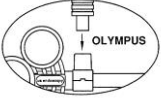

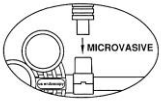





Warning:

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

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Explanation of symbols used on Labels and Instructions for Use

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