



SuperDART®

ONE PASS™ VALIDATED

SuperDART® is a sophisticated Three Stage Single Use Endoscope Channel Cleaning Device. The Three Stage construction results in a validated ONE (1) PASS pull through capability during manual cleaning of the endoscope channels.

SuperDART® ONE PASS™

Cleaning efficacy validation summary and declaration of conformity are available upon request.

Model No. 9292 – Individual Cleaning Device

SuperDART® for Channel sizes: **2.8mm - 4.2mm** inner diameter.

Model No. 9188 – Cleaning Brush Kit

One (1) SuperDART® p/n 9292 Cleaning Device & one (1) Suction Well/Cylinder aka Instrument Port Brush p/n 9990.

Model No. 9144 – Cleaning Brush Kit

One (1) SuperDART® p/n 9292 Cleaning Device & one (1) Suction Well/Cylinder aka Instrument Port and Valve Brush p/n 9992.

Model No. 9253 / 9233 / 9293 – Individual Cleaning Device

SuperDART® for Channel sizes: **2.0mm – 2.8mm** inner diameter.

Model No. 9355 – Cleaning Brush Kit

One (1) SuperDART® p/n 9253 Cleaning Device & one (1) Suction Well/Cylinder aka Instrument Port Brush p/n 9990.

Model No. 9333 – Cleaning Brush Kit

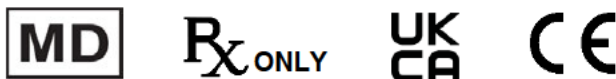
One (1) SuperDART® p/n 9233 Cleaning Device & one (1) Suction Well/Cylinder aka Instrument Port Brush p/n 9990.

Model No. 9399 – Cleaning Brush Kit

One (1) SuperDART® p/n 9293 Cleaning Device & one (1) Suction Well/Cylinder aka Instrument Port Brush p/n 9990.

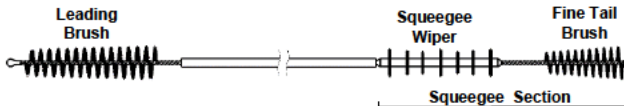


Instructions for Use 2



DEVICE DESCRIPTION

Model No. 9292



Model No. 9253 / 9233 / 9293

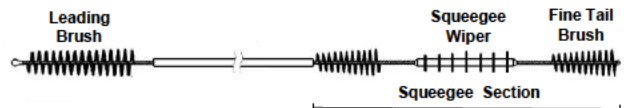


Figure 1A SuperDART® with Squeegee Cleaning Device

Model No. 9990



Figure 1B Suction Well / Cylinder Brush aka Control Head Brush

Model No. 9992



Figure 1C Double Ended Suction Well / Cylinder and Valve Brush

INTENDED USE

These devices are intended for use during manual cleaning of flexible endoscopes. The Three Stage SuperDART® is used to scrub and swipe the inside of the Endoscope Channel and evacuate any debris present. The Suction Well Brush is used to scrub the inside of the Suction Cylinder, Instrument Port, Control Head and/or Valves to loosen and remove any debris present. These devices are for single use only and should be discarded after cleaning of each endoscope. Do not use these brushes for any purpose other than their intended use.

SIGNAL SYMBOLS

WARNING	Indicates a potentially hazardous situation, which could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation, which may result in minor or moderate injury.
NOTE	Indicates additional helpful information.

CONTRAINDICATIONS: Do not use device when
1 channel's diameter is smaller than minimum size indicated on the label.
2 channel's diameter is greater than maximum size indicated on label.
3 channel is known to be occluded or resistance is met during past through.

CAUTIONS

- Follow all cleaning instructions of the endoscope's Original Equipment Manufacturer.
- Do not use for cytological tissue sampling or any other diagnostic or therapeutic purposes. Patient injury, cross-contamination, and/or equipment damage may occur.
- Follow hospital/clinic's infection control protocol and take all appropriate precautions including wearing the appropriate PPE.
- Never coil device into a diameter smaller than 20cm. The device can be damaged if coiled too tightly.
- Only trained and qualified personnel should be given the responsibility to reprocess endoscopes.
- Do not use SuperDART® with incompatible channels. See device label for compatible channel size and length.
- When using detergent and disinfection solution, always follow the manufacturer's recommendations regarding temperature, soaking time and concentration.
- Never insert the Squeegee Section of the SuperDART® into the endoscope first. Doing so may result in blocking the channel and damaging the endoscope.
- Do not attempt to insert the device in any other ways than those specified in manual provided by endoscope manufacturer. Do not attempt to withdraw the device from openings other than those specified in manual provided by endoscope manufacturer. Doing so may cause device to become lodged in the channel.
- Never use excessive force when introducing or withdrawing the device. If a device encounters significant resistance or blockage in the endoscope channel, do not force it through the endoscope. Use of excessive force may damage the device and/or the endoscope channel.
- Always dispose of the SuperDART® and Suction Well Brush after each endoscope is cleaned. The device functionality and cleaning efficacy cannot be guaranteed after one complete endoscope cleaning.
- Do not rotate, twist or torque the device while it is inside the channel. Doing so may damage the device and/or the endoscope being cleaned.
- Do not use damaged devices. Always inspect device for damage before use. See Figures 2 -7. Damaged device may not adequately clean the endoscope channel, which may result in failed high level disinfection of the endoscope.
- Always use the device in a wetted endoscope. Perform cleaning with both the device and the endoscope completely submerged in enzymatic detergent solution to prevent splattering and avoid damage to the device and/or the endoscope.
- Do not put your face too close to the channel opening and do not withdraw the device too quickly from the channel. Doing so may result in splashing the user with contaminated matter and/or enzymatic solution.

- Withdraw the device straight from the channel opening. Do not rub device Shaft, Squeegee Wiper or Bristle against the channel opening. Doing so may damage the device or equipment being cleaned.
- Never transfer a contaminated device between endoscopes; cross-contamination may occur resulting in patient and/or user infection.

WARNINGS

- Patient debris and reprocessing chemicals are hazardous. Before reprocessing endoscope always wear personal protective equipment such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant glove that fit properly and are long enough to cover exposed skin.
- After using, carefully check that no parts of the device have fallen off. Any part of the brush remaining in the channel after cleaning can drop into patient's body during a subsequent procedure. Detached part can be retrieved from inside the endoscope channel by passing a new brush or other endoscope accessory through the channel or retrieve using a biopsy forceps.

REUSE WARNINGS

These cleaning devices are for SINGLE USE ONLY. Do not clean, disinfect or sterilize the devices prior to use. Do not reprocess, resterilize or reuse the devices after the first use. Doing so may damage the device and/or the equipment being cleaned and/or impair its cleaning ability, which may cause infection to the patient. Any institution, practitioner or third party, who reprocesses, refurbishes, remanufactures, resterilizes, and or reuses these devices must bear full responsibility for their safety and effectiveness.

STORAGE

Store cleaning devices in original packaging at room temperature in a dry clean location away from direct sunlight.

EQUIPMENT REQUIRED

- Preparation, Inspection and Use: Endoscope & channel cleaning devices.
- Cleaning: Ultrasonic cleaner, container, enzymatic detergent, high level disinfectant, cleaning brush, sponge & lint-free cloth.

PREPARATION

- Before using, follow instruction manual provided by the endoscope manufacturer regarding endoscope preparation, inspection and cleaning.

INSPECTION

- Read Instruction for Use and get acquainted with the device. Inspect the package and device for shipping or handling damage. Remove the device(s) from the package and carefully unwind the shaft of the SuperDART®. Only open bag containing the device immediately before use.
- Some examples of damages to look for are depicted on Figures 2 to 7 and may include but are not limited to: bent or cracked catheter, missing Bristles, Brush or Squeegee. This inspection is the responsibility of the user. Worn out bristles and wiper disks are ineffective in cleaning, and damaged devices may damage the endoscope. DO NOT USE THESE DEVICES, SAVE THEM AND CONTACT AUTHORIZED DISTRIBUTOR FOR A RETURN AUTHORIZATION.
- If damage is observed, then replace with new device. Do not repair a damaged device. Use of repaired device may damage the endoscope.
- Inspect the device after each use for any detached part as depicted in Figure 7. If parts are detached or missing, make sure all detached parts are retrieved and properly discarded (see "DISPOSAL" instruction).

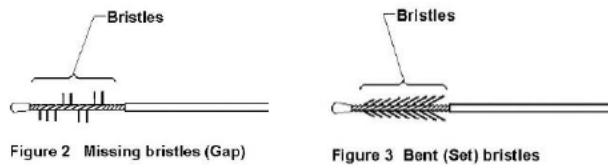


Figure 2 Missing bristles (Gap)

Figure 3 Bent (Set) bristles

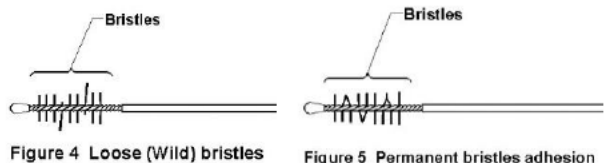


Figure 4 Loose (Wild) bristles

Figure 5 Permanent bristles adhesion

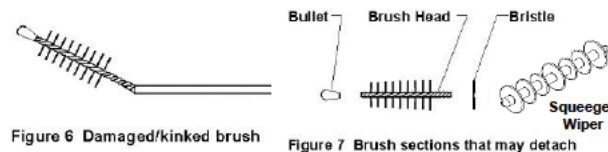


Figure 6 Damaged/kinked brush

Figure 7 Brush sections that may detach

USE – SuperDART® Cleaning Device (Figure 1A)

Always use the SuperDART® Cleaning Device in a wetted scope. Never insert the Squeegee Section of the SuperDART® cleaning device first as it could get lodged in and damage the channel. While the device and the endoscope are submerged in an appropriate amount of enzymatic detergent solution, perform these steps.

(1) Brush Instrument Channel from the Suction Cylinder to the distal end of the Insertion Tube.

Advance the Leading Brush (with the protective bullet, see Figure 1A & 8) through the opening in the Suction Cylinder until you feel less resistance, approximately 8cm. Move the brush back and forth 2-3 times to clean the connection of the Suction Cylinder Port to the Teflon channel tube (see Figure 9). Next, proceed with pushing the device through the Instrument Channel until the Leading Brush appears at the end of the Insertion Tube. Use short strokes as not to kink the device catheter. Hold the distal end of the device and pull it through until the Squeegee Section of the device clears the channel exit (see Figure 10). This device has been validated for cleaning the channel effectively with only ONE PASS™ through. With the device still submerged in the detergent solution, inspect and scrub off all debris present on all Bristles and Squeegee Wiper before proceeding to clean the next channel or accessories.

(2) Brush Suction Channel from the Suction Cylinder to the Endoscope Suction Connector

Advance the Leading Brush through the opening in the Suction Cylinder until you feel less resistance, approximately 8cm. Move the brush back and forth 2-3 times to clean the connection of the Suction Cylinder Port to the Teflon channel tube (see Figure 9). Next, proceed with pushing the device through the Suction Channel until the Leading Brush appears from the Endoscope Suction Connector. Use short strokes as not to kink the device catheter. Hold the distal end of the device and pull it through until the Squeegee Section of the device clears the channel exit (see Figure 11). This device has been validated for cleaning the channel effectively with only ONE PASS™ through. With the device still submerged in the detergent solution, inspect and scrub off all debris present on all Bristles and Squeegee Wiper before proceeding to clean the next channel or accessories.

(3) Brush the connection of the Instrument Channel Port to the Teflon channel tube.

Advance the Leading Brush straight through the opening in the Instrument Channel Port, by approximately 8cm. Move the brush back and forth 2-3 times to clean the connection of the Instrument Channel Port to the Teflon channel tube, see Figure 9. Pull back out the Leading Brush. With the brush submerged in the detergent solution, inspect and scrub off all debris present on all Bristles before proceeding to clean the next channel or accessories.

(4) Use the Leading Brush to clean the Biopsy Valve, Suction Valve and Air/Water Valve according to endoscope manufacturer's instructions.

USE – Suction Well / Valve Brush (Figure 1B & 1C)

While the brush and the endoscope are submerged in cleaning solution, insert brush into the suction well (aka valve/control head) until resistance is felt. Rotate the inserted brush at least one full revolution and pull the brush out of the well. With the brush still submerged, scrub off all debris on the bristles. Repeat cleaning until no debris is observed upon inspection of the brush. Repeat above cleaning steps for the Instrument Channel Port and Instrument Valve. See Figure 12.

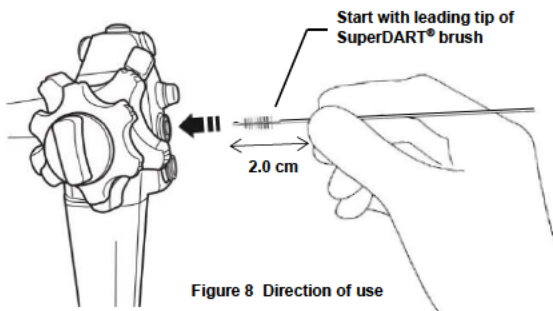


Figure 8 Direction of use

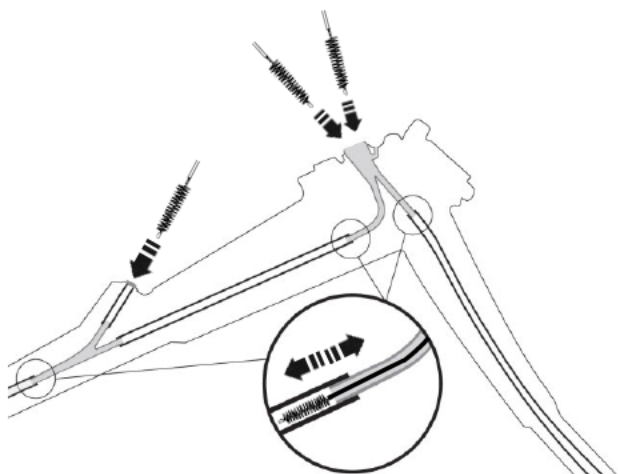


Figure 9 Cleaning the connections between metal port and channel

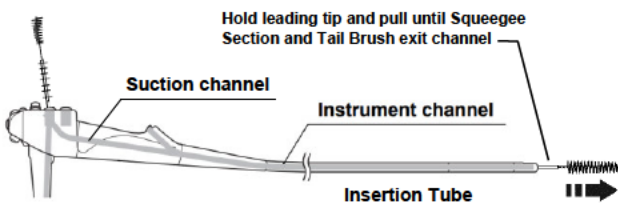


Figure 10 Cleaning Suction and Instrument Channel

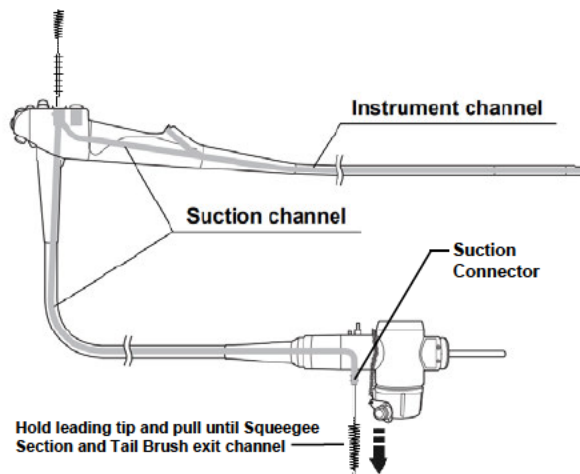


Figure 11 Cleaning Suction Channel

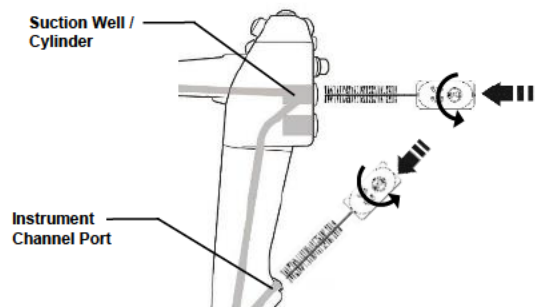


Figure 12 Cleaning Suction Well and Channel Ports

Please scan QR code for a link to the supplementary Instructional Video.



PRODUCT DISPOSAL



Used Cleaning Device may be a potential biohazard. Handle and dispose of in accordance with the hospital/clinic's protocol and applicable regulations.

SYMBOLS MEANING



CE Mark.



Quantity of Units in Case.



Product Number.



Quantity of Units in Dispenser.



This Product is not made with LATEX.



This Product is not made with PHTHALATE.



Indicates Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.



UKCA Mark.

Visit us online at www.primedENDO.com for full list of symbol glossary including those in compliance with ISO 15223-1 standard.

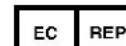
NOTE: Contact PriMed Instruments if you have any questions or comments regarding the content of this document.

If two years has elapsed between the issued date for these instructions and product use, the user should contact PriMed Instruments Inc. to determine if additional information or revisions are available.

SuperDART® ONE PASS™ is a registered trademark of PriMed Instruments Inc.



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