



SuperDART® is a sophisticated brush with built-in squeegee wiper and Triple Action capability to allow for an effective manual cleaning of the channel, ranging from Ø2.8mm to Ø4.2mm inner diameter, with only one pass-through of the brush.

Model No. 9292 – Individual Brush
SuperDART® cleaning brush

Model No. 9188 – Cleaning Brush Kit
One (1) SuperDART® cleaning brush & one (1) Suction Well aka Valve/Control Head Brush

Instructions for Use 2

Rx ONLY

MD

CE

primed

DEVICE DESCRIPTION

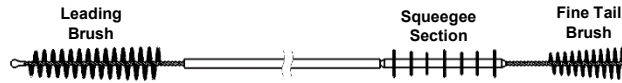


Figure 1A SuperDART® with Squeegee Cleaning brush



Figure 1B Suction Well aka Valve/Control Head Brush

INTENDED USE

These brushes are intended to be used during manual cleaning of a flexible endoscope. The SuperDART® triple action nylon bristles and squeegee combo brushes are used to scrub the inside of the Endoscope Channel to loosen and remove any debris present. The Suction Well brush are used to scrub the inside of the Channel Port and/or Valve/Control Head to loosen and remove any debris present. These brushes 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 brush when

- channel's diameter is smaller than minimum size indicated on the label.
- channel's diameter is greater than brush diameter indicated on label.
- 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 a specific cleaning brush in a specific channel if use is not recommended by the endoscope's Original Equipment Manufacturer.
- Do not use Cleaning Brushes 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 brush into a diameter smaller than 20cm. The brush can be damaged if coiled too tightly.
- Only trained and qualified personnel should be given the responsibility to reprocess endoscopes.
- Do not use cleaning brush with incompatible channel.** See brush 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® cleaning brush first.** Otherwise, it will get stuck within the channel and damage the endoscope.
- Do not attempt to insert the brush in any other ways than those specified in manual provided by endoscope manufacturer. Do not attempt to withdraw the brush from openings other than those specified in manual provided by endoscope manufacturer. Doing so may cause brush to become lodged in the channel.
- Never use excessive force when introducing or withdrawing the brush. If a brush encounters significant resistance or blockage in the endoscope channel, do not force it through the endoscope. Use of excessive force may damage the brush and/or the endoscope channel.

- Always dispose of the cleaning brush after each endoscope is cleaned. The brush's functionality and cleaning efficacy cannot be guarantee after one complete endoscope cleaning.
- Do not rotate, twist or torque the brush while it is inside the channel. Doing so may damage the brush and/or the equipment being cleaned.
- Do not use damaged brushes.** Always inspect brush for damage before use. See Figures 2 -7. Damaged brush may not adequately clean the endoscope channel, which may cause patient infection.
- Always use the brush in a wetted scope.** Perform cleaning and disinfection with both the brush and the endoscope completely submerged in the detergent solution to prevent spattering and avoid damage to equipment.
- Do not put your face too close to the channel opening and do not withdraw the brush too quickly from the channel. Doing so may cause operator' infection or irritation from the splashes of patient blood/mucus and detergent solution.
- Withdraw the brush straight from the channel opening. Do not rub brush shaft, stem or bristle against the channel opening. Doing so may damage the brush or equipment being cleaned.
- Never transfer a contaminated brush between endoscopes;** cross-contamination may occur resulting in patient 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 brush 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.

REUSE WARNINGS

These cleaning brushes are for SINGLE USE ONLY. Do not clean, disinfect or sterilize the brush prior to use. Do not reprocess, resterilize or reuse the brush after the first use. Doing so may damage the brush 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, reesterilizes, and or reuses these brushes must bear full responsibility for their safety and effectiveness.

STORAGE

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

EQUIPMENT REQUIRED

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

PREPARATION

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

INSPECTION

- Read all the Instruction for Use and get acquainted with the device. Inspect the package and device for shipping or handling damage. Remove the brush from the package and carefully unwind the shaft. Only open bag containing the brush immediately before use.
- Some example of damages to look for are depicted on Figures 2 to 7 and may include but not limited to, bent or cracked catheter, missing bristles, brush or squeegee. This inspection is the responsibility of the user. Worn out bristles are ineffective in cleaning, and damaged brushes 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 brush. Do not repair a damaged brush. Use of repaired brush may damage the endoscope.
- Inspect the brush 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).**

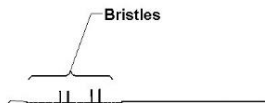


Figure 2 Missing bristles (Gap)

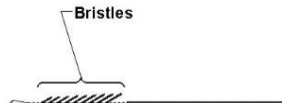


Figure 3 Bent (Set) bristles

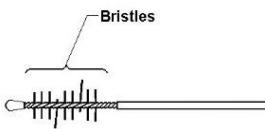


Figure 4 Loose (Wild) bristles

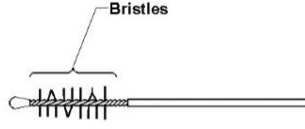


Figure 5 Permanent bristles adhesion

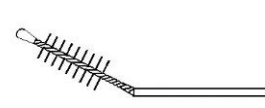


Figure 6 Damaged/kinked brush

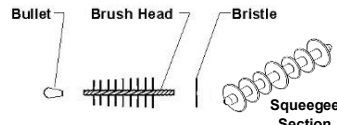


Figure 7 Brush sections that may detach

USE – SuperDART® Cleaning Brush (Figure 1A)

Always use the SuperDART® cleaning brush in a wetted scope. Never insert the squeegee section of the SuperDART® cleaning brush first as it will get stuck and damage the channel. While the brush and the endoscope are submerged in an appropriate amount of detergent solution, advance the leading end of the brush (the end without the squeegee, see Figure 1A & 8) into the endoscope channel opening until the leading brush head emerges out the other end of the channel. Use short strokes to avoid kinking. Hold the leading tip of the brush and pull brush until trailing tail end of the brush clears the channel exit (see Figure 9 to 11). With the brush still submerged in the detergent solution, inspect and scrub off all debris present on the bristles. Perform additional passes through the channel as needed or until no more visible debris are present upon inspection of brush. Repeat the above steps for the other compatible size suction or instrument channel. If cleaning the valve stem or biopsy valve, always use the leading end brush only and scrub off all debris present on the bristle after each cleaning.

USE – Suction Well / Port Brush (Figure 1B)

While the brush and the endoscope are submerged in cleaning solution, insert brush into the suction well (aka valve/control head) or channel port until resistance is felt. See Figure 12. Rotate the inserted brush 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.

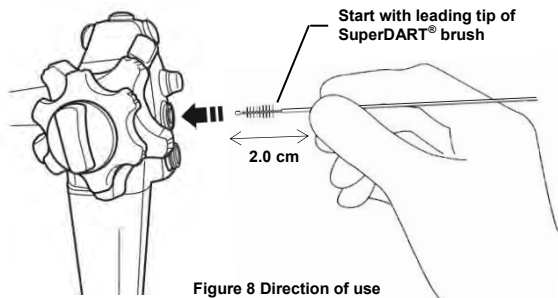


Figure 8 Direction of use

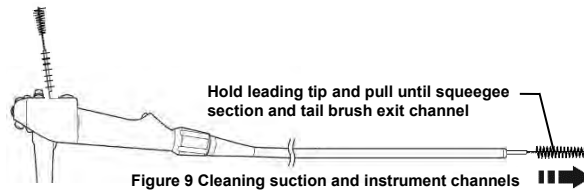


Figure 9 Cleaning suction and instrument channels



Figure 10 Cleaning instrument channel

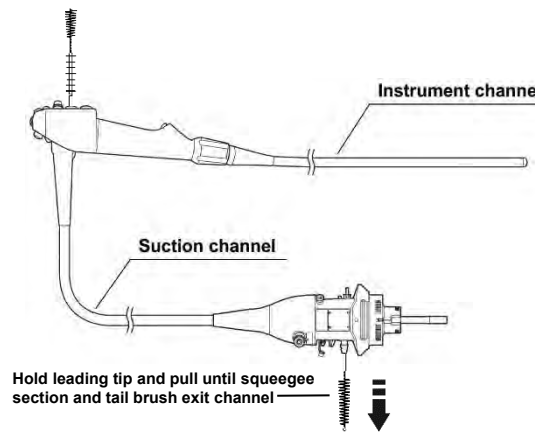


Figure 11 Cleaning suction channel

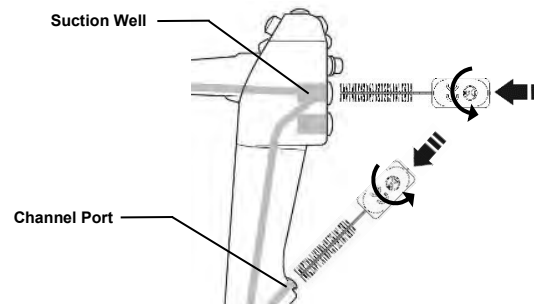


Figure 12 Cleaning suction well and channel ports

PRODUCT DISPOSAL



Used cleaning brush 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.

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 to determine if additional information is available.

SuperDART® is a registered trademark of PriMed Instruments Inc.



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Instructions for Use
W-7.5.3-W15 – SuperDART IFU
Revised & Approved & Effective /
2022-06-27
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