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Koala™

Cleaning Sponge plus Pure™ Enzymatic

Rx ONLY

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

WARNING

Contents supplied NON-STERILE. Do not use if damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse or reprocess. Reuse, reprocessing or sterilizing may compromise the structural integrity of the device and/or lead to device failure. Reuse or reprocessing may also create a risk of contamination of the device or may lead to improper scope cleaning.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Koala Cleaning Sponge plus Pure enzymatic is a single use, non-sterile, hand-held device made of absorbent polyester polyurethane intended to be soaked in water while squeezing the sponge to release the enzymatic detergent. The surface of the endoscope is wiped with the enzymatic detergent soaked sponge after the endoscopic procedure as a pre-cleaning step prior to disinfection or sterilization of the endoscope.

Contents

Package contents include:

(1) Koala Sponge plus Pure Enzymatic

INDICATIONS FOR USE / INTENDED USE

The Koala Cleaning Sponge plus Pure Enzymatic is intended to be soaked in water to wipe the surface of the endoscope after the endoscopic procedure as a pre-cleaning step prior to disinfection or sterilization of the endoscope.

CONTRAINDICATIONS

None known.

PRECAUTIONS

- Keep out of reach of children.
- Ensure proper personal protective equipment (PPE) is worn during use of this device.

CAUTION

Avoid contact with eyes and skin. In case of contact, flush with water. If irritation persists, contact a physician.

DANGER

May cause allergy or asthma symptoms or breathing difficulties if inhaled. See Safety Data Sheet (SDS) for additional information.

ADVERSE EVENTS

None known.

HOW SUPPLIED

Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

- After the endoscopy procedure, create an enzymatic solution by submerging the enzymatic sponge into the EcoBowl, or equivalent, filled with approximately 300 ml of water while squeezing the sponge vigorously at least three times to release the enzymatic detergent.
- Next, suction the enzymatic solution through the endoscope and wipe the exterior surfaces of the endoscope with the wet sponge.
- Place the sponge over the tip of the endoscope during endoscope transport.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**



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Do not use if package is damaged.



Non-Sterile



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Catalog Number



Consult instructions for use.



Contents



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