PEARLCATCH™
SINGLE CHAMBER POLYP TRAP

Instructions for Use.
Read carefully prior to use.

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Not made with natural rubber latex.
Does not contain DEHP

Part Number	Description
GAR014	PEARLCATCH™ Single Chamber Polyp Trap (Non-sterile)

INTENDED USE

The single use **PearlCatch™ Single Chamber Polyp Trap** is used for suction retrieval and transportation of endoscopically removed polyps for histological examination. The Single Chamber Polyp Trap has one chamber to collect the polyps and one open area for straight suction.

The single use Single Chamber Polyp Trap consists of:
- One (1) jar with one (1) filtered trap to collect polyps, and one (1) open areas for straight suction.
- A lid with one tube for connection to the endoscope.
- One Polyp Pick.

WARNINGS AND PRECAUTIONS

Products marked “single-use” are for single-use only. Do not reuse, reprocess, or resterilize single-use products. The materials used in the manufacture of the device may not withstand repeated reprocessing. The device may not perform as intended by the manufacturer if it is reused. This may lead to failure of the device to perform as intended and/or material degradation, which may result in patient injury, illness or death. Reuse, reprocessing, or resterilization may also increase the risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Do not disconnect the pre-installed tubing from the polyp trap lid outer port as this may result in damage to the polyp trap lid and may result in exposure to the contents of the trap during removal.

Protective garments (i.e. gloves, protective eyewear, gowns, etc) should be worn during the use of this device to protect against the risk of cross- contamination and injury.

PRODUCT DISPOSAL

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

INSTALLING THE POLYP TRAP

Connection:
1. Connect barbed fitting of trap to suction system.
2. Connect tube side of trap to endoscope suction fitting.

Capture:
3. Apply suction via the endoscope suction valve to trap polyp.

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Polyp Removal and Transport:

4. After the polyp is trapped, remove the trap from the endoscope and suction system.
5. Separate trap by rotating both halves in opposite directions.
6. Remove polyp and place in specimen jar with fixative, or place trap in specimen jar and fill with fixative. ***Note:*** *To remove the retrieved polyp, use the provided Polyp Pick to transfer the polyp from the strainer to the appropriate specimen container for histopathology in accordance with institutional guidelines.*
7. Transport to pathology.

WARNING

An issued or revision date for these instructions is included for the user's information. In the event three years has elapsed between this date and product use, the user should contact GA Health Company Limited to determine if additional information is available. Report any serious incident that has occurred in relation to the device to the distributor or manufacturer or competent authority of the member state.

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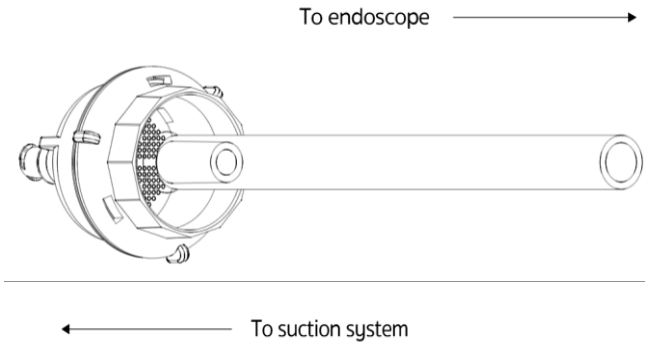

EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE

	Use-by date
LOT	**Batch or lot code**
	Manufacturer
	Date of Manufacture
MD	**Medical Device**
REF	**Catalogue number** **Product Code**
CE	**EC Conformity Quality Assurance**
	Do not re-use **Single use**
LATEX	**Product not made with natural rubber latex**
PHT	**Do not contain DEHP**
	Consult Instructions for Use
EC REP	**Authorized representative in the European Community**
	Keep dry
	Keep away from sunlight
℞ ONLY	**Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.**