

Non-sterile, disposable **UP2 Retrofitter™ tube**

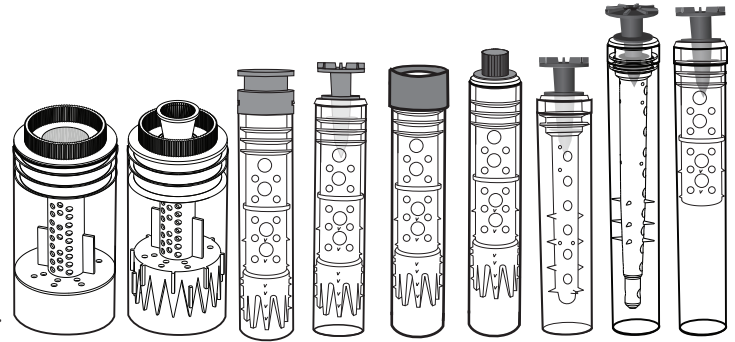
Read the product leaflet carefully before using the product
For *in vitro* diagnostic

Scope of use

The UP2 Retrofitter™ tube is a container used for the collection, storage, preservation, transportation and performance of *in vitro* diagnostic laboratory analysis of specimens. The product is intended to be used by the professional or patient to collect, store and transport secretions, various fluids and substances from the nose, ears, oral cavity, vagina, cervix and anus for further examination. Once closed, the UP2 Retrofitter™ tube no longer allows the collected sample to be touched, keeping the sample between the walls of the UP2 Retrofitter™ and those of the tube.

Models of UP2 Retrofitter™ tube

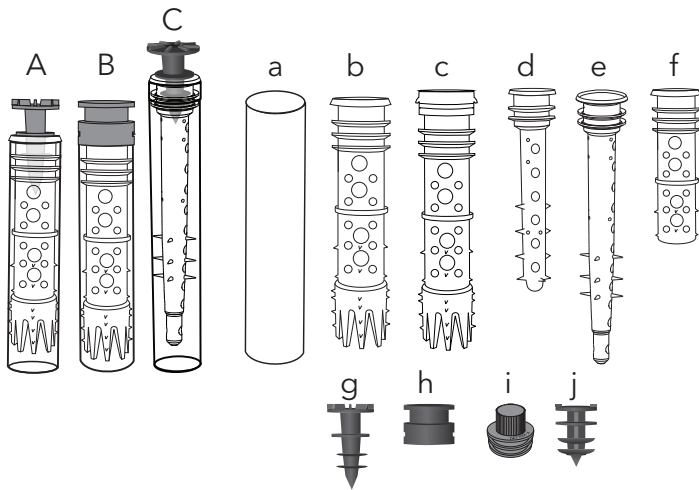
Patents pending



Product description

The UP2 Retrofitter™ tube is a container fitted with UP2 Retrofitter™ - an element that allows the sample to be held between the walls of the tube and its walls. The tube can be closed with a cap, attached to the UP2 Retrofitter™, or the UP2 Retrofitter™ can be provided with an aluminium foil for sealing.

Product overview:



a - Transparent, non-graduated, non-sterile polypropylene (PP) tube

b, c, d, e, f - Transparent, non-sterile, low-density polypropylene (LDPE) UP2 Retrofitter™ (it can be with aluminium foil)

g, h, i, j - non-sterile low-density polypropylene (LDPE) cap

A - The non-sterile, disposable UP2 Retrofitter™ tube formed of: a+b+g

B - The non-sterile, disposable UP2 Retrofitter™ tube is formed of: a+c+h

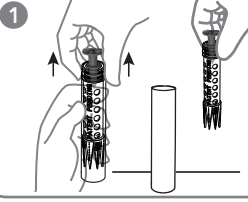
C - The non-sterile, disposable UP2 Retrofitter™ tube is formed of: a+e+g

Safety information and warnings

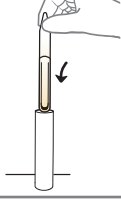
1. Do not use the product if its packaging is damaged.
2. Check each individual package before use and do not use if the packaging is damaged.
3. Do not use the product after the expiry date printed on its packaging.
4. The UP2 Retrofitter™ tube and its cap are disposable, intended for single use only. Dispose of all used products in biohazardous waste containers.
5. Close the container for test systems, when necessary, with the appropriate cap. Used caps should not be put back in the tubes.
6. Handle all biological samples and collection utensils according to your institution's instructions and procedures. In case of direct contact with biological samples, consult a doctor, as there is a risk of transmission of infectious diseases. Always follow your institution's safety instructions and procedures.
7. Store the tube upright and respect the storage conditions specified for the sample material collected.
8. Healthcare professionals must validate the use of the container for their specific assay-instrument/reagent system combinations and specimen storage conditions.
9. For use in devices or automation, follow the device manufacturer's instructions.

Use

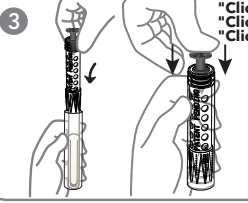
The professional uses or obtains and delivers the UP2 Retrofitter™ tube to the patient



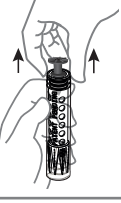
1 Open the UP2 Retrofitter™ cap of the tube and hold it in your hand while placing the tube on a flat, clean surface.



2 Place the sample inside the tube.



3 Close the UP2 Retrofitter™ cap until you hear a "click" 3 times, keeping the sample between the walls of the Retrofitter and those of the tube.



4 To perform the required analysis, remove the cap and follow the standard laboratory procedure according to the analysis you are about to perform.

For (fully) automatic use, follow the manufacturer's instructions for the device you will be using. When necessary, open the cap or puncture the aluminium foil to gain access inside the UP2 Retrofitter™ for further steps or analysis according to your laboratory's protocols.

Storage

Store unused products at room temperature in a clean place, away from heat sources and direct sunlight.

Disposal

1. General hygiene guidelines and regulations for the proper disposal of infectious material must be known and followed by each laboratory.
2. If a specimen contains blood, all specimen collection devices shall be classified as biohazardous in terms of handling and disposal operations. It is the responsibility of each laboratory to handle, treat and dispose of waste in accordance with applicable legislation.
3. Unused containers can be considered non-hazardous and can be disposed of according to these criteria.
4. Correctly label the tubes with the patient's name, ID, date and time of collection, and any additional information required by centre policy.
5. Properly label and package any container used to transport the specimen to an alternate location in accordance with applicable local, state, and federal requirements.

Glossary of symbols

 REF	Catalogue number		Non-sterile
 LOT	Lot code		See the instructions for use on the website
	Expiry date		Do not reuse
	CE marking		Do not use if packaging is damaged
 IVD	Medical device for <i>in vitro</i> diagnostic		Producer
 QTY	Quantity		

Technical changes reserved.

All serious incidents related to the product must be notified to the manufacturer and to the national competent authority of the State where the user is established. A "serious incident" is understood as an incident involving death or severe deterioration in the health of a patient or user or posing a serious threat to public health.

8XX7617ZW/YY
8XX7035ZW/YY

8XX8717ZW/YY
8XX7835ZW/YY

8XX10118ZW/YY
8XX7535ZW/YY

8XX10718ZW/YY
8XX8235ZW/YY