

EN – Instruction for use

Q Path® Cassettes



According to Regulation (EU) 2017/746, Annex I, **EN ISO 15223-1:2021** and **EN ISO 20417:2021**.

PRODUCT NAME	QTY	REF
Description	Pack Size	Cat. No.
Q Path Macrostar I	Box of 4 000 cassettes	720-2242 to 720-2250
Q Path Macrostar I in a hopper	Box of 3 000 cassettes	720-2032 to 720-2040
Q Path Macrostar I – rack of 40	Box of 4 000 cassettes	720-2373 to 720-2381
Q Path Macrostar II	Box of 2 000 cassettes	720-2224 to 720-2232
Q Path Macrostar II in a hopper	Box of 4 000 cassette	720-2050 to 720-2058
Q Path Macrostar II – rack of 40	Box of 2 000 cassettes	720-2391 to 720-2399
Q Path Microstar II	Box of 2 000 cassettes	720-2072 to 720-2080
Q Path Microstar II in a hopper	Box of 4 000 cassettes	720-2041 to 720-2049
Q Path Microstar II – rack of 40	Box of 2 000 cassettes	720-2382 to 720-2390
Q Path Microstar III	Box of 1 500 cassettes	720-2233 to 720-2241
Q Path Microstar III	Box of 1 500 cassettes	720-2081 to 720-2089
Q Path Macrostar V	Box of 1 500 cassettes	720-2215 to 720-2223
Q Path Macrostar V – rack of 40	Box of 2 000 cassettes	720-2099 and 720-2163 to 720-2170
Q Path Microstar V	Box of 1 500 cassettes	720-2192 to 720-2199 and 720-2205
Q Path Microstar V – rack of 40	Box of 2 000 cassettes	720-2090 to 720-2098
Q Path Macrostar VI	Box of 1 500 cassettes	720-2174 to 720-2182
Q Path Macrostar VII	Box of 1 000 cassettes	720-2206 to 720-2214
Q Path Macrostar VIII	Box of 100 cassettes	720-2062 to 720-2065
Q Path Microtwin	Box of 1 500 cassettes	720-2183 to 720-2191
Q Path Microtwin – rack of 40	Box of 2 000 cassettes	720-2400 to 720-2408

The denomination of the cassettes:

MicroStar, Macrostar and Microtwin: Small holes

Macrostar: Large holes

Microtwin: Specific for ultrabioopsy

There are 7 numbers:

- I. no cover
- II. one cover, separate
- III. one cover, mounted
- IV. one cover welded to the cassette, and you can write on the sides
- V. a cover welded to the cassette, wide range of writing in the front and writing is possible on the sides
- VI. cassette for big sample, with a cover welded, wide range of writing in the front and on the sides
- VII. cassette for large samples (6 x 4.5x 1.2 cm), with separate lid, ample space to write on the front face and on the sides.

INTENDED PURPOSE

The device is intended to be used in clinical and diagnostic laboratories to contain clinical tissue specimens to facilitate specimen processing (e.g., fixation, dehydration, infiltration, embedding, sectioning), analysis and storage. It is in the form of a synthetic polymer container of different sizes and colours, with or without a lid, with drainage holes. It provides a writing surface for identification of the appropriate specimen/patient information. This is a single-use device. For in vitro diagnostic use.

WARNINGS AND PRECAUTIONS

Please refer to the packaging of the product for information on handling.

1. Cassettes are intended for single use.
2. Indicate the appropriate specimen/patient information on the inclining part of the cassette in permanent ink, resistant to histological solvents.
3. Adapt the size of the specimen to the size of the cassette. Choose the right model for each specimen size. Do not overfill the cassette.
4. Make sure that the cassettes are clean and free of any debris before being used.
5. You must close the lid on the cassettes securely after putting in the specimen.
6. You must open the lid on the cassette gently when taking out the specimen.
7. Orientation of the sample in the cassette is important. Incorrect orientation of tissues may result in diagnostically important tissue elements being missed or damaged during microtomy.
8. The Q Path® Cassettes are not sectionable cassettes.

INTENDED USER

Intended for laboratory professional use.

INTENDED PATIENT POPULATION

Q Path® Cassettes are intended to contain clinical tissue specimens obtained from the general population to facilitate specimen processing pertaining to patients in need of histological specimen examination.

USE ENVIRONMENT

The Q Path® Cassettes are intended to be used in professional healthcare environments; for example, clinical and diagnostic laboratories.

COMPOSITION

Mixture of plastic components and alcohol- and solvent-resistant colouring agents.

STORAGE AND SHELF LIFE

Store in a dry place, away from sources of heat and direct sunlight.

ADDITIONAL MATERIALS AND SPECIAL EQUIPMENT REQUIRED BUT NOT PROVIDED

- **Consumables:** Biopsy pad (for small samples)
- **Equipment:** Microwriter
- For Q Path MacroStar VII, its dimensions may require changing the tongs on some models of microtome (consult the manufacturer of the microtome).
- With regard to the Q Path® MacroStar VIII, the cassette clamps will have to be changed (consult the manufacturer of the microtome)

SPECIMENS

- **Type of specimen:** Histological samples of a size suitable for the cassette.
- **Special conditions for specimens:** Fresh samples obtained by a microsurgical procedure or a macroscopic session.
- **Pre-treatment:** Sample properly fixed.
- **Storage conditions:** Keep the cassettes in the fixative and continue the protocol for the inclusion of paraffin as soon as possible.

PROTOCOL

1. Take a specimen.
2. Take the cassette and mount the lid.
3. Put the patient's number on the cassette.
4. Put the specimen in a cassette of proper size.
5. Close the lid of the cassette.
6. Place the cassettes in a vacuum-seal apparatus (dehydration, specimen impregnation).
7. Carry out the inclusion of the specimens in an embedding station.
8. Put the cassette on which the sample has been fastened into the tongs of the microtome.
9. Follow the rest of the histological technique as required.

METHODOLOGY

Principle of the method

The cassette enables the transport of the histological specimen in complete safety. The cassette is then used to hold specimens for histological sections.

The principle of the method for Q Path® Cassettes is a synthetic polymer container to transport and protect the samples during the embedding process, as well as in the storage file.

The Q Path® Cassettes keep specimens safely submerged in liquid and the drainage holes allow the easy circulation of the histological solvent to which the cassette is totally resistant. Furthermore, the cassette writing surface allows the identification of the appropriate specimen/patient information.

Method characteristics and performance limitations

Reopening the cassette prior to the process makes it unusable. In this case, it is necessary to replace the cassette lid. Then be sure to write the patient's number on it with a permanent marker or a microwriter of cassettes. If you use this product with decalcifying solution, it is advisable to use Q Path® Decalcifier DC1 slow, Q Path® Decalcifier DC2 Medium and Q Path® Decalcifier DC3 fast.

The sterilisation of cassettes is possible by a method using the wet heat in autoclave. (For instance: 134 °C during 18 min).

DISPOSAL

Handle contaminated packages in the same way as the substance itself.

Dispose according to local legislation. Consult the appropriate local waste disposal expert about waste disposal.

NOTICE FOR THE USER

Any serious incident that has occurred in relation to this product must be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or the patient is established. Please contact your local VWR partner through the **vwr.com** website.

We pay the utmost attention to the quality of our products. In case of any malfunction or dissatisfaction please use the complaints form on the contact page of your local **vwr.com** website and indicate the reference and batch number of the product concerned.

This instruction for use was established in June 2023 and cancels all previous instructions. The information is based on our knowledge and our experience this day. The attention of the users is drawn to the eventual risks when the product is used for a different use than it is dedicated. The user is not exempt to know and implement all the texts regulating their activity. They will take under their responsibility the precautions bound in the use that they make of the product.

Modifications to instructions for use in revision number 8:

- Modified intended purpose.
- Addition of intended user and use environment.
- Update of warnings and precautions.
- Addition of description of symbols used.
- Minor updates and corrections.

SYMBOLS USED (EN ISO 15223-1:2021)

Symbol	Symbol title and description
	In vitro diagnostic medical device: Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Keep away from sunlight: Indicates a medical device that needs protection from light sources.
	Catalogue number: Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Do not re-use: Indicates a medical device that is intended for one single use only.
	Batch code: Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Caution: To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

Symbol	Symbol title and description
	Manufacturer: Indicates the medical device manufacturer.
	Country of manufacture: To identify the country of manufacture of products.
	Consult instructions for use or consult electronic instructions for use: Indicates the need for the user to consult the instructions for use.
	Keep dry: Indicates a medical device that needs to be protected from moisture.
	Use-by date: Indicates the date after which the medical device is not to be used.
	Do not use if package is damaged and consult instructions for use: Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.

CONTACT



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