

Tissue-Tek[®] Paraffin Wax



7052, 4653, 4659, 4508, 4509, 4511, 4523, 4525

Instructions for use

General Information



www.sakura.eu

Description

The device is a highly purified mixture of solid hydrocarbons obtained from petroleum. It contains no dimethyl sulfoxide. It is soluble in xylene and xylene substitutes, and insoluble in water and ethanol. All variants other than 7052 have a melting point of 54° to 57° C. The melting point of the 7052 variant is 56° to 58° C.

Intended purpose

The device is a paraffin-based infiltration and embedding medium used to prepare biological tissue specimens for histopathological examination. It has been tested for its suitability for use with a variety of tissue/specimen types. It is a single-use device.

Application and use

Due to the nature of the device, it is supplied for use by qualified histopathology technicians/professionals only, and it is thus expected that the operator will be adequately trained in its fundamental use.

The device is ready to use. Its use in specific workflows and protocols should be validated in accordance with the procedures followed by the laboratory.

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7052 is to be used with Tissue-Tek® Paraform® Sectionable Cassette System and Tissue-Tek AutoTEC® / Tissue-Tek AutoTEC® a120 Automated Embedding System. Compatible with the processing reagents used with the Tissue-Tek Xpress® x120 Continuous Rapid Tissue Processor.

Infiltration

Here are the steps to follow:

1. Heat the wax until molten and transparent throughout, using a suitable heated container. Maintain heating bath at a temperature of 60–65°C.
2. Immerse specimen according to the processing protocols used in the laboratory to displace the clearing agent completely. Intended for use with any histopathology processing units. No limitations known.
3. Start embedding the tissue. If embedding cannot follow shortly after processing, the specimens should be left at room temperature instead of in the heated wax to avoid damage to the tissue.

Automated embedding:

Here are the steps to follow:

4. Place the wax (7052) in the automated embedding instrument
5. Ensure the specimens are placed in Paraform Cassettes
6. Place the magazine with Paraform Cassettes in the automated embedding instrument
7. Take the embedded blocks from the Output Door, ready for sectioning.

Embedding

Here are the steps to follow:

1. Place infiltrated specimens into a metal base mould. If needs be, orientate to the correct position, and fill the base mould with molten wax.
2. Place the tissue cassette onto the base mould following standard laboratory operating procedures.
3. Place onto a cold plate (0–10°C) and allow the wax to re-solidify, ready for sectioning.

Disposal

Follow local regulations and hospital-specific policies regarding the disposal of regulated medical waste.

Product configurations

Item Code	Name	Specifications
7052	Tissue-Tek® Paraform® Processing/Embedding Medium, Formula 3	Consists of paraffin, no additives 8 bags, each 1 kg/case
4653, 4659	Tissue-Tek® Paraffin Wax Tek II	Consists of paraffin and microcrystalline 4653: 1 bag, 10 kg 4659: 1 bag, 25 kg
4508, 4509, 4511	Tissue-Tek® Paraffin Wax Tek III	Consists of paraffin and polymer 4508: 1 bag, 25 kg 4509: 1 bag, 10 kg

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		4511: 4 bags, each 2.5 kg/box
4523, 4525	Tissue-Tek® Paraffin Wax Tek IV	Consists of paraffin, no additives 4523: 4 bags, each 2.5 kg/box 4525: 1 bag, 25 kg

Storage and shelf life

- Store at a temperature of 0° to 35°C.
- Keep dry and out of direct sunlight.
- Melting point: 54° to 57°C, except for 7052: 56° to 58°C.

The shelf life of the device is three years if stored under the recommended conditions.

Do not use the device beyond the expiration date printed on the label, or if it has not been stored under the recommended conditions.

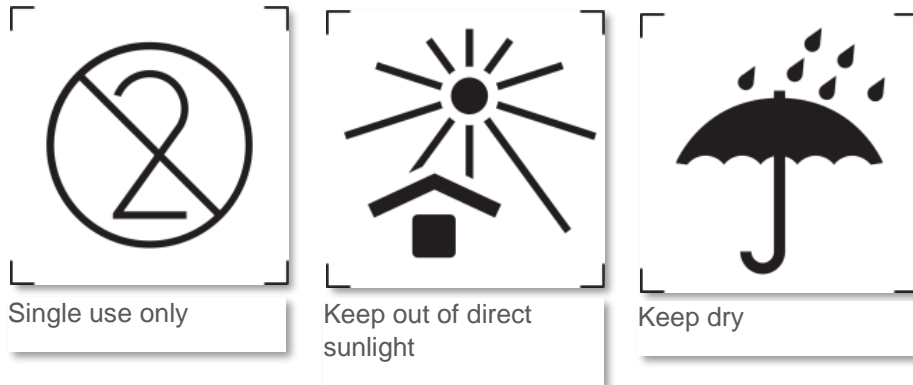
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Warnings and precautions

- For professional use only.
- Single-use device—do not re-use.
- For laboratory use.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.



Steps to take in the event of a malfunction

If flocculation is observed (white fibrous masses suspended in solution), check the bath temperature, and increase to a maximum of 65°C if necessary. If the flocculation persists, a thorough round of troubleshooting is recommended. If that does not solve the issue, please contact the manufacturer.

If any other sediment/contamination is observed (in either solid or molten form) that is not characterised as flocculation, first check the embedding stations and the paraffin oven in the tissue processor, because dust may have accumulated and cleaning or replacement may be required. If these steps do not solve the issue, please contact the manufacturer.

If cracks appear once the wax is re-solidified into blocks, check whether the processing protocol was appropriate for the tissue being processed, and whether the infiltration time was suitable. If that does not solve the issue, please contact the manufacturer.

Online version available

These instructions for use can also be found online at www.sakura.eu.

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