Tissue-Tek[®] Coverslipping Film

Instruction for use

REF 4770-E

Tissue-Tek $^{\otimes}$ Coverslipping Film is a film designed to be used only with the Sakura Finetek Tissue-Tek Film $^{\otimes}.$

Intended Purpose

This product is used to cover a specimen on a microscope slide, to serve as a physical barrier from mechanical force or environmental exposure. The specimen to be protected can be a formalin-fixed and paraffin-embedded (FFPE) section, frozen section or cytology sample on a microscope slide. The adhesion is activated by an actuator and once the adhesive has dried, the coverslipped slides can be used for microscopic evaluation, scanning or transport. This product, if desired, can be removed. It is a single use device and is used in the Film coverslipper.

Intended User

This product is intended to be used by trained professionals in clinical pathology, anatomy or cytology who are trained using the Sakura Finetek Tissue-Tek Film[®].

How to use

- This product only uses xylene as the actuator.
- This product can be used on both hydrophilic and hydrophobic glass slides.
- Allow the film to completely acclimate to the environment in which it will be used. The film package should be opened to allow the film to acclimate for 24 hours prior to use.
- Discard the first 80 cm of film before installing a new roll on the coverslipper. This will ensure removal of the blemished area originally secured with adhesive tape.
- When re-installing, remove 3 to 6 mm of the film using the blade cutter of the instrument.
- At the end of the workday or once you have finished working for the day, remove the roll from the coverslipper, rewind the film onto the roll and store it in the plastic bag to prevent the film taking the curvature of the roller(s).
- For film installation and more detail of use, refer to the operating manual of the device to be used together with this product.
- Note: In the final steps of specimen staining, clean, reagentgrade xylene should always be used to prepare slides for coverslipping.

Removal of the Coverslipping Film

This film can be removed according to the following procedure.

- 1. Dip a film coverslipped slide into a minimum of 50 mL acetone for 6 minutes. When processing multiple slides at once, leave some space between them so that the peeled films on the slide do not come in contact with each other.
- 2. After the slides are soaked in acetone for 6 minutes, remove the film by using tweezers.
- Dip slides up and down in 2 changes of xylene, (each 50 mL) to remove remaining film and adhesive until the white turbidity on the slide disappears. 50 mL of xylene is sufficient for up to 10 coverslipped slides.

Note: The slide(s) can be re-coverslipped with new film.

Precautions for use

- Observe the operating and storage environment as deterioration of the film may cause coverslipping errors.
- Do not use film when stored out of specifications.
- Please confirm if the surface of the slide is dried out before use in a digital slide scanner.
- Inspect slides to reduce and/or limit thickness variations. Cytology specimens may present specimen thickness that may vary within wide extremes. Bubbles may occur and render specimens difficult to diagnose after storage.

Safety measures

Wear gloves and a mask to prevent exposure from actuator (xylene).

Operating and storage environment

Operating and storage: 10°C to 30°C (50°F to 86°F), humidity 30% to 70%. Film coverslipped slide storage (Recommendation): 20°C to 25°C (68°F to 77°F), less than humidity 50%.

Expiration date

The expiration date is printed on the front of 1 case and on top of the 1 roll package.

Disposal

Dispose to an approved waste company or in accordance with applicable local regulations.

Note

Any serious incidents that occurred in relation to the device shall be reported to the manufacturer, authorized representative and your competent authority.



IVD In vitro diagnostic medical device

Consult instructions for use





Do not re-use



Keep away from sunlight Keep dry 10°C Temperature limit Humidity limitation



continuous innovation for pathology

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