



Instructions for Use (IFU)

Product Name: ProWAVE

Product Description: ProWAVE Solution - 4x1gal Case

Catalog Number: 51410C

Unit of Measure: 4 gallons per case

1. Intended Use

ProWAVE is a dehydration/clearing solution suitable for the preparation of histological specimens. Dehydration and clearing are necessary steps in tissue processing.

ProWAVE is a blend of alcohol designed to complete the dehydration and clearing steps for small specimens in a single step.

ProWAVE is formulated for use in In-Vitro-Diagnostic medical devices.

ProWAVE provides exceptional tissue morphology and nuclear detail, while also staining small specimens blue for visibility.

2. Summary and Explanation

ProWAVE is a solution composed of a blend of alcohol to achieve dehydration and clearing in a single step for smaller samples. The reagent has a blue dye that serves two purposes. First, it colors the samples, making tiny specimens visible for the operator. Second, it indicates the level of water contamination, ensuring proper reagent exchange. The proprietary blend of alcohol produces exceptional cytopathological and nuclear detail, especially for gastrointestinal and skin samples.

ProWAVE eliminates the need for xylene while still achieving highly effective clearing of small specimens without over-dehydrating.

3. Materials Required but Not Provided

ProWAVE Solution is ready to use and therefore does not require any dilutions.

4. Warnings and Precautions

The product is intended for use by specialized technical personnel.

Carefully read the information concerning Hazard Statements and Safety Advice stated on the label.

Consult the Safety Data Sheet (SDS) for risks information, precautionary measures to be taken during use, first aid instructions, and hazard information in case of accidental release.

Do not use if packaging is damaged.

ProWAVE Solution is produced according to uniform and controlled methods according to Quality Control Specifications. During and after use, handle all the materials according to Good Laboratory Practice.

Any other use of the product not detailed in this IFU is considered improper and relieves the manufacturer of responsibility.

Medical devices and in-vitro diagnostic medical devices are subject to surveillance by the National Competent Authority for their safety.

In the event of a serious accident, it is required to inform the competent Authority and Milestone by reporting the incident to: applications@milestonemed.com

5. Storage and Stability

ProWAVE is contained in a plastic bottle for light protection, with a sealed cap; store tightly closed, away from light, in a cool and dry place.

The shelf life of the product is 24 months in undamaged packaging and under correct storage conditions. After opening the tank, the reagent can be used until the expiration date indicated on the package.

Close the bottle tightly after each use.

6. Procedures for Use

Milestone tissue processors provide the essential elements to utilize the properties of ProWAVE, enabling dehydration and clearing in a single step.

The processing times of ProWAVE are linked to some variables:

- Dimensions of tissues to be processed
- Quantity of samples
- Type of tissue

ProWAVE is designed to process tissue samples 3mm and smaller in shortened processing times.

Methods and times should be based on individual laboratory validations. This product is developed to provide excellent processing outcomes, and to provide optimal tissue for diagnostic requirements when used per the manufacturer's instructions.

To use the reagent in Milestone processors, refer to the instructions in the following table:

Sample thickness	Total time	Temperature
UP TO 1mm	15 minutes	154.4°F (68°C)
UP TO 2mm	20 minutes	154.4°F (68°C)
UP TO 3mm	30 minutes	154.4°F (68°C)

The use of this product on any processor other than a Milestone processor should be verified and validated for efficacy.



Milestone processors include specific protocols that are specifically developed to achieve the best results. The individual laboratory should fully validate these protocols.

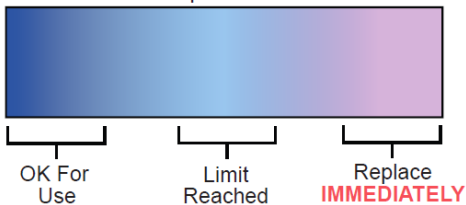


Before making any changes to a program, contact our Applications team by emailing: applications@milestonemed.com

Reagents should be replaced at regular intervals to ensure that the reagent purity meets the standards required for processing. For more information, contact applications@milestonemed.com.

ProWAVE™ Usage Indicator

refer to separate transparent color strip indicator for precise color check



The ProWAVE product label shows an image of the usage indicator, as pictured here. ProWAVE solution has a blue indicator and changes color as it is used. The usage indicator serves as an added visual check for the user, indicating when the reagent needs to be replaced.

7. Waste disposal



Handle with care and store in a cool, dry space using a tightly closed container. Vapors may collect in empty containers. Treat empty containers as hazardous.



Waste material should be handled in accordance with your institutional policies, complying with all applicable federal, state, and local regulations.

For further information, please refer to the Safety Data Sheet (SDS).

8. Manufacturer Information










StatLab Medical Products


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McKinney, TX 75069

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9. Symbols and Definitions

	Instructions with this symbol are important and require more attention
	Biohazard: be careful when you execute the procedure marked with this symbol: danger of biohazard contamination
	IVD medical device according to 2017/746 Regulation (EU)
	Reference number
	Lot number
	Manufacturer
	Expiration date
	<p>DANGER</p> <p>H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled</p> <p>H317: May cause an allergic skin reaction</p> <p>H340: May cause genetic defects</p> <p>H350: May cause cancer</p> <p>H360: May damage fertility or the unborn child</p> <p>H372: Causes damage to organs through prolonged or repeated exposure</p> <p>H373: May cause damage to organs through prolonged or repeated exposure</p> <p>P201: Obtain special instructions before use</p> <p>P280: Wear protective gloves/protective clothing/eye protection/face protection</p> <p>P308+P313: IF exposed or concerned: Get medical advice/attention</p>
	<p>DANGER</p> <p>H220: Extremely flammable gas</p> <p>H225: Highly flammable liquid and vapor</p> <p>H226: Flammable liquid and vapor</p> <p>P210: Keep away from heat/sparks/open flames/hot surfaces — No smoking</p> <p>P233: Keep container tightly closed</p> <p>P370+P378: In case of fire: Use appropriate extinguisher</p>

	<p>WARNING</p> <p>H302: Harmful if swallowed H315: Causes skin irritation H319: Causes serious eye irritation H335: May cause respiratory irritation H336: May cause drowsiness or dizziness H317: May cause an allergic skin reaction P261: Avoid breathing dust/fume/gas/mist/vapors/spray P280: Wear protective gloves/eye protection P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes</p>
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For further information or clarity, please contact our applications team by emailing: applications@milestonemed.com or calling 1-866-995-5300.