



## Instructions for Use (IFU)

**Product Name:** JFC Solution

**Product Description:** JFC Solution - 4x1gal Case

**Catalog Number:** 51408C

**Unit of Measure:** 4 gallons per case

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### 1. Intended Use

JFC Solution is a dehydration/clearing solution suitable for the preparation of histological specimens.

JFC Solution is xylene-free.

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

JFC Solution has a low toxicity formulation which overcomes the drawbacks commonly associated with xylene, a hazardous product for the human nervous system.

JFC Solution provides excellent morphology, nuclear and cytoplasmic detail, and fat cell processing.

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### 2. Summary and Explanation

Dehydration is carried out with anhydrous chemical agents able to replace the water present in the tissues, which are soluble and miscible with the intermediate solvents used before paraffin infiltration.

Clearing requires reagents compatible with both the dehydration reagent and wax, which are able to extract lipids from tissues.

JFC is an innovative solution developed to dehydrate and clear pathology specimens efficiently in a single reagent. The reagent becomes very effective at lipid extraction when appropriate heat is applied, resulting in optimal tissue processing.

JFC Solution is an almost odorless, non-carcinogenic solvent and has the chemical properties to dissolve fat.

JFC Solution is a formulation of low toxicity that overcomes the drawbacks commonly associated with xylene, a hazardous product for the human nervous system. JFC Solution also provides optimal preservation of fat cells structure, nuclear and cytoplasmic morphology.

JFC Solution can replace 100% Ethyl Alcohol and xylene/isopropanol during the dehydration

and clearing steps of tissue processing.

The dehydration/clearing process must always be carried out after adequate fixation of the sample. The miscibility of the three components of JFC Solution allows for dehydration and clearing in a single step, thus representing a significant advantage over conventional processing methods.

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### 3. Materials Required but Not Provided

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

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### 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 an accidental spill.

Do not use if packaging is damaged.

JFC 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 and always remember that the material to be analyzed must be considered as a potential biological risk.

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](mailto:applications@milestonemed.com)

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### 5. Storage and Stability

JFC Solution 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.

Store at room temperature.

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

indicated on the bottle.

Close the bottle tightly after each use.

## 6. Procedures for Use

The dehydration/clearing timing of JFC Solution is linked to some variables:

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

Smaller samples, such as gastric or needle biopsies and similar, only require short exposure to JFC Solution to achieve optimal dehydration without over dehydration or hardening.

For larger specimens containing adipose tissue, such as intestine or breast biopsies, slightly longer times may be necessary.

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.

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

Sample Thickness	Total Time	Temperature
Up to 1mm	20 minutes	154.4°F (68°C)
Up to 2mm	30 minutes	154.4°F (68°C)
Up to 3mm	55 minutes	154.4°F (68°C)
Up to 4mm	1 hour 30 minutes	154.4°F (68°C)
Up to 5mm	2 hours	154.4°F (68°C)

Use of this product on any other processor, which is not a Milestone processor, should be verified and validated for efficacy.



**Milestone processors include specific protocols that are specifically developed to achieve the best results. These protocols should still be fully validated by the individual laboratory.**



**Before making any changes to a program, contact our Applications team by emailing: [applications@milestonemed.com](mailto:applications@milestonemed.com)**

Reagents should be changed at appropriate intervals to ensure reagent purity meets the purity standards for processing. For more information, contact [applications@milestonemed.com](mailto:applications@milestonemed.com).

## 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 materials should be handled per your institutional policies in compliance with all federal, state, and local regulations

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

## 8. Manufacturer Information

### StatLab Medical Products




2090 Commerce Drive

McKinney, TX 75069

1-800-442-3573

## 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><b>DANGER</b>  <b>H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled</b>  <b>H317: May cause an allergic skin reaction</b>  <b>H340: May cause genetic defects</b>  <b>H350: May cause cancer</b>  <b>H360: May damage fertility or the unborn child</b>  <b>H372: Causes damage to organs through prolonged or repeated exposure</b>  <b>H373: May cause damage to organs through prolonged or repeated exposure</b>  <b>P201: Obtain special instructions before use</b>  <b>P280: Wear protective gloves/protective clothing/eye protection/face protection</b>  <b>P308+P313: IF exposed or concerned: Get medical advice/attention</b></p>
	<p><b>DANGER</b>  <b>H220: Extremely flammable gas</b>  <b>H225: Highly flammable liquid and vapor</b>  <b>H226: Flammable liquid and vapor</b>  <b>P210: Keep away from heat/sparks/open flames/hot surfaces — No smoking</b>  <b>P233: Keep container tightly closed</b>  <b>P370+P378: In case of fire: Use appropriate extinguisher</b></p>
	<p><b>WARNING</b>  <b>H302: Harmful if swallowed</b>  <b>H315: Causes skin irritation</b>  <b>H319: Causes serious eye irritation</b>  <b>H335: May cause respiratory irritation</b>  <b>H336: May cause drowsiness or dizziness</b>  <b>H317: May cause an allergic skin reaction</b>  <b>P261: Avoid breathing dust/fume/gas/mist/vapors/spray</b>  <b>P280: Wear protective gloves/eye protection</b>  <b>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes</b></p>

For further information or clarity, please contact our applications team by emailing: [applications@milestonemed.com](mailto:applications@milestonemed.com) or calling 1-866-995-5300.