

	<p align="center"><b>Instructions for Use</b>  <b>SureThin® Filters for Monolayer</b>  <b>Cytology Specimen Preparation</b></p>	<p align="center"><b>Art. No.:</b>  <b>90-1425-00</b>  <b>90-1425-01</b>  <b>90-1426-00</b></p>
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## 1. Intended Use




SureThin® Filters are intended to be used in conjunction with an Automated Cytology Slide Processor, like the SureThin® LBC (Liquid Based Cell) Slide Processor and or as an equivalent filter to be used in other automatic cytology or LBC specimen preparation instrument to prepare thin layer (monolayer) specimens for cytological evaluation by:

- capturing cells from suspension in SureThin® Cell Preservative Solution or an equivalent alcohol-based cell preservative solution, and
- transferring the captured cells to the surface of a microscope slide.
- Including LBC cytology for pap stain-based screening for cervical cancer.

## 2. Product Description

SureThin® Filters are disposable assemblies consisting of a membrane filter that is permanently attached across one end of a hollow cylindrical body. Cells are captured on the surface of the filter membrane and are transferred from the filter onto a microscope slide. The body facilitates the handling of the membrane filters in the laboratory and serves as the interface between the Filter and the slide processor instrument.

The following single use SureThin® Filters are available to accommodate the types of samples processed by a cytology laboratory. The different Filters are visually distinguishable by the color of the Filter body and are selected in accordance with the type of sample to be processed.

 "NON_GYN"	<ul style="list-style-type: none"> <li>• <b>SureThin® “5.5 Blue” Filter.(Cat. No. 90-1425-01)</b></li> <li>• 5.5µ nominal pore size; 20mm spot size</li> <li>• Recommended for use with most “Non-Gyn” samples.</li> <li>• Provides efficient capture of clinically significant cells while reducing the amounts of cell debris, bacteria and similar objects in the deposited spot.</li> </ul>
 "GYN"	<ul style="list-style-type: none"> <li>• <b>SureThin® “7.0 Pink” Filter. (Cat. No. 90-1425-00)</b></li> <li>• 7.0µ nominal pore size; 20mm spot size</li> <li>• Recommended for use with “Gyn” samples</li> <li>• Provides a higher flow rate and reduced amounts of white blood cells, bacteria, and cell debris in the deposited spot than the Blue filters.</li> </ul>
 "URINE"	<ul style="list-style-type: none"> <li>• <b>SureThin® “8.2 Yellow” Filter. (Cat. No. 90-1426-00)</b></li> <li>• 8.2µ nominal pore size; 10mm spot size</li> <li>• Recommended for use with urine and bladder wash samples. May also be useful with samples having a low cell concentration.</li> <li>• Provides a higher flow rate and smaller, more concentrated cell deposit than the Blue and Red filters.</li> </ul>



### 3. Attaching the Filter to the Filter Cap

NOTE: The reusable Filter Cap is the part of the Slide Processor instrument that serves as the interface between the SureThin® Filter and the instrument. Please refer to the slide processor instrument User's Manual for information related to the cleaning and maintenance of the Filter Cap.

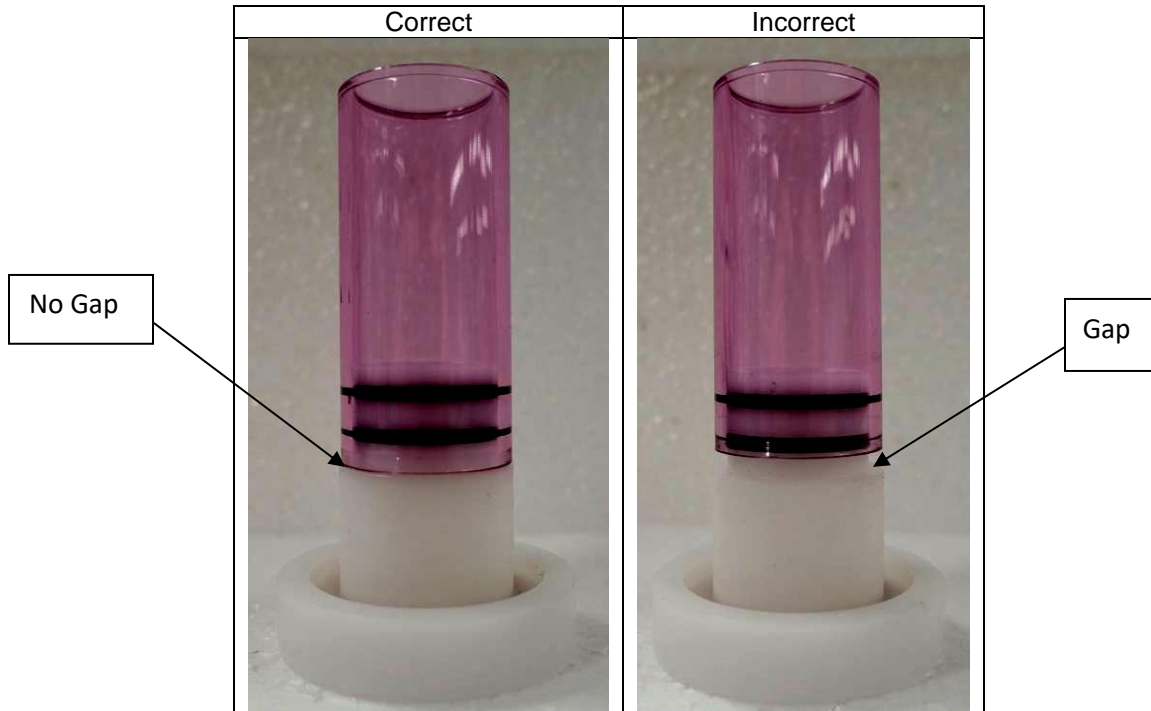


**Never touch the Filter membrane!**  
Touch **ONLY** the body-portion of the Filter  
Powder-Free Gloves are recommended when handling the Filter

- Remove a Filter from its shipping carton.
- Remove the protective sleeve from the Filter.
- Inspect the Filter Membrane and Filter Cap for damage. Replace if necessary.
- Attach the Filter to the Filter Cap by either of the two following methods.

Method 1	
	<ul style="list-style-type: none"> <li>Place the Filter Cap on a clean solid surface with the small end facing up.</li> <li>Grasp the sides of the Filter body without touching the Filter Membrane.</li> <li>Position the open end of the Filter over the small end of the Filter Cap.</li> <li>Firmly push down on the Filter until the lip of the Filter is seated against the Filter Cap. A slight twisting motion might be helpful.</li> </ul>
Method 2	
	<ul style="list-style-type: none"> <li>Hold the large end of the Filter Cap in one hand.</li> <li>Grasp the sides of the Filter body with the other hand. <b><u>DO NOT TOUCH THE FILTER MEMBRANE</u></b></li> <li>Position the open end of the Filter over the small end of the Filter Cap.</li> <li>Push the Filter and Filter Cap together until the lip of the Filter is seated against the Filter Cap. A slight twisting motion might be helpful.</li> </ul>



- Verify that the Filter is properly seated on the Filter Cap. There should be no visible gap between the lip of the Filter and the Filter Cap. Reseat the Filter if necessary.



#### 4. Loading the Filter into the SureThin® Slide Processor



The following illustrations and instructions are for the SureThin® Slide Processor. Other slide processor instruments may differ. Consult your slide processor User's Manual for more information.

<p>Inserting the Filter</p> 	<ul style="list-style-type: none"> <li>• Grasp the Filter Cap as shown.</li> <li>• Position the Filter Cap between the two front bobbins in the instrument with the top of the Filter Cap parallel to the base of the instrument and the Filter pointing down.</li> <li>• When the Filter Cap is properly positioned, push it into the instrument. The right-hand bobbin (when facing the instrument) is spring-loaded. It will move out of the way as the Filter Cap is inserted and will move back to its original position after the Filter Cap has been fully inserted.</li> </ul>
<p>Verifying Filter Placement</p> 	<p>Visually verify that the Filter has been properly loaded into the instrument.</p> <ul style="list-style-type: none"> <li>• The Filter Cap should be held between the two bobbins with its top parallel to the base of the instrument.</li> <li>• The membrane end of the Filter should be above and slightly to the Left of the Preservative Vial.</li> <li>• The Filter should rotate easily between the bobbins.</li> </ul>

## 5. Preparing the Specimen.

The specimen is prepared after the Preservative Vial, Filter, Microscope Slide and Fixative Vial have been loaded into the slide preparation instrument. Refer to the User's Manual for your slide processor for detailed instructions.

## 6. Removing the Filter from the SureThin® Slide Processor



The following instructions are for the SureThin® Slide Processor. Other slide processor instruments may differ. Consult your slide processor User's Manual for more information.

- Open the access door by sliding it to the right.
- Remove the Fixative Bath containing the prepared specimen slide from its holder.



**POTENTIAL FIRE HAZARD.**  
The Fixative Bath contains Ethanol

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### **POTENTIAL BIOHAZARD**

The exterior surface of the used Filter has been in contact with human-sourced biological materials. The Filter should therefore be considered to be biohazardous and should be handled in accordance with the relevant laboratory Standard Operating Procedures and all applicable laws and regulations. Always wear gloves when handling used Filters.

- c) Remove the Filter from the instrument using either of the following two methods:

Method 1:

- Wrap a wipe around the body of the filter
- Grasp the Filter and pull it straight out of the instrument.
- Grasp the Filter body with one hand and the Filter Cap with the other.
- Pull the Filter out of the instrument.
- Separate the Filter from the Filter Cap by pulling them apart with a slight twisting motion.
- Dispose of the used Filter as biohazardous waste in an approved manner.

Method 2:

- Grasp the Filter and pull it straight out of the instrument.
- Grasp the Filter body with one hand and the Filter Cap with the other.
- Pull the Filter out of the instrument.
- Separate the Filter from the Filter Cap by pulling them apart with a slight twisting motion.
- Dispose of the used Filter as biohazardous waste in an approved manner.
- Change your gloves after disposing of the used Filter!

- d) Remove the specimen slide from the instrument. It may now be processed and evaluated in accordance with the test order and the Standard Operating Procedures of the laboratory.

## **7. Filter Specifications**

Pore and Spot Sizes <ul style="list-style-type: none"> <li>• Blue ("Non-Gyn")</li> <li>• Red ("Gyn")</li> <li>• Yellow ("Urine")</li> </ul>	5.5µ +/- 5%; 20mm spot size 7.0µ +/- 5%; 20mm spot size 8.2µ +/- 5%; 10mm spot size
Body Inside Diameter	21.65mm
Body Outside Diameter	25.50mm
Body Length	55mm

## **8. Technical Support**

Please contact your local Medite representative for additional information and assistance or:

Medite Global Technical Support	Medite US Technical Support
Medite GmbH. Wollenweberstr. 12. D-31303 Burgdorf/Germany	Medite, Inc. 4203 SW 34th Street, Orlando, FL 32811 Tel. 888-225-2950 or 407-996-9630 michaelk@Medite-Group.com.