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MST: 0316765196

TÀI LIỆU ĐƯỢC KÝ BẰNG CHỮ KÝ SỐ

Người đại diện hợp pháp của cơ sở
Giám đốc
Võ Trung Việt
(đã ký)

SafeFix™ CER

CSCA

with miLab™ Platform



Instructions for Use

Preface

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This product is covered by one or more patents in Korea, the US, Europe, Japan, China and other countries.

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Chapter 1. Before Reading this Document

This **Instructions for Use** provides a detailed description and understanding of the SafeFix™ CER and its features. All users **MUST** be fully aware of the proper method of operation, safety information, and precautions in this document before using the SafeFix™ CER.









Using the SafeFix™ CER without being suitably qualified or in ways not specified by this document may damage or deteriorate the product, cause misleading results, or even lead to personal injury.




1.1. Safety Alerts

The following safety alert symbols are used throughout this document. Carefully study the meaning of the following signs before reading this document. Make sure to understand and follow any information or instructions following these signs.

| Signs | Explanation |
|--|---------------------------------|
|  Warning! | May cause personal injury. |
|  Caution! | May cause damage to the system. |
|  Important! | May cause misleading results. |

1.2. Symbols on the Product and Product Packaging

| Symbol | Explanation | Symbol | Explanation |
|---|--|---|---|
|  | CE marking; European Conformity |  | <i>In vitro</i> diagnostic medical device |
|  | This way up |  | GHS; Harmful |
|  | Manufacturer |  | GHS; Health hazard |
|  | Authorized representative in the European |  | GHS; Flammable |

| | | | |
|---|-----------------------------|---|-------------|
|  | Temperature limit | LOT | Lot number |
|  | Consult instruction for use |  | Use by date |

1.3. Support

For contacting product-related support, collect the following information:

- Product model number
- Product lot number

If the packaging is damaged or an item is missing or damaged, immediately contact Noul service representatives.

1.3.1. Corporate Headquarters

| | |
|------------------|--|
| Address | Noul Co., Ltd. B-6F, 10F, 338, Gwanggyojungang-ro, Suji-gu, Yongin-si, Gyeonggi-do, 16942, Republic of Korea |
| Telephone | +82 (0) 31 308 6310 |
| Fax | +82 (0) 31 893 6672 |
| Email | cs@noul.com |
| Website | www.noul.com |

1.3.2. European Authorized Representative

| | |
|----------------|--|
| EAR | MT Promedt Consulting GmbH |
| Address | Ernst-Heckel-Straße 7, 66386 St. Ingbert Germany |
| Email | info@mt-procons.com |
| Website | www.mt-procons.com |

1.3.3. Switzerland Authorized Representative

| | |
|----------------|---|
| SAR | Decomplic AG |
| Address | Freiburgstrasse 3, 3010 Bern, Switzerland |
| Website | www.decomplic.com |

Chapter 2. Introduction

2.1. Intended Use

SafeFix™ CER is a dehydrating and decolorizing solution intended for use with the miLab™ Platform (Model Name: DMLA). When used with the miLab™ Platform, SafeFix™ CER dehydrates and decolorizes cytological cells fixed on microscope slides prepared by the Liquid-Based Cytology (LBC) testing.

2.2. Principle of SafeFix™ CER (Model Name: CSCA)

SafeFix™ CER functions as a dehydrating and decolorizing agent by diffusing into cells and tissues, displacing intracellular and extracellular water due to its hygroscopic properties, and simultaneously extracting pigments and dyes.



2.3. Performance and Specification

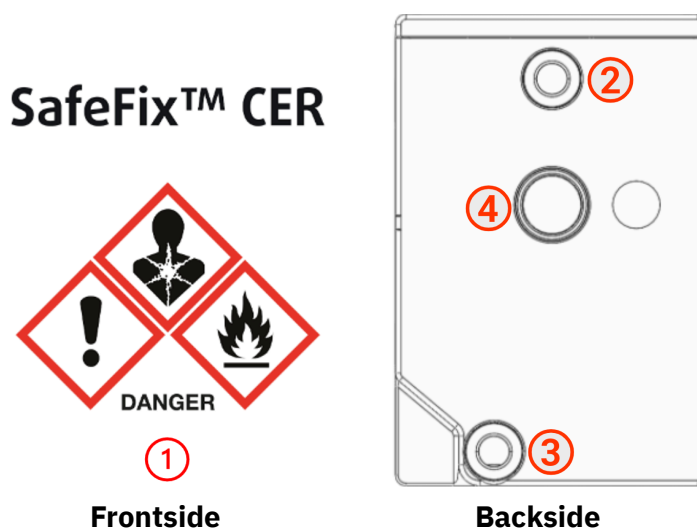
| Category | Specifications |
|---------------------|---------------------------------------|
| Equipment type | Dehydrating and decolorizing solution |
| Operating condition | 15 ~ 35°C |

| Category | Specifications |
|----------------------------------|---|
| Shelf-life and Storage condition | 4 ~ 30°C for 12 months |
| Shelf-life | (Unopened) 12 months from the date of manufacture (Installed) 6 months from installation |
| Volume | 220 ml |

Chapter 3. Components

3.1. Parts Names and Functions

The SafeFix™ CER solution is contained in a plastic container, which **MUST** be inserted into the designated compartment of the miLab. SafeFix™ CER **MUST** have sufficient volume for miLab to run any tests ($\geq 23\text{ml}$ required).



- **Frontside**
 - ① **SafeFix™ CER label**
A product label containing SafeFix information

- **Backside**
 - ② **Vent silicone cap**
Silicone cap for miLab vent needle insertion
 - ③ **Inlet silicone cap**
Silicone cap for miLab inlet needle insertion
 - ④ **Locking magnet**
Magnet to lock the SafeFix container to the SafeFix compartment of miLab

3.2. Warnings and Precautions (for in vitro diagnostic use only)



Caution!

- The reliability of the analysis results cannot be guaranteed if SafeFix™ CER is used beyond the scope of the written intended use or not in accordance with the provided directions for use.
- DO NOT tamper with or forcibly open SafeFix™ CER. Compromising the integrity of SafeFix™ CER may contaminate the dehydrating and decolorizing solution. Contamination of SafeFix™ CER may result in a low quality of staining cells
- DO NOT use expired SafeFix™ CER. The analysis results cannot be guaranteed when expired SafeFix is used.
- Directions should be read and followed carefully.
- Refer to Material Safety Data Sheet for additional information on reagent chemicals.



Warning!

- H225:** Highly flammable liquid and vapor.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H336: May cause drowsiness or dizziness.
H350: May cause cancer.
H372: Causes damage to organs through prolonged or repeated exposure.
P201: Obtain special instructions before use.
P202: DO NOT handle until all safety precautions have been read and understood.
P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233: Keep container tightly closed.
P240: Ground/bond container and receiving equipment.
P241: Use explosion-proof electrical/ventilating/lighting equipment.
P242: Use only non-sparking tools.
P243: Take precautionary measures against static discharge.
P260: DO NOT breathe fume/gas/mist/vapors/spray
P264: Wash exposed skin thoroughly after handling.
P270: DO NOT eat, drink or smoke when using this product.
P271: Use only outdoors or in a well-ventilated area.
P280: Wear protective gloves/clothing/eye protection/face protection.
P312: Call a POISON CENTER/doctor/physician/EMERGENCY NUMBER if you feel unwell.
P314: Get medical advice/attention if you feel unwell.
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313: IF exposed or concerned: Get medical advice/attention.
P337+P313: If eye irritation persists: Get medical advice/attention
P370+P378: In case of fire: Use carbon dioxide (CO₂), powder, alcohol-resistant foam to extinguish.
P405: Store locked up.
P403+P233: Store in a well-ventilated place. Keep the container tightly closed.
P403+P235: Store in a well-ventilated place. Keep cool.
P501: Dispose of contents/container to comply with local, state, and federal regulations.

Noul products are labeled with Hazard Symbols and Risk and Safety Phrases in compliance with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

3.3. Storage and Shelf Life

Store SafeFix™ CER in a well-ventilated place at 4 - 30°C. Keep SafeFix™ CER away from light, heat, sparks, open flame, or any other ignition source. If the SafeFix™ CER container has not been opened, it can be kept until the expiration date printed on the SafeFix™ CER label. After installation, SafeFix™ CER **MUST** be used within 6 months. **DO NOT** remove SafeFix™ CER except when replacing SafeFix™ CER.

 Caution!

- In case SafeFix™ CER was stored in temperature above or below the range as mentioned above, the dehydrating and decolorizing components may become unfit for use. Analysis results cannot be guaranteed if the storage conditions are not kept.

 Warning!

- SafeFix™ CER is highly flammable and **MUST** be stored with **EXTREME CAUTION**, accordingly.

3.4. Transportation

Always transport SafeFix™ CER in its original packaged state to prevent contamination, damage, or exposure to light.

 Caution!

- SafeFix™ CER contains flammable liquid. Be **EXTREMELY CAUTIOUS** when transporting SafeFix™ CER.
- **DO NOT** drop or apply excessive pressure on SafeFix™ CER. The integrity of the SafeFix container may be compromised and may cause leakage.


- DO NOT relocate miLab with SafeFix™ CER installed. In case of inevitable relocation, DO NOT lean on the miLab™ Device. Contents may leak from the vent on the SafeFix™ CER container.
- Follow all necessary precautions when transporting SafeFix™ CER.

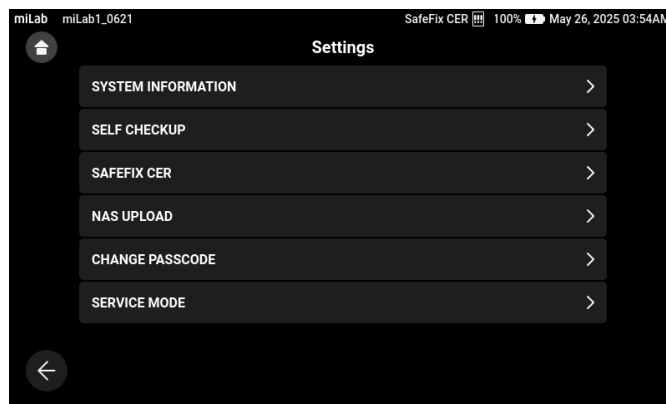
3.5. Disposal Procedures

Disposal procedures should meet the requirements of applicable local regulations. Read the GHS Hazard and Precautionary Statements mentioned in 3.2. Warnings and Precautions (for in vitro diagnostic use only).

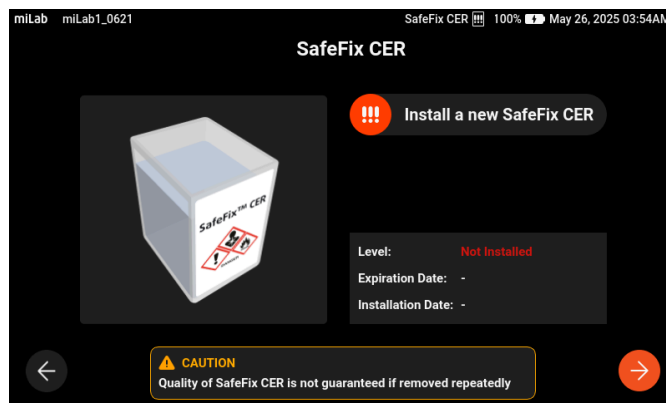
Chapter 4. Operation Instructions

4.1. SafeFix™ CER Installation

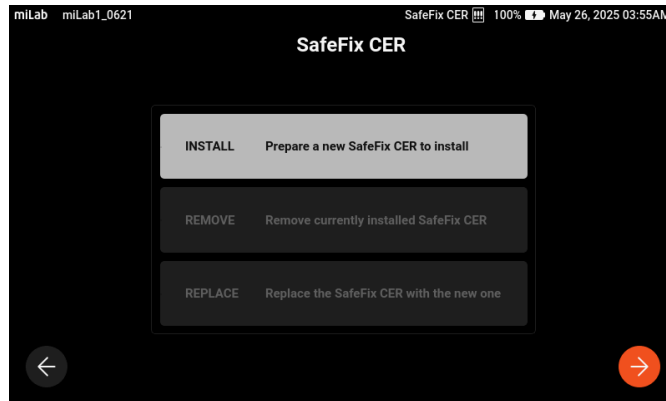
1. Preset miLab™ platform device and install SafeFix™ CER according to the miLab™ platform IFU.
2. Remove SafeFix™ CER from its packaging.
3. Tap the settings button  in the bottom left corner of the home screen, then select [SAFEFIX CER]



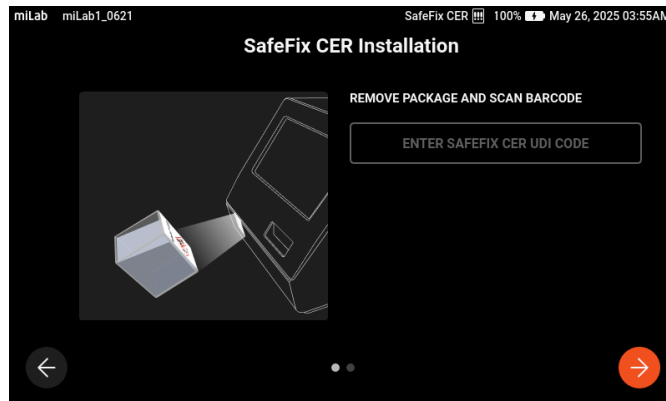
4. Confirm the status of SafeFix™ CER, then touch the [→] button.



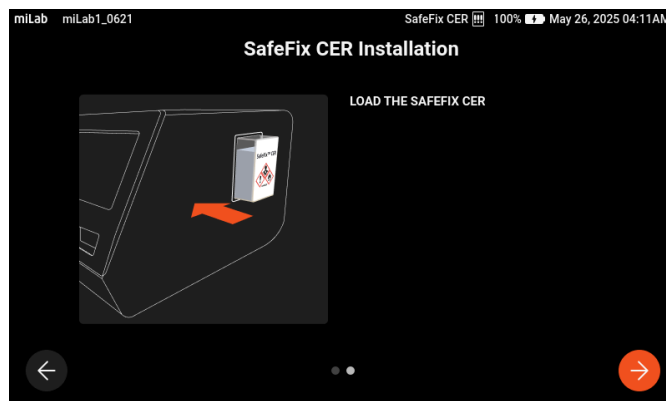
5. Select [INSTALL], then touch the [→] button.



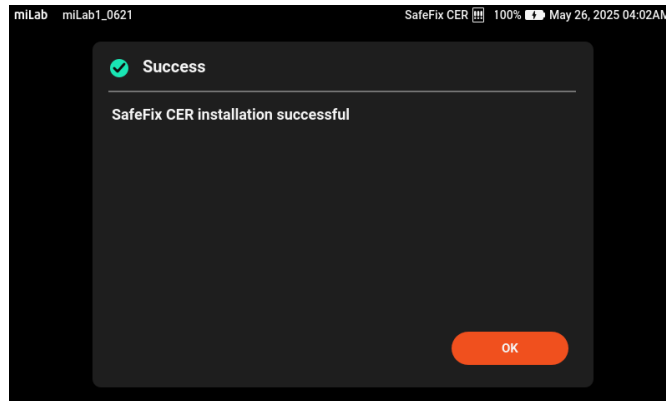
6. Scan the barcode on the product label of a new SafeFix™ CER, then touch the [→] button.



7. Gently insert the new SafeFix™ CER into the miLab™ Device SafeFix compartment, then touch the [→] button.




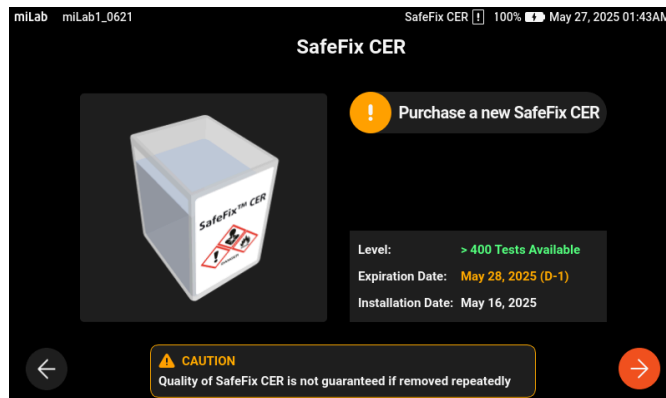
- If SafeFix™ CER is installed successfully, a success message will appear.



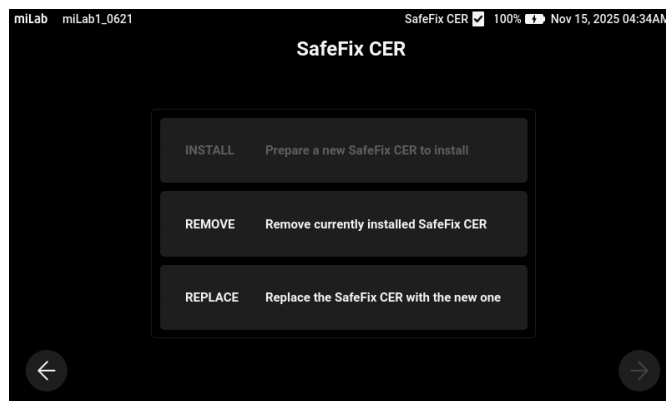
4.2. SafeFix™ CER Removal and Replacement

***If you use an expired SafeFix™ CER, the slide quality is not guaranteed, and it may cause test failure.*

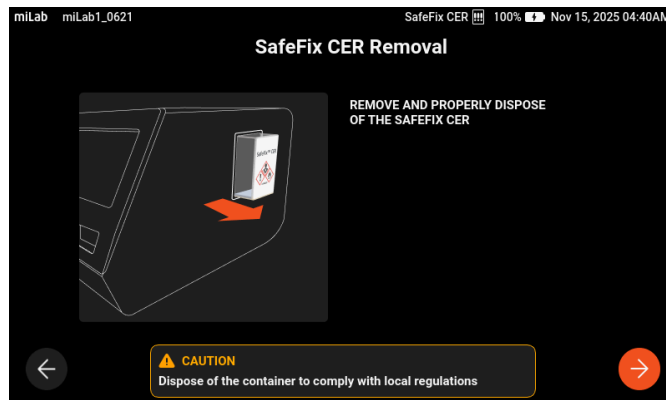
- Tab the settings button  in the bottom left corner of the home screen, then select [SAFEFIX CER].
- Review the information regarding the currently installed SafeFix™ CER, then touch the [→] button.



- Select [REMOVE] or [REPLACE], then touch the [→] button.



- The currently installed SafeFix will be ejected from the miLab™ Device automatically. Gently pull out the SafeFix™ CER, then touch the [→] button.



5. Refer to **4.1. SafeFix™ CER Installation** and install the new SafeFix™ CER.

Chapter 5. Operational Precaution and Hazards

5.1. General Safety Information

 Caution!

- Wipe off spilled fluids immediately with a soft tissue.

5.2. Warnings and Precautions for Safety

 Warning!

- DO NOT drink the decolorization and dehydration solution.
- The SafeFix insertion area on the miLab™ Device contains sharp needles. Avoid contact with the needles.

5.3. Precautions before Use

This product is ready for use and no further preparation is necessary.



Caution!

- This product is for In Vitro diagnostic use and should be used by properly trained individuals.
- This product should not be used for any purpose other than what was indicated in this document.
- Read the manual carefully before using the product.
- SafeFix™ CER is single-use and should not be used again.
- This product MUST be placed on a flat surface and kept in place while in use.
- This product should not be used if (1) the color has changed from a clear liquid, (2) the expiration date has passed or, (3) there are other signs of deterioration.
- The miLab™ Device of SafeFix compartment contains SHARP needles. During the preparation, DO NOT touch the needles.

5.4. Cautions during Use



Caution!

- Read the manual carefully before using the SafeFix™ CER.
- Ensure that there is enough of the dehydrating and decolorizing solution in the container.
- DO NOT leak the dehydrating and decolorizing solution in the miLab™ Device.
- May cause central nervous system depression and damage of liver, kidney, and heart.

5.5. Cautions for Storage



Caution!

- The product shall be stored at a temperature between 4°C and 30°C with adequate ventilation.
- This product shall be placed on a flat surface to keep it from falling.
- This product shall be stored out of direct sunlight.
- This product shall not be stored in areas with high humidity or wet areas.

5.6. Cautions for Disposal & After Use



Caution!

- After the SafeFix™ CER is used, it MUST be disposed of as medical waste.



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