

KYT  PEN

The Future in Cell Discovery & Manufacturing

# Flowfect Buffer™

Instructions for Use

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## 1. Important User Information

The information in this Instructions for Use pertain to Flowfect Buffer™. Instructions for use should be easily accessible to users of the Flowfect Buffer™.

Flowfect® is a registered trademark of the Kytopen Corporation.



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### 1.1 Support

For support contact Kytopen:

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[support@kytopen.com](mailto:support@kytopen.com)

+1 (617) 362-3058

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## 2. Introduction

Kytopen is developing platforms to accelerate the discovery and manufacturing of cell therapies. Flowfect® technology offers a scalable, non-viral solution to deliver genetic payloads to cells in order to augment their functionality. The technology also enables continuous flow genetic manipulation of cells in a platform that can be easily automated and can be used to process both small and large sample volumes.

Kytopen's Flowfect® technology is a proprietary electromechanical technology used for transfection through a combination of the Flowfect Tx™ and Flowfect Cartridge™ or Flowfect Discover™ and Flowfect Tips™.

## 3. Intended Use Statement

Flowfect Buffer™ is specified for use with Kytopen's Flowfect Tx™ and Flowfect Discover™ products only.

Flowfect Buffer™ is currently for Research Use Only (RUO).

**Flowfect® technology is not intended for diagnosis, treatment, or prevention of disease.**






For more information on our transformative technology please visit our website at [www.kytopen.com](http://www.kytopen.com).

## 4. Quality & Regulatory Information

Flowfect Buffer™ is intended for Research Use Only (RUO).

## 5. General Use Instructions

### 5.1 Safety and Environmental Considerations – Please read carefully

Symbol	Definition
	<b>Follow the instructions for use.</b> To ensure safe, reliable operation, always use the Flowfect Buffer™ according to the instructions in this manual.
	<b>Do not reuse-Single Use Only Materials</b> The Flowfect Buffer™ and the is designed for a single use; repeated use is not supported
	<b>Biohazard Waste</b> After using the Flowfect Buffer™ and the Flowfect® Cartridge dispose in a biohazard container and follow your laboratory's safety instructions for proper waste disposal practices.
	<b>Do not use if package is damaged</b> Do not use the Flowfect Buffer™ if the packaging is open or damaged. If the seal is broken, the Flowfect Buffer™ is no longer guaranteed to be sterile.
	<b>Temperature limit</b> Flowfect Buffer™ shall be stored at 2 – 8°C and used at room temperature (20°C).

### 5.2 Waste Disposal

Used Flowfect Buffer™ should be disposed of in compliance with local regulation for liquid biohazardous wastes.

### 5.3 Storage

The Flowfect Buffer™ should be stored in a refrigerator between 2-8°C.

### 5.4 Use

5.4.1 The Flowfect Buffer™ should be used at room temperature (20°C).

5.4.2 The Flowfect Buffer™ shall not be reused.

5.4.3 If the Flowfect Buffer™ looks cloudy or discolored, do not use it.

## 6. Document Change History

Version	Detailed Description of Change
0	Initial Release
1	<ul style="list-style-type: none"> <li>• Formatting changes: includes color updates for branding, image size, alignment, and borders; page breaks</li> <li>• Section 1, Important User Information: updated address and contact information after facility move</li> <li>• Section 2, Introduction: Added additional information about Flowfect® technology (copied language from Flowfect®Tx IFU DOC-408).</li> <li>• Re-sectioned Section 2 to pull Sections 2.1 and 2.2 one level higher</li> <li>• Changed 'Use Instructions' section title to 'General Use Instructions'</li> <li>• Section 5.2, Safety Symbols, added packaging and temperature icons.</li> </ul>
2	<ul style="list-style-type: none"> <li>• Updated formatting on cover page</li> <li>• Branding and Trademark Changes: <ul style="list-style-type: none"> <li>• Changed all instances of Flowfect®Tx to Flowfect Tx™ to reflect current trademark filing status.</li> <li>• Changed all instances of Flowfect® <b>Array</b> to Flowfect Discover™ to reflect current product name and trademark filing status.</li> <li>• Changed all instances of Flowfect® <b>Cartridge</b> to Flowfect Cartridge™ to reflect current trademark filing status.</li> <li>• Changed all instances of Flowfect® <b>Buffer</b> to Flowfect Buffer™ to reflect current trademark filing status.</li> </ul> </li> <li>• Section 4, Quality &amp; Regulatory Information: Removed estimated date of Master File submission; changed to RUO only.</li> <li>• Section 5.1, Restrictions: Removed section and moved Research Use Only to Section 4, Quality &amp; Regulatory Information</li> <li>• Section 5.4, Troubleshooting: Removed section and moved content to new Step 5.4.3</li> </ul>

# Flowfect Buffer Instructions for Use (IFU) (DOC-322) Ver. 1

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**Approved By:**

[\(CO-185\) CO - Updating Flowfect Buffer™ IFU with branding styles](#)

**Description**

Updating Flowfect Buffer IFU with current branding & trademark styles and other minor changes

**Justification**

Marketing

**Assigned To:**

Naomi Druy

**Initiated By:**

Naomi Druy

**Priority:**

Medium

**Impact:**

Minor

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**Version History:**

Author	Effective Date	CO#	Ver.	Status
Naomi Druy	October 13, 2023 10:20 AM EDT	<a href="#">CO-185</a>	1	Published
Naomi Druy	June 7, 2022 6:52 PM EDT	<a href="#">CO-92</a>	0	Superseded