

DATA FILE

# Zeito™ Plus: Cell Encapsulation System

**Zeito™ Plus cell encapsulation system** is an automated, closed unit that enhances the culture of cells during process development and manufacturing of cell therapies and regenerative medicines.

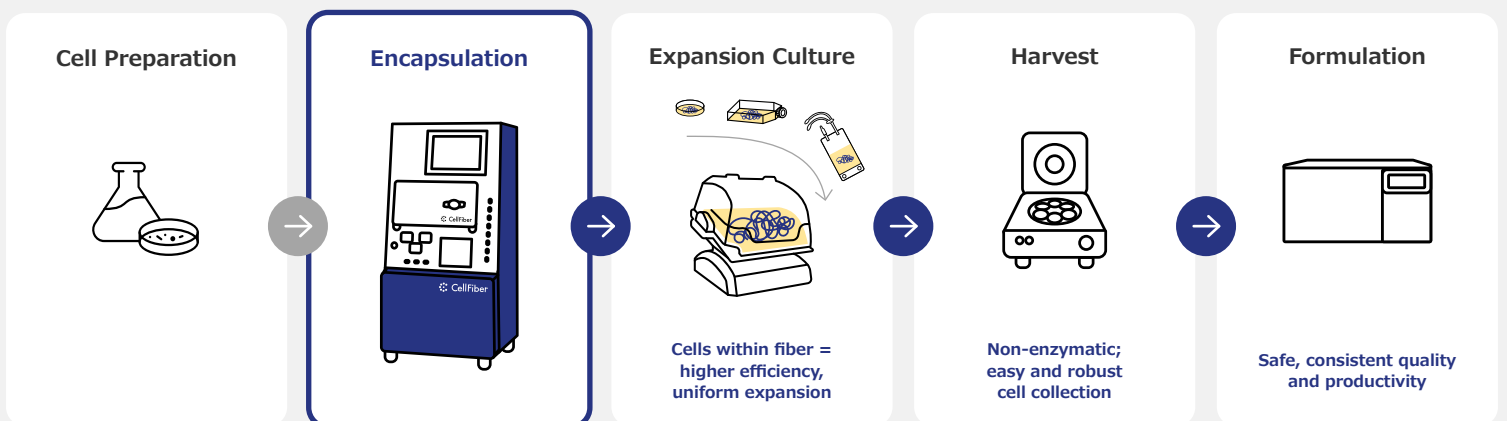
The novel fiber technology is fabricated from medical-grade alginate hydrogel and serves as a nourishing lumen for cells to be cultured biomimetically, ensuring a safe and highly-efficient cell expansion. System features include:

- 1 AUTOMATED**  
Enables automated, reproducible large-scale culture
- 2 FLEXIBLE**  
Compatible with diverse cell types and culture equipment
- 3 FULLY-CLOSED**  
Minimizes contamination risk via single-use design
- 4 TRACEABLE**  
Offers material traceability and software audit trail/user access compliance



## Zeito™ cell encapsulation system in cell therapy manufacture workflow

From PoC to Manufacture



Feature	Specification
Single-Use	Yes
Closed	Yes
Automated	Yes
Data Logging	<ul style="list-style-type: none"> <li>• Full sensor graph</li> <li>• Process log</li> <li>• Error/alarm log</li> <li>• ISBT barcode reader</li> </ul>
Regulatory Compliant Software	<ul style="list-style-type: none"> <li>• User access control</li> <li>• Audit trail</li> <li>• Device management</li> </ul>
User Interface	<ul style="list-style-type: none"> <li>• Color touch panel GUI</li> </ul>
Dimensions	<ul style="list-style-type: none"> <li>• 699 mm W x 565 mm D x 1380 mm H</li> <li>• 128 kg</li> </ul>
Power	<ul style="list-style-type: none"> <li>• 100-120 VAC (50 / 60 Hz)</li> <li>• ≤ 200 VA</li> </ul>
Connectivity	<ul style="list-style-type: none"> <li>• USB3.0</li> <li>• RJ-45 LAN port</li> </ul>
Regulatory Compliance	<ul style="list-style-type: none"> <li>• System: GAMP 5, 21 CFR Part 11</li> <li>• Reagent kit: USP &lt;1043&gt;, ISO 20399</li> <li>• Single-use kit: ISO 11137</li> </ul>

## Single-Use Kit

The **Zeito™ Plus single-use kit** provides a functionally closed environment for seamless cell encapsulation. Integrated sterile connectors facilitate rapid attachment to culture bags and pre-filled CellFiber® reagent bags.

## Reagent Kit

The **Zeito™ Plus reagent kit** includes alginate solutions, crosslinkers, and wash solutions provided in bags for immediate connection. Core solutions are supplied in septum-capped bottles to ensure fresh cell suspension preparation. Specialized kits are available for both adherent and suspension cell cultures.

Each kit is designed for 5 L culture scale, with the following estimated yields:

- Adherent cells:  $>1 \times 10^9$
- Suspension cells:  $>1 \times 10^{10}$

## Ordering Information

Product Code	Product Name
CFE-M01	Zeito™ Plus Cell Encapsulation System
CMT-101	Zeito™ Plus Single-Use Kit
FRM-05A	Zeito™ Plus Reagent Kit for Adherent Culture
FRM-05S	Zeito™ Plus Reagent Kit for Suspension Culture

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