

EVOLVING

THE FUTURE OF CELL THERAPY MANUFACTURING

Cell therapy



Streamlining cell therapy manufacturing with rapid and reliable bead removal

Situation

The successful development of a cell therapy can have a life-changing impact on patients with diseases such as cancer and immune-mediated conditions. In this growing industry, rapid manufacture of a safe and effective therapeutic is vital.

An important step of cell therapy manufacturing is isolating target T cells using magnetic beads, which must then be removed. The T cells can then be transformed into a highly targeted therapeutic product.

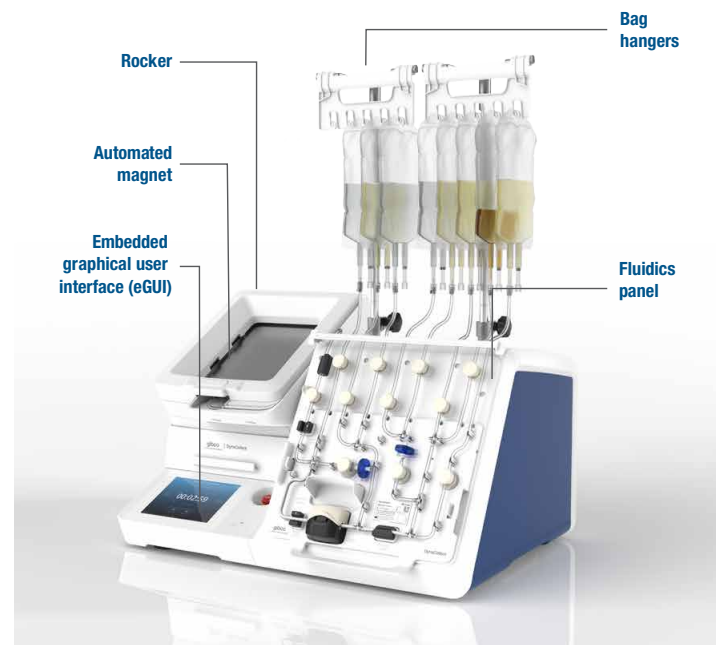
The challenge is to remove the paramagnetic beads quickly while ensuring recovery and viability of the target T cells, so they are ready for downstream applications. Manual bead removal solutions are often labor-intensive and vulnerable to human error and long throughput times. With a manual system, it is also difficult to achieve reproducible results with different operators. With a limited number of cells available to work with and variable cell quality, failure to correctly remove the beads while maintaining high cell recovery could directly impact a patient's treatment. Consequently, the success of bead removal is vital in the manufacturing process and essential for the delivery of effective therapies. Here we outline a customer's transition from a manual to an automated bead removal system, and how this helped to accelerate the process while maintaining cell recovery and viability.

Solution

The customer had an established workflow utilizing the Gibco™ CTS™ DynaMag™ Magnet—a manual cell isolation and bead

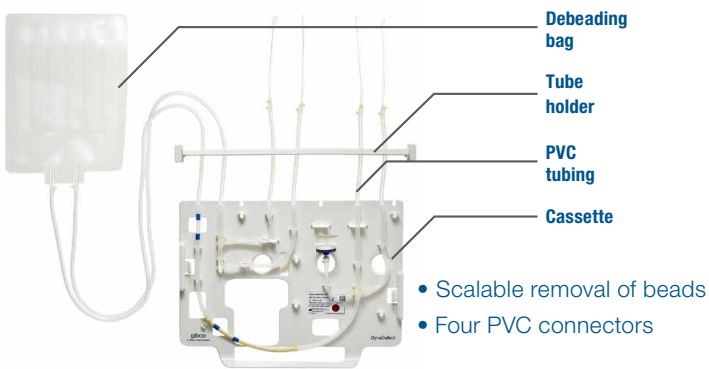
removal device—and was interested in trialling an automated approach. The Gibco™ CTS™ DynaCollect™ Magnetic Separation System was designed to enable closed, fully automated, and rapid cell isolation and bead removal, while decreasing variability in cell therapy manufacturing.

CTS DynaCollect Magnetic Separation System



When used with the dedicated single-use Gibco™ CTS™ DynaCelect™ Bead Removal Kit, the system reduces the manual processes needed for the bead removal step of cell therapy production. The CTS DynaCelect instrument is a flexible and modular system that can run as a stand-alone device or be integrated into an existing workflow for easy scale-up. The customer wanted to see if the system could support a consistent and reliable workflow, with operator-independent results. Replacing the CTS DynaMag Magnet with the CTS DynaCelect system was a simple process requiring little optimization. In addition, reproducible results could be achieved whether the person operating the instrument had used it many times or had little experience.

CTS DynaCelect Bead Removal Kit



The Gibco CTS DynaCelect Bead Removal Kit is specifically designed for bead removal from immune cells for cell processing applications.

Results

As the existing workflow was already optimized around Gibco™ products, the CTS DynaCelect system was easily incorporated with no challenges around technology transfer. Using the CTS DynaCelect system, the customer was able to achieve comparable cell recovery to that obtained with the CTS DynaMag Magnet, at around 90%. The customer was also able to reach around 95% cell viability, exceeding their criteria of 90% (Figure 1). Achieving sufficient cell recovery and viability is vital to rapidly develop a successful therapy.

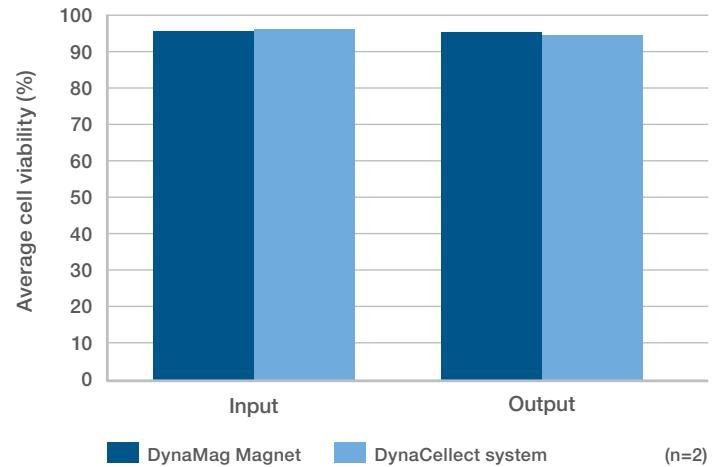


Figure 1. Cell viability is maintained using the CTS DynaMag Magnet and the CTS DynaCelect Magnetic Separation System.

Crucially, bead removal time when using the CTS DynaCelect system was significantly reduced compared to the CTS DynaMag Magnet workflow. The CTS DynaCelect system accelerated the debeading process from 2 hours to 29 minutes, representing a 76% reduction, without impacting cell recovery (Figure 2). Shortening this process and minimizing handling enables developers to accelerate throughput, maximize consistency, and streamline the cell therapy manufacturing workflow.

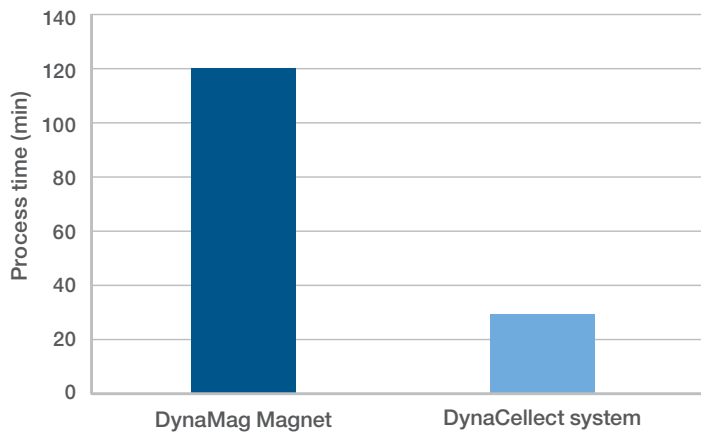


Figure 2. Cell recovery time savings when using the CTS DynaCollect system. Process time was reduced from 120 minutes with the CTS DynaMag Magnet to 29 minutes with the CTS DynaCollect system, representing time savings of 91 minutes.

The ease of use, speed, and consistent performance was evident, with the system demonstrating the same impressive results as part of an existing workflow as the results obtained during development. Furthermore, seamless transition from the CTS DynaMag Magnet to the CTS DynaCollect system meant the customer could experience excellent results without disruption.

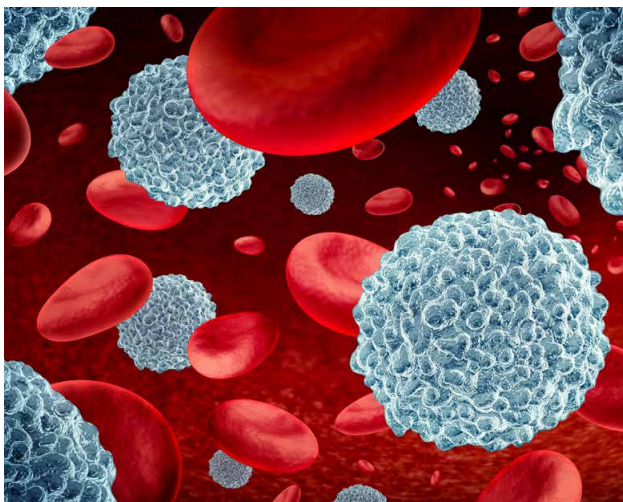
Summary

The CTS DynaCollect system enhanced bead removal by:

- Achieving 90% cell recovery and 95% viability
- Reducing bead removal time by >75%
- Eliminating the need for manual handling

In addition, because the CTS DynaCollect system uses a continuous flow process for bead removal, the processing volume is potentially unlimited, making it well suited for scaling up. By taking advantage of this, users can easily and successfully scale up their process, transitioning from producing a single treatment for one patient to producing for many.

Combining scalability, flexibility, and automation with high speed, proven performance, and modularity, the CTS DynaCollect system can help developers streamline and optimize their workflows. By staying ahead in the rapidly growing cell therapy industry, manufacturers can quickly deliver their essential therapies to patients who urgently need them.



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Learn more at thermofisher.com/dynacollect

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