


Single-use technologies

Maximize your simplicity



We designed the Thermo Scientific™ DynaSpin™ Single-Use Centrifuge with simplified installation and operation, helping to enable a substantial reduction in filter usage. Process optimization maximizes your savings in consumable and material usage, reduces cleanroom footprint and warehouse space, and ultimately lowers the risk to production. With the DynaSpin Single-Use Centrifuge, minimalism is about intentionality.

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The need for innovative single-use technologies for harvest applications that serve the markets for recombinant proteins, monoclonal antibodies (mAbs), and bioengineered vaccines remains high. With a growing need for optimization of processes requiring high cell densities and more efficient processing steps, customers are seeking robust solutions in the harvest step to address unmet needs in the workflow.

Customer challenges with the harvest operation have led to the creation of the DynaSpin centrifuge. This product delivers superior separation and next-generation automation, adding significant value to drug manufacturers.

Next-generation harvest technology delivers closed-system bioprocessing with safe, robust, and ergonomic operation

The DynaSpin centrifuge provides a solution the industry needs with specially designed ergonomic hardware, consumables, and simple software, decreasing both process and facility requirements for the harvest unit operation. The DynaSpin centrifuge is a truly scalable solution that allows process volumes from 50 to 5,000 L and adds efficiency, especially at larger scales where multiple units can be organized in a daisy chain to optimize volumetric pull-down time from the bioreactor. The DynaSpin hardware is a user-friendly device that can be set up and operational in a matter of minutes. The DynaSpin consumable is composed of a rotor and tube set that implements disk stack technology and three line sets with integrated best-in-class sensors that allow analysis and control of critical process parameters. It has one inlet line where cell culture fluid is supplied to the rotor and two outlet lines that carry the separated product (centrate) and concentrate streams. Each line set contains appropriate sensors that communicate with the hardware via the firmware on the built-in touchscreen.

We help enable customers to:

- Operate more dynamically to capitalize on opportunities
- Power processes that enable confident scaling from process development through manufacturing
- Efficiently use cleanroom space by directing reducing filter area requirements

Meeting your needs of:

Process efficiency

Risk mitigation and quality control

Process sustainability

Through:

- Reduction in traditional depth filter surface area across all scales, removing the bottleneck of large-scale bioreactors
- Increased process monitoring automation enabling plug-and-play functionality and reducing risk
- Increased cleanroom efficiency, labor reduction, and decreased unit operation footprint



Fewer filters and single-step processing

Stainless steel centrifugation requires significant capital and facility investment, with clean-in-place (CIP) and steam-in-place (SIP) taxing the facility during both installation and once finalized with labor and operational expenditures. The value of stainless steel centrifuges is not recognized until significantly larger volumes are reached, and, therefore, return on investment (ROI) is deferred until the facility reaches the preplanned maximum volumetric capacity. These challenges have led many manufacturers to single-use systems as a more sustainable and cost-effective alternative to stainless steel. Single-use centrifugation overshadowed the competition because of the significantly increased efficiency in volume processing within reasonable timeframes.

Traditionally, the depth filtration process consists of two filtration stages, one for primary filtration and a second to reach the purification parameters required by the process. In general, depth filters scale up well until large volumes force scaling out.

Massive numbers of depth filters translate into a heavy dependence on the supply chain, increased complexity in facility logistics and storage, increased cleanroom footprint requirements, significant buffer requirements and associated components (e.g., water for injection (WFI), mixing vessels, and filters), and increased labor and hands touching during every step.

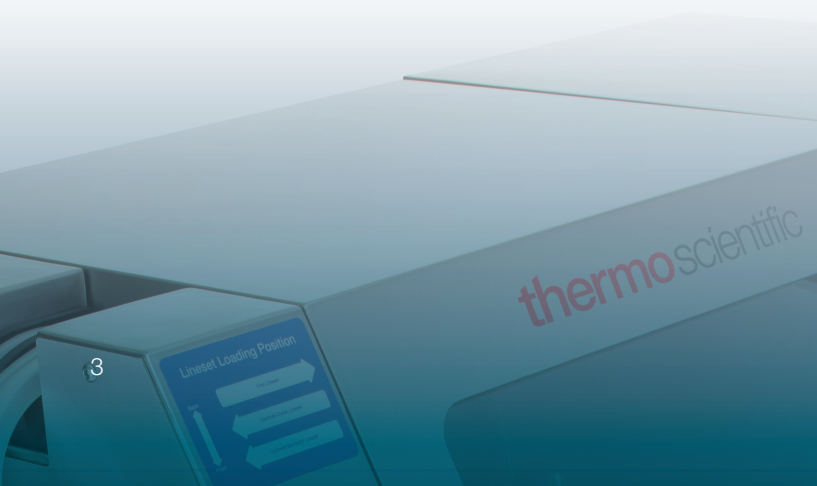
The DynaSpin centrifuge replaces the first stage of depth filtration with single-use centrifugation, directly reducing the quantity of required clarifying filters. This system creates harvest efficiency, allowing a singular step to separate out particulates and enabling customers to accomplish what a normal two-stage depth filtration does at a reduced cost, footprint, and consumable usage. The DynaSpin centrifuge helps bring significant value by decreasing the number of depth filters, in turn reducing inventory and warehouse storage requirements and supporting sustainability by reducing filter and buffer waste.

Bridging the upstream and downstream workflows

The DynaSpin centrifuge fills a key gap in bioproduction workflows by offering a competitive solution to the harvest application. Intensified upstream processes and the adoption of large-scale single-use bioreactors place increased stress on downstream unit operations. The DynaSpin centrifuge demonstrates a significant value-add in the single-use bioproduction workflow.

Key features

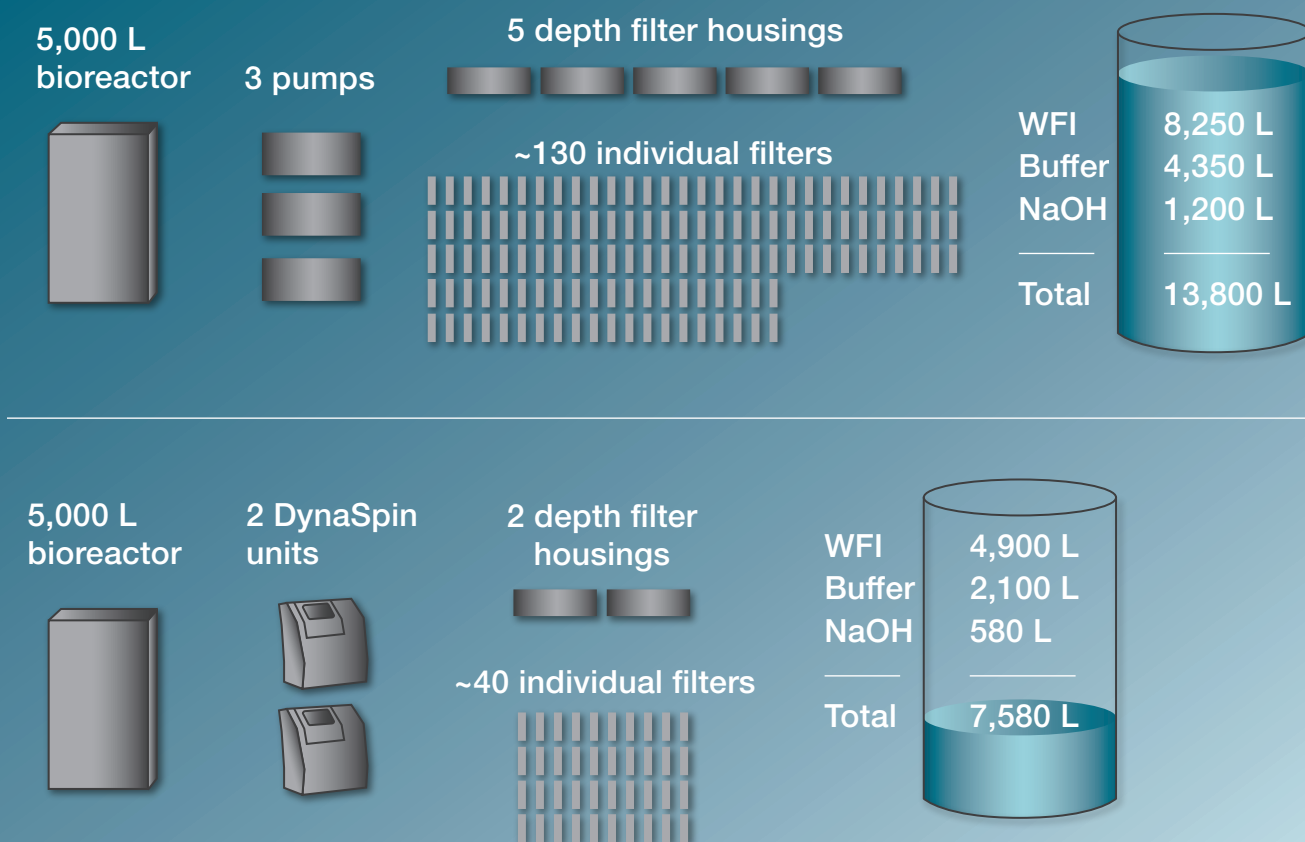
- Reduction in depth filter surface area across all scales
- Mitigates bottlenecks in large-scale bioreactors
- Closed system results in process risk reduction
- Increased process monitoring automation enables plug-and-play functionality
- Increased efficiency helping to enable a reduction in labor
- Decrease in unit operation footprint requirement
- Single-use centrifugal rotor
- Simple installation and operation



Offering significant reduction in depth filters, depth filter hardware, WFI, buffer, and waste requirements

The DynaSpin centrifuge increases filter capacity. This reduction in dependency on filter supplies can help mitigate bottlenecks in facility harvest steps and help increase overall profit for the manufacturer. Traditionally, the harvest process is labor-intensive with each filter received, stored, transported into staging areas, cleaned, transported to the point of use, unpackaged from secondary packaging, cleaned again, and installed into the filter housing hardware individually.

An average 5,000 L process could expect to see 130 individual filters used per run processed. The data below illustrates a reasonable expectation that using the DynaSpin centrifuge results in a significant reduction (~3x) in the number of filters required. Labor, facility requirements, user experience, and ultimately cost are all significantly decreased when DynaSpin technology is implemented into your large-scale bioproduction workflow. In some applications, the DynaSpin centrifuge has demonstrated up to a six-fold reduction in filter area requirements.



Comparison of traditional harvest requirements at 5,000 L scale (top) compared to a 5,000 L process using the DynaSpin centrifuge (bottom).



DynaSpin

Single-Use Centrifuge

Automation

The DynaSpin centrifuge is equipped with novel automation technology not previously available in the harvest unit operation. Automation truly sets this solution apart from the competition. The design was crafted with ease of use in mind, exhibiting plug-and-play technology. Further value is apparent when operational efficiency is driven by helping to reduce cleanroom footprint and labor associated with setup time. The DynaSpin centrifuge is also compliant with the Code of Federal Regulations (CFR) Part 11, making data monitoring and archiving possible with sophisticated automation.

Learn more at thermofisher.com/dynaspin

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