Seitz™ depth filter sheets

IN FILTER MODULE AND CAPSULE FORMATS

The efficient and economical method of biopharmaceutical process filtration

Our experience in filtration, separation and purification technologies has led to the development of a range of depth filters that can increase both efficiency and economy.

The depth filter modules are cost-efficient by incorporating a high filter area into a given size. The extra thickness of Seitz™ depth filter sheets increases their dirt-holding capacity.

In applications where centrifuge equipment and tangential flow (TFF) devices have been traditionally used for primary separation or clarification process steps, depth filter modules offer a simple, yet robust, alternative that requires less equipment, sophistication and labor to operate.

The innovative and robust design offers high resistance to back pressure failure of the depth filter media. Incorporating conjoined inner and outer support layers, SUPRAdisc™ II modules create a rugged structure that both supports and protects the Seitz depth filter sheets.

The industry shift towards disposable biopharmaceutical processing has reduced costs, foused on safety and enhanced process optimization.

Fig 1. Seitz depth filter sheets are available in a range of filter and capsule formats.

Features and benefits

- Depth filter modules offer a very high filter area volume in a single industry-standard size, making it possible to reduce capital investment by using fewer modules per batch.
- Disposable systems save time and money, reduce cleaning and cleaning validation, and reduce operators' exposure to associated hazardous processes.
- A wide range of filter sheet (media) grades is available.
- Exceptional quality control.

Seitz depth filter sheets

Exceptional retention, consistency and quality

- Rigorous manufacturing process control offers consistent performance for a smooth scale-up.
- The filter matrices deliver fine retention ratings down to 0.1 µm.
- The wide range of filter sheet grades make it easier to find a suitable match for the application.
- Validation guides for pharmaceutical grade sheets can be provided to help reduce the time and cost required for validation.

Many years of manufacturing experience have led to producing filter sheets that support the strict requirements of the biotechnology and pharmaceutical industries. Manufacturing uses stringent in-process control methods to maintain constant filtration performance and purity of the filter medium.

Our filter matrices were developed specifically for the needs of the biopharmaceutical industry, supporting nominal retention ratings as low as 0.1 µm for optimal filtration of biological products and protection of downstream processing systems.

All Seitz filter sheets are produced using rigorous quality standards at an ISO 9001 facility that customers may inspect and audit.

Tighter grade sheets are also available for removing the smaller particles required by critical biopharmaceutical processes.

Strict manufacturing process control enables consistent quality, performance and scalability of our Seitz depth filter sheets from batch to batch. A wide range of filter sheet classes and grades are available, with different permeabilities and materials of construction. This means there's a suitable sheet for most biopharmaceutical applications. Our manufacturing capacity can make it possible to deliver up to a year's requirements from a single production run for ultimate process consistency.

Fig 2. Seitz depth filter sheets.

P-Series depth filter sheets

The P-Series depth filter sheets are specially designed to meet the strict requirements of the biotechnology and pharmaceutical industries. They cover a wide range of needs, from bioburden reduction (typical LRV of 9.5 with EKSP grade using *Brevundimonas diminuta*), fine filtration, clarifying filtration to coarse filtration. Strict manufacturing controls maintain purity of the filter medium and constant filtration quality, teamed with strong endotoxin control, low level beta glucan grades, and a complete validation guide. Each product is also delivered with a certificate of test for pharmaceuticalgrade filters.

HP-series depth filter sheets

The HP-series depth filter sheets combine two full-thickness, graded, high-efficiency P-Series depth filter sheets.
This technology compresses clarification processing steps, saving time and resources, and reducing operation costs.
High-purity pharmaceutical grade depth filter sheets are optimized for low endotoxin and low extractable levels.

BIO-series depth filter sheets

BIO-series depth filter sheets have been developed to meet the strict requirements of the biotech and pharmaceutical industries. Manufactured from purified natural and modified cellulose fibers, BIO-series depth filter sheets have reduced levels of ash and heavy metal extractables. The use and arrangement of selected cellulose fibers results in a low protein adsorption in the filter matrix and an excellent rinsing behavior after filtration.

V100 P depth filter sheets

The V100P depth filter sheets are developed for the removal of fine contaminants from feedstreams where virus or virus-like-particles are the product of interest, such as in the production of vaccines or gene therapies.

K-series depth filter sheets

The K series depth sheets have 13 different retention ratings and cover a wide range of needs from bioburden reduction to fine and coarse filtration. Their balanced composition of cellulosic fibers, diatomaceous earth and perlite enables the creation of a well-defined matrix, which specifies the retention ratings of the 13 different grades of the K-series.

T-series depth filter sheets

The T-series depth filter sheets include seven different grades. Similar in composition to the K-series, the T-series depth filter sheets cover a range of coarse filtration, enabling them to be used to remove large contaminants. They are characterized by a more open structure and combine high outputs with long filtration cycles due to their high dirt-holding capacity.

AKS-series depth filter sheets

The AKS-series depth filter sheets use powdered activated carbon (PAC) immobilized within a matrix of cellulosic fibers to eliminate the need for handling bulk powdered carbon. Used primarily for its adsorption of colors and other impurities, AKS depth filter sheets reduce the need to work with PAC, which can contaminate a cleanroom and take significant time to remove and clean.

Fig 3. SUPRAdisc I module with AKS grade media.

SUPRAdisc depth filter modules

Formatting Seitz sheets in an innovative design

- A large filter area per module.
- Up to 5 m^2 (54 ft^2), an exceptionally high level of filter area per industry-standard size module.
- Enables reduction in capital equipment costs by reducing the number of modules.
- More rigid design allows up to four (4) filters to be stacked vertically for substantial density – up to 20 m^2 (215 ft^2) of available surface area.
- Wide range of module styles and sizes and filter media make SUPRAdisc modules suitable for most applications.

Depth filter sheets have been used for a vast range of applications, using an array of equipment primarily based on filter presses. With their excellent mechanical strength, Seitz depth filter sheets can be incorporated into disposable capsules for single-use applications , reducing cleaning and cleaning validation, simplifying installation, and reducing time between batches.

SUPRAdisc depth filter modules provide a significant filter area within industry standard dimensions. The largest 16 in. SUPRAdisc modules offer 5 m^2 (54 ft^2) of filter area. This may help in reducing capital equipment expenditure by filtering the same volume of product with fewer modules.

The individual filter cells that make up each SUPRAdisc module are constructed by joining two or more depth filter sheets, separating them with a single polypropylene drainage plate and edge-sealing them in an injection molding process. The drainage plate aids with the flow distribution as well as providing downstream support to the filter sheets to enable an excellent flow distribution throughout the entire module and to increase filter cell stability.

SUPRAdisc depth filter modules are built around a polypropylene tubular core that carries the load when the modules are stacked vertically. Up to four modules can be stacked without concern over deformation due to weight and stress that might otherwise impact the integrity of the filters.

The SUPRAdisc module adapter has two O-rings and a bayonet lock, a typical configuration in the pharmaceutical industry. As a result, SUPRAdisc modules can be installed quickly and easily into filter housings. A flat gasket adapter is also available for installation into housings that only allow flat gasket sealing arrangements. The flat gasket adapter features an integrated gripping groove that permits the use of a module-lifting device.

All grades of Seitz depth filter media in flat sheet formats may be incorporated into SUPRAdisc modules, so the change from an open-sheet filter system to a modular system is straightforward, requiring little revalidation.

A range of module types is available with different permeabilities, filter media and diameters – 12 in. modules (284 style) and 16 in. modules (410 and 413 style). This enables the filter system to be optimized to suit specific filtration tasks.

Fig 4. 12 in. diameter SUPRAdisc module with a double O-ring and bayonet lock adapter.

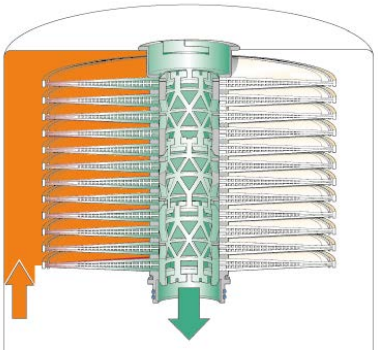

Fig 5. Illustration showing flow path and internal filter cell structure of the modules.

SUPRAdisc II depth filter modules

An evolutionary change

- The dual separator plate design includes support layers that protect filter sheets from pressure surges, reducing the risk of lost product batches caused by pressure blowouts.
- Components are locked together in a unitized body that increases robustness and integrity.
- Efficient use of available filter surface area.
- Limits the need for direct operator handling of filter cells reducing damage and promoting uniform performance.
- The largest 16 in. modules provide a substantial 5 m^2 (54 ft^2) of filter area.

The SUPRAdisc II depth filter module locks together to support every component of the filter to improve robustness and integrity. Through direct support of the filter sheets. Both on the upstream and downstream sides, the SUPRAdisc II design guards against ruptures caused by over-pressurization. The use of both inner and outer separator plates enables more efficient use of the available filter surface area by removing sheet-to-sheet contact. This contact can contribute to loss of available filter area and a reduction in overall expected filter performance.

The enclosed design of the SUPRAdisc II depth filter also guards against damage by limiting direct operator handling of the discs.

The depth filter module can be used with either a double O-ring or flat gasket filter housing. The ability to fit either type of housing enable the modules to be used across a wide range of existing equipment. The molded filter components are made of polypropylene, while the O-rings are made of silicone as standard or with an option of other gasket materials.

As with our SUPRAdisc modules, up to four SUPRAdisc II modules can be stacked without concern of deformation or loss of integrity. This is because the tubular core is capable of carrying the saturated wet weight of the modules, reducing the compressive forces on individual filter cells, and subsequently on the filter sheets, to avoid possible bypass conditions.

Fig 6. SUPRAdisc II - 16 in. diameter modules with flat gasket end fittings.

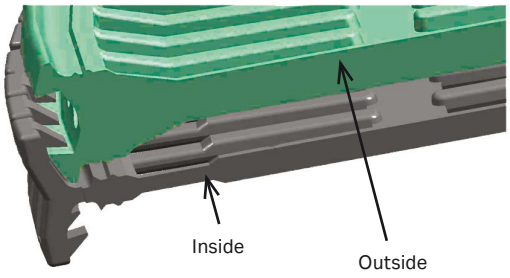

Fig 7. Separator plate design.

SUPRAdisc depth filter modules

Double-layer depth filter modules for high-performance cell clarification

Frequently, single-layer depth filter modules are unable, in a single stage, to remove the variety and quantity of impurities found in today's biopharmaceutical applications.

- Combines pre-clarification and clarification within a single module.
- Increases filtration efficiency by up to 30% more than single-layer formats.
- SUPRAdisc HP depth filter modules incorporate two layers of Seitz filter media into a single module to remove a variety of particle sizes and concentrations.
- The downstream layer enables increased efficiency of the upstream layer.
- Each 16 in. diameter module provides up to 2.5 m^2 (27 ft^2) of available filter area per module.

As a result, multiple stages of filtration or capital-intensive equipment each remove a specific range of particles. SUPRAdisc HP depth filter modules can provide a substantial improvement by incorporating two full-thickness depth filter sheet layers, making it possible, for example, to combine cell harvesting and final clarification into a single step. The SUPRAdisc HP modules offer enhanced clarification capabilities for process steps with high solids content, wide particle distributions and low cell viability. A key advantage of using the SUPRAdisc HP depth filter modules is the wide variety of Seitz depth filter sheets that can be combined to a suitable filter for each specific process need.

The availability of 12 in. and 16 in. – diameter SUPRAdisc I HP modules, and 16 in. diameter SUPRAdisc II HP modules, the optimum module format to be selected for meeting particular process parameters.

Fig 8. SUPRAdisc module with flat gasket adapter.

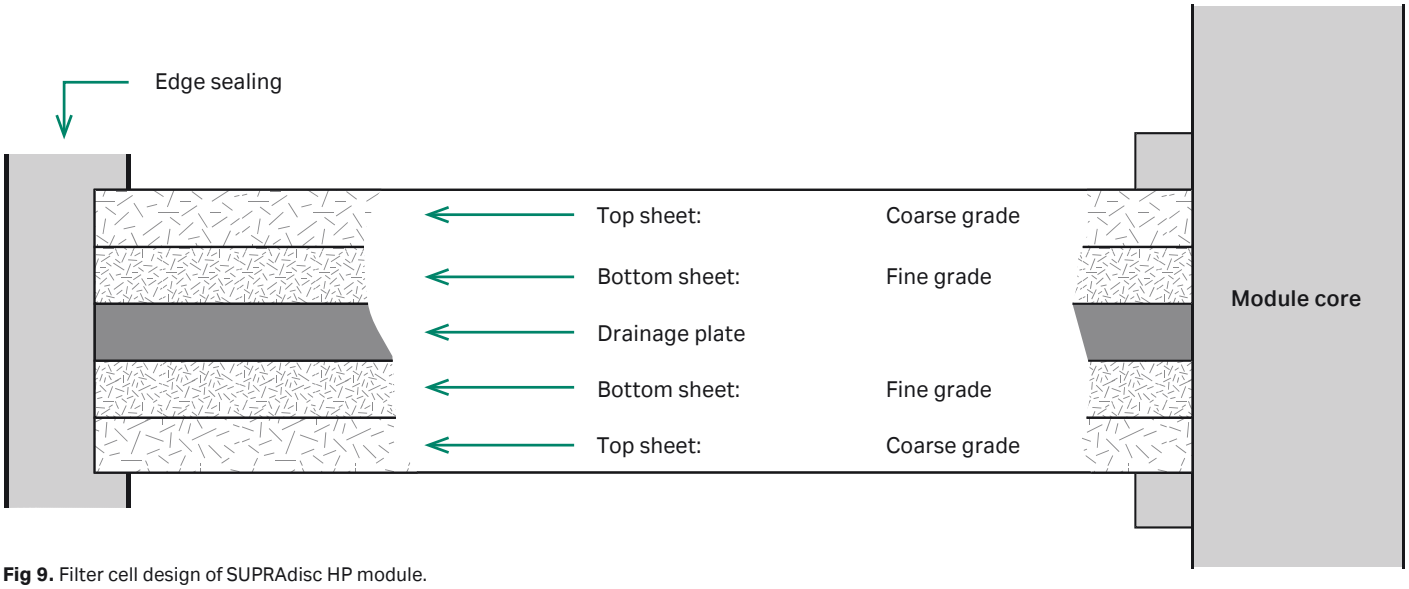

Fig 9. Filter cell design of SUPRAdisc HP module.

Supracap 50 depth filter capsules

Helps get new products to market faster and more efficiently

Supracap 50 capsules are designed for developing and optimizing a process during scale-up and scale-down studies. They can be used to quickly and accurately determine what grade of Seitz depth filter sheet media could optimize performance in a particular process application and also help to estimate the filter area required to meet specific process volume requirements. Supracap 50 capsules are scalable to Supracap 100 and Stax capsules, SUPRAdisc I and SUPRAdisc II depth filter modules. Supracap 50 capsules are also available with Seitz HP sheet media (double-layer) to scale to larger formats.

Supracap 50 capsules are available with a wide range of Seitz depth filter sheet media for optimal grade selection. With 22 cm^2 (3.41 $in.^2$) of filter area of the same Seitz filter sheets used in all SUPRAdisc modules, Supracap 50 capsules provide an optimal product scale for initial process development projects. The hold-up volume of Supracap 50 capsules is very low, which reduces the time and expense of introducing additional flushing fluids at the beginning and the end of the process. The product adds value to applications such as cell harvesting, antibiotics production, serum processing and clarification of fermenter broth.

- Helps process developers get to market faster and more efficiently.
- Ready-to-use format makes it easier for researchers to evaluate filter sheet performance.
- Uses the same filter sheets as production scale filter modules and capsules.
- Filter sheet manufacturing process controls enable more accurate scale-up.

The Supracap 50 capsule offers broad chemical compatibility with a wide range of solutions found in the biopharmaceutical industry. The Supracap 50 capsule is disposable, which saves time during manufacturing and lessens the need for cleaning operations. Instead of having to assemble appropriate filtration products, Supracap 50 capsules are supplied in a ready-to-use format - and feature a connection that is compatible with luer lock access devices for ease of use. An upstream vent valve on the Supracap 50 capsule makes it easier to remove air from the capsules prior to use.

Fig 10. Supracap 50 capsule.

Supracap 100 depth filter capsules

Flexible format filters bring the benefits of disposables to a wide application range

- SUPRAdisc II module concept in an encapsulated cartridge format.
- Scales from just a few liters to full process volumes.
- Disposable capsules lessen the need for cleaning operations and help to protect operators from hazardous substances.
- Choice of in-line or T-styles to fit different footprints and process needs.
- Can be manifolded together or with other Kleenpak™ Nova capsule filters to create disposable systems.

Supracap 100 depth filter capsules offer an innovative format that can be scaled to high volumes. The disposable design removes the time required to assemble and clean filter components, thus saving labor and downtime. As there is no need to clean these filters and ancillary equipment operators are not exposed to related hazardous process flows and cleaning solutions.

The internal depth filter cartridge assembly draws upon the design of the larger SUPRAdisc II modules. By supporting both the upstream and downstream layers of the depth filter sheets, back pressure failure and the associated loss of product batches is unlikely. The dual supporting layers mean that the filter sheets are not in contact, which means as much of the filter area as possible is available for blinding.

Supracap 100 depth filters are offered in a flexible format so that they can be scaled to match your requirements throughout your product's lifecycle. They are available in both in-line and T-styles to fit different footprints and needs. Multiple filters can be manifolded together to scale up production volumes and meet specific application requirements. The T-style is suitable for constructing disposable systems of multiple capsules in series or in parallel configuration.

Fig 11. Supracap 100, in-line capsule with depth filter cartridge shown.

Supracap 100 depth filter modules

The filters can even be purchased as pre-assembled manifold components. As a fully disposable unit, the installed cost of a Supracap 100 capsule is typically lower than a similarly sized stainless steel housing and module arrangement. As a result, they offer an extremely cost-effective alternative.

Supracap 100 filters come in 10, 20 and 30 in. lengths, providing a wide range of filter area.

Single layer capsule

	Surface area
5 in.	0.05 m² (0.54 ft²)
10 in.	0.10 m² (1.08 ft²)
20 in.	0.20 m² (2.15 ft²)
30 in.	0.30 m² (3.23 ft²)

HP version (double layer)

5 in.	0.025 m² (0.27 ft²)
10 in.	0.050 m² (0.54 ft²)
20 in.	0.100 m² (1.08 ft²)
30 in.	0.150 m² (1.61 ft²)

These different configurations can process liquids in batch sizes ranging from 3 to 100+ liters with a single filter. By manifolding filters, the vast majority of batch sizes can be accommodated. The Supracap 100 capsules are available in either single layer format (SL) or HP double-layer format (DL), and scale directly to SUPRAdisc and SUPRAdisc II formats. Supracap 100 capsule filters are available with a wide range of Seitz depth filter sheet grades for optimal grade selection.

Fig 12. Close-up of depth filter cartridge internal of the Supracap 100 capsules.

Camparison of scalability

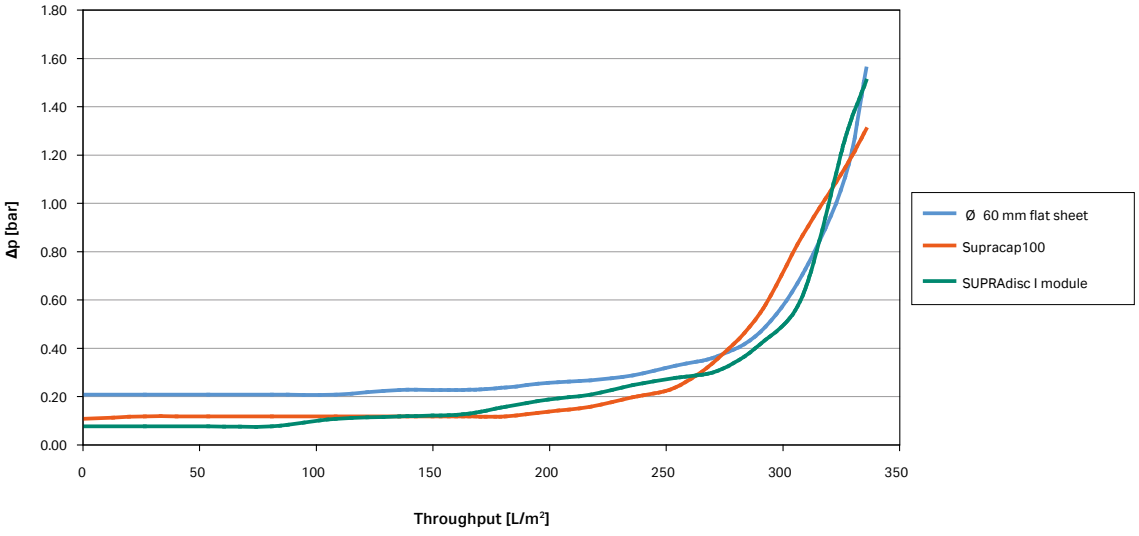

Fig 13. Example of scalability of the Supracap 100 capsules in comparison to 60 mm flat sheet (generally small-scale process development) and SUPRAdisc I modules (generally large-scale clinical or commercial scale manufacturing).

Stax™ disposable depth filter capsules

Versatile, single-use platforms for high-performance filtration

- Disposable format reduces the need for cleaning operations
- Scalable platforms grow as the process scales up

Stax disposable filter capsules are suited to demanding prefiltration and clarification biopharmaceutical applications.

The ready-to-use platform is designed to help streamline your process filtration applications. Stax disposable capsules are scalable in size and performance, and are available in three sizes, with filter areas from 0.025 m^2 to 2 m^2 (2.70 ft^2 to 21.5 ft^2) to meet lab, pilot and process needs.

Stax single-use capsules do not use stainless steel housings which require costly cleaning and cleaning validation. The chassis are designed to be assembled, used and unloaded by a single operator and provide an intuitive platform, ergonomically designed in a vertical arrangement with a small footprint to reduce errors and assist in delivering the clarification performance required in a flexible and versatile platform.

Fig 14. 10-high process chassis for up to 20 m^2 (216 ft^2) filtration area.

Fig 15. Pilot scale chassis for up to 4 m^2 (5.4 ft^2) filtration area.

More than one grade of Stax disposable filter capsule can be installed on a single chassis to deliver serial filtration and further improve the flexibility and economy of operating the Stax platform. The platform is easily integrated into our Allegro™ platforms as a comprehensive single-use system to further realize the benefits of implementing a single-use strategy.

Stax CF modules are configured with increased spacing to accommodate the volume of retained solids during the cake filtration of high-solids loading fluids. The modules deliver the simplicity and scalability of the Stax platform to processes that require the addition of diatomaceous earth or activated carbon to the process fluid and removal prior to subsequent downstream processing.

- Increased spacing options for high solids-loading fluids
- Well suited for the clean retention of processes using diatomaceous earth or activated carbon

Fig 16. Cut away of a Stax CF module showing the internal volume for retained solids of up to 13.2 L per module.

Supracap 200 encapsulated depth filter modules

High-area production filters in a disposable format

Supracap 200 depth filter modules provide the same high process volume capabilities as the 12 in. SUPRAdisc I and SUPRAdisc II depth filter modules in a disposable, encapsulated format. The Supracap 200 disposable module saves time and money because the filtration system is supplied ready to use. Little time and cost are required for assembly, sterilizing and cleaning this filtration system so turnaround time between process runs is kept low.

The disposable modules do not require cleaning, so the cost of cleaning chemicals and water for injection is eliminated. Cleaning validation of the housing is substantially reduced since only a few small parts come into contact with the process fluid. These parts can be placed in a parts washer and cleaned. The modules are used once and then discarded. Operators' exposure to process fluids and chemicals required for cleaning operations is greatly reduced.

Supracap 200 depth filter modules feature an innovative design in which a metal housing supports the soft-sided, polypropylene modules. The use of the housing and a soft-sided encapsulation technique decreases the cost and weight of the disposable modules. The distance between the outside diameter of the capsule and the inside diameter of the housing maintains capsule integrity during use.

The encapsulated module inside the housing reduces the overall void volume of the system, so that less rinse fluid is necessary pre- and post-use compared to conventional module and housing arrangements.

- Disposable format modules reduce the need for cleaning operations and help to protect operators from hazardous substances.
- Suitable for fine chemical filtration operations.
- Available with carbon sheets so that handling powdered carbon is not necessary.

Supracap 200 depth filter modules are offered with a wide range of Seitz filter sheets, including sheets with powdered activated carbon immobilized in a matrix of cellulose fibers. These sheets can utilize carbon for decolorization and the removal of trace contaminants without operators having to handle powdered carbon, which also tends to be dispersed by the air and may contaminate critical process equipment. Impurities in the liquid stream are forced to contact carbon-impregnated filter material as opposed to a bulk carbon process that relies upon diffusion of contaminants to reach the active sites in the carbon.

Fig 17. Supracap 200 with carbon sheets shown.

Fig 18. TUV-rated Cytiva housing for Supracap modules with the dome removed and Supracap 200 modules exposed.

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