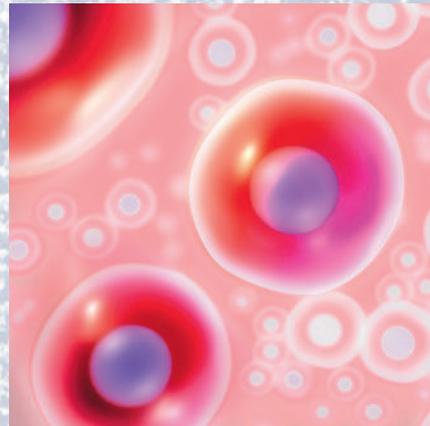
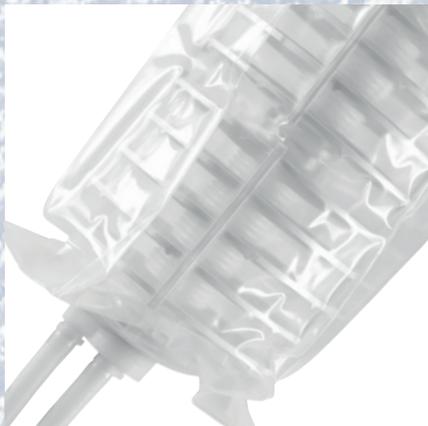




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SINCE 1938.



## LIFE SCIENCES

Microfiltration systems for the biologics, pharmaceutical, cosmetics and natural ingredients industries

## Introduction

### Principle of depth filtration

Depth filters are used to remove particles from a liquid. This means that liquids can be clear, fine or sterile filtered. "Thick" filter media (2.5–4.5 mm) are used with depth filtration. The particles are retained using two filtration principles: 1. surface filtration and 2. depth filtration. The liquid flows through a three-dimensional, asymmetrical fiber network in the depth filter.

The solid components are retained using mechanical and electrokinetic effects. This significantly increases the intake and adsorbing capacity. The purpose of a filtration process is either to purify a liquid (filtrate) or to retain solids (retentate). Depth filtration is mainly concentrated on the production of liquid filtrate. Filter sheets consist of a combination of especially receptive fibers (e.g. cellulose) and powdery, anorganic filter aids such as kieselguhr and/or perlite. The retention rate can be specified by the grinding method and the volume and type of base material used as the filter aid. Small quantities of polymer resin are added as a wet-strength agent. Depending on the type of polymer resin, a lesser or greater positive charge – also called the "zeta potential" – is produced when passing through the filter sheet. The positive charge improves the adsorption of small, negatively-charged particles or microorganisms. The interior absorption volume of a typical depth filter sheet is up to 4 l/m<sup>2</sup> of filter surface. During the filtration process, multiple depth filter sheets are used one after the other in a sheet filter (NOVOX®). This enables a large filter area to be created in a relatively small space. Another method of using depth filter sheets in a less time-consuming and more effortless way is to use depth filter modules (FILTRODISC™).

With this method, a pre-loaded filter pack is installed in a filter housing (DISCSTAR™). Depth filters are exhausted when the inner matrix is filled with slurry particles. One indication of this is the increasing difference in pressure between the inlet (unfiltrate) and the outlet (filtrate) and a lower flow rate of the liquid. After a certain point, the capacity of the depth filter is exhausted (1.5 bar for sterile filtration; 2.5–3 bar for clarifying filtration). Under certain circumstances it is possible for the filter to be regenerated.

With high particle loads (approx. 1.5 %), standard depth filters can blind fast. By using a filter aid such as kieselguhr (alluvial filtration process), the capacity can be increased. With alluvial filtration, filter aids are suspended in a liquid and then floated onto a support sheet in a plate & frame filter to form a filter cake. When doing this, the support sheets themselves function not as filters, but merely as a

support for the filter cakes, which is where the actual slurry removal takes place. The separation of particles in this process uses a mechanism similar to that with filter sheets. As with sheet filtration, an increase in the differential pressure indicates when the filter configuration is exhausted. As the filter cake is usually thicker than the filter sheets, alluvial filters have a longer lifetime due to their greater slurry absorption capacity. After filtration, the filter cake gets removed and disposed of depending on the nature of the slurry.

Nowadays the use of single-use components for the production of therapeutic active ingredients is more and more standard. Depth filtration is one of the most important and unattended steps in these processes.

Biotech processes have become the most popular systems for producing therapeutics and diagnostics in the biotech world. These processes consist of bacterial, yeast, insects or mammalian cells.

The first purification step after fermentation is the cell removal. The goal of the selected method is to remove the cells and cell debris as well as to reach the maximum product yield in compliance with the existing regulatory environment. Very often the first step is a centrifuge step. Followed by a depth filtration. An easy to use, easy scalable, robust and single-use depth filter system needs to be implemented.

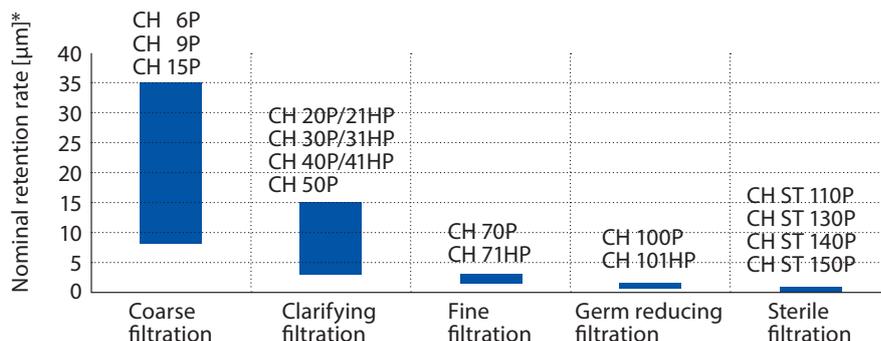
The decision regarding the right depth filtration system involves questions with regard to process performance, economics and existing regulatory requirements. Process performance challenges include higher and higher cell titers, cell debris content, scalability and flexibility for process changes and future processes, higher product yields and constant high quality product flow for further down-stream purification. Economic challenges include consumables costs, capital investment and maintenance costs. Regulatory challenges include adaptation of processes to the changing requirements of the regulatory bodies, with regard to cleaning regulations, cross-contamination and extractables & leachables.

Generally these processes start in research with several ml, scaled up to development with ~1 – ~25 l and to production with up to several thousand liters. Separating the cell mass is the first step in the purification lines followed by the filtration and chromatography steps.

## Depth filter media

Depth filter sheets are used to remove particles from liquids. Filter sheets are ideal for higher particle load filtration, where mere surface filters such as membranes do not provide enough life-time. With a thickness of 3–4 mm, more than 3000 times the size of a 1 micron particle, millions of microparticles can be trapped in every square meter of filter area. Typically, filter sheets consists of matrix of cellulosic or polymer fibers, enriched with mineralic filter aids and held together with a resin binder.

### Grades available



\* Nominal retention values of filter sheets are relative. Actual process conditions influence the effective removal performance.

### PURAFIX® Pharma grade filter sheets

PURAFIX® depth filter sheets have been specifically developed for the use in critical applications in the pharmaceutical or biological industries.



#### PURAFIX® P filter sheets

- Extremely pure, low ion and low pyrogen level
- Retention rates between 35 µm–0.04 µm
- Batch certification/comprehensive validation guide
- Highly charged grades available (PURAFIX® ZP)

#### PURAFIX® PF-P filter sheets

- Low beta glucan level
- Extreme stability
- Various grades available

### Functional filter sheets



#### PURAFIX® ET-R filter sheets

- Specially designed for the removal of endotoxins from pre-clarified solutions
- Different grades available

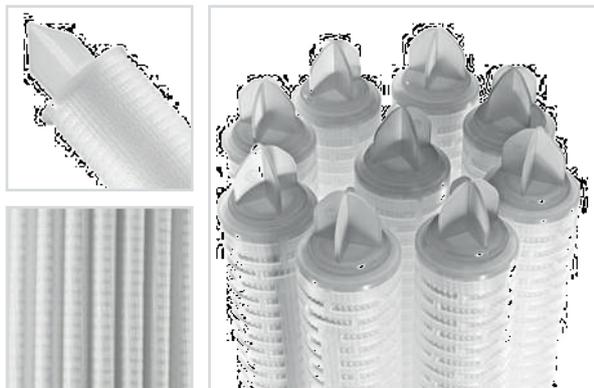
#### CARBOFIL™ activated carbon filter sheets

- Various grades available
- Custom made sheets with your AC grade on request

## Depth filter media

### CLAROX® filter cartridges

CLAROX® filter cartridges represent an approved and established filtration technology in solid/liquid separation. Our range of cartridges offers safe and economical solutions for many different filtration applications. CLAROX® cartridges are available with all common adapter types.



### CLAROX® filter cartridges

- Filtration in a closed system (SECUROX™ filter housing)
- Safe particle retention rating
- No drip loss
- Solid core, easy handling and maximum safety

### FILTRODISC™ lenticular filter modules

FILTRODISC™ depth filter modules allow the user to handle large filter areas easily in a disposable assembly. Filtration is performed in a closed system. Depth filter sheets inside have a high dirt holding capacity.

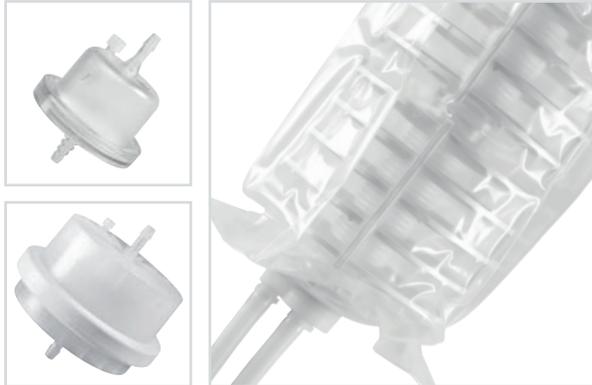


- Filtration in a closed system (DISCSTAR™ filter housing)
- Available in all filter sheet grades (PURAFIX® P, SYNTHAFIX™ and CARBOFIL™)
- High particle retention capacity
- No drip loss
- Solid core, easy handling and maximum safety
- Available with all common adapters (flat gasket adapter DOE and double O-ring/bayonet adapter DOR)
- Available in 12" and 16"
- Different numbers of lenses (3-17) available
- High temperature version up to 180 °C available (FILTRODISC™ HT/UHT)
- Completely conductive module available, without metal strips, for use in ATEX zones (FILTRODISC™ CD)
- Plastic parts in polypropylene (standard) or polyamide
- Short version available (polypropylene only)

## Depth filter media

### FILTRODISC™ BIO SD disposable solution for cell removal (midstream processing)

FILTRODISC™ BIO SD is the first depth filter using the advantages of the alluvial (cake or precoat) filtration technology in a disposable format. With FILTRODISC™ BIO SD, this technology is now also available for single-use cell separation, as the system is fully scalable and disposable, fulfilling all validation requirements.



- Scalable from lab to process
- Fully disposable
- Very small dead volume
- Alternative to centrifuges or acoustic separation systems. To combine with the first depth filtration step.
- Highly adaptive to customer requirements (build your own depth filter)
- Adaptable to all common single-use systems; all common connectors available
- Removal of cells and impurities in one step
- Well-known and accepted technology
- Reduction of cost and downtime

### FILTRODISC™ R2U disposable depth filter solution

FILTRODISC™ R2U modules are an easy to use, robust and linear scalable depth filtration system for various applications.

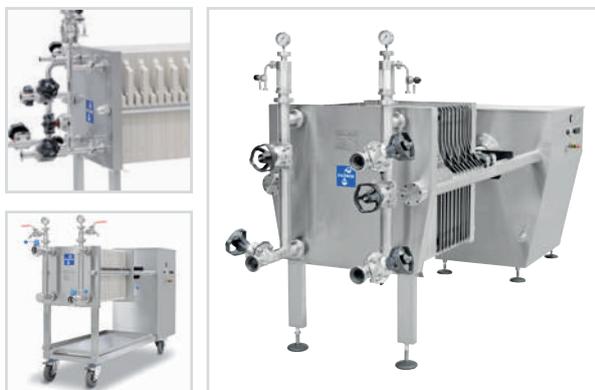


- Scalable from lab to process
- Fully disposable
- Very small dead volume
- Highly adaptive to customer requirements (build your own depth filter)
- Adaptable to all common single-use systems; all common connectors available
- Well-known and accepted technology
- Standard depth filtration in a single-use format
- Production scale from 0.66 m<sup>2</sup> up to 7.2 m<sup>2</sup> in one bag
- Reduction of cost and downtime

## Filter equipment

### NOVOX® OD and CP plate and frame filters

The NOVOX® systems are high precision stainless steel plate & frame filters for heavy duty use. Sizes of the filter plates vary from 100 mm × 100 mm up to 1200 mm × 1200 mm. The filter package is available in several different materials, depending on the application.



- Plates and frames from 100 × 100 mm up to 1200 × 1200 mm
- Special sizes and custom-made solutions upon request
- Filter elements in stainless steel (AISI 316 L), PP, PVDF
- Cake frames in different sizes for different cake volumes
- Available with manual hydraulic/pneumatically or electrically operated hydraulic closing system
- Explosion-proof systems available (ATEX)
- Filter package with or without gaskets available
- Certificates for pharmaceutical applications
- Multiple options (skid system, integrated pumps, etc.)

### DISCSTAR™ lenticular module filter housings

The DISCSTAR™ is a highly precise stainless steel filter housing for filter modules, developed and manufactured for everyday use. The enclosed system enables depth filtration to be carried out without drip loss.



- For all common lenticular filter modules
- Easy handling
- All wet parts are stainless steel AISI 316 L
- From 1 to 4 high, single stack or multi-stack housing (up to 16 modules in one housing)
- For 12" and 16" modules
- Up to 10 bar/145 psi with pressure vessel certificate
- Up to 140 °C/285 °F
- Certificates for pharmaceutical applications
- Temperature-controlled systems
- Multiple options (skid systems, custom-made solutions, etc.)

### DISCSTAR™ BIO SD



- For FILTRODISC™ BIO SD filter modules
- Easy handling
- Pressure vessel design
- Rentable
- Manometer digital or analog
- Small skid versions available incl. pump and control unit
- Production skids available with pump, automated valves, hose assemblies and control unit
- All parts are stainless steel AISI 316 L

## Helpful tools and support

### Test Kits

The disposable mini capsules are designed for filterability trials and filtration method development. They are used for lab scale filtration and do not require extra filter holder. All filter sheet material used in the mini capsules is correspondent to production scale flat sheets and lenticular modules. Thus it is a convenient tool for upscaling. The clear and transparent polymer housing allows easy visual inspection of the filter process.



#### PURAFIX®

- For pharmaceutical and other life science applications
- Contains extremely low levels of extractable ions and pyrogens

#### CARBOFIL™

- Activated carbon filter sheets
- Decolorization
- Taste and odor removal

#### BIO SD™ (2" and 5")

- Single-use cell separation
- Designed to determine dosage and grade of filter aid

### FILTROX Academy

Since its foundation over 80 years ago, FILTROX has collected a lot of experience and knowledge in microfiltration of liquids. The FILTROX Academy offers filtration trainings, seminars, audits and customer specific classes. Please contact us. We look forward to sharing our application and filtration know-how to optimize your process.



#### FILTROX Academy

- Filtration seminars
- Individual training sessions
- Filtration audits

#### Process development and optimization

- Laboratory trials
- Field tests
- Scale-up support
- Validation support
- Process development support

#### Services

- Spare part service
- Upgrade of existing equipment
- Customer service



As a global market leader in depth filtration, FILTROX offers complete solutions for filtration of high value liquids.

We are experts in development, manufacturing and supply of Swiss top quality products for a wide range of applications in pharmaceuticals, biotechnology, chemicals and cosmetics as well as in food and

beverage. Since 1938, we have been developing and manufacturing both filter media as well as filtration equipment in-house. Based on this experience, we can offer our customers a complete range of products.

FILTROX's worldwide distribution network and comprehensive technical support will help you optimize your filtration process.