Sefar solutions for the healthcare industry

The production of extremely accurate mesh openings with defined surface characteristics within strict biological specifications is a prerequisite for medical applications. Sefar has developed the SEFAR MEDIFAB® product line to further enhance its ability to meet the strict manufacturing and cleanliness requirements of the medical industry.
The SEFAR MEDIFAB® fabrics are composed of monofilament yarns, typically polyester (PET) and polyamide (PA). The raw materials (yarns) are produced in compliance with official regulations (e.g. 21CFR177). A separate validated processing line guarantees a high level of cleanliness and biocompatibility.
In addition to the standard testing methods all SEFAR MEDIFAB® fabrics are routinely tested for endotoxins and hemolytic substances.
USP class VI/ISO10993 and cytotoxicity tests are performed at regular intervals.

SEFAR MEDIFAB® applications

Precise pore sizes down to 1 micron, uniform weave and open-mesh structures ensure accurate filtration with minimal flow restriction.
SEFAR MEDIFAB® fabrics act as security filters and as wicking and spreading media for example in infusion and transfusion sets, arterial and cardiotomy blood filters, blood bags, dialysis sets and diagnostic self-test strips.
It is the responsibility of the medical device manufacturer to determine the suitability of all components and raw materials, including Sefar products, used in its final product in order to ensure the safety and compliance with requirements of the regulatory bodies. Sefar products are not designed nor approved for use as implant material.

SEFAR MEDIFAB® attributes

- Precision monofilament fabrics with defined surface characteristics
- Raw materials comply to the Code of Federal regulations (21CFR177), and also to the European guidelines (BGA, EU-directives)
- Sefar's weaving, finishing and fabrication facilities for SEFAR MEDIFAB® products are ISO9001 certified and follow applicable GMP guidelines for lot traceability and documentation control
- No ozone depleting substances used for production
- Low endotoxin content (<< 0.125 EU/ml)
- Non-hemolytic
- Non-cytotoxic
- Low extractables
- Passes USP plastics class VI/ISO10993 tests
- Upon request, polyetheretherketone (PEEK) and polypropylene (PP) fabrics can be finished in SEFAR MEDIFAB® quality
- Customer-specific surface coatings available upon request
- All SEFAR MEDIFAB® fabrics can be tailored to customers' specification
- Fabrication in a clean room class ISO 7 according to ISO 14644-1
- Quality systems ISO9001, version 2000 and ISO13485

SEFAR MEDIFAB® surface treatment

SEFAR MEDIFAB® is manufactured to achieve the specified pyrogen and hemolysis levels without the necessity for coating or surface treatments. However, if required, a further finishing step can be added: Sefar offers a wide range of surface treatments including hydrophilic and hydrophobic coatings and plasma treatments.
For example, fabrics can be surface treated to enhance priming, wetting and wicking properties. In addition fabrics can be dyed in virtually any color.
Customer specific formulations are available upon request.

SEFAR MEDIFAB® fabrication

Filter components are manufactured in a clean room class ISO 7 according which includes conversion technologies such as cutting (laser, heat, US, cold), stamping (US, cold), slitting (US, heat and laser), welding (US), pleating, tubing and crosswinding.
All filter components can be custom fabricated to fit the exact needs of the medical device manufacturer.