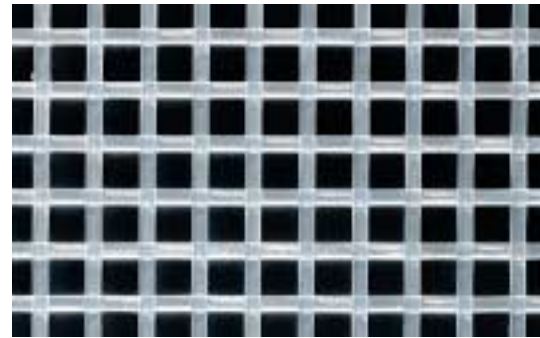
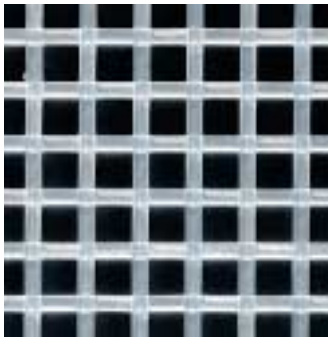
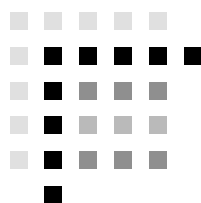


SEFAR MEDIFAB®



Sefar Solutions for  
the Healthcare Industry

*Sefar Lösungen für  
die Medizinindustrie*



S E F A R

### 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/ISO 10993 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 an accurate filtration with a 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 cardiomy 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

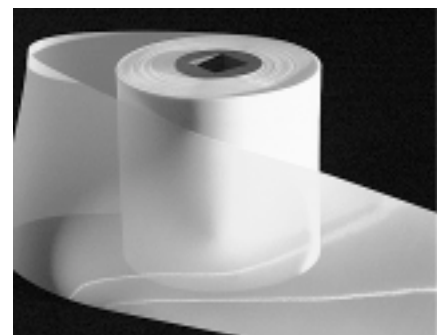
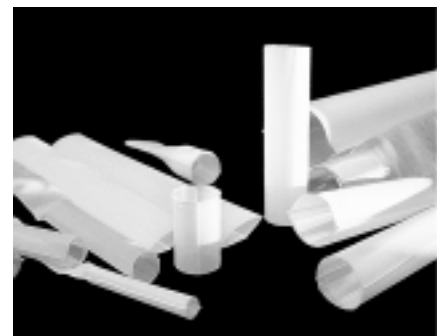
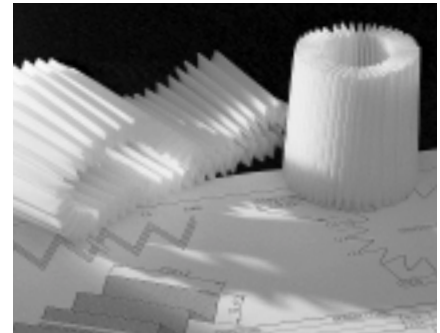
- Precision monofilament fabrics with defined surface characteristics
- Raw materials comply to the Code of Federal regulations (21CFR177), respectively to the European guidelines (BGA, EU-directives)
- Sefar's weaving, finishing and fabrication facilities for SEFAR MEDIFAB® products are ISO 9001 certified and follow applicable GMP guidelines for lot traceability and documentation control
- No oxygen 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
- ISO 9001, version 2000
- ISO 13485

### SEFAR MEDIFAB® surface treatment

SEFAR MEDIFAB® per definition is manufactured to achieve the specified pyrogen and hemolysis levels and is neither coated nor surface treated. 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. Fabrics can be surface treated for example 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 Class 10000 clean room 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.





## Definitions

### SEFAR MEDIFAB® tests

#### LAL-test

[Limulus Amoebocyte Lysate; or Pyrogen/ (Bacterial-) Endotoxin Test]; testing method for detecting bacterial endotoxins which are fever producing, water soluble compounds. Endotoxin is a toxin produced by bacteria and is released after the death of the bacteria.

Limit: 0.125 EU/ml  
(Endotoxin Units per milliliter)  
Regulation: USP 24/NF 19, 2000,  
Chapter <85>;  
FDA guidelines 1987/1993

#### Hemolysis-test

Testing method for detecting compounds which destroy red blood cells.

Limit: No hemolysis  
Regulation: ISO 1135-4

#### Plastics USP class VI-test/ISO 10993

The tests described below are conducted in order to evaluate the biocompatibility of materials (i.e. the ability of the material to exist with/in living organisms without harming them).

Limit: Pass  
Regulation: USP 24/NF 19, 2000,  
Chapter <88>  
ISO 10993, parts 5, 6, 10, 11

#### Acute systemic toxicity

Test for detecting components which may harm the whole organism.

#### Intracutaneous toxicity

Evaluation of intracutaneous toxicity.

#### Implantation test

Evaluation of the potential to be a local irritant or for a toxic response to the material.

#### Cytotoxicity test

Evaluation of leachables extracted from material which may cause cytotoxicity (cell death).

#### Extractables

Evaluation of residues/substances that can be leached from a filter during the filtration process or under other specified conditions.

Limit: The amount of extractables (expressed as percent residue per unit fabric dry weight) has to be lower than specified in 21CFR volume 177.

Regulation: 21CFR177.1500 (Polyamide)  
21CFR177.1630 (Polyester)

### Abbreviations

#### FDA

United States «Food and Drug Administration»; regulatory agency of the US government that is responsible for the regulation of materials used for food production and processing.

#### USP

United States Pharmacopeia; Organization that promotes and establishes officially recognized standards of quality for drugs and healthcare related articles.

#### DIN

Deutsche Industrie Norm; Organization that promotes and establishes officially recognized standards.

#### CFR

Code of Federal Regulations; (published by FDA) Contains/describes guidelines/regulations for food and food related products.

#### ISO

International Standards Organization that promotes and establishes officially recognized standards.

#### 1. Product number

Fiber material **03-5/1 07-5/1**  
03 = PA 6.6  
07 = PET

Mesh opening (w) **03-5/1**

Open area (a<sub>0</sub>) **03-5/1**

#### 2. Mesh opening (w) [µm]

Test equipment: electronic image analysis system.

#### 3. Open area (a<sub>0</sub>) [%]

Test equipment: electronic image analysis system.

$$(a_0) [\%] = \frac{(w)^2 \times 100}{(w + d)^2}$$

#### 4./5. Mesh count (n) [n/cm], [n/in]

Test equipment: electronic image analysis system.

$$n/cm = \frac{10'000}{(w + d)} \quad n/in = \frac{25'400}{(w + d)}$$

#### 6. Thread diameter (d)

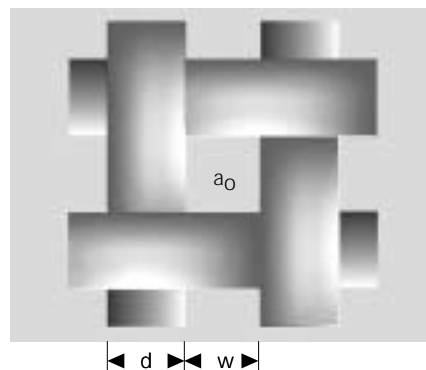
Test equipment: electronic image analysis system.

#### 7./8. Weight [g/m<sup>2</sup>], [oz/yd<sup>2</sup>]

Test method: DIN 53854

#### 9. Thickness [µm]

Test method: DIN 53855 part 1  
Test equipment: long-stroke measuring instrument with digital display.



a<sub>0</sub> Open area  
d Wire diameter  
w Mesh opening

1	2	3	4	5	6	7	8	9
Gewebe- Nummer	Maschenweite (w)	Offene Siebfläche (a <sub>0</sub> )	Siebfeinheit (n)	Siebfeinheit (n)	Garn- durchmesser (d)	Gewicht	Gewicht	Dicke
Product number	Mesh opening (w)	Open area (a <sub>0</sub> )	Mesh count (n)	Mesh count (n)	Wire diameter (d)	Weight	Weight	Thickness
	[µm]	[%]	[n/cm]	[n/in]	[µm]	[g/m <sup>2</sup> ]	[oz/yd <sup>2</sup> ]	[µm]

## SEFAR MEDIFAB®

Polyester

07-5/1	5	1	270/175	686/445	34	65	1.9	80
07-10/2	10	1.5	160	406	47	60	1.8	55
07-11/5	11	5	206	523	38	50	1.5	60
07-15/9	15	8.5	194	493	37	45	1.3	55
07-17/9	17	9	177	450	40	50	1.5	75
07-20/13	20	12.5	177	450	37	40	1.2	60
07-21/12	21	12	163	414	41	45	1.3	70
07-27/19	27	19	162	411	35	35	1.0	55
07-30/21	30	21	153	389	36	35	1.0	50
07-33/10	33	9.5	93	236	75	85	2.5	125
07-33/21	33	20.5	138	351	40	40	1.2	60
07-37/31	37	30.5	146	371	30	28	0.8	50
07-40/25	40	25	126	320	40	35	1.0	60
07-51/33	51	33	113	287	38	30	0.9	60
07-65/26	65	25.5	78	198	64	55	1.6	100
07-74/34	74	33.5	78	198	54	45	1.3	85
07-85/46	85	46	80	203	43	29	0.9	65
07-100/32	100	32	57	145	77	65	1.9	125
07-105/52	105	52	69	175	42	25	0.7	61
07-115/36	115	35.5	54	137	70	55	1.6	105
07-120/50	120	50	58	147	52	31	0.9	80
07-130/37	130	36.5	46	117	86	70	2.1	145
07-135/40	135	39.5	48	122	73	55	1.6	115
07-150/41	150	40.5	43	109	86	65	1.9	140
07-160/35	160	35	37	94	110	90	2.7	165
07-170/41	170	41	38	97	96	70	2.1	150
07-175/46	175	46	39	99	83	55	1.6	130
07-185/41	185	41	34.5	88	105	80	2.4	170
07-200/39	200	39	31	79	121	100	3.0	215
07-200/43	200	43	33	84	104	75	2.2	170
07-210/35	210	34.5	28	71	147	135	4.0	250
07-245/50	245	50	29	74	102	65	1.9	165
07-265/47	265	47	26	66	122	85	2.5	200
07-300/36	300	36	20	51	205	180	5.3	405
07-800/55	800	54.5	9	23	280	165	4.9	520
07-1000/58	1000	57.5	7.6	19	320	185	5.5	585

1	2	3	4	5	6	7	8	9
Gewebe- Nummer	Maschenweite (w)	Offene Siebfläche (a <sub>0</sub> )	Siebfeinheit (n)	Siebfeinheit (n)	Garn- durchmesser (d)	Gewicht	Gewicht	Dicke
Product number	Mesh opening (w)	Open area (a <sub>0</sub> )	Mesh count (n)	Mesh count (n)	Wire diameter (d)	Weight	Weight	Thickness
	[µm]	[%]	[n/cm]	[n/in]	[µm]	[g/m <sup>2</sup> ]	[oz/yd <sup>2</sup> ]	[µm]

## SEFAR MEDIFAB®

Polyamide 6.6

03-5/1	5	1	275/185	699/470	37	60	1.8	100
03-10/2	10	2	190	483	28	40	1.2	45
03-15/10	15	9.5	202	513	35	40	1.2	60
03-20/14	20	14	188	478	34	35	1.0	55
03-22/22	22	22	165	419	40	38	1.1	65
03-25/14	25	14	156	396	40	43	1.3	79
03-30/18	30	18	142	361	40	35	1.0	60
03-36/28	36	27.5	146	371	33	25	0.7	50
03-38/22	38	22	124	315	43	35	1.0	70
03-41/31	41	31	136	345	33	25	0.7	50
03-50/31	50	31	112	284	40	30	0.9	60
03-60/42	60	41.5	108	274	33	20	0.6	50
03-64/45	64	44.5	105	267	33	20	0.6	50
03-100/44	100	44	66	168	51	30	0.9	80
03-150/38	150	37.5	41	104	95	60	1.8	155
03-170/54	170	53.5	43	109	62	32	0.9	100
03-180/47	180	47	38	97	82	50	1.5	135
03-200/47	200	47	34	86	92	55	1.6	150
06-210/33	210	33	27.5	70	155	105	3.1	275
03-220/46	220	46	31	79	105	71	2.1	170
03-300/51	300	51	24	61	122	75	2.2	200

In accordance with Sefar's policy of continuous product improvement, specifications and other information in this publication are subject to change without notice.

The user is responsible for determining fitness, merchantability and suitability of purpose before use.

Quality System ISO 9001

*Im Einklang mit der Sefar-Geschäftspolitik, die eine dauernde Kontrolle und Verbesserung unserer Produkte definiert, behalten wir uns die Änderung der technischen Daten jederzeit vor. Der Endverbraucher ist verpflichtet, die verwendeten Produkte auf deren Eignung zum Verwendungszweck vor dem Einsatz zu prüfen.*

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