US 20200047128A1

(19) United States
(12) Patent Application Publication
BECK et al.
(10) Pub. No.: US 2020/0047128 A1
(43) Pub. Date: Feb. 13, 2020

(54) **FILTRATION DEVICE**

(71) Applicant: **GAMBRO LUNDIA AB**, Lund (SE)

(72) Inventors: **Christof BECK**, Bitz (DE); **Steffen WAGNER**, Messtetten (DE); **Bernd HERTZLER**, Balingen (DE); **Rainer BLICKLE**, Bitz (DE); **Stefan ERMANTRAUT**, Balingen (DE)

(21) Appl. No.: **16/604,288**

(22) PCT Filed: **Apr. 11, 2018**

(86) PCT No.: **PCT/EP2018/059317**

§ 371 (c)(1),
(2) Date: **Oct. 10, 2019**

(30) **Foreign Application Priority Data**

Apr. 12, 2017 (EP) 17166295.0

Publication Classification

(51) **Int. Cl.**

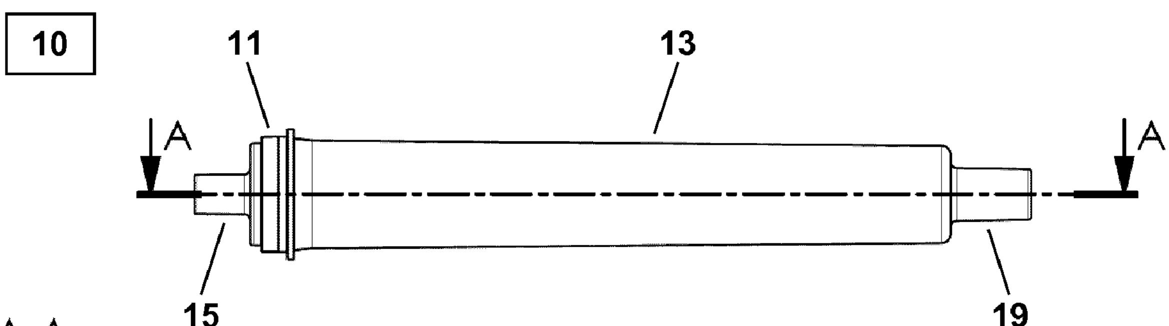
B01D 63/02	(2006.01)
B01D 65/00	(2006.01)
B01D 69/08	(2006.01)
B01D 71/48	(2006.01)
C02F 1/44	(2006.01)
B29C 65/16	(2006.01)
B29C 65/00	(2006.01)
A61M 1/16	(2006.01)

(52) **U.S. Cl.**

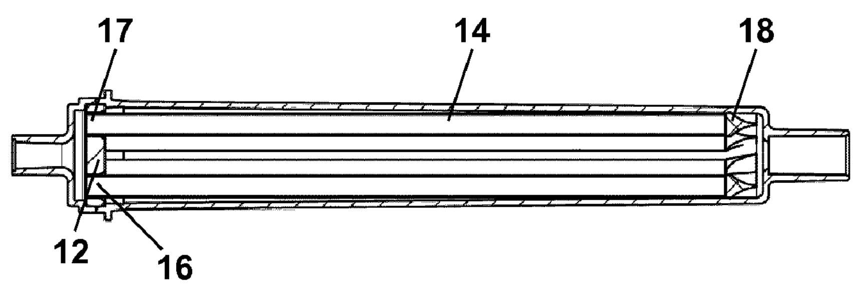
CPC ***B01D 63/024*** (2013.01); *B29L 2031/14* (2013.01); ***B01D 65/003*** (2013.01); ***B01D 69/081*** (2013.01); ***B01D 71/48*** (2013.01); ***C02F 1/44*** (2013.01); ***B29C 65/1616*** (2013.01); ***B29C 65/1677*** (2013.01); ***B29C 66/73921*** (2013.01); ***B29C 66/1222*** (2013.01); ***A61M 1/1672*** (2014.02); *B01D 2313/04* (2013.01); *B01D 2313/21* (2013.01); *B01D 2315/08* (2013.01); ***B01D 63/022*** (2013.01)

(57) **ABSTRACT**

The present disclosure relates to a filtration device comprising a plurality of hollow fiber membranes, a process for its production, and its use for the dead-end filtration of infusion liquids.



A-A



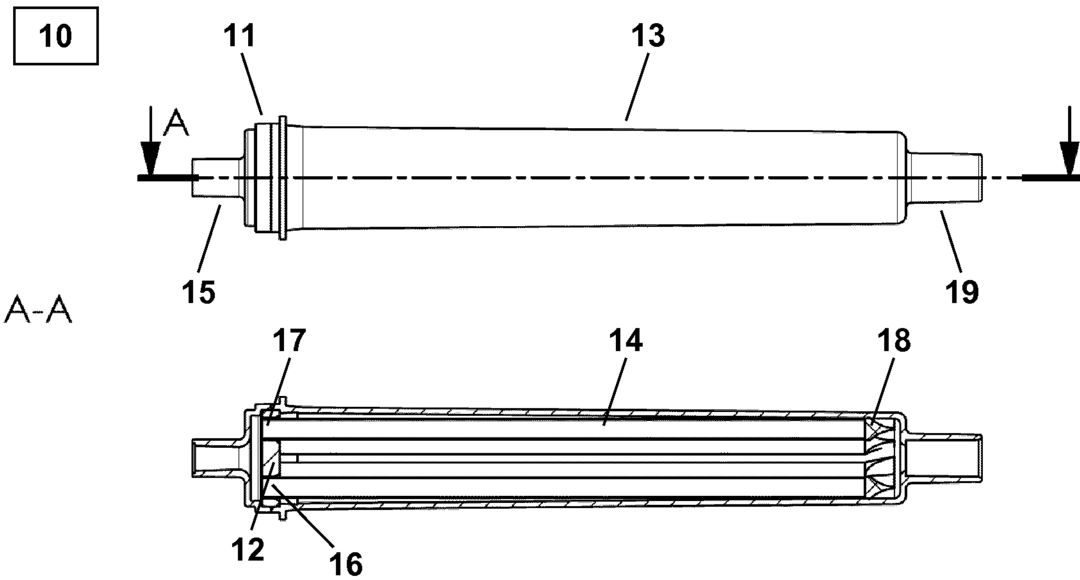


Fig. 1

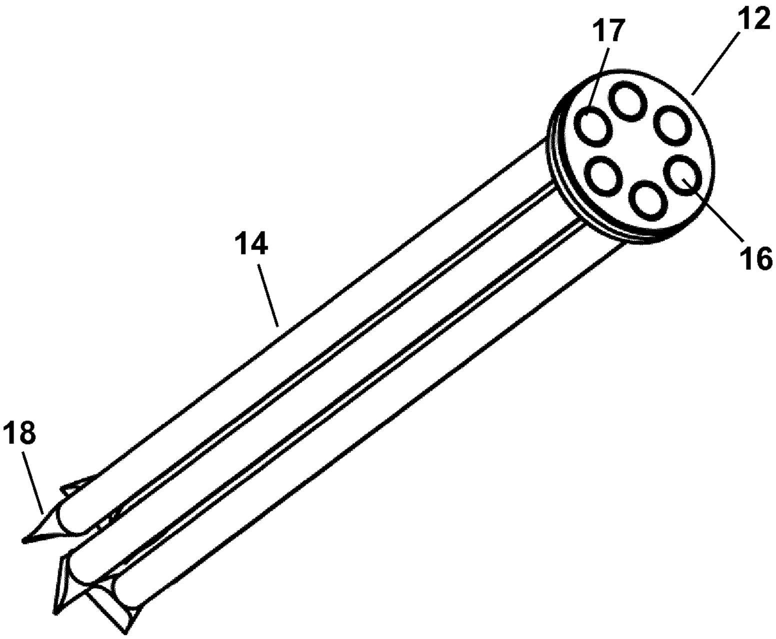


Fig. 2

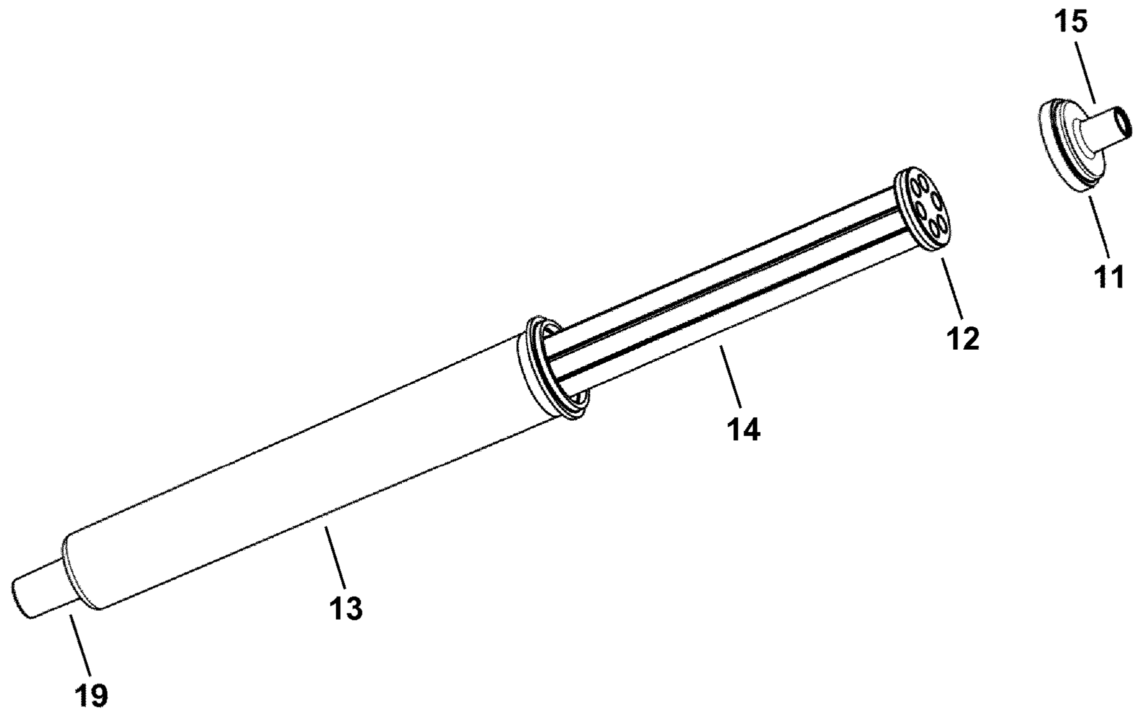


Fig. 3

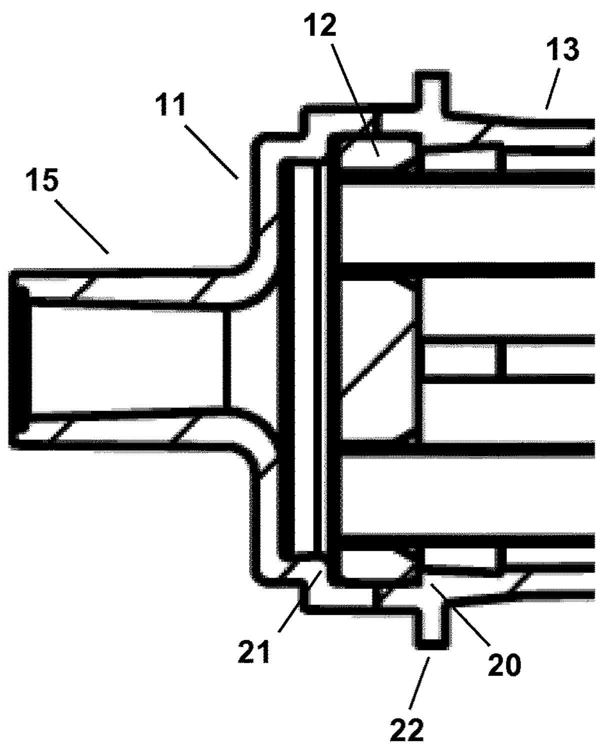


Fig. 4

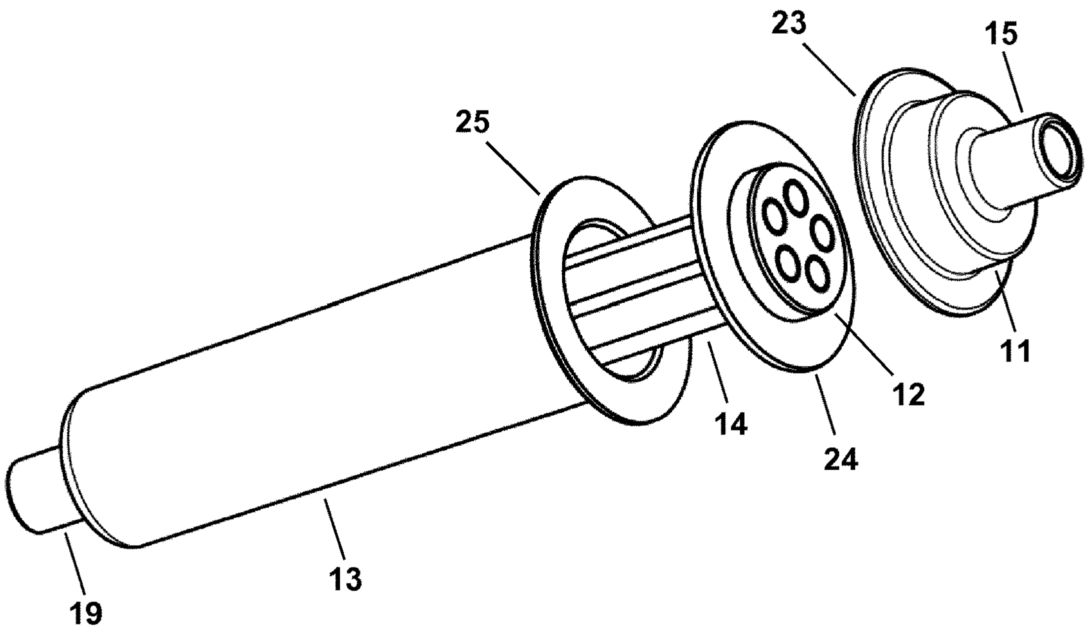


Fig. 5

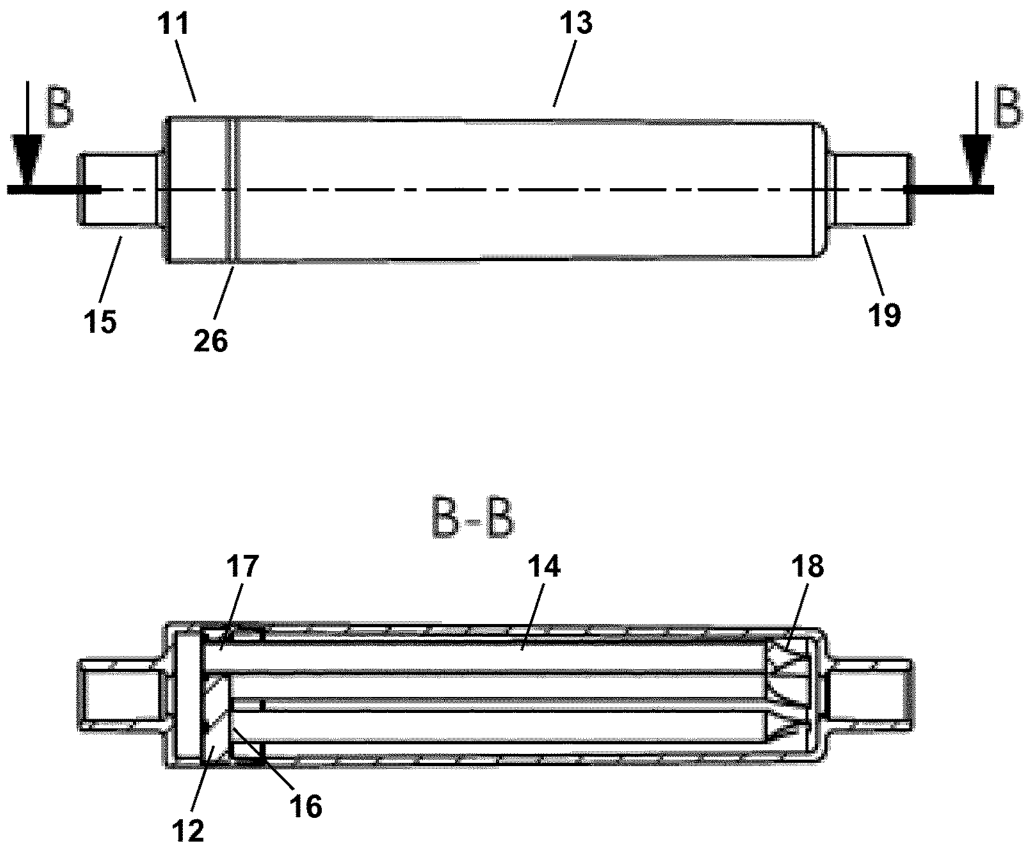


Fig.6

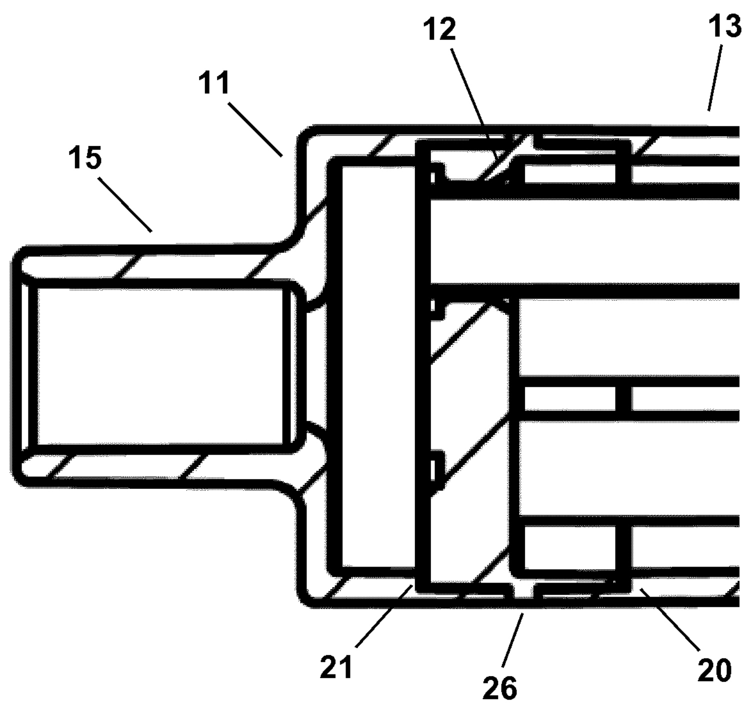


Fig.7

FILTRATION DEVICE

TECHNICAL FIELD

[0001] The present disclosure relates to a filtration device comprising a plurality of hollow fiber membranes, a process for its production, and its use for the dead-end filtration of infusion liquids.

DESCRIPTION OF THE RELATED ART

[0002] Liquids destined to be infused into a patient's body, in particular into the bloodstream of a patient, have to be free of pyrogens and particulate matter. To protect the patient, infusion solutions therefore typically are passed through a filter device installed in the infusion line before they enter the patient's body. Commercially available devices generally comprise a microporous flat sheet membrane. Filter devices comprising hollow fiber membranes instead of flat sheet membranes also have been proposed.

[0003] U.S. Pat. No. 4,267,053 A discloses an inline intravenous final filter unit comprising a casing having an inlet cap at its one end and an outlet cap at the other end. At least one porous hollow fiber having a porosity rating of 0.1 to 5 μm is arranged within the casing parallel to the longitudinal direction thereof. The hollow fiber is closed at its one end opposed to the inlet cap, and open at the other end thereof opposed to the outlet cap. The hollow fiber further is tightly fixed at the outer peripheral portion of its open end to the inner wall of the casing by a securing member; and the ratio of the total effective filtration area of the hollow fiber to the capacity of the casing is at least about 4:1. The hollow fiber membranes have an outside diameter of up to 3 mm and an inner diameter of at least 0.5 mm.

[0004] In the working examples of U.S. Pat. No. 4,267,053 A, a filter device is disclosed comprising 16 porous hollow fibers having 0.5 mm inside diameter and 1.4 mm outside diameter, 60 mm in length and 0.32 μm in porosity rating. The fibers are accommodated in a hollow cylindrical casing 8 mm in inside diameter, 10 mm in outside diameter and 80 mm in length and tightly secured to the inner wall of the casing by securing member made of a silicone-type adhesive material. The porous hollow fibers are made from cellulose diacetate, and the casing, inlet cap and outlet cap from polyethylene. The filter unit has a filtration area, A, of 35.2 cm^2 and an A/V ratio of 5.61. The hollow fiber membranes used have a ratio of inside diameter/wall thickness of 0.5 mm/0.45 mm=1.1. The liquid to be filtered permeates from the outside of the hollow fibers into the lumen. Flow rates of less than 35 ml/cm^2*hr are reported.

[0005] The device of U.S. Pat. No. 4,267,053 A is suitable for filtering infusion solutions at a rate of some 500 ml per hour. By expanding the filtration area, this value might be increased to a certain extent. However, for filtering large volumes of liquid in a short time, a different kind of filtration device is required. It is an objective of the present disclosure to provide a filtration device capable of filtering large volumes of liquid in a short time.

SUMMARY

[0006] The present application provides a filtration device comprising a plurality of microporous hollow fiber membranes having a large inner diameter and a thin wall. The device can be used for sterile dead-end filtration of liquids destined for infusion into a patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. **1** is a side view and a cross-sectional view of an embodiment of the filtration device **10** of the present disclosure;

[0008] FIG. **2** is a perspective view of an embodiment of a disk **12** holding a plurality of semipermeable hollow fiber membranes **14**;

[0009] FIG. **3** is an exploded view of an embodiment of the filtration device **10** of the present disclosure;

[0010] FIG. **4** is a detail of a cross-sectional view of the filtration device **10** shown in FIG. **1**;

[0011] FIG. **5** is an exploded view of another embodiment of the filtration device **10** of the present disclosure;

[0012] FIG. **6** is a side view and a cross-sectional view of still another embodiment of the filtration device **10** of the present disclosure;

[0013] FIG. **7** is a detail of a cross-sectional view of the filtration device **10** shown in FIG. **6**.

DETAILED DESCRIPTION

[0014] The present invention provides filtration devices comprising a plurality of semipermeable hollow fiber membranes.

[0015] The filtration device **10** of the present disclosure comprises a header section **11** having an inlet **15** for a liquid. In one embodiment, the header section **11** shows cylindrical symmetry, the axis running through the inlet **15**. The header section **11** covers a first face of a disk **12** having a plurality of bores **16** and holding a plurality of hollow fiber membranes **14** which protrude from a second face of the disk **12**, opposite to the first face covered by the header section **11**. In one embodiment, a circumferential ledge **21** is present on the inside wall of the header section **11**; and disk **12** is seated on the ledge **21**. In another embodiment, a flange **23** is provided on the mouth of header section **11**.

[0016] The filtration device **10** of the present disclosure comprises a disk **12** having a plurality of bores **16**. The number of bores **16** is not particularly limited. The disk **12** generally comprises three or more bores **16**, for instance, 4 to 36 bores, e.g., 6 to 19 bores, or 5 to 8 bores. In one embodiment, the disk **12** features 5 bores. In another embodiment, the disk **12** features 6 bores. In still another embodiment, the disk **12** features 7 bores. In one embodiment, the thickness of the disk is in the range of from 1 to 10 mm, for instance, 2 to 5 mm.

[0017] In one embodiment, the bores **16** of the disk **12** form a regular pattern. This offers the advantage that the liquid to be filtered is more evenly distributed between the individual bores **16** and the corresponding semipermeable hollow fiber membranes **14** than with a random arrangement obtained by potting the ends of the hollow fiber membranes **14** with a reactive polymer, as described in U.S. Pat. No. 4,267,053 A. A more uniform liquid flow results in enhanced performance of the filtration device **10**. In one embodiment, the bores **16** are arranged in a circular pattern, i.e., their centers are located on the circumference of a circle. In another embodiment, the centers of the bores **16** are located on the circumferences of two coaxial circles. In still another embodiment, the centers of the bores **16** are located on the circumferences of three coaxial circles. In a further embodiment, one bore **16** is located in the center of the disk **12** and the centers of the other bores **16** are located on the circumference(s) of one or more coaxial circles. In another embodiment, the bores **16** form a trigonal or hexagonal mesh; or a rectangular or quadratic mesh.

[0018] Each bore **16** holds a first end **17** of a semipermeable hollow fiber membrane **14**. The diameter of the bore **16** is a little larger than the outer diameter of the semipermeable hollow fiber membrane **14**, in order to facilitate introduction of the first end **17** of the fiber into the bore **16**. In one embodiment, the difference is in the range of from 0.05 to 0.3 mm. The semipermeable hollow fiber membrane **14** protrudes from the disk **12** and is sealed at its second end **18**. In one embodiment, the lip of the first end **17** of the semipermeable hollow fiber membrane **14** is level with one face of the disk **12**; and the semipermeable hollow fiber membrane **14** protrudes from the opposite face of the disk **12**.

[0019] The first end **17** of the semipermeable hollow fiber membrane **14** is fixed to the wall of the bore **16**. In one embodiment, the first end **17** of the semipermeable hollow fiber membrane **14** is welded or fused to the wall of the bore **16**. In another embodiment, the first end **17** of the semipermeable hollow fiber membrane is glued to the wall of the bore **16** using a suitable adhesive, for instance, an epoxy resin or a polyurethane adhesive.

[0020] The second end **18** of the semipermeable hollow fiber membrane **14** is sealed, so that any liquid entering the first end **17** of the semipermeable hollow fiber membrane **14** can only leave the fiber through the membrane wall, being filtered in the process. In one embodiment, the seal is generated by melting the second end **18** of the semipermeable hollow fiber membrane **14**. In another embodiment, the seal is generated by crimping or clamping the second end of the semipermeable hollow fiber membrane **14**. In still another embodiment, the seal is generated by sealing the second end **18** of the semipermeable hollow fiber membrane **14** with a sealing material, e.g., an adhesive or a reactive resin.

[0021] In one embodiment, a circumferential ridge **26** is present on the peripheral surface of disk **12**. The height of the ridge **26** is equal to or less than the wall thickness of header section **11** and tubular section **13**. The outer diameter of disk **12** including the ridge matches the outer diameter of header section **11** and tubular section **13**, while the outer diameter of disk **12** adjacent to the ridge **26** matches the inner diameter of header section **11** and tubular section **13**, respectively. When the filtration device **10** is assembled, the ridge **26** is held between the lips of header section **11** and tubular section **13**, respectively.

[0022] Ridge **26** is joined to the lips of header section **11** and tubular section **13**, respectively, thus sealing filtration device **10**.

[0023] In another embodiment, disk **12** features a collar **24** on its peripheral surface. The outer diameter of collar **24** matches the outer diameter of corresponding flanges **23** and **25** provided on the header section **11** and the tubular section **13**, respectively. The outer diameter of disk **12** adjacent to collar **24** matches the inner diameter of header section **11** and tubular section **13**, respectively. When the filtration device **10** is assembled, collar **24** is held between flanges **23** and **25**. Flange **23** is joined to one face of collar **24**; and flange **25** is joined to the other face of collar **24**, thus sealing filtration device **10**.

[0024] In one embodiment, the outer diameter of the disk **12** at its maximal extension matches an outer diameter of the header section **11** and the tubular section **13**. In another embodiment, the outer diameter of disk **12** at its maximal extension matches an inner diameter of the header section **11** and the tubular section **13**. In one embodiment, disk **12** is seated in a circumferential recess in the inner wall of filtration device **10**. In one embodiment, the circumferential recess spans the interface of header section **11** and tubular section **13**. In another embodiment, the circumferential recess spans the mouths of both header section **11** and tubular section **13**.

[0025] The filtration device **10** of the present disclosure further comprises a tubular section **13** having an outlet **19** for a liquid. In one embodiment, the tubular section **13** shows cylindrical symmetry, the axis running through the outlet **19**. The tubular section **13** encloses the plurality of semipermeable hollow fiber membranes **14** protruding from the disk **12**, i.e., it provides a housing for the fibers. Therefore, the length of the tubular section **13** has to be larger than the length of the semipermeable hollow fiber membranes **14** protruding from the disk **12**, so that the semipermeable hollow fiber membranes **14** fit into the tubular section **13**. Generally, the length of the tubular section **13** will exceed the length of the semipermeable hollow fiber membranes **14** protruding from the disk **12**, so that there is a gap between the second end **18** of the semipermeable hollow fiber membranes **14** and the outlet **19**. In one embodiment, the width of the gap is in the range of from 0.1 to 10 mm.

[0026] In one embodiment, a circumferential ledge **20** is present on the inside wall of the tubular section **13**. Disk **12** is seated on ledge **20**. In one embodiment, circumferential ledges **20** and **21** are present on the inside wall of the tubular section **13** and the header section **11**, respectively. Disk **12** is held by the circumferential ledges **20** and **21**, which together form a circumferential recess in the inner wall of filtration device **10**.

[0027] In one embodiment of the filter device, the header section **11**, the disk **12** and the tubular section **13** each comprise a thermoplastic polymer.

[0028] Suitable materials for the header section **11** and the tubular section **13** include polyesters, polycarbonates, acrylonitrile-butadiene-styrene copolymers (ABS), styreneacrylonitrile copolymers (SAN), styrene-methyl methacrylate copolymers (SMMA), styrene-butadiene-copolymers (SBC), polyvinylchlorides (PVC), polyolefins, and copolymers and blends thereof. In one embodiment of the invention, the materials of the header section **11** and the tubular section **13** comprise polyesters, for instance, polycarbonates, polyethylene terephthalates (PET), or glycol-modified polyethylene terephthalates (PETG). In a particular embodiment of the invention, the polyester is a glycol-modified polyethylene terephthalate (PETG).

[0029] In one embodiment, the header section **11** and the tubular section **13** are comprised of materials substantially transparent to IR light, i.e., showing low absorption in the wavelength range of from 700 to 1,500 nm.

[0030] Suitable materials for the disk **12** include polyolefins; polyesters like polycarbonates; acrylic polymers like MMA or SMMA; polyamides like nylon; SAN; SBA; and ABS. In one embodiment of the invention, the disk **12** comprises glycol-modified polyethylene terephthalate (PETG). Disk **12** does not need to be transparent to IR light. For some embodiments of the filtration device **10** of the present disclosure, it is even essential that the disk **12** absorbs IR radiation.

[0031] In one embodiment, the disk **12** comprises an IR absorber, i.e., a material which absorbs infrared light. The IR absorber is dispersed in the polymer matrix of the disk **12**. Suitable IR absorbers include carbon black; inorganic pigments like Lazerflair® pigments, copper phosphates or indium tin oxide (ITO); and organic pigments which have a high absorption in the wavelength range of from 700 to 1500 nm, for instance, phthalocyanines, naphthalocyanines, metal complexes of azo dyes, anthraquinones, squaric acid derivatives, immonium dyes, perylenes, quaterylenes and polymethins. Of these, phthalocyanines and naphthalocyanines are particularly suitable. Phthalocyanines and Naphthalocyanines having bulky side groups are preferred, due to their improved solubility in thermoplastic polymers. In a particular embodiment, the IR-absorptive material comprises a phthalocyanine. In another particular embodiment, the IR-absorptive material comprises carbon black.

[0032] The amount of IR absorber contained in the thermoplastic polymer of disk **12** is not particularly restricted as long as the desired absorption of laser radiation is ensured. In one embodiment, the thermoplastic polymer contains from 0.1 to 10 wt.-%, e.g., from 1 to 5 wt.-% of IR absorber, relative to the total weight of the thermoplastic polymer. Mixtures of different infrared absorbers can also be used. By mixing IR absorbers having absorption maxima at different wavelengths, the skilled person can optimize the absorption in the wavelength region of the laser used for the welding step. The IR absorber is compounded into the thermoplastic polymer of disk **12** by processes customary in the art. In a particular embodiment, disk **12** is comprised of PETG comprising 3 to 5 wt.-% carbon black.

[0033] In one embodiment, disk **12** is cut or punched out from a sheet of the IR absorber-containing thermoplastic polymer having the desired thickness. In another embodiment of the invention, disk **12** is produced from the IR absorber-containing thermoplastic polymer by way of injection molding.

[0034] In one embodiment of the filtration device **10**, the semipermeable hollow fiber membranes **14** have an inner diameter of from 2.8 to 4.0 mm, for instance, from 3.0 to 3.7 mm, or from 3.1 to 3.5 mm; and a wall thickness of from 100 to 500 μm, for instance, from 180 to 320 μm. The outer diameter of the semipermeable hollow fiber membranes **14** is larger than 3 mm. The ratio of inner diameter to wall thickness of the membranes is larger than 10, or even larger than 15. Membranes having a large ratio of inner diameter to wall thickness, i.e. thin-walled membranes, are more flexible and easily deformable. These membranes are less prone to form kinks on bending than thick-walled membranes. The ends of the thin-walled hollow fibers also can readily be closed by crimping to produce dead-end filter elements.

[0035] In one embodiment of the filtration device **10**, the semipermeable hollow fiber membranes **14** have a mean flow pore size, determined by capillary flow porometry, in the range of from 0.2 to 0.5 μm.

[0036] Capillary flow porometry is a liquid extrusion technique in which the flow rates through wet and dry membranes at differential gas pressure are measured. Before measurement, the membrane is immersed in a low surface tension liquid (e.g., a perfluoroether commercially available under the trade name Porofil®) to ensure that all pores including the small ones are filled with the wetting liquid. By measuring the pressure at which the liquid is pressed out of the pores their corresponding diameter can be calculated using the Laplace equation. With this method, the pore size distribution of those pores that are active in the mass transport is determined. Dead-end and isolated pores are omitted. The hollow fiber membranes are measured inside-out.

Laplace equation: $Dp=4\gamma \cos \theta/\Delta P$

[0037] Dp=diameter of pores [m]

[0038] γ=surface tension [N/m]; for Porofil® 0.016 [N/m]

[0039] ΔP=pressure [Pa]

[0040] Cos θ=contact angle; for complete wetting $\cos \theta=1$

[0041] In one embodiment, the semipermeable hollow fiber membranes **14** comprise polyethersulfone (PESU) and polyvinylpyrrolidone (PVP). In one embodiment, the semipermeable hollow fiber membranes **14** additionally comprise a polymer bearing cationic charges. Examples of suitable polymers bearing cationic charges include polyethyleneimines, modified polyethyleneimines, and modified polyphenyleneoxides. Semipermeable hollow fiber membranes **14** comprising a polymer bearing cationic charges show increased retention of endotoxins.

[0042] The overall effective surface area of the plurality of semipermeable hollow fiber membranes **14** generally is larger than 5 cm^2. The effective surface area is the portion of the surface area of the semipermeable hollow fiber membranes **14** available for the filtration of liquid; i.e., the portion that is not covered by the walls of the bores **16** or sealed, like the second ends **18** of the semipermeable hollow fiber membranes **14**. In one embodiment, the overall effective surface area of the plurality of semipermeable hollow fiber membranes **14** is in the range of from 10 cm^2 to 250 cm^2, e.g., from 20 to 100 cm^2, or from 30 to 60 cm^2.

[0043] The present disclosure also provides a process for operating the filtration device **10** of the present disclosure. The process comprises introducing a liquid through the inlet **15** of the filtration device **10** via bores **16** of disk **12** into the lumen of the plurality of semipermeable hollow fiber membranes **14**; filtering the liquid through the walls of the plurality of semipermeable hollow fiber membranes **14**; and removing the filtered liquid from the filtration device **10** through the outlet **19**.

[0044] The filtration device **10** of the present disclosure is designed and configured for inside-out filtration, i.e., the liquid to be filtered is introduced through inlet **15** into the lumen of the semipermeable hollow fiber membranes **14**, permeates through the membrane wall into the interior space of tubular section **13**, and leaves the filtration device **10** through outlet **19**. This allows for operating the filtration device **10** at pressures exceeding atmospheric pressure. In one embodiment, the filtration device **10** is operated at a pressure in the range of from 0.5 to 4 bar(g), for instance, 1.0 to 3.5 bar(g), or 1.5 to 2.5 bar(g). The filtration device **10** of the present disclosure achieves maximal flow rates, measured with water at 20° C. at 1.5 bar(g), of from 10 to 25 ml/cm^2*min, i.e., 600 to 1,500 ml/cm^2*hr.

[0045] In comparison, the device of U.S. Pat. No. 4,267,053 A achieves a maximal flow rate of 33.5 ml/cm^2*hr, or 0.56 ml/cm^2*min. Using a device of the present invention having an effective surface area of 30 cm^2, 500 ml of liquid can be filtered in about one minute; while it would require about one hour to do it with the device of U.S. Pat. No. 4,267,053 A.

[0046] In one embodiment of the filtration device **10** of the present disclosure, the header section **11** and the tubular section **13** are bonded to the disk **12**. In one embodiment, bonding is achieved using a suitable adhesive, for instance, an epoxy resin or a polyurethane adhesive. In a particular embodiment, bonding is achieved using a UV-curable adhesive. In another embodiment, bonding is achieved using a thermosetting adhesive.

[0047] In one embodiment of the filtration device **10**, the header section **11** and the tubular section **13** are fused or welded to the disk **12**. In another embodiment of the filtration device **10**, the header section **11** is fused or welded to the tubular section **13**. Welding can be performed using customary techniques. Examples include friction welding, spin welding, ultrasonic welding, high frequency welding, radiant heat welding, mirror welding, and laser welding. Welding processes which do not generate particles are preferred. In a particular embodiment, laser welding is used to weld the header section **11** and the tubular section **13** of the filtration device **10** to the disk **12**.

[0048] The present disclosure also provides a process for the production of the filter device **10**. A disk **12** of a thermoplastic polymer comprising an IR-absorptive material is provided between the tubular section **13** and the header section **11**. The disk **12** allows for laser-welding the header section **11** and the tubular section **13** to the disk **12**, laser-welded joints being formed in the process.

[0049] In one embodiment, the present disclosure provides a process for producing a filter device **10** which comprises providing a header section **11** and a tubular section **13**. Both sections comprise a thermoplastic polymer.

[0050] The process also comprises providing a disk **12** of a thermoplastic polymer comprising an IR-absorptive material. The disk **12** features a plurality of bores **16**. Each bore **16** holds a first end **17** of a semipermeable hollow fiber membrane **14** which protrudes from the disk **12**. The semipermeable hollow fiber membrane **14** is sealed at its second end **18**.

[0051] In one embodiment of the process, the disk **12** holding the plurality of semipermeable hollow fiber membranes **14** is assembled in a preceding procedure. Semipermeable hollow fiber membranes **14** having the desired length are provided, and one end **18** of each fiber **14** is sealed, e.g., by-heat sealing or heat crimping. The open end **17** of a semipermeable hollow fiber membrane **14** is introduced into a bore **16** of a disk **12** having a plurality of bores **16**; and the fiber end **17** is fixed to the wall of the bore **16**. In one embodiment of the process, the end **17** of the semipermeable hollow fiber membrane is fused or welded to the wall of the bore **16**. In another embodiment, the end **17** of the semipermeable hollow fiber membrane is glued to the wall of the bore **16** using a suitable adhesive, for instance, an epoxy resin or a polyurethane adhesive. All bores **16** of the disk **12** are subsequently or simultaneously equipped with fibers in this way.

[0052] The process further comprises assembling the header section **11**, the disk **12** holding the plurality of semipermeable hollow fiber membranes **14**, and the tubular section **13**. The three parts are combined in such a manner that the lip of the header section **11** and the lip of the tubular section **13** contact the disk **12**. Header section **11** covers the bores **16** of the disk **12**; and tubular section **13** encloses the plurality of semipermeable hollow fiber membranes **14** protruding from the disk **12**.

[0053] In one embodiment of the process, the lip of the header section **11** and the lip of the tubular section **13** contact disk **12** on opposite faces of disk **12**, or on opposite faces of a ridge **26** or a collar **24** located on the peripheral surface of disk **12**.

[0054] In another embodiment, the inside of the lip of the header section **11** and the lip of the tubular section **13** contact the peripheral surface of disk **12**, and the lip of the header section **11** and the lip of the tubular section contact each other. The outer diameter of disk **12** matches the inner diameter of the header section **11** and the tubular section **13**, so that the peripheral surface of disk **12** touches the insides of both the header section **11** and the tubular section **13**.

[0055] Subsequently to the assembly of the parts, the header section **11** is joined to the disk **12**; and the disk **12** is joined to the tubular section **13** to produce the finished filter device **10**. In one embodiment, header section **11** additionally is joined to tubular section **13**. In one embodiment, joining is achieved by irradiation with laser light having a wavelength in the range of from 800 nm to 1090 nm.

[0056] In one embodiment of the joining process, irradiation with laser light is performed by at least one laser beam moving along a perimeter of the lip of the header section **11** and the tubular section **13**, respectively. In another embodiment of the process, the whole perimeter of the lip of the tubular section **13** and the header section **11**, respectively, is irradiated with laser light simultaneously using ring optics. In still another embodiment, the perimeters of the lip of the header section **11** and the tubular section **13** are irradiated with laser light simultaneously. The laser beam is absorbed by the disk **12** of thermoplastic polymer comprising an IR-absorptive material. The heat generated by the laser melts the thermoplastic polymer and creates a permanent weld, i.e., a laser-welded joint.

[0057] Examples of suitable lasers for the laser-welding step include semiconductor diode lasers having wavelengths in the range of 800 nm to 980 nm; and solid state lasers (e.g., fiber lasers or Nd:YAG lasers) having wavelengths in the range of from 1060 to 1090 nm. Depending on the materials and the desired welding speed, optical power levels of the laser range from 1 W to 200 W, e.g., from 20 to 100 W, for instance, 30 to 80 W.

[0058] In one embodiment of the process, the diameter of the focal spot of the laser beam is in the range of from 0.5 mm to 2 mm, for instance 0.8 mm to 1.5 mm.

[0059] In one embodiment of the process, the parts are pressed together during the joining step while the laser generates the weld seam. Generally, a force in the range of from 100 to 1,500 N is used to press the individual parts together. Depending on the diameter of the filter device **10** and the area the force is applied to, this translates to pressures in the range of from 1 to 5 N/mm^2.

[0060] The filtration device **10** of the present disclosure will typically be sterilized before it is used in a clinical setting. One suitable method is sterilization with ethylene oxide (ETO). In another embodiment, the filtration device **10** is sterilized with gamma radiation. In a particular embodiment, radiation dose used is in the range of from 25 to 50 kGy, for instance, 25 kGy. In still another embodiment, the filtration device **10** is sterilized with steam at a temperature of at least 121° C. for at least 21 min.

[0061] The present disclosure also is directed to the use of the filtration device **10** in the dead-end filtration of liquids. In one embodiment, the filtration device **10** is used for sterile filtration of water or aqueous solutions, e.g. drugs, dialysis liquids, or nutrient solutions, or other liquids destined for infusion into a patient. The filter device **10** retains particles, bacteria, and endotoxins that may be present in the liquid. The filtered liquid is pyrogen-free and may directly be injected into a patient.

[0062] Exemplary embodiments of the filtration device **10** of the present disclosure are shown in the accompanying figures and described below. It will be understood that the features mentioned above and those described hereinafter can be used not only in the combination specified but also in other combinations or on their own, without departing from the scope of the present invention.

[0063] FIG. **1** shows a side view and a cross-sectional view of an embodiment of a filtration device **10** of the present disclosure. The side view of filtration device **10** illustrates header section **11** with inlet **15** and tubular section **13** with outlet **19** together forming the outer shell of the filtration device **10**. The cross-sectional view shows disk **12** holding a plurality of semipermeable hollow fiber membranes **14** arranged within the filtration device **10**. Disk **12** comprises a plurality of bores **16**. Each bore **16** holds the first end **17** of a semipermeable hollow fiber membrane **14**. The wall of semipermeable hollow fiber membrane **14** is attached to the wall of the bore **16** at the first end **17**. The second end **18** of semipermeable hollow fiber membrane **14** is sealed.

[0064] FIG. **2** shows a perspective view of a disk **12** comprising a plurality of bores **16**. Each bore **16** holds the first end **17** of a semipermeable hollow fiber membrane **14**. The wall of semipermeable hollow fiber membrane **14** is attached to the wall of the bore **16** at the first end **17**. The second end **18** of the semipermeable hollow fiber membrane **14** is sealed. The figure shows an embodiment wherein the second ends **18** of semipermeable hollow fiber membranes **14** have been sealed by crimping.

[0065] FIG. **3** shows an exploded view of an embodiment of a filtration device **10**. Disk **12** with a plurality of semipermeable hollow fiber membranes **14** attached thereto is arranged within tubular section **13**, tubular section **13** providing a housing for the semipermeable hollow fiber membranes **14**. Header section **11** covers disk **12** and seals the mouth of tubular section **13**.

[0066] FIG. **4** shows a detail of the cross-sectional view of FIG. **1**. Circumferential ledges **20** and **21** are present on the inside wall of the tubular section **13** and the header section **11**, respectively. Disk **12** is held by the circumferential ledges **20** and **21**, which together form a circumferential recess in the inner wall of filtration device **10**. A collar **22** is present on the outside surface of tubular section **13**. Collar **22** is an optional feature of the device. It is provided as an anchor for fastening the filtration device **10** in a holder.

[0067] FIG. **5** shows an exploded view of another embodiment of a filtration device **10**. Disk **12** with a plurality of semipermeable hollow fiber membranes **14** attached thereto is arranged within tubular section **13**, tubular section **13** providing a housing for the semipermeable hollow fiber membranes **14**. Disk **12** features a collar **24** on its perimeter. A flange **23** is provided on the mouth of header section **11**; and another flange **25** is provided on the mouth of tubular section **13**. The outer diameter of collar **24** matches the outer diameter of flanges **23** and **25**. Collar **24** is held between flanges **23** and **25** when the filtration device **10** is assembled. Flange **23** is joined to one face of collar **24**; and flange **25** is joined to the other face of collar **24**, thus sealing filtration device **10**. Joining can be achieved by bonding the parts together using an adhesive; or by fusing or welding them. In one embodiment, disk **12** including collar **24** is comprised of an IR-absorbing material and flanges **23** and **25** are joined to collar **24** by laser welding.

[0068] FIG. **6** shows a side view and a cross-sectional view of still another embodiment of a filtration device **10** of the present disclosure. The side view of filtration device **10** illustrates header section **11** with inlet **15**; tubular section **13** with outlet **19**; and disk **12** with ridge **26** together forming the outer shell of the filtration device **10**. The cross-sectional view shows disk **12** holding a plurality of semipermeable hollow fiber membranes **14** arranged within the filtration device **10**. Disk **12** comprises a plurality of bores **16**. Each bore **16** holds the first end **17** of a semipermeable hollow fiber membrane **14**. The wall of semipermeable hollow fiber membrane **14** is attached to the wall of the bore **16** at the first end **17**. The second end **18** of semipermeable hollow fiber membrane **14** is sealed.

[0069] FIG. **7** shows a detail of the cross-sectional view of FIG. **6**. A circumferential ridge **26** is present on the peripheral surface of disk **12**. Ridge **26** is held between the lips of header section **11** and tubular section **13**, respectively, when the filtration device **10** is assembled. Header section **11**, tubular section **13**, and ring **12** are joined at ridge **26**, thus sealing filtration device **10**. Joining can be achieved by bonding the parts together using an adhesive; or by fusing or welding them. In one embodiment, disk **12** including ridge **26** is comprised of an IR-absorbing material and tubular section **13** and header section **11** are joined to ridge **26** by laser welding.

LIST OF REFERENCE SIGNS

[0070] **10** filtration device
[0071] **11** header section
[0072] **12** disk
[0073] **13** tubular section
[0074] **14** semipermeable hollow fiber membrane
[0075] **15** liquid inlet
[0076] **16** bore
[0077] **17** first end of hollow fiber membrane
[0078] **18** second end of hollow fiber membrane
[0079] **19** liquid outlet
[0080] **20** ledge
[0081] **21** ledge
[0082] **22** collar
[0083] **23** flange
[0084] **24** collar
[0085] **25** flange
[0086] **26** ridge

1. A filtration device comprising:

i. a header section having an inlet for a liquid;

ii. a disk having a plurality of bores, each bore holding a first end of a semipermeable hollow fiber membrane protruding from the disk, the semipermeable hollow fiber membrane being sealed at its second end; and

iii. a tubular section having an outlet for a liquid;

wherein the header section covers a first face of the disk; and wherein the tubular section covers a second face of the disk opposite to the first face, and enclosing the plurality of semipermeable hollow fiber membranes;

wherein the header section, the disk, and the tubular section each comprise a thermoplastic polymer; and

wherein the disk comprises an IR-absorptive pigment selected from the group consisting of carbon black IR-absorptive inorganic pigments and IR-absorptive organic pigments.

2. The device of claim **1**, wherein the IR-absorptive material comprises a phthalocyanine.

3. The device of claim **1**, wherein the IR-absorptive material comprises carbon black.

4. The device of claim **1**, wherein the thermoplastic polymer is PETG.

5. The filtration device of claim **1**, wherein both the header section and the tubular section are bonded to the disk.

6. The filtration device of claim **1**, wherein both the header section and the tubular section are welded to the disk.

7. The filtration device of claim **1**, wherein the semipermeable hollow fiber membranes have an inner diameter of from about 2.8 mm to about 4.0 mm, and a wall thickness of from about 100 μm to about 500 μm, the ratio of inner diameter to wall thickness being larger than about 10.

8. The filtration device of claim **1**, wherein the semipermeable hollow fiber membranes have a mean flow pore size, determined by capillary flow porometry, in the range of from about 0.2 μm to about 0.5 μm.

9. A process for operating the filtration device of claim **1**, comprising introducing a liquid through the inlet into the lumen of the plurality of semipermeable hollow fiber membranes; filtering the liquid through the walls of the plurality of semipermeable hollow fiber membranes; and removing the filtered liquid from the filtration device through the outlet.

10. The process of claim **9**, wherein the liquid is introduced at a pressure of about 0.5 bar to about 4 bar (g); and the flow rate of the liquid through the filtration device is in the range of from about 10 ml/cm^2*min to about 25 ml/cm^2*min, measured at about 20° C. with water at about 1.5 bar (g).

11. A process for producing a filter device, said process comprising the steps of:

a) providing a header section and a tubular section, each comprising a thermoplastic polymer;

b) providing a disk of a thermoplastic polymer comprising an IR-absorptive material, the disk having a plurality of bores, each bore holding a first end of a semipermeable hollow fiber membrane protruding from the disk, the semipermeable hollow fiber membrane being sealed at its second end;

c) assembling the header section, the disk holding the plurality of semipermeable hollow fiber membranes, and the tubular section, so that the lip of the header section and the lip of the tubular section contact the disk, the header section covering the bores of the disk, and the tubular section enclosing the plurality of semipermeable hollow fiber membranes;

d) joining the header section to the disk; and joining the disk to the tubular section by irradiation with laser light having a wavelength in the range of from about 800 nm to about 1090 nm.

12. (canceled)

13. A method for dead-end filtration of a liquid, said method comprising the step of sterile filtering the liquid using a filtration device comprising:

i. a header section having an inlet for a liquid;

ii. a disk having a plurality of bores, each bore holding a first end of a semipermeable hollow fiber membrane protruding from the disk, the semipermeable hollow fiber membrane being sealed at its second end; and

iii. a tubular section having an outlet for a liquid;

wherein the header section covers a first face of the disk; and

wherein the tubular section covers a second face of the disk opposite to the first face, and enclosing the plurality of semipermeable hollow fiber membranes;

wherein the header section, the disk, and the tubular section each comprise a thermoplastic polymer; and

wherein the disk comprises an IR-absorptive pigment selected from the group consisting of carbon black, IR-absorptive inorganic pigments, and IR-absorptive organic pigments.

14. The method of claim **13**, wherein the liquid is water.

15. The method of claim **13**, wherein the liquid is an aqueous solution.

16. The method of claim **13**, wherein the aqueous solution is selected from the group consisting of a drug solution, a dialysis liquid solution, and a nutrient solution.

17. The method of claim **13**, wherein the filter device is configured to retain particles, bacteria, endotoxins, and combinations thereof from the liquid.

18. The method of claim **13**, wherein the dead-end filtration of the liquid results in a pyrogen-free liquid.

19. The method of claim **18**, wherein the method further comprises injection of the pyrogen-free liquid to a patient.

20. The method of claim **13**, wherein the IR-absorptive material comprises a phthalocyanine.

21. The method of claim **13**, wherein the IR-absorptive material comprises carbon black.

* * * * *