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(54) **Sealing the ends of hollow fibre dialyzers**

(57) A hollow fibre diffusion device comprises a bundle of hollow fibres (12) disposed in a generally rigid, tubular housing (14) having relatively diametrically enlarged manifold members (16) adjacent opposite housing ends. A relatively resilient plastic sleeve member (20) is carried at each end of the housing and sealed to it. Each sleeve member carries an added inner sleeve (26) of smaller inner diameter than the outer sleeve, being coaxially positioned with the housing (14) to receive, hold, and centre the ends of the bundle (12). Preferably, the sleeve is made of a material which sealingly adheres to the potting compound to facilitate the sealing of the system.

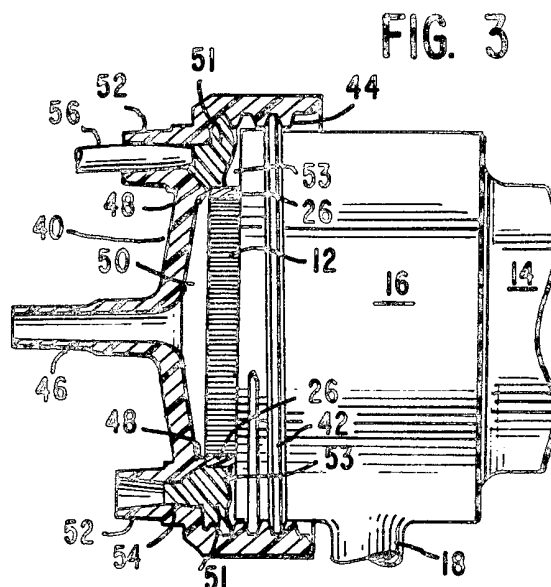


FIG. 1

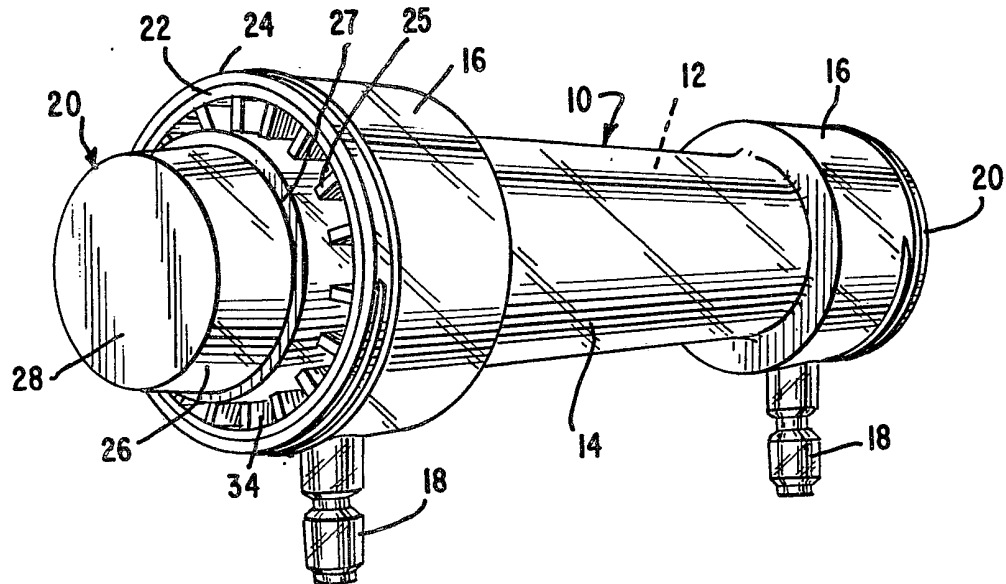


FIG. 2

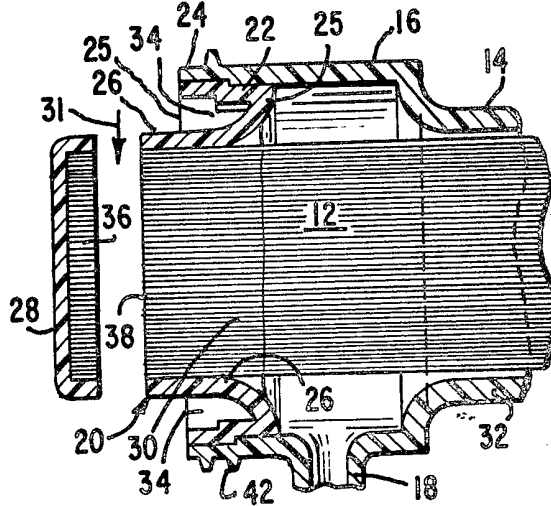


FIG. 3

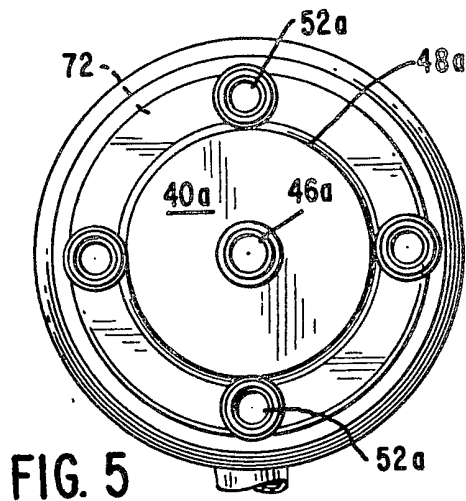
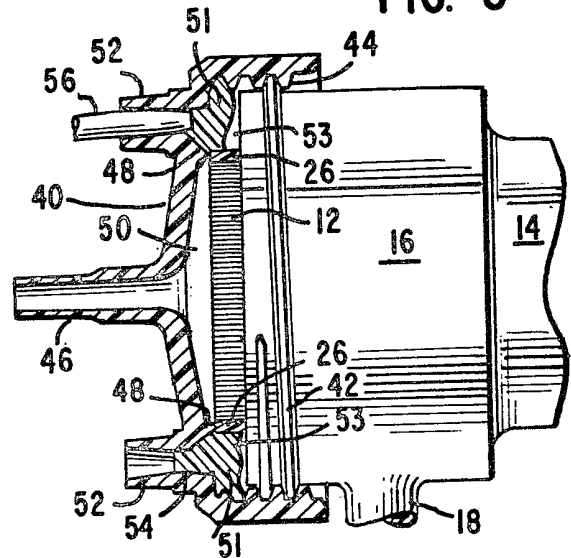


FIG. 5

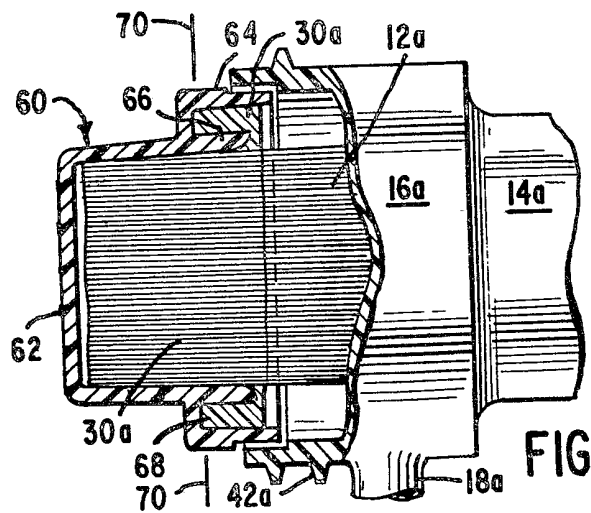


FIG. 4

SPECIFICATION

Sealing the ends of hollow fibre dialyzers

- 5 Capillary fibre dialyzers are sold in large quantities by various companies for use as artificial kidneys for the dialysis of blood. Typically, these various commercial device comprises a bundle of hollow fibres disposed in a generally rigid tubular housing, with
- 10 the bundle and housing having relatively diametrically enlarged manifold members adjacent opposite housing ends. A sealing cap is then placed on each housing end, with the sealing cap defining a central port for the flow of blood from end to end of the
- 15 housing, passing through the bores of the hollow fibres in the bundle.

- Dialysis solution passes through the bundle of fibres in contact with the exterior surfaces of the individual fibres, entering the housing through a
- 20 side port in one of the enlarged manifold members, and being withdrawn from another port in the side of the other enlarged manifold member. The ends of the bundle of hollow fibres are potted with a polyurethane material or the like, to stabilize the
- 25 fibres and to secure them in a single mass, with the bores of the fibres being exposed to permit flow communication along their lengths. Frequently, an O-ring is provided between the end of the manifold member and the end closure member, to provide a
- 30 hermetic seal.

- In the conventional techniques of manufacturing hollow fibre dialyzers, the bundles of fragile fibres, upon assembly into dialyzers, exhibit a substantial number of instances of fibre breakage, occurrence of
- 35 short fibres, and the like which results in leaking units which must be discarded or repaired. Often, some of the fibres misalign, and flare out into the enlarged manifold member, when they should remain in a discrete bundle during the potting process.
- 40 This can result in a leakage situation, for even a single leaking fibre must result in the scrapping of the entire dialyzer unless it can be repaired.

- The unit cost of dialyzers is increased by the need in many designs of a separate O-ring at its end for
- 45 sealing. Also, the O-ring is conventionally compressed as the end closure member is applied to provide the seal. However, in the case of a vinyl O-ring or another material which is subject to cold flow upon storage, the dialyzer may lose its sealing capabilities
- 50 provided by the O-ring because of the cold flow of the ring material in response to the compressive forces. The result of this is that the seal itself is weakened, and small amounts of blood may leak from the end closure of the dialyzer.

- 55 In accordance with the dialyzers described hereafter, an improved sealing system is provided in which a resilient sealing member is not placed under significant initial compression, so that significant cold flow does not take place upon storage. As a
- 60 result of this such dialyzers may be stored indefinitely without a significant diminution of their good end sealing capabilities.

- A capillary fibre diffusion device is provided herein which may be made with a significantly lower scrap
- 65 rate, greatly reducing the unit cost of the dialyzer,

which also has improved shelf life with respect to its end seals, and an intrinsically lower cost because a separate, preformed O-ring is not necessary in the designs proposed.

- 70 In accordance with this invention, there is provided a hollow fibre diffusion device which comprises a bundle of hollow fibres disposed in a substantially rigid, tubular housing, said bundle and housing having relatively diametrically enlarged manifold
- 75 members adjacent opposite housing ends, and being sealed at said opposite ends, and a relatively resilient plastics sleeve member carried at each end of the housing and sealed thereto, each sleeve member having a sleeve of smaller inner diameter
- 80 than the inner diameters of the manifold members, said sleeve being coaxially positioned relative to said housing to receive, hold, and centre the ends of said bundle, said sleeve containing a mass of potting compound which is interspersed throughout the
- 85 exterior surfaces of the fibre of said bundle, said sleeve being made of a material which sealingly adheres to said potting compound.

- The invention also resides in a method of sealing the ends of a hollow fibre diffusion device which
- 90 comprises a bundle of hollow fibres disposed in a substantially rigid, tubular housing, the method comprising:-

- engaging a sleeve member in each end of the housing so as to close said end, each member
- 95 having a sleeve spaced radially inwardly of the remainder of the member, inserting each end of said bundle into a respective sleeve, whereby the ends of said bundle are held and centred coaxially in the housing;

- 100 applying potting compound to the ends of said bundle with the sleeves to permeate and enclose the bundle ends within the sleeves;

- allowing said potting compound to cure;
- slicing away the outer, closed ends of said sleeves
- 105 and the outermost portions of said bundle ends to expose the open bores of the individual fibres of the bundle;

- and attaching to each end of said housing a closure member which has a central port and an
- 110 inwardly pointing, annular sealing ring, and positioning said sealing ring to sealingly press against the cut end of said sleeve to define a manifold chamber within said annular sealing ring for communication between the central port and the bores
- 115 of the fibres.

- The sleeve member which has the sleeve may also have an outer sleeve which fits in telescoping relation into the inner surface of the enlarged manifold members, and may be sealed thereto by
- 120 solvent sealing or the like. Accordingly, a solid, complete seal of the inner ends of the dialyzer is provided, forcing all fluid passing from end to end of the dialyzer to pass through the bores of the fibres, which are centred and held by the sleeve.

- 125 The diffusion device may be used as an oxygenator for blood, an ultrafiltration device, a reverse osmosis module or a membrane plasmapheresis device.

- The hollow fibre diffusion device may be manufactured by applying the sleeve member, which has a
- 130

closed end, to each end of the housing and sealing it within the housing end. An end of the bundle of hollow fibres is inserted into each sleeve, which sleeve is spaced radially inwardly of the remainder of the sleeve member, and coaxially positioned within the housing to hold and centre the bundle ends. The sleeve preferably defines the closed outer end.

Potting compound is then applied to the ends of the bundle to permeate and enclose the bundle ends within the sleeve. This may be done by rotating the dialyzer so that the ends of the housing revolve around the rotational centre, while simultaneously applying the potting compound through the side dialysate ports from where it migrates radially outwardly to the bundle ends, to fill the closed-end inner sleeves to the desired level. Conventional potting compounds, such as polyurethane formulations, used in the commercial manufacture of hollow fibre dialyzers may be used.

After the potting compound has cured, the outer end of the inner sleeve and the outermost portion of the fibre bundle end may be sliced away, to expose the open bores of the individual fibres of the bundle. The sleeve is preferably made of a material such as a polyvinyl chloride formulation which is easily cut by a slicing instrument.

After this, the end closure member which defines a central port and an inwardly pointing, annular sealing ring may be attached to each end of the housing. In one specific embodiment, the end closure may be twisted on by a conventional interlocking screw thread arrangement. However, solvent sealing or other techniques are also contemplated for sealing of the closure members to the housing.

The sealing ring is proportioned to sealingly press against the cut end of the sleeve. It may be solvent-sealed against the cut end of the sleeve for permanent and improved sealing, if desired, or sealed by any other means. The effect of this is to define a manifold chamber within the annular sealing ring, for communication between the central port and the bores of the bundle fibres.

Sealant material may then be applied through ports in the end closure members to form a sealant ring about the exterior of the sealing ring. Since the sealant ring may be under substantially no uncompression since it is formed *in situ*, the quality of its seal does not significantly deteriorate by cold flow upon storage.

Referring to the drawings, Figure 1 is a perspective view of a hollow fibre dialyzer in a semi-finished stage of manufacture, showing an attached, relatively resilient plastics sleeve member carried at each end of the housing.

Figure 2 is a longitudinal sectional view of an end of the dialyzer of Figure 1 showing how, after potting of the fibre bundle, an end portion of the relatively resilient plastics sleeve member is sliced away to expose open fibres of the bundle, embedded in potting compound.

Figure 3 is a fragmentary elevational view, taken partly in longitudinal section, showing how an end closure member is attached to the end of the dialyzer housing to complete the assembly of the dialyzer.

Figure 4 is a fragmentary elevational view, taken partly in longitudinal section, of an alternative embodiment of the dialyzer showing a different design of the relatively resilient plastics sleeve member.

Figure 5 is an end elevational view of the dialyzer of Figure 4, after the step of slicing away an end portion of the relatively resilient plastics sleeve member and application of an end closure member for sealing the dialyzer end.

Referring to the drawings, a hollow fibre diffusion device 10, which is specifically shown to be a dialyzer for blood, comprises a bundle of hollow fibres 12 of a conventional type used in hollow fibre dialyzers, disposed in a substantially rigid, tubular housing 14 of a design generally similar to commercially known hollow fibre dialyzers, except as otherwise described herein.

Housing 14 carries at its opposed ends a pair of relatively diametrically enlarged manifold members 16, each of which has a conventionally designed dialysis solution access port 18, one of which is the inlet and the other the outlet for dialysis solution. Manifolds 16 permit the relatively uniform flow distribution and collection of dialysis solution prior to and immediately following its trip through the bundle of fibres 12 in contact with the exterior surfaces of the fibres.

A relatively resilient plastics sleeve member 20 is carried at each end of the housing 14 and is sealed thereto, conveniently by solvent sealing or the like, at the interface between an outer sleeve 22 of sleeve member 20 and the annular end 24 of the tubular housing, as particularly shown in Figure 2.

Each sleeve member 20 also has an inner sleeve 26 and a closed end 28. As shown in the drawings, inner sleeve 26 is of smaller inner diameter than the inner diameters of the manifold members 16, with inner sleeve 26 being coaxially positioned relative to housing 14 to receive, hold and centre the end parts of bundle 12.

Each inner sleeve contains a mass of potting compound 30 which, within the sleeve, fills the interstices between the exterior surfaces of the fibres of bundle 12. Inner sleeve 26 and preferably the entire sleeve member 20, which may be a single moulded piece, is made of a resilient material such as a polyvinyl chloride plastics formulation, which sealingly adheres to potting compound 30, which in turn, may be a urethane formulation or a similar material capable of bonding with the material of inner sleeve 26. Accordingly, the ends of bundle 12 are firmly secured in a tightly sealed, potted mass.

Preferably, the inner diameter of inner sleeve 26 is substantially the same as the inner diameter of central portions 32 of the tubular housing. An open space 34 is defined about the radially outer surface of the inner sleeve 26 and within the outer sleeve 22. Inner sleeve 26 may have a slight step 27 and while reinforcement members 25 are positioned between inner sleeve 26 and outer sleeve 22 in the space 34.

Potting compound may be applied to the ends of the dialyzer in accordance with U.K. Patent Specification No. 2016358 which shows how the sealant may be inserted by spinning the dialyzer so that manifold

chambers 16 spin around the centre of rotation while simultaneously inserting the potting compound through ports 18 until inner sleeve 16 is filled to the desired level. Thereafter, the potting compound 30 is allowed to cure. One then transversely slices through the inner sleeve 26 at point 31 with a cutting blade or the like, to remove the closed end 28 and the potted end portion 36 of bundle 12, to expose the open bores of the fibres.

Following this, an end closure member 40 may be applied to the end of dialyzer 14, as shown in Figure 3. The specific means shown for securing of the end closure member 40 are the mating screw threads 42, 44, although other sealing techniques such as heat sealing or solvent sealing may be used instead.

End closure member 40 has a central aperture 46, in the conventional manner, but is also provided with an inwardly pointing annular sealing ring 48, which is positioned as shown in Figure 3 to press against the end of the inner sleeve 26. If desired, an organic solvent such as methylisobutylketone may be applied to the sealing ring 48 and/or the end of inner sleeve 26 to provide a solvent seal bond between the closure member 40 and the inner sleeve 26. The closure member 40 may be made of a polystyrene-based plastics material, with other copolymer ingredients added as desired, which material is readily solvent sealable to vinyl plastics material of which the inner sleeve 26 is preferably made.

As the result of this, a small manifold chamber for blood 50 is provided, for communication between central aperture 46 and the interiors of the bores of fibre bundle 12, in which manifold chamber 50 is of substantially smaller diameter than the overall inner diameter of the end closure member 40. The effect of this is to reduce the blood volume of the dialyzer, which is clearly desirable, as well as to avoid peripheral, stagnant areas, where blood in a manifold faces a wall of potting compound which surrounds bundle 12. Also, the amount of potting compound which is needed at each end is greatly reduced, since the potting compound is retained by the inner sleeve, which is spaced radially inwardly from the inner wall of the manifold chamber.

Each closure member 40 also has a plurality of eccentrically positioned hollow projecting members 52, which can communicate with the exterior space about sealing ring 48 and within the end closure member 40. The projecting members 52 may be used as "torquing lugs" to facilitate the screwing down of the end closure member 40. However, when desired, partitions 54, which are found in the members 52, may be broken through (or not provided in the first place) to permit injection nozzles 56 to communicate with the annular exterior space 51 positioned outside of inner sleeve 26 and sealing ring 48, to extrude an O-ring 53 made of sealant, to fill exterior space 51. This O-ring 53 in space 51 can reliably exercise its sealing function without being under such a level of compression that it may tend to cold flow upon storage.

However, in the embodiment of Figure 3, the O-ring 53 need not be provided since the solvent seal between sealing ring 48 and inner sleeve 26 can

provide an adequate hermetic seal for the blood flow path through aperture 46.

Referring to Figures 4 and 5, a different embodiment of dialyzer and seal is disclosed. A dialyzer housing 14 having enlarged manifold ends 16a and access ports 18 is disclosed as in the previous design. A different design of sleeve member 60 is used, having a closed end 62 as before, and also having an outer sleeve 64 and an inner sleeve 66. An annular aperture 68 is defined between the sleeves and is open towards the housing 14, rather than away from the housing as is the corresponding space 34 in the embodiment shown in Figure 2. Fibre bundle 12a is present, as is potting compound 30a, applied in the manner of the previous embodiment, and shown to fill annular aperture 68 as well as inner sleeve 66.

In this instance, after curing of the potting compound 30a, the plastics sleeve member 60 is transversely severed across both of its sleeves 64, 66 at slicing line 70-70, to separate the portion of sleeve member 60 which contains closed end 62 from the rest of the dialyzer, and to expose sleeves 64, 66 and sealant 30a therebetween. Thereafter, an end closure member 40a which may be of a design identical to closure member 40, is applied by rotation about screw threads 42a to bring sealing ring 48a into sealing contact with the end of inner sleeve 66, as in the previous embodiment.

It may be desired to not use a solvent seal between ring 48a and inner sleeve 66, but instead to rely upon an extruded O-ring 72, which may be inserted into the area outside of sealing ring 48a under end closure 40a by extrusion through ports 52a in the manner previously described. O-ring 72 communicates with the sealant in annular space 68, and may form a tight adhesive bond with it, as well as bonding to the peripheral interior areas of end closure 40a, providing a firm, relatively uncompressible end seal, in which the sealant flows into exact sealing conformity with every irregularity of shape present, thus eliminating the need for a pressure seal which may cold flow.

110 CLAIMS

1. A hollow fibre diffusion device which comprises a bundle of hollow fibres disposed in a substantially rigid, tubular housing, said bundle and housing having relatively diametrically enlarged manifold members adjacent opposite housing ends, and being sealed at said opposite ends, and a relatively resilient plastics sleeve member carried at each end of the housing and sealed thereto, each sleeve member having a sleeve of smaller inner diameter than the inner diameters of the manifold members, said sleeve being coaxially positioned relative to said housing to receive, hold, and centre the ends of said bundle, said sleeve containing a mass of potting compound which is interspersed throughout the exterior surfaces of the fibre of said bundle, said sleeve being made of a material which sealingly adheres to said potting compound.

2. The diffusion device of Claim 1 in which said sleeve member including the inner sleeve is made of

a polyvinyl chloride plastics material, and the potting compound is a polyurethane.

3. The diffusion device of Claim 1 or 2 in which each end of the housing is sealed by means of an attached end closure member, said closure member having a central port, and an inwardly pointing annular sealing ring positioned to sealingly press against the end of the inner sleeve.

4. The diffusion device of Claim 3 in which each closure member has a plurality of eccentrically positioned projections which communicate with the exterior space about the sealing ring, and an extruded O-ring filling said exterior space.

5. The diffusion device of Claim 4 in which the inner diameter of said sleeve is substantially the same as the inner diameter of the central portion of said tubular housing.

6. The diffusion device of Claim 3 in which said sleeve is radially spaced inwardly from the end of said housing, and defining an open space about the radially outer surface of said inner sleeve which is surrounded by said housing end.

7. A hollow fibre diffusion device constructed substantially as herein described with reference to Figures 1 to 3 of the accompanying drawings.

8. A hollow fibre diffusion device constructed substantially as herein described with reference to Figures 4 and 5 of the accompanying drawings.

9. A method of sealing the ends of a hollow fibre diffusion device which comprises a bundle of hollow fibres disposed in a substantially rigid, tubular housing, the method comprising:-

engaging a sleeve member in each end of the housing so as to close said end, each member having a sleeve spaced radially inwardly of the remainder of the member, inserting each end of said bundle into a respective sleeve, whereby the ends of said bundle are held and centred coaxially in the housing;

applying potting compound to the ends of said bundle within the sleeves to permeate and enclose the bundle ends within the sleeves;

allowing said potting compound to cure; slicing away the outer, closed ends of said sleeves and the outermost portions of said bundle ends to expose the open bores of the individual fibres of the bundle;

and attaching to each end of said housing a closure member which has a central port and an inwardly pointing, annular sealing ring, and positioning said sealing ring to sealingly press against the cut end of said sleeve to define a manifold chamber within said annular sealing ring for communication between the central port and the bores of the fibres.

10. The method of Claim 9 including the step of applying sealant material through ports in the diffusion device to form a sealant ring about the exterior of said sealing ring which is substantially not under compression.

11. A method according to Claim 1, substantially as herein described with reference to Figures 1 to 3 or Figures 4 and 5 of the accompanying drawings.