# United States Patent [19]

**Goldberg et al.**

[11] **3,818,511**

[45] **June 25, 1974**


[54] **MEDICAL PROSTHESIS FOR DUCTS OR CONDUITS**


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[73] Assignee: **Medical Products Corporation,** Skokie, Ill.



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[21] Appl. No.: **307,641**

[52] **U.S. Cl.** ..... **3/1,** 3/DIG. 1, 128/214 R, 128/334 R, 128/348, 264/257

[51] **Int. Cl.** ..... **A61f 1/24,** A61m 5/00, A61m 25/00

[58] **Field of Search** ..... 3/1, DIG. 1; 128/214 R, 128/214 B, 348, 334 R, 334 C, 1 R



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*Assistant Examiner*—Ronald L. Frinks
*Attorney, Agent, or Firm*—Molinare, Allegretti, Newitt & Witcoff



[57] **ABSTRACT**

Medical prosthesis for ducts or conduits and method of manufacture. An exemplary embodiment is an arteriovenous shunt having a cannula terminated in a funnel in which the interior included angle ranges from 15° – 30°. The funnel is of an implantable, resilient silicone rubber into which a woven, flexible Dacron skirt is molded to enable suturing and tissue ingrowth at the anastomotic juncture. The silicone is of a medical type which is body tissue-compatible, and has sufficient elasticity and resilience to permit compliance during pulsatile fluid flow, storage and return of fluid kinetic energy, and accommodation to various sizes of vessels, ducts, or conduits. Actual experimental use shows improved results compared to prior types of tip-type cannulae.


**9 Claims, 7 Drawing Figures**

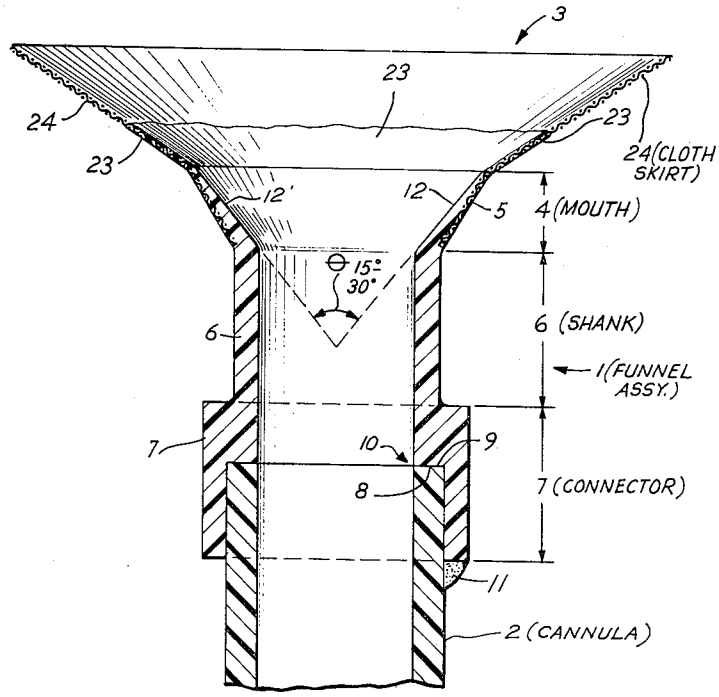
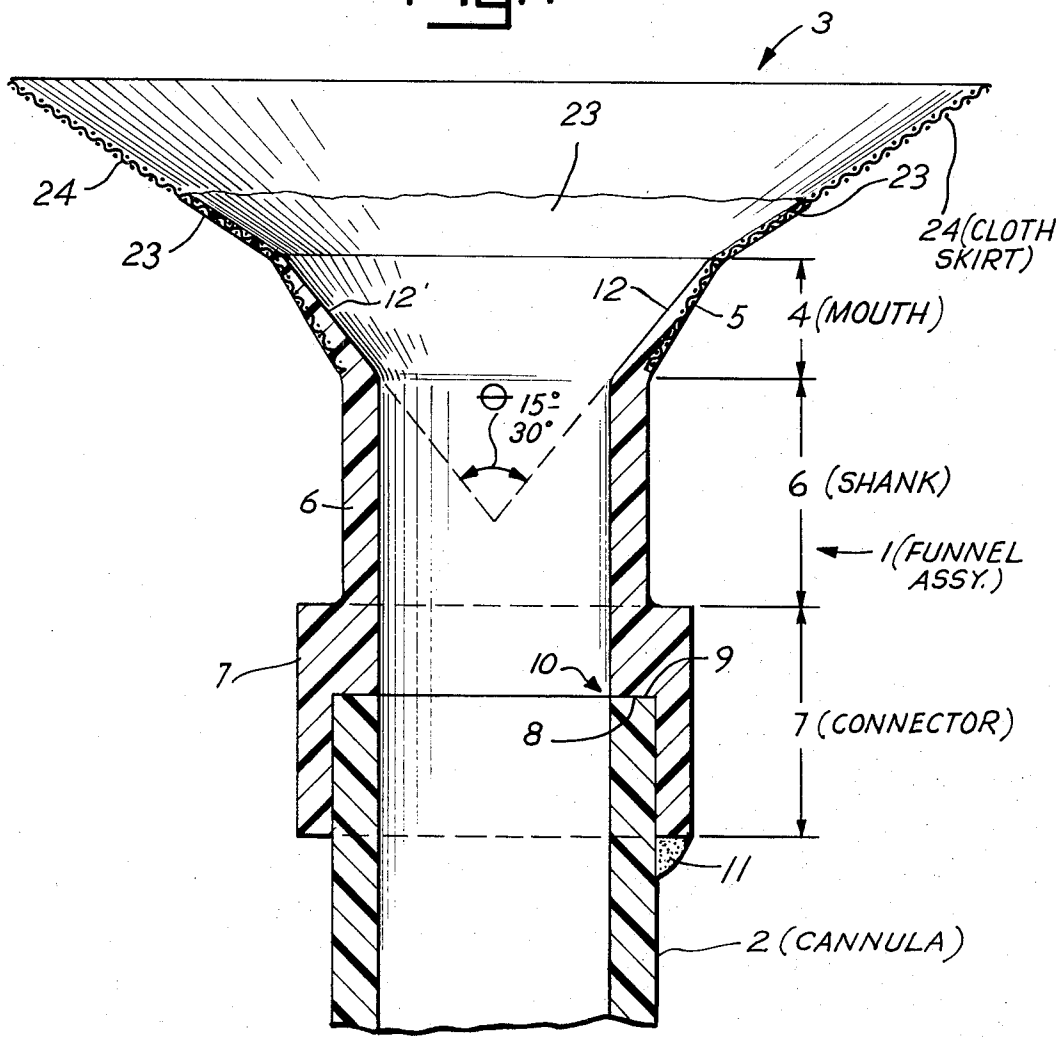


Fig. 1


3
23
24
23
23
24(CLOTH SKIRT)
12'
12
5
4(MOUTH)
15°
30°
6 (SHANK)
6
1(FUNNEL ASSY.)
7
10
9
8
7 (CONNECTOR)
11
2 (CANNULA)

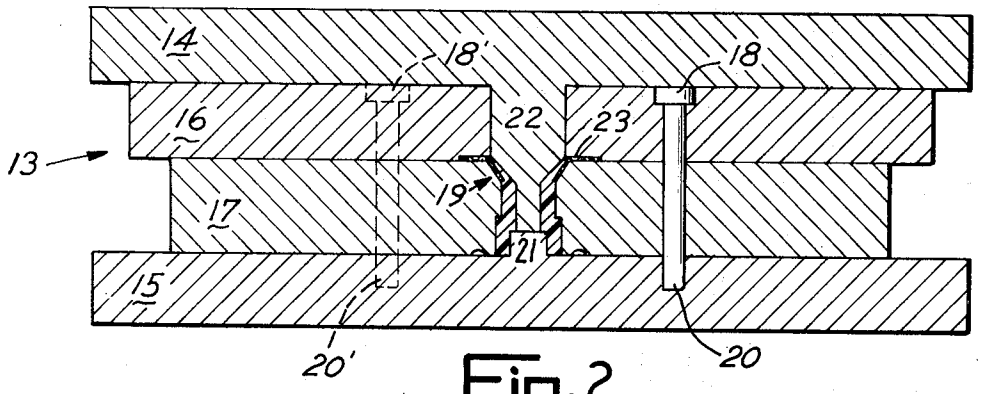

14
18'
18
16
22
23
13
19
17
21
15
20'
20

Fig. 2

Fig. 3

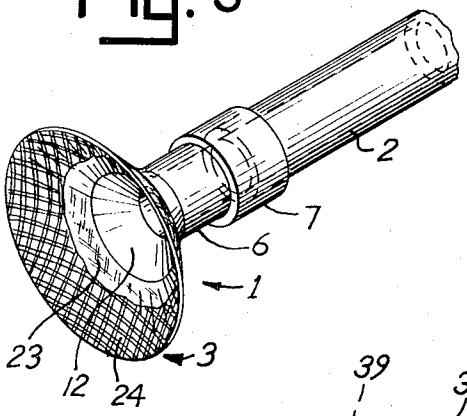
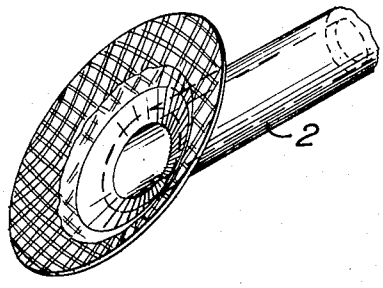



Fig. 4



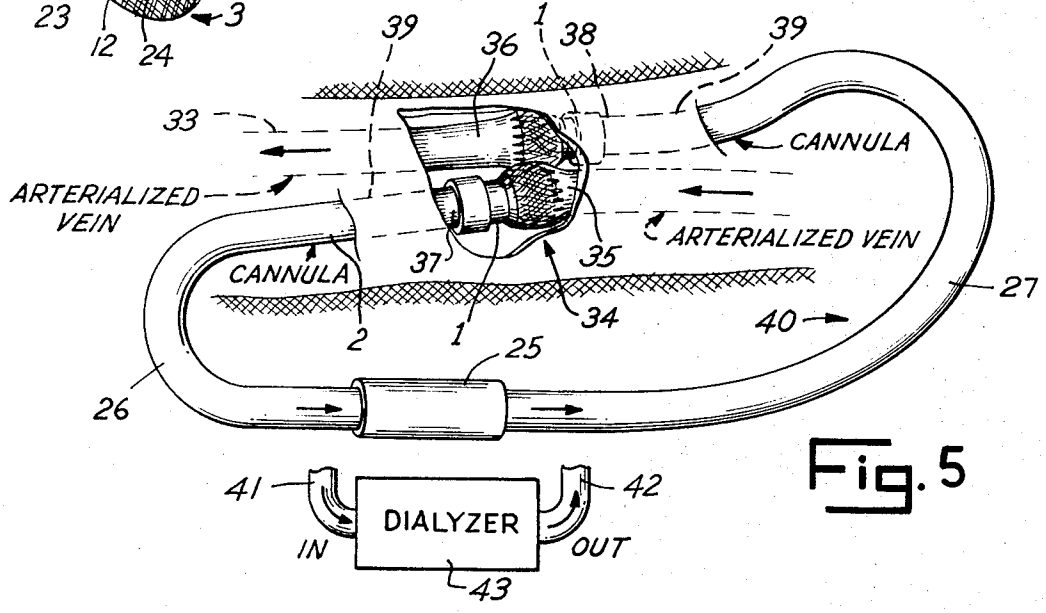




Fig. 5




Fig. 6b

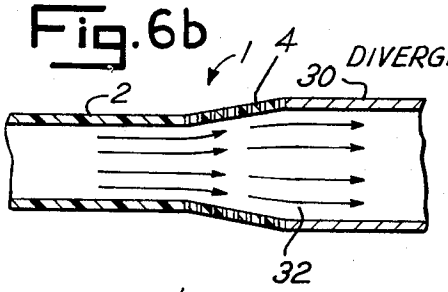
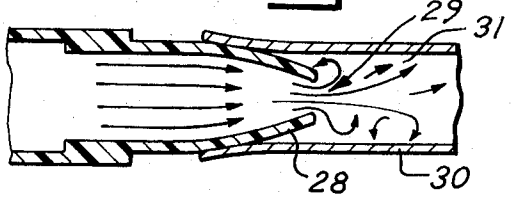
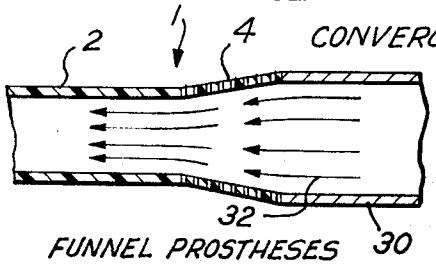
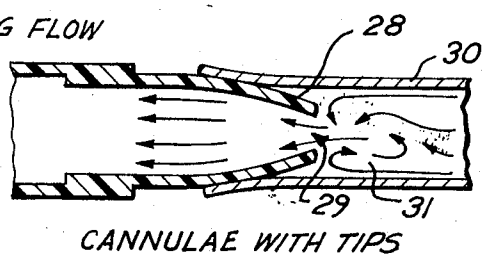



Fig. 6a




FUNNEL PROSTHESES




CANNULAE WITH TIPS

# MEDICAL PROSTHESIS FOR DUCTS OR CONDUITS

## FIELD OF THE INVENTION

This invention is directed to an improved prosthesis for access to, and transport of ducted fluids, such as the vascular, lymphatic, reproductive, regulatory (e.g. glandular) or excretory systems, and repair, extension or access to other body ducts or tubes, such as tracheal, esophago-gastrointestinal systems and the like. The invention also includes methods of manufacture of the prosthetic devices. More specifically, the invention is directed to a tipless, funnel-terminated, tubular prosthesis in which the interior angle of the funnel ranges from 15° – 30°, which funnel is molded of high compliance, body tissue-compatible, flexible, resilient silicone rubber, and has molded therein a Dacron skirt for tissue ingrowth at the anastomotic junctions.

## BACKGROUND OF THE INVENTION

There is a clear need for artificial, implantable duct prosthesis for treatment or cure of various medical conditions in animals and humans. Examples include artificial veins or arteries used in treatment of circulatory conditions. Likewise repair of, or access to the G.I. tract may employ artificial ducting. All of such ducting involves the connecting (anastomosing) of the ducts to body tissue, usually the natural duct which is being replaced or repaired, or connection to the organ or organs which communicate with the natural duct. Frequently the artificial duct prosthesis is led extracorporeally for treatment of the ducted fluid and return to the body, e.g. blood for dialysis in cases of kidney failure.

All such artificial duct prostheses pose serious medical problems at their anastomotic juncture within the body, for example juncture necrosis, chronic infection, leakage, thrombosis, stricture and the like. This invention is directed to an improved juncture prosthesis or duct terminus. The discussion which follows will be with reference to an arteriovenous shunt by way of example, but it is to be understood that the funnel prostheses of this invention may be applied to any artificial implantable duct, or to a natural duct that is being anastomosed to a natural or artificial duct, organ or tissue, as the case may be.

In the United States, approximately 50,000 persons each year suffer some degree of renal (kidney) failure. Of this number, fully 20 percent, or 10,000 patients, can be helped by dialyzing the blood to remove the accumulated urea and other metabolic byproducts.

Kolff introduced direct dialysis of arterial blood, thereby employing arteriostatic pressure to assist in the dialysis. Quinten and Scribner developed an arteriovenous shunt system employing a tipped cannula sutured at 90° to an artery, tunneled subcutaneously, exited through the skin, and connected externally to a similar cannula which analogously was sutured to a vein. When hemodialysis was required, the shunt was disconnected externally and the arterial line was connected to the dialysis machine. The return line from the machine was connected to the venous cannula.

Such Quinten-Scribern shunts are often disfiguring and ineffective, complicated by frequency infections and thrombosis. The tips of the Scriber shunts are very inefficient, with significant turbulence, and low flow rates, which contribute to the thrombosis. The cannula "tip" is attached to the blood vessel by sutures, and causes juncture necrosis and strictures.



Results of using tip-type cannulae were reported by Baillod et al. at the 1969 meeting of the European Dialysis and Transplant Association, reported at Proc. Europ. Dialysis Transplant Assn., 6:65, 1969. 60 patients treated for more than one year exhibited arterial cannula survival of 13.5 months, during which an average of two and one half cannulae were required. Their venous cannulae survived an average of 8½ months, with four cannulae required per patient.

Problems with shunts led Brescia and Cimino to the innovation of the internal arteriovenous fistula which remains post-surgically subcutaneous. In this procedure, the side of an artery is sutured to the side of a vein to form a classical, side-by-side, *h*-shaped shunt. When dialysis is desired the shunt loop is punctured with hypodermic needles attached to the inlet and return lines of the dialysis machine.

However, the Brescia-Cimino internal A-V fistula is not without its serious problems. The use of the fistula requires training and skill in venipuncture, which frequently mitigates against home dialysis by the patient or other unskilled persons. After repeated punctures with large bore needles, hematomas, scarring, induration and false aneurysms develop.

There is, therefore, a great need for improved juncture prostheses for ducts and conduits of all types, both internal and external shunts to provide for vascular access, and access to the lymphatic system, reproductive system, regulatory system, excretory system. G. I. system and the like or to other organs or implanted prostheses to or from which fluid (gas or liquid) transmittal is desired. The ducts should be readily established and perform continuously as long as needed. They must allow adequate fluid (e.g., blood) flow, be non-thrombogenic and free of infection. They should be easily declottable, and should be large enough to provide adequate fluid volume exit or input.

## THE INVENTION

### OBJECTS

It is among the objects of this invention to provide an improved duct juncture prosthesis which overcomes the above-described problems of the prior art tips and achieves the goals set forth for improved medical ducts, e.g., A-V shunts and the like.

It is another object to provide a juncture prosthesis for ducts which has fluid dynamics advantages, and presents improved survival expectancy.

It is another object to provide a funnel juncture prosthesis for ducts which may be used internally or externally, and which may be used for access to any body organ or tissue from any other, or from the exterior, and for transport of any fluid (gas or liquid) which is input, withdrawn, administered or monitored.

It is another object of this invention to provide a funnel juncture for a shunt prosthesis which exhibits low incidence of late failure, thrombosis, provides smooth transition from body organ, duct or tissue to the prosthesis, is simple to declot, has excellent flow rates, an absence of major clinical complications, and exhibits long survival.

Still other objects will be evident from the following summary and detailed description.

## SUMMARY

Our juncture prosthesis employs a "tipless" cannula having a dacron-skirted silicone rubber funnel at an end for transmitting fluids across an anastomotic site. We have discovered that best hemodynamic and medical properties are obtained when the included angle of the funnel ranges from about 15° – 30°, whether the funneled orifice is anastomosed end-to-end or at an acute angle to a body duct, organ or tissue. The flexibility, resilience and compliance of the silicone rubber is selected to permit sufficient elasticity to be responsive to natural pulsatile flow, and to store and return fluid kinetic energy. The funnel is also sufficiently elastic to be self-compensating within small angles, thus permitting anastomosis to vessels or ducts of varying size. The Dacron skirt permits tissue ingrowth with a pseudoendothelium and a fibrous adventitia which prevents buildup of fibrin at the anastomotic juncture. The juncture funnel prostheses of this invention are applicable to internal A.V. fistulae, arterialized vein shunts, external shunts, or to any situation where fluid (gas or liquid) is to be transferred to or from any body duct, organ or tissue to another, or to or from the exterior. Improved results are demonstrated by the prostheses of this invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description makes reference to the FIGURES in which:

FIG. **1** illustrates in sectional view the funnel assembly for a cannula prosthesis in accordance with this invention;

FIG. **2** illustrates in sectional view a molding apparatus employed in the method of manufacture of the prostheses of this invention;

FIG. **3** shows in perspective a funnel assembly in accordance with this invention particularly useful for end-to-end anastomosis;

FIG. **4** shows in perspective a funnel assembly in accordance with this invention for acute angle anastomosis;

FIG. **5** shows an exemplary prosthesis of this invention in use; and

FIGS. **6a** and **6b** compare flow with the funnel prosthesis of this invention to prior art "tipped" cannulae.

## DETAILED DESCRIPTION

Referring to FIGS. **1, 3** and **4,** the prosthesis of this invention comprises a funnel assembly **1** mounted on a cannula tube **2.** The funnel assembly in turn includes a cloth skirt **3,** typically a sterile polyester (Dacron) cloth, for example, one about 0.007 inch thick, embedded in the walls of the funnel mouth portion **4** as at **5.** The Dacron cloth may be flat or formed into a conical shape. Shank portion **6** connects the funnel mouth portion **4** with connector portion **7,** into which is seated a cannula **2.** The cannula **2** may be secured into connector portion **7** with cannula tip **8** abutting against shoulder **9** in a manner to provide a smooth interior passage at **10.** We prefer to use a silicone cement **11** to join the tube **2** to the funnel assembly. The funnel walls may be tapered so that the mouth edge **4'** is thinner and more flexible than the shank end portion **6.** This flexibility permits a range of fit for various sized ducts or blood vessels, and compensates for pulsatile fluid flow by storage and return of kinetic energy.

Critical to our invention is the fact that the included angle $\theta$, defined as the angle lying between the inner surfaces **12, 12'** of the funnel mouth, is in the range of about 15° – 30°. This provides a smooth transition of flow of fluids, e.g., blood, lymph, urine, oxygen or the like in either direction through the tipless cannula prosthesis, and improves system survival. In addition, the entrance energy loss using our prosthesis is tenfold less than a constant diameter orifice anastomosed end-to-end to a duct. In such constant diameter juncture, the entrance loss is 0.5 ($V^2/2g$), where V is flow velocity and g is gravity. In our "tipless" funnel juncture prosthesis, the entrance loss is one tenth, that is, 0.05 ($V^2/2g$) for the same flow velocity.

In addition to the end-to-end anastomosis, we have found that the same type of funnel transition provided for by our tipless funnel cannulae is beneficial when anastomosing vessels end-to-end to ducts or cannulae. As seen in FIG. **6a** in the prior art techniques employing tip-type cannulae **28,** there is almost always a stricture or sudden reduction **29** of the internal diameter of the vessel which is anastomosed to the body vessel or duct **30.** This abrupt narrowing of the diameter results in frictional energy losses and boundary layer separation **31** contributing to hemolysis and the formation of thrombi whether the flow is converging or diverging. In addition, there is a pressure drop with up to 50 percent velocity head loss, occasioned by the use of such tip-type cannula. In contrast, as seen in FIG. *6b*, end-to-end anastomosis using the tipless funnel-type cannula **1** of this invention for either converging or diverging flow affords a smooth translation and flow **32,** improves system survival, promotes more effective declotting, helps eliminate the buildup of fibrin at the junction of the cannula and vessel, and generally exhibits an absence of major clinical complications. We have been able to observe cannula survival of over two years, using the cannula of this invention.

The funnel juncture prosthesis, anastomosed to the arterial limb of a fistula or any afferent flow duct, is the converging channel with a short graduated contraction of diameter. The converging channel or "nozzle" refers to a channel system in which the velocity of the fluid is increased and the pressure is reduced. The fluid is accelerated in the converging channel and some pressure head is converted into velocity head. In general, this conversion is a stable process and can be made with few losses.

The prosthesis anastomosed to the venous limb of the fistula or any efferent flow duct is the diverging channel with a short gradual enlargement of diameter. The diverging channel or diffuser refers to a channel in which the velocity of fluid is decreased and the pressure is increased. The flow involves a conversion of velocity head to pressure head. As the fluid moves down stream, a greater boundary layer forms and grows in thickness. The fluid may not fill the channel completely, but separates by breaking away from the walls. This results in eddy formation and dissipation of energy by turbulent mixing. Flow in a diverging channel is more troublesome than flow in a converging "nozzle" and can be an unstable inefficient process.

In evaluating the efficiency of a diverging channel, it is necessary to consider the velocity variations across the channel. The diverging channel efficiency can be

considered as a function of the total included angle of divergence ($\theta$). Theta represents a particular expansion ratio or ratio of final area to initial area. The efficiency is high (75 – 90 percent) in the region between 0° and 30°. Beyond about 30°, the efficiency decreases with an increase in the included angle.

We further have improved the system by the provision of flexibility and compliance so that in pulsatile flow, the juncture expands upon systoly storing kinetic energy, and delivers the energy to the fluid on diastoly.

Turning now to FIG. **2**, this figure illustrates the method of construction of the funnel assembly of our invention. Mold **13** comprises a skirt holder plate **16** and body-forming plate **17**. In manufacture, a core, ring or "washer" of Dacron cloth, a medical grade such as U.S. Catheter & Instrument Corp. No. 6103, is centered over the central aperture **19** in the body-forming plate **17**. The Dacron cloth may be of any type which has sufficiently large mesh to permit complete inpregnation of the silicone rubber around the fibers. Thereafter, the skirt holder plate **16** is placed thereover to securely retain the Dacron skirt in position during molding. The skirt holder is shown as flat, but may be conical. Centering pins **18, 18'** are inserted to secure the mold parts together, and the mold is then positioned on the bottom plate **15** of the molding press. Centering pins **18** and **18'** extend into recesses **20, 20'** in the bottom plate of the press for proper centering of the shoulder-forming projection **21** in the mold aperture. A tubular slug of vinyl type silicone rubber molding compound, such as a Dow-Corning "Silastic" brand rubber MDX–44512, is dropped into the mold aperture **19**, and top press plate **14** is lowered into position to compression-mold the silicone rubber, for ten minutes at 260°F. In the alternative, a fluorosilicone may be used; this type silicone rubber exhibits lesser clotting characteristics under dynamic flow conditions. The mold pin **22** projecting from the top press plate **14** forces the gum-like silicone rubber into the mold cavity. Optionally, the amount of the silicone rubber slug may be chosen so that there may be very small excess of the silicone rubber which extrudes into the cloth skirt beyond the outward edge of the funnel mount portion **4**. This is best illustrated in FIG. **1** as zone **23**. The extrusion of this silicone provides a zone for anchoring the sutures when anastomising the funnel mouth to the body vessel or duct. The funnel mouth walls **12, 12'** are thus free of turbulence-causing sutures, yet there is a sufficient feather edge of silastic-impregnated Dacron to provide for proper suture anchorage while at the same time sealing against fluid loss. The outer edge of the Dacron skirt **24** is open mesh which provides for tissue ingrowth. The excess skirt may be trimmed as desired to fit any given duct size. For a tipless funnel juncture prosthesis of 0.125 inch I.D. and a funnel mouth opening of 0.250 inches, we employ approximately 0.1 gram of a silicone rubber slug for the molding.

After the compression-molding for ten minutes at 260°F., the funnel assembly part is extracted from the mold and inspected. Thereafter, the molded funnel assembly part is post-cured for four hours at 350°F. All flashing is trimmed from the part, and after final inspection and washing, it is ready for assembly on a cannula tube. In assembling the cannula tube, a clean, transversely cut end of a cannula is painted on its exterior surface with a medical grade silicone rubber adhesive, such as Dow-Corning medical grade "Silastic" brand adhesive Type A, and inserted into the connector portion of the funnel assembly. Excess may build up and form a smooth transition shoulder, as **11**, seen in FIG. **1**. The final tipless funnel cannula prosthesis is best seen in FIGS. **3** and **4**. FIG. **3** illustrates a prosthesis either for end-to-end anastomosis with a body vessel, duct, tissue or organ, or for 90° end-to-side anastomosis. FIG. **4** shows a tipless funnel cannula prosthesis having an oval or eliptical-shaped funnel mouth which is oriented at an angle to the longitudinal axis of the shank and connector portions. This oblique funnel is particularly adapted for acute angle end-to-side anastomosis to body vessels, ducts, tissues or organs.

The method of employing the tipless funnel cannula of this invention may be seen with reference to FIG. **5**. This description is in reference to providing vascular access to an arterialized vein although it should be understood that vascular access is merely exemplary of the more general use of the cannula of this invention. FIG. **5** shows the use, in a 2-step procedure, of our tipless funnel cannula where external access is required. A suitably dilated arterialized vein **33** is selected for cannulation. This vessel is severed transversely at **34** and each end **35, 36** directly anastomosed to a tipless, funnel-shaped skirted cannula **37, 38** of this invention. The cannulae may be buried in subcutaneous tunnels **39** with open cell silicone rubber cuffs for fixation and seal. The exterior loop **40** of the cannula tube **2** may be adapted to come apart at collar **25** for attachment of the outlet segment **26** and inlet segment **27** to the inlet tube **41** and outlet tube **42** of the dialyzer **43**.

Optionally, a direct fistula can be created by directly anastomising a cannula terminated at each end with a funnel prosthesis of this invention and utilizing a vein graft for juncture to the small artery. First, one end of a vein graft is anastomosed to an artery and the other end anastomised to the mouth of the funnel prosthesis-terminated cannula. A vein is then selected for return flow to the heart and the distal branch of this vein anastomised to the funnel prosthesis at the other end of the cannula.

It is also possible to make a vein-to-vein shunt, as in a porto-canal shunt to reduce portal hypertension. In the same manner an artery-to-artery shunt can be performed (artery bypass). As above, for access to small vessels, we use a vein graft anastomosed to a funnel mouth, and for large vessels, we can directly anastomose our funnel juncture prosthesis thereto.

Fourteen or our new external fistula systems using tipless, funnel-skirted prostheses of this invention have been created for external circulatory access useful in chronic hemodialysis. The treatment periods range from 2 to 34 months. In all 14 patients flow exceeded 300 ml/min. Taken as a whole 13 of 14 systems have survived to date, representing an experience of 213 months with a mean survival of 15.2 months. The **14** arterial prostheses had a mean survival of $> 15.0$ months; the **13** venous prostheses had a mean survival of $> 12.4$ months. All arterial and venous prosthesis replacements have not been included in the above analysis. Expression of data in this manner, however, is unsatisfactory. Any series, with a number of patients having a short period of observation will, when calculated in this manner, result in spuriously low survival times. Thus, the survival times will actually be greater than the number of months calculated in the above manner.

If survival data are computed only from patients observed for more than 12 months, (including all failures even under 12 months), the recalculated mean survival times are as follows: for an arterial prosthesis 19.3 months, and for a venous prosthesis 15 months. This compares to 13.5 months (arterial) and 8.5 months (venous) for tipped cannulae of the prior art.

A more meaningful representation of circulatory access survival data would be to express it in terms of estimated survival curves calculated by standard life table techniques described by Merrell and Shulman "Determination of Prognosis of Chronic Disease Illustrated by Systemic Lupus Erythematosus", J. Chronic Dis. 1, (1955). The logarithm of the percent surviving is plotted against the duration in months. These curves are of course provisional since the numbers are small. They show the expected survival of an arterial prosthesis is 80 percent, and for the venous prosthesis about 50 percent under these circumstances.

It is to be understood that various modifications within the scope of this invention can be made by one of ordinary skill in the art without departing from the spirit thereof. We therefore wish our invention to be defined by the scope of the appended claims as broadly as the prior will permit, and in view of this specification if need be.

We claim:

1. A medical prosthesis for providing vascular access to an arterialized vein which comprises:

a. a cannula;

b. a funnel assembly secured to an end of said cannula, said funnel assembly comprising;

i. a connector portion connected to said cannula;

ii. a funnel portion with walls having an included interior angle ranging from about 15° to 30°, said walls tapering to a smaller thickness at the mouth of the funnel;

c. said funnel assembly being a tissue compatible, silicone rubber with sufficient flexibility and compliance so that in pulsatile flow, the funnel walls expand upon systole and deliver energy during diastole;

d. a flexible fabric skirt embedded in the walls of said funnel portion and extending outward from the edges of the funnel mouth a distance sufficient to provide for tissue growth therein and to connect the prosthesis through the skirt to a vein or artery.

2. A prosthesis as in claim 1 wherein a plane defined by the distal edge of said funnel mouth portion is oriented at an angle to the longitudinal axis of said connector portion to provide an elliptical funnel mouth.

3. A prosthesis as in claim 1 wherein a plane defined by the distal edge of said funnel mouth is oriented at substantially a 90° angle to the longitudinal axis of said connector portion.

4. A prosthesis as in claim 1 where a portion of said fabric adjacent said funnel mouth is impregnated with silicone rubber to provide suture anchorage for anastomosis.

5. A prosthesis as in claim 1 wherein said connector portion comprises a collar having an inner diameter suitable for fitting over said cannula and a shoulder to abut the end of said cannula.

6. A prosthesis as in claim 1 wherein said cannula is a body tissue compatible tube.

7. A prosthesis as in claim 6 wherein each end of said cannula has a funnel assembly secured thereto.

8. A prosthesis as in claim 6 wherein said cannula is silicone rubber.

9. A prosthesis as in claim 1 wherein said silicone rubber is a fluorosilicone rubber.

* * * * *