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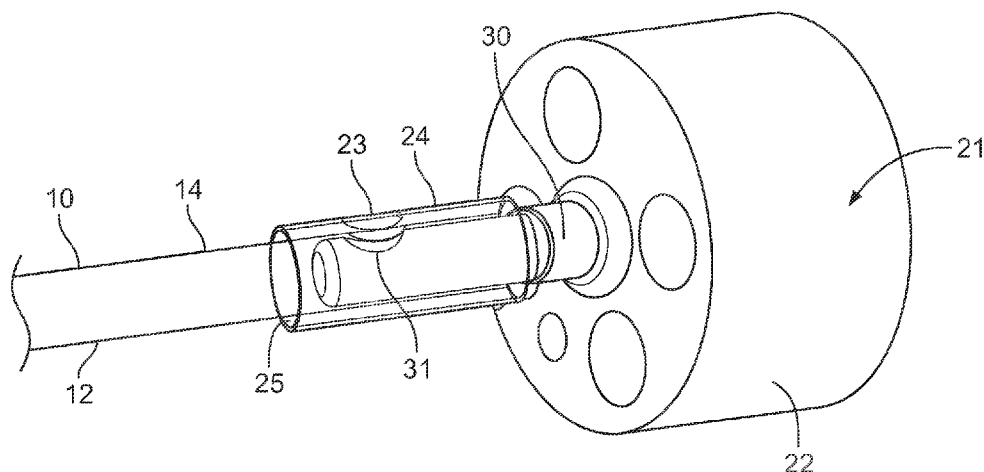


FIG. 3

(57) Abstract: Methods and systems using solvents for forming eyelets in urinary catheters are provided.



Devices and Methods for Forming Eyelets in Urinary Catheters

Cross-Reference to Related Application

5 This application claims the benefit of U.S. Provisional Application Serial No. 63/596,601, filed November 6, 2023, the disclosure of which is hereby incorporated by reference in its entirety.

DESCRIPTION

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TECHNICAL FIELD

[0001] The present disclosure generally relates to devices and methods for creating holes in catheters, and more specifically, to systems and methods for creating at least one eyelet in a urinary catheter.

BACKGROUND

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[0002] Medical tubings, such as urinary catheters, are used in a wide range of medical and surgical applications, e.g., catheterization for the drainage of urine from the bladder. Generally, catheters include polymer tubes with an insertion end that is advanced through a lumen of the patient to a desired location within the body. The insertion end typically includes a hole or eyelet therein to allow

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substances to pass into or out of the lumen of the catheter shaft.

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[0003] Urinary catheter tubes are used to drain urine from the bladder. The catheter tube includes a lumen and a hole/eyelet in the insertion end of the catheter tube. The hole/eyelet is in fluid communication with the lumen of the catheter tube so as to allow urine to drain from the bladder and through the lumen of the tube. In use, the insertion end of the catheter tube is advanced through the urethra of the user and into the bladder. Once in the bladder, urine drains from the bladder through the hole/eyelet in the insertion end and into the lumen of the catheter. The urine is discharged through the distal end of the catheter tube.

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[0004] There are various considerations for forming a hole/eyelet in urinary catheters. Such considerations may include costs, speed of cutting, efficiency, punched/cut-out parts remaining in the shaft, etc.

[0005] Therefore, there remains a need for improved systems and methods for forming eyelets in urinary catheters.

SUMMARY

[0006] There are several aspects of the present subject matter which may be embodied separately or together in the devices and systems described and claimed below. These aspects may be employed alone or in combination with
5 other aspects of the subject matter described herein, and the description of these aspects together is not intended to preclude the use of these aspects separately or the claiming of such aspects separately or in different combinations as set forth in the claims appended hereto.

[0007] In one aspect, a method of forming at least one eyelet in a catheter shaft,
10 wherein the catheter shaft is defined by a wall and has a shaft proximal end portion and a shaft distal end portion. The method includes applying a solvent to at least one portion of a surface of the wall in the shaft proximal end portion and forming at least one eyelet in the wall of the catheter shaft in the shaft proximal end portion.

[0008] In another aspect, a system for forming at least one eyelet in a catheter shaft with a shaft proximal end and a shaft distal end. The system includes a mandrel, a dispenser, and a solvent source. The mandrel is for inserting into a catheter shaft wherein the mandrel has an opening for receiving the solvent. The dispenser is for applying a solvent to at least one surface of the catheter shaft.
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BRIEF DESCRIPTION OF FIGURES

[0009] Fig. 1 is a perspective view of one example of a catheter having an eyelet therein;

[0010] Fig. 2 is a perspective view of the catheter and a mandrel of an
25 exemplary embodiment;

[0011] Fig. 3 is a perspective view of a catheter, a mandrel, and a stencil according to an exemplary embodiment;

[0012] Fig. 4 is a perspective view of a catheter of one embodiment of a system for forming a catheter eyelet and a catheter;

[0013] Fig. 5 is a perspective view of another embodiment of a system for
30 forming a catheter eyelet and a catheter;

[0014] Fig. 6 is a perspective view of one embodiment of a dispenser;

[0015] Fig. 7 is a schematic cross-sectional view of a catheter inserted into a

machining device with a mandrel and stencil according to an exemplary embodiment; and

[0016] Fig. 8 is a schematic cross-sectional view of a catheter inserted into a machining device with a mandrel and stencil according to an exemplary embodiment.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0017] The embodiments disclosed herein are for the purpose of providing a description of the present subject matter, and it is understood that the subject matter may be embodied in various other forms and combinations not shown in detail. Therefore, specific embodiments and features disclosed herein are not to be interpreted as limiting the subject matter as defined in the accompanying claims.

[0018] The present disclosure is directed to devices and methods for creating a hole in the wall of a medical tubing. Turning to Fig. 1, there is shown a urinary catheter 10. Although aspects of the present disclosure are described relative to a urinary catheter, the devices and methods disclosed herein may be used to make a hole in any medical tubing, such as vascular catheters, exploratory devices, etc. The medical tubing may be made from a flexible or elastic material, such as a polymer. The polymer may be a thermoplastic polymer, for example, polyvinyl chloride, EVA, PEBAX, SEBS, etc. The polymer may be polyethylenes, polypropylenes, polyvinylchlorides, polytetrafluoroethylenes, polyvinylacetates, polystyrenes, polyesters, polyurethanes, polyamides, ethylene vinyl acetate copolymers, and combinations thereof.

[0019] The urinary catheter 10 includes a catheter shaft 12 (which is a tubing) with a wall that defines shaft 12. Catheter shaft 12 has a shaft proximal end portion 14 and a shaft distal end portion 16. At least one hole or eyelet 18 extends through the wall of the catheter shaft 12 and is in communication with a lumen (not shown) of the catheter shaft. In the illustrated embodiment, the eyelet 18 is in the shaft proximal end portion 14. A drainage member 20, such as a funnel or connector, may be attached to the shaft distal end portion 16. The drainage member 20 is in communication with the lumen of the catheter shaft 12 for discharge of urine from the shaft 12.

[0020] Fig. 2 shows the urinary catheter 10 and a mandrel 21 used in the process of forming eyelet 18. As shown in Fig. 2, the mandrel 21 may be inserted or applied into the lumen of the catheter shaft 12 through the shaft proximal end portion 14. The mandrel 21 includes a rod 30 that is configured for insertion into the lumen of the catheter shaft 12 and a connector 22 for attaching to an advancing machine or device. The mandrel's rod 30 also includes a hole 31, which coordinates to the at least one eyelet to be formed in the catheter. The hole 31 is in communication with a vacuum source for pulling solvent and catheter waste material through hole 31 during the formation of the eyelet.

[0021] The at least one opening/hole 31 on the mandrel's rod 30 corresponds to the desired eyelet shape and location that will be formed in the urinary catheter shaft. The hole 31 may align or closely align with the desired eyelet location. The hole 31 is sized so that the removed catheter eyelet section (waste material) can be easily suctioned or pulled into the opening/hole 31 along with any excess solvent that is applied.

[0022] The hole 31, which will at least correspond to the shape of the catheter eyelet or eyelets, can be any desired shape or size and customized based on the application. The hole 31 should be sized to comfortably receive the discarded portion of catheter that is removed from the eyelet area after application of solvent. The hole 31 may have rounded edges and may form circles or ovals. Typically, the hole 31 may have a racetrack or oval/elliptical type shape. This may depend on the structural integrity of the tube and so other variants could be possible. The hole(s) 31 can be a range of sizes, depending on the size of the catheter and application. The length of the hole 31 may be in the range of about 1.8 mm to about 5.0 mm. The width may be in the range of about 0.3 to about 2.0 mm.

[0023] The embodiments shown in the figures include one hole 31 in the rod 30 of the mandrel. In another embodiment, there are at least two holes 31 in the rod 30 of the mandrel 21. The two holes 31 in the rod 30 correspond to a desired two eyelet pattern in the urinary catheter shaft. The holes 31 may be arranged on the same side of the rod 30 or on opposite sides of the rod. In one embodiment, the holes 31 are arranged on opposite sides of the rod 30. As shown in Fig. 2, the rod 30 may have only one hole 31 that can be used multiple times by rotating or

moving the catheter to align with another desired catheter eyelet area.

5 **[0024]** The mandrel 21 may be advanced by any known advancing system. This can be done mechanically, pneumatically, hydraulically, or ultrasonically. Any advancing system can be used that can advance and retract the mandrel from the urinary catheter. By way of example, the advancing system may be
10 electromechanically actuatable, utilizing electrical, pneumatic, or hydraulic fluid pressure energy. This can also be done ultrasonically. In one embodiment, the advancing system may comprise a screw, an axle, and a connection member. The advancing system can be flexible or rigid and can be a chain, belt, cable, rod, or
15 shaft. In yet another exemplary embodiment, the advancing system can comprise a cam and a motor that is driven in forward and reverse directions to rotate the cam in opposite directions, thereby moving the mandrel 21 and catheter shaft 12 in opposite directions. The advancing system may alternatively (or additionally) include a magnetic linear motor. In another embodiment, the advancing system
may include a telescoping member.

[0025] The mandrel 21 may be advanced into the catheter shaft 12 from the shaft proximal end portion 14 of the catheter shaft, as shown in Fig. 2. The mandrel may also be advanced into the catheter shaft 12 from the shaft distal end portion 16 of the catheter shaft 12.

20 **[0026]** The rod 30 of the mandrel 21 is similarly shaped to the urinary catheter shaft 12. The rod 30 has an outer diameter that is slightly smaller than the inner diameter of the urinary catheter shaft 12 so that the rod 30 may be inserted into the catheter shaft 12 and provide support or structural integrity for the catheter shaft while applying solvent and forming the eyelet(s).

25 **[0027]** The mandrel 21 can be composed of metal or metallic material. In one embodiment, the mandrel 21 is composed of stainless steel. The mandrel 21 can also be composed of a polymeric material, such as polyurethane, or a ceramic material. It could also be a hybrid material as in Metal/Polymeric, where the metal gives the rigidity and the polymeric allows for pliability, or instead metal/ceramic,
30 etc. The mandrel 21, or at least the rod 30 of the mandrel 21, should be comprised of a material that is able to withstand the possible application of selected solvent. Possible examples of such material include stainless steel, silicon carbide, or palladium microalloy glass or any combination of. The mandrel

21 and/or rod 30 of the mandrel 21 may also be comprised of polytetrafluoroethylene (PTFE) or polyetheretherketone (PEEK) or a combination thereof.

[0028] Fig. 3 shows the urinary catheter 10 with a stencil 24 and a mandrel 21, which may be used, in combination or separately, during the formation of the eyelet. As shown in Fig. 3, the stencil 24 and mandrel 21 may be inserted or applied over the shaft proximal end portion 14 of the urinary catheter shaft 12. The stencil 24 is attached at the base or connector of the mandrel 21. The stencil 24 may include a sidewall that forms a barrel with an end opening 25 for receiving the shaft proximal end portion 14. Stencil 24 also includes at least one opening 23 in the side wall which corresponds to the eyelet 18 on the catheter 10.

[0029] The barrel of the stencil 24 is shaped similarly to the catheter shaft 12. The barrel of the stencil 24 can be a hollow tube or have a hollow tube portion with an open end 25 for sliding over the catheter shaft 12. The barrel of the stencil 24 has a sufficient inner diameter to be placed over the catheter shaft 12, i.e., the inner diameter is slightly larger than the outer diameter of the urinary catheter shaft 12. For example, the inner diameter of stencil's barrel may be in the range of 2.2mm up to 6.2mm (CH06-CH18) depending on the Charriere (Diameter) of the catheter shaft 12 in question and the tolerance of the tube diameter. The stencil has at least one opening 23 corresponding to the desired eyelet shape that will be formed in the urinary catheter shaft. In one alternative, there are at least two openings. In one example, the two openings in the stencil/barrel correspond to a desired two-eyelet pattern in the urinary catheter. The openings 23 may be arranged on the same side of the stencil or on opposite sides of the stencil. As shown in Fig. 3, only one opening 23 may be present. The catheter shaft 12 may be rotated or adjusted so that the dispenser can apply solvent to a first location and then to a second location, resulting in two eyelets.

[0030] The opening 23 of the barrel of the stencil 24, which will correspond to the shape of the catheter eyelet or eyelets, can be any desired shape or size and customized based on the application. The openings 23 may have rounded edges and may form circles or ovals. Typically, the openings 23 may have a racetrack or oval/elliptical type shape. This may depend on the structural integrity of the tube and so other variants could be possible. The openings 23 can be a range of

sizes, depending on the size of the catheter and application. The length of the opening 23 may be in the range of about 1.8 mm to about 5.0 mm. The width may be in the range of about 0.3 to about 2.0 mm.

[0031] The stencil 24 can be composed of metal or metallic material. In one embodiment, the stencil 24 is composed of stainless steel. The stencil can also be composed of a polymeric material, such as polyurethane, or a ceramic material. It could also be a hybrid material as in Metal/Polymeric, where the metal gives the rigidity and the polymeric allows for the punching surface. Preferably, the stencil 24 is comprised of a material that is resistant to degrading by the solvent of the solvent source. Possible examples of such material include stainless steel, silicon carbide, or palladium microalloy glass or any combination of. The stencil 24 may also be comprised of polytetrafluoroethylene (PTFE) or polyetheretherketone (PEEK) or a combination thereof.

[0032] The stencil 24 may be advanced by any known advancing system disclosed herein or any other suitable system. In the embodiment shown in Fig. 3, the advancing system is shared by the stencil and mandrel, so an additional system is not needed. However, if the stencil 24 is applied from the distal end portion, or a different portion than the mandrel 21, a separate advancing system will be required.

[0033] The stencil 24 may be advanced over the catheter shaft 12 from the shaft proximal end portion 14 of the catheter shaft, as shown in Fig. 3. The stencil and mandrel may be formed as part of the same tool and advanced from the same direction. In other embodiments, the stencil and mandrel may be separate tools. The mandrel's rod 30 is a tube within the stencil tube and spaced far enough apart that the catheter can fit in between. The stencil 24 may also be advanced over the catheter shaft 12 from the distal end portion 16 of the catheter shaft 12. The stencil 24 and mandrel 21 may be advanced from opposite sides of the catheter, i.e., if the stencil is advanced over the proximal end of the catheter, the mandrel is advanced through the distal end of the catheter and vice versa.

[0034] Although the rod 30 and stencil 24 are shown as only extending a small amount into/over the catheter shaft 12, the rod 30 and/or stencil 24 may extend further into/over the catheter shaft 12 (as shown in Fig. 4 for the mandrel). In embodiments where the mandrel does not extend far into the catheter shaft (such

as Figs. 2, 3, and 5), the system may also include a separate support 42, as shown in Fig. 5. The support 42 may be used to provide support for the remainder of the catheter tubing. The support 42 may be comprised of material similar to the mandrel 21.

- 5 **[0035]** The support 42 may be advanced into the catheter shaft 12 from the shaft distal end portion 16. The support 42 may also be advanced into the catheter shaft 12 from the shaft proximal end portion 14. In one embodiment, the support 42 is advanced from the opposite side of the catheter that the mandrel 21 is advanced from.
- 10 **[0036]** The support 42 is similarly shaped to the urinary catheter shaft 12. The support 42 may be a rod having an outer diameter that is slightly smaller than the inner diameter of the urinary catheter shaft 12 so that the support 42 may be inserted into the catheter shaft 12 and provide support or structural integrity for the catheter shaft while forming the eyelets.
- 15 **[0037]** The support 42 can be composed of metal or metallic material. In one embodiment, the support 42 is composed of stainless steel. The support 42 can also be composed of a polymeric material, such as polyurethane, or a ceramic material. It could also be a hybrid material as in Metal/Polymeric, where the metal gives the rigidity and the polymeric allows for pliability, or indeed metal/ceramic etc. The support 42 should be comprised of a material which is able to withstand
20 the possible application of a selected solvent. Possible examples of such material include stainless steel, silicon carbide, or palladium microalloy glass or any combination of. The support 42 may also be comprised of polytetrafluoroethylene (PTFE) or polyetheretherketone (PEEK) or a combination thereof.
- 25 **[0038]** The support 42 may be advanced by any of the advancing systems disclosed herein or any other suitable advancing system.
- 30 **[0039]** The system may further include a solvent source 41 and a dispenser 27, shown in Figs. 4 and 5. The system may further include an applicator 28 at the end of the dispenser 27. The solvent source 41 provides a source of solvent for forming the eyelet in the catheter tubing. The solvent source 41 is connected by dispenser 27, which may be a tubing or tube-like structure. The dispenser may include an applicator 28 on the end, for contacting the catheter tube. The applicator applies the solvent to the catheter tubing to form at least one eyelet.

[0040] Fig. 6 shows an enlarged view of the applicator 28 and dispenser 27. The dispenser 27 includes a conduit 29 which transfers the solvent from the solvent source 41 to the applicator 28.

[0041] The dispenser 27, conduit 29 and solvent source 41 can be any shape or size, depending on the amount of solvent needed to transfer in order to create an eyelet or hole in the catheter tubing. The dispenser 27, conduit 29 and solvent source 41 should be comprised of a metal, plastic or ceramic material that does not readily degrade with contact with the solvent. The type of solvent used in the process will determine the type of material for the dispenser 27 and solvent source 41. The solvent source or reservoir may be comprised of stainless steel, silicon carbide, or palladium microalloy glass or any combination of. The solvent source 41 may also be comprised of polytetrafluoroethylene (PTFE) or polyetheretherketone (PEEK) or a combination thereof. The dispenser 27 from the solvent source 41 must also be similarly compatible with the solvent material. The dispenser 27 may be comprised of stainless steel, silicon carbide, or palladium microalloy glass or any combination of. The dispenser 27 may also be comprised of polytetrafluoroethylene (PTFE) or polyetheretherketone (PEEK) or a combination thereof. The conduit 29 may be comprised of stainless steel, silicon carbide, or palladium microalloy glass or any combination of. The conduit 29 may also be comprised of polytetrafluoroethylene (PTFE) or polyetheretherketone (PEEK) or a combination thereof.

[0042] The solvent used can be any desired or medical grade solvent. The solvent will largely depend on the catheter material used in the method of making. Table 1 shown below shows possible solvents based on the catheter material selected. Catheter materials include polyethylenes, polypropylenes, polyvinylchlorides, polyvinylacetates, polystyrenes, polyesters, and polyurethanes. However, the catheter can be comprised of any known medical grade material for catheter manufacturing.

[0043] The solvent can be a single solvent or a blend of solvents. The solvents can contain a blend or mixture of different aliphatic types or aliphatic and/or aromatic hydrocarbons. The solvent may include aliphatic hydrocarbons, including, but not limited to mineral spirits, hexanes, and heptanes. The solvent may also include aromatic hydrocarbons including, but not limited to,

methylbenzene, naphthalene, phenanthrene, trinitrotoluene, and o-dihydroxybenzene. The solvent may also be benzoic acid or phthalic acid. The solvent can also be petroleum naptha, petroleum distillate, cyclohexane, octane, pentane, or isopentane nonane. Additionally, the solvent may be benzene, tetralin,
 5 decalin, xylene-CSz, cyclohexane-CSz, xylene, acetone, methyl ethyl ketone, glycerol, glycol, acetic acid, acetaldehyde, ethyl acetate, dichloromethane, Dimethylformamide, Dimethyl sulfoxide, toluene, tetrahydrofuran, and pyridine. The solvent or acid may also include polyesters with hydrolyzed carbonyl groups.

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TABLE 1

Catheter/Tube material	Solvent/Acid
Polyethylenes	Organic solvents like benzene and acetone also possibly xylene-CSz and cyclo- hexane-CSz
Polypropylenes	Xylene, tetralin and decalin
Polyvinylchlorides	Acetone and Methyl Ethyl Ketone
Polyvinylacetates	Glycerol, glycol, acetic acid, acetaldehyde and benzoic acid
Polystyrenes	Ethyl acetate, dichloromethane, DMF, DMSO, THF, and toluene
Polyesters	Hydrolysis of their carbonyl groups
Polyurethanes	Tetrahydrofuran, Pyridine, Methyl Ethyl Ketone, Dichloromethane

[0044] The system may optionally include a solvent applicator 28 for applying the solvent to the catheter surface and forming the eyelet. The solvent applicator 28
 15 can function to control the amount and area of application of the solvent. The applicator 28 may be any liquid holding composition, such as a sponge. The applicator may also be synthetic fabrics like polyester or nylon weaved in different patterns to optimize application. It may also be a rubber type bushing application at the end of the conduit. The solvent applicator 28 may be placed at the end of
 20 the dispenser for moving the solvent from the solvent source or reservoir. The applicator 28 may be in any shape, but preferably is shaped similarly to the desired eyelet shape. For instance, if the desired shape is an oval, the end of the applicator 28 that is applied to the catheter tubing is shaped like an oval. The overall shape of the applicator 28 may be a cylinder or truncated cone.

[0045] In some embodiments, a punching device may be used in combination with the solvent application. Fig. 7 illustrates one embodiment of a machining device for forming an eyelet in a catheter shaft 12 in combination with the solvent application described above. The machining/Punching device may be used, for example, to form at least one eyelet 18 in the catheter shaft 12 shown in Fig. 1 after the solvent has weakened the material. The machining/Punching device 36 includes a pair of saddles/supports, bottom saddle or member 48 and top saddle/support or member 46. The terms “bottom” and “top” are arbitrarily used herein for convenience in describing that the saddles border the channel for the urinary catheter. It will be understood that these terms are not being used to limit the saddles/supports to “top” and “bottom” positions. These may be arranged vertically and one first and second sides.

[0046] The machining device 36 also may include at least one punch 38. The top saddle 46 includes a punch receiving aperture 62 extending therethrough from the top surface of the saddle to the bottom surface of the saddle. The aperture 62 may be any shape, and may have a shape that corresponds, is commensurate and/or otherwise allows or guides the top punch 38 therethrough. In some embodiments, the system includes at least two punches (Fig. 8). In the illustrated embodiment of Fig. 7, the punch is in the top saddle. In alternate embodiments the punch can be in the bottom saddle. In some embodiments, at least two punches are present. In these embodiments the at least two punches may both be in the same saddle, or in different saddles. In one such embodiment, as shown in Fig. 8, one punch 138 is in the top saddle and a second or bottom punch 140 is in the bottom saddle. After solvent is applied to a portion of the catheter shaft 12, the punch 38, 138 is advanced or moved through apertures in the saddle and an opening 23, 123 in the stencil 24, 124 to cut a portion of the tubing, thereby forming the eyelet. The punch 38, 138 may be inserted into the apertures or may reside within the apertures and be actuated to move or advance within the apertures. Furthermore, the solvent may be applied to the catheter shaft through the apertures of the saddles. For example, after the shaft 12 is placed within the saddles, solvent may be delivered through the aperture(s) of the saddle. In another embodiment, the solvent is applied separately before the punching.

[0047] In the embodiments of Fig. 7 and Fig. 8, the punches 38, 138, and 140

are similarly configured and have a shape that is commensurate with the respective aperture. However, in an alternative, the punches may be differently configured.

5 [0048] In the illustrated embodiments, each punch includes a shaft having a distal end 164 and a proximal end 166. The distal end 164 may be operatively connected to a device that actuates the punch or punches so that they move within respective apertures of the top and bottom saddle. The proximal end 166 of the punch is a cutting end that includes a cutting element that is configured to cut a hole in the shaft. The cutting element may be, for example, a blade. The blades
10 are used to cut an eyelet in the catheter.

[0049] The distal end 164 of the punch 138 is connected to an advancing system for moving the punch. The punching of the machining device can be done mechanically, pneumatically, hydraulically, or by a cam type system. The punching can also be ultrasonic. By way of example, the punch may be
15 electromechanically actuatable, utilizing electrical, pneumatic, or hydraulic fluid pressure energy.

[0050] The machining device 36, 136 includes a channel 34, 134 therein for receiving and holding the urinary catheter. The channel 34, 134 may be defined by at least one wall of the bottom saddle 48, 148 and at least one wall of the top
20 saddle 46, 146. The first and second ends of the channel may be open. This allows for the catheter to move in and out and also for the cooling device, mandrel, and stencil to move in and out freely. The channel may be the length of the catheter or only a portion of the length of the catheter.

[0051] The punched eyelet material can be removed by vacuum through an
25 opening in the mandrel. However, it can also be removed in the optional punching step. It can also be directly pumped into the machining device. Another possible method is to mechanically eject the slug.

[0052] Using the system described above, at least one eyelet may be formed in a catheter shaft. The method includes applying a solvent to at least one portion of
30 a surface of the proximal end portion of the catheter shaft and forming at least one eyelet in the at least a portion of a surface of the proximal end portion of the catheter shaft. The portion of the catheter shaft is preferably the proximal portion of the catheter shaft, but any portion of the catheter shaft where an eyelet is

desired can have solvent applied. The eyelet portion is then removed through an opening in the mandrel.

[0053] The method may also include inserting a mandrel into an end of the catheter shaft. The method may also include placing a stencil over at least a portion of the catheter shaft. Both inserting the mandrel and placing the stencil may be done before applying the solvent to a portion of the catheter shaft. An additional eyelet or eyelets may be formed by moving the catheter shaft axially and/or rotating about its longitudinal axis and applying solvent to an additional portion of the catheter shaft.

[0054] After applying the solvent, an optional punching step may also be executed. The punching of at least one eyelet into the catheter shaft may include punching at least two eyelets into a catheter shaft. The punches may be done simultaneously or consecutively. If the punches are done simultaneously a stencil may be used with two openings corresponding to the pattern of eyelets desired.

The stencil is placed over the catheter shaft and two punches from the machining device are advanced into the catheter shaft, forming the eyelets. If done consecutively, a stencil with a single opening may be used and a machining device with a single punch may also be used. In this case, the stencil may be advanced along the catheter shaft so that the opening aligns with a first desired eyelet location of the catheter shaft and the eyelet punched. Afterward, the catheter may be moved so that the stencil and punch align with a second desired eyelet location of the catheter shaft. If the shaft 12 is repositioned it may be moved axially and/or rotated about its longitudinal axis to create subsequent holes.

[0055] It will be understood that the embodiments described above are illustrative of some of the applications of the principles of the present subject matter. Numerous modifications may be made by those skilled in the art without departing from the spirit and scope of the claimed subject matter, including those combinations of features that are individually disclosed or claimed herein. For these reasons, the scope hereof is not limited to the above description but is as set forth in the following claims, and it is understood that claims may be directed to the features hereof, including as combinations of features that are individually disclosed or claimed herein.

CLAIMS

1. A method of forming at least one eyelet in a catheter shaft, wherein the shaft comprises a wall and a shaft proximal end portion and a shaft distal end portion, the method comprising:
 - 5 applying a solvent to at least one portion of a surface of the wall in the shaft proximal end portion; and
 - forming at least one eyelet in the wall in the shaft proximal end portion.
2. The method of claim 1, further comprising inserting a mandrel into a lumen
10 of the catheter shaft.
3. The method of claim 2, wherein the inserting of the mandrel is done before applying the solvent.
- 15 4. The method of any one of claims 2-3, wherein the mandrel is inserted from the shaft proximal end.
5. The method of any one of the preceding claims, wherein the forming includes forming at least two eyelets.
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6. The method of claim 5, wherein the forming of at least two eyelets is done consecutively.
7. The method of claim 5 or 6, wherein the at least two eyelets comprise a
25 first eyelet formed in one portion of the wall of the catheter shaft and a second eyelet formed in a second portion the wall of the catheter shaft.
8. The method of any of the preceding claims, further comprising placing a stencil over at least a portion of the catheter shaft, the stencil having at least one
30 opening corresponding to a location of eyelet formation in the catheter shaft.
9. The method of claim 8, wherein the placing of the stencil is done before applying the solvent.

10. The method of any one of the preceding claims, wherein the mandrel
suctions any excess solvent during the applying step.
- 5 11. The method of any of the preceding claims, wherein the applying a solvent
is done by a dispenser from a solvent source.
12. The method of any of the preceding claims, wherein the applying a solvent
is done by an applicator.
- 10 13. The method of claim 12, wherein the applicator is a sponge.
14. The method of any of the preceding claims, wherein the solvent comprises
one or more of: mineral spirits, petroleum naphtha, petroleum distillate,
15 cyclohexane, octane, pentane, isopentane nonane, benzoic acid, phthalic acid,
methylbenzene, naphthalene, phenanthrene, trinitrotoluene, o-dihydroxybenzene,
benzene, acetone, xylene, tetralin, decalin, acetone, methyl ethyl ketone, glycerol,
glycol, acetic acid, acetaldehyde, ethyl acetate, dichloromethane, DMF, DMSO,
THF, toluene, tetrahydrofuran, and pyridine.
- 20 15. The method of any one of the preceding claims, wherein the catheter shaft
is comprised of at least one polymer.
16. The method of claim 15, wherein the polymer comprises one or more of:
25 polyethylenes, polypropylenes, polyvinylchlorides, polytetrafluoroethylenes,
polyvinylacetates, polystyrenes, polyesters, polyurethanes, polyamides, ethylene
vinyl acetate copolymers, and combinations thereof.
17. A system for forming at least one eyelet in a catheter shaft with a proximal
30 end and a distal end, comprising:
a mandrel for inserting into a catheter shaft wherein the mandrel has an
opening for receiving a solvent;
a dispenser for applying a solvent to at least one surface of the catheter

shaft; and

a solvent source.

18. The system of claim 17, further comprising an applicator attached to an end
5 of the dispenser.

19. The system of claim 18, wherein the applicator comprises a sponge.

20. The system of claim 17, wherein the system further comprises a stencil for
10 placing over a catheter shaft with at least one opening, wherein the at least one
opening corresponds to the at least one eyelet of the catheter shaft.

21. The system of claim 17, wherein the solvent source comprises a reservoir.

15 22. The system of claim 17, further comprising a machining device for
punching an eyelet in a catheter shaft.

23. The system of any one of claims 18 or 19, wherein a portion of the
applicator which contacts the catheter shaft has an oval shape.

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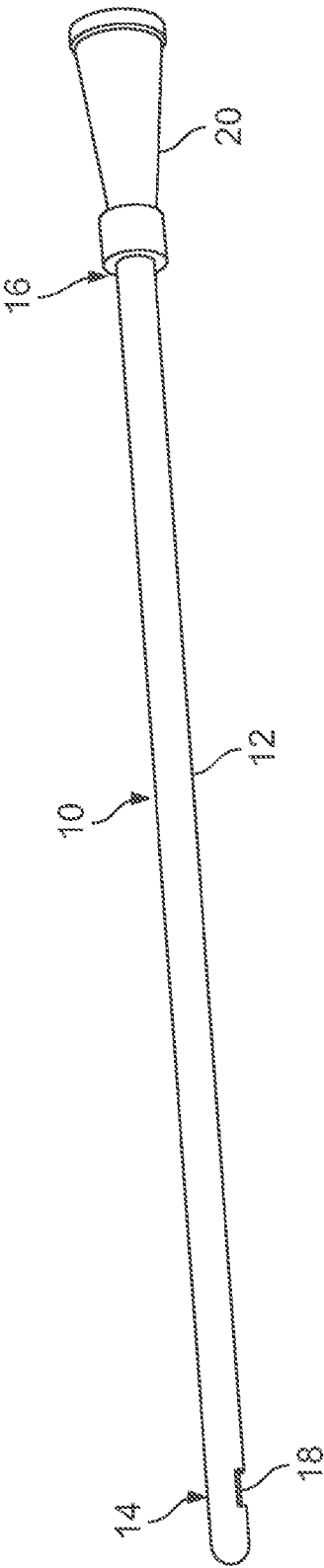


FIG. 1

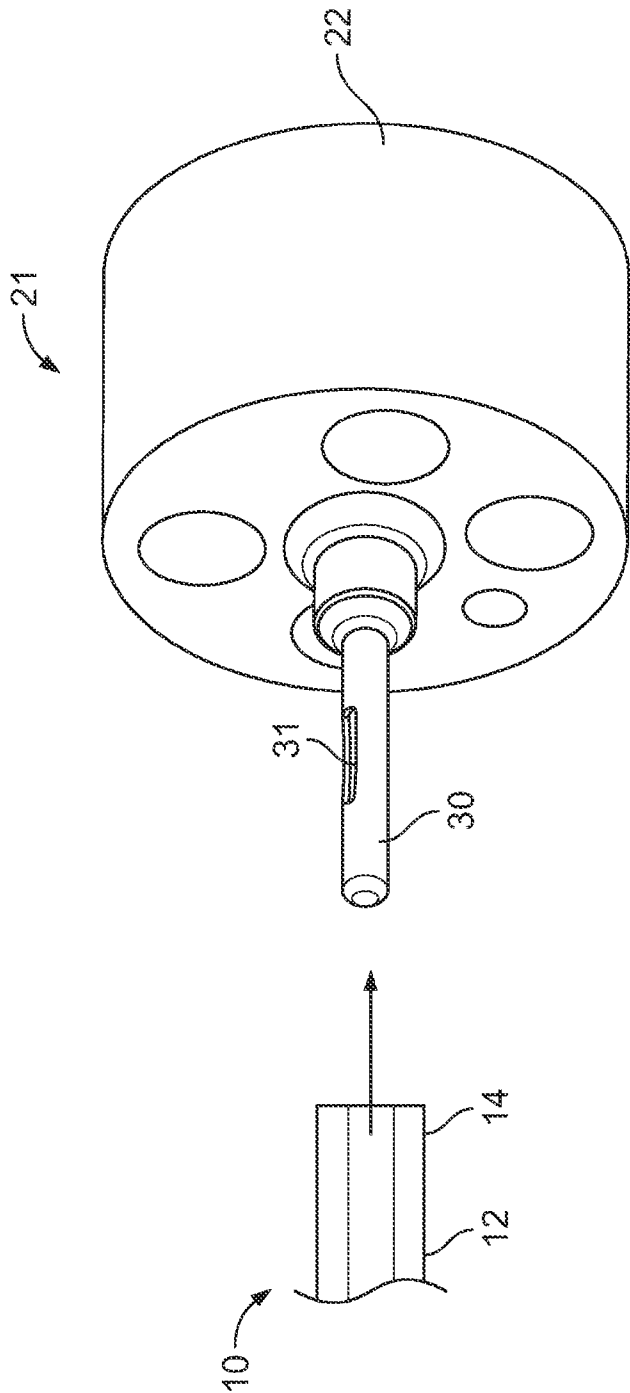


FIG. 2

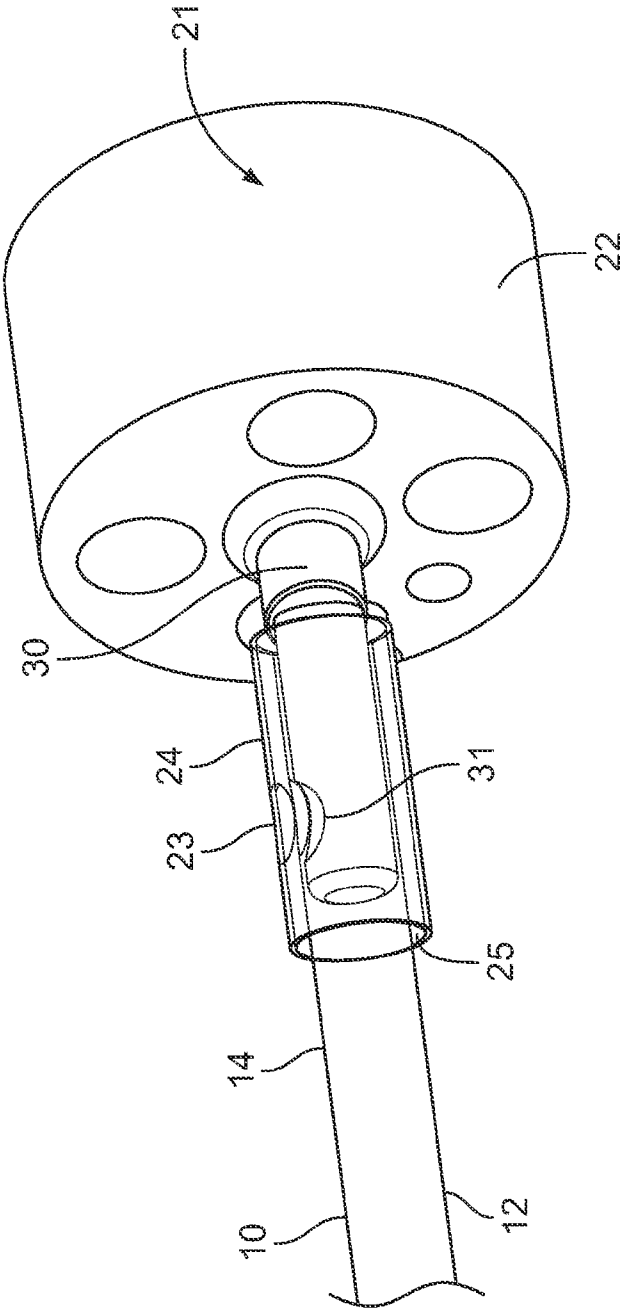


FIG. 3

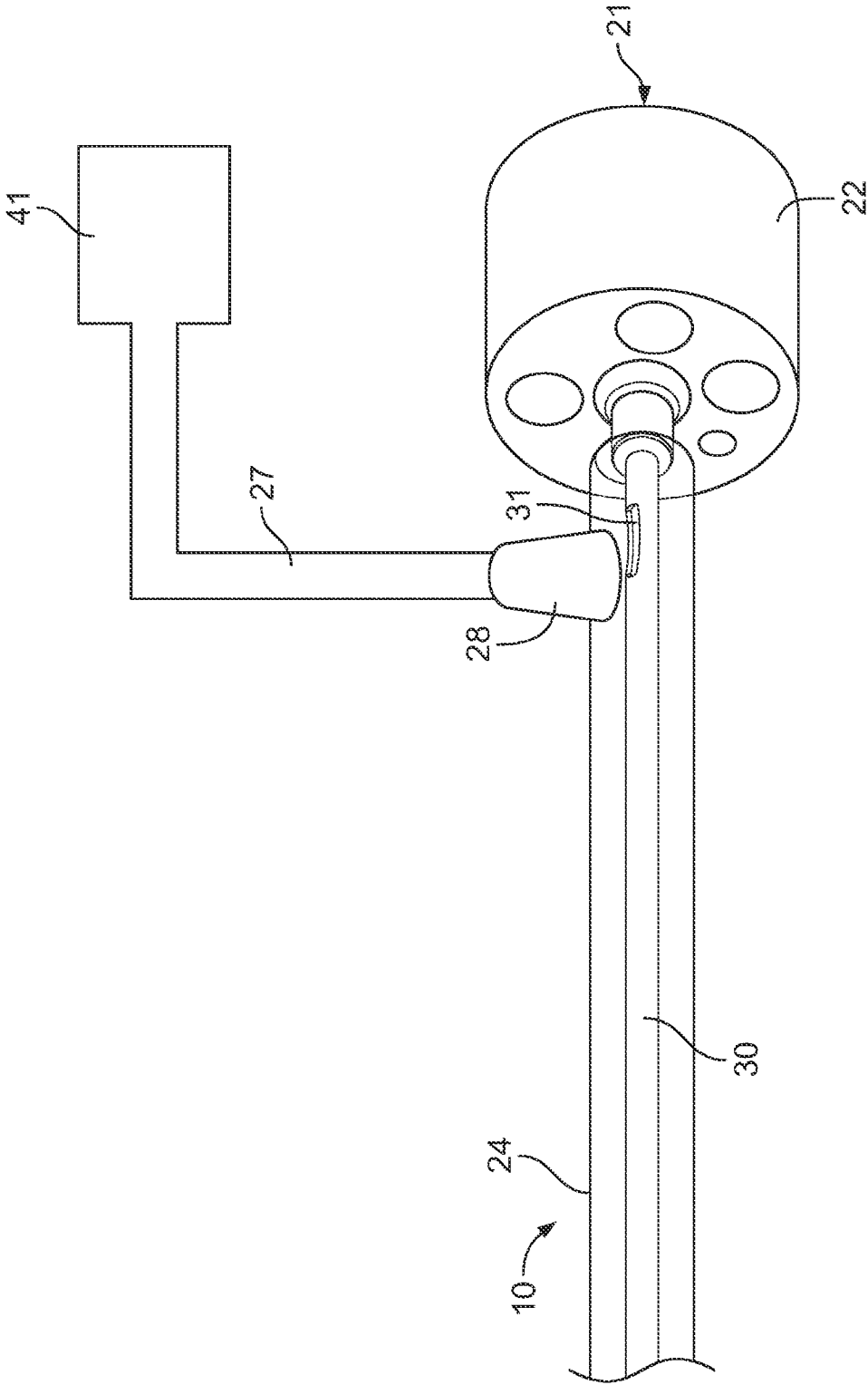
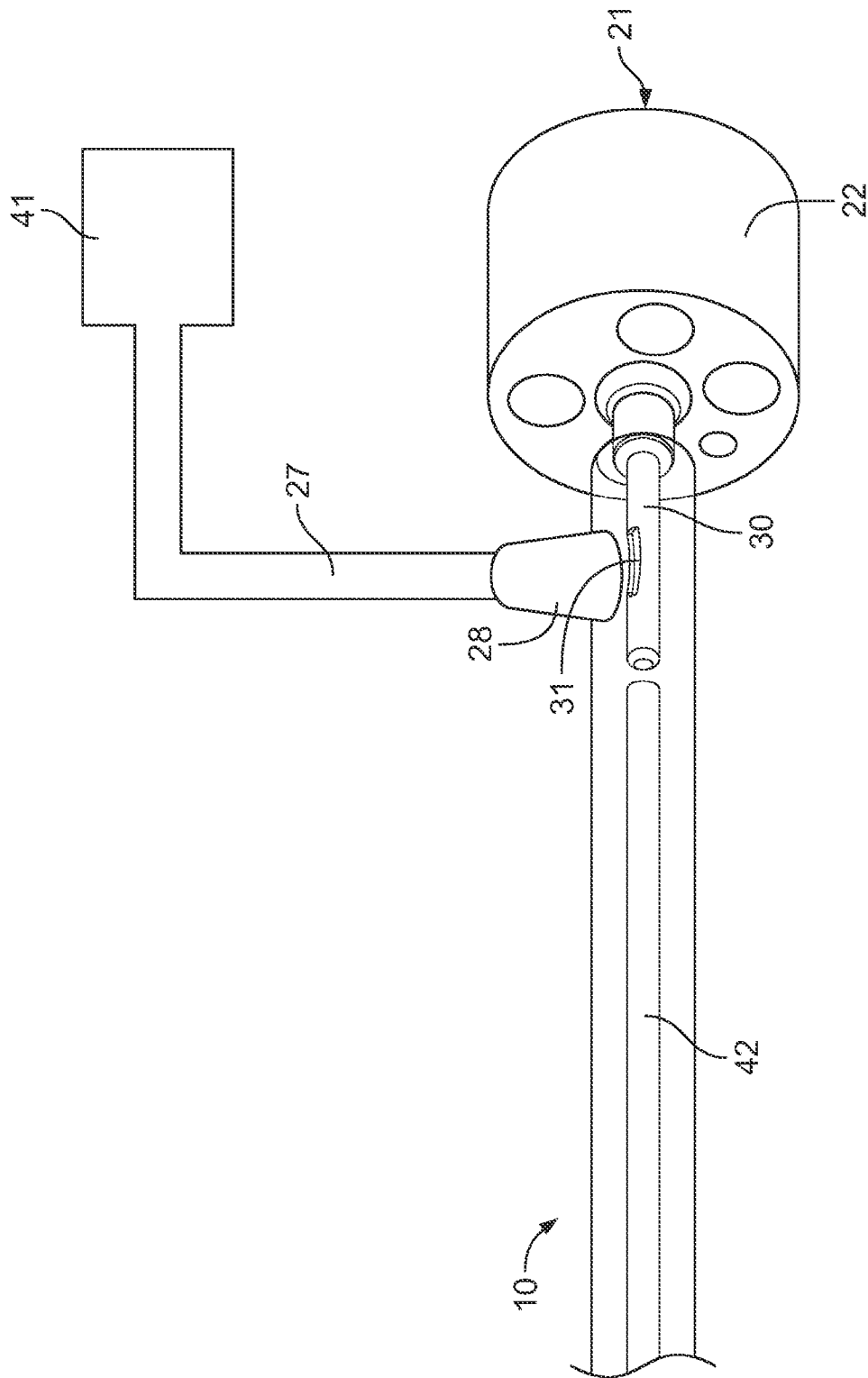


FIG. 4



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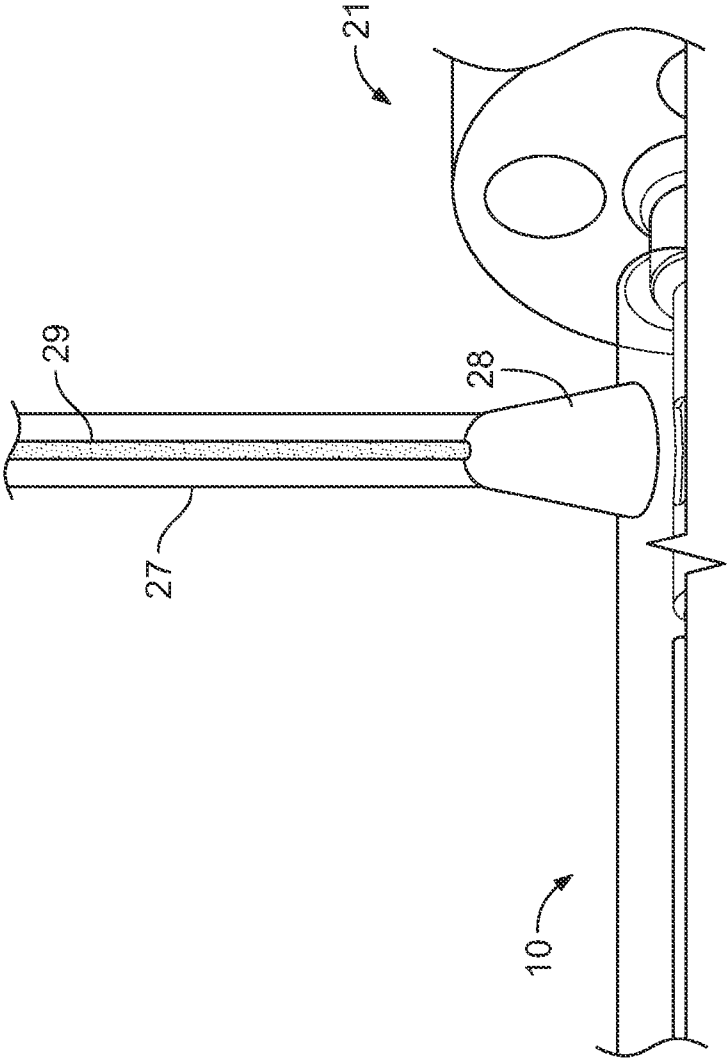
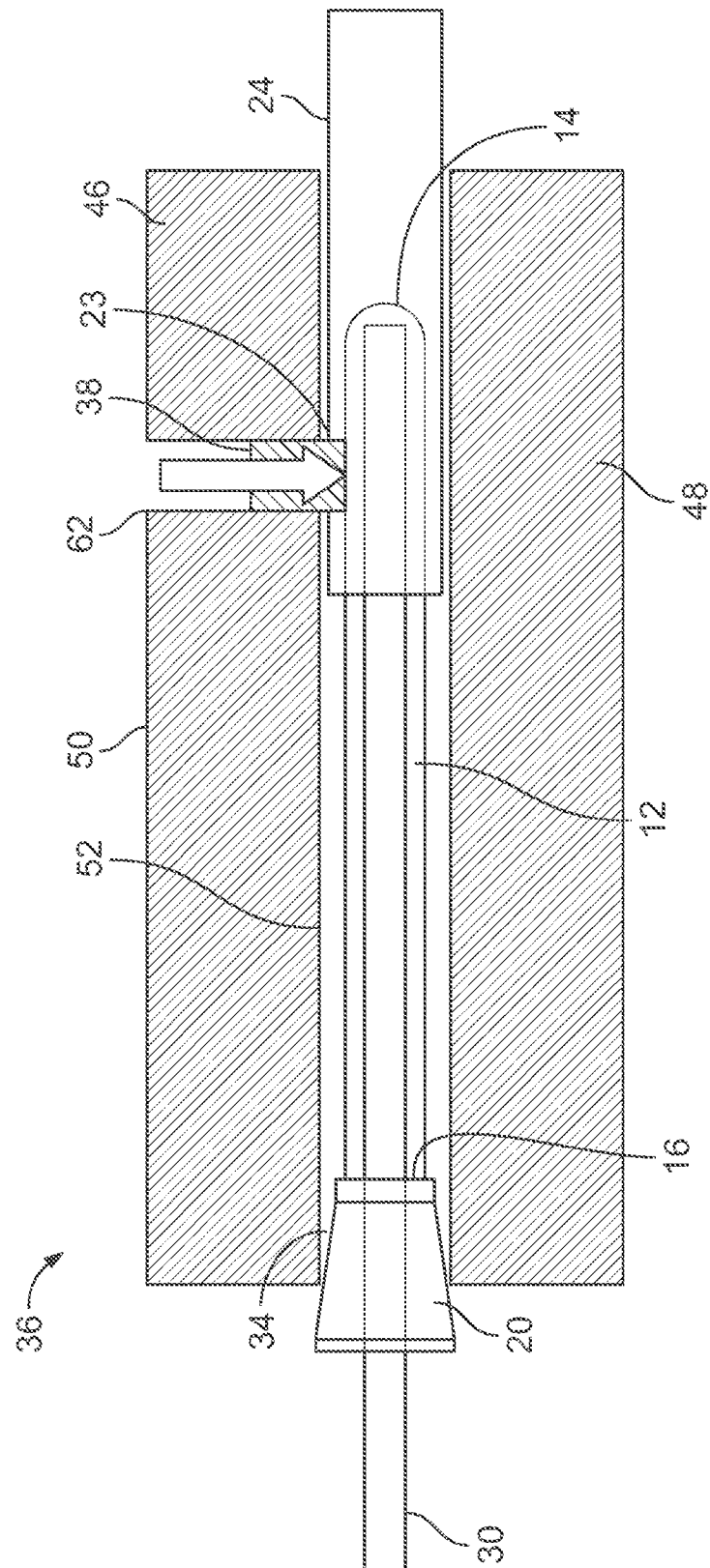


FIG. 6



THE

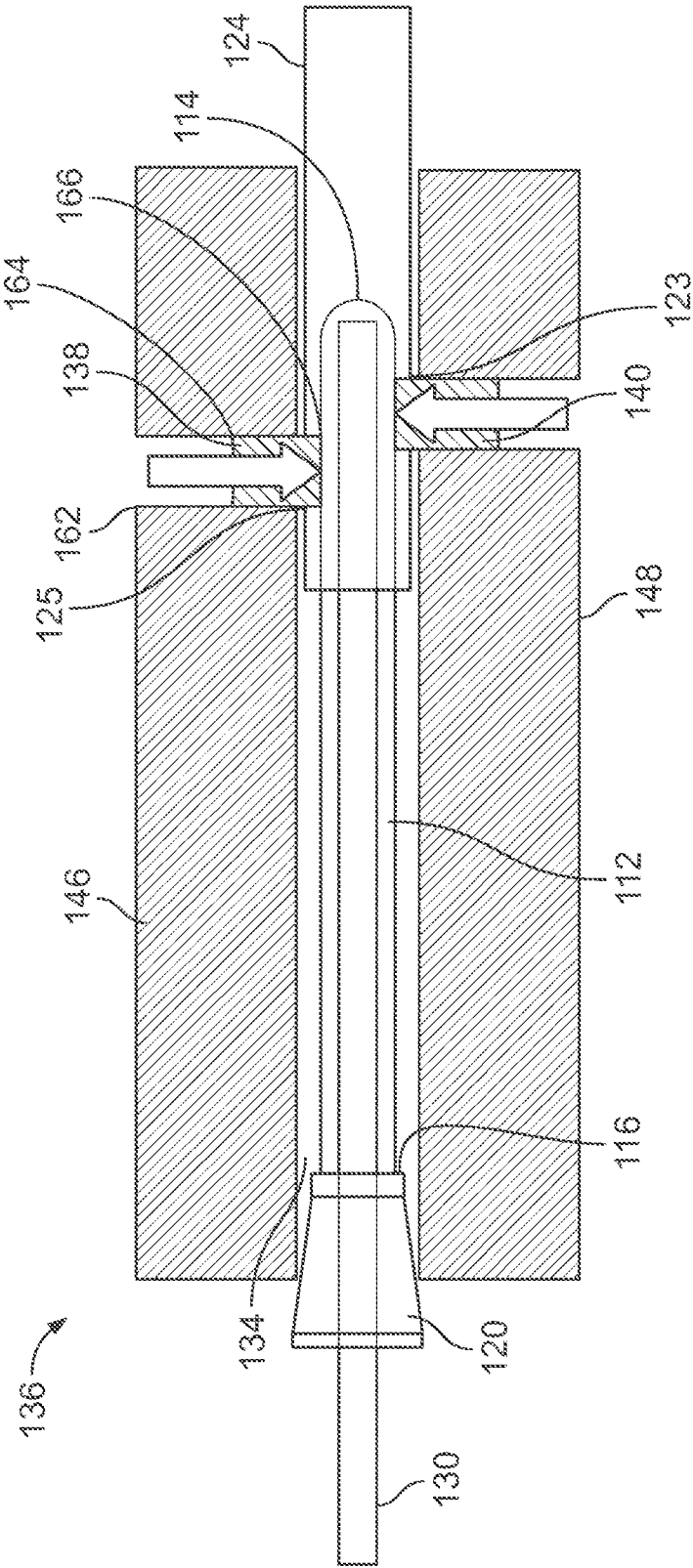


FIG.8

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2024/053847

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M25/00

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 4 073 287 A (BRADLEY WILLIAM E ET AL) 14 February 1978 (1978-02-14) column 2, line 37 - line 49; figures 4-5 column 4, line 59 - column 5, line 44 -----	1-9, 11-16 10,17-23
X	US 2021/038231 A1 (WALZMAN DANIEL EZRA [US]) 11 February 2021 (2021-02-11) paragraphs [0032], [0035], [0108], [0110] -----	1,5,7, 11,12, 14-16
X	EP 0 011 795 A1 (INTERMEDICAT GMBH [CH]) 11 June 1980 (1980-06-11) page 2 - page 3; figures 1-2 ----- -/-	1



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

3 February 2025

Date of mailing of the international search report

19/02/2025

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INTERNATIONAL SEARCH REPORT

International application No

PCT/US2024/053847

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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International application No
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