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Fortsættes ...

The invention relates to a urinary catheter set with a package for a urinary catheter, especially an intermediate urinary catheter, which is introduced into the urinary tube (urethra). The package sheathes the urinary catheter, so as to keep it sterile. Such packages are widely known, since medical instruments must be
5 supplied in a sterile package to their area of application. The package is broken open when the medical instrument is needed. The package ensures that the instrument contained therein remains sterile until it is used.

If the medical instrument is a catheter, the usual practice is to remove the
10 catheter from the package when it is needed by opening the package at one end. One end of an intermediate, i.e. a short-term, urinary catheter is subsequently grasped with one hand and pulled out of the package.

To reduce the sliding friction during catheterisation, it is known to wet the
15 external surface of the catheter with a fluid, for example a lubricating agent or an aqueous saline solution, so as to be able to introduce the catheter as painlessly as possible and without causing further irritation into a hollow organ of the human body. It is also known to wet the external surface of a medical instrument with active medical ingredients, so that these active ingredients can be delivered to the
20 tissue adjacent to the instrument in the hollow organ.

For this purpose, a urinary catheter preferably has a hydrophilic external surface along the length of its shaft, which surface, prior to opening the package, is activated by means of a fluid which is stored in a fluid reservoir provided in the
25 package.

EP 0 959 930 B1 and EP 0 923 398 B1 disclose a urinary catheter set with a package for a urinary catheter integrated therein, which package also comprises a fluid reservoir which is provided for activating the hydrophilic external surface of
30 the catheter contained in the package. The external surface of this urinary catheter has a hydrophilic coating. To apply the urinary catheter, it is removed from the package after the hydrophilic surface has been activated. Another urinary catheter set of this kind is known from GB 2319507 A.

DE 2317839 specifies another possible way of wetting catheters. Here, a catheter is contained in a package which is divided into two areas. One area is filled with a wetting agent and receives the insertable end of the catheter. The other area accommodates the funnel-shaped other end of the catheter. Both areas are
5 separated from one another by a constriction which prevents the wetting agent from spreading into the other area. Alternatively, a pouch containing a wetting agent can also be arranged at the insertable end of the catheter, this pouch opening through pressure and releasing the wetting agent.

10 Finally, from WO 97/41811 a catheter is known which is accommodated in a collecting pouch. A reservoir containing a wetting agent is arranged at the withdrawal opening for the catheter, so that when the catheter is withdrawn it comes into contact with sufficient wetting agent. To store the catheter arrangement, it can be sealed into another plastic pouch.

15

The disadvantage with the urinary catheter sets of the prior art is that after removal from the package the urinary catheter is difficult to handle, particularly for handicapped people, because of the length required for its intended use. In particular, the risk is that by holding the catheter with one hand its external
20 surface may become contaminated with microorganisms. This can lead to inflammations of the urethra and the bladder, which frequently lead to complications which are at least unpleasant.

A urinary catheter set is known from US 4140127 having a sleeve with two
25 opposing side walls and a cuff. The cuff is folded back from the end of the sleeve accommodating the front end of the catheter and serves to receive the finger of the person applying the catheter.

The invention is based on the object of providing a urinary catheter set, with
30 which the disadvantages of the prior art are avoided and which, in particular, is easy, fast and cost-efficient to use.

This object is achieved by the device described in the independent claim. The dependent claims constitute preferred embodiments of the invention.

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According to the invention, the object is achieved by a urinary catheter set according to Claim 1. The catheter set for short-term catheterisation comprises a sterile package, into which the provided urinary catheter, together with a cuff, is preferably sealed. The urinary catheter comprises a catheter shaft, a catheter tip and a preferably funnel-shaped end on the collecting pouch end. The cuff encloses the catheter shaft in at least one section. The cuff is arranged along the catheter shaft so as to be movable. This has the advantage that according to the invention the urinary catheter with the movable cuff can be inserted in a user-friendly manner. Thus, after the catheter has been removed from the package, it can be handled without directly grasping the catheter surface, i.e. by grasping the cuff. The catheter can be applied using an aseptic technique. The cuff has the advantage that sterile sections of the urinary catheter are not improperly infected by inappropriate contact. No additional packaging measures are required. The urinary catheter has a hydrophilic surface. There is a fluid reservoir inside the package, wherein the hydrophilic surface can be activated by means of a fluid stored in the fluid reservoir. The activated hydrophilic surface serves to reduce the sliding friction when the urinary catheter is applied. Activation can be carried out simply and in a user-friendly way without further attachments to the urinary catheter set being required. The cuff is designed in such a way that the fluid, when the hydrophilic surface of the urinary catheter is activated, at least partly collects in the cuff. The cuff thereby forms a kind of funnel and encloses the catheter shaft in such a way that the surface of the catheter shaft can by and large be uniformly wetted with the fluid when the cuff is moved.

The cuff is preferably designed as a plastic bag which preferably has a length of 10 to 15 cm. This length is optimal for grasping the cuff with one hand, since the cuff approximately corresponds to the size of a hand. The design as a plastic bag has the advantage of low manufacturing costs and low volume, which facilitates accommodation of the cuff inside the package.

The fluid reservoir preferably has a rupture point, by means of which the fluid reservoir can be broken open when the package is closed, preferably by exerting pressure on the fluid reservoir. After breaking open the fluid reservoir, the fluid thereby wets the surface of the catheter. This has the advantage that the hydrophilic surface can be activated directly prior to using the catheter.

Inside the package, the fluid reservoir is preferably positioned in an area adjacent to the catheter tip, so that on breaking open the fluid reservoir, bursting of the package is avoided. This can be accomplished by ensuring that a distance of several centimetres between one inner end of the package at the catheter tip and
5 the fluid reservoir is maintained. If the fluid reservoir were to be located directly on the end of the package, there would be the risk of the package rupturing or at least of being damaged by the fluid which is under pressure, especially when the fluid reservoir is broken open by the pressure exerted.

- 10 The fluid is preferably water or preferably a 0.9 per cent weight saline solution or lubricating gel. These substances have been found to be suitable for this purpose.

The cuff can, for example, be in the form of a plastic bag. The catheter passes through the plastic bag, meaning that the plastic bag encloses the catheter shaft,
15 with the plastic bag enclosing the catheter shaft more tightly on one end of the plastic bag than on the other end. Thus, the plastic bag forms a kind of funnel with a filling opening and a discharge hole. The more tightly enclosing end is the discharge hole of the funnel, with the discharge hole tightly enclosing the shaft of the catheter in such a way that when the plastic bag is moved in the direction of
20 the end of the urinary catheter on the collecting pouch end, the fluid which has collected in the plastic bag can flow out from the plastic bag just sufficiently, so that the surface of the urinary catheter is wetted with the fluid. Thus, the fluid flows out through the lumen of the discharge hole, with the wetting being carried out via the volume of the lumen. This has the advantage that uniform wetting of
25 the catheter surface is guaranteed, so that the most painless possible application of the catheter is ensured.

For the generally intended use of the catheter set, wetting the catheter shaft to fully activate the hydrophilic surface by means of the cuff is not necessary, since
30 the fluid provided for activating the hydrophilic surface can be uniformly distributed in the closed package when the fluid reservoir is broken open. The cuff primarily serves to facilitate better handling of the catheter and to reduce the packaging material required for a safe application.

In a special embodiment of the urinary catheter set, a collecting pouch is arranged on the end of the catheter on the collecting pouch end. This makes catheterisation possible even in cases in which a means for the disposal of the discharged fluid is not within reach.

5

The package of the urinary catheter set according to the invention is preferably constructed from a deep-drawn film layer and a paper material layer, wherein the urinary catheter is arranged between the deep-drawn film layer and the paper material layer. This is a particularly cost-effective and safe sterile type of package.

10 The paper material layer has a thickness which ensures that the package is sufficiently stable. The paper material is covered by a layer which ensures the sterility of the catheter and, in particular, the leakproofness of the catheter set after activation of the hydrophilic surface of the catheter, i.e. in particular after breaking open the fluid reservoir.

15

The package of the urinary catheter set, preferably in the area of the end of the catheter on the collecting pouch end (funnel area) and again preferably on an extension line of the catheter shaft, has a suspension hole. The diameter of the suspension hole can be in the centimetre range, which makes it possible to

20 suspend the catheter set, for example from a door handle. This further facilitates handling of the catheter set.

Further advantages follow from the description and the attached drawings. The features of the invention mentioned earlier, as well as those listed below, can be

25 used separately or in combination with one another. The embodiments mentioned are not intended as a definitive list of exemplary embodiments, but instead are provided merely as examples.

The invention will be explained in greater detail below with the aid of exemplary

30 embodiments with reference to the drawings.

Fig. 1, with Figs. 1a and 1b, shows a top view and a lateral view of a catheter set according to the invention with a urinary catheter in its package;

Fig. 2 shows an embodiment of the cuff of the catheter set according to the invention;

Fig. 3 shows the position of the cuff on the catheter shaft of a catheter in a
5 catheter set according to the invention;

Fig. 4 shows a preferred position of the fluid reservoir of a catheter set according to the invention and

10 Fig. 5 shows a segment of a preferred embodiment with a suspension hole in the package of a catheter set according to the invention.

The figures of the drawings show the subject matter of the invention in a highly schematic representation and are not to scale. The individual components of the
15 subject matter according to the invention are represented in such a way as to illustrate their design effectively.

Fig. 1 shows a catheter set 10 according to the invention with a urinary catheter 20 in its sterile package 30. Fig. 1a shows a top view and Fig. 1b shows a lateral
20 view of catheter set 10. Urinary catheter 20 in its full length is located inside the package. Urinary catheter 20 has a catheter tip 21, a catheter shaft 22 and a funnel-shaped end 23 on the collecting pouch end. Inside the package, an axially movable cuff 40 is arranged. This cuff 40 encloses the urinary catheter 20. Cuff 40 is designed as a flat-pressed plastic sheeting tube. In addition, a fluid reservoir 50
25 is provided within package 30.

Urinary catheter 20 has a hydrophilic external surface, which extends along the entire length of its catheter shaft 22, and this hydrophilic external surface can be activated by means of the fluid reservoir 50 which is also integrated into the
30 package 30. By means of a rupture point 51, fluid reservoir 50 in package 30 can be broken open. This is accomplished, for example, by exerting pressure on fluid reservoir 50 until it ruptures. The fluid stored inside fluid reservoir 50 subsequently spreads to predetermined areas of package 30, so that the external surface of the catheter shaft of the urinary catheter 20 stored in the package is
35 activated along the length intended for this.

In the horizontal position of the package as shown in the drawing, direction 33 in which the fluid spreads is indicated by an arrow. The fluid is preferably a physiological saline solution (0.9 per cent weight saline solution). Once the external surface of urinary catheter 20 has been activated, urinary catheter 20 can be removed from the package by grasping it with one hand on the collecting pouch end 23, which is designed as a funnel, and by pulling urinary catheter 20 along its length out of package 30. Formed along catheter shaft 22 is cuff 40, which may, for example, be grasped with the other hand. Cuff 40 is preferably designed so as to be movable along catheter shaft 22 and constitutes an inside cover for catheter 20, so as to protect against contamination the part of the catheter which is to be inserted into the urinary tube. This cuff 40 can be pushed forward along catheter shaft 22 up into the area of the tip.

Fig. 2 shows an embodiment of cuff 40 of the catheter set 10 according to the invention. Cuff 40 is designed as a plastic bag which has the form of a funnel with a filling opening 41 and a discharge hole 42. The area adjacent to filling opening 41 has the form of a cylinder with a preferred length of 10 cm. Filling opening 41 preferably has a diameter of 25 to 30 mm. The cylinder-shaped area tapers into a conical section with a preferred length of 3 cm which ends in the discharge hole 41 with a preferred diameter of 10 mm. Thus, the overall length of cuff 40 is 13 cm. The material of cuff 40 is preferably very thin and/or surface-structured. In addition, for example 6 cm from discharge hole 41, cuff 40 can have a perforation 43 to make it easy to separate cuff 40. This makes it possible to shorten cuff 40 if the user were to find this to be more convenient.

Fig. 3 shows how cuff 40, which is designed as a bag, is positioned on catheter shaft 22 of a catheter in a catheter set according to the invention. The catheter, for example, is 40 cm long. Cuff 40 can be moved along the length of the catheter, i.e. along the catheter shaft 22. At the catheter tip 21, opening 25 through which the urine can be discharged is shown. When, after activation of the hydrophilic surface of the catheter, cuff 40 is moved from catheter tip 21 along catheter shaft 22 in the direction of the collecting pouch end 23 of the catheter, the surface of the catheter is uniformly wetted with the fluid used for activation, since at least parts of the fluid are located inside cuff 40, i.e. in the bag.

Fig. 4 shows a preferred position of the fluid reservoir of a catheter set according to the invention in the package. Fluid reservoir 50 is ruptured, for example when a force of 20 N is exerted on the fluid reservoir. This force can be generated by exerting pressure on package 30. Package 30 preferably consists of a paper material layer and a deep-drawn film layer. The paper material layer may also be fibre-reinforced. Using a conventional method common in packaging technology, the urinary catheter is sealed between these layers, with the urinary catheter being arranged extended in a cavity 34 which is formed by the deep-drawn film layer. Fluid reservoir 50 is arranged approximately 4 cm (plus or minus 1 cm) upstream from the catheter tip end 35 of cavity 34, i.e. in an area adjacent to the catheter tip. The space of approximately 4 cm between the fluid reservoir and the end of the cavity is provided to minimise the risk of the cavity tearing or rupturing when the fluid reservoir is broken open, for example when it is ruptured. The direction in which the fluid stored in the fluid container spreads within the cavity when fluid reservoir 50 is broken open is indicated by the arrows.

Fig. 5 shows a preferred embodiment with a suspension hole 38 in the package of a catheter set according to the invention. The figure shows the area of package 30 of the funnel-shaped end 23 of the catheter on the collecting pouch end. Suspension hole 38 is arranged in this area. For this purpose, the package is lengthened by approximately 4 cm in the direction of an extension line 39 of the catheter shaft beyond a sealing area 37, by means of which the paper material layer is sealed to the deep-drawn film layer. Suspension hole 38, for example, has a diameter of 2 cm and is arranged 1 cm from the sealing area. The suspension hole should be arranged at least 5 mm from the edge 36 of the package.

List of reference numbers

	10	Catheter set
	20	Urinary catheter
5	21	Catheter tip
	22	Catheter shaft
	23	Collecting pouch end
	25	Opening
	30	Package
10	33	Direction of spread
	34	Cavity
	35	Catheter tip end
	36	Package edge
	37	Sealing area
15	38	Suspension hole
	39	Extension line
	40	Cuff
	41	Filling opening
	42	Discharge hole
20	43	Perforation
	50	Fluid reservoir
	51	Rupture point

Patentkrav

1. Blærekateter-sæt (10) der har et blærekateter (20) i en steril emballage (30) som har et kateterskaft (22), en kateterspids (21) og en ende (23) der vender
5 mod en opsamlingsbeholder, hvor der i emballagen (30) er tilvejebragt en tynd folieslange, der afsnitvist omfatter kateterskaftet (22) og er anbragt forskydeligt langs kateterskaftet (22), den tynde folieslange omslutter kateterskaftet (22) tættere ved en ende af folieslangen end ved den anden ende af folieslangen, den tynde folieslange er kortere end blærekateteret (20) og den tynde folieslange er
10 presset flad.

2. Blærekateter-sæt (10) ifølge krav 1, **kendetegnet ved at** blærekateteret (20) har en hydrofil overflade og der er et væskereservoir (50) inde i emballagen (30), hvor den hydrofile overflade kan aktiveres ved hjælp af en væske oplagret i
15 væskereservoiret (50).

3. Blærekateter-sæt (10) ifølge krav 2, **kendetegnet ved at** væskereservoiret (50) har et brudpunkt (51) ved hjælp af hvilket væskereservoiret (50) kan opbrydes når emballagen (30) er lukket, hvor væsken, efter opbrydning af
20 væskereservoiret (50), i vidt omfang befugter overfladen af kateteret (20) helt.

4. Blærekateter-sæt (10) ifølge krav 2 eller 3, **kendetegnet ved at** væskereservoiret (50) er anbragt inde i emballagen (30) i et område som grænser op til kateterspiden (21).
25

5. Blærekateter-sæt (10) ifølge krav 2 til 4, **kendetegnet ved at** væsken er vand eller saltvandsopløsning eller smøregel.

6. Blærekateter-sæt (10) ifølge krav 5, **kendetegnet ved at** væsken er 0,9
30 vægtprocents saltvandopløsning.

7. Blærekateter-sæt (10) ifølge et hvilket som helst af kravene 2 til 6, **kendetegnet ved at** den tynde folieslange er udformet på en sådan måde at væsken, når den hydrofile side af blærekateteret (20) aktiveres, mindst delvis
35 opsamles i den tynde folieslange, idet den tynde folieslange omslutter

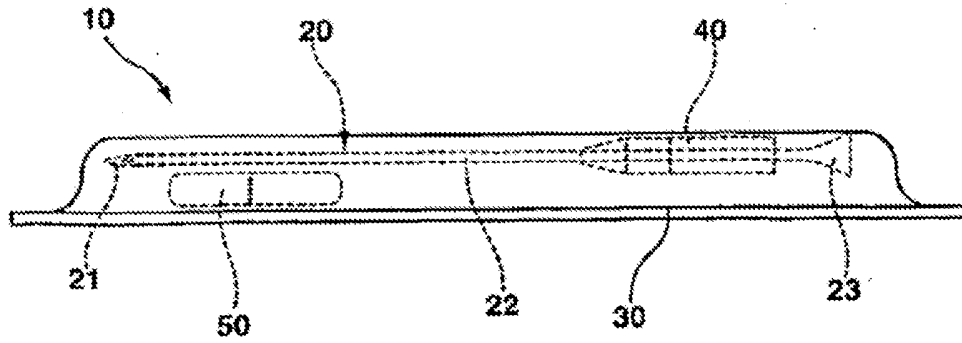
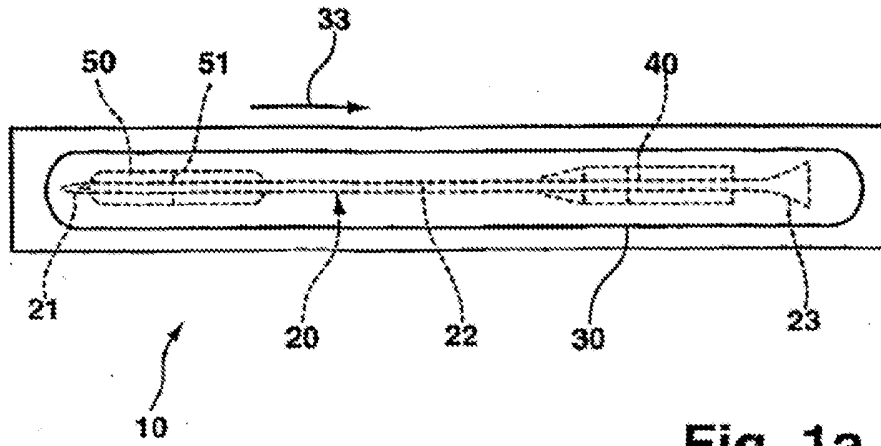
kateterskiftet (22) på en sådan måde at overfladen af kateterskiftet (22) i vidt omfang befugtes ensartet med væsken når den tynde folieslange bevæges.

8. Blærekateter-sæt (10) ifølge mindst ét af kravene 1 til 7, **kendetegnet ved at**
5 en opsamlingspose er anbragt ved enden (23) af kateteret (20) der vender mod opsamlingsbeholderen.

9. Blærekateter-sæt (10) ifølge mindst ét af kravene 1 til 8, **kendetegnet ved at**
10 emballagen (30) er konstrueret fra et dybtrukket filmlag og papirmaterialelag, hvor blærekateteret (20) er anbragt mellem det dybtrukne filmlag og papirmaterialelaget.

10. Blærekateter-sæt (10) ifølge mindst ét af kravene 1 til 9, **kendetegnet ved at**
15 emballagen (30), i området af enden (23) af kateteret (20) der vender mod opsamlingsbeholderen har et ophængningshul (38).

11. Blærekateter-sæt (10) ifølge mindst ét af kravene 7 til 9, **kendetegnet ved at**
20 den mere tætte omsluttende ende (23) af den tynde folieslange omslutter kateterskiftet (22) tæt på en sådan måde at når den tynde folieslange bevæges i retningen af enden (23) af blærekateteret (20) der vender mod opsamlingsbeholderen, kan væsken der er blevet opsamlet i den tynde folieslange flyde frit ud af folieslangen netop tilstrækkeligt til at overfladen af blærekateteret (20) befugtes med væsken.



2/3

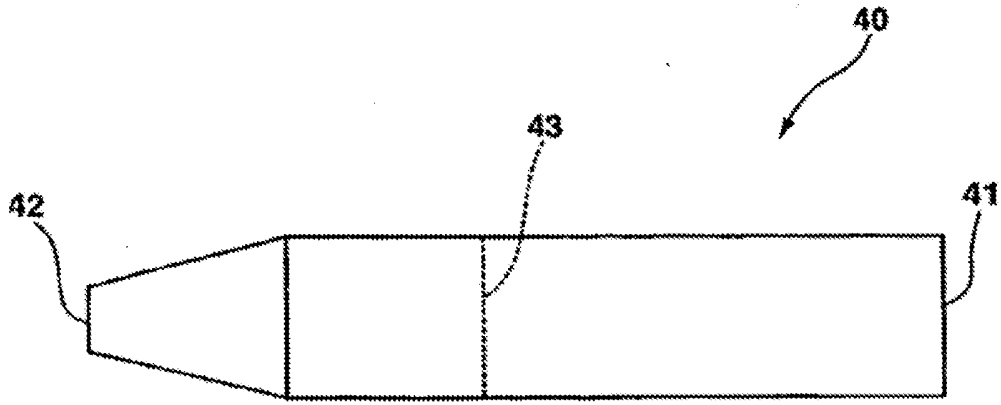


Fig. 2

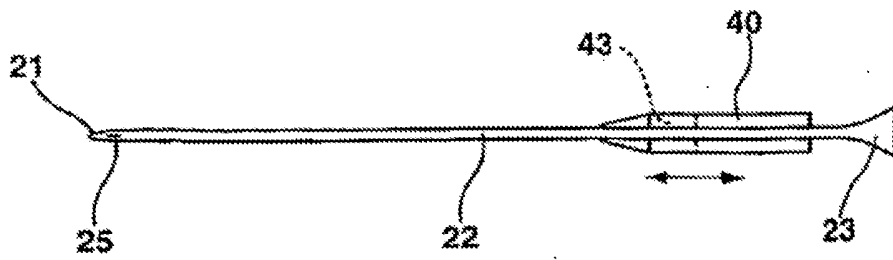


Fig. 3

