BALLOON CATHETER SYSTEM FOR SEALING PUNCTURE POINTS IN BODY CAVITIES, HOLLOW ORGANS OR IN PERCUTANEOUS SYSTEMS IN MAMMALS

Fig. 1

The present invention relates to a balloon catheter system for sealing puncture points or openings in body cavities, hollow organs or in percutaneous drainage operations in mammals, consisting of a filling catheter (14) for a filling medium with a shaft, on the distal end of which a first balloon (20) which can be filled with the filling medium is arranged with a further balloon (22) which can be filled with the filling medium arranged proximally spaced apart therefrom, which balloons close the puncture point or the opening on the two sides in the filled state of the balloon (20, 22), and a hollow needle (12), which is open at the shaft or the shaft end and can be guided in the lumen of the filling catheter (14), for filling the two balloons (20, 22) with the filling medium, wherein the shells of the two balloons (20, 22) enclose the shaft of the filling catheter (14) and the filling catheter (14) in each case has an opening (23.1, 23.2) arranged in the balloon lumen to fill the two balloons (20, 22), whereby, when the hollow needle (12) is drawn back, the distal balloon (20) is firstly filled with the filling medium followed by the balloon (22) proximally spaced apart therefrom.
Balloon catheter system for sealing puncture points in body cavities, hollow organs or in percutaneous systems in mammals

Description

Field of the invention

The present invention relates to a balloon catheter system for sealing puncture points in body cavities, hollow organs or in percutaneous systems in mammals. The catheter is suitable for treatment in a preterm premature rupture of the membranes (PPROM, PROM), a percutaneous gastrostoma and for percutaneous drainage. In particular, the invention relates to a balloon catheter for sealing puncture points or openings in body cavities, hollow organs or in percutaneous drainage operations in mammals. The balloon catheter system according to the invention is suitable for treating a preterm premature rupture of the membranes (PPROM) by amnioinfusion, a gastrointestinal anastomosis, a bowel obstruction (ileus), drainage of bile from the gallbladder, a pleural effusion, a pericardial effusion or a perianal abscess.

Description of the Background Art

An early preterm premature rupture of membranes (PPROM) occurs in about 3 to 17% of all pregnancies and leads to a premature birth within a few days in most cases. PPROM is therefore the cause of child morbidity and mortality in the early weeks of pregnancy, in particular before the completed 34th week of pregnancy. Ascending infections from the lower genital tract, which can lead to PPROM through the increase in the intraamnial pressure and the occurrence of shear forces, are one reason for the occurrence of a preterm premature rupture of the membranes.

Therapeutic measures for treating PPROM aim to restore and maintain the normal fluid volume in the amnion. To increase the amniotic fluid index (AFI), the volume of fluid of the amnion is continuously increased by means of an amnioinfusion (Tan L.-K et al., Test Amnioinfusion to Determine Suitability for Serail Therapeutic Amnioinfusion in Midtrimester Premature Rupture of Membranes, Fetal Diagn Ther (2003), 18: 183-189; Luigi A. et al., Transabdominal amnioinfusion in preterm premature rupture of membranes: a randomised controlled trial, BJOG: an International Journal of Obstetrics and Gynaecology (2005), Vol.
112, pp. 759-763; Tian-Lun Hsu et al., The Experience of Amnioinfusion for Oligohydramnios during the early second trimester, Taiwan J Obstet Gynaecol (2007), Vol. 46 (4):

The previously known methods for amnioinfusion for treating PROM are unsatisfactory, as the artificial amniotic fluid introduced from outside (physiological saline solution) very rapidly flows out of the uterus again, so the effect of the amnioinfusion is greatly reduced. The known methods related, for example, to a cervical occlusion with a fibrin gel (Zamlynski J, Bodzek P, Olejek A, Grettka K, Manka G., Results of amnioinfusion in pregnancies with oligohydramnios and non-ruptured fetal membranes, Med Wieku Rozwoj 2003; 7: 187-94) or the infusion of a fluid by means of a transcervical catheter (Machalski T, Síkora J, Bakon I, Magnucki J, Grzesiak-Kubica E, Szkodny E. Short-term and long-term fetal heart rate variability after amnioinfusion treatment of oligohydramnios complicated pregnancy, Ginekol Pol 2001; 72: 1107-11).

Catheters are used in the most varied areas of medicine. A balloon catheter is described in EP 1 557 193 B1, which is used to treat a congenital heart disease such as tricuspid atresia, pure pulmonary atresia or a complete reversal of large vessels. A balloon catheter is described in US 5,226,889 A, which consists of a flexible shaft and at least one pair of inflatable balloons, the proximally situated balloon carrying a vessel support (stent). The vessel support is to be implanted into a patient by means of the balloon catheter. The above-mentioned catheters would not be suitable for use in an amnioinfusion. One problem is that the catheters cannot be fixed in the uterus wall. Furthermore, the problem of loss of fluid exists in amnioinfusion owing to the non-sealed puncture point in the uterus wall, so a continuous supply of fluid is necessary during the amnioinfusion. The danger of peritonitis is reduced or prevented by sealing using the balloon catheter system according to the invention.

A double balloon catheter for treating PPROM consists of a silicone tube with two separate balloons close to the cervical tip and a hole between these balloons, so an antiseptic solution, which is introduced from the outer end, can flow through the walls and branched channels into each balloon (Gramellini D, Fieni S, Kaihura C, Faiola S, Vadora E., Transabdominal antepartum amnioinfusion, Int J Gynaecol Obstet 2003; 83: 171-8). The described catheter is introduced via the cervix and the balloons are filled by infusion with PVP iodine solution through the branched channels. The balloons fix the catheter in the
cervical channel, which is partly closed by operation clamps between the two balloons and is tightened after the filling thereof. The catheter described therein is to prevent the outflow of amniotic fluid via the cervix. However, when using this method there is a risk of an amnion infection syndrome (AIS) owing to infected amniotic fluid and extraneous bodies (catheters) in the cervix, as no continuous amnioinfusion takes place with fresh saline solution.

Summary of the Invention

It is therefore an object of the present invention to provide a balloon catheter, which, on the one hand, can be securely and atraumatically fixed to the puncture point and, on the other hand, seals the puncture channel of the opening in a fluid-tight manner.

This object is achieved by a balloon catheter system for sealing puncture points or openings in body cavities, hollow organs or in percutaneous drainage operations in mammals with the features of claim 1. Preferred embodiments are to be found in the sub-claims.

The balloon catheter system according to the invention is suitable in general for sealing puncture points or openings in body cavities, hollow organs or in percutaneous drainage operations in mammals and consists of a filling catheter or a filling channel for a filling medium with a shaft, at the distal end of which a first balloon which can be filled with the filling medium is arranged with a further balloon which can be filled with the filling medium arranged proximally spaced apart therefrom, which balloons close the puncture point or the opening on the two sides. Arranged in the lumen of the filling catheter is a guidable hollow needle, which is open at the shaft or shaft end, for filling the two balloons with the filling medium. The two balloons surround the shaft of the filling catheter. The filling catheter has a respective opening arranged in the balloon lumen to fill the two balloons, whereby when the hollow needle is drawn back, the distal balloon is firstly filled with the filling medium followed by the balloon proximally spaced apart therefrom.

The two balloons press against the walls of the body cavity or of the hollow organ so the puncture point or the opening is closed when the balloons are filled. The balloon catheter system can be introduced by means of a hollow needle (for example 18 G needle) into the body cavity (for example the uterus during amnioinfusion) under sonographic control. Apart from the filling catheter, the balloon catheter system comprises a further infusion channel or infusion catheter for the infusion with drainage of fluid into or out of body cavities, hollow
organs or in percutaneous passages in mammals. In a preferred embodiment, arranged on
the filling catheter is a further infusion catheter, the distal end of which passes through the
two balloons. For sealing, the shells of the two balloons enclose both the filling catheter and
the infusion catheter. The filling catheter is used to fill the two balloons, while the infusion
catheter can be used for the infusion of infusion fluids into the body cavity. As an alternative,
the infusion channel is also suitable for draining fluids from organs or drainage operations. In
one embodiment, the infusion catheter can be moved relative to the guide catheter through
the balloons.

In a particular embodiment, the filling catheter and the infusion catheter are present in one
component, i.e. the component has a channel for filling the balloon and a further infusion
channel for the fluid supply or drainage.

Using the hollow needle which can be guided through the filling catheter, the balloon at the
distal end of the filling catheter is firstly filled with the filling medium (for example
physiological saline solution). The filling process for the proximal balloon takes place by
drawing back the hollow needle, so the proximally situated balloon can be filled via the
opening present in the guide catheter. So the two balloons remain inflated, the filling
catheter is constantly filled with filling medium and is therefore under pressure. Alternatively,
check valves may also be provided in the filling channel. These may be located either at the
foot end of the balloon or directly in the filling catheter. Alternatively, the check valves may
also be arranged on the adapter or the filling device. These valves prevent the filling medium
from flowing back owing to the balloon pressure.

The two balloons are preferably filled by means of a port system or other subcutaneous
filling device, which is connected to the proximal end of the filling catheter and/or the hollow
needle. The port system is implanted under the skin of the patient. It can ... to fill the balloon
by means of a membrane. A further port system may be subcutaneously implanted for the
infusion of physiological saline solution or for drainage by means of the infusion catheter.
The port system thereby allows controlled refilling of the two balloons and the infusion or
drainage of fluid into or out of the body through the infusion catheter or infusion channel. The
port system is preferably a double port for the filling catheter and the infusion catheter. The
hollow needle is preferably connected to an adapter for the port system or the subcutaneous
filling device.
Once the two balloons have been inflated, the guide catheter is drawn back to the skin and expediently clamped off with a soft clamp by the operator to avoid the balloon collapsing and the catheter thereby being dislocated.

If the filling catheter and the infusion catheter are not configured in one component, it may be expedient for a guide wire which can be drawn out of the catheter to be additionally arranged in the lumen of the infusion catheter. As a result, the infusion catheter is stiffened and can be better guided to the puncture point of the body cavity or the hollow organ.

The type of filling medium depends on the respective purpose of use of the balloon catheter system according to the invention. The filling medium is physiological saline solution to treat a preterm premature rupture of the membranes (PPROM) by amnioinfusion. Continuous amnioinfusions can be carried out by means of the infusion catheter or the infusion channel, so the effect of the amnioinfusion is considerably increased during the treatment of PPROM. The filling medium may also be a contrast medium during use in patients.

In principal, the two balloons can also be simultaneously filled with the filling medium via the corresponding openings mentioned in the filling catheter. However, a serial filling is to be preferred to fix the catheter under sonographic control. A further possibility for serial filling of the two balloons is for the two balloons to consist of shells having different inflation resistances. As a result, the balloon with the lower inflation resistance is firstly inflated. Only when the pressure is increased further is the balloon with the higher inflation resistance also filled.

Instead of a port system, the hollow needle and/or the filling catheter may also be connected to an adapter, which is preferably equipped with a check valve so no filling medium can escape from the balloon. In one variant, the check valve is located in the catheter itself or at the foot end of the balloon.

Depending on the purpose of use, it may be advantageous if the two balloons and/or the catheters consist of biodegradable material, so the components of the balloon catheter system automatically dissolve after a certain time. A further operative intervention is thereby avoided.
The balloon catheter system according to the invention can in general be used anywhere where puncture points or openings have to be closed or fluids have to be drained/supplied from or into organs or body cavities.

One area of use of the balloon catheter system according to the invention is in amnioinfusion for treating a preterm premature rupture of the membranes (PPROM), in particular before the 34th completed week of pregnancy. This purpose of use is described in more detail in the example below.

In addition, the balloon catheter system according to the invention can be used for the infusion or drainage of fluid into or out of body cavities, hollow organs or in percutaneous passages of (non-human) mammals. The present invention therefore also relates to the use of the balloon catheter system according to the invention in the treatment of a gastrointestinal anastomosis. In the case of a bowel obstruction, the balloon catheter system according to the invention can contribute to relief, whereby peritonitis is prevented.

Furthermore, it is suitable for draining bile from the gallbladder (for example in a pancreatic carcinoma). A further area of use is the drainage of fluid in a pleural effusion or a pericardial effusion. Perianal abscesses, in which transcutaneous or transrectal drainage can likewise take place by means of the balloon catheter system according to the invention, are a further application example.

The mode of operation of the balloon catheter system according to the invention is to be described in more detail by means of an example.

Example

The balloon catheter system according to the invention is used together with a port system to treat a preterm premature rupture of the membranes (PPROM) before the completed 34th week of pregnancy. PPROM was previously treated by repetitive amnioinfusions. However, the introduced amniotic fluid (physiological saline solution) flows away very rapidly in the patient, so the effect of the amnioinfusion is only slight. The balloon catheter system, which consists of a filling catheter for the two balloons and a further infusion catheter, is introduced into the uterus by an 18 G needle under sonographic control. A port system is implanted under the skin of the patient. The distal balloon arranged at the end of the catheter is filled with physiological saline solution using a hollow needle guided in the guide catheter. The
filling catheter together with the distal balloon is then drawn back to the uterus wall so the
distal balloon seals the puncture point from inside. The hollow needle is drawn back in order
to then fill the second balloon located proximally outside the uterus via the opening in the
filling catheter. The opening of the uterus produced by the puncture is sealed on the two
sides by the two balloons. The guide catheter can then be drawn back to the skin and
clamped off with a soft clamp in order to avoid the balloon being deflated and therefore
translocation of the catheter. The balloons optionally have to be refilled and this takes place
by means of the filling catheter and the port system implanted under the skin. The filling level
of the balloon can be checked by means of ultrasound. Physiological saline solution (NaCl
solution) is introduced via the infusion catheter into the uterus for continuous amnioinfusion.

The filling of the two balloons brings about an atraumatic fixing of the catheter and seals the
opening in the uterus between the two balloons. The danger of ascending peritonitis
triggered in the abdominal cavity by infected amniotic fluid is sharply reduced thereby. The
development of lung hyperplasia and therefore the risk of a neonatal death of the child in a
preterm premature rupture of the membranes is reduced by the use of a continuous
amnioinfusion. This allows an extension of the pregnancy by up to several months.

A further advantage of the balloon catheter system according to the invention is that the
infusion catheter can be introduced by means of a relatively large hollow needle to the
puncture point or opening. As a result, the risk of injury from pain during the implantation is
considerably reduced for the patient. A further advantage compared to known systems and
methods is that the balloon catheter system can be guided with relatively thin hollow
needles. In order to facilitate the guidance of the infusion catheter, a guide wire extending in
the lumen is used. The guide wire can easily be removed again once the placing of the
catheter has been effected. By using biodegradable material, the latex of the balloon
dissolves in a few months, thus clearly facilitating the removal of the prenatal catheter.

The previously used catheters regularly dislocate from the uterus in a preterm premature
rupture of the membranes after about a week, which can be avoided by using the balloon
catheter system according to the invention, as the catheter can be visibly fixed in the
amniotic sac.
Brief description of the drawings

The invention is described in more detail in the drawing below.

Fig. 1 shows an embodiment of a balloon catheter system according to the invention. A hollow needle 12 is arranged in the filling catheter 14. Two fillable balloons 20, 22 are located at the distal end of the filling catheter 14. The proximal end of the hollow needle 12 is connected to an adapter 10 for filling the two balloons 20, 22. The filling medium (for example physiological NaCl solution) is introduced into the balloon 20, 22 via the hollow needle 12 and the filling catheter 14 (after removal of the hollow needle 12). The two balloons 20, 22 surround the filling catheter 14 and have a respective opening 23.1, 23.2 arranged in the balloon lumen for filling.

The distal balloon 20 is firstly filled with the filling medium via the opening 23.2 of the filling catheter 14 using the hollow needle 12. The filling catheter 14 is drawn back together with the filled distal balloon 20 to the uterus wall. The hollow needle 12 is then drawn back through the filling catheter 14 to the proximally situated balloon 22 in such a way that said balloon can be filled with the filling medium via the opening 23.1. The balloons 20, 22 are filled under sonographic control. The two balloons 20, 22, when filled, seal a puncture point or opening. The hollow needle 12 is drawn out of the filling catheter 14 and the proximal end 9.1 of the filling catheter 14 is connected to a port system, adapter or other filling device.

Provided for the infusion or drainage is a further channel, which is shown as an infusion catheter 16 in the embodiment shown. A guide wire 18, which can be drawn out again once the catheter has been placed, is guided in the infusion catheter for easier introduction. The proximal end 9.2 of the infusion catheter 16 is connected to a port system (for example double port together with the filling catheter 14). The distal end 17 of the infusion catheter 16 projects into the body lumen. Physiological saline solution is continuously let into the uterus via the infusion catheter 16 for amnioinfusion.

The two balloons 20, 22 are preferably filled under sonographic control.

The puncture point is sealed and the catheter system fixed. A dislocation of the catheter is avoided, and this is a decisive advantage compared to conventionally used catheters.
Claims

1. Balloon catheter system for sealing puncture points or openings in body cavities, hollow organs or in percutaneous drainage operations in mammals, consisting of:
   - a filling catheter (14) for a filling medium with a shaft, on the distal end of which a first balloon (20) which can be filled with the filling medium is arranged with a further balloon (22) which can be filled with the filling medium arranged proximally spaced apart therefrom, which balloons close the puncture point or the opening on the two sides in the filled state of the balloon (20, 22), and
   - a hollow needle (12), which is open at the shaft or the shaft end and can be guided in the lumen of the filling catheter (14), for filling the two balloons (20, 22) with the filling medium,

wherein the shells of the two balloons (20, 22) enclose the shaft of the filling catheter (14) and the filling catheter (14) in each case has an opening (23.1, 23.2) arranged in the balloon lumen to fill the two balloons (20, 22), whereby, when the hollow needle (12) is drawn back, the distal balloon (20) is firstly filled with the filling medium followed by the balloon (22) proximally spaced apart therefrom.

2. Balloon catheter system according to claim 1, characterised in that a further infusion catheter (16), the distal end (17) of which passes through the two balloons (20, 22), is arranged on the filling catheter (14), the shells of the two balloons (20, 22) enclosing both the filling catheter (14) and the infusion catheter (16).

3. Balloon catheter system according to either claim 1 or claim 2, characterised in that the filling catheter (14) and the infusion catheter (16) or the catheter channels are configured in one component.

4. Balloon catheter system according to any one of the preceding claims, characterised in that a guide wire (18) which can be drawn out of the catheter is additionally arranged in the lumen of the infusion catheter (16).

5. Balloon catheter system according to any one of the preceding claims, characterised in that the proximal end (9.1) of the filling catheter (14) and/or the hollow needle (12) is connected to a port system or another subcutaneous filling device to fill the two balloons (20, 22).
6. Balloon catheter system according to claim 5, characterised in that the proximal end (9.2) of the infusion catheter (16) is also connected to a port system or another subcutaneous filling device.

7. Balloon catheter system according to any one of the preceding claims, characterised in that the hollow needle (12) and/or the filling catheter is connected to an adapter (10), which is equipped with a check valve.

8. Balloon catheter system according to any one of the preceding claims, characterised in that the filling medium is physiological saline solution.

9. Balloon catheter system according to any one of the preceding claims, characterised in that the two balloons (20, 22) consist of shells, which have different inflation resistances.

10. Balloon catheter system according to any one of the preceding claims, characterised in that the two balloons (20, 22) and/or the catheters (14, 16) consist of biodegradable material.

11. Balloon catheter system according to any one of the preceding claims, characterised in that the filling catheter (14) and/or the infusion catheter (16) can be introduced by means of a relatively large hollow needle to the puncture point or opening.

12. Use of a balloon catheter system according to any one of claims 1 to 11 for sealing puncture points or openings in body cavities, hollow organs or in percutaneous drainage operations in mammals.

13. Use according to claim 12 for the infusion or drainage of fluid into or out of body cavities, hollow organs or percutaneous passages in mammals by means of an additional infusion catheter.

14. Use according to either claim 12 or claim 13 for treating a preterm premature rupture of the membranes (PPROM) by amnioinfusion, a gastrointestinal anastomosis, a bowel obstruction (ileus), drainage of bile from the gallbladder, a pleural effusion, a pericardial effusion or a perianal abscess.
Method for filling a balloon catheter system comprising a plurality of fillable balloons with a filling medium, characterised in that a balloon catheter system consisting of
- a filling catheter (14) for a filling medium with a shaft, on the distal end of which a first balloon (20) which can be filled with the filling medium is arranged with a further balloon (22) which can be filled with the filling medium arranged proximally spaced apart therefrom, which balloons close the puncture point or the opening on the two sides in the filled state of the balloons (20, 22), and
- a hollow needle (12), which is open at the shaft or the shaft end and can be guided in the lumen of the filling catheter (14), for filling the two balloons (20, 22) with the filling medium, the shells of the two balloons (20, 22) enclosing the shaft of the filling catheter (14) and the filling catheter (14) in each case having an opening (23.1, 23.2) arranged in the balloon lumen to fill the two balloons (20, 22),
is used, in which the balloon (20) arranged at the distal end of the filling catheter (14) is filled with the filling medium by means of the hollow needle (12), the filling catheter (14) together with the filled distal balloon (20) is drawn back to the puncture point or opening, the hollow needle (12) is then returned to the proximally situated balloon (22) and is then also filled with filling medium.
AMENDED CLAIMS
received by the International Bureau on 29 August 2011 (29.08.2011)

1. Balloon catheter system for sealing puncture points or openings in body cavities, hollow organs or in percutaneous drainage operations in mammals, consisting of
   - a filling catheter (14) for a filling medium with a shaft, on the distal end of which a first balloon (20) which can be filled with the filling medium is arranged with a further balloon (22) which can be filled with the filling medium arranged proximally spaced apart therefrom, which balloons close the puncture point or the opening on the two sides in the filled state of the balloon (20, 22), and
   - a hollow needle (12), which is open at the shaft or the shaft end and can be guided in the lumen of the filling catheter (14), for filling the two balloons (20, 22) with the filling medium, wherein the shells of the two balloons (20, 22) enclose the shaft of the filling catheter (14) and the filling catheter (14) in each case has an opening (23.1, 23.2) arranged in the balloon lumen to fill the two balloons (20, 22), whereby, when the hollow needle (12) is drawn back, the distal balloon (20) is firstly filled with the filling medium followed by the balloon (22) proximally spaced apart therefrom, characterised in that a further infusion catheter (16), the distal end (17) of which passes through the two balloons (20, 22), is arranged on the filling catheter (14), the shells of the two balloons (20, 22) enclosing both the filling catheter (14) and the infusion catheter (16).

2. Balloon catheter system according to either claim 1, characterised in that the filling catheter (14) and the infusion catheter (16) or the catheter channels are configured in one component.

3. Balloon catheter system according to any one of the preceding claims, characterised in that a guide wire (18) which can be drawn out of the catheter is additionally arranged in the lumen of the infusion catheter (16).

4. Balloon catheter system according to any one of the preceding claims, characterised in that the proximal end (9.1) of the filling catheter (14) and/or the hollow needle (12) is connected to a port system or another subcutaneous filling device to fill the two balloons (20, 22).

5. Balloon catheter system according to claim 4, characterised in that the proximal end (9.2) of the infusion catheter (16) is also connected to a port system or another subcutaneous filling device.
6. Balloon catheter system according to any one of the preceding claims, characterised in that the hollow needle (12) and/or the filling catheter is connected to an adapter (10), which is equipped with a check valve.

7. Balloon catheter system according to any one of the preceding claims, characterised in that the filling medium is physiological saline solution.

8. Balloon catheter system according to any one of the preceding claims, characterised in that the two balloons (20, 22) consist of shells, which have different inflation resistances.

9. Balloon catheter system according to any one of the preceding claims, characterised in that the two balloons (20, 22) and/or the catheters (14, 16) consist of biodegradable material.

10. Balloon catheter system according to any one of the preceding claims, characterised in that the filling catheter (14) and/or the infusion catheter (16) can be introduced by means of a relatively large hollow needle to the puncture point or opening.

11. Use of a balloon catheter system according to any one of claims 1 to 10 for sealing puncture points or openings in body cavities, hollow organs or in percutaneous drainage operations in mammals.

12. The use according to claim 11 for the infusion or drainage of fluid into or out of body cavities, hollow organs or percutaneous passages in mammals by means of an additional infusion catheter.

13. The use according to either claim 11 or claim 12 for treating a preterm premature rupture of the membranes (PPROM) by amnioinfusion, a gastrointestinal anastomosis, a bowel obstruction (ileus), drainage of bile from the gallbladder, a pleural effusion, a pericardial effusion or a perianal abscess.

14. Method for filling a balloon catheter system comprising a plurality of tillable balloons with a filling medium, characterised in that a balloon catheter system consisting of

   - a filling catheter (14) for a filling medium with a shaft, on the distal end of which a first balloon (20) which can be filled with the filling medium is arranged with a further balloon (22) which can be filled with the filling medium arranged proximally spaced
apart therefrom, which balloons close the puncture point or the opening on the two sides in the filled state of the balloons (20, 22), and

- a hollow needle (12), which is open at the shaft or the shaft end and can be guided in the lumen of the filling catheter (14), for filling the two balloons (20, 22) with the filling medium, the shells of the two balloons (20, 22) enclosing the shaft of the filling catheter (14) and the filling catheter (14) in each case having an opening (23.1, 23.2) arranged in the balloon lumen to fill the two balloons (20, 22), is used, in which the balloon (20) arranged at the distal end of the filling catheter (14) is filled with the filling medium by means of the hollow needle (12), the filling catheter (14) together with the filled distal balloon (20) is drawn back to the puncture point or opening, the hollow needle (12) is then returned to the proximally situated balloon (22) and is then also filled with filling medium.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/00 A61B17/42 A61M25/10 A61M29/02
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)
A61B 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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 2005/027247 AI (CARRISON ET AL.) 3 February 2005 (2005-02-03)</td>
<td>1,3,5,</td>
</tr>
<tr>
<td></td>
<td>abstract; figures 7-11 paragraphs [0078] - [0088]</td>
<td>7-15</td>
</tr>
<tr>
<td></td>
<td>abstract; figures 1,2 col umn 3, line 55 - col umn 4, line 31</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>US 2009/204099 AI (FELONEY) 13 August 2009 (2009-08-13)</td>
<td>1,3,</td>
</tr>
<tr>
<td></td>
<td>abstract; figures 1-4 paragraphs [0015] - [0023]</td>
<td>5-10, 12-15</td>
</tr>
</tbody>
</table>

X Further documents are listed in the continuation of Box C. X See patent family annex.

* Special categories of cited documents:
  "A" document defining the general state of the art which is not considered to be of particular relevance
  "E" earlier document but published on or after the international filing date
  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  "O" document referring to an oral disclosure, use, exhibition or other means
  "P" document published prior to the international filing date but later than the priority date claimed
  "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
  "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
  "S" document member of the same patent family

Date of the actual completion of the international search
28 June 2011

Date of mailing of the international search report
05/07/2011

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer
Gimenez Burgos, R
<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>US 5 104 377 A (LEVINE) 14 April 1992 (1992-04-14) abstract; figures</td>
<td>1,15</td>
</tr>
<tr>
<td>A</td>
<td>US 3 509 884 A (BELL) 5 May 1970 (1970-05-05) abstract; figures</td>
<td>1,15</td>
</tr>
<tr>
<td>Patent document cited in search report</td>
<td>Publication date</td>
<td>Patent family member(s)</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>-----------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>US 2005027247 A1</td>
<td>03-02-2005</td>
<td>WO 2005011787 A2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 5354270 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 9311716 A2</td>
</tr>
<tr>
<td>US 2009204099 A1</td>
<td>13-08-2009</td>
<td>NONE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CN 101970040 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2195072 A1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>KR 20100072029 A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 2009042429 A1</td>
</tr>
<tr>
<td>US 5104377 A</td>
<td>14-04-1992</td>
<td>NONE</td>
</tr>
<tr>
<td>US 3509884 A</td>
<td>05-05-1970</td>
<td>NONE</td>
</tr>
</tbody>
</table>