

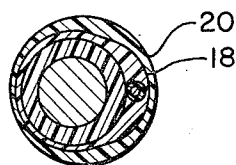
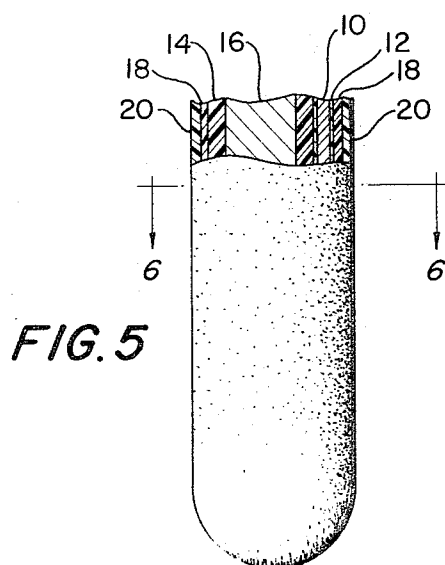
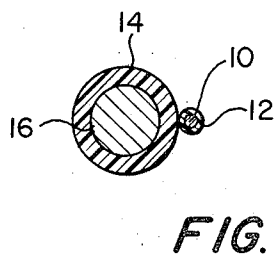
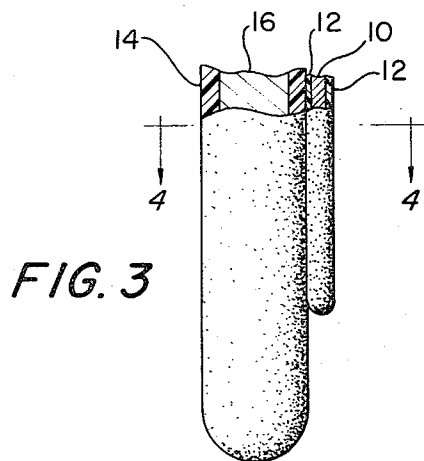
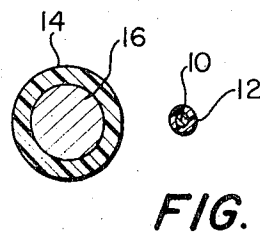
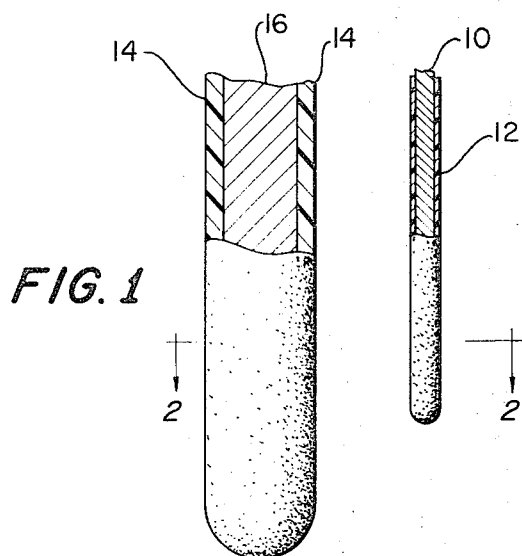
June 18, 1974

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3,817,809

BARE WIRE PROCESS FOR MAKING RETENTION CATHETERS

Filed March 20, 1972



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3,817,809

BARE WIRE PROCESS FOR MAKING RETENTION CATHETERS

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Filed Mar. 20, 1972, Ser. No. 236,490

Int. Cl. B32b 1/08

U.S. Cl. 156—296

10 Claims

ABSTRACT OF THE DISCLOSURE

Two-lumen catheters, such as inflatable catheters having a drainage lumen and an inflation lumen, are formed by applying a thin film of an aqueous adhesive composition, that dries to form a water pervious film, directly to the inflation lumen forming wire. The film is dried to form a water pervious, thin, tacky tubular member on the inflation lumen forming wire. The tubular member is then pressed into adhering, parallel, abutting contact with a latex tubular member previously formed on the drainage lumen forming rod. Subsequently, the conventional two-lumen catheter forming operations including coating the joined tubular members with rubber to build up a smooth exterior surface are followed.

FIELD OF THE INVENTION

This invention relates to the production of catheters, and more particularly, to processes for making catheters having a pair of parallel lumens, such as inflatable catheters.

BACKGROUND OF THE INVENTION

Inflatable catheters which include a drainage lumen and an inflation lumen are in commercial practice conventionally formed using an anode dip technique in which a forming member is dipped into liquid latex. The forming member comprises a drainage lumen forming rod and an inflation lumen forming wire held together by a hinge. The forming rod and the forming wire of the forming member are coated with a slurry of diatomaceous silica and calcium nitrate before the first latex dip. The forming rod and the forming wire are held in a separated and parallel relationship by the forming member during this initial dip.

There are several problems which result from the initial anode dip operation of the conventional process for forming inflatable catheters.

It has been difficult or impossible to obtain uniform deposition of latex on the forming wire due to variations in the calcium content on the surface of the wire. Also, variations in latex quality cause variations in the total amount of latex deposited on the forming wire. Thus, the thickness of the latex film picked up at the surface of the forming wire in the conventional forming process can vary from 0.004 to 0.007 in. after the latex has been dried. The upper portion of the thickness range tends to produce catheters having flat outer surface areas and a generally oval cross section. The deposition of only a thin layer of latex on the forming wire is regarded in the art as a cause for non-deflation of the inflatable catheters.

It is critical that retention catheters of the inflatable type be deflatable to permit removal from the body. After the end of an inflatable catheter is inserted into a body cavity, a balloon located near the end of the catheter is inflated with fluid. The inflated balloon retains the catheter within the body cavity and when removal of the catheter from the body is desired, the balloon must be deflated. This deflation is accomplished by draining the fluid from the balloon via the inflation lumen. If for some reason it becomes impossible to remove the fluid used to inflate the balloon via the inflation lumen, a surgical procedure

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is necessary. All known surgical procedures for causing the deflation of the balloon of a retention catheter are traumatic to the patient. Thus, it is critical that inflation catheters be provided with a fool-proof deflation capability.

The interlumen wall area of an inflation catheter having a drainage lumen and an inflation lumen is very critical to providing the desired 100% deflation capability. It has been found that the step of pressing two films of latex together as in the present conventional process for making inflation catheters, can create microscopic imperfections between the two films, and in the apex of the two crevices created by the abutting contact of the tubular latex films. These imperfections can preferentially absorb large quantities of water. The absorption of water into these imperfections can result in a blister or delamination of the two films, and cause an occlusion of the inflation lumen. Such an occlusion can lead to a non-deflating catheter.

BRIEF DESCRIPTION OF THE INVENTION

The invention provides an improved process for forming a two-lumen catheter, such as an inflatable catheter having a drainage lumen and a second (inflation) lumen. Such a process includes the steps of coating a drainage lumen forming rod and second lumen forming wire to form a pair of tubular films, joining the tubular films in a generally parallel abutting relationship, and coating the joined tubular films with rubber to provide a smooth exterior surface. The improvement provided by this invention comprises the steps of: applying directly to the lumen forming wire, a film of an aqueous film-forming adhesive composition that will dry to form a water permeable film, the thickness of said film being no more than .0015 in.; drying the film to form a thin tacky tubular member on the lumen forming wire; and pressing the thin tacky tubular member into adhering, parallel, abutting contact with a tubular film on the previously coated drainage lumen forming rod.

The present invention essentially eliminates one of the two fluid barrier layers present at the interlumen wall of conventionally formed inflation catheters. The presence of only a single barrier layer prevents the possibility of blistering and delamination of adjacent layers which is present in a two-layer construction. Thus, there is a greatly reduced possibility of occluding the inflation lumen which could lead to a non-deflating catheter. Imperfections and voids in the crevices between the forming rod and the forming wire are no longer of importance, since, when the inflation forming wire is removed, the only result is that the inflation lumen has a slightly larger cross section at that point which is penetrable by fluid within the inflation lumen.

Further, the rounder catheter shaft which is provided by the present process permits an inflation balloon to be mounted concentrically on the shaft of the catheter. The latex deposited by the finish latex dips, which anchor the balloon in place on the shaft of the catheter, is deposited evenly. The slightly uneven pick up of latex on an out-of round catheter shaft produced by the prior art conventional process tended to result in the lop-sided mounting of balloons, that is, balloons that were not concentrically aligned on the shaft of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

Of the drawings:

FIG. 1 illustrates the bottom end, partly in section, of a lumen forming rod and unconnected lumen forming wire;

FIG. 2 is a sectional view along line 2—2 of FIG. 1;

FIG. 3 is an elevation view, partly in section, of the bottom end of the coated forming rod of FIG. 1 and the

coated forming wire of FIG. 1 placed in abutting parallel contact;

FIG. 4 is a section view taken along line 4—4 of FIG. 3;

FIG. 5 is an elevation view, partly in section, of the bottom end of a partially formed inflation catheter after completion of latex dipping steps which provide a substantially round outer surface for the catheter; and

FIG. 6 is a sectional view taken along line 6—6 of FIG. 5.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

The invention provides improvements in a process for forming two-lumen catheters in which the catheter forming process includes the steps of coating a drainage lumen forming rod and a lumen forming wire to form a pair of tubular members. Subsequently, the tubular members are usually dried and then joined in a parallel abutting relationship. The joined tubular members are coated with a number of coats of rubber, for example by dipping, to provide a smooth exterior surface. Such processes are widely used to form inflatable catheters in which the second lumen is a small diameter inflation lumen which communicates with an extensible bag or balloon.

In accordance with the present invention, a latex tubular member is formed on a drainage lumen forming rod, and an aqueous adhesive composition is directly applied to a lumen forming wire.

The step of forming the continuous latex tubular member on the drainage lumen forming rod can proceed according to the customary anode type latex deposition procedure which is widely used in making catheters. In such a procedure, the metal forming rod is first coated with a slurry of diatomaceous silica and calcium nitrate before the first latex dip. This latex dip preferably forms a film having a dry thickness of from .010 to .015 in. thickness. The continuous latex film is dried by, for example, passing the latex coated drainage lumen forming rod through an oven held at 120° to 150° F.

The dried latex film on the drainage lumen forming rod is desirably dipped in a latex adhesive or the latex adhesive is sprayed thereon to deposit a layer of latex adhesive of less than 0.001 inch. This latex adhesive can be a composition containing about equal parts of rubber latex and resin solution, or rubber latex and resin emulsion. The application of adhesive to the dried latex film is a desirable, but not critical procedure to assist in adhering the dried latex film and the adhesive composition deposited on the inflation lumen forming wire, as described below.

In accordance with the invention, an aqueous adhesive composition is applied directly to the lumen forming wire to form a thin water pervious film on the lumen forming wire. The thickness of this film, when applied, should be no more than 0.0015 inches, and preferably is from 0.0004 to 0.001 inches. Typically, the preferred dried thickness of such a film is from 0.0005 to 0.001 inches. The film of adhesive composition can be applied by a number of coating techniques including spraying, dipping, or mechanical application.

The aqueous adhesive composition must be one which will when dried form a water pervious tubular member on the inflation lumen forming wire. The term "water pervious" as used in the specification and claims refers to the ability of water to be transferred across a unit area of the adhesive film at a faster rate than across a unit area of latex film of comparable thickness under similar conditions.

The thin layer of adhesive should be capable of being partially dried to provide a tacky surface that will adhere the thin tubular member on the bare forming wire to the latex coated lumen forming rod that was previously rubberized in a conventional manner. Also, the adhesive composition should lose at least some of its adhesive qualities

during the normal catheter buildup and curing process to permit stripping of the catheter from the lumen forming wire.

Adhesive compositions containing starch and latex have been found to provide satisfactory initial adhesion, good stripping results and to produce water-pervious tubular members that result in inflation lumens which are essentially free of blockage problems. Such starch-latex adhesives preferably contain from 5 to 15 parts by weight of starch and 7.5 to 25 parts by weight of latex on a solids basis. The starch can be U.S.P. starch, an oxidized starch such as that sold under the trade designation "Fibersize" by National Starch & Chemical Corp., or an acid converted starch such as that sold under the designation "Flogel 90" by National Starch & Chemical Corp.

The preferred starch-latex adhesive compositions contain a small amount, from .001 to .04 parts by weight of an enzyme. The enzyme helps control the viscosity of the starch-based adhesive and can also be used to cause the removal of starch from the interior of the lumen wall during the customary leaching step which is performed after the catheter is removed from the metal rods or wires on which it is formed. This aqueous leaching step is customarily conducted at an acid pH and at a temperature above 100° F. These conditions and the presence of Ca⁺⁺ ions are conducive to the enzymatic digestion of starch.

It is presently preferred to apply the film of adhesive to a bare metallic forming wire by dipping the bare forming wire in the adhesive composition. Viscosity of the adhesive for this dipping operation is preferably 700 to 1200 cps. as measured by Brookfield viscometer model LVF at 6 r.p.m. using a number 2 spindle.

Other suitable aqueous adhesive compositions which can be used to form water pervious films in accordance with the invention include latex with a corn starch converted with acetic anhydride such as Flozyme 3008 sold by National Starch & Chemical Corp.

Spray application of the starch-rubber adhesive composition can also be used to apply the composition to the lumen forming wire. The starch-rubber compositions can be applied at viscosities as high as 30,000 plus cps. by utilizing a spray technique.

The adhesive film on the lumen forming wire is dried to form a thin tacky water-pervious tubular member on the inflation lumen forming wire. This drying step can be accomplished by exposing the tubular member at room temperature for 10 to 45 minutes, or by circulating hot air at temperatures from 120–160° F. for 30 to 90 seconds.

The tacky film on the inflation lumen forming wire is pressed into adhering parallel abutting contact with the latex tubular member of the drainage lumen forming wire. This pressing action can be accomplished by hand, or by utilizing the various tools which have been developed for pressing two conventional latex-coated lumens, together. In general, the tubular member formed from the adhesive composition tends to be easily adhered to the latex coated forming rod.

After the tacky tubular adhesive member and the latex tubular member have been joined, the catheter is built up by conventional coating processes, such as dipping, to provide a smooth outer wall surface for the shaft of the catheter. Subsequent to the dipping operation, the conventional catheter finishing operations, including attachment of a balloon or distensible bag and cutting and trimming of apertures, can be performed in the usual manner.

Preferably, when a starch-containing adhesive formulation is used, and an enzyme is added thereto, the formed catheters are subjected to an aqueous leaching step at temperatures above 100° F. The pH of the leaching fluid is desirably maintained at an acidic level to promote the digestion of starch from the wall of the lumen formed on the forming wire.

The following illustrative example is presented with reference to the drawings. All percentages referred to in

the specification and claims are by weight unless otherwise specifically indicated.

An adhesive composition is prepared that contains about 18 parts latex, and about 10 parts of an oxidized starch on a dry solids basis. The starch is cooked in about 56 parts of water just to the point of solubilization, and then blended with the latex.

Just prior to using the adhesive composition, 0.02 parts of an enzyme sold under the trade name "Milezyme Tenase" by Marschall Division of Miles Laboratories, Inc. is added to the composition.

With reference to FIG. 1, the adhesive composition is directly applied to a bare metal forming wire 10 by dipping the metal forming wire in the adhesive composition. The dipping operation applies a film of adhesive directly on forming wire 10.

This film of adhesive is dried by circulating air at 80° F. and a relative humidity of 38–50% for 10 minutes. The drying step produces a tacky tubular member 12 having a thickness of 0.0005 to 0.0015 in.

A latex film 14 which dries to about 0.12 in. in thickness is applied to a drainage lumen forming rod 16 using a conventional anode dip technique in which diatomaceous silica, and calcium nitrate are applied to rod 16 prior to the latex dip.

The latex film is coagulated and then dried. Subsequently, and as illustrated in FIGS. 3 and 4, tubular member 12 is pressed into adhering parallel, abutting contact with the latex tubular member 14 while these tubular members are still on forming wire 10 and forming rod 16, respectively.

After tubular member 12 is adhered to latex tubular member 14, the assembly is repeatedly dipped into latex to deposit latex layers 18 and 20, illustrated in FIGS. 5 and 6, which have progressively more circular cross sections.

In accordance with the conventional procedure after the cross-section buildup dipping step, the latex coated assembly is dried and then an opening (not shown) is cut at the end of forming wire 10 which will place the interior of tubular member 12 in fluid flow communication with the exterior of latex layer 20 after the removal of forming wire 10. An inflatable balloon (not shown) is then slipped over the distal end of the catheter and positioned so that the interior of the balloon is in communication with the above-described opening.

The balloon is then attached to the distal end of the catheter by the application of more coats of latex.

Subsequently, the catheters are dried, cured in an oven, and then leached in 180°–190° water for ¾ to 1 hour. The leaching step causes the digestion of at least some of the starch in tubular member 12. This digestion of the starch makes tubular member 12 even more water pervious. After the leaching step, the catheters are stripped off forming wire 10 and forming rod 16 and tied in bundles for further conventional processing.

Over 8500 catheters produced according to the bare wire forming technique have been subjected to a rigorous simulated use test involving water immersion. None of the over 8500 tested catheters failed to deflate due to blister formation or delamination in the wall between the lumens.

Normally, inflation catheters produced according to the conventional prior art process in which both lumens are formed by a simultaneous latex dip undergo about 1 failure due to blistering or delamination per 1000 catheters subjected to the same rigorous simulated use test. The new process of this invention appears to have completely eliminated the possibility of blistering or delamination at the interlumen wall.

What is claimed is:

1. In a process for forming a catheter having a drainage lumen and a second lumen, the process including the steps of coating a drainage lumen forming rod and a lumen forming wire to form a pair of tubular members, joining the tubular members in a generally parallel abutting rela-

tionship, and coating the joined tubular members with rubber to provide a smooth exterior surface, the improvement comprising the steps of:

- (a) forming a continuous latex tubular member on the drainage lumen forming rod;
- (b) applying a thin water-pervious film of no more than 0.0015 inch thickness of an aqueous adhesive composition directly to the lumen forming wire;
- (c) drying the film to form a thin water-pervious tubular member on the inflation lumen forming wire; and
- (d) pressing the thin water-pervious tubular member into adhering, parallel, abutting contact with the latex tubular member on the drainage lumen forming rod.

2. In a process for forming a catheter having a drainage lumen and a second lumen, the process including the steps of coating a drainage lumen forming rod and a lumen forming wire to form a pair of tubular members, joining the tubular members in a generally parallel abutting relationship, and coating the joined tubular members with rubber to provide a smooth exterior surface, the improvement comprising the steps of:

- (a) forming a continuous latex tubular member on the drainage lumen forming rod;
- (b) applying a thin water-pervious film of an aqueous adhesive composition containing 5 to 15 parts by weight starch and 7.5 to 25 parts by weight latex on a solids basis directly to the lumen forming wire;
- (c) drying the film to form a thin water-pervious tubular member on the inflation lumen forming wire; and
- (d) pressing the thin water-pervious tubular member into adhering, parallel, abutting contact with the latex tubular member on the drainage lumen forming rod.

3. The process of claim 2 in which the aqueous adhesive composition is sprayed on the lumen forming wire.

4. The process of claim 2 in which the film applied to the lumen forming wire is less than 0.0015 in. thick.

5. The process of claim 2 in which the lumen forming wire is metallic and a film of adhesive is applied to the bare forming wire by dipping the bare forming wire in the aqueous starch-containing adhesive composition.

6. The process of claim 5 in which the viscosity of the aqueous starch adhesive is 700 to 1200 cps. during the dipping step.

7. The process of claim 2 including the step of adding an enzyme to the aqueous adhesive composition prior to applying the composition to the lumen forming wire.

8. The process of claim 7 in which the joined tubular films, after being coated with rubber to provide a smooth exterior surface, are subjected to an aqueous leaching step conducted at an acidic pH and temperatures above 100° F. to digest starch at the interior wall surface of the lumen formed on the forming wire.

9. The process of claim 2 including the step of adding 0.001 to 0.04 parts by weight of an enzyme to the aqueous adhesive composition prior to applying the composition to the lumen forming wire.

10. The process of claim 9 in which the lumen forming wire is metallic and a continuous film of adhesive is applied to the bare forming wire by dipping the bare forming wire in the aqueous starch-containing adhesive composition.

References Cited

UNITED STATES PATENTS

2,330,399	9/1943	Winder	128—349 B
2,690,595	10/1954	Raiche	156—242
2,927,584	3/1960	Wallace	128—349 B

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U.S. Cl. X.R.

128—349 R, 349 B; 156—305

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 3,817,809
DATED : June 18, 1974
INVENTOR(S) : Paul Dereniuk

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 5, line 21, "0.12" should read --0.012--.

Signed and Sealed this

Fourth Day of January 1977

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks