

(21) Application No 8813752
(22) Date of filing 10 Jun 1988
(30) Priority data
(31) 8714657 (32) 23 Jun 1987 (33) GB

(71) Applicant
Smiths Industries Public Limited Company

(Incorporated in United Kingdom)

765 Finchley Road, London NW11 8DS
(72) Inventor
Peter Henry Hannam
(74) Agent and/or Address for Service
J M Flint
765 Finchley Road, London, NW11 8DS

(51) INT CL⁴
C08J 5/24 A61M 25/00 C08J 7/00

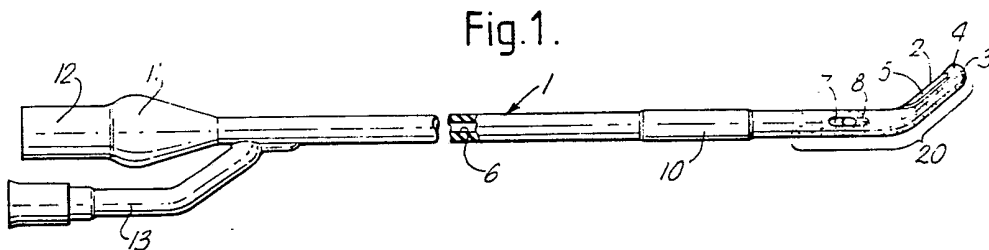
(52) Domestic classification (Edition J):
C3B 1D2C Q
A5R CG
U1S 1052 A5R C3B

(56) Documents cited
None

(58) Field of search
C3B
C3L

(54) Rubber articles having a stiffened region

(57) A region of a rubber article, e.g. the tip (3) of a urethral catheter (1) is stiffened by immersing the region (tip) in a solution of an epoxy resin. After equilibrium swelling is achieved the article is removed from the solution, the solvent is evaporated and the resin is cured, thereby stiffening the desired region (tip).



//

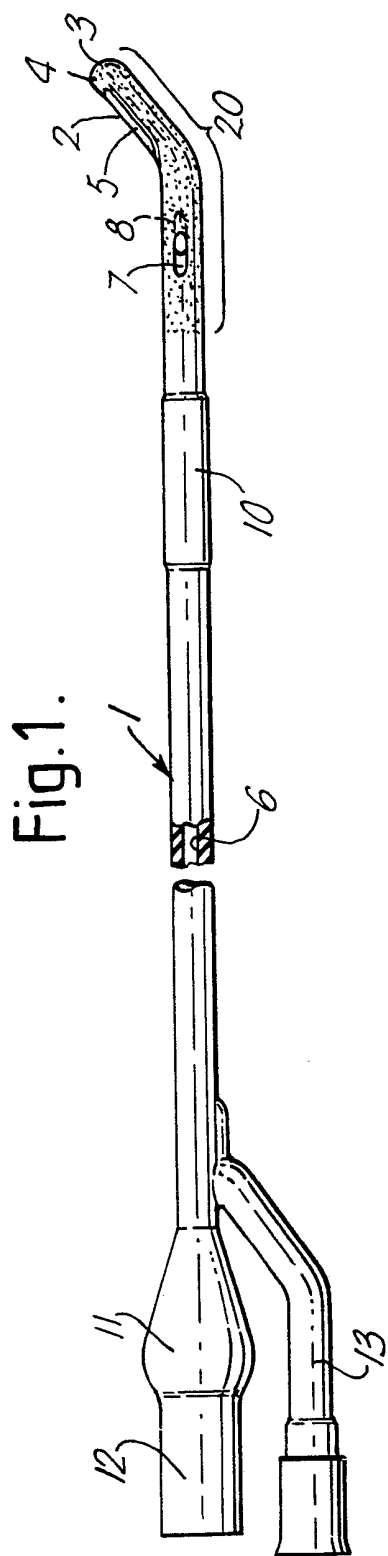


Fig.2.

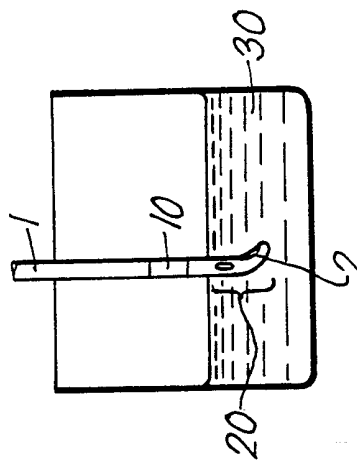
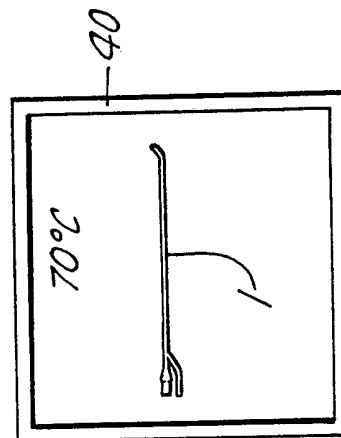


Fig.3.



RUBBER ARTICLES

This invention relates to rubber articles and to methods of making such articles.

Natural rubber latex is still used extensively, especially in medical applications, despite the availability of a wide range of plastics materials. This is because of the superior nature of some properties of rubber such as its softness and flexibility. In particular, natural rubber latex is used extensively for the manufacture of some medical catheters that need to be soft and highly flexible, such as for example, urethral catheters.

Although the softness of the material is an advantage it can also present problems. For example, in urethral catheters it is desirable that the tip of the catheter is somewhat stiffer than the remainder of the catheter so as to make insertion easier, without the tip folding and occluding the opening into the catheter. Conventional ways of stiffening the tip include locally increasing the thickness of the catheter wall; using a separate tip of stiffer material joined to the catheter; or using stiffening inserts, such as fabrics or layers of stiffer latex or polymer materials incorporated in the tip. All these techniques, however, have various disadvantages such as the increased manufacturing costs, the risk of components becoming detached from the catheter, the increase in external diameter or reduction in diameter of the fluid passage.

It is an object of the present invention to provide rubber

articles and methods of their manufacture and treatment that can be used to produce a localised stiffened region and avoid to a substantial extent the previous disadvantages.

According to one aspect of the present invention there is provided a rubber article having a region integral with the article that has an increased stiffness, the region being produced by diffusion of an epoxy resin into the rubber in that region only.

The article is preferably of a rubber crosslinked by accelerated sulphur. The article may be a catheter or a part of a catheter such as a urethral catheter. The tip of the catheter may be closed, the catheter having a lateral opening close to the tip, the tip and the opening being located in the stiffened region. The catheter may have a bend in its length in the stiffened region.

According to another aspect of the present invention there is provided a method of stiffening a region of a rubber article, including the steps of immersing the region in a solution of an epoxy resin in a solvent capable of diffusing into the rubber until the region is swollen by diffusion of the solvent and resin into the region, removing the article from the solution and allowing the solvent to evaporate and the epoxy resin to cure so as thereby to produce stiffening of the region by the resin diffused into the region.

The rubber used in the method is preferably crosslinked by accelerated sulphur. The epoxy resin is preferably of a low viscosity, and of low molecular weight. The solvent may be a hydrocarbon or

chlorinated hydrocarbon. The region is preferably immersed in the solution until equilibrium swelling is achieved. The article may be held at elevated temperature after removal to promote evaporation of the solvent and curing of the resin:

According to a further aspect of the present invention there is provided an article made by a method according to the above other aspect of the present invention.

A urethral catheter and a method of making the catheter with a stiffened tip, in accordance with the present invention, will now be described, by way of example, with reference to the accompanying drawing, in which:

Figure 1 is a side elevation view of the catheter;
and

Figures 2 illustrate steps in stiffening of the
and 3 tip of the catheter.

The urethral catheter 1 is of a soft, flexible natural rubber latex material having an external diameter of 6mm and an overall length of about 420mm. At its patient, distal end 2 the tip of the catheter is formed with a bent tip 3 of length about 18mm that is inclined to the length of the catheter at an angle of about 45 degrees. The tip 3 is provided with a closed, rounded end 4 and a lateral opening 5, of oval shape, into the bore 6 of the catheter. Two additional, smaller openings 7 and 8 are formed at the patient end 2 just to the rear of the tip 3. The size and positioning of these openings would normally weaken the region of the tip making it relatively easy to occlude the bore 6 through the catheter.

An inflatable cuff 10 encircles the catheter at a distance of about 45mm from the patient end 2, to the rear of the openings 5, 7 and 8.

At the rear, proximal end 11, the catheter tapers outwardly to form a connector 12 of increased diameter. A side passage 13 joins the catheter just forwardly of the connector 12 and opens into an inflation lumen (not shown) that communicates with the interior of the cuff 10.

The distal end 2 of the catheter is stiffened over a region 20 that extends for a distance of about 40mm from the patient end, thereby including the tip 3 and openings 7 and 8, but not the cuff 10. The stiffened region 20 is integral with the remainder of the catheter 1, but differs in that it contains a diffused epoxy resin.

The method by which the patient end 2 of the catheter 1 is stiffened will now be described with reference to Figures 2 and 3.

The two components of an epoxy resin having a low viscosity before curing (such as Permabond E27 made by Permabond Ltd. Eastleigh, Hampshire) are dissolved in a solvent, such as toluene, to form a 10% solution.

The distal end 2 of the catheter 1 in which stiffening is required is immersed in a solution 30 of the epoxy resin and solvent. While the catheter is immersed in the solution 30, the solvent and epoxy resin diffuse into the rubber material causing swelling of the immersed region. When equilibrium swelling has been achieved, the catheter is withdrawn from the solution and placed in an oven 40 (Figure 3) at 70 degrees Centigrade to allow the solvent to evaporate and the two components of the resin to react together and produce stiffening of the rubber material in the region 20 of immersion. Evaporation and curing can also occur at room temperature. The swelling during immersion is considerable, but this is caused primarily by the solvent. After evaporation of the solvent any swelling is caused only by the presence of epoxy resin and is relatively small. The increase in wall thickness from the epoxy resin is substantially less than would be required to produce an equivalent stiffness with material not diffused by epoxy resin.

The method may be used to stiffen parts of other articles of natural rubber or of synthetic rubber crosslinked by accelerated sulphur. It is preferable that the rubber is crosslinked as this

prevents the rubber being dissolved by the solvent. For this reason, some thermoplastic rubbers may not be suitable for stiffening by this method.

Other epoxy resins could be used, preferably, having a low viscosity and low molecular weight prior to curing. Paste-like epoxy resins such as Araldite 2001 tend to diffuse only into the surface of the rubber article thereby producing only a limited stiffening effect.

Other solvents could be used providing these are capable both of swelling the rubber material and dissolving both components of the epoxy resin. Other hydrocarbon or chlorinated hydrocarbon solvents may be suitable.

The degree of stiffening produced can be adjusted by altering the concentration of epoxy resin components in the solution. The rate of reaction of the epoxy resin components in solution will, however, increase with concentration, thereby limiting the concentration possible. The ability to achieve sufficient swelling of the rubber network will also be limited by the amount of solvent available. If only a limited stiffening is required, this may be achieved by removing the article from the solution before equilibrium swelling occurs.

It is possible that reimmersion of the article after evaporation and curing may produce an additional stiffening effect.

Instead of immersing only a part of the article, localised stiffening can be achieved by coating those regions where stiffening is

not required with a layer impervious to the resin and then immersing the entire article in the resin and solvent solution. The impervious layer can be subsequently removed if desired.

It will be appreciated that the method is not confined to use with catheters, but could be used with other rubber articles that need to be stiffened only in a localised region.

CLAIMS

1. A rubber article having a region integral with the article that has an increased stiffness, wherein the region is produced by diffusion of an epoxy resin into the rubber in that region only.
2. An article according to Claim 1, wherein the article is of a rubber crosslinked by accelerated sulphur.
3. An article according to Claim 1 or 2, wherein the article is a catheter or a part of a catheter.
4. An article according to Claim 3, wherein the article is a urethral catheter.
5. An article according to Claim 3 or 4, wherein the tip of the catheter is closed, wherein the catheter has a lateral opening close to the tip, and wherein the tip and the opening are located in the stiffened region.
6. An article according to any one of Claim 3 to 5, wherein the catheter has a bend in its length in the stiffened region.
7. A catheter substantially as hereinbefore described with reference to the accompanying drawings.
8. A method of stiffening a region of a rubber article including the steps of immersing the region in a solution of an epoxy resin

in a solvent capable of diffusing into the rubber until the region is swollen by diffusion of the solvent and resin into the region, removing the article from the solution and allowing the solvent to evaporate and the epoxy resin to cure so as thereby to reduce stiffening of the region by the resin diffused into the region.

9. A method according to Claim 8, wherein the rubber is crosslinked by accelerated sulphur.
10. A method according to Claim 8 or 9, wherein the epoxy resin is of low viscosity.
11. A method according to any one of Claims 8 to 10, wherein the epoxy resin is of low molecular weight.
12. A method according to any one of Claims 8 to 11, wherein the solvent is a hydrocarbon or chlorinated hydrocarbon.
13. A method according to any one of Claims 8 to 12, wherein the region is immersed in the solution until equilibrium swelling is achieved.
14. A method according to any one of Claims 8 to 13, wherein the article is held at elevated temperature after removal to promote evaporation of the solvent and curing of the resin.
15. A method substantially as hereinbefore described with reference to the accompanying drawings.

16. An article made by a method claimed in any one of Claims 8 to 15.

17. Any novel feature or combination of features as hereinbefore described.