MEDICAL DEVICE WITH LUBRICAIOUS COATING

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to coated substrates for medical purposes. The invention is particularly directed to medical devices or other substrates having lubricious coatings that are stored together where they can touch each other or are tortuously wrapped and folded upon themselves prior to use and are unfolded during use. In particular, one aspect of the present invention relates to lubriciously coated balloons that are folded and wrapped upon themselves for storage and are unwrapped and expanded to a size that is considerably greater than the stored size by the introduction of an expansion fluid into the balloon without having portions stick to each other and possibly removing the lubricious coating or tearing the substrate.

2. Description of the Prior Art

Medical balloon catheters are used surgically for insertion into blood vessels, urethra, or body conduits. Conventionally, such catheters are made of materials such as Nylon, Selar®, polyethylene terephthalate (PET), polyethylene (PE) or similar materials. Also, such balloon catheters can be made of several layers with polyethylene terephthalate blended with polyethylene. Also they can be made with blends of polyethylene terephthalate and Hytrel. Hytrel is a randomized block co-polymer of polyethers and polyesters. Catheters have been rendered lubricious by coating them with a layer of silicone, glycerine or olive oil. Such coatings are not necessarily satisfactory in all cases because they tend to run off and lose the initial lubricity rather rapidly and they can also lack abrasion resistance. Hydrophilic coatings have also been disclosed such as polyvinyl pyrrolidone with polyurethane interpolymers or hydrophilic polymer blends of thermoplastic polyurethane and polyvinyl pyrrolidone.

SUMMARY OF THE INVENTION

Accordingly, the present invention provides a biocompatible surface for a device which can impede blocking or sticking of two polymer surfaces when the surfaces are placed in tight intimate contact with each other such as is the case when the balloon is wrapped for storage or when a surface of one device will contact a surface of another device. Especially, the present invention can be applied to balloon angioplasty catheters and other polymeric devices used for insertion into the body of a mammal which have to be folded and provide contact between the surfaces.

According to one aspect of the present invention, we utilize a continuous polymeric surface that is expandable from a folded, wrapped configuration with the surfaces touching each other into a balloon when inflated. While such polymeric surfaces provide excellent balloon stock they are not necessarily sufficiently lubricious to be used by themselves because the material can be somewhat lacking in lubriciousness. As is conventional, lubricious, biocompatible, hydrophilic coatings called hydrogels are disposed on the polymeric surface. After sterilization or storage, such coatings can become delaminated from the polymeric surface upon expansion of the balloon because they stick to each other, that is they cross polymerize or bridge. The bridging, in some cases, can be so severe that the polymeric surface itself can be ruptured upon inflation.

According to another aspect of the present invention, we utilize other medical devices suitable for insertion into the body of a mammal, e.g., catheters and guidewires. Often, such medical devices are coated with hydrogels in a bundled state and may also be stored or packaged in a bundled state. As a result, hydrogel surfaces from adjacent devices can contact each other and bridge. Thus, the present invention is also directed to inhibiting a first polymeric surface and a second polymeric surface from adhering to each other by applying the anti-blocking agents of the present invention to the surfaces. Typically, the first polymeric surface and the second polymeric surface are comprised of the same material, e.g., a polyolefin. Preferably, both the first polymeric surface and the second polymeric surface comprise a first coating, e.g., a lubricious biocompatible, hydrophilic polymer, disposed thereon and a second coating comprising the anti-blocking agents of the present invention.

According to the invention we provide a thin, lubricious, biocompatible, blood-compatible coating or complex upon the hydrogel coating as an anti-blocking agent. The coating prevents abutting surfaces from adhering to each other, e.g., during inflation of a balloon, and prevents delamination of the hydrophilic coating from the polymeric surface. In particular, we have found that certain polyalkylene glycols and alkoxypolyethylene glycols can provide a thin, lubricious, biocompatible coating that is necessary to prevent the bridging of such surfaces. The polyalkylene glycols and alkoxypolyethylene glycols suitable for use in accordance with the present invention have a molecular weight of about 100 to 30,000 grams per gram mole, preferably from about 100 to 20,000 grams per gram mole and more preferably from about 500 to 10,000 grams per gram mole. At molecular weights greater than about 500 grams per gram mole, the glycols have a desirable waxy consistency. As used herein, the term "molecular weight" means number average molecular weight. Methods for determining number average molecular weight are known to those skilled in the art.

Preferably, the polyalkylene glycols and alkoxy polyalkylene glycols are water soluble. As used herein, the term "water soluble" means that at least 1 weight percent of the polyglycol is soluble in water.

Preferably, the alkylene portion of the polyglycol comprises from about 2 to 4 and more preferably from about 2 to 3 carbon atoms per repeat unit. Preferably, the alkoxy portion of the polyglycol comprises alkyl groups having from 1 to 6 carbon atoms per molecule. The polyglycols can be homopolymers, e.g., polyethylene glycol, or copolymers, e.g., a copolymer of ethylene glycol and propylene glycol. Preferred polyalkylene glycols and alkoxypolyethylene glycols have the formula:

$$R_1O(CH_2-CH_2-O)_x(\underset{\displaystyle CH_3}{\underset{|}{CH}}-CH_2-O)_yR_2$$

wherein:

(a) R1 and R2 can be the same or different and can be H or an alkyl group having 1 to about 6 carbon atoms;

(b) x is from 2 to about 500; and

(c) y is from 0 to about 100.

The polyalkylene glycols and alkoxy polyalkylene glycols may also contain functional groups such as, for example, hydroxyl, sulfur, nitrogen or oxygen. Polyethylene glycol and methoxy polyethylene glycol are particularly preferred for use in accordance with the present invention. Preferably, the coating has a thickness effective to inhibit the surfaces from adhering to each other. The coating typically has a