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Oil coated sutures

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(56) Related Art

US 5584857

US 4027676

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/09495

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC(7) : A61B 17/04
US CL : 606/228
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)
U.S. : 606/228,135-158,229-233,222-227

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 practicable, search terms used)
Please See Continuation Sheet

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 4,027,676 A (MATTEI) 07 June 1977, see entire document. | 1,4,7,8 |
| --- | | --- |
| Y | | 2,3,5,6,9-11 |
| Y | US 5,405,358 A (LIU et al.) 11 April 1995, see entire document. | 9-11 |

☐ Further documents are listed in the continuation of Box C. ☐ 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 application or patent 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

"&" document member of the same patent family

Date of the actual completion of the international search
06 September 2004 (06.09.2004)

Date of mailing of the international search report
24 SEP 2004

Name and mailing address of the ISA/US
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**Continuation of B. FIELDS SEARCHED Item 3:**
**EAST**
suture, ligature, coat$, oil, castor, mineral, solvent, carrier, fray, resist$

2007202724 13 Jun 2007

S&F Ref: 650574D1

AUSTRALIA

PATENTS ACT 1990

**COMPLETE SPECIFICATION**

FOR A STANDARD PATENT

| | |
|---|---|
| Name and Address of Applicant : | Tyco Healthcare Group LP, of 150 Glover Avenue, Norwalk, Connecticut, 06856, United States of America |
| Actual Inventor(s): | John Kennedy<br>Mark Roby<br>Richard Stevenson |
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| Invention Title: | Oil coated sutures |

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

5845c(826455_1)

2007202724 13 Jun 2007

# OIL COATED SUTURES

## BACKGROUND

1. Technical Field

The present invention relates generally to coatings for filaments. More particularly, the present invention relates to oil coatings for filaments or sutures.

2. Background of Related Art

Many synthetic materials are presently used as surgical sutures. These materials may be used as single filament strands, i.e., monofilament sutures, or as multifilament strands in a braided, twisted or other multifilament construction. Synthetic sutures have been made from materials such as polypropylene, nylon, polyamide, polyethylene, polyesters such as polyethylene terephthalate, and segmented polyether-ester block copolymers. In addition, absorbable synthetic sutures have been prepared from synthetic polymers such as polymers containing glycolide, lactide, dioxanone and/or trimethylene carbonate. Natural materials have also been used to make sutures. For example, silk has been used to make non-absorbable sutures. As another example, catgut sutures are absorbable sutures made from a natural material.

Sutures intended for the repair of body tissues must meet certain requirements: they must be non-toxic, capable of being readily sterilized, they must have good tensile strength and have acceptable knot-tying and knot characteristics. The sutures should also be sufficiently durable from the point of view of fray resistance.

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## SUMMARY

It has now been found that a suture formed from one or more filaments and coated with an oil, such as for example, mineral oil or castor oil, exhibits good durability as reflected by fray resistance. In another aspect, the present invention embraces a method for improving the handling characteristics of a suture by applying to the suture a coating comprising an oil. Preferred coating comprise castor oil or mineral oil.

In a further aspect of the present invention there is provided a suture comprising:

a filament made from a synthetic, non-absorbable polymer composition; and a liquid coating comprising a fray-reducing amount of an oil selected from the group consisting of castor oil and mineral oil,

wherein the coating remains a liquid after application to the suture.

In a further aspect of the present invention there is provided a suture comprising:

a filament made from a composition comprising polypropylene and polyethylene glycol distearate; and

a liquid coating, the coating comprising a fray-reducing amount of castor oil in a solvent,

wherein the coating remains a liquid after application to the suture.

In a further aspect of the present invention there is provided a method of improving the fray resistance of a suture made from a polypropylene-containing composition, the method comprising:

applying a liquid coating to the suture, the coating comprising a fray-reducing amount of castor oil ,

wherein the coating remains a liquid after application to the suture.

In a further aspect of the present invention there is provided a method of making a suture comprising:

providing a composition comprising polypropylene;

melt spinning the composition to form a filament;

stretching the filament;

applying a liquid coating to the filament, the coating comprising a fray-reducing amount of castor oil, wherein the coating remains a liquid after application to the suture; and

annealing the coated filament.

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**DESCRIPTION OF PREFERRED EMBODIMENTS**

Sutures in accordance with the present invention are prepared by applying a coating to one or more filaments. Preferably, the suture is made from a synthetic material. Suitable synthetic materials include, but are not limited to polypropylene, nylon, polyamide, polyethylene, polyesters such as polyethylene terephthalate, segmented polyether-ester block copolymers and polyurethanes. When more than one filament is used, the filaments may be braided, twisted, entangled, intertwined or arranged in some other multifilament configuration. A particularly useful braid structure for sutures is the sparoid braid structure described in U.S. Pat. Nos. 5,019,093 and 5,059,213 and the disclosures of which are incorporated herein by reference.

The coating applied to the monofilament or multifilament structure comprises an oil. Suitable oils include but are not limited to, mineral oil and castor oil.

Castor oil, the fixed oil obtained from the seed of *Ricinus communis*, is a well known and widely available material. Castor oil is a non-drying oil whose chief constituent is ricinolein, a glyceride of ricinoleic acid. It is a transparent, viscous liquid having a specific gravity in the range of 0.945 to 0.965, and iodine value between 83

and 88 and a saponification value between 176 and 182. While castor oil containing no added substances is preferred for use herein, other castor oil products, such as, for example, acetylated castor oil, dehydrated castor oil, hydrogenated castor oil and sulfonated castor oil, can also be used.

Mineral oil is also a well known and widely available material. Mineral oil is a mixture of liquid hydrocarbons obtained form petroleum. Frequently, a stabilizer is added. Mineral oil generally has a specific viscosity between 0.845 and 0.905 and a kinematic viscosity of about 33 to 35 centistokes at 40°.

The oil coating is applied to the monofilament or multifilament in an amount of between about 0.01 to 20 percent by weight based upon the weight of the filament or filaments to which the coating is applied. Preferably, the coating is applied in an amount of from about 0.1 to 10 weight percent. Most preferably, the amount of coating is between about 0.5 and 5 weight percent. The amount of coating applied to the suture may be adequate to coat all surfaces of the suture. Preferably, the amount of coating applied will be that amount sufficient to improve the handling characteristics of the suture, regardless of whether the entire surface of the suture is coated. The term coating as used herein is intended to embrace both full and partial coatings.

The oil coating may be applied by any conventional method. The coating composition may be applied to sutures by dipping the suture in a reservoir of coating composition, moving sutures past a brush or applicator wetted with the composition, or by spraying the composition onto sutures. The amount of coating composition may be varied depending on the construction of the sutures, e.g., the number of filaments and tightness of braid or twist. A less viscous composition will penetrate further into the

suture than a more viscous composition. In addition, viscosity of the composition can be adjusted depending on the method of application. For example, a suitable solvent such as, for example, isopropanol can be used to adjust the viscosity of the oil composition prior to application.

The coatings may optionally contain other materials including colorants, such as pigments or dyes, fillers of therapeutic agents, such as antibiotics, growth factors, etc. Depending on the amount of coating present, these optionally ingredients may constitute up to about 25 percent by weight of the coating.

The following examples should be considered as illustrative and not as limitations of the present description. The examples show illustrative formulations and the superiority of the present coating composition in enhancing properties of sutures.

EXAMPLES 1-6

Size 5/0 polypropylene sutures prepared in accordance with the procedures described in the Examples of commonly owned provisional application entitled POLYOLEFIN SUTURES HAVING IMPROVED PROCESSING AND HANDLING CHARACTERISTICS, Serial No. 60/278,686, filed March 26, 2001 and published as International Publication No. WO 02/076521. The polypropylene from which the sutures were prepared contained 0.3% by weight PEG distearate. Coating compositions containing various amounts of castor oil in isopropanol solvent were prepared as shown in Table 1, below. The coating was applied using a spin finish applicator. The castor oil coating was applied after stretching but before annealing. The isopropanol evaporated during annealing.

Table 1

| Example # | % Castor oil |
|---|---|
| 1 | 20 |
| 2 | 10 |
| 3 | 5 |
| 4 | 2.5 |
| 5 | 1.25 |
| 6 | 0.625 |

The sutures coated with solutions containing at least 2.5% castor oil were found to exhibit improved fray resistance compared to polypropylene/PEG distearate sutures prepared under identical conditions but without application of the castor oil containing compositions. The sutures coated with composition containing castor oil also possessed a lower coefficient of friction, generally below about 0.2, compared to polypropylene/PEG distearate sutures prepared under identical conditions but without application of the castor oil containing compositions.

It will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications within the scope and spirit of the claims appended hereto.

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**The claims defining the invention are as follows:**

1. A suture comprising:

a filament made from a synthetic, non-absorbable polymer composition; and a liquid coating comprising a fray-reducing amount of an oil selected from the group consisting of castor oil and mineral oil,

wherein the coating remains a liquid after application to the suture.

2. A suture as in claim 1, wherein the synthetic, non-absorbable polymer composition comprises a polypropylene.

3. A suture as in claim 1, wherein the synthetic, non-absorbable polymer composition comprises polypropylene and a fatty acid diester.

4. A suture as in claim 1, 2 or 3, wherein the coating comprises caster oil.

5. A suture comprising:

a filament made from a composition comprising polypropylene and polyethylene glycol distearate; and

a liquid coating, the coating comprising a fray-reducing amount of castor oil in a solvent,

wherein the coating remains a liquid after application to the suture.

6. A suture as in claim 5, wherein the solvent is isopropanol.

7. A method of improving the fray resistance of a suture made from a polypropylene-containing composition, the method comprising:

applying a liquid coating to the suture, the coating comprising a fray-reducing amount of castor oil,

wherein the coating remains a liquid after application to the suture.

8. A method in accordance with claim 7, wherein the step of applying a coating comprising applying a coating comprising castor oil in a solvent.

9. A method of making a suture comprising:

providing a composition comprising polypropylene;

melt spinning the composition to form a filament;

stretching the filament;

applying a liquid coating to the filament, the coating comprising a fray-reducing amount of castor oil, wherein the coating remains a liquid after application to the suture; and

annealing the coated filament.

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10. A method as in claim 9, wherein the step of providing a composition containing polypropylene comprises providing a composition containing polypropylene and polyethylene glycol distearate.

11. A method as in claim 9 or 10, wherein the step of applying a coating to the filament comprises applying a coating comprising castor oil in a solvent.

12. A suture substantially as hereinbefore described with reference to any one of the examples.

13. A method for making a suture comprising the steps substantially as hereinbefore described with reference to any one of the examples.

14. A suture made by the method of any one of claims 7 to 11 or 13.

15. The suture of claim 5 or 6, wherein the coating remains a liquid at all times after application to the suture.

16. The method of any one of claims 7 to 11, wherein the coating remains a liquid at all times after application to the suture.

**Dated 11 March, 2009**
**Tyco Healthcare Group LP**

**Patent Attorneys for the Applicant/Nominated Person**
**SPRUSON & FERGUSON**

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