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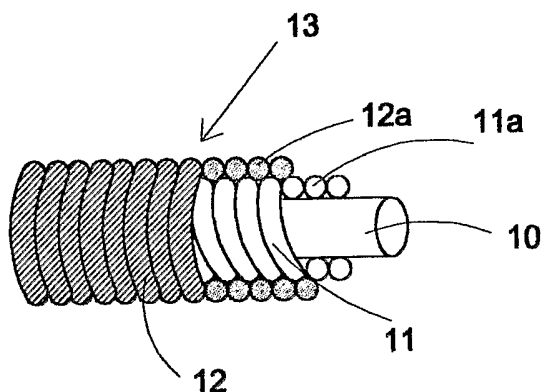
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ance Notes on Codes and Abbreviations" appearing at the begin-
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(54) Title: SHEATHED ELASTIC SURGICAL THREAD



(57) Abstract: Surgical thread (13), that has an elastic core (10) and a non-elastic sheathing, in which the elastic core (10) consists of one or more bio-compatible elastic threads, and the sheathing consists of one or more non-stretch threads (11, 12) made of bio-compatible material. The non-stretch threads of the sheathing may be absorbable or non-absorbable. Chemical substances and/or medications can be incorporated into the sheath. Different attachments between suture and needle are also covered.



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“SHEATHED ELASTIC SURGICAL THREAD”**DESCRIPTION**

The present invention concerns a sheathed elastic thread for use in surgery, In accordance with the usual techniques, non-stretch threads are normally used in surgery, and threads that stretch by only a few millimetres when subjected to traction are considered to be elastic. Such threads are supplied in bobbins, and are subsequently cut, sterilised and mounted manually on surgical needles equipped, at the non-pointed end, with an open eye, to which the thread is secured, or are utilised in various ways for different surgical purposes.

In the most commonly used technique, the thread is fixed industrially to an atraumatic surgical needle. The atraumatic surgical needle is a needle without an eye, which, when fixed to a thread, forms a single unit with no appreciable variation in diameter. The fact that the needle has no eye means that the needle and thread cause only minimal damage on passing through the tissues. In traditional atraumatic surgical needles, the thread is fixed into a hole or groove situated at the non-pointed end of the needle. In the two-tipped atraumatic needle described in patent application N. GE 2002 A 00056 in the name of the same inventor, the thread is inserted into the needle and fixed inside it.

There exists a type of elastic thread for surgical suturing that is able to stretch by 50% to 100% or more of its original length and then to return immediately to its original length once traction ceases.

Described in patent N. EP0792622, this suturing thread is made of silicone elastomer. It is used for cutaneous expansion, before or after large excisions, and for suturing wounds prone to diastasis. The silicone elastomer thread described in patent N. EP0792622 has the following disadvantages.

One disadvantage of the silicone elastomer thread is that sometimes a fine elastic thread of 0.01- 1 mm in diameter is required, for instance to lift facial tissues or to suture the skin. However, such fine threads can easily be cut

during handling with surgical instruments and may snap when pulled through the tissues by the surgeon. Indeed, if a fine silicone elastomer thread is attached by the usual technique to a surgical needle with an open eye, it is very likely to be severed.

- 5 Another disadvantage of the silicone elastomer thread, even if its diameter is greater than 1 mm, is that the silicone surface is very slippery, which makes it difficult to exert proper traction during handling with surgical gloves.

The slippery surface of the silicone elastomer thread gives rise to a further disadvantage. If used as a permanent implant for tissue lifting, according to
10 the usual technique, when placed under elastic tension it exerts pressure exclusively on the loops at the two extremities, as the rest of the thread offers no resistance to traction. This feature of the silicone elastomer thread leads to an uneven distribution of the thread's resistance in the tissues and consequently to the risk of cutting through the tissues (cheese-wire effect). If
15 the silicone elastomer thread were to be woven, for instance in order to repair a breach in the abdominal wall, the above disadvantage would remain. Moreover, since silicone rubber cannot be colonised by the tissues, but only encapsulated, the thread would not provide the adhesion necessary for a secure plastic repair.

20 In accordance with the most commonly adopted technique, normal surgical threads inserted into a hole or groove in the rear end of the traditional single-tipped atraumatic needle are held in place by pinching. However, an elastomer thread, on account of its intrinsic elasticity and its poor resistance to compression, cannot guarantee sufficient resistance to traction when secured
25 by pinching. Moreover, even when glued to the needle, the elastomer thread cannot guarantee resistance to traction on account of the characteristics of this material.

Patent EP0960600 describes a particular patented method of fixing a silicone elastomer thread to a surgical needle. This method, however, presents the
30 following disadvantages.

The method exploits the capacity of the extremity of the silicone elastomer thread, following polymerisation, to adhere around a length of traditional non-stretch suturing thread. In the said patent, the traditional suturing thread is fixed to the atraumatic surgical needle according to the usual techniques.

5 In order to form a secure bond between the two merged threads, the patented method involves marked polymerisation of the silicone rubber. This has the disadvantage of stiffening the initial length of thread, precisely in its most critical zone, where the thread needs to be flexible when drawn through the tissues. Furthermore, this joint is not as secure as a normal industrial
10 attachment of a thread to an atraumatic surgical needle.

Another disadvantage of this method of attachment is that the silicone elastomer thread, at the point where it is fixed to the non-stretch thread connected to the needle, has a larger diameter than the needle itself. This makes it difficult for the needle/thread junction to pass through the tissues and
15 may cause the thread to detach from the needle; alternatively, the two-tipped atraumatic needle may jerk completely out through the skin, owing to the force that the surgeon has to exert in order to overcome the resistance of the needle/thread junction.

Similar problems of inconsistency in size and poor flexibility are encountered
20 in the other solutions proposed in the same patent EP0960600.

The aim of the present invention is to create an elastic thread that is flexible, resistant to traction and non-slippery. This thread must display good adhesion to the tissues when used as an implant and be able to be attached to open-eye surgical needles without the risk of snapping. In addition, it must be
25 directly attachable to traditional atraumatic surgical needles, without requiring further polymerisation or causing noticeable variations in diameter. The said thread must be able to be woven easily in order to create the implants necessary in various surgical applications. To be used in surgery, the thread described in the present patent must be bio-compatible and cause as little
30 inflammatory reaction as possible if left permanently in the tissues. To this

end, a thread has been created that consists of an elastic core and a non-elastic sheath. The core consists of one or more bio-compatible elastic threads, and the sheath of one or more bio-compatible non-stretch threads.

5 The non-stretch sheathing threads may or may not be absorbable by the organism.

Preferably, the non-stretch sheathing threads are wound in a spiral fashion, with the windings and/or other modalities set in such a way as to limit the maximum extension of the elastic thread to a precise value suited to the specific application.

10 The sheathed elastic thread is capable of stretching by up to 100% of its length or more and returning immediately to its original length; once the maximum extension of the sheath has been reached, the thread can be stretched no further. This thread withstands far greater traction than the same elastic thread without a sheath.

15 Several advantages are gained by sheathing a bio-compatible elastic thread with one or more non-stretch threads.

Firstly, the elastic thread cannot be stretched beyond its breaking point.

Secondly, the elastic thread is protected against cutting by the sharp edges of the surgical instruments with which it is handled.

20 Thirdly, the outer sheathing enables the thread to be gripped more easily in the hand.

Fourthly, the sheathing allows the thread to be knotted more securely.

A further advantage of the sheathed elastic thread is that it can be woven more easily than a silicone elastomer thread with a slippery surface.

25 Yet another advantage of the present invention is that, when a permanent implant is inserted into the tissues, the outer sheathing of the elastic thread, as created in the present invention, is colonised by the histiocytic-fibroblastic cells, which bind the thread to the tissues through which it passes; this enables the tension of the sheathed elastic thread to be distributed along its
30 entire surface. If colonisation of the sheathing is not required, such as, for

example, in the case of skin sutures that are to be removed within a few days, the surface of the sheathed elastic thread will have to be treated with special non-stick substances in accordance with standard techniques.

A further advantage of the present invention is that the sheathing of the elastic thread enables the thread to be mounted on an open-eye surgical needle
5 without the risk of cutting the elastic core.

Moreover, the thread described in the present invention can be attached directly to a single-tipped atraumatic surgical needle. Indeed, the sheathing thread or threads can be pinched in the hole or groove at the rear end of the
10 needle, thereby providing an adequate bond that will withstand traction. Even if the end of the thread is glued to the needle, the sheathing provides secure adhesion. When the sheathed thread is inserted into a two-tipped atraumatic needle, the risk of the thread being cut by the edges of the hole during surgical manoeuvres is considerably reduced.

15 The elastic core and the sheathing thread or threads can be made of natural and/or synthetic fibres. For example, the said elastic thread may be made of methylvinyl-polysiloxane silicone rubber or other bio-compatible elastic materials, such as purified natural rubber, 1,4 cis-polyisoprene, acrylonitrile butadiene copolymer, isoprene cisobutylene, conjugated ethylene-
20 propylene/diene terpolymer or derivatives.

The non-stretch absorbable sheathing threads may, for example, be made of collagen, polyglactin 910, polydioxanone, polyglycolic acid, polyglecaprone, polyglyconate or derivatives.

Among the materials used for the non-stretch non-absorbable sheathing
25 threads, we may quote, by way of example, PTFE, polypropylene, polyurethane, polyether, polyurethane-polyether, PVDF (polyvinylidene fluoride), polyamide and derivatives, or silk and other natural fibres.

The type and windings of the non-stretch sheathing threads vary according to whether the thread is destined for use as an implant or as an elastic suture.

30 Chemical substances and/or medications can also be incorporated into the

sheathing.

The sheathing of the thread described in the present invention can be produced according to the techniques used in the textile industry in accordance with specifications and utilising materials suited to surgical
5 applications.

The applications of the sheathed elastic thread, as described in the present invention, can be extended to permanent implants to lift the tissues and to the permanent suturing of cutaneous and subcutaneous tissues. If the sheathed elastic thread is woven, it can be used in the plastic repair of hernias,
10 breaches in the abdominal wall, etc.

The sheathed elastic thread, as described in the present invention, can usefully substitute traditional non-stretch stitching materials in surgical operations. The advantage that the sheathed elastic thread described in the present invention has over traditional non-stretch threads, when used for
15 suturing, is that it adapts to the swelling of the tissues, thereby maintaining firm adhesion of the tissues, and is easier to remove. When used as a permanent implant in the tissues, the sheathed elastic thread proves useful for suturing the derma or the subcutaneous or vascular tissue and for lifting facial tissues, as it counteracts drooping. In this application, it is superior to non-
20 stretch threads in that it does not hinder the movements of the facial muscles; it neither cuts into the tissues nor forces the features to remain unnaturally static. When woven, for example into a web, the sheathed elastic thread has the advantage of creating a bio-compatible elastic surface that can be colonised by the tissues; it is therefore stable, well integrated and spreads
25 tension over its entire surface. A web of sheathed elastic thread offers a more physiological plastic repair of hernias, for instance. Indeed, owing to its elastic and adhesive properties, it is better than webs woven from non-stretch threads at adapting to sudden increases in endoabdominal pressure, which may cause a recurrence of the hernia.

30 All of the above-mentioned advantages, and many others, will be seen from

the description of the following figures, which are attached by way of illustration and are not regarded as limiting.

Fig. 1 depicts a sheathed elastic thread as described in the present invention;

Fig. 2 depicts a sheathed elastic thread with a reduced diameter at one end;

5 Fig. 3 shows a sheathed elastic thread inserted into the hole or groove of a single-tipped atraumatic needle;

Fig. 4 shows a sheathed elastic thread inserted into a two-tipped atraumatic needle;

Fig. 5 shows a sheathed elastic thread woven into a web;

10 In the various figures, the same elements are indicated by the same numbers. In Figure 1, a sheathed elastic thread (13) as described in the present invention is illustrated by way of example.

The core (10) of the thread is made of bio-compatible elastic material capable of stretching by up to 100% of its length or more and of returning immediately
15 to its original length.

The elastic core (10) is sheathed by a non-stretch thread (11) wound in a spiral fashion, for example anti-clockwise, the windings of which, seen in section, are indicated (11a).

The spiral of the non-stretch thread (11) is covered by a second outer thread
20 (12) wound in a spiral in the opposite direction, for example clockwise, the windings of which, seen in section, are indicated (12a).

In order to facilitate insertion of the thread (13) into a needle (14), the diameter of one end of the thread (13) is reduced by stretching this portion of the thread to its maximum. The thinned end (13') is then fixed by means of a bio-
25 compatible glue, as illustrated in Figure 2. Alternatively, a low-temperature treatment can be used to maintain the thinning of the end (13') of the thread.

In Figure 2, a normal atraumatic suturing needle (14) with an axial hole (16) at the non-pointed end is seen in front of the thread (13).

In Figure 3, the sheathed elastic thread (13) is shown with the thinned end
30 (13') inserted into the hole (16) of the needle (14). The thread (13) can be

attached to the needle (14) in the usual ways, by compressing the non-stretch threads (11 and 12) of the sheathing, comprising or not comprising the elastic core (10).

Another recommended method of attaching the thread (13) to the needle (14) is to use bio-compatible glue.

The end of the thread (13) that is not attached to the needle (14) can also be treated with a glue that has suitable characteristics of bio-compatibility and resistance to sterilisation, in order to prevent the sheathing from fraying.

Obviously, production of the materials used in the sheathed elastic thread (13) and attachment of the thread to the needle (14) must take place in a controlled environment and in conformity with current regulations.

Figure 4 shows the sheathed elastic thread (13) with its thinned end (13') inserted into the hole (17) of a two-tipped atraumatic needle (15) by means of the modalities described in the above-mentioned patent application N. GE 2002 A 00056.

Figure 5 depicts a sheathed elastic thread woven into a web.

Traction with forceps (19) illustrates the elasticity and pliability of the web (18), owing to the elastic features of the sheathed thread as described in the present invention.

The present invention comprises all those variations in detail and all modifications that may prove obvious to a technician in this field, and which do not lie outside the ambit of the present invention, but which are understood to be included within the area of the following claims.

C L A I M S

1. Surgical thread (13), characterised by the fact that it has an elastic core (10) and a non-elastic sheathing, in which the elastic core (10) consists of one or more bio-compatible elastic threads, and the sheathing consists of one or
5 more non-stretch threads (11, 12) made of bio-compatible material.

2. Surgical thread (13), according to claim 1, in which the non-stretch sheathing thread (11) is wound in a spiral fashion, with the windings and/or other modalities set in such a way as to limit the maximum extension of the elastic thread to a precise value suited to the specific application.

10 3. Surgical thread (13), according to claim 1, characterised by the fact that the non-stretch sheathing threads (11, 12) are wound in overlying spirals in opposite directions.

4. Surgical thread (13), according to claim 1, in which the elastic core (10) and the sheathing thread or threads are made of natural and/or synthetic
15 materials.

5. Surgical thread (13), according to claim 1, characterised by the fact that it has an elastic core (10) made of methylvinyl-polysiloxane silicone rubber or other bio-compatible elastic materials, such as purified natural rubber, 1,4 cis-polyisoprene, acrylonitrile butadiene copolymer, isoprene cisobutylene,
20 conjugated ethylene-propylene/diene terpolymer.

6. Surgical thread (13), according to claim 1, characterised by the fact that the non-stretch sheathing thread or threads (11, 12) are made of absorbable material.

7. Surgical thread (13), according to claim 1, characterised by the fact that
25 the non-stretch sheathing thread or threads (11, 12) are made of non-absorbable material.

8. Surgical thread (13), according to claims 1 and 4, characterised by the fact that the absorbable material used in the non-stretch sheathing thread or threads (11, 12) is constituted by collagen or polyglactin 910, polydioxanone,
30 polyglycolic acid, polyglecaprone, polyglyconate or derivatives.

9. Surgical thread (13), according to claims 1 and 5, characterised by the fact that the non-absorbable material used in the non-stretch sheathing thread or threads (11, 12) is constituted by PTFE or polypropylene, polyurethane, polyether, polyurethane-polyether, PVDF (polyvinylidene fluoride), polyamide
5 or derivatives of these, or by silk or other natural fibres.

10. Surgical thread (13), according to claim 1, characterised by the fact that chemical substances and/or medications can be incorporated into the non-stretch sheathing threads (11, 12).

11. Surgical thread (13), according to claim 1, in which the sheathing can
10 be colonised by living tissues.

12. Surgical thread (13), according to claim 1, in which the sheathing can be rendered impervious to colonisation by living tissues by treating with special non-stick substances.

13. Surgical thread (13), according to claim 1, characterised by the fact that
15 sheathing (11, 12) of the elastic core (10) is performed according to standard techniques used in the textile industry with specifications and materials that are suited to surgical applications.

14. Surgical thread (13), according to claim 1, characterised by the fact that
20 the extremity of the thread (13) to be attached to the needle (14, 15) is thinned (13') by applying maximum tension, and that this thinned end (13') is fixed in place by means of bio-compatible glue.

15. Surgical thread (13), according to claim 1, characterised by the fact that
25 the extremity of the thread (13) to be attached to the needle (14, 15) is thinned by applying maximum tension, and that the thinning of the end (13') is maintained by means of low-temperature treatment.

16. Surgical thread (13), according to claims 1 and 12 or 13, characterised by the fact that the thinned end (13') is inserted into the hole (16) of an atraumatic surgical needle (14).

17. Surgical thread (13), according to claim 1, characterised by the fact that
30 the thread (13) is fixed to the needle (14, 15) by means of bio-compatible

glues.

18. Surgical thread (13), according to claim 1, characterised by the fact that the thread (13) is attached to the needle (14) by compressing the non-stretch sheathing thread or threads (11, 12), comprising or not comprising the elastic core (10).

19. Surgical thread (13), according to claim 1, characterised by the fact that the extremity of the thread (13) that is not attached to the needle (14, 15) is treated with a glue that has suitable characteristics of bio-compatibility and resistance to sterilisation.

20. Surgical thread (13), according to claim 1, characterised by the fact that the thread (13) is thinned at one end (13') for insertion into the hole (17) of a two-tipped atraumatic needle (15).

21. Surgical thread (13), according to claim 1, which is woven in order to create an elastic surface for implantation.

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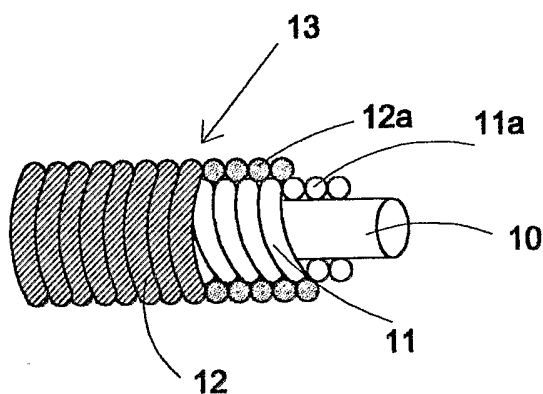


FIG. 1

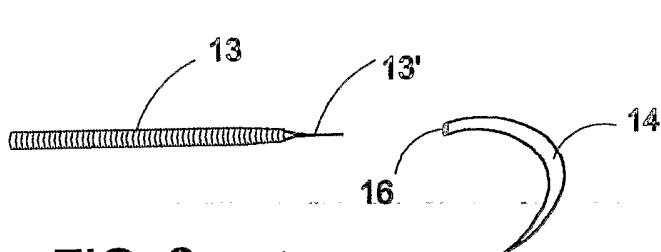


FIG. 2

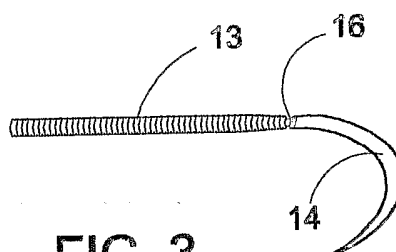


FIG. 3

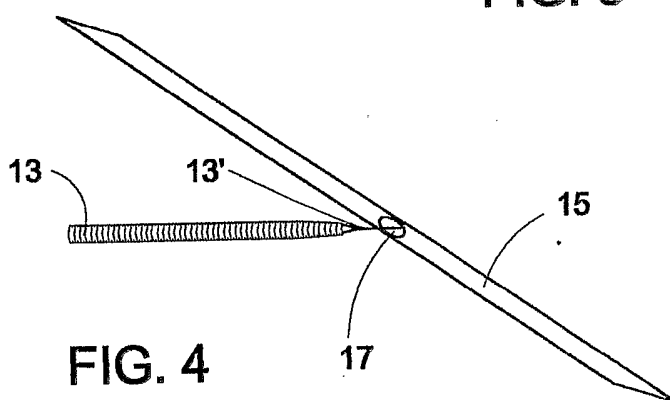


FIG. 4

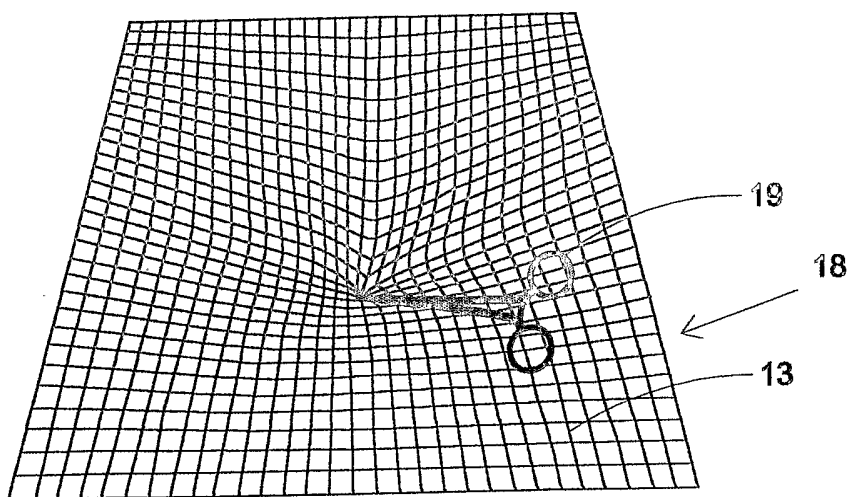


FIG. 5

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B17/06 A61L17/06 D02G3/32

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)
 IPC 7 A61B A61L D02G

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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

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International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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