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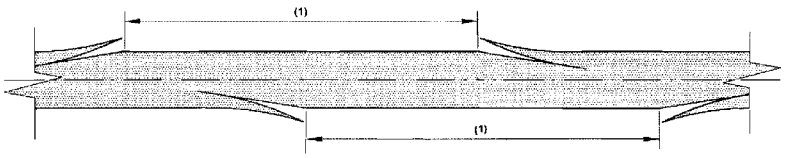

FIG. 5

(57) Abstract: A suturing thread (F) has a structure that differs from that of known suturing threads in so far as it is bi-directional in the sense that it can be introduced into tissues in one direction or the other, is free to fluctuate (i.e. it is without anchorage points) and is provided with sequences of inclined protuberances or spines (S) that have the peculiarity of being alternately divergent, the spines of one sequence being oriented in directions opposite to those of the adjacent sequences. Said spines are present throughout the length of the thread but absent at the midpoint of the suture and at the end areas of the thread itself. In a first embodiment, the arrangement of the spines along the thread is such that the spines of one sequence are on the side of the thread diametrally opposite to where the spines of the adjacent sequences are arranged; i.e., they are set at an angular distance of 180° with respect to the spines of the other adjacent sequences.

WO 2014/170921 A1

THREAD FOR PLASTIC, DERMATOLOGIC OR COSMETIC SURGERY, IN PARTICULAR FOR USE AS A SUTURE FOR INCREASING THE VOLUME OF LIPS

DESCRIPTION

The present invention relates to the medical sector and in particular to that of spined surgical threads, i.e., ones provided with inclined protuberances or hooks or protrusions of any shape, to be used for plastic-surgery, dermatological, aesthetic, general-surgery, and emergency-surgery operations, and in all specialist forms of surgery.

More in particular, the spined suturing thread forming the subject of the present invention has an innovative structure that enables it to be used in all specialist forms of surgery on the tissues of the upper and lower lips and in the anatomical area surrounding the aperture of the mouth in so far as it guarantees an optimal suspension and relaxation of the soft tissues in particular of the buccal and peribuccal region.

Forming the subject of the invention is also the method for using the aforesaid suturing thread in the buccal and peribuccal region in order to improve the aesthetic and volumetric effects of surgical treatment of the mouth in those patients who are affected by hypovolumetry or asymmetry of the lips, including dermatochalasis of the corners of the mouth.

PRIOR ART

Surgical threads provided with spines or protrusions with characteristic arrangements and shapes have been amply described for some time now (Alcamo,

Patent No. USA 3,123,077, Fukuda, Patent No. USA 4,4467,805, Ruff, Patent No. USA 5,342,376).

Disclosed by the present inventor is the surgical thread described in the patent application No. RM2004A000599, where the spines or protuberances are distributed in a helix and arranged in sequences alternately inclined in opposite directions so as to hinder sliding or displacement of the thread in the two opposite directions.

It is known that sliding or translation according to the major axis of the thread is produced by tensile forces exerted on both of the ends of the thread. Said tensile forces arise owing to the dynamic actions due to the activity of the voluntary or involuntary muscles, for example, during facial mimics, the action of chewing, etc.

Following upon the evolution and refinement of techniques of plastic and aesthetic surgery, there has, however, arisen the need to provide a spined thread that is able not only to hinder sliding or translation according to the major axis of the thread, but can also be used as suturing thread for a marginal increase in volume both of the upper lip and of the lower lip as likewise for lifting the buccal commissure, guaranteeing over time a sustained action of repositioning of the soft tissues in their proper anatomical position, creating and restoring a proper three-dimensional volumetric contour.

BRIEF SUMMARY OF THE INVENTION

The task of the present invention is to meet the

above need by providing a suturing thread according to Claim 1.

The innovative characteristic of the present invention lies in a particular arrangement and orientation of the spines, which, unlike what is known so far, enable, in combination, a suturing thread to be provided that is particularly indicated in the anatomical-cutaneous area of the mouth and its marginal areas in order to increase the lips for relaxing smoker's wrinkles, for remodelling the lips, and for raising the corner of the mouth.

According to the invention, said thread has a structure that differs from the known suturing threads in so far as:

it is bi-directional in the sense that it can be introduced into tissues in one direction or in the other,

it is free to fluctuate (i.e., without anchorage points upstream or downstream or craniodistally or in the mediolateral direction of the human body), and

it is provided with sequences of inclined protuberances or spines that have the peculiarity of being alternately divergent, the spines of one sequence being oriented in directions opposite to those of the adjacent sequences,

said spines being present throughout the length of the thread but absent at the midpoint of the suture and at the end areas of the thread itself.

Furthermore, in a first embodiment the arrangement of the spines along the thread is such that the spines of one sequence are on the side of the thread

diametrally opposite to the side where the spines of the adjacent sequences are arranged, i.e., set at an angular distance of 180° with respect to the spines of the other adjacent sequences.

In particular, in this first embodiment, the arrangement of the spines of each sequence on the thread is preferably linear; namely, the spines are arranged along the thread in a line that is diametrally opposite to the one in which the spines of the adjacent sequences are arranged.

In a second embodiment the spines are, instead, distributed on two helices that arise on opposite sides of the thread itself.

Both in the first embodiment and in the second embodiment, the particular arrangement together with the divergence, affords for the spines the capacity not only of hindering sliding or displacement of the thread (along its major axis), in the two opposite directions, when the thread is introduced into the soft human tissues or in the white roll, but also of guaranteeing elongation or lengthening of the soft tissue into which the thread is introduced, for example eliminating the so-called upper-lip "barcode".

Consequently, the presence of such formations on the axis of the thread prevents it from being shifted either to the right or to the left (in the case where we were to imagine exerting tensile stresses on the ends of the thread), once it has been introduced into the soft tissues of the human body whether its ends emerge from the cutaneous surface or whether they are embedded in the hypodermal thickness of the human

cutis, or at the level of the connective bands (superficial muscular aponeurotic system - SMAS), or at a muscular level.

It should be pointed out that the action of opposition to shifting or sliding manifests itself in the tissues, even when the thread is totally embedded, at any level of human soft tissue and in the planes of the aponeurotic bands and in the muscular plane, or at the subperiosteal level, following upon the physiological movements that arise in the soft tissues as a result of muscular movements.

The above characteristics render the suturing thread forming the subject of the invention particularly indicated for insertion in anatomical areas such as the upper and lower lips, the naso-buccal sulcus of the mouth, the marionette lines (the long vertical lines that delimit the chin laterally), the glabellar sulci, etc.

Advantageously, the thread is introduced through a cannula needle in the lip at the hypodermal level.

Thanks to the innovative shape of the suturing thread, the surgical technique for its introduction does not require anchorage points upstream and downstream in the points where it can be introduced (white roll), and enables not only reduction of the duration of the operation as compared to the techniques already mentioned, but also a reduction of the stay of the patient in the health-care facility (which amounts only to half an hour), and reduction of the period of post-operative rehabilitation.

The operating technique consists in carrying out

beforehand topical or truncular anaesthesia on the emergences of the upper and lower canine nerves in the gengivodental arch, and at the side of the frenula of the upper and lower lips, with 2% xylocaine or carbocaine, with addition of 1/100000 diluted adrenaline, infiltrating not more than 0.5 - 0.7 ml for each individual passage of the needle. The guide needle is introduced into the hypodermis following the white roll, i.e., the path marked beforehand on the margin of the mouth, and is made to exit in the commissure of the mouth. The suturing thread, with its divergent spines staggered by 180° is introduced into the core of the guide needle until its distal end projects from the opposite corner of the mouth. Next, after the commissures of the mouth have been held up between the index finger and the thumb of the left hand for right-handed operators, the needle is removed whilst the thread remains *in situ* providing the desired volumetric plasticity to the upper and lower lips. At this point, the ends of the thread must be "pulled", so that each spine finds its engagement, and are then cut and submerged at a hypodermal level. The indications for the operation using this new method are in particular: ptosis of the corners of the mouth, marginal volumetric correction of the upper lip or lower lip, treatment of so-called "smoker's wrinkles" that normally involve the upper lip, etc.

The method just described for re-definition of the mouth and for its marginal increase in volume is a simple, conservative method that reduces the operating times and does not leave or produce visible scars on

the mouth or on its neighbouring areas.

The description of the invention will be better followed with reference to the attached plates of drawings and photographs that illustrate purely by way of non-limiting example some preferred embodiments of the invention. In the plates of drawings:

Figure 1 is a cross-sectional portion of the surgical thread forming the subject of the invention that shows two mutually divergent sequences of spines;

Figure 2 shows in detail the spines of a portion of thread;

Figure 3 shows in detail a first cross-sectional stretch of thread increasing from the midpoint MP towards the end, and a second stretch of thread, where the cross section increases from one end to the other;

Figure 4 is a detail of the thread that enables identification of the different areas occupied by the spines and the free ones and of the repetition unit;

Figure 5 shows in sectioned detail a portion of thread with the spines positioned along two helices;

Figure 6 is a photograph that illustrates the buccal area and the nomenclature used for the various anatomical parts;

Figure 7 is a photograph that shows the sterilization step;

Figure 8 shows the step of drawing of the path that the cannula will follow during its insertion in the white roll of the lips;

Figures 9a, 9b, 9c, and 9d show the steps of subdermal local anaesthesia along the entire white roll of the upper and lower lips and the philtral columns;

Figures 10, 11, 12 and 13 show in succession the steps of insertion of the cannula through the derma starting from a corner of the mouth following the white roll and the cupid's bow in the middle of the lip until it comes out of the opposite corner of the mouth;

Figure 14 illustrates the step of extraction of the mandrel from the cannula;

Figure 15 shows the step of extraction of the cannula after introduction of the suturing thread;

Figure 16 shows the profile of the lips remodelled by the suturing thread, after extraction of the cannula, with the smooth ends of the thread that project from the two sides of the mouth;

Figure 17 shows the step of cutting of one of the ends of the thread at one corner of the mouth;

Figure 18 shows the step of cutting of the other end of thread at the opposite corner of the mouth; and

Figures 19 and 20 compare the lips before and after the operation.

With reference to Figures 1 and 2, a surgical thread F for operations of plastic surgery has a plurality of inclined protuberances or spines S, arranged in sequence throughout the length of the thread, except for short segments of connection between on repetition unit, designated by U, and the contiguous one.

We shall define as "repetition unit" the part of thread comprised between two ends LH and RH, of given length (or pitch of the repetition unit) ranging from 0.05 cm to a maximum length of 50 cm, provided with a midpoint MP, and in which, with respect to the

midpoint, the spines are divergent, i.e., in the segment that goes from LH to MP, they are directed from MP to LH, and in the second half that goes from RH to MP they are directed from MP to RH (see Figure 1 and Figure 4). We shall designate by "recurrent units" an integer number of repetition units present on the thread.

The repetition unit may have the same pitch or length, or may have different lengths or pitches, ranging from a minimum length of 0.05 cm to a maximum length of 50 cm.

The number of the recurrent units depends upon the total length of the thread on which they are produced or manufactured and upon the length of the repetition units that will be regularly repeated throughout the length of the thread. For instance, for a thread 1 m long, on which there are repetition units 0.05 cm long, there will be 2000 recurrent units.

The inclined protuberances (or spines) are of multiple shapes and pre-set dimensions, according to the specific use, are variable in their technico-geometrical parameters, in a defined range, but are arranged according to an orderly sequence, determined by a mathematical formula. The variables are the following:

- constant pitch of the spines (from 0.50 mm to 25.00 mm);
- variable pitch of the spines (from 0.50 mm with parameterized increase, in scale, according to the Fibonacci series, e.g., 1, 2, 3, 5, 8, 13, 21, 34, etc.);

- Depth of cut (from a minimum of 10% to a maximum of 50% of the USP calibre of the suture);
- length of the spines (ranging from 0.05 mm to 5 mm);
- angle of cut, i.e., the angle that the tangent to the spine forms with the axis of the thread (from a minimum of 5° to a maximum of 85°, or alternatively from 95° to 175°);
- density of the spines per unit length, i.e., the number of spines present for example in 1 cm of length of the thread;
- shape that the thread can assume in space (for example, it can have a helical shape with a well-defined internal diameter or a linear shape);
- section of the thread or diameter, which may be circular, or polyhedral, or variable in shape, with a cross section of a constant calibre (ranging from 0.05 mm to 7.00 mm), or with a cross section of increasing or decreasing calibre (ranging from 0.05 mm to 5.00 mm, for the end 1, and ranging from 0.50 mm to 10.00 mm for the end 2, as in Figure 3), within the repetition unit and along the major axis, or again may vary according to a very precise mathematical formula or be determined according to the Fibonacci series;
- chemical nature (Polypropylene $-(CH_2=CH-CH_3)-$ or other composition, e.g., very-long-life single-threaded re-absorbable material such as caprolactone, with possible addition of hyaluronic acid and/or vitamins, or polydioxanone, or treated or multi-stranded catgut); and

- physical nature of the material of which the thread is made.

As mentioned previously, each repetition unit has two inclined sequences of spines that, starting from the midpoint MP, face the respective end of the repetition unit so as to be mutually divergent. Each sequence, throughout the length of the thread except for a brief interval astride of the midpoint MP and of the free ends of the thread, is set on just one side of the thread diametrally opposite to the side on which the adjacent sequences are arranged, staggered by 180° with respect to the longitudinal axis of the thread (Figure 1). Said characteristic has the purpose of hindering sliding or displacement (along the major axis of the thread) in the two opposite directions, when the thread has been introduced into the soft human tissue or in the white roll. As already mentioned repeatedly, sliding or translation according to the major axis of the thread is produced by the tensile forces that are exerted on both ends of the thread and that arise owing to dynamic actions due to the activity of the voluntary or involuntary muscles, for example, during facial mimics, chewing, etc.

Furthermore, the divergence of the spines guarantees elongation or lengthening of the soft tissue into which the thread is introduced, eliminating, for example, the so-called upper-lip "barcode".

The above protuberances can be designed either with sharp terminations or without cusps, or flexible, or elastic or rigid. Said protrusions are provided with a given angle of cut (designated by 2 in Figure 2),

which corresponds to the angle that the tangent to the spine in its root point on the thread forms with the axis of the thread passing through the same point and is comprised between 5° and 85°, including the complementary angles 95° and 175°(see Figures 1 and 2).

The length 3 of the aforesaid spines or protuberances is variable between 0.05 mm and 7.00 mm, but may even be greater.

The pitch 4 or distance of their root points along the axis of the thread may be constant and comprised between 0.05 mm and 25.00 mm or be variable according to the Fibonacci series appropriately proportioned and parameterized to the order of magnitude of the thickness of the thread. Whereas in Figure 1 the diameter of the thread is constant, and preferably comprised between 0.05 mm and 7 mm, Figure 3 shows a thread of diameter that increases between the end 1 and the end 2.

In this case, the minimum diameter will be preferably comprised between 0.05 mm and 0.50 mm, whilst the maximum diameter will be comprised between 3.00 and 7.00 mm.

The opposed arrangement of the protuberances is referred to the half-length of the thread, midpoint of the repetition unit (see Figure 1), or to the midpoint (MP) of the recurrent units (constituted by an integer number of repetition units).

In greater detail, of the divergent spines illustrated in Figures 1 and 2, one is oriented from the midpoint to the right-hand end, i.e., with the apex of the spines or protuberances that faces the right-

hand end, whilst the other sequence of spines faces in a direction opposite to the first starting from the midpoint of the entire suture.

With a precise internal calibre, of 6-0, included in the USP designation, and with a precise distance of the turns between 0 mm and 17.00 cm, the helical arrangement (see Figure 5) may be obtained from different mathematical formulae, such as the formula of the Fibonacci-series logarithmic spiral with additional constant, the formula of the logarithmic spiral with constant radius and constant pitch, the formula of the logarithmic spiral with constant radius and pitch variable according to the Fibonacci series (appropriately modified) or according to other numerical series.

It should be understood that the arrangement of the divergent spines set opposite with respect to the major axis of the thread is applicable also to a thread, which, starting from the midpoint of the repetition unit, presents a calibre (radius) that increases progressively (per unit length in centimetres) according to the Fibonacci series appropriately parameterized by us, i.e., a calibre that ranges from a minimum of 0.05 mm to a maximum of 7 mm. According to an advantageous characteristic of the invention, thanks to the arrangement and to the divergence with which the spines are provided, it is possible to have for each individual repetition unit a greater number of protuberances (density of the spines per unit length), i.e., a larger number of areas of interaction with the soft human tissue, which guarantee

a gathering, lifting, and hold of the soft tissues or of the margins of a surgical suture, that is much greater than that of any other similar pre-existing structure, albeit preserving the longitudinal ultimate strength of the thread used.

This is confirmed by the tests conducted, which have documented a stable hold of the tissues, their perfect gathering, and the approach and hold of the margins of the cutaneous lesions resulting from surgery or from trauma, without any ischaemic damage due to excessive tensile stress exerted by the surgeon operating in the act of stitching the point of suture. Added to this is a lasting lifting action, also as a result of the intense fibrosis produced around the thread by the tissues of the host, a fibrosis that is induced by the specific structural modification produced on the surface of the thread, as indicated previously. Said actions in the host, as also the absence of specific immune reactions, document the absolute tolerance of said modifications of the thread in regard to the tensile force applied, suspension, lifting of the human tissues or organs, or tissues or organs of other animal species.

A further advantageous aspect lies in the fact that the particular structure of the thread forming the subject of the invention also guarantees the capacity of introduction thereof into the tissues in just one or in both of the opposite directions, guaranteeing in any case an optimal suspension and relaxation of the soft tissues, in particular of the buccal and peribuccal region.

BRIEF DESCRIPTION OF THE SURGICAL TECHNIQUE

We shall now describe the surgical technique adopted using the nomenclature appearing in Figure 6, which specifically shows the anatomical parts of the buccal and peribuccal region.

With reference to Figures 7 onwards, the operating steps are the following:

a) Using Duval clamps, we take gauzes and moisten them with Betadine®. We disinfect the area of the face adjacent to the lips, and then we apply a sterile cloth starting from the area of the chin (Figure 7).

b) Using a sterile dermographic pencil, the path that the cannula will follow during its insertion is drawn on the white roll of the lips, just below the red line in the upper and lower lips, in the subdermal plane (Figure 8).

c) This is followed by preparation of the anaesthesia (Figures 9a-9d): after marking the path, we execute the topical or local block and/or the block of the truncular canine nerve. We carry out subdermal local anaesthesia; we follow the entire white roll of the upper and lower lips and the philtral columns. It is possible to use 2/3% lidocaine + adrenaline at a dilution of 1:100000, without adrenaline when we carry out truncular nerve anaesthesia, if we need a stronger anaesthesia. Before doing this, to reduce the slight discomfort of the anaesthesia a topical anaesthetic cream can be applied, with lidocaine or prilocaine or other drugs, 40/45 minutes prior to the surgical operation, and then cover the mouth area and the lips with a transparent compress.

TECHNIQUE AND PROTOCOL

a) The 20-gauge cannula CN 15 cm long is to be inserted (Figure 10) passing through the derma, reaching in the hypodermis the virtual tunnel that we call "white roll" starting from the right-hand corner of the mouth or vice versa, and following the white roll throughout the length of the margin of the lips previously traced; in the middle in the white roll we also have to follow the cupid's bow (see Figure 11).

b) The cannula continues its course in the cupid's bow until it comes out of the opposite corner of the mouth (Figures 12 and 13). Of course, the cannula will produce an evident stretching of the lip.

c) The mandrel is extracted from the spinal cannula CN (Figure 14). The thread is introduced into the cannula CN until both of the spined portions are completely inserted. The assistant will block the end of the suture, after which the cannula will be extracted slowly (Figure 15) whilst both of the sides of the mouth are kept open with the index finger and the thumb of the other hand until the cannula is completely removed. There will appear (Figure 16) the two smooth ends of the thread, said ends having to be of the same length in so far as the central part of the suture (without spines) must be positioned in the cupid's bow. In other words, the equidistance of the ends of the thread that emerge from the skin ensures the coincidence of the smooth central part of the

suture with the apex of the cupid's bow. The two ends of the thread are raised delicately one at a time; then, with the use of curved forceps (Figure 17), a slight pressure is exerted to lower the skin by approximately 2 mm, and after a slight rotation the thread is cut. The same process must be repeated on the other end of the suture (Figure 18). Then, it is necessary to proceed with proper positioning of the thread.

d) First we block the cupid's bow with the index finger and the thumb, in order to block the suture in its midpoint corresponding to the cupid's bow.

e) Then, the edge of the lip is pulled delicately towards the side and downwards at the corner on both sides of the lips, whilst the cupid's bow is blocked with the thumb and the index finger, pulling one at a time the right-hand and left-hand end parts of the red line.

f) This will produce the result immediately after the operation (Figure 20). The absorbable internal suture made of P (LA-CL) or DOP, will absorb in time (1/1.5 years), but the aesthetic effect will increase on account of the histological lifting, which will be obtained owing to the microfibrosis due to the foreign body (the suture). The same procedure can be repeated in the lower lip, if necessary. If the patient moreover presents smoker's wrinkles on the upper lip, a third suture can be introduced, which will have to be inserted at the subdermal level of the upper lip approximately 5-7 mm from the edge of the upper

lip.

After the surgical operation, all the patients must follow the common compulsory postoperative therapy, which comprises:

f) antibiotics (amoxicillin plus clavulanic acid for 5-7 days);

- anti-inflammatory with protease for 10 days (bromelain, seaprose);
- analgesic, only if necessary (Nimesulide or other drugs).

During the first 3-4 days after the operation, is it is recommended to:

- try to speak less, not to laugh, and to avoid trauma to the area treated, to chew less, and not to eat solid food;
- not to touch the area treated and to minimize any mechanical action for at least three weeks.

The area treated should be photographed before and after treatment.

The advantages are: permanent results over time, innovative increase of the volume of the lips, disappearance of smoker's wrinkles, absence of major side effects, safe technique, technique that can be carried out in a doctor's surgery, and possibility of combining use with a hyaluronic-acid-based filler.

CLAIMS

1) A surgical thread to be used for plastic-surgery, dermatological, aesthetic, general-surgery, and emergency-surgery operations, and in all specialist forms of surgery, in the anatomical area of the mouth and neighbouring areas, provided with inclined protuberances or spines distributed along its length, characterized in that said protuberances or spines are arranged in sequences where they are alternately positioned on one side of the thread that is opposite or at an angular distance from the side of the subsequent sequence and divergent with respect to the spines of the subsequent sequence, thereby on the one hand hindering sliding or displacement of the thread in the two opposite directions and on the other guaranteeing elongation or lengthening of the soft tissue into which the thread is introduced.

2) The surgical thread as per Claim 1, characterized in that identifiable thereon is at least one or more repetition units, namely, the part comprised between two ends (LH) and (RH) with a midpoint (MP) at which the spines reverse their own inclination giving rise to two sequences of spines that are divergent with respect to said midpoint (MP), the spines of the right-hand sequence being inclined towards the right-hand end (RH) and the spines of the left-hand sequence being inclined towards the left-hand end (LH), whilst the right-hand sequence of said protuberances or spines is distributed on one side of the thread that is diametrally opposite to that on which the spines of the left-hand end are distributed.

3) The surgical thread as per Claim 1, characterized in that for each repetition unit said divergent spines or protrusions are distributed on two opposed helices, i.e., having opposite direction, one being oriented from the midpoint (MP) towards the right-hand end of the thread, and the other being oriented in the direction opposite to the first one, i.e., from the midpoint (MP) towards the left-hand end.

4) The surgical thread as per Claim 3, characterized in that the length of the repetition unit is comprised between 0.05 cm and 50 cm.

5) The surgical thread as per Claim 4, characterized in that the length of the repetition unit is constant throughout the length of the thread.

6) The surgical thread as per Claim 5, characterized in that the length of the repetition unit is not constant throughout the length of the thread so as to increase or reduce the density of the spines in some areas of the thread itself and have a differentiated gathering according to the type of soft tissue traversed.

7) The surgical thread as per Claim 6, characterized in that each repetition unit is separated from the next one by a short stretch of thread in which the spines are absent.

8) The surgical thread as per the preceding claims, characterized in that the section of the thread, irrespective of its shape, is constant.

9) The surgical thread as per Claims 1 to 8, characterized in that its section is increasing and/or decreasing, comprised, within the repetition unit,

between 0.05 mm to 5.00 mm for the end (1) and between 0.50 mm and 10.00 mm for the end (2).

10) The surgical thread as per the preceding claims, characterized in that the pitch of the spines on the axis of the thread is constant.

11) The surgical thread as per Claim 10, characterized in that the pitch of the spines is comprised between 0.50 mm and 25.00 mm.

12) The surgical thread as per Claims 1 to 11, characterized in that the pitch of the spines is variable according to the Fibonacci series appropriately proportioned and parameterized to the order of magnitude of the thickness of the thread.

13) The surgical thread as per Claim 1, characterized in that it is obtained getting a straight thread to assume in space a permanent helical shape with a well-defined internal diameter, which bestows elastic characteristics thereon; on said thread the spines having a linear or helical pattern.

14) The surgical thread as per the preceding claims, characterized in that the length of the spines or protuberances is comprised between 0.05 and 7 mm.

15) The surgical thread as per the preceding claims, characterized in that the angle of cutting of the spines is comprised between 5° and 85° or alternatively from 95° to 175°.

16) The surgical thread as per the preceding claims, characterized in that it is made of a very long-life single-stranded re-absorbable material, such as caprolactone with possible addition of hyaluronic acid and/or vitamins, polydioxanone, or treated or

multi-stranded catgut.

17) A surgical technique for re-definition of the mouth and its marginal increase in volume, with the use of a suturing thread according to the preceding claims, characterized in that it envisages the following steps:

a) using a dermographic sterile pencil there is drawn on the area of mouth of the patient the path to be followed by a cannula during its insertion into the white roll of the lips just below the red line in the upper and lower lips, in the underlying plane;

b) local subdermal anaesthesia is performed;

c) a cannula is inserted, passing through the derma until the virtual tunnel known as "white roll" is reached in the hypodermis, starting from the right-hand corner of the mouth or vice versa and following the white roll throughout the length of the margin of the lips previously traced, including, in the middle, in the white roll, also the cupid's bow, until it comes out of the opposite corner of the mouth;

d) the mandrel is extracted from the cannula.

e) the spined thread is inserted into the cannula until both of the spined portions are completely inserted.

f) the assistant blocks the end of the suture, after which the cannula is extracted slowly while both of the sides of the mouth are kept open with the index finger and the thumb of the other hand until the cannula is completely removed, leaving in view the two smooth ends of the thread;

g) a check is made to ensure that the ends of the thread are of the same length in so far as the

central part of the suture (without spines) must correspond to the cupid's bow; in other words, the equidistance of the ends of the thread that emerge from the skin ensures the coincidence of the smooth central part of the suture with the apex of the cupid's bow;

h) one of the ends of the thread is raised delicately and, with the use of the curved forceps, a slight pressure is exerted to lower the skin by approximately 2 mm and, after a slight rotation, the thread is cut, the same operation being repeated on the other end of the suture;

i) the thread is then positioned properly, first of all blocking the cupid's bow with the index finger and the thumb in order to block the suture in its midpoint at the cupid's bow;

l) the edge of the lip is then pulled delicately towards the side and downwards at the corner on both sides of the lips, while the cupid's bow is blocked with the thumb and the index finger, pulling one by one the right-hand end part and left-hand end part of the red line, thus achieving a valid aesthetic result immediately after the operation;

m) the aesthetic effect will increase over time on account of the histological lifting due to the microfibrosis linked to the presence of the suturing thread that will be re-absorbed over time;

n) the steps from c) to m) are repeated in the lower lip, if necessary.

18) The surgical technique as per Claim 17, characterized in that if the patient moreover has

smoker's wrinkles in his or her upper lip, a third suture can be introduced, inserting it in the subdermal level of the upper lip to approximately 5-7 mm from the edge of the upper lip.

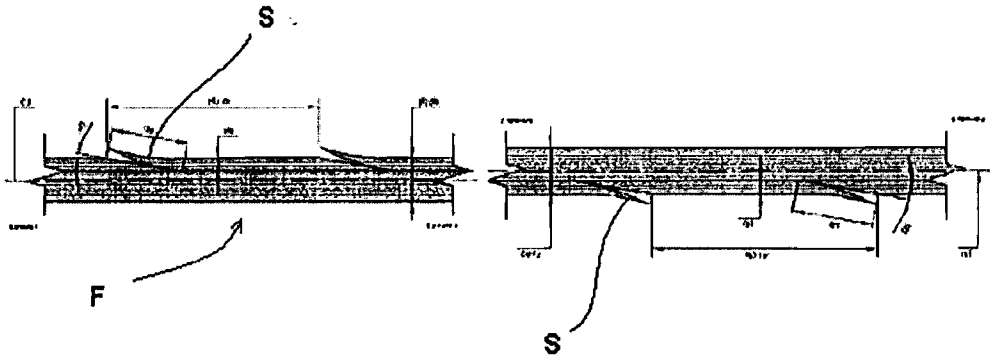

FIG. 1

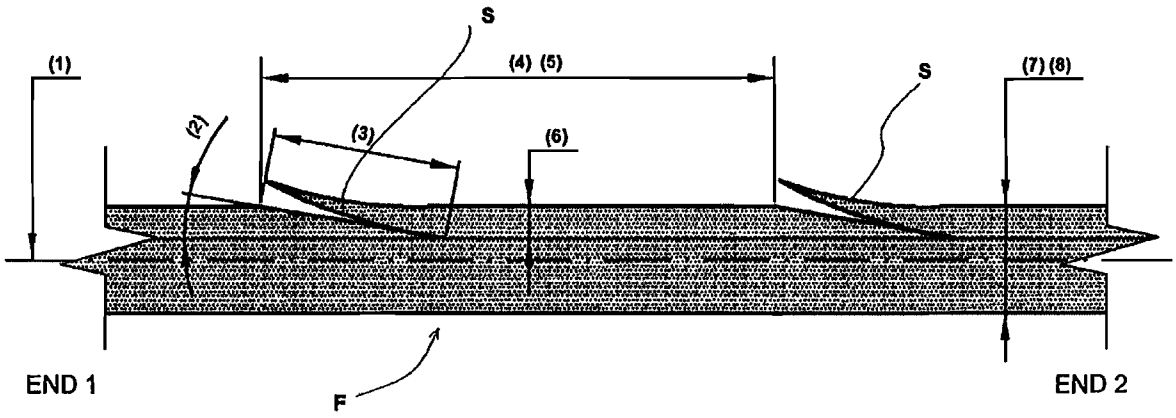

FIG. 2

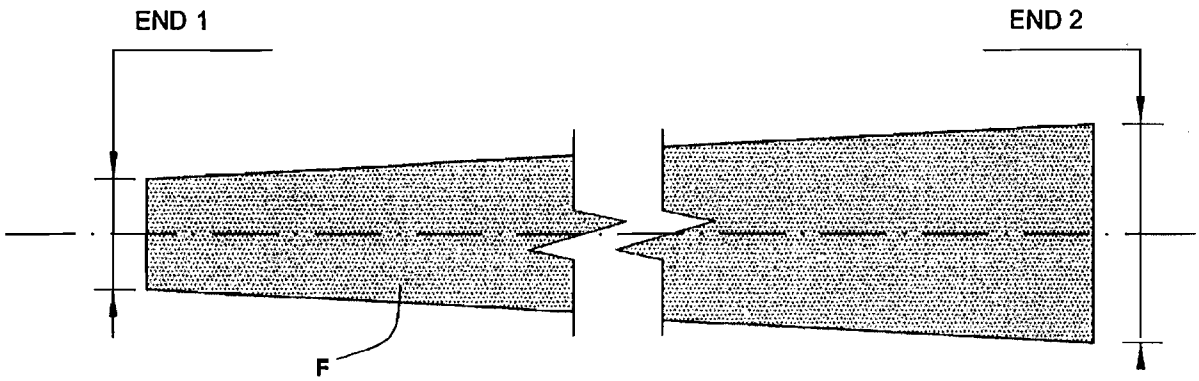

FIG. 3

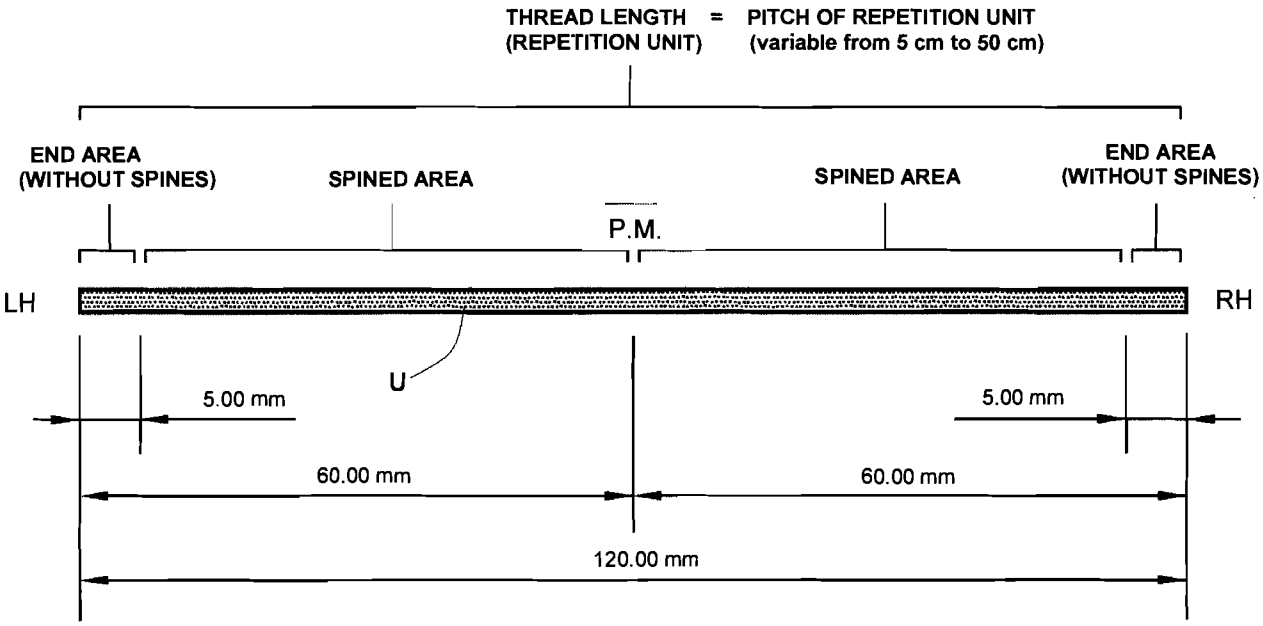
THREAD LENGTH = PITCH OF REPETITION UNIT
(REPETITION UNIT) (variable from 5 cm to 50 cm)
END AREA
(WITHOUT SPINES)
SPINED AREA
SPINED AREA
END AREA
(WITHOUT SPINES)
P.M.
LH
RH
U
5.00 mm
5.00 mm
60.00 mm
60.00 mm
120.00 mm

FIG. 4

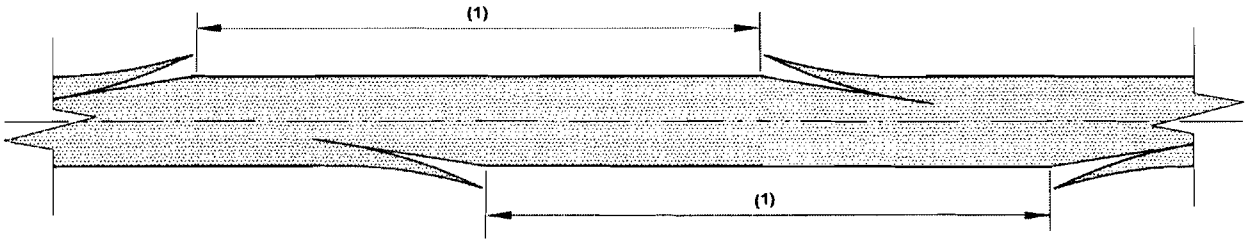
(1)
(1)

FIG. 5

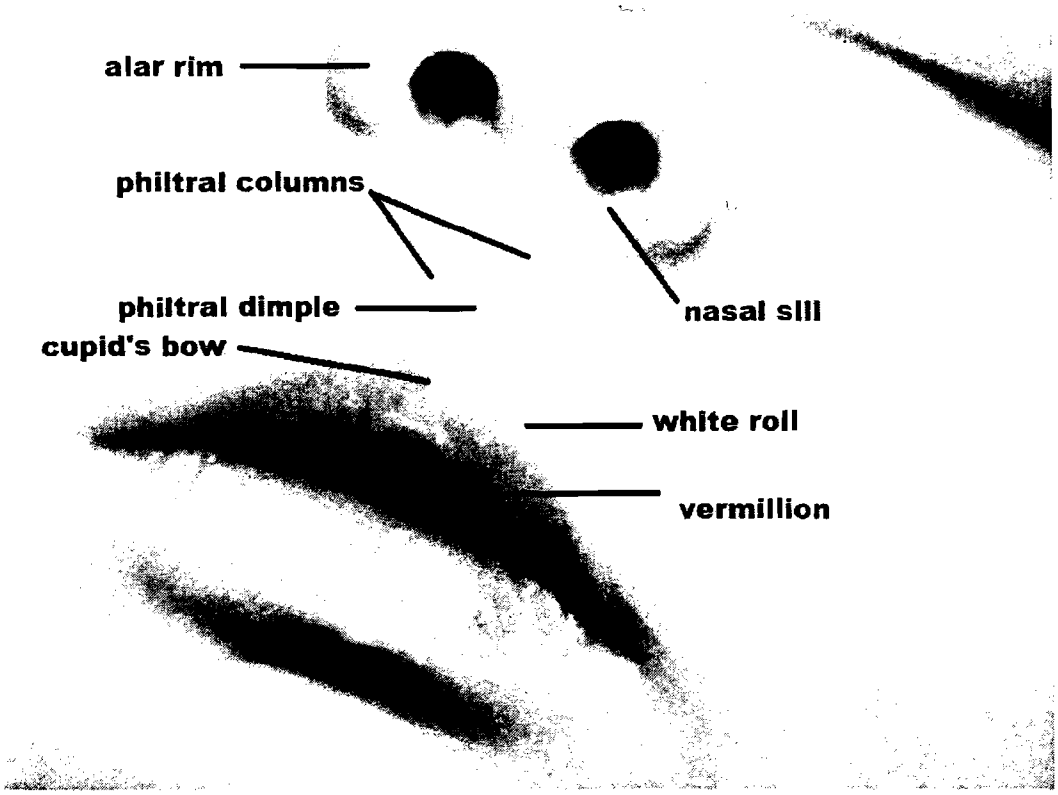
alar rim
philtral columns
philtral dimple
nasal sill
cupid's bow
white roll
vermillion

FIG. 6

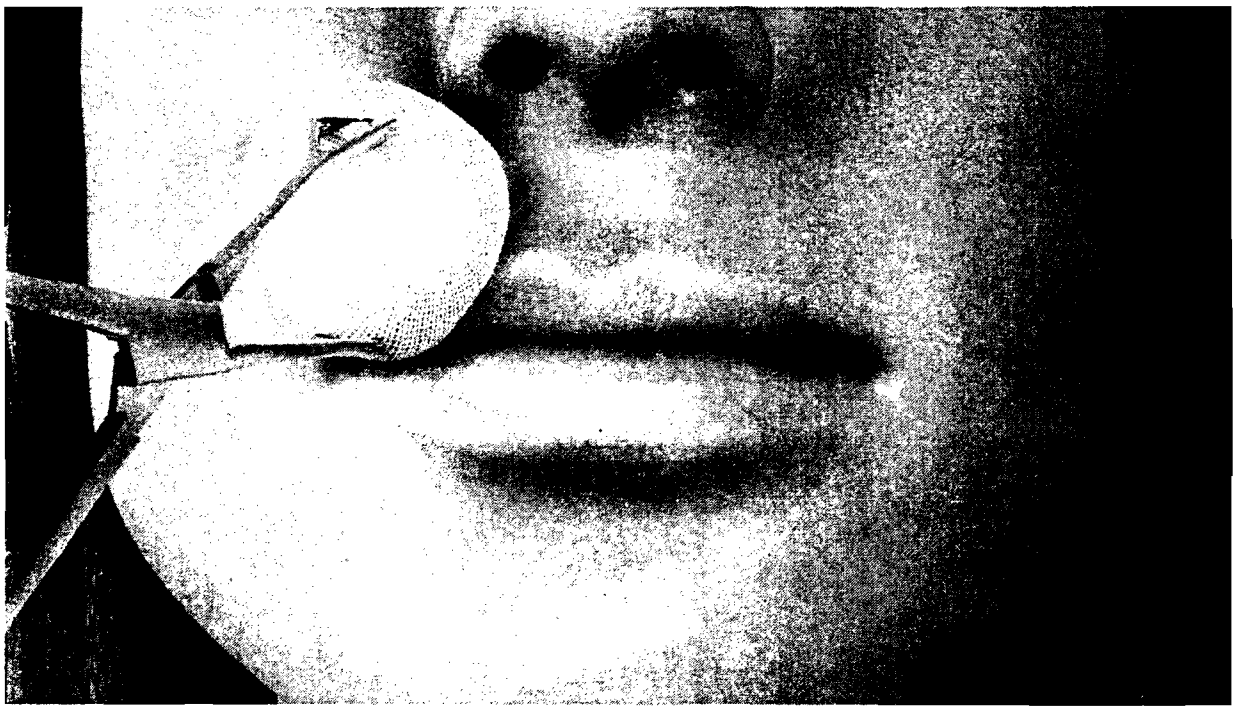

FIG. 7

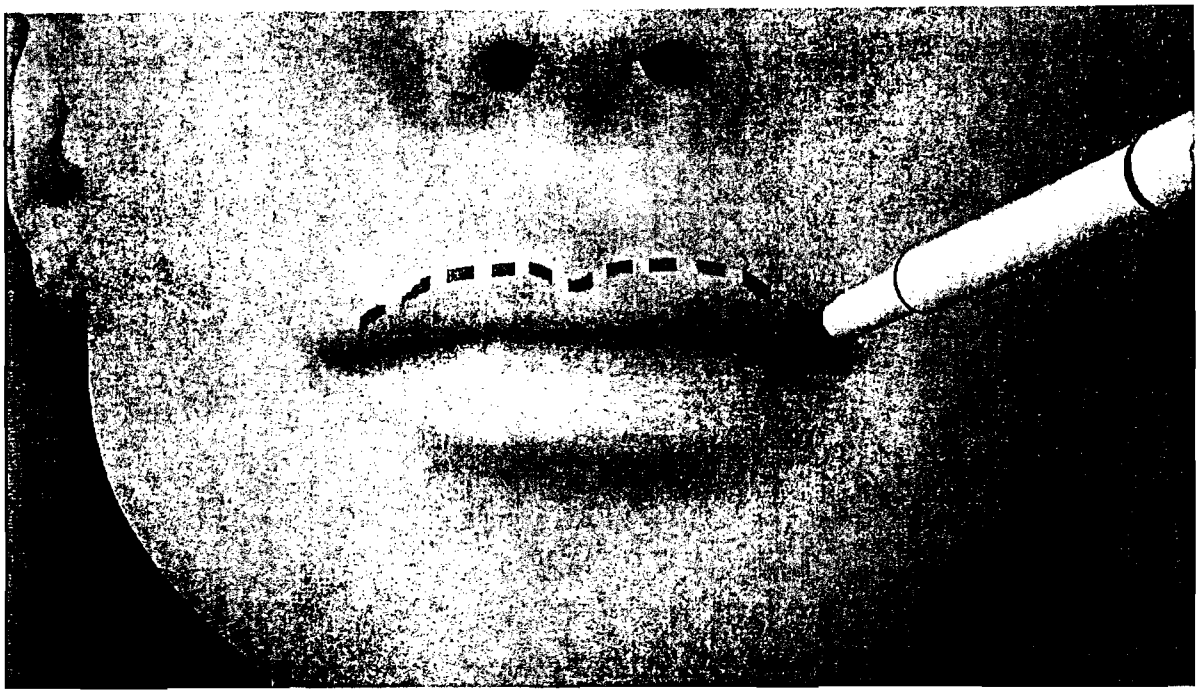

FIG. 8

FIG. 9A

FIG. 9B

FIG. 9C

FIG. 9D

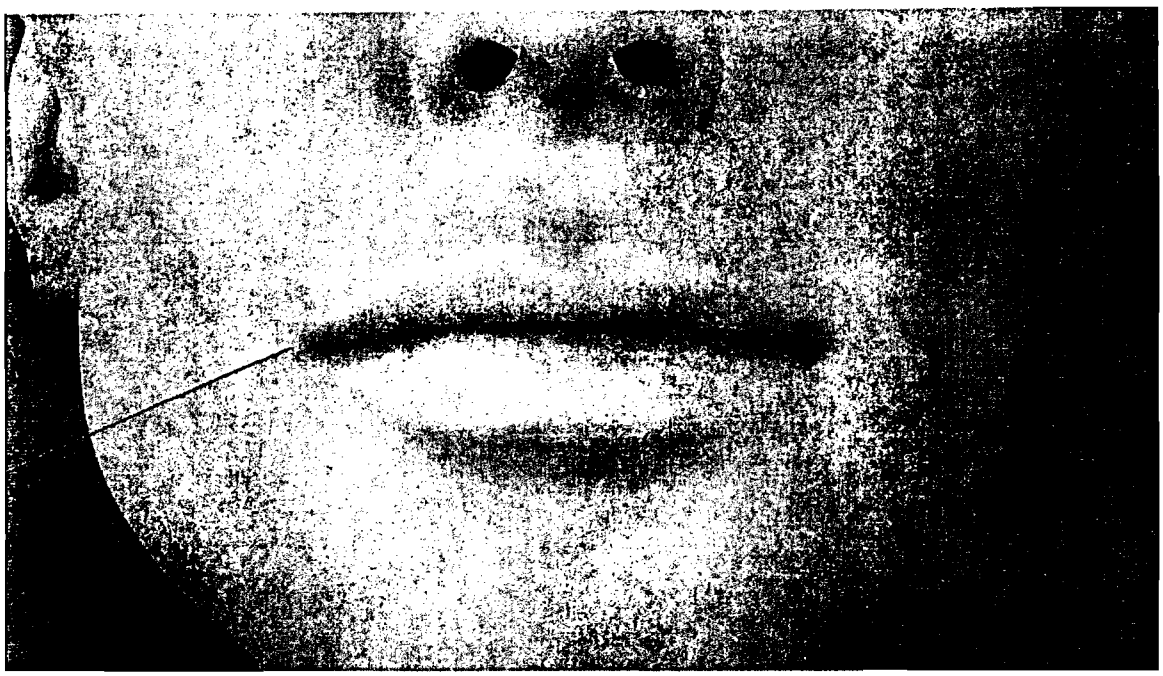

FIG. 10

FIG. 11

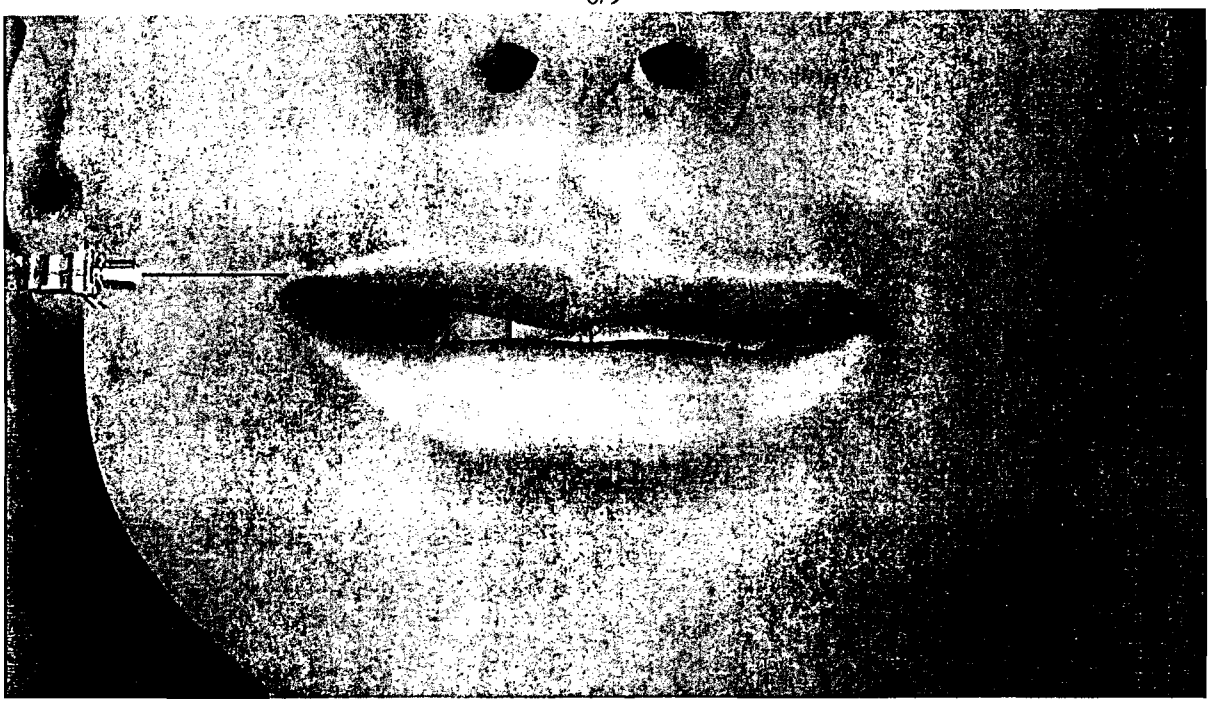

FIG. 12

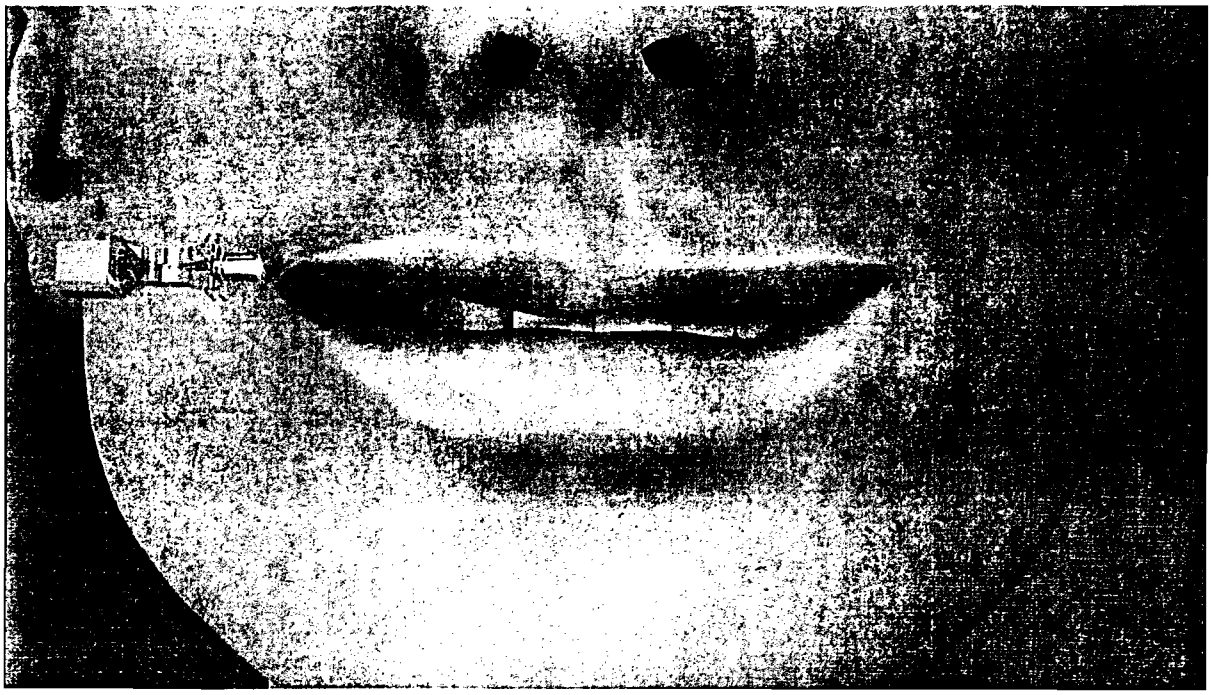

FIG. 13

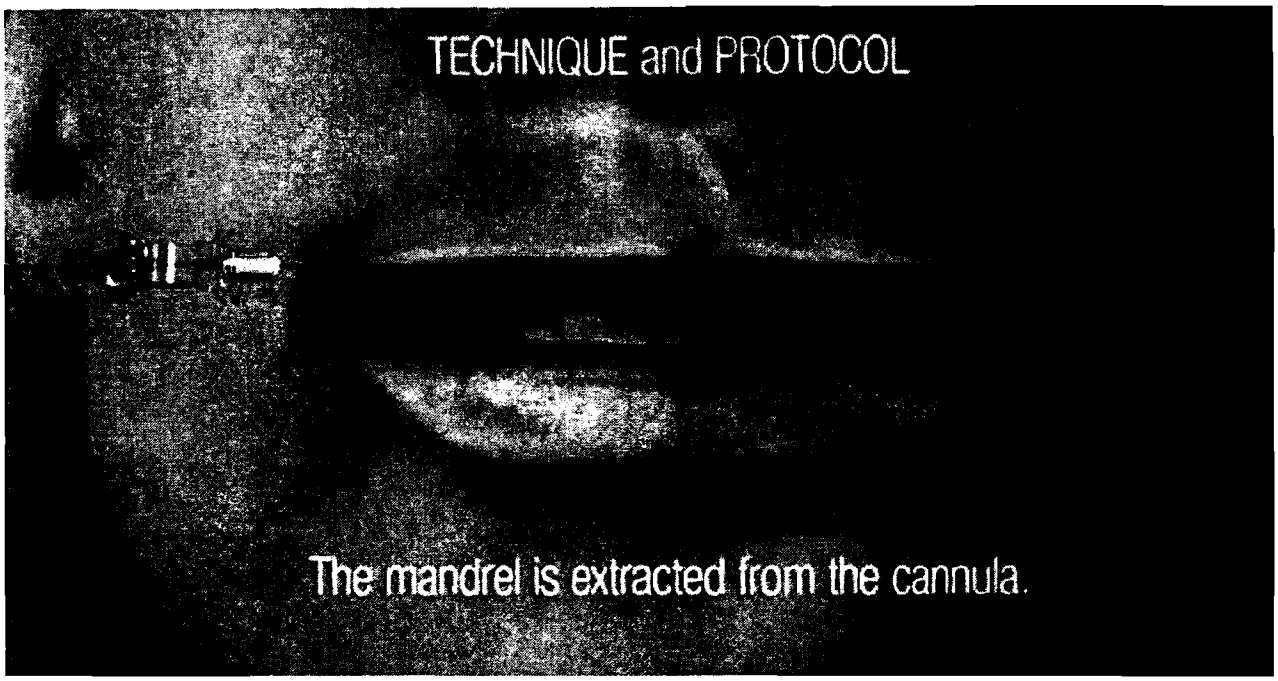
TECHNIQUE and PROTOCOL
The mandrel is extracted from the cannula.

FIG. 14

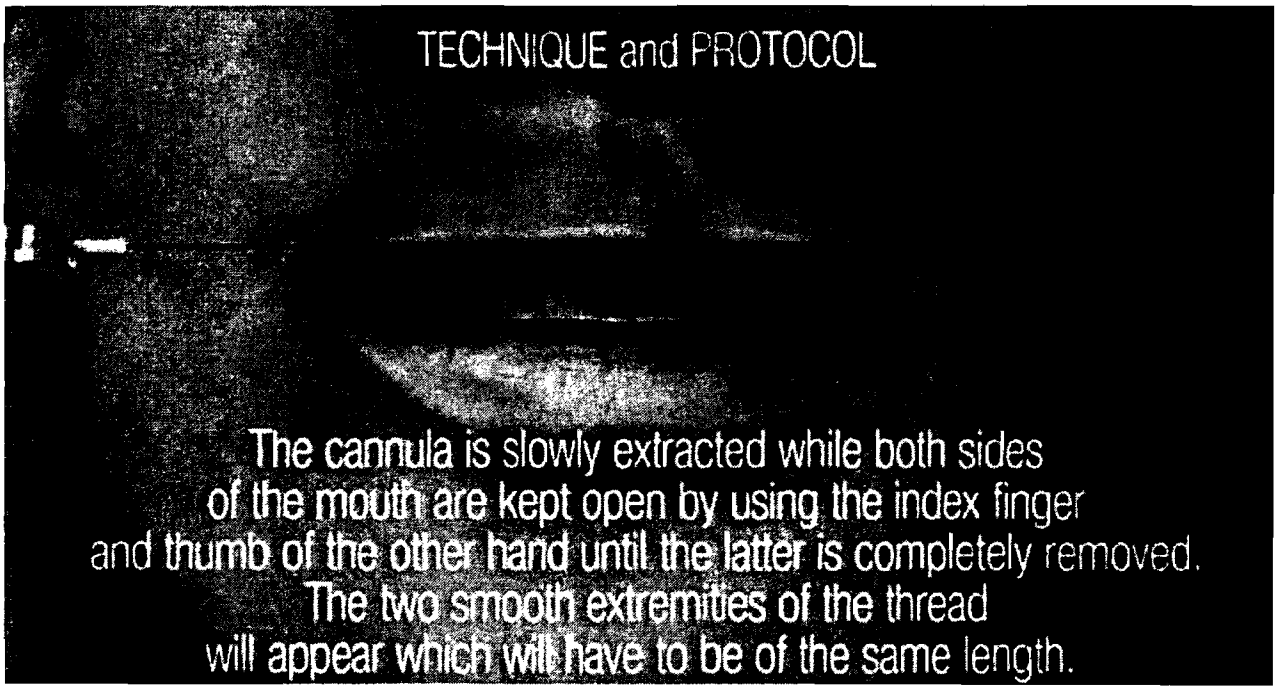
TECHNIQUE and PROTOCOL
The cannula is slowly extracted while both sides
of the mouth are kept open by using the index finger
and thumb of the other hand until the latter is completely removed.
The two smooth extremities of the thread
will appear which will have to be of the same length.

FIG. 15

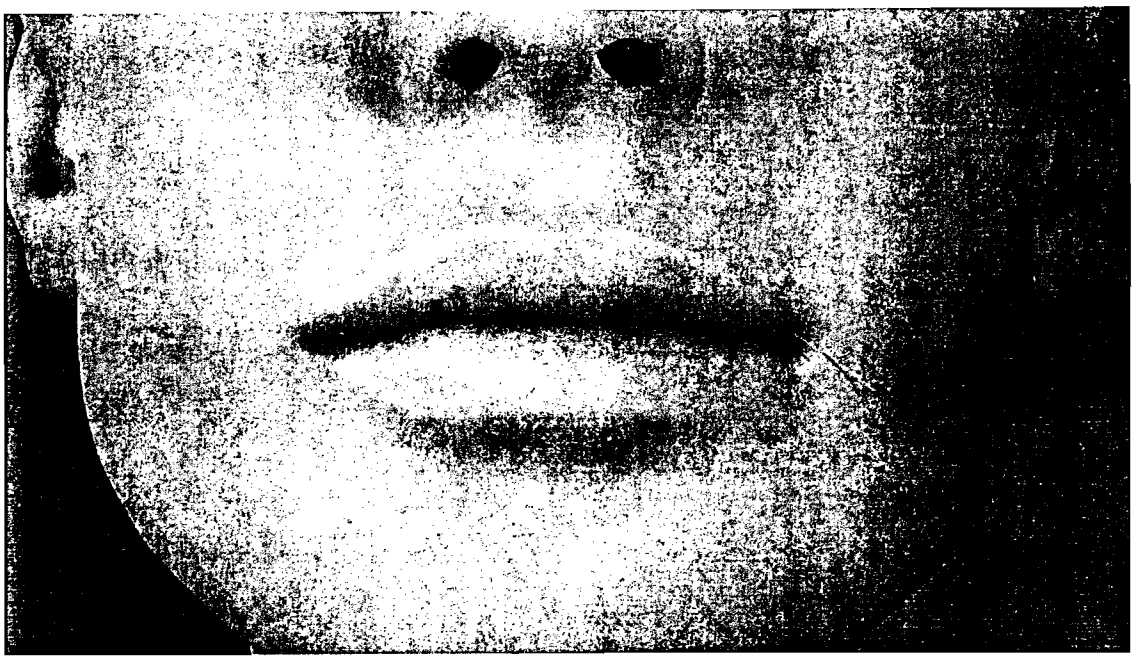

FIG. 16

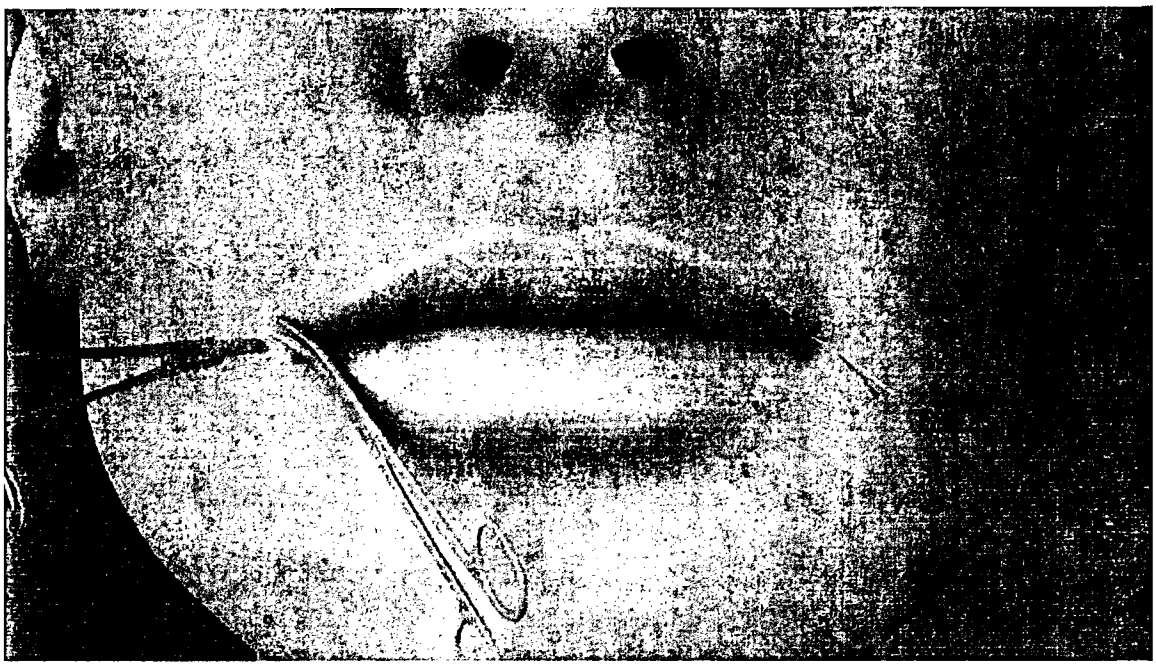

FIG. 17

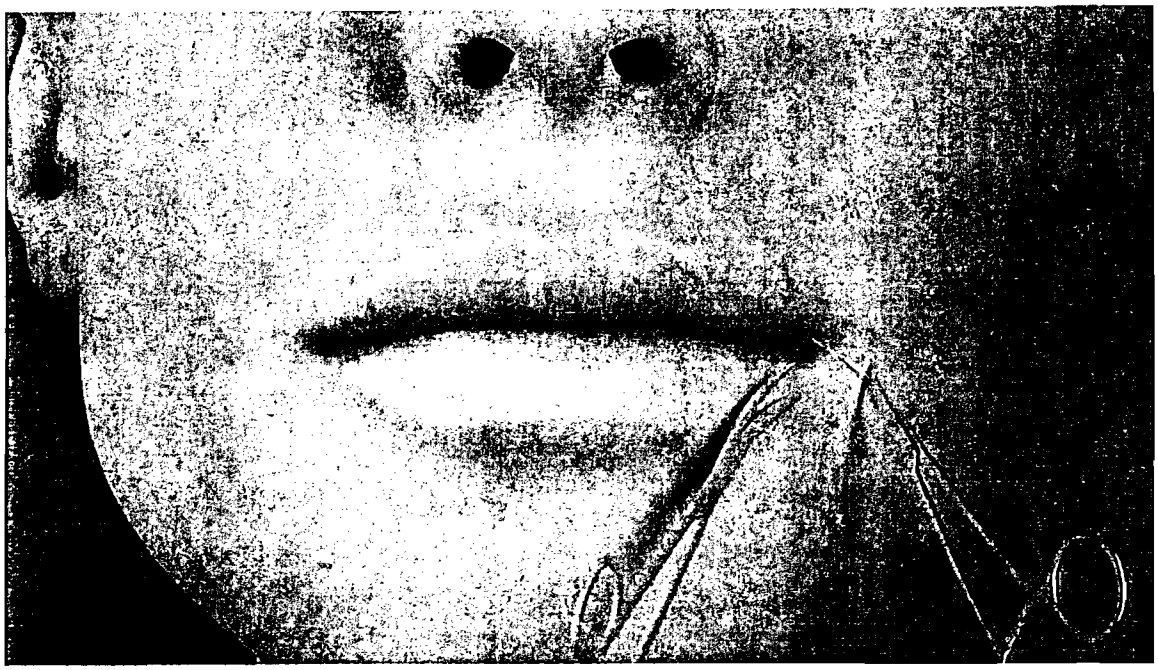

FIG. 18

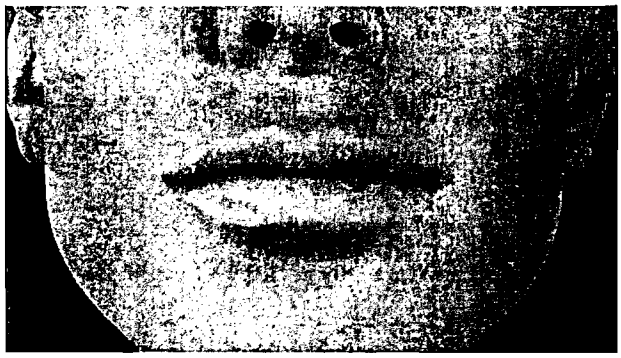

FIG. 19

FIG. 20

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2013/000113

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/06
ADD.

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)
A61B

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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 386 323 A2 (LEE HEE-YOUNG [KR]) 16 November 2011 (2011-11-16)	1-5, 8-12, 14-16
Y	paragraphs [0001], [0009], [0011] - [0017], [0034] - [0038] figure 5(a)	13

X	WO 2009/132284 A2 (ANGIOTECH PHARM INC [CA]; GORALTCHOUK ALEXEI [US]; LAI JOHN [CA]; HERR) 29 October 2009 (2009-10-29)	1
Y	figures 6D-6F paragraphs [0081], [0112]	13

X	WO 2006/061868 A1 (PROMOITALIA INTERNAT SRL [IT]; ACCARDO CIRO [IT]) 15 June 2006 (2006-06-15) pages 1-5,8-12 figures 1-5	1-16

	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] 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 but 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	Date of mailing of the international search report
27 November 2013	06/12/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Erbel, Stephan

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IT2013/000113

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17, 18
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2013/000113

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	AU 2011 250 869 A1 (QUILL MEDICAL INC ETHICON LLC) 8 December 2011 (2011-12-08) figures 20,22 -----	1-5,11, 14-16 13
Y	EP 1 726 317 A1 (SULAMANIDZE MARLEN ANDREEVICH [RU]; SULAMANIDZE GEORGIIH MARLENOVI [RU]) 29 November 2006 (2006-11-29) paragraphs [0001], [0007]; figure 1 -----	13

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IT2013/000113

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 2386323 A2	16-11-2011
		JP 2012515015 A	05-07-2012
		KR 20100083006 A	21-07-2010
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		US 2011270304 A1	03-11-2011
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		WO 2006061868 A1	15-06-2006
AU 2011250869 A1	08-12-2011	NONE	
EP 1726317 A1	29-11-2006	EP 1726317 A1	29-11-2006
		US 2007167958 A1	19-07-2007
		WO 2005087283 A1	22-09-2005

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 17, 18

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Claims 17 and 18 explicitly relate to a method for treating the human body by surgery. According to Rule 39.1 (iv) PCT the international search authority is not required to search subject matter falling under this category.