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DEVICE FOR REINFORCING AND SUSTAINING THE CAP OF THE ROTATORS OF A HUMAN SHOULDER JOINT

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(57) Claim

1. A device for the surgical therapy of the rupture or weakening of the rotator cuff of a shoulder joint of a person, said device comprising a strip having a rear heel adapted to be fixed onto the trochiter or on the tendinous mass of the cuff of a shoulder joint and being, in use, of linear extent towards the top of the cuff of the joint and adapted to be fixed onto the tendon(s).

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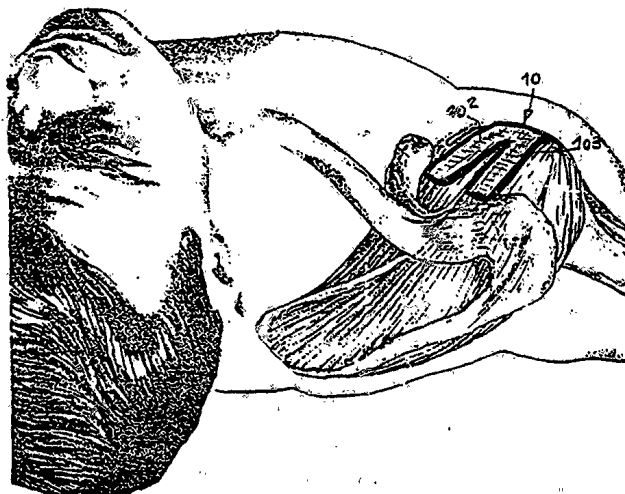
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(21) Numéro de la demande internationale: PCT/FR90/00291 (22) Date de dépôt international: 25 avril 1990 (25.04.90) (30) Données relatives à la priorité: 89/06005 27 avril 1989 (27.04.89) FR (71)(72) Déposants et inventeurs: GAZIELLY, Dominique, François [FR/FR]; 47, rue Henri-Déchaud, F-42100 Saint-Etienne (FR). BLONDEL, Pierre [FR/FR]; La Forie, F-63600 Ambert (FR). (74) Mandataire: DUPUIS, François; Cabinet Charras, 3, place de l'Hôtel-de-Ville, B.P. No. 203, F-42005 Saint-Etienne Cédex 1 (FR).	(81) Etats désignés: AT (brevet européen), AU, BE (brevet européen), BR, CA, CH (brevet européen), DE (brevet européen), DK (brevet européen), ES (brevet européen), FR (brevet européen), GB (brevet européen), IT (brevet européen), JP, LU (brevet européen), NL (brevet européen), SE (brevet européen), US. Publiée <i>Avec rapport de recherche internationale.</i> <i>Avant l'expiration du délai prévu pour la modification des revendications, sera republiée si de telles modifications sont reçues.</i>	

628976

(54) Title: DEVICE FOR REINFORCING AND SUSTAINING THE CAP OF THE ROTATORS OF A HUMAN SHOULDER JOINT

(54) Titre: DISPOSITIF DE RENFORT ET DE SOUTIEN DE LA COIFFE DES ROTATEURS D'UNE ARTICULATION D'EPAULE D'INDIVIDUS



(57) Abstract

The reinforcing device is characterized in that it is comprised of a band (10) presenting a rear heel (10.1) forming a common trunk fixed to the great tuberosity and extended by at least two divergent branches applied and fixed to the tendons, and in that one of the branches is secured to the repaired tendon in order to reinforce and protect it, and one or the other branches are fixed to the or other sane tendons.

(57) Abrégé

Le dispositif de renfort est remarquable en ce qu'il est constitué par une bande (10) présentant un talon (10.1) arrière constituant un tronc commun fixé sur le trochiter, et se prolongeant par au moins deux branches divergentes s'appliquant et se fixant sur les tendons, et en ce que l'une des branches est fixée sur le tendon réparé afin de le renforcer et le protéger, et l'une ou les autres branches sont fixées sur les ou les autres tendons sains.

The present invention relates to a reinforcement and supporting device for the rotator cuff of a shoulder joint of a person.

The subject invention relates to the technical field
5 of surgery of the shoulder and in particular, means to provide therapy for shoulder injuries. In order to understand the object and advantage of the invention, its environment with regard to degenerative ruptures of the rotator cuff shall be discussed with reference to Figs. 1,
10 2 and 3.

The rotator cuff of a shoulder joint is made up by melting the distal tendinous portion of the four muscles, supraspinatus and subspinatus (1) (2), subscapularis (3) and teres minor (4), (figures 1 and 2). It is inserted on
15 the upper, anterior and posterior faces of the trochiter (5) by covering the upper pole of the humeral head. The power of this tendinous cuff, 3 to 4 millimetres thick, depends on the fundamental centering and stabilizing role of the humeral head with respect to the sliding action
20 during anterior and lateral lifting and rotational movements of the arm.

The musculotendinous cuff passes under an osteofibrous arch made up from the front to the rear by the portion of the acromion (7), the coracoacromial
25 ligament (8) and the coracoid process (9), (figure 3), thereby forming a canal. (6) represents the clavicle as a partial section. A sliding bursa is inserted between the musculotendinous cuff and the walls of the osteofibrous arch. Therefore, there is potential and real conflict
30 between the musculotendinous cuff and the acromioclavicular arch, particularly during lateral and anterior lifting movements of the arm. The repeated rubbing of the cuff against the osteofibrous wall results in wearing of the tendinous cuff by progressive abrasion. The rubbing can be increased in as much as the arthrosis



lesions with aggressive osteophytes may thicken the walls of the aforementioned canal becoming more aggressive as the cuff gets older.

- 5 With time, gradual thinning is brought about then a trophic perforation (less than 1 cm²) of the cuff, particularly in the hypo-vascularized and fragile area where the supraspinatus

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muscle is inserted. A fall may provide a more extensive rupture by disinsertion of the supraspinatus muscle, with extension towards the front (subscapularis muscle) or the rear (subspinatus muscle). The degenerative rupture of the rotator or musculotendinous cuff may be of a varied size :

- grade 1 - perforation (less than 1 cm²) reaching the supraspinatus muscle
- grade 2 - supraspinatus rupture (greater than 1 cm²)
- grade 3 - Massive rupture concerning the supraspinatus, subspinatus, subscapularis muscles and sometimes the teres minor muscle.

It is possible to carry out surgery to reconstruct the rotator cuff. This is aimed at recovering the humeral head, giving back the cuff its capturing and stabilizing role and re-establishing a harmonious scapulohumeral rhythm.

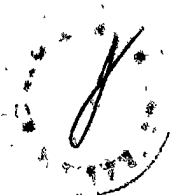
Reconstruction is compulsorily associated with excision of the coracoacromial ligament and cleaning the subacromial space, including suppression of the arthrosis lesions and thinning of the anterior portion of the acromion.

Several processes are therefore possible in order to cover the humeral head.

Certain processes do not use the rotator cuff. The tendinous cuff has disappeared due to wear or major retraction. It is technically possible to fill in the space corresponding to the cuff by covering the humeral head with a natural or synthetic, inert material. However, it appears preferable, in the case of major ruptures, where the humeral head is uncovered, to carry out plasty by the anterior deltoid muscular flap, which offers the advantage of covering the humeral head and having a lowering effect of the humeral head by active contraction of the flap.

Other surgical processes use the rotator cuff.

The rotator cuff is disinserted. The humeral head is uncovered and there is a more or less significant lack of covering (grades 1, 2, 3). The tendons are retracted according to a



variable degree, however it is possible to free the adherences in order to bring them to their initial trochiterian insertion area. Just like a mobile roof, the cuff, retracted towards the scapula, covers the humeral head again. Therefore, only the tendons need to be attached to the trochiter by sutures using non-reabsorbable thread, made at the bottom of a bone trench. The reconstruction must be isometric enabling, a visual examination during operation of the internal and external rotation movements and with the elbow against the body, and bending and extension movements, without the transosseous reinsertion sutures giving way.

If the extent of the loss of tendinous substance and/or the degree of retraction, prevent solid and reliable reinsertion authorizing immediate and post-operative rehabilitation, it is preferable to call for a deltoidian flap rather than try to fill in the space left free by a cuff, remaining after random reinsertion by a synthetic or other type of material. In the case of average retraction, not allowing for direct reinsertion of the supraspinatus muscle tendon, some authors recommend rotation flaps of the subscapularis muscle and/or the subspinatus muscle.

According to the above explanations, it can be understood that surgery of the shoulder is delicate, complex and a maximum of precautions have to be taken in order to guarantee or make the operation carried out reliable. It is also necessary to take into account the fact that the tissues are worn, thin and old.

~~It is for this reason that a first aim according to the invention was to look into reinforcing the tendons reinserted but thin or made fragile, including by infiltrations of corticoids and thus provide surgical therapy of the rupture or weakening of the rotator cuff of a shoulder joint of a person.~~

Another aim according to the invention was to produce a simple device, easily manufactured and biologically compatible.

Another aim according to the invention was to provide a pure ~~mechanical reinforcement by adding a substance enabling the~~



It is for this reason that there arises a need to look into reinforcing the tendons reinserted but thin or made fragile, including by infiltrations of corticoids and thus provide surgical therapy of the rupture or weakening of the rotator cuff of a shoulder joint of a person. An aim according to the invention was to produce a simple device that provides a pure mechanical reinforcement by adding a substance enabling the

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tendinous reinsertion zone to be protected and authorising more active post-operative rehabilitation.

By use of a device to the invention it is intended to obtain thickening of the tendons, enabling a final
5 biological reinforcing effect by integration of the material initially added.

According to the present invention there is provided a device used for the surgical therapy of the rupture or weakening of the rotator cuff of a shoulder joint of a
10 person, said device being made up of a strip with a rear heel adapted to be fixed onto the trochiter or the tendinous mass of the cuff of a shoulder joint and extending, in a linear manner, or by at least two divergent legs towards to the top of the cuff and adapted
15 to be applied against and fixed onto the tendon(s).

According to embodiment, the device is characterised wherein the strip comprises at least two divergent legs wherein one of the legs is fixed to a repaired tendon in order to reinforce it and protect it and the other leg(s)
20 are fixed onto other healthy tendon(s) according to the biomechanical working axes of the shoulder rotator cuff tendons.

According to another embodiment, the device is characterised wherein the strip is made of a thin, sterile
25 biocompatible material.

These characteristics and other will be made well apparent from the following description.

In order to clarify the invention, however without limiting it, embodiment of the invention are illustrated
30 by the accompanying drawings wherein:

Figures 1 and 2 are partial views of the anterior and posterior face of the top end of the right humerus of a person:

Figure 3 is an external side view of the joints of
35 the right shoulder:



Figure 4 is a top view showing the rotator cuff,

Figure 5 is a view of a tendon holding and supporting device according to the invention comprising a heel extended by two legs;

5 Figure 6 is a view of the device as an alternative model comprising a heel and three legs;

Figure 7 is a view illustrating the application of the device according to the invention in order to support certain tendons;

10 Figure 8 shows the device seen in a plan view, in a simple geometrical form; and

Figures 9 and 10 are views showing the device of figures 5 and 6 provided with fixing means at its ends.

The features of the invention will become more
15 apparent from the following non-limitating detailed description, when considered in conjunction with the drawings.

The device according to the invention is used in the surgical therapy of the rupture or weakening of the
20 rotator cuff of a shoulder joint.

The device as shown in the drawings is in the form of a strip (10) of a simple, rectangular or trapezoidal geometrical shape, or complex with two or several legs (10.2, 10.3, 10.4, 10.5, 10.6). The device is produced
25 according to a strip capable, for example, of being braided, knitted, woven, and more generally, made of all biocompatible materials. This strip is thin, sterile, biocompatible and short. The strip has, firstly, a base or heel (10.1) fixed by its ends (10.7) on the
30 trochiterian support or the tendinous mass of the cuff, and, secondly, is extended in a linear manner, or by two or three legs diverging towards the top of the cuff according to the biomechanical working axes of the rotator cuff tendons.



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The strip is extended towards the front by at least two divergent legs (10.2 - 10.3) defining a Y shape, likely to be applied and fixed against the tendons (figure 5). As an

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alternative form, according to figure 6, the strip has three diverging legs (10.4, 10.5, 10.6) ~~in a V shape~~. The general aspect of the strip as such, is rectangular or trapezoidal shaped and enables the reinforced cuff to work according to the biomechanical lines of forces, in the direction of the different tendons. According to a specific positioning, one of the legs (10.2 - 10.3) or (10.4, 10.5, 10.6) of the strip, is fixed and sewn by the end (10.8) onto the repaired tendon, thinned down and thus reinforced thereby protecting it, whereas the other leg(s) of the strip are sewn to the ends (10.8) on the other healthy tendon(s). The shape of the strip with three legs thereby enables sewing onto the supraspinatus, subspinatus and subscapularis tendons.

The legs (10.2, 10.3, 10.4, 10.5, 10.6) can be the same length or different lengths.

In its linear shape, the strip provides support of the tendon during weakening before rupture.

According to another arrangement, the ends (10.7 and 10.8) of the strip, are made up of a semi-rigid or flexible mass resulting from melting the component threads. They may include holes (11) made in this mass, facilitating the binding of the device on the trochiter or tendinous mass and on the healthy tendon(s). These holes exist in a number adapted to provide the binding and fixing.

Therefore, the shape with the holding and supporting device according to the invention, enables it to match the tendons of the rotator cuff perfectly thereby taking up the minimum of space so as not to cause an iatrogenic subacromial anterior conflict by increasing the bulk of the contents.

Furthermore, the device must be positioned on a reconstructed cuff, in an isometric manner, in order to enable the tendons to operate in the direction of the fibres and without excessive pulling.

According to another arrangement of the invention, the holding and supporting strip is made of a biologically compatible



material, thus enabling it to be biologically integrated
into living tissues. In an advantageous manner, this is a
braided polypropylene material. The material selected,
enables gradual integration of the reinforcing and holding
5 strip thereby providing thickening of the reconstructed
cuff and therefore, biological reinforcement.

It will be appreciated by persons skilled in the art
that numerous variations and/or modifications may be made
to the invention as shown in the specific embodiments
10 without departing from the spirit or scope of the
invention as broadly described. The present embodiments
are, therefore, to be considered in all respects as
illustrative and not restrictive.

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CLAIMS

1. A device for the surgical therapy of the rupture or weakening of the rotator cuff of a shoulder joint of a person, said device comprising a strip having a rear heel
5 adapted to be fixed onto the trochiter or on the tendinous mass of the cuff of a shoulder joint and being, in use, of linear extent towards the top of the cuff of the joint and adapted to be fixed onto the tendon(s).
2. A device according to claim 1, wherein the strip
10 comprises at least two divergent legs, wherein one of the legs is adapted to be fixed onto a repaired tendon in order to reinforce and protect it, and the other leg(s) are adapted to be fixed onto other healthy tendon(s) of the mass according to the biomechanical working axes of
15 the tendons of the rotator cuff of the shoulder.
3. A device according to claim 2, wherein the strip comprises two legs defining a complex Y shape.
4. A device according to claim 2, wherein the strip comprises three legs.
- 20 5. A device according to any one of the preceding claims, wherein the strip is braided, knitted or woven.
6. A device according to any one of the preceding claims, wherein the strip is made out of biocompatible material.
- 25 7. A device according to any one of the preceding claims, wherein the strip is made of braided polypropylene.
8. A device according to any one of claims 1, 2, 3, and 4, wherein the strip is trapezoidal shaped.
9. A device according to any one of claims 1, 2, 3 and
30 4, wherein the strip is adapted to be fixed at the end of its heel part, to the trochiter or tendinous mass and the ends (10.8) of its legs on healthy tendon(s) of said tendinous mass.
10. A device according to any one of claims 1, 2, 3 and
35 4, wherein ends of the device are made up of a semi-rigid



or flexible mass resulting from melting component threads, and including in these masses, holes facilitating the binding of the device onto the trochiter or tendinous mass and onto healthy tendon(s).

- 5 11. A device for the surgical therapy of the rupture or weakening of the rotator cuff of a shoulder joint of a person substantially as hereinbefore described with reference to any one of Figures. 5-10 of the accompanying drawings.

DATED this 18th day of June 1992

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Patent Attorneys for the
Applicant:

F.B. RICE & CO.

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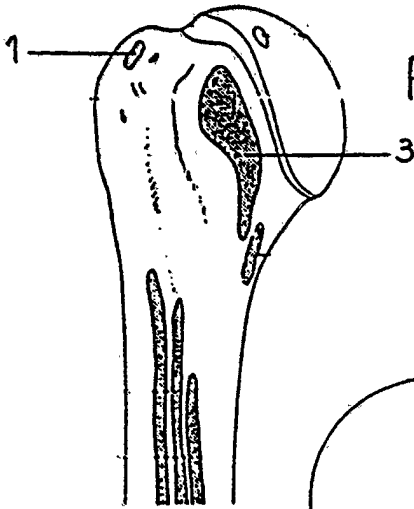


FIG. 1

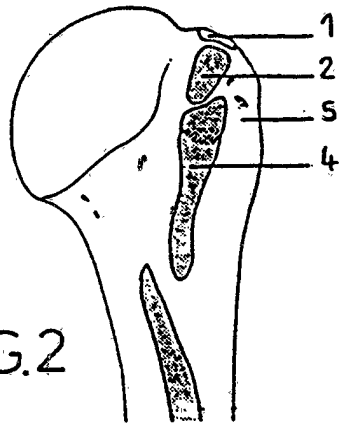


FIG. 2

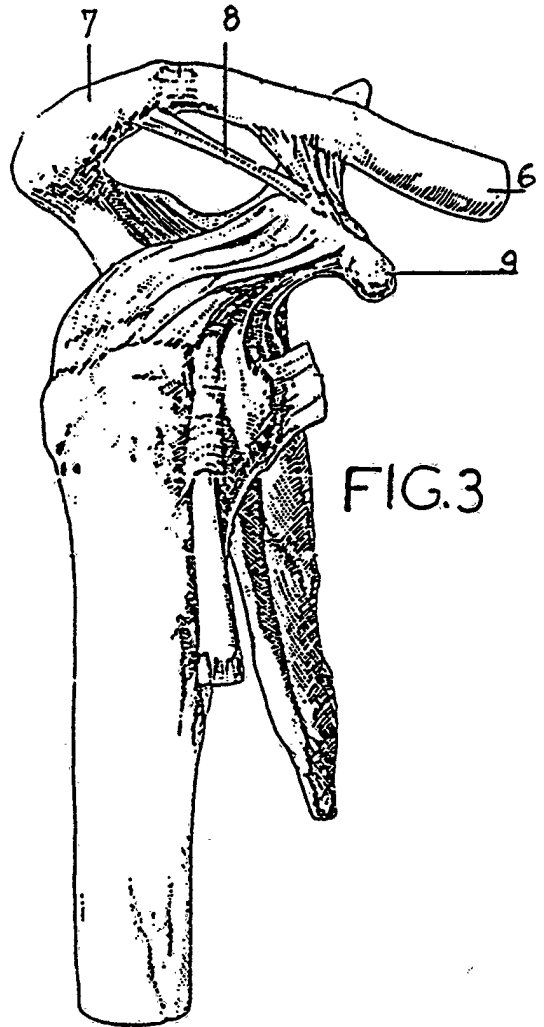
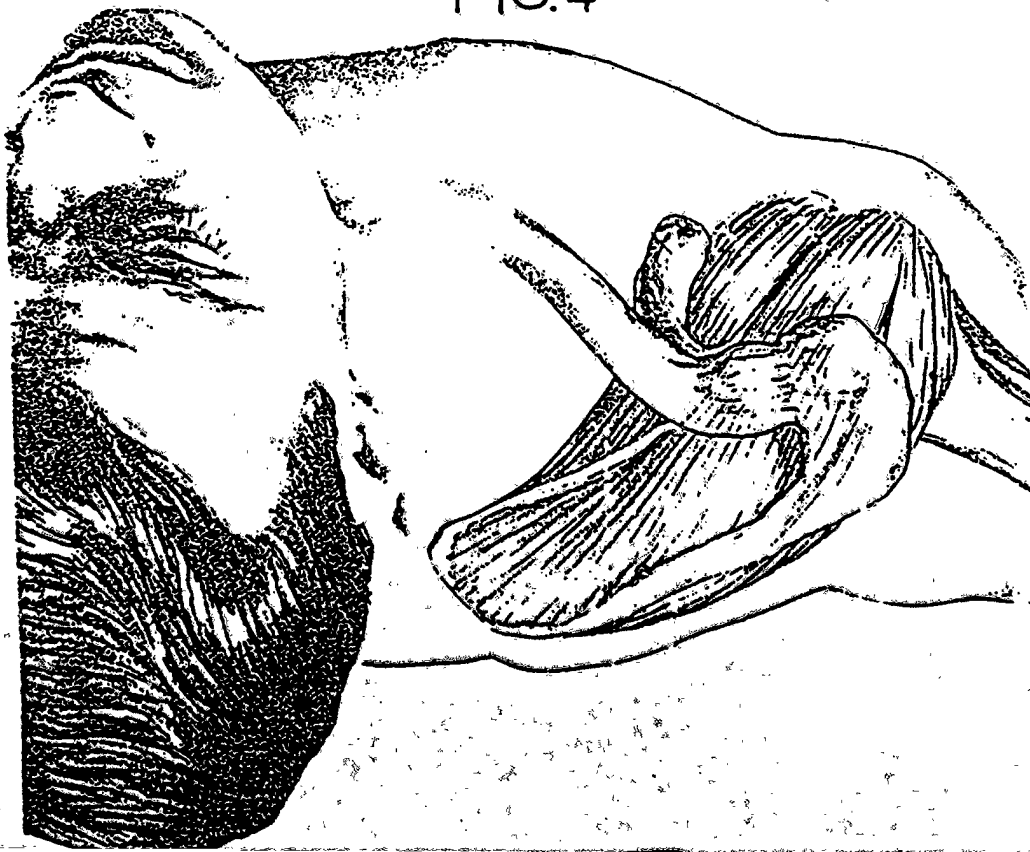


FIG. 3

FIG. 4



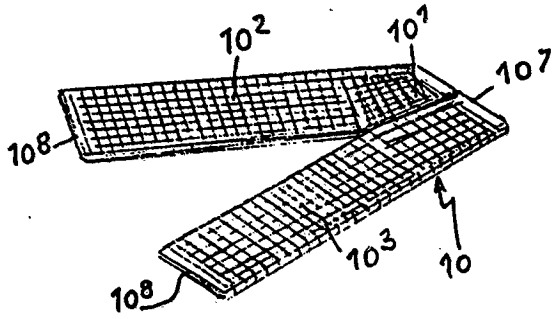


FIG. 5

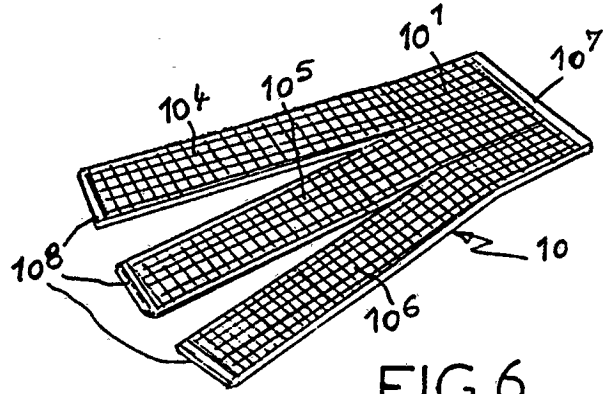
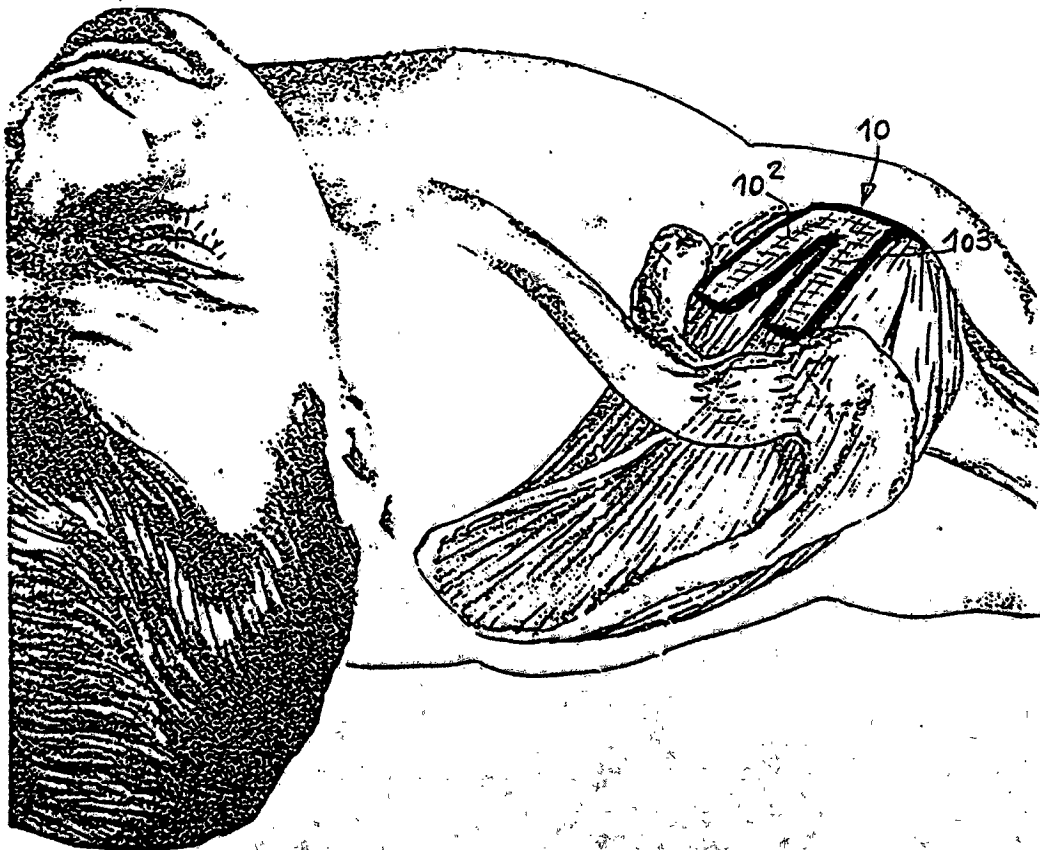


FIG. 6

FIG. 7



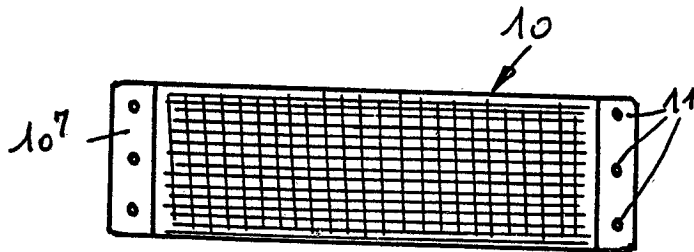


FIG. 8

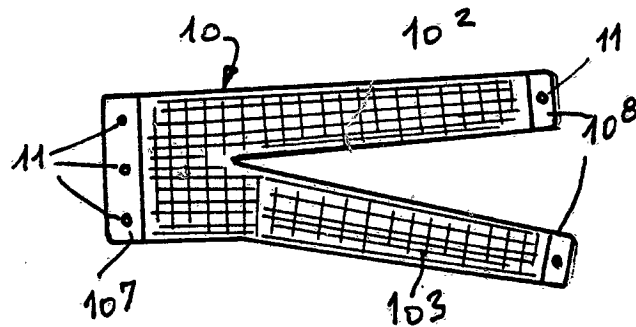
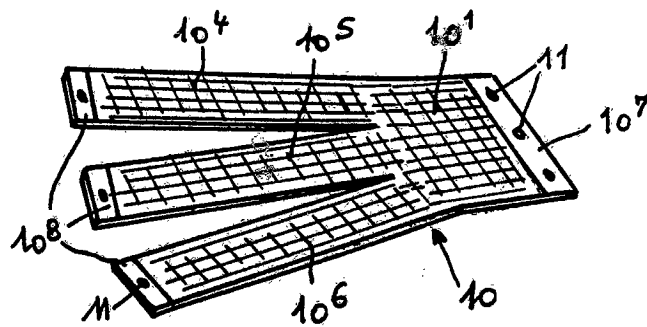


FIG. 9

FIG. 10



INTERNATIONAL SEARCH REPORT

International Application No PCT/FR 90/00291

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. ⁵ A 61 F 2/08, A 61 F 2/40, A 61 F 2/02		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. ⁵	A 61 F	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	DE, A, 3008270 (MEADOX MEDICALS) 17 September 1981 see claim 1; page 5, lines 6-17 ---	1
A	EP, A, 0169045 (JOHNSON & JOHNSON) 22 January 1986 see claim 1; figures 7,8; page 4, lines 23-35 ---	1
A	EP, A, 0239775 (AMERICAN CYANAMID) 7 October 1987 see claims 1,3,7; page 11, lines 17-20 ---	1
A	US, A, 4347847 (USHER) 07 September 1982 see column 2, lines 3-8; column 3, lines 41-47; claims 1,2 ---	1,4-6
A	US, A, 4769038 (BENDAVID) 6 September 1988 see claim 1; figure 1 -----	1
<p>¹⁰ * Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"G" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
13 August 1990 (13.08.90)		14 September 1990 (14.09.90)
International Searching Authority		Signature of Authorized Officer
EUROPEAN PATENT OFFICE		

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

FR 900291
SA 36911

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 12/09/90. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A- 3008270	17-09-81	None	
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		CA-A- 1236652	17-05-88
		US-A- 4642119	10-02-87
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		AU-B- 594435	08-03-90
		AU-A- 6959887	10-09-87
		JP-A- 62270152	24-11-87
		US-A- 4942875	24-07-90
		ZA-A- 8701489	21-08-87
US-A- 4347847	07-09-82	US-A- 4452245	05-06-84
US-A- 4769038	06-09-88	None	

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