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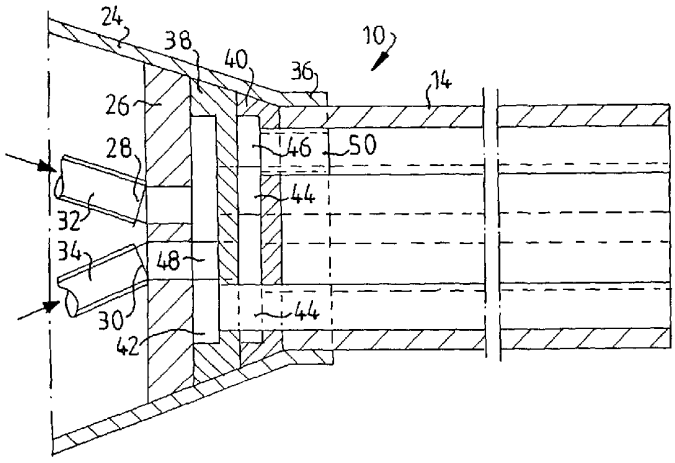
(54) **Title:** A DEVICE AND A METHOD FOR DISPENSING AT LEAST TWO MUTUALLY REACTIVE COMPONENTS



(57) **Abstract:** A device for dispensing at least two mutually reactive components, such as fibrino-gen and thrombin, comprising a supplier (12A, 12B) having a primary channel for supplying a respective one of said at least two reactive components to a dispenser (14) having secondary channels (18A, 18B) for separately discharging said compo-nents at a distal end orifice thereof opening into a target area for external intimate mixing of the respective reactive components outside a distal tip end of said dis-penser (14). A distributor (38, 40) is interposed between said supplier and said dis-penser for multiplying the number of the respective primary channels with at least a factor 2. Adjacent ones of said secondary channels (18A, 18B) are adjoined to pri-mary channels (32, 34) intended for supply of reactive components of different kind.

WO 02/055138 A1

A DEVICE AND A METHOD FOR DISPENSING AT LEAST TWO MUTUALLY REACTIVE COMPONENTS

BACKGROUND OF THE INVENTION

1. Field of the invention

The present invention relates in general to a device for dispensing at least two mutually reactive components. In particular, but not exclusively, the present invention is related to a device for applying an accurately mixed solution of reactive sealant components, such as fibrinogen and thrombin, to biological tissue, for example for effecting hemostasis or for achieving any other therapeutic objective.

The invention also relates to a method for dispensing at least two mutually reactive components.

2. Description of related art

Various kinds of apparatuses are known for applying a two-component sealant mixture of fibrin or fibrinogen and thrombin to a human tissue in order to stop bleeding or to close blood vessels.

E.g. US-A- 5 322 510 discloses an injection-type apparatus for injecting at least two mutually reactive sealant components, wherein the apparatus comprises a hollow needle member having parallel, coaxially extending or side-by-side arranged lumens for each sealant component. The components are supplied to the injection needle through a corresponding number of hoses, which, at a proximal end thereof, are provided with syringe coupling connections for the supply of the respective reactive components. The distal end orifices of the lumens all lie in a common plane so that a mixing and a reaction of the components will commence as they emerge therefrom thereby forming a fibrin glue at the site of delivery. However, due to the fact that the

number of outlet lumens are equal to the number of reactive components to be mixed, an optimal or sufficient mixing of the components will not always be ensured.

Many previously known devices for dispensing a mixture of various fluids, i.a. reactive liquids and gaseous media, (see e.g. WO 97/17133, WO 00/18469, SE-B-432 059) are provided with at least two primary inlet channels for supplying respective fluids to be mixed to a mixing member which divides the fluid streams from the primary inlet channels into a plurality of smaller secondary fluid streams, which may cross each other at outlet orifices of the mixing member so as to be efficiently mixed in a separate mixing chamber downstream thereof before the mixture is delivered to the site of its application. However, in such devices clogging may occur in the mixing chamber and at the outlet opening thereof between the cycles of application, which necessitates either an ejection of the solidified material therein or a removal and change of the tip end piece before it can be reused.

EP 0 858 775 A1 discloses a fibrin sealant applicator (fig. 15) for mixing two different fluid components, one supplied through a plurality of radially inwardly directed holes of a circular conduit, and the other supplied through a single axial orifice of a central conduit. This structure does not have a distributor between each primary component supplying channel and respective secondary component discharging channels, wherein each distributor multiplies the number of respective primary channels with at least a factor 2, such that adjacent ones of the secondary channels are adjoined to primary channels intended for supply of reactive components of different kind.

SUMMARY OF THE INVENTION

An object of the present invention is to solve the above-mentioned problems of the previously known devices and to provide an improved two- (or more) component

applicator which is capable of dispensing a plurality of discrete adjacent streams of the components and to bring the same to be accurately mixed and cured at target site of application on various occasions and at timely spaced intervals without any clogging problems occurring at the outlet of the device.

According to the present invention these problems are solved by a device for dispensing at least two mutually reactive components, such as fibrinogen and thrombin, comprising a component supplier having a primary channel for supplying a respective one of said at least two reactive components to a component dispenser having secondary channels for separately discharging said reactive components at a distal end orifice thereof opening into a free target area for external intimate mixing of the respective reactive components outside a distal tip end of said dispenser, wherein a distributor is interposed between said supplier and said dispenser for multiplying the number of the respective primary channels with at least a factor 2 , and adjacent ones of said secondary channels are adjoined to primary channels intended for supply of reactive components of different kind.

The method of the present invention for dispensing at least two mutually reactive components so as to allow for an intimate and accurate mixture and reaction thereof upon reaching a target site for their application is characterized by the steps of:
feeding a primary flow of said at least two reactive components through respective primary conduits, and
dispensing through distal end orifices of secondary conduits a plurality of secondary flows of said reactive components, derived from each of said primary flows of reactive components, in a pattern such that different reactive components are dispensed in close proximity through adjacent secondary conduit end orifices.

Other features and structural details of the device and the method of the present invention are disclosed in the following description and set forth in the accompanying dependent claims with reference to the attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic perspective view of a first embodiment of a device of the present invention for dispensing two reactive sealant components;

Fig. 2 is an enlarged perspective view of the encircled section of the device in fig. 1;

Figs. 3a-e illustrate alternative outlet end orifice configuration of the inventive device;

Fig. 4 is a schematic, sectional side view of a further embodiment of a device of the present invention for dispensing two reactive sealant components; and

Fig. 5 is an end view of the device in fig. 4.

DESCRIPTION OF PREFERRED EMBODIMENTS

Figs. 1 and 2 schematically show a first structural embodiment of a device 10 of the present invention for dispensing two reactive sealant components, such as fibrinogen and thrombin, for obtaining an intimate mixture of the respective reactive components immediately after exiting the distal outlet end of the device while avoiding clogging of sealant material within the device after a dispensing sequence. The device 10 comprises a component supplier in form of a first piston-activated supply container 12A and a second piston-activated supply container 12B which through two merging tubes 13A and 13B are adapted to supply a respective reactive fluid component (typically fibrinogen and thrombin) to an elongate tubular dispenser or applicator member 14 for separately discharging the components at a distal end thereof. In order to ensure an accurate and intimate mixture of the two reactive sealant components directly at a site for its application to human tissue the device is provided with a distributor 16A and 16B (fig. 2) for distributing the supply of the

sealant components from the respective container 12A and 12B to a plurality of respective secondary channels or lumens 18A and 18B being alternately separated in the circumferential direction of the tubular applicator member 14. In the embodiment shown in figs. 1 and 2, the distributor 16A and 16B thus multiply the number of each component supply flow with a factor 3, i.e. the flow of e.g. fibrinogen from the container 12A is split into three flows in tubes 20, whereas the flow of thrombin from the container 12B is likewise split into three flows in tubes 22. As shown more clearly in fig. 2, there are thus all together six channels or lumens 18A and 18B evenly separated circumferentially and alternately in the tubular member 14. Owing to the splitting up and a finely division of each main flow of reactive component into three secondary flows and allowing them to exit alternately and closely to one another as separate streams from free external distal outlet orifices of the lumens 18A and 18B, the secondary flows or streams of reactive components will create a well-defined sealant mixture at the target site where the two components are unified through diffusion without need for any additional mechanical mixing equipment. It should be noted that the mixing phase is not taking place in a mixing chamber defined by the device downstream of the outlet orifices where the subsequently solidified or cured sealant can clog the outlets of the tubular member 14 but in a free target area at the site of the application of the components, e.g. to human tissue where a bleeding is to be stopped.

The cross-section of the secondary channels 18A, 18B may have any suitable configuration, such as circular (figs. 2 and 3a and e), or sector-shaped (figs. 3b and c), or ring-shaped (fig. 3d). The perimeter of the tubular applicator 14 is preferably circular but may have any other suitable configuration, such as rectangular (fig. 3e). The number of secondary channels for each sealant component should be at least two (fig. 3b and d) but preferably three or more (figs.2, 3a and 3c). The distal outlet orifices of the lumens 18A and 18B preferably lie in a common plane which may be normal or inclined to the longitudinal axis of the tubular member 14.

Furthermore, in order to obtain the desired well-defined mixture of the two components it is necessary to divide the two main flows from the containers 12A, 12B into fine part streams emitting from the distal end orifices of the lumens 18A, 18B. For this purpose the diameter of the lumens 18A, 18B and/or the distal end orifices thereof should, in dependence of the actual number thereof, generally lie within the interval 0,01-2 mm, preferably 0,05-1 mm, and most favourably 0,1-0,8 mm. Thus, in a suitable embodiment of the device of the present invention the diameter of the lumens 18A, 18B (or their orifices) may be 0,3 mm, in which case the outer diameter of the tubular applicator 14 is 1,7 mm. Preferably, the tubular applicator 14 is flexible so as to make it easier to reach more remotely located target areas, e.g. in various hollows of a human body.

In figs. 4 and 5 there is shown a second embodiment of a device for dispensing two mutually reactive sealant components according to the present invention. This embodiment comprises a connector housing 24 having a proximal insert piece 26 provided with two inlet fittings 28 and 30 for a respective tube 32 and 34. The tubes 32, 34 are, at a proximal end thereof, connected to a respective supply container or luer coupling (not shown) to which a respective syringe or the like may be connected for supplying a respective reactive fluid component, such as fibrinogen and thrombin. The housing 24 has a hub portion 36 to which a proximal end of an elongate tubular applicator member 14 having six secondary channels 18A and 18B - like in the embodiment of figs. 1 and 2 - can be attached. In the housing 24, between the insert piece 26 and the proximal end of the tubular applicator member 14, there are mounted two elements 38 and 40 for distributing the respective fluid components from the inlet tubes 32 and 34 to the six corresponding secondary channels 18A and 18B such that, as shown in fig. 5, the respective fluid components are evenly separated circumferentially and alternately in the tubular member 14. A first one 38 of said distribution elements has a collection chamber 42 for receiving a flow of e.g. fibrinogen from the inlet tube 32 via the fitting 28, and three tubular outlet fittings 44 inserted into corresponding lumens 18A in the applicator member 14, whereas a

second one 40 of said distributing elements has a collection chamber 46 for receiving a flow of e.g. thrombin from the inlet tube 34 via the fitting 30 and a leading-in tube 48 extending through said first distributing element 38. The second distributing element 40 has likewise three tubular outlet fittings 50 inserted into corresponding lumens 18B in the applicator member 14. Also this embodiment provides a well-defined sealant mixture by diffusion outside the distal end of the tubular applicator member 14 without causing any clogging of solidified sealant material inside the secondary channels or lumens 18A and 18B.

CLAIMS

1. A device for dispensing at least two mutually reactive components, such as fibrinogen and thrombin, comprising a first component supplier (12A, 12B) having a primary channel for supplying a respective one of said at least two reactive components to a component dispenser (14) having secondary channels (18A, 18B) for separately discharging said components at a distal end orifice thereof opening into a free target area for external intimate mixing of the respective reactive components outside a distal tip end of said dispenser (14), **characterized** by a distributor (16A, 16B; 38, 40) interposed between said supplier (12A, 12B) and said dispenser (18A, 18B) for multiplying the number of the respective primary channels with at least a factor 2, adjacent ones (18A, 18B) of said secondary channels being adjoined to primary channels (16A, 16B) intended for supply of reactive components of different kind.

2. A device as set forth in claim 1, wherein each distributor (38, 40) comprises an inlet collection chamber (42, 46) communicating with respective secondary channels (18A, 18B) through at least two tubular branch fittings (44, 50).

3. A device as set forth in claim 1, wherein each distributor (16A, 16B) comprises at least two branch tubes (20, 22) connecting each supplier (12A, 12B) to the respective dispenser (14).

4. A device as set forth in any one of claim 1-3, wherein said secondary channels are formed as elongate, parallel lumens (18A, 18B) extending side by side and evenly distributed circumferentially in a common cylindrical body (14).

5. A device as set forth in claim 4, wherein said lumens (18A, 18B) have a circular cross-section.

6. A device as set forth in claim 4, wherein said lumens (18A, 18B) have a segment-shaped cross-section

7. A device as set forth in claim 1, wherein said secondary channels (18A, 18B) are formed as elongate, parallel lumens having a substantially annular cross-section and extending coaxially within a cylindrical body.

8. A device as set forth in claim 1, wherein said secondary channels are formed by a bundle of individual tubular elements.

9. A device as set forth in any one of claims 1-6, wherein the number of secondary channels (18A, 18B) is six.

10. A device as set forth in any one of claims 1-6, wherein the number of secondary channels (18A, 18B) is eight.

11. A device as set forth in any one of claims 1-10, wherein the diameter of the secondary channels (18A, 18B) is between 0,01 and 2 mm.

12. A device as set forth in claim 11, wherein the diameter is between 0,05 and 1 mm.

13. A device as set forth in claim 12, wherein the diameter is preferably between 0,1 and 0,8 mm.

14. A method for dispensing at least two mutually reactive components so as to allow for an intimate and accurate mixture and reaction thereof upon reaching a target site for their application, **characterized by** the steps of:
feeding a primary flow of said at least two reactive components through respective primary conduits (12A, 12B), and

dispensing through distal end orifices of secondary conduits (18A, 18B) a plurality of secondary flows of said reactive components, derived from each of said primary flows of reactive components, in a pattern such that different reactive components are dispensed in close proximity through adjacent secondary conduit end orifices.

15. Method as set forth in claim 14, wherein the secondary flows of reactive components exiting from said distal end orifices are applied directly to the target site without coming into contact with any intermediate surface.

16. Method as set forth in claim 14, wherein the secondary flows of reactive components are brought to immediate mutual contact and mixture when exiting from said distal end orifices.

17. Method as set forth in claim 14, wherein the diameter of the secondary flows is between 0,01 and 2 mm.

18. Method as set forth in claim 17, wherein the diameter is between 0,05 and 1 mm.

19. Method as set forth in claim 18, wherein the diameter is preferably between 0,1 and 0,8 mm.

20. Method as set forth in claim 14, wherein the number of secondary flows is six.

21. Method as set forth in claim 14, wherein the number of secondary flows is eight.

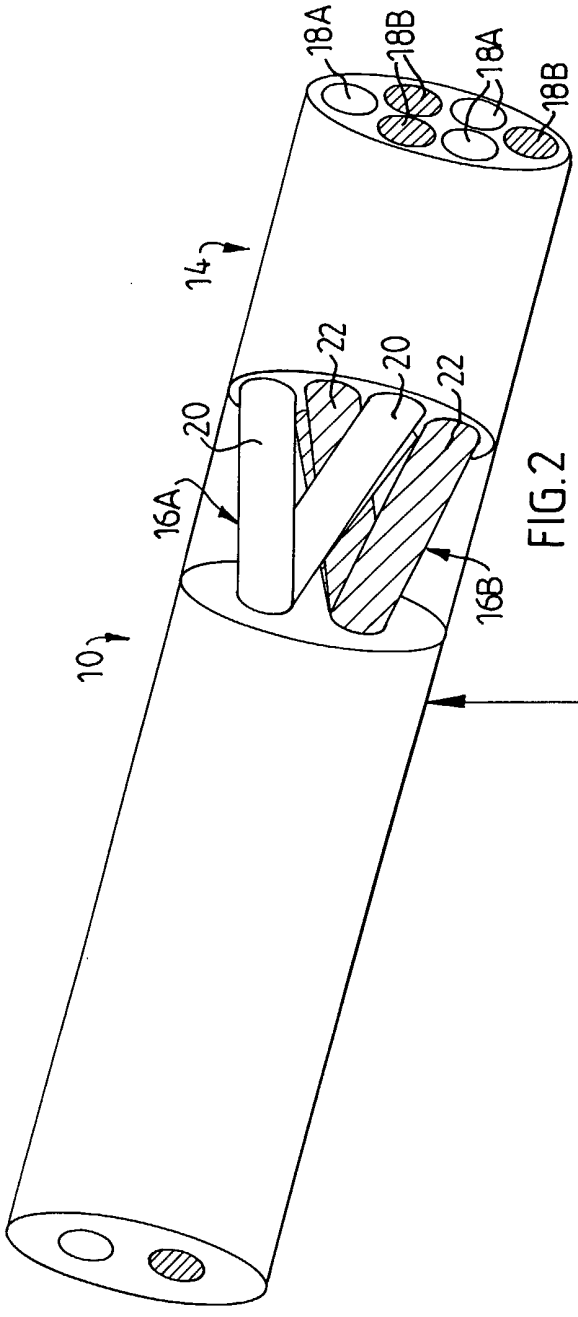


FIG.2

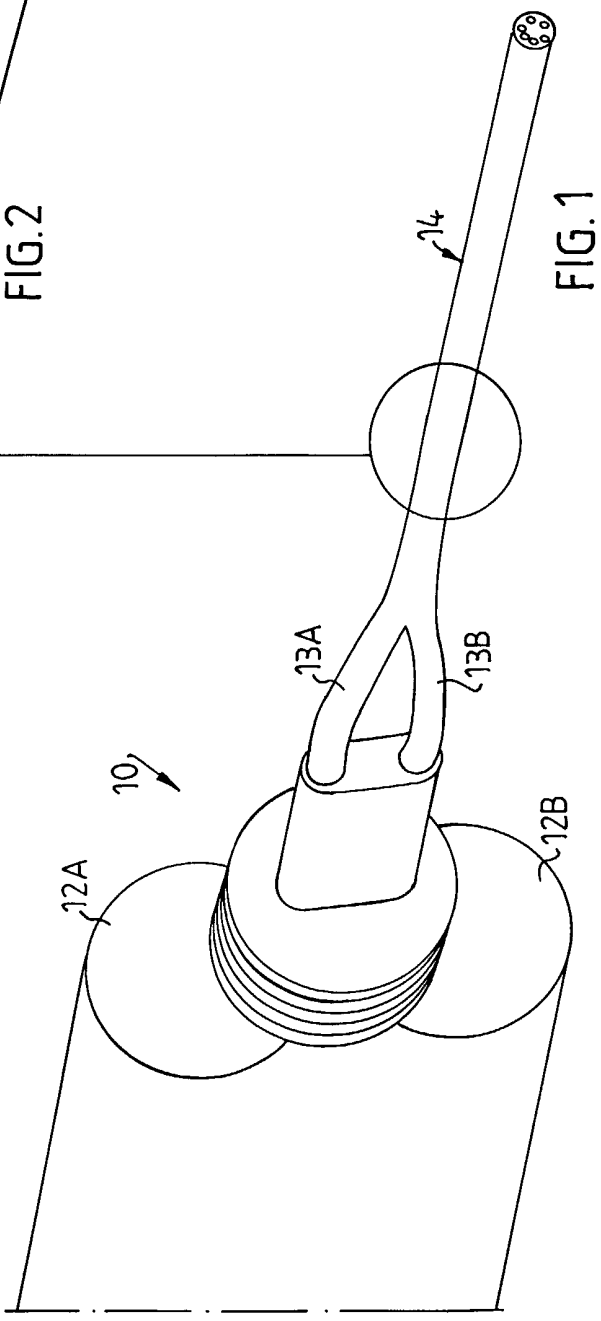


FIG.1

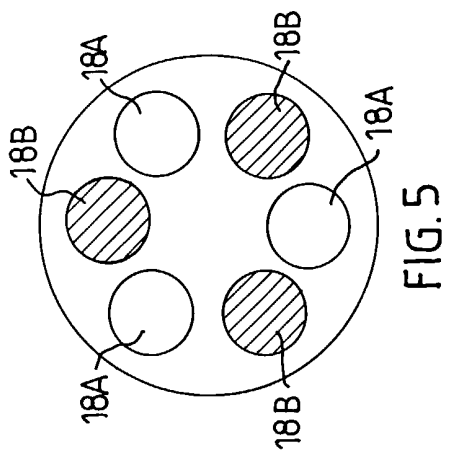


FIG.5

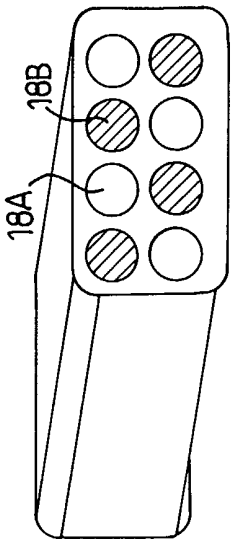


FIG.3e

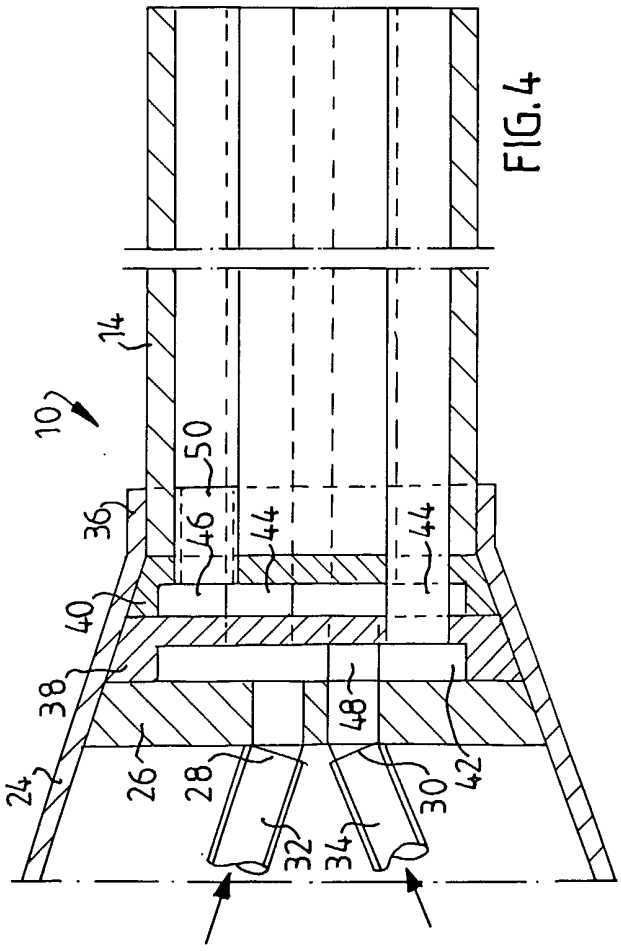


FIG.4

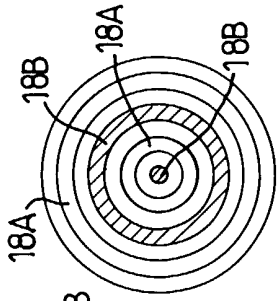


FIG.3d

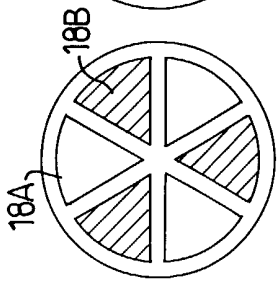


FIG.3c

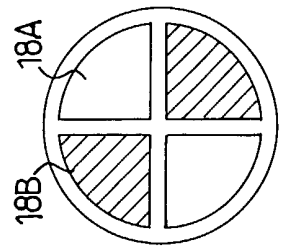


FIG.3b

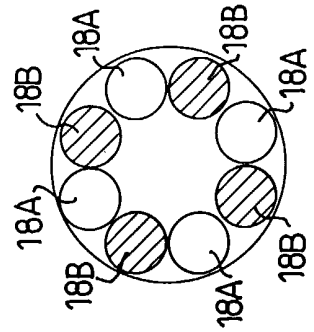


FIG.3a

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 01/02707

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 5/19
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)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0858775 A1 (UNITED STATES SURGICAL CORPORATION), 19 August 1998 (19.08.98), figures 15,1b, details 132 and 136 --	1-2,14-19
A	US 5605541 A (NIELS-ERIK HOLM), 25 February 1997 (25.02.97), figures 1-5, claims 1-16 --	1-21
A	EP 0424068 A2 (JOHNSON & JOHNSON MEDICAL, INC.), 24 April 1991 (24.04.91), figures 1-5, claims 1-16 --	1-21
A	WO 9639212 A2 (QUANTIC BIOMEDICAL PARTNERS), 12 December 1996 (12.12.96), figures 1-4, claims 1-20 --	1-21

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"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
15 March 2002	15 -03- 2002
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Agneta Änggård/Els Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

28/01/02

International application No.
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