



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/NL97/00390 (22) International Filing Date: 7 July 1997 (07.07.97) (30) Priority Data: 1003542 8 July 1996 (08.07.96) NL (71) Applicant (for all designated States except US): B.V. OPTISCHE INDUSTRIE "DE OUDE DELFT" [NL/NL]; Postbus 72, NL-2600 MD Delft (NL). (72) Inventors; and (75) Inventors/Applicants (for US only): LÖFFLER, Edgar, German [DE/DE]; Bresserbergstrasse 72, D-47533 Kleve (DE). SPEISER, Burton, Lyle [US/US]; 9901 N. 50th Street, Scottsdale, AZ 85253 (US). (74) Agent: VAN DER BURG, Louis; B.V. Optische Industrie "De Oude Delft", Postbus 72, NL-2600 MD Delft (NL).</p>		<p>(81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> <i>In English translation (filed in Dutch).</i></p>
<p>(54) Title: NEEDLE ASSEMBLY FOR BRACHYTHERAPY</p> <div data-bbox="290 1220 1372 1487" data-label="Image"> </div> <p>(57) Abstract</p> <p>Needle assembly for brachytherapy, comprising a needle with a sharp point, and a sleeve, in which the needle with the sharp point just fits, with the sharp point extending past the distal end of the sleeve, it being possible, in operation, to retract the needle with the sharp point at least sufficiently far into the sleeve for the sharp point to disappear into the sleeve.</p>		

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Needle assembly for brachytherapy

The invention relates to a needle assembly for brachytherapy.

5 A needle assembly of this kind usually comprises a needle with a hollow shank, which is open at a proximal end and is provided with a sharp point at the distal end.

10 Needles of this kind are used to treat internal tumours and the like (brachytherapy). To do this, one or more needles are inserted in a predetermined pattern into the tissue of a patient in the vicinity of the tumour to be treated. The tumour is then irradiated with the aid of miniature radioactive sources which have been pushed into the hollow needles.

15 A drawback of this known method is that the needles frequently have to remain in the body of the patient for some time (up to several days). In this event, movements of the patient may lead to the sharp points of the needles, which are necessary in order to apply the needles accurately and with as little discomfort as possible for the patient, damaging the tissue of the patient unnecessarily.

The object of the invention is to obviate the abovementioned drawback.

25 The invention will be described in more detail below with reference to the accompanying drawing of an exemplary embodiment.

Figure 1 diagrammatically shows in longitudinal section an example of a conventional needle for brachytherapy;

30 Figure 2 diagrammatically shows an exemplary embodiment of a needle assembly according to the invention in the insertion position;

Figure 3 diagrammatically shows the needle assembly of Figure 2 in the therapeutic position.

35 Figure 1 shows in longitudinal section an example of a known needle 1 for brachytherapy. The needle has a hollow shank 2, which at the distal end is closed off by a point 3 of the trocar type. At the proximal end, the needle is provided with a handle 4 for manipulating the needle. The needle is intended to be inserted into the body of a

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patient, generally together with a number of similar needles, until it is close to a tumour. After a needle has been introduced, a radiation source is pushed into the hollow shank of the needle, in order to irradiate the adjacent tumour.

The needles sometimes have to remain in the therapeutic position, that is to say the position in which the irradiation takes place, for a relatively long period of time. Since the points of the needles are very sharp, there is the danger here of the internal tissue of the patient being damaged unnecessarily, which obviously is undesirable. Another risk is that the points project past the organ to be irradiated and are situated (very) close to other organs, resulting in a considerable risk of damaging these other organs. However, sometimes it is necessary to insert the points past the organ to be irradiated, since the radioactive source cannot move to the front of the point.

Figure 2 diagrammatically shows an example of part of a needle assembly 10 for brachytherapy according to the invention, in the position in which it is ready to be introduced into the body of a patient. The needle assembly shown comprises a sleeve 11, which is open at the distal end and at the proximal end is provided with a handle 12 for manipulating the needle. The actual needle 13 is situated inside the sleeve and is provided with a point 14, which extends past the distal end of the sleeve 11 and may be closed, as shown, or open. After the needle 13 provided with the sleeve 11 has been introduced into the body of a patient at the desired location, the needle, which is provided with a separate handle 15, is pulled out of the sleeve 11, the sleeve remaining in the original location in the body of a patient. A hollow needle with a blunt point is then pushed into the sleeve 11.

Figure 3 shows an example of a hollow needle 16 of this kind, which is provided with a rounded end 17. A wire 18 or the like, which at the distal end bears a capsule 19 containing radioactive material 20, can then be pushed in the conventional manner into the hollow needle arranged in this way in the sleeve in the body of a patient.

Using a needle with a blunt point, which has replaced the needle with a sharp point, during the therapy prevents unnecessary damage to the tissue of the patient.

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Also, the radioactive material can move closer to the end of the blunt, hollow needle. In addition, the blunt, hollow needle may be made of thinner or weaker material, since the sleeve contributes to the strength of the overall assembly.

5 Since the sharp needle 13 is not used during the therapeutic phase, the needle 13 does not have to be hollow. The needles 13 and 16 and the sleeve 11 may be made from a suitable metal, such as for example stainless steel, but also from a suitable plastic. Combinations are also

10 possible, in which for example the sharp needle is a metal needle and the sleeve and/or the blunt needle are made of plastic. Furthermore, the needles and the sleeve may have a straight or curved form.

The sharp needle and the blunt, hollow needle may be

15 provided with coupling means at the proximal end, in order to fix the needles and the sleeve with respect to one another during the introduction of the sharp needle and the sleeve, respectively, during the therapeutic treatment. For this purpose, for example the handles 12 and 15 and/or a

20 similar handle of the blunt needle and the handle 15 may be connectable by means of a suitable, known coupling mechanism, such as for example a coupling of the bayonet coupling type, a knurled screw coupling, or the like.

As an alternative, it is possible to retract the sharp

25 needle only partially, so that the sharp point comes to rest inside the sleeve and can no longer cause any damage. Then, the radioactive source required for the irradiation therapy is introduced into the sharp needle, which for this purpose then needs to be hollow.

30 It should be noted that, in view of the above, various modifications will be obvious to the person skilled in the art. For example, as shown in Figure 4, the sleeve 11 could be provided at the distal end with a collar 30 which extends inwards and is able to interact with a shoulder

35 which is situated just behind the point 32 of the sharp needle or of the blunt needle. The needles are then unable to slide through past the distal end of the sleeve. However, this effect can also be achieved by means of the abovementioned coupling mechanism at the proximal end.

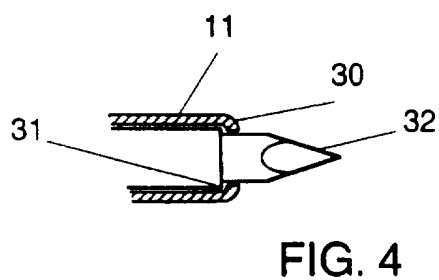
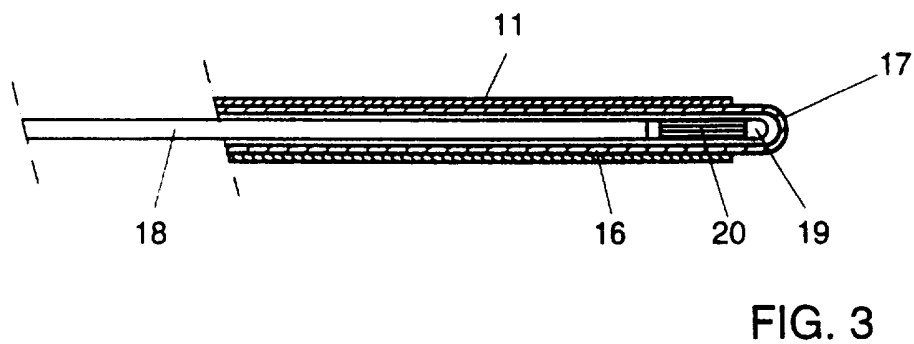
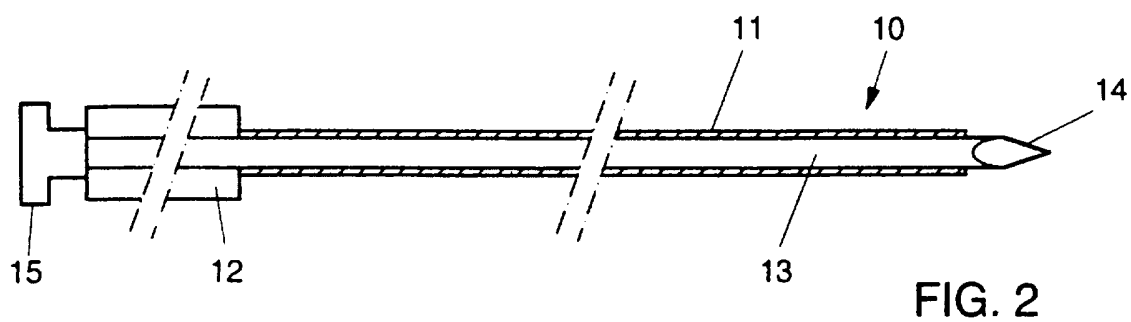
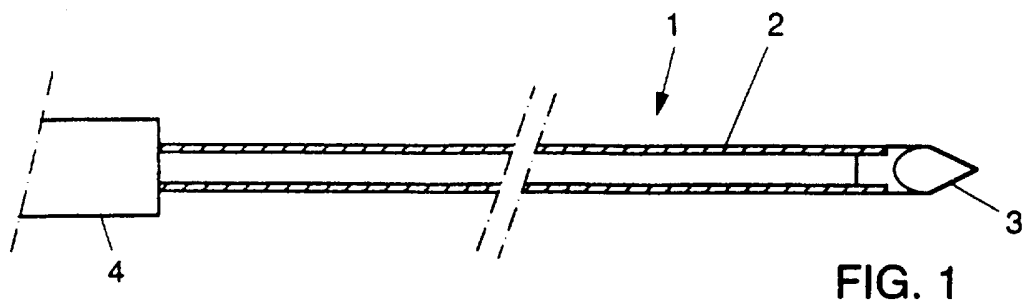
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CLAIMS

1. Needle assembly for brachytherapy, comprising a needle with a sharp point, and a sleeve, in which the needle with the sharp point just fits, with the sharp point extending  
5 past the distal end of the sleeve, it being possible, in operation, to retract the needle with the sharp point at least sufficiently far into the sleeve for the sharp point to disappear into the sleeve.
2. Needle assembly according to Claim 1, characterized in  
10 that the needle with a sharp point is a hollow needle, in which a radioactive source can be arranged.
3. Needle assembly according to Claim 1, characterized in that the needle with a sharp point can be retracted completely out of the sleeve, and in that a hollow needle  
15 with a blunt point is provided, which can be pushed into the sleeve and in which a radioactive source can be arranged.
4. Needle assembly according to one of the preceding claims, characterized in that the sleeve has, at the distal end, an  
20 internal collar which is able to interact with a shoulder situated behind the point of a needle to be accommodated in the sleeve.
5. Needle assembly according to one of the preceding claims, characterized in that the sleeve is provided at the  
25 proximal end with a coupling mechanism which is able to interact with coupling means at the proximal end of the needles which can be accommodated in the sleeve.
6. Needle assembly according to Claim 5, characterized in that the coupling means are provided on a handle of a  
30 needle which can be accommodated in the sleeve.
7. Method of positioning a radioactive source with the aid of a hollow needle, characterized in that a needle with a sharp point is provided with a closely fitting sleeve, the sharp point extending past the distal end of the needle;  
35 in that the needle provided with the sleeve is inserted into a desired position in the body;  
in that the needle with a sharp point is pulled out of the sleeve while retaining the positioning of the sleeve;  
in that a closely fitting hollow needle with a blunt distal  
40 end is then pushed into the sleeve; and  
in that at least one radioactive source is arranged in the blunt, hollow needle.
8. Method according to Claim 7, characterized in that the

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hollow needle is pushed into the sleeve over a length which is based on the distance between the proximal end of the sleeve and the point of the sharp needle before the sharp needle is pulled out of the sleeve.





# INTERNATIONAL SEARCH REPORT

International application No  
PCT/NL 97/00390

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61M25/06 A61N5/10

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61N

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

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

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 402 308 A (SCOTT) 6 September 1983 see column 3, line 43 - column 5, line 17; figures ---	1-3,5,6
A	US 4 610 242 A (SANTANGELO) 9 September 1986 see column 5, line 3 - line 46; figures 2A,2B ---	1,3,5,6
A	GB 2 120 947 A (NATIONAL RESEARCH DEVELOPMENT CORPORATION) 14 December 1983 see page 1, line 34 - line 92; figure 1 ---	1,4
A	EP 0 255 123 A (SUMITOMO PHARMACEUTICALS) 3 February 1988 see abstract; figures -----	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

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Date of the actual completion of the international search

26 August 1997

Date of mailing of the international search report

03 November 1997 803.11.97)

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/NL 97/00390**Box I Observations where certain claims were found unsearchable (Continuation of item 1 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. ☒ Claims Nos.: 7,8  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

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

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2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
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.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/NL 97/00390

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US 4402308 A	06-09-83	NONE	
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