



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification⁶ : A61C 8/00</p>	<p>A1</p>	<p>(11) International Publication Number: WO 95/17135</p> <p>(43) International Publication Date: 29 June 1995 (29.06.95)</p>
<p>(21) International Application Number: PCT/SE94/01226</p> <p>(22) International Filing Date: 20 December 1994 (20.12.94)</p> <p>(30) Priority Data: 9304208-3 20 December 1993 (20.12.93) SE</p> <p>(71) Applicant (for all designated States except US): NOBEL-PHARMA AB [SE/SE]; P.O. Box 5190, S-402 26 Göteborg (SE).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): RANGERT, Bo [SE/SE]; Klarbärsvägen 1, S-435 43 Mölnlycke (SE). LANGER, Burton [US/US]; 404 East 79 Street, New York, NY 10020 (US). JOHANSSON, Ulf [SE/SE]; Blåsippevägen 14, S-439 00 Onsala (SE).</p> <p>(74) Agent: OLSSON, Gunnar; Nobelpharma AB, P.O. Box 5190, S-402 26 Göteborg (SE).</p>		<p>(81) Designated States: AU, CA, FI, JP, NO, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published With international search report. In English translation (filed in Swedish).</p>
<p>(54) Title: SECURING ELEMENT</p>		
<p>(57) Abstract</p> <p>The invention relates to a screw-type securing element, made of titanium, for permanent anchoring in bone tissue, in particular for permanent anchoring of artificial teeth and dental bridges in the jaw bone, the securing element having an outer threaded portion which at the far top merges into a smooth, conical and/or cylindrical flange (5, 9). The thread end is such that the thread (1) in the periosteal part of the securing element merges into the flange (5, 9) via a cylindrical groove (7) which has the geometry of the threading die. By means of maintaining, in this way, a correct thread pitch and thread depth right up to the flange, a geometrically satisfactory match is obtained, in which the previously threaded hole matches the geometry of the thread right up to the flange, which means that the cortical bone can be better utilized.</p> <div data-bbox="973 1209 1372 2016" style="text-align: right;"> </div>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

- 1 -

SECURING ELEMENT

The invention relates to a screw-type securing element, made of titanium, for permanent anchoring in bone tissue, in particular for permanent anchoring of artificial teeth and dental bridges in the jaw bone, the securing element having an outer threaded portion which at the far top merges into a smooth, conical and/or cylindrical portion. The front part of the screw is preferably provided with one or more recesses whose margins adjoining the circular symmetrical surface of the securing element form cutting edges in order to permit self-tapping when the element is being screwed into the bone tissue.

Screw-type securing elements, made of titanium, for replacing lost teeth have been shown to have many advantages. The outer thread of the securing element constitutes a natural positive locking in the bone and gives initial stability, and it distributes the load favourably to the surrounding bone tissue. Recent long-term clinical follow-up studies have underlined the fact that threaded securing elements are in this respect more advantageous than unthreaded ones. The position of the boundary area where the thread merges into a smooth, cylindrical or conical surface is for this reason of great importance as regards the function of the securing element, the implant. This position usually determines where, on the securing element, long-term stabilizing of the bone tissue occurs.

In order to obtain an initial stabilizing of the securing element, and to place the latter in a predetermined position, it is already known to have the thread end with a flange. The flange means that there is a possibility of a mechanical resistance with increased initial stability and a more reliable positioning. The initial stability is considered to be important for ensuring incorporation, and the improved positioning in the axial direction affords greater protection against penetration into the nerve channel of the mandible.

The flange also makes it possible for the soft tissue to seal off the oral cavity directly against the

- 2 -

fixture. This means that any bacterial leakage through the spacer piece does not reach the bone level. The flange can thus be regarded as a first part of the spacer system attached to the fixture (or a first part of the implant part penetrating the soft tissue).

However, when the thread is being chased, the flange represents an obstacle to the runout of the thread cutter, for which reason a turned recess is usually formed under the flange so as to be able to lift the cutter out without damaging the flange. However, this method means that approximately one thread turn is lost on the securing element, which leads to the marginal bone height coming to lie correspondingly further down on the securing element. This loss is critical in some cases, since it means that it is not possible to use the outermost bone edge, which normally has the best mechanical properties. It is also important, particularly in the case of thin bone, that the thread be used to the full, in order to obtain a good initial stability of the implanted securing element.

An alternative production procedure is to allow the thread cutter to be drawn out only radially, but this results in an increasingly shallower thread, which does not fit in the already threaded hole, and an undefined flange is obtained. Thus, this method too does not solve the problem of how to use the outermost bone edge to the full.

The loss of marginal bone height is especially critical in the use of a small number of implants in the molar areas of the jaw, since an unfavourable loading can occur in this region, especially in the case of an individual molar. A considerable increase in the strength of the implant can of course be obtained simply by increasing the dimensions of the implant, but it is far from certain that the existing bone volume will permit this. Omitting the flange, and allowing the thread to run right to the top, is not an optimal solution either, considering the advantages which a flange affords, namely those of being a counterstay for the initial tightening,

- 3 -

and an active, sealing part of the area of the implant passing through the soft tissue.

The hardness of the bone in the molar areas of the jaw can vary greatly. In some patients, only a very
5 thin outer layer, the cortical bone, is hard, while the remaining inner bone, the so-called spongiosa, is very soft. In these bone types, it is already known to use self-tapping fixtures, see for example SE 468,154.

The advantage of the self-tapping fixtures is
10 that the implantation of the fixture in the jaw bone is simplified. The normal procedure in fact involves drilling a hole in the bone. In this connection, drills of increasing diameter are successively used until the diameter of the hole corresponds with the core diameter
15 of the threaded fixture. A thread tap is then used, which forms the thread in which the implant is then placed. When using a self-tapping fixture of the type which is described in the abovementioned patent, the implantation is performed without using a thread tap. However, the use
20 of self-tapping fixtures does not in itself solve the problem of loss of marginal bone height.

The object of this invention is to provide an implant which is based on today's basic design and dimensions, but in which the boundary area where the
25 thread merges into the smooth, cylindrical or conical portion, viz. the thread end, has been given a novel configuration, with the intention of having the marginal bone height lie higher up on the implant, so that the cortical bone is better utilized. According to the
30 invention, this is achieved by means of the fact that the thread in the periosteal part of the implant merges into (ends at) the smooth, cylindrical or conical portion via a cylindrical groove which has the geometry of the threading die.

35 In a first embodiment, the smooth portion, against which the thread ends, is formed by a cylindrical flange. As has been pointed out in the introduction, the flange constitutes a counterstay for the initial tightening of the implant and permits positioning of the

- 4 -

implant at a precisely determined height. By having the thread now end against the flange via a cylindrical groove which has the profile of the thread, no thread turn is lost on the implant, which means that the cortical bone can be utilized right up to the flange.

In a second embodiment, the smooth portion, against which the thread ends, is formed by a conical portion. In this case too, the thread ends against the conical portion via a cylindrical groove which has the profile of the thread, in direct connection with the conical portion, and the cortical bone can be utilized right up to the conical portion. The conical portion in some cases affords the additional advantage, as compared with a cylindrical flange, that precise preparation of the position of the conical implant flange is made possible by using a conical countersink. This will be described in greater detail below.

The invention will be described in greater detail hereinbelow with reference to the attached drawing, in which Figure 1 shows a previously known implant (prior art), Figure 2 shows a first illustrative embodiment of an implant according to the invention, with a cylindrical flange, Figure 3 shows a second example of an embodiment according to the invention, in which the flange is conical, Figure 4 shows an example in which the flange is made up of a combination of a conical and a cylindrical surface, and Figure 5 shows an enlarged view of the thread end.

Figure 1 shows a self-tapping fixture according to the BRÄNEMARK SYSTEM which is marketed by Nobelpharma AB. The fixture consists of an essentially cylindrical screw with an outer thread 1, which merges into a wider cylindrical flange 2 via an unthreaded transition portion 3 with a so-called shallowing-out thread. The screw is intended to be introduced into a hole already drilled in the jaw bone for permanent anchoring of artificial teeth and dental bridges. The screw has an upper hexagonal portion 4 intended to cooperate with a tool for implanting the screw. The screw is preferably made of

- 5 -

commercial pure titanium with a surface structure in accordance with SE-PS 79.02035-0. The screw is self-tapping by virtue of the fact that its lower part is provided with three recesses 5 formed in the circular symmetrical surface of the screw. The recesses are designed in such a way that they form, in connection with the circular symmetrical surface, cutting edges 6 and together they have such a volume that the bone slivers cut off by the cutting edges are accommodated within the recesses; see also abovementioned SE-PS 91.02451-3.

As has been pointed out in the introduction, there are certain applications where this fixture does not give the best results, namely in the molar areas of the jaw where there is a relatively thin, hard cortical bone and an inner, porous and soft bone. When the screw is implanted in this region, the relatively elongate transition portion 3 with the shallowing-out thread comes to lie opposite the hard cortical bone, which means that the advantages of the thread, with regard to positive locking and stability, are not exploited to the full.

Figures 2 and 3 show how it has been possible according to the invention for the said transition portion 3 to be minimized by allowing the thread to end against the flange via a cylindrical groove 7 which has the profile of the thread at the point of connection to the flange. In this way, no thread turn is lost on the fixture, which means that the cortical bone can be utilized to the full right up to the flange.

The thread end is produced in principle in two stages. When the thread cutter reaches the flange during production, the cutter is drawn radially outwards at an angle which, with respect to the axis of the screw, is at least as great as the angle of the thread flank. In this way, a correct thread pitch is obtained right up to the flange, and the thread merges into the flange with a shallowing-out thread. In what is essentially the second stage in the production of the thread end, that part of the flange which adjoins the thread is then chased with a profile which corresponds to the profile of the thread.

- 6 -

In this way, the thread comes to merge into a groove 7 having the profile of the thread, which groove constitutes the connection of the flange to the thread, with gradually decreased thread width and height, but with the thread depth being maintained. The thread in this way runs right up to the flange, and at the same time the flange remains completely intact, and the shallowing-out thread has been eliminated. This also means that no part of the hole already threaded in the bone is destroyed when the securing element is implanted. With the previously known, shallowing-out thread, there was a possible risk of asymmetrical clamping effects, which can thus be avoided with the novel thread end.

One effect of the cylindrical groove under the flange is that there is no full contact between the flange and the uppermost thread turn in the bone. However, this disadvantage is considered small compared to the disadvantage of having a thread which presses the bone asymmetrically under the flange.

The cylindrical flange 5 in Figure 2 otherwise corresponds entirely to the flange on the previously known fixture, which is shown in Figure 1. The pitch and cross-section of the thread are also the same as present day standards. By virtue of the fact that a correct thread pitch and thread depth are maintained right up to the flange, the profile angle of the flank 8, which is that part of the groove 7 which adjoins the flange 5, comes to be equal in size to the flank angle of the thread, which in this case is 60°.

In Figure 3, the invention is illustrated in respect of a conical flange 9. In this case too, the thread adjoins the conical portion 9 via a cylindrical groove 7, the flank 10 of the groove against the thread having the same profile angle as the flank angle of the thread, while the "flank" of the groove against the flange 9 in this case consists of the flange itself.

Fixtures with conical flanges are already known per se; see, for example, Swedish design registration 38.454. What is new in this case is the thread ending

- 7 -

against the conical flange in the form of the cylindrical groove 7. In addition, the conical flange has the same height as the cylindrical flange, i.e. a comparatively short flange in relation to the conical flange which is shown in the aforementioned design. In the present case, the flange has a height of 1.1 mm, its diameter at the thread connection is the same as the core diameter of the thread, i.e. 4.9 mm, and its diameter at the upper plane 11 is 5.2 mm. The diameter of the fixture, the outer thread, is nominally 5.0 mm.

The reason why it is desirable, in certain applications, to work with a conical flange is that the latter, in conjunction with a conical countersink, permits a more exact anchoring of the implant. By providing the already drilled hole with a conical countersinking, which corresponds to the conical flange, a more exact adaptation between the cortical bone and the implant is obtained. The flange also helps in this way (together with the thread) to give the desired initial stability, which is especially important in the comparatively thin cortical bone. Upon application in areas with thin cortical bone and a soft trabecular core, it is sometimes desirable to eliminate the countersinking completely. Even in such a situation, the conical spacer is considered to be advantageous since it provides a gradually increasing resistance, which should give better protection against the flange losing its hold than is possible with a cylindrical flange. In this type of bone, it is often desired to place the fixture in a previously drilled seat, of under-dimensioned diameter, in the trabecular bone, while it is desired to widen the entrance in the cortical bone. The conical countersink here makes it possible to widen the cortical bone carefully in this area.

The conical countersink can be used for holes measuring from 3 mm upwards. An advantage of the conical flange geometry is that the same countersink can be used for different fixture diameters. The surgeon can choose which degree of clamping effect is desired upon fitting

- 8 -

each fixture, since the conical flange presses the bone out essentially radially. As long as the flange is not drawn under the bone edge, the stability will thus be maintained.

5 The conical countersink can also be used for widening the cortical entrance, instead of using a twist drill. The advantage of this is that, in such a reaming operation, the bone is worked radially, i.e. essentially in the plane of the bone, which means that it is possible
10 to shape the hole to the desired diameter with considerably less risk of fracture of the cortical plate. When a twist drill is used, the work is performed essentially axially, which involves pressing on the bone shell. In addition, the twist drill has a tendency to cut
15 a groove-shaped hole in thin plates, in which case there is a risk of fragmentation.

The thread end for the conical spacer is also produced in principle in two stages, see above.

20 In Figure 4, the invention is illustrated in respect of a flange which has a lower conical part 12 and an upper, narrower cylindrical part 13. In this case too, the cylindrical groove 7 has a flank 10 against the thread, which flank has the same flank angle as the flank angle of the thread, i.e. 60°. The cylindrical groove 7
25 merges directly into the conical flange 12, which in this case has a cone angle of 23°. This is shown on an enlarged scale in Figure 5a.

30 Figure 5b shows an enlarged view of the case in which the flank 14, of the cylindrical groove 7, which adjoins the flange also has the geometry of the threading die, i.e. a flank angle of 60°. The case with a cylindrical flange 15 and the case with a conical flange 16 have both been indicated in the figure.

35 The invention is not limited to the embodiments shown by way of example, but instead can be varied within the scope of the patent claims attached.

PATENT CLAIMS

1. Screw-type securing element, made of titanium, for permanent anchoring in bone tissue, in particular for permanent anchoring of artificial teeth and dental bridges in the jaw bone, the securing element having an outer threaded portion which at the far top merges into a smooth, conical and/or cylindrical portion, characterized in that the thread (1) in the periosteal part of the securing element merges into (ends at) the smooth, conical and/or cylindrical portion (5, 9) via a cylindrical groove (7) which has the geometry of the threading die.
2. Securing element according to Patent Claim 1, characterized in that the smooth portion, against which the thread ends, is formed by a cylindrical flange (5), in which case that part of the groove (7) which adjoins the cylindrical flange (5) consists of a flank (8) whose profile angle is the same size as the flank angle of the thread.
3. Securing element according to Patent Claim 1, characterized in that the smooth portion, against which the thread ends, consists of a conical flange (9), in which case that flank (10) of the groove (7) against the thread has the same profile angle as the flank angle of the thread, while that flank of the groove against the conical flange (9) consists wholly or partly of the conical surface.
4. Securing element according to Patent Claim 3, characterized in that the diameter of the conical flange (9) at the thread connection is equal in size to the core diameter of the thread, while its diameter at the upper plane (11) slightly exceeds the outer diameter of the thread.
5. Securing element according to Patent Claim 1, characterized in that its front part is provided with one or more recesses whose margins adjoining the circular symmetrical surface of the securing element form cutting edges in order to permit self-tapping when the element is being screwed into the bone tissue.

- 10 -

6. Method for producing a securing element according to Patent Claim 1, characterized in that when the thread cutter reaches the flange (5) during production, the cutter is drawn straight out at an angle which, in
5 relation to the longitudinal axis of the securing element, is at least as great as the angle of the thread flank, after which that part of the flange (5) which adjoins the thread is chased with the profile of the thread.

Fig. 1

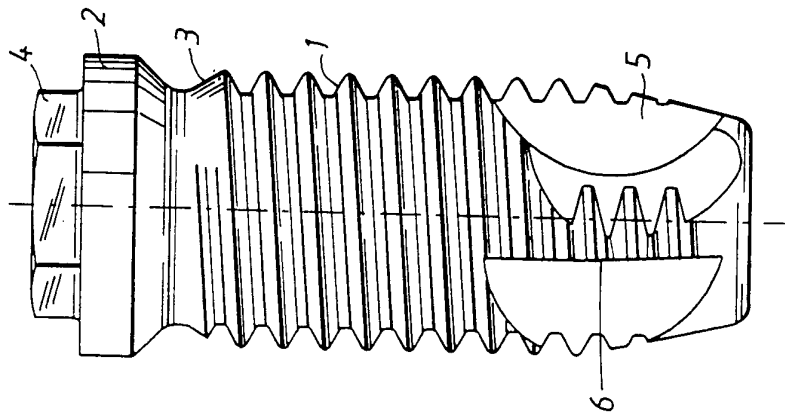


Fig. 2

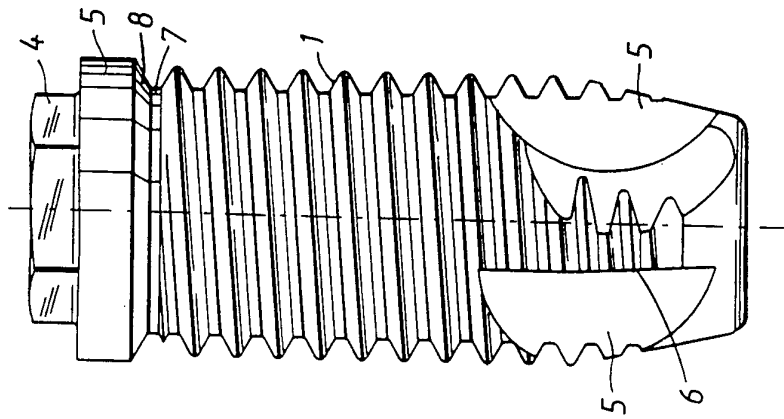


Fig. 3

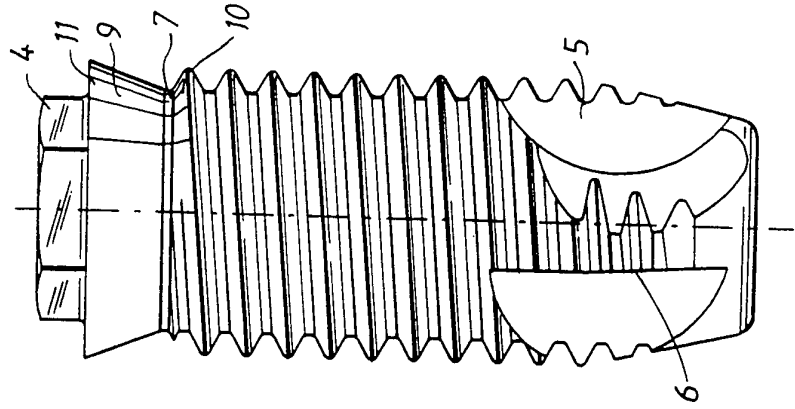


Fig. 4

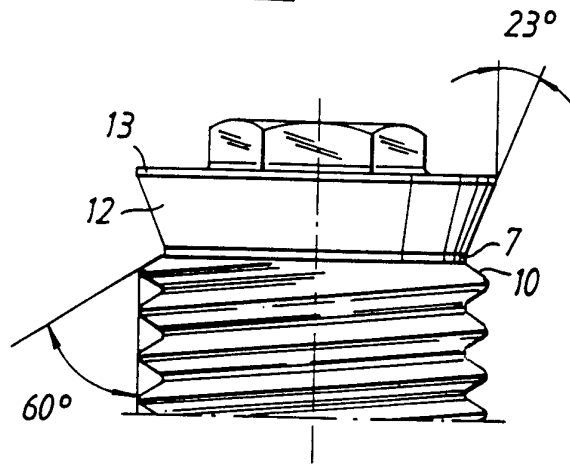


Fig. 5a

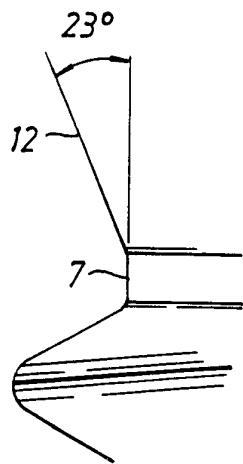
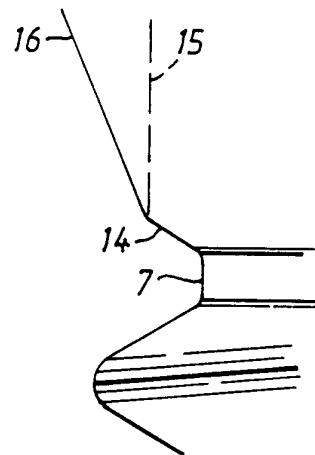


Fig. 5b



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 94/01226

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61C 8/00

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)

IPC6: A61C

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, A2, 0288702 (VENT-PLANT CORPORATION, INC.), 2 November 1988 (02.11.88), figure 2 --	1-6
X	EP, A1, 0537101 (SCORTECCI, GERARD), 14 April 1993 (14.04.93), figure 1 -----	1-6

 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

"E" earlier document 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

20 March 1995

Date of mailing of the international search report

24-03-1995

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

Jack Hedlund
Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

Information on patent family members

25/02/95

International application No.

PCT/SE 94/01226

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A2- 0288702	02/11/88	AU-B- 617307	28/11/91
		AU-A- 1313588	15/09/88
		CA-A- 1304968	14/07/92
		CA-A- 1311948	29/12/92
		JP-A- 1008963	12/01/89
		US-A- 4842518	27/06/89
		US-A- 4932868	12/06/90

EP-A1- 0537101	14/04/93	FR-A,B- 2682283	16/04/93
		US-A- 5312256	17/05/94
