(19) World Intellectual Property **Organization**

International Bureau





(43) International Publication Date 8 January 2004 (08.01.2004)

PCT

(10) International Publication Number WO 2004/002333 A1

(51) International Patent Classification⁷: A61B 17/17,

(21) International Application Number:

PCT/US2003/019098

(22) International Filing Date: 19 June 2003 (19.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10/184,829 28 June 2002 (28.06.2002) US

(71) Applicant: SMITH & NEPHEW, INC. [US/US]; 1450 Brooks Road, Menphis, Tennessee 38116 (US).

(72) Inventors: GABRIEL, Stefan; 7 Alderberry Lane, Mattapoisett, MA 02739 (US). DYE, Justin; 120 School Street, Mansfield, MA 02048 (US).

(74) Agents: STACEY, George et al.; Smith & Nephew, Inc., 1450 Brooks Road, Memphis, TN 38116 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

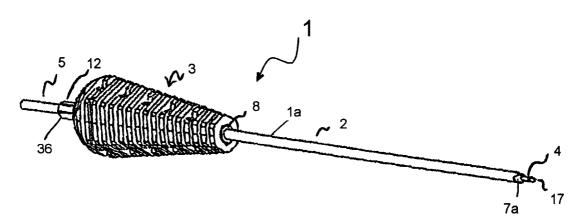
(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SOFT TISSUE REPAIR TOOL



(57) Abstract: A surgical tool includes a member, a guide wire received within the member by a friction fit, and a guide wire pusher for application of a force to the guide wire to overcome the friction fit and advance the guide wire relative to the member. The member includes a guide wire retainer that provides the friction fit and allows the guide wire to be held in such a way that it is pre-assembled and secure while the tool is being introduced to a surgical site. At the same time, once a hole is drilled into bone, the guide wire retainer allows the remainder of the tool to be removed leaving the guide wire in place at the site. The guide wire pusher allows the guide wire to be impacted into the bone before drilling and limits any possibility of drilling past the end of the guide wire.



SOFT TISSUE REPAIR TOOL

This invention relates to a soft tissue repair tool, and more particularly to a tool for preparing soft tissue and bone for implantation of a tissue fastener.

BACKGROUND

When a tissue, or a portion of a tissue, is torn away from its bone attachment site, surgery to repair the detached soft tissue is often required. This is often currently done using push-in tack implants which are used to fix tendinous and ligamentous tissue to the bone at the reattachment site. To prepare the tissue for the implant, a hole is made through the soft tissue and into the bone. The implant is subsequently passed through the soft tissue and into the bone with a portion of the implant remaining outside the hole to hold the soft tissue against the bone. Because of the need to pass the tack through the soft tissue to be reattached, most instrument systems include a cannulated drill and guide wire. The drill and guide wire are passed through the tissue together and the drill is then used to make a hole in the bone. The guide wire is left in place in the bone hole to mark its location and provide alignment for placement of the implant. The implant is advanced over the guide wire, with a distal end of the implant passing through the soft tissue and into the bone.

25

30

5

10

15

20

SUMMARY

According to an aspect of the invention, a surgical tool includes a member, a guide wire received within the member by a friction fit, and a guide wire pusher for application of a force to the guide wire to overcome the friction fit and advance the guide wire relative to the member.

2

Embodiments of this aspect of the invention may include one or more of the following features.

5

10

15

20

25

30

The member includes a guide wire retainer that receives the guide wire in the friction fit. The member includes a handle and a shaft coupled to the handle. The guide wire has a sharp distal end for penetrating soft tissue and bone. The member has a drill tip for forming a hole in bone. The guide wire pusher is arranged relative to the member to limit a depth to which the member can be advanced into bone. The member defines an internal shoulder which the guide wire pusher contacts to limit relative movement between the member and the guide wire pusher. The member is configured to provide the friction fit such that the guide wire is preassembled and secure within the member when the member is being introduced to a surgical site, and the friction fit is overcome when the guide wire is inserted into bone and the member is retracted relative to the guide wire.

According to another aspect of the invention, a method includes advancing a surgical tool to a surgical site, the surgical tool including a member, a guide wire received in the member, and a guide wire pusher, and applying a force to the guide wire pusher to advance the guide wire into bone moving the guide wire relative to the member to overcome a friction fit securing the guide wire to the member.

Embodiments of this aspect of the invention may include one or more of the following features.

The method includes advancing the member relative to the guide wire to form a hole in the bone for receiving an implant. The advancement of the member relative to the guide wire is limited by interaction of the guide wire pusher with the member. The method includes withdrawing the member from the surgical site while maintaining the guide wire at the

5

10

15

20

25

surgical site by overcoming the friction fit, and advancing an implant over the guide wire and into the bone hole.

The guide wire retainer provides the friction fit and allows the guide wire to be held in such a way that it is pre-assembled and secure while the tool is being introduced to a surgical site. At the same time, once a hole is drilled into bone, the guide wire retainer allows the remainder of the tool to be removed leaving the guide wire in place at the site. The guide wire pusher allows the guide wire to be impacted into the bone before drilling and limits any possibility of drilling past the end of the guide wire.

Advantages of the invention may include one or more of the following features.

A soft tissue repair tool for bone preparation and implant deployment is easy to use, is presented pre-assembled in a single-case, pre-sterilized format, does not require separate assembly and dis-assembly steps, controls the relative position between the guide wire and shaft both before, during, and after drilling, requires only two instrument components, a drill tool and an inserter, to deploy an implant, and can be used arthroscopically or in an open or mini-open procedure.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

Fig. 1 is a perspective view of a drill tool according to the invention;

Fig. 2 is a cross-sectional view of the drill tool;

Fig. 3A is a cross-sectional view of a handle region of the drill tool;

4

Fig. 3B is a cross-sectional view of the handle region showing a guide wire pusher advanced distally;

Fig. 4 is an exploded view of the drill tool;

Fig. 5 is an exploded view of a packaged tissue preparation and 5 implant deployment assembly; and

Figs. 6A - 6E show the drill tool in use.

DETAILED DESCRIPTION

Referring to Figs. 1 and 2, a drill tool 1 for preparing tissue to receive an implant includes an elongate member 1a having a shaft 2 and a handle 3 attached to a proximal region 8 of shaft 2, e.g., by pressing, gluing or welding. Shaft 2 defines a lumen 30, and handle 3 defines a lumen 32. Lumens 30, 32 are aligned and create a through passage 34 from a proximal end 36 of handle 3 to a distal end 7 of shaft 2. Tool 1 includes a guide wire 4 received within lumen 30 of shaft 2 and axially translatable relative to shaft 2, a guide wire pusher 5 received within lumen 32 of handle 3 and axially translatable relative to handle 3, and a guide wire retainer 6 received within proximal region 8 of shaft 2 that frictionally engages guide wire 4, for purposes described below. Guide wire 4 has a distal, sharp point 17 for penetrating soft tissue and bone, and shaft distal end 7 is formed to a sharp drilling tip 7a for forming a hole in bone. Handle 3 has a proximal hex feature 12 that allows releasable attachment of tool 1 to a power drilling tool (not shown).

25

30

10

15

20

Referring to Fig. 3A, handle 3 has a first internal shoulder 10 extending into lumen 32, against which shaft 2 and guide wire retainer 6 are held, and a second internal shoulder 11 extending into lumen 32, which limits the proximal translation of the guide wire pusher 5 (arrow, A) by engagement of an enlarged, distal end 13 of guide wire pusher 5 with shoulder 11. Guide wire pusher distal end 13 defines an axially oriented blind hole 15 opening distally for removably receiving a proximal end 18 of

5

guide wire 4. As shown in Fig. 3B, guide wire pusher 5 is used to distally advance guide wire 4 relative to shaft 2.

Referring also to Fig. 4, surrounding proximal region 8 of shaft 2 is an outer cylindrical member 38 having an enlarged inner diameter region 38a for receiving guide wire retainer 6. Shaft 2 has a proximal end 8a that abuts against guide wire retainer 6. Guide wire retainer 6 defines a channel 19 through which guide wire 4 passes. There is a frictional fit between guide wire 4 and guide wire retainer 6 such that guide wire 4 is retained within tool 1 until guide wire 4 is fixed in the bone and tool 1 is removed from the bone, as described below.

Referring to Fig. 5, tool 1 is preferably packaged sterile with an implant inserter 20 and extra guide wires 21 in a foam carrier 22 (in case the guide wire 4 supplied in tool 1 is damaged during a procedure before all implants for that procedure are implanted) in a disposable tray 23. The components of tool 1 are preferably manufactured by polymer molding processes and machining and pressed assembled, though other methods using biocompatible metal(s) and polymer(s) can be used.

20

25

30

5

10

15

Referring to Fig. 6A, in use, with guide wire 4 positioned relative to shaft 2 as shown in Fig. 1, i.e., with guide wire pusher 5 against internal shoulder 11, the operator passes distal point 17 of guide wire 4 and distal end 7 of shaft 2 through soft tissue 60 and against bone 62 at the reattachment site 64 on the bone. Referring also to Fig. 6B, the operator than impacts guide wire pusher 5 (arrow, B) with, e.g., a hammer, overcoming the friction fit between guide wire 4 and guide wire retainer 6 to advance guide wire 4 relative to shaft 2, until a proximal end 14 of guide wire pusher 5 is flush with a proximal end 40 of handle hex feature 12. This action lodges the distal end of guide wire 4 in bone 62 a distance equal to the length, I, of guide wire pusher 5 that extends from proximal end 40 when guide wire pusher 5 is against internal shoulder 11.

6

Referring to Fig. 6C, the operator then advances (arrow, C) and rotates (arrow, D) handle 3 and shaft 2, either by hand or with a power drill coupled to hex feature 12, to form a hole 66 in bone 62 greater than or equal to the length of the portion of the implant to be deployed within the bone. This can be aided by length markings (not shown) on shaft 2. The advancement of shaft 2 moves shaft 2 relative to guide wire 4 such that guide wire pusher 5 again protrudes from proximal end 40 of handle 3, and guide wire 4 is retained within shaft 2 by the friction fit with retainer 6. The operator then gives guide wire pusher 5 a few taps to dislodge any debris which may have become lodged in lumen 30 of shaft 2.

10

15

20

25

30

Referring to Fig. 6D, the operator then removes shaft 2, handle 3, pusher 5, and retainer 6 from the patient. The friction fit is selected such that the force to overcome the lodgement of guide wire 4 within the bone is greater than the force to overcome the friction fit, such that guide wire 4 remains in place in the bone when the remainder of tool 1 is removed. The operator then places an implant 50, such as a Suretac® tissue tack available from Smith & Nephew, Inc., Andover, MA, catalogue number 014567, on guide wire 4, and uses inserter 20 (Fig. 5) to push implant 50 into the bone. Impaction is usually necessary to aid in this step. The operator then removes guide wire 4 from the bone.

Referring to Fig. 6E, implant 50 is preferably a tack with a shaft 52 and a head 54. Shaft 52 is implanted into hole 66 drilled in the bone, and head 54 captures and holds down the soft tissue 60 being re-attached to bone 62.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention.

7

Accordingly, other embodiments are within the scope of the following claims.

8

WHAT IS CLAIMED IS:

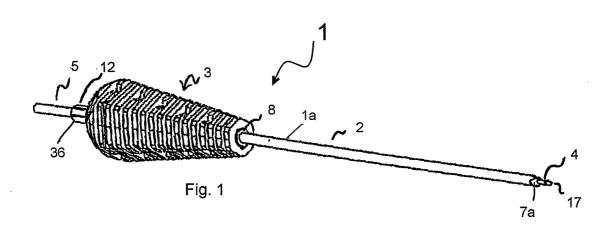
- 1. A surgical tool, comprising:
 - a member,
- a guide wire received within the member by a friction fit, and a guide wire pusher for application of a force to the guide wire to overcome the friction fit and advance the guide wire relative to the member.
- The surgical tool of claim 1 wherein the member includes a guidewire retainer that receives the guide wire in the friction fit.
 - 3. The surgical tool of claim 1 wherein the member includes a handle and a shaft coupled to the handle.
 - 4. The surgical tool of claim 1 wherein the guide wire has a sharp distal end for penetrating soft tissue and bone.
- 15 5. The surgical tool of claim 1 wherein the member has a drill tip for forming a hole in bone.
 - 6. The surgical tool of claim 1 wherein the guide wire pusher is arranged relative to the member to limit a depth to which the member can be advanced into bone.
- 7. The surgical tool of claim 6 wherein the member defines an internal shoulder which the guide wire pusher contacts to limit relative movement between the member and the guide wire pusher.
- 8. The surgical tool of claim 1 wherein the member is configured to provide the friction fit such that the guide wire is pre-assembled and secure within the member when the member is being introduced to a surgical site, and the friction fit is overcome when the guide wire is inserted into bone and the member is retracted relative to the guide wire.

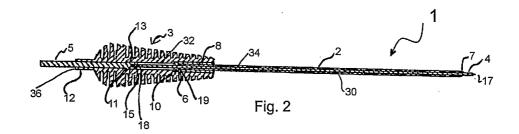
9

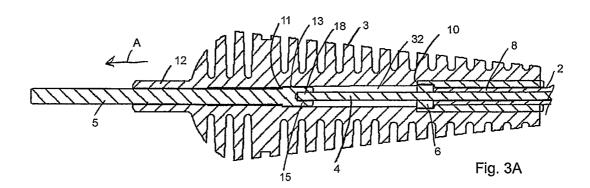
9. A method comprising:

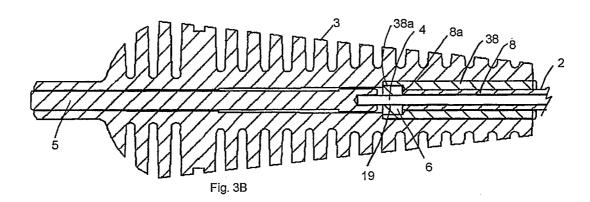
10

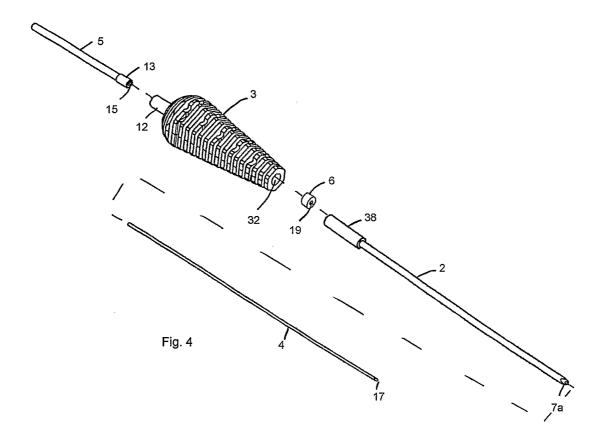
- advancing a surgical tool to a surgical site, the surgical tool including a member, a guide wire received in the member, and a guide wire pusher, and
- applying a force to the guide wire pusher to advance the guide wire into bone moving the guide wire relative to the member to overcome a friction fit securing the guide wire to the member.
 - 10. The method of claim 9 further comprising advancing the member relative to the guide wire to form a hole in the bone for receiving an implant.
 - 11. The method of claim 10 wherein the advancement of the member relative to the guide wire is limited.
 - 12. The method of claim 11 wherein the advancement of the member is limited by interaction of the guide wire pusher with the member.
- 13. The method of claim 10 further comprising withdrawing the member from the surgical site while maintaining the guide wire at the surgical site by overcoming the friction fit.
 - 14. The method of claim 13 further comprising advancing an implant over the guide wire and into the bone hole.











WO 2004/002333

PCT/US2003/019098

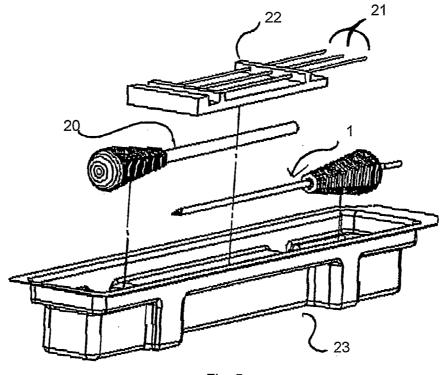
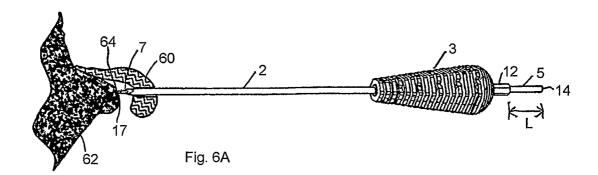
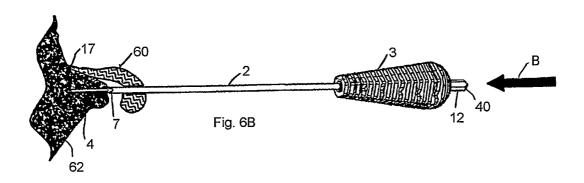
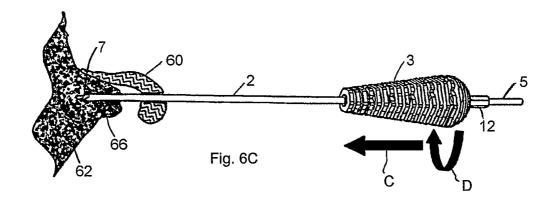
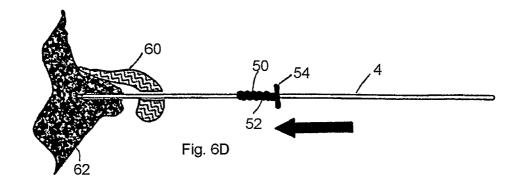


Fig. 5

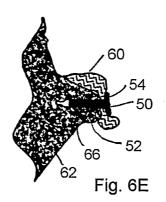








5/5



INTERNATIONAL SEARCH REPORT

Internati Application No PCT/US 03/19098

			PC1/US U3/19U98							
A. CLASSII IPC 7	FICATION OF SUBJECT MATTER A61B17/17 A61B17/16									
	(10151), 11 (10151), 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 7	A61B	53.1.12 6.167								
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched										
Electronic da	ata base consulted during the international search (name of data bas	se and, where practical,	search terms used)							
EPO-In	ternal									
2.0										
7	ENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the rele		Delevent to alein No							
Category °	Cliation of document, with indication, where appropriate, of the rele	evant passages	Relevant to claim No.							
Α	US 4 450 835 A (ASNIS STANLEY E	FT AL)	1,4,5							
^	29 May 1984 (1984-05-29)	LI AL)	1,7,5							
	column 5, line 36 -column 6, line	12;								
	figures 5,6									
Α	US 2001/044633 A1 (KLINT HENRIK		1							
,,	SONDERSKOV) 22 November 2001 (200	1-11-22)	-							
	paragraph '0093!; figure 13									
Α	US 5 374 270 A (HENDRICKS STEPHEN	D FT	1,4,5							
^	AL) 20 December 1994 (1994-12-20)	1,7,5								
	the whole document									
Α	 EP 0 556 570 A (ARTHREX MED INSTR	1								
^	25 August 1993 (1993-08-25)	j *								
	column 3, line 55 - line 58; figure 2									
			1							
	and designate are listed in the combination of host O	D-1								
Further documents are listed in the continuation of box C. Patent family members are listed in annex.										
° Special ca	tegories of cited documents:	"T" later document publ	shed after the international filing date							
A document defining the general state of the art which is not considered to be of particular relevance or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention										
"E" earlier o	ar relevance; the claimed invention									
"L" docume	ent which may throw doubts on priority claim(s) or	ed novel or cannot be considered to e step when the document is taken alone								
which is cited to establish the publication date of another citation or other special reason (as specified) "O" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document referring to an oral disclosure, use, exhibition or document is combined with one or more other such document is combined.										
other r	ned with one or more other such docu- nation being obvious to a person skilled									
"P" docume later th	of the same patent family									
Date of the actual completion of the international search Date of mailing of the international search			ne international search report							
8	October 2003	16/10/2003								
Name and r	mailing address of the ISA	Authorized officer								
	European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tol. (121.70) 400. 2040, Tv. 31.651 apo pl	_								
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Ducreau, F								

INTERNATIONAL SEARCH REPORT

International application No. PCT/US 03/19098

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. χ Claims Nos.: $9-14$ 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							
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:							
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 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

Internat Application No
PCT/US 03/19098

				101,00	03/ 19090	
Patent document cited in search report		Publication date	Patent family member(s)		Publication date	
US 4450835	A	29-05-1984	US CA CA DE DE	4383527 A 1175722 A1 1177351 A2 3265702 D1 3277170 D1	17-05-1983 09-10-1984 06-11-1984 03-10-1985 15-10-1987	
			EP EP JP JP	0059044 A2 0134514 A2 1410545 C 57164049 A	01-09-1982 20-03-1985 24-11-1987 08-10-1982	
US 2001044633	A1	 22-11 - 2001	JP EP	62016101 B 	10-04-1987 01-08-2001	
			EP EP EP AU	1120094 A1 1120128 A1 1120088 A1 3400901 A	01-08-2001 01-08-2001 01-08-2001 07-08-2001	
	<u> </u>		CA WO JP	2397697 A1 0154761 A2 2003520651 T	02-08-2001 02-08-2001 02-08-2001 08-07-2003	
US 5374270	A	20-12-1994	US US US US US US	5257996 A 5366457 A 5391169 A 5464407 A 5865834 A 5683400 A 5797918 A	02-11-1993 22-11-1994 21-02-1995 07-11-1995 02-02-1999 04-11-1997 25-08-1998	
			US US	5681320 A 5391170 A	28-10-1997 21-02-1995	
EP 0556570	Α	25-08-1993	US AT DE DE EP	5320626 A 143581 T 69305099 D1 69305099 T2 0556570 A1	14-06-1994 15-10-1996 07-11-1996 20-02-1997 25-08-1993	