



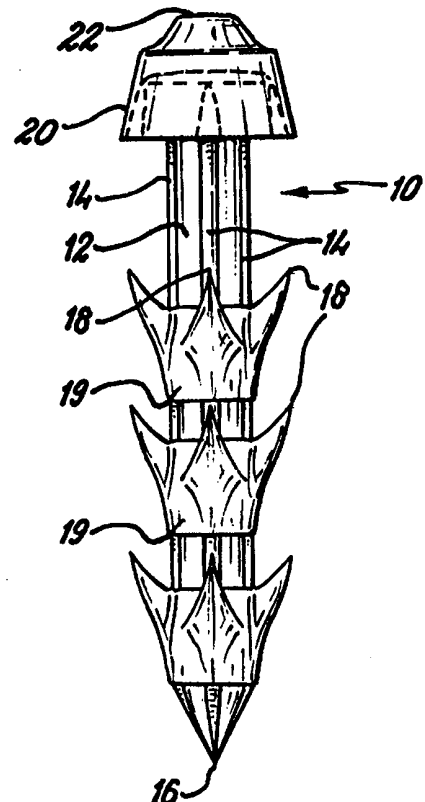
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<p>(21) International Application Number: PCT/GB99/03744 (22) International Filing Date: 10 November 1999 (10.11.99) (30) Priority Data: 9825681.1 25 November 1998 (25.11.98) GB (71) Applicant (for all designated States except US): BIOCOM- POSITES LIMITED [GB/GB]; Etruscan Street, Etruria, Stoke-on-Trent, Staffordshire ST1 5PQ (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): BRATT, John, Stephen [GB/GB]; Biocomposites Limited, Etruscan Street, Etruria, Stoke-on-Trent, Staffordshire ST1 5PQ (GB). WATERS, Russell, David [GB/GB]; Biocomposites Limited, Etruscan Street, Etruria, Stoke-on-Trent, Staffordshire ST1 5PQ (GB). COOPER, John, Joseph [GB/GB]; Biocomposites Limited, Etruscan Street, Etruria, Stoke-on-Trent, Staffor- dshire ST1 5PQ (GB). (74) Agent: SALES, Robert, Reginald; Swindell & Pearson, 48 Friar Gate, Derby DE1 1GY (GB).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, 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, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i></p>

(54) Title: A SURGICAL DEVICE FOR CLOSING TISSUE

(57) Abstract

A surgical device (10) for closing bodily tissue, the device (10) comprising a shaft (12) which can be inserted into the tissue, a hollow flexible frusto conical cap (20) at the end of the shaft which is engageable against the surface of the tissue, and a plurality of tissue engagement formations (18, 46) on the shaft (12) to prevent the device (10) from being withdrawn from the tissue.



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A SURGICAL DEVICE FOR CLOSING TISSUE

This invention concerns a surgical device, and particularly but not exclusively a surgical device for closing torn or incised soft bodily tissue.

A number of arrangements have been devised for closing tears, wounds and incisions in soft bodily tissue, and in particular for repairing torn menisci. These devices include sutures, clamps, clips, pins and staples, which have met with varying success. In such situations it is desired to cause as little trauma as possible whilst providing a good repair to the tissue and preferably not requiring further surgery to remove the device to reduce the risk of long term infection from non-absorbable devices.

According to the present invention there is provided a surgical device for closing bodily tissue, the device comprising a shaft which can be inserted into the tissue, a hollow flexible cap at the proximal end of the shaft which is engageable substantially against the surface of the tissue, and a plurality of tissue engagement formations on the shaft to prevent the device from being withdrawn from the tissue.

The distal end of the shaft may be provided with a sharp tip, which may be enlarged relative to the shaft. Alternatively the distal end of the shaft may be blunt, and may be rounded.

The cap is preferably arranged such that in use it contacts the surface of the tissue substantially circumferentially even when the shaft is inserted other than normally to the tissue surface.

The cap may have a substantially frusto conical shape with the shaft being attached to the proximal smaller end thereof. One or more openings may be provided extending partway up the side walls of the cap from the distal larger end thereof.

The engagement formations are preferably provided at a 120° or less spacing around the shaft. The formations may be provided in a plurality of groups of formations, with each group spaced longitudinally from each other on the shaft. The formations are preferably circumferentially equispaced. The formations may be in the form of barbs, which are preferably rearwardly pointing. Engagement formations may be provided on or adjacent the distal end of the shaft.

The shaft preferably has a uniform cross-section along its length from the distal end to the cap. The shaft cross-section may be circular, elliptical or polygonal, and especially triangular or square. Alternatively the cross-section may have a plurality of circumferential lobes, which lobes are desirably equispaced.

The cap preferably comprises a formation engageable with a surgical tool, and the formation is preferably provided on the proximal end of the cap, and may comprise a recess or projection. The formation is preferably such as to permit the device to be used arthroscopically.

The device is preferably made of a resorbable material, and desirably includes a resorbable polymer or copolymer. The polymer or copolymer may be from the range of bioabsorbable polymers including β -hydroxybutyrate (hydroxybutanoate), hydroxyvalerate (hydroxypentanoate), lactic acid (2-hydroxypropanoic acid) or glycolic acid (2-hydroxyethanoic acid).

The resorbable material is preferably a composite and also comprises a particulate or fibrous solid material. The solid material may comprise any of hydroxyapatite, tri-calcium phosphate, calcium carbonate, calcium sulphate, magnesium oxide or bioactive glass

Embodiments of the present invention will now be described by way of example only and with reference to the accompanying drawings, in which:-

Fig. 1 is a diagrammatic isometric side view of a device according to the invention;

Figs. 2-5 are diagrammatic cross-sectional side views of a top part of the device of Fig. 1 in use; and

Figs. 6-12 show diagrammatic side views of further devices according to the invention.

Figs. 1-5 show a surgical device 10 suitable for use for closing tears, wounds and incisions in bodily tissue, and is particularly suited to the repair of torn menisci in the knee. The device 10 comprises a shaft 12 which has a basic circular cross-section with four equispaced circumferential lobes 14 extending therefrom. The shaft 10 is provided with a sharp point 16 at its distal end.

A plurality of tissue engagement formations are provided on the shaft 12 in the form of barbs 18. The barbs 18 are provided on sleeves 19 which intimately fit on the shaft 12, and the barbs 18 are provided on the lobes 14.

A cap 20 is provided on the proximal end of the shaft 12 and the cap has a hollow frusto conical configuration pointing away from the distal end, with a dome 22 of a smaller diameter provided on the proximal end thereof. The dome 22 is engageable with a pusher or other tool to permit the device to be arthroscopically inserted.

Figs. 2-4 shows an upper part of the device 10 being inserted into bodily tissue 24. In Fig. 2 the bottom edge of the cap 20 is just engaging against the top surface of the tissue 24. In Fig. 3 the device 10 has been pushed further in causing the bottom edge of the cap 20 to deform outwardly. In Fig. 4 due to the softness of the tissue 24 the bottom edge of the cap 20 has entered the tissue but due to the construction of the head can only enter a relatively short distance. Fig. 5 illustrates the condition where the shaft 12 has been inserted into the tissue 24 at an inclined angle. In this instance the cap 20 deforms to

provide a circumferential engagement with the tissue 24.

The device 10 therefore provides a good circumferential engagement with the surface of the tissue or engaging slightly into the tissue irrespective of whether the shaft is normally inserted thereinto. If movement of the tissue occurs as a result of movement of the body, this can be accommodated by the cap so as to maintain circumferential engagement throughout the movement yet permitting movement to occur.

The device 10 is made of polylactide which will resorb within the body thus eliminating the need for further surgery to remove the device and also preventing the risk of long term infection which a non-absorbable device would present. Other bioabsorbable polymers such as polyglycolide or polydioxanone are suitable materials for this device.

Figs. 6-12 show further devices according to the invention. In Fig. 6 a device 26 is shown. The shaft 12 of the device 26 has an ellipsoidal cross-section, and two sets of six barbs 18 are provided on opposite sides of the shaft 12. The cap 20 is a similar shape to that provided on the device 10 except that a recess 28 is provided instead of a dome to engage with a pusher. A split 30 is provided extending partway up the edge of the cap 20 to permit further flexing of the cap.

Fig. 7 shows a device 32 of triangular cross-section with three sets of three barbs 18 mounted on each of the faces of the triangular cross-section. The cap 20 is provided with a dome 22 and also a split 30. Fig. 8 shows a further device 34 which is similar to the device 32 except that the barbs 18 are provided on the apices of the cross-section, and three equispaced splits 30 are provided in the cap 20.

Fig. 9 shows a smaller device 36 of circular cross-section with four barbs 18 equispaced around the shaft 12 adjacent the distal end thereof. The cap 20 of the device 36 is similar to that of the device 32. Fig. 10 shows a device 38 of

square cross-section with two barbs 18 on each face of the shaft 12. Fig. 11 shows a further device 40 which is similar to the device 32 except that an enlarged distal head 42 is provided.

Fig. 12 shows a still further surgical device 44. The device 44 has a similar configuration of barbs 46 to the device 10, but each barb 46 is mounted separately on the shaft 48. The cap 50 is similar to the cap 20. The distal end 52 of the shaft 48 is in contrast rounded. The rounded end 52 means that the device 44 is not self-penetrating and therefore a tract would initially require to be made in the tissue. A rounded end has the advantage of causing less tissue irritation than usually occurs with a pointed end.

Various other modifications or combinations of the above features can be included. For instance different cross-sections of the shaft could be provided and different shape barbs could also be provided. A different shaped cap and perhaps with a different number or size of splits therein could be used.

Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

Claims:-

- 1) A surgical device for closing bodily tissue, the device comprising a shaft (12, 48) which can be inserted into the tissue, a hollow flexible cap (20, 50) at the proximal end of the shaft (12, 48) which is engageable substantially against the surface of the tissue, and a plurality of tissue engagement formations (18,46) on the shaft (12, 48) to prevent the device from being withdrawn from the tissue.
- 2) A surgical device according to claim 1, characterised in that the distal end of the shaft (12, 48) is provided with a sharp tip (16).
- 3) A surgical device according to claim 1, characterised in that the distal end (52) of the shaft (12, 48) is blunt.
- 4) A surgical device according to claim 3, characterised in that the distal end (52) of the shaft (12, 48) is rounded.
- 5) A surgical device according to any of the preceding claims, characterised in that the distal end (52) is enlarged relative to the shaft (12, 48).
- 6) A surgical device according to any of the preceding claims, characterised in that the cap (20, 50) is arranged such that in use the cap (20, 50) contacts the surface of the tissue substantially circumferentially even when the shaft (12, 48) is inserted other than normally to the tissue surface.
- 7) A surgical device according to any of the preceding claims, characterised in that the cap (20, 50) has a substantially frusto conical shape with the shaft (12, 48) being attached to the proximal smaller end thereof.
- 8) A surgical device according to claim 7, characterised in that one or more openings (30) may be provided extending partway up the side walls of the cap

(20, 50) from the distal larger end thereof.

9) A surgical device according to any of the preceding claims, characterised in that the engagement formations (18,46) are provided at a 120° or less spacing around the shaft (12, 48).

10) A surgical device according to any of the preceding claims, characterised in that the engagement formations (18,46) are provided in a plurality of groups of formations, with each group spaced longitudinally from each other on the shaft (12, 48).

11) A surgical device according to any of the preceding claims, characterised in that the engagement formations (18,46) are circumferentially equispaced.

12) A surgical device according to any of the preceding claims, characterised in that the engagement formations are in the form of barbs (18, 46).

13) A surgical device according to claim 12, characterised in that the barbs (18, 46) are rearwardly pointing.

14) A surgical device according any of the preceding claims, characterised in that engagement formations (18,46) are provided on or adjacent to the distal end (52) of the shaft (12, 48).

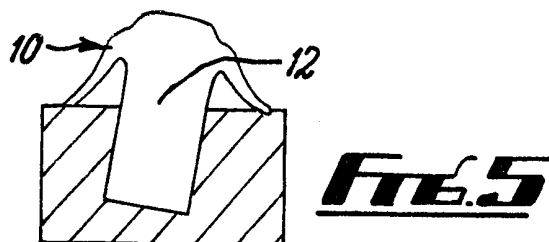
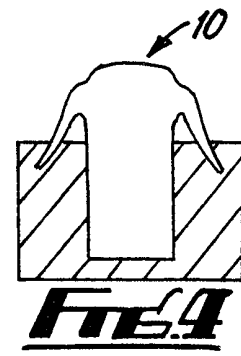
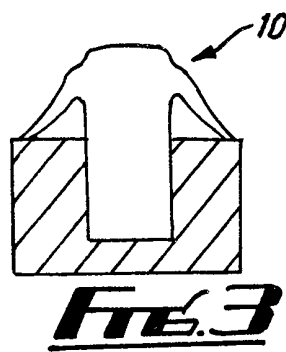
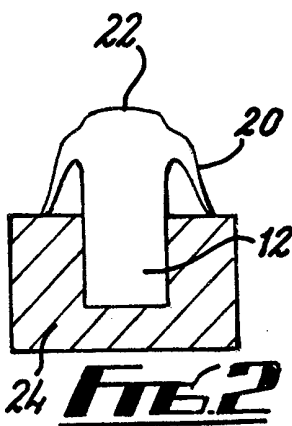
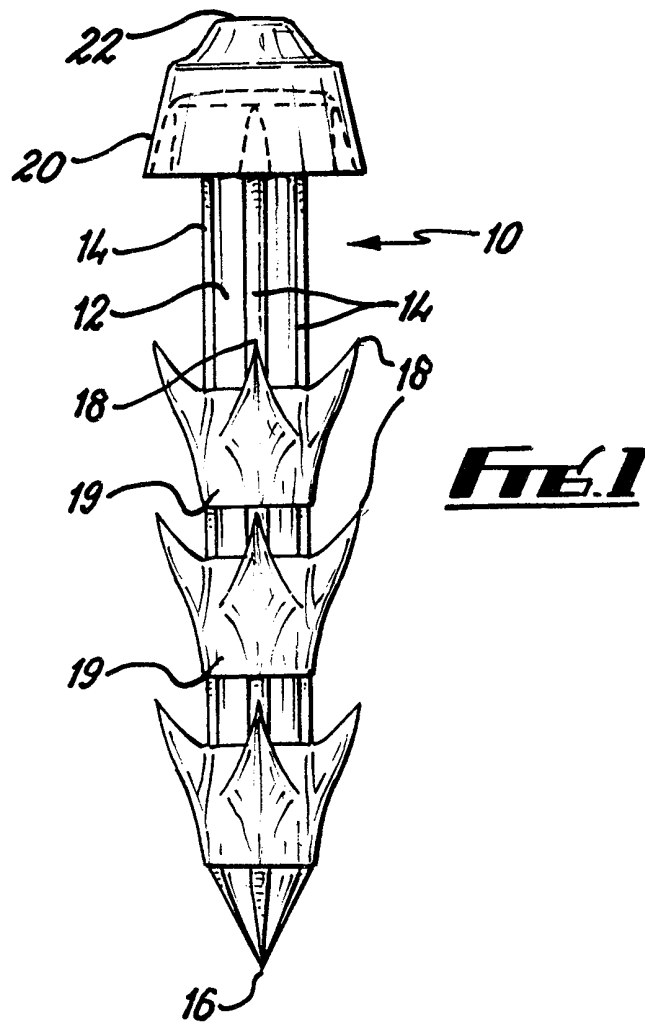
15) A surgical device according any of the preceding claims, characterised in that the shaft (12, 48) has a uniform cross-section along its length from the distal end (52).

16) A surgical device according any of the preceding claims, characterised in that the shaft (12, 48) cross-section is circular, elliptical or polygonal.

17) A surgical device according any of the preceding claims, characterised in that the shaft (12, 48) cross-section is triangular or square.

- 18) A surgical device according any of the preceding claims, characterised in that the shaft (12, 48) cross-section has a plurality of circumferential lobes (14).
- 19) A surgical device according to claim 18, characterised in that the lobes (14) are equispaced.
- 20) A surgical device according any of the preceding claims, characterised in that the cap (20, 50) comprises a formation (22) engageable with a surgical tool.
- 21) A surgical device according to claim 20, characterised in that the formation (22) is provided on the proximal end of the cap (20, 50).
- 22) A surgical device according to claim 20 or 21, characterised in that the cap (20, 50) comprises a recess (28) or projection (22).
- 23) A surgical device according to any of claims 20 to 22, characterised in that the formation (22) is shaped such as to permit the device to be used arthroscopically.
- 24) A surgical device according any of the preceding claims, characterised in that the device is made of a resorbable material.
- 25) A surgical device according to claim 24, characterised in that the resorbable material includes a resorbable polymer or copolymer.
- 26) A surgical device according to claim 25, characterised in that the polymer or copolymer is from the range of bioabsorbable polymers including β -hydroxybutyrate (hydroxybutanoate), hydroxyvalerate (hydroxypentanoate), lactic acid (2-hydroxypropanoic acid) or glycolic acid (2-hydroxyethanoic acid).
- 27) A surgical device according to any of claims 24 to 26, characterised in that the resorbable material is a composite.

- 28) A surgical device according to claim 27, characterised in that the composite comprises a particulate or fibrous solid material.
- 29) A surgical device according to claim 28, characterised in that the solid material comprises any of hydroxyapatite, tri-calcium phosphate, calcium carbonate, calcium sulphate, magnesium oxide or bioactive glass.
- 30) Any novel subject matter or combination including novel subject matter disclosed herein, whether or not within the scope of or relating to the same invention as any of the preceding claims.



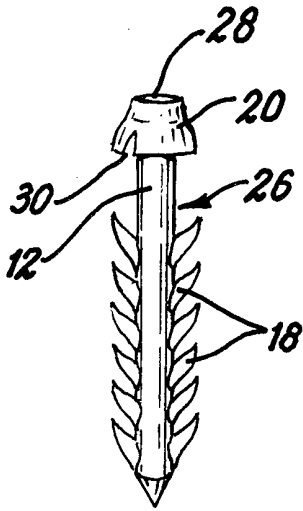


Fig. 6

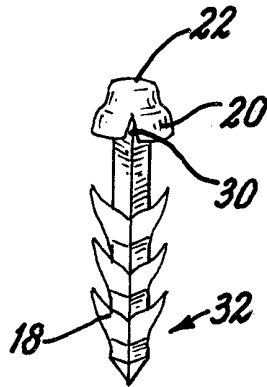


Fig. 7

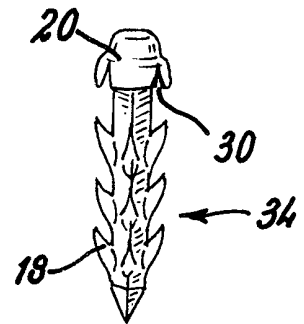


Fig. 8

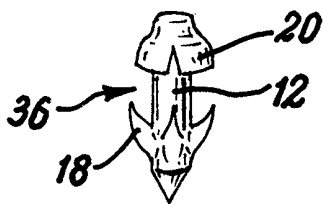


Fig. 9

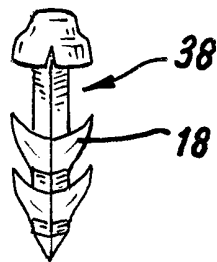


Fig. 10

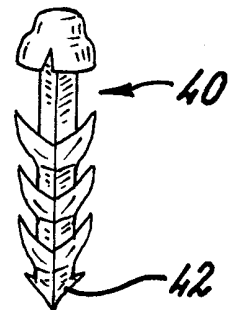


Fig. 11

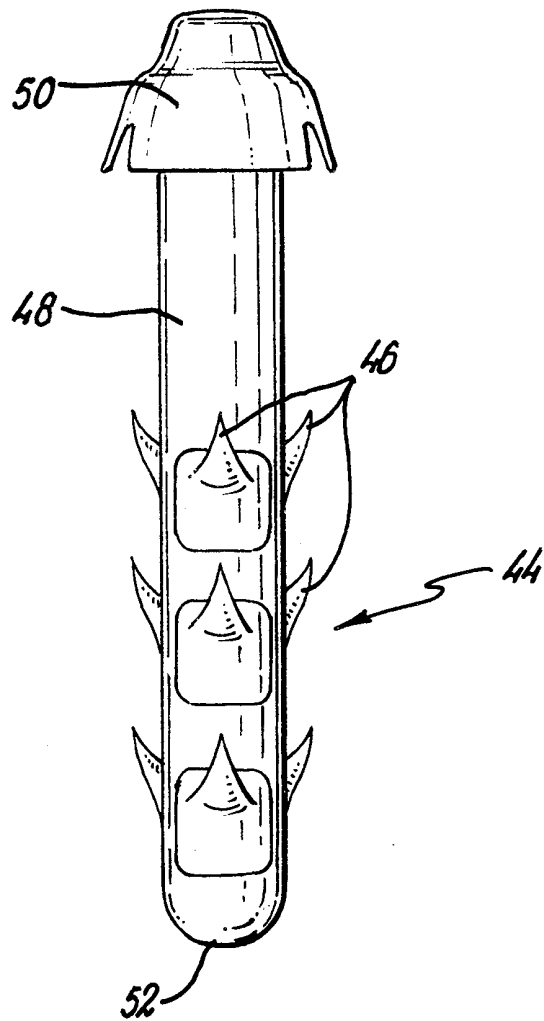


FIG. 12

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 99/03744

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/064

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 A61F

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 ^o	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 827 298 A (HART RICKEY D ET AL) 27 October 1998 (1998-10-27) column 5, line 16 - line 56 ---	1
A	US 5 562 704 A (KRISTENSEN GERT ET AL) 8 October 1996 (1996-10-08) column 3, line 6 - line 50 ---	1
A	US 5 013 316 A (GOBLE E MARLOWE ET AL) 7 May 1991 (1991-05-07) figures 3,5 -----	1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

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Gérard, B

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report	A	Publication date	Patent family member(s)	Publication date
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US 5562704	A	08-10-1996	FI 920305 A AT 178772 T AU 3353793 A CA 2127556 A DE 69324475 D DE 69324475 T EP 0623005 A ES 2129514 T WO 9314705 A JP 2960166 B JP 7507694 T	25-07-1993 15-04-1999 01-09-1993 05-08-1993 20-05-1999 16-09-1999 09-11-1994 16-06-1999 05-08-1993 06-10-1999 31-08-1995
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