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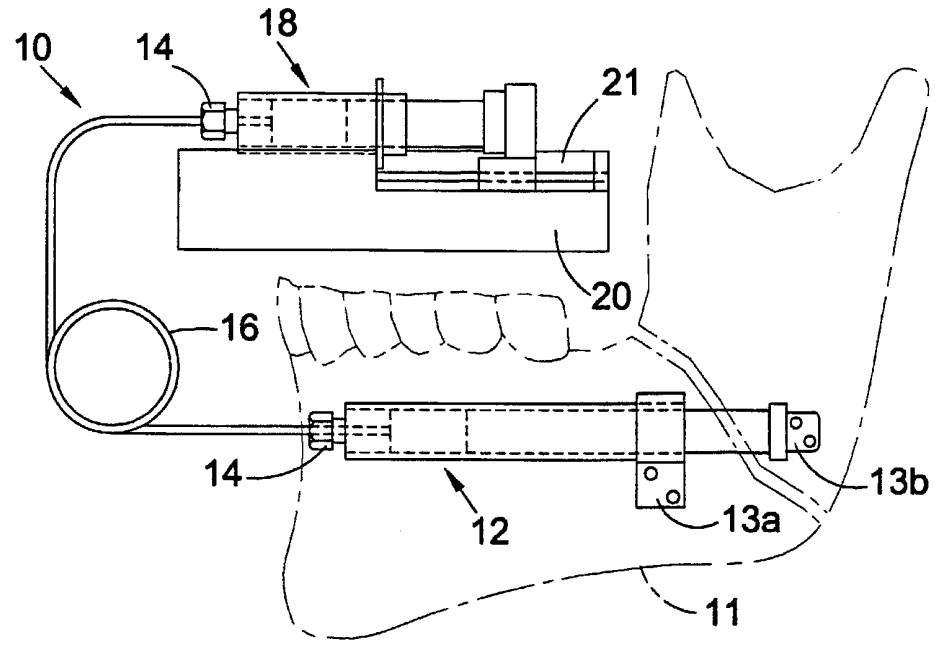
(54) Title: OSSEO-DISTRACTOR




(57) Abstract: A distraction device (10) particularly for use in osseo-distraction is described in which first and second portions (13a, 13b) of a piston and cylinder distractor (12) are anchored to parts of bones which are to be moved apart. A bellows expansion element (30a, 30b, 30c) within the piston and cylinder distractor is coupled to a compression unit (18) which contains a fluid reservoir and fluid pressure from the compression unit (18) causes the bellows to expand and move the piston, and bone to which the piston (22) is anchored (13b), relative to the cylinder (24) and bone to which the cylinder is anchored (13a).

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*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.*

# OSSEO-DISTRACTOR

The present invention relates to an apparatus for use as a distraction device; and in particular an osseo-distraction device. The invention has particular application as, but is not limited to, a maxillofacial osseo-distraction device.

Distractors are devices which drive apart two or more parts of an object. They find common application in bone repair and alteration: in cases where a bone is to be lengthened, the bone is cleaved into two parts, and a distractor fitted between the parts. The distractor gradually separates the fragments of bone, which are simultaneously healing. The result is that the bone is elongated, with the healing process generating a length of new bone at the cleavage site.

Distractors are frequently used in treatment of achondroplasia or hypochondroplasia, in which the skeletal bones need to be lengthened. The lower mandible may be a target for such treatment, and similarly may be subject to cosmetic surgery.

Conventional distractors are typically mechanically-driven. The simplest type may be manually set to a desired position, and periodically readjusted. However, this requires frequent surgery, or at least intervention, to achieve, which may therefore put the patient at risk.

Alternative distractors may be driven by a compression spring or the like, and expand at a predetermined rate once implanted. However, these distractors are not subsequently rate-adjustable after implantation without further surgery, and furthermore must be available with a range of accurately-calibrated springs to be of wide utility.

Hydraulically driven distractors are known; however, existing systems require sophisticated custom-made hydraulic driver mechanisms, which increase the cost of providing such distractors. Further, current systems make use of simple piston-and-cylinder arrangements,

which can be prone to leakage, resulting in the hydraulic fluid entering the body tissue.

It is among the objects of embodiments of the present invention to obviate or alleviate these and other disadvantages of known distractor devices.

This is achieved in part by the provision of a hydraulic distractor device which is simply mechanically driven, and provided with sealed hydraulic chambers.

According to a first aspect of the present invention, there is provided an apparatus for use in osseo-distraction, the apparatus comprising substantially sealed fluid-actuated expansion means coupled to first and second relatively movable portions for securing to respective first and second portions of a bone to be distracted, and inlet means adapted to permit entry of fluid into the substantially sealed expansion means.

The term "fluid" may be used herein to denote either a liquid or a gas. In a preferred embodiment the fluid used is sterile distilled water, although any suitable fluid may be used.

The present invention provides a hydraulically- or pneumatically-driven sealed distractor device, with the expansion means being driven by a co-operating fluid introduction means. Such an apparatus is simple and robust, and minimises the disadvantages of prior art hydraulic distractors. In particular, the sealed expansion means minimises the risk of fluid leakage into the patient.

Preferably, the apparatus further comprises compression means adapted to be coupled to the inlet means for introducing fluid into the sealed expansion means.

Preferably, the compression means comprises a reservoir of fluid operatively connected to the expansion means. Preferably also the reservoir is sealed with respect to the exterior of the apparatus. Preferably, the reservoir comprises a sealed bellows. Preferably,

the reservoir comprises a sealed metal bellows. Most preferably, the bellows are electrodeposited nickel bellows.

Bellows provide precision movement in combination with a sealed environment, which ensures that the fluid used may not leak out of the apparatus.

In one embodiment of the invention, the bellows may be mounted inside a piston-and-cylinder arrangement. Compression of the piston-and-cylinder arrangement will cause compression of the bellows. Such an arrangement will provide the advantages of bellows while providing the accessibility and compatibility with existing components and systems of piston-and-cylinder arrangements.

Preferably, the sealed expansion means comprise a reservoir of fluid. Preferably, the reservoir comprises a sealed bellows. Conveniently, the bellows may be of the same type as the bellows of the means for introducing fluid. In a preferred embodiment, the bellows are mounted inside a piston-and-cylinder arrangement.

Preferably, the expansion means and introduction means are in fluid communication by means of a conduit. Preferably, the conduit is flexible. Preferably, the conduit is of plastics material. Most preferably, the conduit is of polytetrafluoroethane (PTFE). Preferably, the conduit is coupled to the inlet means.

Preferably, the compression means for introduction of fluid comprises a controllable dispenser of fluid. Conveniently, this may be provided in conjunction with a reservoir of fluid operatively connected to the expansion means. The dispenser may dispense fluid continuously, or in discrete steps. Preferably, the dispenser comprises a motor means and a plate which is urged forward by the motor means. In a preferred embodiment, the plate is in contact with the reservoir of fluid, so putting the fluid under pressure. In embodiments with bellows mounted inside piston-and-cylinder arrangements, the plate may be

arranged to urge the piston into the cylinder, so compressing the bellows. Conveniently, the dispenser may be a conventional portable syringe driver. This eliminates the need for expensive custom-made driver units.

Preferably, the first and second relatively movable portions are adapted to be coupled, in use, to respective first and second portions of a bone to be distracted.

These and other aspects of the present invention will now be described by way of example only with reference to the accompanying figures, in which:

Figure 1 shows an osseo-distractor unit in accordance with an embodiment of the present invention;

Figure 2 shows a selection of connecting pieces for use with the apparatus of Figure 1;

Figure 3 shows an enlarged and more detailed view of the expansion unit of the osseo-distractor of Figure 1;

Figure 4 shows an end view of the outer sleeve anchor of the expansion unit of Figure 3 in the direction of arrow 4-4;

Figure 5 is a view taken in the direction of arrow 5 in Figure 3 and shows the inner sleeve anchor of the expansion unit; and

Figure 6 shows the compression unit of the osseo-distractor of Figure 1.

Referring firstly to Figure 1, this shows an apparatus 10 for osseo-distraction, in accordance with one embodiment of the present invention. The apparatus 10 includes an expansion unit 12 for mounting on the bone 11 to be distracted, which is connected via connecting piece 14 and flexible PTFE tubing 16 to a compression unit 18, which is itself driven by a syringe driver 20, including a motor (not shown) and a pressure plate 21. Both compression unit 18 and expansion unit 12 are of similar construction, having a piston movable within a cylinder to define a cavity into which is located a bellows expansion unit connecting to the PTFE tube but

otherwise sealed. The bellows units and the PTFE tube are primed with sterile distilled water. Each unit 18, 12 includes three bellows units. The bellows units are substantially sealed, having outlets only to the adjacent bellows or to the PTFE tubing 16.

Before use, the system is primed with a sufficient quantity of sterile distilled water, such that putting the water of the compression unit 18 under pressure will cause equivalent pressure in the expansion unit 12, and sufficient expansion of the bellows of the expansion unit 12 is possible throughout the desired range of expansion.

In this example, the syringe driver 20 is a standard MS26 model, produced by Graseby. This is capable of delivering fluid at a user-adjustable rate of from 1 to 99mm in 24 hours. Suitable alternative drivers may be used.

In use, the motor of the syringe driver 20 urges the pressure plate 21 against the piston of the compression unit 18. As the piston is driven into the cylinder, the bellows units mounted therein are compressed, so urging fluid along PTFE tube 16 (in this embodiment, having a 1/16 inch outer diameter, and a 0.1 inch bore; sufficient to withstand the expected fluid pressures). The fluid enters the identical bellows units mounted within the cylinder of the expansion unit 12, which expand and urge the piston out of the cylinder. This drives apart the portions of each of the piston and cylinder which are fixed to jawbone 11 at locations 13a, 13b as shown, so driving the two parts of the jawbone apart.

Figure 2 shows a selection of suitable connecting pieces 14 for use with the apparatus of the present invention. These show pieces 14 constructed with a) a flared tube, b) a flange-free system and c) a double-sided ferrule.

Figure 3 shows in more detail the expansion unit 12 of Figure 1. The unit 12 comprises cylindrical stainless steel inner and outer sleeves 22, 24. Mounted at one end

of the outer sleeve 24 is a flared tube connector piece 14, which connects the unit 12 to PTFE tubing 16. Mounted at location 13a the other end of the outer sleeve 24 is first anchor 26, by which the unit 12 may be fixed to a bone. At location 13b, second anchor 28 is mounted to one end of the inner sleeve 22.

A view of the first anchor 26 of expansion unit 12 along the direction of the arrows 4-4 is shown in figure 4. The anchor 26 comprises an annular portion 34, which is silver soldered to the outer sleeve 24, and an offset flange portion 36. The flange portion 36 is silver soldered to a standard bone fixing right angle plate 38 (shown in outline on figure 3) for receiving a bone screw (not shown) for anchoring the sleeve in place as shown in figure 1.

Figure 5 shows a view of the second anchor 28 of expansion unit 12 along the direction of arrow 5, comprising a disc-shaped portion 40 and an offset flange portion 42. As with the first anchor 26, the anchor 28 is fixed to the bone via a standard fixing plate 44.

Inside the inner sleeve 22, and interconnected, are 3 electrodeposited nickel bellows 30a, 30b, 30c arranged in series and spaced apart by axially movable annular spacer rings 32. The bellows 30 are 0.375" outside diameter, 0.75" free length nickel bellows, supplied by the Servometer Corporation, USA. One end of the bellows 30a abuts the connector piece 14, while the other end of bellows 30c abuts a blank end connector 29 connected to the second bore anchor 28. Thus, one end of bellows 30a is fixed with respect to the outer sleeve 24, while the other end of bellows 30c is fixed with respect to the inner sleeve 22. Expansion or contraction of the bellows 30 will therefore cause relative axial movement of the two sleeves 22, 24.

In the present embodiment the bellows are joined to the other system components by epoxy resin; although alternative means may be used; for example, electron beam

welding.

The compression unit 18 of the distractor 10 is shown in more detail in Figure 6. Like the expansion unit 12, the compression unit 18 comprises an inner and outer cylindrical stainless steel sleeve 46, 48, with three bellows 50a, 50b, 50c and spacers 52 mounted therein. At one end of the outer sleeve 48 is mounted a flared tube outlet connector 54, which connects the first bellows 50a to the PTFE tubing 16. At the other end of the outer sleeve 48 is a flange 56, while at an end of the inner sleeve 46 is a plunger end piece 58 which abuts the third bellows 50c. Both flange 56 and end piece 58 cooperate with matching portions on the syringe driver 20, such that urging of the pressure plate 21 drives plunger 58 toward flange 56, urging the inner sleeve 46 into outer sleeve 48, and thereby causing compression of the bellows 50.

It will be seen that the foregoing provides a distractor device which may be hydraulically driven with conventional readily-available parts, with minimal risk of leakage over previous hydraulic distractors. Further, the use of conventional syringe drivers enables the distraction procedure to be readily modified and adapted for different clinical situations. In alternative embodiments, the number of bellows 30, 50 used may be modified. The use of three bellows, as described herein, enables up to 20mm of distraction movement to occur; the use of only two bellows provides up to 10mm of movement. The form of the compression unit 18 may also be modified in order to be compatible with numerous alternative syringe drivers without departing from the scope of the invention.

CLAIMS

1. Apparatus for use in osseo-distraction, the apparatus comprising substantially sealed fluid-actuated expansion means coupled to first and second relatively movable portions for securing to respective first and second portions of a bone to be distracted, and inlet means adapted to permit entry of fluid into the substantially sealed expansion means.

2. Apparatus as claimed in claim 1 wherein the fluid is sterile distilled water.

3. Apparatus as claimed in claim 1 or 2 wherein the apparatus further comprises compression means adapted to be coupled to the inlet means for introducing fluid into the sealed expansion means.

4. Apparatus as claimed in claim 3 wherein the compression means comprises a reservoir of fluid operatively connected to the expansion means.

5. Apparatus as claimed in claim 4 wherein the reservoir is sealed with respect to the exterior of the apparatus.

6. Apparatus as claimed in claim 4 or 5 wherein the reservoir comprises a sealed bellows.

7. Apparatus as claimed in claim 6 wherein said bellows is a metal bellows.

8. Apparatus as claimed in claim 6 or 7 wherein the bellows are mounted inside a piston-and-cylinder arrangement.

9. Apparatus as claimed in any preceding claim wherein the sealed expansion means comprises a reservoir of fluid.

10. Apparatus as claimed in claim 9 wherein the reservoir comprises a sealed bellows.

11. Apparatus as claimed in claim 9 wherein said bellows is a metal bellows.

12. Apparatus as claimed in claim 10 or 11 wherein the bellows are mounted inside a piston-and-cylinder arrangement.

13. Apparatus as claimed in any preceding claim wherein the expansion means and introduction means are in fluid communication by means of a conduit.

14. Apparatus as claimed in claim 13 wherein the conduit is flexible.

15. Apparatus as claimed in claim 13 or 14 wherein the conduit is made of a polymer material.

16. Apparatus as claimed in claim 15 wherein the conduit is of polytetrafluoroethane (PTFE).

17. Apparatus as claimed in any one of claims 13 to 16 wherein the conduit is coupled to the inlet means.

18. Apparatus as claimed in any one of claims 2 to 18 wherein the compression means for introduction of fluid comprises a controllable dispenser of fluid.

19. Apparatus as claimed in claim 18 wherein the dispenser comprises a motor means and a plate which is urged forward by the motor means.

20. Apparatus as claimed in claim 19 wherein the plate is in contact with the reservoir of fluid, so putting the fluid under pressure.

21. Apparatus as claimed in claim 19 or 20 wherein when a bellows is mounted inside a piston-and-cylinder arrangement, the plate is arranged to urge the piston into the cylinder, compressing the bellows.

22. Apparatus as claimed in any one of claims 2 to 21 wherein the dispenser may be a conventional portable syringe driver.

23. Apparatus as claimed in any preceding claim wherein the first and second relatively movable portions are adapted to be coupled, in use, to respective first and second portions of a bone to be distracted.

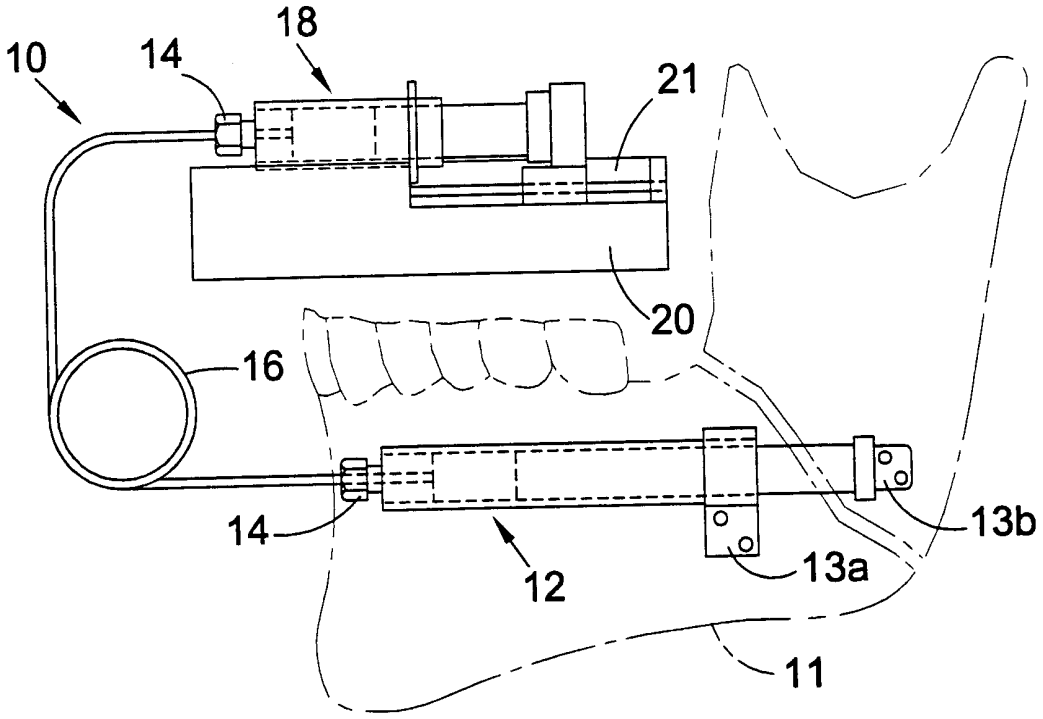
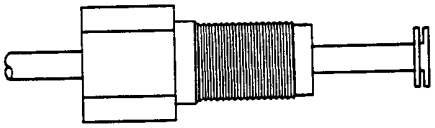
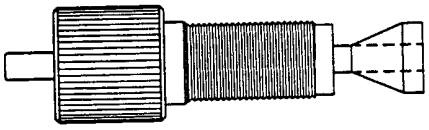



Fig.1

Fig.2



(a)



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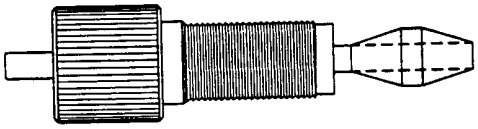

(c)

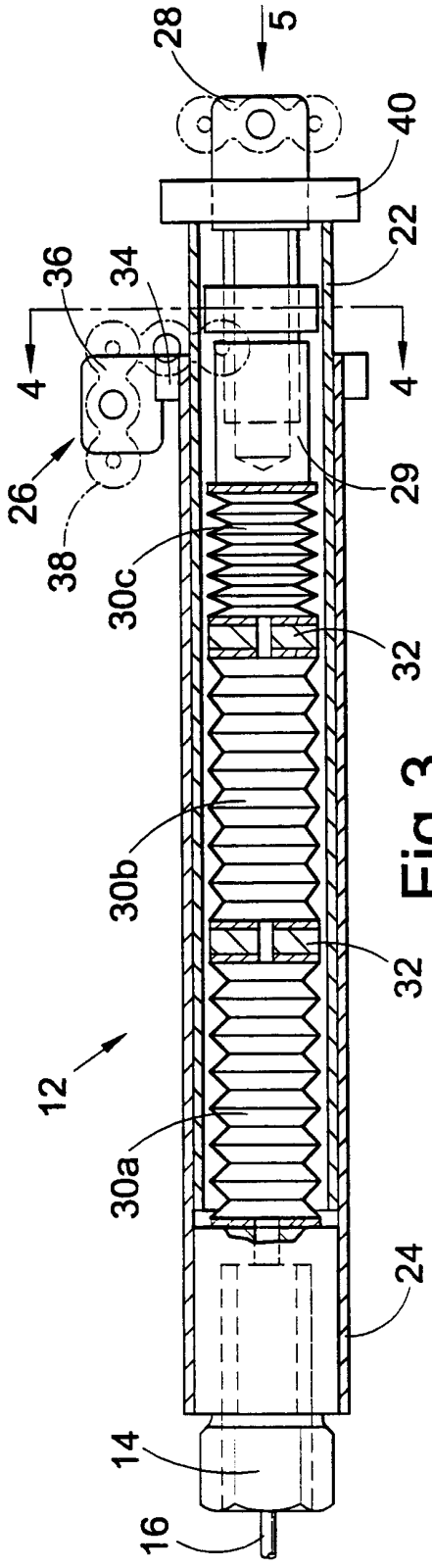


Fig.3

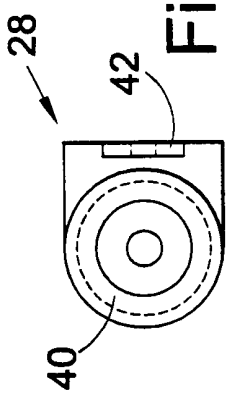


Fig.5

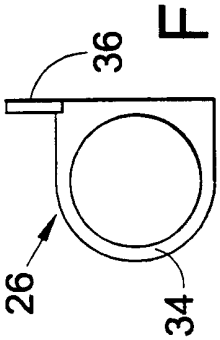


Fig.4

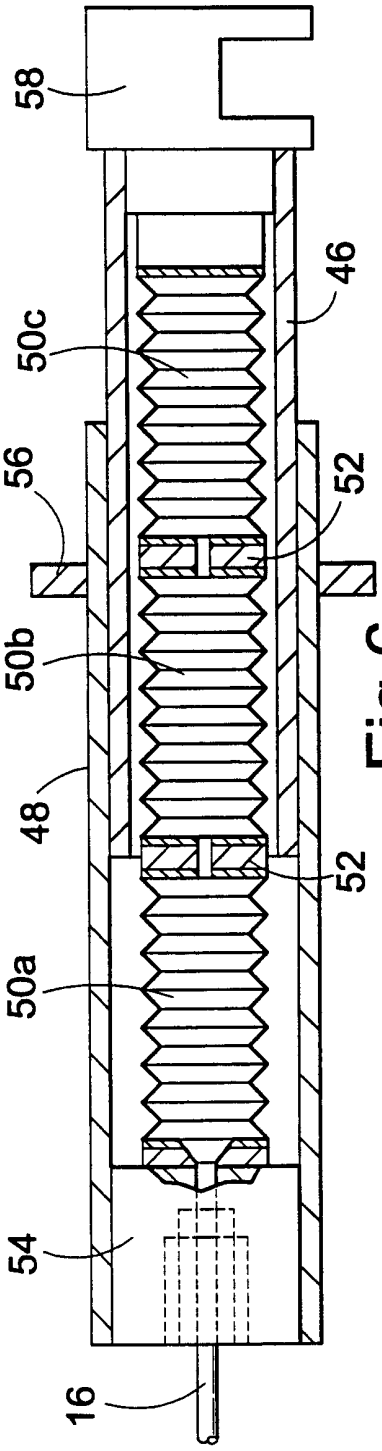


Fig.6

# INTERNATIONAL SEARCH REPORT

Interr. ,nal Application No
PCT/GB 00/03637

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/66

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

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)
PAJ, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| X | DE 299 04 696 U (AESCULAP)<br>2 June 1999 (1999-06-02)<br>page 2, line 17 - line 20<br>page 3, line 17 - line 20<br>page 4, line 16 - line 29<br>page 6, line 27 -page 7, line 16<br>figure 1<br>--- | 1-5,9,<br>13-18,23 |
| X | PATENT ABSTRACTS OF JAPAN<br>vol. 1998, no. 02,<br>30 January 1998 (1998-01-30)<br>& JP 09 271478 A (S.NISHIMOTO),<br>21 October 1997 (1997-10-21)<br>abstract<br>---<br>-/-- | 1-5,9,<br>13-18,<br>22,23 |

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication,where appropriate, of the relevant passages | Relevant to claim No. |
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| P,X | US 6 113 599 A (S.E.LANDSBERGER) 5 September 2000 (2000-09-05)<br><br>column 20, line 24 -column 21, line 10<br>----- | 1-6,9, 10, 13-18,23 |

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...ormation on patent family members

Inter... nal Application No
PCT/GB 00/03637

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