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(71) Applicant(s): **Edward Boyle** 30 Peebles Drive, DUNDEE, Angus, DD4 0TF, **United Kingdom**

(72) Inventor(s): **Edward Boyle**

(74) Agent and/or Address for Service: **Edward Boyle** 30 Peebles Drive, DUNDEE, Angus, DD4 0TF, **United Kingdom**

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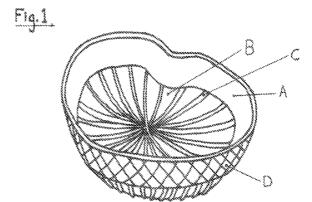
(56) Documents Cited:

US 6093022 A US 4828491 A US 4721465 A US 3781994 A US 0741890 A

(58) Field of Search: INT CL A61C

Other: EPODOC, WPI, INTERNET

- (54) Title of the Invention: One piece, single item rubber dam Abstract Title: Single piece rubber dental dam
- (57) A self-retentive, single piece rubber dam has an incorporated elastomeric wedge retention system C in the dam membrane B and integrated, two mode (active and passive) self-retaining flexible frame A. The dam can be flipped from concave to convex modes, gently gripping the patient's face and hooks under the chin (see figures 3-6). The dam may also have a dental napkin material D bonded to the patient-contacting side to improve patient comfort. The wedges C, which radiate from the centre of the dam to the periphery, may be of thickened rubber in a variety of cross-sections (see figure 7). The dam isolates teeth from secretions of the oral cavity and also protects the oral cavity and respiratory or digestive tracts from procedural debris.



A = Frame

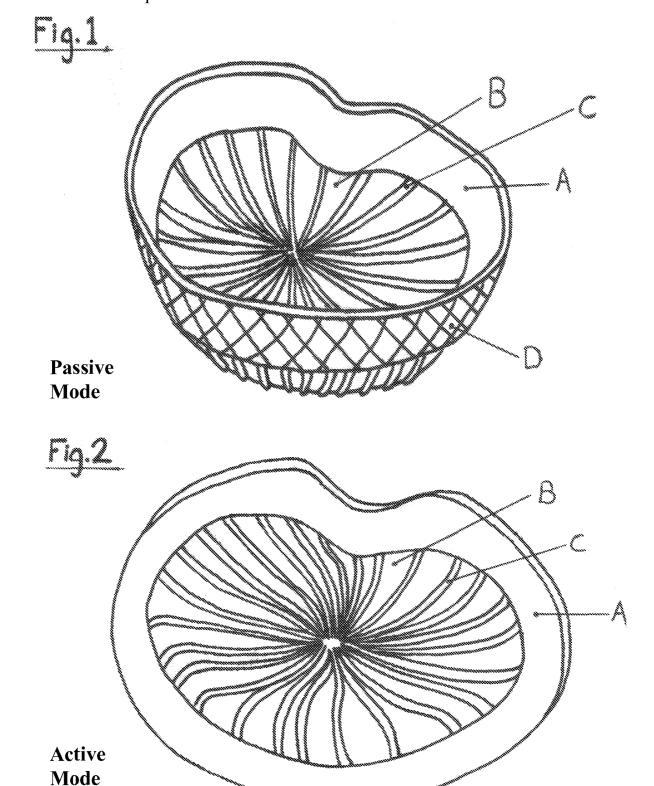
B = Dam Membrane

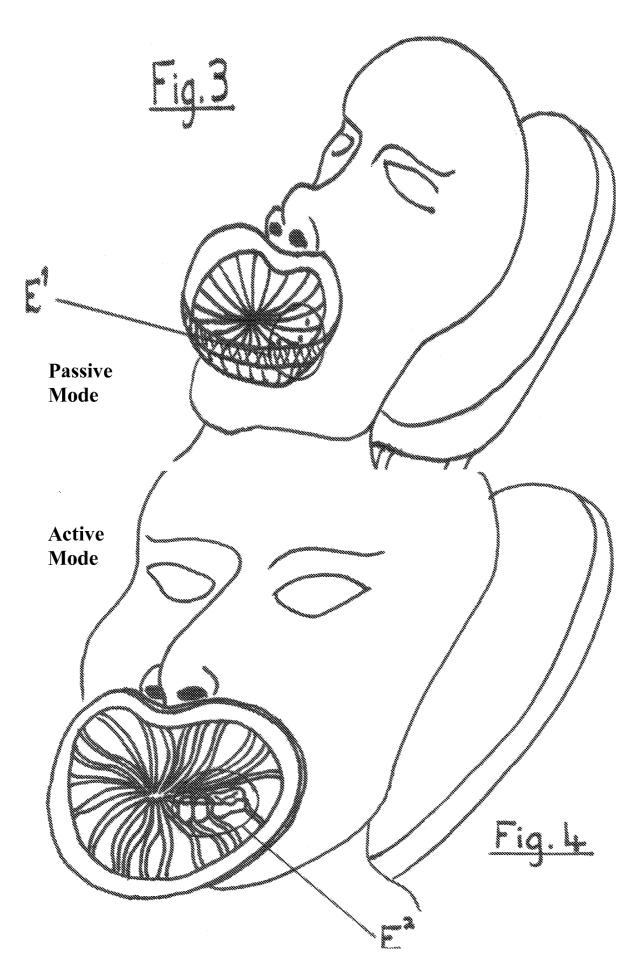
C = Incorporated Wedges

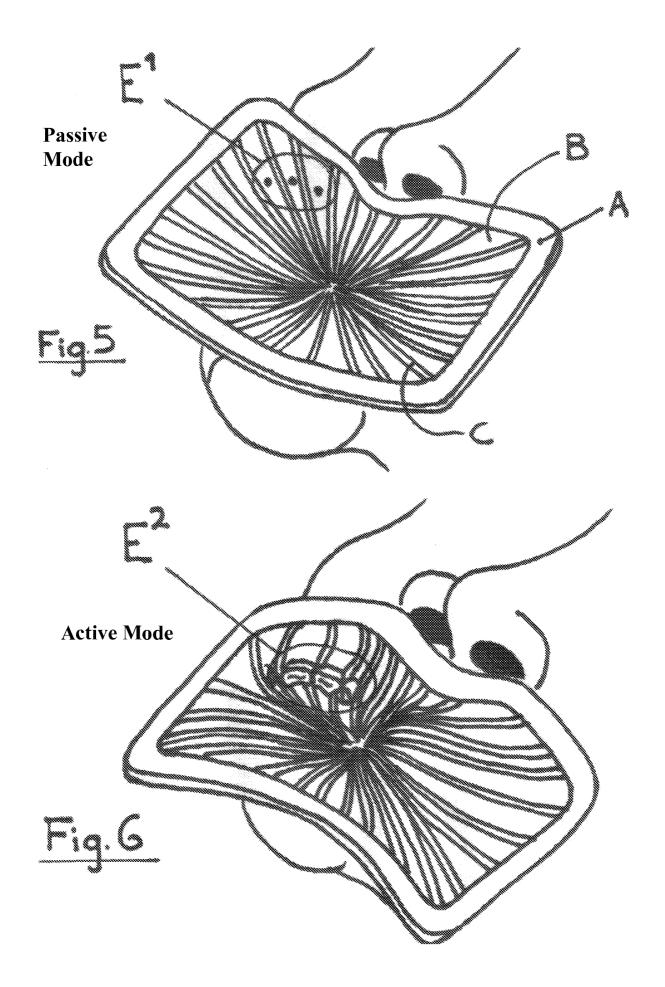
D = Dental Napkin Material

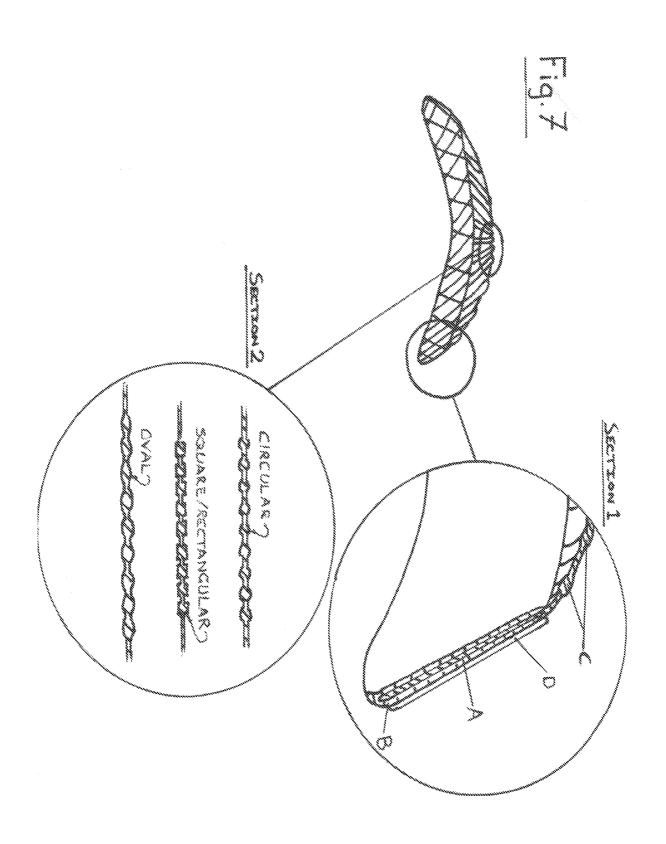
 $\frac{\textbf{Key}}{E_1 = \text{Holes punched in dam membrane}}$

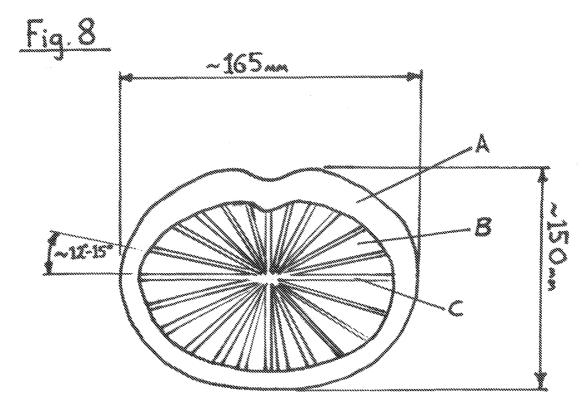
 $E_2 = Dam$ in place with teeth isolated



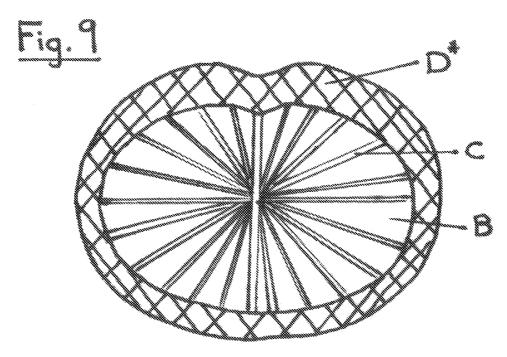






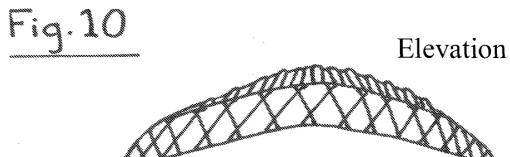


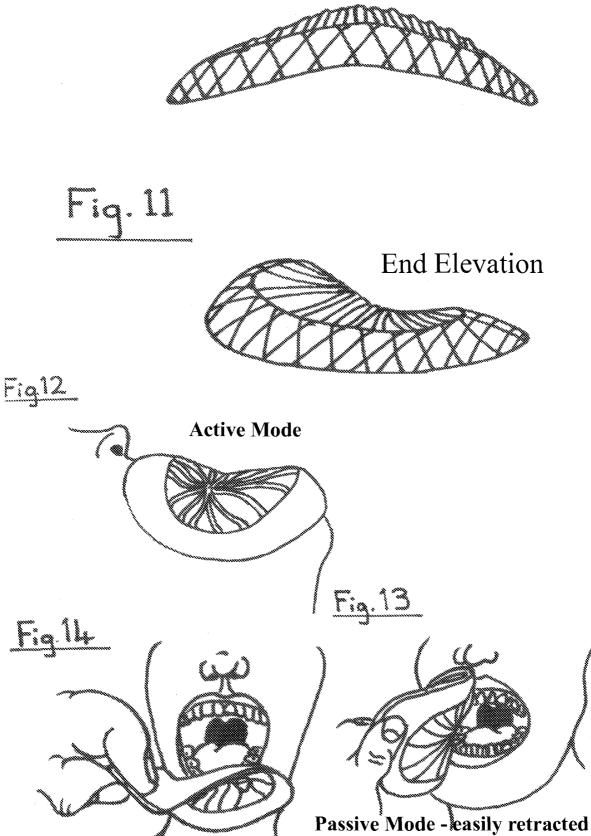
- · PLAN VEEW SIDE OF DEVICE FACENGELLINICIAN
 - · ALL SIZES ARCKIMATE



PLAN VIEW-SIDE OF DEVICE THAT CONTACTS PATIENTS FACE

* - OVERLYING A





for radiographs (Figs 13,14)

One Piece, Single Item Rubber Dam (also known as 'Dental Dam')

This invention is used to isolate single or multiple teeth from the oral cavity during dental procedures and reduces the need for multiple components of the conventional rubber dam system.

Background

Current Problems with Conventional Rubber Dam

Today the use of rubber dam is mandatory for any and all endodontic treatment and is indeed recommended for many others, this premise indicates that it's use will become ubiquitous in the future.

However, dentists have been reserved regarding the general uptake of rubber dam, even for treatments where its use is essential.

This lack of enthusiasm for the uptake of rubber dam is intrinsically linked to the limitations inherent in the componentry and interplay between these components within current system; these include –

- Difficulty of application;
- · Time spent during application;
- Need for sterilisation of equipment used with conventional rubber dam;
- All current systems are clamp retained;
- Patient dislike of clamp use in general;
- Patient complaints of pain during and after clamp placement;
- Many separate components that need manipulated and some sterilised;
- Poor anthropometrics/anatomical adaptation of the current components;
- Estimation of punched hole placement;
- Difficulty in taking radiographs when using conventional and other rubber dam systems.

Current Solutions

There are a number of current solutions to the problems associated with conventional rubber dam, the problems with these current solutions, in my opinion, are listed below.

Insta-Dam (Zirc Dental)

- · Clamp retained;
- Little advantage of pre-punched hole, as more than one tooth may require isolation;
- Hole may not be in correct place for tooth to be treated (although manufacturer claims rotation of dam solves this);
- Little consideration given to patient anthropometrics /anatomy;
- Retraction for radiographs may prove troublesome due to frame spring back.

Handidam (Dentsply)

- Clamp retained;
- Consideration given to anthropometrics /anatomy still inadequate;
- Rubber of dam against patient's skin may cause discomfort;
- Handle used for retraction when taking radiographs may be uncomfortable for patients to tolerate.
- Frame spring back during retraction.

Drydam (SDI)

- Clamp retained;
- Patients may find ear loops uncomfortable;
- Still little consideration given to anthropometrics /anatomy.

My Alternative Solution

Taking into account the disadvantages of conventional rubber dam and the current alternatives, it is clear that improvements can be made in the following areas –

- Reduce the need for clamp use to a minimum;
- Improve adaptation to anthropometrics/anatomy of the patient;
- Improve patient comfort;
- Improve ease of application for clinicians;
- Improve the ease of placement of punched hole for clinicians;
- Improve ease of access for the taking of radiographs during dam use;
- Reduce the need for sterilisation of multiple components;
- Reduce the need for multiple components to a minimum.

Description

Bearing these aspects in mind I have devised another solution and in essence my concept can be described as follows –

One Piece, Single Item Rubber Dam

A self retentive, single item, all in one rubber dam with incorporated elastomeric wedge retention system and integrated, two mode (active and passive), self retentive flexible frame (Figs. 1,2,3,4). This device is designed to be used for the isolation of single or multiple teeth, in one dental arch or both dental arches simultaneously, from the secretions of the oral cavity during dental procedures while simultaneously protecting the oral tissues and cavity, alimentary and respiratory tracts from the ingestion or inhalation of items or medicaments used during such dental procedures (Figs. 3,4,5,6,12). This one piece, single item, all in one rubber dam is composed of an integrated, flexible, self retentive frame with a similar shape to the elastomeric sheet that it is bonded to or enveloped by and can come in a variety of shapes such as rectangular or oval (Figs. 1,2,3,4,5,6,7). The elastomeric sheet has thickened areas, which originate and radiate from the centre of the elastomeric sheet and terminate at the periphery of the elastomeric sheet at the inner border of the integrated frame (Figs. 1 to 11); with these thickened areas being circular, oval or square in cross section (Fig. 7). Each segment between the thickened areas allows the operator to use each segment to isolate a single tooth, or multiple segments to isolate multiple teeth (Figs. 1 to 6). This all in one dam reduces the need to use rubber dam clamps/ tooth clamps/tooth clamping methods to a minimum via two principle forces that originate from and are generated by the self retentive, single item, all in one rubber dam (Figs. 3,4,5,6,7,12). Firstly, the application of gentle pressure from the flexible self retentive, active/passive modes frame on the extra oral tissues immediately surrounding the oral cavity to include the upper and lower lips, cheeks and chin when the frame is activated (Figs. 1,2,3,4,5,6,12,13,14). Secondly, retention is further increased by the utilisation of the integrated elastomeric wedges, composed of the same material as the elastomeric dam membrane, being wedged between and below the contact points of the tooth/teeth being isolated and their surrounding counterparts (Figs. 3,4,5,6,7). This self retentive, single item, all in one rubber dam is produced in three thickness grades, these being light, medium and heavy; correspondingly, the wedges incorporated into the elastomeric sheet increase in cross sectional area (while maintaining their circular, square or oval cross sectional form) as elastomeric sheet thickness increases, this allows the clinician to select a grade of dam to match the variety of spacing between contact points that occurs with different patients (Fig. 7). It can be used with or without rubber dam clamps/tooth clamps/tooth clamping methods and the use of this self retentive, single item, all in one rubber dam does not preclude the use of rubber dam clamps/tooth clamps/tooth clamping methods if the clinician feels the situation requires their use. In addition, the dam can be utilised with or without the use of the incorporated wedges as the clinician sees fit. The device provides easy access for radiographs with minimal force required to retract the dam to facilitate this when the frame is reversed from active to passive mode(Figs. 12,13,14). This self retentive, single item, all in one rubber dam also has a soft, dental napkin like material bonded to the side of the dam in contact with the patient's extra oral tissues to improve patient comfort and tolerance of the dam material (Figs. 1,3,7,9,10,11). Patient comfort is also increased via greater consideration of patient anatomy and anthropometrics and the adaptation of the dam and frame to these (Figs. 4,6,12).

These aspects are achieved by the following features with further description:

The dam is retained via the use of an integrated frame in conjunction with incorporated wedges in
the dam sheet to retain the dam without clamps (in most cases) (Figs. 1 to 7), however clamp use is
still an option and is not precluded by the use of this type of dam.

- The goal of little or no clamp use is achieved by employing a modified truncated elliptical cone form as the integrated frame, or if square or rectangular in shape, the frame would flip from concave to convex (Figs. 1,2,3,4,5,6,7,12). When the frame is in its passive state it allows easy fitting of the dam and also dam retraction when radiographs are required (Figs. 3,4,5,6,12,13,14). When in its active form, the frame applies gentle pressure to the patient's face and 'hooks' under the chin, thus providing a degree of retention, while maintaining patient comfort (Figs. 3,4,5,6,9,12).
- In addition, the wedges incorporated into the dam sheet are engaged by using a 'flossing action' to slide them between the contact points of the tooth/teeth to be isolated, further increasing retention and, for the most part, negating the need for the use of clamps.
- The pattern of the incorporated wedges allows each tooth to be isolated within each separate segment of the dam sheet (due to the 12°-15° division between each wedge Fig. 8), so allowing single or multiple units to be isolated as required (Figs. 3,4,5,6).
- By combining the two aspects of frame design and incorporated wedges the need for clamps, in most cases, will be negated.
- Time for fitting and removal and the need for sterilisation of many components are reduced as this is a single piece, single use item, that could be non-sterile or pre-sterilised prior to packaging; thus there is no need for assembly and disassembly of multiple components.
- If manufactured in an industrial setting I would suggest using an injection moulding machine with a water cooled mould, where the dam frame (composed of a suitable plastic, e.g. polypropylene) is pre-manufactured then inserted into the mould. Heated acrylonitrile butadiene rubber or latex would then be injected and flow to form the elastomeric dam sheet and incorporated wedges encapsulate the frame within the dam material. The materials suggested are in general use presently in rubber dam devices and thus no investment in the development of a new material would be required and the health and safety records of these materials is well established.
- The dam is simply punched as usual (just as with present rubber dam systems) while in its passive state (Figs. 3,5), then the dam and wedges are then simply flossed between the contacts and the dam then 'flipped' into its active form to combine both retentive aspects (Figs. 4,6,12). Ease of placing the punched hole is increased due to the incorporated wedges providing a segmented layout in which the operator simply punches a hole in the segment that relates to the tooth/teeth requiring to be isolated (Figs. 3,4,5,6,8).
- To retract the dam for taking radiographs, the dam is simply 'flipped' from its active to its passive mode and retraction with one finger is possible (Figs. 13,14).
- By creating a notch in the superior aspect of the dam, the patient will find breathing through the nose easier than with conventional dam. In addition, the form of the dam adapts to the patients face and the flexibility of the dam will allow conformation of the dam to a varied spectrum of differing patient anthropometrics/ anatomy (Figs. 1 to 14). Furthermore addition of a soft, dental napkin like material to the side of the device in contact with the patient's extra oral tissues further improves comfort (Figs. 1,3,7,9,13,14).

Claims

- A self retentive, single item, all in one rubber dam with incorporated elastomeric wedge
 retention system and integrated, two mode (active and passive) self retentive flexible frame
 which is used for the isolation of single or multiple teeth, in one dental arch or both dental
 arches simultaneously, from the secretions of the oral cavity during dental procedures while
 simultaneously protecting the oral tissues and cavity, alimentary and respiratory tracts from the
 ingestion or inhalation of items or medicaments used during such dental procedures (Figs. 1 to
 14).
- 2. Reducing the need for clamp use to a minimum is achieved via two principle forces that originate from and are generated by the device, firstly, by application of gentle pressure from the flexible self retentive, active/passive frame on the extra oral tissues immediately surrounding the oral cavity to include the upper and lower lips, cheeks and chin when the frame is activated, and secondly, retention is further increased by the utilisation of the integrated elastomeric wedges, being wedged between and below the contact points of the tooth/teeth being isolated and their surrounding counterparts (Figs. 1,2,3,4,5,6,7,12).
- 3. Improved adaptation to anthropometrics/anatomy of the patient is achieved via the flexible self retentive frame adapting to, and interacting with the circumoral tissues (Figs. 3,4,5,6,12).
- 4. Improved patient comfort is achieved via reducing the need for clamp use to a minimum, as in 'Claim 2', and through the inclusion of the soft dental napkin like material bonded to the side of the device in contact with the patient's skin (Figs. 1 to 14).
- 5. Improved ease of application for clinicians is achieved via the creation of the device as a one piece system, thus the clinician only has one item to handle during dam fitting as opposed to at least five with conventional rubber dam (dam, clamp, clamp forceps, frame and napkin) and four with current solutions (dam, dental napkin, clamp forceps and clamp); also ease of application is improved due to the fact that no other tools (such as clamp forceps) need to be handled during fitting of the device as this is done by simply using a 'flossing' action to slide the wedges between and below the contact points of the tooth/teeth to be isolated and their counterparts (Figs. 1 to 14).
- 6. Improved ease of placement of punched hole for clinicians is achieved via the segmented design created by the incorporation of the wedges in the elastomeric sheet of the dam, thus the clinician simply punches a hole in the segment(s) that corresponds to the tooth/teeth requiring isolation, no longer needing to 'guesstimate' where to punch or have to use another system to mark the dam prior to punching (Figs. 3,4,5,6,7,8).
- 7. Improved ease of access for the taking of radiographs during dam use is achieved via the active/passive design of the integrated frame of the device, as when the frame is 'flipped' from active to passive a degree of tension on the dam sheet is reduced (while the wedges retain the dam on the tooth/teeth) allowing the clinician to simply move the dam aside for radiographs to be taken and also 'Claim 5' supports this due to the device being a one piece system the clinician no longer needs to disassemble the conventional dam, current systems also have no active/passive states and are constantly under tension (Figs. 1 to 14).
- 8. Reducing the need for sterilisation of multiple components is achieved via 'Claim 1', 'Claim 2' and 'Claim 5' (Figs. 1 to 14).
- 9. Reducing the need for multiple components to a minimum is achieved via 'Claim 1', 'Claim 2', 'Claim 4', 'Claim 5' and 'Claim 6' (Figs. 1 to 14).



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Application No: GB0912469.4 **Examiner:** Gabrielle Cowcill

Claims searched: 1-9 Date of search: 13 January 2010

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

| Category | Relevant to claims | Identity of document and passage or figure of particular relevance |
|----------|-----------------------|---|
| X | 1-3, 5-9 | US 4828491 A (GRAY) See column 6, line 67, to column 7, line 11, and figure 5 |
| A | - | US 3781994 A (HESSELGREN) See the whole document |
| A | - | US 6093022 A (SWALLOW) See the summary of the invention, and the figures |
| A | - | US 4721465 A (BARASZ) See the whole document |
| A | - | US 741890 A (CRAIGIE) See the whole document |

Categories:

| | X Documen | t indicating lack of novelty or inventive | Α | Document indicating technological background and/or state |
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| | step | | | of the art. |
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| | combined | with one or more other documents of | | before the filing date of this invention. |
| | same cate | gory. | | |
| - - | & Member of | of the same patent family | Е | Patent document published on or after, but with priority date |
| | | | | earlier than, the filing date of this application. |

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X :

Worldwide search of patent documents classified in the following areas of the IPC

A61C

The following online and other databases have been used in the preparation of this search report

EPODOC, WPI, INTERNET

International Classification:

| Subclass | Subgroup | Valid From |
|----------|----------|------------|
| A61C | 0005/12 | 01/01/2006 |