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(56) Documents Cited:
GB 2172806 A EP 0181138 A1
US 5207652 A US 3782378 A

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(54) Abstract Title: **Restraint for use in attaching drip**

(57) A restraint or splint for medical use comprising a flexible layer 1 having an underside with a rigid bracing member 5 attached thereto. The underside of the flexible layer 1 and the rigid member 5 is covered with an adhesive cushioning layer 6 which is preferably a hydro-gel material. The cushioning layer 6 also acts as an adhesive layer to attach the restraint to a patient. The adhesive layer 6 is preferably covered with a release paper 9.

The restraint restricts movement of the patient's joint to which it is applied thereby allowing the easy application of a cannula of an intravenous infusion to the wearer's limb and preventing further movement of the joint which could cause the cannula to become detached.

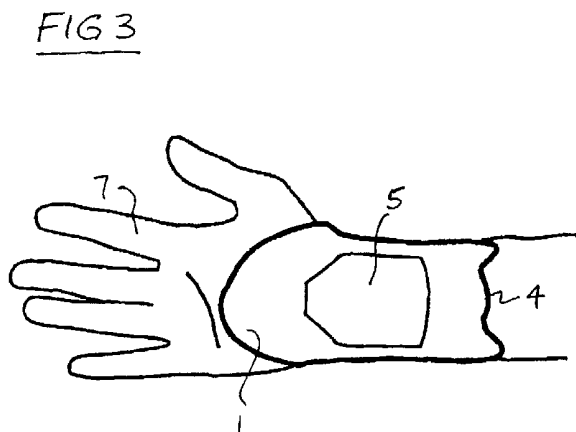
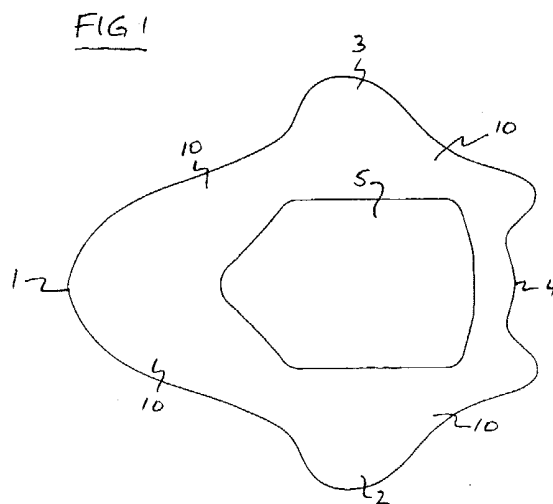


FIG 1

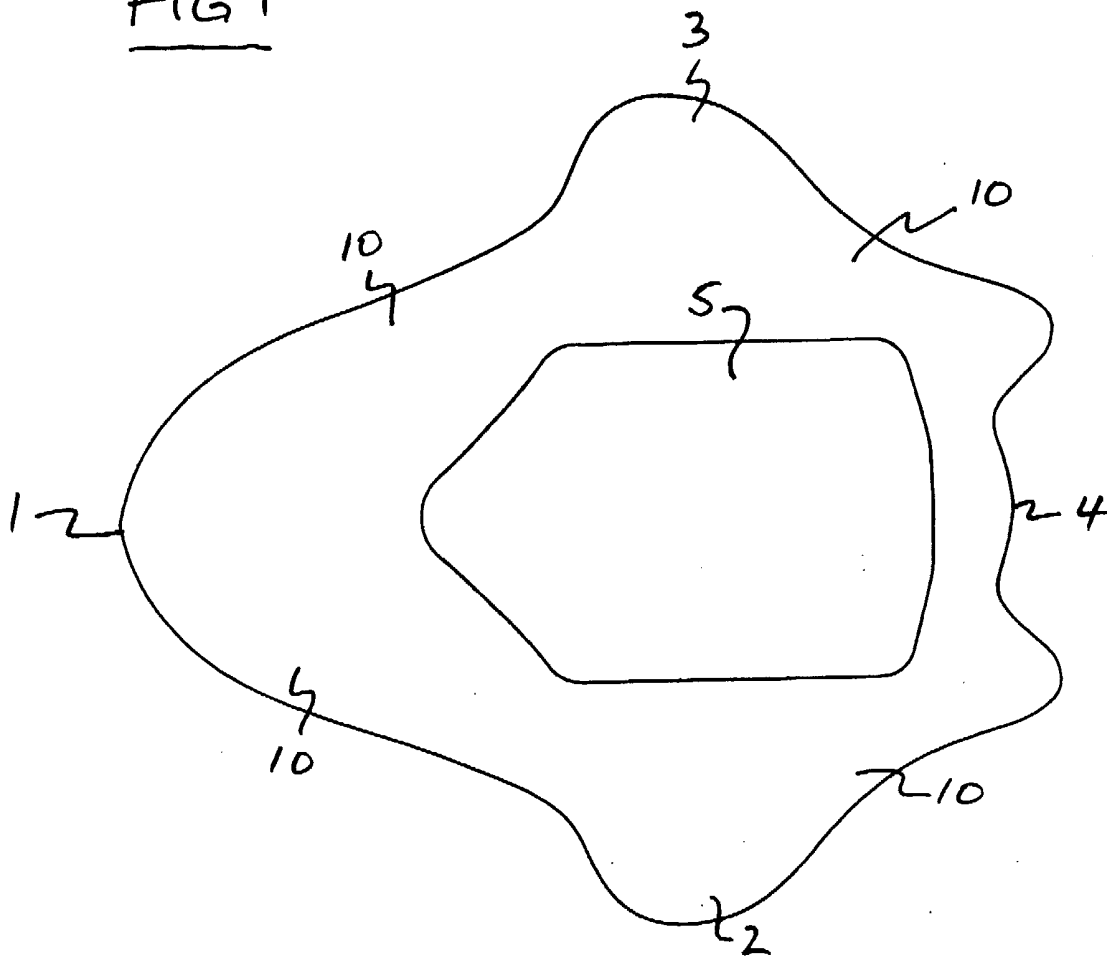


FIG 2

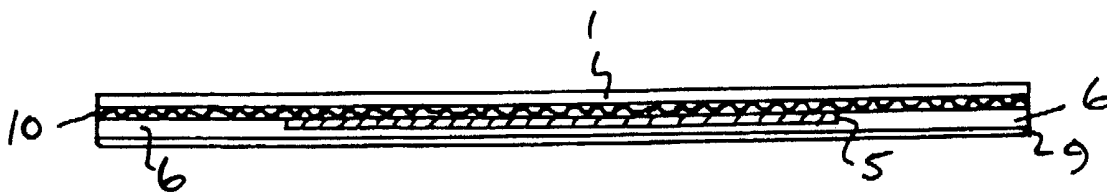


FIG 3

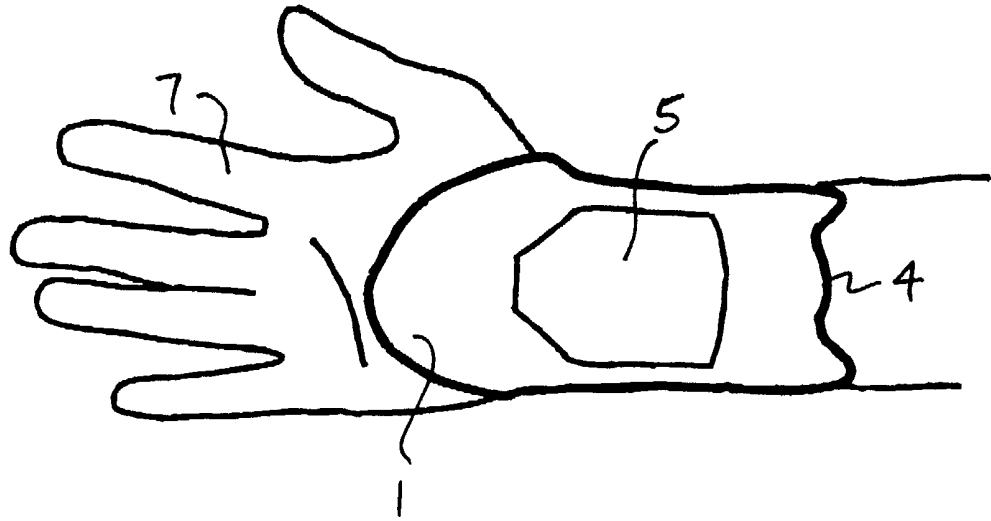
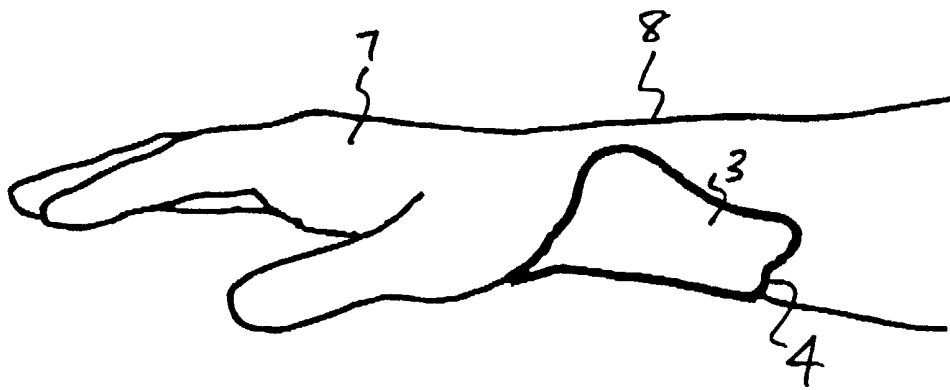


FIG 4



Restraint for Medical Use

This invention relates to a restraint for medical use and more particularly but not exclusively to a restraint which not only facilitates the application of an
5 intravenous drip to a patient but it also contributes to keeping it in place after insertion by limiting movement of the patient's joint. Although the restraint of the invention will be explained in terms of its use in connection with children, it can equally well be used with any age group.

10 An intravenous drip is usually inserted into a patient's hand although sometimes it can be inserted into an area adjacent one of their feet or elbows. It is undesirable to have any movement of the patient while the drip is being applied because such movement can dislodge the cannula and thereby put the patient at risk. A common problem in paediatric wards in hospitals when applying an
15 intravenous drip to a child's hand is that the child will often bend its hand or wrist as the drip is being inserted which can cause problems. If the patient is a very young child, the child is likely to cause the drip to come out due to excessive flexing of the wrist (or foot, elbow, etc.). It is therefore desirable to use some form of restraint to limit or restrict any movement of the joint while
20 the intravenous infusion is being applied and thereafter.

Current practice is to use a restraint made from wood or a rigid plastics material, the restraint being held in position over to the patient's joint by means of Velcro (RTM) and/or bandaging. The problem with the use of bandages is that they can cover
25 the cannula or IV drip so that if there is any trouble with the infusion, the whole wrist has to be unbandaged to gain access to the cannula or drip. A further problem with prior art devices of this type is that they tend to be re-used so there is a potential risk of infection to the patients.

30 It is an object of the invention to provide an improved restraint which overcomes or substantially reduces the aforementioned problems.

According to the invention, there is provided a restraint for medical use comprising a restraint for medical use comprising a flexible layer having an underside with a rigid member attached thereto, said flexible layer having an adhesive thereon to enable the restraint to be attached to a wearer, said
5 underside being covered with a protective cushioning layer encapsulating the rigid member between said flexible layer and said protective layer.

The rigid member can be planar or it can be shaped to conform to the part of the wearer's body to which it is to be fitted.

10

Preferably the rigid member has a surface area less than the area of the flexible layer thereby leaving a boundary region on said flexible layer surrounding said rigid member. The rigid member can be made of a polymer material such as polypropylene or high impact polystyrene but any other suitable stiff material
15 could be used such as wood or metal.

Conveniently, the flexible layer is a film of plastics material which is coated with an adhesive layer which can be a water, natural or rubber based adhesive. The flexible film layer can be a breathable foam material of, for instance,
20 polyurethane or polypropylene.

Preferably the cushioning layer is a coating of either a natural or synthetic polymer which swells but does not dissolve in water (hydrogel) or a mixture of synthetic or natural rubber and water absorbing powders of varying types
25 (hydrocolloid). Alternatively a layer of flexible foam may be used.

The rear of the restraint is preferably protected by a removable covering such as a release paper.

30 A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a plan view of a restraint of the invention shown in its open unfolded configuration;

Figure 2 is an enlarged schematic cross sectional view of the restraint shown in Figure 1;

5 Figure 3 is a plan view showing the restraint applied to a wearer's wrist; and
Figure 4 is a side view of the restraint shown in Figure 3.

Referring to the drawings, there is shown in Figures 1 and 2 a restraint of the invention which comprises a flexible layer 1 which is preferably made from a
10 film of plastics material such as polyurethane or polyethylene or a breathable foam. The layer of flexible material 1 has opposed side flaps 2,3 and an end portion 4.

As can be seen more clearly in Figure 2, the whole of the underside of the
15 flexible layer 1 is coated with an adhesive 10 and a rigid member 5 is attached to the flexible layer 1 by means of the adhesive 10. Both the rigid member 5 and exposed adhesive layer 10 on the flexible layer 1 are totally covered by a protective layer 6 of cushioning material e.g. a known hydrocolloid or a hydrogel layer (for instance as supplied by AMGEL TECHNOLOGIES under their
20 product No. AG735). The layer 6 acts as both an adhesive layer and a cushioning layer to stop the rigid member 5 digging into the wearer's skin. The protective layer 6 also has excellent adhesion to the skin properties combined with easy pain-free removal leaving no stickiness behind.

25 A peel-off protective covering layer 9 is attached to and covers the protective layer 6 and the rigid member 5.

As can be seen from Figure 2, the rigid member 5 is sandwiched between the flexible film layer 1 and the protective layer 6.

30

The restraint just described works on the same principle as a splint but has the advantage that it can be applied to the patient in much the same way as a

disposable dressing. Because of its adhesive layer 10, (very similar to that used on a common plaster), it does not need bandages to hold the rigid section 5 in place.

5 As can be seen more clearly in Figures 3 and 4, the restraint 1 is fitted round the patient's wrist on the underside thereof and the side flaps 2 and 3 are folded round the patient's wrist and stuck to it by means of the adhesive layer 10. This leaves the back 8 of the wearer's hand totally exposed to accept an intravenous drip (not shown), the rigid member 5 bracing the wrist joint to prevent any
10 movement thereof.

The cushioning or gel layer 6 extends over the whole of the exposed surface of the rigid member 5 and stops any point sores developing on the patient's skin so the restraint is much more comfortable to wear.

15

As the restraint of the invention is designed to be used in a similar manner to a dressing, it is a single use device and can be readily removed after use and thrown away thereby avoiding any risk of infection which may arise due to its re-
use.

20

Claims

1. A restraint for medical use comprising a flexible layer having an underside with a rigid member attached thereto, said flexible layer having an adhesive thereon to enable the restraint to be attached to a wearer, said underside being covered with a protective cushioning layer encapsulating the rigid member between said flexible layer and said protective layer.
2. A restraint as claimed in claim 1 wherein the rigid member is substantially planar.
3. A restraint as claimed in claim 1 wherein the rigid member is shaped to conform to the part of the wearer's body to which it is to be fitted.
4. A restraint as claimed in any preceding claim wherein the rigid member is made from a polymer material.
5. A restraint as claimed in claim 4 wherein the polymer material is polypropylene.
6. A restraint as claimed in claim 4 wherein the plastics material is a high impact polystyrene or similar material.
7. A restraint as claimed in any preceding claim wherein the flexible layer is a film made of a plastics material.
8. A restraint as claimed in claim 7 wherein the film is coated with an adhesive layer.
9. A restraint as claimed in claim 6 wherein the adhesive layer is a breathable foam material.

10. A restraint as claimed in claim 9 wherein the adhesive layer is a water, natural or rubber based adhesive.

11. A restraint as claimed in any preceding claim wherein the cushioning layer
5 is a layer of flexible foam.

12. A restraint as claimed in any of claims 1-11 wherein the cushioning layer is a coating of a natural or synthetic polymer which swells but does not dissolve in water.

10

13. A restraint as claimed in claim 12 wherein the cushioning layer is a hydro-gel layer.

14. A restraint as claimed in any preceding claim wherein the protective
15 cushioning layer has a readily removable covering attached thereto.

15. A restraint as claimed in claim 14 wherein the protective layer is a release paper.

20



INVESTOR IN PEOPLE

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Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): A5R (REYA, RFB, RGBA).

Int Cl (Ed.7): A61M 5/52, 25/02.

Other: ONLINE : WPI, EPODOC, JAPIO.

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
A	GB 2,172,806 A (TECNOL). See Figs	
X	EP 0,181,138 A1 (M M M). See Figs & note flexible layer 16, rigid layer 14, cushioning layer 20, adhesive 22 & release sheet 27	1, at least
X	US 5,207,652 (KAY). See Figs & note flexible layer 1 with adhesive, cushion 3 & rigid part 2.	1, at least
X	US 3,782,378 (PAGE). See Figs & note cushioning layer 18, rigid part 20, flexible layer 21, 23.	1, at least

X Document indicating lack of novelty or inventive step

Y Document indicating lack of inventive step if combined with one or more other documents of same category.

& Member of the same patent family

A Document indicating technological background and/or state of the art.

P Document published on or after the declared priority date but before the filing date of this invention.

E Patent document published on or after, but with priority date earlier than, the filing date of this application.