Title: PROTECTING MEDICAL INSTRUMENTS AGAINST CONTAMINATION AND CROSS-INFECTION

Abstract: The invention provides an assembly comprising an adhesive, flexible, sterile or sterilisable, sheet barrier for a medical (e.g., ophthalmic) instrument, and first and second protective release layers associated with respective first and second faces of the barrier. At least the first face of the barrier is adhesive and the first release layer is provided with slit means adapted to assist release of the first release layer. The arrangement is such that, on flexing of the assembly, at least a portion of the first release layer comes away from the barrier to expose at least a portion of the first face of the barrier for adhering to the instrument. The barrier is preferably disposable and serves to protect a patient-contacting part of the instrument against contamination and/or to prevent cross-infection of patients by such instruments.
PROTECTING MEDICAL INSTRUMENTS AGAINST CONTAMINATION
AND CROSS-INFECTION

Field of the Invention

The present invention relates to a method, assembly and apparatus for protecting a medical instrument, for example an eye-contacting part of an ophthalmic instrument, against contamination and for preventing cross-infection of patients by such instruments.

The expression "medical instrument", used herein refers to all forms of instrument capable in use of contacting patients or biological material under conditions where sterile conditions are required, and includes therapeutic, clinical, diagnostic, testing, surgical and laboratory instruments and apparatus, including for human, veterinary, research and microbiological use. Specific examples of ophthalmic instruments are given below.

Background of the Invention

WO-A-01/05299, the disclosure of which is incorporated by reference, describes a disposable sterile or sterilisable barrier in sheet form which in use adheres to the head of an ophthalmic testing probe to sterilise the eye-contacting surface of the head of the probe and to prevent cross-infection of patients via eye fluids which would otherwise contact the head of the probe. Between tests, the barrier can be removed from the head of the probe and replaced with a fresh barrier for the next test.

The prior art describes in general terms a number of ways of applying the barrier to the instrument, and offers certain specific examples. However, none of the prior art examples offers an easy way of applying the barrier to a medical instrument without risk of hand contact with the adhesive or eye-contacting surfaces. Even when the user wears sterile gloves, hand contact with the adhesive face of the prior art barrier can be inconvenient as the glove will stick to the barrier.
The present invention is based on our surprising finding that a certain arrangement of at least one of the release sheets between which the barrier is protected before use leads to substantially easier application of the barrier to the medical instrument.

**Brief Description of the Invention**

According to a first aspect of the present invention, there is provided an assembly comprising an adhesive, flexible, sterile or sterilisable, sheet barrier for a medical instrument, and first and second protective release layers associated with respective first and second faces of the barrier, wherein at least the first face of the barrier is adhesive and the first release layer is provided with slit means adapted to assist release of the first release layer, whereby on flexing of the assembly at least a portion of the first release layer comes away from the barrier to expose at least a portion of the first face of the barrier for adhering to the instrument.

The first release layer that has come away from the barrier is preferably removed by being grasped and pulled off by the user.

The barrier is preferably a disposable barrier for protecting an eye-contacting part of an ophthalmic instrument against contamination and for preventing cross-infection of patients by such instruments. The barrier will be appropriately dimensioned, and substantially planar. For further details of the general construction of such barriers, please refer to WO-A-01/05299.

The assembly may, for example, contain a single barrier piece per assembly piece. In this arrangement, it is preferred that the first and second release layers will correspond substantially exactly in shape and size to the barrier piece protected between them. However, even in this arrangement, one or both of the release layers may if desired be provided with tabs or protrusions extending beyond the periphery of the barrier piece, to assist removal of the release layer(s) from the barrier.

The second release layer is preferably adapted to be removed from the barrier layer after at least a portion of the first face of the barrier layer has been adhered to the instrument.
Generally speaking, the second release layer, being associated with a non-adhesive face of the barrier, will be the easier to remove. The action of conforming the barrier to the contours of the instrument may preferably cause the second release layer to come away.

The release layers are suitably constructed in generally conventional manner, e.g. using a relatively non-stick polymer or a paper or other sheet coated with a relatively non-stick coating such as wax or a silicone. However, the provision of the slit means in the first release layer is novel in the context of the present invention. The slit means are suitably provided in the first release layer by known cutting methods, which do not need to be described in detail.

It can be beneficial in some instances for a portion of the first face of the barrier to be adhered to the medical instrument while the remainder of the first face of the barrier is still protected by the first release layer, and for one or more other portions of the first release layer to be removed sequentially. For this, the slit means of the first release layer can be arranged so that, on flexing of the assembly along a first line, a first portion of the first release layer comes away from the first face of the barrier, and on flexing of the assembly along a second line, a second portion of the first release layer comes away from the first face of the barrier. Indicia can be provided on the assembly, and/or instructions can be provided to the user, as to which line of flexing is to be the first used. Generally speaking, it may be convenient for a portion initially removed to be a central portion of the first release layer, and a portion later removed to be a peripheral portion of the first release layer.

The slit means may take any suitable form. For example, they may comprise curved slits, straight slits, or any combination of the two. Perforations or gaps of any form or arrangement which provide the same effect as a slit will be considered as slits for the purposes of this application and subsequent patents. If desired, portions of slits may be separated by one or more web of the material of the first release layer.

The term “flexible” used herein refers particularly, but without limitation, to a degree of flexibility such as that exhibited by the existing commercially available product PU
Film Intellicoat 2301. More generally, all degrees of flexibility that provide a workable system for the intended purpose of this invention are covered by the term.

According to a second aspect of the present invention, there is provided a method of applying an adhesive, flexible, sterile or sterilisable, sheet barrier to a part of a medical instrument, the sheet barrier having first and second faces and the first face being adhesive, the method comprising:

(a) providing the barrier in an assembly according to the first aspect of the present invention;

(b) flexing the assembly to flex the first release layer and the first face of the barrier and subsequently removing at least a portion of the first release layer from the first face of the barrier;

(c) offering the thus exposed portion of the first face of the barrier to the part of the instrument, to adhere the first face of the barrier to the instrument;

(d) if necessary, removing any remainder of the first release layer from the first face of the barrier before or after (c); and

(e) flexing the partially adhered assembly to conform and fully adhere the barrier to the instrument and optionally simultaneously to cause the second release layer to come away from the second face of the barrier, and removing the second release layer from the barrier.

Where the assembly of the first aspect of the invention is to be flexed in two different directions to remove different portions of the first release layer sequentially, steps (b) and (d) are suitably performed by using the different respective directions.

According to a third aspect of the present invention, there is provided an apparatus for applying an adhesive, flexible, sterile or sterilisable, sheet barrier to a part of a medical
instrument, the sheet barrier having first and second faces and the first face being adhesive, the apparatus comprising:

(a) a device, system, part or means for holding at least one assembly according to the first aspect of the present invention;

(b) a device, system, part or means for flexing a held assembly to flex the first release layer and the first face of the barrier and for removing at least a portion of the first release layer from the first face of the barrier;

(c) a device, system, part or means for presenting the thus exposed portion of the first face of the barrier in a manner suitable for offering to the part of the instrument, to permit that portion of the first face of the barrier to be adhered to the instrument; and

(d) optionally, a device, system, part or means for removing any remainder portion of the first release layer from the first face of the barrier before or after operation of part (c).

The partially adhered assembly can be subsequently manually flexed *in situ* to conform and fully adhere the barrier to the instrument and to cause the second release layer to come away from the second face of the barrier. The second release layer can thereafter be removed from the barrier. Alternatively, the apparatus may include a device, system, part or means for flexing the partially adhered assembly *in situ* to conform and fully adhere the barrier to the instrument and/or to cause the second release layer to come away from the second face of the barrier for removal manually or by using the apparatus.
Detailed Description of the Invention

The Barrier

5 The barrier may, for example, be constructed in the ways described generally in WO-A-01/05299.

In one particularly suitable form, the barrier comprises a sheet consisting of or including a biocompatible barrier layer and an adhesive hydrogel layer, the adhesive hydrogel layer comprising a plasticised three-dimensional matrix of cross-linked polymer molecules which are selected from polymers and copolymers of: 2-acrylamido-2-methylpropane sulphonic acid or a substituted derivative thereof or a salt thereof (e.g. an ammonium or alkali metal salt such as sodium, potassium or lithium salts); acrylic acid or a substituted derivative thereof or a salt thereof (e.g. an alkali metal salt such as sodium, potassium or lithium salt); a polyalkylene glycol acrylate or a substituted derivative thereof; a polyalkylene glycol methacrylate or a substituted derivative thereof; acrylic acid (3-sulphopropyl) ester or a substituted derivative thereof or a salt thereof (e.g. an alkali metal salt such as sodium, potassium or lithium salt); diacetone acrylamide (N-1,1-dimethyl-3-oxobutyl-acrylamide); a vinyl lactam (e.g. N-vinyl pyrrolidone or a substituted derivative thereof); an optionally substituted N-alkylated acrylamide; an optionally substituted N,N-dialkyalted acrylamide; and/or N-acryloyl morpholine or a substituted derivative thereof; optionally with one or more further comonomer.

25 The use of such an adhesive hydrogel has been found to provide an adhesive layer having excellent adhesiveness on application, coupled with substantial absence of deposited residue on removal. The adhesive barrier is readily removed by hand from the instrument after use, for example by pulling or rolling.

30 The adhesive barrier used in the present invention may if desired comprise one or more further layers, which may if desired be interposed between the barrier and adhesive layers.
The barrier layer and hydrogel layer may be substantially optically transparent, for example when the barrier is to be used with ophthalmic instruments. The preferred hydrogel materials described herein have excellent optical properties for this purpose. The adhesive barrier using the preferred hydrogel materials described herein is particularly suitable for use with the following ophthalmic instruments and their eye-contacting parts, although the invention is not to be considered as limited in this way: tonometer heads, for example Goldmann tonometer heads; gonioscope lenses; A-scan ultrasound probes; ultrasound pachometers; 3-mirror Goldmann lenses; YAG laser lenses; retinal laser lenses; vitrectomy lenses; transillumination devices; and contact or suction dynamometers.

The expression “substantially optically transparent” and like expressions, used herein, means that the material, in the thickness as used, is sufficiently transparent to light of the desired wavelengths so that the barrier does not substantially impede the normal operation of the ophthalmic instrument. Generally speaking, a greater than about 90% transmittance of visible light is desirable.

The expression “biocompatible” and like expressions, used herein, means that the material, when in contact with living cells or tissue such as the eye, does not cause any substantial detriment or trauma to the tissue which would compromise the operation of the instrument. In particular, as far as use of the barrier with ophthalmic instruments is concerned, it is preferred that the material of the barrier layer in contact with the eye is wettable by the eye fluid so that an optically refracting interface is established when the barrier is in contact with the eye. Furthermore, it is preferred that the material of the barrier layer is sufficiently inert in a saline or aqueous environment that no adverse chemical reaction takes place during the period of contact with the eye.

The Barrier Layer

The material of the barrier layer should be impervious to face-to-face internal transmigration of infectious agents over the time period of use of the barrier on the instrument. Infectious agents include, for example, viruses, bacteria, virally-infected cells and prion particles, such as, for example, adenoviruses, human immunodeficiency
virus (HIV), prions and the infectious agents for herpes simplex, conjunctivitis, and Creutzfeld-Jacob Disease and its variants (CJD).

The material of the barrier layer should be light enough that the weight of the barrier does not substantially interfere with the accuracy of the instrument, or necessitate repeated recalibration. It is generally preferred that the total weight of the barrier is less than about 0.1 g, although this will depend on the instrument and in some cases a greater barrier weight may be permissible.

Preferred materials for forming the barrier layer include, for example, polymers such as polyurethane, polyethylene, polyesters, polycarbonates, polamides, ethylene/vinyl acetate copolymer, polyvinyl chloride and its copolymers, polysulphones, cellulose acetate and other cellulose derivatives.

The eye-contacting face of the barrier layer is preferably sterilised in conventional manner, although alternatively a film or layer of a sterilising material may overlie the eye-contacting face of the barrier layer according to the present invention.

For further details of appropriate materials and construction of the barrier layer, please refer to the description in WO-A-01/05299.

The Hydrogel Layer

The hydrogel layer preferably has a thickness less than about 500 μm, more preferably less than about 250 μm, and most preferably between about 50 μm and about 150 μm, e.g. about 100 μm. The amount of hydrogel used should be such that the weight of the barrier is within the desirable limit discussed above.

The preferred hydrogel layer in the present invention comprises a plasticised three-dimensional matrix of cross-linked polymer molecules, and has sufficient structural integrity to be self-supporting even at very high levels of internal water content, with sufficient flexibility to conform to the surface contours of the instrument part to be covered.
The hydrogel generally comprises, in addition to the cross-linked polymeric network, an aqueous or non-aqueous plasticising medium including an organic plasticiser.

The hydrogel is preferably the product of a polymerisation reaction performed on a polymerisable mixture (pre-gel) comprising the monomer(s), cross-linking agent, plasticiser, and optionally water and other ingredients as desired. The polymerisation reaction is preferably a free-radical polymerisation with cross-linking, which may for example be induced by light, heat, or radiation, as is well known. A photoinitiator may be used to assist initiation of the polymerisation and cross-linking, as is well known in this art.

If desired, certain ingredients of the hydrogel may be added after the polymerisation and cross-linking reaction. However, it is generally preferred that substantially all of the final ingredients of the hydrogel are present in the pre-gel, and that – apart from minor conventional conditioning – substantially no chemical modification of the hydrogel takes place after completion of the polymerisation reaction.

**Monomers**

Optional substituents of the monomers used to prepare the hydrogels used in the present invention may preferably be selected from substituents which are known in the art or are reasonably expected to provide polymerisable monomers which form hydrogel polymers having the properties necessary for the present invention. Suitable substituents include, for example, lower alkyl, hydroxy, halo and amino groups.

Particularly preferred monomers include: the sodium salt of 2-acrylamido-2-methylpropane sulphonic acid, commonly known as NaAMPS, which is available commercially at present from Lubrizol as either a 50% aqueous solution (reference code LZ2405) or a 58% aqueous solution (reference code LZ2405A); acrylic acid (3-sulphopropyl) ester potassium salt, commonly known as SPA or SPAK (SPA or SPAK is available commercially in the form of a pure solid from Raschig); and N-acryloyl morpholine.
Cross-linking Agents

Conventional cross-linking agents are suitably used to provide the necessary mechanical stability and to control the adhesive properties of the hydrogel. The amount of cross-linking agent required will be readily apparent to those skilled in the art such as from about 0.01% to about 0.5%, particularly from about 0.05% to about 0.4%, most particularly from about 0.08% to about 0.3%, by weight of the total polymerisation reaction mixture. Typical cross-linkers include tripropylene glycol diacrylate, ethylene glycol dimethacrylate, triacrylate, polyethylene glycol diacrylate (polyethylene glycol (PEG) molecular weight between about 100 and about 4000, for example PEG400 or PEG600), and methylene bis acrylamide.

Organic Plasticisers

The one or more organic plasticiser, when present, may suitably comprise any of the following either alone or in combination: at least one polyhydric alcohol (such as glycerol, polyethylene glycol, or sorbitol), at least one ester derived therefrom, at least one polymeric alcohol (such as polyethylene oxide) and/or at least one mono- or polyalkylated derivative of a polyhydric or polymeric alcohol (such as alkylated polyethylene glycol). Glycerol is the preferred plasticiser. An alternative preferred plasticiser is the ester derived from boric acid and glycerol. When present, the organic plasticiser may comprise up to about 45% by weight of the hydrogel composition.

Surfactants

Any compatible surfactant may optionally be used as an additional ingredient of the hydrogel composition. Surfactants can lower the surface tension of the mixture before polymerisation and thus aid processing. The surfactant or surfactants may be non-ionic, anionic or cationic, alone or in any mixture or combination. The total amount of surfactant, if present, is suitably up to about 10% by weight of the hydrogel composition, preferably from about 0.05% to about 4% by weight.
In a preferred embodiment of the invention the surfactant comprises at least one propylene oxide/ethylene oxide block copolymer, for example such as that supplied by BASF Plc under the trade name Pluronic P65 or L64.

Other additives

The hydrogel composition for use in the present invention may include one or more additional ingredients, which may be added to the pre-polymerisation mixture or the polymerised product, at the choice of the skilled worker. Such additional ingredients are selected from additives known in the art, including, for example, water, organic plasticisers, surfactants, polymers, electrolytes, pH regulators, colorants, chloride sources, bioactive compounds, enzymes and mixtures thereof. The polymers can be natural polymers (e.g. xanthan gum), synthetic polymers (e.g. polyoxypropylene-polyoxyethylene block copolymer or poly-(methyl vinyl ether alt maleic anhydride)), or any combination thereof. By “bioactive compounds” we mean any compound or mixture included within the hydrogel for some effect it has on living systems, whether the living system be bacteria or other microorganisms or higher animals such as the patient.

Additional polymer(s), typically rheology modifying polymer(s), may be incorporated into the polymerisation reaction mixture at levels typically up to about 10% by weight of total polymerisation reaction mixture, e.g. from about 0.2% to about 10% by weight. Such polymer(s) may include polyacrylamide, poly-NaAMPS, polyethylene glycol (PEG), polyvinylpyrrolidone (PVP) or carboxymethyl cellulose.

The hydrogel composition of the present invention preferably consists essentially of a cross-linked hydrophilic polymer of a hydrophilic monomer and optionally one or more comonomer, together with water and/or one or more organic plasticiser, and optionally together with one or more additives selected from surfactants, polymers, pH regulators, electrolytes, chloride sources, bioactive compounds and mixtures thereof, with less than about 10% by weight of other additives.
For further details of the adhesive hydrogel material for use in the present invention, and its preparation, please refer to the following publications: PCT Patent Applications Nos. WO-97/24149, WO-97/34947, WO-00/06214, WO-00/06215, WO-00/07638, WO-00/46319, WO-00/65143 and WO-01/96422, the disclosures of which are incorporated herein by reference.

Construction of the Barrier

The barrier will have any suitable configuration, e.g. may be configured as a disc or generally regular polygon, optionally with tabs, protrusions or flanges as desired. It will preferably be of a dimension selected to cover both the directly eye-contacting part of the ophthalmic instrument and any surrounding part that might in use come into contact with the patient or the patient's eye fluid, for example if the patient blinks or the if patient's eyes water. On the other hand, the barrier must be light enough that it does not adversely affect the operation of the instrument.

We have found, for example, that for a barrier for a tonometer head, a disc of diameter up to about 30 mm, e.g. between about 10 and about 30mm, e.g. between about 12 and about 26mm, e.g. between about 15 and about 24mm, e.g. between about 20 and about 30mm, e.g. between about 22 and about 28 mm is preferred, giving a barrier weight, when in position on the tonometer head, of less than about 0.1 g. The thickness of the hydrogel layer is in this example about 100 μm.

The barrier is preferably thin enough that it can easily be conformed to the shape of the part of the instrument to be covered, if necessary with overlapping and flattening of folds of the barrier as it is applied to the instrument. It may generally be preferable for the barrier to be applied to the instrument after at least partial removal of the release layer protecting the adhesive face of the barrier, but before removal of the release layer covering the other face of the barrier.

In order to facilitate easy location of the barrier on the instrument, one or more indicia, for example, coloured markers or other indicators, may be provided on the barrier. For example, a barrier for a tonometer head may be provided with a ring, or dots, or lines, or
arcs, marked around its centre, whereby in use one aligns the ring with the perimeter of the tonometer head. In addition to providing a simple means of locating the barrier on the probe head, the colour indicator may also provide an indication as to which surface of the barrier is sterile where only one surface is sterile.

The barriers can conveniently be manufactured using a conventional roll-to-roll laminating process where the adhesive layer is applied to the barrier layer in sheet form. Alternatively, a liquid pre-gel for the hydrogel layer may be spread or cast onto a pre-formed barrier layer and then polymerised *in situ* to form the adhesive layer. Individual barriers can then be cut or pressed from the resulting laminate, in conventional manner. The release sheets may be added before or after the individual barriers are formed, again in conventional manner. In one preferred method, the barrier layer is initially formed on the second release layer, prior to *in situ* formation of the hydrogel layer on the pre-formed barrier layer and subsequent application of the first release layer to the hydrogel layer. The slits of the first release layer are preferably cut separately, prior to applying the second release layer to the hydrogel layer.

The adhesive barrier is substantially planar, and is preferably disposable. It is suitably supplied in a sterile pack, with both external faces protected by sterile first and second release layers in an assembly according to the present invention.

*The Assembly, and Mode of Application of the Barrier to the Instrument*

It is preferred that there are slits only in the first release layer, and not in the second.

In one preferred embodiment, slits may be located in the first release layer between a central and a peripheral portion of the underlying barrier piece. The slits in this preferred embodiment generally define a central portion of the first release layer, which can come away from the barrier piece when the assembly is flexed. This central portion is frangibly connected to a peripheral portion of the first release layer by at least one thin webs of the material of the first release layer, to maintain the portions in position until the flexing occurs. By flexing the assembly, the central portion of the first release layer overlying the barrier piece can be removed – with grasping and pulling to
break the frangible connecting webs - to expose a central region of the adhesive first face of the barrier, while a peripheral annular portion of the adhesive face of the barrier is still protected by the peripheral portion of the first release layer. The assembly can therefore be held at its protected peripheral portion, easily and without contaminating the barrier or hindering a clean contact between the exposed central portion of the barrier and the part of the instrument to be covered.

Most preferably, a further pair of slits is provided in the annular peripheral portion of the first release layer, which serve to divide the annular peripheral portion into two parts. The purpose of this pair of slits is to enable the peripheral annular portion of the first release layer to be detached from the barrier separately from, and after, the central region of the first release layer. The line along which the assembly is flexed to release the central portion of the first release layer is preferably different from, e.g. at an angle to, e.g. at right angles to, the line along which the assembly is flexed to release the peripheral portion of the first release layer.

Additional slits or pairs of slits may also be provided, if desired. For example, a total of at least two pairs, e.g. one pair, two pairs or three pairs, of slits, may be present. Each one of a pair may suitably be generally diametrically opposed to the other.

In this way, the release of the central portion of the first release layer, and the partial attachment of the barrier to the medical instrument in the central region of the barrier, can be completed before the peripheral region of the adhesive first face of the barrier is exposed. This considerably simplifies the operation of adhering the barrier to the instrument without hand or glove contact with any portion of the barrier itself.

After the peripheral region of the first release layer has been removed, if said removal is desired, the assembly is smoothed down onto the part of the instrument to be covered, and conformed and fully adhered to the contours of the instrument. In the process, the second release layer – which, in comparison with the first release layer adhered to the (adhesive) first face of the barrier, is preferably relatively weakly adhered to the second (non-adhesive) face of the barrier – relatively easily works loose as a result of the
relatively severe flexing of the assembly to conform to the contours of the instrument, and can easily be removed from the second face of the barrier.

Alternatively, the peripheral region of the first release layer, or at least portions of the said peripheral region, may be retained in contact with the barrier. The projecting portion(s) of the peripheral region of the first release layer can then serve as deflectors or splash protectors to prevent or restrict contact between the patient’s eyes or eye region (e.g. eyelid) and the ophthalmic instrument, either through direct contact or by splashing of fluids.

The projecting portion(s) of the peripheral region of the first release layer retained in contact with the barrier can also serve as parts on which a user can grasp the barrier for removal from the ophthalmic instrument.

In this way, the adhesive barrier can accurately, cleanly and efficiently be adhered onto the part of the medical instrument to be covered, and removed therefrom after use.

The above description is set out as it applies to manual operation. A corresponding mechanised operation can readily be understood, in which an apparatus holds a magazine or array of barrier assembly items either as individual pieces, or in sheet form as illustrated in WO-A-01/05299, and the portions of the first release layer are mechanically removed to expose first the adhesive first face of the barrier, which can then be adhered to the part of the medical instrument to be covered, and then—mechanically, manually or by a combined mechanical and manual action—the second face of the barrier can be exposed and the barrier conformed to the part of the instrument to be covered.

**Brief Description of the Drawings**

For further illustration of the present invention, but without limitation, an embodiment will now be described with reference to the accompanying drawings, in which:
Figure 1 shows an assembly according to the present invention, looking from above the first release layer; and

Figure 2 shows the assembly of Figure 1 in vertical cross-section, the thicknesses of the layers exaggerated for clarity and not to scale.

**Detailed Description of the Drawings**

Referring to the drawings, there is shown an assembly comprising an adhesive, flexible, sterile or sterilisable, sheet barrier 1 for covering a part of a medical instrument, and first 2 and second 3 protective release layers associated with respective first and second faces of the barrier 1.

The barrier 1 is configured as a planar disc, dimensioned to overlie the part of the medical instrument to be covered. The sheet barrier is flexible and conformable to the contours of the instrument. The assembly is a discrete unit piece having a single barrier piece and the dimensions and configuration of all layers correspond.

The sheet barrier 1 as illustrated consists of a biocompatible barrier layer 1a and an adhesive hydrogel layer 1b. The hydrogel layer 1b provides in use a first adhesive face of the barrier, which will therefore be denoted 1b in the following description, whereby the barrier can be adhered to the medical instrument. The non-adhesive, sterile or sterilisable, second face of the barrier 1 will be denoted 1a in the following description.

The chemical composition and method of construction of such barrier and hydrogel layers is described above, and will not be repeated here.

The first release layer 2 is provided with slits 4, adapted to assist release of the first release layer, whereby on initial flexing of the assembly in one direction a central portion 2' of the first release layer 2 can be detached in preference to a peripheral portion 2'' of the first release layer and in preference also to the second release layer 3, to expose a corresponding underlying central portion of the first face 1b of the barrier for adhering to the instrument, as will be described in more detail below.
The slits 4 are located in a region of the first release layer 2 between the central 2' and peripheral 2'' portions. The slits 4 generally define within them the central portion 2' of the first release layer 2, which has the form of a pair of mutually opposed tongues 5 of the first release sheet extending outwardly from central line 6-6, which tongues 5 can come away from the barrier piece when the assembly is flexed along the line 6-6. The two tongues are connected at the central line to each other and, at the same place, are frangibly connected to the peripheral portion 2'' of the first release layer 2 by two thin webs 7 of the material of the first release layer. In this way, by flexing the assembly along the central line 6-6 between the tongues 5, at least one of the tongues comes away from the barrier piece and can be grasped by the user, whereby the central portion 2' of the first release layer 2 can be removed – with breaking of the frangible connecting webs 7 - to expose a central portion of the adhesive first face 1b of the barrier 1. At the same time, a peripheral annular portion of the adhesive face 1b of the barrier 1 is still protected by the peripheral portion 2'' of the first release layer 2 and can therefore be held easily by the user, without contaminating the barrier 1 or hindering a clean contact between the central portion of the barrier 1 and the part of the instrument to be covered.

The slits 4 include a pair of slits provided in the annular peripheral portion 2'' of the first release sheet 2, which serve to divide the annular peripheral portion 2'' into two semicircular parts. This pair of slits lies at right angles to the common central line 6-6 between the central tongues 5. The purpose of this pair of slits is to enable the peripheral annular portion 2'' of the first release layer 2 to be detachable from the barrier 1 separately from, and after, the central region defined by the tongues 5. Moreover, the line 6-6, along which the assembly must generally be flexed to release the tongues 5 of the central portion 2' of the first release layer 2, is orthogonal to the line of the pair of slits being described, along which the assembly must be flexed to release the peripheral portion 2'' of the first release layer 2.

If desired, further pairs of slits may also be present (not shown), as described in more detail above.
In this way, the release of the central portion 2' of the first release layer, and the partial attachment of the barrier 1 to the medical instrument in the central region of the barrier, can be completed before the peripheral portion 2'' of the adhesive first face 1b of the barrier 1 is exposed. This considerably simplifies the operation of adhering the barrier to the instrument without hand or glove contact with any portion of the barrier itself.

After the peripheral region 2'' of the first release layer 2 has been removed, the assembly is smoothed down onto the part of the instrument to be covered, and conformed to the contours of the instrument. In the process, the second release layer 3 – which, in comparison with the first release layer 2 adhered to the (adhesive) first face 1b of the barrier, is relatively weakly adhered to the (non-adhesive) second face 1a of the barrier – relatively easily works loose as a result of the relatively severe flexing of the assembly to conform to the contours of the instrument, and can easily be removed from the second face 1a of the barrier.

The above broadly describes the present invention, without limitation. Variations and modifications as will be readily apparent to those of ordinary skill in this art are intended to be covered by this application and all subsequent patents.
CLAIMS

1. An assembly comprising an adhesive, flexible, sterile or sterilisable, sheet barrier for a medical instrument, and first and second protective release layers associated with respective first and second faces of the barrier, wherein at least the first face of the barrier is adhesive and the first release layer is provided with one or more slit adapted to assist release of the first release layer, whereby on flexing of the assembly at least a portion of the first release layer comes away from the barrier to expose at least a portion of the first face of the barrier for adhering to the instrument.

2. An assembly according to claim 1, wherein the first release layer is removable by being grasped and pulled off by the user.

3. An assembly according to claim 1 or claim 2, wherein the barrier is a disposable barrier for protecting an eye-contacting part of an ophthalmic instrument against contamination.

4. An assembly according to claim 1 or claim 2, wherein the barrier is a disposable barrier for preventing cross-infection of patients by ophthalmic instruments.

5. An assembly according to claim 3 or 4, wherein the ophthalmic instrument or eye-contacting part thereof is selected from: tonometer heads, gonioscope lenses, A–scan ultrasound probes, ultrasound pachometers, 3-mirror Goldmann lenses, YAG laser lenses, retinal laser lenses, vitrectomy lenses, transillumination devices and contact or suction dynamometers.

6. An assembly according to any one of the preceding claims, comprising a single barrier piece per assembly piece.

7. An assembly according to claim 6, wherein the first and second release layers correspond substantially exactly in shape and size to the barrier piece protected between them.
8. An assembly according to claim 7, wherein one or both of the release layers are provided with tabs or protrusions extending beyond the periphery of the barrier piece

9. An assembly according to claim 8, wherein the tabs or protrusions assist removal of the release layer(s) from the barrier.

10. An assembly according to any one of the preceding claims, wherein the second release layer is adapted to be removed from the barrier layer after at least a portion of the first face of the barrier layer has been adhered to the instrument.

11. An assembly according to any one of the preceding claims, wherein the second face of the barrier is non-adhesive.

12. An assembly according to any one of the preceding claims, wherein the second face of the barrier and the second release layer are adapted so that the action of conforming the barrier to the contours of the instrument causes the second release layer to come away from the second face of the barrier.

13. An assembly according to any one of the preceding claims, wherein the release layers comprise a relatively non-stick polymer, or a sheet coated with a relatively non-stick coating.

14. An assembly according to any one of the preceding claims, wherein the one or more slit comprises one or more curved slit, straight slit, or any combination of the two.

15. An assembly according to any one of the preceding claims, wherein the one or more slit comprises perforations or gaps.
16. An assembly according to any one of the preceding claims, wherein portions of the one or more slit are separated by one or more web of the material of the first release layer.

5 17. An assembly according to any one of the preceding claims, wherein the sheet barrier comprises a substantially optically transparent biocompatible barrier layer and a substantially optically transparent adhesive hydrogel layer, the adhesive hydrogel layer comprising a plasticised three-dimensional matrix of cross-linked polymer molecules selected from polymers and copolymers of: 2-acrylamido-2-methylpropane sulphonic acid or a substituted derivative thereof or a salt thereof; acrylic acid or a substituted derivative thereof or a salt thereof; a polyalkylene glycol acrylate or a substituted derivative thereof; a polyalkylene glycol methacrylate or a substituted derivative thereof; acrylic acid (3-sulphopropyl) ester or a substituted derivative thereof or a salt thereof; diacetone acrylamide; a vinyl lactam; an optionally substituted N-alkylated acrylamide; an optionally substituted N,N-dialkylated acrylamide; and/or N-acryloyl morpholine or a substituted derivative thereof; in the case of copolymers, said copolymer being formed optionally with one or more further comonomer.

10 18. An assembly according to claim 17, wherein the vinyl lactam is N-vinyl pyrrolidone or a substituted derivative thereof.

19. An assembly according to claim 17 or 18, wherein the plasticised three-dimensional matrix of cross-linked polymer molecules comprises polymer molecules which are selected from polymers and copolymers of: 2-acrylamido-2-methylpropane sulphonic acid (AMPS); an alkali metal salt of AMPS; acrylic acid (3-sulphopropyl) ester (SPA); an alkali metal salt of SPA; and/or N-acryloyl morpholine; in the case of copolymers, said copolymer being formed optionally with one or more further comonomer.

20. An assembly according to any one of claims 17 to 19, wherein the plasticised three-dimensional matrix of cross-linked polymer molecules comprises polymer molecules which are selected from polymers and copolymers of 2-acrylamido-2-
methylpropane sulphonlic acid (AMPS) or an alkali metal salt thereof; in the case of copolymers, said copolymer being formed with one or more further comonomer.

21. An assembly according to any one of claims 17 to 19, wherein the plasticised three-dimensional matrix of cross-linked polymer molecules comprises polymer molecules which are selected from polymers and copolymers of acrylic acid (3-sulphopropyl) ester (SPA) or an alkali metal salt thereof; in the case of copolymers, said copolymer being formed with one or more further comonomer.

22. An assembly according to any one of claims 17 to 19, wherein the plasticised three-dimensional matrix of cross-linked polymer molecules comprises polymer molecules which are selected from polymers and copolymers of N-acryloyl morpholine; in the case of copolymers, said copolymer being formed with one or more further comonomer.

23. An assembly according to any one of claims 17, 18 and 19 to 21, wherein the salt is a sodium, potassium or lithium salt.

24. A method of applying an adhesive, flexible, sterile or sterilisable, sheet barrier to a part of a medical instrument, the sheet barrier having first and second faces and at least the first face being adhesive, the method comprising:

(a) providing an assembly comprising the said barrier and first and second protective release layers associated with respective first and second faces of the barrier, wherein the first release layer is provided with one or more slit adapted to assist release of the first release layer, whereby on flexing of the assembly at least a portion of the first release layer comes away from the barrier to expose at least a portion of the first face of the barrier for adhering to the instrument;
(b) flexing the assembly to flex the first release layer and the first face of the barrier and subsequently removing at least a portion of the first release layer from the first face of the barrier;

(c) offering the thus exposed portion of the first face of the barrier to the part of the instrument, to adhere the first face of the barrier to the instrument;

(d) if necessary, removing any remainder of the first release layer from the first face of the barrier before or after (c); and

(e) flexing the partially adhered assembly to conform and fully adhere the barrier to the instrument and optionally simultaneously to cause the second release layer to come away from the second face of the barrier, and removing the second release layer from the barrier.

25. A method according to claim 24, wherein the assembly is as defined in any one of claims 2 to 23.

26. A method according to claim 24 or 25, wherein the assembly is flexed in two different directions in steps (b) and (d) respectively, to remove different portions of the first release layer sequentially.

27. An apparatus for applying an adhesive, flexible, sterile or sterilisable, sheet barrier to a part of a medical instrument, the sheet barrier having first and second faces and at least the first face being adhesive, the apparatus comprising:

(a) a device, system, part or means for holding at least one assembly comprising the said barrier and first and second protective release layers associated with respective first and second faces of the barrier, wherein the first release layer is provided with one or more slit adapted to assist release of the first release layer, whereby on flexing of the assembly at least a portion of the first release layer comes
away from the barrier to expose at least a portion of the first face of the barrier for adhering to the instrument;

(b) a device, system, part or means for flexing a held assembly to flex the first release layer and the first face of the barrier and for removing at least a portion of the first release layer from the first face of the barrier;

(c) a device, system, part or means for presenting the thus exposed portion of the first face of the barrier in a manner suitable for offering to the part of the instrument, to permit that portion of the first face of the barrier to be adhered to the instrument; and

(d) optionally, a device, system, part or means for removing any remainder portion of the first release layer from the first face of the barrier before or after operation of part (c).

28. An apparatus according to claim 27, wherein the assembly is as defined in any one of claims 2 to 23.

29. An apparatus according to claim 27 or 28, further comprising a device, system, part or means for flexing the partially adhered assembly in situ to conform and fully adhere the barrier to the instrument.

30. An apparatus according to any one of claims 27 to 29, further comprising a device, system, part or means for flexing the partially adhered assembly in situ to cause the second release layer to come away from the second face of the barrier for removal manually or by using the apparatus.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B1/00 A61B3/10 A61B3/13 A61B3/16 B32B35/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Maximum documentation searched (classification system followed by classification symbols)
IPC 7 H04R B65B A61B C09J B32B

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)

EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

Date of the actual completion of the international search 13 May 2005

Date of mailing of the international search report 24/05/2005

Name and mailing address of the ISA European Patent Office, P.O. Box 1070, 2280 CA The Hague, The Netherlands, TEL. +31-30-346-1800, FAX: +31-30-346-1801

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