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TITLE

Fluid applicators

DESCRIPTION5 Technical field

The invention relates to the field of fluid applicators for applying a fluid to a subject. It is particularly suitable for applicators that are intended to aseptically apply a sterilizing, antiseptic, anaesthetic or wound management fluid to the skin of a patient in a medical context, for example before a hypodermic needle or cannula is inserted
10 into the skin. However, it also has applications in non-medical contexts, such as for cosmetic uses or general cleaning purposes.

Background of the invention

The skin provides an important barrier to prevent harmful entities such as bacteria
15 entering the body. Therefore, before carrying out surgery or any other medical procedure that will pierce the skin of a patient, it is standard practice to ensure that the relevant area of the skin is made clean and sterile. This is typically done using a disposable fluid applicator to wipe the skin with an antiseptic fluid such as chlorhexidine diluted in alcohol or water. The applicator comprises a handle
20 containing a source of the fluid and a head that is applied to the skin. Typically, the head comprises a pad made from, for example, an open-cell foam, that conducts the fluid from the source and distributes it over the skin.

Published patent application WO 99/63934 discloses one example of such an
25 applicator. Its delivery system includes an antimicrobial alcohol gel formulation contained within a sealed, flexible container and a gel formulation dispenser connected to the container. The gel formulation dispenser includes a container connector connected to the flexible container and a gel applicator having a sealed piercing member which is slidably engaged with the container connector. An
30 applicator pad is secured to an angled gel applicator head of the gel applicator. The applicator pad is porous and also has enlarged holes for passage of the gel formulation. The gel formulation dispenser pierces a seal in the container and

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delivers the antimicrobial alcohol gel formulation from the container to the surgical site. Once the gel applicator has been moved to an activated position, a lock prevents it from sliding away again. In this manner, the lock contributes to a single use feature of the skin-preparation delivery system.

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For environmental and economic reasons, it is no longer desirable that an applicator should be single use, which provides an inefficient return on the materials and energy that were used to make and transport it, and on the financial outlay of the medical provider that acquired it. On the other hand, re-use of the applicator risks cross-
10 infection between patients if it is not thoroughly sterilized, which itself consumes resources.

Summary of the invention

The invention provides an effective compromise between an applicator that is entirely
15 single-use and one that is completely re-usable. The applicator comprises a head that is removable from the handle after use, whereby the head that has been in contact with the skin of a subject can be safely disposed of, while the handle that has not been in contact with the skin of the subject can be retained and sterilized for re-use with minimal risk of cross-infection. Preferred embodiments of the invention provide
20 designs of applicator that minimize the quantity of material in the disposable head.

Specifically, the invention provides a fluid applicator comprising a handle suitable for containing a source of a fluid and a head suitable for applying the fluid to the skin of a subject. The handle engages the head so as to permit linear movement of the head
25 parallel to an axis of the handle, said movement being from a first position, in which the head is releasably secured to the handle and is isolated from the source of fluid, to a second position, in which the head is releasably secured to the handle and is in communication with the source of fluid, then to a third position, in which the head is released from the handle. The head comprises an arm that extends generally parallel
30 to the axis along one side of the handle. Each of the first and second positions is a position where a projection on one of the handle and the arm locates in a recess in the other of the handle and the arm.

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The handle may itself be a reservoir for containing the fluid or it may be designed to receive a discrete reservoir of the fluid, such as a flexible pouch or a rigid cartridge. The fluid may be a liquid or a flowable gel.

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When the head is in the first position, the fluid remains contained within the handle and the head is secured against movement relative to the handle unless a predetermined force is applied. In this configuration, the applicator is suitable for transport and storage without the risk that the fluid will leak out or become contaminated.

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When the head is in the second position, fluid can flow from the handle to the head, either under gravity or by the user applying pressure to the fluid reservoir. The head can then be used to apply the fluid to the skin of a subject, for example by the fluid soaking into a foam pad that forms part of the head, and the user wiping the pad over the skin of the subject.

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When the head is in the third position, it can be removed from the handle. Thereby, the head, which has been in contact with the skin of the user, can be safely disposed of, while the handle can be retained and sterilized for re-use. This avoids wasted construction materials (when considered as an alternative to disposing of the whole applicator) or wasted energy and cleaning materials (when considered as an alternative to sterilizing the whole applicator for re-use to the standard required when it has been in contact with the subject).

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Preferably, the arm comprises a projection that can locate in either one of two recesses in the handle to define the first and second positions respectively. Locating a projection in a recess positively defines each position when a user of the applicator is moving the head along the handle and also serves to secure the head releasably in that position.

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The arm may be resilient, such that when a projection becomes located in a recess, the projection snaps into the recess. This provides a positive indication of the position of the head as the user slides the head along the handle and the spring force of the resilient arm must then be overcome in order to move the head to a different position.

5 In some embodiments, the resilient arm further comprises a grip projecting away from the handle, whereby the user can apply a force to the grip to move the head between the first, second and third positions. If a projecting grip is combined with a resilient arm, then the grip may act as a lever to disengage the projection from the recess and thereby to release the head from its current position relative to the handle.

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The engagement between the handle and the head is preferably via a track that extends parallel to the axis along only said one side of the handle. Because the track is on only one side of the handle, the head only needs to extend along the side of the handle that comprises the track, thereby saving materials in the disposable head. The head also becomes easy for the user to move, for example by grasping the handle with the fingers of one hand and using the thumb of the same hand to slide the head along the handle. Note that in this context, a “side” of the handle can refer to a portion of the handle that faces in any direction about the axis of the handle, including the “front side” or the “rear side”.

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Preferably, the first position is between the second and third positions along the axis. As a result, the movement between the first position and the second position to make the applicator ready for use is in the opposite direction from the movement between the second position and the third position to separate the head from the handle after use. This provides a clear distinction between the two functions and ensures that when moving the head into its active second position, the user cannot accidentally “overshoot” to reach the third position and disengage the head from the handle.

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In preferred embodiments of the invention, when the head is in the first position, the source of fluid in the handle is isolated from the head by a seal. Moving the head from the first position to the second position breaks the seal to permit the fluid to flow from the source to the head. The use of a seal permits sterility of the fluid to be

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ensured until the time of use of the applicator, while providing mechanical means such as a sharp point to break the seal is simple, cheap and reliable compared with possible alternatives such as a valve arrangement.

- 5 The head may comprise a pin that is adapted to pierce or break the seal when the head is moved from the first position to the second position.

10 The head may comprise a pad (e.g., an open cell foam pad) that defines a planar surface adapted to apply fluid to the skin of a subject. The axis of the handle may be inclined to the plane of the pad. The head may comprise an apertured plate adapted to mount the pad.

15 In this specification, terms such as “upper” and “lower” are used with reference to the orientation of the fluid applicator as illustrated in the drawings. This is a typical orientation of the applicator during its use, which allows the fluid to flow from the handle to the head under gravity. It should be understood that the applicator can be made, stored, transported and sold in any orientation and that, in at least some embodiments of it that do not depend on gravity to transport the fluid, it can also be used in any orientation.

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Drawings

Figure 1 is a side view of a fluid applicator according to the invention, configured for use.

Figure 2 is a perspective view of the fluid applicator of Figure 1 seen from above.

- 25 Figure 3 is a perspective view of the fluid applicator of Figure 1 seen from below.

Figure 4 is an exploded perspective view of the fluid applicator of Figure 1 seen from below.

Figure 5 is an enlargement of Figure 4, showing part of the handle.

- 30 Figure 6 is an enlarged perspective view of the fluid applicator of Figure 1, showing part of the head.

Figure 7 is a side view of the fluid applicator of Figure 1, configured for storage.

Figure 8 is a cross-section in side view of the fluid applicator of Figure 1.

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The fluid applicator shown in the drawings comprises a head 2 that is releasably coupled to a handle 4. The handle 4 is generally elongate and of a suitable size and shape to be gripped comfortably in the hand of a user. The head 2 can slide along the handle 4 in a direction parallel to an axis 6 of the handle 4. A pad 8 is mounted on the head 2 and comprises a generally planar surface 10, which is used to apply fluid, such as an antiseptic liquid, to the skin of a subject. In the illustrated embodiment, the axis 6 of the handle 4 is inclined to plane of the pad 8. This permits a user who is gripping the applicator to hold their wrist at a comfortable angle but it is not essential to the invention.

The pad 8 is typically made from a flexible and permeable material such as an open cell foam so that, during use, the pad 8 can adapt its shape to the contours of the skin, while fluid flows through the pores to the surface 10. The pad 8 may be formed as a discrete component that is permanently fixed to the head 2 during manufacture or is fitted to the head 2 immediately before use of the applicator. The invention does not exclude a head 2 that can be used without a distinct pad 8, for example, a head (not illustrated) that itself comprises a surface for application to the skin, the surface being perforated by small holes to allow passage of the fluid.

The handle 4 provides the source of fluid for supply to the head 2. As seen in Figure 8, the handle 4 is generally hollow, being closed at the end remote from the head 2 and open at the end adjacent to the head 2. During manufacture of an applicator according to the illustrated embodiment of the invention, the handle may be sterilized then held in an inverted position compared with Figure 8 and filled directly with the fluid. A septum or seal 12 can then be fixed in a fluid-tight manner across the open end of the handle 4 to prevent the fluid escaping prior to use and to prevent contaminants entering. The seal 12 is typically a flexible foil or membrane. In alternative embodiments (not illustrated), instead of filling the handle 4 directly with the fluid, the fluid could be provided in a pre-sealed reservoir designed to fit into the handle 4, for example in a pouch with flexible walls or a cartridge with generally rigid walls and itself closed by a septum. Replacement pouches or cartridges could easily

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be inserted to allow re-use of the handle 4 without the need to return it to the manufacturer for re-filling and re-sealing.

5 The handle 4 further comprises a pair of parallel rails 13, which define a track 14 that extends along part of the rear side of the handle 4, parallel to the axis 6.

10 The head 2 is illustrated in isolation in Figures 4 and 6. (In these figures, the pad 8 has been omitted for clarity.) The head 2 comprises an apertured plate 15 that can be used to mount the pad 8. On an upper face of the plate 15 is a collar 16, which is shaped to fit around a lower end 18 of the handle 4. The head 2 further comprises a pair of rigid arms 20, which extend parallel to one another and are formed to engage the rails 13 of the handle 4. When the rigid arms 20 and the rails 13 are engaged, the head 2 is constrained to slide along the track 14 of the handle 4 parallel to the axis 6. Between the two rigid arms 20, and extending generally parallel to them, the head 2 further comprises a resilient arm 22, which is anchored at an end close to the plate 15 and is free at an end remote from the plate 15. A grip 24 projects from the free end of the arm 22 in a direction away from the handle 4. By applying a force to the grip 24, a user can cause the head 2 to slide in either direction along the handle 4. When the force is applied to the grip 24 in a direction towards the plate 15, it can also act as a lever to cause the resilient arm 22 to bend slightly away from the handle 4 in a resilient manner.

As seen in Figure 6, a face of the resilient arm 22 that faces towards the handle 4 comprises a projection or rib 26 that extends transversely to the length of the arm 22. 25 As seen in Figure 5, between the rails 13 of the track 14 there are two recesses or notches 28,29 that extend transversely to the length of the track 14 and are each shaped to receive the rib 26 of the resilient arm 22. When the head 2 slides upwards along the handle 4, flexure of the resilient arm 22 causes the rib 26 to snap first into the lower notch 28 and then into the upper notch 29, defining first and second 30 positions of the head 2 respectively. When the rib 26 is located in one of the notches 28,29, additional force must be applied to move the head 2 away from that defined position. The notches 28,29 and/or the rib 26 may be formed with an

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asymmetrical profile such as a sawtooth to make it easier to move the head 2 in one direction – further onto the handle 4 – than in the opposite direction. This reduces the risk that the head 2 may accidentally become separated from the handle during use, which is not only inconvenient and risks spillage of excess fluid but, if the applicator
5 is being used in an operating theatre, may also contravene any protocols in place for strictly tracking the whereabouts of every item. The two notches 28,29 do not need to have the same profile.

In alternative embodiments of the invention (not illustrated), the positions of the rib
10 and notches may be exchanged so the rib is on the handle and the notches are on the resilient arm. Of course, further notches could easily be provided to define additional releasably secured positions of the head 2 on the handle 4 if this were seen to be advantageous. One possible use for an additional position would be to re-seal the fluid in the handle 4, if the use of the applicator has been finished but unused fluid
15 remains inside. Further alternative embodiments comprising two or more ribs and one notch are also possible.

The illustrated fluid applicator may be used in the following manner. During the manufacturing process, the handle 4 has been filled with fluid and closed with a
20 seal 12 as previously described. The head 2 is fitted onto the handle 4 and is slid along the track 14 until the rib 26 of the resilient arm 22 snaps into the lower notch 28 of the handle 4. The head 2 is then releasably secured in the first position and cannot move in either direction along the handle 4 unless a predetermined force is applied, which is sufficient to bend the resilient arm 22 out of engagement with the notch 28.
25 The required level of force can be determined to prevent accidental movement of the head 2 during normal handling of the fluid applicator so, when configured in this first position, it can be safely transported and stored. When the head 2 is in its first position, the seal 12 remains intact and the fluid within the handle 4 is securely contained. Figure 7 shows the applicator configured in the first position for transport
30 and storage. A small gap 30 in the outer surface of the applicator shows that the head 2 has not been pushed fully onto the handle 4.

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When the fluid applicator is to be used, the user grasps the handle 4 and pulls on the grip 24 to overcome the resistance offered by the resilient arm 22 and slide the head 2 upwards until the rib 26 snaps into the upper notch 29. This defines the second position of the head 2. In moving from the first position to the second position, a sharp spike or pin 32 mounted in the head comes into contact with the seal 12 and pierces it to release the fluid from the handle 4 to flow through the head 2 and enter the pad 8 for application to the skin of a subject. It may be noted that the movement of the pin 32, being parallel to the axis 6, is not perpendicular to the plane of the seal 12. Therefore there will be a component of sideways motion of the pin 32 relative to the seal 12, which tends to form a tear instead of a neat hole that risks being plugged by the pin 32. The shape of the pin 32 may be designed to enhance this effect. The pin 32 does not need to be located so as to pierce the seal 12 in its centre. Multiple pins 32 (not illustrated) could be provided. Alternative means of breaking a seal as a result of relative movement between the head 2 and the handle 4 could easily be designed, for example by causing a rigid sealing member to crack, optionally along predetermined lines of weakness. The broadest scope of the invention includes still other means for bringing the fluid in the handle 4 into communication with the head 2 as a result of relative movement between the head 2 and the handle 4: for example, by using that movement to open a valve.

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After the applicator has been used to apply fluid to the skin of the subject, the head 2 that has been in contact with the skin should be safely disposed of but it is desirable to keep the handle 4 for sterilization and re-use. The head 2 may be separated from the handle by applying an axial force on the grip 24 in a direction towards the plate 15 of the head 2. As previously noted, the notches 28,29 may be formed with a sawtooth profile to prevent the head 2 being removed too easily from the handle 4. However, applying pressure in this direction to the grip 24 causes it to act as a lever and bend the resilient arm 22 so that it lifts the rib 26 out of engagement with the second notch 29. The applied force is then able to slide the head 2 all the way down the track 14 until the arms 20 of the head 2 disengage from the ends of the rails 13 and the head 2 is no longer secured to the handle 4. The point where this occurs may be defined as "the third position" of the head 2.

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The illustrated embodiment of the invention is described in relation to a substantially rigid handle 4, from which fluid will flow to the head 2 under gravity as soon as the seal 12 is broken (assuming the applicator is in a substantially upright orientation, as shown in the drawings). In other embodiments, the fluid may be a gel, which has the advantages of being less liable to leak from the device and being easier to control when applied to the skin of a subject. However, the force of gravity alone may not be sufficient to cause such a gel to flow to the head. In such cases, means (not illustrated) may be provided for exerting pressure on the fluid to urge it to move towards the head. For example, part of the handle 4 could be made from a material that is sufficiently flexible for it to be squeezed and reduce the volume of the interior, thereby displacing the fluid towards the head 2. In other embodiments, mechanical means such as a piston could be provided and be operated to displace the fluid.

CLAIMS

1. A fluid applicator comprising:

a handle (4) suitable for containing a source of a fluid; and

a head (2) suitable for applying the fluid to the skin of a subject;

wherein:

the handle (4) engages the head (2) so as to permit linear movement of the head (2) parallel to an axis (6) of the handle (4), said movement being from a first position, in which the head (2) is releasably secured to the handle (4) and is isolated from the source of fluid, to a second position, in which the head (2) is releasably secured to the handle (4) and is in communication with the source of fluid, then to a third position, in which the head (2) is released from the handle (4);

the head (2) comprises an arm (22) that extends generally parallel to the axis (6) along one side of the handle (4); and

each of the first and second positions is a position where a projection (26) on one of the handle and the arm (22) locates in a recess (28, 29) in the other of the handle (4) and the arm.

2. A fluid applicator according to claim 1, wherein the arm (22) comprises one projection (26) that can locate in either of two recesses (28, 29) in the handle (4) to define the first and second positions respectively.

3. A fluid applicator according to claim 1 or claim 2, wherein the arm (22) is resilient, such that when a projection (26) becomes located in a recess (28, 29), the projection (26) snaps into the recess (28, 29).

4. A fluid applicator according to claim 2 or claim 3, wherein the resilient arm (22) further comprises a grip (24) projecting away from the handle (4), whereby a user of the applicator can apply force to the grip (24) to move the head (2) between the first, second and third positions.

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5. A fluid applicator according to any preceding claim, wherein the engagement between the handle (4) and the head (2) is via a track (14) that extends parallel to the axis (6) along only said one side of the handle (4).

6. A fluid applicator according to any preceding claim, wherein the first position is between the second and third positions.

7. A fluid applicator according to any preceding claim, wherein:
in the first position of the head (2), the source of fluid in the handle is isolated from the head by a seal (12); and
movement of the head (2) from the first position to the second position breaks the seal (12) to permit the fluid to flow from the source to the head (2).

8. A fluid applicator according to claim 7, wherein the head (2) comprises a pin (32) adapted to pierce the seal (12) when the head (2) is moved from the first position to the second position.

9. A fluid applicator according to any preceding claim, wherein the head (2) comprises a pad (8) that defines a planar surface (10) adapted to apply fluid to the skin of a subject.

10. A fluid applicator according to claim 9, wherein the axis (6) of the handle (4) is inclined to the plane of the pad (8).

11. A fluid applicator according to claim 9 or claim 10, wherein the head (2) comprises an apertured plate (15) adapted to mount the pad (8).