

## Description

This invention relates to a sterilizing dressing according to the preamble of claim 1.

The conventional procedure used by medical practitioners for drawing blood from, or injecting a substance into, a live host body, has been for years to do the following steps:

1. sterilizing the skin to be punctured by vigorous abrasive rubbing with an alcohol swab,
2. removing a needle or cannula from a needle case and inserting it into a syringe holder fitted with a vacutainer or a drug-containing syringe,
3. injecting through the skin in the swabbed area and drawing blood or injecting a drug,
4. destroying the needle,
5. removing and labeling of the vacutainer containing the sample (if blood has been taken),
6. swabbing the wound to disinfect and remove blood leaking from the wound, and
7. covering the wound with a covering.

This practice continues, even though it is now well recognized that alcohol swabbing of the skin is inadequate protection from infection. Not only is the alcohol swab deficient in skin cleansing, but also the cannula can be contaminated and require cleansing. Alcohol is bactericidal against vegetative forms of bacteria through the denaturation of cellular proteins. However, it is far from ideal as a skin or surface disinfectant. Alcohol is flammable, it evaporates too fast to be very effective (it should remain on the skin surface for about 10 minutes), and it dries and irritates the skin.

It would thus be highly desirable to provide a means for sterilizing human skin prior to venipuncture, without abrasion, and in the same step provide protection from infection of the patient by the needle and continued protection of the patient after injection while minimizing the potential of infection of others by the patient's blood as a result of aerosols, leakage from the wound, handling of a swab before dressing the wound, or leakage from the cannula.

Some early attempts have been made to provide alternate procedures. For example, US-A-3367332 discloses the use of a resealable patch and membrane bandage through which the needle is inserted, at least the bandage having been sterilized with an antiseptic prior to injection of the host. However, the patch does not contain a sterilizing agent, and therefore the needle encounters only a thin layer of the sterilizing agent presented by the membrane. Furthermore, although the membrane may be thin and transparent, the patch is not and has substantial thickness, so that the phlebotomist is unable to correctly identify the injection site by sight or by feel through the patch. In the case of a blood draw, stabbing "in the dark" is unacceptable. For these and other reasons, the technology disclosed in this patent

has failed to replace the traditional use of alcohol swabs, however deficient the latter might be.

Thus, prior to this invention there has been a problem in providing for a sterilizing medium to be used with a needle, and a method of phlebotomy or drug injection, which more adequately sterilizes the needle while permitting precise location of the injection site.

It is therefore an object of the present invention to provide a sterilizing device which overcome the disadvantages discussed above. This has been achieved by the features of the characterizing portion of claim 1.

The patch of this invention is considered superior because it is transparent, admixes well with the sterilizing agent, provides no objectionable contaminant of the host, and is manipulatable enough to allow the site, at least in the case of a vein, to be identified by feel. This is in contrast to alternative media such as fibers, which tend to interfere both with seeing the site and feeling the site for the injection. Furthermore, fibers can be objectionable if the needle inadvertently injects one of them into the host.

It is an advantageous feature of this invention that a gel medium forming the patch properly sterilizes both the skin of the host to be penetrated and the penetrating instrument, without interfering with the proper detection of the injection site.

It is another advantageous feature of the invention that a sterilizing medium and method are provided which are free of the use of alcohol and its attendant disadvantages.

The present invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1 is a sectioned elevational view of a sterilizing dressing constructed in accordance with the invention; and

Figure 2 is a view similar to that shown in Figure 1, and which illustrates the use of the dressing according to the present invention.

The invention is hereinafter described with respect to a preferred embodiment, namely, that in which a dressing is used with a needle to draw blood from a site. In addition, it is useful with a syringe needle used to inject medicaments into a site.

As is customary with skin dressings, the dressing 10 according to the present invention comprises a first non-absorptive cover or base portion 12, a second non-absorptive cover or top portion 14 permanently affixed along margin portion 16 only, to the first cover by means such as an adhesive layer 18, and a patch 20 sandwiched between the two covers 12, 14. All three are most preferably symmetric about a central axis 22, that is, they are generally disc-shaped. Both covers 12 and 14 are preferably apertured at 24 and 26 respectively for reasons which will become apparent. Patch 20 is held in place by non-

attached inside margin portions 28 of covers 12 and 14.

The outer surface 30 of cover 12 has at least a portion thereof coated with a conventional releasable adhesive layer 32 suitable for contact with skin. As sold, dressing 10 includes a plastic, paper, metal foil or a laminate release sheet 34 adhered to adhesive layer 32, until that sheet is peeled away by the user to allow the dressing 10 to be stuck to the skin. Sheet 34 is preferably a solid disk having a shape and size effective to cover adhesive layer 32.

Conventional plastics materials or plastic-covered paper, metal foil or laminates can be used for covers 12 and 14.

In accordance with one aspect of the invention, patch 20 comprises a transparent, resealable, puncturable gel which contains throughout its volume, a sterilizing agent preincorporated therein. As used herein, "sterilizing agent" is any anti-bacterial agent, fungicide, anti-yeast agent or anti-viral agent or combination thereof. The selection, of course, is dependent upon the end use, a combination of an anti-viral agent and a anti-bacterial agent being preferred. Useful examples include parachlorometaxylenol (PCMX), chlorhexidine gluconate (CHG), triclosan, alcohol, iodophores and povidone-iodine, Nonoxynol-9™, phenolic compounds, quaternary ammonium compounds, chlorine solutions (sodium hypochlorite or chlorine dioxide), and glutaraldehyde. In addition, a topical anesthetic is optionally included, for example, benzocaine, xylocaine, menthol, pramoxine or dimesethisoquin, which is effective upon contact with the skin.

Any gel material is useful for patch 20 if it provides the above functions. Most preferred is a hydrogel which is an interlaced network of agar and a copolymer of acrylamide crosslinked with the monomer N,N'-methylenebisacrylamide, and 96% by weight bound water. A preferred example is the gel sold by Geistlich Pharma of Switzerland under the trademark "Geliperm"™. Other useful examples include gels which are copolymers of 2-hydroxyethyl methacrylate. The water is essential to keep the polymer network expanded, and to disperse the sterilizing agent. The polymer network serves to hold the liquid in place. The net result is a patch which is transparent, has no fibers to be injected into the skin, and distributes the sterilizing agent throughout. Thus, no matter which portion of patch 20 is penetrated by the needle, the agent will be effective to sterilize the needle.

Although for ease in manufacturing, the sterilizing agent is preferably dispersed throughout the patch, the sterilizing agent will also function if it is located primarily at the upper and lower surfaces of the patch, that is, where the needle and the skin encounter the gel medium from which the patch 20 is made.

The gel medium is also effective to reseal the patch 20 when the needle is withdrawn, and to wipe

the needle of any blood on its exterior. The sterilizing agent is preferably effective to sterilize any harmful virus or bacteria which might remain on the removed needle, for example, the HIV-1 virus or hepatitis B virus which can be present in the blood withdrawn by the needle.

The thickness of patch 20 is not critical, other than it must be sufficiently thick as to hold together, and thin enough to permit the user to feel the skin underneath. For example, 100 microns is useful.

The purpose of aperture 26 will become more apparent in the description of the use of the dressing 10 when referred to Figure 2. In use, release sheet 34 is stripped off the dressing 10 and discarded. This exposes both the adhesive layer 32 and gel patch 20 to the skin S to which dressing 10 is to be attached. Dressing 10 is maneuvered to cover the site to be penetrated by the needle, and to this end, aperture 26 or its equivalent is used to aid in finding the proper site. For example, vein V can be seen through aperture 26 and the transparent patch 20, and properly located vis-a-vis patch 20. In addition, the vein V can be felt through patch 20, since it is devoid of fibers which could camouflage the feel of the vein's location.

After patch 20 is properly located on the site, patch 20 is preferably massaged onto the site to disperse the sterilizing agent over the site. Such massaging further confirms the proper location by the sense of touch.

After dressing 10 is in contact with skin S at the site, a needle 50 is positioned at aperture 26, and then inserted via arrow 52 first through patch 20 and then into the skin S (not shown).

Thus, an equivalent to aperture 26 in cover 14 is a transparent portion (not shown) of the cover which physically covers patch 20 in its entirety, while still making it possible to see and feel through dressing 10 to the site. In such a case, patch 20 is fully covered and protected against premature exposure. Alternatively, if aperture 26 is present as such, the entire dressing is wrapped and stored in protective plastic material.

Preferably, dressing 10 is thrown away after a single use. However, and particularly if used with a syringe to deliver a medicament, because of the gel nature of patch 20, dressing 10 can be re-used if a second injection is to occur elsewhere on the patient. In this case, when the needle is withdrawn the gel medium completely reseals, and becomes an integral member in which the sterilizing agent is still uniformly dispersed. Thus, additional needles can penetrate the same patch, without fear of the sterilizing agent no longer being effective.

Other agents can be optionally added to gel medium of the patch 20 as desired for particular applications. For example, perfumes, silicones, antioxidants, and even coagulating agents can be added.

**Claims**

1. A sterilizing dressing (10) for use with a needle to inject into or remove a liquid from a site on a live host body, the dressing (10) comprising:  
a protective base portion (12);  
a resealable patch (20) in contact with the base portion (12);  
retaining means (14, 18) for retaining the patch (20) in contact with the base portion (12);  
and  
adhesive means (32) on the base portion (12) for attaching the dressing (10) to a live host body;  
characterized in that a sterilizing agent is pre-incorporated throughout the resealable patch (20);  
and in that the retaining means (14, 18), the base portion (12) and the patch (20) are sufficiently transparent that the site on the live host body can be seen through the patch (20), the base portion (12) and the retaining means (14, 18).
2. A dressing according to claim 1, wherein the retaining means (14, 18) comprise a protective cover portion (14) and an adhesive layer (18) for adhering the cover portion (14) to the base portion (12) so as to retain the patch (20) therebetween, the cover portion (14) having an aperture (26) formed therein to permit viewing of the patch (20).
3. A dressing according to claim 1 or 2, wherein the patch (20) comprises an interlaced network of agar and an acrylamide copolymer.
4. A dressing according to any one of the previous claims, wherein the adhesive means comprises an adhesive layer (32) disposed on a surface portion of the cover portion (12) which is positioned adjacent to the live host body.
5. A dressing according to any one of the previous claims, wherein the sterilizing agent is an agent selected from the group consisting of an antibacterial agent, a fungicide, an anti-yeast agent, an antiviral agent and mixtures thereof.

**Patentansprüche**

1. In Verbindung mit einer Nadel verwendbares sterilisierendes Verbandspflaster (10), das zum Injizieren oder Entnehmen einer Flüssigkeit am Körper eines Patienten angebracht ist, mit einer abdichtenden Unterlage (12), einem mit der Unterlage (12) in Berührung ste-

henden, sich nach dem Nadeleinstich wieder schließenden Polster (20), das Polster (20) mit der Unterlage (12) in Berührung haltenden Haltemitteln (14, 18) und einem auf der Unterlage (12) vorgesehenen Klebemittel (32) zum Befestigen des Verbandes (10) am Körper, dadurch gekennzeichnet, daß in das gesamte sich nach dem Nadeleinstich wieder schließende Polster (20) ein Sterilisierungsmittel eingebracht worden ist und daß die Haltemittel (14, 18), die Unterlage (12) und das Polster (20) so transparent sind, daß die Stelle, an der sie am Körper angebracht sind, durch das Polster (20), die Unterlage (12) und die Haltemittel (14, 18) hindurch sichtbar ist.

2. Verbandspflaster nach Anspruch 1, dadurch gekennzeichnet, daß die Haltemittel (14, 18) aus einem schützenden Abdeckteil (14) sowie aus einer Klebeschicht (18) bestehen, mit der das Abdeckteil (14) an der Unterlage (12) so festgeklebt ist, daß das Polster (20) fest zwischen diesen Teilen liegt, und daß das Abdeckteil eine Öffnung (26) besitzt, durch die das Polster (20) sichtbar ist.
3. Verbandspflaster nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß das Polster (20) aus einer vernetzten Zellenstruktur von Agar Agar und einem Acrylamid-Mischpolymerisat besteht.
4. Verbandspflaster nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß das Klebemittel aus einer Klebeschicht (32) besteht, die auf einem Oberflächenbereich der dem Körper direkt benachbarten Unterlage (12) angeordnet ist.
5. Verbandspflaster nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß es sich bei dem Sterilisierungsmittel um ein Bakterizid, ein Antimycotikum, ein das Wachstum von Hefepilzen hemmendes Mittel, ein Antivirumittel oder aber um Mischungen aus diesen Mitteln handelt.

**Revendications**

1. Champ collé (10) stérile utilisable avec une aiguille pour injecter ou ponctionner un liquide dans un ou à partir d'un site localisé sur le corps d'un hôte vivant, le champ (10) comprenant :  
un support protecteur (12)  
un élément refermable (20) en contact avec le support protecteur  
un moyen de maintien (14, 18) pour retenir l'élément (20) au contact du support (12), et



un moyen adhésif (32) solidaire du support (12) pour fixer le champ (10) sur le corps de l'hôte vivant,

caractérisé en ce qu'on incorpore à l'avance un agent stérilisant à l'élément refermable (20), 5

et en ce que le moyen de maintien (14, 18), le support (12), et l'élément refermable (20) sont suffisamment transparents de manière à permettre de voir le site localisé sur le corps de l'hôte vivant au travers de l'élément refermable (20) du support (12) et du moyen de maintien (14, 18). 10

2. Champ suivant la revendication 1, dans lequel le moyen de maintien (14, 18) comprend une partie protectrice supérieure (14) et une couche adhésive (18) pour fixer la partie protectrice (14) et une couche adhésive (18) pour fixer la partie protectrice (14) au support de manière à retenir l'élément refermable (20) entre eux, la partie protectrice (14) présentant une ouverture (26) permettant de visualiser l'élément refermable (20). 15 20

3. Champ selon l'une des revendications 1 ou 2, dans lequel l'élément refermable (20) comprend un réseau entrelacé d'agar-agar et de copolymère d'acrylamide. 25

4. Champ selon l'une quelconque des revendications précédentes, dans lequel le moyen adhésif comprend une couche adhésive (32) située sur une partie de la surface du support (12) disposée en regard du corps de l'hôte vivant. 30

5. Champ selon l'une quelconque des revendications précédentes, dans lequel l'agent stérilisant est un agent choisi parmi le groupe constitué des agents antibactériens, des fongicides, des agents anti-levures et des agents anti-virus ou des mélanges de ceux-ci. 35 40

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