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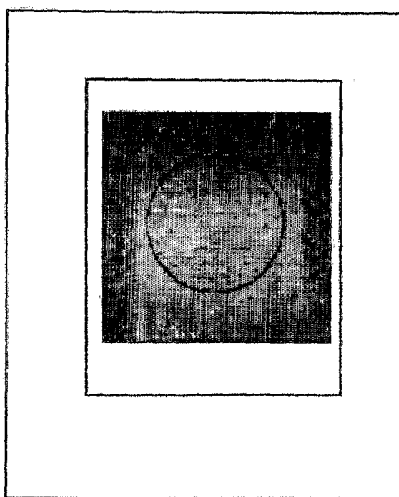
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(54) Title: SAFETY BLOOD PAD FOR DIALYSIS VENIPUNCTURES



(57) Abstract: Safety blood pads for dialysis venipunctures comprising a multi layered or multifold gauze pads for stemming bleeding from post dialysis venipunctures to effectively reduce cross contamination among public. Such a pad has a thick gauze pad for absorbing large amounts of blood from relatively large post-dialysis punctures. Onset of homeostasis is frequently delayed for up to 1/2 an hour but can be accelerated by application of localized finger thumb pressure by the patient, the primary elements of the pad are a planar multiply absorbent pad, of up 48 gauze layers about 2x2x0.5 inches after folding, which is enclosed in a pouch of a fluid impermeable flexible film consisting of a first layer and a second layer opposite to layer, which hermetically sealed or bonded at all four sides to form seals, thereby to form a sealed pouch or enclosure, for pad, the first layer has a circular or otherwise shaped opening located near the center of layer, which constitutes the contact between the puncture and the enclosed pad is the hole in layer which further serves to permit escape of air from the pad, so as to fully utilize the blood absorbing capacity of the pad.

WO 2004/060245 A1

SAFETY BLOOD PAD FOR DIALYSIS VENIPUNCTURES

TECHNICAL FIELD

This invention relates to multi layered or multifold gauze pads for effectively, and safely stemming bleeding from post-dialysis venipunctures. These pads effectively reduce cross contamination among patient population, medical workers, and the general public.

Description of Prior Art

Conventional gauze pads known in the art do not adequately protect the medical workers or other persons from contracting a blood borne disease as a result of potential exposure to the blood of infected patient.

This is particularly true for routing procedures such as withdrawal of dialysis needle, which create relatively large venipunctures that tend to bleed more profusely than conventional phlebotomy punctures. Dialysis patients are also routinely heparinized to minimize clotting problems during dialysis and frequently also take blood thinning medications such as comedians. Both these factors further tend to prolong bleeding times extending up to 30 minutes or more requiring one or more thick blood pads to absorb and prevent bleeding continues localized thumb pressure applied by the patient is necessary to reduce bleeding.

Conventional gauze pads and gloves are frequently the main or only protection for preventing contact of the medical worker with the patient's blood. The patient does not need to be protected from his or her own blood, but bloody fingers or gloves thus exposed clearly pose a threat of contaminating every thing he or she touches, Gloves may prevent direct exposure of the wearer to blood but, unless care is used to immediately clean the suspected area or article, it can indirectly spread infected blood to any article subsequently touched with the contaminated gloves.

Further more the conventionally worn latex gloves when stretched during donning become inherently micro porous and frequently macro porous due to flaws in manufacturing like condoms, latex gloves effectively block passage of larger particles like semen, but are less effective in preventing the transmission of far smaller infectious viruses such as HIV, Hepatitis A, B, C. The increased incidence of infectious viral diseases has promoted the authority to issue federal regulations for preventing exposures to blood borne pathogens under 29 CFR 1910, 1030, (1993) entitled OSHA blood borne Pathogens Regulations. These regulations require employers to provide adequate protective clothing, equipment and training to all personnel potentially exposed to pathogens in a work place environment. It is apparent that the current procedures and the currently available protective devices in the art, as practiced, for instance in the dialysis centers, do not adequately protect medical personnel and other patients from blood contact and potential infection.

Unlike conventional phlebotomy, dialysis procedures have rather unique requirements for controlling the relatively profuse bleeding from the puncture wound created by larger needles, typically 14G, 15G, 16G & 17G compared to the smaller 18 or 20 G needles used for phlebotomy.

A larger gauze and localized finger pressure usually applied by the patient for a prolonged period of time are required. A bandage as used in phlebotomy is unsatisfactory. The gauze usually become heavily soaked with blood and the patient generally wears at least one glove to prevent their fingers touching blood. Once the bleedings has stopped the blood soaked pads and the contaminated glove must be safely deposited by the untrained patient either into an intermediary container or directly into a bio-hazard container without touching an object.

Herein the patient has to be trained to remove both the blood soaked pads and gloves (if used) to be deposited the biohazard container without contaminating any object with blood. In case of leak into the gloves then the patient will have to wash their hands. All these procedures are clearly not without exposure risk to the medical personnel and the other dialysis patients when performed by an untrained person and are unlikely to meet OOTA requirements.

Cellulosic absorbent pads, bandages, sponges and gloves are currently the primary protective devices used in the dialysis centers. Other devices potentially applicable but not clearly for use with dialysis patients are cited in the following patents:

US Patent 4,829,995 and 4,915,765 disclose medical dressing attached to an impervious barrier layer also bearing a handle the dressing in place. While this design protects the fingers from exposure to blood, it does not permit application for localized pressure and also exposes a large portion of the dressing to the open air.

US Patent 5,009,652, discloses disposable laminated planar sponge or pad enclosed in a liquid previous lower layer facing the blood source and a liquid impervious but air permeable upper layer for holding the pad in place and for applying pressure. While this device permits application of localized pressure and also shields the fingers from contact with blood to certain extent, it lacks a pouch to hold the blood thus making disposal open for contamination.

US Patent 5,558,918 describes a multiplayer bandage for protecting the patient from contact with blood. It consist of a non-porous first layer also serving as a gripping surface and a gauze pad affixed to one side of the non-porous first layer which also bears one or two straps for securing the pad to the wound. Again this design appears too thick and too rigid to permit application of localized finger pressure, the straps

will not effectively perform this function. This device is clearly intended for larger wounds rather than for localized application for venipuncture wounds.

In summary the devices of Prior Art fail to address the unique needs of dialysis patients in that they do not.

- a) Uniquely address the needs of dialysis protocols.
- b) Minimize potential contact of medical personnel with pathogenic blood. Provide or disclose means for safe disposal of potentially pathogenic blood soaked pads.

In contract, the disclosed invention provides the following:

- (i) Safe and efficient means for controlling blood flow that can be easily implanted by the patient with minimal attention from medical personnel.
- (ii) Safe methods for applying thumb pressure to the puncture site through a single or double layer of an impervious flexible and transparent film wherein such pressure is highly localized over and transmitted to the puncture to effectively stop bleeding.
- (iii) A dual function transparent plastic enclosure also effectively holds blood into needing no special receptacle to dispose the same without contaminating ones hand.

The device and the method of this invention provide a safer procedure allowing controlled localized application of finger pressure to a puncture in direct contact with a small exposed portion of a gauze pad located inside a primary flexible

impervious square enclosure. The primary enclosure can be safely held in place by a patient while concurrently applying localized thumb pressure to stem the bleeding. In a preferred mode a glove can be used to use pressure and for removal of the pads. While removing the blood pads the gloves can be inverted over the blood soaked pads in one simple motion which will enclose the pads for safe disposal into the biohazard container.

At the outset of the description which follows it is to be understood that ensuing description only illustrate a particular form of this invention. However, such particular form is only an exemplary embodiment, and without intending to imply any limitation on the scope of this invention. Accordingly, the description is to be understood as an exemplary embodiment and reading of the invention and not intended to be taken restrictively.

Summary of Invention

According to the invention safety blood pads for dialysis venipunctures comprises a multi layered or multifold gauze pads for stemming bleeding from post dialysis venipunctures to effectively reduce cross contamination among public.

Safety Blood pads for dialysis venipuncture comprises a thick gauze pad for absorbing large amount of blood from relatively large post-dialysis punctures, Onset of homeostasis is frequently delayed for up to $\frac{1}{2}$ an hour but can be accelerated by application of localized finger thumb pressure by the patient, the primary elements of the pad are a planar multiply absorbent pad of up 48 gauze layers about 2x2x0.5 inches after folding, which is enclosed in a pouch of a fluid impermeable flexible film consisting of a first layer and a second layer opposite to first layer, which hermetically sealed or bonded at all four sides to form seals, thereby to form a sealed pouch or enclosure, for pad the first layer has a circular or otherwise shaped

opening located near the center of layer, which constitutes the contact are between the puncture and enclosed pad the hole in layer further serves to permit escape of air from the pad so as to fully utilize the blood absorbing capacity of the pad, pad material is typically any compressible open-pore absorbent, such as but not limited to Cellulose or cotton gauze, polyurethane foamed sponge, and the like that can be heated or gas sterilized. The flexible non-porous layer material can be made of polypropylene, polyethylene, PVC or other synthetic or natural polymers, the preferred thickness of the layer material is guided for each polymer by optimal flexibility strength and fluid impermeability and should typically be 0.05 to 0.1 inches, the assembled pouch is sealed inside a gas permeable paper enclosure prior to heat or gas sterilization.

Safety blood pad according to invention is compact and with high blood absorbing capacity.

Safety blood pad according to invention is fully enclosed, except for the contact area, and flexible leak-proof pad pouch for safe containment of blood.

Safety blood pad according to invention is flexible thus permitting focused or localized application of pressure over the puncture thereby decreasing the time to cessation of bleeding.

Safety blood pad according to invention has an open contact area, which permits escape of air inside the pad thereby permitting full saturation of the pad with blood.

Safety blood pad according to invention is simple to apply and control by the patient with minimal intervention by lab personnel.

Safety blood pad according to invention is of very low potential for inadvertent post-dialysis contamination of the patient area or other persons with infected blood.

Safety blood pad according to invention is safe disposal of potentially infected blood inside the pouch with minimal exposure to air and formation of respirable aerosol.

Safety blood pad according to invention is simple functional and low-cost design anticipating wide acceptance unlike several other prior art devices which are never successfully commercialized.

Brief Description of the Drawings

Fig. 1 is a top view of the preferred embodiment of the safety blood pad.

Fig.2 is a rear view of the preferred embodiment of the safety blood pad.

Fig.3 is a side view of the preferred embodiment of the blood pad.

Fig.4 is an isometric view of a preferred embodiment of the blood pad.

Detailed Description of an Embodiment of Invention

Fig. 1,2 and 3 depict the preferred embodiment of a thick gauze pad for absorbing large amount of blood from relatively large post-dialysis punctures. Onset of homeostasis is frequently delayed for up to ½ an hour but can be accelerated by application of localized finger thumb pressure by the patient. The primary elements of the pad area a planar multiply absorbent pad, 10, of up 48 gauze layers about 2x2x0.5 inches after folding, which is enclosed in a pouch of a fluid impermeable flexible film consisting of a first layer 11 and a second layer opposite to first layer 11, which hermetically sealed or bonded at all four sides to form seals 14, thereby to form a sealed pouch or enclosure, 13 for pad 10. The first layer has a circular or otherwise shaped opening located near the center of layer 11, which constitutes the

contact are between the puncture and enclosed pad 10. The hole in layer 11 further serves, to permit escape of air from the pad 10, so as to fully utilize the blood absorbing capacity of the pad. The pad material is typically any compressible open pore absorbent, such as but not limited to Cellulose or cotton gauze, polyurethane foamed sponge, and the like that can be heated or gas sterilized. The flexible non-porous layer material can be made of polypropylene, polyethylene, PVC or other synthetic or natural polymers. The preferred thickness of the layer material is guided for each polymer by optimal flexibility strength and fluid impermeability and should typically be 0.05 to 0.1 inches. The assembled pouch is sealed inside a gas permeable paper enclosure prior to heat or gas sterilization.

In summary the blood pad of this invention has the following characteristics or advantages over prior devices.

- (a) Compact yet with high blood absorbing capacity.
- (b) Fully enclosed, except for the contact area, and flexible leak-proof pad pouch for safe containment of blood.
- (c) Flexible thus permitting focused or localized application of pressure over the puncture thereby decreasing the time to cessation of bleeding.
- (d) The open contact area also permits escape of air inside the pad thereby permitting full saturation of the pad with blood.
- (e) Simple to apply and control by the patient with minimal intervention by lab personnel.

- (f) Very low potential for inadvertent post-dialysis contamination of the patient area or other persons with infected blood.
- (g) Safe disposal of potentially infected blood inside the pouch with minimal exposure to air and information of respirable aerosol.
- (h) Simple, functional and low –cost design anticipating wide acceptance unlike several other prior art devices which were never successfully commercialized.

The invention has been explained in relation to specific embodiment. It is inferred that the forgoing description is only illustrative of the present invention and it is not intended that the invention be limited or restrictive thereto. Many other specific embodiments of the present invention will be apparent to one skilled in the art from the forgoing disclosure. All substitution, alteration and modification of the present invention which come within the scope of the following claims are to which the present invention is readily susceptible without departing from the spirit of the invention.

The scope of the invention should therefore be determined not with reference to the above description but should be ascertained with reference to appended claims along with full scope of equivalent to which such claims are entitled

Claims

1. Safety blood pads for dialysis venipunctures comprising a multi layered or multifold gauze pads enclosed in a pouch, the pad having a circular shaped opening located near the centre of first layer, pad intended to stem bleeding from post dialysis venipunctures to effectively reduce cross contamination among public.
2. Safety blood pads for dialysis venipuncture comprises a thick gauze pad for absorbing large amount of blood from relatively large post-dialysis punctures, Onset of homeostasis is frequently delayed for upto $\frac{1}{2}$ an hour but can be accelerated by application of localized finger thumb pressure by the patient, the primary elements of the pad are a planar multiply absorbent pad, of up 48 gauze layers about 2x2x0.5 inches after folding, which is enclosed in a pouch of a fluid impermeable flexible film consisting of a first layer and a second layer opposite to layer, which hermetically sealed or bonded at all four sides to form seals, thereby to form a sealed pouch or enclosure, for pad the first layer has a circular or otherwise shaped opening located near the center of layer, which constitutes the contact are between the puncture and enclosed pad, the hole in the layer further serves to permit escape of air from the pad, so as to fully utilize the blood absorbing capacity of the pad.
3. Safety blood pads as claimed in claim 1 wherein the pad material is typically any compressible open-pore absorbent, such as but not limited to Cellulosic or cotton gauze, polyurethane foamed sponage, and the like that can be heated or as sterilized.

4. Safety blood pads as claimed in claim 1 wherein the flexible non-porous layer material can be made of polypropylene, polyethylene, PVC or other synthetic or natural polymers, the preferred thickness of the layer material is guided for each polymer by optimal flexibility, strength and fluid impermeability.
5. Safety blood pads as claimed in claim I wherein each layer should typically be 0.05 to 0.1 inches, the assembled pouch is sealed inside a gas permeable paper enclosure prior to heat or gas sterilization.
6. Safety blood pad as claimed in claim I which is Compact and with high blood absorbing capacity.
7. Safety blood pad as claimed in claim I which is fully enclosed, except for the contact area, and flexible leak-proof pad pouch for safe containment of blood.
8. Safety blood pad as claimed in claim I which is flexible thus permitting focused or localized application of pressure over the puncture thereby decreasing the time to cessation of bleeding.
9. Safety blood pad as claimed in claim I which has an open contact area also permits escape of air inside the pad thereby permitting full saturation of the pad with blood.
10. Safety blood pad as claimed in claim I which is simple to apply and control by the patient with minimal intervention by lab personnel.

11. Safety blood pad as claimed in claim I which is of very low potential for inadvertent post-dialysis contamination of the patient area or other persons with infected blood.
12. Safety blood pad as claimed in claim I which is of safe disposal of potentially infected blood inside the pouch with minimal exposure to air and formation of respirable aerosol.
13. Safety blood pad as claimed I which when compared to prior art devices which are never simple functional and low-cost design anticipating wide acceptance unlike several other successfully commercialized.
14. Safety blood pad as described in the description and as illustrated by way of drawings accompanying the description.

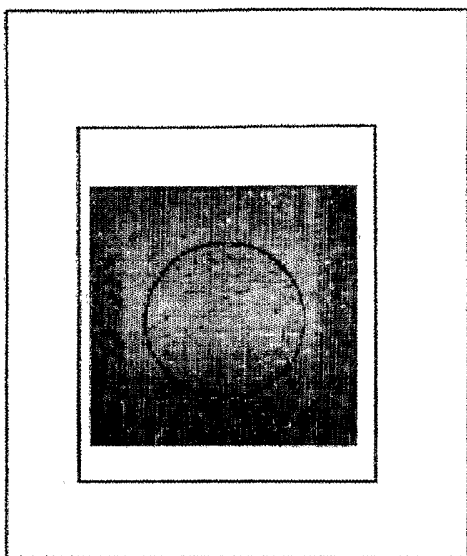


Fig 1

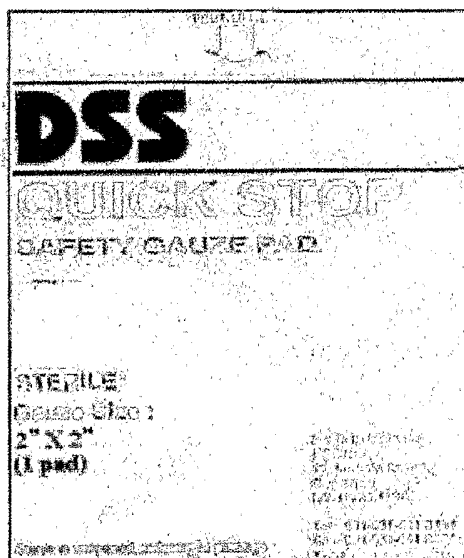


Fig 2

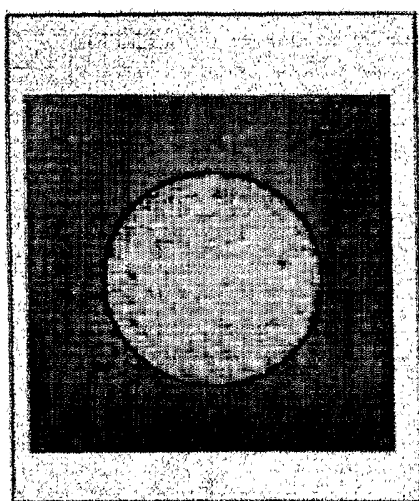


Fig 3

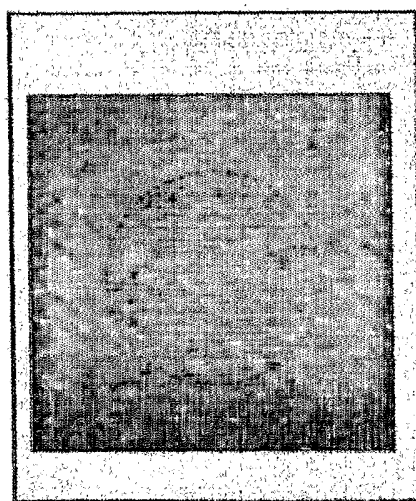


Fig 4



INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN 03/00007

CLASSIFICATION OF SUBJECT MATTER

IPC⁷: A61F 13/36

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC⁷: A61F 13/00

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 practicable, search terms used)

WPI, EPODOC, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	EP 0355554 A1 (SEALED AIR CORPORATION) 28 February 1990 (28.02.90) <i>claims 1-13; figures 1-3.</i>	1
A	US 5771524 A (WOODS J.M. et al.) 30 June 1998 (30.06.98) <i>figures 1 -5,9-11,14-16,19-21; claims.</i>	1
A	FR 2681526 A1 (SCHLEE S.) 26 March 1993 (26.03.93) , (abstract) World Patents Index [online] [retrieved on 2003-09-10]. Retrieved from EPO WPI Database, DW 199325; AN.: 1993-199062[25]. <i>abstract and First Page Image.</i>	1

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

„A“ document defining the general state of the art which is not considered to be of particular relevance

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„T“ later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

„X“ document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

„Y“ document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

„&“ document member of the same patent family

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IN 03/00007

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 1596891 A (CARL FREUDENBERG KG) 3 September 1981 (03.09.81) <i>page 1, lines 82-99; claims 1,2.</i> -----	1

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IN 03/00007

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