PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :		(11) International Publication Number:
A61F 13/00	A1	WO 90/06735
		(43) International Publication Date: 28 June 1990 (28.06.90)

(21) International Application Number: PCT/US89/05506

(22) International Filing Date: 13 December 1989 (13.12.89)

(30) Priority data:
283,825 13 December 1988 (13.12.88) US

(71) Applicant: KALT MEDICAL CORP. [US/US]; 2255 Glades Road, Suie 324, Atrium, Boca Raton, FL 33431 (US).

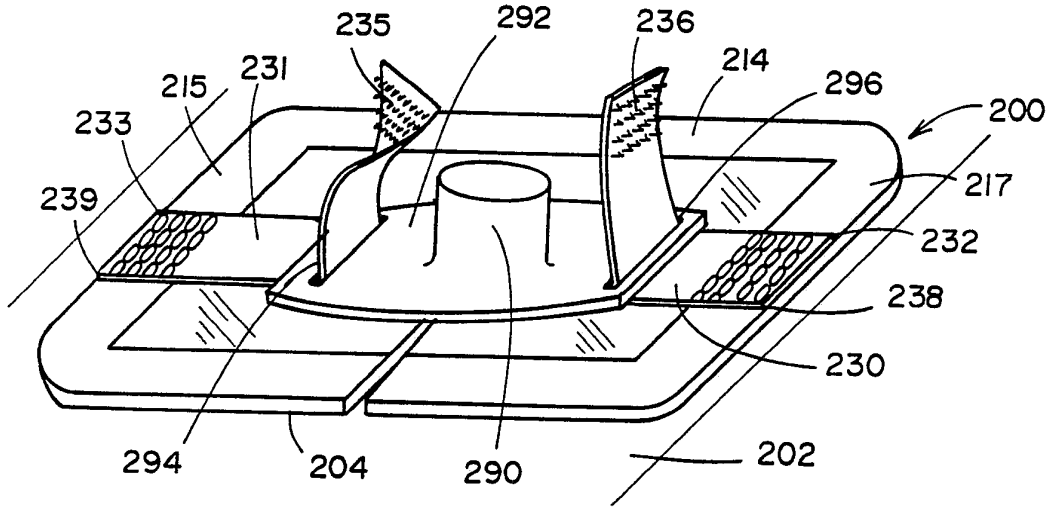
(72) Inventor: KALT, Glenda, G. ; 7676 Courtyard Run West, Boca Raton, FL 33433 (US).

(74) Agents: GROSSMAN, Jon, D. et al.; Dickstein, Shapiro & Morin, 8300 Boone Boulevard, Suite 800, Vienna, VA 22182 (US).

(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DE (Utility model), DK, ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent).

Published
With international search report.

(54) Title: TRANSPARENT TRACHEOSTOMY TUBE DRESSING



(57) Abstract

A transparent dressing (200) for substantially sealing a wound consisting of a semi-rigid frame (214) for defining an opening and a resilient transparent membrane (218) substantially covering the opening in order to form a transparent window. The transparent material (218) allows air and vapor to permeate the material in a first direction and prevent contaminants and fluids from entering the wound area in an opposite direction. Several embodiments of the invention are shown for firmly holding a tracheostomy tube (290) to the dressing (200).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	**ES**	Spain	**MG**	Madagascar
AU	Australia	**FI**	Finland	**ML**	Mali
BB	Barbados	**FR**	France	**MR**	Mauritania
BE	Belgium	**GA**	Gabon	**MW**	Malawi
BF	Burkina Faso	**GB**	United Kingdom	**NL**	Netherlands
BG	Bulgaria	**HU**	Hungary	**NO**	Norway
BJ	Benin	**IT**	Italy	**RO**	Romania
BR	Brazil	**JP**	Japan	**SD**	Sudan
CA	Canada	**KP**	Democratic People's Republic of Korea	**SE**	Sweden
CF	Central African Republic			**SN**	Senegal
CG	Congo	**KR**	Republic of Korea	**SU**	Soviet Union
CH	Switzerland	**LI**	Liechtenstein	**TD**	Chad
CM	Cameroon	**LK**	Sri Lanka	**TG**	Togo
DE	Germany, Federal Republic of	**LU**	Luxembourg	**US**	United States of America
DK	Denmark	**MC**	Monaco		

TRANSPARENT TRACHEOSTOMY TUBE DRESSING

BACKGROUND OF THE INVENTION

The present invention relates in general to a tracheostomy tube dressing for covering the wound about a patient's neck such that the wound area can be covered while it is also allowed to heal.

Although opaque dressings have long been in use, their designs suffer from several drawbacks. First, the patient or person treating the patient has no idea how well the wound is healing until the dressing is entirely removed. Second, removal of the dressing increases the danger that the scab or skin covering the wound will be removed along with the dressing. Another drawback is that many dressings fail to adequately aerate the wound. In such instances, the healing of the wound is much slower. Another drawback of many conventional dressings is that part of the wound area is contacted by an adhesive portion of the dressing. Thus, when the dressing is removed, the tacky surface of the dressing will possibly harm the partially healed area.

These drawbacks are compounded in tracheostomy tube dressings where the dressing must serve the dual function of protecting the wound and holding the tracheostomy tube in place. Such a dressing must avoid the above drawbacks common to all dressings and still present a sufficiently rigid clamp for the tracheostomy tube.

To date, those transparent dressings and tracheostomy dressings that have been devised fail to avoid these drawbacks.

For example, the 3-M Corporation markets a transparent dressing under the trademarked name "TEGADERM" and the Johnson & Johnson Company sells a transparent dressing under the name "BIOCLUSIVE". Both dressings consist of a transparent air and vapor permeable film that have the surface of one side entirely coated with an adhesive. The dressings are supplied with releasable paper frames adhered to the non-adhesive side of each sheet. A paper frame is used in each dressing to maintain the integrity of the dressing's shape before it is applied to the patient's skin. Once applied, the frame is removed.

Although the "TEGADERM" and "BIOCLUSIVE" dressings are relatively simple in their construction, their adhesive surfaces may harm healing tissue when the dressings are removed. Another problem is that water or contaminants may seep into the wound site from the sides of the dressing due to the lack of a sealing frame.

The "TEGADERM" product also includes a design for use as a tracheostomy dressing. In this application, a slit is cut to extend from an edge of the dressing to the center. A center hole having the same diameter as a tracheostomy tube is then cut so that the slit contacts one side of the hole. The combination of the slit and center hole allow the bandage to be spread apart along the slit in order that a tracheostomy tube and cuff can easily slide into the center hole. When the slit is closed, the center hole surrounds the tube below the cuff and collar substantially enclosing the tube. However, the "TEGADERM" tracheostomy dressing does not contain a structure for securing the tracheostomy tube to the patient's neck. Instead, the tube is independently secured to a patient's neck by means of cloth ties which completely encircle the patient's neck. Thus, the cloth ties do not adequately hold the tube to the bandage. Movement of the ties or of the dressing will cause stress on the tube. The cloth ties also create a substantial risk of infection to

patients having undergone recent surgery to the head and/or neck. Moreover, if the ties are made too tight, they can potentially choke the patient. The cloth ties are also susceptible to bacteria, creating a greater risk of infection around the puncture area for the tube. The cloth ties also create a substantial risk of infection to patients having undergone recent surgery to the head or neck. Finally, the cloth ties are inconvenient, requiring the treating nurse or physician to physically untie or retie a knot each time they wish to remove or adjust the tube.

Another transparent dressing is sold under the registered trademark "VENI-GARD" by the Conmed Corporation. "VENI-GARD" is a disposable dressing for holding an IV needle or catheter in a patient's vein. The "VENI-GARD" provides a sterile barrier over the puncture site and incorporates a transparent semi-permeable membrane material as the covering over the site. The purpose of the transparent membrane is to allow unobstructed visualization of the puncture locus while at the same time enabling the evaporation of any moisture that collects around the puncture site. However, the construction of the VENI-GARD dressing is complex. Further, the membrane is coated with an adhesive that renders the VENI-GARD unsuitable for use in covering a wound because the adhesive surface may harm the healing tissue when the dressing is removed.

Another example of a transparent dressing is shown in the Gordon patent, U.S. Patent No. 4,341,208. The Gordon dressing has a transparent window and a flexible frame for adhering the window to the patient's skin. Thus, unlike "VENI-GARD," the Gordon dressing does not contact the adhesive layer to the wound. However, the material used with the window does not allow for the passage of air or moisture from the patient's skin to the exterior surface of the dressing. Moreover, the construction of the Gordon dressing requires a multiple layered

window which employs an applicator layer adjacent to the transparent layer. The applicator spaces the window from the skin by the thickness of the frame which is not as sterile as an adjacent film because the spaced film traps air or other substances adjacent to the skin.

Another transparent dressing is illustrated by the Klein patent, U.S. Patent No. 2,273,873. The Klein dressing involves a transparent adhesive sheet adapted to be used as a dressing for a wound. The wound is not sealed from outside contaminants since air passages are provided along portions of the frame of the dressing. In addition, the transparent material used in the Klein dressing is neither air nor vapor permeable, and the sheet does not contact the skin.

The Linsky et al. patent, U.S. Patent No. 4,181,127, illustrates a non-adherent wound dressing employing an absorbent pad border that removes moisture from the area around the wound. A transparent film covers the wound and has its edges overlapped by an adhesive frame. However, the film is placed on top of the frame rather than below it, the materials of the frame are primarily webbing, and the film is an imperforate material that does not offer the advantages of a transparent air/vapor permeable barrier.

The Merriam et al. patent, U.S. Patent No. 2,949,443, illustrates a water vapor permeable dressing applied directly to a surgical wound. The material of the dressing is primarily transparent and water and vapor permeable. However, the material is either applied to the skin through the use of an adhesive layer formed along the outer edge of the dressing, or through the application of an alcohol solvent applied to the skin directly. Such a construction does not adhere strongly to the patient's skin and may easily come loose from the wound area.

The Faasse, Jr. patent, U.S. Patent No. 4,744,355, discloses a hinged releasable wound dressing in which a thin flexible polymeric film having an adhesive layer coated on one side of the dressing is applied directly to the site of the wound. The Faasse, Jr. dressing has the drawback of directly contacting the wound with adhesive which could cause the healing layer of skin to be pulled up when the dressing is removed.

Finally, the Dellas dressing illustrated in U.S. Patent No. 4,485,809 provides for a transparent moisture vapor permeable film dressing. As in Faasse, Jr., the Dellas film also employs an adhesive in order to directly contact the dressing to the patient's skin. Therefore, the construction of the Dellas dressing can cause tearing of the partially healed wound when the dressing is removed from the patient's skin.

SUMMARY AND OBJECTS OF THE INVENTION

The present invention alleviates to a great extent the disadvantages presented by the prior art devices by providing for a transparent tracheostomy dressing of simple construction that completely seals a wound with a transparent gas/vapor permeable membrane, while avoiding contact between the dressing's adhesive surface and the wound. Moreover, the dressing secures the tracheostomy tube to the frame of the dressing such that the tube is firmly supported. The material of the transparent member is gas/vapor permeable only in the direction away from the wound such that outside contaminants cannot enter inside the dressing. The frame that adheres the transparent membrane to the wound is sufficiently rigid to adequately secure the tracheostomy tube yet sufficiently flexible so that the dressing can be comfortably worn while not folding over itself when applied to the skin.

The transparent dressing is substantially rectangular. The frame portion consists of a rectangular piece having a centrally defined opening. A similarly shaped but smaller rectangular transparent membrane is attached to the bottom of the frame such that a tacky adhesive border surrounds the transparent membrane. Two ties are adhered to opposing sides of the frame. The ties are oriented to loop around a tracheostomy tube located in the center of the rectangular opening. Moreover, a slit runs from one edge of the frame to the center of the transparent membrane. A center hole is formed out the center surrounded by a frame formed about the circumference of the center hole.

In another aspect of the invention, the dressing is substantially circular.

In still yet another embodiment of the invention, the dressing has a frame with two fingers at opposing ends of the frame. A transparent window is formed in the center of the frame.

It is an object of the invention to provide for a transparent dressing yielding to the foregoing advantages that effectively holds a tube against a patient's body.

It is still an additional object of the invention to provide for a transparent dressing where the dressing does not have to be removed in order for the patient to observe the site of the wound.

It is still a further object of the invention to provide for a dressing of simple construction having a frame consisting of a single piece of material.

It is still a further object of the invention to provide for a dressing yielding to the foregoing advantages and that can clamp to a variety of sizes of tubes and yield to any skin surfaces of the body.

It is still an object of the invention to provide for a dressing that securely clamps a tracheostomy tube to the neck of a patient without requiring the use of cloth ties.

These and other objects of the invention are accomplished by the present invention as described by the drawings and detailed description herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top view of the first embodiment of a transparent dressing according to the present invention;

FIG. 2 is a cutaway view taken along section line II-II of FIG. 1;

FIG. 3 is a bottom view of transparent dressing 10 of FIG. 1;

FIG. 4 is a perspective view of a second embodiment of a transparent dressing according to the present invention;

FIGS. 5a-5b are top views of a third embodiment and fourth embodiment of a transparent dressing according to the present invention;

FIGS. 6a-6b are perspective views of the fifth embodiment of FIG. 5a in use;

FIG. 7 is a perspective view of a sixth embodiment of the transparent dressing of the present invention;

FIG. 8 is a top view of a seventh embodiment of the transparent dressing of the present invention; and

FIGS. 9a-9b are respectively perspective views of the first embodiment in use and the seventh embodiment in use.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As referred to herein, the inner surfaces of various component parts of the preferred embodiments of the present invention are those surfaces oriented towards the object to which the dressing is adhered. Similarly, the outer surfaces of the various component parts of the preferred embodiments are those surfaces oriented away from such an object. Such an object may be any kind that is used for transparent dressings but will most likely be a patient's skin, their clothing, hair, or the like.

Referring now to the figures, wherein like parts are represented by like reference numerals, FIGS. 1-3 illustrate a first embodiment of the present invention designated by reference numeral 10. In the first embodiment, a transparent dressing 10 is shown. This embodiment is particularly suited for use in covering the wound of a medical patient. The transparent dressing 10 is designed such that it includes a centrally located opening 12. A frame surrounds the opening 12 creating a window at the center of the dressing 10.

The frame is preferably formed from a stretchable adhesive electrode foam material. Suitable materials for the frame include the adhesive foam marketed under the federal trademark "MACROLYTE" by the Conmed Company or marketed under the trademarked name, "MICROFOAM" by the 3-M Corporation. The advantages of such materials is that they are sufficiently flexible to be comfortably worn by the patient and sufficiently rigid to retain the shape of the dressing when it is not adhered to the patient's skin. Thus, the frame insures that the dressing will not fold upon itself during application or not retain its shape when packaged. Moreover, the foam material is substantially water-resistant, thus providing a barrier to contamination by bacteria or liquids.

While the shape of frame 14 is shown as being rectangular in FIGS. 1 through 3, it can be formed into any desired configuration. It is to be noted that by incorporating different shapes and sizes, the dressing can more effectively accommodate different parts of the body. Thus, different shapes would necessarily be contemplated by the present invention to cover elbows, knees, fingers, bony prominences or different objects such as tubes or the like. For example, it is contemplated that the frame can be substantially oval, triangular or formed into a fanciful design such as a star, fish or heart. Other shapes of the present invention are illustrated in the remaining figures.

Returning now to FIG. 1, the opening 12 is enclosed along the bottom side by a transparent membrane 18. The membrane is adhered to frame 14 in such a manner that it cannot easily separate during use.

The material of the membrane 18 is preferably a hypo-allergenic non-adhesive flexible plastic that allows vapor and gasses to escape through the material in one direction but blocks contaminants and moisture from coming into the material in a second direction. It is preferred that the material for membrane 18 is either "TEGADERM™" marketed by the 3-M Corporation or "BIOCLUSIVE™" marketed by the Johnson & Johnson Company. However, any other material having similar characteristics as described above can be employed.

The frame 14 is coated on its bottom surface with a medical grade adhesive, preferably a hypo-allergenic synthetic acrylic pressure sensitive adhesive. The adhesive is used to secure the membrane 18 to the frame 14 as well as to secure the frame 14 to the patient's skin. The acrylic adhesive is of sufficient tackiness to seal the wound from liquids or air seepage that may occur between the base of frame 14 and the

patient's skin. The adhesive thus serves in combination with the frame to create a water tight barrier between the interior of the dressing and the exterior environment. However, the adhesive is sufficiently weak that the dressing 10 can be removed with a minimum of resistance.

FIG. 2 shows a cut-away view of a cross-section of dressing 10 taken along reference lines II-II of FIG. 1. The membrane 18 is substantially smaller in width than the width of frame 14. When frame 14 is adhered to the membrane 18 by means of adhesive layer 15, those portions of frame 14 that extend beyond the membrane serve as an adhesive border that is used to adhere the dressing 10 to the patient's skin. Although adhesive layer 15 is shown covering the entire bottom surface of frame 14, different types of adhesives can be used on different portions of frame 14. For example, a stronger adhesive can be employed to adhere the membrane 18 to the frame portion 14 while a weaker adhesive can be used along the adhesive border.

In a preferred embodiment, a liner 16 extends substantially across the adhesive border of frame 14 and the entire bottom surface of membrane 18. As shown, the liner 16 adheres against the membrane as a result of the tacky adhesive surface 15. By employing liner 16, the membrane 18 is protected and the adhesive surface 15 remains unexposed. In use, the liner 16 is peeled off of the frame 14 exposing the tacky adhesive surface for contact with a patient's skin. The materials of the liner can consist of any conventionally used paper or plastic liner.

FIG. 3 is a bottom view of the first embodiment illustrated in FIG. 1. More particularly, FIG. 3 shows the relationship between the membrane 18 and the frame 14. The perimeter 17 of the frame 14 is of such dimension that it is substantially wider and longer than the perimeter 19 of the membrane 18. The difference in perimeters defines a border area 13 formed around

the membrane 18. As the adhesive material 15 covers the surface area of border 13, the border provides a complete adhesive frame around the non-adhesive bottom surface of the membrane 18. The wound area, which is primarily covered by the membrane 18, will thereby not contact adhesive surface 15.

Referring now to FIG. 4, a second embodiment 100 consisting of a circular dressing, is shown. The dressing according to the second preferred embodiment of the invention is generally similar in construction to the first embodiment described in conjunction with FIGS. 1-4. One major difference between the first and the second embodiments, however, is flap 120 for covering the transparent opening 121.

The dressing 100 includes a frame 114 composed of a medical grade foam that is similar to that described for use with the first preferred embodiment. The base 114 is coated with a medical grade adhesive (not shown) along its bottom surface in order to adhere a transparent membrane to the frame and the frame to the patient's skin. The adhesive, in turn, can secure a circularly shaped membrane material 118 such that it surrounds and covers the opening 121. The circumference 119 of the membrane 118 is less than the circumference of frame 114. Thus, a border referenced by radial arrow 113 is defined by the differences in size of these two elements. As previously discussed, the tacky adhesive surface (not shown) on the border of frame 14 is employed to adhere the circular dressing 100 to the skin.

The dressing further includes a flap 120 which is formed integrally with the frame 114. As shown, the flap is configured to substantially fit within opening 121 to cover the surface of transparent membrane 118. In order to open the flap, it is folded back towards the frame along fold line 122.

Although the flap 120 is shown to be configured to fit within opening 121, alternate shapes and constructions can be used. For example, flap 120 can be shaped to extend beyond the edge of opening 121 (not shown). The advantage of this latter design is that a person can readily grip the edge of flap 120 extending beyond the opening 121. The material of the flap can also be modified so as to allow air/vapor passage out to the exterior of the dressing. Such materials can include, but not be limited to an opaque "TEGADERM" sheet having the same characteristics as membrane 18. Alternatively, the flap can be made of the same material as that of the frame 114 but can further include a plurality of air holes to allow air passage into and out of opening 121.

FIGS. 5a, 5b, 6a and 6b each illustrate tracheostomy tube holder embodiments 200 and 250 yielding many of the afore-described advantages described above in FIGS. 1-4.

The tracheostomy tube holder 200 shown in FIG. 5a includes a frame 214 formed from similar material to that described with reference to the first and second embodiments. The frame substantially surrounds an opening 221. As previously described, the opening is then covered by a transparent membrane portion 218 formed of a similar transparent material described above. Located at the center of the membrane 218 is a central tube hole 225 and a tube hole collar 229. The material of collar 229 is the same stretchable medical foam that forms frame 214. The collar 229 is attached to both the inner and outer surfaces of the membrane 218. Only the outer surface with upper collar 229 is shown. In addition, an adhesive layer is coated on the upper collar 229 and the lower collar below membrane 218 in order that the collars adhere both to the skin around the tracheostomy tube and to the cuff of the tube itself. A slit 227 extends through frame 214, membrane 218, and collar 229 to the tube hole 225.

The slit enables the tracheostomy tube dressing 200 to sufficiently accommodate insertion of the tube into hole 225 and inside the collar 229. In addition to tracheostomy tubes, the dressing of FIG. 5a is adaptable for use as a stoma or fisula dressing.

A pair of tracheostomy tube ties 230, 231 are mounted on the sides 215, 217 of the frame 214 in a manner that they are generally oriented perpendicular to the longitudinal axis of the slit 227. Each tie is made of a flexible material that is adapted to substantially retain its shape under tension. Each tie respectively includes a first end 232, 233 having an inner surface that is coated with an adhesive layer (not shown). An outer surface of each first end consists of a loop fabric pad 234, 235, which is attached to the flexible material in any conventional manner. Each tie 230, 231 further includes a respective second end 236, 237, having a hook material also adhered to the tie 230, 231. The size and orientation of the tie material is designed to allow the tie to loop around a tracheal tube collar (see FIGS. 6a, 6b) in order that each second end 236, 237 of each tie respectively loops around the collar and mates with each respective first end 234, 235. The provision of ties 230, 231 enables a tracheostomy tube to be firmly held in place without placing any stress on a patient's neck or exposing the trachea wound to potential contaminants.

FIG. 5b illustrates a fourth embodiment of the present invention. As shown, an oval tracheostomy tube holder 250 includes a foam frame 264 formed of a similar material to that described above. The frame defines an opening 221 which is substantially covered by a vapor and gas permeable transparent membrane 268. An upper collar 279 made of a tacky foam material, in turn, surrounds the tube hole 275 centrally located in membrane 268. Moreover, a slit 277 is formed extending radially

from tube hole 275 to the edge of frame 264. A pair of tracheostomy tube ties 280 and 281 are mounted on frame 264, as described above, such that ends 282, 283 are adapted to loop around a tube and respectively mate with ends 284, 285.

FIGS. 6a and 6b illustrate the fifth embodiment 200 in use. The tracheostomy tube holder 200 is adhered to a user's skin 202 by means of an adhesive layer 204 located on the inner surface of frame 214. A tracheostomy tube 290 is secured at its cuff (not shown) by a collar 292. The collar 292 includes slots 294 and 296 located at respective ends of the collar adjacent frame sides 215 and 217. The tracheostomy tube ties 230, 231 are adhered to sides 215 and 217 by an adhesive layer 238 and 239 located underneath each first end 234, 235 of each of the ties 230, 231. The ties 230, 231 are then looped through slots 294 and 296 in order that their respective second ends 236, 237 can fold back over the collar 292 and mate with respective first ends 232, 233.

A slit 227 opens the tube holder 200 to accommodate the curve of the patient's neck. The tube is held firmly to the dressing 200 by means of the adhesive collar 229 such that the skin around the tracheostomy tube is both visible and substantially covered by the membrane 218.

FIG. 6b shows the clamp 200 mounted on a patient's skin 202. The tube collar 292 is securely tied onto the frame 214 by means of ties 230, 231 in the manner described above.

FIG. 7 illustrates a sixth embodiment 300 of the transparent dressing suitable for special application over raised portions of a patient's body. The frame 314 is formed of a substantially similar stretchable foam material to that described above. However, the frame includes a pair of finger portions 330 located at opposed ends such that the overall "H" shaped

frame is formed. The arrangement of membrane 318, opening 312 and adhesive border 320 are identical to that described in the first through fourth embodiments of the present invention.

FIG. 8 illustrates a seventh embodiment of the present invention 400. As shown, the construction of dressing 400 is identical to the first embodiment (FIG. 1) except for slit 410 along one side of frame 408. The dressing of FIG. 8 is useful for securing any tube or line that must enter a sterile field under the membrane 418. The dressing 400 is of particular importance for Hickman catheters, jugular intra-venous lines, central intra-venous catheter dressings and gastrostomy tube dressings.

The slit 410 is incorporated into the frame 408 in order to prevent contaminants from entering the wound site. This is accomplished by using the slit 410 as the channel through which a tube 69 is inserted into the dressing as shown in FIG. 9b. When the tube 69 is placed in the slit, the slit closes along the sides of the tube, sealing the area around the tube 69 from contaminant/moisture seepage into the puncture site. Thus, the use of the slit avoids the drawback of having the dressing 10 lift up as shown in FIG. 9a around the edges of the tube 69. By keeping the wound site sterile, the infection potential about the wound is substantially decreased.

The dressings shown in the various embodiments of the present invention also have the advantage of maintaining an effective barrier to allow for the insertion of various medications and salves, without spillage. Such materials can be contained close to the wound while the dressing and its foam frame enables a patient to shower or even submerge the dressing without affecting such medications.

The dressing as described in the preferred embodiments is shown in use in a hospital setting. Although, as already pointed out, the dressing may be used in other settings both medical, and non-medical, for holding articles to objects or for securing and sealing objects. For example, one such setting is in the electronics industry where transparent sealing devices may be used to secure wires within, around or between equipment. Another application is in shipping for holding labels to boxes, in dentistry for securing tubes to a patient's mouth, or in packaging for containing spoilable goods in a breathable package.

What is new and desired to be protected by letters Patent of the United States is:
WE CLAIM:

1. A transparent dressing for a tracheostomy tube comprising:

a frame having an opening substantially surrounded by said frame;

a transparent non-adhesive membrane positioned below said frame and over said opening wherein a perimeter of said frame substantially surrounds said transparent membrane, said membrane having a central aperture for accommodating said tracheostomy tube through said aperture;

an adhesive layer on a bottom surface of said frame such that said membrane is secured to a portion of said frame and said frame portion that extends beyond said membrane forms an adhesive border such that said transparent dressing is adhered to a patient's skin by said adhesive border; and

a pair of ties each having a first end attached to said frame and a second end adapted to attach said tracheostomy tube extending through said central aperture to said frame.

2. The transparent dressing according to claim 1, wherein said frame is formed of a semi-rigid foam material.

3. The transparent dressing according to claim 2, wherein said transparent membrane consists of an air permeable flexible material such that said transparent dressing allows visual observation of such wound.

4. The transparent dressing according to claim 2, further comprising a liner located below said membrane and attached to said adhesive border such that said liner is adapted to be peeled off of said adhesive border, exposing said adhesive border for contact with such patient's skin.

5. The transparent dressing according to claim 4, wherein said liner consists of a paper material.

6. The transparent dressing according to claim 1, wherein said frame and said transparent membrane are substantially rectangular.

7. The transparent dressing according to claim 1, wherein said frame, and said transparent membrane and opening are substantially circular.

8. The transparent dressing according to claim 1, wherein said central aperture contacts a slit that extends from one edge of said central aperture to an edge of said transparent dressing such that said central aperture can hold said tracheostomy tube to such skin while accommodating curvatures in a patient's neck and still prevent contaminants or liquid from entering a wound site.

9. The transparent dressing according to claim 8, further comprising semi-rigid flexible collar surrounding said tube hole and located on an outer and inner surface of said transparent membrane.

10. The transparent dressing according to claim 9, wherein said collars have respective adhesive surfaces enabling said collars to be adhered to said inner and outer surfaces of said transparent membrane, to a patient's skin and to said tracheostomy tube.

11. The transparent dressing according to claim 10, wherein said first end of each of said ties includes a loop material and said second end of each of said ties includes a hook material whereby a respective second end is adapted to mate with a respective first end of each of said ties.

12. The transparent dressing according to claim 11, wherein each of said second ends is adapted to loop through a slit located on a collar of said tracheostomy tube and back toward said respective first end of each of said tie thus firmly securing said tracheostomy tube to said transparent dressing.

13. A dressing for a tube, comprising:

a frame member surrounding a window;

a transparent membrane attached to said frame member, and covering said window and having a tube opening for accommodating a tracheostomy tube;

an adhesive border formed on said frame around the perimeter of said transparent membrane such that when adhered to a patient's skin, a chosen area of such skin shows through said membrane covered window opening; and

a pair of ties attached to said frame member wherein each of said ties is adapted to secure said tube to said frame thereby holding said tube in place in said tube opening.

14. The dressing according to claim 13, wherein said frame member incorporates a slit extending from said tube opening to an end of said frame member to prevent lifting up of said

dressing when said tube is inserted into said dressing and to insure said dressing is sealed around said tube such that contaminants and fluids are prevented from entering said dressing.

15. A dressing for covering a patient's skin comprising:

an outer skin contacting layer having an opening substantially surrounded by said outer layer

a pliable transparent inner skin contacting membrane positioned throughout said opening wherein a perimeter of said outer layer substantially surrounds said membrane; and

an adhesive layer on a bottom surface of said outer layer such that said membrane is secured to a portion of said outer layer and said perimeter of said outer layer forms an adhesive perimeter in order that said dressing is adhered to such patient's skin only at said adhesive perimeter.

16. The dressing according to claim 15, wherein said outer layer is formed of a semi-rigid foam material.

17. The dressing according to claim 16, wherein said transparent membrane consists of an air permeable pliable material such that said dressing allows visual observation of such patient's skin.

18. The dressing according to claim 17, further comprising a liner located below said membrane and attached to said adhesive perimeter, exposing said adhesive perimeter for contact with such patient's skin.

19. The transparent dressing according to claim 18, wherein said flap has a plurality of airholes such that air passes through said flap and through said membrane.

20. The dressing according to claim 19, wherein said outer layer, said membrane and said opening are rectangular.

21. The dressing according to claim 20, wherein said outer layer, said membrane and said opening are circular.

22. The dressing according to claim 21, wherein said outer layer further comprises a pair of finger portions, each pair extending from opposed ends of said outer layer such that said outer layer forms a substantially "H" shaped dressing.

23. A dressing for a patient's skin, comprising:

an outer layer surrounding a window opening;

a pliable transparent inner skin contacting layer attached to said outer layer and extending throughout said window opening; and

an adhesive border formed on said outer layer around the perimeter of said inner layer such that when adhered to such patient's skin a chosen area of skin shows through said window opening.

24. A method for applying a dressing comprising a pliable transparent membrane attached at its perimeter to a semi-rigid adhesive border having a liner secured to said adhesive border, comprising the steps of:

removing said liner from said adhesive border in order to expose a tacky adhesive surface;

centering said transparent membrane over a wound such that said window contacts such wound; and

applying said dressing to such wound in order that said tacky adhesive surface substantially contacts skin surrounding such wound rendering such wound entirely visible through said transparent membrane as well as isolated from contact with said semi-rigid adhesive border.

25. A dressing for covering a patient's skin, comprising:

an adhesive frame having an opening substantially surrounded by said adhesive frame; and

a pliable transparent non-adhesive skin contacting membrane attached to said frame and extending throughout said opening where a portion of said adhesive frame extends beyond said membrane and forms an adhesive border to substantially adhere said transparent dressing to such skin at said adhesive border.

26. The dressing according to claim 25, wherein said adhesive frame is formed of a semi-rigid foam material.

27. The dressing according to claim 26, wherein said adhesive frame consists of a single piece of material.

28. The dressing according to claim 27, wherein said adhesive frame substantially retains the shape of said dressing when packaged.

29. The dressing according to claim 28, wherein said transparent membrane consists of an air permeable pliable material such that said dressing allows visual observation of a patient's wound.

30. The dressing according to claim 29, wherein said transparent membrane is hypo-allergenic allowing the passage of vapor and gases through said transparent membrane in one direction and blocking contaminants and moisture coming into said transparent membrane in a second direction.

31. The dressing according to claim 30, further comprising a liner located on a skin contacting surface of said transparent membrane and attached to said adhesive border such that said liner is adapted to be peeled off of said adhesive border, exposing said adhesive border and transparent membrane to a patient's skin.

32. The dressing according to claim 31, wherein said liner consists of a paper material.

33. The dressing according to claim 32, wherein said adhesive frame is coated with a hypo-allergenic synthetic acrylic pressure sensitive adhesive of sufficient tackiness to seal a wound from liquid and/or air seepage into said dressing.

34. The dressing according to claim 33, wherein a first adhesive is employed to adhere said transparent membrane to said adhesive frame and a second adhesive is employed to adhere said transparent dressing to such patient's skin.

35. A transparent dressing for covering a patient's wound, comprising:

a frame having an opening substantially surrounded by said frame;

a transparent non-adhesive skin contacting membrane positioned below said frame and throughout said opening wherein

a perimeter of said frame substantially surrounds said transparent membrane;

an adhesive layer on a skin contacting surface of said frame such that said membrane is secured to a portion of said frame and said frame portion that extends beyond said membrane forms an adhesive border enabling said transparent dressing to be adhered to a patient's skin at said adhesive border; and

a flap for substantially covering said opening.

36. The dressing according to claim 35, wherein said flap is formed integrally with said frame.

37. The dressing according to claim 36, wherein said flap is made of a substantially air permeable material.

38. The dressing according to claim 37, wherein said flap has a plurality of air holes such that gas passes through said flap.

39. The dressing according to claim 38, wherein the perimeter of said flap is larger than the perimeter of said opening.

FIG. 2

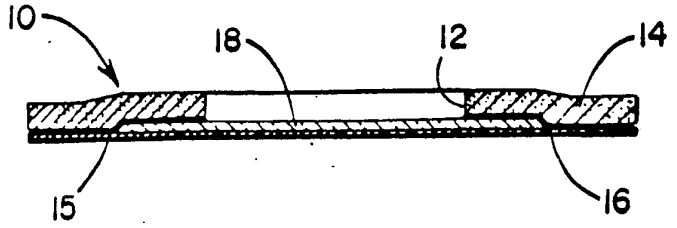


FIG. 1

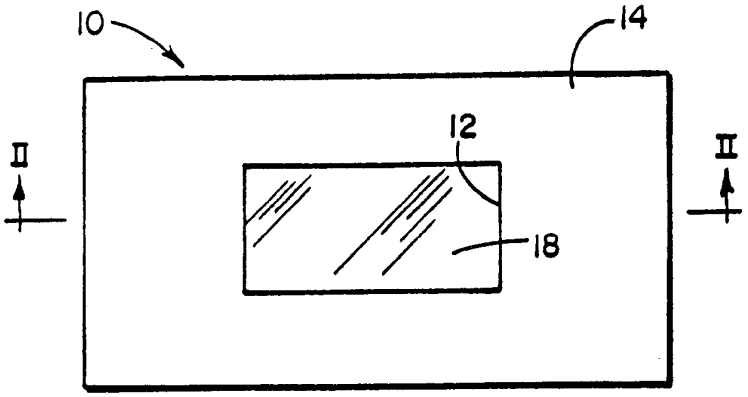


FIG. 3

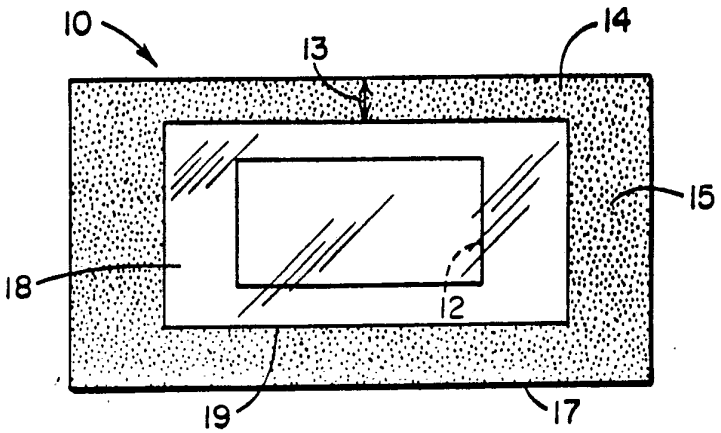


FIG. 4

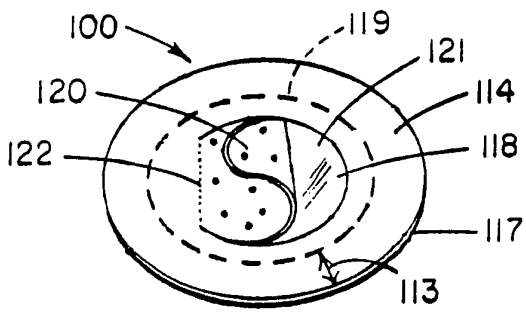


FIG. 5a

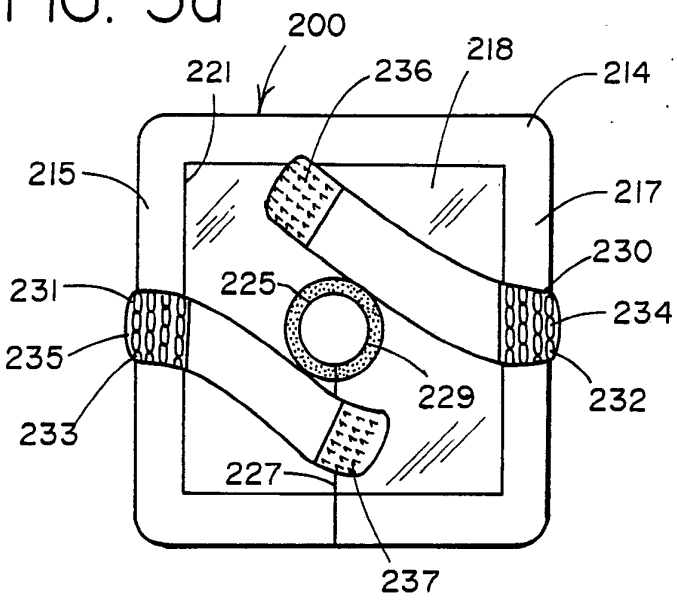


FIG. 5b

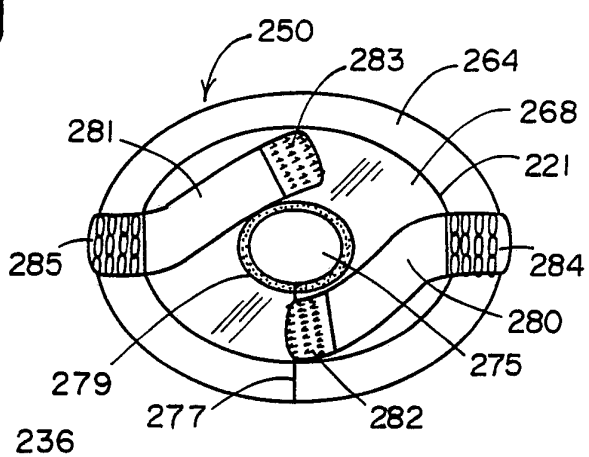


FIG. 6a

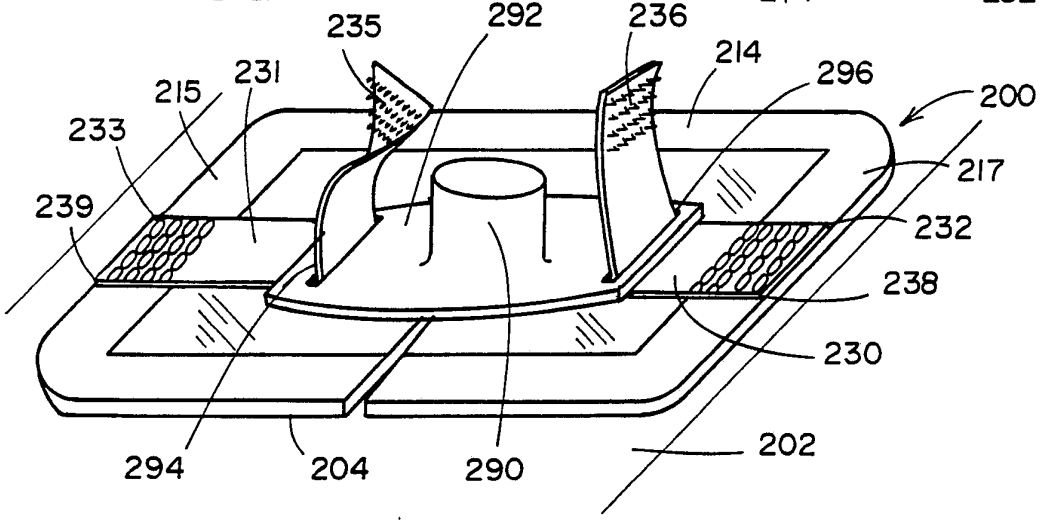


FIG. 6b

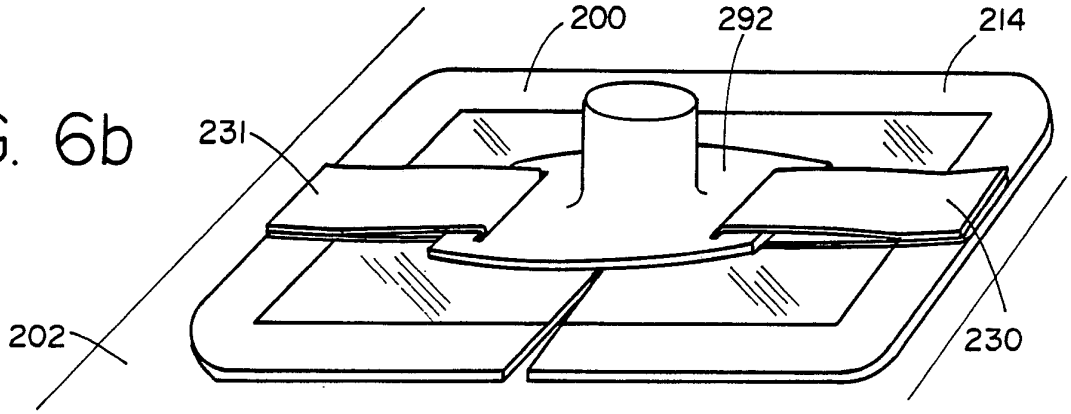


FIG. 7

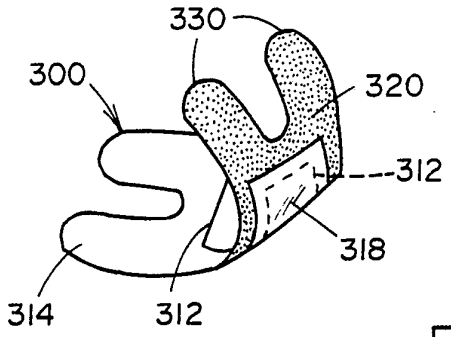


FIG. 8

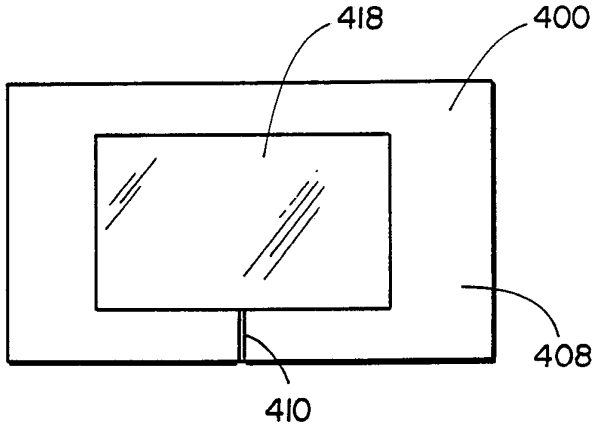


FIG. 9a

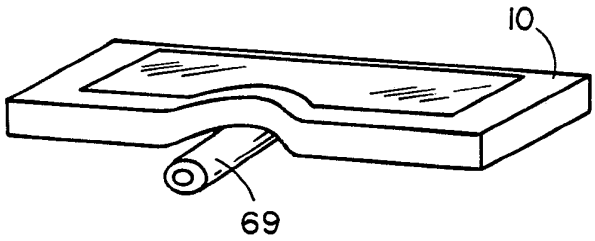
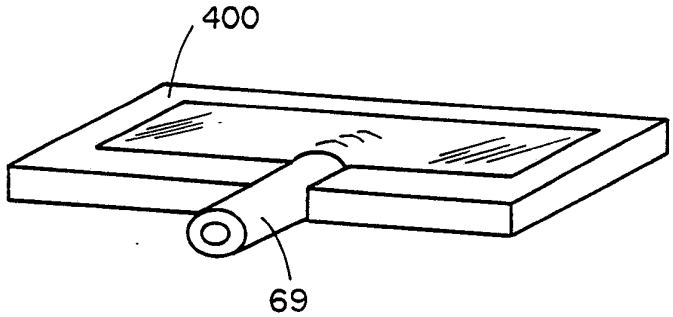


FIG. 9b



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US89/05506

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5) A61F 13/00
U.S. CL 604/179

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	604/174,177-180,305,307,308,332,338,344 128/207.14,207.17,887,888,Dig 26

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X Y	US,A 2,221,758 (ELMQUIST) 19 NOVEMBER 1940 See line 45, column 1-line 47, column 2	15,16,23,25-28 21
X Y	US,A 2,273,873 (KLEIN) 24 FEBRUARY 1942 See line 20, column 3-line 67, column 4	15-20, 23-39 21,22
A	US,A 3,713,448 (ARROTT) 30 JANUARY 1973 See abstract	1-4
A	US,A 4,331,144 (WAPNER) 25 MAY 1982 See abstract	1-14
X Y	US,A 4,485,809 (DELLAS) 04 DECEMBER 1984 See column 2, line 22-column 4, line 38	15-20, 23-39 21,22
X Y	US,A 4,678,462 (VAILLANCOURT) 07 JULY 1987 See column 4, line 48-column 9, line 33	15-20, 23-39 21,22
A,P	US,A 4,838,878 (KALT ET AL) 13 JUNE 1989 See Figure 32	1-14
X Y	TEGADERM Transparent Dressing Brochure 70-2008-2385-7 (873) BPH, 3M Medical Surgical Division, ST.Paul, Min 1984	15-20, 23-39 21,22

* Special categories of cited documents: [10]

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"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

"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

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
13 FEBRUARY 1990	22MAR 1990
International Searching Authority	**Signature of Authorized Officer**
ISA/US	RALPH LEWIS

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

I. Claims 1-14, A Tube Securing Device

II. Claims 15-39, A Surgical Bandage

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.