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P. CREAGER, JR., ET AL  
PROTECTOR FOR INCISED WOUNDS

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Fig. 1

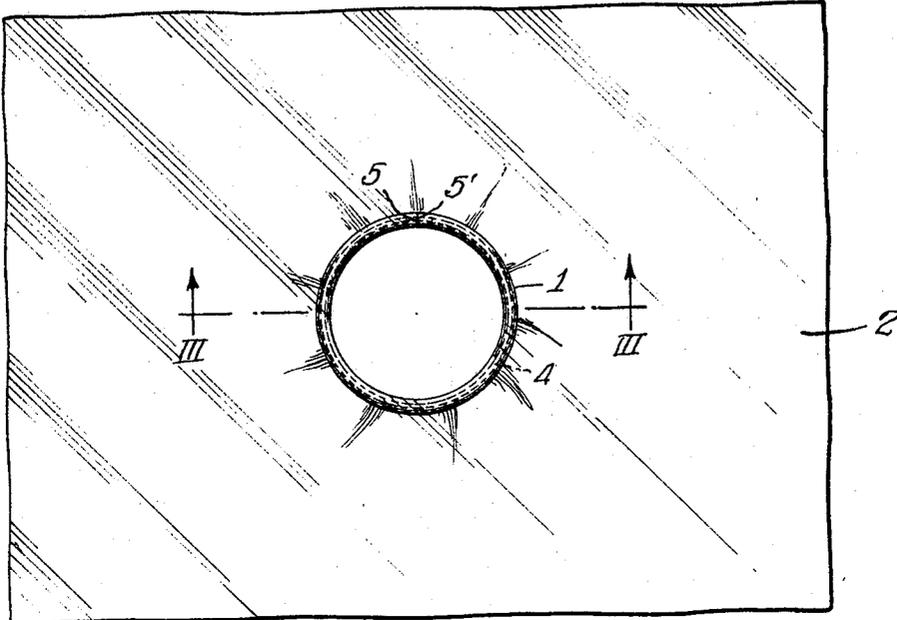


Fig. 2

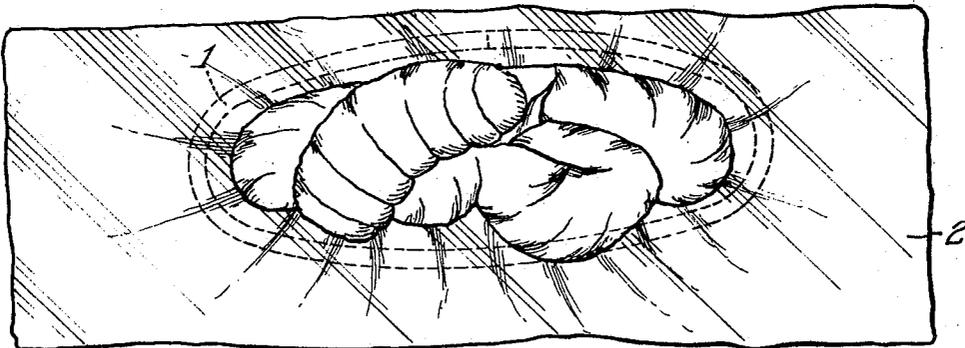


Fig. 3

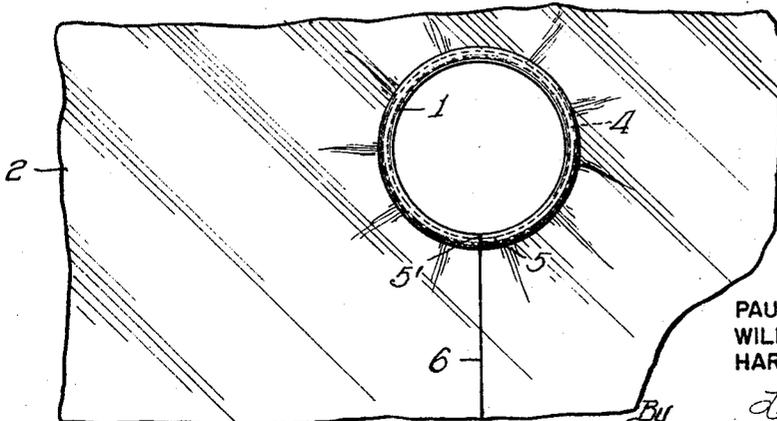
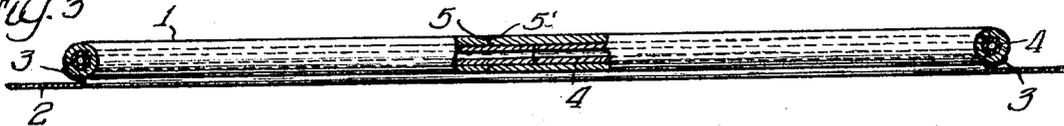


Fig. 4

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3,397,692

**PROTECTOR FOR INCISED WOUNDS,**

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The present invention relates to devices useful in sur-  
gery to protect the edges of incised wound from con-  
tamination.

It has been proposed to avoid contamination in surgical  
procedures by covering the body with a sterile plastic  
drape or other coating, and making the incision through  
such coating as described in Patent 3,146,884 issued to  
Pereny et al. However, such devices do not protect the  
edge of the incised wound from possible contamination  
from sources within the body cavity or externally thereof.

Frequently, the incision in an abdominal operation is  
relatively small, and sometimes the incision must be en-  
larged as the operation proceeds. It is necessary that a  
wound edge protector in such use be easily applied and  
removed, should not injure the tissue, and should be use-  
able for a variety of sizes of incisions. Further, the pro-  
tector should not hinder spreading the wound or interfere  
with other operative procedures, and it should be readily  
removable.

According to the present invention, there is provided  
a wound edge protector comprising an anchor member,  
preferably in the form of a resilient, self sustaining rod  
or rods of any desired cross section shape, to the running  
edge of which is suitably attached a thin plastic mem-  
brane serving as a drape. Preferably the membrane is a  
flat sheet with a centrally located aperture therein serv-  
ing as a hand hole that corresponds generally to the size  
of the anchor member, and the member is attached adja-  
cent the edge of such aperture to the anchor member.  
In use the anchor member is threaded through the inci-  
sion into the body cavity, where it underlies the peritoneum  
and spreads and anchors the protective membrane secured  
thereto. The protective membrane extends from the an-  
chor member and protrudes externally through the incision  
and the protruding portion can be spread out or draped  
over the body of the patient. Thus, the edge of the inci-  
sion is kept covered and protected by the membrane.

The anchor member may be in the form of an annulus  
and should be sufficiently resilient and self-sustaining so  
that after being collapsed for threading through the inci-  
sion it will expand substantially to circular shape when  
released. However, it should not be so stiff as to prevent  
its ready collapse by squeezing it by hand. For example,  
an anchor ring which can be flattened to a narrow ellipse  
by not substantially more than about two pounds pres-  
sure is satisfactory. An alternative form of anchor mem-  
ber comprises two or more rods attached to the edge of  
the aperture of the membrane and longer than the inci-  
sion. When inserted in the incision they underlie the peri-  
toneum, and the spreader used in conventional procedure  
keeps the membrane against the wound edge. Or the flat  
rods may be joined at their ends to form an oval or tri-  
angle or other polygon shape.

The anchor member may be a preformed ring, or it  
may be made from a straight rod bent into a circle and

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having its ends releasably or permanently held together.  
For example, the anchor member is conveniently made  
from plastic tubing with the ends united by a dowel which  
is secured against removal in only one end of the tube,  
or in both ends as desired. The dowel may also be a tube,  
as in general, tubing is commercially available. If only  
one end of the dowel is secured, the ring can be opened  
by sliding the loose or receiving end of the tube off of  
the dowel.

The membrane can be of rectangular shape or of any  
other suitable shape at its outer periphery, and its size may  
vary from about sixteen radial inches upward. If desired,  
the membrane may be in the form of a planar frusto-  
conical development so that when rolled into the form  
of a wide angle (nearly flat) cone there is a suitable size  
opening at the small end to receive the anchor member.  
Where the membrane attached at its opening to the anchor  
ring is continuous, it is preferable to make the anchor in  
permanent ring form. However, in some instances it is  
advantageous to cut the protective membrane generally  
radially from the opening to its outer periphery; in such  
case it is preferred to employ an anchor ring which is  
capable of being opened. An example of a ring capable  
of being opened is one made of tubing with its ends con-  
nected by a dowel that is secured in only one end of  
tubing as above described. The opening of the ring may  
be substantially in alignment with the cut of the mem-  
brane. Using such a device, the anchor ring can be re-  
duced in periphery by cutting away part of the receiving  
end of the tube as desired. Preferably the ring only and  
not the sheet is cut in this way so when the ends of the  
anchor ring are reunited by the dowel there is an over-  
lap of the cut edges of the sheet. It is preferred however,  
to place the receiving end of the anchor out of alignment  
with the corresponding cut edge of the sheet so that nor-  
mally, when the anchor ring is closed the edges of the  
membrane overlap. In such modification, by cutting away  
part of the receiving end of the anchor member it forms  
a ring of reduced diameter and the overlap of the edges of  
the membrane is increased. Such modifications therefore  
can be adjusted, if desired, to smaller incisions by cutting  
away the anchor ring as above described.

It will be understood that the device of this invention  
will be sterile at the time of use. The device can be ster-  
ilized just prior to use or can be sterilized and packed in  
a sterile sealed package which keeps the device sterile  
until the package is opened. The material used for mak-  
ing the anchor member and membrane accordingly will  
be chosen to serve the purpose herein described and so  
that it can be sterilized by the desired sterilizing treatment.  
Examples of suitable membrane material includes poly-  
vinyl chloride, polyvinylidene chloride, polyethylene, poly-  
propylene, polyethylene terephthalate, or copolymers, such  
as 80 to 90 percent by weight vinyl chloride with 20 to 10  
percent by weight of another material such as vinyl acetate  
or vinylidene chloride. Transparency of the diaphragm  
material is preferred but is not essential. The diaphragm  
material need not have great strength but should not be  
so fragile as to tear in use.

When the device includes a flat membrane, the mem-  
brane is wrinkled and folded to some extent where it  
passes over the cut faces or edges of the incision. This  
is not a material disadvantage as the membrane preferably  
is thin enough and pliable enough to wrinkle and fold

in this manner without creating undesired bulkiness. Or a membrane may be employed that is easily stretched so that it will conform to the incision edge with less wrinkling. The wrinkling can be reduced by the use of a membrane of wide angle frusto-conical shape attached to the anchor member at the smaller diameter portion of the cone. In using such membrane it should form a very wide angle cone so that the part overlying the patient's body is practically flat, and if desired, it may be made from flat sheet as a cone development.

An important advantage in this construction of wound protector is that it adequately covers and protects all surfaces of the wound adjacent the body cavity, including the terminal corners of the wound, yet the anchor is beyond the periphery of the incision and cannot interfere with the operating procedure. The portion of the membrane overlying the body on the outside may be large enough to serve as a drape, and in any event, its periphery is far enough removed from the wound edge so that it cannot get in the way during the operating procedure and cannot become accidentally entangled with or caught by an operating instrument as it is being passed over the body. The membrane can be rectangular, square, circular or any other desired shaped. If desired, a molded or formed membrane may be employed, but this may increase substantially the cost of manufacture.

It is preferred to construct the anchor member of standard diameter polyvinylchloride tubing and construct the membrane of polyvinylchloride sheeting. Such materials can be sterilized by heating and have properties which are desirable for this invention. The desired pliability is obtained by using sheeting for example, about two mils thick, and tubing for example, of about  $\frac{3}{16}$  inch diameter. The membrane is conveniently attached at its opening to the anchor member by heat welding or by cement, and the like. Or, if desired, the opening in the membrane may be hemmed to provide a casing into which the anchor rod is loosely inserted.

The invention is described in greater detail in connection with the accompanying drawings wherein are illustrated preferred embodiments of the invention by way of example, and wherein:

FIGURE 1 shows an embodiment of the invention spread out flat,

FIGURE 2 is a top perspective view showing the invention in operative position in a patient for operative procedure the peripheral part of the membrane being broken away,

FIGURE 3 is an enlarged cross sectional view taken on line III—III of FIGURE 1 with parts broken away, and

FIGURE 4 shows a plan view of a modification similar to FIGURE 1.

Referring to the drawing, the wound edge protector includes an anchor member in the form of an annulus 1 and a membrane 2 having a central aperture therein. The edge 3 (FIG. 3) of the membrane at the aperture is suitably attached to the anchor member, as by cement. In the preferred construction the anchor member comprises a hollow cylindrical rod bent into an annulus and held in such form by a dowel 4 which fits into the hollow of the rod and overlaps the ends 5, 5' of the rod. Preferably the dowel is the same length as the rod so as to completely fill the hollow core. This construction simplifies the manufacture and assembly of the anchor member.

The use of the protector is illustrated in FIGURE 2 in connection with an abdominal incision. Before making the incision the patient may be covered by a drape as described in the Pereny et al. Patent 3,146,884, and the incision made through the drape, and accordingly, the cut edges of the abdominal wall are not covered or protected by the drape. To apply the wound protector the annulus 1 is held in generally horizontal position so as to allow the membrane to drape naturally downwardly, and one hand is inserted beneath the draping membrane to

grasp the anchor ring and compress it to a narrow oval shape. The ring is now inverted while still being compressed, and is threaded through the incision into the abdominal cavity. In the cavity the anchor expands by its inherent resilience so as to underlie the cut edge of the peritoneum, and thus anchors the membrane. The part of the membrane protruding outward from the incision is draped or spread out flat over the patient. The membrane wrinkles as required to pass through the incision, and thus completely covers and protects the cut edge or faces of the incision within the abdominal cavity as well as at the skin surface. The membrane does not interfere with the use of retractors, which now can be applied to the incision, or with the operative procedure. Because the membrane lies substantially flat and its edges are remote from the wound, there is little likelihood that the membrane can become tangled with the instruments used, or interfere with the operative procedure.

When the operative procedure is finished the surgeon can reach into the cavity, grasp and compress the annulus into oval shape, and thread it through the incision to remove it. The wound edges then can be reunited in the usual manner, as by sewing.

The embodiment described can be used unchanged for a variety of sizes of incisions because the anchor ring expands in the abdominal cavity away from the edges of the incision. The size of the membrane is large enough to allow for the gathering in the abdominal cavity and to adequately cover the area adjacent the incision on the exterior of the patient. For example, the annulus may be made in three standard sizes of five, nine and eleven inches in diameter, and the membrane may be about 36 inches by 36 inches.

The embodiment shown in FIGURE 4 is useful in some situations. In this embodiment the membrane is severed generally radially at 6 from the anchor to the outer edge of the membrane. The cut 6 preferably is made adjacent the juncture of the rod ends 5, 5'. This allows the dowel 4 to be withdrawn from one end of the rod. A portion of the end of the rod and the dowel therein can be cut off and the dowel projecting from the other end is inserted to make a smaller annulus that allows the edges at cut 6 to overlap. The cut edges also in some cases make it easier to smoothly drape the membrane over the patient.

If desired the protector can be used without reuniting the ends of the rod, but allowing the rod to expand to a generally C-shaped or a spiral form within the abdominal cavity, in which case provision is made to prevent excessive spreading thereof, or damage to the viscera from the ends.

In a further modification the membrane may be in the form of a wide angle cone frustum with the annulus at the smaller edge of the cone.

The invention can be sterilized and packaged within a suitable sterile sealed envelope or other external covering, from which it can be removed at the time it is to be used. Sterilization can be effected by treatment with steam, ethylene oxide, or by treatment with any other suitable medium or by any other suitable method.

Various modifications of the invention may be made without departing of the spirit thereof.

We claim:

1. A wound edge protector for use in surgical procedures comprising: a thin drape membrane of pliable material for covering a patient's body, and having a generally central hand opening therein, and anchor means attached adjacent the membrane edge of the opening said anchor means comprising a resilient rod formed into an annulus, the anchor means being generally capable of being compressed under restraint and expandable when released so that when inserted through an incision the anchor means underlies the incision edges and anchors the drape internally around the incision to cover the wound surface.

2. A wound edge protector as specified in claim 1 wherein the ends of the rod are united by a dowel.

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3. A wound edge protector as specified in claim 1 wherein the drape membrane is divided substantially radially from the anchor means to the outer edge.

4. A wound edge protector as specified in claim 1 wherein the ends of said annulus are removably united by a dowel.

5. A wound edge protector as specified in claim 1 wherein the drape membrane is in the form of a cone of relatively wide angle.

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