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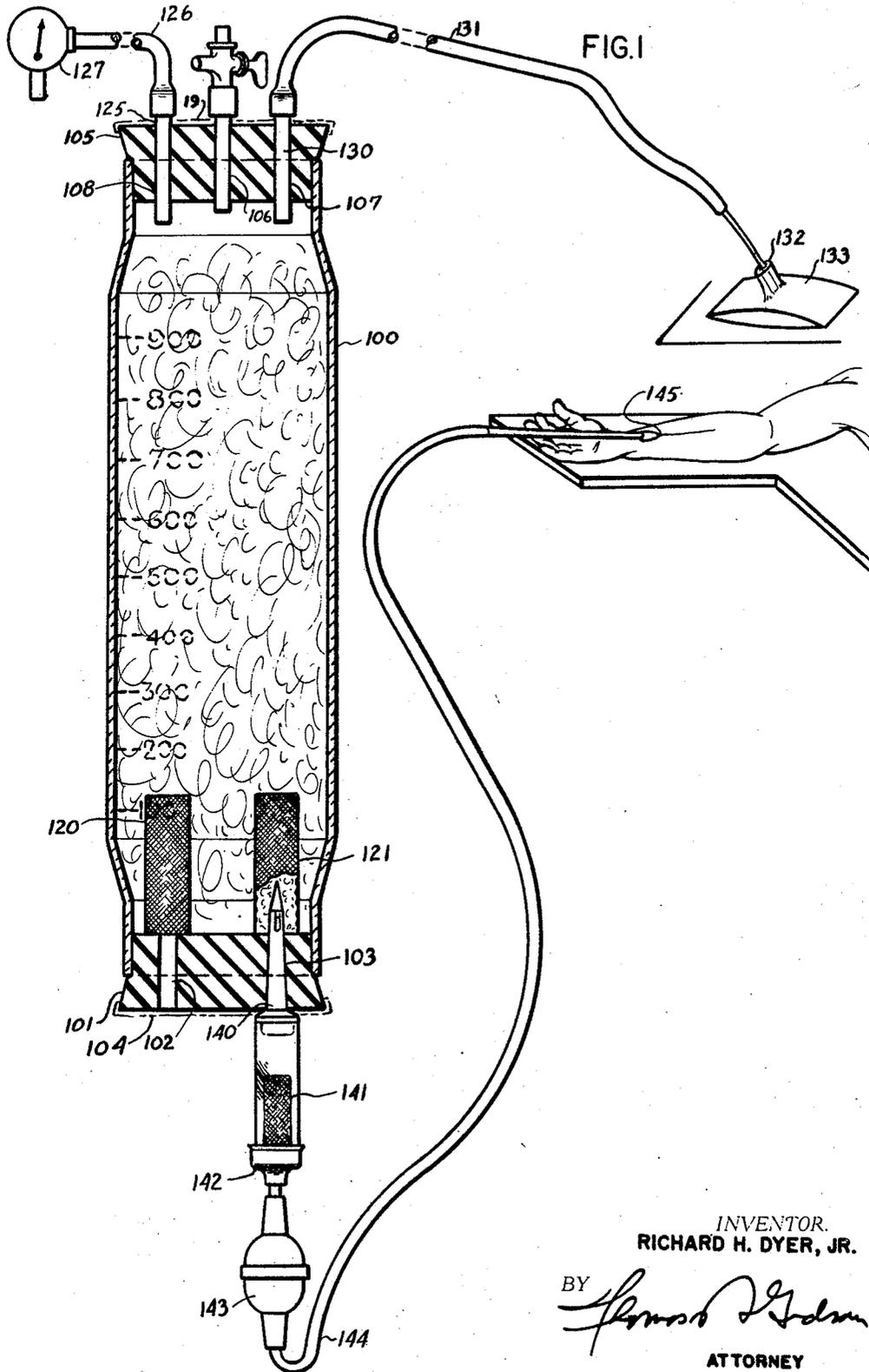
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3,492,991

AUTOTRANSFUSION APPARATUS

Filed Feb. 23, 1967

2 Sheets-Sheet 1



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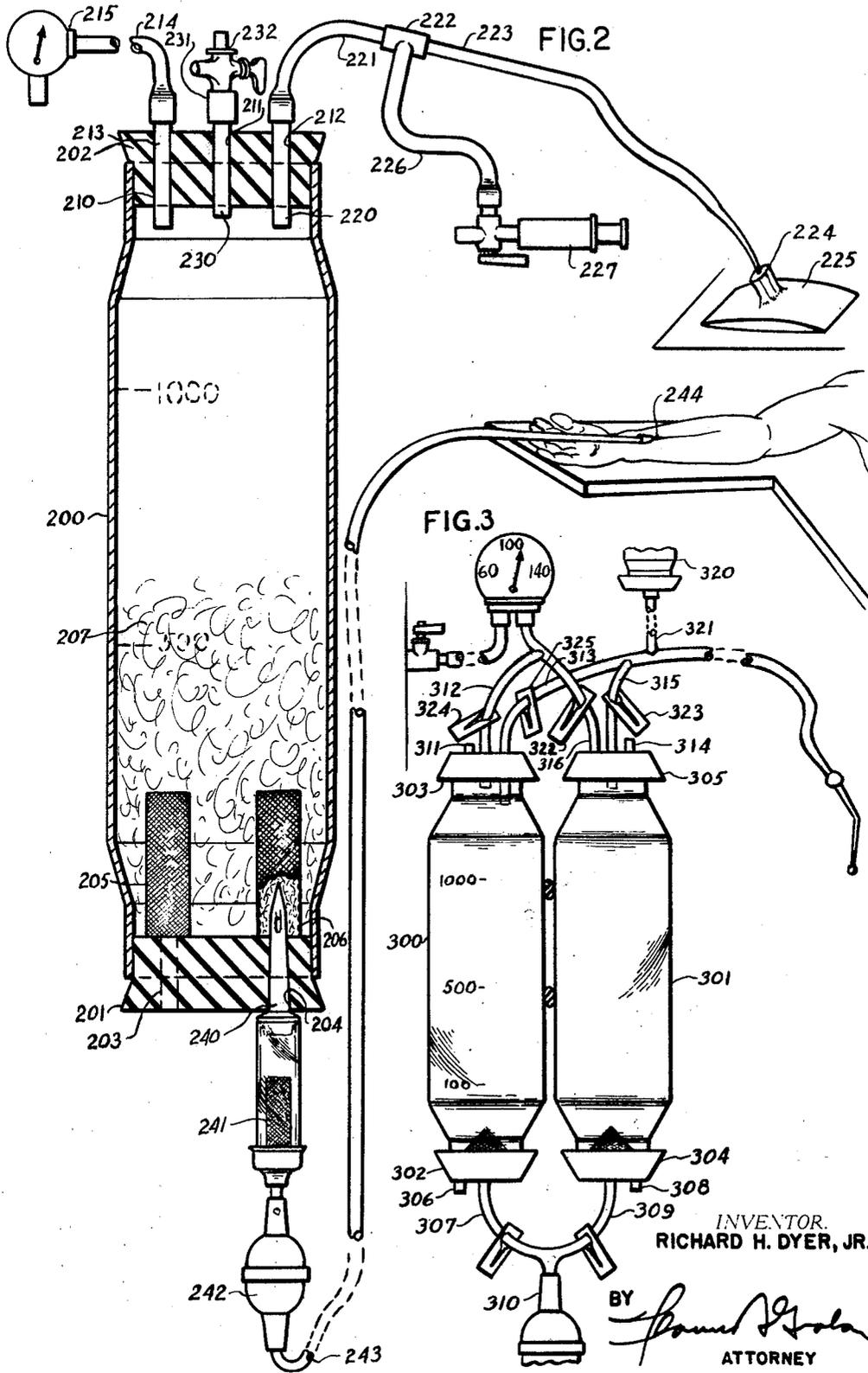
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AUTOTRANSFUSION APPARATUS

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2 Claims

ABSTRACT OF THE DISCLOSURE

The device embodying the invention consists of container equipped with blood defoaming and filtering means, the container being closed and connected by tubing to a pump which serves as a source of motive power, the vessel also being connected by tubing and catheter to the field from which the blood comes, which tubing is also connected to means for injecting anti-coagulants into the blood, and taking the blood to the container where it is defoamed. The container also is equipped with a filter through which the blood will pass to remove all particulate matter, such as clots, fibrin as well as particles of fat. The exit from the container is a conventional gravity type feed for transfusion connected through an intravenous catheter and/or needle for re-transfusion (Autotransfusion) into a vein of the subject.

This invention is concerned with a method and device for collecting, defoaming, anti-coagulating, defatting, filtering and reinfusing blood in large and small volumes during surgery, or during emergencies, from the thoracic and abdominal cavities and extra peritoneal spaces and the like of living mammals. (See American Journal of Surgery, 112, December 1966.)

OBJECTS

This process and method of intraoperative autotransfusion is intended to provide an immediately available supply of whole blood which, being an autotype, requires no costly time consuming procurement, typing, or cross matching. It is also to provide blood for patients with rare blood types or allergic blood sensitivities, for those patients for whom very limited donor blood would be available by modern means of laboratory testing in vitro. Also certain religious sects (Jehovah's Witnesses) will allow this immediate autotransfusion, but would not accept donor transfusion, or delayed autotransfusion.

The time consumed from collection to redelivery of salvaged blood can be less than 2 minutes, and the volume of returned blood may exceed 1000 cc. per minute, depending upon the needs at the time of hemorrhage, as determined by the surgeon and anesthesiologist.

Utilization of intraoperative autotransfusion does not preclude or prevent the use of donor indirect transfusion when necessary, or the many methods of fluid therapy designed to support the hypovolemic patient.

It is an object of the invention to provide a simple, uncomplicated self-contained apparatus for making blood transfusions of an autotype during elective surgery or on an emergency basis in which there is considerable hemorrhage after an accident at the scene. The apparatus has particular value in war time, for battlefield use, and in hospitals serving highway accidents or high crime rate areas.

It is another object of the invention to provide an apparatus, self-contained, having a sterile, closed, flow system suitable for picking up blood at a surgical field or wound cavity, whether the wound be surgical or an accidental one, conducting blood through the closed system to a container, treating it with anti-coagulant, defoaming material, filtering it, defatting and passing it to a trans-

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fusion apparatus for reinfusion to a patient. The vacuum means is provided to cause flow through the system.

The prevention of fat re-infusion is provided for by

(a) The coarse and fine filters to be described

(b) The fat adsorbant properties of silicone and silicized plastics

(c) The lipolytic effects of small amounts of aqueous heparin anti-coagulant

(d) The elongated cylinder design which allows the lighter weight fat globules, when present to coalesce and float on the surface of the blood level in the chamber. The final 100 milliliters of salvaged blood is not infused from the chamber

(e) The final filter of the blood recipient set.

DETAILED DESCRIPTION OF THE INVENTION

The invention consists of a blood autotransfusion apparatus which is characterized by its uncomplicated nature, its safety, economy, effectiveness and ease of use in collecting, defoaming, anti-coagulating, defatting, filtering and reinfusing blood in large and small volumes into a patient, human or animal. Intraoperative autotransfusion is applied to pooled blood or active bleeding resulting from severe accident or other hemorrhage into thoracic and abdominal cavities and other extraperitoneal spaces preceding or during surgery. The apparatus, in one embodiment, consists of a single or paired transparent calibrated cylinder of appropriate size, preferably 1/2 to 1.2 liter glass or plastic, the cylinder being closed at both ends by rubber or plastic seals to form a calibrated container. The upper plug is provided with a minimum of 3 ports, each of the ports having an outside diaphragm which remains intact until the container is to be entered for use in an autotransfusion operation. One of the ports is used to apply vacuum to the container by way of a sterilized, flexible polyethylene or plastic tube or catheter and stylette. The second port accepts a similar stylette and flexible tube or catheter, as an inflow route from the operative field or source of blood and contains an inline side valve to deliver sterile anti-coagulant medication such as 50 cc. of 2% to 4% citrate USP or aqueous heparin solution USP to salvaged whole blood. The third port is closed to complete the chamber vacuum except to deliver blood from the chamber in which case it is opened to release the vacuum. The inline side valve may also deliver antibiotics such as Aqueous Penicillin, or Kamamycin if desired. The variation in the connections to the top ports is arranged to introduce medicine into the line through which the blood comes, and for this to provide a clamp, a valve or petcock control on the third opening to allow quick adjustment of pressure within the cylinder. The third opening can also be used for auxiliary pumping which applies positive pressure to increase rate of blood re-infusion. The bottom plug carries two blood exit ports, similarly provided with protective outer diaphragms. These outlets are for the retransfusion of processed blood by conventional gravity drip means via standard blood administration set pump back into the patient.

To prevent foaming of the blood, the inner surface of the glass or plastic container is coated with silicone antifoaming agent (Dow Corning Antifoam "A"). It may also be filled or partially filled with a coarse metal or plastic wool, for example, steel wool, which is surface treated with silicone (Dow Corning) to reduce foaming. Fine 200 U (micra) metal wire screen of stainless steel or Monel metal or other conventional, surgical metal or fine plastic weave is placed over each of the exit ports to act as a final chamber filter to prevent the possibility of introducing into a patient some bit of fibrin or other debris not otherwise separated by the metal wool.

A third filter is provided in blood recipient apparatus connected to the outflow.

The structure and operation of the device will be better understood by reference to the drawings accompanying the description, wherein:

FIGURE 1 is a diagrammatic section through an apparatus made in accordance with the invention, showing the basic relationship of the parts;

FIGURE 2 is a similar diagrammatic section showing the relationship of the parts and an alternative connection to the vacuum and medication portions; and

FIGURE 3 is a diagrammatic representation of an apparatus built in accordance with the invention employing a dual blood receiving container, so that one side can be available for a reservoir, for processing of the blood, while the other side performs transfusion duty of collected and treated whole blood. The pump and medication connections to the two chambers are such that they permit connection to a single container at a time, at the will of the surgeon or anesthesiologist.

Referring now to FIGURE 1, 100 represent a cylinder, which commonly would be made of clear Pyrex glass or other transparent material suitable for sterilization and have a capacity of the order of ½ liter to 1½ liters to 2 liters. Its walls should be such that internally a vacuum approximating half an atmosphere can be drawn. The cylinder is closed at both ends by means of plugs 101 and 105, which may be finished in any manner desired to provide a good air-tight liquid-tight closure for the system to be subjected to the pressures anticipated. They must, of course, be heat sterilizable.

Closure 101 is provided with two apertures 102 and 103, which conventionally, when the container is in condition prepared for use, will be protected by external diaphragms as indicated at 104. Similarly, plug 105 is provided with apertures 106, 107 and 108, which likewise, in periods of non-use, will be covered by external, protective rubber diaphragms as indicated at 19. The entire apparatus may be wrapped and sterilized in a plastic container for storage until use.

For operative use, the cylinder is provided internally with fine mesh filters over the outlet ports, the filters being identified as 120 and 121. These are generally formed of stainless steel or plastic and are of a fineness to catch small blood clots, i.e., with a 100 to 300 U fineness. Polytetrafluoroethylene plastics (Teflon) would be suitable; the only requirement is that the filter be fine enough to remove any residual debris in the blood and that it contribute nothing of a chemical nature to contaminate the blood. Essentially, this latter is a requirement of all parts of the apparatus, namely, that they be inert enough that no material from the apparatus be transferred chemically or physiochemically from the apparatus to the blood. (The apparatus is designed to conform to established EDA requirements.)

The outlet port openings 102, 103, and 106, 107, 108 will generally be of the order of 3-6 millimeters in diameter.

At the other end of the cylinder, connection through stylette 125 and tube 126 is made to vacuum source 127. The vacuum source may be an ordinary laboratory supply such as is universally available in an operating room or surgery, which frequently is operated by water pump and, hence, can draw a controlled vacuum of the order of 20-200 millimeters of mercury. A small vacuum pump is also suitable. In the device, which is also suitable for emergency field use, a hand aspirator of conventional rubber bulb type can be used. The requirement is that a vacuum strong enough to reduce the pressure in the cylinder 100 sufficiently to cause blood to flow in through stylette 130, tube 131 and through pickup stylette 132 from an operating field suction tip 133 be available. In most cases, 20-140 millimeters of mercury will be adequate, depending on the volume of blood to be salvaged at any time during surgery.

As inspection of the diagram will show, this is the closed blood flow system suitable for the practice of the invention and, it will be seen, that the field 133 can be the wound, peritoneal or thoracic cavity of the patient and, by drawing a vacuum at 127, blood is lifted from the patient through tube 131, filtered, defoamed, defatted and deoagulated in the chamber and re-transfused by gravity drip in conventional style. Thus it is transfused through stylette 140, filter 141, catheter 142, cylinder 143, tube 144 and stylette 145.

In making the apparatus some what more refined for use and to provide for the introduction of medication into the blood being transfused, and also to provide for better pressure control within the container itself, the apparatus consists as shown in FIGURE 2 of the cylinder 200, equipped with plugs 201 and 202. The structure of the cylinder is essentially the same as shown in FIGURE 1. Herein the bottom is provided with a pair of orifice outlets 203 and 204, covered by the metal blood filters 205 and 206, the cavity of the container containing the siliconized steel wool 207. The other stopper is equipped with orifices 210, 211, 212, through which provision is made by way of stylette 213, tube 214, for connection to a valve 215 and associated community vacuum service in a hospital. The advantage of this arrangement is in the fact that the line will usually carry its pressure indicator (or an indicator can be inserted in the live vacuum to monitor the vacuum). Connection to the operating field is made by stylette 220 through tube 221, T 222 and tube 223 to stylette 224 at field 225. Though the branch of the T connection is made through tube 226 to injection cylinder 227 which may be of any conventional form suitable for introducing medication, or other solution, or anti-coagulant solution, into the blood stream, flowing it through the T and into the cylinder 200.

Pressure control is provided by introducing stylette 230 through the stopper, through tube 231, carrying petcock 232 so that as the operator desires, air pressure can be regulated by the petcock to maintain the total net pressure in the vessel itself at an indicated safe operating level as shown by gauge.

Rapid blood delivery is accomplished by the standard types of blood administration equipment labeled 143 in FIGURE 1, 242 in FIGURE 2, and 310 in FIGURE 3.

Here, the operation is as indicated: by applying appropriate vacuum to the container 200, blood is drawn from the field 225 through the stylette 224, its associate tubing and into the container 200, where it is filtered through the steel wool, defoamed, defatted and mixed with anti-coagulant and/or antibiotic added through cylinder 227 and line 226. A good mixture is attained and final filtering accomplished at screens 206 or 205 and, the processed blood is introduced within minutes into the patient through stylette 240, cylinder 241, container 242-tube 243 and stylette 244 which is the point of intravenous autotransfusion into a subject.

Referring now to FIGURE 3, the apparatus there shown employs a dual blood container and, therefore, a dual tubing system connecting the two sides of the chamber to the vacuum line, the blood suction line and the medication line. For convenience, surgical clamps or any conventional clamping means may be used for closing one line or the other, so that they can be used in alternation. A 3-way petcock could be substituted here, provided that the internal orifices are 3 to 6 millimeters internal diameter. The design and process of the dual cylinders is based directly on the preceding simple chamber designs. The advantages of the dual chambers are: (1) Absolute control of blood volume collected and re-infused. (2) Absolute control of anti-coagulant diluent used. (3) Independent collection and re-infusion operation.

Specifically, the apparatus consists of the two calibrated cylinders in parallel, 300 and 301, equipped with end plugs 302, 303, 304 and 305. The connections to

the tubes are as described in connection with FIGURES 1 and 2, namely, outlets 306 and 307, 308, and 309, from the tubes 300 and 301, respectively, joined in infusion tube 310 for application to the patient.

At the other end of the apparatus, outlets 311, 312 and 313 together with outlets 314, 315 and 316 provide the three connections, respectively, for blood inflow vacuum control, each of these connections feeding to an appropriate T paralleling it, so that 312 and 316 constitute the two vacuum connections, 311 and 314 constitute the two pressure connections and 313 and 315 constitute the two blood infusion connections. Medication (e.g. anti-coagulant, preservative or antibiotic) is provided from the cylinder 320 feeding through tube 321 to the dual connection for taking blood from the field of operation. Clamps 322, 323, 324, 325 permit alternate use of the containers. The clamps may be pinchcocks; surgical clamps; or best, the simple slide clamp wherein the tubing is threaded through an opening large enough to take it and pinched by sliding it into a slot. (Abbot, U.S. Patent 2,503,327.)

It is important in arranging the tubing, the T connections and clamps, to avoid pockets in the system wherein blood can stagnate and possibly form clots. All connections should be 3 to 6 millimeters in internal diameter, and with smooth "rounded" bends to minimize blood trauma and stasis of flow.

It will be apparent that the arrangement of the two identical reservoirs in parallel makes possible the independent use of one chamber or the other by clamping off the appropriate blood line from one or the other, thereby causing all the activity to take place through one tube. In this fashion, the second tube can be used as a reservoir in which the blood is processed before reinfusion. Accurate measurement of volume infused is thus possible.

As materials of construction for the apparatus, glass is indicated for the containers in which blood is collected and plastic flexible tubing for the lines. Similarly, polyethylene, polypropylene and polytetrafluoroethylene tubing may be used for the catheter connections; vinyl plastic will also be suitable. The entire apparatus can be made of transparent non-breakable plastic and, in such case, it is necessary merely to have the container of somewhat strong, heavy, semi-rigid plastic, that is, 3-4 millimeters thick, sufficient to resist significant collapse under the application of vacuum to the container. Where the device is fabricated of such plastic, it is suitable for field use and can actually be discarded after a single use. Obviously, it is sterile prior to use. It is made of a material which can be stored for periods of time up to 1 or more years, as in a sealed envelope, and be impervious to climate variables of temperature. In the field use, pumping or vacuum may be applied to the blood continuously by means of a hand aspirator.

USE OF THE APPARATUS AND APPLICATION OF THE METHOD

Purpose.—The apparatus and method are of course intended to conserve and re-use vital blood lost by intra-operative or emergency hemorrhage by sterile collection and reinfusion during surgery.

Primary indications.—When hemorrhage has occurred, or there is active bleeding into a serious body cavity, intra-operative autotransfusion by this method may be used. It should be considered on a planned basis as in vascular reconstructive surgery, and electively when rare blood type or limited donor blood is available. It may be indicated for use in any major vascular catastrophe, especially in the face of uncontrolled loss from traumatic, obstetrical or operative technical hemorrhage. Because of their religious beliefs, it is the only completely acceptable type of blood transfusion that Jehovahs Witnesses will receive.

It is not intended as the only source of blood replace-

ment, e.g. some bank blood may also be needed; rather, at this stage, intro-operative autotransfusion is intended primarily as an adjunctive measure.

Primary contra-indications.—The method should not be used to reinfuse blood which is known to have remained in a serous body cavity for three (3) or more days. It should not be used in the presence of gross bile or fecal contamination when compatible donor blood is available. However, the reinfusion of such blood, though undesirable, may be life-saving when there is no available alternative source and exsanguination is imminent. It is not to be employed in the presence of known carcinoma near the operative field.

THE APPARATUS

It should be available, autoclaved and wrapped ready for use, as described herein.

Anticoagulant solution.—Citrate solution 2% to 4% USP should be available in ample amount in 0.5 liter bottles (Upjohn Company pharmaceuticals). Heparinized saline (20 milligrams e.g. 2,000 Upjohn units per 50 to 100 milliliters normal saline). Use one volume anti-coagulant to four volumes hemorrhage. If the patient is systematically heparinized, a more dilute or smaller amount ($\frac{1}{2}$ approximately) of anti-coagulant solution will be satisfactory. The physiological effects of protamine do not appear to be significantly altered. Mixing of the anti-coagulant solution with the hemorrhage is important. It may be easily accomplished by (1) systemic heparinization or (2) direct contact in body cavity (regional anti-coagulation), or (3) by agitation of the auto-transfusion chamber (chamber anti-coagulation).

To set up apparatus for the method

- (1) Unwrap and suspend the autotransfusion unit from a pole.
- (2) Connect suction in series through vacuum control valve to vacuum intake at top of autotransfusion set.
- (3) Attach surgeon's suction tip via sterile vivosol (included with set) or rubber tube to adjacent suction intake, also at top of set.
- (4) Place three-way stop cock (or clamp) on remaining top intake. (This will serve later as a decompression valve to release chamber vacuum for rapid or gravity autotransfusion.)
- (5) Connect conventional blood administration infusion pump set (or sets) to outflow at bottom of the autotransfusion set. Clamp the unused outlets.
- (6) Interplace "Y" tube in surgeon's suction per diagram FIGURE 3.

To prime pump and use

- (1) Adjust vacuum within chamber by occluding all outlets, stop cock and surgeon's suction. The control vacuum indicator should be adjusted to about 120 mm. Hg.
- (2) Immerse the surgeon's suction tip in normal saline, to test all connections are secured. Then lift approximately 25 to 50 milliliters of saline.
- (3) With the system set at suction, blood can then be lifted from the field at will.
- (4) The chosen anti-coagulant, preservative or antibiotic may be introduced via surgeon's suction tube "Y" tube insert.
- (5) Occasional clearing of surgeon's suction tube of blood by dipping tip in normal saline of measured anti-coagulant solution will prevent clotting in the tube.
- (6) Frequent gentle agitation of the chambers will adequately mix the salvaged blood with the anti-coagulant, antibiotic and/or preservatives.

To administer blood

- (1) The technique and equipment of blood reinfusion (autotransfusion) is identical to conventional methods.

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(2) When a volume of blood has been collected (for example 300 to 500 milliliters) fill the administration pump set and transfuse.

(3) In the single chambered apparatus, more rapid infusion will be accomplished by opening the stop cock on top of the autotransfusion chamber, or by decreasing the vacuum to allow outflow.

(4) When transfusing do not administer the final 100 milliliters from chamber.

(5) Simultaneous collection and autotransfusion is accomplished without difficulty in the dual chambers by changing the clamps and valves as previously described.

(6) If the outlet(s) become clogged there probably was inadequate mixing of blood and anti-coagulant. Excess debris may be on filter screen. This may often be freed by agitation of chamber.

(7) If the blood administration pump does not fill turn off vacuum and agitate chamber.

What is claimed is:

1. In a blood suction apparatus, the combination of

(1) a source of vacuum capable of being maintained at a substantially steady level

(2) a receivers for blood connected to said source of vacuum

(3) a suction tip for immersion in a pool of blood and tube connection from said suction tip to said receivers for blood

(4) said receivers for said blood being capable of carrying a substantial volume thereof

(5) said receivers for said blood being internally treated to defoam the blood and also housing a filter therein and

(6) outlets from said receivers so that the blood before passing out of the receivers, must pass through said filter

(7) means between the suction tip and the receivers for introducing medication into the blood suction

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tube as blood is drawn into the receivers, said means comprising a branch in said blood suction tube and a tube connecting said branch to a source of medication,

(8) and means for introducing blood from said receivers into a patient, wherein said medication and blood tubes feed to a single tube, a branch from said single tube passing to each of two receivers, each of said tubular branches carrying a clamp making it capable of being closed off, vacuum connection to each of said two receivers, each of said receivers being equipped with pressure release and regulating means, each of said receivers containing siliconized steel wool for defoaming blood, each of said receivers having outlets therefrom equipped with filter for said blood, the outlets from these receivers supplying blood to an infusion means for introduction into a patient.

2. The apparatus in accordance with claim 2 wherein clamp means is provided for employing one receiver at a time in the branched tubes.

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U.S. Cl. X.R.

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