This invention relates to a novel and useful means for the medical injection of fluids directly from fluid filled ampules of special construction. It is especially adaptable to certain high pressure procedures such as angioraphy and heart catheterization. It is also adaptable to most routine low-pressure procedures.

It teaches the principle of factory packaging of such fluid containing ampules under laboratory controlled sterile environment, and their further containment within a hermetically sealed plastic envelope to prevent contamination prior to use. Such a method of packaging provides simple means for temperature adjustment of the injectable fluid just prior to use; this may be accomplished by placement of the hermetically sealed container in a temperature controlled water-bath or other such means without danger of contamination.

The fluid containing ampule and its component parts are constructed of moulded non-toxic, non-pyrogenic, and pliable plastic or other suitable material. The shape of such an ampule and its component parts is such that when its attached flat leader component is introduced between the revolving faces of two parallel and proximal pressure rollers forward linear travel will be assured which, if continued, will pull the attached fluid filled ampule component between such rotating pressure rollers and thereby cause a progressive collapse of its fluid filled central cavity with a resultant pressure discharge of its fluid contents through an attached tube component and its attached surgical needle or surgical catheter. It is obvious that injection pressure at the surgically selected site will be in direct proportion to the rotational speed of the pressure rollers.

Any electrical, mechanical, or manual means to cause rotation of the pressure rollers, in combination with such a constructed fluid filled ampule assembly must be considered the basic concept of this invention.

A wide variety of high-pressure injection apparatus has been offered in the past, all of which employ the same means to contain the injectable fluid and permit its pressure injection. The injectable fluid is introduced into a special high-pressure plunger type syringe, to be placed within the power inject mechanism so that when high pressure is applied to the plunger of such a syringe, pressure discharge of its fluid contents will result. Pressure means employed include manual lever, mechanical spring, motor driven linear actuator, hydraulic pressure, air pressure, and carbon dioxide pressure. Generally, placement and removal of the fluid filled syringe is time consuming, and presents the problem of possible contamination. Most such mechanisms provide means to adjust pressure discharge. Generally they provide for auxiliary control operations such as X-ray exposure start and EKG signal injection switches. They also provide for injection fluid temperature regulation by means of a thermostatically controlled heater surrounding the syringe component.

From the foregoing description of my invention and a review of the present state of the art, it should be apparent to anyone versed in the art that my invention is both novel and useful for a wide variety of medical injections.

These, and other features of my invention, will be more clearly understood from the following detailed description and the accompanying drawings, in which like characters designate corresponding parts in all figures, and in which:

FIGURE 1 is a side view of the ampule assembly shown in partial cut-out section of its central fluid filled component, and the attached exit tube component, and its attached flat leader component shown in section.

FIGURE 2 is an end view of the central fluid filled ampule component showing the flat leader ampule component attached.

FIGURE 3 is a top view showing the central fluid filled ampule component passing between two rotating pressure rollers, and indicating a progressive collapse of its central fluid cavity, with fluid discharge from an attached surgical needle or surgical catheter.

FIGURE 4 is a side view in partial cut-out section showing a power driven mechanism for providing pressure roller rotation, with the ampule assembly shown in position between such rollers. It shows the micro-switch control module being actuated by the flat leader ampule component.

FIGURE 5 is an end view of the removable pressure rollers, indicating their ribbed cylindrical surface and attachment means to their drive shaft.

FIGURE 6 is an end view of the removable ampule guide clip showing attachment means to the top of mechanism housing.

FIGURE 7 is a top view of the removable micro-switch module assembly, showing the attachment means to the end of mechanism housing.

These figures, and the following detailed description, disclose a preferred and specific embodiment of my invention, but the invention is not limited to the details disclosed since it may be embodied in other equivalent forms.

The preferred and specific embodiment of this invention teaches the principle of the construction of a fluid filled ampule assembly capable of being fed between a set of rotating pressure rollers in such a manner as to cause collapse and discharge of its fluid contents at a variety of discharge pressures. The construction of the fluid filled ampule assembly can be best seen in FIGURES 1 and 2, from which it is seen:

The ampule assembly and its component parts are moulded from non-toxic, non-pyrogenic and pliable plastic or other suitable material. Such an ampule assembly consists of a hollow cylindrical leader component 1, having one end closed by a generally spherical wall surface, having at its central axis an opening into an attached length of hollow tubing 3 terminated on its distal end by a surgical Linden connector 4, and a capping device 5; the opposite end of the generally cylindrical hollow ampule component 1 is to be closed by compression and bonding together of its side walls so as to form a flat leader component of appreciable length 6, whose function shall be to enable initial engagement between the rotating pressure rollers 9. The hollow cavity 2 thus formed within the central ampule component 1 is then filled under laboratory controlled sterile environment with the medically injectable fluid 7, and the ampule assembly sealed by the placement of capping device 5. The whole liquid filled ampule assembly is now hermetically sealed within a sterile plastic envelope 8 to assure against contamination prior to use, and to provide a safe means for pre-injection temperature regulation of the fluid contents of the ampule. The above described ampules are to be provided in a variety of fluid content, and fluid volume as may be required for various procedures.

The basic concept of my invention is best seen from FIGURE 3, from which it may be seen:

The previously described fluid filled ampule assembly has its flat leader component 6 fed between two parallel
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and adjacent pressure rollers 9, which are rotating in opposite directions so as to propel the flat leader ampule component 6 forward in a linear direction which, if continued, will cause the central fluid filled ampule component 1 to pass between the rotating pressure rollers 9, and thereby progressively collapse the walls of fluid filled cavity 2 and cause the pressure discharge of fluid left to flow into the attached hollow tube ampule component 3, and the attached surgical needle 10 or the attached surgical catheter 11, and thence into the surgically selected site. It should be obvious that the injection pressure will be in direct proportion to the rotation speed of the pressure rollers 9.

Means to provide the required rotation of the pressure rollers 9 include a motor driven mechanism and associated control components shown in FIGURES 4 through 7, from which it may be seen:

The driven mechanism is housed in a cabinet 12, having a top component 13; a reversible variable speed electric motor 19 is attached to reduction gear 20, from which is extended two parallel vertical drive shafts 16, geared to rotate in opposite directions. These shafts have sets of pins 17 placed at right angle to their shafts as engagement means for removable pressure rollers 9 which have centrally located slots 18 to engage with pins 17, the cylindrical faces of the pressure rollers 9 are vertically ribbed to provide traction when the flat leader ampule component 6 is placed between their rotating faces. A removable ampule guide 14 having attachment means 15 to the cabinet top 13 is provided to slidably support and properly align the ampule component 1 with the pressure rollers 9. Various relays 21 necessary for control operation are provided, whereby a fixed low-speed rotation is assured in either direction for initial set-up procedure and for removal of the exhausted ampule 1. Such a fixed speed operation is controlled by a reversing switch 25 and a panel push-switch 26; it also provides a variable high-speed rotation for “power inject” which is dial calibrated 22 and set by switch 23, control being by means of a remote hand-push 24. Pilot lights 27 are provided to indicate various control conditions.

In addition to the drive mechanism the apparatus has a removable and interchangeable micro-switch module 25, having means 42 for attaching it to the end of cabinet 12. An actuator bar 30 extending vertically through a slot 29 in the top of the module 25 is arranged so that its extending end is contacted by the advancing proximal end of the flat leader component 6 of the ampule assembly. This actuator bar 30 has a pointer 32 to indicate “injection volume” on a calibrated scale 33. The internally housed end of the actuator bar 30 is slidably attached at its lower end by a bearing block 31 to a horizontal rod 34 and is held in compression toward the start position adjacent to cabinet 12 by a spring 35. The positions of micro-switches 38, 39 and 40 are adjustable by a screw-slot arrangement 36. In the specific embodiment described, it is the function of micro-switch 38 when actuated by the bearing block to terminate fixed low-speed-cut up rotation and to signal pilot-light 27 to indicate a “ready” condition. The subsequent start of “power inject” at dial 23 selected speed is accomplished by closure of the remote hand push-switch 24, which will start the rotation of pressure rollers 9 and thereby cause a progressive collapse of the ampule component 1 with a resultant discharge of liquid contents 7 from the cavity 2 into the attached tubular ampule component 3 and the attached surgical needle 10, or the surgical catheter 11 placed within the surgically selected site. Such injection will continue, and when forward travel of the actuator bar 30 causes actuation of micro-switch 39 the X-ray exploder engaging opposite sides of said said and having just sufficient clearance between them to accommodate only the pliable material of the sack; power means for rotating the rollers in opposite...
directions, said power means being adjustable for various speeds of roller rotation; indicating lights; adjustable switch responsive to the relative position of the sack between rollers for controlling the power means, the illumination of the indicating lights and the initiation of the medical procedure; and a remote switch means for manually controlling the power means.

4. An apparatus for the controlled injection of fluid through an injection device and in connection with a medical procedure comprising, in combination, an ampule having a hollow portion circular in cross section and filled with said fluid and a solid portion rectangular in cross section; two cylindrical rollers positioned on opposite sides of the ampule and with a distance between their cylindrical surfaces which will permit the cylindrical surfaces to securely grip the solid portion of the ampule when it is placed between them; power means for rotating the two cylindrical rollers in opposite directions, said power means being adjustable to permit adjustment of the rotation speed of the rollers; means for removably positioning the ampule with its solid portion between the two cylindrical rollers and which permits sliding motion of the ampule toward the cylindrical rollers; a plurality of switch modules, each having a movable actuator bar extending from it, each being removably positionable so that the extending end of its actuator bar will be engaged and moved by the solid portion of the ampule as the ampule moves between the cylindrical rollers, each having a scale mounted on it with units related to the volume of fluid in a unit length of the hollow portion of the ampule, each having an indicator associated with its actuator bar and whose position along the scale is related to the length of the ampule extending between the actuator bar and the cylindrical rollers, each having a plurality of micro-switches adjustable positioned within it and in locations which will cause said micro-s-switches to be successively activated by motion of the actuator bar, and each differing from other modules in the number of micro-switches within it and in the scale units used; and means for controlling the power means in response to the actuation of the micro-switches in one of the plurality switch modules or in response to other electrical signals.

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