Title: RECHARGEABLE AND RESTERILIZABLE MIXING DEVICE WITH PHYSIOLOGICAL GAS AND SOLUTION TO CREATE FOAM WITH MICROBUBBLES, USED IN ENDOVASCULAR TREATMENTS.

Abstract: This patent application describes a rechargeable, resterilizable, portable, and easy-handling mixer (1) to create foam with microbubbles using physiological gases currently used in sclerotherapeutic treatments of varicose veins. It may be used to create foam for other therapeutic purposes by endovascular means. This reservoir has anatomical and compact dimensions and is built with material resistant to sterilization and pressure, designed to be used in treatments provided in regular medical appointments at clinical or hospital centers.
RECHARGEABLE AND RESTERILIZABLE MIXING DEVICE WITH PHYSIOLOGICAL GAS AND SOLUTION TO CREATE FOAM WITH MICROBUBBLES, USED IN ENDOVASCULAR TREATMENTS.

This patent application refers to a rechargeable, resterilizable, portable, and easy-handling reservoir to create foam with microbubbles using physiological gases; foam currently used in sclerotherapeutic treatments of varicose veins. It may be used also to create foam for other therapeutic purposes by endovascular means.

This reservoir has anatomical and compact dimensions and is elaborated with material resistant to sterilization and pressure, designed to be used in treatments at doctor's offices, clinics or hospital centers.

BACKGROUND OF THE INVENTION

As widely known, the endovascular treatment is carried out inside vessels in order to treat circulatory diseases in blood vessels, arteries, or veins.

Sclerotherapy is the name given to the method that consists of the injection of some product into varicose veins in order to sclerose them.

Today, a liquid widely used in this method is the hypertonic glucose. It is often used separately in a concentration of 75% or lower (50%), with
the addition of another substance to increase its sclerosing capacity.

The foam is applied in this context, that is, in order to increase the sclerosis capacity. It consists of the mixing of a medication, currently Polydocanoli or tetradecil-sulphate, mixed with regular air and then vigorously agitated to form a dense foam that, when injected in the varicose vein, remains in contact with it for a longer period for being denser than the liquid, thereby increasing its sclerosing capacity and enabling the treatment of varicose veins larger than 0.4 cm in diameter.

In current treatments, a liquid or foam is used and referred to as sclerosants, which are injected through needles of several sizes, depending on the size of the vein to be treated. This liquid or foam causes an alteration in the blood vessel wall cells that later causes its occlusion. When the liquid or foam remains in the circulation, it is diluted by the blood and loses its concentration and effect.

The foam used today is produced in a homemade way, using syringes, a three-way key, regular air, and a liquid. This foam contains irregular, large bubbles, which dilute its density and cohesion. Consequently, this homemade foam dilutes more easily inside the blood stream and loses its function, which is to lesion the internal
wall of the varicose vessel. That is, it is less effective when compared with foam with microbubbles.

In order to obtain the microbubbles, a chemical sclerosing foam of good quality has to be prepared with a detergent solution and physiological gases under properly calibrated pressure that, when injected in the vessel, provides better density and higher efficacy in the treatment of larger varices. The use of physiological gases allows physicians to use a higher quantity of foam in each treatment session with higher safety, providing better and quicker results in the proposed treatment. This new technique using foam with microbubbles is less invasive, does not require resting periods, and the patient does not have to interrupt its daily activities as the procedure is not surgical.

Prior Art

Reservoirs or equipments intended to create foam are already known in several areas, such as pesticide reservoirs, fire extinguishers, shaving foam, and others. These containers have different sizes and characteristics that suit each functionality, with different means of recharge or creation of foam.

Today, professionals in the field are aware of the use of "three-way taps" in endovascular treatments to create homemade sclerosing foam adaptable
directly to syringes, where the connection is done and the direction of the flow is controlled with three different lines: two infusion lines in "iter lock" female ends, and a third infusion line or venous access device in its male "luer slip" or "luer lock" connection. It also includes a knob that acts as flow shutter and switch.

Patent application BR 0407003-8, filed on 08/19/2004, describes a foam forming unit comprised of: a mixing chamber (12) that communicates with the output (14) of a pump in order to mix liquid and air, a distribution part (22) equipped with an output flow channel (24) with a foam opening (26) to distribute foam, where the output flow channel has communication with the mixing chamber (12) and the first foam forming element (28) placed in the output flow channel, so that the foam that flows through the output flow channel passes through the foam forming element (28) at least twice, where the distribution part is also equipped with a nozzle element (51) that includes at least a final part of the output flow channel and the foam opening, where the output flow channel includes a cavity (32) after the first passage through the first foam forming element, with this cavity positioned before the nozzle element, as observed in the flow direction.

Patent application BR 0414281-0, filed on 09/09/2004, describes a foam transfer device (600) to be
used with an aerosol containing device to produce sclerosing foam for the treatment of varicose veins, among other things. This device enables the deviation of an initial quantity of foam with the specification below from the container to be dispensed, for instance, into a full dispensing changer before releasing an additional quantity of foam to be used in treatments. The flow switching from the dispensing chamber to a different output (618) for use is done without interruption in the flow from the aerosol container, as this causes the foam to go down under specification again. The dispensing chamber may be transparent, so that the foam entering it can be observed, allowing the user to decide when to stop sending foam to be dispensed. Alternatively, the foam can be deviated automatically, for instance, at the end of a preset time or present volume of foam to be dispensed. The foam is usually released into a syringe for injection into a varicose vein of the patient.

In view of the techniques and devices found in the current state of art, the applicant proposes an unprecedented mixing device used to create sclerosing foam with microbubbles, also introducing advantages and improvements to the deficiencies found in the current techniques and models.

BRIEF DESCRIPTION OF THE FIGURES
For better visualization and understanding of the object intended to be protected by this patent application, the object will be described below with the aid of the attached figures;

Figure 1 illustrates a side view of the mixing device in a first embodiment, as held by the hand of a professional;

Figure 2 illustrates a side view of the mixing device in a second embodiment, as held by the hand of a professional;

Figure 3 shows a top view of the device in its first embodiment, indicating the cross section A-A;

Figure 4 shows the cross sectional view A-A indicated in the previous figure;

Figure 5 shows a cross sectional view of one device in the previous figure being used;

Figure 6 shows an exploded view of the device in its first embodiment, according to the previous figure;

Figure 7 shows a top view of the device in its second embodiment, indicating the cross section B-B;

Figure 8 shows the cross section B-B indicated in one previous figure with the device being used; and
Figure 9 shows an exploded view of the device in its second embodiment, according to the previous figure.

DETAILED DESCRIPTION AND ADVANTAGES OF THE DEVICE

This patent application is explained in details in accordance with the attached figures.

Figure 1 shows an embodiment of the object of this patent application with a front view of the rechargeable, resterilizable mixing device, with physiological solution and gas to create foam with microbubbles used in endovascular treatments. Figure 2 shows a different embodiment from the object shewn in figure 1.

According to figures 3 to 6, the mixing device (1) claimed in this patent application comprises a body (2) with the shape of two inverted cones joined by their bases, a central cylindrical channel (3) and inclined downward channels (4) that intercept the central cylindrical channel (3) at its bottom end (5). The inclined downward channels (4) include a cylindrical recess (6) in its top end to receive the syringe body by coupling.

The mixing device (1) also includes a central valve support (7), a cylindrical base (9), and a head (8) in the shape of a cone. The base (9) of the central support (7) has a sealing ring (10) on the outer
surface and an internal opening (11) inside it, which crosses the central valve support (7) throughout its length. This opening (11) has a cylindrical recess (12) in its bottom end with an upward conical protrusion (13) that reaches half the length of the central support (7). Between the conical protrusion (13) and the cylindrical recess (12) there is a conical recess (14) that includes an inclined through hole (15), which enables the communication between the internal opening (11) with the external cylindrical surface of the central support (7). Above the conical protrusion (13) there is a cylindrical channel (16) that communicates with the head seat opening (11), located in the region of the head (8) of the central support (7). This head seat opening (17) includes conical housing recesses (18) in which the conical tip of the head (21) seats to form small passing openings (22) for the foam with microbubbles.

The head (20) is comprised of a cylindrical part with a tip (21) of staggered conical shape that forms a step (23) in its middle region to enable the formation of the passing channel (22) of the foam with microbubbles (figures 4 and 5). Above the tip (21) there are openings (24) that communicate with the luer channel (25) that receives the external part of the syringe to be fitted into the orifice (26) of the head (20).
At the bottom of the device (1) a connector (27) is connected and comprised of a thin cylindrical disc (28) that is supported by the bottom part of the body (2) and couples into the internal opening (11) of the central valve support (7) by means of a threaded protrusion (29). This connector (27) has a fitting nozzle (30) in its bottom part to receive a hose (31), through which a gas enters and flows into the internal opening (11) of the central valve support (7) through the passage (32).

Figures 3, 4, and 5 explain the operation of the mixing device (1). The arrow in figure 1 indicates the direction of rotation of the body (2) to which the syringes shown in figure 5 are coupled. These syringes contain several solutions with different concentration levels to form the foam with microbubbles. It is possible to observe that each inclined downward channel (4) in the body (2) communicates with the internal opening (11) through the inclined passing hole (15) of the central valve support. Each rotation of the body (2) presents a single inclined downward channel (4) that communicates with the through hole (15). Therefore, only a given syringe containing a solution with a given concentration level will have fluid communication with the opening (11) and consequently with the passage of gas (32) and luer channel (25). The gas flow causes the solution to flow through the
narrow passages (22), enabling the formation of the
microbubbles in the foam that enter the syringe inserted
into the head (8). Alternatively, to assist in the
formation of microbubbles, a small sponge of micro-porous
material can be placed in the inner channel (25).

Figures 7, 8, and 9 show an embodiment of
one object of the rechargeable, resterilizable mixing
device with physiological solution and gas to create foam
with microbubbles used in endovascular treatments. In this
embodiment, the mixing device (lb) comprehends a body (2b)
with cylindrical shape on the top part and the shape of an
inverted eerie body on the bottom part, with a central
cylindrical channel (3D) and inclined downward channels
(4b) that intercept the central cylindrical channel (3b) at
its bottom end (5b). These inclined channels (4b) include a
cylindrical recess (6b) at their top ends in order to
receive a hermetic lid (60) by coupling fit.

The mixing device (lb) also includes a
central valve support (7b), a cylindrical base (9b), and a
head (8b) in the shape of a cone. The base (9b) of the
central support (7b) has a sealing ring (10b) on the outer
surface and an internal opening (lib) inside it, which
crosses the central valve support (7b) throughout its
length. This opening (lib) has a cylindrical recess (12b)
in its bottom end with an upward conical protrusion (13b)
that reaches half the length of the central support (7b).
Between this conical protrusion (13b) and the cylindrical recess (12b) there is a conical recess (14b) that includes an inclined through hole (15b), which enables the communication between the internal opening (11b) and the external cylindrical surface of the central support (7b).

Above the conical protrusion (13b) there is a cylindrical channel (16b) that communicates with the head seat opening (17b), located in the region of the head (8b) of the central support (7b). This head seat opening (17b) includes conical housing recesses (18b) in which the conical tip of the head (21b) seats to form small passing openings (22b) (figure 8; for the foam with microbubbles).

The head (20b) is comprised of a cylindrical part with a tip (21b) of staggered conical shape that forms a step (23b) in its middle region to enable the formation of the passing channel (22b) of the foam with microbubbles (Fig. 8). Above the tip (21b) there are openings (24b) that communicate with the luer channel (25c) that receives the external part of the syringe to be fitted into the orifice (26b) of the head (20b). This opening also receives a hermetic lid (50).

At the bottom of the device (1b) a connecting base (27b) is connected and comprised of a cylindrical lia (28b) that is supported by the bottom part
of the body (2b) and couples into the internal opening (1ib) of the central valve support (7b) by means of a threaded protrusion (29b). Internally, this lid (28b) contains a fitting nozzle (30b) to receive a hose (31b), through which a gas enters and flows through the passage (32b) into the internal opening (1ib) of the central valve support (7b). The cylindrical lid (28b) has a groove (33) on its side to receive the gas hose (31b).

The operation of the next device (1b) is similar to the description of the device above (1), differing only by the fact that, in lieu of syringes, the solutions are placed in small reservoirs (6b) contained in the body (2b). The foam formed with microbubbles is stored in the head (20b).

Therefore, as observed in the description detailed above, the device is comprised of a set of disassemblable and interchangeable parts that lock against each other for easy sterilization and handling, and resistance against extremely low or high temperatures. The device at hand is fully mounted on the body (2,2b) around an essentially cylindrical axle comprised of the central valve support (7,7b), while the top conical body portion comprehending the head (8,8b) is crossed in its center by a flow orienting duct (25, 25b). This axle, comprised of the central valve support (7,7b), is coupled at the center of a
spinning circular reservoir constituted of the body (2,2b), containing several housings (6,26) for the application of several solutions with different concentration levels. These parts are locked by a connector (27) at the bottom to the gas duct (31) with a spray nozzle. Each housing (26) has a channel (4) that can be aligned to communicate with the inside of the flow orienting duct (11) of the central axle (7), responsible for orienting the produced mixture to a top reservoir with a foam-making nozzle.
CLAIMS

1. Rechargeable, resterilizable device with physiological solution and gas to create foam with microbubbles, used in endovascular treatments, characterized for comprehending a body (2) in the shape of two inverted cones united by their bases, with a central cylindrical channel (3) and inclined downward. Channels (4) that intercept the central cylindrical channel (3) at its bottom end (5). This inclined channels (4) contain a cylindrical recess (6) at their top end, the mixing device (1), also comprehends a central valve support (7), a cylindrical base (9), and a cone-shaped head (8), the base (9) of the central support (7) has a sealing-ring (10) on the external surface and an internal opening (11) inside it, crossing the central valve support (7) throughout its length; this opening (11) has a cylindrical recess (12) on its bottom end with a conical protrusion (13) upward until the middle region of the length of the central support (7). Between this conical protrusion (13) and the cylindrical recess (12) there is a conical recess (14) containing an inclined passage hole (15) that enables the communication between the internal opening (11) and the external cylindrical surface of the central support (7). Above the conical protrusion (13) there is a cylindrical channel (16) that communicates with the opening of the head seat (17), located in the region of
the head (6) of the central support (7i). This opening in the head seat (7) contains conical housing recesses (18) to receive the conical tip of the head (21), forming small passage openings (22). The head (20) is comprised of a cylindrical part with a staggered conceal tip (21) that forms a step (23) on its middle, enabling the formation of the passage channel (22). Above the tip (21) there are openings (24) that communicate with the luer channel (25). At the bottom part of the device (1; there is a coupled connector (27) comprised of a thin cylindrical disk (28) supported by the bottom part of the body (2) and coupled with the internal opening (11) of the central valve support (7) by means of a threaded protrusion (29), at its bottom, this connector (27) has a fitting nozzle (30) to receive a hose (31).

2. Rechargeable, resterilizable device with physiological solution and gas to create foam with microbubbles, used in endovascular treatments, wherein the device (1b) is characterized for comprehending, alternatively, a body (2b) with cylindrical shape on the top part and the shape of an inverted cone body on the bottom part, with a central cylindrical channel (3b) and inclined downward channels (4b) that intercept the central cylindrical channel (3b) at its bottom end (5b). These inclined channels (4b) include a cylindrical recess (6b) at their top ends in order to
receive a hermetic lid (60), the mixing device (lb) also includes a central valve support (7b;), a cylindrical base (9b), and a head (8b) in the shape of a cone. The base (9b) of the central support (7b) has a sealing ring (10b) on the external surface and an internal opening (lib) inside it, which crosses the central valve support (7b) throughout its length. This opening (lib) has a cylindrical recess (12b) in its bottom end with an upward conical protrusion (13b) that reaches half the length of the central support (7b).

Between this conical protrusion (13b) and the cylindrical recess (12b); there is a conical recess (14b) that contains an inclined passage hole (15b;). Above the conical protrusion (13b) there is a cylindrical channel (16b) that communicates with the head seat opening (17b), located in the region of the head (8b) of the central support. (7b). This head seat opening (17b) includes conical housing recesses (19b) in which the conical rip of the head (21b) seats to form small passing openings (22b), the head (20b) is comprised of a cylindrical part with a tip (21b) of staggered conical shape that forms a step (23b) in its middle region. Above the tip (21b; there are openings (24b) than communicate with the luer channel (25b). At the bottom of the device (lb) a connecting base (27b) is connected and comprised of a cylindrical lid (28b) that is supported by the cotton part of the body (2b) and couples into the
internal opening (lib) of the central valve support (7b) by means of a threaded protrusion (29b), internally, the lid (28b; has a fitting nozzle (30b) and a groove (33) on its side.
INTERNATIONAL SEARCH REPORT

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

Minimum documentation searched (classification system followed by classification symbols)
A61M  B01F  B05B  B65B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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