

[54] INTRAUTERINE DEVICE AND PROCESS OF MAKING THE SAME

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[22] Filed: Mar. 6, 1973

[21] Appl. No.: 338,560

[52] U.S. Cl. 128/129

[51] Int. Cl. A61f 5/46

[58] Field of Search 128/127, 128, 129, 130, 128/131, 260

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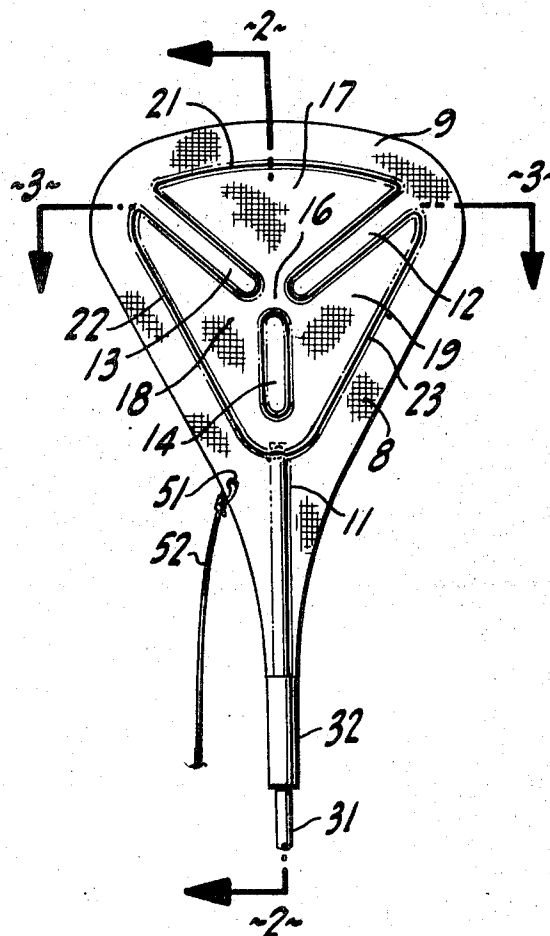
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[57] ABSTRACT

An intrauterine device has a pair of initially flat, registering, triangle-shaped sheets of soft, rubber-like, substantially liquid-impervious, non-toxic flexible material of about the same dimensions as the undistorted human uterine cavity. The sheets are reinforced by a mat of flexible or pliable, non-stretchable fibers to prevent stretching of the sheets. The initially flat sheets are thermally preformed into a three-dimensional final shape and size and are then secured together in a marginal area forming a flat band all around the edges except for a gap at one apex. The sheets are also secured together along internal areas preferably bisecting the apices of the triangle except at said gap and except at a central location. This leaves unsecured or free zones in communication with each other and with said gap and extending approximately parallel to the sides of the triangle. In use, the unsecured zones are filled with fluid, such as liquid, introduced through the gap. This stiffens them so that, although they remain soft, they act somewhat like beams and are not readily distorted. The liquid can contain hormone crystals for slow release through a governing polymer coating.

8 Claims, 10 Drawing Figures



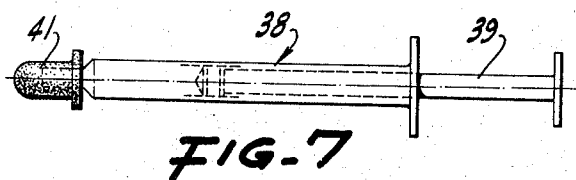
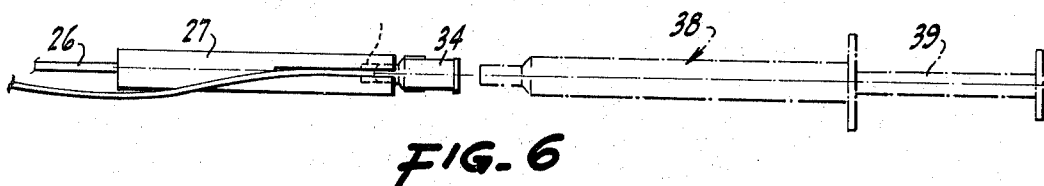
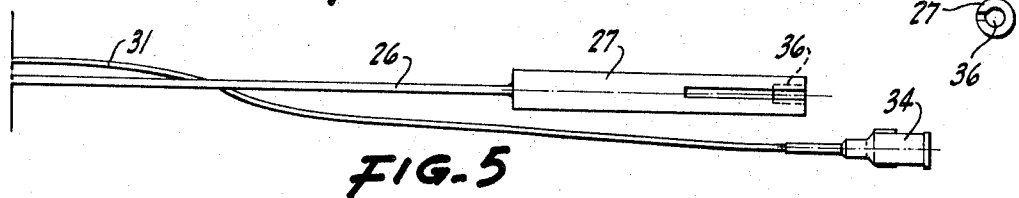
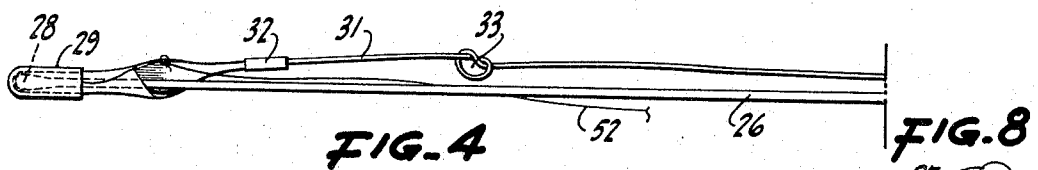
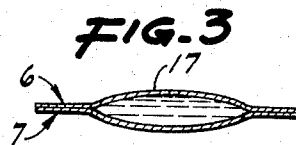
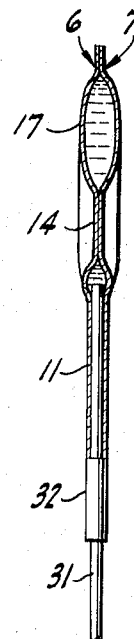
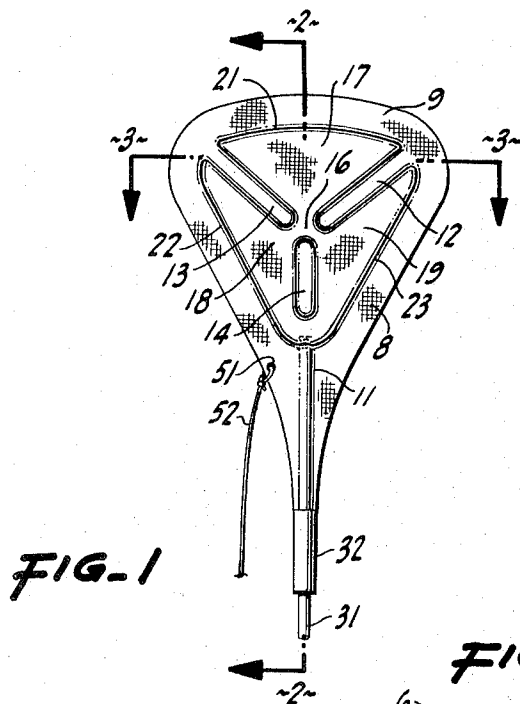


FIG. 10

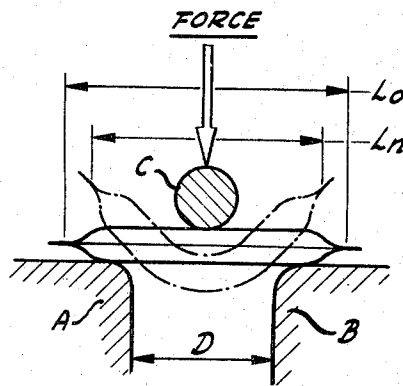
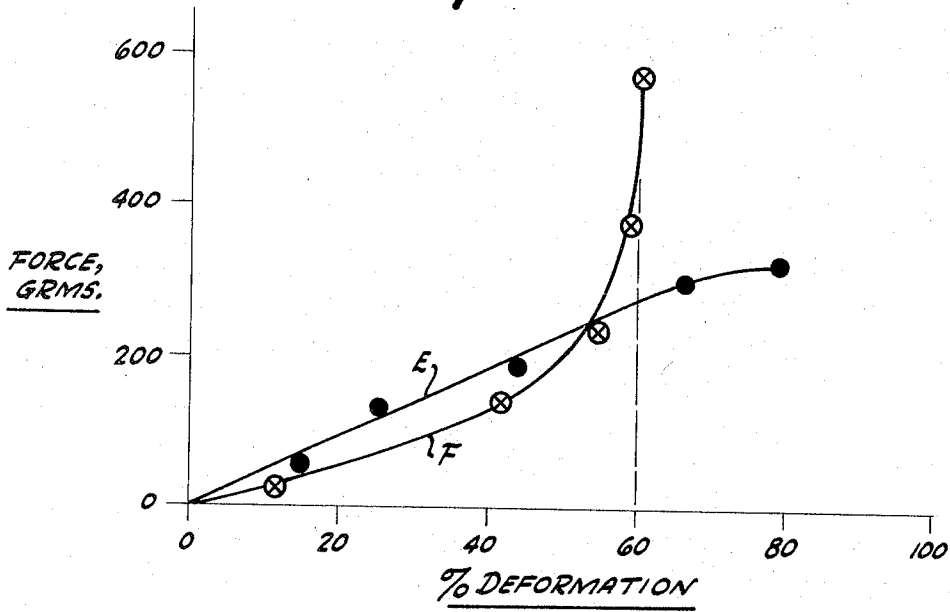


FIG. 9

INTRAUTERINE DEVICE AND PROCESS OF MAKING THE SAME

Most intrauterine devices are either solid, rigid objects or hollow, soft objects expanded by inflation for use. It has been learned that most rigid devices do not accommodate the normal, continuous uterine muscular movements. Being stiff they produce local pressure points and stimulate the uterine and cervical walls to substantial contractions and thus to expel the intrauterine device. The relatively soft, inflatable structures adapt to two main procedures. One procedure is to inflate the stretchable device like a balloon within the uterus, likewise stretching the uterus. The theory is that if the uterus is substantially expanded it will grip or hold the intrauterine device in position. Another procedure is to make the inflated device very pliable and deformable to yield to its surroundings. Clinical experience indicates that the normal uterus by itself or as stimulated by localized pressure points or expansive distortion of the uterine wall is subject to peristaltic contractions. These tend to move the expanded, deformable device into a generally spherical shape and to dislodge the spherical device into the cervical canal and finally to expel it. Devices of both main types may have substantial efficacy for their intended purpose, as long as they are comfortably in place, but they cannot work in the event they are easily or readily expelled or in the event they produce discomfort and cramps. Clinical experience shows that a large proportion of both types of such devices are in fact expelled either within a very short time after introduction or within a few months thereafter.

Some of the inflatable soft devices are filled with contraceptive material for slow release but experience shows that material concentration and release rate vary over a period of time. Also, the soft devices usually require related holding and insertion devices some of which are awkward.

It is therefore an object of the invention to provide an intrauterine device that is so constructed and arranged as not to provide undue pressure or pressure points within the uterus and thus not to traumatize or excite extraordinary muscular contractions leading to expulsion.

Another object of the invention is to provide an inflatable intrauterine device that is soft and of a limited or predetermined size to accommodate the normal movements, contractions and peristaltic motions of the uterus without triggering expulsion contractions.

Another object of the invention is to provide an intrauterine device that can be inserted in compact form and then inflated or expanded to its normal fixed size after insertion but which cannot be made any larger than its initial, predetermined size even by excessive inflation.

Another object of the invention is to provide an inflated intrauterine device that can move readily with the uterus to accommodate various movements thereof and without giving rise to pressure points or localized stresses.

Another object of the invention is to provide an intrauterine device that, although soft, is retentive of its predetermined shape and so cannot assume a shape favorable to expulsion.

A further object of the invention is to provide an intrauterine device which, although soft and inflatable, is

nevertheless able substantially to maintain its designed or original shape.

A further object of the invention is to provide an inflatable intrauterine device that is not subject to expulsion in most cases.

A further object of the invention is in general to provide an improved intrauterine device.

Another object of the invention is to provide a method of making an improved intrauterine device.

Another object of the invention is to provide for closely controlled release over a long time of a contraceptive material carried in the contraceptive device.

A further object of the invention is to provide for an improved holding and insertion device for the intrauterine device.

Other objects, together with the foregoing, are attained in the embodiment of the invention described in the accompanying description and illustrated in the accompanying drawings, in which:

FIG. 1 is a plan view, to a somewhat enlarged scale, of an inflated intrauterine device constructed pursuant to the invention, a portion of the filling tube being broken away;

FIG. 2 is a cross-section to the same scale as FIG. 1 and is taken along the line 2—2 of FIG. 1;

FIG. 3 is a cross-section to the same scale as FIG. 1 and is taken along the line 3—3 of FIG. 1;

FIGS. 4, 5 and 6 are illustrations of an applicator for use with the intrauterine device, each figure showing a separate one of the normally linearly arranged parts of the applicator, the intrauterine device being shown in position thereon for insertion;

FIG. 7 is a side elevation of a syringe utilized in connection with the applicator of FIGS. 4, 5 and 6 and carrying a material such as liquid for the appropriate inflation of the intrauterine device;

FIG. 8 is an end view of the applicator;

FIG. 9 is a diagram of a test arrangement; and

FIG. 10 is a plot of force against deformation developed by a test of a device according to the invention and made according to FIG. 9.

A somewhat related disclosure is in the application of Bartosik et al. entitled "Intrauterine Device" and filed Feb. 2, 1971 with Ser. No. 111,943, now abandoned. Also of interest may be the reference patent cited therein as follows:

3,464,409	Murphy	September 2, 1969
3,401,689	Greenwood	September 17, 1968
2,893,385	Millar	July 7, 1959
3,490,456	Kortum	January 20, 1970
3,633,574	Lerner	November 14, 1968

To avoid previous difficulties there is now provided a soft, inflatable device which is inflatable to and remains substantially in its predetermined shape even when subjected to the normal peristaltic or other muscular motions of the uterine wall. The device is so constructed and configured that, though soft, it has some characteristics of a beam and so does not readily deform under external forces. To this end there is provided a pair of sheets 6 and 7 that are, when flat, substantially triangular in plan, albeit the corners of the triangle are somewhat rounded. The shape is not precisely that of a triangle but is relatively close thereto and can be so denominated. The sheets 6 and 7 are conveniently fabricated of a very flexible, soft, non-toxic material substantially impervious to usual inflat-

ing liquids. Silicone rubber sheeting is suitable since it retains liquid used for inflation but can pass some germicidal or spermicidal materials.

Such sheeting is subject to expansion or extension or stretching, particularly in an envelope under internal pressure. To avoid that unwanted characteristic of the elastomeric material, there is either included within the rubber-like sheets themselves or firmly attached thereto a non-extensible mat 8 of fibers of material such as Dacron. These are not extensible under the forces encountered in this environment. The fibers are preferably arranged by weaving in closely arrayed form. Each of the sheets 6 and 7, although it can fold, is thereby prevented from changing its surface extent and from stretching by the closely allied or imbedded, non-stretchable Dacron cloth fibers. The cloth is coextensive with the rubber sheets and is either well imbedded in the rubber sheet or is attached on one side thereof so as to leave an exposed rubber surface. When the rubber faces of the sheets are in immediate touch or in surface juxtaposition, the rubber portions can easily be sealed together.

In producing a device, two of the triangular sheets are arranged in registry with the rubber sides together. They are then put into a mold with vacuum on the exterior of the sheets to draw them apart in many areas into mold cavities having the designed contour or configuration of the ultimate, fully inflated device. This is a carefully arranged, predetermined, three dimensional configuration and leaves the sheet margins in abutment.

By heat sealing, applied adhesive or like technique, the two mold-configured, three dimensional sheets 6 and 7, together with their included restraining mats 8, are secured together all around the periphery of the triangle. This results in a relatively planar or flat, continuous, peripheral sealing band 9 of substantially uniform width except for a gap 11 at one apex of the triangle defined by the sheets. In this way there is afforded a three dimensional pouch completely closed all around its edges by a two-thickness circumferential band except at the gap 11.

While the wide band so afforded tends to establish and hold the shape of the pouch, the technique is continued farther. At convenient locations; for example, along each of the bisectors of the triangle apices, is afforded an additional adhesively secured or heat sealed area. Of these three areas the one near one apex is denominated 12, another near the other apex is denominated 13 and the one adjacent the gap 11 is denominated 14. There are thus provided sealed areas 12, 13 and 14 corresponding to the bisectors of the triangle apices and extending in the case of the areas 12 and 13 from the margin or band 9 toward and close to but not exactly into a central zone 16 which is left unsealed and free.

Open to the central zone 16 and defined between the sealed areas 12, 13 and 14 are unsealed or free zones 17, 18 and 19 completely intercommunicating. The zones are all open to the gap 11 and are partly bounded along one side by walls 21, 22 and 23 substantially parallel to the adjacent side walls of the triangle. The zones 17, 18 and 19 are so contoured or configured by the prior vacuum molding and by the sealed portions adjacent to them that each zone when fully inflated, as appears hereafter, has the shape and approximate effect of a structural beam.

Preferably, the gap 11 in free communication with the interior zones is supplied with sufficient fluid such as a gas or a liquid so that the relaxed, unsecured, somewhat flaccid, molded sheet portions are displaced from each other into their molded contour but are not stretched because of the restraint imposed upon them by the fibrous mat. When fully inflated the various zones 17, 18 and 19 bulge or round from the initial, somewhat wrinkled, approximately planar contour of the uninflated device into the maximum three dimensional, predetermined shape as preset by the mold contour. The beam-like portions afford a structural stiffness toward the maintenance of a flattish, certainly non-spherical, relatively strong triangular configuration.

When in position and normally inflated the various zones 17, 18 and 19 can yield locally in small areas to externally imposed stresses by some fluid displacement since the material of the device is pliant. Thus pressure is not concentrated in any one localized area to produce a pressure point or a local abrasion. The zones 17, 18 and 19, particularly when normally inflated, do not fold or wrinkle easily and tend to act as beams with small deflection under load. The usual muscular contractions and uterine movements are not effective to displace one part of the structure toward or onto another part to make the device assume the configuration of a ball. The clinical experience has been that the normal uterine contractions and muscular movements are readily accommodated without any resulting cramping. The shape of the device is maintained and there is no expulsion. Of a number of the present devices installed, some under unfavorable physiological conditions, the expulsion rate has to the date of filing this application been zero.

It appears that the three elongated areas 12, 13 and 14 of contact between the adjacent walls of the device, in effect forming a sealed "Y," render the unsealed and inflated portions of the structure substantially equivalent to three firm beams forming the three sides of a stable triangle.

As an illustrative test, a tool as shown in FIG. 9 was made. This includes two supports A and B spaced apart a distance D leaving a gap about half the width of the intrauterine device. A bar C was supported centrally of the distance D and above the supports A and B and movable vertically downward. A Dalkon shield (a stiff or rigid IUD) of a known size was placed on the supports spanning the gap between them and the bar C was lowered with a force measured in grams as shown in FIG. 10. The percentage of deformation of the Dalkon shield with the imposed force was substantially linear up to about 325 grams load and 70 percent deformation. Thereafter, with greater load, the Dalkon shield yielded abruptly and broke at a load of about 350 grams and 80 percent deformation as shown by the curve E. The device described herein, of a size substituting for the Dalkon shield, and inflated was similarly positioned on the supports A and B as shown in FIG. 9. Load was imposed by lowering the bar C. The increasing loads were accompanied by the percentage deformation shown by the curve F. The device bent from the original length L_0 to the deformed length L_n , as shown in FIG. 9. From zero up to a load of 100 grams, the present device had a percentage deformation about twice that of the Dalkon shield and between that load and about 250 grams the percentage deforma-

tions of the two devices converged until both were about 50 percentage deformation at above 250 grams. Thereafter, up to a load of about 600 grams the percentage deformation of the present device increased only to about 60. Thus, the present device has a non-linear relationship between load and percentage deformation with a sharp decrease in percentage deformation between about 100 grams and 600 grams.

Since there is an increasing resistance to bending or distortion of shape as load increases, the present, inflated intrauterine device remains properly in the uterus and does not form a readily expelled ball. Even though there is increasing resistance to deformation of the device by the uterine muscles, they may still impinge upon local areas of the relatively soft device without themselves being traumatized or mechanically abraded.

Some of the prior art teaches that if the intrauterine device is made bigger than or is inflated to a larger size than the cervical canal or is inflated to expand against and dilate the uterine wall the device cannot be expelled. This ignores the fact that the uterus is an active muscle constantly in motion and that the os can and does undergo manifold changes in diameter. In fact expulsion is often triggered by pressure on the uterine wall due to the expanded nature of even a pliant device. Other prior art indicates that if the device is provided with sprags or projections or points, it will interengage with the muscle wall of the uterus and thus be anchored. The difficulty is that the anchoring force is the very force which triggers contractions and causes the myometrium to respond to the mechanical pressure by expulsive contractions.

In the present device there is no increase in local pressure, for the device is substantially of the same dimensions as the normal uterine cavity. The device avoids pressure points and abrasion points. It abruptly resists deformation at higher pressures because of the beam-like triangular sides. This precludes folding or wadding of the device into a ball easily expelled through the cervical canal.

Because of the compliant nature of this intrauterine device it tends, as shown by clinical trials, to be well retained over protracted times. It therefore is a suitable vessel for containing contraceptive material for slow release over protracted times. A difficulty is that many suitable liquid materials do not afford the desired, substantially constant release rate. Consequently, in this instance, the inflation liquid, usually isotonic saline solution, preferably contains hormonal small crystals; for example, progesterone. These afford a compact, long-term, supply diffusing into the liquid and maintaining its concentration. In addition, since there is sometimes a variation in the porosity of the material of the intrauterine device itself, there is provided an inner or outer coating of a material such as polyurethane having known or closely controlled porosity or interstitial gaps for release of the fluid hormonal contraceptive. In this way long-term release is stabilized.

For application of the intrauterine device there is preferably provided a relatively long, thin probe 26 having a handle 27 at one end and having a slight, bulbous enlargement 28 at the other end. The uninflated IUD is wrapped around the bulbous portion 28 and is temporarily held in wrapped position by a removable, rounded cap 29. The cap can be of a material subject

to disintegration in uterine surroundings. There is attached to the intrauterine device a tube 31 entering into the gap 11 and surrounded by a sleeve 32 which also encompasses and is fixed to an apex of the device in the vicinity of the gap 11. There is free communication between the tube 31 through the gap with the zones 17, 18 and 19. The tube 31 is provided with a loosely tied knot 33 and extends to a fitting 34. It is convenient to clip the fitting 34 into an appropriate socket 36 on the handle 27. A syringe 38 with a movable plunger 39 is normally closed by a removable cap 41.

When the device is to be installed and inflated the cap can be left in place or can be removed. The syringe is inserted into the fitting 34, as indicated in FIG. 6. If the cap is not initially removed, it shortly disintegrates or dissolves. The contents of the syringe are expelled through the tube 31 and cause full inflation of the device in situ. The tube 31 is then pulled, thus tightening the knot 33 and preventing release of the injected fluid. Thereafter the probe 26 is withdrawn and any excessive length of the tube 31 is cut off. The installation has then been accomplished. In some instances, although not generally, there may be a preference for providing something other than the tube 31 as an extracting means. In that instance, part of the band 9 near the gap apex is provided with a perforation 51 and a fine cord 52 is inserted therethrough and tied and is extended out alongside the tube 31 to a more accessible location.

What is claimed is:

1. An intrauterine device comprising a pair of sheets of soft, rubber-like, substantially liquid-impervious, non-toxic material, said sheets having the approximate shape in plan of a triangle and being arranged in registry with each other, said sheets having about the same dimensions as the undistorted human uterine cavity, a non-stretchable mat of pliable fibers united with said sheets to prevent stretching thereof, means securing said sheets together in a planar band all around the edges of said sheets except for a gap at one apex thereof, and means securing said sheets together along areas bisecting the apices of said triangle except at said gap and except at a region at the center of said triangle leaving three unsecured zones communicating with each other and with said gap and extending approximately parallel to the sides of said triangle.

2. A device as in claim 1 in which said fibers of said mat are woven.

3. A device as in claim 1 in which said sheets are of silicone rubber.

4. A device as in claim 1 in which said fibers are of Dacron.

5. A device as in claim 1 including a tube joined to said sheets and communicating through said gap with said unsecured zones.

6. A device as in claim 1 in which said unsecured zones are preformed to a predetermined three dimensional configuration.

7. A device as in claim 1 including a fluid filling said unsecured zones and separating said sheets into said predetermined configuration.

8. A device as in claim 1 in which said zones are preformed to receive a predetermined maximum liquid volume when inflated.

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