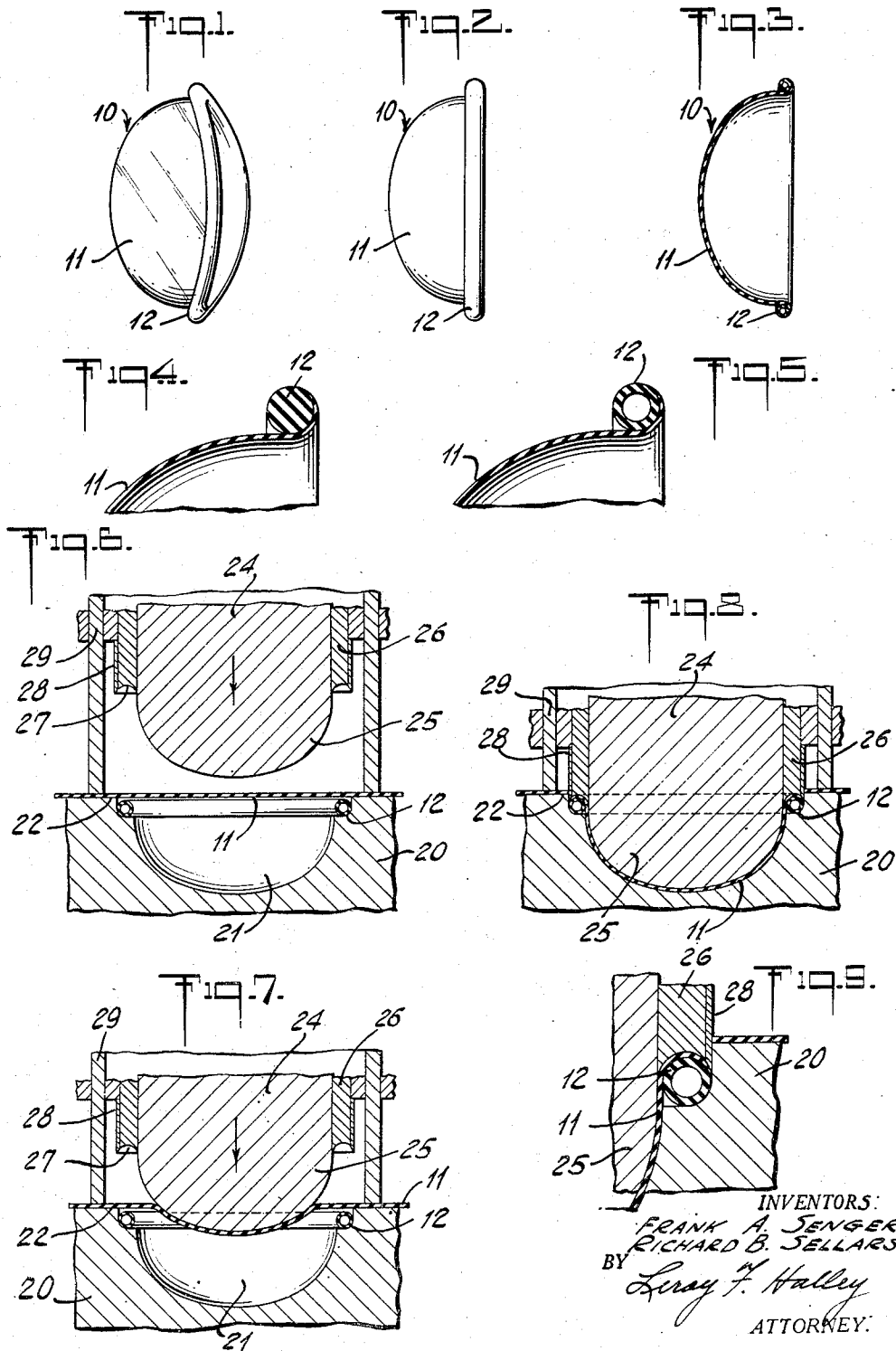


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METHOD OF MAKING A DIAPHRAGM
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METHOD OF MAKING A DIAPHRAGM

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2 Claims. (Cl. 154-110)

This invention relates to occlusive vaginal diaphragms or pessaries and particularly to a diaphragm or pessary having a rim portion without a metallic assembly therein functioning as resilient means and to the method and apparatus for making them.

Heretofore it has been the practice to manufacture occlusive diaphragms or pessaries of high grade natural rubber such as pale crepe. Such pessaries have been composed of a dome-shaped thin rubber element which is sealed or vulcanized to a continuous rim in circular or oval conformation. In such an assembly, it has been necessary, in order that the pessary function properly in pressing against the vaginal walls, to have a resilient metallic member or members embedded in the circular edge or rim. The resilient member most commonly used has been a single coiled spring although in some instances two coiled springs have been used. The manufacture of such pessaries having resilient members embedded in the rim or edge has been expensive, and, consequently, such pessaries are not customarily disposed of after a single use but are used repeatedly over extended periods of time. A number of difficulties have been encountered in the manufacture of such pessaries by a molding process, for it is necessary to overcome the undesirable and disadvantageous feature which commonly prevails which consists of the resilient member not being completely coated with rubber. This has been overcome by manually applying latex to that portion of the rim at which the metallic resilient member is exposed. The latex dip process has been used to manufacture pessaries, but it is time consuming and expensive and requires such careful control of its numerous steps that it results in many defective pessaries.

Among the objects of the present invention is the provision of a new and improved pessary which is fabricated of a material other than rubber and preferably of a synthetic thermoplastic substance.

Another object of the invention is the provision of a new and improved method for manufacturing a pessary from a synthetic thermoplastic substance.

Still another object of the invention is the provision of a new and improved pessary of a synthetic thermoplastic substance in which the resilient means, by which the pessary closely conforms to and contacts the vaginal walls, is a synthetic thermoplastic substance.

Another and further object of the invention is the provision of a pessary which is sufficiently low in cost of construction and materials to be economically disposed of after a single use.

Another object of this invention is the provision of a new and improved molded article having a dome-like shape and a resilient rim or edge without the inclusion of metal resilient means.

With these and other objects in view, the invention as hereinafter more fully set forth and pointed out in the claims may be illustrated in the accompanying drawing in which:

Fig. 1 is a perspective view of the pessary;
Fig. 2 is a view in elevation of the pessary;
Fig. 3 is a vertical cross-sectional view of the pessary;
Fig. 4 is an enlarged fragmentary view in cross-section showing the diaphragm ring in one modification;
Fig. 5 is an enlarged fragmentary view in cross-section showing a modification of the diaphragm;
Fig. 6 is a cross-sectional view of the elements of a mold, shown spaced apart, used in manufacturing diaphragms;

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Fig. 7 is a view similar to that of Fig. 6 but showing the mold partly closed;

Fig. 8 is a view similar to Figs. 6 and 7 but showing the mold elements in closed position and filled with a thermoplastic composition; and

Fig. 9 is an enlarged fragmentary view of Fig. 8 showing the relation of the membrane to the rim of the diaphragm and the manner in which it is sealed to the rim when the mold is closed.

Referring particularly now to Figs. 1 and 2, there is shown a pessary 10 including a membrane 11 of a synthetic, nontoxic, flexible, impermeable, thermoplastic substance and a marginal rim portion 12. The rim portion 12 may be of any desired shape such as that of a circle or an ellipse. The rim portion 12 may be composed of the same material as that of which membrane 11 is composed or rim portion 12 may be composed of a different synthetic, thermoplastic, non-toxic, flexible, impermeable substance, but in all instances it is necessary that membrane 11 be capable of being heat sealed to marginal rim portion 12. As specifically illustrated in Fig. 5, the rim portion in the preferred embodiment is in the nature of a continuous hollow tube, but it is contemplated that it may be in the form of a solid continuous rod, as illustrated in Fig. 4. The rim portion 12 may be made from an extruded tube or rod, which has been cut into suitable lengths, by juxtaposing the ends thereof and locally applying heat sufficient to fuse the ends together.

Dome-shaped membrane 11 is separately formed and then heat sealed at its edges to the marginal rim portion 12. The dome-shaped membrane 11 is preferably of a thickness of from one to four thousandths of an inch.

Any synthetic thermoplastic substance may be used which is non-rigid, non-toxic, non-irritating, and capable of being formed into flexible impermeable membranes and into a resilient tubular shape. The preferred synthetic thermoplastic substance for use in fabricating the pessaries of this invention is a polymerized ethylene known as "polythene" or "polyethylene" which is solid or semisolid but non-rigid at room temperature and which may be further described as the saturated straight-chain hydrocarbon, of which the average molecular weight has a minimum of about 15,000. Polymerized ethylene having an average molecular weight as high as 38,000 may also be used, but it is preferred that polymerized ethylene be used which has an average molecular weight of from 15,000 to 22,000. Other non-rigid thermoplastic substances, solid at room temperature, which may be used in fabricating the pessary or diaphragm include: plasticized polyvinyl chloride such as that which is plasticized with tricresyl phosphate or dibutyl phthalate; copolymers of vinyl chloride with vinylidene chloride, vinyl acetate, or ethyl maleate; and a blend of polyvinyl chloride with a copolymer of butadiene and acrylonitrile.

The process or method by which the pessary is manufactured and suitable equipment used in the manufacture thereof are illustrated in Figs. 6, 7, and 8 which show a mold having bottom and top members which when in a closed position have a clearance not greater than five thousandths of an inch. Bottom member 20 of the mold, as shown in these figures, has a central recessed or open portion 21 and an annular groove or recess 22. Top member 24 of the mold has a central dome portion 25 and an annular heating element 26 having an annular groove or recess 27 encircled by a searing element 28. A spring biased ring 29 (the spring is not shown) which acts as a pressure clamp is positioned in an annular recess in top member 24 of the mold.

In the manufacture of a pessary according to the preferred method of this invention, the first step is the formation of the rim portions and this is done by sealing together the two ends of a piece of thermoplastic synthetic material in the form of tubing of proper length by placing the side ends in touching relation when they are at a heat sealing temperature, which is near 112° C. when polythene is used, for polythene having an average molecular weight within the range of from 15,000 to 38,000 has a melting point of approximately 112° C. The formed rim 12 is then placed in the annular groove 22 of the bottom portion of the mold. The formed rim should be of such a size as to fit snugly into the annular

groove. A sheet of synthetic thermoplastic substance 11 having a thickness of from one to four thousandths of an inch is then placed over the recessed portion of the bottom member of the mold, which bottom member is maintained at the temperature at which the thermoplastic substance being used is softened but below its melting temperature. The top member of the mold is also maintained at a temperature at which the thermoplastic substance is softened but just below its melting temperature, and to shape the dome portion of the pessary the top member is slowly lowered whereby the dome-shaped portion of the top member of the mold comes in contact with the synthetic thermoplastic sheeting 11; and because of the temperature at which it is maintained, it causes the sheeting to conform to its dome-like shape. Before the dome portion of the top member of the mold comes in contact with the sheeting, the spring biased ring, which is at a comparatively lower temperature than the top or bottom mold elements, comes in contact with the sheeting and firmly holds it in place. At approximately the same time at which the annular groove around the dome portion of the top member of the mold comes in contact with the rim portion of the pessary, the searing element, which is maintained at the melting temperature of the thermoplastic substance, comes in contact with the sheeting and cuts the said sheeting in a circular form by melting it at the point with which it comes in contact with the searing element. The surface of the annular groove 27 around the dome portion of the top member of the mold is maintained at a temperature near the melting point of the thermoplastic substance and acts as a heat sealing element to seal the sheeting to the preformed diaphragm ring. The sheeting is sealed to the inner surface of the diaphragm ring, as illustrated in Figs. 3, 4, and 5.

In the closed position there is a clearance between the top and bottom mold members, the dome and recessed portions, of from about one to four thousandths of an inch, in the preferred form. The top portion of the mold is allowed to remain in its lowered position and in contact with the sheeting only during the time it is lowered into the recessed portion of the bottom element of the mold and momentarily after it has reached its lowermost position. The fusing or sealing of the membrane to the rim portion of the diaphragm is accomplished practically instantaneously on contact, and immediately after such contact the top member of the mold is raised. The formed diaphragm is then immersed in a cooling bath which causes the dome-shaped portion of the diaphragm to "set" in the shape of the mold.

Some changes may be made in the details of procedure

involved in the practice of the method of this invention and in the construction and parts of the apparatus used in carrying out the method and of the synthetic thermoplastic materials used in the fabrication of the pessary without departing from the spirit and scope of the invention; it is the intention of the inventors to include within the scope of the invention any variant modes of procedure and any modified forms of structure or use of mechanical equivalents and any synthetic thermoplastic materials which may be reasonably included within the scope of the invention as embodied in the following claims.

This application is a division of our U. S. application, Serial No. 66,912, filed December 23, 1948, now abandoned.

We claim:

1. The method of making a diaphragm which comprises positioning a sheet of flexible, impermeable, synthetic thermoplastic substance on one side of a circular rim of synthetic, resilient, thermoplastic substance, having a diameter less than the sheet, so that the sheet is substantially flat, in touching relation to the rim, and extends beyond the outer circumference of the rim; firmly holding in place the portion of the sheet extending beyond the outer circumference of the rim, deforming the sheet at an elevated temperature into a dome, heat sealing the sheet to the rim, the dome being positioned at the inner circumference and beyond the rim on the side opposite the seal of the sheet to the rim, and removing the portion of the sheet then extending beyond the outer circumference of the rim, whereby a diaphragm is made with a continuous rim integral with a flexible dome-shaped membrane.

2. A process according to claim 1 in which the substance of the rim and sheet is polymerized ethylene having an average molecular weight within the range of 15,000 to 22,000.

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