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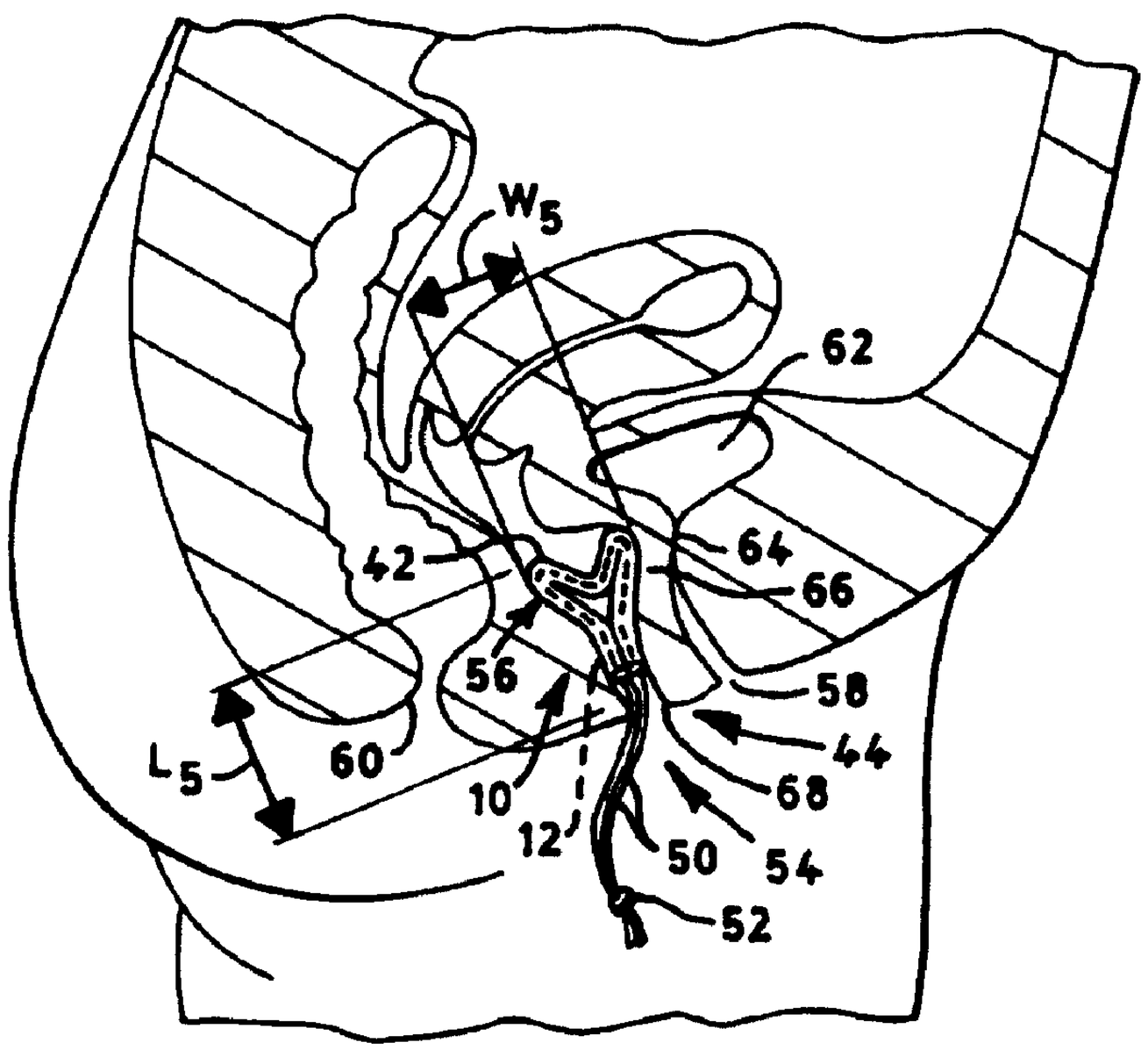


(57) Abrégé/Abstract:
A urinary incontinence device and a method of making the device. The device includes a resilient member and a non-absorbent which at least partially encloses the resilient member. The non-absorbent and the resilient member are formed into an elongated softwind having a first end and a second end. The softwind is folded upon itself such that the first and second ends are aligned adjacent to one another and the softwind contains at least two folds therebetween. The resilient member extends between at least two of the folds. The softwind is then compressed into an elongated pledget having an insertion end and a trailing end with the resilient member located at least in the insertion end. The resilient member is capable of expanding at least a portion of the pledget to provide a supportive backdrop for a woman's urethra when inserted into a woman's vagina.

ABSTRACT

A urinary incontinence device and a method of making the device. The device includes a resilient member and a non-absorbent which at least partially encloses the resilient member. The non-absorbent and the resilient member are formed into an elongated softwind having a first end and a second end. The softwind is folded upon itself such that the first and second ends are aligned adjacent to one another and the softwind contains at least two folds therebetween. The resilient member extends between at least two of the folds. The softwind is then compressed into an elongated pledget having an insertion end and a trailing end with the resilient member located at least in the insertion end. The resilient member is capable of expanding at least a portion of the pledget to provide a supportive backdrop for a woman's urethra when inserted into a woman's vagina.

A URINARY INCONTINENCE DEVICE AND A METHOD OF MAKING THE SAME

FIELD OF THE INVENTION

This invention relates to a urinary incontinence device and a method of making the device. More specifically, this invention relates to a non-absorbent urinary incontinence device which is designed to be placed in a woman's vagina for providing support to a woman's urethra to prevent the involuntary urine loss commonly associated with stress urinary incontinence.

BACKGROUND OF THE INVENTION

Some women, especially women who have given birth to one or more children, and older women, can experience incidences of involuntary urine loss due to stress urinary incontinence or combined stress and urge incontinence. A sneeze or cough can increase the intra-abdominal pressure impinging on a persons bladder and cause the involuntary release of urine. The frequency and severity of such urine loss can increase as the muscles and tissues near the urethro-vaginal myofascial area grow weaker. It has also been recognized that the urinary sphincter muscle, which is located at the upper end of the urethra adjacent to the bladder, works well at sealing off the passing of urine from the bladder to the urethra when it has a round or circular cross-sectional configuration. However, when this passageway becomes distorted into a cross-sectional configuration having more of an elliptical or oval appearance, the sphincter muscle can not close properly, therefore, the tendency for involuntary urine loss increases.

As the world's female population ages, there is an ever increasing need for a non-surgical procedure to reduce the involuntary urine loss commonly associated with "stress urinary incontinence." Today, there are a number of products available for this purpose. Essentially all of these products can only be purchased with a prescription and they need to be physically inserted and/or adjusted by a medical doctor or a nurse practitioner in order to perform correctly. Currently, no products are commercially available, without a prescription, to prevent involuntary urine loss from stress urinary incontinence.

In view of the lack of commercially available non-prescription urinary incontinence devices, it is recognized that there is a need for a urinary incontinence device which can be purchased without a prescription. There is also a need for a urinary incontinence device which is more user friendly and can be managed by the consumer without the

intervention of a medical practitioner. Furthermore, there is a need for a urinary incontinence device which is easy for women to insert into and remove from their bodies, be more comfortable to wear and provide psychological and realistic assurance that it is capable of properly performing over an extended period of time.

SUMMARY OF THE INVENTION

Briefly, this invention relates to a urinary incontinence device and a method of making the device. The device includes a resilient member and a non-absorbent which at least partially encloses the resilient member. The non-absorbent and the resilient member are formed into an elongated softwind having a first end and a second end. The softwind is folded upon itself, such that the first and second ends are aligned adjacent to one another and the softwind contains at least two folds therebetween. The folding of the softwind gives it a generally M-shaped configuration. The softwind is then compressed into an elongated pledget having an insertion end and a trailing end with the resilient member located at least in the insertion end. The resilient member is capable of expanding at least a portion of the pledget to provide support for a woman's urethra when properly inserted into a woman's vagina.

The method of making the urinary incontinence device includes the steps of cutting a non-absorbent into a configuration having a central longitudinal axis. Aligning a resilient member adjacent to the central longitudinal axis of the non-absorbent. Folding the non-absorbent around the resilient member, preferably at least two folds, to form an elongated softwind having a first end and a second end. Then folding the softwind upon itself such that the first and second ends are aligned adjacent to one another and the softwind contains at least two folds therebetween. The resilient member extends between at least two of the folds. The softwind is then compressed into an elongated pledget having an insertion end and a trailing end with the resilient member located at least in the insertion end. The resilient member is capable of expanding at least a portion of the pledget to provide support for a woman's urethra when the pledget is properly inserted into a woman's vagina.

According to an aspect of the present invention there is provided a urinary incontinence device and a method of making the device. According to an aspect of the present invention there is provided a non-absorbent urinary incontinence device which is designed to be placed in a woman's vagina for providing support to a woman's urethra to prevent involuntary urine loss commonly associated with stress urinary incontinence.

Embodiments of the present invention may advantageously provide a urinary incontinence device which is easy to insert and remove and which is comfortable to wear.

Embodiments of the present invention may advantageously provide a method of making a urinary incontinence device which is efficient and economical.

Embodiments of the present invention may advantageously provide a urinary incontinence device which can be purchased by a consumer without a prescription.

Embodiments of the present invention may advantageously provide a urinary incontinence device which can be used along with a sanitary napkin during a woman's menstrual period.

Other aspects and advantages of the present invention will become more apparent to those skilled in the art in view of the following description and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a resilient member position on a non-absorbent and a cover.

Fig. 2 is a perspective view of the combination shown in Figure 1 after being folded along it's longitudinal central axis.

Fig. 3 is a perspective view of the folded member shown in Figure 2 after being folded a second time along it's longitudinal central axis.

Fig. 4 is a perspective view of the twice folded sofwind showing the cover overlapping itself.

Fig. 5 is a side view of the softwind folded into a generally M-shaped profile with the first and second ends being aligned adjacent to one another.

Fig. 6 is a side view of the softwind shown in Figure 5 after it has been compressed into a pledget and has a withdrawal string attached to the first and second ends.

Fig. 7 is a mid-sagittal section of a human torso showing the urinary incontinence device positioned in the vagina and expanded to provide support for the musculature and tissue near the urethro-vaginal myofascial region and the urethra.

Fig. 8 is an alternative embodiment showing a resilient member sandwiched between two adjacent layers.

Fig. 9 is a perspective view of an alternative embodiment of a urinary incontinence device having a short resilient member positioned on a non-absorbent such that the resilient member is aligned adjacent to the central longitudinal axis of the non-absorbent and is offset to one side of the central transverse axis of the non-absorbent.

Fig. 10 is a perspective view of the combination shown in Figure 9 after it has been folded along the central longitudinal axis.

Fig. 11 is a side view of the softwind shown in Figure 10 after it has been folded into a generally M-shaped profile with the first and second ends being aligned adjacent to one another and retained by a withdrawal string.

Fig. 12 is a flow diagram of a method of forming a urinary incontinence device.

Fig. 13 is a flow diagram of an alternative method of forming a urinary incontinence device.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A urinary incontinence device 10, see Fig. 6, is depicted which is designed to be inserted into a woman's vagina and expand so as to relieve or eliminate the involuntary passage of urine through the urethra from the bladder. The expansion of the non-absorbent urinary incontinence device 10 provides a stable backdrop to the musculature and body tissue located at the urethro-vaginal myofascial compressed upon itself. In addition, the expansion of the urinary incontinence device 10 in the vagina assists the urinary sphincter muscle in maintaining a circular cross-sectional configuration. When this circular cross-sectional configuration is maintained, the sphincter muscle can close properly and decrease the tendency for the involuntary escape of urine due to stress urinary incontinence.

Referring to Figs. 1- 6, the urinary incontinence device 10 includes a resilient member 12 and a non-absorbent 14. The resilient member 12 can be non-absorbent or at least partially absorbent of body fluids. However, there is no functional advantage to making the resilient member 12 absorbent because the urinary incontinence device 10 does not function in a similar manner as does a catamenial tampon. In fact, the urinary incontinence device 10 functions entirely different from an absorbent catamenial tampon.

The resilient member 12 can be a natural or synthetic material which has the ability to quickly recover or return to approximately its original shape and/or dimension. Such change to the resilient member 12 can be created by changes in the intra-abdominal pressure. A resilient material is a material which can return to or resume its original shape or position after being bent, stretched or compressed. The resilient member 12 should also exhibit elasticity and flexibility so that it can be stretched or compressed and still retain the capability of returning to approximately it's original shape.

Two natural materials from which the resilient member 12 can be formed include natural rubber and wool. The number of synthetic materials from which the resilient

member 12 can be formed is much greater. Synthetic materials which can be used include polyolefins, polyurethanes, polyethylene oxide (PEO), polyvinyl alcohol (PVA) as well as blends thereof. The resilient member 12 can also be formed from resilient fibers constructed from polyolefin based fibers, polyethylene oxide fibers, hydrophobic rayon fibers and the like, which preferably will have characteristics similar to those of a resilient foam. The resilient fibers may be formed from twisted, curled or chemically cross-linked cellulose fibers or a mixture thereof. Furthermore, the resilient member 12 can be formed from either an open cell or a closed cell foam.

The resilient member 12 can also be made from a wettable foam. An open cell foam which works well and has good resilient properties is commercially available under the trademark ACQUELL®. "ACQUELL" is sold by Sentinel Products Corporation having an office located at 70 Airport Road, Hyannis, Massachusetts 02601. A polyethylene closed cell foam having good flexibility characteristics also works well. This foam is commercially sold under the trademark VOLARA®. "VOLARA" is available from Voltex, a Division of Sekisui America Corporation having an office located at 100 Shepard Street, Lawrence, Massachusetts 01843.

The resilient member 12 should also be capable of having what is known as "dry and wet" expansion characteristics. In other words, the resilient member 12 should be made from a material which is capable of expanding or contracting back to or towards its original configuration in a dry state, a wet state or in a semi-dry-wet state. Dry expansion of the urinary incontinence device 10 is beneficial in that the device does not have to be wetted by body fluid before the resilient member 12 is capable of expanding within the vagina.

In Figure 1, the resilient member 12 is depicted as a narrow strip of material which is rectangular in cross-section. However, the resilient member 12 can have a square, circular, oval or any other desired cross-sectional configuration. Preferably, the resilient member 12 will have a uniform thickness and width. If desired, the dimensions of the resilient member 12 do not have to be uniform. The narrow strip of resilient member 12 has a length L_1 which is equal to the length L_2 of the non-absorbent 14. However, the length L_1 of the resilient member 12 can be less than the length L_2 of the non-absorbent 14. The resilient member 12 also has a width W_1 which can range between about .25 inches (about 6.4 millimeters) to about 1.5 inches (about 38.1 mm), preferably between about .5 inches (about 12.7 mm) and about 1 inch (about 25.4 mm), and more preferably, about 1 inch (about 25.4 mm). The resilient member 12 also has a thickness T_1 which can range between about .1 inches (about 2.5 mm) to about 1 inch

(about 25.4 mm), preferably less than about .5 inches (about 12.7 mm), and most preferably, less than about .4 inches (about 10 mm).

When the resilient member 12 has a round or circular cross-sectional configuration, the diameter can range between about .25 inches (about 6.4 millimeters) to about 1.5 inches (about 38.1 mm), preferably, between about .25 inches (about 6.4 millimeters) to about 1 inch (about 25.4 mm), and most preferably, less than about .5 inches (about 12.7 mm). For odd cross-sectional shapes like an oval, a bilobal, a trilobal, an ellipse, etc. the larger dimension should be no greater than about 2 inches (about 50 mm).

Referring to Figure 1, the resilient member 12 is positioned upon a non-absorbent 14 such that it lies parallel and adjacent to the central longitudinal axis X—X of the non-absorbent 14. It does not matter as to which side of the central longitudinal axis X—X the resilient member 12 is aligned. For best results, the non-absorbent 14 should have a length L_2 which is equal to or greater in dimension than the length L_1 of the resilient member 12. In addition, the non-absorbent 14 should have a width W_2 which is about two to about eight times the width W_1 of the resilient member 12, preferably, the width W_2 is about four times the width W_1 of the resilient member 12. The thickness T_2 of the non-absorbent 14 can be less than, equal to or greater than the thickness T_1 of the resilient member 12. The non-absorbent 14 can be a single ply of material or be constructed of two or more plies or layers.

The non-absorbent 14 is constructed from materials that exhibit little, and preferably, no absorbent characteristics. The non-absorbent 14 differs from a catamenial tampon in that it does not function to absorb body fluid. Instead, the non-absorbent 16 is designed to bridge across the vagina and support the musculature and body tissue located in the urethro-vaginal myofascial area. By doing so, the urethra can be compressed sufficiently to stop the flow of urine and support can be provided to the urinary sphincter muscle so that it can function properly.

For purposes of this invention, a non-absorbent is defined as a material wherein the fibers do not absorb significant quantities of moisture within the fiber itself. It is to be recognized that virtually all materials will absorb some small quantity of moisture. A fiber is considered to be non-absorbent for present purposes if it will intrinsically gain no more than about 6 percent in weight when a bone dry fiber is maintained at 21 C° and at 65 percent relative humidity for 24 hours. Non-absorbent materials include but are not limited to nylons, rayons, spun cellulose, LYCRA®, KEVLAR®, carbon fibers and the like. "LYCRA" and "KELVAR" are trademarks of E. I. DuPont de Nemours & Company which has an office at 1007 Market Street, Wilmington, Delaware 19801. One such

non-absorbent 14 is a web made from bicomponent fibers which are commercially available from Chisso Corporation having an office at 1411 Broadway, 35 th floor, New York, New York. Such fibers are sold under the name "Chisso ESC Bicomponent Fiber™" and consist of a polypropylene core surrounded by a polyethylene sheath. Fibers that work well have a denier of 3 and are 38 millimeters in length. Other bicomponent fibers made from polypropylene, polyethylene, etc. are commercially available from suppliers such as Exxon and Dow Chemical, as well as from other vendors.

Alternatively, the non-absorbent 14 could be an absorbent material such as a cotton/rayon blend which has been chemically treated with a surfactant to make it non-absorbent. However, materials comprised of truly non-absorbent fibers work best.

Referring again to Figure 1, the non-absorbent 14 is shown being positioned on a liquid permeable or liquid-impermeable cover 16. The cover 16 is an optional element and need not be present to form the urinary incontinence device 10. However, the cover 16 can provide a smooth outer surface which may or may not be chemically treated to facilitate insertion and/or removal into and out of a woman's vagina. When present, the cover 16 should have a length L_3 which is equal to or greater than the length L_2 of the non-absorbent 14. The cover 16 should have a width W_3 which is greater than the width W_2 of the non-absorbent 14. The purpose of the greater dimension for the width W_3 is that it allows the cover 16 to be folded over upon itself and be bonded to itself by heat, pressure, a combination of heat and pressure, or by some other conventional means known to those skilled in the art. If the cover 16 is formed from a material which does not readily bond to itself, an adhesive, glue or other bonding or fastening medium can be used. If desired, the cover 16 may be simply folded over upon itself.

The cover 16 can be either liquid-permeable or liquid-impermeable. When the cover 16 is liquid-impermeable, it serves to block body fluids from contacting the non-absorbent 14. Since the non-absorbent 14 is not designed to absorb any body fluid, it can be liquid-permeable. Liquid permeable materials include woven and nonwoven materials having a porous substrate. Woven materials include textile fabrics which can be made from rayon, cotton, or polyolefins. The polyolefins can be either staple or continuous filaments. The nonwoven materials can include spunbond, bonded carded webs and hydroentangled webs. Spunbond and bonded carded webs are commercially sold by Kimberly-Clark Corporation having an office at 401 N. Lake street, Neenah, Wisconsin 54956. Another nonwoven material which can be used as the cover 16 is formed from 100 percent polyester fibers held together by a binder. This material is known as powder-bonded-carded web (PBCW). PBCW is commercially available from

HDK Industries, Inc. having an office at 304 Arcadia Drive, Greenville, South Carolina 29609.

The cover 16 can also be constructed from a liquid-impermeable material. A good liquid-impermeable material is a micro-embossed, polymeric film, such as polyethylene or polypropylene. Bicomponent films can also be used. A preferred liquid-impermeable material is polyethylene film. The thickness of the cover 16 can range from between about .1 mm to about 5 mm, preferably less than about .5 mm, and most preferably, less than about .2 mm.

Referring to Figures 1- 4, the combination resilient member 12, non-absorbent 14 and cover 16, shown in Fig.1, are folded along the central longitudinal axis X—X to obtain a folded member 18 having a central longitudinal axis X_1—X_1. The folded member 18, see Figure 2, is then folded a second time along its central longitudinal axis X_1—X_1 to obtain an elongated softwind 20 having a central longitudinal axis X_2—X_2, see Figure 3. The free end of the cover 16 can then be folded over upon itself and be bonded or attached, or left unattached if desired, to form a cylindrically shaped, elongated softwind 22, see Figure 4. The softwind 22 has a first end 24 and a second end 26.

It should be noted that the above discussion is directed to folding the layers of material 12, 14 and 16 upon themselves to form the softwind 22. However, the softwind 22 could be formed by rolling, wrapping, bending and/or manipulating one or more of the layers in a known fashion to obtain a cylindrical or elongated member.

Referring to Figure 5, the softwind 22 is folded or bent upon itself such that the first and second ends, 24 and 26 respectively, are aligned adjacent to one another and the softwind 22 contains at least two folds 28 and 30 located therebetween. By being aligned "adjacent to one another" it is meant that the first and second ends, 24 and 26 respectively, are positioned side by side, parallel to one another or offset axially or spaced radially apart from one another, or are positioned in some other type of arrangement whereby the first and second ends, 24 and 26 respectively, are close to one another. Preferably, the bonded or open edges of the cover 16 should be positioned to the inside when the first and second ends, 24 and 26 respectively, are aligned adjacent to one another.

Preferably, the softwind 22 will contain three folds 28, 30 and 32 which are located between the first and second ends, 24 and 26 respectively, to give the softwind 22 a generally M-shaped profile. In the generally M-shaped profile, the softwind 22 is folded at 28 to form a first portion 34 and is folded a second time at 30 to form a second portion 36 and a third portion 38. The first and third portions, 34 and 38 respectively, preferably have approximately the same length, although their lengths can differ if desired. It is also

possible to form the first, second and third portions 34, 36 and 38 to have approximately the same length. For example, if the softwind 22 has a length of about 6 inches (about 152 mm), each of the portions 34, 36 and 38 can have a length of approximately 2 inches (about 51 mm).

The resilient member 12 should extend between at least two of the folds 28, 30 and 32. In Figure 5, the resilient member 12 extends the full length of the softwind 22 from the first end 24 to the second end 26. However, it is not necessary that the resilient member 12 extend for a distance greater than the distance between two adjacent folds. For example, the resilient member 12 can span the distance between the folds 28 and 30, between 28 and 32 or between 30 and 32.

Depending upon the material from which the resilient member 12 is constructed, it is advantageous to use a resilient member 12 which has a length which bridges across and extends slightly beyond the folds 28 and 30. This arrangement will assure that the softwind 22 will open completely once placed within a woman's vagina.

Still referring to Figure 5, the third fold 32 provides the softwind 22 with the generally M-shaped profile. The third fold 32 can be positioned an equal or an unequal distance between the first and second folds, 28 and 30 respectively. When the third fold 32 is positioned an equal distance between the first and second folds, 28 and 30 respectively, the third fold 32 will be axially aligned along a central longitudinal axis Z--Z. The central longitudinal axis Z--Z, see Figure 5, vertically divides the generally M-shaped profile of the softwind 22 into left and right mirror images. It is also possible to form the third fold 32 closer to either the first or second folds, 28 and 30 respectively, if desired. The third fold 32 causes the middle portion of the resilient member 12 to be folded into two parts such that a V-shape is obtained.

Referring to Figure 6, the softwind 22 is compressed into a pledget 40 having an insertion end 42 and a trailing end 44. The pledget 40 can have any desired shape but preferably, it will have a generally cylindrical shape with a circular cross-sectional configuration. An alternative profile would be a rectangular cross-sectional configuration. The pledget 40 is an elongated member having a length L_4 and a width W_4. When the pledget 40 is round in cross-section, its diameter will be equal to the width dimension W_4. The length L_4 can range from about .4 inches (about 10 mm) to about 4.7 inches (about 120 mm), preferably the length L_4 ranges from between about 1.5 inches (about 38 mm) to about 2.5 inches (about 64 mm). Most preferably, the length L_4 is about 2 inches (about 51 mm). The width W_4 can range from between about .2 inches (about 5 mm) to about 2.5 inches (about 64 mm), preferably the width W_4 ranges from between about .5 inches (about 12.7 mm) to about 2.3 inches (about 60 mm). Most preferably, the width

W_4 is less than about 1.6 inches (about 40 mm). The pledget 40 also has a dimension R_4 which is a diagonal line drawn between the apex of fold 28 and the bottom surface of the fold 32. This dimension R_4 is also equal in distance to a diagonal line drawn between the apex of fold 30 and the bottom surface of the fold 32. The dimension R_4 can range from between about .2 inches (about 5 mm) to about 1.2 inches (about 30 mm). Preferably, the dimension R_4 will be about 1 inch (about 25.4 mm) in length. Another way of stating the length of the dimension R_4 is to say that it should have a length which is equal to at least about 25 percent of the length L_4 of the pledget 40. This length will be sufficient to insure that the pledget 40 can laterally expand outward and provide pressure against the interior walls of the woman's vagina.

Still referring to Figure 6, the insertion end 42 of the pledget 40 is designed to be the first part of the pledget 40 which enters the woman's vaginal cavity. It should be noted that, while in use, the pledget 40 will be entirely positioned within the woman's vagina. The insertion end 42 contains a cleft 46 formed by the fold 32. Because the softwind 22 has a generally M-shaped profile, the insertion end 42 can contain an equal amount and, preferably, a greater amount of non-absorbent material than the trailing end 44. Even though a greater amount of non-absorbent 14 maybe present at the insertion end 42, the outside diameter of the insertion end 42 should be equal to the outside diameter of the trailing end 44. The amount of non-absorbent material in the insertion end 42 will have to be densified to a greater extent than the non-absorbent material making up the trailing end 44. By having a greater amount of non-absorbent 14 present at the insertion end 42, the urinary incontinence device 10 is better able to expand and support the musculature and the body tissue located adjacent to the urethra and cause it to be compressed. This will eliminate the involuntary escape of urine through the urethra.

When the pledget 40 is formed, the resilient member 12, the non-absorbent 14 and the cover 16, if present, are all compressed. The pledget 40 can be compressed radially and lengthwise or it can be compressed only in the radial direction. The resilient member 12 should be located at least in the insertion end 42 of the pledget 40. The compression step should not detrimentally effect the function of the resilient member 12. In other words, the resilient member 12 has to be capable of expanding outward towards or to its original configuration once the urinary incontinence device 10 is inserted into a woman's vagina. The resilient member 12 must be capable of expanding at least a portion of the pledget 40 to provide support for a woman's urethra when properly inserted into a woman's vagina.

Still referring to Figure 6, the compressed pledget 40 is pierced at its trailing end 44 to form an aperture or opening 48 which extends completely through the first and

third portions, 34 and 38 respectively. The aperture 46 can be formed perpendicular to the central longitudinal axis Y--Y or at an angle thereto. Preferably, the aperture 48 is spaced a short distance from the first and second ends, 24 and 26 respectively. The aperture 48 can be located a distance of from between about .1 inches (about 2.5 mm) to about .5 inches (about 12.7 mm) from the first and second ends, 24 and 26 respectively. Most preferably, the aperture 48 is located about .25 inches (about 6.4 mm) from each of the first and second ends, 24 and 26 respectively. The aperture 48 is designed to allow a withdrawal string 50 to be looped therethrough and be secured to the pledget 40. The withdrawal string 50 will assist in removing the urinary incontinence device 10 from a woman's vagina. The withdrawal string 50 is attached to the non-absorbent 14, and preferably, to the first and second ends 24 and 26 respectively, of the softwind 22. The aperture 48 can be formed with a needle, an awl or some other type of piercing device known to those skilled in the art. The withdrawal string 50 is threaded through the aperture 48 and looped upon itself so as to cinch it secure to the non-absorbent 14. The free ends of the withdrawal string 50 are then tied in a knot 52 to assure that the withdrawal string 50 will not separate from the pledget 40. The knot 52 also serves to prevent fraying of the withdrawal string 50 and to provide a place or point where a woman can grasp the withdrawal string 50 when she is ready to remove the urinary incontinence device 10 from her vagina.

It should be noted that the withdrawal string 50 holds the first and second ends, 24 and 26 respectively, in direct contact with one another and will limit the amount they can expand while positioned within the woman's vagina. It should also be noted that the withdrawal string 50 can be secured to and/or attached to various areas of the pledget 40 and can pass through one or more of the resilient member 12, the non-absorbent 14, the cover 16, if present, or through all three members, if desired. The aperture 48 can alternatively be formed in the softwind 22 before it is compressed and the withdrawal string 50 can be attached either before the softwind 22 is compressed or after the softwind 22 is compressed into the pledget 40.

The withdrawal string 50 can be constructed from various types of threads or ribbons. A thread or ribbon made from 100 percent cotton fibers works well. The withdrawal string 50 should have a length which extends beyond the end of the urinary incontinence device 10 of from between about 2 inches (about 51 mm) to about 8 inches (about 203 mm), preferably, from between about 4 inches (about 102 mm) to about 6 inches (about 152 mm), and most preferably, about 5 inches (about 127 mm). The withdrawal string 50 can be dyed and/or treated with an anti-wicking agent, such as wax, before being secured to the pledget 40. The anti-wicking agent will reduce and hopefully

prevent body fluids from wicking along the withdrawal string 50 and contacting the inner surface of a woman's undergarment. A dry, clean withdrawal string 50 is preferred by the user, especially when she goes to remove the urinary incontinence device 10 from her vagina.

Referring to Figure 7, the compressed pledget 40 is depicted having been inserted into a woman's vagina 54 and is shown in an expanded state 56. The expanded pledget 56 has a length L_5 and a diameter or width W_5. . The expanded pledget 56 also has a generally triangular shape which is closed at the bottom or trailing end 44 by the attachment of the withdrawal string 50. While within the vaginal cavity 54, the resilient member 12 will expand thereby causing the first and third portions, 34 and 38 respectively, to spring or expand outward and spread across the vaginal opening. The urinary incontinence device 10 should be positioned below the cervix. The resilient, elastic and flexible characteristics of the resilient member 12 enables the pledget 40 to recover quickly from its compressed and deformed shape. This allows the urinary incontinence device 10 to intimately contact and conform more ideally to the space within the vaginal walls and press against the inside walls and convolutions of a woman's vagina 54.

A woman's urethra 58 is located adjacent to and anterior to the vagina 54. The woman's anus 60 is located on the posterior side of the vagina 54. The urethra 58 is a passageway which provides a means of removing urine from the woman's body. The urethra 58 is a conduit for removing urine which has accumulated in the woman's bladder 62 to an external orifice located at the lower end of the urethra 58. A urinary sphincter muscle 64 is situated at the upper portion of the urethra 58 adjacent to the bottom surface of the bladder 62. The sphincter muscle 64 operates to prevent the involuntary loss of urine. However, with age the pelvic floor muscles begin to sag and the cross-sectional configuration of the sphincter muscle can change from a circular profile to a non-circular profile. Such a change increases the likelihood that a woman will experience involuntary urine loss. Between the vagina 54 and the urethra 58 is the urethro-vaginal myofascial area 66. This area 66 is made up of musculature and body tissue and the body tissue is extremely pliable. The vagina 54 contains a plurality of rugosities (not shown) which line its inside walls 68. The rugosities consist of wrinkles or creases in the body tissue which allows for expansion and contraction of the side walls 68 of the vagina 54.

Comparing the compressed pledget 40, shown in Figure 6, to the expanded pledget 56, shown in Figure 7, one will quickly recognize that the width W_5 of the expanded pledget 56 is much greater than the width W_4 of the compressed pledget 40.

However, the length L_5 of the expanded pledget 56 is approximately equal to the length L_4 of the compressed pledget 40. Preferably, the length L_5 of the expanded pledget 56 will be slightly larger than the length L_4 of the compressed pledget 40. The thickness (T) of the softwind 22 or dimension in the z-direction (see Figure 4) should range from between about .5 inches (about 13 mm) to about 1.5 inches (about 38 mm). This distance will not change substantially once the urinary incontinence device 10 is inserted into the vagina 54. As the pledget 40 expands by the action of the resilient member 12, to the expanded state 56, the expanded pledget 56 will apply pressure against the body tissue in the urethro-vaginal myofascial area 66. This action will provide a stable backdrop to allow the woman's urethra 58 to become compressed when intra-abdominal pressure increases. In other words, a part of the urethra 58 which is about 1.5 inches (about 38 mm) long and through which urine flows, will be compressed or pinched upon itself thereby preventing the urine from passing through. In addition, support will be provided to the region near the sphincter muscle 64 so that it has a higher tendency to maintain a circular cross-sectional configuration and operate properly. One or both of these actions will reduce and/or prevent involuntary urine loss due to stress urinary incontinence.

Referring to Figure 8, an alternative embodiment of a composite 70 is shown wherein a resilient member 72 is sandwiched between two layers of non-absorbent material 74 and 76. The resilient member 72 can be constructed to be similar in size and configuration to at least one of the non-absorbent layers 74 or 76, and preferably, is constructed so as to be similar in size and configuration to the two non-absorbent layers 74 or 76. When the composite 70 is a laminate, it will be easy to handle and form into a softwind. The composite 70 can be constructed to be a narrow strip, for example, having an elongated rectangular configuration or it can be formed as a large sheet or web which can then be cut into more manageable sizes. The composite 70 can be substituted for the three layer combination shown in Figure 1. Therefore, the composite 70 can be folded upon itself one or more times and can then be folded along its length to form a generally M-shaped softwind similar to that depicted in Figure 5.

Referring now to Figures 9 -11, another embodiment of a urinary incontinence device 78 is depicted which is constructed of a resilient member 80 and a non-absorbent 82. The resilient member 80 has a length L_6 which is less than 50 percent, and preferably from between about 20 percent to about 40 percent of the length L_7 of the non-absorbent 82. The resilient member 80 is positioned relative to a surface of the non-absorbent 82 such that it lies adjacent to both the central longitudinal axis X—X and the central transverse axis Y—Y. The resilient member 80 and the non-absorbent 82 can then be folded in half to obtain a folded member 84, as is depicted in Figure 10. The

folded member 84 can be folded transversely one or more times as was explained above in reference to Figures 1 -4, if desired. The folded member is then folded in two or more locations along its length to obtain a generally M-shaped profile as is shown in Figure 11.

In Figure 11, the urinary incontinence device 78 clearly shows the resilient member 80 being situated on only one side of the central vertical axis Z—Z. The resilient member 80 can be offset from the central vertical axis Z—Z any desired distance or it can have an edge which is coterminous with the central vertical axis Z—Z. One will notice that the resilient member 80 is located between the folds 28 and 32. However, the resilient member 80 can be positioned between the folds 30 and 32. Alternatively, the resilient member 80 can extend between the folds 28 and 30, if desired. For this to occur, the resilient member 80 must span across the central vertical axis rather than being positioned on only one side of it as is shown in Fig. 9.

The resilient and elastic properties of the resilient member 80 must be adequate to insure that the insertion end 42 will open and expand outward a sufficient amount so that the urinary incontinence device 78 can function properly.

Although not shown in any of the drawings, it is contemplated that the compressed pledget 40 can be housed in a paper, cardboard or plastic applicator to facilitate insertion of the urinary incontinence device 10 or 78 into a woman's vagina 54. The applicator can be identical to a tampon applicator, if desired, and can be constructed of one or more hollow tubes which will retain the urinary incontinence device 10 or 78 at a set diameter and/or cross-sectional configuration until the user is ready to use the product. Furthermore, insertion of the urinary incontinence device 10 from the applicator into the human body can be accomplished by using a plunger, such as a two piece applicator, or by digital insertion whereby the user can use one of her fingers. One example of a tampon applicator is taught in U.S. patent 5,795,346 which issued to Achter et al. on August 18, 1998 and is entitled: "TAMPON HAVING A RESILIENT MEMBER."

METHOD

The method of forming the urinary incontinence device 10 or 78 will now be explained with reference to the flow diagrams shown in Figures 12 and 13. The method includes the steps of forming or cutting a non-absorbent 14 into a desired geometrical shape. A preferred shape for the non-absorbent 14 is a rectangle although many other shapes will work. The non-absorbent 14 will have a desired length, width and thickness. A resilient member 12 is positioned on or adjacent to one surface of the non-absorbent 14

to form an assembly of two elements. For best results, the resilient member 12 can be aligned adjacent to the central longitudinal axis X--X of the non-absorbent 14. By "adjacent to" it is meant that the resilient member 12 can have an edge which is coterminous with the central longitudinal axis X--X or the resilient member 12 can be offset or spaced apart from the central longitudinal axis X--X.

The non-absorbent 14 can be positioned on a cover material 16 such that the cover 16 is located adjacent to one surface of the non-absorbent 14 and the resilient member 12 is located adjacent to an opposite surface of the non-absorbent 14. The cover 16 is an optional feature and need not be present to make a useful urinary incontinence device 10 or 78. The non-absorbent 14, along with the cover 16 are then folded around the resilient member 12. One method of folding is to fold the non-absorbent 14 and the cover 16, if present, transversely upon themselves such that a folded member 18 is formed and the resilient member 12 is now located adjacent to the longitudinal fold line X_1—X_1. The folded member 18 can then be folded a second time in a similar fashion to yield a softwind 20 as depicted in Figure 3. When a cover 16 is present, the cover 16 can be wrapped or folded over upon itself and be bonded or attached to another portion of the cover 16 to form an elongated, cylindrical softwind 20, see Figure 4.

It should be noted that the different materials forming the resilient member 12, the non-absorbent 14 and the cover 16 can be folded one or more times to obtain a predetermined diameter or cross-sectional configuration. Furthermore, the materials can be rolled, wrapped, bent or otherwise manipulated to arrange them into a softwind 22. Folding has been found to be a preferred way of accomplishing the formation of a softwind wherein the resilient member 12 is correctly aligned therein.

Once a softwind 22 is formed, it is folded or bent at two or more locations along the length of the softwind 22 to arrive at a generally triangular profile when viewed perpendicular to the folds. Preferably, the softwind 22 is folded such that it contains three folds and acquires a generally M-shape profile. An example of the generally M-shape is depicted in Figure 5. The location or position of the folds 28, 30 and 32 can vary but one preferred embodiment is depicted in Figure 5.

After the softwind 22 has been folded into a generally triangular or M-shape profile, it is compressed radially into a pledget 40, as depicted in Figure 6. The softwind 22 can be compressed only in the radial direction or it can be compressed both axially and radially. Since the pledget 40 contains more material at the insertion end 42 than at the trailing end 44, the insertion end 42 will be denser since the pledget 40 has the same diameter or cross-sectional area throughout its entire length. This added material at the

insertion end 42 will assure that as the pledget 40 opens and expands, once it is inserted into a woman's vagina, that it will provide a stable backdrop for the urethra and be able to provide the required pressure against the neighboring body tissue located in the urethro-vaginal myofascial area so as to restrict the involuntary flow of urine through the urethra.

The compressed pledget 40 can then have a hole or aperture 48 formed through its trailing end 44 for receiving a withdrawal string 50. The aperture 48 can be formed with a needle, an awl or some other mechanical, electrical, chemical, hydraulic or pneumatic means. The aperture 48 should be aligned parallel to the first and second ends, 24 and 26 respectively, of the softwind 22 and be sufficiently spaced apart from the ends 24 and 26 to insure that as one pulls on the withdrawal string 50 that it will not tear through the material and be separated from the pledget 40. The withdrawal string 50 can be inserted through the aperture 48 and be looped upon itself to cinch it tight against the pledget 40. The pair of free ends of the withdrawal string 50 can then be tied in a knot 52 for added assurance that the withdrawal string 50 will not separate from the pledget 40.

It should be noted that the above discussion described piercing the pledget 40 to form the aperture 48. Another option would be to pierce the softwind 22. It should also be noted that Figure 6 shows the aperture 48 passing through the resilient member 12, the non-absorbent 14 and the cover 16 while in Figure 11, the aperture 48 passes only through the non-absorbent 14. It is also possible to form the aperture 48 through only the non-absorbent 14 and the cover 16.

While the invention has been described in conjunction with several specific embodiments, it is to be understood that many alternatives, modifications and variations will be apparent to those skilled in the art in light of the aforegoing description. Accordingly, this invention is intended to embrace all such alternatives, modifications and variations which fall within the spirit and scope of the appended claims.

We claim:

1. A urinary incontinence device comprising:

a) a resilient member; and

b) a non-absorbent at least partially enclosing said resilient member, said non-absorbent and said resilient member being formed into an elongated softwind having a first end and a second end, said softwind being folded upon itself such that said first and second ends are aligned adjacent to one another and said softwind contains at least two folds therebetween, said resilient member extending between at least two of said folds, said softwind being compressed into an elongated pledget having an insertion end and a trailing end with said resilient member located at least in said insertion end and said resilient member capable of expanding at least a portion of said pledget to provide a supportive backdrop for a woman's urethra when inserted into a woman's vagina.

2. The urinary incontinence device of claim 1 wherein said resilient member is sandwiched between two layers of non-absorbent.

3. The urinary incontinence device of claim 2 wherein said resilient member is similar in size and configuration to at least one of said layers of non-absorbent.

4. The urinary incontinence device of claim 3 wherein said resilient member is similar in size and configuration to said two layers of non-absorbent.

5. A urinary incontinence device comprising:

a) a resilient member;

b) a non-absorbent at least partially enclosing said resilient member, said non-absorbent and said resilient member being formed into an elongated softwind having a first end and a second end, said softwind being folded upon itself such that said first and second ends are aligned adjacent to one another and said softwind contains at least two folds therebetween, said resilient member extending between at least two of said folds, said softwind being compressed into an elongated pledget having an insertion end and a trailing end with said resilient member located at least in said insertion end and said resilient member capable of expanding at least a portion of said pledget to provide a supportive backdrop for a woman's urethra when inserted into a woman's vagina; and

c) withdrawal means for removing said incontinence device from the woman's vagina.

6. The urinary incontinence device of any one of claims 1 to 5 wherein said resilient member is polyurethane.

7. The urinary incontinence device of any one of claims 1 to 5 wherein said resilient member is natural rubber.

8. The urinary incontinence device of any one of claims 1 to 5 wherein said resilient member is an open cell foam.

9. The urinary incontinence device of any one of claims 1 to 5 wherein said resilient member is a closed cell foam.

10. The urinary incontinence device of any one of claims 1 to 5 wherein said resilient member is formed from twisted, curled or chemically crosslinked cellulose fibers or a mixture thereof.

11. A urinary incontinence device comprising:

a) a resilient member;

b) a non-absorbent at least partially enclosing said resilient member, said non-absorbent and said resilient member being formed into an elongated softwind having a first end and a second end, said softwind being folded upon itself such that said first and second ends are aligned adjacent to one another and said softwind contains at least two folds therebetween, said resilient member extending between at least two of said folds, said softwind being compressed into an elongated pledget having an insertion end and a trailing end with said resilient member located at least in said insertion end and said resilient member capable of expanding at least a portion of said pledget to provide a supportive backdrop for a woman's urethra when inserted into a woman's vagina;

c) a cover enclosing said softwind; and

d) withdrawal means for removing said incontinence device from the woman's vagina.

12. The urinary incontinence device of claim 11 wherein said device has a central vertical axis and said resilient member is situated only on one side of said central vertical axis.

13. The urinary incontinence device of claim 12 wherein said resilient member is wool.

14. The urinary incontinence device of any one of claims 11 to 13 wherein said cover is non-absorbent.

15. The urinary incontinence device of any one of claims 11 to 14 wherein said softwind is compressed only in a radial direction.

16. A method of making a urinary incontinence device, said method comprising the steps of:

a) cutting a non-absorbent into a configuration having a central longitudinal axis;

b) aligning a resilient member adjacent to said central longitudinal axis of said non-absorbent;

c) folding said non-absorbent and said resilient member to form an elongated softwind having a first end and a second end;

d) folding said softwind upon itself such that said first and second ends are aligned adjacent to one another and said softwind contains at least two folds therebetween, said resilient member extending between at least two of said folds; and

e) compressing said softwind into an elongated pledget having an insertion end and a trailing end with said resilient member located at least in said insertion end, whereby said resilient member is capable of expanding at least a portion of said pledget to provide a supportive backdrop for a woman's urethra when said pledget is inserted into a woman's vagina.

17. The method of claim 16 wherein said softwind is radially compressed.

18. The method of claim 16 or 17 wherein said trailing end of said pledget is pierced to provide an opening for attaching withdrawal means.

19. The method of claim 18 wherein a withdrawal string is inserted through said opening and looped upon itself and said withdrawal string has a pair of free ends which are tied together to prevent said withdrawal string from separating from said pledget.

20. The method of any one of claims 16 to 19 wherein said non-absorbent is aligned on a cover before said resilient member is aligned on said non-absorbent and all three members are folded to form an elongated softwind.

21. A method of making a urinary incontinence device, said method comprising the steps of:

a) cutting a non-absorbent into a rectangular configuration having a central longitudinal axis;

b) aligning a rectangular strip of resilient member parallel and adjacent to said central longitudinal axis of said non-absorbent;

c) folding said non-absorbent around said resilient member to form a combination and folding said combination again to form an elongated softwind having a first end and a second end;

d) folding said softwind upon itself such that said first and second ends are aligned adjacent to one another and said softwind contains at least two folds therebetween, said resilient member extending between at least two of said folds;

e) radially compressing said softwind into an elongated pledget having an insertion end and a trailing end with said resilient member located at least in said insertion end, whereby said resilient member is capable of expanding at least a portion of said pledget to provide a supportive backdrop for a woman's urethra when said pledget inserted into a woman's vagina; and

f) securing a withdrawal string to said pledget to form the urinary incontinence device.

22. The urinary incontinence device of any one of claims 1 to 15, said non-absorbent being constructed from a fibrous material wherein said fibers do not absorb significant quantities of moisture within said fibers.

23. The method of any one of claims 16 to 21, said non-absorbent being constructed from a fibrous material wherein said fibers do not absorb significant quantities of moisture within said fibers.

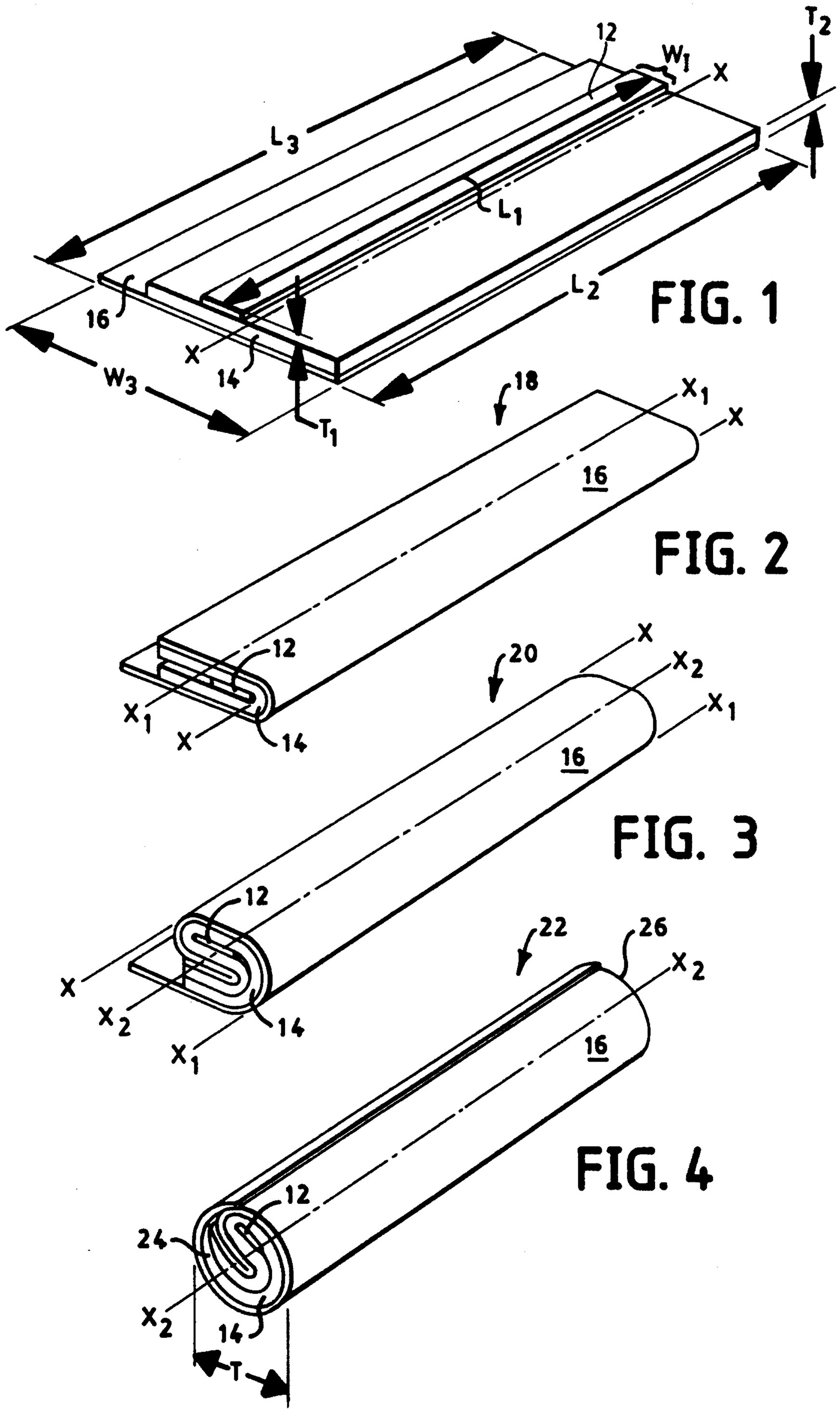


FIG. 1

FIG. 2

FIG. 3

FIG. 4

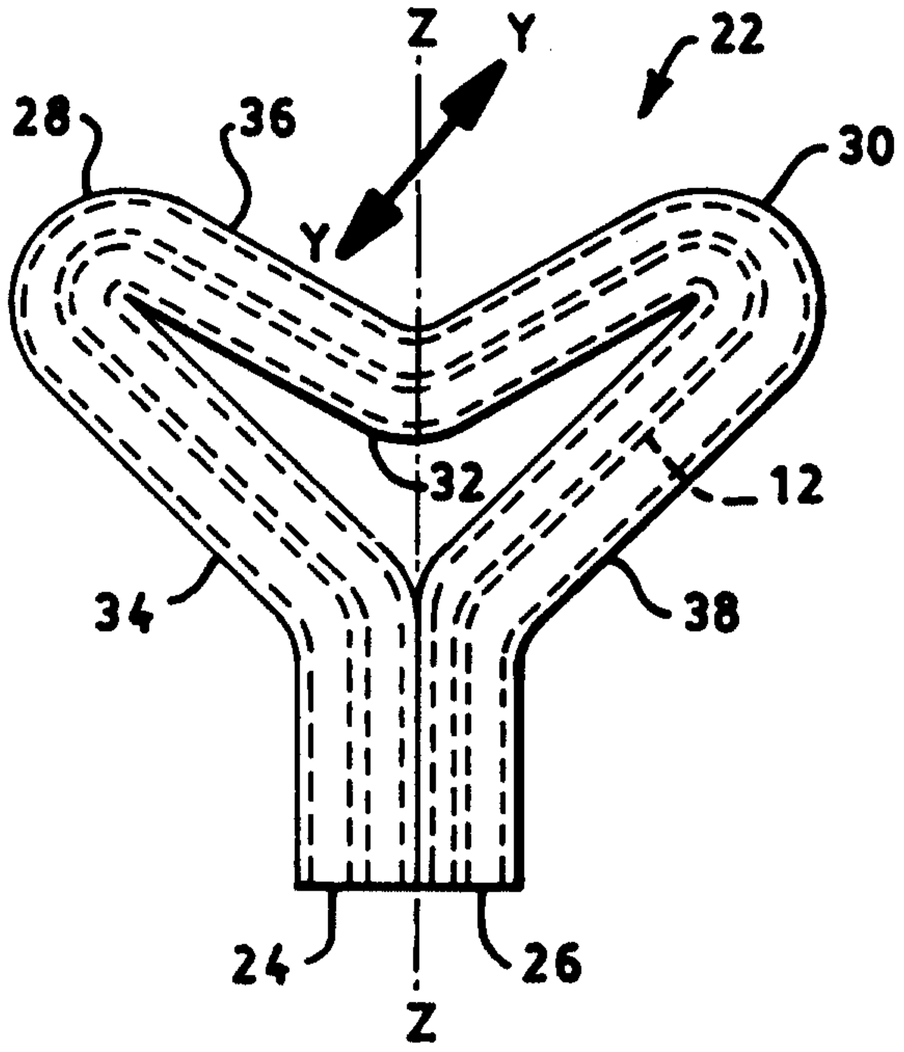


FIG. 5

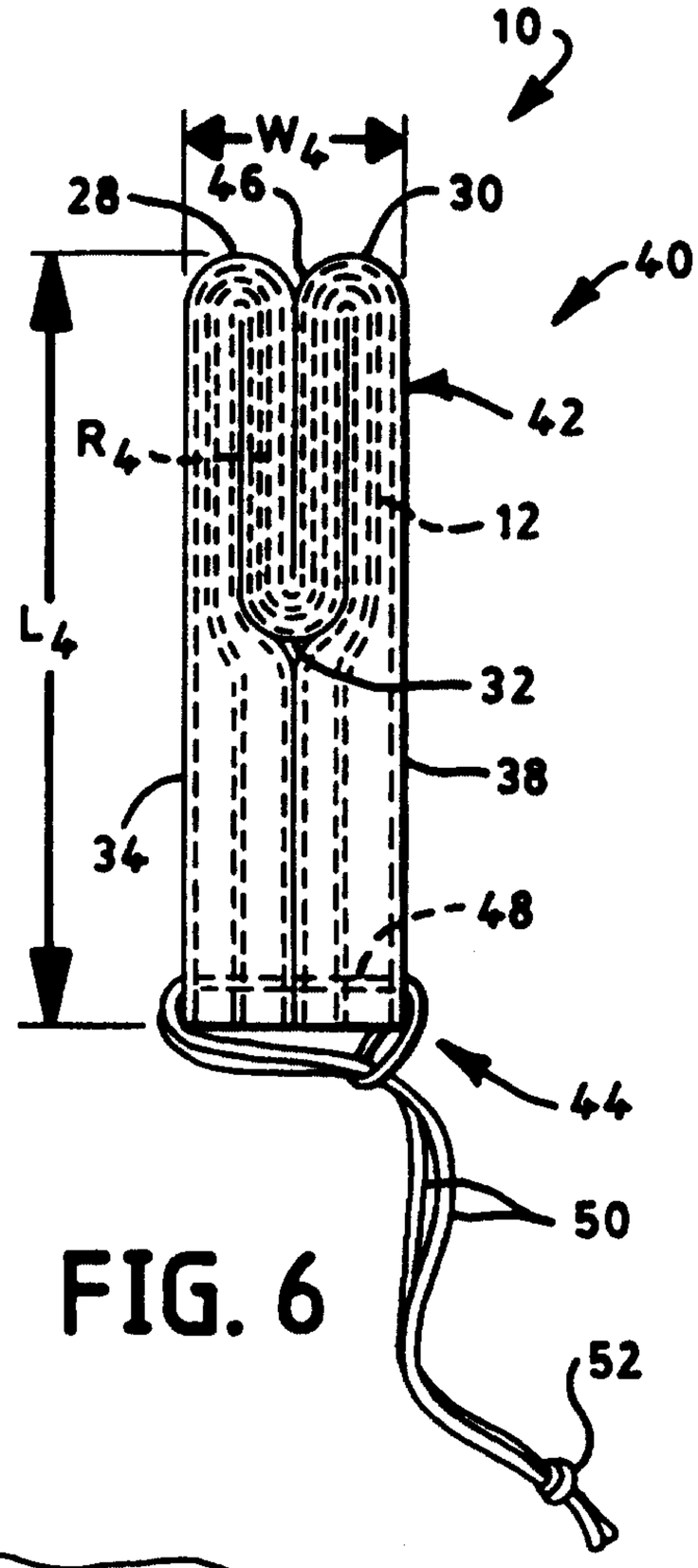


FIG. 6

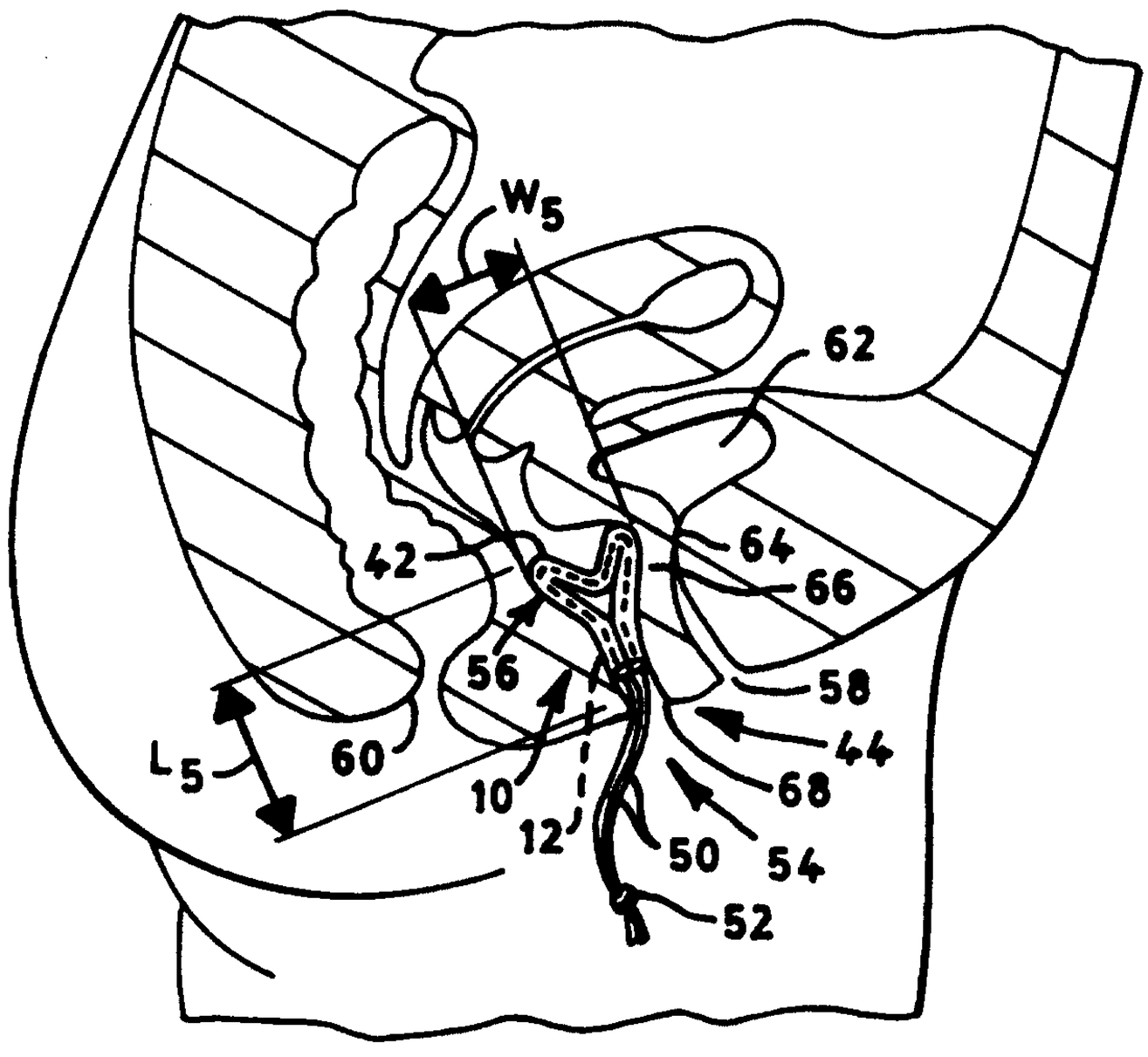


FIG. 7

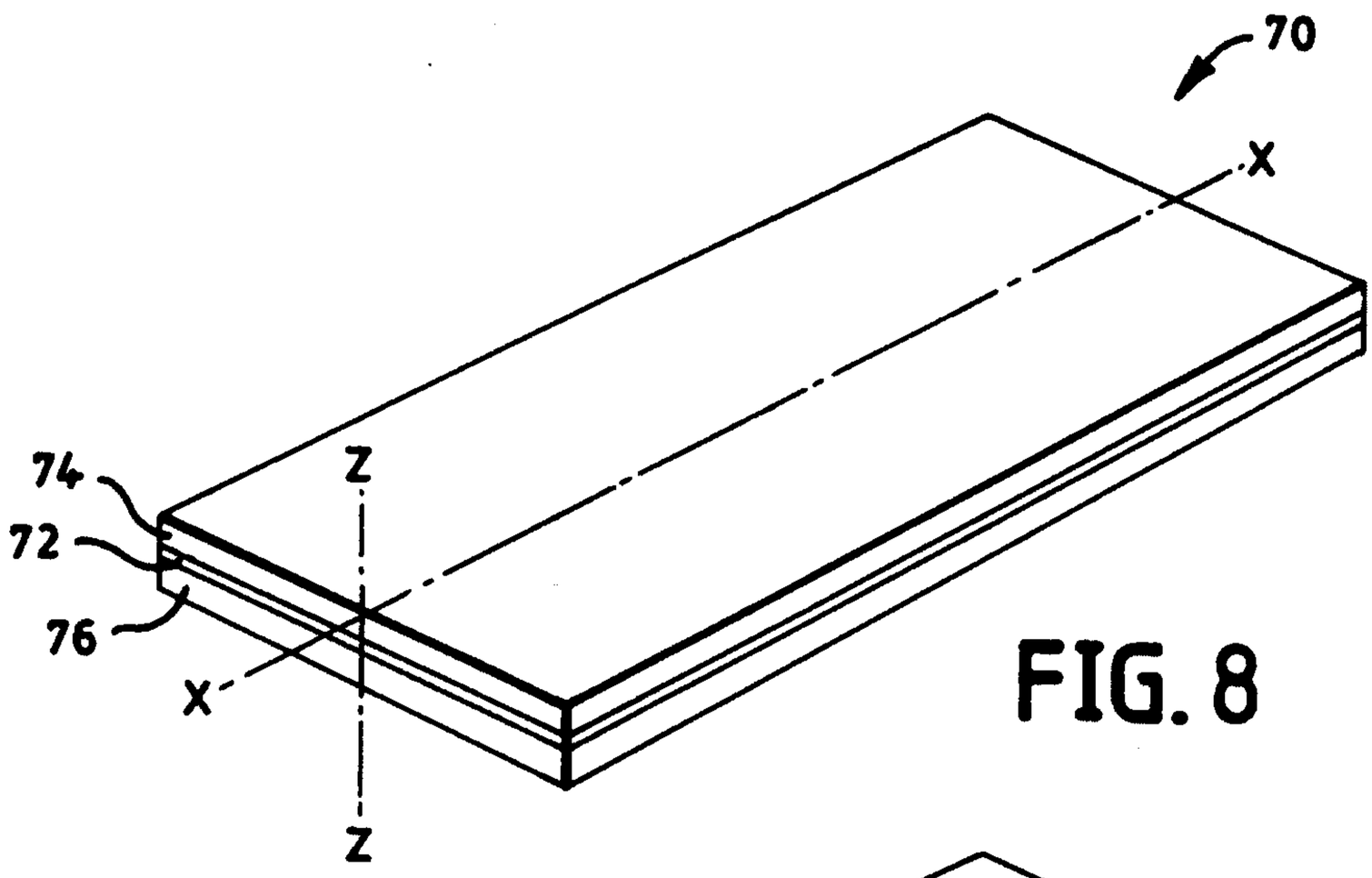


FIG. 8

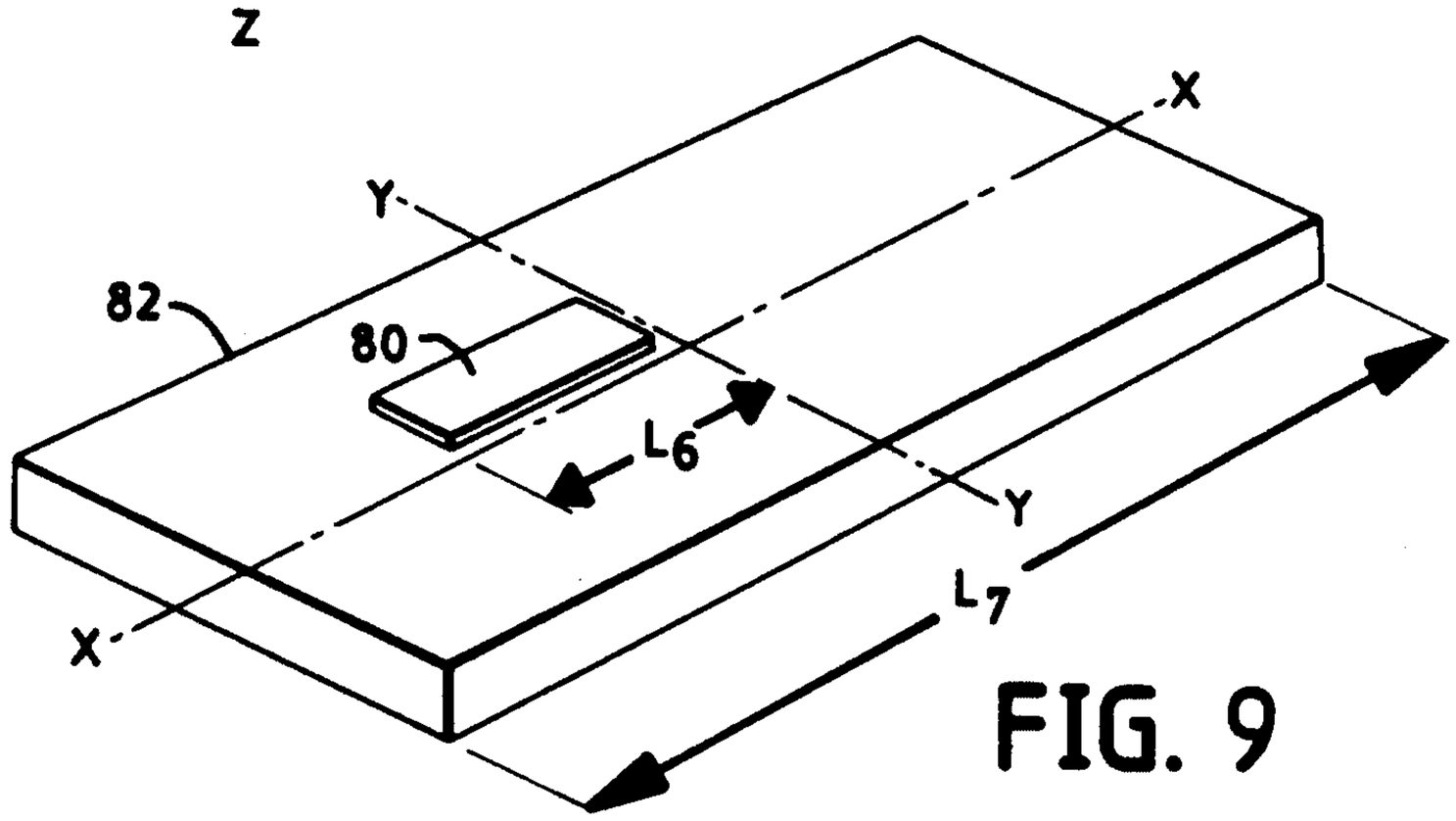


FIG. 9

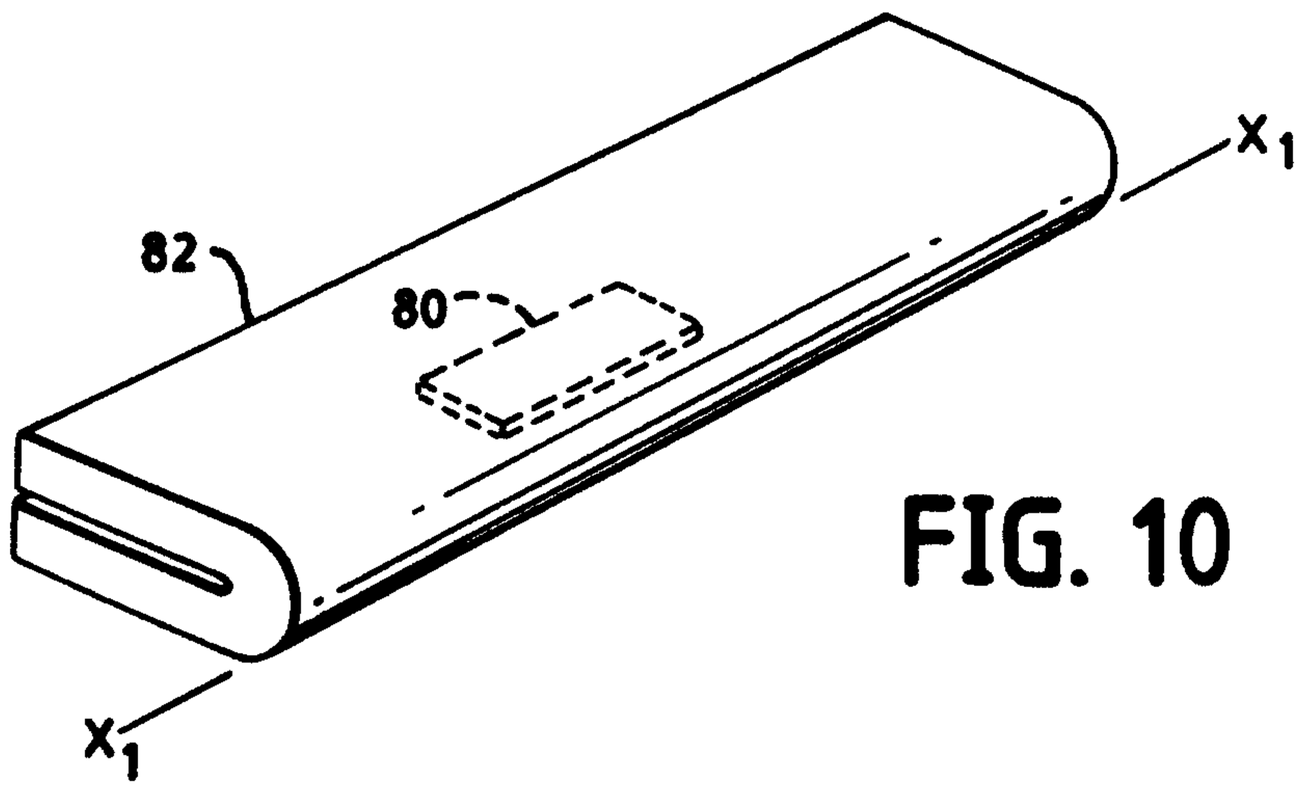


FIG. 10

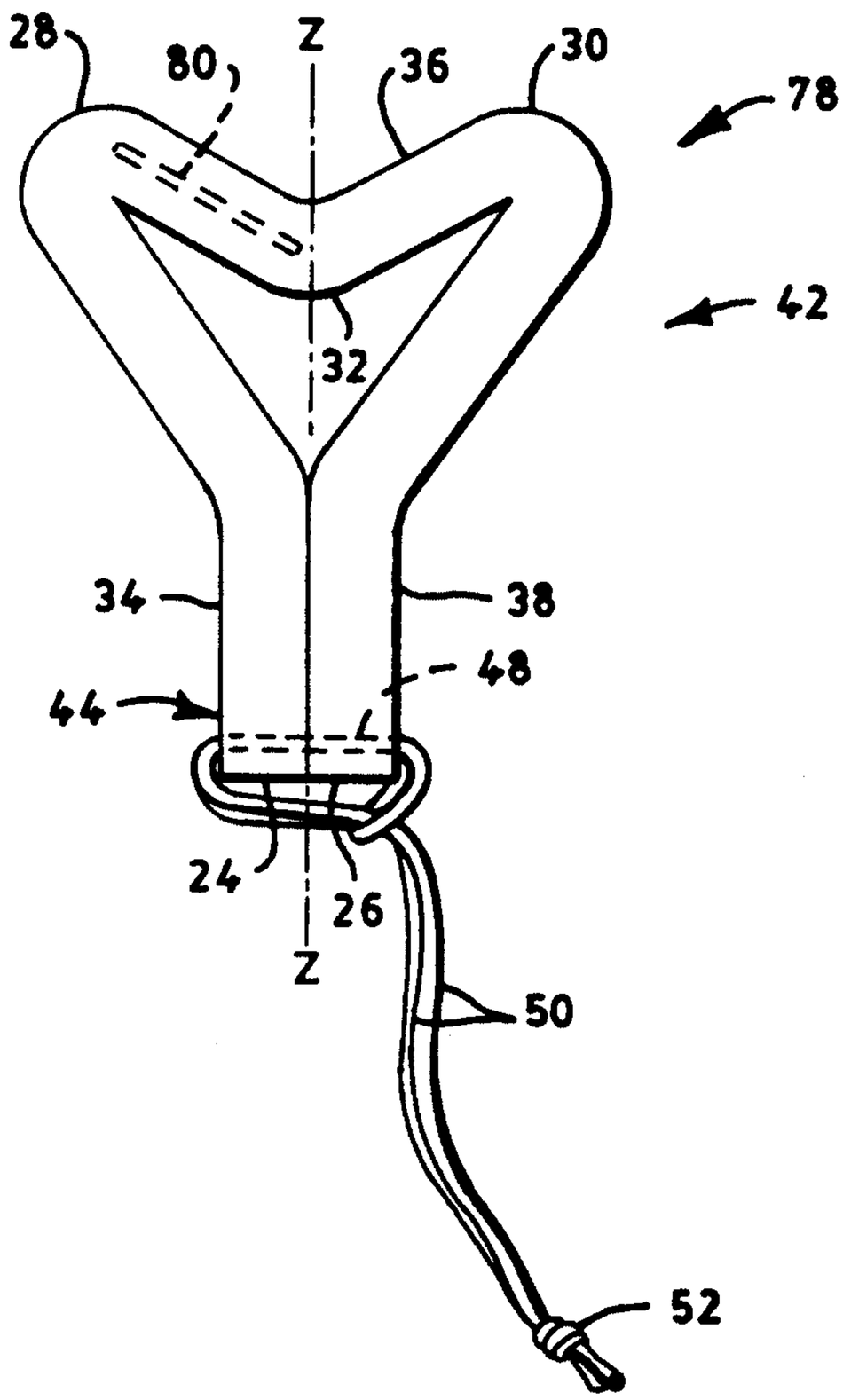


FIG. 11

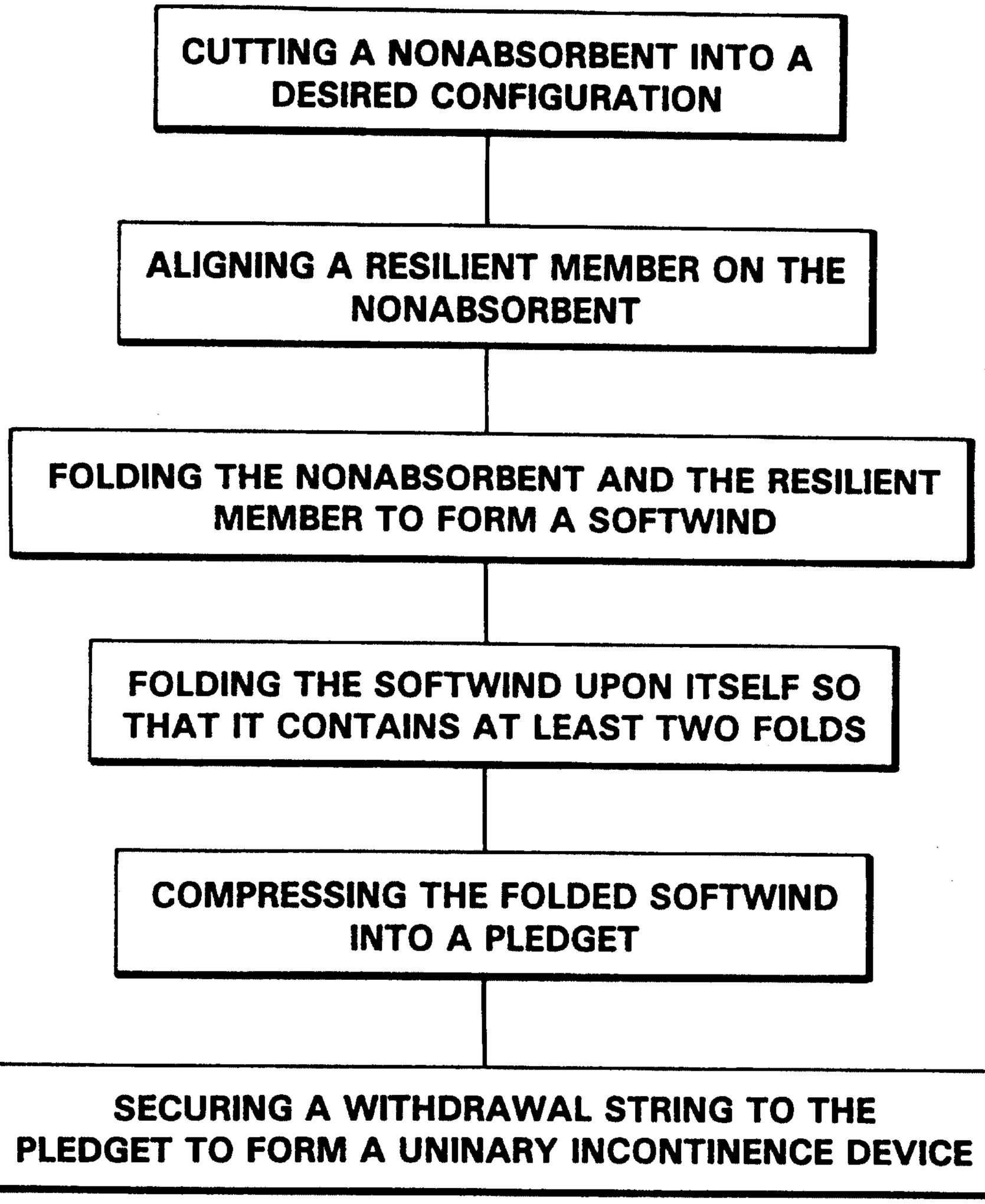

CUTTING A NONABSORBENT INTO A DESIRED CONFIGURATION
ALIGNING A RESILIENT MEMBER ON THE NONABSORBENT
FOLDING THE NONABSORBENT AND THE RESILIENT MEMBER TO FORM A SOFTWIND
FOLDING THE SOFTWIND UPON ITSELF SO THAT IT CONTAINS AT LEAST TWO FOLDS
COMPRESSING THE FOLDED SOFTWIND INTO A PLEDGET
SECURING A WITHDRAWAL STRING TO THE PLEDGET TO FORM A UNINARY INCONTINENCE DEVICE

FIG. 12

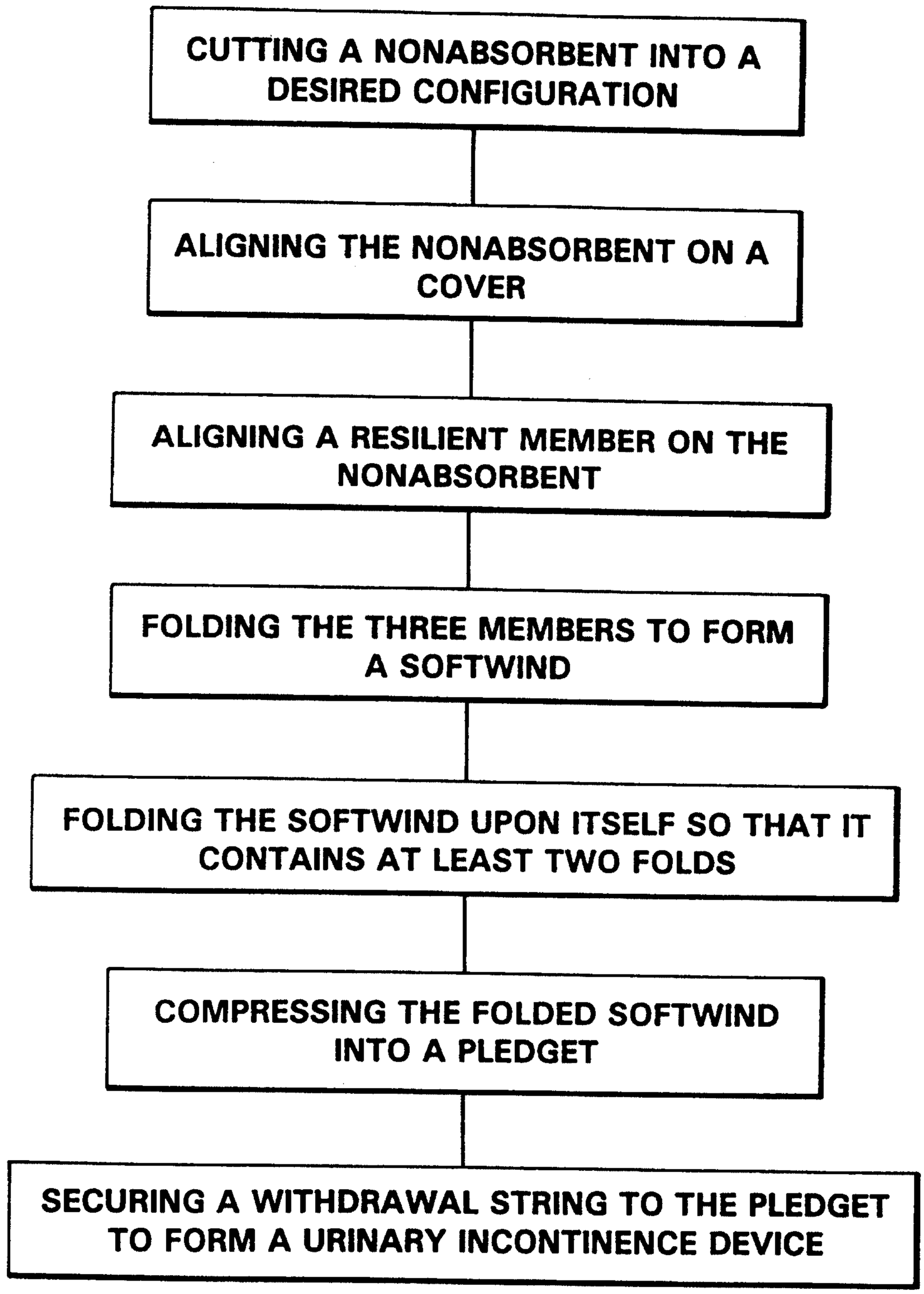
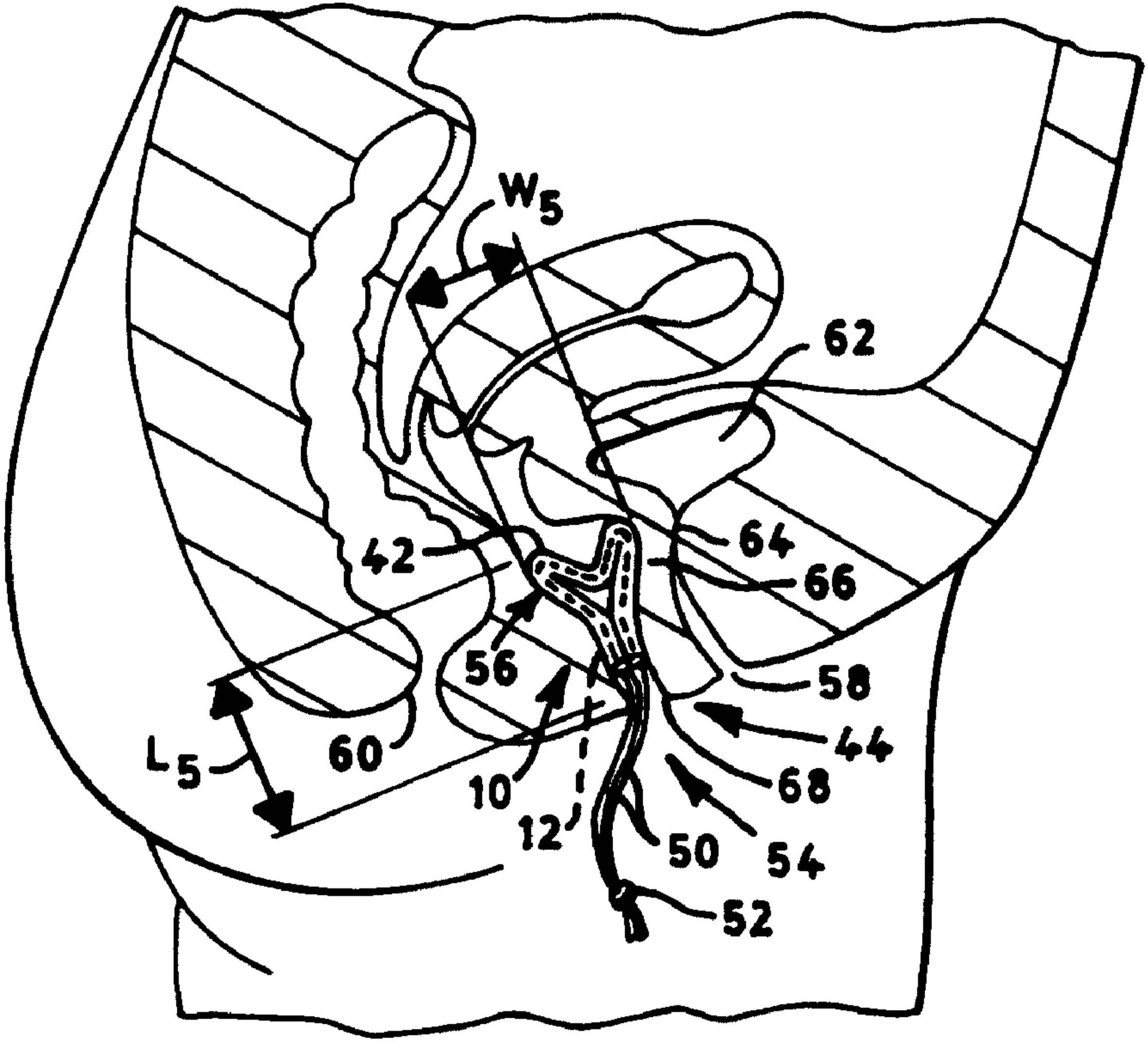

CUTTING A NONABSORBENT INTO A DESIRED CONFIGURATION
ALIGNING THE NONABSORBENT ON A COVER
ALIGNING A RESILIENT MEMBER ON THE NONABSORBENT
FOLDING THE THREE MEMBERS TO FORM A SOFTWIND
FOLDING THE SOFTWIND UPON ITSELF SO THAT IT CONTAINS AT LEAST TWO FOLDS
COMPRESSING THE FOLDED SOFTWIND INTO A PLEDGET
SECURING A WITHDRAWAL STRING TO THE PLEDGET TO FORM A URINARY INCONTINENCE DEVICE

FIG. 13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