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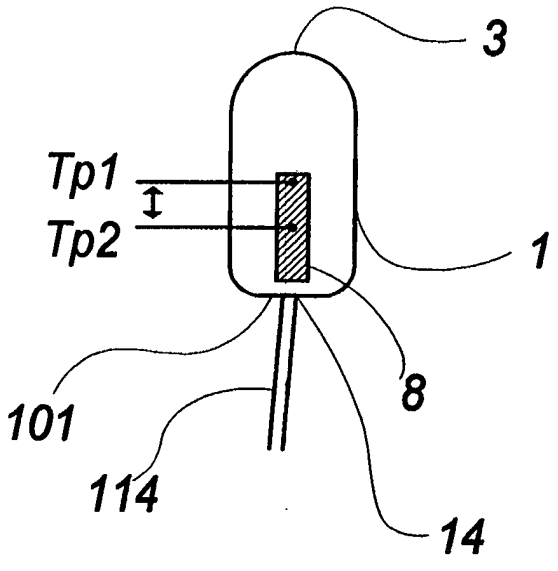
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(54) Title: VAGINAL WEIGHT AND SET OF VAGINAL WEIGHTS

(57) Abstract

The invention relates to a vaginal weight for insertion into the vagina for exercising and examining the striated musculature of the pelvic floor, having the special characteristic that the vaginal weight is shaped asymmetrically weight-wise, said weight comprising a weight member (8; 14) or a plurality of weight members inside the vaginal weight, the center of gravity of the weight member (Tp2) or the total centre of gravity of the weight members inside the vaginal weight being below the centre of gravity (Tp1) of the vaginal weight without weight member or members, the lower termination of the vaginal weight being provided with an anchorage (14) for securing a string (114). The invention thus allows optimun positioning of the vaginal weight in the vagina.



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VAGINAL WEIGHT AND SET OF VAGINAL WEIGHTS

Field of the art

The invention relates to a vaginal weight as stated in the introductory portion of claim 1, a set of vaginal weights as stated in the introductory portions of claim 10 and claim 11, a method of treating incontinence as stated in the introductory portion of claim 12, and a vaginal weight as stated in the introductory portion of claim 16.

Exercising of the striated muscles of the pelvic floor has been used to prevent and treat problems of incontinence for decades. A too slack and weak pelvic floor musculature frequently results in a state of incontinence (involuntary loss of urine and/or faeces). The causes have many different explanations. However, at least three parameters appear to influence the state: the striated musculature with its fascia and ligamentous tissue, the smooth musculature and the vascularization.

Ultrasonic scannings have demonstrated significant differences in the position of the neck of bladder in the pelvic cavity between continent and incontinent women, which means in practice that the urethral pressure for incontinent women will frequently be lower than the bladder pressure, and that the pressure transformation to the urethra at a pressure increase in the abdomen will be poorer, and therefore leakage can easily occur.

It has moreover been demonstrated that when particularly the levator ani is affected, the pressure increases in the urethra, in particular mid-urethrally, and the position of the neck of the bladder is moved anterior cranially toward the os pubis.

The above-mentioned pressure increase in the urethra may be generated voluntarily by means of Kegel (squeezing) exercises.

The teaching of Kegel exercises, however, have involved many problems, since correct use of the deep pelvic floor musculature is difficult because of the position of the muscles. When being taught correct muscular use elsewhere in the body, one can frequently move the muscle via a joint while using so-called facilitation techniques which help the learning.

Assessment of the strength of the pelvic floor in order to evaluate the result of the treatment also involves some problems. Influence from the pressure in the abdomen and use of synergists for the pelvic floor musculature are difficult to exclude when using e.g. various forms of biofeedback. It has been attempted to standardize vaginal palpation performed by a physiotherapist, but, naturally, a subjective measuring method has its limitations with respect to use and reproducibility.

Further, biofeedback and vaginal palpation as an examination method have been performed by most people exclusively in a supine position, which corresponds poorly with the fact that only in a standing position does the pelvic floor exhibit its functional strength and endurance.

With these problems in view, so-called vaginal weights have been used for some years as a supplement to examination as well as exercising. Good results have been obtained, and the method is easy to understand and use by the patient. However, there have been some problems in connection with the use of vaginal weights, as the ana-

tomical conditions vaginally vary much from patient to patient, just as the anatomical conditions vary depending on the cause of the problem of incontinence.

The principle of using vaginal weights for exercising is to facilitate the muscular tissue for contraction via sensory input from the contact of the weight with the muscular tissue. This requires that the weight has a shape and a size which enable contact with the tissue. Studies have shown, however, that up to 17% of a group of women could not use common vaginal weights because the size of the levator gap made tissue contact impossible.

Measurement of endurance and strength by means of vaginal weights requires a reasonably differentiated weight distribution, and there are weights where diameter and weight "fit together", i.e. have a certain mutual size ratio. Existing vaginal weights, however, have the drawback that the weights are dimensioned so that diameter and weight are proportional, which means that larger diameter results in greater weight. This, however, is extremely inexpedient. Physiologically, however, inverse proportionality is required because the use of the largest weight takes place in the case where the levator gap of the woman is so wide that other diameters merely slip out. The problem is thus that a wide levator gap generally is a symptom of weak muscles, for which reason the patient cannot retain the weight.

A further drawback of certain known vaginal weights is the geometrical shape of the weight, as several of these have a conical shape at one or both ends, which may mean that the weight, after insertion and during contraction of the musculature, slides further up into the vagina and tilts so that its position becomes horizontal, and

consequently is placed so high that the exercise has no effect.

A further drawback of the known vaginal weights is that, under certain conditions, they may be extremely difficult to position in the vagina, in particular if the user has a backwardly bent vagina, which in the standing position, in combination with the bend already possessed by the vagina, causes a shelf to be formed on which the weight can lie without the musculature being used.

Summary of the invention

When, as stated in claim 1, the weight comprises a weight member or a plurality of weight members inside the vaginal weight, the centre of gravity of the weight member or the total centre of gravity of the weight members inside the vaginal weight being below the centre of gravity of the vaginal weight without weight member or members, a particularly advantageous embodiment of the invention is achieved, since directional stability in use is obtained. Thus, it is ensured that the vaginal weight is stabilized toward a vertical position when positioned inside the vagina, which improves the effect of the exercise. In a standing position, the vagina has an inclination of 40° with respect to the supporting plane, and, in contrast to the known weights, the weight of the invention will follow the 40° inclination, which means that the relevant muscles are exercised. According to the invention, it is also ensured that vaginal weights will not assume a transverse position if the weight is placed too high and/or if the pelvic floor is very weak.

It will be appreciated that the weight member may advantageously form part of the shell, so that it may be retrieved, inserted and adjusted in a single operation.

According to the invention, when used correctly, even physical activities will not cause the weight to slide higher up or out.

When, as stated in claim 2, the centre of gravity of the weight member or the total centre of gravity of the weight members inside the vaginal weight is at least 10%, preferably 25 to 50% below the centre of gravity of the vaginal weight without weight member or members, a particularly advantageous embodiment of the invention is achieved, as the vaginal weight has a strong stabilizing arm which is lengthened when the centre of gravity of the weight member or members is moved further down relatively to the centre of gravity of the vaginal weight.

When, as stated in claim 3, the mass of the vaginal weight is inversely proportional to the diameter of the vaginal weight, a particularly advantageous embodiment of the invention is obtained, it being ensured that a vaginal weight may be used correctly, with a view to adapting the use of the individual vaginal weights to the actual physical conditions of a user. This applies especially to women who suffer from a particularly severe degree of incontinence, since vaginal weights may thus be formed with a large diameter, but with a relatively small total mass, thereby enabling the user to retain the vaginal weight in use. This means that an actual therapeutic effect may be obtained in the use of a vaginal weight according to the invention, even when the user suffers from a particularly severe degree of incontinence.

Thus, it is possible to use a weight according to the invention in a physiologically extremely advantageous manner, since the use of the largest vaginal weight takes place in the case where the levator gap of the woman is

so wide that other diameters merely slip out, without the weight being so great that this in itself causes the weight to slip out.

When, as stated in claim 4, the vaginal weight has upper and lower parts, said upper part being formed with a larger diameter than the lower part, the intended position of the vaginal weight in the vagina will be maintained safely.

When, as stated in claim 5, the upper part constitutes about 2/3 of the total length of the weight, and preferably the upper part has a fine-structured facilitation surface and the lower part has a coarse-structured facilitation surface, a particularly advantageous embodiment of a vaginal weight according to the invention is achieved.

When, as stated in claim 6, the weight member forms part of the total surface of the vaginal weight, an embodiment of a vaginal weight according to the invention is achieved which will be simple to manufacture.

When, as stated in claim 7, the side face of the vaginal weight has generatrices which are substantially parallel with the longitudinal axis of the vaginal weight, and the side faces form the lower termination of the vaginal weight via a rounded curvature having a radius of curvature which is smaller than the radius of the vaginal weight, a particularly advantageous embodiment of the invention is achieved, as the lower termination of the weight may be formed with an edge which is rounded, thereby allowing the weight to maintain its position in a particularly effective manner.

When, as stated in claim 8, the radius of curvature is smaller than half the radius of the vaginal weight, preferably smaller than 20% of the radius of the vaginal weight, a particularly advantageous embodiment is achieved, as the lower termination forms a rounded edge, thereby achieving a weight whose outer shape does not cause or induce displacement of the weight from its position of use.

When, as stated in claim 9, the vaginal weight is conical at the top, an advantageous embodiment of the invention is achieved, as the weight relative to its shape is easy to insert into the vagina.

When, as stated in claim 10, the vaginal weight is formed wholly or partially with a rough surface, a certain form of roughness on the surface of the vaginal weight is achieved, which causes the facilitation provided by the vaginal weight to be increased, since surface roughness on the parts of the vaginal weight surface concerned, when touching muscular tissue, provides or enhances the afferent input when the muscle tone apparatus of the muscle is affected.

Thus, it is possible according to the invention to perform improved facilitation of the muscular tissue for contraction via a sensory input from the contact of the weight with the muscular tissue.

It will be appreciated that the roughness provided on the surface of the vaginal weight must not be capable of damaging the mucosa of the vagina, just as it must be ensured that the roughness itself cannot keep the vaginal weight positioned as the therapeutic effect is then lost.

Optionally, the rough surface may be formed by a rubber coating on the surface of the weight.

When, as stated in claim 11, the rough surface of the vaginal weight is formed wholly or partially by an assembly of discrete embossings and/or projections in the surface, an advantageous embodiment of the invention is achieved, as the actual finishing of a surface of a vaginal weight may be performed in a simple manner such that the facilitation provided by the vaginal weight in use may be enhanced, while maintaining an advantageous shape with respect to cleaning and hygiene.

When the weight is formed with e.g. grooves, the surface roughness of the weight will thus be achieved by means of discrete "macroscopic" formations in the surface, and these may therefore be subjected to thorough and sufficient cleaning without the use of a special apparatus.

It must be ensured when providing this surface structure that the surface structure is suitably small and/or rounded, so that the weight does not damage the mucosa of the vagina in use.

The assembly or assemblies of discrete embossings and/or projections in the surface comprise e.g. small grooves, small studs or small bosses, which per se may have a microscopic roughness.

When, as stated in claim 12, the rough surface is formed preferably on the side walls of the vaginal weight, while the upper termination and the lower termination of the vaginal weight are formed with a smooth surface, an advantageous embodiment of the invention is achieved, as facilitation according to the invention is obtained in the position of use, just as insertion and retrieval of

the vaginal weight are not obstructed by the rough surface.

It should be stressed in this context that, in several aspects, the invention is precisely intended to avoid retention of the vaginal weight by the rough surface itself in a given position in use.

When, as stated in claim 13, the pattern is formed by small bosses in the surface of the vaginal weight, a particularly advantageous embodiment of the invention is achieved.

When the weight is formed with bosses, the surface roughness of the weight will thus be achieved by means of discrete "macroscopic" formations in the surface, and these may therefore be subjected to thorough and sufficient cleaning without the use of special apparatus.

It is also possible to control the degree of roughness in a simple manner on the basis of at least one of the following parameters: boss height, boss density, boss pattern and boss roundness with respect to the surface of the vaginal weight.

When, as stated in claim 14, the lower termination comprises a substantially plane end face, a particularly advantageous embodiment is achieved, as the self-aligning effect, in combination with the plane end face, provides a physiologically advantageous position and stimulation by stationary positioning in the vagina.

When, as stated in claim 15, the mass of the individual vaginal weights is inversely proportional to their diameter, it is possible to design a set of weights which may be used in practice by a clinician for the treatment of

women having different anatomical structures and degrees of incontinence. In particular, it is possible to design the set so that there will be a weight of suitable mass and diameter corresponding to an optimum parameter of treatment.

Finally, it should be noted that according to the invention it is possible to make a very flexible kit or set of weight components permitting the design of a vaginal weight that may be adapted to the special anatomical conditions which apply to a specific patient.

Additionally, it is an advantage that such a set according to the invention may be formed by a set of different geometrical shapes having exchangeable rough surfaces in the form of bands, elements that may be snapped on to the weight, or the like, as well as exchangeable weight members.

Such a set thus enables a practitioner to make a controlled optimum adaptation of one or more vaginal weights, and also enables current adjustment of weight as well as surface in step with the development that takes place in the course of the treatment.

When, as stated in claim 16, the mass of the individual weights is inversely proportional to their diameter, it is possible to design a set of weights which may be used in practice by a clinician for the treatment of women having different anatomical structures and degrees of incontinence. In particular, it is possible to design the set so that there will be a weight of suitable mass and diameter corresponding to an optimum parameter of treatment, while achieving the advantages in terms of position and facilitation which are achieved in general.

Finally, it should be noted that according to the invention it is possible to make a very flexible kit or set of weight components permitting the design of a vaginal weight that may be adapted to the special anatomical conditions which apply to a specific patient.

Additionally, it is an advantage that such a set according to the invention may be formed by a set of various geometrical shapes having exchangeable rough surfaces in the form of bands, elements that may be snapped on to the weight, or the like, as well as exchangeable weight members.

Such a set thus enables a practitioner to make a controlled optimum adaptation of one or more vaginal weights, and also ensures current adjustment of weight as well as surface in step with the development that takes place in the course of the treatment.

When, as stated in claim 17, the set comprises at least two, preferably five, vaginal weights having e.g. the following ratio of weight to diameter:

mm	32	30	28	26	26	25	25	24
g ±20%	10	20	30	40	30	40	50	60

a practical embodiment of the invention is achieved, optimally corresponding to the possible and necessary uses.

The weights of the set may typically be dimensioned within the dimensional parameters 10-100 mm and 5-150 g.

When, as stated in claim 18, inserting into patients, in dependence on the levator gap width of the patients, vaginal weights having a diameter which is proportional

to the levator gap width, but with the mass of the vaginal weight being inversely proportional to the diameter of the vaginal weight, an advantageous method of treating incontinence is achieved, as the treatment can optimally allow for the special anatomical conditions of the individual patients.

When, as stated in claim 19, the vaginal weight is formed wholly or partially with a rough surface, a certain form of roughness on the surface of the vaginal weight is achieved, which means that the facilitation provided by the vaginal weight is enhanced, since surface roughness on the parts of the vaginal weight surface concerned, when touching muscular tissue, in itself provides or enhances the afferent input when the muscle tone apparatus of the muscle is affected.

Thus, according to the invention it is possible to perform improved facilitation of the muscular tissue for contraction via a sensory input from the contact of the weight with the muscular tissue.

It will be appreciated that the roughness provided on the surface of the vaginal weight must not be capable of damaging the mucosa of the vagina, just as it must be ensured that the roughness in itself cannot keep the vaginal weight positioned, as the therapeutic effect is then lost.

Optionally, the rough surface may be formed by a rubber coating on the surface of the weight.

When, as stated in claim 20, the rough surface of the vaginal weight is formed wholly or partially by an assembly of discrete embossings and/or projections in the surface, an advantageous embodiment of the invention is

achieved, as the actual finishing of the surface of a vaginal weight may be performed in a simple manner such that the facilitation provided by the vaginal weight in use may be enhanced, while maintaining an advantageous shape with a view to cleaning and hygiene.

When the weight is formed e.g. with grooves, the surface roughness of the weight will thus be achieved by discrete "macroscopic" formations in the surface, and these may therefore be subjected to thorough and sufficient cleaning without the use of special apparatus.

When providing this surface structure, it must be ensured that the surface structure is suitably small and/or rounded so that the weight in use does not damage the mucosa of the vagina in use.

The assembly or assemblies of discrete embossings and/or projections in the surface e.g. comprise small grooves, small studs or small bosses which themselves may have a microscopic roughness.

When, as stated in claim 21, the rough surface is formed preferably on the side walls of the vaginal weight, while the upper termination and the lower termination of the vaginal weight are formed with a smooth surface, an advantageous embodiment of the invention is achieved, as facilitation is achieved according to the invention in the position of use, just as insertion and retrieval of the vaginal weight are not hampered by the rough surface.

It should be stressed in this context that in many connections the invention is precisely intended to avoid retention caused by the rough surface of the vaginal weight in a given position in use.

When, as stated in claim 22, the pattern is formed by small bosses in the surface of the vaginal weight, a special advantageous embodiment of the invention is achieved.

When the weight is formed with bosses, the surface roughness of the weight will be achieved by discrete "macroscopic" formations in the surface, and these may therefore be subjected to thorough and sufficient cleaning without the use of special apparatus.

It is also possible to control the degree of roughness in a simple manner on the basis of at least one of the following parameters: boss height, boss density, boss pattern and boss roundness with respect to the surface of the vaginal weight.

When, as stated in claim 23, the weight comprises a weight member or a plurality of weight members inside the vaginal weight, the centre of gravity of the weight member or the total centre of gravity of the weight members inside the vaginal weight being below the centre of gravity of the vaginal weight without weight member or members, a particularly advantageous embodiment of the invention is achieved, as directional stability in use is obtained. It is thus ensured that the vaginal weight is stabilized toward a vertical position when it is positioned inside the vagina, which improves the exercising effect. In a standing position the vagina has an inclination of about 40° with respect to the supporting plane, and, contrary to the known weights, the weight of the invention will follow the 40° inclination, which means that the relevant muscles obtain an exercising effect. It is also ensured according to the invention that vaginal weights will not assume a transverse position if the

weight is placed too high and/or if the pelvic floor is very weak.

It will be appreciated that the weight member may advantageously form part of the shell, thereby allowing it to be retrieved, inserted and adjusted in a separate operation.

According to the invention, when correctly used, even physical activities will not cause the weight to slide further up or out.

When, as stated in claim 24, the centre of gravity of the weight member or the total centre of gravity of the weight members inside the vaginal weight is at least 10%, preferably 25 to 50% below the centre of gravity of the vaginal weight without weight member or members, a particularly advantageous embodiment of the invention is achieved, as the vaginal weight has a strong stabilizing arm which is lengthened when the centre of gravity of the weight member or members is moved further down relatively to the centre of gravity of the vaginal weight.

When, as stated in claim 25, the mass of the vaginal weight is inversely proportional to the diameter of the vaginal weight, a particularly advantageous embodiment of the invention is achieved, it being ensured that a vaginal weight may be used correctly with a view to adapting the use of the individual vaginal weights to the actual physical conditions of a user. This especially applies to women who suffer from a particularly severe degree of incontinence, as vaginal weights may thus be formed with a large diameter, but with a relatively small total mass, thereby enabling the user to retain the vaginal weight in use. This means that an actual therapeutic effect may be achieved using a vaginal weight according to the inven-

tion, even when the user suffers from a particularly severe degree of incontinence.

It is thus possible to use a weight according to the invention in a physiologically advantageous manner, as the use of the largest vaginal weight takes place in the case where the levator gap of the woman is so wide that other diameters merely slip out, without the weight being so great that this in itself causes the weight to slip out.

When, as stated in claim 26, the side face of the vaginal weight has generatrices which are substantially parallel with the longitudinal axis of the vaginal weight, and the side faces form the lower termination of the vaginal weight via a rounded curvature having a radius of curvature which is smaller than the radius of the vaginal weight, a particularly advantageous embodiment of the invention is achieved, as the lower termination of the weight may be formed with an edge which is rounded, thereby allowing the weight to maintain its position in a particularly effective manner.

When, as stated in claim 27, the radius of curvature is smaller than half the radius of the vaginal weight, preferably less than 20% of the radius of the vaginal weight, a particularly advantageous embodiment is achieved, as the lower termination forms a rounded edge, thereby achieving a weight whose outer shape does not cause or induce the weight to be displaced from its position of use.

When, as stated in claim 28, the vaginal weight is conical upwardly, an advantageous embodiment of the invention is achieved, as the weight relative to its shape is easy to insert into the vagina.

Drawing

The invention will be described below with reference to the drawing, in which

fig. 1 shows a lateral view of a vaginal weight according to the invention,

fig. 2 shows the vaginal weight shown in fig. 1, from above,

fig. 3 shows a cross-section of the vaginal weight shown in fig. 1,

fig. 4 shows a further embodiment of the invention,

fig. 5 shows a cross-section of the vaginal weight shown in fig. 4,

figs. 6-11 show lateral views of further embodiments of the invention,

fig. 12 shows a preferred embodiment of the invention,

fig. 13 shows the preferred embodiment of a vaginal weight according to the invention, and

figs. 14 and 15 show further embodiments of the invention.

Example

Fig. 1 shows a lateral view of a preferred embodiment of the invention, where a vaginal weight 1 comprises a lower termination 2 and an upper termination 3.

The vaginal weight 1 additionally comprises a rough surface 6 which is formed by a plurality of grooves 5.

The grooves 5 are formed with a very small depth, just as the grooves are suitably rounded so that they do not irritate or strain touching mucosae.

The lower termination 2 of the vaginal weight 1 is also formed with a relatively distinct edge having a small radius of curvature r, which ensures that the vaginal weight in use maintains the intended position in the vagina.

The upper termination is suitably rounded so that insertion of the weight into the vagina poses no problems.

The weight is additionally provided with an anchorage for a string or the like (not shown) which may be used when the weight is to be retrieved from its position of use.

According to the invention, the weight shown may e.g. be part of a set of weights comprising a plurality of the weights mentioned below, where the upper row indicates the total diameter of the vaginal weight, while the lower row indicates the total mass and possible tolerance of the vaginal weight.

mm	32	30	28	26	26	25	25	24
g ±20%	10	20	30	40	30	40	50	60

It will be appreciated that according to the invention it is possible to construct the contact area 6 formed by the grooves 5 with other types of roughness elements, such as embossings, small knobs, depressions or the like.

It will likewise be appreciated that the roughness area 6 may cover the entire surface of the vaginal weight or parts of it, if this is advantageous in a specific desired facilitation profile.

Fig. 2 is a top view of the vaginal weight shown in fig. 1, it being noted that the weight is rotationally symmetrical.

Fig. 3 shows a cross-section of the vaginal weight 1 shown in fig. 1, it being visible that the weight comprises a weight member 8.

The weight member 8 is so positioned in the weight 1 that the centre of gravity Tp2 of the weight member is considerably below the centre of gravity Tp1 of the vaginal weight.

The weight is additionally mounted by a string 114 at an anchorage point 14 e.g. by embedding.

The string, which is used for retrieving the weight from the vagina when this is no longer to be used, is particularly important in connection with the invention, as the special shape of the lower termination of the weight also constitutes an important facilitation surface when pulling the string 114. In addition, the string ensures in a natural and simple manner that the weight member is inserted with the upper termination uppermost, thereby achieving correct use of the weight.

The weight also has a substantially plane lower termination.

According to the present embodiment, the weight itself may be made of PPO, which is frequently used for injection moulding of medical devices.

An alternative material may e.g. be polyethylene.

The weight members used will preferably be made of stainless steel.

Fig. 4 shows a cross-section of a further embodiment of the invention.

As will appear from the figure, the vaginal weight shown comprises a shell 11 which forms the upper part of a vaginal weight. The shell 11 may be made of PPO or e.g. polyethylene. The shell forms a cavity 12 which is closed by a weight member 13 at its lower termination. The weight member 13 is e.g. made of stainless steel. According to the invention, the weight member may e.g. be snapped, glued or screwed on, e.g. as a bayonet socket.

An advantage of the invention is furthermore that the weight member forms part of the total surface of the vaginal weight and may be inserted separately, thereby making it possible to obtain a maximum lowering of the centre of gravity, and also possible to exchange or adjust the weight according to the use. It is thus possible to change a given weight, just as it is possible to adjust the associated centre of gravity.

The weight member 13 additionally has an anchorage 14 which may be used for securing a string or the like for retrieving the weight from its position of use.

Fig. 5 shows a cross-section of the embodiment of the invention shown in fig. 4, illustrating the specific asymmetrical shape of the shell 15 with respect to the position of the weight member 16 in the weight.

Alternative embodiments may e.g. include making the vaginal weight itself or its shell of a resilient material.

With respect to the so-called rough surface used according to the invention, this may e.g. be made as an adaptive surface relatively to the moisture of the environment of use. For example, for such purposes, it is possible to use exchangeable fibre materials which may be fixed to and removed from the surface of the vaginal weight in a suitable manner.

The rough surface in the form of bosses, grooves or similar embossings or projections may e.g. be made by knurling, and it may also be made during the actual injection moulding of the vaginal weight or its shell by texturing.

It will likewise be appreciated that it is possible to give the vaginal weights suitable anatomical shapes, such as symmetrical or asymmetrical ones, which is moreover more attractive since, as is the case according to the invention, the positioning and the directional orientation of the vaginal weight in use become more distinct.

A further example of such an embodiment of the invention is shown in fig. 6, in which a vaginal weight 20 is formed with a rough surface corresponding to the one shown in fig. 1, a plurality of knobs 21 being superim-

posed on the groove pattern, thereby providing two types of facilitation faces, a macroscopic facilitation face consisting of the knobs 21 and a microscopic facilitation face consisting of the grooves.

Fig. 7 shows a further embodiment of the invention. A vaginal weight 30 is here formed with macroscopic facilitation faces 31, 32 and 33, which each comprise a microscopic rough surface respectively consisting of a studded rough surface 31 and grooved rough surfaces 32 and 33. Two types of facilitation faces are achieved, a macroscopic facilitation face and a microscopic facilitation face, on the same vaginal weight.

Fig. 8 shows a further embodiment according to the invention. A vaginal weight 40 is formed with macroscopic facilitation faces 41 in the form of knobs, which each are formed with a microscopic facilitation face in the form of a rough surface which e.g. consists of a studded rough surface 31.

As a variant of this, the knobs themselves may be smooth, while the rest of the weight may have a microscopic facilitation face.

Fig. 9 shows a further embodiment of the invention. A vaginal weight 50 is formed with a macroscopic facilitation face in the form of a twisted band 51. The band may also be formed with a microscopic facilitation face in the form of a rough surface, which e.g. consists of a studded rough surface.

As a variant of this, the band 51 itself may be smooth, while the rest of the weight may have a microscopic facilitation face.

Fig. 10 shows a further embodiment of the invention. A vaginal weight 60 is formed with a macroscopic facilitation face in the form of longitudinal bands 61. The bands may also be formed with a microscopic facilitation face in the form of a rough surface, which e.g. consists of a studded rough surface.

As a variant of this, the band 61 itself may be smooth, while the rest of the weight may have a microscopic facilitation face.

Fig. 11 shows a further embodiment according to the invention. A vaginal weight 70 is formed with a macroscopic facilitation face in the form of depressions 71 and an annular band 72. As shown, the bands may also be formed with a microscopic facilitation face in the form of a rough surface, which e.g. consists of a grooved surface.

The individual rough surfaces in the above figures may e.g. be exchangeable in the form of rubber bands or faces which may be snapped on, and the facilitation surfaces may moreover be embedded.

Fig. 12 shows a lateral view of the preferred embodiment of the invention, in which the vaginal weight has a lower base part 128 and an upper top part 129. At the bottom the base part 128 is provided with anchoring means 114 for securing the string, which may be used partly for exercising purposes partly for retrieving the weight from the vagina. It is moreover formed with embossings 131 in a relatively coarse structure.

At the top the upper part 129 is terminated with a rounding 133 so that the insertion of the weight into the vagina may be performed without any problems. The side face

and the rounding 133 are formed with a fine-structured facilitation surface.

The top and base parts are separated by a ring-shaped depression 127.

Fig. 13 shows a preferred structure in which the top part 129 is formed with a larger diameter than the base part 128.

The lower termination 126 of the vaginal weight is also formed with a relatively distinct edge having a relatively small radius of curvature r, which ensures that the vaginal weight in use maintains the intended position in the vagina. The lower termination of the upper part - immediately above the depression 127 - is formed with a corresponding termination 126 having a different preferably smaller radius of curvature. Alternatively, the two terminations 126 may be formed with the same radius of curvature.

As will appear from figs. 14 and 15, the vaginal weight shown comprises a shell 11, which is divided into upper and lower parts. The shell 11 may be made of PPO or e.g. polyethylene. The shell forms a cavity 12 which is provided with a weight member 13 at its lower termination. The weight member 13 may e.g. be made of stainless steel. According to the invention, the weight member may e.g. be snapped, glued or screwed on, e.g. as a bayonet socket.

An advantage of this embodiment of the invention is furthermore that the weight member may be selected in a given size and be inserted separately, thereby making it possible to achieve a given lowering of the centre of gravity. It is also possible to change a given weight, just as it is possible to adjust the associated centre of

gravity, as will appear from fig. 14 compared with fig. 15.

The weight member 13 or the shell 11 additionally has an anchorage 14 which may be used for securing a string or the like to retrieve the weight from its position of use.

Fig. 15 shows a cross-section corresponding to the embodiment of the invention shown in fig. 14, in which the weight member 13 occupies a larger part of the cavity 12, so that the downward displacement of the centre of gravity is not as great as in the embodiment shown in fig. 14. Moreover, the total weight has been increased.

Finally, it should be noted that according to the invention it is possible to make a very flexible kit or set of weight components permitting the design of a vaginal weight that may be adapted to the special anatomical conditions which apply to a specific patient.

Such a kit may e.g. be formed by a set of different geometrical shapes having exchangeable rough surfaces in the form of bands which may be snapped on to the weight, or the like, as well as exchangeable weight members.

Such a kit enables a practitioner to make a controlled optimum adaptation of one or more vaginal weights, and also allows current adjustment of weight as well as surface in step with the development that occurs in the course of the treatment.

PATENT CLAIMS

1. A vaginal weight for insertion into the vagina for exercising and examining the striated musculature, comprising upper and lower terminations, c h a r a c t e r i z e d in that the weight comprises a weight member (8; 14) or a plurality of weight members inside the vaginal weight, the centre of gravity of the weight member (Tp2) or the total centre of gravity of the weight members inside the vaginal weight being below the centre of gravity (Tp1) of the vaginal weight without weight member or members, said lower termination of the vaginal weight being formed with an anchorage (14) for securing a string (114).

2. A vaginal weight according to claim 1, c h a r a c t e r i z e d in that the centre of gravity (Tp2) of the weight member or the total centre of gravity of the weight members inside the vaginal weight being at least 10, preferably 25 to 50% below the centre of gravity (Tp1) of the vaginal weight without weight member or members.

3. A vaginal weight according to claims 1-2, c h a r a c t e r i z e d in that the mass of the vaginal weight is inversely proportional to the diameter of the vaginal weight.

4. A vaginal weight according to claims 1-3, c h a r a c t e r i z e d in that the weight has upper and lower parts, and that the upper part is formed with a larger diameter than the lower part and preferably a smaller radius of curvature in the lower termination of the upper part than the termination of the lower part.

5. A vaginal weight according to claim 4, c h a r a c -

t e r i z e d in that the upper part constitutes the greater part of the total length of the weight, and that preferably the upper part has a fine-structured facilitation surface and the lower part has a coarse-structured facilitation surface.

6. A vaginal weight according to claims 1-5, c h a r a c t e r i z e d in that the weight member or members form part of the outer surface of the vaginal weight.

7. A vaginal weight according to claims 1-6, c h a r a c t e r i z e d in that the side face of the vaginal weight has generatrices which are substantially parallel with the longitudinal axis of the vaginal weight, said side faces forming the lower termination of the vaginal weight via a rounded curvature having a radius of curvature (r) which is smaller than the radius of the vaginal weight.

8. A vaginal weight according to claims 1-7, c h a r a c t e r i z e d in that the radius of curvature is smaller than half the radius of the vaginal weight, preferably smaller than 20% of the radius (r) of the vaginal weight.

9. A vaginal weight according to claims 1-8, c h a r a c t e r i z e d in that the vaginal weight is conical upwardly.

10. A vaginal weight according to claims 1-9, c h a r a c t e r i z e d in that the vaginal weight is formed wholly or partially with a rough surface (6).

11. A vaginal weight according to claims 1-10, c h a r a c t e r i z e d in that the rough surface of the vaginal weight is formed wholly or partially by an assembly

of discrete optionally exchangeable embossings (5) and/or projections in the surface.

12. A vaginal weight according to claims 1-11, c h a r a c t e r i z e d in that the rough surface is preferably formed on the side walls of the vaginal weight, while the upper termination (3) and the lower termination (2) of the vaginal weight are formed with a smooth surface.

13. A vaginal weight according to claims 1-12, c h a r a c t e r i z e d in that the rough surface is formed by small bosses in the surface of the vaginal weight.

14. A vaginal weight according to claims 1-13, c h a r a c t e r i z e d in that the lower termination comprises a substantially plane end face (101).

15. A set of vaginal weights having different diameters, c h a r a c t e r i z e d in that that the mass of the individual vaginal weights is inversely proportional to their diameter.

16. A set of vaginal weights according to claims 1-14 having different diameters, c h a r a c t e r i z e d in that the mass of the individual vaginal weights is inversely proportional to their diameter.

17. A set of vaginal weights according to claim 15 or 16, c h a r a c t e r i z e d in that the set comprises at least two, preferably five, vaginal weights having e.g. the following ratio of diameter to total mass:

mm	32	30	28	26	26	25	25	24
g ±20%	10	20	30	40	30	40	50	60

18. A method of treating incontinence by means of vaginal weights, c h a r a c t e r i z e d by inserting into patients, depending on the levator gap width of the patients, vaginal weights having a diameter which is proportional to the levator gap width, but with the mass of the vaginal weight being inversely proportional to the diameter of the vaginal weight.

19. A vaginal weight for insertion into the vagina for exercising and examining the striated musculature of the pelvic floor, c h a r a c t e r i z e d in that the vaginal weight is formed wholly or partially with a rough surface (6).

20. A vaginal weight according to claim 19, c h a r a c t e r i z e d in that the rough surface of the vaginal weight is formed wholly or partially by an assembly of discrete optionally exchangeable embossings (5) and/or projections in the surface.

21. A vaginal weight according to claim 19 or 20, c h a r a c t e r i z e d in that the rough surface is formed preferably on the side walls of the vaginal weight, while the upper termination (3) and the lower termination (2) of the vaginal weight are formed with a smooth surface.

22. A vaginal weight according to claims 19-21, c h a r a c t e r i z e d in that the rough surface is formed by small bosses in the surface of the vaginal weight.

23. A vaginal weight according to claims 19-22, c h a r a c t e r i z e d in that the weight comprises a weight member (8; 14) or a plurality of weight members

inside the vaginal weight, the centre of gravity of the weight member (Tp2) or the total centre of gravity of the weight members inside the vaginal weight being below the centre of gravity (Tp1) of the vaginal weight without weight member or members.

24. A vaginal weight according to claim 23, c h a r - t e r i z e d in that the centre of gravity (Tp2) of the weight member or the total centre of gravity of the weight members inside the vaginal weight is at least 10, preferably 25 to 50% below the centre of gravity (Tp1) of the vaginal weight without weight member or members.

25. A vaginal weight according to claims 19-24, c h a r a c t e r i z e d in that the mass of the vaginal weight is inversely proportional to the diameter of the vaginal weight.

26. A vaginal weight according to claims 19-25, c h a r a c t e r i z e d in that the side face of the vaginal weight has generatrices which are substantially parallel with the longitudinal axis of the vaginal weight, said side faces forming the lower termination of the vaginal weight via a rounded curvature having a radius of curvature (r) which is smaller than the radius of the vaginal weight.

27. A vaginal weight according to claim 26, c h a r - a c t e r i z e d in that the radius of curvature is smaller than half the radius of the vaginal weight, preferably smaller than 20% of the radius (r) of the vaginal weight.

28. A vaginal weight according to claims 19-27, c h a r a c t e r i z e d in that the vaginal weight is conical upwardly.

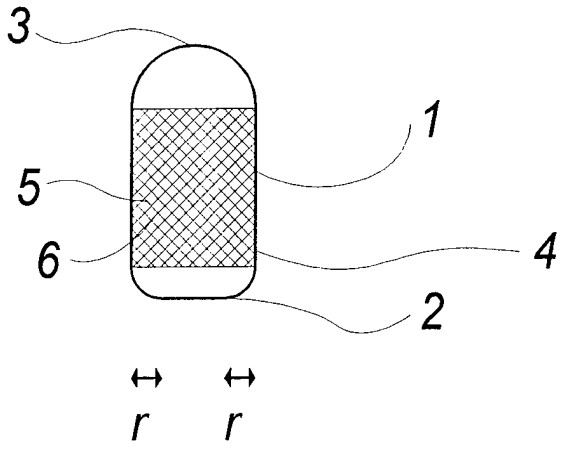


Fig.1

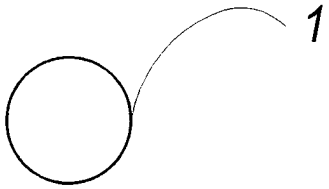


Fig.2

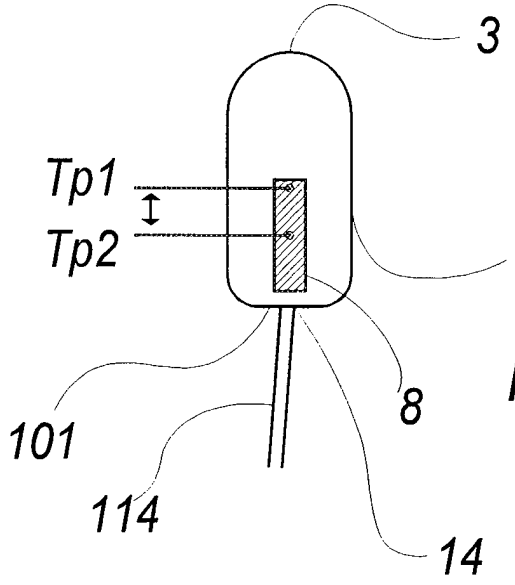


Fig.3

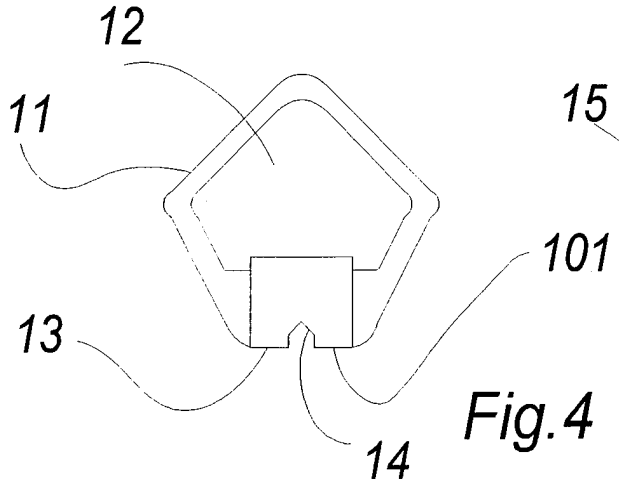


Fig.4

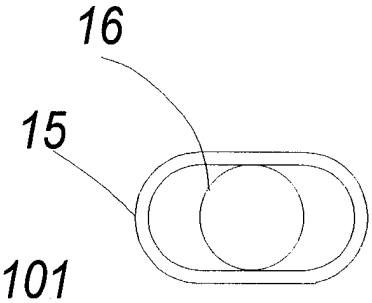


Fig.5

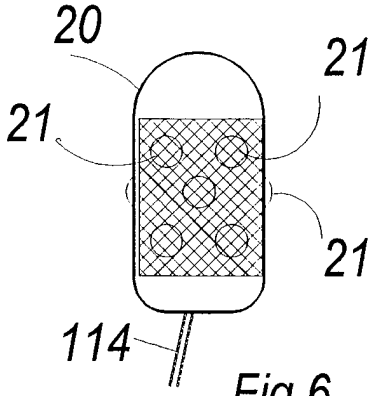


Fig.6

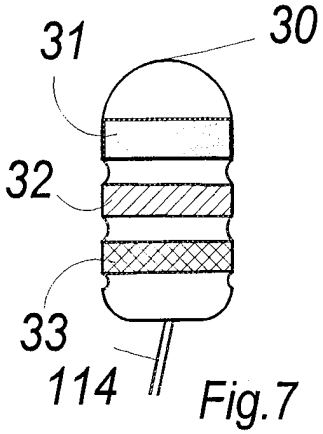


Fig.7

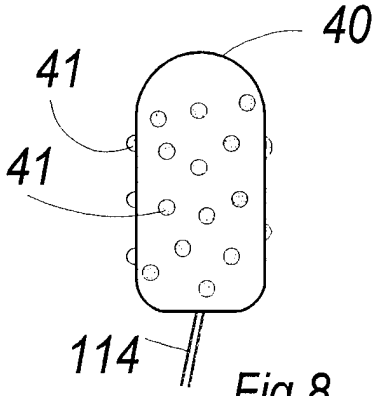


Fig.8

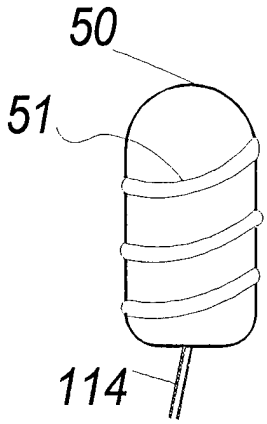


Fig.9

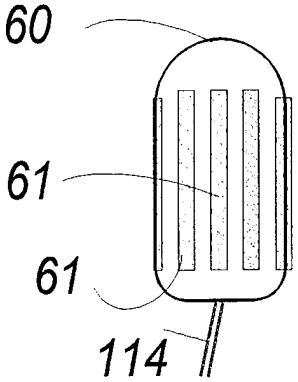


Fig.10

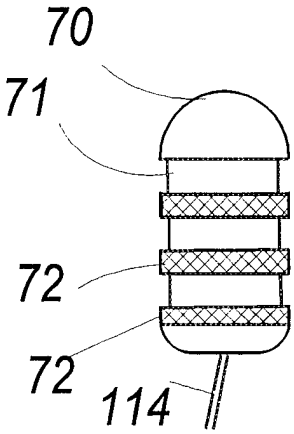


Fig.11

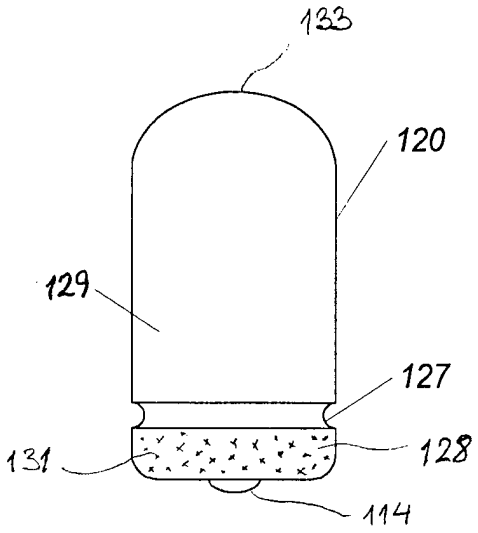


Fig.12

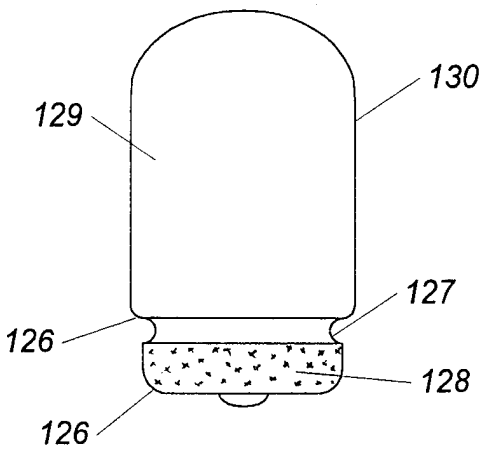


Fig.13

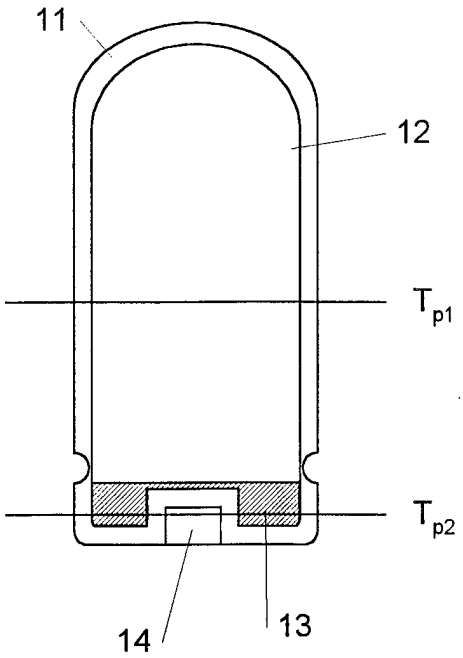


Fig.14

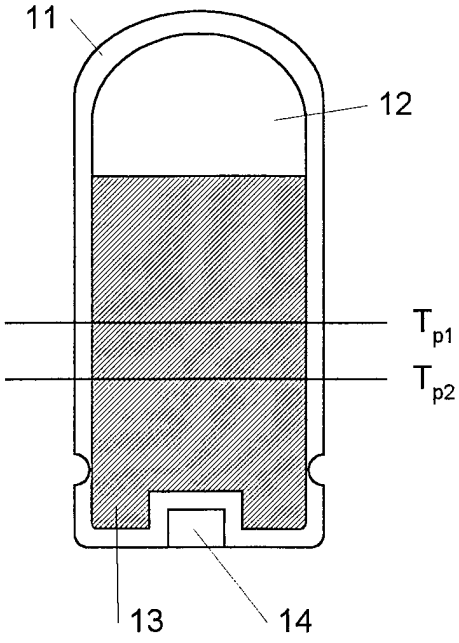


Fig.15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 98/00169

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A63B 23/20
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A63B

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

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0392854 A1 (FIRTH, JOHN), 17 October 1990 (17.10.90) --	1-28
A	GB 2272168 A (ALISON MARY BEAGRIE), 11 May 1994 (11.05.94) --	1-28
A	US 5554092 A (HARPSTEAD ET AL), 10 Sept 1996 (10.09.96) --	1-28
A	US 5407412 A (PLEVNIK ET AL), 18 April 1995 (18.04.95) -- --------	1-28

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 July 1998	23 -07- 1998
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Christer Bäcknert Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 98/00169

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

.../...

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

International application No.
PCT/DK 98/00169

Invention A according to Claims 1-14 and 16-17.
The invention relates to a vaginal weight and a set of vaginal weights, the individual weight including separate weight inlays and wherein the centre of gravity for the inlays themselves are lower than the centre of gravity for the vaginal weight only, without the inlays.

Invention B according to Claims 15 and 18.
The invention relates to a set of vaginal weights and a method of treating incontinence by inserting a vaginal weight, wherein the mass of the vaginal weight is reciprocally proportional to the diameter of the vaginal weight.

Invention C according to Claims 19-28.
The invention relates to a vaginal weight with a roughened or embossed surface.

These three inventions are not so linked as to form a single general inventive concept. There is no such technical relationship among these inventions as stated in PCT Rule 13.2 ("...involving one or more of the same or corresponding special technical features."). Thus, the requirement of unity of invention is not fulfilled.

INTERNATIONAL SEARCH REPORT

Information on patent family members

30/06/98

International application No.
PCT/DK 98/00169

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0392854 A1	17/10/90	SE 0392854 T3	
		CA 2014598 A	14/10/90
		DE 69003150 D,T	05/05/94
		DK 392854 T	07/02/94
		ES 2045800 T	16/01/94
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		WO 9533527 A	14/12/95
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		JP 2724865 B	09/03/98
		EP 0198641 A,B	22/10/86
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		US 4895363 A	23/01/90