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J. S. RITTER ET AL

2,898,913

SURGICAL DEVICE

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FIG. 1.

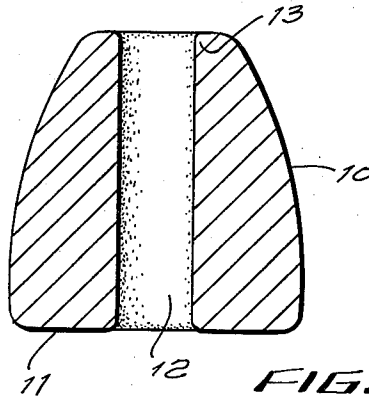
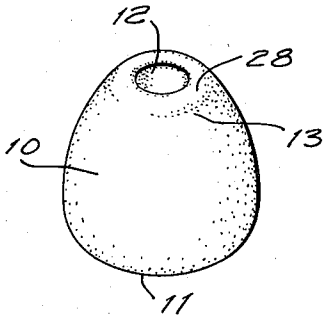


FIG. 3.

FIG. 2.

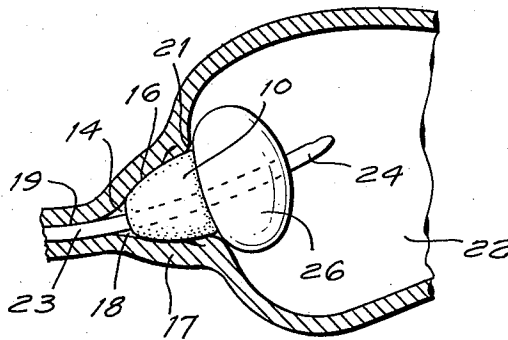
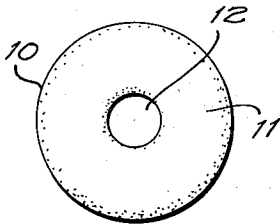


FIG. 4.

INVENTORS
J. SYDNEY RITTER
MILTON FEIER
MYRON PANTZER
BY
A. A. Orlinger
ATTORNEY

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SURGICAL DEVICE

Jay Sydney Ritter and Milton Feier, New York, and Myron Pantzer, Brooklyn, N.Y., assignors to The Panray Corp., a corporation of New York

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3 Claims. (Cl. 128—296)

This invention is that of a surgical device especially applicable in prostatectomy. There inserted in the fossal cavity it serves as a hemostatic and at the same time enhances the general healing process. It need not be operatively removed from where it is inserted as it is digested and absorbed or eliminated.

This surgical device is of generally conical shape and composed of body-liquid-digestible and absorbable starch sponge. It has a substantially cylindrical bore extending relatively centrally through it from its base to its top or narrower end. The various dimensions of this cone are so proportioned that it can readily be fitted into the prostatic fossa with its narrower end nearer the urethra and its base generally as the junction of the fossa and the bladder.

In prostatectomy, among others, two major complications, namely infection and hemorrhage, regularly confronted the surgeon. The seriousness of infection has been reduced in a large measure by the availability of highly effective bacteriostatic agents especially the antibiotics. Thus, the danger of hemorrhage has become the more serious concern to the surgeon in removing the prostate gland. However, the prior need to open the site of the operation more than once, for example, to remove packing used, left considerable concern as to the possibility of infection.

Heretofore, after removal of the prostate gland, to facilitate hemostasis, it was customary to use packing of gauze or material that then had to be removed from the prostatic bed. This gave only immediate control, but the possibility of secondary hemorrhage following pulling away some of the fibrinous coating with the gauze still remained.

Introduction of certain materials that might be left in the operative cavity to disintegrate slowly presented some encouragement. However, they required mechanical packing such as with the balloon catheter to be drawn into or held in the fossal cavity to be effective there. This introduced other disadvantages by the necessary subsequent manipulation, especially since the distended bag of the catheter did not yield by itself to the normal contraction of the fossa as healing progressed. This could actually retard the healing.

Then too, these disintegratable materials presented an additional danger because they left in the prostatic bed a residue that had to be removed. Some of these residues had to be removed surgically. The removal of others needed irrigations with suitable solutions indicated by the circumstances. However, the activity in such procedures mechanically contracted the bladder and similarly activated the sphincters, thereby frequently prematurely removing the clots and causing active hemorrhage.

At times, such particles of residues left in the prostate region might act as seeds for bladder stone formation.

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Moreover, many of the agents there acted as local irritants and caused vesical and urethral spasms with consequent distress.

These various shortcomings and disadvantages are overcome by the use of the surgical device of this invention. This device is more readily understood by reference to the accompanying drawings, in which—

Fig. 1 is a perspective view of the digestible starch sponge cone;

Fig. 2 is a bottom plan view of it;

Fig. 3 is a vertical, transverse view on a plane through the middle of the cone; and

Fig. 4 shows the soluble starch cone inserted into, and held in place in, the fossal cavity.

Referring to the drawings, the complete digestible starch sponge cone 10 (Fig. 1) has its base 11 and a bore 12 extending relatively centrally through the entire height or length of the cone to its top or narrow end 13.

Fig. 4 shows the absorbable cone 10 inserted in and substantially completely occupying, the prostate cavity or fossa 14, with the entire lateral wall 16 of the cone resting against the wall 17 of the fossa. The narrow end 13 of the cone is at the neck 18 of the urethra 19. The base 11 of the cone extends across the neck 21 of the bladder, as if it were a plane closing off the junction between the bladder 22 and the prostate cavity 14.

The shaft 23 of a balloon catheter inserted through the urethra 19 extends through the bore 12 of the cone, and the catheter tip 24 and distended entire balloon or bag 26 project into the bladder with the lower part of the bag in easy contact with the base of the cone.

In addition to its characteristics given in the first two paragraphs of this specification, the flexible character of the fine network of specially prepared starch surrounding the relatively small air spaces in the general fine cellular structure of the absorbable starch sponge gives it a soft texture and easy and resilient compressibility.

When wetted by aqueous liquids, such as body liquids, the absorbable starch sponge cone expands to about one and one-half times its original volume, and often even sometimes more to about twice its original volume. However, even in that expanded state is manifests, to a significant extent, the resilient type of compressibility that it exhibits in its normal size.

The body-fluid-digestible starch sponge surgical cone of the invention is not limited in its general conical shape or as to its specific size. Since the cone has no sharp apex because of the foreshortening due to presence of the generally central bore 12, its narrow end 13 generally is flat. Thereby the surgical cone is relatively frusto-conical and generally with not too wide an annular ring or rim 28 surrounding the bore. Except for the latter, the cellular, sponge-like structure is continuous throughout the rest of the cone. Thereby it has an uninterrupted resilient structure throughout its entire volume.

In its general frusto-conical shape, the lateral walls of the absorbable starch sponge can be relatively straight from its base to its narrow end. If necessary, they may even be slightly concave. However, most generally it is advantageous for the lateral walls to be rather convex so that the cone has the shape of either half of an egg cut by a plane perpendicular to its longer axis, and more advantageously like the narrower half. The base generally is flat, although it can be slightly concave or convex.

As indicated above, this absorbable starch sponge should be of such shape, and its dimensions so proportioned, that it will readily fit into and completely occupy

the prostatic fossa after excision of the gland. Thus, its height generally beneficially is a little greater than the diameter of its base—although both of these dimensions can be equal, where necessary, or even with the diameter of the base just slightly greater than the height.

A convenient mold for a small size body-liquid-digestible starch sponge cone has a diameter for its base of approximately forty-three millimeters, height of around forty-five millimeters, and a diameter of about four to six millimeters across the narrow end, giving the mold a gross volume of forty cubic centimeters. A mold for a large size absorbable starch cone, having a gross volume of one hundred and twenty cubic centimeters, has a diameter for its base of around sixty-seven millimeters, height of about sixty millimeters, and a diameter across the narrow end of approximately twenty millimeters. If needed, there can be prepared an absorbable starch cone from a mold somewhat lesser in volume than the small one just above described, although the cone from the latter is readily suitable for insertion in the smallest fossae generally found after prostate excision. Likewise, there can be prepared also such starch sponge of somewhat greater volume than that made with the largest mold above described, although such cone is readily suitable for the largest fossae found in prostate removals.

Soluble starch cones of any size intermediate this small and large one, for example, a medium sized one, can be prepared from a mold having seventy-five cubic centimeters gross volume with diameter for its base of about fifty-six millimeters, height of around fifty-five millimeters, and diameter across the narrow end of approximately eight to ten millimeters. Another mold of the same gross volume has a diameter for its base of approximately sixty-seven millimeters, height of about fifty millimeters and diameter across the narrow end of around thirty millimeters. The inclined lateral walls of any of these molds for the cones may be either straight or curved, as already indicated.

The absorbable starch cones of the invention can be made by suitable methods involving preparation of a homogeneous starch paste, pouring it into suitable molds, carefully freezing it in the molds under conditions permitting the development of relatively small ice crystals; then thawing the frozen cones, ridding them of their water, preferably after removing them from the molds; for example, by stirring them in a suitable water-miscible, inert organic solvent that evaporates at a temperature below that at which the sponge-like structure of the starch can be destroyed. The water resulting from thawing the cones can also be removed by a combination of mechanical means, such as squeezing without injuring the starch-like structure, with use of the solvent.

The several different shapes and sizes of absorbable starch sponges made from the molds described above, to exemplify, without limiting the invention, are presently preferably prepared by the following detailed procedure, by way of illustration without limitation:

Two hundred and fifty to three hundred grams of cornstarch are mixed in five hundred to seven hundred cubic centimeters of distilled or demineralized water to produce a smooth slurry. In the meantime, the balance of five liters of the water is heated to boiling in a stainless steel or aluminum steam pot. While waiting for it to boil, the starch slurry is strained or filtered through a nylon filter cloth of a texture or mesh to allow the wet starch particles to pass through but to retain dirt particles usually larger than the starch particles (nylon filter cloth, No. MN1601, made by National Filter Media, of New Haven, Conn., is suitable).

The starch slurry is then added, while stirring, to the boiling water. Stirring and heating are continued until the starch gelatinizes to form a homogeneous starch paste suspension. This latter is then poured into suitably sized molds of stainless steel, aluminum or suitable plastic of inverted frusto-conical shape, preferably having

a central upright rod, to produce cones of the various desired sizes and with a central bore. The five liters of starch paste yield about one hundred and twenty-five of the above described small size cones, or sixty-five of the medium size cones, or forty of the large size.

To prevent the formation of a skin over the exposed top surface of the starch paste, that occurs during the subsequent freezing operation, the surface of the paste in the various molds is covered with a close textured cloth, such as nylon. The paste in the molds is allowed to cool to room temperature and then frozen over eighteen to twenty-four hours at a temperature ranging from about minus 5° C. to minus 12° C. The smaller the cone, the higher the temperature, and vice versa, and likewise as to the load in the freezer. Uniform conditions during the freezing develop a uniform texture in the cones.

When the freezing is finished, the molds containing the cones are removed from the freezer. The nylon cover cloths are removed from their tops. The frozen cones are allowed to thaw at room temperature till they can be slid out of the molds, about ten to fifteen minutes. The thus removed frozen starch paste cones are introduced into about five to six and one-half liters of 99% isopropyl alcohol in a stainless steel pail and allowed to thaw out completely at room temperature, about ten to twenty hours, with occasional stirring to permit better diffusion between the water and the alcohol.

The thus thawed out cones which now are very resilient (showing a foam rubber-like resilience) are removed from the diluted alcohol and squeezed free of excess of it. On releasing the squeezing pressure, the deformed cones directly spring back to their conical shape. They are then dried in circulating air at a temperature between room temperature and about 10° higher, over about forty-eight hours.

It is advantageous to make the starch paste from starch granules having an average size of fifteen microns. Usually the starch contains a small portion as small as five microns and likewise a small portion in the upper limit of about twenty-five to about twenty-six microns. While a concentration of starch of from about five to about six percent in the paste suspension yields sponge cones with the most effective texture, a lower concentration preferably not under about three percent can be used. With such lower concentration, quick freezing of the starch suspension is beneficial. A higher concentration to about nine or ten percent can be used, but requires a still slower freezing rate to develop a suitable texture. Instead of nylon, the starch slurry can be filtered through any other preferably lintless filter cloth. Any other good quality filter cloth can be used.

The starch paste suspension can be prepared by any other process that does not destroy the texture or absorbability of the starch. For example, all the starch can be agitated in the entire quantity of water under pressure cooking, say, at between about five to ten pounds per square inch and possibly up to about fifteen pounds per square inch, or equivalent to about 115° C., for a maximum of about fifteen minutes.

Instead of covering the hot paste in the molds with nylon, any other close textured fabric can be used to separate the suspension from close contact with the atmosphere, for example, rayon, Orlon, Dacron, or any other substantially lintless fibre. Also, advantageously effective is a non-porous film such as cellophane or any other that could not impart to the paste any substance that might be toxic to the system if it remained in the starch cone. In place of such organic flexible film, a metal foil, such as aluminum foil, can be used.

Instead of allowing the starch paste in the molds to cool to room temperature before freezing it, the paste in the molds can be placed in a freezer held initially at about 1° C. or some other temperature just slightly above freezing. The paste, after reaching such tem-

perature, then can be frozen at a lower temperature within the above indicated range. Generally, the slower the freezing rate (i.e. the higher the freezing temperature), the coarser will be the texture in the finished starch cone, and vice versa.

Generally, the volume of isopropyl alcohol used in thawing the above described batch of frozen starch paste cones gives a final dilution of about fifty to sixty percent of this alcohol. Instead of this one, any other suitable water-miscible and easily soluble solvent inert to the starch can be used, for example, absolute ethanol. Instead of stirring the cones in the solvent, the liquid can be circulated around and through the cones. Instead of removing the excess liquid from the cones by squeezing, they can be centrifuged.

If too little of the water-miscible solvent is used in the thawing out so that thereby some of the ice or water is left behind in some cones, they are left water-logged. Then upon subsequent processing for removal of excess liquid, the cone has a dough-like consistency and lacks the necessary resilience. If too much of the solvent is used, the starch cones lose their natural water of hydration and are hard and powderable.

As the mold used in the detailed examples had no upright central rod to form the central bore in the cone, the bore 12 is produced by drilling through the center of the dry cone a bore about ten centimeters in diameter. The bore can be produced without this drilling step, by using a mold having a central rod projecting upright from the bottom to the top of the mold.

The moist cones, on drying, shrink to from about three-quarters to about one-half of their original volume. Thus, a finished dry cone from a forty cubic centimeter mold has a volume of about twenty cubic centimeters; one from a seventy-five cubic centimeter mold has a dry volume of forty-five cubic centimeters; and the one hundred and twenty cubic centimeter mold produces a seventy-five cubic centimeter dry cone. The dry cones generally lack the resilience on compression.

The unique features of the body-fluid-digestible, soluble starch sponge, especially with the central bore, that enables it to provide fundamental advantages in open prostatectomy are evidenced in the following description of that use made of it:

After the prostate gland has been excised and the warm, moist gauze packing inserted into the fossa to stem bleeding is removed, a balloon catheter is inserted through the urethra into the bladder and then guided through the incision made for the open operation. The tip, bag and shaft of the catheter below the bag, are wiped dry. The catheter is then drawn through a cone of suitable size, by inserting the catheter tip through the narrow end of the cone and the cone is moved down over the catheter to a point below the bag with some of the shaft showing between the cone and the bag. The bag is partially inflated.

The cone is then guided down over the dry catheter shaft through the dry bladder and, with a dry gloved hand manually placed into the prostatic fossa with the base of the cone at the bladder neck. The catheter is then drawn back through the urethra to bring the lower end of the bag in light contact with the base of the cone. The bag is then inflated, if necessary, only sufficiently to be able to hold the cone in place, to about thirty cubic centimeters.

Very slight traction is placed on the catheter as it is taped down. Strong traction on the catheter should be avoided to avoid injuring the cone and forcing its base away from the bladder neck where it serves most to control the bleeding.

The distended bag need, and should, not be used to pull the cone into the described position nor as a means of packing the cone into the fossa. The bag and catheter should be left to protrude wholly within the bladder with the fossa occupied only by the cone.

As the cone rapidly absorbs the blood, it expands to about fifty percent over its original volume, thereby exerting immediate and resilient compression on the venous system.

5 Except for the usual drain, the incision into the bladder is closed. The compressibility, and ultimate complete digestion and absorbability by the body fluids, of the cone avoids any interference with the normal contraction of the fossa and the healing process.

10 The vast multitude of cell-like spaces of the starch cone enhance hemostasis by exposing an extensive surface area to the blood that is shed. This accelerates clotting thereby damming blood flow. Apparently, the breakdown of the starch into sugar products thus released in high concentration all over the surface of the cone causes agglutination of the blood and facilitates the clotting.

Any medicament needed to be applied in the fossal cavity after the prostatectomy can be incorporated in the digestible starch cone of the invention, so long as the medicament does not destroy the cone's capacity to be digested by contacting body liquids and does not react with the cone to produce a substance injurious to the contacted tissues.

Any such medicament that is water-soluble and stable at an elevated temperature under the boiling point of water and insoluble in the aqueous solution of organic solvent used in the drying step, can be incorporated in the suitably required concentration in the step of preparing the starch paste.

Alternatively, if the medicament is soluble in the water-miscible organic solvent used for removing the water resulting from the thawing, it can be incorporated at a convenient stage of that step by inclusion in the solvent in a suitable concentration to leave the necessary amount of medicament in the dry cone. The incorporation of the medicament is not restricted to any particular method such as just indicated. Any method that enables incorporation of the medicament without injury to it or the starch can be used.

There can thus be incorporated into the cones of the invention, for example, a sulfa drug as sulfamerazine, sulfadiazine or sulfathiazole, advantageously as an alkali metal salt as the sodium salt, or an applicable antibiotic, or any non-toxic quaternary ammonium salt, or any other suitable medicament.

While the invention has been described in detail in relation to certain specific embodiments of it, various substitutions or modifications can be made within the scope of the appended claims which are intended also to cover equivalents of the various specific embodiments.

What is claimed is:

1. A surgical device effective at least to enhance hemostasis in the prostatic fossal cavity after prostatectomy and composed essentially of starch sponge that swells and becomes resilient on absorbing an aqueous liquid, being relatively conically shaped and so proportioned relatively fully to occupy the fossal cavity after insertion therein and swelling on absorbing liquid there, and capable of yielding by itself to the normal contraction of the fossa as healing progresses, said device being digestible by the body liquids contacting it thereby to avoid the need to open any incision for its removal.

2. A surgical device effective at least to enhance hemostasis in the prostatic fossal cavity after prostatectomy and composed essentially of starch sponge that swells and becomes resilient on absorbing an aqueous liquid, being generally frusto-conically shaped with a relatively circular bore extending longitudinally axially through it from base to narrow end to permit snug passage therethrough of a catheter shaft, and so proportioned relatively fully to occupy the fossal cavity with its base at the bladder neck after insertion in the fossa and swelling on absorbing liquid to exert resilient pressure on the wall of the fossa, and capable of yielding by itself to the normal contraction of the fossa as healing progresses, said device

being digestible by the body liquids contacting it thereby to avoid the need to open any incision for its removal.

3. A device as claimed in claim 2, composed of corn starch sponge and in the dry state occupying a total overall volume of from about twenty to about seventy-five cubic centimeters.

References Cited in the file of this patent

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 2,898,913

August 11, 1959

Jay Sydney Ritter et al.

It is hereby certified that error appears in the printed specification of the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 5, line 27, for "centimeters" read -- millimeters --; line 41, for "startch" read -- starch --; line 42, for "ables" read -- able --; column 6, line 16, for "agglutination" read -- agglutination --.

Signed and sealed this 1st day of March 1960.

(SEAL)

Attest:

KARL H. AXLINE

Attesting Officer

ROBERT C. WATSON
Commissioner of Patents