Jan. 23, 1968 P. CREAGER, JR., ET AL 3,364,928

SURGICAL DRAPE

Filed Sept. 6, 1966 3 Sheets-Sheet 1

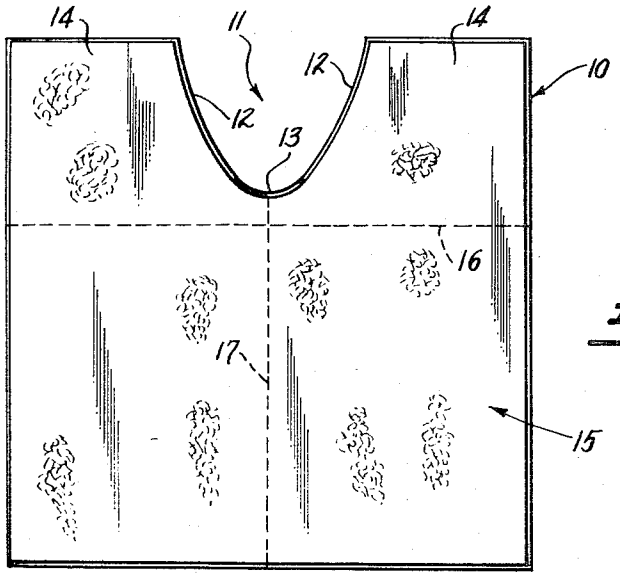


Fig. 1.

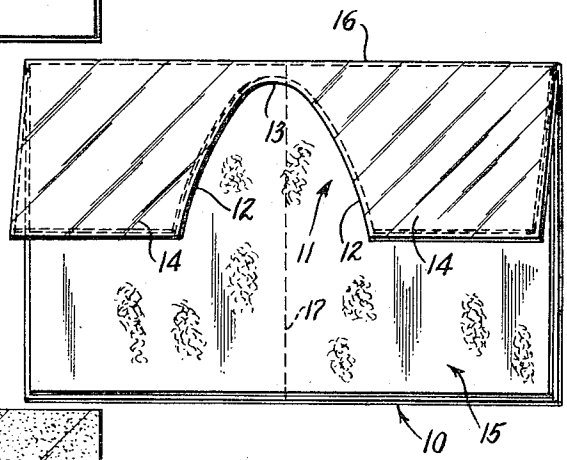


Fig. 2.

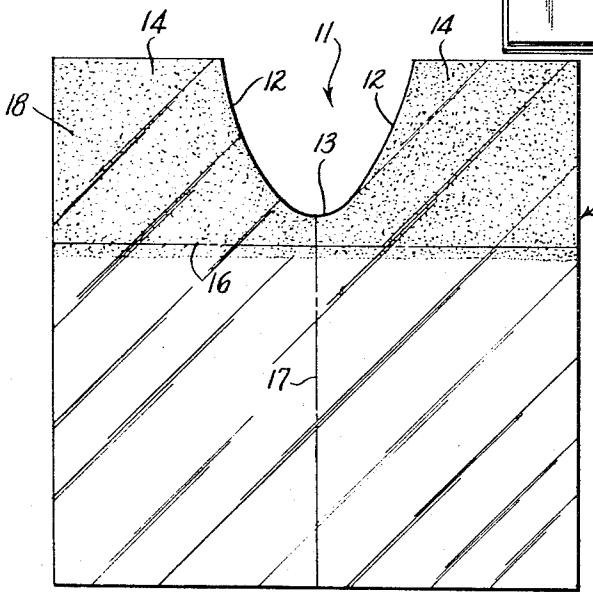


Fig. 3.

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SURGICAL DRAPE

Filed Sept. 3, 1966 3 Sheets-Sheet 2

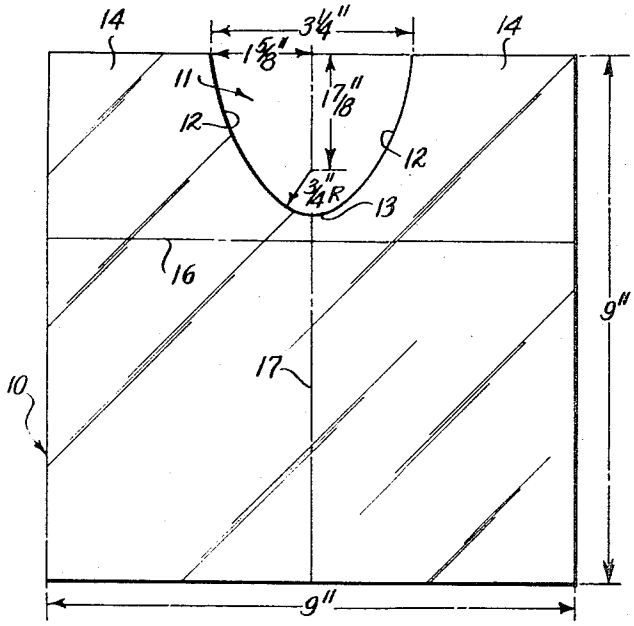


Fig. 4.

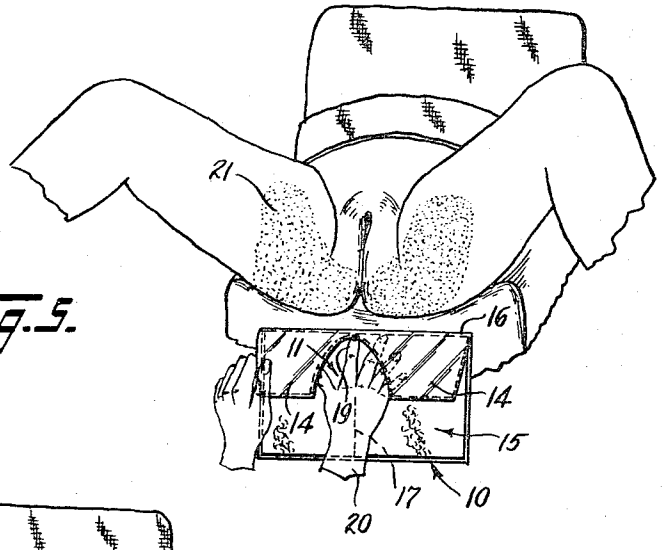
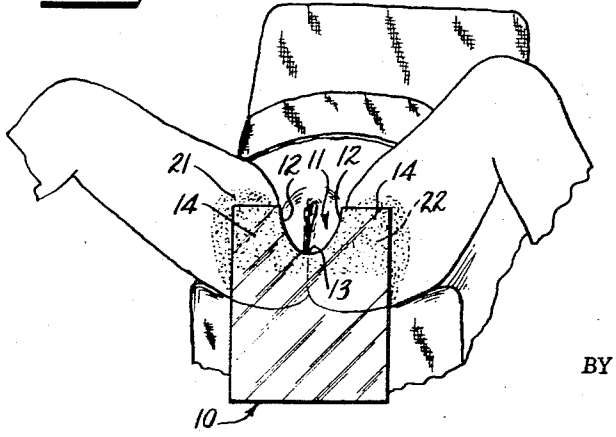


Fig. 5.

Fig. 6.



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SURGICAL DRAPE

Filed Sept. 8, 1966 3 Sheets-Sheet 3

Fig. 7

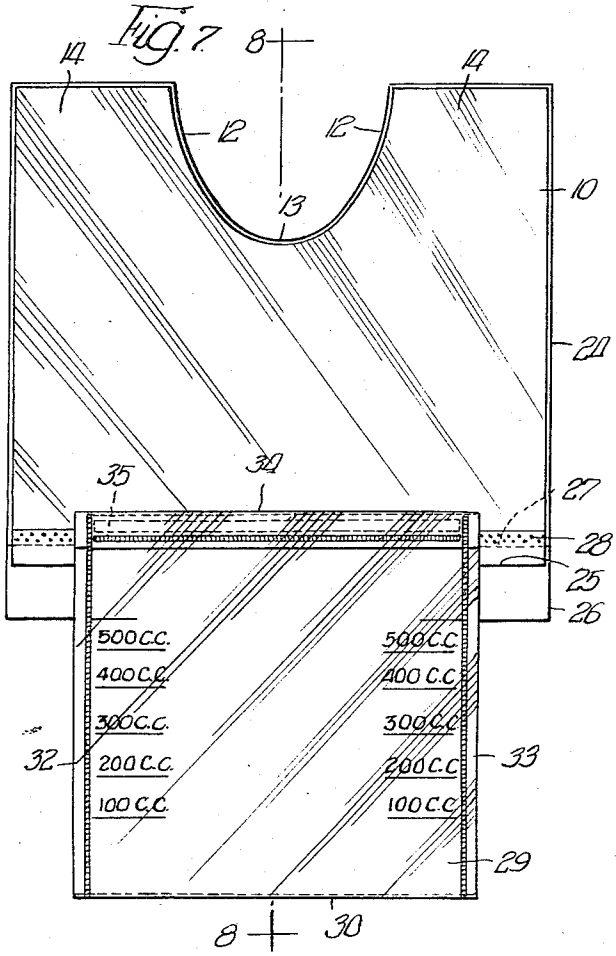


Fig. 8

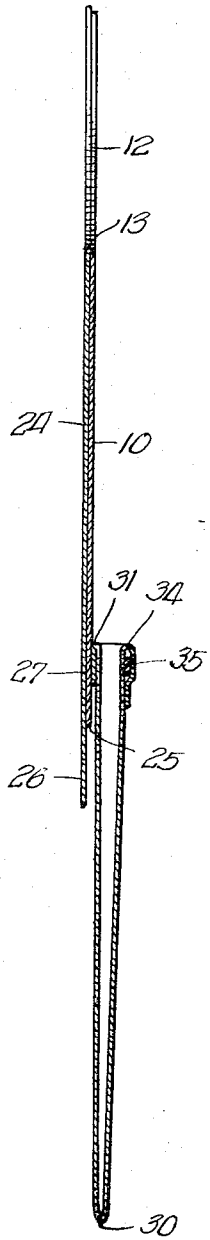
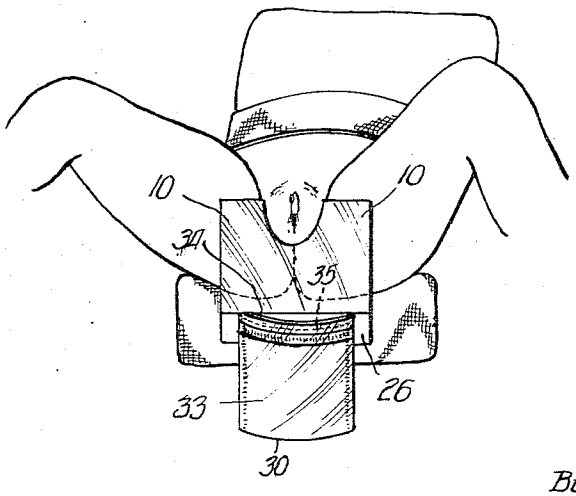


Fig. 9



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3,364,928

SURGICAL DRAPE

Paul Creager, Jr., and Thomas N. Zinck, Dayton, Ohio, and Louis Pereny, deceased, late of Dayton, Ohio, by Evelyn Pereny, executrix, Dayton, Ohio, assignors, by mesne assignments, to Parke, Davis & Company, Detroit, Mich., a corporation of Michigan

Continuation-in-part of application Ser. No. 325,733, Nov. 22, 1963, now Patent No. 3,288,135, dated Nov. 29, 1966. This application Sept. 8, 1966, Ser. No. 578,100
2 Claims. (Cl. 128—132)

The present invention relates to a bifurcated plastic surgical drape useful in connection with operative procedures in the vaginal area and child deliveries. This is a continuation in part of our application Serial No. 325,733 filed November 22, 1963, now Patent No. 3,288,135.

During any surgical operation conducted in the vaginal area, and especially during child delivery, contamination of the mother or child from the anal area, including any fecal extrusion which may occur during the operation, is a serious problem. Especially in the case of a child delivery, a problem arises in adhesively securing a drape around the vaginal area which will adequately tolerate the extensive expansion in the vaginal area which occurs during delivery without the drape tearing or becoming separated from the skin so as to destroy asepsis. Also, where bleeding is involved in surgical procedures it is important to determine the amount of blood lost so that it can be determined if a transfusion is required.

According to the invention, we provide a bifurcated plastic drape adhesively secured to the patient and which extends across the space between the vaginal and anal areas. The bifurcated configuration of the drape tolerates the extensive expansion in the vaginal area which occurs during delivery without destroying asepsis. The drape is useful also in surgical procedures, and includes a pouch or pocket opening in the upper face as applied, to collect blood emanating from the vaginal area. By calibrating the pouch in hundred cubic centimeter units the amount of blood lost can be visually determined. The provision of the bifurcated structure of the drape carrying the pouch is preferred.

The surgical drape of the present invention comprises a sheet of flexible plastic material, preferably a clear vinyl film, having a central arcuate cut-out portion in one end thereof defining a pair of upper end portions (the bifurcation) adapted to be adhesively secured to the thighs of the patient adjacent the buttocks, the arcuate bottom of the cut-out portion being adapted to be adhesively secured across the space between the vaginal area and the anal area. When the thighs are referred to, it should be understood that the upper end portions may also, in part, be secured to part of the perineal area and, indeed, off center application of the drape is also contemplated.

The curved configuration of the cut-out portion in combination with the upper end portions is especially designed to tolerate the extensive expansion in the vaginal area during delivery without tearing the drape and without imposing non-uniform stresses on the edges of the cut-out portion of the drape which causes the drape to be separated from the skin. As will be evident, the tearing and separation referred to are undesirable since either of them will destroy asepsis. The cut-out portion of the drape is defined by a curved bottom smoothly joined with two side portions which flare outwardly from the cut-out portion to the upper edge of the drape.

The pouch is formed by two sheets of transparent material sealed along their edges and open at the top, and the pouch is applied adjacent the lower end of the drape. A preferred mode of attachment is to fold over one edge at

the opening and cement it to the drape. The other edge of the opening may be hemmed and receives a stiff stay of wire, stiff plastic, or similar material. Thus, when the drape is applied the stay causes the mouth of the pouch to gape.

A further feature of the present invention is the utilization of a relatively stiff liner of suitable material approximately the same size and shape as the drape which facilitates the handling and application of the drape which, without the liner, is difficult to handle and apply due to the flexible and limp nature of the plastic material especially where the drape is coated one one side with an adhesive. To facilitate convenient and accurate application of the drape, it is desirable that the drape be combined with the liner to facilitate application of the drape to the patient with one hand while the other hand holds the drape, the paper liner, or the combination of drape and paper liner. For this purpose it is preferred to provide a stiff border more or less permanently attached adjacent one edge with the liner terminating adjacent thereto.

The invention will be more fully understood in connection with the accompanying drawings which illustrate examples, and in which:

FIG. 1 is a plan view showing an embodiment of the invention;

FIG. 2 shows the embodiment of FIG. 1 in a folded position;

FIG. 3 shows a drape with adhesive applied to a portion of its surface;

FIG. 4 shows the preferred dimensions of the cut-out portion of the drape;

FIG. 5 shows a mode of applying the drape to a patient;

FIG. 6 shows the drape in position on a patient;

FIG. 7 is a view similar to FIG. 1 of a modification;

FIG. 8 is a cross section taken on line VIII—VIII of FIG. 7; and

FIG. 9 shows the modified drape in position on a patient.

Referring more particularly to FIG. 1 which shows a preferred construction, the drape **10** is generally rectangular, preferably square, and formed from a single sheet of limp and flexible membrane, for example, polyvinyl chloride plastic material. Cut-out portion **11** is formed in the upper end of the drape **10** and is defined by the flared out sides **12** joined at the bottom by a curved or arcuate bottom **13** which merges with the flared out sides **12** more or less tangentially. The sides **12** of the cut-out portion **11** define the inner edge of two upper end portions **14** which, together, form the bifurcated upper end which is adapted for adhesive securement to the patient.

Overlying the configurated plastic drape is a stiff liner **15** of paper or other suitable material which is preferably the same size and shape as the drape but, for clarity of representation, is shown in a modified form in which the liner is of slightly smaller size. This stiff liner facilitates handling of the drape as has been noted.

As a feature of the invention, the stiff liner **15** is temporarily and removably adhesively secured to the upper or outer surface of the drape **10** (that is, the surface not attached to the patient) at least over the upper portion thereof. This temporary securement is easily achieved by a thin coating of wax applied to the contacting surface of the paper liner. The wax coated paper liner is then lightly heat-sealed to the drape. This temporary securement is not shown in the drawing because of the difficulty of illustration.

The drape and the paper liner are preferably folded in a particular manner to facilitate application of the drape to the patient. As can be seen in FIGURES 1 and 2, the drape and liner are folded along the line **16** which parallels the upper end of the drape and extends across

the drape a short distance beneath the bottom **13** of the cut-out **11** so that the paper liner is between the plastic drape in the folded state as can be seen in FIGURE 2. This folded structure is highly useful in the application of the drape to the patient as will appear more fully hereinafter. The drape may, optionally, be folded vertically along line **17** for packaging purposes, or may be rolled as hereinafter described.

Various techniques, not shown, may be used to facilitate separation of the paper liner after the drape has been adhesively secured to the patient including tabs, upward folding of the lower end of the drape **10** beneath the downwardly folded upper end of the drape **10** shown in FIG. 2, inwardly folded corners, etc.

The drape of the invention is adhesively secured to the patient with a pressure sensitive adhesive which holds the drape securely in place. Adhesives specially adapted for application to the patient are described in United States Patent 3,090,694.

An adhesive may be applied to the bottom or patient contacting surface of the drape during its manufacture or just prior to its use. Appropriate areas for adhesive application are shown in FIGURE 3 and identified by numeral **18**. In the embodiment wherein a pressure sensitive adhesive is applied to the drape during manufacture, it is protected by a relatively non-adherent coextensive stiff liner wihich is removed during or just prior to application of the drape to the patient. In such embodiment the liner **15** may be omitted, or may be applied only to the bottom or patient contacting surface of the drape instead of the top surface of the drape.

When the adhesive is applied directly to the patient, it is desirably sprayed onto the region where the thighs join the buttocks and across the space between the vaginal and anal areas. The adhesive is applied uniformly so that the upper portion of the drape **10** is uniformly adhered to the patient in the areas which have been noted. These areas are pictured in FIGURE 5 and identified by numeral **21**. Application of the adhesive to the patient avoids any problem of inadvertent adhesion prior to application.

The adhesive is desirably applied as an aerosol spray since spray application is quite convenient as is disclosed in United States Patent 3,090,694. When using spray application, the vagina is preferably sealed off by the insertion therein of a surgical sponge or like material.

The application of the drape is preferably accomplished using the folded structure previously noted to assist guiding the drape to its proper location with one hand. This is shown in FIGURE 5, the forefinger **19** of the hand **20** being placed at the center of the drape at the fold line **16** to facilitate accurate placing of the drape. The thumb and the other fingers remain beneath the fold to support the drape and the other hand may be used, as shown, to hold and position the combination of drape and liner.

The applicator directs his forefinger to a point beneath the vagina and presses the drape to adhesively secure it at this point. The hands are then moved upwardly to smoothly adhere the end portions **14** on the thighs adjacent the buttocks. The areas covered by adhesive on the patient are shown by shading and identified by numerals **21** in FIGS. 5 and 6.

The paper liner **15** assists in this operation by making the plastic drape stiff enough for easy handling. It can be readily understood that the paper liner is preferably not larger than the drape itself as the liner would then adhere to the adhesive on the patient. The paper liner is pulled away from the drape and discarded once the drape is adhered in its desired position.

FIG. 6 shows the drape in position on the patient. As is shown by the shaded portion **22**, the adhesive secures the upper bifurcated portion of the drape completely to the patient's thighs, buttocks and perineal area to thereby aseptically wall off the anal area.

The cut-out portion **11** of the drape **10** is shaped, as previously indicated, to include outwardly tapering side margins **12** and an arcuate or curved bottom **13** which merges therewith. Of particular importance to optimum performance is the omission of sharp corners provided by the curvature of the bottom **13** which can vary from a curve corresponding to a circle having a radius from ½ inch to 1 inch, but which is preferably about ¾ inch. While circles are referred to, it is not essential that the curve used correspond precisely with the arc of a circle, though this is preferred. The outwardly flaring side margins **12** are also desirably curved so that the entire cut-out portion **11** resembles one-third of an ellipse severed across its shorter diameter. The depth of the cut-out portion **11** is roughly the same as its width where it joins the upper margin of the drape **10**. While overall dimensions are not of prime significance, these dimensions of depth and width of the cut-out **11** may vary between 1½ inch to 4 inches, the particular dimensions preferred being based upon the size and shape of the average patient. A preferred cut-out depth is 2⅝ inches and a preferred width at the top of the cut-out is 3¼ inches. The preferably curved side margins **12** of the cut-out **11** are preferably curved to correspond with a circle having a radius of 3¼ inches with its center at the opposite juncture of the cut-out portion and the upper margin of the drape. Preferred dimensions for the cut-out are shown in FIGURE 4.

In the modification shown in FIGURES 7 through 9, corresponding parts are designated by like reference numerals. The plastic sheet **10**, constituting the drape, is coated on its under face with a suitable pressure sensitive adhesive, and a stiff backing sheet **24**, of paper or the like (previously treated with a silicone or similar material to reduce adherence) covers the adhesive face. The backing may be slightly wider than the drape and may extend slightly beyond the bifurcated end as shown. The lower end of the drape is indicated at **25**. At this end it is permanently attached to a handling member, preferably in the form of a stiff sheet **26**. Adjacent the end **27** of the sheet **24**, it is coated with wax or similar material to prevent adherence to the sheet **10** as indicated at **28**. Thus, to peel off the drape **10** the handle sheet **26** is located at the bottom and grasped by one hand and the end **27** is grasped by the fingers of the other hand with the adhesive coated side facing the patient, and is pulled away from the drape until the bottom of the notch is uncovered. The drape then may be touched to the buttocks so as to free one hand, and then the drape may be pressed against the perineum and smoothed into place while the rest of the backing is peeled off. This construction conveniently may be packaged by rolling it and sealing the roll in an outside envelope or wrapper.

The pouch **29** consists of a sheet of plastic folded double at its bottom at **30**, and one edge is folded over at **31** and attached to sheet **10**, as by heat bonding. The edges **32**, **33** also may be heat bonded together. The edge **34** is folded over and heat bonded to form a casing which contains a stay **35** of wire, stiff plastic or similar material, and the ends of the casing are heat bonded to seal the casing. The pouch **29** is graduated, as for example, in 100 cubic centimeter units.

As shown in FIGURE 9, when the drape is attached to the patient, the pouch is located to receive any blood discharged from the vaginal area, and it is possible to determine how much blood has been lost merely by visual inspection. This serves as a guide to determine if a blood transfusion is indicated. The drape protects the speculum handle from contamination during hysterectomy and the pouch may serve as a receptacle for holding tissue specimens taken during diagnostic procedures. While it is preferred to utilize a rectangular drape, variations in shape of the lower portion of the drape may be made such as rounded, triangular, trapezoidal, etc.

The invention is not limited to the specially folded

structure as the drape may also be provided in roll form with or without a paper liner.

Since the drape is utilized in surgical operations, each drape is preferably separately packaged under sterile conditions to provide an immediately usable product.

The invention is defined in the claims which follow.

We claim:

1. A vaginal drape comprising a sheet of pliable plastic material having its upper end configurated to define a central arcuate cut-out portion separating a pair of upwardly extending upper end portions, the said cut-out portion being defined by a curved bottom smoothly joined with outwardly flaring sides defining the inner edges of said upper end portions, said upper end portions being adapted for adhesive securement around the vagina to the thighs of a patient adjacent the buttocks with the arcuate bottom of said cut-out portion being adapted to be adhesively secured to the perineum of the patient, and one surface of said drape being temporarily secured to a backing sheet and the reverse surface of the drape having an upwardly open gaped pouch attached adjacent the lower end of the sheet of plastic material.

2. A vaginal drape comprising a pliable thin plastic sheet coated on its surface with a pressure sensitive adhesive, a liner removably adhesively secured to one face thereof, one end of the plastic sheet having an arcuate notch defined by outwardly flaring side margins therein of such dimensions that upon adhesively attaching the sheet at the base of the notch to the perineum, the sides forming the notch are adhesively attached to the thighs of the patient adjacent the buttocks so as to cover the anal section and isolate it from the vaginal area, an upwardly open plastic pouch attached to the other end of the plastic sheet, and a reinforcing member secured to the open end of the pouch to cause the pouch to gape open to serve as a receptacle for holding tissue specimens taken during diagnostic procedures.

References Cited

UNITED STATES PATENTS

2,715,902	8/1955	Shaffer et al.	128—132
3,251,360	5/1966	Melges	128—132
3,260,260	7/1966	Questel	128—132

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