Aug. 29, 1967 R. J. TREWELLA ETAL 3,338,019

METHOD OF PACKAGE MANUFACTURE

Original Filed Aug. 22, 1962 3 Sheets-Sheet 1

Fig. 1.

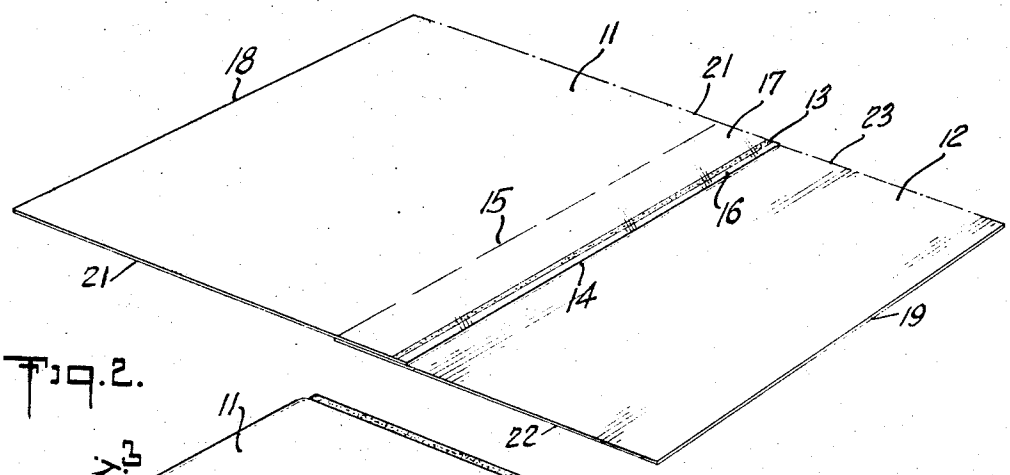


Fig. 2.

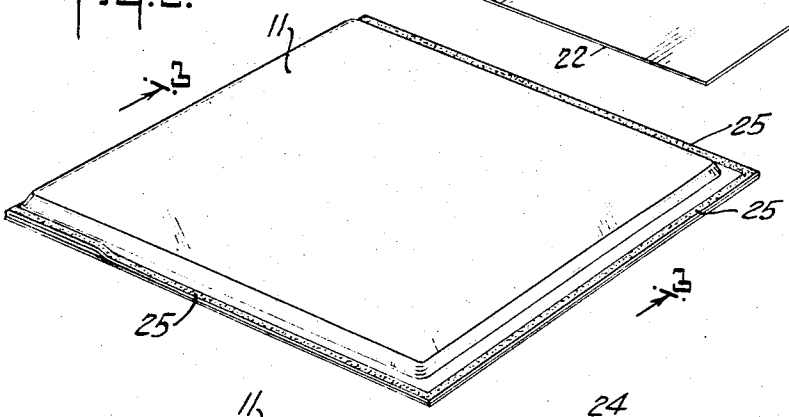
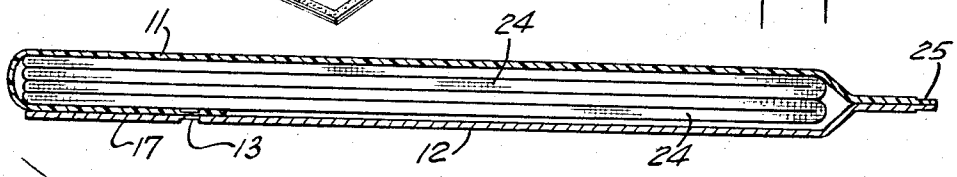


Fig. 3.



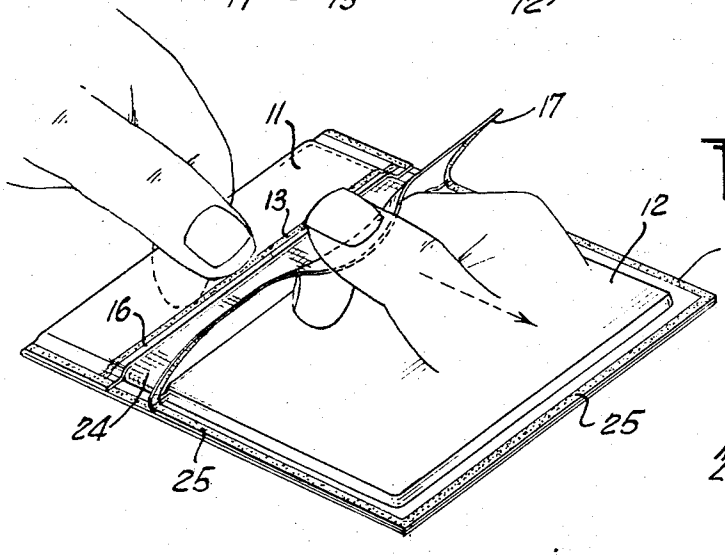


Fig. 4.

INVENTORS
ROBERT J. TREWELLA
LAWRENCE JERZEWSKI JR.

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Fig. 5.

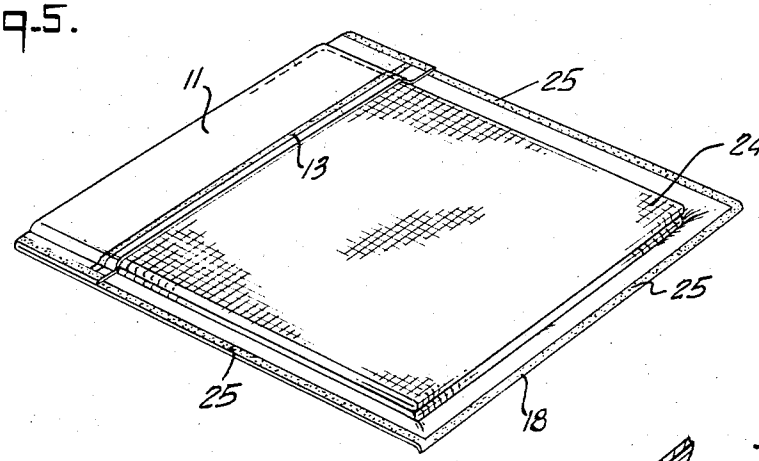


Fig. 7.

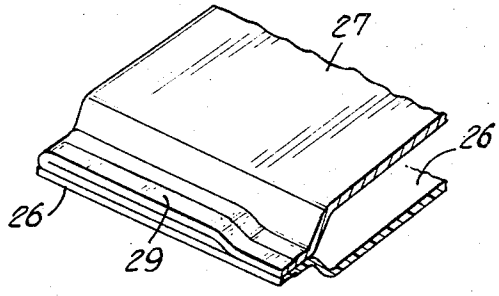
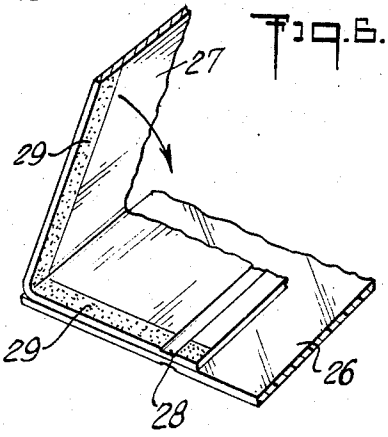


Fig. 6.



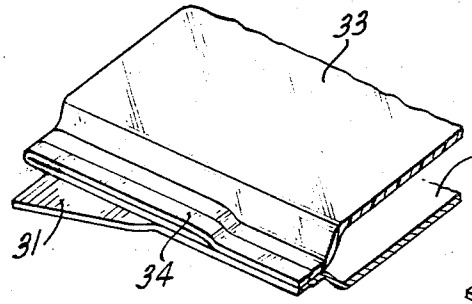
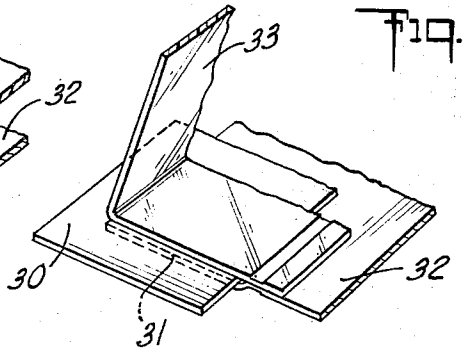


Fig. 9.

Fig. 8.



INVENTORS
ROBERT J. TREWELLA
LAWRENCE JERZEWSKI JR

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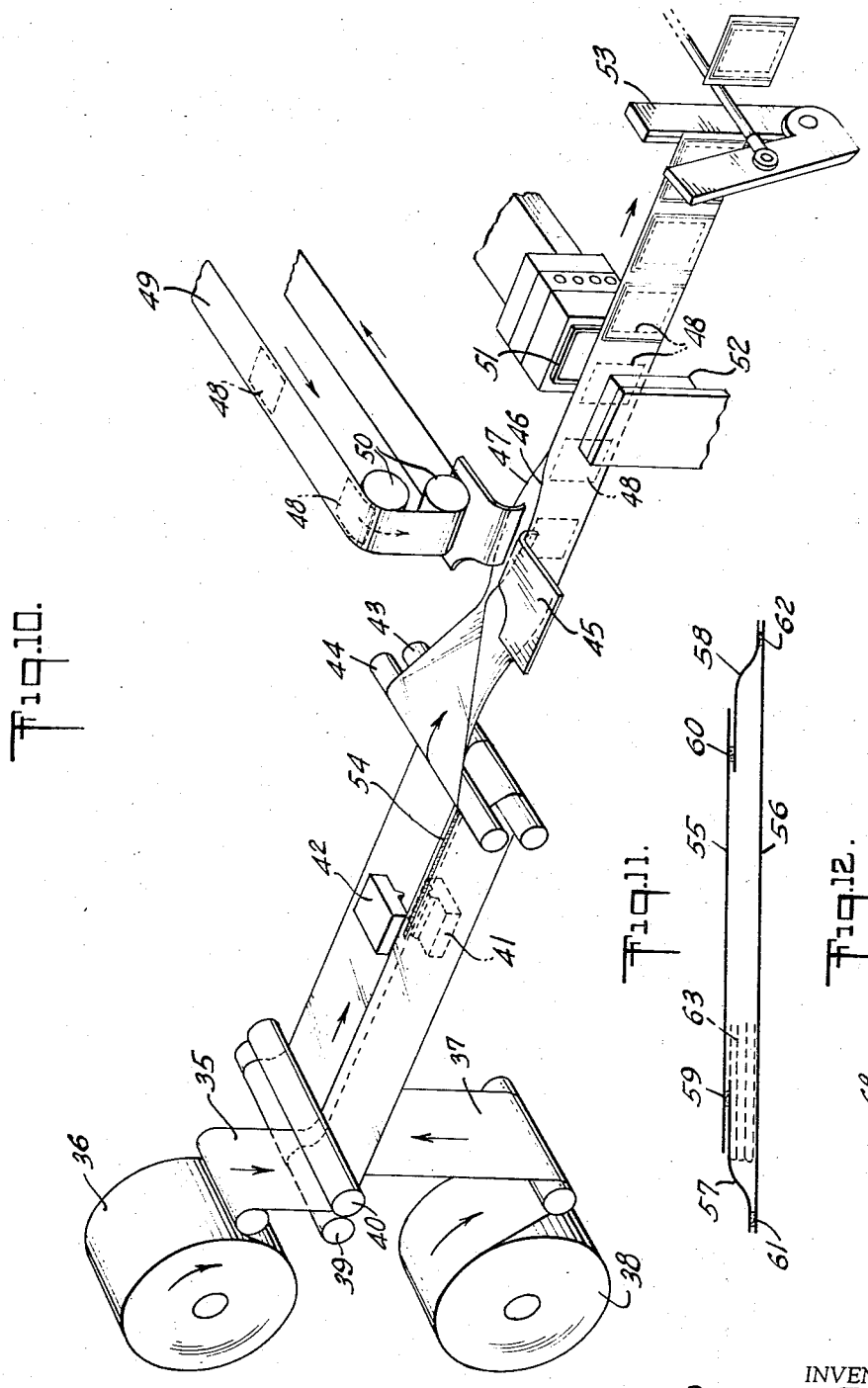

Fig. 10.

Fig. 11.

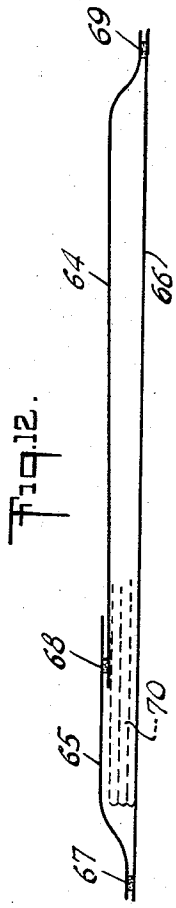

Fig. 12.

INVENTORS:
ROBERT J. TREWELLA
LAWRENCE JERZEWSKI JR.

United States Patent Office 3,338,019
Patented Aug. 29, 1967

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METHOD OF PACKAGE MANUFACTURE

Robert J. Trewella, North Brunswick, and Lawrence Jerzewski, Jr., East Millstone, N.J., assignors to Johnson & Johnson, a corporation of New Jersey

Original application Aug. 22, 1962, Ser. No. 218,709. Divided and this application Dec. 3, 1965, Ser. No. 529,166

2 Claims. (Cl. 53—14)

This application is a division of application Ser. No. 218,709, filed Aug. 22, 1962, now abandoned.

The present invention relates to improved packages and, more particularly, to packages which can be sterilized both internally and externally by conventional means after sealing, which are capable of maintaining the sterility of the contents, which can be readily opened and which provide for the controlled removal of tthe contents by a sterile technique. The invention includes both novel packages and a method for their manufacture and is especially useful in the packaging of sterile surgical dressings.

Surgical articles have been packaged and then sterilized in order to reduce the hazard of cross-infection in hospitals. Many of the packages previously employed for sterile surgical articles have, however, been found to have serious disadvantages. For example, some previously available packages are composed of materials which do not permit sterilization of the contents of the package after sealing. This makes it necessary to conduct the packaging operation under aseptic conditions which is both difficult and expensive. Some of the packages employed previously have also be difficult to open, requiring tearing or cutting of the packaging material. This is disadvantageous since withdrawal of the surgical article through the resulting opening exposes it to contamination by the nonsterile, exterior torn or cut edges of the package. Still other packages previously employed for sterile surgical dressings have the disadvantage that they are sealed by means of a pressure-sensitive adhesive which permits the package to be opened and then resealed by merely pressing the adhesive-coated surfaces together. Packages of this type are objectionable since there is no assurance that the package has not been opened, the sterile surgical dressing contaminated and the package inadvertently or deliberately resealed. Another disadvantage of many of the packages previously employed for sterile surgical articles has been that they did not permit positive control of the sterile contents while opening the package to prevent the contents from dropping out and being contaminated. Certain packages currently in use for sterile surgical articles have also been found to have unsealed channels through the seal lines closing the package at points where more than two sheets of packaging material are joined. Packages of this type tend to breath, particularly when stored under conditions where there is a wide variation in temperature or atmospheric pressure. This is highly disadvantageous since it makes possible the introduction of airborne bacteria which may contaminate the contents of the package and cause loss of sterility. It is apparent, therefore, that a need has existed in the art for a package for surgical dressings which can be sterilized both internally and externally by conventional means after sealing, which maintains the sterility of the contents, which can be readily opened without cutting or tearing the packaging material, and which permits removal of the contents of the package with positive control by means of a sterile technique.

The disadvantages of previously available packages for sterile surgical articles are obviated according to the present invention by providing a package formed by placing

in overlapping relationship two sheets of flexible packaging material, at least one of which permits sterilization of the contents of the package by conventional procedures after sealing, joining the two sheets together along a rupturable seal line within the overlapping area, folding the joined sheets of packaging material together to form a pocket, placing the article to be packaged in the pocket and closing the package by forming at least one additional rupturable seal line between the adjacent folded-together portions of the previously joined sheets.

The invention will now be described in greater detail in conjunction with the accompanying drawings in which:

FIG. 1 is a perspective view showing a sheet of plastic film and a sheet of paper in overlapping relationship joined together along a rupturable seal line within the overlapping area.

FIG. 2 is a perspective view of a preferred embodiment of the invention consisting of a package formed by folding and sealing the assembly of FIG. 1.

FIG. 3 is a cross sectional view of the package of FIG. 2 taken along the line 3—3 and showing the contents of the package.

FIG. 4 is a perspective view of the package of FIG. 2 partially opened.

FIG. 5 is a perspective view of the package of FIG. 2 which has been opened by stripping one element of the package from the other.

FIG. 6 is a partial perspective view of joined sheets of flexible packaging material one of which is partially coated with adhesive.

FIG. 7 is a partial perspective view partly in section of a second embodiment of the invention formed from the assembly of FIG. 6.

FIG. 8 is a partial perspective view of still another preferred embodiment of the invention showing a sheet of interleaving material inserted between the overlapping portions of two joined sheets of flexible packaging material prior to forming a package.

FIG. 9 is a partial perspective view partly in section of a package formed from the assembly of FIG. 8.

FIG. 10 is a schematic view of an apparatus capable of forming the packages of the present invention.

FIG. 11 is a schematic cross sectional view of another package of the invention composed of four sheets of flexible packaging material.

FIG. 12 is a schematic cross sectional view of still another package of the invention composed of three sheets of flexible packaging material.

The preferred embodiment of the invention illustrated in FIGS. 1 through 5 is formed from a sheet of polypropylene film **11** and a sheet of paper **12** placed in overlapping relationship as shown in FIG. 1 and joined together along a rupturable seal line **13** within the overlapping area. Although the seal line **13** may be formed by any suitable means, it is preferred to employ heat and pressure applied by means of a suitable die according to conventional procedures. Polypropylene film is the preferred material for sheet **11** since it is heat sealable to itself and to the paper of sheet **12** without adhesive and thus provides a seal which is readily rupturable and which cannot be casually resealed by mere manual pressure. The package is formed by folding the joined sheets **11** and **12** together in a direction generally perpendicular to the seal line **13** and the edges **14**, **15**, **18** and **19** of the sheets **11** and **12**. The edge **18** of sheet **11** is placed in coincidence with the edge **19** of sheet **12**. Folding the blank in this manner brings the edges **20** and **21** of sheet **11** into coincidence with the edges **22** and **23** respectively of sheet **12**. The pocket formed in this way is adapted to receive articles to be packaged such as surgical sponges **24**. The package is then completed by sealing sheets **11** and **12** together at the three open sides of the pocket along seal

line **25** which may be a single continuous U shaped seal line or a plurality of seal lines which taken together completely close the package. As with seal line **13** the seal line **25** is formed by means of heat and pressure alone in the preferred embodiment of the invention, although this seal may also be obtained by the use of an adhesive or other suitable means. The integrity of the package against invasion by airborne bacteria is assured by the fact that the polypropylene film **11** fuses and flows under conventional heat sealing conditions to take the conformation of the more rigid and nonfusable sheet of paper **12**. This serves to prevent the formation of an unsealed channel at points in the sealed area of the package where the polypropylene film and paper might be spaced apart somewhat. More specifically, it may be seen that the thickness of the polypropylene sheet **11** at the corner where edges **14** and **21** meet would tend to separate the main portion of the polypropylene sheet **11** from the paper **12** along the seal line **25**. It is seen in FIG. 2, however, that there is no opening at the point in seal line **25** where the step-down from three to two thicknesses of flexible packaging material occurs. This is due to the fact that the polypropylene film **11** fuses under the influence of heat and pressure during the formation of seal line **25** by conventional heat sealing techniques and flows into and fills the opening which would otherwise be present thus causing the edge of the polypropylene sheet **11** to take the conformation of the paper sheet **12**. The package formed in this way has a flap **16** inside and a flap **17** outside, each of which is adjacent to the first rupturable seal line **13**. Although the flap **17** may be sealed to the body of the package along its lateral edges during the formation of the seal line or lines **25**, the portion of the flap intermediate to the lateral edges is free to move relative to the body of the package and thus may be grasped for use as a tear tab for opening the package.

The package is conveniently opened as shown in FIG. 4 by grasping the body of the package adjacent to the seal line **13** in one hand, grasping the flap **17** in the other hand and partially or completely stripping the sheet **12** from the main body of the package composed of sheet **11** thus rupturing the seal lines **13** and **25**. When the sheet **12** is completely stripped from the main body of the package as shown in FIG. 5 the transverse edge **18** of the polypropylene film **11** has a tendency to curl downward away from the exposed contents of the package. It should be noted that the sponges **24** are held firmly in the folded-over portion of the main body of the package during and after the removal of sheet **12** thus maintaining positive control of the sterile product.

The contents of the sealed package can be sterilized through the paper sheet **12** by steam or sterilizing gasses according to conventional procedures.

As noted above the seal lines **13** and **25** may also be formed by means of an adhesive which may be coated over the entire area of sheet **11** or sheet **12** or both or may be applied only in the areas where the seal is desired on either or both of the sheets according to conventional practice. When the package is sealed by means of adhesive it is preferred to employ an adhesive which does not retain sufficient tackiness after rupture of the seal lines to permit reclosure of the package after it has once been peeled open. Less desirably an adhesive may be used which joins the sheets **11** and **12** so firmly that when the package is opened the packaging material is torn thus making it impossible to reclose the package.

Another embodiment of the invention is illustrated in FIG. 6 which shows a fragment of a package blank comprising a sheet of polypropylene film **26** joined to a sheet of paper **27** along a seal line **28** formed by a heated die according to conventional procedures. The lateral edge of the sheet of paper **27** is coated with an adhesive **29** which permits the lateral edges of the folded sheet to be sealed to each other as shown in FIG. 7 to form the package. If desired, the adhesive **29** may be applied only where paper **27** is sealed to itself and omitted where polypropylene film **26** is sealed to the paper **27** since the latter seal may be formed by heat and pressure alone. It should be noted, however, that when it is desired to seal paper sheet **27** to polypropylene film **26** by means of adhesive, care must be taken to avoid imperfect seals at any point in the package where more than two sheets of flexible packaging material are joined. At such points the two outermost sheets will be separated by the thickness of an inner sheet which will hold the two outer sheets apart, thus causing an unsealed channel through the intended seal line adjacent to the edge of the intermediate sheet of flexible packaging material. The integrity of the package against invasion by airborne bacteria may be maintained by filling the resulting channels with adhesive.

Still another embodiment of the invention is illustrated in FIGS. 8 and 9 which show the use of an interleaving sheet **30** between a flap **31** forming a part of a paper sheet **32** and the adjacent body of a package composed of a sheet of polypropylene film **33**. The interleaving sheet **30**, which is preferably composed of a material which will not heat seal to polypropylene, prevents the formation of a seal between the lateral edges of the flap **31** and the body of the package when the package is closed along seal line **34** by the use of a heated die according to conventional procedures. Alternate methods of preventing the formation of a seal between flap **31** and sheet **33** include the use of an interleaving sheet of paper, for example, which is adapted to seal to the polypropylene sheet **32** to become part of the package but which does not seal to the paper flap **31**. Another method of preventing the formation of a seal between the tear flap and the body of the package is to coat the flap **31** or sheet **33** with a conventional release coating material in the area in which it is desired to prevent the formation of a seal. Still another method is preventing the formation of a seal between flap **31** and sheet **33** is to fold flap **31** away from the body of the package so that it is not in contact therewith during the formation of the seal line **34**. In this way a package can be formed similar to that illustrated in FIGS. 1 through 5 except that the tear flap is more readily grasped since it is not adhered to the body of the package at its lateral edges. Packages of this type are especially preferred embodiments of the invention.

Although the packages of the invention described above are composed of two sheets of flexible packaging material, it will be obvious to those skilled in the art that either the sheet of polypropylene film **11** or the sheet of paper **12** shown in FIG. 1 could be replaced by a sheet made up of one or more smaller sheets of either plastic film or paper sealed together either by heat sealing techniques where appropriate or by means of an adhesive. A package of this type is illustrated in FIG. 11. This package is composed of one sheet of paper **55** and three sheets of polypropylene film **56**, **57** and **58**. The illustrated seals **59**, **60**, **61** and **62** are made by means of an adhesive. Seals **59** and **60**, which are between paper and polypropylene, could also be made without the use of an adhesive by conventional heat sealing techniques. The package of FIG. 11 can be opened in the same way as the package shown in FIG. 4 by grasping either protruding end of the paper sheet **55** and stripping it way from the body of the package to rupture seal **59** or **60**. Both seals may be ruptured, if desired, and the paper sheet completely removed from the package to expose the surgical dressings **63**. This package functions in substantially the same way as that shown in FIGS. 1 through 5 but may be more convenient to manufacture on some equipment.

The packages of FIG. 12, which represents still another embodiment of the invention, is composed of a sheet of paper **65** and two sheets of a plastic film such as polypropylene sheets **64** and **66**. The sheets are joined at seal lines **67**, **68** and **69** by means of an adhesive, although seal lines **67** and **68** could also be formed by heat sealing techniques without adhesive, if desired. The tear tab for

opening this package is the end of paper sheet **65** extending beyond seal line **68**. FIG. 12 may also be considered to represent the longitudinal cross section of a plastic, e.g. polypropylene, tube in the machine or extruded directions. In this event polypropylene sheets **64** and **66** could be separate sheets sealed together along two longitudinal seal lines (not shown) or could be replaced by a seamless tube of polypropylene. The tube is provided with a lip at the left end as viewed in FIG. 12 by cutting away a portion of the top wall of the tube so that the lower wall extends beyond the end of the top wall as shown. The cut away portion is conveniently the width of the package. In this way a tube is formed having a flap at the left end. The paper sheet **65** is then sealed to the body of the tube at **68** and to the flap at **67**. The end of the tube on the right in FIG. 12 can be used for filling the package before final sealing at **69**.

It should be noted that it is immaterial in the formation of the packages of the present invention which of two sheets joined together at a seal line is uppermost. For example, the paper sheet **55** in FIG. 11 could as well be sealed to the bottom side of polypropylene sheet **58** as to the top side. For this reason a very large number of variations of the several packages illustrated are possible, all of which are considered to be within the scope of the invention.

The packages of the present invention may be formed manually or by means of suitable automatic machinery. The method of forming the packages is illustrated schematically in FIG. 10 of the drawings in which a web of polypropylene film **35** from a stock roll **36** and a web of paper **37** from a stock roll **38** are fed through a pair of rollers **39** and **40** with the webs partially overlapping. The overlapping webs **35** and **37** are then joined together by a suitable sealing means such as the stationary die member **41** and the movable die member **42**. When die member **42** is heated and pressed against the overlapped webs **35** and **37** and the stationary die member **41** a seal line **54** is formed between the polypropylene web **35** and paper web **37** in the overlapping area. The seal line **54** may, of course, be formed by any other suitable means. The joined webs are then fed between a pair of tensioning rollers **43** and **44** and drawn through a suitable folding device **45** which folds the joined webs in half longitudinally. The outer edges **46** and **47** of the polypropylene web **35** and the paper web **37** respectively are spaced apart by a suitable means and articles to be packaged such as surgical sponges **48** are deposited in the traveling folded web at predetermined intervals. This may be accomplished as illustrated in FIG. 10 by allowing the sponges **48** to drop by gravity into the folded composite web from a conveyer belt **49** which travels over rollers **50**. The package is then completed by sealing the polypropylene web to the paper web around each of the sponges **48**. This may be accomplished by pressing the heated U shaped die **51** against the paper-polypropylene assembly and stationary die **52** to form the seal line. Registration of the die **51** around the sponges **48** may be accomplished by conventional means such as a photoelectric cell. The individual packages formed in this way are then severed from the web by a suitable cutting means **53**.

Although the packages of the invention are conveniently formed by the apparatus described above, it will be obvious to those skilled in the art that any other apparatus can be employed which is adapted to place two webs or sheets of flexible packaging material in a partially overlapping relationship, join the two sheets together along a rupturable seal line within the overlapping area, fold the joined sheets to form a pocket, introduce an article to be packaged to the pocket and close the package by the formation of at least one additional rupturable seal line between adjacent sheets of flexible packaging material around the article to be packaged.

As noted above, although it is preferred to employ polypropylene film and paper for the components of the package, other suitable flexible packaging materials may be substituted. It is preferred, however, that at least one element of the package be composed of a flexible packaging material which permits sterilization of the contents of the package subsequent to sealing. Paper is most suitable for this purpose since it permits sterilization by steam or sterilizing gasses according to conventional procedures. All of the elements of the package may be composed of paper if a suitable adhesive is employed. The adhesive may be coated uniformly over one or both sheets of paper to be joined or it may be applied only in the areas where a seal is required. Although the packages may be formed entirely of a plastic film, such as polypropylene, this is not preferred since films of this type do not permit sterilization of the contents subsequent to sealing by the use of steam or the usual sterilizing gases. Especially suitable materials for forming the packages of the present invention include polypropylene film about 1 mil in thickness and 35 lb. basis weight sterilizable, bacterial barrier paper. These materials may be joined by heat sealing at a temperature of about 390° F. under 140 lbs./sq. in. pressure with a contact time of about 0.3 second. The sealing conditions will vary with the particular paper, film or other packaging material chosen as will be apparent to those skilled in the art. Heat seals formed in this manner are readily peelable and yet maintain the sterility of the contents of the package until opened.

Sterile surgical articles enclosed in packages of the present invention can be easily and conveniently removed from the packages according to several sterile techniques. For example, one element of the package may be partially peeled off as shown in FIG. 4 and the contents removed by the use of sterile forceps. Alternatively the package may be opened as shown in FIG. 5 by completely removing one sheet of the flexible packaging material. When this is done the sponges may be dropped out of the folded portion of the remaining sheet of packaging material onto a sterile surface, or they may be applied to a wound directly using the folded sheet as a sterile holder.

The invention is obviously susceptible of many modifications within its spirit and accordingly it is to be limited only by the scope of the appended claims.

We claim:

1. A method of forming a package adapted to permit sterilization of its contents and interior surfaces subsequent to sealing and removal of the contents without loss of sterility after opening, which comprises placing two sheets of flexible packaging material in overlapping relationship, joining the two sheets together by forming a first rupturable seal line between them within the area in which the sheets overlap, said rupturable seal line being spaced from the transverse edges of said overlapping area, so that the edge of each of the two sheets adjacent said rupturable seal line is free, folding the joined sheets of flexible packaging material together in a direction generally perpendicular to a straight line connecting the ends of the first rupturable seal line to form a pocket, placing an article to be packaged within said pocket and forming at least one additional rupturable seal line between the folded-together portions of the previously joined sheets to close said pocket around said articles whereby a package is formed having two flaps adjacent to said first seal line, one of said flaps being inside and one outside the package.

2. A method of forming a package adapted to permit sterilization of its contents and interior surfaces subsequent to sealing and removal of the contents without loss of sterility after opening, which comprises placing two sheets of flexible packaging material in overlapping relationship, joining the two sheets together by forming a first rupturable seal line between them within the area in which the sheets overlap, said rupturable seal line being spaced from the transverse edges of said overlapping area, so that the edge of each of the two sheets adjacent said

rupturable seal line is free, folding the joined sheets of flexible packaging material together in a direction generally perpendicular to a straight line connecting the ends of the first rupturable seal line to form a pocket, placing an article to be packaged within said pocket and forming at least one additional rupturable seal line between the folded-together portions of the previously joined sheets exclusive of the portion of one of said sheets which protrudes from the outside of the package adjacent to said first rupturable seal line, to close said pocket around said articles whereby a package is formed having two flaps adjacent to said first seal line, one of said flaps being inside and one outside the package.

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TRAVIS S. McGEHEE, *Primary Examiner.*

N. ABRAMS, *Assistant Examiner.*