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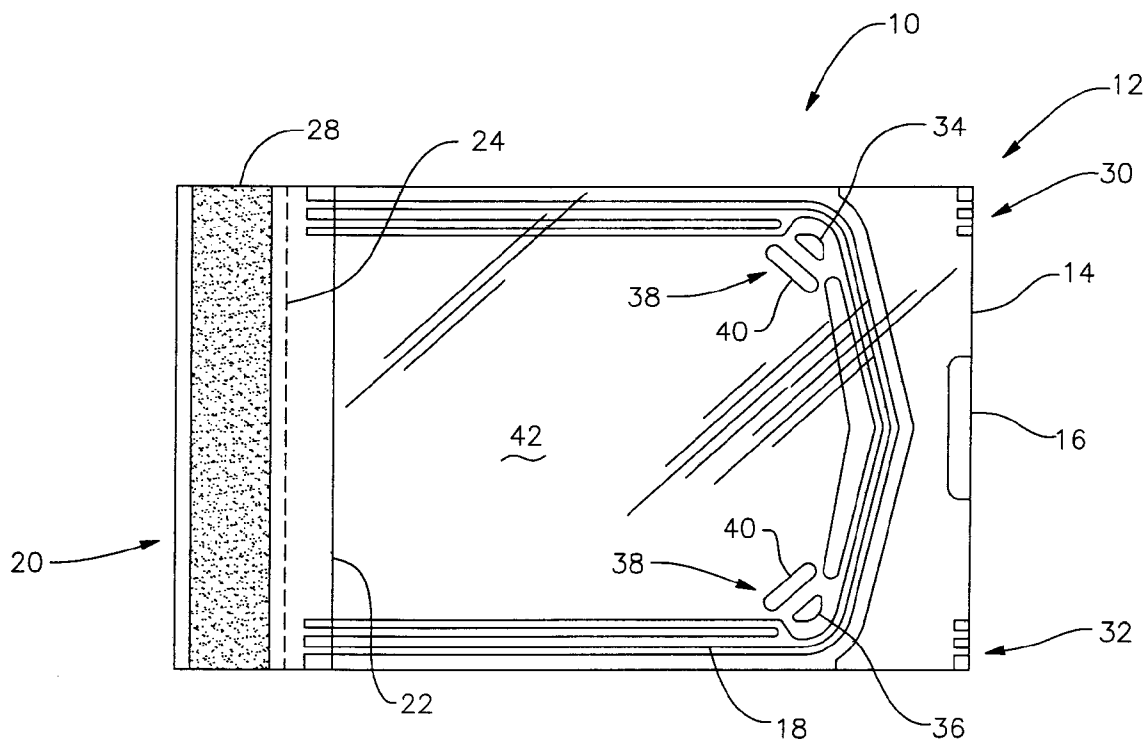
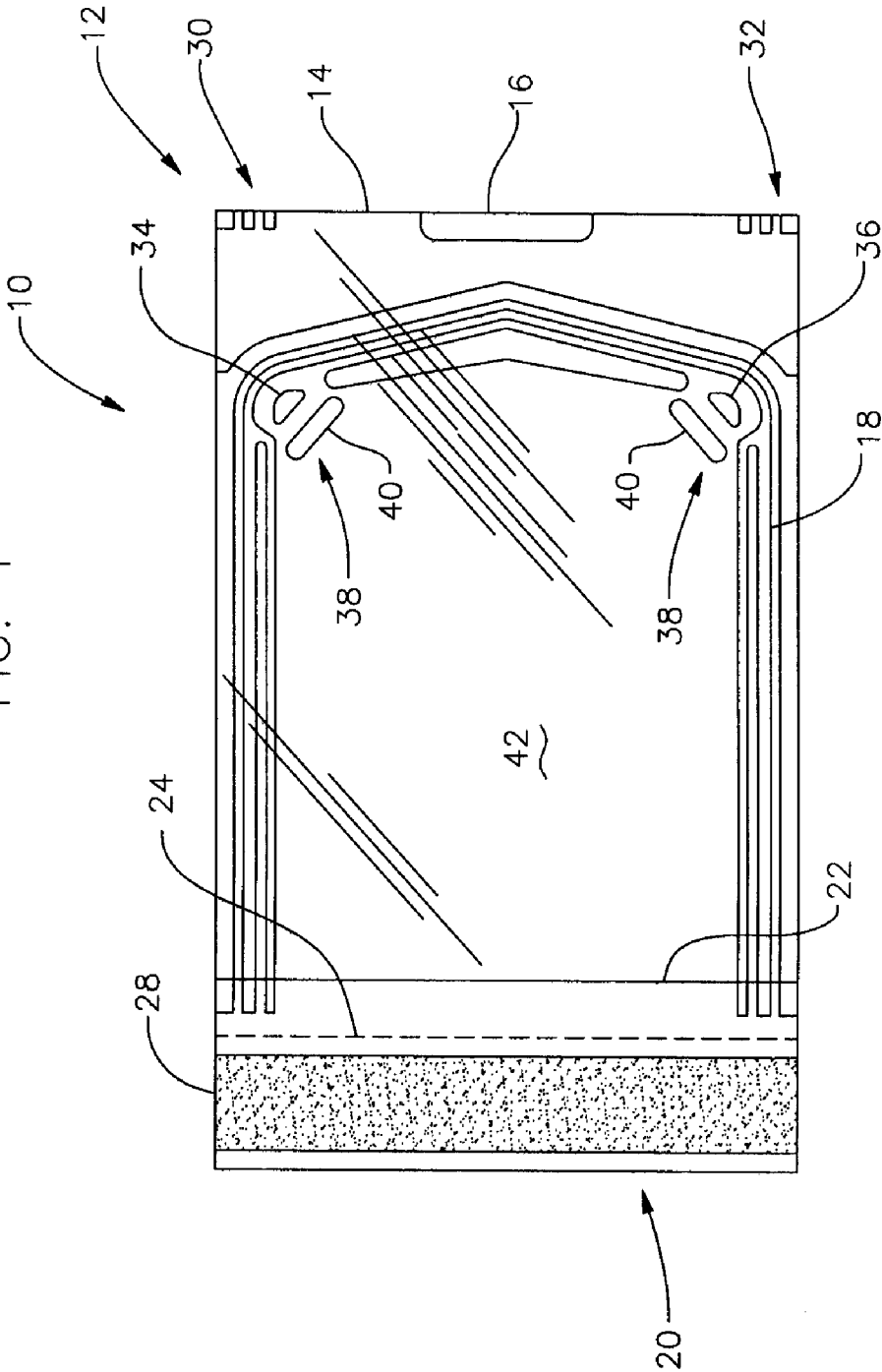


FIG. 1



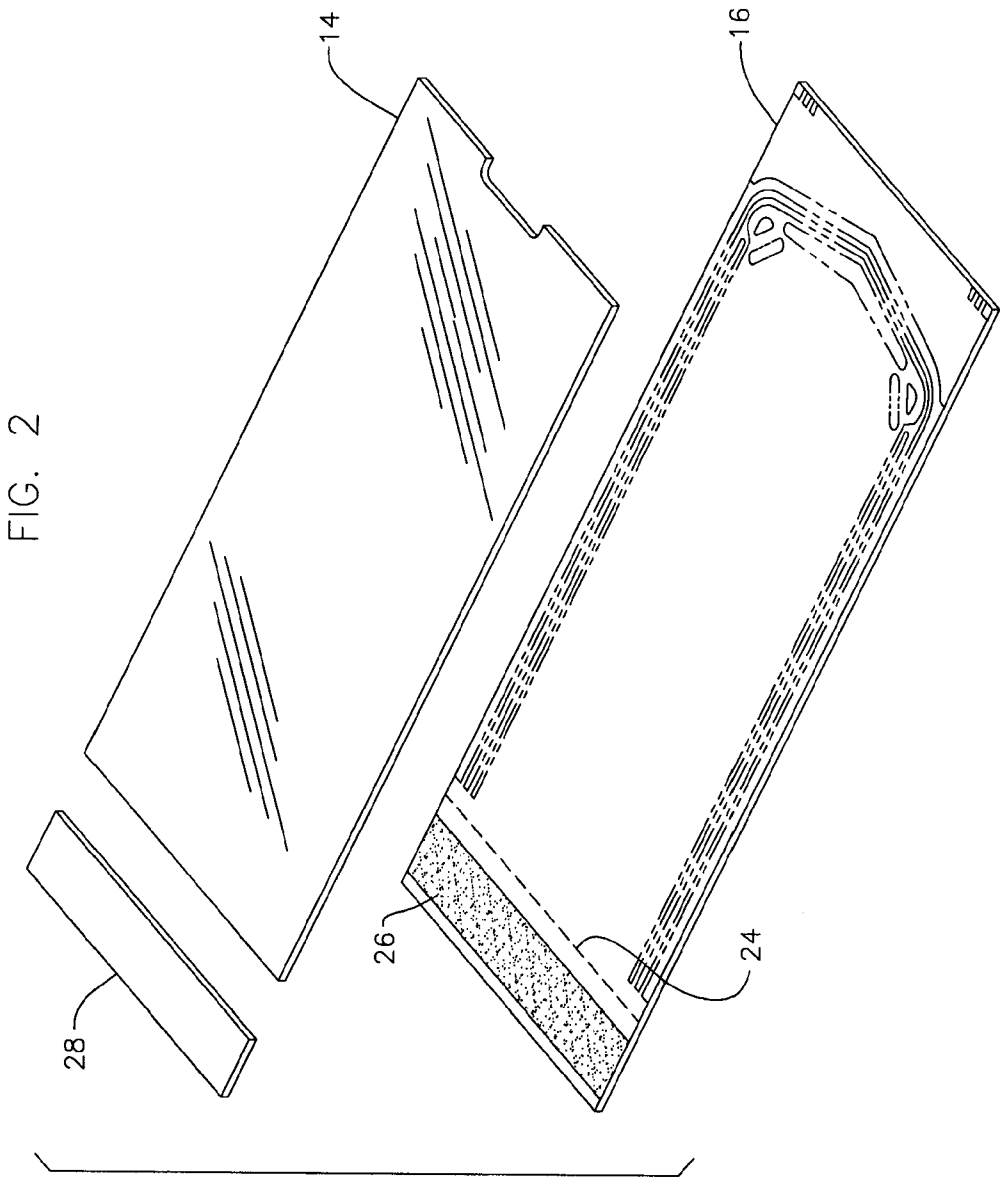


FIG. 3

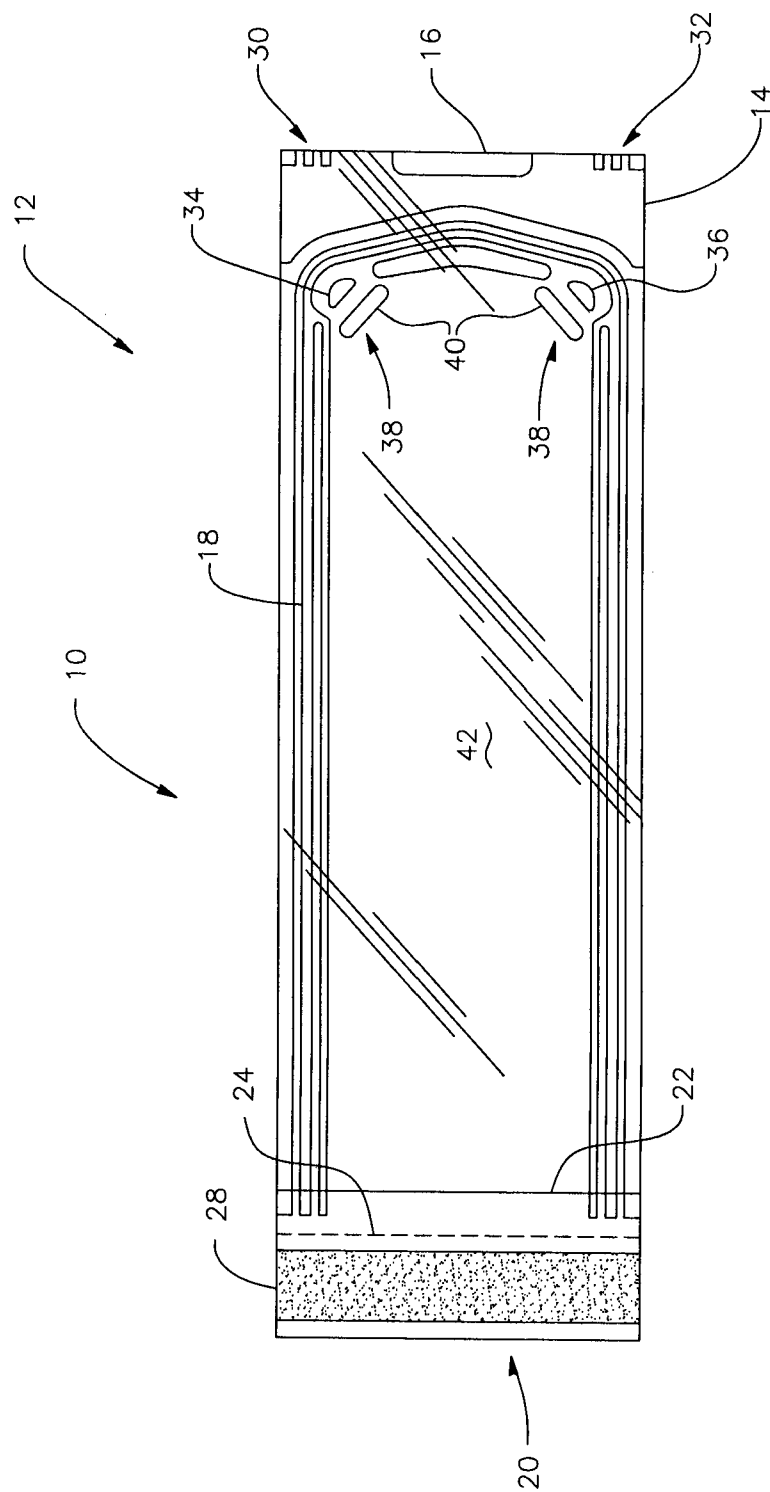


FIG. 4

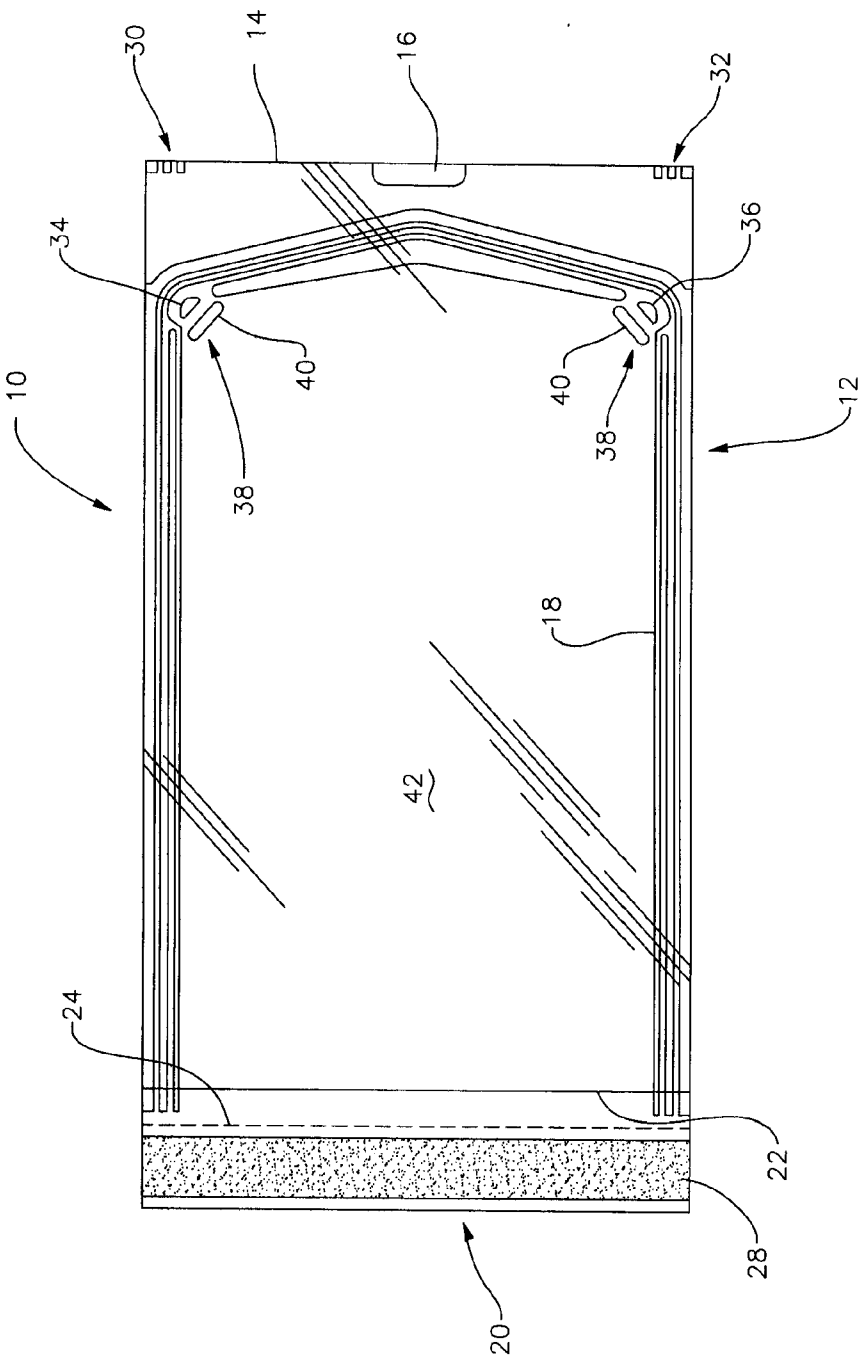
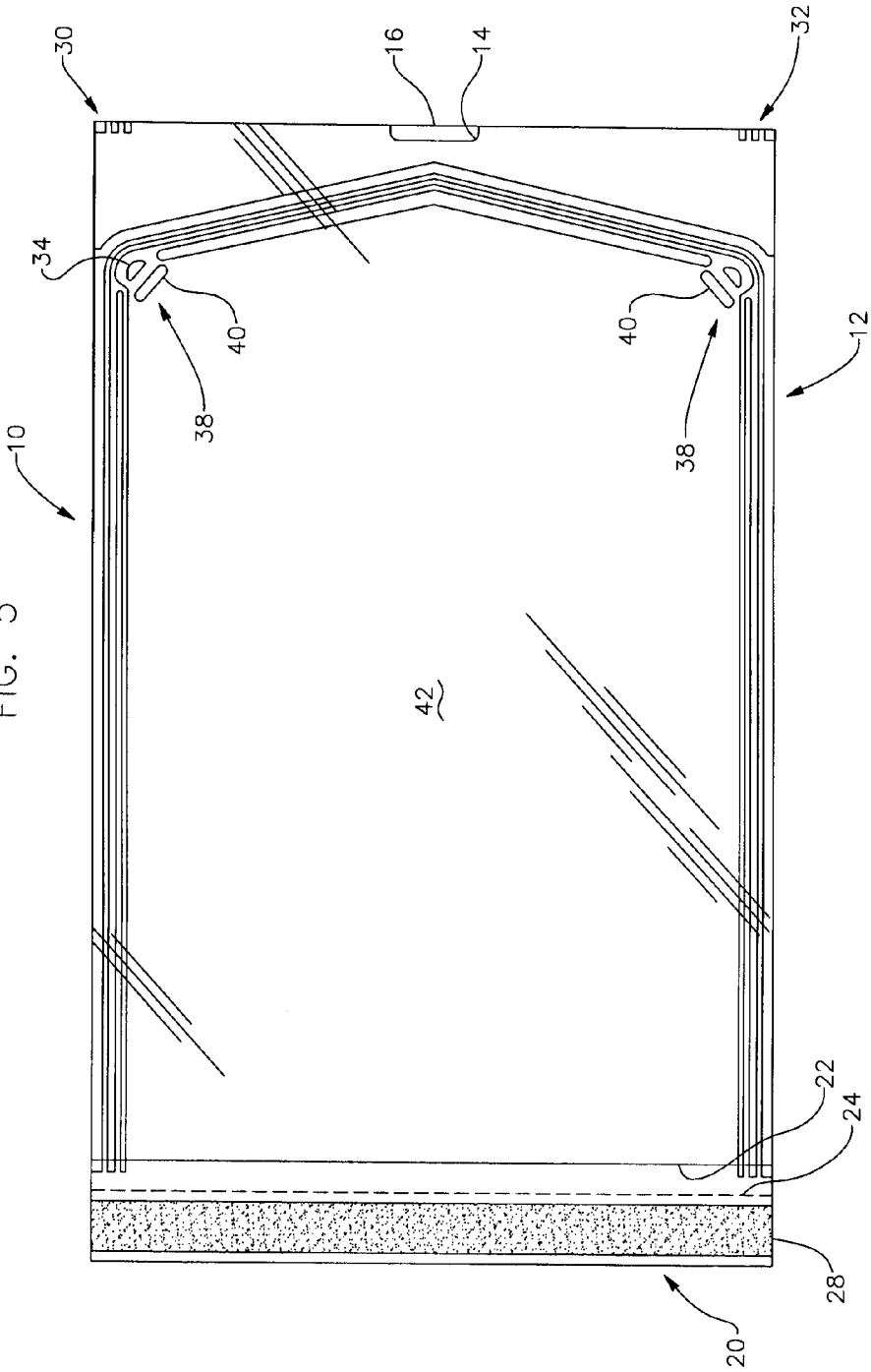


FIG. 5



STERILIZATION POUCH WITH INTERNAL AND EXTERNAL INDICATORS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 61/021,104, filed Jan. 15, 2008, the entire contents of which are hereby expressly incorporated by reference.

TECHNICAL FIELD

[0002] This invention relates to the field of sterilizable packaging using color-changing indicators to display the sterilization status thereof.

BACKGROUND

[0003] In the past, packages such as pouches were used to retain contents for medical or veterinary or dental applications and to enable sterilization thereof, with an indication of whether the packaging had undergone sterilization. The two most popular techniques of sterilization for such packages are processing using either steam or ethylene oxide (hereinafter referred to as "ETO").

[0004] In the prior art, as discussed in the "BACKGROUND" section of U.S. Pat. No. 4,091,921, it was known to apply indicator ink to the exterior of the package, with a color change indicating that the package was subject to the sterilization process. Different inks were used for steam and ETO as the sterilizing medium. Indicator inks were also applied to the interior of the package, to indicate that the interior sealed chamber containing the contents to be sterilized was subject to at least a partial exposure to a sterilization process. U.S. Pat. Nos. 4,091,921 and 5,344,017 each illustrate a prior art approach in which the indicator ink was sealed in a segregated interior compartment in the pouch to prevent the pouch contents from coming in contact with the interior ink indicator. U.S. Pat. No. 3,093,242 relates to an internal indicator not protected from contact with the contents of the pouch. The entire contents of each of U.S. Pat. Nos. 4,091,921, 5,344,017, and 3,093,242 are expressly incorporated herein by reference.

SUMMARY

[0005] The present invention is an improvement over the prior art in that it provides a package having both exterior and interior indicators, for either steam or ETO, or both, with at least the interior indicator having a multi-parameter indicium responsive to steam as the sterilizing medium. This arrangement has the advantage of indicating when a package has been subjected to "partial" steam sterilization conditions such that the external indicator may change color to a desired ending color while the steam responsive multi-parameter indicium of the internal indicator does not change to the same desired ending color, giving an indication of "deficient" (in contrast to "absent") sterilization, informing users to troubleshoot and correct their sterilization procedure and/or equipment. The desired ending color may also be referred to as a "designated end color."

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] FIG. 1 shows a plan view of a first embodiment of the present invention.

[0007] FIG. 2 is an exploded perspective view of the embodiment shown in FIG. 1.

[0008] FIG. 3 is a plan view of a second embodiment of the present invention.

[0009] FIG. 4 is a plan view of a third embodiment of the present invention.

[0010] FIG. 5 is a plan view of a fourth embodiment of the present invention.

DETAILED DESCRIPTION

[0011] Referring to the Figures and most particularly to FIGS. 1 and 2, a sterilizable package 10 in the form of a pouch 12 useful in the practice of the present invention may be seen. Pouch 12 preferably has a first layer 14 preferably formed of a polyester/polypropylene film bonded to a second layer 16 preferably formed of kraft paper. The bond is formed by a perimeter seal 18 (such as by heat sealing) preferably extending around 3 of the 4 sides of layers 14 and 16 to form the pouch 12 with an initially open end 20, formed by an open edge 22 of the layer 14 not bonded to layer 16. Layer 16 may be perforated along a fold line 24 and preferably has a strip of contact adhesive 26 along open end 20. A release layer 28 initially covers the strip of adhesive 26.

[0012] In the practice of the present invention, a pair of first indicia 30, 32 make up the first indicator and are located on the package 10 and exterior of the pouch 12; and a pair of second indicia 34, 36 make up the second indicator and are located on the package 10 and interior of the pouch 12. It is to be understood that the locations of each of the first indicia 30 and 32 may be interchanged; similarly the locations of the second indicia 34 and 36 may be interchanged. As shown, there is one pair of indicia 30, 32 making up the first indicator and another pair of indicia 34, 36 making up the second indicator. One indicium (for example indicium 30) of the first indicator and one indicium (for example indicium 34) of the second indicator may each be responsive to multi-parameter steam sterilization, and the other indicium (for example indicium 32) of the first indicator and the other indicium (for example indicium 36) of the second indicator are each responsive to gas sterilization. The gas is preferably ethylene oxide. The package 10 may thus be seen to include first and second indicators, each of which include a separate indicium for indicating the results of one of steam and gas sterilization, with at least the steam sterilization responsive indicium 34 of the second indicator being a multi-parameter responsive steam sterilization indicium. Preferably both indicia 30 and 34 are responsive to multi-parameter steam sterilization. Each of the indicia 32, 36 may be responsive to multi-parameter gas (such as ethylene oxide) sterilization, as well. Alternatively, the indicia 32 and 36 may undergo a color change simply in response to some exposure to a sterilizing gas medium such as ethylene oxide.

[0013] The package 10 may be the same as is used in pouches available from Medi-Plus Laboratories, division of CurMed Healthcare Packaging of Chicago, Ill., and marketed as a Self-Seal Pouch by Medi-Plus Laboratories. Alternatively, the package 10 may be the same or substantially equivalent to the ProView Sterilization Pouch marketed by Cottrell, Ltd, of Englewood Colo. Neither Medi-Plus nor Cottrell offer pouches that have both process external and multi-parameter internal indicators, however.

[0014] The chemical indicators may be in the form of indicia formed by ink printed on one of the layers 14 and 16, preferably layer 16. These indicia undergo a visibly percep-

tible color change to a desired ending color to indicate that successful sterilization has occurred at the indicator.

[0015] Specifically, in one embodiment, the steam sterilization process indicator changes color from one designated initial color (for example, pink) to another, readily distinguishable color (for example, dark brown may be the desired ending color) upon sufficient exposure to complete sterilization conditions (i.e., when exposed to a complete multi-parameter steam sterilization process). The color change to the desired ending color i.e., “designated end color change” may be caused by a chemical reaction in the ink, such as a copper or lead compound reacting with a source of sulfur to produce copper or lead sulfide at the indicia.

[0016] Also, in one embodiment, the ETO (ethylene oxide) process indicator changes color from one designated initial color (for example, a blue/grey) to another designated, readily distinguishable color (for example, a gold/brown may be the desired ending color). The color change from blue/grey (as the desired starting color) to gold/brown (as the desired ending color) may be achieved by a pyridine derivative acetylated in a direct reaction with the ETO.

[0017] Preferably, the minimum process conditions necessary to cause complete color change (corresponding to “successful sterilization”) resulting in achieving the desired ending color in the multi-parameter sterilization process are as follows:

[0018] For the steam process sterilization: 10 minutes exposure to steam at 250° F.

[0019] For ETO: 60 minutes exposure to ETO at 8 psi and 135° F.

[0020] It may be noted that there may be some color change in the steam process indicia with longer periods of exposure below 250° F. or with shorter periods of exposure at temperatures greater than 250° F. Similarly, some color change may be observed for the ETO process indicia with extended exposure at normal room ambient temperatures, and with times as low as 15 minutes with elevated temperature/pressure, and at pressures as low as normal atmospheric ambient pressures with extended time/elevated temperatures. However, when the package or pouch is subjected to only incomplete or insufficient sterilization process conditions in the practice of the present invention, the internal multi-parameter sterilization process indicium will not change to the desired ending color.

[0021] In the practice of the present invention, it has been found preferable to include an independent barrier seal **38** in the form of a bar **40** blocking contact by a conventional medical device (not shown) when placed in the interior **42** of the pouch **12** with either of the internal indicators or indicia **34** or **36**. Bar **40** is preferably not connected to perimeter seal **18**. This has the advantage of preventing contamination of the pouch contents with the ink and also permitting the internal indicators to be in the same compartment as the pouch contents being sterilized. The steam or gas present in the pouch interior **42** is allowed to reach the indicators **34**, **36**.

[0022] To use the package **10** as a pouch for sterilization, contents (such as a medical device) are placed in the pouch interior **42**, by insertion past the open edge **22** of the first layer **14**. The release layer **28** is then removed, and the second layer **16** is folded along fold line **24** to present adhesive region **26** against the first layer, sealing the open end **20** of the pouch **12**.

[0023] It is to be understood that the indicators **30** and **32** may be located under respective corners of the first layer **14**, however, in the practice of the present invention, the first layer

is not secured to the second layer in the corners where indicators **30** and **32** are located, thus presenting indicators to the external environment in which package **10** is located.

[0024] Once the package **10** is sealed as described above, it is preferably placed in an appropriate sterilization chamber (not shown) and desirably exposed to the appropriate sterilization process, which may be either steam or gas (such as ETO) at the appropriate conditions and for the appropriate time for that sterilization process.

[0025] Both the external and internal indicators undergo a visually perceptible change to the desired ending color when the package is subjected to complete sterilization conditions. However, when steam is the sterilizing medium, only the first (external) indicator may undergo a visually perceptible change to the desired ending color when the package is subjected to an incomplete sterilization conditions. The second (internal) indicator will not undergo a complete color change to the desired ending color in the event the interior **42** of the pouch **12** is not subjected to complete steam sterilization conditions, and thus a color change of the external indicator to the desired ending color without a color change of the internal indicator to the desired ending color will thereafter indicate to a user that steam sterilization was attempted, but was incomplete.

[0026] In one aspect, the present invention may thus be seen to be a method of providing a visually perceptible indication of successful or unsuccessful exposure to a proper steam sterilization cycle for the contents of a package of the type having a generally planar polymer layer and a paper member joined together by a marginal seal extending around a portion of a perimeter of the package to form a pouch. The method includes providing the first indicator located on the package and exterior of the pouch; and providing the second indicator located on the package and interior of the pouch.

[0027] The method further includes subjecting the package to a steam sterilization process and observing the first and second indicators. In this method, both the first and second indicators undergo a visually perceptible change to a desired ending color when the package is subjected to complete sterilization conditions, but only the first indicator may undergo a visually perceptible change to the desired ending color when the package is subjected to incomplete sterilization conditions. The method includes having the first and second indicators responsive to steam sterilization, and may include indicators responsive to gas sterilization. The method also may include having the first and second indicators each with (separate) indicia responsive to steam or gas sterilization, with the preferred gas being ethylene oxide.

[0028] Examples of other shapes and sizes of pouches useful in the practice of the present invention may be seen in FIGS. 3-5, where like features are numbered the same as in the embodiment shown in FIG. 1. In FIG. 1, the pouch is about 3.5 inches wide by about 5.25 inches in length; the pouch of FIG. 3 is about 2.75 inches wide by about 9 inches in length. The pouch in FIG. 4 is about 5.25 inches wide by about 10.125 inches long. The pouch in FIG. 5 is about 7.5 inches wide by about 13.125 inches long. Dimensions given are for the width of the layers **14** and **16**, and lengths are for the length of the first or top layer **14**.

[0029] The International Organization for Standardization (ISO) is a worldwide federation of national standards entities. ISO/TC 198, Sterilization of Healthcare Products, has developed sterilization standards for medical devices and related healthcare products.

[0030] In addition, AAMI standards have been recognized by the United States Food and Drug Administration (FDA). The applicable standard is ANSI/AAMI/ISO 11140-1: 2005, "Sterilization of healthcare products—Chemical Indicators—Part 1: General Requirements" (Arlington, Va.: AAMI, 2005).

[0031] Single parameter chemical indicators have been developed to meet the requirements of indicating whether a particular temperature has been reached in a medical device or packaging sterilization process.

[0032] In contrast, multi-parameter sterilization chemical indicators respond not only to temperature, but also require sufficient time and/or the presence of sterilizing medium such as steam or ethylene oxide to confirm that sufficient sterilization has been achieved when a medical device package has been subjected to a process intended to sterilize the contents of the package.

[0033] The invention may thus be seen to be a sterilizable package comprising a generally planar polymer layer and a paper member joined together by a marginal seal extending around a portion of a perimeter of the package to form a pouch, the package comprising a first indicator located on the package and exterior of the pouch; and a second indicator located on the package and interior of the pouch such that both indicators undergo a visually perceptible change to a desired ending color when the package is subjected to complete multi-parameter steam sterilization conditions, while, at most, only the first indicator will undergo a visually perceptible change to the desired ending color when the package is subjected to incomplete steam sterilization conditions. The first and second indicators include steam sterilization indicators and may include gas sterilization indicators, and the gas may be ethylene oxide. In one embodiment, the first and second indicators may each comprise a separate indicia for indicating one of steam and gas sterilization, again with the gas being ethylene oxide.

[0034] The invention may also be characterized as a method of providing a visual indication, such as a color change, of successful or unsuccessful steam sterilization of the contents of a package of the type having a generally non-porous membrane such as a planar polymer layer and a porous membrane such as a paper member joined together by a marginal seal extending around a portion of a perimeter of the package and including an adhesive region on one of the porous and non-porous membranes foldable against the other of the non-porous and porous membranes to form a pouch, with the method comprising providing a first indicator located on the package and exterior of the pouch; and providing a second indicator located on the package and interior of the pouch; subjecting the package to a steam sterilization process; and observing the first and second indicators wherein both the first and second indicators undergo a visual change to a desired ending color when the package is subjected to complete multi-parameter steam sterilization conditions, while, at most, only the first indicator will undergo a visual change to the desired ending color when the package is subjected to incomplete sterilization conditions, as measured multi-parametrically. The method may be further characterized wherein the first and second indicators are responsive to steam sterilization, or to gas sterilization. The method may be further characterized by the first and second indicators each having indicia responsive to steam and gas sterilization. The method may be still further characterized by having the gas be ethylene oxide.

[0035] The invention is not to be taken as limited to all of the details thereof, as modifications and variations thereof may be made without departing from the spirit or scope of the invention.

What is claimed is:

1. A method of providing a visual indication of successful or unsuccessful exposure to a proper sterilization cycle for the contents of a package having a pouch formed from a generally planar polymer layer and a paper member joined together by a marginal seal extending around a portion of a perimeter of the package and wherein the pouch can be sealed, the method comprising the steps of:

- a) providing a first indicator located on the package and exterior of the pouch; and
- b) providing a second indicator located on the package and interior of the pouch, wherein the second indicator includes a multi-parameter sterilization chemical indicia responsive to a steam sterilization process and further wherein both the external and internal indicators undergo a visual change to a desired ending color when the package is subjected to complete sterilization conditions, and further wherein only the first indicator undergoes a visual change to the desired ending color when the package is subjected to incomplete sterilization conditions.

2. The method of claim 1 wherein the visual change is a change to a designated end color and wherein the second indicator will not undergo a complete color change to the designated end color in the event the interior of the pouch is not subjected to complete sterilization conditions when steam is used as the sterilizing medium.

3. The method of claim 2 wherein the first indicator includes a multi-parameter sterilization chemical indicator and a color change to the designated end color of the first indicator without the second indicator changing to the designated end color indicates that sterilization was attempted, but was incomplete when the package is subjected to steam as the sterilizing medium.

4. The method of claim 1 wherein the first indicator includes a multi-parameter sterilization chemical indicia responsive to a steam sterilization process and the method further comprises the additional steps of:

- c) subjecting the package to a sterilization process using steam as the sterilizing medium; and
- d) observing the first and second indicators.

5. The method of claim 1 wherein the first indicator includes a multi-parameter sterilization chemical indicia responsive to a steam sterilization process and the method further comprises the additional steps of:

- c) subjecting the package to complete sterilization conditions using steam as the sterilizing medium; and
- d) causing both the first and second indicators to undergo a visual change to the desired ending color.

6. The method of claim 1 wherein the first indicator includes a multi-parameter sterilization chemical indicia responsive to a steam sterilization process and the method further comprises the additional steps of:

- c) subjecting the package to incomplete sterilization conditions; and
- d) causing at most the first indicator to undergo a visual change to the desired ending color, without the second indicator undergoing a visual change to the desired ending color.

7. The method of claim 1 wherein the first and second indicators are responsive to at least one of steam sterilization and gas sterilization.

8. The method of claim 1 wherein the first and second indicators each include a first indicium responsive to steam sterilization and a second indicium responsive to gas sterilization.

9. The method of claim 8 wherein the gas sterilization comprises using ethylene oxide.

10. The method of claim 1 wherein the first and second indicators each comprise multi-parameter sterilization chemical indicium responsive to a complete sterilization process that maintains the package at a predetermined temperature for a predetermined time in the presence of steam as a sterilizing medium.

11. The method of claim 10 wherein the first and second indicators each comprise a first sterilization chemical indicium and a second sterilization chemical indicium, with the first sterilization chemical indicium responsive to steam and the second sterilization chemical indicium responsive to ethylene oxide.

12. A sterilizable package comprising:

- a) a generally planar polymer layer; and
- b) a paper member joined together by a marginal seal extending around a portion of a perimeter of the package and an adhesive region foldable against the polymer layer to form a pouch;
- c) a first indicator located on the package and exterior of the pouch; and
- d) a second indicator located on the package and interior of the pouch wherein the second indicator includes a multi-parameter sterilization chemical indicium responsive to a steam sterilization process such that the second indicator undergoes a visual change to a desired ending color when the package is subjected to complete multi-parameter sterilization conditions using steam as a sterilizing medium.

13. The package of claim 12 wherein at most only the first indicator will undergo a visual change to the desired ending color when the package is subjected to incomplete steam sterilization conditions.

14. The sterilizable package of claim 12 wherein the first indicator comprises a steam sterilization indicium.

15. The sterilizable package of claim 12 wherein the first and second indicators each comprise a gas sterilization indicium.

16. The sterilizable package of claim 15 wherein the gas sterilization indicia are responsive to sterilization using ethylene oxide.

17. A method of providing a visual indication of successful or unsuccessful steam sterilization of the contents of a package of the type having a generally planar non-porous membrane and a porous membrane joined together by a marginal seal extending around a portion of a perimeter of the package and an adhesive region on an extension of one of the porous and non-porous membranes which is foldable against the other of the non-porous and porous membranes to form a sealed pouch, the method comprising:

- a) providing a first indicator located on the package and exterior of the pouch wherein the first indicator includes a multi-parameter sterilization chemical indicium responsive to a steam sterilization process;
- b) providing a second indicator located on the package and interior of the pouch wherein the second indicator includes a multi-parameter sterilization chemical indicium responsive to a steam sterilization process;
- c) subjecting the package to a sterilization process using steam; and
- d) observing the first and second indicators

wherein the multi-parameter sterilization chemical indicium of both the first and second indicators undergo a visual change to a desired ending color when the package is subjected to complete multi-parameter steam sterilization conditions, while at most only the multi-parameter sterilization chemical indicium of the first indicator will undergo a visual change to the desired ending color when the package is subjected to incomplete steam sterilization conditions.

18. The method of claim 17 wherein the non-porous membrane is a polymer layer.

19. The method of claim 17 wherein the porous membrane is a paper member.

20. The method of claim 17 wherein the multi-parameter sterilization conditions conform to ANSI/AAMI/ISO 11140-1: 2005, "Sterilization of healthcare products—Chemical Indicators—Part 1: General Requirements" as promulgated by the American National Standards Institute and the Association for the Advancement of Medical Instrumentation.

21. The method of claim 17 wherein the multi-parameter sterilization conditions conform to ISO/TC 198, Sterilization of Healthcare Products as promulgated by The International Organization for Standardization.

22. The method of claim 17 wherein the first and second indicators each include a separate indicium responsive to ethylene oxide sterilization.

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