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(54) THERMAL AND/OR LIGHT PROTECTIVE CONTAINER ASSEMBLIES AND THEIR METHODS OF USE

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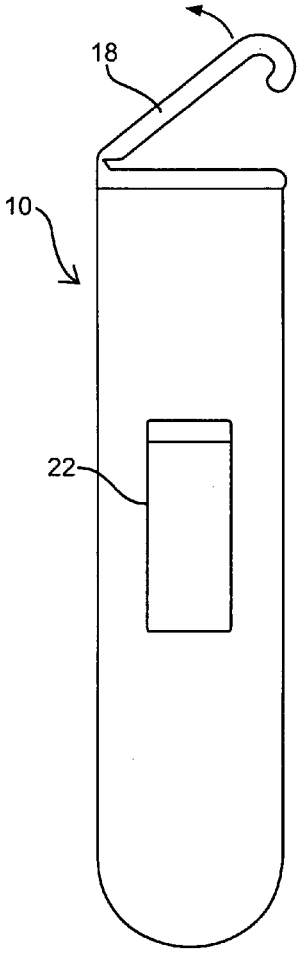
(57) **ABSTRACT**

The invention features a thermal and/or light-protective container assembly that includes a flexible outer and inner layer, as well as a thermoregulatory material disposed between said outer and inner layers. In general, the invention is directed to a thermal and/or light-protective container assembly, such as a form-fitting sleeve, that includes a flexible layered wall having an opened end and a contiguous closed end, wherein the wall defines a centrally located cavity. The wall further includes an outer layer and an inner layer, wherein uniformly disposed between the outer and inner layers is a thermoregulatory material that is configured for insulating an object, and/or for transferring heat or cold to the object, and/or maintaining the temperature of the object disposed within the defined cavity of the sleeve.



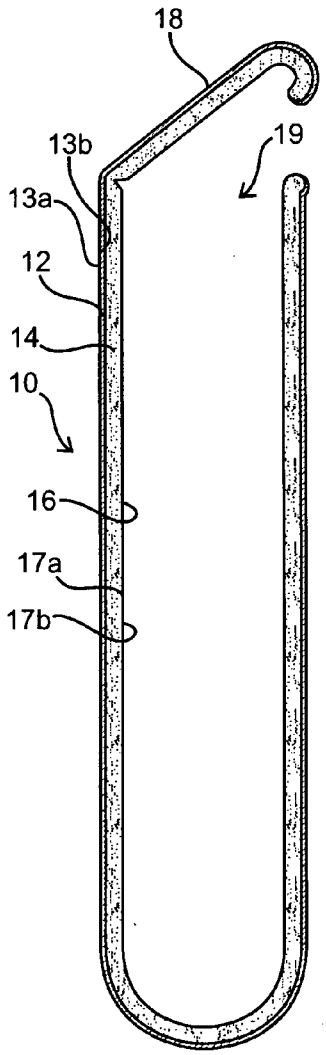


FIG. 1

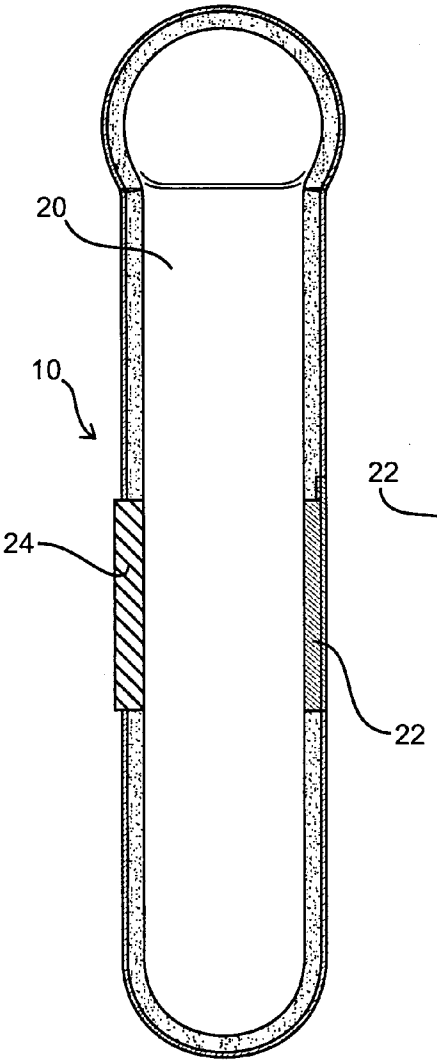


FIG. 2

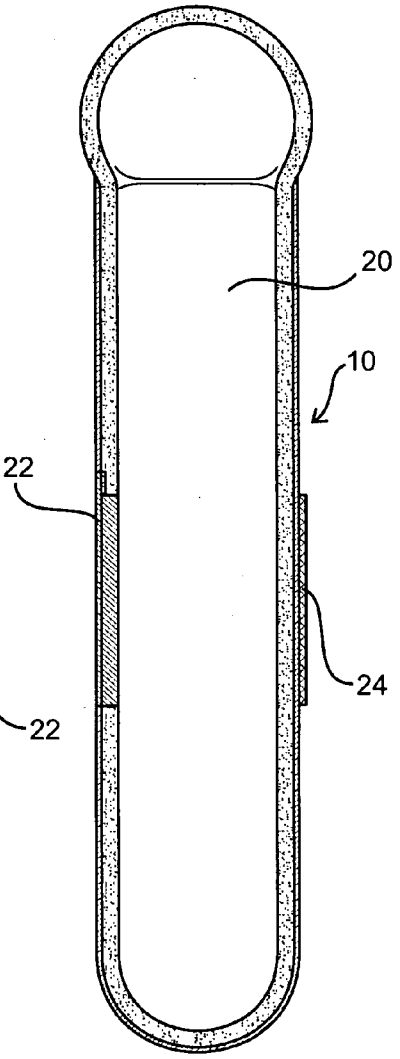


FIG. 3

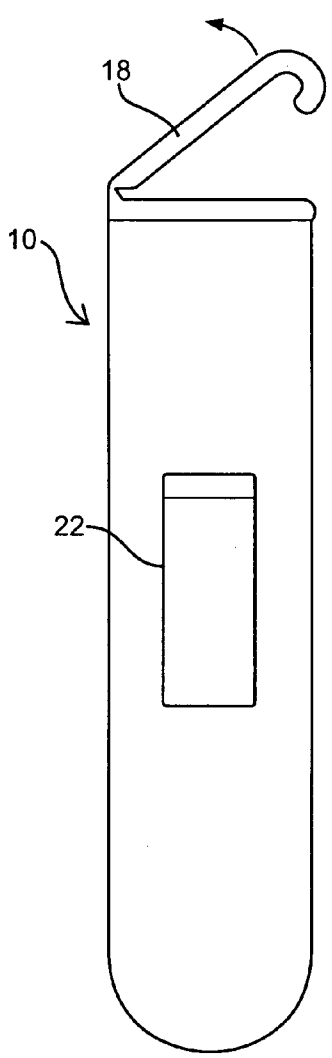


FIG. 4

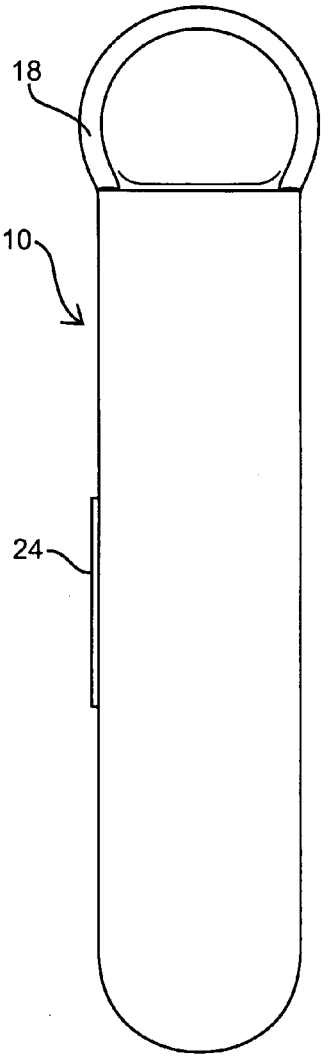


FIG. 5

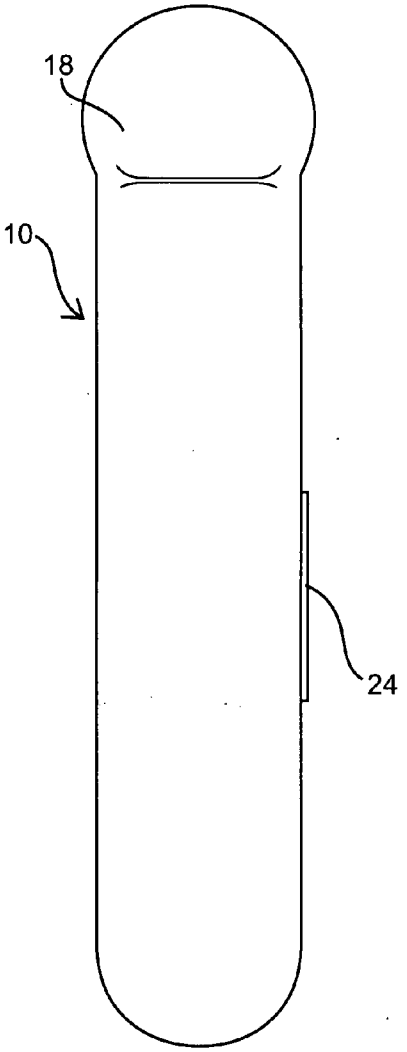


FIG. 6

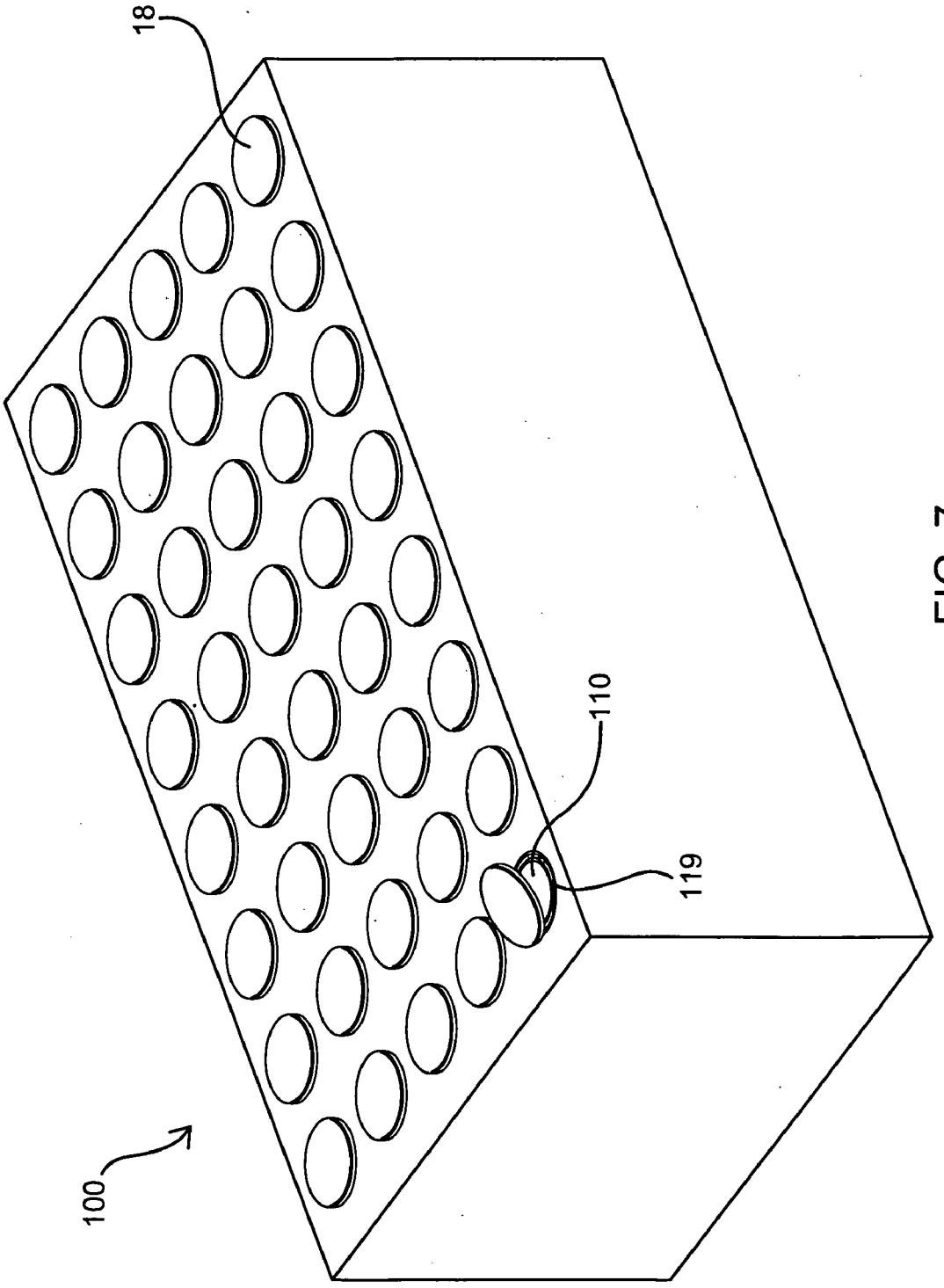


FIG. 7

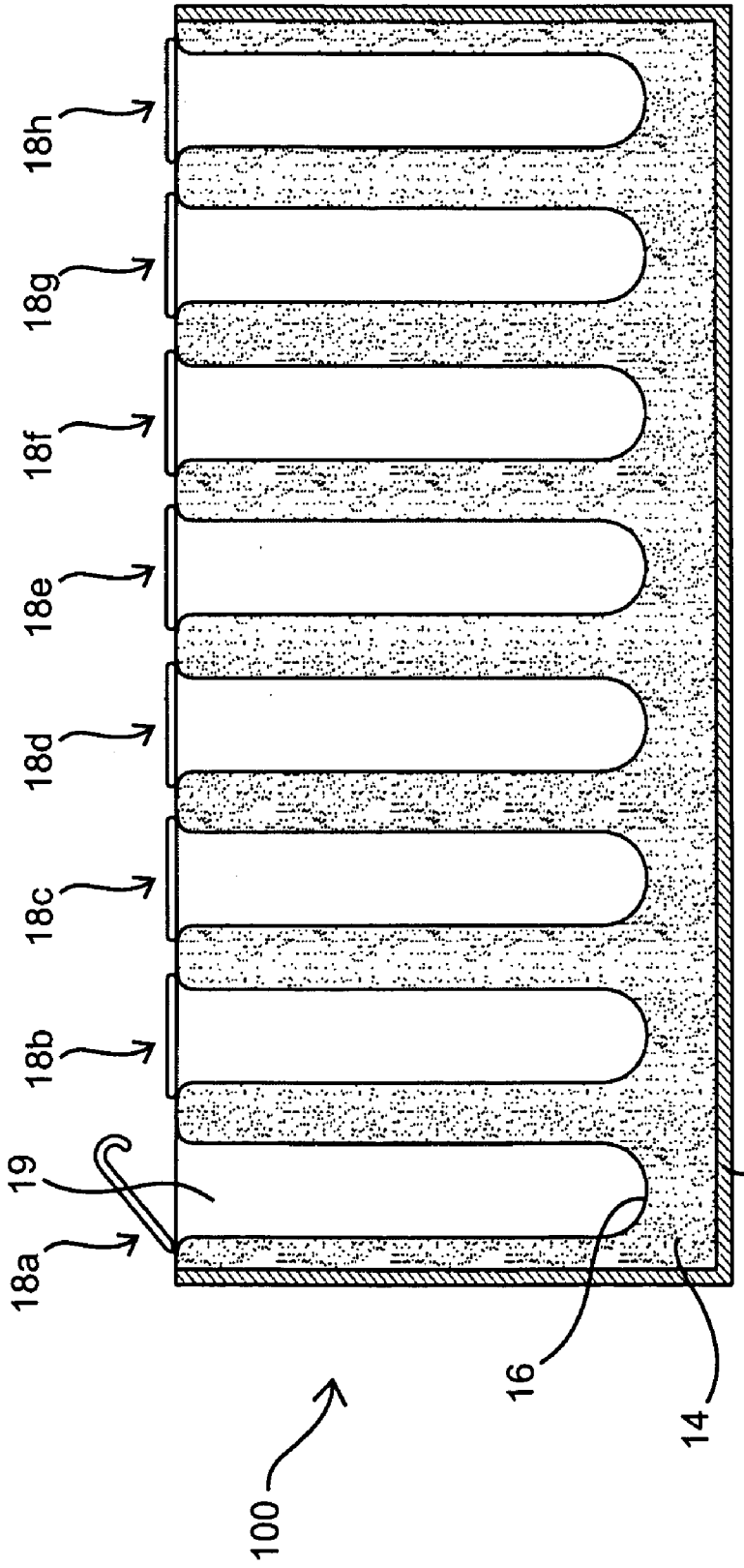


FIG. 8

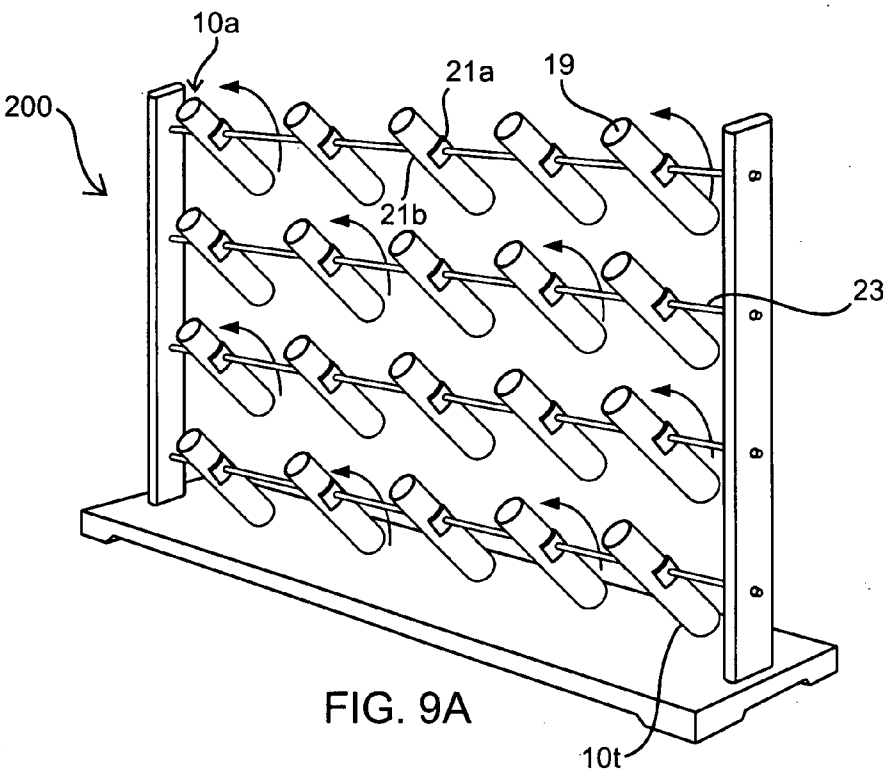


FIG. 9A

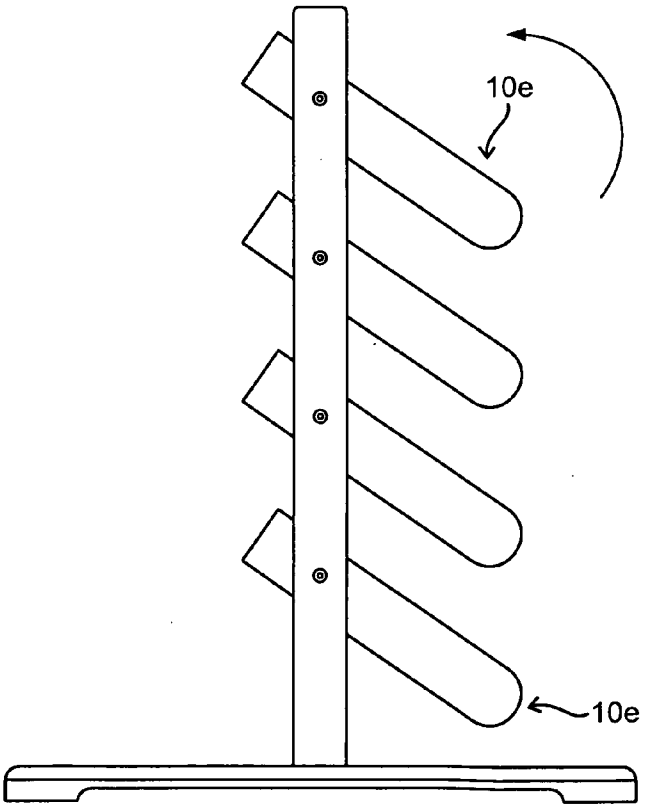


FIG. 9B

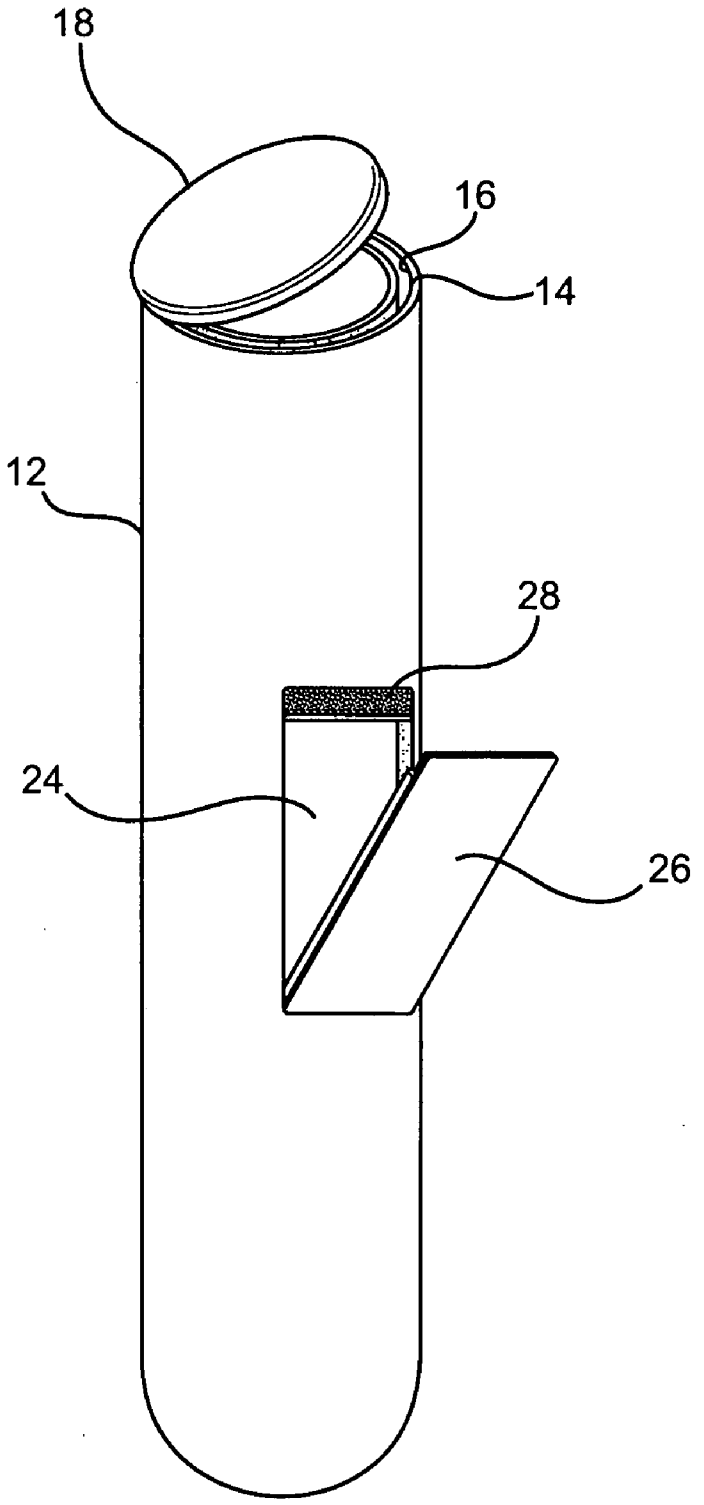


FIG. 10

THERMAL AND/OR LIGHT PROTECTIVE CONTAINER ASSEMBLIES AND THEIR METHODS OF USE

FIELD OF THE INVENTION

[0001] This invention is related to the field of thermal and/or light protection for containers.

BACKGROUND OF THE INVENTION

[0002] Many samples for use in a variety of analyses are at least partially sensitive to temperature, light, or both. For instance, certain samples may be extremely sensitive to a rise in temperature or to particular wavelengths of light, such as within the visible light spectrum. Upon extended exposure to unfavorable temperatures and/or light, these samples may be susceptible to degradation of the analyte or undesirable impurities that may result from degradation of other sample components.

[0003] Containers such as test tubes, slides, wells, plates, bottles, columns, beakers, flasks, and other like storage and/or reaction vessels are commonly used to store analytes for analysis in various assays, as well as to store drugs or other agents to be administered to subjects. Typically these containers are made from a translucent or transparent material to allow visual inspection, which make the contents of the containers susceptible to light and/or temperature fluctuations. Accordingly, in certain instances, a delay in analysis of samples or use of drugs stored in such containers can result in sample or drug degradation in a matter of minutes.

[0004] Where the sample is an analyte, such undesirable circumstances may lead to erroneous results or inconclusive data. For instance, analytes such as alanine transaminase, creatine kinase, creatine, serum potassium, gamma-glutamyl transferase, and the like are especially heat sensitive and subject to degradation if not maintained at cold temperatures. Hence, assays wherein such heat sensitive reactants are involved are particularly susceptible to data irregularities if not protected from heat absorbance. Additionally, analytes such as porphyrins, carotene, RBC folate, Vitamin B12, and the like are especially light sensitive and therefore subject to degradation if not protected from light. Accordingly, assays involving these reactants may also be susceptible to data irregularities.

[0005] In certain situations, such unfavorable temperature and light conditions may be life threatening. For instance, bilirubin is very sensitive to electromagnetic radiation in the visible spectrum of light. The determination, measurement, and control of the level of bilirubin in newborns are important in ensuring the health of the new born infant. Unhealthy bilirubin levels lead to jaundice, the accumulation of bile pigments in the brain, and can lead to brain damage or death. However, bilirubin values decay about 9% after two hours of sample processing if not protected from light exposure. By protecting the bilirubin sample from light exposure the decay rate may be slowed and a more accurate measurement of the level in a newborn can be determined.

[0006] Therefore, there is a need for an improved thermal and/or light-protective container assembly. Accordingly, such a thermal and/or light protecting assembly consistent with the present invention and described herein below is therefore provided to meet those needs.

SUMMARY OF THE INVENTION

[0007] The invention features a thermal and/or light-protective container assembly that includes an outer and inner layer, as well as a thermoregulatory material disposed between said outer and inner layers. In general, the invention is directed to a thermal and/or light-protective container assembly, such as a form-fitting sleeve, that includes a flexible layered wall having an opened end and a contiguous closed end, wherein the wall defines a centrally located cavity. The wall further includes an outer layer and an inner layer, wherein uniformly disposed between the outer and inner layers is a thermoregulatory material that is configured for insulating an object, and/or for transferring heat or cold to the object, and/or maintaining the temperature of the object disposed within the defined cavity of the sleeve. The thermoregulatory material may be uniformly disposed throughout the entire sleeve but is at least uniformly disposed at the contiguous closed end.

[0008] Accordingly, in one embodiment, the invention provides a thermal protective sleeve capable of maintaining the temperature, or at least reducing the rate of heat exchange from a sample in a container disposed in the sleeve. In addition to its thermal regulating characteristics, a protective sleeve of the subject invention may also be light protective and thereby protect an encased object from light. In one embodiment, the invention provides a thermal and/or light protective sleeve, as described above, that further contains a test-tube, vial, ampule, cup, bottle, beaker, flask, titer plate, slide, substrate, vase, or the like disposed within the cavity of the sleeve.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. **1** is a cross section view of a thermal sleeve with a contiguous enclosed end or bottom portion and a top portion that is configured for opening and closing, wherein said thermal sleeve is in an open and empty configuration.

[0010] FIG. **2** is a cross section view of a thermal sleeve with a contiguous enclosed end portion and a top portion that is configured for opening and closing, wherein said thermal sleeve is in a closed and full configuration.

[0011] FIG. **3** is a cross section view of a thermal sleeve with a contiguous enclosed end portion and a top portion that is configured for opening and closing, wherein said thermal sleeve is in a closed and full configuration.

[0012] FIG. **4** is a perspective view of a thermal sleeve with a contiguous enclosed end portion and a top portion that is configured for opening and closing, wherein said thermal sleeve is in an open and empty configuration.

[0013] FIG. **5** is a perspective view of a thermal sleeve with a contiguous enclosed end portion and a top portion that is configured for opening and closing, wherein said thermal sleeve is in a closed and full configuration.

[0014] FIG. **6** is a perspective view of a thermal sleeve with a contiguous enclosed end portion and a top portion that is configured for opening and closing, wherein said thermal sleeve is in a closed and full configuration.

[0015] FIG. **7** is a perspective view of an embodiment of a rectangular thermal sleeve configured as an array (e.g., in a micro-titer plate configuration) suitable for receiving materials.

[0016] FIG. **8** is a cross section view of an embodiment of a thermal sleeve rack.

[0017] FIG. **9**A is a perspective view of another embodiment of a thermal sleeve rack.

[0018] FIG. **9**B is a cross section view of another embodiment of a thermal sleeve rack.

[0019] FIG. **10** is a perspective view of a thermal sleeve with a removable top portion and a window for viewing materials contained in the assembly.

DETAILED DESCRIPTION OF THE INVENTION

[0020] The invention features a thermal and/or light-protective container assembly that includes an outer and inner layer, as well as a thermoregulatory material disposed between said outer and inner layers. In general, the invention is directed to a thermal and/or light-protective container assembly, such as a form-fitting sleeve, that includes a flexible layered wall having an opened end and a contiguous closed end, wherein the wall defines a centrally located cavity. The wall further includes an outer layer and an inner layer, wherein uniformly disposed between the outer and inner layers (in at least the contiguous closed end) is a thermoregulatory material that is configured for insulating an object, and/or for transferring heat or cold to the object, and/dr maintaining the temperature of the object disposed within the defined cavity of the sleeve.

Thermal and/or Light-Protective Container Assemblies of the Invention

[0021] The invention provides for a thermal and/or light-protective container assembly, which may be configured as a thermal protective sleeve, that includes a layered wall having an outer layer, an inner layer, and a thermal regulating material disposed in between the outer and inner layers. The wall may further be flexible, include an opened end, a contiguous closed end, and may be configured to define a centrally located cavity. A feature of the thermal regulating material is that it is capable of maintaining the temperature of a contained object over a prolonged period of time. For instance, because of the unique configuration of the individual components, the thermal and/or light-protective container assembly can both reduce the effects of unfavorable temperature changes and protect item(s) contained in the assembly from light. Therefore, when used in conjunction with a contained object for the protection of a sample that includes an analyte, the invention not only promotes more accurate data measurements, by protecting thermo and/or light sensitive reactants from degradation, but also leads to increased sample life.

[0022] Additionally, the thermal and/or light protective container assembly (e.g., protective sleeve) may include an additional inner layer that contains one or more color elements that may be responsive to thermal or electromagnetic changes and thereby create a visual effect that indicates whether a contained item is above or below a specific set point. Such color changing elements include, but are not limited here to:

[0023] A thermal and/or light protective container assembly of the subject invention may have any form so long as it includes at least a layered wall with an outer layer, an inner layer, and a thermalregulatory material disposed in between said outer and inner layers, wherein the wall defines at least one cavity (e.g., a centrally located cavity). For simplicity and clarification of description, and not in anyway to be limited thereto, the thermal and/or light protective container assembly will be referred to as a thermal protective sleeve, but may as well be any form of container that has a layered wall (e.g., a flexible layered wall) with an outer layer, an inner layer, and a thermoregulatory material in between said outer and inner layers, such as an envelop, a pouch, a rack, or the like. A "protective sleeve," therefore generally refers to a thermal and/or light protective container assembly, as discussed herein, which is adapted for containing and/or enclosing an item and thereby protecting said item from unfavorable temperature changes and/or electromagnetic radiation (e.g., light), as described below in more detail.

[0024] A thermal and/or light protective container assembly (e.g., sleeve) of the subject invention may be constructed in any manner from any suitable material well known, usually including those used in the fabrication industry for the manufacture of thermo-resistant and/or electromagnetic radiation protective articles. This includes fireproof and/or solar proof fabrics, composites, weaves, and/or the like, as will be described in greater detail below.

[0025] Furthermore, a thermal- and/or light protective container assembly (e.g., sleeve) of the subject invention may have any shape and be constructed to contain and protect any item, so long as it contains a layered wall portion with an outer layer that is configured for resisting temperature changes, an inner layer that is configured for rapidly transferring thermal energy, and a thermoregulatory material that is disposed between the outer and inner layers and is configured for transferring or absorbing heat, wherein the wall defines at least one cavity. The thermoregulatory material may be uniformly disposed throughout the entire sleeve but is at least uniformly disposed at the contiguous closed end. For instance, the thermal and/or light protective sleeve of the subject invention may be configured to contain a test-tube, a vial, an ampule, a cup, a bottle, a beaker, a flask, a cylinder, titer plate, micro-titer plate, an array assembly, a substrate, Petri dish, a vase, one or more flowers, or the like within a centrally defined cavity. Accordingly, a container assembly of the subject invention, e.g., a sleeve, may have a square, rectangular, circular, triangular, spherical shape or the like. Accordingly, in certain embodiments the invention is directed to a thermal protective sleeve that includes a contained test-tube, vial, ampule, cup, bottle, beaker, flask, cylinder, titer plate, micro-titer plate, array assembly, substrate, Petri dish, vase, one or more flowers, or the like. The contained item may further include a sample, ligand, analyte, or other material to be tested. Hence, a container assembly of the invention having an item as described herein disposed within the assembly is also contemplated by the invention. Additionally, one or both of the outer and inner layers of the wall of the thermal and/or light protective container assembly of the subject invention may be clear, light resistant (e.g., opaque), and/or be configured to go from clear to opaque in response to a change in temperature or light, as will be described in greater detail below.

[0026] As summarized above the subject invention is directed, in representative embodiments, to a thermal and/or light-protective container assembly, such as a thermal protective sleeve, that includes a layered wall having an opened

end, a contiguous closed end, and defining a centrally located cavity. A feature of the wall is that it is layered, having an outer layer, an inner layer, and a thermoregulatory material disposed between the outer and inner layers. In general, the outer layer and inner layers are made from separate materials that are joined by means well known in the art and described in more detail below. However, in certain embodiments the thermal and/or light protective container assembly of the subject invention may be fabricated from one or several different materials and contain at least 1, at least 2, at least 3, at least 4 or more layers and/or coatings. In certain embodiments, the thermoregulatory material is a solute (e.g., ammonium nitrate or calcium chloride) that is separated from a solvent (e.g., water) by a dividing layer that is configured for being ruptured upon the application of a sufficient force. In certain embodiments, the thermoregulatory material is a homogenous mixture that is not divided into separate compartments (e.g., the container assembly does not include a dividing layer configured for being ruptured).

[0027] A feature of the subject invention is a thermoregulatory material that is positioned between the outer and the inner layers of the wall of the thermal and/or light protective container assembly (e.g., sleeve). "Thermoregulatory material" as used herein includes a material that provides for insulation for an item disposed in the assembly (e.g., so as to provide for maintenance of the temperature of the item in the assembly, or to slow the change in temperature of the item), as well as a thermal transferring material, such as a material that can provide for transfer of cold or heat to the item disposed in the assembly. These various components will now be described below with particular regard given to the function they perform and how they interconnect with the various other components of the thermal and/or light-protective container assembly.

[0028] The protective container assemblies of the invention can be composed of any suitable materials, and the outer layer and inner layer of the layered wall can be made of materials selected so as to enhance the thermal qualities of the material disposed between the inner and outer layer. The materials used in the manufacture of the protective container assemblies of the invention can be selected to provide for a disposable assembly, and may further be selected so as to provide a desired rigidity or flexibility to the assembly. In certain embodiments it is desired that the layered wall be flexible, in which case the inner and outer layers will be composed of a flexible material. In certain embodiments it is desired that the layered wall be semi-flexible, in which case the inner and/or outer layers will be composed of a semi-flexible material. In certain embodiments it is desired that the layered wall be rigid, in which case the inner and/or outer layers will be composed of a rigid material.

[0029] The outer layer of the layered wall may optionally be configured for resisting changes in temperature, and may be fabricated out of foamed or vulcanized rubber, neoprene, polyurethane, nylon, lycra, plastic, metal, or the like. The outer layer includes both an outer surface and an inner surface. It should be noted that, as used herein "outer surface" in reference to an outer layer or inner layer of the wall of the assembly refers to that surface of the layer which is exposed to the environment. As used herein "inner surface" in reference to an outer layer or inner layer of the assembly wall refers to that surface that is in contact with the thermoregulatory material disposed between the outer and inner layers. Thus the outer surface of the outer layer is defined generally as the portion of the outer layer that in normal use is in contact with the ambient environment, and which can serve as an interface for the user in manipulating a contained item. An "inner surface" of the outer layer is defined generally as the portion of the outer layer that in normal use is facing or is in contact with the thermoregulatory material.

[0030] Accordingly, in one embodiment, the "outer surface" of the outer layer of the layered wall may be coated with a protective material, such as a silicon, Teflon, metallic material, plastic coating, or the like so as to protect the assembly from damage due to contact with the ambient environment. In another embodiment, the "inner surface" of the outer layer is coated with at least one other material so as to make the "inner surface" of the outer layer non-absorbent and/or hydrophobic, and therefore not likely to absorb a substantial amount of the thermoregulatory material. Materials of the subject invention may be inherently hydrophobic or made hydrophobic by treatment in accordance with well known methods known and practiced in the arts. For instance, a material of the invention may be contacted with a swelling agent and a base and heating to alter the material, and then acidifying the treating bath and contacting the material with a hydrophobic polymer, as taught in U.S. Pat. No. 4,803,256, incorporated herein its entirety by reference. One advantage of this hydrophobic finish treatment is that the resultant hydrophobicity of the treated fabric is permanent. Chemicals for this treatment are available from Dow Corning, Inc. Midland, Mich. under the trademark VESTAR™. Other hydrophobic finishes that may also be employed are MILESASE T™, available from ICI America, Inc., Wilmington, Del.; ALKARIL QFC™ available from Chemical, Inc., Winds, Ga.; SCOTCHGARD™ Stain Release Fabric Treatment FC-22, available from the 3M Company, St. Paul, Minn.; TEFLON™, available from DuPont; and the like.

[0031] The thermal protective container assembly (e.g., the outer layer) may further include an attachment element for attaching the assembly to a rack, housing, or the like. The attachment element may be any form of attachment element known in the art, such as but not limited to a snap, draw string, button element, zip-fastener (e.g., a zipper mechanism), hook and loop fastener attachment (e.g., Velcro™), a screw element, a hook element, or the like. The outer layer may also include a sensor indicator for indicating the temperature of a contained item (for instance, a thermo strip).

[0032] In certain embodiments, the outer layer of the layered wall is configured for protecting an enclosed item against the effects of electromagnetic radiation, such as light. Accordingly, in one embodiment, the outer layer may be fabricated out of or be otherwise combined with a solar-resistant (e.g., a light resistant) material such as, but not limited to: metallized polyester fabrics, such as aluminized polyester, aluminized Mylar™, polyimide and/or metallic foil, and the like. The outer layer may include various film coatings, such as black polymer filters or fully exposed, maximally dense black and white film, and the like. In this embodiment, the film and/or other outer coating may be prepared from acrylic polymers which are cross-linkable, thermosettable, and self-bondable, as taught in U.S. Pat.

Nos. 4,803,256 and 6,800,367 both of which are incorporated herein in their entirety by reference. In certain embodiments, the outer surface of the inner layer of the layered wall may also be configured as above to protect against the effects of heat transference.

[0033] The outer layer may be opaque, semi-opaque, or clear but coated with an opaque material. The outer layer may be any color or mix of colors. In one embodiment, the outer layer is reflective of light. In another embodiment, the outer layer is absorbent of light. In a further embodiment the outer layer is transparent and the thermoregulatory material contains an additive that changes color in response to temperature or light. Such an additive may include silver chloride and/or copper chloride crystals, or the like.

[0034] Another feature of the thermal and/or light protective container assembly (e.g., sleeve) of the subject invention is a layered wall with an inner layer. In certain embodiments, the inner layer is configured for rapidly transferring thermal energy. The inner layer of the layered wall includes both an outer surface and an inner surface. An "inner surface" of the inner layer is defined generally as the portion of the inner layer that in normal use is facing, or is in contact with, the thermoregulatory material. Accordingly, in one embodiment, the "inner surface" of the inner layer is coated with a non-absorbent material, such as with those described above, so as to make the inner layer non-absorbent, and therefore not likely to absorb a substantial amount of the thermoregulatory material. An "outer surface" of the inner layer is the portion of the inner layer that in normal use contacts a contained item. As will be apparent, any surface of any layer may be coated with one or more non-absorbent and/or hydrophobic materials as set forth above, including the "outer surface" of the inner surface.

[0035] In certain embodiments, the inner layer of the layered wall is configured for protecting an enclosed item against the effects of electromagnetic radiation, such as light. Accordingly, in one embodiment, the inner layer may be fabricated out of a solar-resistant material such as, but not limited to, those set forth above. The inner layer may be opaque, semi-opaque, or clear but coated with an opaque material. The inner layer may be any color or mix of colors, it may be reflective or absorbent of light, or may be transparent.

[0036] The outer and inner layers of the layered wall may be joined or attached to one another by any means known in the art, including but not limited here to any one or more of the following: stitching, blind-stitching, gluing, taping, fusing, welding, ultrasonic welding, adhesives, hook-and-loop fasteners, chemical bonding, thermal-chemical bonding, and the like. In one embodiment, the outer and inner layers are attached to one another by blind stitching. In another embodiment, the outer and inner layers are attached to one another by thermal-chemical bonding wherein a reactive hot melt adhesive is used to join the various layers.

[0037] Another feature of the thermal and/or light protective container assembly of the subject invention is a thermoregulatory material that is in between the outer and inner layers. The thermoregulatory material may include any material capable of being inserted between an outer and inner layer and configured for absorbing heat from, or transferring heat to, an enwrapped or enclosed item. Accordingly, in one embodiment the thermoregulatory material is a cold thermoregulatory material that is configured for absorbing heat from a contained item through the inner layer. In one embodiment, the cold thermoregulatory material includes, but is not limited to: ammonium nitrate, liquid nitrogen, water, or the like. In certain embodiments, the thermoregulatory material is non-freezable. In certain embodiments, the cold transferring material is configured for maintaining the temperature of a contained item or at least reducing heat absorbance of the contained item for at least about 1 hour, for at least about 2 hours, for at least about 6 hours, for at least about 12 hours, for at least about 24 hours or more. In one embodiment, the cold transferring material may be cooled or frozen by placing the protective container assembly within an appropriate cold environment, such as but not limited to a refrigerator, cold room, freezer, or the like. In certain embodiments, the container assembly is configured in such a way so that the thermal regulatory material may be added or removed from between the outer and inner layers (e.g., the thermal regulatory material is replaceable). Accordingly, in this embodiment, the container assembly may include a nozzle, stem, or the like, for the introduction and removal of a thermoregulatory material in between the outer and inner layers of the container assembly.

[0038] In another embodiment, the thermoregulatory material is a heat thermoregulatory material that is configured transferring heat to a contained item through the inner layer of the layered wall. In one embodiment, the heat thermoregulatory material includes, but is not limited to: calcium chloride, or the like. In certain embodiments, the heat transferring material is configured for maintaining the temperature of a contained item or at least reducing heat loss for at least about 1 hour, for at least about 2 hours, for at least about 6 hours, for at least about 12 hours, for at least about 24 hours or more. In one embodiment, the heat transferring material may be heated by placing the protective container assembly within an appropriate warm environment, such as but not limited to a stove, oven, microwave, or the like.

[0039] Other components of the thermal and/or light protective container assembly (e.g., sleeve) of the subject invention is a layered wall with a top and a bottom portion. The top portion and bottom portion of the assembly may be provided in different configurations, as will be described in greater specificity below. In general, in one embodiment, the top and bottom portions of the container assembly are open and the assembly is in the configuration of a band that slides over the item to be contained, such that the item to be contained in the band may extend through the top portion, the bottom portion, or both. In another embodiment, the top portion is open, and the bottom portion is closed, such that the assembly provides a blind-ended sleeve (or pouch) into which the item is received. In this configuration, the bottom portion may be a contiguous, closed end portion of the wall. In a further embodiment, the container assembly is in the form of an envelop that is configured for encasing an item to be contained and is capable of securely attaching to itself by a suitable attachment or locking element and thereby enclosing the item within the envelop. Accordingly, in this embodiment, the top and bottom portions of the envelop are relative to the item therein contained.

[0040] In yet another embodiment, the container assembly includes a rack support that is configured for housing a plurality of items, for instance a plurality of container assemblies (e.g., sleeves) into which may be inserted various

vessels, such as tube elements, test tubes, microarray tubes, Eppendorf tubes, vials, ampules, cylinders, centrifuge tubes, micro-centrifuge tubes, shaker tubes, and the like. In another embodiment, the fabrication of the container assembly includes a stretchable weave material configured to make the assembly form fitting. These exemplary embodiments are described in greater detail below.

[0041] An additional component that may be added to the wall of the thermal and/or light protective container assembly of the subject invention is a viewing, or transparent element, for instance in the form of a window. The viewing element may be in any configuration and made from any material so long as it allows a viewer to view the contents within the protective container. For instance, the viewing element may be a transparent section of material, for instance a clear plastic, that is incorporated into the wall (e.g., the outer and inner layers), and allows visual access to the centrally located cavity of the container assembly, whereby a contained item (e.g., vessel) may be observed. The viewing element may fabricated from any transparent material well known in the art, including but not limited hereto: plastic, silica, or the like. The viewing element may also include a flap or cover element that is configured for opening and closing so as to prevent or minimize the access of electromagnetic radiation, such as light, from contacting a contained sample when visual access is not desired. The flap or cover element may also contain a locking element for securing the flap or cover element in a closed configuration. The locking element may be any locking element known in art and including, but not limited hereto, a snap, draw string, button element, zip-fastener (e.g., a zipper mechanism), hook and loop fastener attachment (e.g., Velcro™ strip), a screw element, a hook element, or the like.

[0042] A further component that may be added the thermal and/or light protective container assembly (e.g., sleeve) of the subject invention is a lid, cap, or flap portion for enclosing a top (i.e., an opened end portion of the layered wall) or bottom portion of the assembly. The lid, cap, or flap portion may include one lid, cap, flap, etc. or may include a plurality of such elements. The cap or flap portion may be attached or detachable and is configured for opening and closing and thereby enclosing a contained item within the bounds of an interior space or lumen of the container assembly. The container assembly may also include a locking element that may be configured for securing a top or bottom portion, a top, a flap, a cover, or the like in a closed configuration or may be configured for attaching one portion of the container assembly to itself, as discussed above in relation to the wrap configuration. The locking or attachment element may be any kind of element so long as it is capable of securing a top, bottom or side portion, cap, flap, cover, wrap, or the like in a closed configuration. In certain embodiments, and not to be limited hereby, the locking element is in the form of a snap, draw string, button, zip-closure (e.g., a zipper or zip-and-lock mechanism), hook and loop fastener (e.g., Velcro™) attachment, or the like.

[0043] Another component that may be added to the thermal and/or light protective container assembly is one or more sensors, such as a temperature, pressure sensor, or the like, and a sensor indicator for indicating a sensed parameter. In one embodiment, a protective container assembly includes a temperature sensor and a temperature indicator for indicating the temperature of a contained item.

[0044] A feature of the thermal and/or light protective container assembly of the subject invention is that it is adapted for containing one or more items and protecting them from unfavorable thermal or electromagnetic conditions. Accordingly, such a container may have a variety of configurations, shapes, sizes, colors, and the like, and may have a mesh-like configuration. Exemplary embodiments of various configurations will now be described in greater detail below.

[0045] In a further object of the invention, a method of using the subject thermal and/or light protective container assembly is provided, which includes using the protective container assembly of the subject invention, e.g., cooling or heating the container assembly, for instance by placing the assembly in a refrigerator, freezer, oven, microwave, of the like, opening the container, inserting a vessel into a lumen of the container, and if a closure element is provided closing and securing the closure element and thereby encasing or enwrapping the vessel within the protective container assembly.

EXEMPLARY EMBODIMENTS

[0046] Various embodiments of the subject invention will now be described with reference to the figures. For clarity and convenience, the container assembly is exemplified in the figures and below as a sleeve (e.g., a pouch) or rack assembly. However, as described above, other embodiments of container assemblies, such as thermal envelop assemblies, are contemplated by the invention. FIGS. **1-3** show cross sectional views of an exemplary thermal and/or light protective container assembly **10** according to an illustrative, but non-limiting embodiment of the present invention. FIGS. **4-6** show perspective views of the container assembly **10**.

[0047] As can be seen in FIGS. **1-3**, in certain embodiments, the thermal and/or light protective container assembly (e.g., thermal protective sleeve) of the invention **10** includes a flexible layered wall with an outer layer **12**, an inner layer **16**, and an in-between layer **14** (i.e., a thermal resistant layer). The layered wall defines a centrally located cavity **19**. The outer layer **12** includes an outer surface **13***a* and an inner surface **13***b*. Outer surface **13***a* contacts the ambient environment and may be coated with a protective coating such as a silicon coating, so as to protect the assembly from damage. Inner surface **13***b* contacts the in-between layer **14** and may be coated with a non-absorbent material so as to prevent or reduce absorbance of the thermal resistant in-between layer **14**. The outer layer **12** is configured for resisting changes in temperature and/or protecting the cavity of the container assembly from electromagnetic radiation, e.g., light. The inner layer **16** includes an inner surface **17***a* and an outer surface **17***b*. Inner surface **17***a* contacts the in-between layer **14** and may also be coated with a non-absorbent material. The inner layer **16** is configured for rapidly transferring thermal energy and/or protecting the lumen of the container assembly from electromagnetic radiation, e.g., light. The in-between layer **14** is in-between the outer layer **12** and the inner layer **16** and is made of a thermal resistant material. The in-between thermo resistant layer may be configured for absorbing heat through said inner layer (e.g., thereby maintaining or lowering the temperature of a contained item) or transferring heat through

said inner layer (e.g., thereby maintaining or increasing the temperature of a contained item or decreasing the rate of heat loss).

[0048] FIG. **1** shows a thermal and/or light protective container assembly **10** in accordance with one embodiment of the invention, wherein the container is configured as a sleeve that includes an attached cap element **18** and is in an empty configuration. FIG. **2** shows a protective container assembly **10** with an attached cap element **18**, wherein the container encloses an item, such as a test tube (not shown). It is to be noted that although with respect to the figures, the protective container assembly (e.g., sleeve) is depicted as an assembly for containing a test tube, this is for illustrative purposes only, as the configuration of the assembly will vary with the item to be contained. For instance, the assembly can be configured to contain a microarray tube, Eppendorf tube, centrifuge tube, micro-centrifuge tube, shaker tube, a vial, an ampule, a cup, a bottle, a beaker, a flask, a cylinder, titer plate, micro-titer plate, an array assembly, a substrate, Petri dish, a vase, or the like.

[0049] As can be seen with reference to FIGS. **2** and **3**, the protective container assembly **10** may include a transparent (window) portion **22**, for allowing visual access to a contained item, and/or my include a thermal strip **24** for indicating the temperature of an enclosed item.

[0050] With respect to FIGS. **4-6**, FIG. **4** shows a front perspective view of a thermal and/or light protective sleeve assembly **10** of the present invention. As can be seen, the protective container **10** includes an attached lid **18**, configured for opening and closing and thereby enclosing, containing, and protecting an inserted vessel. Accordingly, in certain embodiments the invention is directed methods of containing an item and to items contained within the container assembly of the subject invention. For instance, in one embodiment, the invention is directed to a method for containing an item within an assembly of the invention which includes positioning an item so as to be inserted into the centrally defined cavity of the layered wall and inserting the item therein so as to cause the item to be encased within the assembly. The method may further include closing an included cap or top portion so as to completely enclose the contained item within the assembly and may include securing the cap portion in a closed position via a locking element. Additionally, in certain embodiments the invention is directed to a thermal protective container assembly of the invention that contains an item inserted therein, for instance a microarray tube, Eppendorf tube, centrifuge tube, micro-centrifuge tube, shaker tube, a vial, an ampule, a cup, a bottle, a beaker, a flask, a cylinder, titer plate, micro-titer plate, an array assembly, a substrate, Petri dish, a vase, or the like.

[0051] With respect to FIG. **4**, the protective container assembly **10** further includes a transparent element **22**, such as a window element, that is configured for allowing visual access to a contained vessel. Transparent element **22** includes a cover or flap portion configured for opening, closing, and being locked in place. FIG. **5** shows a side perspective view of the protective container assembly **10** with an attached lid **18** in a closed position. The container may additionally include an attached thermo strip (not shown). FIG. **6** shows an opposite side perspective view of the assembly of FIG. **5**. As can be seen in FIGS. **5** and **6**, the protective container assembly **10** contains a vessel (not shown) such as a test-tube.

[0052] FIG. **7** shows a perspective view of another embodiment of a thermal and/or light protective container assembly of the present invention. In this embodiment, a rack support includes a plurality of protective container assemblies that are fit into orifices of the rack support and attached to the rack. The support rack **100** is adapted for receiving and retaining (e.g., housing) one or more, for instance a plurality, of protective container assemblies (i.e., sleeves). Accordingly, in one embodiment, the support rack **100** includes a plurality of protective container assembly sleeves **110** that are supported within orifices **119** in the rack support **100**. A sample may be contained within a tube, such as an Eppendorf tube, test tube, or the like, which is then placed within a centrally located cavity of an individual protective assembly sleeve **110**, within the rack support **100**. Protective container assembly sleeves **110** are configured in accordance with the teachings of the present invention, as set forth above, and include attached lids **118**, that are configured for opening and closing. In this manner, a plurality of vessels may be inserted into the one or more assembly pouches within the rack support and thereby be protected from thermal and/or electromagnetic radiation, e.g., light.

[0053] A thermal and/or light protective container assembly of the present invention may also be configured as a titer plate container (pouch assembly), such as a micro-titer plate container. In this embodiment, a portion of the layered wall may contain a plurality of orifices or openings **119** that open up to the centrally located cavity of the protective container pouch assembly, which may be included as a portion of a rack support. For instance, instead of housing one or more protective assembly sleeves, as described above, the assembly **100** could itself be a protective container assembly of the present invention that has a single, centrally located cavity (not shown) that is configured for receiving a vessel, such as a micro-titer plate. The cavity can be accessed by an openable end (not shown), which may be positioned at a side opposite or adjacent the plurality of orifices. In this embodiment, a micro-titer-plate may be inserted into the cavity, and the cavity may then be closed by a fold, cap, or other closure element (not shown). Individual portions (e.g., wells) of the microtiter plate may then be accessed by the plurality of openings **119** included in the wall of the protective container assembly **100**. A plurality of flap elements **118** may also be included to close the plurality of openings **119** when access to the encased item (e.g., micro titer plate) is not desired. In this embodiment, each opening **119** and flap element **118**, if included, should be aligned with a single well of the enclosed micro-titer plate. It is to be understood that although this embodiment is disclosed with reference to a micro-titer plate, this is for illustrative purposes only, as the actual configuration, number of orifices or openings and closure elements, etc. within the wall of the assembly may vary with the item to be contained. For instance, the item to be contained may be a Petri dish, slide, substrate, micro-array slide, etc. in which case the actual dimensions of the assembly will be configured accordingly so as to enclose the item to be contained and thereby protect it from temperature (e.g., heat) and/or light.

[0054] FIG. **8** shows a thermal and/or light protective container assembly in accordance with another embodiment

of the present invention. FIG. **8** is a cross sectional view of a of a thermal and/or light protective container assembly in the configuration of a rack. In the embodiment of FIG. **8**, the protective container assembly itself is configured as an assembly rack **100**, accordingly in this embodiment the layered wall portion is not flexible but rather is semi-rigid or rigid and contains a plurality of cavities (e.g., 19). Assembly rack **100** is configured for holding one or more vessels and includes outer layer **12**, inner layer **16**, and an in-between layer **14** that includes a thermoregulatory material. Assembly rack **100** further includes lids **18***a*-**18***h*. Although only 8 orifices and lids are shown, it is understood that this is for purposes of exemplification only, as an assembly rack of the invention may include any feasible number of orifices into which a vessel may be inserted. Accordingly, in the embodiment of FIG. **8**, any one of lids **18***a*-**18***h* may be opened, a vessel, such as a test-tube, may be placed inside a lumen **19** of the container assembly, the lid closed, and the vessel may thereby be protected from thermal and/or electromagnetic radiation e.g., light.

[**0055**] FIGS. **9**A-**9**B show another embodiment of a rack support of the present invention. FIG. **9**A is a perspective view of the subject rack. FIG. **9**B is a side view of the subject rack. As can be seen in FIGS. **9**A-**9**B, the rack **200** includes a plurality of thermal and/or light protective container assemblies **10***a-t*, each of which are configured in accordance with the invention as described above. Although only 20 thermal and/or light protective container assemblies are shown, it is understood that this is for purposes of exemplification only, as any feasible number of assemblies may be included. Accordingly, in this embodiment, a vessel, such as a test-tube, may be placed inside a centrally defined cavity **19** of any one of protective container assemblies **10***a*-**10***t* which may then be closed by a lid, and thereby be protected from thermal and/or electromagnetic radiation, e.g., light. Additionally, each protective container assembly includes attachment elements **21***a* and **21***b* (not shown) for attaching the assembly to a rack attachment portion **23**. In this manner the protective container assemblies **10** may be rotated by the rotation of rack attachment portion **23**.

[**0056**] FIG. **10** shows a perspective view of a thermal and/or light protective container assembly of the invention. The protective container assembly contains a transparent element **24** with a cover flap **26**, wherein the cover flap **26** is in an open configuration. Also included is an attachment element **28**, such as a hook and loop fastener (e.g., a Velcro™ strip), for securing a cover flap in a closed position. A detachable lid **18** is also included. As can be seen in FIG. **10**, a vessel **30**, such as a test tube, has been inserted into the protective container assembly.

What is claimed is:

1. A thermal protective sleeve, comprising:

a flexible layered wall having an open end and a contiguous closed end, and defining a centrally located cavity, said layered wall comprising an outer layer and an inner layer; and

a thermoregulatory material disposed uniformly between said outer and said inner layers of said wall in at least said contiguous closed end,

wherein said thermoregulatory material is capable of maintaining the temperature of a substance disposed within the cavity.

2. The thermal protective sleeve of claim 1, wherein said thermoregulatory material is ammonium nitrate or calcium chloride.

3. The thermal protective sleeve of claim 1, wherein said outer layer comprises a material selected from the group consisting of foamed rubber, vulcanized rubber, neoprene, polyurethane, nylon, lycra, plastic, and metal.

4. The thermal protective sleeve of claim 1, wherein said outer layer further comprises a protective silicon coating.

5. The thermal protective sleeve of claim 1, wherein at least one surface of a layer of the thermal protective sleeve comprises a non-absorbent material so as to make the layer non-absorbent.

6. The thermal protective sleeve of claim 5, wherein an inner surface of said outer layer comprises a non-absorbent material so as to make the inner surface of said outer layer non-absorbent.

7. The thermal protective sleeve of claim 5, wherein at least one of the outer or inner surface of said inner layer comprises a non-absorbent material.

8. The thermal protective sleeve of claim 1, wherein at least one of said outer and inner layers is light-resistant.

9. The thermal protective sleeve of claim 1, wherein the sleeve is configured for receiving a material selected from the group consisting of a test tube, vial, ampule, titer plate, a micro array substrate, a Petri dish, a vase, a bottle, a flask, a beaker, a cup, and a flower.

10. The thermal protective sleeve of claim 11, wherein the sleeve comprises a member selected from the group consisting of a test tube, vial, ampule, titer plate, a micro array substrate, a Petri dish, a vase, a bottle, a flask, a beaker and a cup disposed in said cavity.

11. The thermal protective sleeve of claim 1, wherein said sleeve further comprises a detachable top for closing said open end.

12. The thermal protective sleeve of claim 11, wherein said sleeve comprises a locking element configured for securing said detachable top in a closed position.

13. The thermal protective sleeve of claim 1, wherein said sleeve comprises an attachment element for attaching said assembly to an external member, wherein said attachment element is a member selected from the group consisting of a snap, a draw string, a button, a zip closure, and a hook and loop fastener attachment.

14. The thermal protective sleeve of claim 1, further comprising a transparent element.

15. The thermal protective sleeve of claim 14, further comprising a cover element configured for covering and uncovering said transparent element and a locking element configured for locking said cover element in a closed position.

16. The thermal protective sleeve of claim 15, wherein said locking element comprises a member selected from the group consisting of a snap, a draw string, a button, a zipper, and a hook and loop fastener attachment.

17. The thermal protective sleeve of claim 16, wherein said transparent element is made from plastic or silica.

18. The thermal protective sleeve of claim 1, wherein a portion of said wall further comprises a plurality of openings, so as to allow a user to access an object disposed in the cavity; and a plurality of flaps configured for closing said openings.

19. The thermal protective sleeve of claim 1, further comprising a sealable valve for introducing and removing said thermoregulatory material into said sleeve.

20. A rack support containing one or more of the thermal protective sleeves of claim 1.

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