

AN ADAPTER FOR RELEASABLY COUPLING A DRAPE ASSEMBLY TO OPERATING ROOM EQUIPMENT

TECHNICAL FIELD

[001] Various embodiments relate generally to an adapter for releasably coupling a drape component to an operating room equipment, and more particularly a drape assembly capable of being suspended from an operating room equipment to form a shield over at least a portion of a table or surface that a procedure (operating or laboratory) is being conducted upon.

BACKGROUND

[002] Various surgical procedures, such as Mastoid surgery, involve the use of high-speed drills and irrigation fluid that are highly droplet and aerosol-generating procedures. There are no reasonable alternative instruments to perform these procedures, and even with the use of standard personal protective equipment (PPE), there is significant contamination of the surgeon and the surgeon's surroundings occurring as a result. The droplets and aerosols generated during these procedures have been shown to travel significant distances, putting not only the surgeon but also support staff in an operating theatre at risk for contamination.

[003] To compound the aforementioned problem, certain PPE such as eye goggles and face shields are unable to be worn while using a surgical microscope as the surgeon's eyes need to be reasonably close to the microscope's eyepieces. This has significance with regard to the potential transmission of infective agents via mastoid surgery. Although this is a problem that received attention during the recent Covid-19 pandemic, it is a perpetual problem that should be addressed for the safety of healthcare workers beyond the pandemic.

[004] In particular, it is known that the mastoid cavity and middle ear communicate with the upper respiratory tract via the Eustachian tube; and is frequently involved in upper respiratory tract infections. In congruence, various studies have found common viruses in the nasopharynx and the middle ear. More recently, a cadaveric study has isolated the SARS-CoV-2 virus from the mastoid and middle ear during a post-mortem study of deceased Covid-19 positive patients. Further, it is also of note that urgent/semi-urgent mastoidectomy is frequently indicated for a myriad of ontological conditions, including mastoid abscess, complicated cholesteatomas, cancers and lateral skull base tumours. Many of these surgeries cannot be postponed during a pandemic without significant risk of acute deterioration or even death of the afflicted patients.

[005] Mastoid drilling involves the use of high-speed irrigation drills under the surgical microscope. This creates a large number of droplets and aerosols which contaminate not only the surgeon but also the operating theatre and support staff^{1,2}. Conventional PPE does not adequately protect the surgeon from droplets from mastoidectomies². In the post-pandemic era, this increased awareness

has created a paradigm shift where it is recognized that droplets generated during mastoidectomies may pose significant risks to the surgical team. Acknowledging this problem, studies have been published on the recommended personal protective equipment (PPE) for use during mastoid surgery². Unfortunately, the use of ideal PPE often creates problems with visualisation during surgery. PPE such as safety goggles, face shields, and powered air-purifying respirators affect the surgeon's use of the surgical microscope to varying degrees².

[006] Accordingly, during the Covid-19 pandemic, various short-term solutions were proposed for this problem, including: 1) Avoiding and postponing non-urgent mastoid surgery, however, this is not feasible in the longer term; 2) Avoiding the use of high-speed surgical drills/ irrigation fluid and using instruments like curettes and chisels instead, however, this is unsafe in fine ontological surgery; and 3) **Cutting up and modifying currently available drapes to create a "tent" around the surgical field**, however, this can be unwieldy, and a lack of a support frame around the floppy drapes makes it frustrating to use. It is also difficult to attach securely to a microscope. It will be appreciated that this problem applies beyond the Covid-19 pandemic, and it is more evident now than ever, that healthcare workers and personnel in operating theatres should be better protected during surgical operations that generate fluid droplets and aerosol, such as during mastoid surgery, in a manner that is feasible and sustainable in the long term.

[007] In addition, various studies have proposed the use of barrier drapes around the operative field to reduce the risk of droplet and aerosol dispersion during mastoid surgery¹⁻⁷. As most of the drapes described have been improvised for use from existing drapes made for other purposes⁴⁻⁷, they may be more tedious to set up and often affect the dexterity of the surgeon.

[008] A specialised barrier drape for mastoid drilling has been recently developed by Grace Medical, termed the "OtoShield", attempting to alleviate these problems. However, there exist several design features of this drape that present their own problems and make it difficult to use. For example, the barrier drape is attached to the microscope on one end and the surgical field on the other – this limits the degree of movement of the surgical microscope without causing disturbance to the surgical field. This is a problem as in ontological surgery, the microscope needs to be moved and angled in various directions to complete the various steps of the operation. In addition, the "Otosshield" **requires the surgeon's arms to be placed through plastic tubings to enter and exit the surgical field** – this restricts the movement of the surgeon's arms and makes it more cumbersome for the surgeon's hands to enter and exit the surgical field.

[009] Therefore, there is still need in the art for improved barrier drapes and means of their attachment to various operating equipment to alleviate the abovementioned problems.

SUMMARY

[010] Various embodiments meet this need by providing an adapter and drape assembly to couple to operating room equipment.

[011] In a first aspect, there is provided an adapter for releasably coupling a drape component to an operating room equipment, comprising: an adapter body comprising: a first portion having a coupling arrangement couplable to a complementary coupling arrangement of the operating room equipment, a second portion opposite to the first portion; and a cavity extending internally along the adapter body from the second portion towards the first portion, the cavity having an opening at the second portion; and an attachment unit housed within the cavity of the adapter body and exposed through the opening of the cavity at the second portion, the attachment unit being capable of forming a quick-release engagement with the drape component.

[012] In various embodiments, the adapter body comprises a first face at the first portion, and a second face at the second portion, wherein the cavity is recessed into the second face.

[013] In various embodiments, the first face and second face are parallel planar surfaces directed in opposite directions.

[014] In various embodiments, the quick-release engagement between the attachment unit and the drape component comprises a quick-release magnetic engagement, a quick-release snap fit engagement, a quick-release pin engagement, a quick-release clamp engagement, a quick-release lever-type engagement, a quick-release push button engagement, or a quick-release hook and loop engagement.

[015] In various embodiments, the adapter further comprises an alignment arrangement disposed at the second portion of the adapter body for alignment of the drape component to the adapter.

[016] In various embodiments, the alignment arrangement comprises at least one alignment element at the second portion of the adapter body for cooperating with a corresponding alignment element of the drape component to bring the drape component into alignment with the adapter.

[017] In various embodiments, the alignment arrangement comprises two alignment elements, wherein the two alignment elements are respectively positioned in an opposing manner across the opening at the second portion such that the opening is positioned therebetween.

[018] In various embodiments, the adapter further comprises a retaining arrangement for retaining the attachment unit within the cavity, wherein the retaining arrangement comprises at least one

protruding rim extending perpendicularly with respect to an inner wall surface of the cavity along a segment of the opening of the cavity.

[019] In various embodiments, the coupling arrangement comprises a male coupling element for releasably coupling with the complementary coupling arrangement of the operating room equipment comprising a complimentary female coupling element.

[020] In various embodiments, the male coupling element comprises a plurality of trapezoidal or wedge-shaped elements, and the complementary female coupling element comprises a mount comprising one or more recesses for slidably receiving the trapezoidal or wedge-shaped elements such that the adapter body may be securely and releasably held in position on the operating room equipment.

[021] In various embodiments, the coupling arrangement is integrally formed with the adapter body as a single-piece.

[022] In various embodiments, the adapter body comprises a main piece and a secondary piece having the coupling arrangement, wherein the secondary piece is releasably secured to the main piece to form the adapter body, wherein the secondary piece is a plate-like structure, and wherein the main piece and secondary piece are secured together via one or more fasteners.

[023] In various embodiments, the attachment unit is fitted into the cavity in a manner to cover the opening of the cavity at the second portion.

[024] In various embodiments, the attachment unit comprises an engagement element exposed through the opening of the cavity at the second portion for releasably coupling with a corresponding engagement element of the drape component.

[025] In various embodiments, the engagement element of the attachment unit comprising a magnet, preferably a neodymium magnet, that releasably couples to the corresponding engagement element of the drape component comprising a magnetic material in a manner so as to magnetically couple with the adapter and the drape component.

[026] In various embodiments, the magnet is embedded or integrally formed within the engagement element, or the magnet is attached to an external surface of the engagement element.

[027] In various embodiments, the attachment unit is detachable from the drape component in a tool-free manner such that the adapter is coupled to, and decoupled from, the drape component without need for external tools or components for said coupling or decoupling, such as threaded screws, nuts, bolts, clamps, or other fasteners.

[028] In another aspect, there is provided a drape assembly capable of being suspended from an operating room equipment to form a shield over at least a portion of a table or surface, the drape assembly comprising: a drape component comprising a drape having a peripheral region and a central region, and a frame fixedly attached to the central region of the drape; and an adapter comprising an adapter body comprising: a first portion having a coupling arrangement couplable to a complementary coupling arrangement of the operating room equipment, a second portion opposite to the first portion; and a cavity extending internally along the adapter body from the second portion towards the first portions, the cavity having an opening at the second portion; and an attachment unit housed within the cavity of the adapter body and exposed through the opening of the cavity at the second portion, wherein the drape component is releasably coupled to the adapter with the frame of the drape component and the attachment unit of the adapter forming a quick-release engagement.

[029] In various embodiments, the drape is a single sheet of fully transparent flexible material, wherein the peripheral region defines a continuous perimeter of the drape, which hangs down from the central region when the adapter is coupled to the operating room equipment.

[030] In various embodiments, the drape forms a dome shape that is substantially spherical or hemispherical forming the shield to mitigate fluid movement from an interior space into an exterior space thereby mitigating droplet, particulate, and aerosol movement from the interior space into the exterior space.

[031] In various embodiments, the attachment unit of the adapter comprises an engagement element releasably coupled to a corresponding engagement element of the drape component, wherein the corresponding engagement element of the drape component is fixedly coupled to the frame of the drape component such that a portion of the drape is sandwiched between the frame and the corresponding engagement element of the drape component.

[032] In various embodiments, the adapter comprises an alignment arrangement having at least one alignment element disposed at the second portion of the adapter body, wherein the engagement element of the drape component and/or the frame of the drape component comprises at least one corresponding alignment element, wherein the at least one alignment element and the at least one corresponding alignment element cooperatively aligns the drape component with the adapter.

[033] In various embodiments, the frame is attached to an interior surface of the drape such that a top surface of the frame is covered by the drape.

[034] In various embodiments, the frame comprises a first planar part comprising a plurality of elongate supporting members extending radially outwards from the first planar part, wherein, when the adapter is coupled to the operating room equipment, the first planar part is orientated substantially

horizontal relative to a surface of the table or surface; and a second planar part comprising a plurality of elongate supporting members extending radially outwards from the second planar part, wherein the second planar part forms an obtuse angle with the first planar part, preferably at an angle of 140-160°, more preferably at an angle of 145-150°.

[035] In various embodiments, each elongate supporting member comprises a proximate section co-planar with their respective first planar part or second planar part from which they extend; and a distal section that bends from the proximate section, preferably to form an angle of 150-170°, more preferably to form an angle of 155-165°.

[036] In various embodiments, the first planar part comprises three elongate supporting members, and the second planar part comprises two elongate supporting members extending in opposite directions to each other.

[037] In various embodiments, the second planar part further comprises two arms extending parallel to each other in a same outwards direction from the second part, wherein the two arms are co-planar with the second planar part.

[038] In various embodiments, the first planar part comprises a port, preferably the port comprises a closing flap or valve for sealing the port, preferably the port is configured for a suction device to be attached.

[039] In various embodiments, the corresponding engagement element of the drape component is fixedly coupled to the second planar part of the frame.

[040] In various embodiments, the corresponding engagement element of the drape component comprises a metal sheet-like structure, preferably comprising steel or other magnetic material, and a plurality of flexible pins passing through a plurality of corresponding pin holes in the second planar part and gripping the second planar part for fixedly coupling the sheet-like structure to the frame.

[041] In another aspect, there is provided a system for forming a shield over at least a portion of a table or surface during a procedure using an operating room equipment, comprising the drape assembly disclosed herein, and the operating room equipment, wherein the operating room equipment comprises a complementary coupling arrangement that is releasably coupled to the coupling arrangement of the adapter.

[042] In various embodiments, the coupling arrangement of the adapter comprises a male coupling element and the complementary coupling arrangement comprises a complementary female coupling element, whereby the male coupling element is releasably coupled to the complementary female coupling element.

[043] In various embodiments, the operating room equipment is a magnifying instrument, preferably an operating microscope, wherein the complementary female coupling element is positioned on the magnifying instrument housing above a lens, and the adapter, and consequently the lens, is orientated at substantially the same angle as the second planar part of the frame.

[044] In various embodiments, the system further comprises a suction device attached in a sealing engagement to the drape assembly for extracting aerosols from the interior space, wherein the suction device is part of a suction system, preferably a scavenger system.

[045] All embodiments described above in the context of the adapter and concerning the drape assembly as such are similarly applicable to the system of the various embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[046] Various embodiments will be better understood with reference to the detailed description when considered in conjunction with the non-limiting examples and the accompanying drawings.

[047] FIG. 1 shows a side-view of an exemplified embodiment of the drape assembly coupled to a microscope.

[048] FIG. 2 shows a (A) top perspective view of an exemplified embodiment of the adapter body of the adapter disclosed herein; (B) bottom perspective view of the exemplified embodiment of the adapter body of the adapter disclosed herein; (C) bottom view (i.e. plan view of the second portion) of the adapter body; (D) top view (i.e. plan view of the first portion) of the adapter body; (E) cross-section E-E in (C); (F) cross-section of F-F in (D); (G) cross-section G-G in (C); and (H) cross-section H-H in (D).

[049] FIG. 3 shows a perspective and exploded view of an exemplified embodiment of the adapter disclosed herein and individual components separately.

[050] FIG. 4A-D shows different views of an exemplified embodiment of the attachment unit of the adapter disclosed herein.

[051] FIG. 5 shows a (A) bottom view (i.e. plan view of the second portion) of the adapter as shown in FIG. 3; (B) a cross-section of B-B shown in (A); (C) top view (i.e. plan view of the first portion) of the adapter as shown in FIG. 3; (D) side-view of the adapter shown in (C).

[052] FIG. 6 shows a (A) top perspective view (i.e. View from a first portion) and (B) bottom perspective view (i.e. view from a second portion) of an exemplified embodiment of the adapter body disclosed herein; (C), (D) and (E) side-views of the adapter body of (A) and (B); (F) bottom view (i.e. plan view of the second portion) of the adapter body; and (G) top view (i.e. plan view of the first portion) of the adapter body.

[053] FIG. 7 shows a (A) top perspective view (i.e. view from a first portion) and (B) bottom perspective view (i.e. view from a second portion) of an exemplified embodiment of the adapter body disclosed herein that differs from the adapter body of FIG. 6 in the depth dimension; (C), (D) and (E) side-views of the adapter body of (A) and (B); (F) bottom view (i.e. plan view of the second portion) of the adapter body; and (G) top view (i.e. plan view of the first portion) of the adapter body..

[054] FIG. 8 shows a plan view and side view of exemplified embodiments of the drape without the frame in a circular or substantially square shape, forming a dome shape when suspended.

[055] FIG. 9 shows (A) a plan view of an exemplified embodiment of the frame; (B) a perspective view of the frame of (A) showing the top surface; (C) a perspective view of the frame of (A) showing the bottom surface; (D) a side-view of the frame with the first planar part being orientated along a horizontal axis; (E) a side-view of the frame with the first planar part being orientated along a horizontal axis; (F) cross-sectional (R-R and L-L) side-view of FIG. 9A indicating the angular orientation of the distal section of the elongate supporting member relative to the proximate section.

[056] FIG. 10 shows a (A) perspective view of the top surface of an exemplified embodiment of the corresponding engagement element in the form of a sheet-like structure; (B) perspective view of the bottom surface of the corresponding engagement element of (A); and (C) perspective view of the corresponding engagement element coupled to the second planar part of the frame illustrated in FIG. 9B.

[057] FIG. 11 shows a (A) and (B) plan view and (C) side view of exemplified embodiments of the drape component, forming a dome shape whereby the drape has either a circular (A) or substantially square (B) shape when laid flat.

[058] FIG. 12 shows an aerial view of a table and microscope with markings around the operative site.

[059] FIG. 13 shows the maximum trajectory of droplets from operative site 'A' in FIG.12. Differing lines and areas refer to Condition A in which no microscope was used, Condition B, in which the microscope was used alone, and Condition C in which the microscope was fitted with the drape assembly disclosed herein (i.e. otodome).

[060] FIG. 14 shows the Degree of contamination seen at 30 cm and 60 cm from point A in FIG.12, in all 3 conditions (A, B and C), (A) without a microscope, (B) with the microscope alone, and (C) with the microscope fitted with the novel barrier drape. The differing lines and areas refers to mild contamination, moderate degree of contamination, and severe contamination.

DETAILED DESCRIPTION

[061] The following detailed description refers to, by way of illustration, specific details and embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention. Other embodiments may be utilized and structural and logical changes may be made without departing from the scope of the invention. Embodiments described below in context of the adapter and drape component are analogously valid for the respective drape assembly and system, and *vice versa*. The various embodiments are not necessarily mutually exclusive, as some embodiments can be combined with one or more other embodiments to form new embodiments.

[062] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art. The singular terms "a," "an," and "the" include plural referents unless context clearly indicates otherwise. Similarly, the word "or" is intended to include "and" unless the context clearly indicates otherwise. The term "comprises" means "includes." In case of conflict, the present specification, including explanations of terms, will prevail. Unless specified or limited otherwise, the terms "mounted," "connected," "supported," and "coupled" and variations thereof are used broadly and encompass both direct and indirect mountings, connections, supports, and couplings. In various embodiments, the terms "connected" and "coupled" are restricted to physical or mechanical connections or couplings.

[063] "About", as used herein in connection with numerical values refers to the referenced numerical value $\pm 10\%$ or $\pm 5\%$.

[064] Also, the use the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "right", "left", "front", "back", "upper", "lower", "above", "below", "top", or "bottom" and variations thereof herein is for the purpose of description and should not be regarded as limiting.

[065] Conditional language, such as, among others, "can," "could," "might," or "may," unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or steps. Thus, such conditional language is not generally intended to imply that features, elements and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements and/or steps are included or are to be performed in any

particular embodiment. The headings used herein are for the convenience of the reader only and are not meant to limit the scope of the inventions or claims.

[066] There is provided herein a drape assembly intended in use to reduce exposure of personnel in a surgical operating theatre or laboratory room (i.e. surgeons, operating theatre support staff, dentists, or lab technicians) to droplets and aerosol produced during highly droplet and aerosol-generating procedures. For example, mastoid surgery or other similar procedures that involve high-speed drilling and irrigation fluids that generate aerosol and droplets.

[067] The drape assembly disclosed herein assists in reducing splatter and spreading of fluid to the surroundings of the operating area or room. Accordingly, the drape assembly disclosed herein improves protection and reduces the risk of contamination of the personnel in the room (e.g. surgeons, dentists, lab technicians, operating theatre staff) who may or may not be protected by standard Personal Protective Equipment (PPE). Better protection of such personnel will reduce rates of transmission of infectious agents or contaminants and will indirectly protect others from cross-contamination. The utility of such a drape assembly as disclosed herein to block transmission of containment between individuals has also been emphasized and proved to be effective during the COVID-19 pandemic. This can also in turn reduce healthcare costs related to the treatment of infectious diseases.

[068] Although the drape assembly disclosed herein may be described in reference to personnel conducting an operatory procedure on a patient (e.g., a surgery on a patient such as, a neurosurgical procedure, a general surgery procedure, a vascular surgery procedure, an ear nose and throat ("ENT") surgery procedure, an internal medicine procedure, an anesthesia procedure, a gastrointestinal procedure, a genitourinary procedure, an intensive care unit ("ICU") procedure, an emergency medicine procedure, an orthopedic procedure, other aerosol generating procedures, etc.), it will be appreciated that in alternative non-limiting examples the drape assembly disclosed herein may be utilized for laboratory procedures, experiments, tests, or the like, where personnel may interact with a sample that can spontaneously generate pathogen laden aerosols, tissue particulates, or droplets, or which can generate pathogen laden aerosols, or tissue particulates, during manipulation of the sample (e.g. during drilling of the sample). For example, these samples can include tissue biopsies, pathology screenings, testing swabs (e.g. from the SARS-CoV-19).

[069] The term "drape component" as used herein, refers to an apparatus comprising a drape, a frame and/or additional features, whereby a "drape assembly" as used herein, refers to the drape component coupled to the adapter disclosed herein.

[070] The drape assembly disclosed herein generally includes a drape component and an adaptor for releasably coupling the drape component to an operating room equipment. In addition, the

assembly disclosed herein may also be a part of a system comprising the operating room equipment itself.

[071] FIG.1 illustrates an exemplary, non-limiting, embodiment of the drape assembly comprising the adapter **100** and drape component **400** (comprising a drape **200** and a frame **300**) releasably coupled to the operating room equipment **500** (e.g. microscope) to form a system, whereby the coupling and positional relationship between the components are shown when, in use, to form a shield over at least a portion of a surface **600** (e.g. operating table or laboratory table).

[072] The adapter of the drape assembly of the various embodiments is described in the following.

[073] The adapter disclosed herein functions to ensure that the drape component is securely held in the desired and predetermined position of a user (i.e. operating personnel such as a surgeon) throughout the use of the operating room equipment by the user. In this regard, the adapter is suitably configured to be securely coupled to both the drape component and the operating room equipment and acts as an attachment point between the drape component and the operating room equipment.

[074] In use, the adapter disclosed herein is releasably coupled to both the drape component and the operating room equipment, and is configured to allow for a quick and secure attachment of the drape component, as well as quick-release of the drape component anytime during and/or after use of the assembly.

[075] The term "quick-release" as used herein refers to the rapid and easy coupling or decoupling of two components without the need for complex tools or procedures, such that either of these actions may take a user less than 30 seconds, or less than 10 seconds or a shorter time frame to couple or decouple the two components. In this regard, a quick-release attachment may include one or more of the following characteristics: 1) simple engagement/disengagement, where the adapter can be coupled and decoupled with simple actions like pushing, pulling, twisting, or snapping; 2) no tool requirement (i.e. tool-free), where the operation doesn't require special tools or equipment such as threaded screws, nuts, bolts, clamps, or other fasteners, allowing for hand-operated engagement and release; and/or 3) positive locking, whereby once engaged, the coupling securely locks in place to prevent accidental disconnection.

[076] Accordingly, the adapter disclosed herein is a separate individual component that is capable of forming a quick-release engagement with the drape component. The ability of the adapter to quickly attach and release the drape component means that the adapter may be reusable, and also may be configured to be used with the same or a different drape component, such that the adapter is versatile in use and may facilitate the quick coupling and decoupling of drape components to operating room equipment. It will be appreciated that the adapter can only attach a single drape component to a single operating room equipment when in use.

[077] In various embodiments, the adapter may comprise an adapter body comprising a first portion having a coupling arrangement couplable to a complementary coupling arrangement of the operating room equipment, a second portion opposite to the first portion and a cavity extending internally along the adapter body from the second portion towards the first portion, the cavity having an opening at the second portion, and an attachment unit housed within the cavity of the adapter body and exposed through the opening of the cavity at the second portion, whereby the attachment unit is capable of forming a quick-release engagement with the drape component.

[078] In various embodiments, the first portion may comprise a first face or surface, and the second portion may comprise a second face or surface. The first and/or second faces may be substantially planar surfaces, and more preferably parallel planar surfaces directed in opposite directions, that may abut with or contact the respective surfaces of the drape component and the operating room equipment. The first face may abut with or be in close proximity to the complementary coupling arrangement and/or the operating room equipment, whereas the second face may abut with or be in close proximity to the drape component.

[079] In various embodiments, the adapter body may comprise outer side walls, and inner side walls that connect and join the first face and second face, where the inner side walls define the boundary and size of the cavity. The intersection of the inner side walls with the first face and second face define the respective openings of the cavity. As will be appreciated, the number of side walls will depend on the shape of the adapter body, whereby an adapter body that is rectangular or square in shape and form will have four side walls joining the first and second faces.

[080] The cavity may be recessed into the second face of the second portion and may define an internal passageway through a central region of the adapter body from the first portion to the second portion. In various embodiments, the shape of the cavity may conform to the shape of the adapter body, where the boundary of the cavity (i.e. inner side wall(s)) may be at a substantially consistent distance away from the respective edges or boundary of the adapter body (i.e. outer side walls).

[081] In various embodiments, the adapter body may comprise one or more protruding rim(s) extending perpendicularly with respect to the inner side wall of the cavity along at least a segment, or entire, length of the opening of the second portion. In various embodiments, the adapter body may comprise two protruding rims extending along opposing inner side walls of the cavity. The protruding rim(s) may be positioned adjacent to, or at, the opening of the second portion. The one or more protruding rim(s) function to prevent the attachment unit from exiting or passing through the opening of the second portion (e.g. fall out or dislodge from the opening of the second portion) while allowing the attachment unit to be housed and retained within the cavity such that the attachment unit is capable of forming the quick-release engagement with the drape component.

[082] In various embodiments, the adapter body may comprise two protruding rims extending perpendicularly with respect to the inner side wall of the cavity and along the entire length of opposing inner side walls of the cavity at the opening of the second portion. In various embodiments, the one or more protruding rim(s) may extend perpendicularly with respect to the inner side wall of the cavity by about 1-10mm, preferably 1-5mm, more preferably 1-2mm.

[083] In various embodiments, the adapter body may comprise an alignment arrangement disposed at the second portion of the adapter body for alignment between the drape component and the adapter. In various embodiments, the alignment arrangement may be disposed on the second face of the second portion. In various embodiments, the alignment arrangement may comprise at least one alignment element at the second portion for cooperating with a corresponding alignment element of the drape component to bring the drape component into alignment with the adapter. The alignment element may include a protrusion that extends perpendicularly relative to the second face, whereby the corresponding alignment element may include a recess or hole configured to receive and fit the protrusion. It will also be appreciated that the protrusion and corresponding recess or hole can be reversed such that the alignment element on the adapter body may be the recess or hole and the corresponding alignment element of the drape component may be the protrusion.

[084] In various embodiments, the alignment arrangement may comprise two alignment elements, wherein the two alignment elements are respectively positioned in an opposing manner across the opening at the second portion such that the opening is positioned therebetween. Two corresponding alignment elements of the drape component will be positioned accordingly for cooperation with the two alignment elements of the adapter body.

[085] In various embodiments, the alignment arrangement may comprise one or more pins or bolts with a shaft and a head part, whereby each pin or bolt is received within one or more corresponding holes extending into a portion of the adapter body or through the entire adapter body from the first portion to the second portion. In various embodiments, the one or more holes may extend into the first face of the first portion of the adapter body towards the second face of the second portion. The one or more pins or bolts and corresponding holes are respectively positioned in an opposing manner across the opening at the first and second portions such that the opening is positioned therebetween. In this regard, the one or more pins or bolts, more particularly the end of the shaft opposite to the head part, protrude out of the second face of the second portion for alignment with a corresponding alignment element of the drape component.

[086] In various embodiments, the adapter body may be substantially rectangular in shape, and may comprise rounded edges between adjoining outer side walls. In various embodiments, where the adapter body is substantially rectangular in shape, the cavity may also be substantially rectangular in shape to conform to the shape of the adapter body.

[087] In various embodiments, the adapter body may have a width of about 20-40mm, a length of about 40-60mm, and a depth of about 5-40mm, wherein the cavity may have a width of about 10-20mm, a length of about 20-40mm and a depth that coincides with that of the adapter body. It will be appreciated that the size of the adapter and adapter body may be suitably configured and modified depending on the operating room equipment and use, so long as its function is achieved.

[088] In various embodiments, the adapter may be made of any suitable solid rigid material, such as a metal, wood or a plastic that are ideally durable and are optionally able to withstand sterilization processes without degrading. In various embodiments, the adapter may be made of, or comprise a metal or metal alloy material that may be selected from, but not limited to stainless steel, titanium, tantalum, aluminum, chromium, molybdenum, cobalt, silver, and gold, or alloys of such metals that are known to those of skill in the art.

[089] In various embodiments, the coupling arrangement of the first portion and complementary coupling arrangement may refer to two components that physically interact and couple together to create a secure connection such that the adapter and operating room equipment are not moveable relative to each other. In various embodiments, the coupling arrangement may be releasably coupled to allow for the adapter to be decoupled from the operating room equipment when not in use. As will be appreciated, the complementary coupling arrangement may be positioned on, and releasably or permanently affixed, to the operating room equipment.

[090] In various embodiments, the coupling arrangement and complementary coupling arrangement may comprise a male coupling element and a complementary female coupling element. In various embodiments, the male coupling element may comprise a plurality of trapezoidal or wedge-shaped elements, and the complementary female coupling element may comprise a mount comprising one or more recesses for slidably receiving and retaining the trapezoidal or wedge-shaped elements such that the adapter body is securely and releasably held in position on the operating room equipment. The trapezoidal or wedge-shaped elements may comprise a horizontal planar upper or top surface and a side surface angled relative to the upper surface. In various embodiments, the adapter may comprise the male coupling element and the operating room equipment may comprise the complementary female coupling element; however, it will be appreciated that the male and female elements may be reversed so long as the adapter is able to releasably and securely couple to the operating room equipment.

[091] In various embodiments, the male coupling element may comprise one or more threaded screws, and the complementary female coupling element may comprise one or more corresponding threaded holes positioned on the operating room equipment, whereby each threaded hole in the operating room equipment is in-registration with the threaded screw for receiving the threaded screw. In various embodiments, the adapter may comprise the male coupling element and the operating room equipment may comprise the complementary female coupling element; however, it will be

appreciated that the male and female elements may be reversed so long as the adapter is able to releasably and securely couple to the operating room equipment.

[092] In various embodiments, the coupling arrangement may be integrally formed with the adapter body as a single-piece. That is, the adapter may be manufactured with the coupling arrangement integrally formed as part of the adapter body.

[093] In various embodiments, the coupling arrangement may be a part of a separate piece to be combined with another piece to form the adapter body, whereby the separate piece comprising the coupling arrangement may be releasably secured to the other piece in forming the adapter body. In particular, the adapter body may comprise a main piece and a secondary piece having the coupling arrangement, wherein the secondary piece is releasably secured to the main piece to form the adapter body. In various embodiments, the secondary piece may be a plate-like structure, wherein the main piece and secondary piece are secured together via one or more fasteners. In various embodiments, the one or more fasteners may be threaded screws that are received within one or more corresponding threaded holes positioned on the secondary piece and the main piece, whereby each threaded hole in the secondary piece is in-registration with a threaded hole in the main piece for receiving a single threaded screw.

[094] The terms "sheet" or "plate" as used herein, means in particular that a thickness of the component or structure is much smaller than the other dimension(s), such that the sheet or plate has a large surface area relative to its thickness, and may be uniformly flat and even. For example, if a sheet or plate structure has a circular shape, the aforementioned terms mean that the thickness of the structure is much smaller than its diameter. Accordingly, if the sheet or plate structure has a rectangular shape, the aforementioned terms mean that the thickness of the structure is much smaller than a length of its sides. The term "side length" refers to the length of any of the sides of the rectangular shape. The plate or sheet comprises two surfaces or faces which are larger in area compared to its thickness. **In this regard, the term "plate-like structure", as used herein refers to any structural element or assembly that behaves like a plate.** This means that while it may not be a single, thin piece of material (like a plate), it acts in a similar manner in terms of how it bears loads and deforms. A plate-like structure can be made up of multiple components or materials, and its overall shape or form might be more complex than a simple flat plate.

[095] In various embodiments, the plate-like structure of the secondary piece may be sized and shaped in conformity with the size and shape of the main piece such that the outer side walls of the plate-like structure and the outer side walls of the main piece are in alignment with each other and are coplanar.

[096] Advantageously, by having the coupling arrangement comprised on a separate piece, the user may change and use different coupling arrangements to account for various differing coupling

arrangements that may be on the operating room equipment. This improves the versatility and adaptability of the adapter in releasably coupling to different complementary coupling arrangements and operating room equipment.

[097] The attachment unit described herein refers to a component that quickly interacts and engages with the drape component to create a secure connection such that the adapter and drape component are not moveable relative to each other when engaged. The attachment unit is releasable from the drape component to allow for the adapter to be decoupled from the drape component. The attachment unit is housed within the cavity of the adapter, such that the attachment unit is retained within the cavity of the adapter body while also being exposed with an uncovered visible portion allowing for engagement with the drape component.

[098] In various embodiments, the attachment unit may be configured in respect of size, shape and form to fit snugly (i.e. fit within a desirable and acceptable mechanical tolerance), and be retained, within the cavity, and more particularly exposed through the opening of the second portion. In various embodiments, the attachment unit may be slidably received within the cavity, such that the attachment unit can be easily housed and subsequently removed from within the cavity.

[099] In various embodiments, the attachment unit may comprise a retaining arrangement for retaining the attachment unit within the cavity, while preventing the attachment unit from exiting or passing through the opening of the second portion such that the attachment unit is capable of forming the quick-release engagement with the drape component. In various embodiments, while the attachment unit cannot be removed via, or pass through, the opening at the second portion of the adaptor body, it may be removed, or pass, through the opening at the first portion of the adaptor body. This allows the attachment unit to be replaceable and interchangeable with other types of attachment units for quick-release engagement with the drape component, which improves the versatility and adaptability of the adapter in using differing quick-release engagement mechanisms.

[0100] In various embodiments, the adaptor body may be configured to include one or two slot(s) extending from the outer side wall of the adapter to the inner side wall, which is sized and shaped to allow the attachment unit to pass through the slot and into the cavity, where it is retained, and exposed through the opening of the cavity at the second portion. In various embodiments with two slots, each of the two slots may be positioned in an opposing manner across the cavity in the adapter body and extending from opposite outer sidewalls towards the cavity. The attachment unit may be retained and held in place (i.e. in the cavity at the opening of the second portion) by mechanical fit with the slots, or by a simple mechanical catch. The slots may be horizontal slots (i.e. extending perpendicular with respect to the cavity, and outer/inner side walls of the adapter), whereby, when in use, the horizontal direction of the slot(s) will counter the vertical forces acting on the attachment units through its interaction with the corresponding engagement element on the drape component. Advantageously, the use of these slots will allow the insertion and removal of the attachment unit from within the cavity

when it cannot be removed or passed through the opening at the first portion of the adaptor body, for example, when the opening at the first portion is closed by the secondary piece.

[0101] In various embodiments, the retaining arrangement of the attachment unit may comprise one or more protruding rim(s) that are configured to mate and interact with corresponding one or more protruding rim(s) on the adapter body. This mating engagement and interaction between the respective protruding rims ensure proper alignment of the attachment unit and functions to prevent the attachment unit from exiting or passing through the opening of the second portion.

[0102] As will be appreciated by those skilled in the art, the protruding rim(s) of both the adapter body and retaining arrangement may have various profiles, such as circular, square, or any other shape that suits the design requirements. The shape and dimensions of the protruding rim(s) determine how these components will fit together. In use, when the attachment unit is housed within the cavity the respective protruding rim(s) on each component are brought together, to interact. These protruding rim(s) and their interaction may ensure correct alignment, whereby the protruding rim(s) of the adapter body guide the attachment unit into the correct position relative to one another. Depending on the design, the protruding rim(s) may simply butt against each other, or they might have features that allow them to interlock. For example, one protruding rim(s) might have a groove while the other has a corresponding tongue, and when the components are pushed together, the tongue of one protruding rim(s) slides into the groove of the other, creating a more secure and stable connection. Once aligned and engaged, the protruding rim(s) may themselves provide sufficient holding power, and no additional securement is necessary for retaining the attachment unit in the desired position. Further, the protruding rim(s) may also allow disengagement of the attachment unit from the adapter body. In this regard, the protruding rim(s) of the adapter body may be releasably secured to the corresponding protruding rim(s) of the attachment unit. These protruding rim(s) may also play a role in the transfer of mechanical forces, whereby when the components are mated, the protruding rim(s) bear against each other, allowing forces to be transferred from one component to the other without excessive stress on any single point, which may be important where the adapter must withstand mechanical loads, vibrations, or other stresses from the user and/or operating room equipment.

[0103] In various embodiments, the attachment unit may cover or close the opening of the second portion when housed within the cavity.

[0104] In various embodiments, the attachment unit may fill a substantial portion of, or entire, space of the cavity, that is, the thickness of the attachment unit may be configured to coincide with the height of the adapter body such that the attachment unit fills the space of the cavity. However, the attachment unit does not need to fill the entire space of the cavity, and may instead fill only a portion of the cavity. In various embodiments, the adapter may further comprise a spacer element that is also housed within the cavity to function in filling the majority or remaining space of the cavity in addition to the attachment unit without protruding out of the first opening and above the surface of the first face. In

various embodiments, the spacer element may be exposed through the opening of the cavity at the first portion. In various embodiments, the spacer may be integrated with the secondary piece. The spacer element may function in retaining and holding the attachment unit in position at the opening of the second portion in order to further facilitate engagement of the attachment unit to the drape component. In various embodiments, the spacer element may be configured in respect of size, shape and form to fit snugly (i.e. fit within a desirable and acceptable mechanical tolerance), and be housed and retained, within the cavity.

[0105] In various embodiments, the attachment unit may be a separate component or piece to the adapter body, whereby the attachment unit may be releasably secured within the cavity of the adaptor body in forming the adapter, and allows the attachment unit to form the quick-release engagement with the drape component.

[0106] In various embodiments, the attachment unit may comprise an engagement element for releasably coupling to a corresponding engagement element positioned on the drape component. In various embodiments, the engagement element may be releasably coupled to the corresponding engagement element of the drape component. In this regard, the engagement element may be exposed through the opening of the cavity for releasably coupling with the corresponding engagement element of the drape component. In various embodiments, the corresponding engagement element may form an integral part of the drape component, more particularly the frame, or represent a region of the drape component (i.e. frame), where the attachment unit couples to.

[0107] As indicated above, the attachment unit, and engagement element, is configured to be capable of forming a quick-release engagement with the drape component. In this regard, the quick-release engagement formed between the attachment unit and the drape component may be selected from, but not limited to, a quick-release magnetic engagement, a quick-release snap-fit engagement, a quick-release pin engagement, a quick-release clamp engagement, a quick-release lever-type engagement, a quick-release push button engagement, a quick-release hook and loop engagement and combinations thereof.

[0108] The term "quick-release magnetic engagement" as used herein, refers to a type of connection mechanism that uses magnets to attach and detach components quickly and easily with minimal effort and time. The mechanism uses magnets to create an attractive force that automatically aligns and secures the components together. When the parts are brought close to each other, the magnetic force pulls them into the correct alignment and holds them in place. This eliminates the need for precise manual alignment and makes the connection process much faster and easier. The quick-release feature allows for the immediate disconnection of the components with minimal effort. This can be achieved through various designs, such as a simple mechanical lever, a push-button, or a twist action, which counteracts the magnetic force, allowing the parts to be separated easily.

[0109] The term "quick-release snap-fit engagement" as used herein, refers to a type of fastening mechanism used in the assembly of parts that allows for easy and rapid connection and disconnection without the need for tools or additional hardware. Typically, this will involve one part with a protruding element, such as a hook or bead, and another part with a corresponding recess or slot. When the parts are pushed together, the protruding element flexes slightly and then snaps into place in the recess, creating a secure joint. This action is often accompanied by a noticeable "snap" sound, hence the name. To disengage the parts, a specific amount of force is applied in the right direction, which allows the protruding element to flex again and come out of its recess. This makes the disassembly process quick and straightforward, often without the need for tools.

[0110] The term "quick-release pin engagement" as used herein, refers to a fastening mechanism designed for easy and rapid insertion and removal without the need for tools. Quick-release pins typically consist of a pin body, which can be solid or hollow, and a mechanism to lock the pin in place once inserted. The locking mechanism varies but often includes a button, handle, or ring at one end of the pin. The pin usually has one or more balls or detents near one end, held in place by a spring. When the button or handle is pressed or pulled, these balls retract into the body of the pin, allowing it to be easily inserted into or removed from a hole. Releasing the button or handle allows the balls to spring back out, locking the pin in place.

[0111] The term "quick-release clamp engagement" as used herein, refers to a fastening mechanism that allows for rapid and easy opening and closing of a clamp without the need for tools. Quick-release clamps typically consist of a band or frame that encircles the objects to be clamped, with a tightening mechanism that can be easily and quickly operated. This mechanism usually involves a lever or a trigger that can be actuated by hand. The quick-release feature often works by using a lever or handle that, when engaged, applies tension to the clamp, securing it in place. When the lever or handle is released or opened, the tension is released, allowing for the clamp to be quickly opened and removed or adjusted. Some designs use a ratchet system, while others may use a cam or wedge mechanism to achieve the clamping action.

[0112] The term "quick-release lever-type engagement" as used herein, refers to a mechanism that allows for fast and easy attachment or detachment of components using a lever. The quick-release lever typically consists of a lever attached to a bolt or screw mechanism. The lever provides a mechanical advantage, allowing the user to apply a significant amount of force without needing tools. This mechanism is often designed to be operated by hand, requiring minimal effort. To engage or tighten the mechanism, the user flips the lever into the closed position, which tightens the bolt or screw. To release or loosen it, the user flips the lever back into the open position. The action of flipping the lever either pulls or releases tension, thereby securing or loosening the attachment.

[0113] The term “quick-release hook and loop engagement” as used herein, refers to a fastening system that uses two components: a “hook” side and a “loop” side, which interlock to create a secure yet easily removable connection. This system is widely known by the brand name Velcro, although there are many other brands and types of hook and loop fasteners. The “hook side” consists of a piece of fabric or material covered with tiny hooks, with the “loop side” being a corresponding piece covered with smaller, softer loops. When the two sides are pressed together, the hooks catch in the loops, creating a secure bond that can withstand a reasonable amount of force. To disengage the connection, one simply pulls the two sides apart, which can be done quickly and without the need for tools. The distinctive ripping sound is often associated with separating hook and loop fasteners.

[0114] In various embodiments, the attachment unit may form a quick-release magnetic engagement with the drape component. In this regard, the engagement element of the attachment unit may comprise a magnet that releasably couples to the corresponding engagement element comprising a suitable magnetic material, in a manner so as to magnetically couple the adapter to the drape component. The magnet may be composed of any material that produces its own persistent magnetic field even in the absence of an applied magnetic field and creates a force that pulls on other magnetic materials, such as iron, steel, nickel, cobalt, etc. and attracts or repels other magnets. In various embodiments, the magnet may include but is not limited to a neodymium magnet (NdFeB), a ferrite magnet (ceramic magnet), a samarium cobalt magnet (SmCo), and an alnico magnet. In various embodiments, the magnet may be a neodymium magnet.

[0115] In various embodiments, the magnet may be embedded or integrally formed within the attachment unit, or more particularly the engagement element. In various embodiments, the magnet may be attached to an external surface of the attachment unit, or more particularly the engagement element, specifically the external surface that is exposed through the opening of the cavity at the second portion of the adapter body to allow engagement with the corresponding engagement element of the drape component.

[0116] In various embodiments, the attachment unit may comprise one or more plate-like structures, wherein each plate-like structure may comprise an outer substantially planar surface exposed and facing out of the cavity at the opening of the second portion, and an inner planar surface facing into the cavity. In various embodiments, each plate-like structure may comprise one or more protruding rim(s) extending perpendicularly with respect to the side walls of the plate-like structure and along at least a segment, or entirety, of the length of the plate-like structure. In various embodiments, each plate-like structure may comprise two protruding rims extending along opposing sides of the plate-like structure. The protruding rim(s) may be co-planar with the inner planar surface, such that one or more sides of the plate-like structure has a stepped configuration.

[0117] In various embodiments, the one or more plate-like structure(s) of the attachment unit may have a width of about 10-20mm, a length of about 10-40mm, and a depth of about 2-40mm, wherein

the protruding rims may extend perpendicularly with respect to the side walls of the plate-like structure by about 1-10mm, preferably 1-5mm, more preferably 1-2mm. It will be appreciated that the size of the one or more plate-like structure(s) may be suitably configured and modified depending on the cavity size and shape.

[0118] Exemplary, non-limiting, embodiments of the adapter **100** is illustrated in **FIG. 2** to **7**, indicating the various components described herein and their relationship to each other.

[0119] **FIG. 2A** to **2H** illustrate an exemplary, non-limiting, embodiment of a main piece of the adapter body **110** (without a secondary piece having a coupling arrangement) that is substantially rectangular in shape and form, comprising a first portion **112**, a second portion **114** opposite to the first portion, and a cavity **116** extending internally along the adapter body from the second portion towards the first portion, where the cavity has an opening **118** at the first portion and an opening **120** at the second portion. The shape of the cavity is rectangular in conformity with the shape of the adapter body and is positioned centrally. The first portion comprises a first face **122**, and the second portion comprises a second face **124**, both the first and second faces are planar or flat surfaces. The adapter body comprises four outer side walls **126a**, and four inner side walls **126b** that connect and join the first face and second face, where the four inner side walls define the boundary and size of the cavity and the intersection of the inner side walls with the first face and second face define the respective openings. The outer side walls comprise rounded edges **126c** between adjoining and adjacent outer side walls. On the first portion, there are four threaded holes **128** positioned at each corner which extend from the first face into the adapter body towards the second portion, whereby these threaded holes are configured to receive complementary threaded screws for securing the coupling arrangement on a secondary piece (not shown) to the first portion of the main piece of the adapter body. At the opening of the second portion, two protruding rims **130** extend perpendicularly with respect to the inner side wall of the cavity along the entire length of opposite sides of the opening of the second portion. Further, the first portion also comprises two holes **132** which extend from the first face into the adapter body towards the second portion, whereby these holes are configured to receive complementary pins or bolts (not shown). The two holes are respectively positioned in an opposing manner across the opening at the second portion such that the opening is positioned therebetween, the diameter of the the holes at the second face is smaller than the diameter of the holes at the first face.

[0120] The dimensions of the adapter body in **FIG. 2** include a width of about 28mm, a length of about 48mm, and a depth of about 30mm, wherein the cavity may have a width of about 15mm, a length of about 30mm and a depth that coincides with the adapter body. It will be appreciated that the size of the adapter and adapter body may be suitably configured and modified depending on the operating room equipment and use.

[0121] FIG. 3 illustrates the main piece 111 of the adapter body 110 shown in FIG. 2A-H, in combination with an exemplary, non-limiting, embodiment of the secondary piece 138 having the coupling arrangement 134 and the attachment unit 136 to be housed within the cavity 116 of the adapter body and exposed through the opening of the cavity at the second portion 114. As illustrated, the coupling arrangement is a plurality of trapezoidal or wedge-shaped elements 140 comprised on the secondary piece that is a plate-like structure 138 that is to be releasably secured to the main piece of the adapter body via threaded screws 137a being received and threaded through threaded holes 128 in both the plate-like structure and the first portion 112 of the main piece of the adapter body. The attachment unit comprises two plate-like structures 142 with protruding rims 144 extending along two opposite lengths, whereby the plate-like structures comprise a magnet as the engagement element 151 in the outer planar surface (not shown) of the plate-like structure for quick-release magnetic engagement with the drape component. A spacer element 146 is also included that is sized and shaped to fill the remaining void in the rectangular cavity and abut with the inner planar surface 148 of the plate-like structure. Bolts 150 with a head portion 150a and shaft 150b are received by respective holes 132 positioned in an opposing manner across the opening at the second portion such that the opening is positioned therebetween. When housed in holes 132, the bolts 150 protrude out of the second face of the second portion for alignment with a corresponding alignment element (e.g. hole or recess) of the drape component.

[0122] FIG. 4A-D further illustrates the attachment unit 136 and each plate-like structure 142 shown in FIG. 3, with an outer planar surface 152 protruding rims 144 forming a square stepped profile on the side walls 143 of the plate-like structure, and extending along opposite lengths and perpendicularly relative to the side walls. The outer planar surface comprising the engagement element 151 which is a magnet integrally formed with the plate-like structure. The outer planar surface 152 and magnetic engagement element 151 is to be exposed through the opening of the cavity at the second portion when combined with the adapter body. The dimensions of the plate-like structure include a width of about 15mm, a length of about 15mm including the protruding rims extending perpendicularly relative to the side walls by about 1mm each, and a depth of about 3mm.

[0123] FIG. 5A-D illustrates the adapter and all respective components shown in FIG. 2-4 combined together for use in releasably coupling the drape component to the operating room equipment.

[0124] FIG. 6 to 7 illustrate an alternative exemplary, non-limiting, embodiment of the adapter body 110 that is substantially the same as the adapter body shown in FIG. 2 and 3, with the difference being that the coupling arrangement is integrally formed with the adapter body as a single-piece, whereby the plurality of trapezoidal or wedge-shaped elements 140 extend outwards from the outer side walls 126a of the adapter body with an upper surface 140a that is coplanar with the surface of the first face 122 of the first portion 112, and an angled side surface 140b. The threaded holes and corresponding threaded screws, as well as the two bolts and corresponding holes in the adapter body of FIG. 2 and 3, are not included or necessary. The second portion 114 of the adapter body comprises

an alignment arrangement **154** comprising two alignment elements that are protrusions **154a** extending perpendicularly outwards relative to the second face. The protrusions are positioned in an opposing manner across the opening at the second portion such that the opening is positioned therebetween. The adapter body shown in **FIG. 6** and **7** differ only in their depth dimension with the adapter body in **FIG. 6** having a depth of about 8.5mm, excluding the protrusion that protrudes by about 4mm, in contrast the adapter body in **FIG. 7** has a depth of about 29mm, excluding the protrusion that protrudes by about 4mm. By changing the depth of the adapter body, the distance of the drape component spaced apart from the operating room equipment can be modified to suit any particular needs depending on the operating room equipment and its operating function, where it may be preferable for the drape component to be either further away or closer to the operating room equipment based on user preference and/or in order to optimize the function of said operating room equipment when in use. In this regard, a plurality of adapters may be interchangeably used with the drape component and operating room equipment.

[0125] The drape component of the drape assembly of the various embodiments is described in the following.

[0126] The drape component disclosed herein generally comprises a drape, and a frame attached to the drape and, in use, the drape component is releasably coupled to the adapter disclosed herein which is in turn releasably coupled to the operating room equipment.

[0127] In use, the drape component functions to enclose and separate an interior space containing the inspection/operation site from an exterior space to mitigate fluid movement, that may contain pathogen-laden aerosols or droplets, tissue particulates, etc., from the interior space and into the exterior space thereby mitigating droplet, particulate, and aerosol movement in the flow path of the fluid from the interior space and into the exterior space. In particular, the drape component may be useful during clinical or laboratory procedures that produce aerosolised debris (e.g., tissue, bone, fluids such as mucosa, etc.), whereby some aerosolised debris (e.g., tissue) pose a greater risk to contraction of a disease as compared to other particulates (e.g., small droplets that contain the infectious agent, such as bacteria, fungi, and viruses) that are not produced during these types of procedures (e.g., aerosol producing procedures).

[0128] For example, during a surgical operation, the drape component may enclose and separate a portion of a patient's body from surgeons performing the operation or other personnel in the operating room. Accordingly, the drape component is positioned external to the patient, and provides a protective barrier for effectively isolating personnel in the operating room from the portion of a patient's body that is potentially infected thereby allowing the personnel to effectively complete a procedure, while simultaneously ensuring that the personnel are adequately protected from possible pathogen transmission.

[0129] In various embodiments, the drape may comprise one or more sheets of material with an outer surface and an inner surface, a peripheral region and a central region. In various embodiments, the drape may be a single sheet of material in the form of any desirable shape and size depending on the use. In various embodiments, the drape may be a single sheet of material in a substantially circular or square shape. In various embodiments, the drape be a single sheet of material and may have a length of about 1300mm to 1700mm, and a width of about 1300mm to 1700mm, preferably the drape may have a length of about 1500mm, and a width of about 1500mm. In various embodiments, the drape may be a single sheet of material in a substantially square shape and may have a length of about 1300mm to 1700mm, and a width of about 1300mm to 1700mm, preferably the drape may have a length of about 1500mm, and a width of about 1500mm.

[0130] In various embodiments, in use, the drape may form a three-dimensional (3D) structure that isolates or otherwise mitigates fluid movement from the internal space and into the exterior space, or *vice versa*. The 3D structure may embody many different shapes, such as, for example, a dome or hemisphere, a cone, a frustoconical structure, pyramidal structures, or prisms. In various embodiments, the drape may form a dome shape that is substantially spherical or hemispherical thereby forming a shield or barrier to mitigate fluid movement from the interior space into the exterior space.

[0131] In various embodiments, at least a portion, or entirety, of the drape may be partially (or fully) transparent so as to allow the personnel to view within the interior space and the inspection/operation site. In various embodiments, at least a portion of the drape may be non-transparent, so long as another portion, or the remaining portion of the drape is partially and/or fully transparent to allow the personnel to view the contents of the interior space and the inspection/operation site.

[0132] In various embodiments, the drape may comprise a material that is non-transparent, partially transparent, fully transparent or combinations thereof. Accordingly, the drape may comprise a non-transparent portion, and/or a partially transparent portion, and/or a fully transparent portion. In various embodiments, the drape may comprise a partially transparent portion and a fully transparent portion, or the drape may be entirely transparent. For example, the central portion of the drape may be transparent with the remaining portion of the drape being partially and/or non-transparent. In various embodiments, the drape may comprise or consist of a material that is fully transparent, that will provide the user with all round visibility within the interior space.

[0133] Materials that are non-transparent, partially transparent, or fully transparent may be suitably selected by those skilled in the art to have the desired optical clarity, or lack thereof, to minimize or maximise the visibility of the inspection/operation site from the surrounding exterior space. It will be appreciated that the material(s) of the drape may be suitably selected by those skilled in the art based on the use and degree of visibility through the drape at one or more regions needed during a procedure. In this context, “fully transparent material” as used herein refers to a material that allows light to pass through without significant scattering, absorption or reflection enabling objects to be seen

clearly through and offering unimpeded visibility; **"partially transparent material"** as used herein refers to a material that allows some, but not all, light to pass through allowing visibility through the material to a certain extent but not with complete clarity, for example, translucent plastic or thin fabric; and **"non-transparent material"** as used herein refers to opaque material that does not allow any light to pass through. In various embodiments, the material of the drape may comprise or consist of a plastic material. The plastic material may be selected from, but not limited to, the group consisting of: polyethylene (PE), polyvinyl chloride (PVC), polypropylene (PP), polyurethane (PU), polyethylene terephthalate (PET), polylactic acid (PLA), and combinations thereof. In various embodiments, the plastic material may be Low-Density Polyethylene (LDPE).

[0134] In various embodiments, the drape may comprise (i.e. made from) a single sheet of fully transparent material. In various embodiments, a portion or the entire outer surface (or inner surface) of the drape, may have antireflective properties or include an antireflective coating, so as to reduce glare from any lighting.

[0135] In various embodiments, the drape may have a degree of flexibility such that the drape may be easily folded and unfolded for storage, and also a degree of rigidity such that the drape may maintain the desired 3D structure defining the interior space. In various embodiments, the drape may be a single sheet of fully transparent flexible material, preferably a fully transparent flexible plastic material.

[0136] In various embodiments, the peripheral region of the drape may define a continuous perimeter or outer edge of the drape, which, in use, hangs freely down from the central region when the adapter is coupled to the operating room equipment. In use, the peripheral region may not be attached to any other component including any individual (i.e. personnel or patient), this allows the user or other personnel to freely move their arms, hands, and any instruments from the exterior space under the peripheral region and into the interior space without impedence or need to detach/attach any component of the drape. As such, in one embodiment, the drape may not comprise any arm ports or holes for personnel to insert their arms, and any instruments, from the exterior space and into the interior space. However, in another embodiment, it will be appreciated that the drape may comprise arm ports and holes for personnel to insert their arms, and any instruments, from the exterior space and into the interior space. These arm ports and holes may be suitably positioned in the drape in consideration of the positioning of the frame and operating room equipment when in use. The arm ports or holes may be closed or sealed when not in use with a corresponding flap, cover or valve.

[0137] In various embodiments, the peripheral region of the frame is not coupled, either directly or indirectly, with any other component or to an individual, including a patient. In various embodiments, the peripheral region of the drape hangs freely and does not need to contact with any other surface of personnel.

[0138] In various embodiments, the thickness of the drape may vary or be consistently the same. In various embodiments, the thickness of the drape may be increased near the peripheral region that,

in use, is closer to the ground. This way, the inherent increased weight of the drape at its periphery may pull other portions of the drape to maintain the 3D structure (e.g., pulls other portions of the drape taut). In some cases, the increased thickness of the drape can be located along circumferential portions, or otherwise along portions of the peripheral region, of the drape. In various embodiments, the thickness of the drape may be consistent, and may be about 0.01-0.1mm, preferably about 0.04mm.

[0139] In various embodiments, the drape may comprise one or more opening(s). The opening(s) may be configured to be any desired shape and size (e.g. circular, square, rectangle, and about 90x90mm in length and width), such as an opening to be used as a viewing window to allow a user to see through the opening without any impedance, and/or allow the optical axis or line of sight of an operating microscope to pass through, and/or allow a part of the operating room equipment to pass through the opening. However, it will be appreciated that the one or more opening(s) will not be detrimental to the structural form and shape of the drape. In various embodiments, the drape may comprise one or more flap(s) or cover(s) for closing the one or more opening(s) to provide a fluid seal. In various embodiments, the one or more flap(s) may be removably coupled to the drape or may be integrally formed with the drape. In various embodiments, the drape may comprise a single opening and a single flap for closing the opening.

[0140] An exemplary, non-limiting, embodiment of the drape **200** is illustrated in **FIG. 8**, whereby the drape is a single sheet of fully transparent flexible plastic material (LDPE) that is substantially circular or square in shape and, in use, forms a dome shape (substantially spherical or hemispherical) with a peripheral region **202** and a central region **204**. The dome shape of the drape has an apex **206** within the central region with the surrounding material hanging down therefrom to define and separate the interior space **208** and exterior space **210**. Also shown is the inner surface **212** and outer surface **214** of the drape.

[0141] The frame disclosed herein is attached to the drape in forming the drape component, and functions as a support structure or scaffold to provide a certain degree of rigidity to the drape, to assist in maintaining a desired three-dimensional (3D) structure of the drape and a desired volume of the interior space. In use, the frame assists in spreading apart the peripheral region of the drape to increase the volume of the interior space, thereby reducing or preventing the drape from harbouring or interfering with the actions of the user or other personnel when performing a procedure. In essence, the frame acts to reinforce the drape in forming and maintaining the interior space to facilitate, or not impede, a procedure while still providing an effective barrier and shield against fluid movement out of the interior space. Thus, the person skilled in the art will appreciate that the frame may embody many different forms so long as this function is achieved once the frame component is releasably coupled to the adapter.

[0142] In various embodiments, the frame is a substantially flat structure that comprises a top surface and a bottom surface, whereby, in use, the frame is orientated such that the top surface faces upwards (i.e. towards a ceiling), and the bottom surface faces downwards towards the ground.

[0143] In various embodiments, the frame may be fixedly attached to the central region of the drape, such that, the frame is not releasable or removable from the drape once attached during manufacture and is integrated with the drape. In various embodiments, the frame may be fixedly attached to the inner surface of the drape, and more particularly the top surface of the frame may be fixedly attached to the inner surface of the drape such that the top surface of the frame is covered by the drape, and the bottom surface of the frame is exposed to the interior space. In this regard, the drape component may be a single-use consumable that is pre-assembled and is not to be re-used. Advantageously, unlike with other reusable frames and drapes, the single-use drape component disclosed herein avoids the need for time-consuming or labour-intensive processes to clean and sterilise the frame and/or drape for subsequent re-use.

[0144] In various embodiments, the frame may be substantially rigid while also having a degree of flexibility, for example, the frame may have a degree of flexibility and a degree of rigidity. In various embodiments, the frame may have a degree of rigidity that is greater than that of the drape and a degree of flexibility that is less than that of the drape. It will be appreciated that the material(s) of the frame may be suitably selected by those skilled in the art based on the degree of rigidity and flexibility to support the drape and maintain its 3D structure. In various embodiments, the frame may comprise (i.e. made from) at least one material that is substantially rigid while still having a degree of flexibility to allow an acceptable degree of flex when force is applied. In various embodiments, the frame may have a degree of flexibility such that the drape component may be easily stored, and also a degree of rigidity such that when the frame may maintain the desired 3D structure of the drape.

[0145] The material of the frame may comprise or consist of at least one metal material(s), plastic material(s), polymer material (s), wood, heavy-duty cardboard, corrugated fibreboard, chipboard and/or composites. In various embodiments, the material of the frame may comprise or consist of at least one metal material(s), plastic material(s), polymer material (s), and/or composites.

[0146] In various embodiments, the frame may comprise a first planar part, a second planar part, a plurality of elongate supporting members, and a plurality of arms, wherein the plurality of elongate supporting members and the plurality of arms extend outwards from the first planar part and/or the second planar part.

[0147] In various embodiments, the first planar part and the second planar part may be any suitable shape and size, and may be configured to be as light as possible while still being able to fulfill its function as a support structure. In various embodiments, the first planar part and the second planar part may each be a flat piece of material, such as a sheet or plate-like piece of material.

[0148] In various embodiments, the first planar part and the second planar part are not orientated coplanar to each other, where the second planar part may be orientated at an angle relative to the first planar part. In this regard, the second planar part may be bent from the first planar part, and there may be a joint region (e.g. a portion of thinner malleable material) connecting the two parts to allow said bending and formation of the angle. In various embodiments, in use, the first planar part may be orientated substantially along a horizontal plane (i.e. parallel to the surface of the ground). In various embodiments, the second planar part may be orientated at an obtuse angle with the first planar part, preferably at an angle of 140-160°, more preferably at an angle of 145-150°.

[0149] In various embodiments, the plurality of elongate supporting members may be oriented in many different ways or configurations extending from the first and second planar parts. As will be appreciated by the skilled artisan, the length, orientation and structural configuration (i.e. angular positioning) of the elongate supporting members may be configured to provide a coverage area and interior volume by the drape that is sufficiently large to enclose the desired area (e.g. the head and shoulders of a patient during a mastoid surgery), while at the same time avoiding hindrance to the user or other personnel during the procedure. For example, the elongate supporting members may extend out radially relative to the first planar part and/or the second planar part. As another example, the elongate supporting members may be circumferentially oriented around the first planar part and/or the second planar part, with elongate supporting members separated substantially equally from each other (i.e. spaced out apart from each other at substantially even intervals).

[0150] In various embodiments, the first planar part may comprise a plurality of elongate supporting members extending radially outwards from the periphery of the first planar part, and the second planar part may comprise a plurality of elongate supporting members extending radially outwards from the periphery of the second planar part. In various embodiments, the plurality of elongate supporting members extend in opposite directions to each other. Each elongate supporting member may comprise a proximate section that is joined to and is co-planar with their respective first planar part or second planar part from which they extend, and a distal section that bends from the proximate section, preferably to form an angle of 145-170°, more preferably to form an angle of 150-160°. In this regard, each elongate supporting member may comprise a joint region (e.g. a portion of thinner malleable material) connecting the distal and proximate sections to allow said bending and formation of the angle.

[0151] It will be appreciated that the length of each elongate supporting member may vary depending on the size of the drape and volume needed for the interior space and procedure to be performed. In various embodiments, all the elongate supporting members may be of the same length and dimensions. In various embodiments, the elongate supporting members may differ in length. In various embodiments, the length of the elongate supporting members may be about 100-250mm, preferably about 180mm, whereby the proximate section may be about 5-30mm, preferably about 10mm, in length and the distal section may be about 95-220mm, preferably about 125-165mm, in length.

[0152] In various embodiments, the elongate supporting members may have rounded edges to avoid damage and tearing of the drape.

[0153] In various embodiments, the frame may comprise at least 2 elongate supporting members, preferably 3-8 elongate supporting members, more preferably 4-6 elongate supporting members, and even more preferably 5 elongate supporting members.

[0154] In various embodiments, the first planar part may comprise three elongate supporting members. Each of the elongate supporting members may extend from different sides of the first planar part. When viewed along the axis perpendicular to the planar surface (i.e. birds-eye view), the elongate supporting member positioned either side of a middle elongate supporting member may be oriented at an angle of about 20-90°, more preferably about 60-70°, relative to the longitudinal axis of the middle elongate supporting member, defining a symmetrical configuration.

[0155] In various embodiments, the first planar part may comprise a port that may allow fluid and air to pass through. In this regard, when integrated with the drape, the drape may also comprise a corresponding port such that fluid and air contained in the interior space may be allowed to flow out and into the exterior space, and air and fluid within the exterior space may be allowed to flow into the interior space. The port may function to allow the volume of the interior space to be substantially constant. In various embodiments, the port may comprise a filter with pores sized to block at least one of pathogens, and tissue particulates. In various embodiments, the port may be configured for a suction device to be attached in a sealing engagement, that is, the port may be sized to receive and be releasably coupled to a suction attachment of a suction system for extraction of fluid (i.e. aerosol). The suction system may be a scavenger system for extracting aerosols from the interior space, thus improving aerosol containment. It will be appreciated that a port may be positioned at a suitable location on the drape in addition to a port on the frame, or instead of a port on the frame.

[0156] In various embodiments, the port may comprise a valve that may be configured to sealingly engage the suction attachment of the suction system when the suction attachment is inserted through the valve and into the interior space. In various embodiments, the port may comprise an attachment element that may be configured to engage with the suction attachment to provide a sealing engagement between the port and the suction attachment. In various embodiments, the port may comprise a closing flap for sealing the port to prevent fluid or air from passing through, and/or the port may comprise a one way valve that only allows fluid or air or a suction attachment to pass through into the interior space while preventing fluid or air passing through into the exterior space.

[0157] In various embodiments, the first planar part and/or the second planar part may comprise one or more cut-outs. These cut-outs may be any suitable shape and size whereby the removal of material of the frame will function to reduce the overall weight of the frame, and thus improve the stability of the frame components coupling to the adapter and reduce the likelihood that the frame component will accidentally decouple from the adapter.

[0158] In various embodiments, the second planar part may comprise at least two elongate supporting members. Each of the elongate supporting members may extend from different opposing sides of the second planar part. When viewed along the axis perpendicular to the planar surface, the elongate supporting member may be oriented at an angle of about 80-150°, more preferably about 90-110°, relative to the longitudinal axis of the middle elongate supporting member of the first planar part, defining a symmetrical, configuration.

[0159] The second planar part may also comprise at least two arms extending outwards and parallel to each other in the same direction from the second planar part, wherein the at least two arms may be co-planar with the second planar part. In various embodiments, the at least two arms may extend outwards in an opposite direction to the direction that the middle elongate supporting member of the first planar part extends. When the frame is integrated with the drape to form the drape component, the at least two arms in combination with one side of the second planar part, may partially surround and provide support for an opening or viewing window in the drape. In this regard, the at least two arms may provide a degree of structural integrity and tautness to the drape surrounding the opening. In various embodiments, the two arms may be the same length in the range of about 65-105mm, preferably about 85mm. In various embodiments, an elongate supporting member may extend from each of the arms.

[0160] In various embodiments, the second planar part may comprise a means for coupling the corresponding engagement element to the second planar part of the frame. The corresponding engagement element is for engaging the engagement element of the attachment unit of the adapter so as to releasably couple the drape component to the adapter.

[0161] In various embodiments, the second planar part may comprise a plurality of pin holes for releasable coupling with a plurality of flexible pins comprised on the corresponding engagement element, whereby the plurality of flexible pins may pass through the plurality of corresponding pin holes in the second planar part and be bent to grip the second planar part for securely coupling the corresponding engagement element to the frame. The corresponding engagement element may be released from the second planar part by bending the flexible pins to allow them to pass through the pin holes. In another embodiment, the means for coupling the corresponding engagement element to the second planar part of the frame may include the use of an adhesive, preferably a strong adhesive, whereby suitable adhesives are readily known to those skilled in the art. In another embodiment, the means for coupling the corresponding engagement element to the second planar part of the frame may include a recessed slot extending into a portion of the second planar part of the frame that is configured to house and retain the corresponding engagement element by mechanical fit, thus avoiding the need for the flexible pins and pin holes or other coupling means.

[0162] In another embodiment where the frame (i.e. second planar part of the frame) is made of magnetic material and the attachment unit comprises a magnet, it will be appreciated that there is no need for inclusion of the corresponding engagement element or the means for coupling the

corresponding engagement element to the second planar part of the frame, since the attachment unit will be able to directly couple to the frame itself (with the drape sandwiched therebetween). In such an embodiment, the adapter may be suitably or correctly positioned on the drape component by the alignment arrangement.

[0163] In various embodiments, the corresponding engagement element may comprise a sheet of material. In various embodiments, the corresponding engagement element may comprise a metal sheet-like structure, preferably comprising steel or other magnetic material. It will be appreciated that the corresponding engagement element may embody any size and shape for coupling with the second planar part of the frame and function to releasably couple the drape component to the adapter.

[0164] In various embodiments, the engagement element of the drape component and/or the frame of the drape component comprises at least one corresponding alignment element, wherein the adapter comprises an alignment arrangement having at least one alignment element disposed at the second portion of the adapter body, and wherein the at least one alignment element of the alignment arrangement of the adapter and the at least one corresponding alignment element cooperatively aligns the drape component with the adapter.

[0165] In various embodiments, the corresponding engagement element may comprise at least one alignment element corresponding to an alignment element on the adapter, wherein the at least one alignment element of the adapter and the at least one corresponding alignment element of the corresponding engagement element cooperatively align the drape component with the adapter. In various embodiments, the second planar part of the frame may also comprise at least one alignment element corresponding to an alignment element on the adapter for cooperatively aligning the drape component with the adapter.

[0166] An exemplary, non-limiting, embodiment of the frame **300** is illustrated in **FIG. 9A-G**, which comprises a first planar part **302**, a second planar part **304**, five elongate supporting members **306a-e**, and two arms **308**. Three elongate supporting members **306b**, **306c**, **306d** extend radially outwards from the periphery of the first planar part, with elongate supporting members **306b**, **306d** being spaced apart from the middle elongate supporting member **306c** at substantially the same distance or interval. Two elongate supporting members **306a**, **306e** extend radially outwards from the periphery of the first planar part on opposing sides of the second planar part, which also comprises the two arms extending in a parallel manner outwards from the second planar part, and in an opposite direction to the extension of the middle elongate supporting member. The first planar part also comprises a circular port **310** and an elliptical cutout **312**, and the second planar part also comprises four pin holes **314** to receive corresponding pins on a corresponding engagement element, and two corresponding alignment elements **316**, in the form of a hole or a recess, to receive a protrusion on the adapter.

[0167] As shown in **FIG. 9A** the frame has a symmetrical configuration with the line of symmetry running through the middle elongate supporting member and between the two arms (i.e. longitudinal

axis of the middle elongate supporting member). **FIG. 9B-9F** further illustrates the angled relationship between the first planar part and second planar part joined together at a joint region **318**, as well as the angled relationship between the distal section **320** and proximate section **322** of each elongate supporting member joined together at a joint region **324**. The distal section of the middle elongate supporting member **306c** is greater in length than the other elongate supporting members **306a**, **306b**, **306d**, **306e**, whereby the distal section of the elongate supporting members **306b** and **306d** is greater in length than the elongate supporting members **306a** and **306e**. **FIG. 9B** and **9C**, show the top surface **326** of the frame, and bottom surface of the frame **328**, respectively, whereby the frame has rounded edges. **FIG. 9D** and **9E** illustrate the first planar part orientated substantially along a horizontal plane (i.e. parallel to the surface of the ground), with the second planar part orientated at an obtuse angle (i.e. about 145°) with the first planar part, and the distal section of elongate supporting members orientated (bent) at an obtuse angle (i.e. about 150-160°) relative to their proximate section, whereby the distal section of the middle elongate supporting member (i.e. **306c** in **FIG. 9A**) is bent at an angle of about 150° (**FIG. 9E**), and the distal section of the other elongate supporting members (i.e. **306a,b,d,e** in **FIG. 9A**) are bent at an angle of about 160° (**FIG. 9F**).

[0168] An exemplary, non-limiting, embodiment of the corresponding engagement element **330** is illustrated in **FIG. 10A** and **10B**, whereby the corresponding engagement element is a metal sheet-like structure, that is magnetic and capable of quick-release magnetic engagement with a magnet comprised in the attachment unit of the adapter. The metal sheet-like structure comprises a top surface **334** that contacts with the adapter (i.e. attachment unit), and a bottom surface **336** that contacts the drape component. A flexible pin **332** comprised on the metal sheet-like structure is positioned at each corner and is in alignment with a corresponding pin hole **314** of the frame. In addition, the metal sheet-like structure comprises two corresponding alignment elements **338**, in the form of a hole, to receive a protrusion on the adapter, whereby these two corresponding alignment elements are in-line with the corresponding alignment elements **316** of the frame. **FIG. 10C** illustrates the metal sheet-like structure **330** (blocked in black for illustrative purposes and ease of viewing) releasably coupled to the top surface of the frame.

[0169] In various embodiments, the drape component disclosed herein may be releasably coupled to the adapter via the corresponding engagement element of the frame and the attachment unit of the adapter forming a quick-release engagement. In various embodiments, the attachment unit of the adapter comprises an engagement element that releasably couples to the corresponding engagement element of the drape component, wherein the corresponding engagement element of the drape component may be fixedly coupled to the frame such that a portion of the drape is sandwiched between the frame and the corresponding engagement element. This fixed coupling and positioning of the corresponding engagement element relative to the frame and drape allows, reduces or eliminates any interference of the quick-release engagement between the adapter and drape component.

[0170] An exemplary, non-limiting, embodiment of the drape component **400** is illustrated in **FIG. 11A, 11B** and **11C**, with the frame positioned in the central region of the drape and the two arms of the second planar part of the frame partially surrounding an opening **216** in the drape, whereby the opening allows a part of the operating room equipment to pass therethrough, for example a lens of a microscope.

[0171] The drape assembly including the adapter and drape component of the various embodiments is described in the following.

[0172] The drape assembly is capable of being suspended from an operating room equipment to form a shield over at least a portion of a table or surface, comprising the adapter disclosed herein and drape component disclosed herein, wherein the drape component is releasably coupled to the adapter with the frame of the drape component and the attachment unit of the adapter forming a quick-release engagement.

[0173] All embodiments described above in the context of the adapter and drape component (i.e. the drape and frame) and concerning their features and coupling relationship to each other are similarly applicable to the drape assembly, and thus need not be repeated in detail with respect to the drape assembly for clarity and conciseness. In other words, various embodiments described herein in the context of the adapter and drape component are analogously valid for the respective drape assembly comprising the adapter and drape component releasably coupled together, and *vice versa*.

[0174] In particular, the drape assembly may comprise (a) a drape component comprising a drape having a peripheral region and a central region, and a frame fixedly attached to the central region of the drape; and (b) an adapter comprising an adapter body comprising: i) a first portion having a coupling arrangement couplable to a complementary coupling arrangement of the operating room equipment, ii) a second portion opposite to the first portion; and iii) a cavity extending internally along the adapter body from the second portion towards the first portions, the cavity having an opening at the second portion; and iv) an attachment unit housed within the cavity of the adapter body and exposed through the opening of the cavity at the second portion, wherein the drape component is releasably coupled to the adapter with the frame of the drape component and the attachment unit of the adapter forming a quick-release engagement.

[0175] In use, the drape assembly disclosed herein may not create an airtight seal around the inspection/operative site (i.e. the peripheral region of the drape does not form a sealing engagement with a surface of a table and/or a portion of a patient). As a result, the drape assembly may not completely eliminate the risk of droplet and aerosol dispersion during surgery, but instead may substantially and significantly reduce or mitigate the risk of droplet and aerosol dispersion in an exterior space during a procedure. In particular, if the drape assembly did create an airtight seal around the operative site, this would likely hinder with the passage of instruments during the procedure (e.g. surgery) and also be more cumbersome to use as any movement allowed with the

operating room equipment will be limited. As such, a compromise between mitigating risks of transmission of infectious agents and creating a user-friendly drape assembly has to be made.

[0176] The system including the drape assembly and operating room equipment, of the various embodiments is described in the following.

[0177] The system is for forming a shield over at least a portion of a table or surface during a procedure using an operating room equipment, comprising the drape assembly disclosed herein and the operating room equipment, whereby the drape assembly is releasably coupled to the operating room equipment. In particular, the system may comprise the drape assembly disclosed herein and an operating room equipment comprising a complementary coupling arrangement that is releasably coupled to the coupling arrangement of the adapter.

[0178] In various embodiments, the coupling arrangement of the adapter may comprise a male coupling element and the complementary coupling arrangement may comprise a complementary female coupling element, whereby the male coupling element may be releasably coupled to the complementary female coupling element.

[0179] In various embodiments, the complementary female coupling element may comprise a mount that slidably receives the male coupling element such that the adapter body is securely and releasably held in position on the operating room equipment.

[0180] In various embodiments, the operating room equipment may be a magnifying instrument, preferably an operating microscope, wherein the complementary female coupling element is positioned on the magnifying instrument housing above a lens (as in **FIG.1**), and the adapter, and consequently the lens, is orientated at substantially the same angle as the second planar part of the frame. In various embodiments, the drape comprises an opening or viewing window, and the lens of the magnifying instrument is positioned such that the line of sight (i.e. optical axis) of the magnifying instrument passes through the opening of the drape. In various embodiments, the complementary coupling arrangement may be positioned on a magnifying instrument housing above the lens.

[0181] All embodiments described above in the context of the adapter, drape component (i.e. the drape and frame) and drape assembly concerning their features and coupling relationship to each other are similarly applicable to the system, and thus need not be repeated in detail with respect to the system for clarity and conciseness. In other words, various embodiments described herein in the context of the adapter, drape component and drape assembly are analogously valid for the respective system, and *vice versa*.

[0182] A kit including the adapter and drape component, of the various embodiments is described in the following.

[0183] The kit is for releasably coupling a drape component to an operating room equipment, comprising one or more adapters disclosed herein, and one or more drape components disclosed herein.

[0184] In various embodiments, the kit may comprise a plurality of adapters which may be interchangeably used with one or more drape component(s) and various operating room equipment, whereby different adapters, more particularly the coupling arrangement, may be needed for releasably coupling with various different complementary coupling arrangements located on the operating room equipment. In various embodiments, the kit may comprise a plurality of coupling arrangements provided on separate secondary pieces that may be releasably secured to one or more main pieces of the adaptor body in forming the adapter, and interchangeably selected dependent upon the complementary coupling arrangements located on the operating room equipment. Accordingly, the kit may comprise one or more adapter body(s) comprising one or more main piece(s) and one or more secondary piece(s) having the coupling arrangement. In various embodiments, the one or more main piece(s) may differ only in their depth dimension, and the one or more secondary piece(s) may differ only in their coupling arrangement.

[0185] In various embodiments, the kit may comprise two or more adapters, wherein the depth dimension of each adapter are different. By changing the depth of the adapter, the distance of the drape component spaced apart from the operating room equipment can be modified to suit any particular needs depending on the operating room equipment and its operating function, where it may be preferable for the drape component to be either further away or closer to the operating room equipment based on user preference and/or in order to optimize the function of said operating room equipment when in use.

[0186] In various embodiments, the kit may comprise one or more attachment unit(s), or more particularly one or more engagement element(s), for engagement with the drape component, which improves the versatility and adaptability of the adapter in using differing quick-release engagement mechanisms. In this regard, the kit may also comprise one or more corresponding engagement elements for releasably securing to the drape component.

[0187] In various embodiments, the kit may comprise a plurality of drape components, whereby each drape component may differ from each other in relation to their size and shape to be interchangeably used depending on the procedure to be performed and volume of interior space needed.

[0188] All embodiments described above in the context of the adapter, drape component (i.e. the drape and frame) and drape assembly concerning their features and coupling relationship to each other are similarly applicable to the kit, and thus need not be repeated in detail with respect to the kit for clarity and conciseness. In other words, various embodiments described herein in the context of the adapter, drape component and drape assembly are analogously valid for the respective kit, and *vice versa*.

[0189] Various embodiments are further illustrated by the following examples demonstrating the operation of the exemplified embodiments. However, it should be understood, that various embodiments are not limited to the exemplified embodiments.

[0190] In the following, the use of the exemplified embodiments are described in the context of mastoid surgery. In particular, the following working example use the drape assembly as illustrated in FIG. 3 whereby the attachment unit of the adapter forms a quick-release magnetic engagement with the drape component.

[0191] Mastoid drilling involves the use of high-speed irrigation drills and creates a large amount of droplet dispersion. Accordingly, the degree of contamination that is generated by mastoid drilling, and the extent that this can be mitigated by the use of the drape assembly disclosed herein which contains the surgical field was investigated.

[0192] **Methods & Materials:** Cortical mastoidectomy with a high-speed self-irrigating drill was performed under 3 test conditions in a cadaveric lab, including A, without a microscope, B, with the microscope alone and C, with a microscope fitted with the drape assembly disclosed herein. Fluorescent solution was used as irrigation fluid. The degree (mild, moderate or severe), distribution, and distance of contamination of the surroundings was collected in each of the 3 test conditions. The extent of contamination of the surgeon was also noted.

[0193] This experiment was performed at a temporal bone laboratory. Fresh frozen cadaveric head specimens were prepared and mounted for dissection using the set-up as shown in FIG. 12. The microscope was placed at the head of the table. 8 different markings were made circumferentially around the operative site at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° and 360° with the operative site being the centre of the axis. For the purposes of this experiment, all 3 set-ups utilized the right ear of the cadaver. Standard postauricular incisions were made and the mastoid cortex exposed. Mastoid drilling was performed with the Midas Rex Legend Drill (Medtronic, Minneapolis, USA) set at 60,000 revolutions per minute, with a 6mm cutting drill bit. An integrated irrigation system was used, with Schülke optics fluorescent solution (Schülke & Mayr, Norderstedt, Germany) as irrigation fluid and irrigation speed set to 37ml/minute. The same surgeon performed a cortical mastoidectomy under 3 conditions: A) without a microscope, with the surgeon wearing a face shield, B) microscope only and C) microscope with the attached drape assembly disclosed herein.

[0194] After each cortical mastoidectomy, the extent of contamination of the surgeon and the surroundings was elucidated with ultraviolet LED (wavelength 365nm). The furthest distance that droplets travelled from the operative site (point A in FIG. 12) was measured at 8 different circumferential points (as shown in FIG. 12). Additionally, the degree of contamination at 30 cm and 60 cm from point A were determined, and classified as mild, moderate or severe.

[0195] The presence of contamination of the surgeon's face/ mask area, head, chest, lap, right arm and left arm was recorded in each drilling condition.

[0196] **Results:** Condition A had the worst degree of contamination of both the surgeon and surroundings, with the furthest distance and heaviest density of droplet spread after a cortical mastoidectomy. Droplets were dispersed up to 290cm from the surgical field. The use of the drape assembly disclosed herein in Condition C significantly reduced the droplet dispersion to a maximum of 78cm from the surgical field. There was also a significant reduction in the density of contamination of the surroundings. Most of the heavy contamination was confined within the drape assembly disclosed herein. Additionally, there **are no contamination of the surgeon's face and head region.**

[0197] Mastoid drilling produces an extensive amount of droplet dispersion. Improvised barrier drapes have been shown to mitigate this problem but are cumbersome to use.

[0198] Distance of droplet dispersion: Condition A, in which the surgeon performed the cortical mastoidectomy without the presence of the microscope there was an extensive amount of droplet generation and it showed the greatest area of contamination (**FIG. 13** and **Table 1**), with the greatest trajectory of droplets anterior and 45° to the left of the surgeon, at 272 to 290 cm (**FIG. 13** and **Table 1**).

Table 1: Shows the maximal trajectory that droplets were detected from Point A under the 3 test conditions, namely A: without a microscope, B: with the microscope alone, and C: with microscope fitted with the drape assembly disclosed herein. These were measured at 8 different points circumferentially.

Degrees	Condition A(cm)	Condition B(cm)	Condition C(cm)
0	272	235	50
45	227	143	45
90	180	183	72
135	162	186	45
180	210	239	52
225	234	250	78
270	265	122	38
315	290	116	78

[0199] The presence of the microscope (without the drape assembly) i.e. Condition B significantly attenuated the trajectory of the droplets to the left of the surgeon (**FIG. 13**) due to its location at the head of the bed (**FIG. 13**). However, there continued to be contamination from 0-225° with a maximum trajectory of 239 cm at 180°.

[0200] Finally, in condition C, where the microscope was fitted with the the drape assembly disclosed herein, the drape assembly was effective in catching splash and droplets generated. The spread of

droplets were significantly attenuated in all directions with the maximum trajectory being only 78cm (FIG. 13 and Table 1)

[0201] Density of droplet dispersion: In Condition A, the greatest degree of heavy contamination was noted. Heavy contamination was present in the entire field 30 cm from the operative site. At 60 cm, heavy contamination was noted at 180° and 225°, while moderate contamination was noted at 90° and 135° (FIG. 14A).

[0202] In Condition B, there was a only mild contamination of both quadrants anterior to the surgeon, i.e. 0-90° and 270-0° (FIG. 14B). In condition C, heavy contamination was only noted in the at 4 of 8 points within the 30 cm diameter (FIG. 14C) and only mild contamination was noted at 4 of 8 points in the 60 cm radius.

[0203] Droplet contamination of Surgeon: In condition A, there was moderate to heavy contamination of the surgeon – **with moderate contamination of critical areas including the surgeon's scrub cap and face.** Notably, despite the use of a face shield, there was still apparent contamination of the surgeon's face by the droplets.

[0204] The presence of the microscope in Condition B reduced the number of droplets on the surgeon's face, with only mild contamination. However, there continued to be heavy contamination of surgeon's chest, lap and both arms.

[0205] With the use of the novel barrier drape, i.e. drape assembly disclosed herein, (Condition C), there was also no visible contamination of the head, face or mask regions of the surgeon with mild contamination of the surgeon's chest and moderate contamination of the surgeon's lap.

[0206] Table 2: shows the degree of contamination on different subsites of the surgeon in the 3 conditions. Condition A , where no microscope was used for the cortical mastoidectomy. Condition B, where the microscope was used alone and Condition C where the microscope was fitted with the drape assembly disclosed herein.

	Condition A	Condition B	Condition C
Head	Moderate	Mild	None
Face/Mask	Moderate	Mild	None
Chest	Heavy	Heavy	Mild
Right arm	Heavy	Heavy	Heavy
Left arm	Heavy	Heavy	Heavy

Lap	Heavy	Heavy	Moderate
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[0207] As seen in FIG. 14, there was at least moderate contamination of 60 cm radius from 90- 225° in condition A, where no microscope was used. In contrast, the use of the drape assembly disclosed herein confined most of the heavy contamination to be within a limited area within a 30 cm radius as this was the area under the barrier drape. Typically, the scrub nurse would be on the opposite side of the patient, facing the surgeon, corresponding to 315-0°. The significant reduction in the contamination at this location highlights that the drape assembly disclosed herein is not only helpful in preventing the contamination of the primary surgeon but also significantly reduces risks of contamination to the rest of the surgical team.

[0208] The drape assembly disclosed herein can be attached securely to the operating room equipment such as the microscope. The above working example has demonstrated that the drape assembly disclosed herein is capable of mitigating the degree of splash and droplet dispersion during mastoidectomy. There was a significant reduction in the droplet distribution with the use of the drape assembly disclosed herein as compared to the two other conditions, with the microscope alone and without microscope. Importantly, the use of the drape assembly disclosed herein prevented any droplet generation onto critical areas, such as the surgeons head, face and mask areas.

[0209] Further, the above working example has also demonstrated that the drape assembly described herein was quick to set up and did not affect visualization or hinder dexterity during surgery. For example, the drape assembly described herein has structural supports, dedicated adapter and quick-release engagement improving the ease of setting up, as well as allowing stable attachment while preserving manoeuvrability and view of the microscope and access for the surgeons.

[0210] The invention has been described broadly and generically herein. Each of the narrower species and subgeneric groupings falling within the generic disclosure also form part of the invention. This includes the generic description of the invention with a proviso or negative limitation removing any subject matter from the genus, regardless of whether or not the excised material is specifically recited herein. Other embodiments are within the following claims.

[0211] One skilled in the art would readily appreciate that the present invention is well adapted to carry out the objects and obtain the ends and advantages mentioned, as well as those inherent therein. Further, it will be readily apparent to one skilled in the art that varying substitutions and modifications may be made to the invention disclosed herein without departing from the scope and spirit of the invention. The adapter, drape component, drape assembly, system and kits described herein are presently representative of preferred embodiments are exemplary and are not intended as limitations on the scope of the invention. Changes therein and other uses will occur to those skilled in the art which are encompassed within the spirit of the invention are defined by the scope of the

claims. The listing or discussion of a previously published document in this specification should not necessarily be taken as an acknowledgement that the document is part of the state of the art or is common general knowledge.

[0212] The invention illustratively described herein may suitably be practiced in the absence of any element or elements, limitation or limitations, not specifically disclosed herein. Thus, it should be understood that although the present invention has been specifically disclosed by exemplary embodiments and optional features, modification and variation of the inventions embodied therein herein disclosed may be resorted to by those skilled in the art, and that such modifications and variations are considered to be within the scope of this invention.

[0213] References cited herein:

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CLAIMSWhat is claimed is:

1. An adapter for releasably coupling a drape component to an operating room equipment, comprising:
 - an adapter body comprising:
 - a first portion having a coupling arrangement couplable to a complementary coupling arrangement of the operating room equipment,
 - a second portion opposite to the first portion; and
 - a cavity extending internally along the adapter body from the second portion towards the first portion, the cavity having an opening at the second portion;
 - and
 - an attachment unit housed within the cavity of the adapter body and exposed through the opening of the cavity at the second portion, the attachment unit being capable of forming a quick-release engagement with the drape component.
2. The adapter of claim 1, wherein the adapter body comprises a first face at the first portion, and a second face at the second portion, wherein the cavity is recessed into the second face.
3. The adapter of claim 2, wherein the first face and second face are parallel planar surfaces directed in opposite directions.
4. The adapter of any one of claims 1-3, wherein the quick-release engagement between the attachment unit and the drape component comprises a quick-release magnetic engagement, a quick-release snap fit engagement, a quick-release pin engagement, a quick-release clamp engagement, a quick-release lever-type engagement, a quick-release push button engagement, or a quick-release hook and loop engagement.
5. The adapter of any one of claims 1-4, further comprising an alignment arrangement disposed at the second portion of the adapter body for alignment of the drape component to the adapter.
6. The adapter of any one of claim 5, wherein the alignment arrangement comprises at least one alignment element at the second portion of the adapter body for cooperating with a corresponding alignment element of the drape component to bring the drape component into alignment with the adapter.
7. The adapter of claim 6, wherein the alignment arrangement comprises two alignment elements, wherein the two alignment elements are respectively positioned in an opposing

manner across the opening at the second portion such that the opening is positioned therebetween.

8. The adapter of any one of claims 1-7, further comprising a retaining arrangement for retaining the attachment unit within the cavity, wherein the retaining arrangement comprises at least one protruding rim extending perpendicularly with respect to an inner wall surface of the cavity along a segment of the opening of the cavity.
9. The adapter of any one of claims 1-8, wherein the coupling arrangement comprises a male coupling element for releasably coupling with the complementary coupling arrangement of the operating room equipment comprising a complimentary female coupling element.
10. The adapter of claim 9, wherein the male coupling element comprises a plurality of trapezoidal or wedge-shaped elements, and the complementary female coupling element comprises a mount comprising one or more recesses for slidably receiving the trapezoidal or wedge-shaped elements such that the adapter body may be securely and releasably held in position on the operating room equipment.
11. The adapter of any one of claims 1-10, wherein the coupling arrangement is integrally formed with the adapter body as a single-piece.
12. The adapter of any one of claims 1-10, wherein the adapter body comprises a main piece and a secondary piece having the coupling arrangement, wherein the secondary piece is releasably secured to the main piece to form the adapter body, wherein the secondary piece is a plate-like structure, and wherein the main piece and secondary piece are secured together via one or more fasteners.
13. The adapter of any one of claims 1-12, wherein the attachment unit is fitted into the cavity in a manner to cover the opening of the cavity at the second portion.
14. The adapter of any one of claims 1-13, wherein the attachment unit comprises an engagement element exposed through the opening of the cavity at the second portion for releasably coupling with a corresponding engagement element of the drape component.
15. The adapter of claim 14, wherein the engagement element of the attachment unit comprising a magnet, preferably a neodymium magnet, that releasably couples to the corresponding engagement element of the drape component comprising a magnetic material in a manner so as to magnetically couple with the adapter and the drape component.

16. The adapter of claim 15, wherein the magnet is embedded or integrally formed within the engagement element, or the magnet is attached to an external surface of the engagement element.
17. The adapter of any one of claims 1-16, wherein the attachment unit is detachable from the drape component in a tool-free manner such that the adapter is coupled to, and decoupled from, the drape component without need for external tools or components for said coupling or decoupling, such as threaded screws, nuts, bolts, clamps, or other fasteners.
18. A drape assembly capable of being suspended from an operating room equipment to form a shield over at least a portion of a table or surface, the drape assembly comprising:
 - a drape component comprising
 - a drape having a peripheral region and a central region, and
 - a frame fixedly attached to the central region of the drape; and
 - an adapter comprising
 - an adapter body comprising:
 - a first portion having a coupling arrangement couplable to a complementary coupling arrangement of the operating room equipment,
 - a second portion opposite to the first portion; and
 - a cavity extending internally along the adapter body from the second portion towards the first portions, the cavity having an opening at the second portion; and
 - an attachment unit housed within the cavity of the adapter body and exposed through the opening of the cavity at the second portion,wherein the drape component is releasably coupled to the adapter with the frame of the drape component and the attachment unit of the adapter forming a quick-release engagement.
19. The drape assembly of claim 18, wherein the drape is a single sheet of fully transparent flexible material, wherein the peripheral region defines a continuous perimeter of the drape, which hangs down from the central region when the adapter is coupled to the operating room equipment.
20. The drape assembly of claim 18 or 19, wherein, the drape forms a dome shape that is substantially spherical or hemispherical forming the shield to mitigate fluid movement from an interior space into an exterior space thereby mitigating droplet, particulate, and aerosol movement from the interior space into the exterior space.

21. The drape assembly of any one of claims 18-20, wherein the attachment unit of the adapter comprises an engagement element releasably coupled to a corresponding engagement element of the drape component, wherein the corresponding engagement element of the drape component is fixedly coupled to the frame of the drape component such that a portion of the drape is sandwiched between the frame and the corresponding engagement element of the drape component.
22. The drape assembly of any one of claims 18-21, wherein the adapter comprises an alignment arrangement having at least one alignment element disposed at the second portion of the adapter body, wherein the engagement element of the drape component and/or the frame of the drape component comprises at least one corresponding alignment element, wherein the at least one alignment element and the at least one corresponding alignment element cooperatively aligns the drape component with the adapter.
23. The drape assembly of any one of claims 18-22, wherein the frame is attached to an interior surface of the drape such that a top surface of the frame is covered by the drape.
24. The drape assembly of any one of claims 18-23, wherein the frame comprises:
- a first planar part comprising a plurality of elongate supporting members extending radially outwards from the first planar part, wherein, when the adapter is coupled to the operating room equipment, the first planar part is orientated substantially horizontal relative to a surface of the table or surface; and
 - a second planar part comprising a plurality of elongate supporting members extending radially outwards from the second planar part, wherein the second planar part forms an obtuse angle with the first planar part, preferably at an angle of 140-160°, more preferably at an angle of 145-150°.
25. The drape assembly of claim 24, wherein each elongate supporting member comprises:
- a proximate section co-planar with their respective first planar part or second planar part from which they extend; and
 - a distal section that bends from the proximate section, preferably to form an angle of 150-170°, more preferably to form an angle of 155-165°.
26. The drape assembly of claim 24 or 25, wherein the first planar part comprises three elongate supporting members, and the second planar part comprises two elongate supporting members extending in opposite directions to each other.
27. The drape assembly of any one of claims 24-26, wherein the second planar part further comprises two arms extending parallel to each other in a same outwards direction from the second part, wherein the two arms are co-planar with the second planar part.

28. The drape assembly of any one of claims 24-27, wherein the first planar part comprises a port, preferably the port comprises a closing flap or valve for sealing the port, preferably the port is configured for a suction device to be attached.
29. The drape assembly of any one of claims 24-28 insofar as dependent upon claim 21, wherein the corresponding engagement element of the drape component is fixedly coupled to the second planar part of the frame.
30. The drape assembly of claim 29, wherein the corresponding engagement element of the drape component comprises a metal sheet-like structure, preferably comprising steel or other magnetic material, and a plurality of flexible pins passing through a plurality of corresponding pin holes in the second planar part and gripping the second planar part for fixedly coupling the sheet-like structure to the frame.
31. A system for forming a shield over at least a portion of a table or surface during a procedure using an operating room equipment, comprising the drape assembly according to any one of claims 18-30, and the operating room equipment, wherein the operating room equipment comprises a complementary coupling arrangement that is releasably coupled to the coupling arrangement of the adapter.
32. The system of claim 31, wherein the coupling arrangement of the adapter comprises a male coupling element and the complementary coupling arrangement comprises a complementary female coupling element, whereby the male coupling element is releasably coupled to the complementary female coupling element.
33. The system of claim 32, wherein the operating room equipment is a magnifying instrument, preferably an operating microscope, wherein the complementary female coupling element is positioned on the magnifying instrument housing above a lens, and the adapter, and consequently the lens, is orientated at substantially the same angle as the second planar part of the frame.
34. The system of any one of claims 31-33, further comprising a suction device attached in a sealing engagement to the drape assembly for extracting aerosols from the interior space, wherein the suction device is part of a suction system, preferably a scavenger system.