

STERILE SURGICAL TRAY

BACKGROUND

Field

[0001] The invention is related to a sterile surgical tray that functions as both a pack to transport surgical materials and devices to a surgery site and as a sterile tray for receiving a plurality of surgical instruments. More specifically, embodiments of the invention relates to a sterile surgical tray that includes a pump contained within the sterile tray and where the pump remains within a sterile field during surgery. The sterile surgical tray may also include a plurality of electrical input and output connectors attached to the tray.

Description of the Related Art

[0002] It is well known to use, in surgery, a sterile pack shipped from a manufacturer to a surgery center, an example of which is ophthalmic surgery (vitreoretinal or cataract surgery, in particular). These packs typically contain several items that are typically used in surgery and include one-time use surgical instruments, fluid cassettes, tubing sets, drapes, needles, and other devices. The particular content of a pack depends on the type of surgery and perhaps the individual preference of the surgeon or surgery center.

[0003] When preparing for surgery, typically a sterile drape is placed over what is commonly referred to as a Mayo tray. The contents of the sterile pack and perhaps additional sterile instruments and materials are spread-out over the tray so that the materials and instruments necessary for the surgery are readily available to a nurse or surgeon.

[0004] It is also known to provide a sterile pack where many of the instruments and tubing sets are organized and placed in mating recesses of the pack so that the pack can act as a tray for at least some of the instruments in surgery.

[0005] Some of the surgical instruments are electrically or pneumatically powered by a surgical console or system that is outside of the sterile field defined by the surgical site and the sterile instruments and materials on the tray and used in the surgery. Some of the sterile materials are removed from the sterile field or a portion is removed from the sterile field prior to surgery. The materials removed include the pump cartridges and tubing sets which are connected to the non-sterile surgical console. The surgical console also typically

includes a large display screen for displaying and inputting parameters that will control the devices used during surgery. This surgical set-up typically requires a surgeon and one or two support persons so that surgery can be performed efficiently while also adjusting the parameters on the console and switching to a different surgical instrument to perform a different procedure.

[0006] However, with the present trend of surgeries moving away from hospital and into ambulatory surgery centers (ASCs) and even into a doctor's own office, coupled with reduced reimbursements for surgical procedures, there is a need to allow surgeons to perform surgery with little or no assistance. In addition, because of personnel and cost restraints the assistant provided to the surgeon is typically not trained in the particular surgical procedure to be performed, so that the interaction between the surgeon and assistant may not be particularly efficient.

[0007] Therefore, a need exists for a surgical system and surgical products that allow a surgeon to perform safe, efficient, and cost-effective surgery with little or no assistance during surgery.

SUMMARY

[0008] In certain embodiments, a sterile surgical tray comprises a sterile tray, a pump within the sterile tray, and a motor within the sterile tray connected to the pump. Desirably, the tray includes structure for receiving a plurality of surgical instruments. It is also desirable that the tray contain at least one pump fluid reservoir and that the reservoir be operatively connected to the pump. In a distinct embodiment, a sterile surgical tray comprises a plurality of electrical input and output connectors attached to the tray.

[0009] In certain embodiments, an infusion fluid reservoir comprises a multiple chamber fluid reservoir for holding a different fluid in each chamber; a pressure pump connected to two or more chambers for pressurizing the chambers; and a multiple position valve connected to the multiple chambers for selectively opening one of the multiple chambers to allow a fluid contained in a selected chamber to flow out of the selected chamber.

[0010] In certain embodiments, a sterile surgical tray comprises a receiving area for holding a plurality of surgical instruments; a fluid reservoir disposed apart from the

receiving area; a pump operatively connected to the fluid reservoir; a motor drivingly coupled to the pump; and a plurality of input and output connectors attached to the sterile tray, at least one of the input and output connectors being connected to the motor. A sterile surgical tray system can comprise in certain embodiments a tray with a top surface defining a sterile surface for holding a plurality of surgical instruments; at least one surgical instrument held on the top surface; a pump fluid reservoir for use with the at least one surgical instrument; a pump operatively connected to the at least one surgical instrument and to the pump fluid reservoir; a motor connected to the pump for driving the pump; and wherein at least the pump remains within a sterile field during surgery.

[0011] In certain embodiments, a sterile surgical tray comprises a top surface for holding a plurality of surgical instruments; a pump connected to the sterile tray and for connection to a fluid pump reservoir; and a motor connected to the pump for powering the pump. A sterile surgical tray can comprise in certain embodiments a tray having a sterile top surface for holding a plurality of surgical instruments; a pump fluid reservoir prepackaged and sterilized with the tray; a pump in the tray for operative connection to at least one surgical instrument and the pump fluid reservoir; and a motor connected to the pump for powering the pump.

[0012] In certain embodiments, an independent system for a surgical procedure comprises a control device including a processing unit; and a plurality of instruments associated with the surgical procedure and operably coupled to the control device, wherein the control device and the plurality of instruments are prepackaged together, and the processing unit is configured to control at least one of the prepackaged instruments. In certain embodiments, at least one of the plurality of electrical instruments comprises a processing unit. The processing unit can be configured to establish communication between each of the plurality of electrical instruments. In certain embodiments, the communication can be wireless communications. In certain embodiments, the processing unit can be configured to: receive status updates from the plurality of electrical instruments; and communicate with status updates to a user of the system.

[0013] In certain embodiments, a surgical system comprises a portable surgical tray including a processing unit; a plurality of instruments operably coupled to the processing

unit; and a user input device providing a user input for controlling an operating parameter of one or more of the plurality of instruments, wherein the processing unit is configured to receive the user input and transmit an operating command to the one or more of the of the plurality of instruments. In certain embodiments, the processing unit is further configured to receive and/or monitor operating parameters from the plurality of instruments. In certain embodiments, the processing unit is further configured to transmit a shut down command to a handpiece in the event that at least one operating parameter meets a threshold, for example, as a safety mechanism.

[0014] In certain embodiments, a self-powered surgical system for a surgical procedure, comprises a surgical tray; a plurality of handheld instruments; a power source in at least one of the surgical tray and a handheld instrument; and a processing unit; wherein the processing unit is configured to execute program instructions, the program instructions including instructions for: detecting power from the at least one power source; directing power to the plurality of handheld instruments from the at least one power source; and establishing communication with each of the plurality of handheld instruments.

[0015] In certain embodiments, a portable biological cutting and aspiration device comprises a cutting tip; a fluid aspiration device; and an integrated control unit coupled to the cutting tip and fluid aspiration device, wherein the control unit is configured to control cutting and aspiration of the cutting tip and fluid aspiration device.

[0016] In certain embodiments, a surgical system comprises a portable surgical platform configured to perform at least one of cutting, resecting, illuminating, lasering, aspirating, infusing, cauterizing, cryopreserving biological tissue and fluids, and infusing and aspirating fluids in a human body during surgical procedures, wherein the surgical platform is at least in part disposable; and a monitoring center coupled to the surgical platform for monitoring one or more operating parameters during the surgical procedures.

[0017] In certain embodiments a personal surgical center comprising a portable computer unit in wireless communication with at least one of a plurality of handheld instruments, the portable computer unit including a processor and memory having program instructions stored therein, the processor being operable to execute the program instructions, the program instructions including: automatically identifying at least one of the plurality of

handheld instruments; wirelessly receiving operation status of the identified handheld instruments; monitoring changes in the operation status of the identified handheld instruments; and displaying the operation status on a display.

[0018] In certain embodiments, a surgical system comprises a control system accessible by a surgeon for controlling operational parameters of a one or more medical instruments; a monitoring system including a general purpose computer in wireless communication with the control system, the general purpose computer including a processor and memory having program instructions stored therein, the processor being operable to execute the program instructions, the program instructions including: wirelessly identifying the medical instruments controlled by the control system; wirelessly receiving the operational parameters of the one or more medical instruments from the control system; monitoring changes in the operational parameters of the one or more medical instruments; and displaying the operational parameters of the one or more medical instruments on a display coupled to the general purpose computer.

[0019] For purposes of this summary, certain aspects, advantages, and novel features of the invention are described herein. It is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment of the invention. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves one advantage or group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The foregoing and other features, aspects and advantages of the present inventions are described in detail below with reference to the drawings of preferred embodiments, which are intended to illustrate and not to limit the invention. The drawings comprise several figures in which:

[0021] FIG. 1 is a top view of a sterile surgical tray in accordance with a preferred embodiment of the invention;

[0022] FIG. 2 is a bottom view of the tray of FIG. 1;

[0023] FIG. 3 is a view of an alternate shape of a sterile surgical tray in accordance with a preferred embodiment of the invention;

[0024] FIG. 4 is a top view of an alternate embodiment of a sterile surgical tray in accordance with a preferred embodiment of the invention;

[0025] FIG. 5 is a partial elevation view of FIG. 4;

[0026] FIG. 6 is an alternate embodiment of a portion of a sterile surgical tray in accordance with a preferred embodiment of the invention;

[0027] FIG. 7 is a partial view of another embodiment of a sterile surgical tray in accordance with a preferred embodiment of the invention;

[0028] FIG. 8 is a perspective view of yet another embodiment of a sterile surgical tray in accordance with a preferred embodiment of the invention;

[0029] FIG. 9 is a perspective view of a foot controller to be used with a sterile surgical tray in accordance with a preferred embodiment of the invention;

[0030] FIG. 10 is a perspective view of an alternate embodiment of an infusion fluid reservoir in accordance with a preferred embodiment of the invention;

[0031] FIG. 11 is a top view of a sterile surgical tray for a specific surgery in accordance with a preferred embodiment of the invention;

[0032] FIG. 12 is a top view of a sterile surgical tray for another specific surgery in accordance with a preferred embodiment of the invention;

[0033] FIG. 13 is a functional block diagram of a fluid-air exchange system to be used with a sterile surgical tray in accordance with a preferred embodiment of the invention;

[0034] FIG. 14 is a block diagram illustrating an independent surgical center coupled to a personal surgical center, surgical or other instruments, and hospital and/or medical office systems in accordance with a preferred embodiment of the invention;

[0035] FIG. 14A is a block diagram depicting one embodiment of a computer hardware system configured to run software for implementing one or more embodiments of the system described herein, for example, the personal surgical center;

[0036] FIG. 15 is a flow diagram of various processes executed by the processing unit and/or the surgical tray in accordance with a preferred embodiment of the invention; and

[0037] FIG. 16 is a flow diagram of a process executed by the processing unit of the independent surgical center in accordance with a preferred embodiment of the invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENTS

[0038] The following description will be disclosed relative to ophthalmic surgery but this is only for illustrative purposes and those skilled in the art will appreciate that the embodiments as described herein and as claimed may equally apply to other types of surgery, for example but not limited to ortho surgery, neurosurgery, cardiovascular surgery, gastrointestinal surgery, plastic and dermatological surgery, general surgery, head and neck surgery, including without limitation to ear, nose, and throat, maxillofacial surgery, vascular surgery, thoracic surgery (lung), transplant surgery, or the like.

[0039] Enabling a surgeon to perform effective surgery with minimal assistance from another and to perform surgery in a surgery center or office setting without a large capital investment, requires control of the surgical instruments and devices to be in the sterile surgical field. The sterile field is typically defined by the area adjacent the surgical site that is covered by a sterile drape and the area where the surgical instruments and materials are placed for access by the surgeon during surgery. The area where the surgical instruments are placed for surgery is typically a non-sterile tray, commonly referred to as a Mayo tray, covered by a sterile drape.

[0040] The embodiments of the invention described herein provide the surgeon with sterile field control of the surgery by providing the surgeon with a sterile surgical tray that has been manufactured and assembled as a prepackaged sterile pack that functions as a tray during surgery. The term pack is meant to collectively identify the surgical instruments and other items contained in a sterile package that is shipped from the manufacturer to a customer (hospital, ASC, doctor's office) and is for use by a surgeon to perform surgery. The term tray refers to a structure that defines at least a portion of a surgical field and holds fluid handling devices, surgical instruments, and other miscellaneous items to be used during surgery.

[0041] In a preferred embodiment, the pack can be synonymous with the tray. As will be seen below, in a preferred embodiment the inventive surgical tray may be manufactured and assembled with the necessary equipment for surgery and then enclosed in a

bag or other container and sterilized. Then when the bag is opened, the tray is removed from the bag, a lid or cover is potentially removed, revealing several if not all the instruments and other items needed for surgery. Of course, variations on the preferred embodiment may be made without departing from the scope and claims. For example, while it is contemplated that the preferred sterile tray can be packaged and sterilized with a pump reservoir, pump, and motor, it may be that the reservoir, pump, or motor can be packaged without being sterilized. For example if the motor were contained in a chamber that was sealed off from the tray the motor may not need to be sterilized. As used herein, the term "motor" means and includes without limitation a device that receives and modifies energy to drive at least the pump.

[0042] A sterile surgical tray 10 is shown in FIG. 1. The tray 10 includes structure 12 for receiving a plurality of surgical instruments 14. The structure 12 for receiving the instruments 14 may be a mating structure, such as shown, that generally conforms to the shape of a particular instrument. As used herein the term "mating" means without limitation a receptacle having a complementary shape for recessing part or all of an article. Alternatively, the structure 12 could be a recess (not shown) in the tray 10 having a shape that may hold a variety of instruments 14 or the structure 12 may be cavities (not shown) formed in tray 10 that retain instruments 14 in a generally vertical orientation relative to top surface 16, or even some other suitable structure 12 may be used. The tray 10 should have sufficient area on top surface 16 to receive the surgical instruments 14 necessary for the surgery to be performed with sufficient space between the instruments 14 to allow the surgeon to easily and conveniently pick-up an instrument and return it to the tray 10.

[0043] The sterile tray 10 may be molded of such materials as acrylonitrile butadiene styrene (ABS) or similar thermoplastic material. The tray 10 may take the place of the traditional Mayo tray and may be placed between the surgeon and the surgical site. Therefore, it is preferred that tray 10 be sturdy enough to withstand the weight of a surgeon's arms resting on the structure forming arm rests 18. However, other accommodation may be made for a surgeon's arms and tray 10, in which case, tray 10 need not be as robustly constructed.

[0044] Tray 10 also may include structure forming a priming fluid reservoir 20 for receiving one or more instruments 14 during priming of one or more instruments with a surgical fluid such as balanced-salt solution (BSS), as is well known. If a reservoir 20 is not provided the user may need to use a beaker or other container for priming (for example, filling) the surgical instruments and tubes with BSS.

[0045] Structure 22 for attaching a drape 24 to the tray 10 may also be provided. The drape 24 may be placed over a patient, such as a portion of a patient's head (not shown) during ophthalmic surgery. Structure 22 may be any suitable structure such as adhesive tape, hook and loop material, or other structure that will attach drape 24 to tray 10. Using drape 24 allows for the use of at least one fluid retention trough 26 to collect fluid runoff from the drape 24 that occurs during surgery. FIG. 1 shows two troughs 26, but a single trough (not shown) could also be formed that surrounds the entire center section 28 where a patient's head (not shown) will be placed during surgery.

[0046] The surgical instruments 14 may include a plurality of instruments, and in particular ophthalmic surgical instruments prepackaged and sterilized with the tray 10. Also, at least one surgical instrument 14 may be connected at manufacture to a pump fluid reservoir 30 via tubing 32 and/or 34, as shown in FIG. 1. If the sterile surgical tray 10 is for ophthalmic surgery the plurality of surgical instruments 14 preferably includes at least a tissue isolation instrument, an aspiration instrument, and an infusion instrument. The tissue isolation instrument may be at least one of a vitreous cutter, a lens emulsification, fragmentation, or cutting device, a scissors, and a cautery knife, all of which are well known. The aspiration instrument may be incorporated into the tissue isolation instrument, such as is known in vitreous cutters and phacoemulsification (phaco) devices. The aspiration and infusion instruments may be a combined infusion and aspiration instrument, commonly referred to as an irrigation/aspiration (I/A) handpiece. If the surgical tray 10 is for vitreoretinal surgery the infusion instrument may be an infusion cannula and connected tubing.

[0047] Additional surgical instruments may include an illumination instrument, which is preferably self-illuminating. That is the illumination instrument preferably has a built-in light source and not the commonly known remote light source-fiber optic

combination. In addition tray 10 may include additional items such as entry site alignment cannulas 36, commonly used in sutureless vitreoretinal surgery.

[0048] Preferably tray 10 includes all or nearly all the instruments necessary to perform the desired surgery. For instance tray 10, if the desired surgery is a vitrectomy of the eye, includes the instruments for a vitrectomy, which are a vitreous cutter, an irrigation instrument, an illumination instrument, an aspiration source, an infusion source, and passive surgical instruments (for example, not powered), and possibly an air/fluid exchange source. If the desired surgery is a cataract removal from the eye, the instruments included in tray 10 would be a cataract extraction instruments such as a phaco device, a phaco needle, a capsule polish tool, an aspiration source, an infusion source, and passive surgical instruments, and possibly an oil filled syringe. Tray 10 also preferably includes structure for receiving additional instruments beyond the plurality of instruments that are prepackaged and sterilized with the tray 10; an example of which is the empty space, shown generally at 38 in FIG. 1.

[0049] In certain embodiments, the sterile surgical tray 10, as best seen in FIG. 2, also includes a pump(s) 40 contained within the sterile tray 10 operatively connected to the pump fluid reservoir 30. In certain embodiments, a motor(s) 42 is also contained within the sterile tray 10 and is connected to the pump 40. In certain embodiments, the sterile surgical tray 10 can be configured to releasably receive a motor(s) and a pump(s), and/or be mechanically and/or electrically coupled to a motor(s) and a pump(s), which may or may not be partially or entirely sterile because in certain embodiments, the motor(s) and/or pump(s) may be reused with other sterile surgical trays. In the embodiment shown in FIG. 2, which is a bottom view of tray 10, reservoir 30 is not easily removable from tray 10. Other embodiments (see for example FIG. 6 discussion below) may provide a reservoir, pump, motor assembly that is self-contained and placed in a pocket or cavity (not shown) of tray 10 so that the assembly can be removed from tray 10 easily before, during, or after surgery.

[0050] Reservoir 30 may be an aspiration pump fluid reservoir for collecting aspirated tissue and fluid during surgery or reservoir 30 may be infusion pump fluid reservoir for infusing fluid into a surgical site. Another embodiment of reservoir 30 is that shown in FIG. 2 where reservoir 30 is actually both an aspiration reservoir 44 and an infusion pump fluid reservoir 46; such that infusion reservoir 46 and aspiration reservoir 44 form a single

fluid reservoir 30 with separate chambers for infusion and aspiration and a pump operatively connected to each chamber. Therefore, in the configuration of FIG. 2 pump 40 is an infusion pump and pump 48 is an aspiration pump. Motors 42 and 50 are preferably electric motors and may be the same type motor or different motors depending on the performance needed to drive the pumps 40 and 48. Aspiration pump 48 is preferably a suitable pump for aspirating a sufficient amount of tissue and fluid at an acceptable rate for the type of surgery to be performed. For ophthalmic surgery, pumps 40 and 48 may be one of a vacuum pump (for example, a rotary vein or diaphragm) or a positive displacement pump (for example, peristaltic or scroll). Tray 10 may also include a syringe pump (not shown) for injecting oil or other fluids into the eye.

[0051] In certain embodiments, the inclusion of a pump and reservoir in tray 10 provides particular fluidics advantages over traditional console based systems. For example, fluidics advantages can be achieved because the construction and functionality of tray 10 allow the pump fluid reservoir to be less than two feet from a surgical site, such as an eye. This close proximity can allow for infusion and aspiration tubing lengths of less than two feet and perhaps less than 18 inches to be used. By using such short tubing lengths compliance of the fluidics circuit defined by the path from the infusion reservoir 46 through infusion tubing and a surgical instrument into the eye followed by an aspiration out of the eye through aspiration tubing and into the aspiration reservoir 44, can be greatly reduced compared to the conventional console based surgeries known today. Conventional console based surgeries use several feet (as much as 6-8 feet) of tubing for both the infusion path and the aspiration path. Furthermore, a reduced aspiration and infusion tubing length reduces fluid propagation delays and increases responsiveness of the aspiration and infusion functions. The 6-8 feet tubing length can negatively impact fluidic performance as compared to the much shorter tubing lengths possible in the preferred embodiments. The longer tubing lengths have longer delays in pressure and vacuum level changes introduced into the surgical instruments and an eye compared to the much shorter lengths of the preferred embodiments. These longer delays are the result of the increase tubing length and the compliance of the tubing. The effect of any tubing compliance will be amplified by longer tubing lengths. The shorter tubing lengths can also reduce the complexity of the surgical operation for the surgeon because with

multiple lengthy tubes in the surgical room the surgeon generally must take care not to entangle the lengthy tubes or to pinch the lengthy tubes during the surgery.

[0052] Tray 10 may have a shape that conforms to a contour of a body portion adjacent a surgical site. As can be seen from FIGs. 1 and 2 tray 10 is curved so that the tray 10 may be placed around a patient's head (not shown) during ophthalmic surgery. Tray 10, which can be said to be generally U-shaped, would be placed such that a top of the patient's head is placed nearest the wall 52 or, put another way, at the bottom of the U-shaped section 28. The sterile surgical tray for ophthalmic surgery may also be semi-circular in shape, as shown at 54 in FIG. 3. Fluid reservoir 30 is preferably located to a side of the patient's head during surgery, as shown in the embodiment of FIGs. 1 and 2.

[0053] Fluid reservoir 30 may be a rigid housing formed of suitable material such as some form of plastic or resin. The Pump fluid reservoir may also be a bag 56, shown in FIG. 4. A sterile surgical tray 58 similar to tray 10, in the embodiment of FIG. 4, includes a remotely located infusion source 60, such as a BSS bottle that may be hung from an IV pole (not shown). Infusion source 60 is connected to a surgical instrument 62 via tubing 64 (preferably included in tray 58 during manufacture). Instrument 62 is connected to a pump 66 via tubing 68. Pump 66 is powered by a motor 70, seen in FIG. 5. FIG. 5 is a partial elevation view of the inside of tray 58 taken along line 5-5 of FIG. 4. Pump 66 aspirates tissue and fluid from a surgical site into bag 56 via tubing 72. Bag 56 may be hung from structure on tray 58 such as hooks 74.

[0054] In reference to FIGs. 1 and 2, fluid reservoir 30 preferably includes a filler port 76 for allowing a user to fill the fluid reservoir 46 with a surgical fluid to be infused into a surgical site. Fluid reservoir 44 preferably includes a discharge port for emptying aspirated fluid when the reservoir 44 becomes full during surgery.

[0055] FIG. 6 shows an aspiration and infusion reservoir 100, including isolated aspiration reservoir 102 and infusion reservoir 104. Reservoir 100 includes a separate pump and motor for each chamber 102 and 104. An aspiration pump 106 and motor 108 will aspirate fluid and tissue from a surgical site through surgical instrument 110 via tubing 112. Infusion fluid contained within infusion reservoir 104 is forced from reservoir 104 through tubing 114 to an infusion instrument (not shown) by infusion pump 116 and motor 118

pressurizing reservoir 104. An example of an infusion instrument can be an infusion cannula that is inserted into the eye to allow infusion fluid to enter the eye and maintain internal eye pressure to prevent collapse of the eye. As can be seen pumps and motors 106, 108, 116, and 118 are contained within a chamber 120 of reservoir 100. It is possible that because of the isolation of the pumps and motors in chamber 120 that they may not need to be sterilized along with reservoir 100 and its associated tray and surgical instruments after packaging at a manufacturer. It is accepted protocol that any surface that comes in direct contact with the infused or aspirated fluids should be sterile. Though an associated tray is not shown with reservoir 100 it is easily understood that reservoir 100 could be retained in and prepackaged and sterilized with a tray in a similar fashion to that described above relative to tray 10. In addition, it is possible that reservoir 100 may be removed from a tray and placed or hung by ledge 122 at a convenient location for surgery.

[0056] Tray 10 further includes a power connector 80 connected to motors 42 and 50 for connecting motors 42 and 50 to a power source 82 via lines 84. Power source 82 is shown in FIG. 2 as a battery but the power source could be at least one of a direct current (DC) source, an alternating current (AC) source, a fuel cell, or a wireless power source, such as Witricity, or some other suitable power source. So power connector 80 can be at least one of an AC connector, a fuel cell connector or a wireless power connector instead of the battery connector shown. FIG. 2 shows one power source connection but it is to be understood that multiple power sources may be used. In addition, power source 82 may not be prepackaged and sterilized with tray 10 as shown, but rather, may be a power source that is connected to tray 10 after tray 10 is opened and is being prepared for surgery. Power connector or connectors 80 may be attached to a portion of tray 10, such as in a side wall of tray 10, as shown in FIG. 7; where power connector 80 is for connection to a DC source, an AC source, or an AC cord (not shown) to be plugged into a wall socket (not shown). If wireless power transmission is used it is possible that lines 84 can be eliminated if the surgical instruments are able to incorporate the power transmission apparatus. Obviously not all surgical instruments need power and some instruments may be self-powered by battery or fuel cell.

[0057] In the case where a power source is connected after tray 10 is opened, it may not be necessary for the power source to be sterile. For instance, the lower portion of

tray 10 may have an opening for accepting a battery pack or fuel cell. In this case a non-sterile battery pack or fuel cell could potentially be used because it is below the sterile field top surface 16 of tray 10.

[0058] Power connector 80 may be connected directly to motors 42 and 50 and at least one surgical instrument 14 such that power source 82 powers the pumps and at least one surgical instrument 14, as shown in FIG. 2. At least one surgical instrument 14 is connected to power connector 80 through one of lines 84, an input and output connector 86, and line 88 (shown in FIG. 1). Of course more than one surgical instrument 14 may also be connected to power connector 80 through other input and output connectors 86, though these are not shown. The surgical instruments that can be connected include a vitreous cutter, a lens emulsification, fragmentation, or cutting device, an illumination device, and a scissors. In addition, the surgical instruments 14 may be prepackaged and sterilized with tray 10 and connected to pump reservoir 30 and input and output connectors 86.

[0059] Though power connector 80 may be connected directly to motors and surgical instruments, a power distributor 90, shown in FIG. 2, may be desired for distributing power throughout the sterile tray 10 for powering a plurality of surgical instruments. Depending on the power source used and the instruments needed for surgery power distributor 90 may take on many forms, such as a voltage transformer, a DC-to-DC converter, and an AC-to-DC converter. In addition power distributor 90 may also include a processor for performing control functions to operate the surgical instruments, motors, and operator feedback or status indicators, in other words power distributor 90 may also be the central controller for the entire surgical operation to be performed.

[0060] Tray 10, because of the desire to enable a surgeon to perform surgery with little or no assistance, preferably includes structure for connecting a sterile barrier to tray 10, such as slots 92. A sterile barrier 94 is attached to tray 10 in FIG. 8. Sterile barrier 94 includes a pliable sheet 96 that has at least one pocket 95 formed in the sheet 96 for allowing a non-sterile user (not shown) outside a sterile field to manipulate items within the sterile field without compromising the sterile field. The sheet 96 is attached to supports 98 that are in turn held within slots 92 of tray 10. Pocket 95 is shown as two pockets in FIG. 8 that form gloves for a user. It should be easily understood, that pocket 95 may take on other forms than

gloves. For example, pocket 95 could simply be a cavity without any structure forming finger openings.

[0061] Tray 10, in addition to having structure for receiving a plurality of surgical instruments, preferably includes a plurality of input and output connectors 86 attached to tray 10, as seen in FIGs. 1 and 2. So as best seen in FIG. 2, sterile surgical tray 10 preferably includes pump fluid reservoir 30 contained within sterile tray 10, a pump or pumps 40 and 48, and a motor or motors 42 and 50 connected to the pumps and at least one of the input and output connectors 86 is connected to the motors 42 and 50 for connecting the motors 42 and 50 to a power source 82, such as the battery shown.

[0062] Tray 10 further may include at least one status indicator 130 attached to at least one of the output connectors 86. The status indicator may be a light emitting diode (LED) or an audible signal generator. In FIG. 1, on the left side three status indicators 130 are shown adjacent a surgical instrument 14. Depending on the type of instrument 14 the three status indicators 130 could provide different types of feedback to a user. For example, if reservoir 30 included a sensor the indicators 130 could be red, yellow, and green in color to indicate to the user that a vacuum level is unacceptable (red), a vacuum level is approaching an unacceptable level (yellow), or the vacuum level is acceptable (green). Another example is that the indicators 130 could indicate a speed or energy level of the instrument where all three indicators are on when the speed or energy level is high, two indicators are on when the speed or energy level is at an intermediate level, and one indicator is on when the speed or energy level is low.

[0063] Because tray 10 is used in an operating room that may be dark for certain surgeries, such as ophthalmic surgery, it is desirable that a plurality of LEDs 132 are connected to a plurality of output connectors 86 and at least one LED 132 is connected to tray 10 adjacent each of a plurality of surgical instrument retaining recesses 12 for illuminating a location of the surgical retaining recesses 12 on the tray 10. Preferably, a plurality of surgical instruments 14 are retained in tray 10 and connected to a portion of the plurality of input and output connectors and prepackaged and sterilized with the tray.

[0064] Depending on the type of surgery for which tray 10 is intended it may be desirable for tray 10 to be sufficiently narrow at a location 134 that will be immediately

between a patient and a surgeon to allow the surgeon unrestricted access to a surgical site. In the example of FIG. 1, location 134 is in the center of tray 10 and forms the bottom of the U-shape of tray 10. It also may be desirable where tray 10 includes a plurality of surgical instruments retained in tray 10 and connected to a portion of the plurality of input and output connectors 86, that the input and output connectors 86 connected to the plurality of surgical instruments are attached to tray 10 at a generally central location 134, so that the connected instruments may be placed on either side of the tray to accommodate either a left or right handed surgeon.

[0065] The status indicators 130, in a similar fashion to the discussion above, may also be placed on tray 10 to indicate a power level of a battery or fuel cell, a fluid level of a pump fluid reservoir attached to the input and output connectors or an illumination level of an illuminator attached to the input and output connectors. An alternative or supplement to the status indicators and LEDs 130 may be a display 136 for displaying, via numbers, icons, bar graphs, and the like, the status of the instruments and/or other apparatus connected to tray 10. As discussed above, tray 10 may also have a processor attached to the input and output connectors 86 for receiving inputs from a user and a plurality of surgical instruments 14 and devices attached to the input and output connectors 86 and for transmitting signals to a user and the plurality of surgical instruments 14 and devices. The processor may be part of power distributor 90 or it may be a separate device. The processor may also be prepackaged and sterilized with tray 10 or it may be connected to tray 10 after tray 10 is opened and is being prepared for surgery.

[0066] Tray 10 may also include a wireless transceiver 138 connected to the input and output connectors 86 for transmitting and receiving signals to and from remote devices and surgical instruments. Wireless transceiver 138 may be any acceptable type of wireless communication device such as an infrared or radio frequency transceiver. Known examples of radio transceivers include Bluetooth®, Zigbee®, Wifi or IEEE 802.11 transceivers, or other known wireless communication devices. The wireless transceiver 138 can be connected a processor connected to tray 10 and to a laptop computer (not shown) in the operating room or elsewhere for monitoring or controlling a surgical procedure through the information flowing throughout tray 10 and the input and output connectors 86. For the sake

of clarity and simplicity only some of the wires or lines 84 and some of the input and output connectors 86 have been shown in the drawings but it should be understood that potentially the processor could be remotely located from tray 10, and the control, monitoring, feedback, and/or communication signals could flow wirelessly between the processor and tray 10 via wireless transceiver 138.

[0067] In addition to the devices disclosed above some of the input and output connectors 86 may be connected to user input buttons, knobs 33, or the like. Also, a foot control connector 140 may be attached to tray 10 for connecting a foot controller 142 shown in FIG. 9. Of course, foot controller 142 may also be connected to tray 10 via wireless transceiver 138 as indicated by symbol 144 in FIG. 9. It is also desirable that a portion of the input and output connectors 86 are for connection to additional instruments beyond the plurality of instruments prepackaged and sterilized in tray 10. For example, a surgeon performing vitreoretinal surgery may require a fragmentation instrument that is not included in prepackaged and sterilized tray 10 but it can be connected to tray 10 using a mating input and output connector 86.

[0068] Another example of an infusion fluid reservoir that may be used with a sterile surgical tray, is shown in FIG. 10. Infusion reservoir 150 is a multiple chamber fluid reservoir for holding a different fluid in each chamber. A pressure pump 152 is connected to two or more chambers 154, 156, and 158 for pressurizing the chambers. A multiple position valve 160 is connected to the multiple chambers 154, 156, and 158, via tubing 162. Valve 160 allows a fluid contained in a selected chamber to flow out of the selected chamber and into an eye or other surgical site through tubing 164 and a surgical instrument (not shown). Valve 160 is shown as a well known three position stop cock but valve 160 could also be individual valves or mechanically or electrically actuated valves depending on the design. If valve 160 is electrically actuated it could be attached or contained within tray 10 and connected to a portion of the input and output connectors 86 to support other than manual selection of the position of valve 160. The infusion fluid reservoir 150 shown has three chambers 154, 156, and 158, each chamber holding one of BSS, silicone oil, and a gas, which are particularly useful in ophthalmic surgery; but other fluids could be held in the chambers depending on the requirements of the particular surgery to be performed. For example, one

of the chambers could contain viscoelastic. Infusion reservoir 150 is also preferably transparent so that a user can easily see the fluid levels in chambers 154, 156, and 158. It should also be appreciated that infusion fluid reservoir 150 has use beyond use with tray 10 and could be used with other surgical systems.

[0069] Infusion pump 152, powered by motor 166 pressurizes multiple chambers 154, 156, and 158 for infusing multiple fluids into a surgical site. It should be understood that motor 166 is connected to input and output connectors 86 (not shown) for power and control. Chambers 154, 156, and 158 also preferably include access ports 168 for filling or refilling the chambers. Ports 168 can require caps or closure devices to prevent fluids from leaking and to allow the chambers to be adequately pressurized. The chamber 154 shows a bag 170 partially filled with a fluid 172. Fluid 172 may be BSS or other liquid. Chamber 154 includes bag 170 at least partially filled with BSS such that pump 152 pressurizes the fluid reservoir chamber 154 during surgery to force BSS 172 from the fluid reservoir 150. Chamber 156 may hold silicone oil 174 and chamber 158 may hold a gas 176.

[0070] FIG. 11 shows an example of a sterile surgical tray 180 including a plurality of surgical instruments including the instruments to perform a vitrectomy of an eye. To perform a vitrectomy at least an illumination instrument, a tissue cutting instrument, an infusion instrument, an entry site alignment system, and a surgical knife would typically be included in a sterilized tray such as tray 180.

[0071] FIG. 12 shows an example of a sterile surgical tray 182 including a plurality of surgical instruments including the instruments to perform a cataract removal from an eye. To perform a cataract removal at least a lens emulsification device, an infusion device, viscoelastic, a rhexis forceps, an intraocular lens insertion instrument, and a surgical knife would typically be included in a sterilized tray such as tray 182.

[0072] FIG. 13 is a functional block diagram of a fluid-air exchange system 300 is an alternative to pump reservoir 150 that may be incorporated into a sterile surgical tray, such as tray 10. System 300 preferably includes a BSS reservoir 302, a reservoir 304 of air, connected to a selector valve 306 for selecting which fluid, BSS or air, will be allowed to flow into infusion pump 308. Infusion pump 308 may be any suitable pump for infusing fluid into an eye or other body part. A bypass valve 310 connects a flow path from infusion

pump 308 and an oil reservoir 312. Oil reservoir 312 is connected to a source of oil 314 via a check valve 316. Oil source 314 may be a syringe, as shown or may be another source that is connected to a pump (not shown) for automatically pumping oil into reservoir 312. Oil reservoir is then connected to a three-way stopcock valve 318 via another check valve 320. Depending on the positions of the valves 306, 310, and 318 air, BSS, or oil (typically silicone oil) will be infused into an eye. Bypass valve 310 allows infusion pump and air or BSS to push oil from reservoir 312 into an eye.

Independent Surgical Center and Personal Surgical Center

[0073] In certain embodiments, the independent surgical tray 1402 can include at least the sterile surgical tray as described herein as illustrated in FIG. 14. The independent surgical center 1402 can be coupled to various surgical/medical or other devices 1401, a personal surgical center 1410, and/or a hospital/medical office system 1414.

[0074] In reference to FIG. 14, the independent surgical center can be operable without the use of an external surgical console, and can act as a standalone system. Alternatively, the independent surgical center can also be coupled to various surgical and/or other devices 1401 (also referred to herein as handpieces), for example but not limited to an illumination device 1407, foot pedal input device 1406, cutting device 1408 (also referred to as a biological tissue cutting device, as further described below), irrigation device, infusion device, viewing device, aspiration device, lasering device, cauterizing device, resecting device, lens emulsification device, fragmentation device, lens cutting device, scissor device, or any other like devices. In certain embodiments, the foregoing surgical and/or other devices can comprise a power source (internal or external, AC/DC), processing unit, network interface (wired or wireless), electronics, memory, audio mechanism, and the like. In certain embodiments, the independent surgical center 1402 communicates and/or is coupled/connected to the various surgical and/or other devices through a network interface 1440. The network interface 1440 can operate on a wired connection and/or a wireless connection using Bluetooth®, Zigbee®, Wifi or IEEE 802.11, or any other wireless communication protocol.

[0075] As illustrated in FIG. 14, the network interface 1440 can be coupled to a battery pack 1442, which can be received in, coupled to, and/or removed from the

independent surgical center 1402. In certain embodiments, the battery pack 1442 comprises without limitation a battery or a plurality of batteries 1444, and a processing unit 1446. In certain embodiments, the processing unit can be in the independent surgical center 1402, the personal surgical center, a separate console, and/or the surgical devices, as described herein. The battery pack 1442 can comprise electrical contact and/or connectors for allowing the battery 1444, the processing unit 1446 (for example, Intel® 8085 microprocessor), and/or the network interface 1440 to be coupled and/or to connect to the circuitry and/or electronics 1412. In certain embodiments, the processing unit 1446 is configured to execute programming instructions stored in memory within the electronics 1412 to control light emitting diodes (LEDs) 1448, and/or receive user input through control knobs, buttons, or other input devices 1450. For example, the processing unit can be configured to control the LEDs to indicate/show the cutting device's status, speed, or other like indicators. The processing unit 1446 can also be configured to communicate with the motors 1452 coupled to the pumps 1454. The processing unit 1446 can also be configured to communicate and/or transmit commands to the surgical and/or other devices 1401 or to the personal surgical center 1410.

[0076] In reference to FIG. 14, the battery pack 1442 can be disposable or can be reused with other independent surgical centers 1402. The battery pack 1442 can be sterile or non-sterile, in which case the battery pack cannot be within the surgical field. In a preferred embodiment, the battery pack 1442 is reused with other independent surgical centers 1402 because of the cost of the batteries 1444, the processing unit 1446, and/or the network interface 1440, but in certain embodiments, the battery pack 1442 is disposable for purposes of sterility. The independent surgical center can also be coupled to a personal surgical center 1410.

[0077] With reference to FIG. 14, in certain embodiments, the personal surgical center 1410 can control the independent surgical center 1402. The personal surgical center 1410 can also include without limitation a console, general purpose computer, laptop computer, networked device(s), or the like that can be configured to monitor and/or display the settings of the various medical instruments (for example, the handpieces and/or surgical devices) on display or a touch screen input display 1428. Additional embodiments of the

personal surgical center 1410 are described below. The personal surgical center 1410 can include without limitation a log database 1430 for storing real-time data and/or periodic data and status levels obtained and/or received from the independent surgical center. Based on the data, status levels, and/or patient information received from the independent surgical center and/or surgeon/technician, the personal surgical center 1410 can generate and/or store reports using the reports system and/or database 1432. The personal surgical center 1410 can also initiate billing procedures using the billing module 1434 that can interface with a billing system and database 1420. The personal surgical center 1410 can also store the data, status levels, and/or patient information in the patients records database 1422 using patient records module 1436, or can store this data in the hospital information system (HIS) 1424 using the HIS interface module 1438. In certain embodiments, the personal surgical center 1410 monitors and displays the settings and status of the various surgical and/or other devices while the independent surgical center controls the medical instruments via the circuitry and electronics 1412 in the independent surgical center, and the circuitry and controls in the various surgical and/or other devices. In certain embodiments, the personal surgical system 1410 can be coupled to other hospital/medical office systems 1414.

[0078] FIG. 14 also illustrates one embodiment of a hospital/medical office system 1414, which can include without limitations systems and databases 1416 for logging data from the personal surgical center 1410, systems and databases 1418 for generating reports, systems and databases 1420 for producing invoices, bills, and/or insurance claims, systems and databases 1422 for storing patient records, systems 1424 for interfacing with hospital information systems (HIS).

[0079] In reference to FIG. 14, in certain embodiments, the independent surgical center 1402 and surgical and/or other devices can be located within the sterile field in which a surgery is performed, while the personal surgical center, and the hospital/medical office systems can be located outside the sterile field.

Biological Tissue Cutting Device

[0080] With reference to FIGs. 6 and 14, in certain embodiments, the biological tissue cutting and/or aspiration handpiece (for example, vitrectomy handpiece or other like handpieces) is portable, lightweight and can be powered by battery to power the cutter and/or

aspiration. It can be used in the field, offices, surgery centers and operating rooms. The biological tissue cutting and/or aspiration handpiece may be used as a standalone instrument or in conjunction with the independent surgical center discussed above. The handpiece may be disposable and can be connected to the aspiration/infusion cassette, which provides aspiration pressure to the cutter. FIG. 6 illustrates an example of an aspiration/infusion cassette 100 with the infusion line 114 and the biological tissue cutting and aspiration handpiece 110. The left side of the cassette functions to provide aspiration pressure to the biological tissue cutting and aspiration handpiece, while the right side provides infusion.

[0081] In certain embodiments, for example, the biological tissue cutting and/or aspiration handpiece is a disposable handpiece such as that described in co-pending U.S. Patent Publication No. 2008-0208233 A1 (U.S. Patent Application No. 11/963,749) titled Disposable Vitrectomy Handpiece, filed December 21, 2007, the entire content of which is incorporated herein by reference. In addition, the biological tissue cutting and/or aspiration handpiece can incorporate battery power or other power supply, and a flow controller/pinch valve. The handpiece may wirelessly communicate (for example, Bluetooth or the like) with other surgical instruments, an internal or external monitor or speaker, or a control center in the aspiration/infusion cassette. Alternatively, the handpiece may wirelessly communicate with a personal surgical center and/or an independent surgical center. Surgical parameters (for example, cut speed, frequency, aspiration pressure/flow rate) may be controlled directly on the handpiece, or via a foot pedal wirelessly connected to the handpiece. Such parameters may control a cutting tip, aspiration pump, and the like. The drive circuitry may be incorporated directly in the handpiece, in the surgical tray, or aspiration/infusion cassette depending on how the handpiece is powered (for example, by battery or through the aspiration/infusion cassette).

[0082] As noted above, according to certain embodiments, the biological tissue cutting and/or aspiration handpiece can be a stand-alone instrument, not used with an external control center. In certain embodiments, the handpiece can be used in conjunction with other standalone instrumentation, such as an illumination device. The controls for the handpiece are located on the handpiece itself, eliminating the need for a surgical console. The handpiece itself or the surgical tray may have a display or speaker to inform the surgeon of

current surgical settings and instrument faults. According to certain embodiments, the handpiece includes a control unit or processing unit which may be, for example, a microprocessor based unit, an ASIC, or the like, and other circuitry.

[0083] In certain embodiments, the biological tissue cutting and/or aspiration handpiece can be used in conjunction with an aspiration/infusion cassette that includes a control center or in conjunction with an external, laptop control center. Although it may be possible to plug the system into an outlet, battery power can enable better maneuverability of the handpiece. The battery may be placed inside the handpiece, surgical tray or at the aspiration/infusion cassette itself. When the battery is placed inside the handpiece, it adds weight and size to the unit, and can reduce maneuverability and ergonomics. The aspiration/infusion cassette can be larger and heavier because ergonomics on this instrument are not as critical. However, when the battery is placed at the aspiration/infusion cassette or surgical tray, an electrical line would need to be tethered to the handpiece along with the aspiration line.

[0084] The wireless control (for example, Bluetooth) may be mounted in the handpiece, the aspiration/infusion cassette, the surgical tray, or all of the above. If the handpiece uses battery power and includes no link to the aspiration cassette or surgical tray, wireless communication will generally be within the handpieces, surgical tray, and other devices. However, if there is a direct-wired link between the two, wireless communications may then be with certain devices, for example the surgical tray. In certain embodiments, the wireless communication will be within the aspiration/infusion cassette or surgical tray to reduce the weight of the handpiece. In certain embodiments, the battery / power source for the biological tissue cutting and/or aspiration handpiece, the network communication, and the aspiration originate from the surgical tray through a direct wire connection.

[0085] In certain embodiments, the handpiece may include a display and/or speaker for relaying information regarding instrument status, fault, cut speed, or the like. For example, the handpiece may include a LED and/or speaker on the handpiece itself. In certain embodiments, the instrument and operation information may also be shown on a display or speaker on the surgical tray or may be displayed on a personal surgical center or a laptop center to allow the surgeon to more easily review such information.

[0086] When used in conjunction with a personal surgical center or a laptop center, the biological tissue cutting and/or aspiration handpiece may communicate with the personal surgical center or the laptop directly or indirectly through the independent surgical tray or surgical tray. The personal surgical center or laptop center can indicate the instrument and operation information, such as current cut speed, battery life (if applicable), any faults, or any other indicator or status information. It may also receive additional information, such as the maximum cut speed permissible and other surgical parameters. Upon startup, the biological tissue cutting and/or aspiration handpiece can identify itself to the independent surgical center, and/or personal surgical center and/or laptop center, and indicate whether it has been used before. If flow sensing or flow control is used, the sensors and actuators may be placed close to or directly on the biological tissue cutting and/or aspiration handpiece.

Personal Surgical Center

[0087] With reference to FIGs. 14A, there is illustrated one embodiment of a computer system and/or device for the personal surgical center. FIG. 14A illustrates a block diagram of one embodiment of a computing system (which can be a fixed system or mobile device) that is in communication with one or more independent surgical centers 910 and/or one or more surgical devices 915 via one or more networks 910. The computing system 900 may be used to implement one or more of the systems and methods described herein. In addition, in one embodiment, the computing system 900 may be configured to process status data and/or information from surgical devices. While FIG. 14A illustrates one embodiment of a computing system 900, it is recognized that the functionality provided for in the components and modules of computing system 900 may be combined into fewer components and modules or further separated into additional components and modules.

[0088] In one embodiment, the system 900 comprises processing and analysis modules 906 that carry out the functions, methods, and/or processes described herein. The processing and analysis modules 906 may be executed on the computing system 900 by a central processing unit 904 discussed further below.

[0089] Computing System Components

[0090] In one embodiment, the processes, systems, and methods illustrated above may be embodied in part or in whole in software that is running on a computing device. The

functionality provided for in the components and modules of the computing device may comprise one or more components and/or modules. For example, the computing device may comprise multiple central processing units (CPUs) and a mass storage device, such as may be implemented in an array of servers.

[0091] In one embodiment, the computing system 900 also comprises a laptop computer suitable for controlling and/or communicating with databases, performing processing, and generating reports from databases. The computing system 900 also comprises a central processing unit ("CPU") 904, which may comprise a microprocessor. The computing system 900 further comprises a memory 905, such as random access memory ("RAM") for temporary storage of information and/or a read only memory ("ROM") for permanent storage of information, and a mass storage device 901, such as a hard drive, diskette, or optical media storage device. Typically, the modules of the computing system 900 are connected to the computer using a standards based bus system. In different embodiments, the standards based bus system could be Peripheral Component Interconnect (PCI), Microchannel, SCSI, Industrial Standard Architecture (ISA) and Extended ISA (EISA) architectures, for example.

[0092] The exemplary computing system 900 comprises one or more commonly available input/output (I/O) devices and interfaces 903, such as a keyboard, mouse, touchpad, and printer. In one embodiment, the I/O devices and interfaces 903 comprise one or more display devices or touch screen display devices, such as a monitor, that allows the visual presentation of data to a user. More particularly, a display device provides for the presentation of GUIs, application software data, and multimedia presentations, for example. In the embodiment of FIG. 14A, the I/O devices and interfaces 903 also provide a communications interface to various external devices. The computing system 900 may also comprise one or more multimedia devices 902, such as speakers, video cards, graphics accelerators, and microphones, for example.

[0093] Computing System Device/Operating System

[0094] The computing system 900 may run on a variety of computing devices, such as, for example, a server, a Windows server, a Structure Query Language server, a Unix server, a personal computer, a mainframe computer, a laptop computer, a cell phone, a

personal digital assistant, a kiosk, an audio player, and so forth. The computing system 900 is generally controlled and coordinated by operating system software, such as z/OS, Windows 95, Windows 98, Windows NT, Windows 2000, Windows XP, Windows Vista, Linux, BSD, SunOS, Solaris, or other compatible operating systems. In Macintosh systems, the operating system may be any available operating system, such as MAC OS X. In other embodiments, the computing system 900 may be controlled by a proprietary operating system. Conventional operating systems control and schedule computer processes for execution, perform memory management, provide file system, networking, and I/O services, and provide a user interface, such as a graphical user interface ("GUI"), among other things.

[0095] Network

[0096] In the embodiment of FIG. 14A, the computing system 900 is coupled to a network 910, such as a LAN, WAN, or the Internet, for example, via a wired, wireless, or combination of wired and wireless, communication link 915. The network 910 communicates with various computing devices and/or other electronic devices via wired or wireless communication links. In the exemplary embodiment of FIG. 14A, the network 910 is communicating with one or more independent surgical centers 910 and/or one or more surgical devices 915.

[0097] Computing system may comprise a browser module or other output module that may be implemented as a combination of an all points addressable display such as a cathode-ray tube (CRT), a liquid crystal display (LCD), a plasma display, or other types and/or combinations of displays. In addition, the browser module or other output module may be implemented to communicate with input devices 903 and may also comprise software with the appropriate interfaces which allow a user to access data through the use of stylized screen elements such as, for example, menus, windows, dialog boxes, toolbars, and controls (for example, radio buttons, check boxes, sliding scales, and so forth). Furthermore, the browser module or other output module may communicate with a set of input and output devices to receive signals from the user.

[0098] The input device(s) may comprise a keyboard, roller ball, pen and stylus, mouse, trackball, voice recognition system, or pre-designated switches or buttons. The output device(s) may comprise a speaker, a display screen, a printer, or a voice synthesizer. In

addition a touch screen may act as a hybrid input/output device. In another embodiment, a user may interact with the system more directly such as through a system terminal connected to the score generator without communications over the Internet, a WAN, or LAN, or similar network.

[0099] In some embodiments, the system 900 may comprise a physical or logical connection established between a remote microprocessor and a mainframe host computer for the express purpose of uploading, downloading, or viewing interactive data and databases on-line in real time or periodic basis. The remote microprocessor may be operated by an entity operating the computer system 900, including the client server systems or the main server system, an/or may be operated by one or more of the surgical devices 915 and/or one or more of the independent surgical centers 910.

[0100] Other Systems

[0101] In addition to the systems that are illustrated in FIG. 14A, the network 910 may communicate with other data sources or other computing devices, for example billing systems or hospital information systems. The computing system 900 may also comprise one or more internal and/or external data sources. In some embodiments, one or more of the data repositories and the data sources may be implemented using a relational database, such as DB2, Sybase, Oracle, CodeBase and Microsoft® SQL Server as well as other types of databases such as, for example, a flat file database, an entity-relationship database, and object-oriented database, and/or a record-based database.

[0102] In some embodiments, the acts, methods, and processes described herein are implemented within, or using, software modules (programs) that are executed by one or more general purpose computers. The software modules may be stored on or within any suitable computer-readable medium. It should be understood that the various steps may alternatively be implemented in-whole or in-part within specially designed hardware. The skilled artisan will recognize that not all calculations, analyses and/or optimization require the use of computers, though any of the above-described methods, calculations or analyses can be facilitated through the use of computers.

Example Process Flow

[0103] FIG. 15 is a flow diagram of a process executed by the processing unit 1446 of an independent surgical center in accordance with an embodiment of the invention.

[0104] In some embodiments, the process of FIG. 15 represents the process which is performed by the processing unit housed or received in the sterile surgical tray as described herein. In some embodiments of the invention, the process may be performed in another instrument or component of the system, based on where the processing unit is located in the system. In some embodiments, the system may include multiple processing units, and the process of FIG. 15 may be performed by one or more of the multiple processing units.

[0105] In block 611, the process receives a signal from an instrument in communication with the independent surgical center. In the embodiment, the tray may receive the signals from an instrument through a wired connection, for example, the handpiece, or may receive the signals from an instrument through a wireless connection, for example, from the illumination device.

[0106] In block 613, the process determines whether the received signal is a status update signal or an adjustment request signal. In some embodiments, the processing unit may be used to adjust operation parameters of selected instruments, and may also be used to process and communicate to a user the status of the same or other instruments. If the processing unit determines that the signal is an adjustment request signal, the process proceeds to block 615. If the processing unit determines that the signal is a status update signal, the process instead proceeds to block 619.

[0107] In block 615, the process determines the device for which the adjustment signal is directed. In some embodiments, the adjustment signal may be received by a user control directly connected to the processing unit. For example, the adjustment signal may originate from a user control controlling the infusion device located alongside the processing unit in the tray. In other embodiments, the adjustment signal may be received wirelessly from a user control located on a remote instrument, for example, a foot pedal associated with the tray. Some of the adjustment requests may be meant for the device or component from which the signal originated, while some other of the adjustment requests may be meant for a different device, whether it is a device on the tray or on a completely separate instrument in

the surgical system. Regardless of the source of the adjustment signal, the processing unit determines the intended destination device or instrument.

[0108] In block 617, the process sends an adjustment command to the destination device or instrument. Depending on the configuration of the system, the adjustment command may be an unaltered adjustment signal, where the processing unit acts as a switch or routing device for the system, or the adjustment command may be a wholly new command signal generated by the processing unit based on a received adjustment request signal, for example, a received signal as was described above with respect to block 611. In most embodiments of the system, after an adjustment command is sent to a respective device or instrument, the operational settings or parameters of the device are adjusted in accordance with the adjustment command.

[0109] If the signal is a status update signal, the process, in block 619, determines the source of the status update signal. In most embodiments, status update signals include status update information of the device from which the status update signal originated. The status update information may include various information about an originating device, for example, current settings, operating parameters, remaining power levels, instrument fault conditions, and other information. Status information for each specific instrument in the system is different depending on the functionality of the instrument. For example, a handpiece may provide status of cut speed of a cutter or aspiration levels, whereas an illumination device may provide illumination level status.

[0110] In block 621, the process updates the status of a device or instrument. Whether the originally received signal was an adjustment signal or a status update signal, the processing unit of the system may update status information pertaining to the received signal. In cases where the signal was an adjustment signal, the processing unit may update the status information of the destination device to which the adjustment request was sent. In cases where the signal was a status update signal, the processor may directly update the status information of the device from which the status update signal originated, based on the contents of the status update signal. The processing unit may display the status updates on, for example, a monitor located on the instrument housing the processing unit. Alternatively, the status updates may be expressed visually through changes to, for example, LED

indicators, or aurally through, for example, audio alerts outputted through available speakers. In some embodiments, visual or aural status indicators may be available on various other instruments of the system in addition to, or in lieu of, the instrument housing the processing unit. In these embodiments, the processing unit may send the status update information to an appropriate instrument for output or user feedback purposes. According to one embodiment of the invention, the update information is transmitted to the personal surgical center for logging in a log file generated for the surgical procedure. After the status updates have been applied to or recorded by the system, the process returns.

Safety Mechanism Procedures

[0111] As illustrated in FIG. 16, in certain embodiments, the independent surgical center 1402 and/or the processing unit 1446 and/or the personal surgical center 1410 as described herein can be configured to receive status and/or adjustment data from, or determine the status of the various surgical and/or devices 1401. In analyzing and/or monitoring the status of the various surgical and/or devices 1401, the independent surgical center 1402, and/or the processing unit 1446, and/or personal surgical center 1410 can be configured to invoke various safety mechanism procedures, for example but not limited a cutter safety mechanism procedure and a low fluid safety mechanism procedure.

[0112] With reference to FIG. 16, the illustrated process 1601 can be segmented into at least four different stages, initial setup, steady state, cutter safety mechanism procedure, and the low fluid safety mechanism procedure. Process 1601 starts at block 1602. The user and/or surgeon powers on the independent surgical center, the surgical and/or other devices at block 1604. In powering on the independent surgical center, at block 1606 the processing unit and/or the electronics in the independent surgical center searches, detects, and/or locates available surgical and/or other devices to be employed during the surgery. At block 1608, the processing unit and/or the independent surgical center registers the available surgical and/or other devices for the surgery. In registering, the surgical and/or devices can communicate and/or send to the processing unit and/or the independent surgical center parameter and/or identification information, including but not limited to surgical device identification number, lot number, part number, surgical device name and/or type, current status of device, available options on device (for example, on or off; low, medium, or high

speed; or the like). After registering and/or establishing communication with all the surgical and/or other devices, the processing unit and/or the independent surgical center obtains and/or receives periodic information/data from the surgical and/or other devices in order to determine at block 1610 the status or adjustments made in or to the surgical and/or other devices.

[0113] In reference to FIG. 16, in one embodiment, processing unit and/or the independent surgical center enters a steady state, wherein the processing unit and/or independent surgical center pings, requests, or receives data and/or information from the surgical and/or other devices at block 1612. At block 1614, the surgical and/or other devices can be configured to gather, obtain, and/or analyze status and/or other data for sending or transmitting to the processing unit and/or independent surgical center. The surgical and/or other devices can be configured to send or transmit, on a real-time, substantially real-time, periodic basis, data and/or other information to the independent surgical center at block 1616, wherein the data and/or other information can comprise without limitation device status information (for example, on or off, activated or deactivated, speed levels, temperature, battery levels, elapsed time, fluid levels, warning and/or error messages, or the like), user inputted adjustment data, device data, or the like. After sending or transmitting the data, the procedure returns to block 1610 to repeat the process.

[0114] With reference to FIG. 16, in certain embodiments, the processing unit and/or independent surgical tray can detect when the user or surgeon has activated the cutter device by receiving a status message from the cutter device at block 1618. In certain embodiments, the processing unit and/or the independent surgical center can initiate a cutter safety mechanism procedure before and/or while allowing the cutter device to be activated. In certain embodiments, before allowing the cutter device to be activated, or simultaneously with the activation of the cutter, the processing unit and/or the independent surgical center at block 1620 can be configured to transmit an activation command or signal to the infusion motor and/or pump to initiate delivery of infusion fluids to the surgical site. In certain embodiments, before allowing the cutter device to be activated, or simultaneously with the activation of the cutter, the processing unit and/or the independent surgical center at block 1622 can also be configured to transmit an activation command or signal to the aspiration

motor and/or pump to generate a vacuum for removing excess fluid and/or tissue/debris from surgical site, and/or to prime the fluid in the cutter before cutting begins. In certain embodiments, the processing unit and/or the independent surgical center at block 1624 can be configured to transmit an activation command or signal to the cutter motor device. After sending or transmitting the activation commands or signals, the procedure returns to block 1610 to repeat the process.

[0115] The cutter safety mechanism procedure can prevent surgical errors and/or harm to the patient by ensuring that the necessary surgical and/or devices are activated before cutting is initiated. For example, in various eye surgeries, the infusion motor must be activated prior to cutting to prevent the collapse of the eye caused by reduced internal eye pressure due to aspirated or leaked vitreous. The foregoing procedure can reduce the complexity of the surgery for the surgeon by reducing the number of steps to activate the various necessary devices for the surgery.

[0116] In reference to FIG. 16, in certain embodiments, the processing unit and/or independent surgical tray at block 1626 can detect when fluid levels are low and/or high in the various fluid reservoirs by receiving a status message from a fluid chamber device, for example, infusion reservoir 104. In certain embodiments, the processing unit and/or the independent surgical center can initiate a low/high fluid safety mechanism procedure before and/or while the cutter device is activated. In certain embodiments, before allowing the cutter device to be activated, or while the cutter device is activated, the processing unit and/or the independent surgical center at block 1628 can initiate and/or activate an alarm sound circuitry within the independent surgical center and/or other surgical device, wherein an audible sound/alarm would be generated to alert the user/surgeon of the low and/or high fluid levels in the various reservoir chambers. The processing unit and/or the independent surgical center at block 1630 can also be configured to wait for a period of time (predetermined or user defined), for example, ten seconds, ten minutes, or the like, before receiving and/or obtaining status information from the cutting device. In other embodiments, the processing unit and/or the independent surgical center can also obtain data and/or information from other surgical devices, such as the fluid reservoir chambers to determine if the fluid levels have been changed. If the cutting device is on and/or the fluid levels have not changed and/or have

become worse, then the processing unit and/or the independent surgical center at block 1632 can transmit and/or send a deactivation command to the cutter device and/or the aspiration device. In certain embodiments, the processing unit and/or the independent surgical center will continue to maintain infusion to prevent collapse of the eye. After sending or transmitting the deactivation commands or signals, the procedure returns to block 1610 to repeat the process.

[0117] The high/low safety mechanism procedure can prevent surgical errors and/or harm to the patient by ensuring that the necessary reservoir chambers have sufficient fluid levels during the surgery. For example, in various eye surgeries, the infusion of the eye should be continuous to prevent collapse of the eye due to leakage/remove of vitreous fluids, and therefore, low levels of infusion fluids in the infusion reservoir can pose a risk for eye collapse during surgery. The foregoing procedure can also reduce the complexity of the surgery for the surgeon by reducing the need for the surgeon and/or the assistant to constantly monitor the fluid levels of the reservoir chambers.

[0118] In general, the term “module,” as used herein, refers to logic embodied in hardware or firmware, or to a collection of software instructions, possibly having entry and exit points, written in a programming language, such as, for example, Java, C or C++, or the like. A software module may be compiled and linked into an executable program, installed in a dynamic link library, or may be written in an interpreted programming language such as, for example, BASIC, Perl, Lua, or Python. It will be appreciated that software modules may be callable from other modules or from themselves, and/or may be invoked in response to detected events or interrupts. Software instructions may be embedded in firmware, such as an EPROM. It will be further appreciated that hardware modules may be comprised of connected logic units, such as gates and flip-flops, and/or may be comprised of programmable units, such as programmable gate arrays or processors. The modules described herein are preferably implemented as software modules, but may be represented in hardware or firmware. Generally, the modules described herein refer to logical modules that may be combined with other modules or divided into sub-modules despite their physical organization or storage.

[0119] Although the inventions have been disclosed in the context of a certain preferred embodiments and examples and in the context of use with an endoilluminator, for example, an endoilluminator having an LED illumination light source, it will be understood by those skilled in the art that the present inventions extend beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the inventions and obvious modifications and equivalents thereof. In addition, while a number of variations of the inventions have been shown and described in detail, other modifications, which are within the scope of the inventions, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or subcombinations of the specific features and aspects of the embodiments may be made and still fall within one or more of the inventions. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combine with or substituted for one another in order to form varying modes of the disclosed inventions. Thus, it is intended that the scope of the present inventions herein disclosed should not be limited by the particular disclosed embodiments described above.

Claims

1. A sterile surgical tray (10) comprising:
a surface (16) for holding a plurality of surgical instruments (14) including at least one instrument connected to a pump fluid reservoir (30); and
wherein the sterile surgical tray releasably receives at least one of a motor (42) and a pump (40) configured to pump fluid to or from the pump fluid reservoir (30).
2. The tray of claim 1 including:
a plurality of electrical input and output connectors (86) attached to the tray; and
a plurality of surgical instruments (14) retained in the tray and connected to a portion of the plurality of input and output connectors (86).
3. The tray of claim 2 wherein the input and output connectors (86) connected to the plurality of surgical instruments are attached to the tray at a generally central location (134) so that the connected instruments may be placed on either side of the tray to accommodate either a left or right handed surgeon.
4. The tray of claim 2 wherein the plurality of surgical instruments (14) are prepackaged and sterilized with the tray and wherein another portion of the input and output connectors (86) are for connection to additional instruments beyond the plurality of instruments (14) prepackaged and sterilized with the tray.
5. The tray of claim 1 or 3 wherein the shape of the tray is generally U-shaped and the generally central location is at the portion of the tray forming the bottom of the U-shape.
6. The tray of claim 1 wherein the pump or motor is mechanically coupled to the tray.
7. The tray of claim 1 or 6 wherein the pump or motor is electrically coupled to the tray.
8. The tray of any of claims 1 to 7 wherein the pump fluid reservoir (30) is contained within the tray.
9. The tray of any of claims 1 to 8 wherein the pump fluid reservoir (30) includes multiple chambers (44, 46) for holding a different fluid in each chamber.

10. The tray of claim 9 wherein two or more chambers (154, 156, 158) are connected to a pressure pump (152) for pressurizing the chambers.
11. The tray of claim 9 or 10 wherein the tray includes a multiple position valve (160) connected to the multiple chambers (154, 156, 158) for selectively opening one of the multiple chambers to allow a fluid contained in a selected chamber to flow out of the selected chamber.
12. The tray of any of claims 9 to 11 wherein at least one of the multiple chambers (44, 46) is for aspiration and at least one of the multiple chambers (44, 46) is for infusion and wherein the tray releasably receives at least one of an infusion pump (40) and infusion motor (42) and at least one of an aspiration pump (48) and aspiration motor (50).
13. The tray of any of claims 1 to 12 wherein the pump (40, 48) is one of a vacuum pump and a positive displacement pump.
14. The tray of claim 1 wherein at least one of the motor (42, 50) and pump (40, 48) is not sterile.
15. The tray of claim 1 wherein the tray includes structure (22) for attaching a drape (24) to the tray and wherein the drape is to be placed over a patient.
16. The tray of claim 15 wherein the tray includes structure forming at least one fluid retention trough (26) for collecting fluid runoff from the drape (24) that occurs during surgery.