SAFETY SCALPEL WITH REPLACEABLE BLADE CARTRIDGE AND SAFETY BRAKE

Be it known that we, Patrick Yi, a citizen of Singapore, and legal resident of USA residing at 8895 Willowbrae Lane, Roswell, Georgia 30092; and Hong-Minh Le, a citizen of Vietnam, residing at 474A River Valley Rd., Singapore 248359, have invented certain new and useful improvements.

CROSS REFERENCE TO RELATED APPLICATION AND CLAIM OF BENEFIT

This application is a continuation-in-part application of U.S. Patent Application No. 11/259,939, filed on 26 October 2005, which claims priority to U.S. Provisional Patent Application No. 60/623,741, filed on 29 October 2004.

FIELD OF THE INVENTION

The present invention relates generally to scalpel devices and, in particular, to safety scalpels for medical use.

BACKGROUND OF THE INVENTION

Health care is the second fastest growing sector of the U.S. economy, employing over 12 million workers. Health care workers face a wide range of hazards on the job, including needlestick and sharps injuries, back injuries, latex allergies, violence, and stress. Although it is possible to prevent or reduce health care worker exposure to these hazards, health care workers are actually experiencing increasing numbers of occupational injuries and illnesses. Rates of occupational injury to health care workers have risen over the past decade. By contrast, two of the most hazardous industries, agriculture and construction, are safer today than they were a decade ago.

Precise national data is not available on the annual number of needlestick and other percutaneous injuries among health care workers; however, estimates indicate that 600,000 to 800,000 such injuries occur annually. About half of these injuries go unreported. Data from EPINet (the Exposure Prevention Information Network) suggests that at an average hospital, workers incur approximately thirty needlestick injuries per 100 beds per year.

Most reported needlestick and sharps injuries involve nursing staff; but laboratory staff, physicians, housekeepers, and other health care workers are also injured. Some of these injuries expose workers to bloodborne pathogens that can cause infection. The more serious of these pathogens are the hepatitis B virus

(HBV), the hepatitis C virus (HCV), and the human immunodeficiency virus (HIV). Infections by each of these pathogens are potentially life threatening, yet preventable.

The emotional impact of needlestick and sharps injuries can be severe and long lasting, even when a serious infection is not transmitted. This impact is particularly severe when the injury involves exposure to HIV. In one study of twenty health care workers with an HIV exposure, eleven reported acute severe distress, seven had persistent moderate distress, and six quit their jobs as a result of the exposure. Other stress reactions requiring counseling have also been reported. Not knowing the infection status of the source patient can accentuate the health care worker's stress. In addition to the exposed health care worker, colleagues and family members may suffer emotionally.

Safety and health issues can best be addressed in the setting of a comprehensive prevention program that considers all aspects of the work environment and that has employee involvement as well as management commitment. Implementing the use of improved engineering controls is one component of such a comprehensive program. Other prevention strategy factors that must be addressed, however, include modification of hazardous work practices, administrative changes to address needle hazards in the environment (*e.g.*, prompt removal of filled sharps disposal boxes), safety education and awareness, feedback on safety improvements, and action taken on continuing problems.

Improved engineering controls are often among the most effective approaches to reducing occupational hazards and, therefore, are an important element of a needlestick prevention program. Such controls include eliminating the unnecessary use of needles and implementing devices having safety features. A number of sources have identified several desirable characteristics for safety devices, which include preferences for safety devices that: do not use needles; incorporate the safety feature as an integral part of the device; work passively (i.e., requires no activation by the user); have a safety feature that can be engaged with a single-hand technique and allows the worker's hands to remain behind the exposed sharp, if user activation is necessary; allow the user to easily determine whether the safety feature is activated; have a safety feature that cannot be deactivated and remains protective through disposal; perform reliably; are easy to use and practical; and are safe and effective for patient care.

Although each of these characteristics is desirable, some are not feasible, applicable, or available for certain health care situations. For example, needles will always be necessary where alternatives for skin penetration are not available. Also, a safety feature that requires activation by the user might be preferable to one that is passive in some cases. Each device must be considered on its own merit and ultimately on its ability to reduce workplace injuries.

Regarding specifically scalpels, the conventional scalpel currently used in the healthcare industry includes a metal handle and a disposable blade that is mounted on the handle prior to use, and removed after use. The process of mounting and dismounting of the blade is a difficult and dangerous procedure, which exposes the medical practitioner to potential injury from the exposed blade and contamination due to blood that may be present on the blade. Further, sharps injuries may also occur during an operation as the surgeon passes the exposed scalpel to a colleague.

Surgeons who have developed a feel for the shape and weight of the metal handle dislike the current disposable safety scalpels as, among other things, the plastic handle is too light and feels "different." During use, the plastic handle of the scalpel incurs undesirable flexibility than that of a metal handle scalpel. In addition, the disposable safety scalpel is significantly more expensive than the regular disposable blade. These two factors currently limit the adoption of safety scalpels in the healthcare industry.

What is needed is a safe and reliable scalpel that overcomes the present objections from the healthcare practitioner of current designs, while providing adequate protection for the medical workers handling the scalpel. It is to such a device that the present invention is primarily directed.

SUMMARY OF THE INVENTION

Briefly described, in a preferred form, the present invention is an improvement over the conventional scalpel by providing a safety scalpel that incorporates a reusable metal scalpel handle similar in shape and feel to the conventional metal handle preferred by most surgeons, and a disposable blade cartridge that covers the blade before, during, and after use, and is easily mounted and released from the metal scalpel handle.

The present safety scalpel comprises a blade with similar cutting profiles as standard surgical blades, a blade holder that is fixed to the blade, a blade guard that covers the blade and within which the blade holder is able to slide, a scalpel handle

that receives a blade cartridge (being the blade, blade holder and blade guard assembled together), and a locking assembly. The scalpel handle is reusable, while the blade cartridge is disposable.

While prior art designs have incorporated disposable blade cartridges where the blade guard slides off the releaseably fixed blade, the present invention is based on the blade sliding out of the releaseably fixed guard.

The present invention comprises a safety disposable blade cartridge that can be used with either a preferably reusable metal, or disposable plastic, scalpel handle, having the weight and feel of conventional designs. The blade cartridge easily fixes onto the scalpel handle, and yet is securely and releasably locked on the scalpel handle. The blade is preferably movable through at least three distinct positions - open, closed, and locked.

Attaching and detaching the blade cartridge to the scalpel handle utilizes an easy, longitudinal sliding motion. When fixed to the scalpel handle, only the blade and blade holder of the blade cartridge can move in a longitudinal direction, as the blade guard experiences limited or no longitudinal movement.

In other preferred embodiments, the blade cartridge is itself a standalone mini-scalpel, which is securely fixed to a passive metal handle or the blade can move within a hollow metal holder.

In still other embodiments, the blade is immobilized against movement when the reusable handle is removed.

A method of operation and construction is also provided herein.

For example, there is disclosed a safety scalpel having, a disposable blade cartridge which has a blade., a blade holder in communication with the blade; and

a blade guard adapted to receive the blade and blade holder; and a non-disposable scalpel handle having a distal end, wherein the disposable blade cartridge is slideable onto the distal end of the non-disposable scalpel handle, the disposable blade cartridge for lockable to the non-disposable scalpel handle.

The safety scalpel may also include a catch for engaging the extending member, and wherein the catch engaging the extending member locks the disposable blade cartridge to the scalpel handle.

The scalpel of may also have a blade holder with a holder knob, the blade moveable from a closed position, wherein the blade is not exposed beyond the

disposable blade cartridge, to an open position, and wherein the blade is exposed beyond the disposable blade cartridge.

The safety scalpel may also include an extending member, wherein the disposable blade cartridge includes a catch for engaging the extending member, wherein the catch engaging the extending member locks the disposable blade cartridge to the scalpel handle, and wherein the blade holder further comprises a holder knob, the holder knob enabling the blade to move from a closed position, wherein the blade is not exposed beyond the disposable blade cartridge, to an open position, wherein the blade is exposed beyond the disposable blade cartridge.

The scalpel may also include a latching assembly comprising a locking mechanism that is adapted to engage an aperture of the scalpel handle, such that the latching assembly locks the blade cartridge to the scalpel handle.

Another embodiment of the scalpel may also include a mechanical brake to supply frictional force to prevent movement of the blade and the brake make at least one element which supplies frictional force to prevent movement of the blade only when the handle is removed.

The scalpel may includes a space for receiving said handle and wherein said brake element includes a finger which flexibly protrudes into said space allowed for the handle, whereby the brake is prevented from interfering with the movement of the blade and the finger may be configured to flexibly engage at least a portion of the blade holder when said handle is not in place, thereby preventing movement of the blade without the handle.

The scalpel may include a finger with a contact land, said land having a chamfered surface proximate the point where said land contacts said blade holder when so engaged.

The scalpel may further include a locking safety feature of a safety catch for preventing accidental retraction of the blade when in use,having a slider knob at least partly external to the blade guard and in mechanical communication with the blade, so that movement of the slider causes movement of the blade, said slider including a base portion and releaseable engagement portion, a catch portion sized to receive said engagement portion, said catch located on said guard such that said catch and engagement portion are engaged when the blade is in a fully extended position.

In addition the safety feature may include a resilient portion extending from said base, having a free end and being spaced apart from said base. The resilient portion may arcuate and depressible and include a catch at its free end and wherein said catch portion includes a receiver sized to receive said catch, so that when said resilient portion is undepressed, said catch may be engaged within said receiver thereby preventing movement of the blade.

The scope of the invention is determined by the claims and this summary is only intended to give the reader a preview of the remainder of the entire specification.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A illustrates a perspective view of a safety scalpel in accordance with a preferred embodiment of the present invention.

Fig. 1B illustrates a perspective view of a safety scalpel in accordance with another preferred embodiment of the present invention;

Fig. 2A illustrates a perspective view of an unassembled blade and a blade holder in accordance with a preferred embodiment of the present invention;

Fig. 2B illustrates a perspective view of the assembled blade and blade holder of **Fig. 2A**;

Fig. 2C illustrates a perspective view of a front face of a blade holder in accordance with preferred embodiment of the present invention;

Fig. 2D illustrates a perspective view of a back face of the blade holder of **Fig. 2C**;

Fig. 3A illustrates a perspective view of a front face of a blade guard in accordance with a preferred embodiment of the present invention;

Fig. 3B illustrates a perspective view of a back face of the blade guard of **Fig. 3A**;

Fig. 3C illustrates a perspective view of a front face of a blade guard in accordance with another preferred embodiment of the present invention;

Fig. 3D illustrates a perspective view of a back face of the blade guard of **Fig. 3C**;

Fig. 3E illustrates a perspective view from a proximal end of the blade guard of **Fig. 3C**;

Fig. 4 illustrates a perspective view of assembly of a blade cartridge in accordance with a preferred embodiment of the present invention;

Fig. 5 illustrates a front face, perspective view of the blade cartridge attached to a scalpel handle;

Fig. 6A illustrates a perspective view of a front face of a safety scalpel with the blade housed in the blade cartridge, in accordance with a preferred embodiment of the present invention;

Fig. 6B illustrates a perspective view of the front face of the safety scalpel of **Fig. 6A** with the blade extending from the blade cartridge, in accordance with a preferred embodiment of the present invention;

Fig. 6C illustrates a perspective view of a back face of the safety scalpel of **Fig. 6A** with the blade housed in the blade cartridge, in accordance with a preferred embodiment of the present invention;

Fig. 7 illustrates a close-up, front face view of a distal end of a blade cartridge with a blade extending from a blade guard, in accordance with a preferred embodiment of the present invention;

Fig. 8 illustrates a perspective view of the back face of a safety scalpel like that in Fig 5c except with the blade housed in the blade guard, the blade guard having integrated mechanical stops, in accordance with a preferred embodiment of the present invention;

Fig 9 is a close up fragmentary perspective view of a portion of the view in Fig. 8 magnified to show detail concerning stops 1301;

Fig. 10 is a fragmentary close up view like Fig. 9 except from the opposite side; and

Fig. 11 is a fragmentary close up view of a portion of another embodiment of the safety scalpel.

DETAILED DESCRIPTION

Referring now in detail to the figures, wherein like reference numerals represent like parts throughout the several views, the present safety scalpel **10** of **Figs. 1A**, **1B**, and **6A-6C**, comprises a blade **100** is fixable to a blade holder **200**, which subassembly is slideable within a blade guard **300**. The combination of the blade **100**, the blade holder **200**, and the blade guard **300** forms a blade cartridge **400**, attachable to a scalpel handle **500**.

The present safety scalpel **10** comprises the blade cartridge **400** and the scalpel handle **500**, such that the blade cartridge **400** is configured for secure attachment to and safe detachment from the scalpel handle **500**. In a preferred

embodiment of the present invention, the blade cartridge **400** is disposable, while the scalpel handle **500** is non-disposable. Accordingly, a new blade cartridge **400** can be attached to the scalpel handle **500** for use by, for example, a medical practitioner. After the medical practitioner has finished using the safety scalpel **10**, the blade cartridge **400** can be safely removed from the scalpel handle **500**, so that the blade cartridge **400** can be disposed of properly.

The blade cartridge **400** can comprise the blade **100**, the blade holder **200** adapted to securely engage the blade **100**, and the blade guard **300** configured to slideably receive the blade **100** and blade holder **200**. Further, the blade holder **200** is adapted to move the blade **100**, or a portion thereof, between a closed and open position. In the closed position, the blade **100** is safely and fully contained within the blade guard **300**. In the open position, the blade **100**, or a portion thereof, extends beyond the blade guard **300**. As designed, the blade **100** is in the closed position during non-use of the safety scalpel **10** and in the open position during active use of the safety scalpel **10**. The safety scalpel **10** of the present invention, therefore, provides a safe and effective surgical tool.

As illustrated in **Figs. 2A** and **2B**, the blade **100** includes a cutting edge **110** located at a distal end **102** of the blade **100**. Further, at a proximal end **107**, the blade **100** defines an aperture **120**; preferably an elongated aperture **120** such as a slot. Other than perhaps the profile of the cutting edge **110**, the blade **100** preferably has a similar front and back face.

One skilled in the art will recognize that the blade **100** can be made of a variety of suitable materials including, but not limited to, both carbon and stainless steel. Generally, the carbon and stainless steel used to create the blade **100** are manufactured in compliance with several industry standards including British Standard ("BS") 2982:1992, International Organization for Standardization ("ISO") 7740:1985 and European Standard ("EN") 27740:1992. The blade **100** further can be sterilized by, for example, gamma radiation.

The blade holder **200** is designed to mate with blade **100**. Unlike the blade **100**, the front face **210** and back/rear face **225** of the blade holder **200** are dissimilar, and the thickness of the blade holder **200** is non-uniform. A distal end **202** of blade holder **200** comprises a holder protrusion **205** extending from the front face **210** of the blade holder **200**, in a profile that generally corresponds to the aperture **120** of

the blade **100**. The holder protrusion **205** is adapted to be securely engaged in the aperture **120** of the blade **100**.

The blade holder **200** can further comprise a protrusion notch **215** located on a proximal end of the holder protrusion **205**, such that the protrusion notch **215** locks the blade **100** to the blade holder **200**. As the holder protrusion **205** engages the blade aperture **120**, the blade **100** preferably snaps into the protrusion notch **215**, thereby preventing the blade **100** from accidentally disengaging with the blade holder **200**.

The blade holder **200** further comprises, at a proximal end **207**, a holder knob **220** extending from the front face **210** of the blade holder **200**. The surface of holder knob **220** can include a number of ridges **222** for increased traction when in contact with a finger during use of the safety scalpel **10**. As described more fully below, the holder knob **220** is adapted to move the blade **100** between the closed and open positions when in communication with the blade guard **300**.

The rear face **225** (see **Fig. 2D**) of the blade holder **200** can include a track **240** for receiving the scalpel handle **500**, preferably the blade receiving portion **550** of the scalpel handle **500**. The track **240** defines lateral movement of the blade cartridge **400** when secured to the scalpel handle **500**.

As illustrated in **Figs. 3A-3E** and **4**, the blade guard **300** is designed to slideably receive the blade **100** and blade holder **200**. When the blade **100** is in the closed position, the blade guard, or blade sheath, **300** adequately surrounds the blade **100**, so that the blade **100** cannot inadvertently cut, puncture, or otherwise damage materials or individuals.

There are at least two preferred embodiments of the blade guard **300**. A first embodiment is illustrated in **Figs. 3A-3B**, while a second embodiment is illustrated in **Figs. 3C-3E**. The embodiment selected can depend on the type of scalpel handle **500** used.

The blade guard **300** comprises an aperture **320** (also referred to herein as slot **320**) for providing a track for the holder knob **220** of the blade holder **200** to slide between the closed and open positions. Consequently, as the holder knob **220** moves between retracted and forward positions, the blade **100** moves between the closed and open positions, respectively. More particularly, a directional force applied to the holder knob **220** of the blade holder **200** permits the holder knob **220** to slide

along the slot **320** when moving the blade **100** and blade holder **200** between the closed and open positions.

The blade guard **300** defines therein a cavity **305**. The blade **100** and blade holder **200** are positioned within the cavity **305** for sliding, when the holder knob **220** slides within the slot **320**. The holder knob **220** is positioned near a proximal end **327** of the slot **320** when the blade **100** is in the closed position and the holder knob **220** is positioned near a distal end **322** of the slot **320** when the blade **100** is in the open position.

The blade guard **300** comprises a forward catch **325** and rear catch **330**, such that the forward catch **325** is positioned near the distal end **322** of the slot **320** and the rear catch **330** is positioned near the proximal end **327** of the slot **320**. The forward catch **325** is adapted to engage the holder knob **220** when the blade **100** is in the open position. The forward catch **325** prevents the blade holder **200** from moving the blade **100** forwardly beyond the open position. The forward catch **325** can include a flexible locking member **326** that locks the blade holder **200**, so as to prevent unmistaken unlocking of the blade **100** in the open position. Similarly, the rear catch **330** is adapted to engage the holder knob **220** when the blade **100** is in the closed position. The rear catch **330** can prevent the blade holder **200** from moving the blade **100** rearwardly beyond the closed position. Alternatively, the rear catch **330** prevents the blade holder **200** from moving the blade **100** rearwardly beyond the fully locked position. Further, the rear catch **330** can prevent accidental unlocking of the blade holder **200**, in an attempt to prevent accidents.

The blade guard **300** can include a plurality of grooves **340** positioned on the rear face **315** of the blade guard **300**, as illustrated in **Figs. 3B** and **3D**. The plurality of grooves **340** can prevent slippage of the safety scalpel **10** during use.

The blade guard has a front face **310**, as shown in **Figs. 3A** and **3C**, and a back/rear face **315** as shown in **Figs. 3B**, **3D**, and **3E**. The front faces **310** of the two embodiments are preferably the same. The rear face **315**, however, can have different attributes.

A beneficial feature of the differing rear faces **315** includes a method of releasing the blade guard **300**, and consequently the blade cartridge **400** from the scalpel handle **500**.

The blade guard **300** of **Figs. 3C** and **3D** further includes a latching assembly **345** for releasing the blade guard **300** from the scalpel handle **500**. The latching

assembly **345** includes a knob **350** extending from the rear face **315** of the blade guard **300**, and a locking mechanism **355**. The surface of knob **350** can include ridges **352** for increased traction when in contact with a finger during removal of the blade guard from the scalpel handle **500**. As described more fully below, the knob **350** is adapted to remove the blade cartridge **400** from the scalpel handle **500**.

One skilled in the art will recognize that the blade holder **200** and blade guard **300** can be made of a variety of materials including, but not limited to, plastic, such as acrylonitrile-butadiene-styrene (ABS) copolymer plastic.

As described above, the blade **100** and blade holder **200** fit into the blade guard **300**. Collectively, these three elements form the blade cartridge **400**. The blade cartridge **400** is attachable to and detachable from a distal end of the scalpel handle **500**.

The scalpel handle **500**, as shown in **Figs. 1A** and **1B**, comprises a handle portion **540** and a blade receiving portion **550**. The handle portion **540** extends from an approximate midpoint **555** of the scalpel handle **500** to the proximal end **507** of the scalpel handle **500**, while the blade receiving portion **550** extends from the approximate midpoint **555** to the distal end **502** of the scalpel handle **500**.

The distal end **502** of the scalpel handle **500** can be cut on the front face **510** to accommodate the blade cartridge **400**. Preferably, the distal end **502** of the scalpel handle **500** can have a tapered portion **504** for improved assembly of the safety scalpel **10**.

The scalpel handle **500** comprises at least one extending member **530** on the front face **510** of the proximal end **557** of the blade receiving portion **550**, such as near the approximate midpoint **555**. The extending member **530** extends outwardly from the scalpel handle **500** and is adapted to enable the securing of the blade cartridge **400** to the scalpel handle **500**.

That is, the at least one extending member, or medial notch, **530** is adapted to engage at least one catch **335** of the blade cartridge **400** (*e.g.*, catch **335** of the blade guard **300**). When the blade cartridge **400** is attached to the scalpel handle **500**, the catch **335** of the blade cartridge **400** can engage, or snap about, the extending member **530** to prevent longitudinal movement of the blade cartridge **400**. In addition, lateral movement of the blade cartridge **400** is limited due to the form fitting blade receiving portion **550**.

For increased traction of the scalpel handle **500** when in contact with a finger during use of the safety scalpel **10**, the handle portion **550** can include a plurality of grooves **525** positioned on a back face **515** of the scalpel handle **500**, as illustrated in **Fig. 6C.** The plurality of grooves **525** can prevent slippage of the safety scalpel **10** during use.

As illustrated in **Figs. 1A**, **1B**, **6A**, and **6B**, the handle portion **550** of the scalpel handle **500** can include indicia **520**. The indicia **520** is generally located on the front face **510** and near the proximal end **507** of the scalpel handle **500**. While one skilled in the art will recognize that the indicia **520** of the present invention can include multiple markings or printings, the indicia **520** are preferably units of measurement such as, but not limited to, the metric system, the Imperial system, or many other appropriate measuring systems.

The scalpel handle **500** is designed to accept the blade cartridge **400**, and provide the user with the feel of a conventional scalpel when used. It is thus provided of materials, weight, and design for comfortable use by the user.

Assembly of Blade Cartridge 400

The blade cartridge **400** includes the fitted cooperation of the blade **100**, the blade holder **200** and the blade guard **300**, as shown in **Fig. 4**. Preferably, the blade cartridge **400** is assembled offsite from where the present safety scalpel **10** is ultimately used, for example, in a factory, such that only the assembled blade cartridge **400** is delivered to the user. Also, the blade **100** can be attached to the blade holder **200** through insert molding, wherein the blade holder **200** is actually formed and molded around the blade **100**. With the use of insert molding, the blade **100** need not be subsequently attached to the blade holder **200**.

The blade cartridge **400** can be delivered in its own sterilized wrapping such as, for example, a foil wrap. Thus, the blade cartridge **400** is not intended for the user to assemble, but is intended only for the mating of the blade cartridge **400** with the scalpel handle **500**.

As described above, the blade **100** is fixed to the blade holder **200** by aligning the blade aperture **120** with the corresponding holder protrusion **205** of the blade holder **200**. The protrusion notch **215** permits the blade **100** to be secured onto the blade holder **200**, as shown in **Figs. 2A** and **2B**.

The blade holder **200** with the blade **100** is then attached to the blade guard **300** by sliding and slotting the blade holder **200** into the aperture **305** of the blade guard **300**. This is shown by the arrow in **Fig. 4**.

To attach the blade **100** and blade holder **200** into the blade guard **300**, the blade **100** and blade holder **200** are inserted into the blade guard **300**, such that the blade **100** is aligned within the cavity **305** defined by the lateral sides of the blade guard **300** and the holder knob **220** fits into slot **320**. As illustrated in **Fig. 4** (see arrow), the blade holder **200** is slotted into the blade guard **300** such that the stopper rib **230** on the blade holder **200** engages the rear retaining slot **370** of the blade guard **300**.

The blade holder **200** and the blade **100** are kept temporarily locked in the blade guard **300** by the holder stopper rib **230** engaging and locking to the matching rear retaining slot **370** on the blade guard **300**. Accordingly, the blade **100** can be kept in the closed position.

In the assembled blade cartridge **400**, the blade **100** is wholly enclosed in the blade guard **300** until mounted on the scalpel handle **500** for use.

Mounting of Blade Cartridge 400 to Scalpel Handle 500

As shown in **Figs. 1A** and **1B**, the process of mounting the assembled blade cartridge **400** to the scalpel handle **500** is fairly simple. The distal end **502** of the scalpel handle **500**, *i.e.*, the blade receiving portion **550**, can be inserted into the cavity **305** of the blade cartridge **400**, preferably at the proximal end **307**. Indeed, the blade receiving portion **550** of the scalpel handle **500** can be housed in the track **240** of the rear face **225** of the blade holder **200** to secure the blade cartridge **400** to the scalpel handle **500**. The blade cartridge **400** slides to the point where the catch **335** engages an extending member **530**.

The catch **335** of the blade cartridge **400** is arranged to latch around the extending member **530**. Further, the proximal end **307** of the blade cartridge **400** (*e.g.*, proximal end **307** of the blade guard **300**) is adapted to abut against the approximate midpoint **555** of the scalpel handle **500**, such that the blade cartridge **400** has limited, or no, longitudinal and/or lateral movement. **Fig. 5** illustrates a close up of the blade cartridge **400** secured to the scalpel handle **500**, such that the catch **335** is latched to the extending member **530**.

In addition, when the scalpel handle **500** includes an aperture **505**, the blade cartridge **400** can be further secured to the scalpel handle **500**. The blade cartridge

400 (*e.g.*, the blade guard **300**) can include the latching assembly **345**. The latching assembly **345** includes a locking mechanism **355** that engages the aperture **505** of the rear face the scalpel handle **500**. This engagement further secures the blade cartridge **400** to the scalpel handle **500**.

Use of Safety Scalpel 10

When first mounted, the blade **100** in the blade cartridge **400** is in the closed position, as illustrated in **Figs. 6A** and **6C**. The blade **100** can be extended out of the blade guard **300** by depressing the holder knob **220** of the blade holder **200** (*e.g.*, pushing the holder knob **220** downward) or alternatively simply pushing outward towards the distal end **202** of the blade holder **200**; releasing the stopper rib **230** on the blade holder **200** from the rear retaining slot **370** on the blade guard **300**; sliding the holder knob **220** along the slot **320** of the blade guard **300** until the blade **100** reaches the open position, upon which the holder knob **220** is released such that the stopper rib **230** on the blade holder **200** engages the front retaining slot **375** on the blade guard **300**. Thus, the blade **100** is temporarily locked in the open position. When the blade guard **300** engages the front retaining slot **375**, the flexible locking member **326** can be moved outwardly toward an edge of the blade guard **300**, such that it locked.

In this open position, as shown in **Fig. 6B**, the safety scalpel **10** is ready for use, *i.e.*, cutting and/or slicing. Further, in this position, the blade **100** is prevented from moving laterally and transversally during use of the safety scalpel **10**.

The blade cartridge **400** (*e.g.*, the blade guard **300**) can further comprise a plurality of indentations **380**, as illustrated in **Figs. 1A**, **3A**, and **3B**. The plurality of indentations **380** are positioned on at least one lateral side/edge of the blade guard **300**, such that the plurality of indentations **380** provide increased grip of the safety scalpel **10** during use.

If the user needs to hand the safety scalpel **10** to a colleague, she first moves the blade **100** into the closed position by depressing the holder knob **220** on the blade holder **200** to release the stopper rib **230** from the front retaining slot **375**. Alternatively, she can move the holder knob **220** towards the proximal end **307** of the blade guard **300**. In either case, this causes a sliding of the holder knob **220** back along the slot **320** of the blade guard **300**, until the blade **100** reaches the closed position, upon which the holder knob **220** is released such that the stopper rib **230** on the blade holder **200** re-engages the rear retaining slot **370** on the blade guard

300. The blade **100** is now temporarily locked in the closed position. The blade **100** can be moved any number of times between the open and closed positions until the operation is completed.

Dismounting of Blade Cartridge 400 from Scalpel Handle 500

Because there are at least two embodiments of the scalpel handle **500** that can use two different blade guards **300**, there are two different processes of dismounting the blade cartridge **400** (*e.g.*, blade guard **300**) from the safety handle **500**.

In a first embodiment, the blade guard **300** of **Figs. 3A** and **3B** is secured to the scalpel handle **500** of **Fig. 1A**. That is, there is no aperture **505** (see **Fig. 1B**).

The blade guard **300** in this first embodiment is removed by having the holder knob **220** placed in the rear retaining slot **370**, such that the blade **100** is in the closed position and does not extend from the blade guard **300**. The holder knob **220** can be slid slightly further towards the proximal end **307** of the blade cartridge **400** (*e.g.*, proximal end **307** of the blade guard **300**), or towards the approximate midpoint **555**. When the holder knob **220** slides in this direction, the catch **335** moves away from the extending member **530** of the scalpel handle **500**. This can release the blade cartridge **400** from the scalpel handle **500**. Then, the user need only slide the entire blade cartridge **400** towards the distal end **502** of the scalpel handle **500**, or off the scalpel handle **500**.

In a second embodiment, the scalpel handle **500** includes an aperture **505** in proximity to the extending member **530**, preferably slightly offset towards the distal end **502**. In this embodiment, the blade cartridge **400** (*e.g.*, the blade guard **300**) further includes the locking mechanism **355** about its rear face **315**.

Once the locking mechanism **355** is removed from the aperture **505**, the catch **335** can be released from the extending member **530**, as described above. Then, the blade cartridge **400** is loose enough to be released from the scalpel handle **500**. In essence, the latching assembly **345** is an additional safety feature to help ensure the blade cartridge **400** does not mistakenly release from the scalpel handle.

The rear face **315** of the blade cartridge **400** (*e.g.*, the rear face **315** of the blade guard **300**) matches up with the rear face **515** of the scalpel handle **500**. When the blade cartridge **400** is secured to the scalpel handle **500**, the latching assembly **345** is adapted to engage the aperture **505** of the scalpel handle **500**. The latching assembly **345** includes the knob **350** and the locking mechanism **355**.

Because the locking mechanism is an inwardly extending mechanism, it engages the aperture **505** in its normal state. If the knob **350** is depressed, however, the locking mechanism **355** disengages from the aperture **505**. The knob **350** can include a plurality of ridges for increased traction in disengaging the locking mechanism **355** from the aperture **505**.

Disposable Safety Scalpel 10

In another alternative embodiment of the present invention, the safety scalpel **10** comprises a disposable scalpel handle **500**, such that the disposable scalpel handle **500** is separate and passive from the blade cartridge **400**. The disposable scalpel handle **500** is adapted to attach to the blade cartridge **400**. Preferably, the blade cartridge **400** and the disposable scalpel handle **500** are permanently fixed to each other at the factory during the manufacturing process of the safety scalpel **10**. After use, the blade cartridge **400** and disposable scalpel handle **500** can be properly discarded.

Alterative preferred embodiment

In order to further increase the safety of the scalpel, the preferred embodiment in Figs 8-10 disclose additional features to secure the blade from accidental movement even if the user attempt to operate the device improperly. In describing this embodiment, to the extent it coincides with the prior embodiment, the same reference numerals are used and reference should first be had to the previously described figures. In this embodiment of the present invention the safety scalpel **10** comprises a non-disposable scalpel handle **500**, such that the non-disposable scalpel handle **500** is separate and passive from the disposable blade cartridge **400**. The non-disposable scalpel handle **500** is adapted to attach to the disposable blade cartridge **400**. In this embodiment, for safety reasons, it is preferable to ensure that the scalpel blade 100 remains securely housed within the blade guard 300 when latching assembly 345 is disengaged from catch 355 and the entire blade guard 300 is discarded.

Figure 8 illustrates a perspective view of the back face of the safety scalpel 10 in accordance with the preferred embodiment of the present invention with the blade 100 (not shown) housed entirely within the blade guard 1300 . Components in figure 8 that correspond directly with components in figure 1A have a prefix "1" added thereto (i.e. increased by 1000) . The blade guard 1300 may be made of a plastic-

like material and a region of the blade guard 1300 may be configured to protrude into the interior region of the blade guard 1300. The protrusions into the interior region of the blade guard 1300 will hereafter be referred to as mechanical stops or brakes 1301. Figure 8 shows mechanical stops 1301 located near the edge of the back surface of the blade guard 1300. The mechanical stops 1301 may protrude inboard into space allotted for the scalpel to traverse The stops/guards mechanically secure the scalpel blade 100 directly, or by engagement with the blade holder 200, within the blade guard 300 when the blade guard is removed from the handle 500 This is done by creating frictional contact (i.e. a bias force) between the stops 1301 and holder 200 (or blade 100). In effect stops 1301 are fingers which protrude into the spaced to be occupied by the holder 200, thereby applying a frictional drag thereon . The drag force can preferably be easily overcome by insertion of the handle 500 which lifts the brakes 1301 out of their protrusion into that space. In the preferred construction, the stops 1301 will be "deactivated" when the handle is inserted.

The stops 1301 can be built in many ways and be positioned in may places. The preferred position is shown in Fig 10. In that embodiment, there are a pair of stops 1301 which are formed in the plastic guard as fingers 1301a which are cut out from the guard material itself and inclined to be biased into the travel path of the scalpel blade.

The fingers are actually two parts. See Figs. 9-10. A first portion 1301e extending from the plastic housing and being resiliently connected therewith and a second portion 1301c at the distal end, a land, extending into the space of sliding blade. The land is preferably chamfered 1301d (edges rounded/beveled) to prevent the blade from getting stuck (hanging up) when engaging the blade holder 200 and also increases the force per unit area at the contact point.

There are other ways to accomplish this important braking action. First, only one stop may be used. It may also be provided on the sidewall instead of the bottom or top wall as shown. The braking action itself may be accomplished by a friction pad affixed inside of the safety housing or by a magnet embedded in the housing to cause a magnet drag against the steel blade (unless non magnet stainless is used). The scope of this invention includes other mechanical means for stopping the inadvertent movement of the blade once the lock has been released.

The degree of bias and resilience of the fingers should be such that the blade cannot move without being urged by the user, but that insertion of the handle 500 is

not obstructed by resistance created by the stops 1301. In practice, the handle can easily lift the stops out of the way when inserted, partly because of the chamfered edges on fingers 1301d.

In one embodiment of the present invention the mechanism by which the mechanical stops 1301 secure the scalpel blade 100 within the blade guard 1300 during disposal thereof is described below.

In preparation of disposing the blade guard 1300, the surgeon may first retract the scalpel blade 100 entirely within the blade guard 1300. Next, the surgeon may begin to disengage the non-disposable scalpel handle 1500 from within the blade guard 1300 by applying force to latching assembly 1345 in a direction towards the distal end 1302 of the blade guard 1300. When the distal end 502 (see Figure 1, item 502) of the non-disposable scalpel handle 1500 passes underneath the mechanical stops 1301, the mechanical stops may now mechanically engage the stops 1301 and possibly distal end of ridges 223a and 223b (see Figs. 2C , 2D) of the blade holder 200 and secure the scalpel blade 100 within the blade guard assembly 1300. In the normal surgical use of the safety scalpel 10, when the non-disposable scalpel handle 1500 is inserted into the blade guard 1300 (with enclosed scalpel blade 100) the distal end 502 (see Figure 1A) of the handle slides along the top surface of ridges 223a and 223b (Figures 2C and 2D) of the blade holder 200 until the distal end 502 of the handle first engages the mechanical stops 1301. In one embodiment of the present invention, the mechanical stops may be deformable, and the top surface of the scalpel surface may apply a sufficient force to deform the mechanical stops flush with the surface of the blade guard 1300, thereby interposing the scalpel handle between the mechanical stops 1301 and the ridges of the of the blade holder 200, thereby allowing the scalpel blade to be moved freely within the blade guard 1300 by applying force to holder knob 220 (See Figure 1A). In a preferred embodiment of the present invention, the mechanical stops 1301 may be located proximate to grooves 1340 in figure 8, in this location the mechanical stops 1301 may engage the distal end of ridges 223a and 223b (Figures 2C and 2D) in a position where the scalpel blade 100 is abutted near the proximate end 207 (see Figure 1A) of the blade holder, thereby ensuring the scalpel blade 100 is safely housed entirely within the blade guard 1300.

One skilled in the art will recognize that the disposable scalpel handle **500** can be made of a variety of materials including, but not limited to, plastic, such as acrylonitrile-butadiene-styrene (ABS) copolymer plastic.

In yet another alternative embodiment of the present invention, the safety scalpel **10** comprises a disposable scalpel handle **500** having a slideable blade **100** and blade holder **200** received therein. Accordingly, the blade guard **300** is an integral part of the disposable scalpel handle **500** and, therefore, does not detach from the scalpel handle **500**. Further, the entire safety scalpel **10** is disposable after use.

The blade cartridge **400** and scalpel handle **500** can be attached and detached as described above.

One skilled in the art will recognize that the scalpel handle **500** (*e.g.*, the entire safety scalpel **10**, minus the blade **100**) can be made of a variety of materials including, but not limited to, plastic, such as acrylonitrile-butadiene-styrene (ABS) copolymer plastic.

Fig. 11 illustrates a further safety feature as an alternative to the knob slider 220 in Fig. 1A.

In general terms, there may be a safety catch for preventing accidental retraction of the blade when in use, having a slider knob at least partly external to the blade guard and in mechanical communication with the blade, so that movement of the slider causes movement of the blade, said slider including a base portion and releaseable engagement portion, a catch portion sized to receive said engagement portion, said catch located on said guard such that said catch and engagement portion are engaged when the blade is in a fully extended position.

In addition the safety feature may include a resilient portion extending from said base, having a free end and being spaced apart from said base. The resilient portion may arcuate and depressible and include a catch at its free end and wherein said catch portion includes a receiver sized to receive said catch, so that when said resilient portion is undepressed, said catch may be engaged within said receiver thereby preventing movement of the blade.

In place of slider knob 220 is a compressible slider 2220 which provides a means for the user to extend or retract the blade. Fig. 11 shows the blade in a fully extended position. In addition to other means provided for herein, slider 2220 provides an additional locking means for preventing the blade from retracting

accidentally. Slider 2220 may include ridges 2222 to provide good frictional grip. Extending from the base of the slide is a resilient loop 2224 which is preferably attached at one end of the base of the slider and free at the other. The free end includes a hook like structure 2226 which is in the form of a one way barb or a mere land extending radially away from the free end loop 2224, for example, a land extending orthonally from the base of the free end to form a right angle of flat surfaces. On the distal side of the land, the surface may be chamfered or rounded to allow the land to slide under the bridge with less resistance.

Loop 2224 is preferably formed in an arcuate shape or at least spaced from the base 2230 of the slider. This provides a gap for the resilient loop to flex within. By applying pressure to the loop, the hook/barb is depressed an it will easily slide under the gate 2228 which is a receiving channel or bridge sized to receive the hook/barb. When pressure is released from the loop, it returns to its stead state position where the barb 2226 is engaged with a sidewall of the bridge 2228 such that retraction of the blade is prevented unless the user further depresses loop 2224 to release the hook 2226 from the gate 2228 long enough to withdraw the hook backwards out of the gate.

In this manner a further safety feature may be included in the scalpel which prevents unexpected retraction of the blade when in use but provides easy of retraction when desired.

While the invention has been disclosed in its preferred forms, it will be apparent to those skilled in the art that many modifications, additions, and deletions can be made therein without departing from the spirit and scope of the invention and its equivalents, as set forth in the following claims.

WE CLAIM:

1. A safety scalpel comprising:

a disposable blade cartridge comprising:

a blade;

a blade holder in communication with the blade; and

a blade guard adapted to receive the blade and blade holder; and

a non-disposable scalpel handle having a distal end,

wherein the disposable blade cartridge is slideable onto the distal end of the non-disposable scalpel handle, the disposable blade cartridge for lockable to the non-disposable scalpel handle.

2. The safety scalpel of claim 1, wherein the non-disposable scalpel handle includes an extending member, wherein the disposable blade cartridge includes a catch for engaging the extending member, and wherein the catch engaging the extending member locks the disposable blade cartridge to the scalpel handle.

3. The safety scalpel of claim 1, wherein the blade holder further comprises a holder knob, the blade moveable from a closed position, wherein the blade is not exposed beyond the disposable blade cartridge, to an open position, and wherein the blade is exposed beyond the disposable blade cartridge.

4. The safety scalpel of claim 1, wherein the non-disposable scalpel handle includes an extending member, wherein the disposable blade cartridge includes a catch for engaging the extending member,

wherein the catch engaging the extending member locks the disposable blade cartridge to the scalpel handle, and

wherein the blade holder further comprises a holder knob, the holder knob enabling the blade to move from a closed position, wherein the blade is not exposed beyond the disposable blade cartridge, to an open position, wherein the blade is exposed beyond the disposable blade cartridge.

5. The safety scalpel of claim 1, wherein the disposable blade cartridge further comprises a latching assembly comprising a locking mechanism that is adapted to engage an aperture of the scalpel handle, such that the latching assembly locks the blade cartridge to the scalpel handle.

6. The safety scalpel of claim 1, wherein the blade cartridge includes a mechanical brake to supply frictional force to prevent movement of the blade

7. The safety scalpel of claim 6 wherein said brake includes at least one element which supplies frictional force to prevent movement of the blade only when the handle is removed.

8. The scalpel of claim 7 wherein the cartridge includes a space for receiving said handle and wherein said brake element includes a finger which flexibly protrudes into said space allowed for the handle, whereby the brake is prevented from interfering with the movement of the blade.

9. The scalpel of claim 8 wherein said finger is configured to flexibly engage at least a portion of the blade holder when said handle is not in place, thereby preventing movement of the blade without the handle.

10. The scalpel of claim 8 wherein said finger includes a contact land, said land having a chamfered surface proximate the point where said land contacts said blade holder when so engaged.

11. The scalpel of claim 6 further including a safety catch for preventing accidental retraction of the blade when in use, comprising:

a. a slider knob at least partly external to the blade guard and in mechanical communication with the blade, so that movement of the slider causes movement of the blade,

b. said slider including a base portion and releaseable engagement portion

c. a catch portion sized to receive said engagement portion, said catch located on said guard such that said catch and engagement portion are engaged when the blade is in a fully extended position.

12. The scalpel of claim 11 wherein said engagement portion includes a resilient portion extending from said base, having a free end and being spaced apart from said base.

13. The scalpel of claim 12 wherein said resilient portion is arcuate and depressible and includes a catch at its free end and wherein said catch portion includes a receiver sized to receive said catch, so that when said resilient portion is undepressed, said catch may be engaged within said receiver thereby preventing movement of the blade.

14. A safety scalpel comprising:

a scalpel handle having a longitudinal axis;

a blade cartridge attachable to the scalpel handle,

wherein the blade cartridge is only slideably, releasably attached to the scalpel handle in a direction generally along the longitudinal axis.

15. A method of attaching a blade cartridge to a scalpel handle, the method comprising:

positioning an aperture located at a proximal end of a blade cartridge into a distal end of a scalpel handle; and

sliding the blade cartridge in a direction along the longitudinal axis of the scalpel handle.

16. The method of claim 15, wherein a catch of the blade cartridge engages an extending member of the scalpel handle.

17. The method of claim 16, wherein a latching assembly engages an aperture of the scalpel handle.

18. The method of claim 16 further including the steps of preventing movement of the blade within the cartridge except when said handle is in place partially received within said cartridge.

19. The method of claim 15 further including the steps of applying a frictional force to prevent movement of the blade, and removing said force when said handle is inserted within said cartridge