SAFETY SCALPEL

CROSS REFERENCE TO RELATED APPLICATION AND CLAIM OF BENEFIT

This application claims the benefit of U.S. Provisional Application 60/623,741 filed on October 29, 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. Women represent nearly 80% of the health care work force. 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 sharp 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.

Current safety scalpels have been designed around the concept of a retracting guard or retracting blade on a plastic handle, where the entire scalpel is disposable. Because the entire scalpel is disposable, there is no need to mount and dismount the blade. The guard covers the blade before, during, and after use, and therefore protects the user from sharps injury.

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 permanently 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 lock. 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. The blade cartridge easily fixes onto the scalpel handle, and yet is securely 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 a lateral approach generally perpendicular to a longitudinal axis of the scalpel handle. 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 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 handle.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a perspective view of a blade cartridge and passive scalpel handle in accordance with preferred embodiments of the present invention.

Fig. 2 illustrates a perspective view of a blade and a blade holder, wherein the blade is detached from the blade holder, in accordance with preferred embodiments of the present invention.

Fig. 3 illustrates a perspective view of the blade and blade holder, wherein the blade is securely attached to the blade holder, in accordance with preferred embodiments of the present invention.

Fig. 4 illustrates a perspective view of a blade guard engaging the blade and blade holder in accordance with preferred embodiments of the present invention.

Fig. 5 illustrates a bottom view of the blade guard engaging the blade and blade holder, such that the blade holder is slideably received within the blade guard in accordance with preferred embodiments of the present invention.

Fig. 6 illustrates a bottom view of the blade guard engaging the blade and blade holder, such that a portion of the blade holder is received by a rear retaining slot in accordance with preferred embodiments of the present invention.

Fig. 7 illustrates a perspective view of the blade guard engaging the blade and blade holder, wherein the blade holder is in a closed position in accordance with preferred embodiments of the present invention.

Figs. 8A-8C, collectively referred to as **Fig. 8**, illustrate bottom views of the blade cartridge received by a distal end of a scalpel handle in accordance with preferred embodiments of the present invention.

Figs. 9A-9B, collectively referred to as **Fig. 9**, illustrate perspective views of the blade cartridge received by the distal end of the scalpel handle, such that support ribs of the scalpel handle secure the blade cartridge on the scalpel handle in accordance with preferred embodiments of the present invention.

Fig. 10 illustrates a top view of the blade cartridge received by the distal end of the scalpel handle, such that the blade is wholly enclosed by the blade guard when the blade holder is in the closed position in accordance with preferred embodiments of the present invention.

Fig. 11 illustrates a perspective view of the blade cartridge received by the distal end of the scalpel handle, wherein the blade cartridge includes a slot for allowing a holder knob to slide between the closed position and an open position in accordance with preferred embodiments of the present invention.

Fig 12 illustrates a perspective view of the blade cartridge received by the distal end of the scalpel handle, such that the blade and blade holder are in the open position in accordance with preferred embodiments of the present invention.

Figs. 13A-13B, collectively referred to as **Fig. 13**, illustrate perspective views of the blade and blade holder of the blade cartridge in the open position, such that the blade is prevented from lateral and transverse movement in accordance with preferred embodiments of the present invention. **Fig. 13B** illustrates an alternative embodiment wherein a boss of the blade holder engages the blade guard to prevent the blade from lateral and transverse movement.

Fig. 14 illustrates a perspective view of the blade cartridge engaging with the distal end of the scalpel handle in accordance with an alternative embodiment of the present invention.

Fig. 15 illustrates a perspective view of the blade and blade holder in the closed position in accordance with an alternative embodiment of the present invention.

Fig. 16 illustrates a perspective view of the blade and blade holder in a fully locked position in accordance with an alternative embodiment of the present invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Referring now in detail to the figures, wherein like reference numerals represent like parts throughout the several views, the present safety scalpel **10** of **Fig. 1** comprises a scalpel handle **500** and a blade cartridge **400**, 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.

For purposes of describing directional relationship of the various components of the safety scalpel **10**, the safety scalpel **10** includes a longitudinal axis **X** extending along the length of the safety scalpel **10**, a lateral axis **Y** that extends generally perpendicular to the longitudinal axis **X** along the width of the safety scalpel **10**, and a transverse axis **Z** that extends generally perpendicular to the longitudinal axis **X** and the lateral axis **Y** along the height of the safety scalpel **10**. Accordingly, as used herein, longitudinal movement refers to movement along the longitudinal axis **X**, lateral movement refers to movement along the lateral axis **Y**, and transverse movement refers to movement along the transverse axis **Z**.

The blade cartridge **400** can comprise a blade **100**, a blade holder **200** adapted to securely engage the blade **100**, and a 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 outside 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 tool.

As illustrated in **Figs. 2** and **3**, the blade **100** includes a cutting edge **110** located at a distal end **105** 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** 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.

As illustrated in **Fig. 2**, blade holder **200** is designed to mate with blade **100**. Unlike the blade **100**, the front and back face of the blade holder **200** are dissimilar, and the thickness of the blade holder **200** is non-uniform. A distal end of blade holder **200** comprises a holder protrusion **205** extending vertically from the front face 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 securely engage the aperture **120** of the blade **100**.

The blade holder **200** can further comprise a protrusion notch **210** located on a proximal side of the holder protrusion **205**, such that the protrusion notch **210** locks the blade **100** to the blade holder **200**. As the holder protrusion **205** passes through the blade aperture **120**, the blade **100** snaps into the protrusion notch **210**, thereby preventing the blade **100** from disengaging with the blade holder **200**.

During assembly of the blade cartridge **400**, the blade **100** is fixed to the blade holder **200** by aligning the aperture **120** of the blade **100** with the corresponding holder protrusion **205** of the blade holder **200**. The holder protrusion **205** and the protrusion notch **210** allow the blade **100** to slide, slot, and snap onto the blade holder **200**, as shown in **Figs. 2** and **3**. Alternatively, the blade **100** can be connected to the blade holder **200** through insert molding, such that the blade holder **200** is formed around the blade **100** during the manufacturing process.

The blade holder **200** further comprises, at a proximal end, a holder knob **215** vertically extending from the front face of the blade holder **200**. The surface of holder knob **215** can include ridges **220** for increased traction when in contact with a finger during use of the safety scalpel **10**. As described more fully below, the holder knob **215** is adapted to move the blade **100** between a closed and open position when in communication with the blade guard **300**.

As illustrated in **Figs. 4-6,** 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 **300** adequately surrounds the blade **100**, so that the blade **100** cannot inadvertently cut, puncture, or otherwise damage materials or individuals.

The blade guard **300** comprises an aperture **315** (also referred to herein as slot **315**), see **Fig. 7**, for providing a track for the holder knob **215** of the blade holder **200** to slide between the closed and open positions. Consequently, as the holder knob **215** moves between the closed and open positions, the blade holder **200** and the blade **100** also move between the closed and open positions. More particularly, a directional force applied to the holder knob **215** of the blade holder **200** permits the holder knob **215** to slide along the slot **315** when moving the blade **100** and blade holder **200** between the closed and open positions.

The blade guard **300** also comprises at least one lateral rail **305**, such that the at least one lateral rail **305** defines a cavity within the blade guard **300**. The blade **100** and blade holder **200** are positioned between preferably two lateral rails **305**, such that the blade **100** and blade holder **200** slide within the cavity when the holder knob **215** slides within the slot **315**. The holder knob **215** is positioned near a proximal end of the slot **315** when the blade **100** is in the closed position and the holder knob **215** is positioned near a distal end of the slot **315** when the blade **100** is in the open position.

As further illustrated in **Fig. 7**, the blade guard **300** comprises a forward catch **350** and rear catch **355**, such that the forward catch **350** is positioned near the distal end of the slot **315** and the rear catch **355** is positioned near the proximal end of the slot **315**. The forward catch **350** is adapted to engage the holder knob **215** when the blade **100** is in the open position. The forward catch **350** prevents the blade holder **200** from moving the blade **100** forwardly beyond the open position. Similarly, the rear catch **355** is adapted to engage the holder knob **215** when the blade **100** is in the closed position. The rear catch **355** prevents the blade holder **200** from moving the blade **100** rearwardly beyond the closed position. Alternatively, rear catch **355**

prevents the blade holder **200** from moving the blade **100** rearwardly beyond the fully locked position.

For the safety scalpel **10** to be effectively used and safely stored, the blade **100** can be temporarily locked in the closed and open positions. To facilitate the temporary locking of the blade **100** in the closed position, the blade holder **200** further comprises a stopper rib **225**, see **Figs. 5** and **6**, positioned near the holder knob **215**. Generally, the stopper rib **225** laterally extends from the front face of the blade holder **200**.

The stopper rib **225** is adapted to engage a rear retaining slot **325** of the blade guard **300**. The rear retaining slot **325** is located near the proximal end of the blade guard **300**, such that the stopper rib **225** engages the rear retaining slot **325** when the blade **100** is in the closed position. During the engagement of the stopper rib **225** and the rear retaining slot **325**, the blade **100** is temporarily maintained in the closed position.

To facilitate the temporary locking of the blade **100** in the open position, the blade guard **300** further comprises a front retaining slot **330** positioned near the distal end of the blade guard **300**. The stopper rib **225** of the blade holder **200** engages the front retaining slot **330** when the blade **100** is in the open position. During the engagement of the stopper rib **225** and the front retaining slot **330**, the blade **100** is temporarily maintained in the open position.

Alternatively, to further ensure that the blade **100** is adequately locked in the open position during use of the safety scalpel **10**, the blade holder **200** can include a boss **230** generally positioned on the top of the holder protrusion **205**. As illustrated in **Figs. 9B** and **13B**, the boss **230** of the blade holder **200** is configured to engage (by interference fit) a front slot **340** of the blade guard **300**. The front slot **340** is positioned on a bottom face of the blade guard **300** near the distal end of the blade guard **300**. When the blade **100** is moved to the open position, the boss **230** of the blade holder **200** snaps into the front slot **340** of the blade guard **300**, such that the blade **100** is prevented from moving laterally or transversally during use.

In another alternative embodiment of the present invention, the blade **100** can be locked into a fully-locked position, prior to dismounting the blade cartridge **400** from the scalpel handle **500** or after surgery has been completed. As illustrated in **Figs. 15** and **16**, the blade holder **200** includes at least one locking slot **235** positioned near the proximal end of the blade holder **200**. The at least one locking slot **235** can

snap into at least one locking rib **345** of the blade guard **300** (located near the proximal end of the blade guard **300**), thereby moving the blade **100** to a fully locked position. When the locking slot **235** engages the locking rib **345**, the blade holder **200** is prevented from moving the blade **100** between the closed and open position.

Moreover, when the blade **100** is moved to the locked position, the blade **100** can no longer be released and extended forward to the open position for re-use. Typically, a rearwardly directional force is applied to the holder knob **215** of the blade holder **200**, such that the blade **100** is moved beyond the closed position to the locked position.

In a preferred embodiment, the blade guard **300** further comprises a plurality of tabs **365**, see **Figs. 7, 9A**, and **13A**, positioned within the front slot **340**. As the holder protrusion **205** of the blade holder **200** slides within front slot **340** when moved into the open position, the plurality of tabs **365** engage (by interference fit) the holder protrusion **205**, such that the blade **100** is prevented from moving in a lateral or transverse direction.

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 distal end **505** of the scalpel handle **500** is cut on the front face **510** to accommodate the blade cartridge **400**. The scalpel handle **500**, as illustrated in **Figs. 8A-8C**, comprises at least one lateral extension **540**, a lower wall **560**, a lower protrusion **550**, and, alternatively, at least one medial notch **530** (see **Fig. 9B**). Preferably, two lateral extensions **540** are positioned near a distal end **505** of the scalpel handle **500**, such that the first lateral extension **540** extends in a direction opposite the second lateral extension **540**. Accordingly, the first lateral extension **540**, the second lateral extension **540**, and the scalpel handle **500** from a generally T-shape. The lateral extensions **540** are adapted to engage a distal end of the blade cartridge **400**, when the blade cartridge **400** is attached to the scalpel handle **500**.

The lower wall **560**, as shown in **Fig. 9A**, communicates with a proximal end of the blade cartridge **400**, when the blade cartridge **400** is attached to the scalpel handle **500**. Generally, the distance between the lateral extensions **540** and the lower wall **560** of the scalpel handle **500** is generally equal to the length of the blade cartridge **400**. Together, the lateral extensions **540** and lower wall **560** prevent longitudinal movement of the blade cartridge **400** when attached to the scalpel handle **500**.

The lower protrusion **550** is positioned on the front face **510** of the scalpel handle **500** and extends longitudinally from the lower wall **560**. Typically, the blade cartridge **400** is seated onto the lower protrusion **550** during attachment to the scalpel handle **500**.

Alternatively, as illustrated in **Figs. 9B** and **14**, the at least one 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** snaps into the notch **530** to prevent longitudinal movement of the blade cartridge **400**.

In another embodiment, the lateral edges of the blade guard **300** include slanted ends at the proximal end of the blade cartridge **400**. The slanted ends of the blade guard **300** engage the lower wall **560** of the scalpel handle **500** and are adapted to prevent longitudinal movement of the blade cartridge **400** during use of the safety scalpel **10**.

For proper attachment of the blade cartridge **400** to the scalpel handle **500**, the scalpel handle **500** further comprises at least one support rib **535**. Preferably, two support ribs **535** are positioned on each lateral side of the distal end **505** of the scalpel handle **500**. The blade cartridge **400** includes at least one rail **305** adapted to engage a support rib **535** of the scalpel handle **500**. The engagement of the rail **305** and the support rib **535** temporarily maintains the attachment of the blade cartridge **400** to the distal end **505** of the scalpel handle **500**.

As illustrated in **Fig. 8A**, the scalpel handle **500** further comprises a tapered portion **545** positioned near the lateral extensions **540**. The tapered portion **545** of the scalpel handle **500** assists in the attachment and detachment of the blade cartridge **400** to the scalpel handle **500**. Consequently, the tapered portion **545** of the scalpel handle **500** causes the support ribs **535** of the scalpel handle **500** to slightly taper. Because the scalpel handle **500** includes a tapered portion **545**, only a portion of the lateral

rails **305** of the blade cartridge **400** need to overcome the support ribs **535** of the scalpel handle **500** during attachment to and detachment from the scalpel handle **500**.

For increased traction of the scalpel handle **500** when in contact with a finger during use of the safety scalpel **10**, the scalpel handle **500** includes a plurality of grooves **525** positioned on a back face **515** of the scalpel handle **500**. As illustrated in **Fig. 8**, the plurality of grooves **525** are positioned on the distal end **505** of the scalpel handle **500**, such that the plurality of grooves **525** prevent slippage of the safety scalpel **10** during use.

As illustrated in **Figs. 1**, **9**, and **10**, the scalpel handle **500** can include indicia **555**. The indicia **555** are 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 **555** of the present invention can include multiple markings or printings, the indicia **555** are preferably units of measurement such as, but not limited to, the metric system, the Imperial system, or any other appropriate measuring system.

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 Cartridge

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. 1**. 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, as described above, 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 **210** permits the blade **100** to slide, slot, and snap onto the blade holder **200**, as shown in **Figs. 2** and **3**.

The blade holder **200** with the blade **100** is then attached to the blade guard **300** by sliding and slotting the blade holder **200** onto the first rail **305** of the blade guard **300**. The lateral rails **305** of the blade guard **300** do not run the full length of the blade guard **300** and, therefore, the cavity within the blade guard **300** is wider near the proximal end of the blade guard **300**. Such a wider cavity assists in the insertion of the blade **100** and blade holder **200** into the blade guard **300**. To attach the blade **100** and blade holder **200** into the blade guard **300**, the blade **100** and blade holder **200** are pushed into the blade guard **300**, so that the blade **100** is aligned within the cavity defined by the lateral sides of the blade guard **300** and the holder knob **215** fits into slot **315**. As illustrated in **Figs. 4-6**, the blade holder **200** is slotted onto the blade guard **300** such that the stopper rib **225** on the blade holder **200** engages the rear retaining slot **325** 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 **225** engaging and locking to the matching rear retaining slot **325** 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. As illustrated in **Fig. 11**, to disengage the blade **100** from the closed position, the user needs to depress the holder knob **215**, and then push the holder knob **215** forward. Accidental release of the blade **100** is thus prevented.

Mounting of Cartridge

To attach the blade cartridge **400** to the scalpel handle **500**, the blade cartridge **400** must approach the scalpel handle **500** in a direction generally perpendicular to a longitudinal axis **X** of the scalpel handle **500**. Generally, the blade cartridge **400** is attached to the scalpel handle **500** between the lateral extensions **540** and the lower wall **560**.

Holding the blade cartridge **400** in one hand, the user positions a first inner edge of the blade cartridge **400** (e.g., a first rail **305** of the blade cartridge **400**) onto a first outer edge of the scalpel handle **500** (e.g., a first support rib **535**). The user then rotates the blade cartridge **400** in a direction generally perpendicular to the longitudinal axis **X** of the scalpel handle **500**, such that a second inner edge of the

blade cartridge **400** (e.g., a second rail **305** of the blade cartridge **400**) approaches a second outer edge of the scalpel handle **500** (e.g., a second support rib **535**). The second inner edge **305** of the blade cartridge **400** snaps, clicks, and engages the second support rib **535** of the scalpel handle **500**.

Alternatively, the catches **335** of the blade cartridge **400** snap, click, and engage the medial notches **530** of the scalpel handle **500**. Thus, the blade cartridge **400** is secured snugly to the scalpel handle **500**.

As illustrated in **Figs. 9A-9B**, longitudinal movements of the blade guard **300** are limited, and preferably prevented by the lateral extensions **540** and the lower wall **560** of the scalpel handle **500**.

Further, as illustrated in **Figs. 7** and **10**, the blade cartridge **400** (e.g., the blade guard **300**) includes at least one groove **360** positioned near one lateral side of the blade cartridge **400**. Preferably, two grooves **360** each positioned at opposite lateral sides of the blade cartridge **400** provide increased flexibility of the blade cartridge **400** during detachment from the scalpel handle **500**. The grooves **360** of the blade cartridge **400** allow the lateral sides of the blade cartridge **400** to flex upwardly during the detachment of the blade cartridge **400** from the scalpel handle **500**.

Use of Safety Scalpel

When first mounted, the blade **100** in the blade cartridge **400** is in the closed position, as illustrated in **Fig. 10**. The blade **100** is extended out of the blade guard **300** by depressing the holder knob **215** of the blade holder **200** (e.g, pushing the holder knob **215** downward); releasing the stopper rib **225** on the blade holder **200** from the rear retaining slot **325** on the blade guard **300**; sliding the holder knob **215** along the slot **315** of the blade guard **300** until the blade **100** reaches the open position, upon which the holder knob **215** is released such that the stopper rib **225** on the blade holder **200** engages the front retaining slot **330** on the blade guard **300.** Thus, the blade **100** is temporarily locked in the open position.

The blade **100** and blade holder **200** are secured within slot **340**, when in the open position, by interference fit of the tabs **365** and the holder protrusion **205**, as illustrated in **Figs. 7** and **9A**. In this open position, the safety scalpel **10** is ready for use. The interference fit between the tabs **365** and the holder protrusion **205** prevent the blade **100** from moving laterally and transversally during use of the safety scalpel **10**.

Alternatively, the blade **100** and blade holder **200** are further secured to the blade guard **300** by interference fits of the boss **230** on blade holder **200** and the front slot **340** on the blade guard **300**, as illustrated in **Figs. 9B** and **13B**. The interference fit between the boss **230** and the front slot **340** prevent the blade **100** from moving laterally and transversally during use of the safety scalpel **10**.

The blade cartridge **400** (e.g., the blade guard **300**) further comprises a plurality of indentations **310**, as illustrated in **Figs. 4, 13** and **14**. The plurality of indentations **310** are positioned on at least one lateral side of the blade guard **300**, such that the plurality of indentions **310** provide increased grip of the safety scalpel **10** during use.

If the surgeon 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 **215** on the blade holder **200** to release the stopper rib **225** from the front retaining slot **330**; sliding the holder knob **215** back along the slot **315** of the blade guard **300**, until the blade **100** reaches the closed position, upon which the holder knob **215** is released such that the stopper rib **225** on the blade holder **200** re-engages the rear retaining slot **325** 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 Cartridge

To detach the blade cartridge **400** from the scalpel handle **500**, the blade cartridge **400** must be removed from the scalpel handle **500** in a direction generally perpendicular to the longitudinal axis **X** of the scalpel handle **500**. Accordingly, a user cannot push the blade cartridge **400** off of the scalpel handle **500** in a longitudinal direction, because of the lateral extensions **540**. If it were possible to remove the blade cartridge **400** from the scalpel handle **500** in a longitudinal direction, one can accidentally project or propel the blade cartridge **400** towards an open incision previously created by the safety scalpel **10**, or in another undesirable direction or location. The present invention eliminates this possibility.

Removal of the blade cartridge **400** occurs after the blade **100** has been moved to the closed or fully locked position. To remove the blade cartridge **400** from the scalpel handle **500**, the user slightly disengages one edge of the blade cartridge **400** (e.g., a first rail **205** of the blade cartridge **400**) from the corresponding outer edge of the scalpel handle **500** (e.g., a support rib **535**). The user then rotates the blade

cartridge **400** in a direction generally perpendicular the longitudinal axis **X** of the scalpel handle **500**. Such a rotation will fully disengage a first edge of the blade cartridge **400** (e.g., a first rail **205** of the blade cartridge **400**) from the outer edge of the scalpel handle **500** (e.g., a first support rib **535**). The used blade cartridge **400** is then disposed of safely.

In an alternative embodiment, the blade cartridge **400** further provides at least one ridge **370** positioned on at least one lateral side of the blade guard **300**, as illustrated in **Figs. 4**, **8B**, and **8C**. The at least one ridge **370** of the blade cartridge **400** provides increased traction and support for the user during detachment of the blade cartridge **400** from the scalpel handle **500**. The user can apply a finger to the at least one ridge **370** to assist in disengaging a first edge of the blade cartridge **400** with a first outer edge of the scalpel handle **500**.

Further, as illustrated in **Figs. 7** and **10**, the two grooves **360** positioned at opposite lateral sides of the blade cartridge **400** provide increased flexibility of the blade cartridge **400** during detachment from the scalpel handle **500**. The grooves **360** of the blade cartridge **400** allow the lateral sides of the blade cartridge **400** to flex upwardly during the detachment of the blade cartridge **400** from the scalpel handle **500**.

Disposable Safety Scalpel

In still 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** are properly discarded.

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 **100** and blade holder **200** can be attached as described above, by aligning the aperture **120** of the blade **100** with the holder protrusion **205** of the blade holder **200**. Alternatively, the blade **100** and blade holder **200** can be attached through insert molding, such that the blade holder **200** is formed around the blade **100** during the manufacturing process.

At a proximal end, the blade holder **200** further comprises a holder knob **215** vertically extending from the front face of the blade holder **200**. The surface of the holder knob **215** can include ridges **220** for increased traction when in contact with a finger during use of the safety scalpel **10**.

The blade guard **300** is integral to the disposable scalpel handle **500** and defines a cavity that slideably receives the blade **100** and blade holder **200**. When in the closed position, the blade guard **200** completely surrounds the blade **100**, but in the open position, a portion of the blade **100** extends outside the blade guard **300**.

The blade guard **300** further comprises an aperture **315** (or slot **315**) that provides a track for the holder knob **215** to slide between the closed and open positions. As described above, the holder knob **215** is positioned near a proximal end of the slot **315** when the blade **100** is in the closed position and the holder knob **215** is positioned near a distal end of the slot **315** when the blade **100** is in the open position.

The blade guard **300** comprises a forward catch **350** and rear catch **355**, such that the forward catch **350** is positioned near the distal end of the slot **315** and the rear catch **355** is positioned near the proximal end of the slot **315**. The forward catch **350** is adapted to engage the holder knob **215** when the blade **100** is in the open position. The forward catch **350** prevents the blade holder **200** from moving the blade **100** forwardly beyond the open position. Similarly, the rear catch **355** is adapted to engage the holder knob **215** when the blade **100** is in the closed position. The rear catch **355** prevents the blade holder **200** from moving the blade **100** rearwardly beyond the closed position. Alternatively, rear catch **355** prevents the blade holder **200** from moving the blade **100** rearwardly beyond the fully locked position.

For the safety scalpel **10** to be effectively used and safely stored, the blade **100** can be temporarily locked in the closed and open positions. To facilitate the temporary locking of the blade **100** in the closed position, the blade holder **200** further comprises a stopper rib **225**, see **Figs. 5** and **6**, positioned near the holder knob **215**.

Generally, the stopper rib **225** laterally extends from the front face of the blade holder **200**.

The stopper rib **225** is adapted to engage a rear retaining slot **325** of the blade guard **300**. The rear retaining slot **325** is located near the proximal end of the blade guard **300**, such that the stopper rib **225** engages the rear retaining slot **325** when the blade **100** is in the closed position. During the engagement of the stopper rib **225** and the rear retaining slot **325**, the blade **100** is temporarily maintained in the closed position.

To facilitate the temporary locking of the blade **100** in the open position, the blade guard **300** further comprises a front retaining slot **330** positioned near the distal end of the blade guard **300**. The stopper rib **225** of the blade holder **200** engages the front retaining slot **330** when the blade **100** is in the open position. During the engagement of the stopper rib **225** and the front retaining slot **330**, the blade **100** is temporarily maintained in the open position.

Alternatively, to further ensure that the blade **100** is adequately locked in the open position during use of the safety scalpel **10**, the blade holder **200** can include a boss **230** generally positioned on the top of the holder protrusion **205**. As illustrated in **Figs. 9B** and **13B**, the boss **230** of the blade holder **200** is configured to engage (by interference fit) a front slot **340** of the blade guard **300**. The front slot **340** is positioned on a bottom face of the blade guard **300** near the distal end of the blade guard **300**. When the blade **100** is moved to the open position, the boss **230** of the blade holder **200** snaps into the front slot **340** of the blade guard **300**, such that the blade **100** is prevented from moving laterally or transversally during use.

Alternatively, the blade **100** can be locked into a fully-locked position, prior to discarding the safety scalpel **10** after surgery has been completed. As illustrated in **Figs. 15** and **16**, the blade holder **200** includes at least one locking slot **235** positioned near the proximal end of the blade holder **200**. The at least one locking slot **235** can snap into at least one locking rib **345** of the blade guard **300** (located near the proximal end of the blade guard **300**), thereby moving the blade **100** in a fully locked position. When the locking slot **235** engages the locking rib **345**, the blade holder **200** is prevented from moving the blade **100** between the closed and open position.

Moreover, when the blade **100** is moved to the locked position, the blade **100** can no longer be released and extended forward to the open position for re-use. Typically, a rearwardly directional force is applied to the holder knob **215** of the blade

holder **200**, such that the blade **100** is moved beyond the closed position to the locked position.

The blade guard **300** further comprises a plurality of tabs **365** positioned within the front slot **340**. As the holder protrusion **205** of the blade holder **200** slides within front slot **340** when moved into the open position, the plurality of tabs **365** engage (by interference fit) the holder protrusion **205**, such that the blade **100** is prevented from moving in a lateral or transverse direction.

For increased traction of the scalpel handle **500** when in contact with a finger during use of the safety scalpel **10**, the scalpel handle **500** includes a plurality of grooves **525** positioned on a back face **515** of the scalpel handle **500**. As illustrated in **Figs. 8A-8C**, the plurality of grooves **525** are positioned on the distal end **505** of the scalpel handle **500**, such that the plurality of grooves **525** prevent slippage of the safety scalpel **10** during use.

As illustrated in **Figs. 1, 9A**, and **10**, the scalpel handle **500** can include indicia **555**. The indicia **555** are 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 **555** of the present invention can include multiple markings or printings, the indicia **555** are preferably units of measurement such as, but not limited to, the metric system, the Imperial system, or any other appropriate measuring system.

The blade **100** is extended out of the blade guard **300** by depressing the holder knob **215** of the blade holder **200** (e.g, pushing the holder knob **215** downward); releasing the stopper rib **225** on the blade holder **200** from the rear retaining slot **325** on the blade guard **300**; sliding the holder knob **215** along the slot **315** of the blade guard **300** until the blade **100** reaches the open position, upon which the holder knob **215** is released such that the stopper rib **225** on the blade holder **200** engages the front retaining slot **330** on the blade guard **300.** Thus, the blade **100** is temporarily locked in the open position.

The blade **100** and blade holder **200** are secured within slot **340**, when in the open position, by interference fit of the tabs **365** and the holder protrusion **205**, as illustrated in **Figs. 7, 9A,** and **13A**. In this open position, the safety scalpel **10** is ready for use. The interference fit between the tabs **365** and the holder protrusion **205** prevent the blade **100** from moving laterally and transversally during use of the safety scalpel **10**.

Alternatively, the blade **100** and blade holder **200** are further secured to the blade guard **300** by interference fits of the boss **230** on blade holder **200** and the front slot **340** on the blade guard **300**, as illustrated in **Figs. 9B** and **13B**. The interference fit between the boss **230** and the front slot **340** prevent the blade **100** from moving laterally and transversally during use of the safety scalpel **10**.

The blade guard **300** further comprises a plurality of indentations **310**, as illustrated in **Figs. 4, 13A-B,** and **14**. The plurality of indentations **310** are positioned on at least one lateral side of the blade guard **300**, such that the plurality of indentions **310** provide increased grip of the safety scalpel **10** during use.

If the surgeon 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 **215** on the blade holder **200** to release the stopper rib **225** from the front retaining slot **330**; sliding the holder knob **215** back along the slot **315** of the blade guard **300**, until the blade **100** reaches the closed position, upon which the holder knob **215** is released such that the stopper rib **225** on the blade holder **200** re-engages the rear retaining slot **325** 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 till the operation is completed.

Further, the blade guard **300** can comprise a plurality of knob tabs adapted to engage the holder knob **215** of the blade holder **200** when in the open and closed position. The interference fit of the holder knob **215** and the knob tabs prevents longitudinal movement of the holder knob **215** during use of the safety scalpel **10**.

The blade guard **300** can further comprise a plurality of retaining slot tabs positioned in the front retaining slot **330**, such that the retaining slot tabs are adapted to engage the stopper rib **225** when the blade **100** is in the open position. The interference fit between the retaining slot tabs and the stopper rib **225** prevents longitudinal movement of the blade **100** during use of the safety scalpel **10**.

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.

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; and
a non-disposable scalpel handle having a distal end,
the safety scalpel being arranged for a user to attach the disposable blade cartridge to the distal end of the non-disposable scalpel handle by positioning a first inner edge of the blade cartridge onto a first outer edge of the scalpel handle, executing a rotational movement about an axis substantially parallel to a longitudinal axis of the non-disposable scalpel handle, such that a second inner edge of the blade cartridge engages in a snap fit with a second outer edge of the scalpel handle.

2. The safety scalpel of claim 1, the 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.

3. The safety scalpel of claim 2, wherein the blade defines an aperture near a proximal end of the blade and the blade holder comprises a protrusion positioned near a distal end of the blade holder, such that the protrusion of the blade holder is adapted to engage the aperture of the blade, and wherein the protrusion of the blade holder comprising a notch adapted to lock the blade securely onto the blade holder.

4. The safety scalpel of claim 2, wherein the blade is attached to the blade holder through insert molding, such that the blade holder is formed around the blade.

5. The safety scalpel of claim 3, wherein the blade holder is adapted to move a portion of the blade between a closed position inside the blade guard and an open position outside the blade guard.

6. The safety scalpel of claim 5, the blade holder further comprising a holder knob positioned near a proximal end of the blade holder, wherein the holder knob is movable along a slot of the blade guard.

7. The safety scalpel of claim 6, the blade guard further comprising a forward catch adapted to engage the holder knob at the distal end of the slot and a rear catch

adapted to engage the holder knob at the proximal end of the slot, wherein the forward catch prevents the blade holder from moving the blade forwardly beyond the open position and the rear catch prevents the blade holder from moving the blade rearwardly beyond the closed position or locked position.

8. The safety scalpel of claim 6, the blade holder further comprising a stopper rib adapted to engage a rear retaining slot of the guard when the blade is in the closed position and adapted to engage a front retaining slot of the guard when the blade is in the open position, wherein the engagement of the stopper rib and the rear retaining slot temporarily maintains the blade in the closed position and the engagement of the stopper rib and the front retaining slot temporarily maintains the blade in the open position.

9. The safety scalpel of claim 8, the slot of the blade guard comprising a plurality of tabs adapted to engage the protrusion when the blade is in the open position, wherein the engagement of the tabs and the protrusion prevent lateral and transverse movement of the blade during use.

10. The safety scalpel of claim 8, the blade holder further comprising at least one locking slot adapted to engage at least one locking rib of the guard when the blade is in a locked position, wherein the blade holder is prevented from moving the blade.

11. The safety scalpel of claim 2, the non-disposable scalpel handle comprising:
at least one lateral extension adapted to engage a distal end of the disposable blade cartridge; and
a lower wall adapted to engage a proximal end of the disposable blade cartridge, wherein the at least one lateral extension and lower wall prevent longitudinal movement of the disposable blade cartridge when attached to the non-disposable scalpel handle.

12. The safety scalpel of claim 11, the non-disposable scalpel handle further comprising at least one support rib adapted to engage at least one rail of the disposable blade cartridge, wherein the engagement of the at least one support rib and the at least one rail temporarily maintains the attachment of the disposable blade cartridge onto the non-disposable scalpel handle.

13. The safety scalpel of claim 2, the disposable blade cartridge further comprising at least one groove positioned near the at least one lateral side of the disposable blade

cartridge, wherein the at least one groove increases flexibility of the disposable blade cartridge during attachment to and detachment from the non-disposable scalpel handle.

14. The safety scalpel of claim 2, the blade cartridge further comprising at least one laterally extending catch positioned near the proximal end of the blade guard, such that the at least one laterally extending catch engages at least one medial notch positioned on at least one lateral side of the blade handle when the blade cartridge is attached to the blade handle, wherein the engagement of the at least one laterally extending catch and the at least one medial notch prevents longitudinal movement of the blade cartridge.

15. The safety scalpel of claim 2, the blade guard further comprising at least one ridge positioned on at least one lateral side of the blade guard, wherein the at least one ridge provides increased traction and support during the detachment of the blade cartridge from the scalpel handle.