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The risks associated with “Sharps Injuries” within the surgical environment are well documented and high on the agenda of most healthcare facilities. Notwithstanding the possible trauma from an injury, the biggest risk is the transfer of blood borne diseases like HIV/AIDS, hepatitis etc.

Attaching and removing a surgical blade from a traditional scalpel handle is a cumbersome and high-risk process. Very little has been done to change or improve this original design of blade fitment. The passing of a surgical blade on a scalpel handle during use poses a risk. It is also important to ensure that there are no protruding or misplaced surgical blades in the operating environment or after disposal.

Studies conducted worldwide have calculated the risks and financial costs associated with these injuries. We must not forget the social and emotional impact that “Sharps Injuries” have on healthcare workers and the healthcare industry.

Countries including the USA and continents including Europe have revised their Occupational Health and Safety legislation with the view to improving healthcare worker and patient safety.

Legislation is motivating the introduction of safety solutions to prevent “Sharp Injuries” within the healthcare environment. These solutions involve product innovation, training and continual policy and protocol review.
SAFETY + SCALPEL™
TOP ACTIVATED - RETRACTABLE - SINGLE USE SCALPEL

BLADE + MANAGEMENT SYSTEM™

SCALPEL + HANDLE
GRADUATED STAINLESS STEEL SURGICAL HANDLE
SURGICAL SCALPEL SAFETY DEVICES

Medi-Safe has designed and developed two devices both aimed at protecting healthcare workers from scalpel/surgical blade injuries, these are:

- The Medi-Safe MS+ plastic retractable Safety Scalpel with a stainless steel surgical blade

- The Medi-Safe MS+ Blade Management Safety Cartridge for those surgeons who still want the weight and feel of the traditional stainless steel scalpel handle. This device attaches easily and effortlessly to a standard scalpel handle. It provides safety during use and safe attachment and removal of the surgical blade with the scalpel handle

Each Medi-Safe device has its own specific use, based on the requirements and preferences of the individual surgeon.

SUMMARY

At Medi-Safe we are well aware of the resulting impact of an injury on productivity, the ensuing family or social issues, stress on healthcare workers and the cost of treatment following a disease transmitted through a sharps injury.

For this reason we have designed these two unique devices that reduce the risks inherent to surgical procedures performed with traditional scalpels. Both our devices are patent protected worldwide, including the USA, Europe, South Africa, China, India and Australia.

Why take the risk of touching a surgical blade, especially a used surgical blade when you can use a disposable safety device that is sterile, ready for immediate use and can easily and safely be disposed of?
The Medi-Safe MS+ Safety Scalpel is supplied in single sterile peel pouches. The blade size number is clearly indicated on the pouch and by the number and colour coded top activated button.
Remove scalpel from sterile pack. (Sterile only if package is NOT opened, damaged or broken. Intended for single use only. Do NOT re-sterilise)

Push the slide latch forward until the latch clicks into position. The scalpel is now ready for use.

To retract the blade; pull the slide latch back until the latch clicks into position. Visually check that the blade is fully retracted. The scalpel is now in the safety position. To use again repeat step 2.
4 Once the procedure is complete: Repeat step 3 then pull slide latch further back with force until the latch clicks into the final lock position. The scalpel is now ready for disposal.

5 Dispose safely into provided sharps disposal container.
Medi-Safe MS+ RETRACTABLE SAFETY SCALPEL

THE MEDI-SAFE MS+ SAFETY SCALPEL FEATURES PLACE THIS DEVICE IN A CLASS OF ITS OWN:

1. Top activated button – designed for both left and right handed users (Ambidextrous)
2. Holdfast top activated button fits with natural placement of the user’s fingers and acts as a “front lock”
3. Audible “clicks” indicate blade position (retracted, extended and final lock for disposal)
4. Ribbed ergonomic handle affords comfortable, well balanced grip
5. Crystalcut transparent blade holder and slider ensures an unobstructed view over the blade and cutting area
6. Time saving – packed sterile for immediate use (No need to attach a surgical blade to a pre-sterilised scalpel handle)
7. No blade movement
8. Can be supplied non-sterile for inclusion in surgical procedure packs (Can be gamma or EO sterilised)
9. Largest range of surgical blade sizes available; 10,11,12,15, 20, 22, 23, 24, E11 and Stitch Cutter
10. MS+ “FINAL LOCK” feature prevents re-use – this is a WHO requirement
11. Supplied with a high quality stainless steel surgical blade
12. Intuitive use

A TRAINING VIDEO CAN BE VIEWED ON THE MEDI-SAFE WEBSITE

The various Safety brands on the market may be grouped by design features:

- Top activated slide button
- Side activated slide button
- Top activated sliding sheath or cover

The top activated slide button and sliding cover design scalpel is suitable for both right and left-handed use (ambidextrous). The side activated button design scalpel is preferable for right-handed use but will require some adjustment for left-handed use – any adjustment or additional step needed is a safety risk.

Other features to consider that enhance safety:
- Final lock
- Audible clicks indicating blade position
- Intuitive use
- Blade stability – does not flex during use
- Quality of surgical blade

A final lock prevents re-use and is a requirement of the World Health Organisation.

Audible “clicks” are a safety feature additional to a visual check as they indicate intended position of the blade, whether fully retracted or fully extended. There is a risk of injury if the blade is not fully retracted into the handle or cover.

A non-intuitive safety scalpel may cause frustration for the user and incorrect activation of the safety features. This could ultimately result in injury. An intuitive safety scalpel requires minimal training to assure correct use of the scalpel and its safety features.

Many safety scalpels are made from plastic so it is important the design be robust to prevent bending and movement of the blade during use.

The Medi-Safe MS+ Safety Scalpel offers all these features, including a high quality stainless steel surgical blade.
OTHER ASPECTS TO CONSIDER

- Weight (similar to traditional scalpel)
- General appeal to medical staff – visual appearance of quality
- Accommodation of most commonly used blade sizes
- Feel (ergonomics) – does the handle feel substantial?
- Quality – packaging, smooth activation, flexibility, ribbed handle, solid construction, does not rattle and feel cheap

While the Medi-Safe MS+ Safety scalpel does not have the weight of a traditional scalpel its general appeal and ergonomics make it stand out above its competitors. The MS+ high quality safety scalpel is available in a large range of blade sizes.

Beware of scalpels that use springs to retract the blade – the blade retraction may cause contamination through blood spatter, as the retraction is violent and sudden.

You should familiarise yourself with other safety scalpels on offer to your clients and assess them based on the points discussed in this manual. You will then be equipped to give meaningful input and make them aware of the benefits of using the Medi-safe MS+ Safety Scalpel.

The Medi-Safe MS+ Safety Scalpel is supplied both sterile and non-sterile. The sterile packs are convenient and ready for immediate use in any situation. This is why the Medi-Safe MS+ Safety Scalpel is popular in Emergency Rooms, ambulances, first-aid kits, Doctors Surgeries and in the Operating Theatre.
Surgical kit manufacturers use non-sterile scalpels in a wide range of surgical kits. The various kit components are sterilised after assembly into the kit. Medi-Safe MS+ Safety Scalpels are used in the following surgical kits: Circumcision, venous catheters, various implants etc.

Sterile scalpels are packed individually in peel pouches. There are 10 scalpels per inner box and 50 inner boxes per shipper. Non-sterile scalpels are packed in blister trays of 20 scalpels.
To understand the features and benefits of the BMS it is important to review the attachment of a surgical blade to a standard stainless steel scalpel handle and the removal of the blade from the handle.

Once you understand how scalpel handles and surgical blades are used you will fully appreciate how to use the BMS Cartridge and the value that it offers surgeons and nurses in the Operating Room.

**Standard practice: Fitting and removal, using a standard surgical blade and handle**

Remove a sterile surgical blade from the foil packaging taking care not to contaminate the blade or to injure yourself. Carefully align the surgical blade with the two side channels at the tip of the scalpel handle before sliding the blade with force onto the handle. When attached the blade will make a loud click sound.

The blade is exposed during passing and use – strictly follow procedures and protocols as enforced at your hospital or surgical environment.

Great care must be taken when removing the surgical blade. The used blade is sharp and may be contaminated.

To remove the blade from the handle, lift the back end of the blade up while exerting a forward force. It is advisable to use forceps and to work away from your body and not in the direction of anyone close to you. The surgical blade is then disposed of in a sharps safety container.

A commercially available surgical blade-removing device may also be used. This is a much safer option but is an extra cost and must be made accessible to the nurse or surgeon otherwise the blade remover will not be used.
THE IMPORTANCE OF USING A QUALITY SURGICAL BLADE AND SCALPEL HANDLE

Surgical blades and handles should both be manufactured to the ISO 7740 Standard. This standard governs the critical dimensions of both the surgical blade and handle. If the surgical blade or handle is not manufactured to specification the blade may not fit at all to the handle or the blade may feel loose on the handle and may even dislodge during use. It is very important that healthcare workers use surgical blades and handles manufactured by certified manufacturers who comply with this standard. Most hospitals use surgical blades manufactured to the ISO 7740 standard however many hospitals may use cheaper generic handles that are not manufactured to the ISO 7740 standard.

Note from figures 1 and 2 that the dimension tolerances are extremely fine and require skill and good quality control to maintain in production.

Figures 1 and 2 extracted from the ISO 7740 standard
As you will see from figure 2, the ISO 7740 Standard does not govern all scalpel handle dimensions and features therefore many handle brands have a number of visual differences in shape and size.

For example some handle brands may have a particularly thick nose. If the handle nose is very thick it may not fit into the BMS cartridge. Due to the many variations in handle shape and dimensions, the MS+ cartridge had to be designed to fit the more commonly used handle brands.

If you do find handles in a hospital that do not fit properly to the MS+ BMS Cartridge you will have to supply the hospital with MS+ Scalpel handles or another high quality brand with a thinner nose.
Here are examples of different nose thickness handles:

![Image of three handles](image)

**IMPORTANT TO NOTE**
Some manufacturers have moved away from the standard scalpel handle dimensions.

Please contact us should your preferred handle not fit our system and we will recommend a suitable alternative.

Handle 3 in the photograph will not fit into a Medi-safe MS+ BMS Cartridge

**IMPORTANT TO NOTE**

The BMS cartridge is fitted with a high quality stainless steel surgical blade, manufactured to the ISO 7740 standard. The instructions for use illustrate how the scalpel handle attaches directly to the surgical blade, housed within the BMS cartridge. The handle does not attach to any other part of the BMS cartridge. This means it performs and behaves with the same rigidity as a standard scalpel blade on a standard handle. It is important that the surgical blade is properly attached to the handle. If a poor quality handle (not manufactured to the ISO 7740 standard) or worn handle is used it may affect the blade fitment and therefore the functionality of the BMS cartridge. We discuss this further on in the training manual.
INSTRUCTIONS FOR USE

You have now learned how to attach a surgical blade to a scalpel handle. Using this knowledge, the following instructions will guide you through the same procedure but using a BMS cartridge.

The procedure is exactly the same except now the surgical blade is safely housed and protected within the cartridge. Instead of holding the blade you will now be holding the same blade but housed within the cartridge.

Please note that you are still handling a sharp object - keep hands away from the front end of the cartridge, never use excessive force to attach or detach the BMS Cartridge.

ATTACHING THE MS+ BLADE MANAGEMENT SYSTEM

1. Insert scalpel handle (B) into the back end of the Blade Management System (A). Push handle (B) forward – it will be guided towards the blade (C) and will engage the blade.

Ensure that the scalpel handle is turned in the correct direction so as to engage into the blade, as with typical blade loading.

Push the handle fully forward until a loud ‘click’ is heard. Hold and squeeze point (A) between both fingers to ensure proper fitment.
INSTRUCTIONS FOR USE

IMPORTANT TO NOTE
Surgical blades and handles vary in dimension one to another. If you experience any difficulty attaching the blade to a handle proceed as follows: Follow the instructions for attaching the cartridge and observe as the handle tip enters the blade opening, then apply small manipulations to the handle and the BMS cartridge in order to engage the blade. Once the blade is successfully engaged push the handle fully forward as per the instructions above.

If the blade is properly attached the handle cannot be pulled out of the cartridge.

ATTACHING THE MS+ BLADE MANAGEMENT SYSTEM

After you have attached the BMS cartridge it is always a good idea to try and pull the cartridge off using a moderate force – this ensures that the handle is securely attached to the handle. (Excludes risk of using an old, worn or poor quality handle and assumes that the correct procedure has been used)

A VISUAL CHECK IS ALWAYS A GOOD IDEA
INSTRUCTIONS FOR USE

EXPOSING THE BLADE

Place thumb on sheath clip (D). Pull back with slight downward force to expose blade for use. Pull sheath backwards towards rear of the scalpel handle as far as it will go.

IMPORTANT TO NOTE

Ensure that thumb is positioned on top of button clip (D) as this disengages the lock and ensures an easy backward movement of the cartridge sheath. Holding thumb too far forward and onto flat surface of the sheath will make retraction of the sheath more difficult. This is a common error and something to observe if a user reports difficulty in sliding the sheath back to expose the surgical blade.
CLOSING THE SHEATH AND COVERING THE BLADE

4. Place thumb behind sheath clip (D), push forward until a loud click is heard.

PROTECTION DURING PASSING

The surgeon and/or nurse can slide the Sheath forward over the blade to prevent accidental injury during passing and when not in use.

The surgeon can easily retract the Sheath using one hand, to expose the blade for use, after receiving the scalpel from the nurse.

It is important that hospitals revise their protocols to ensure the safe implementation of the Medi-Safe MS+ BMS Cartridge.
INSTRUCTIONS FOR USE

DETACHING Medi-Safe MS+ BLADE MANAGEMENT SYSTEM

One-handed method (right hand only) - Hold scalpel in right hand with blade pointing away from your body and with sharp edge facing right. With thumb on sheath clip (D) and forefinger on blade-removing lever (H), push down and forward simultaneously. Cartridge ejects from the handle with used blade safely housed within the sheath.

Two-handed method (ambidextrous) - Hold scalpel handle in either hand with blade pointing away from your body and with sharp edge facing right. With right hand thumb on blade removing lever (H) and left hand thumb on sheath clip (D) push down and forward simultaneously. Blade Management System cartridge will eject from handle with blade safely housed in cartridge.

ACTIVATING THE FORWARD LOCK

A slight force may be applied to the lock (F) to prevent movement of the Sheath during a procedure. The lock is only necessary to use if the surgeons’ grip is solely on the Sheath and a stabbing force is required for the procedure.
INSTRUCTIONS FOR USE

The cartridge can be ejected directly off the scalpel handle and into a sharps safety container as per the healthcare facilities protocol. Note that there is no risk of injury as the surgical blade is safely housed in the cartridge.

NOTE
As the user becomes more familiar with the BMS cartridge they may find alternative adaptations of removing the device. This is perfectly acceptable if performed in a safe manner.

You can now fully appreciate the “tag line” on the Medi-Safe MS+ Blade Management packaging

- ATTACHES
- DETACHES
- PROTECTS

You are handling a sharp object in a sterile environment, please pay attention to the caution as indicated on the packaging.

CAUTION:

Sterility guaranteed unless pack is opened or damaged. The blade is extremely sharp. Handle with care. Always place sheath in “sheath closed” position when passing and when not in use. Used sharps are contaminated. Disease may occur from contact or injury. Dispose of cartridge in a puncture resistant container with sheath in “closed” position.

NB: KEEP HANDS AWAY FROM OPEN END OF CARTRIDGE AT ALL TIMES.

A TRAINING VIDEO CAN BE VIEWED ON THE MEDI-SAFE WEBSITE

INSTRUCTIONS FOR USE

REMEMBER THE FOLLOWING POINTS:

- Always handle with care

- Cartridge is designed to work with most handles that conform to the ISO 7740 standard. If the nose of the handle is very thick it will not fit into the cartridge and your client will have to use either a MS+ SS Scalpel handle or other handle with a suitably thin nose.

- If cartridge does not fit properly to the handle used in a healthcare facility, check the quality of the handle and ensure that it is not old or worn. (A good test would be to try the cartridge on a MS+ SS Scalpel handle)

- VISUAL CHECKS must be performed continuously during use to confirm all the steps above and to ensure that there is no risk of injury.

The Medi-Safe MS+ BMS Cartridge is supplied in single sterile peel pouches, with 50 pouches per inner box.
IMPORTANT BENEFITS

THE MOST IMPORTANT BENEFITS OF THE MS+ BMS CARTRIDGE.

- Attaches surgical blade to handle – effortlessly and safely without ever touching the surgical blade

- **Surgical blade attaches directly to scalpel handle.** Plastic cartridge only assists with the attachment – zero blade movement because the surgical blade is attached directly to the handle

- Protective Sheath covers and protects blade, when attaching, when passing, when not in use and during disposal

- Built in blade remover – no need to add the extra cost of a blade remover

- Removes the blade from the handle safely without having to touch or manipulate the blade directly

- Self activating lock to prevent movement of cover during use

- Surgeon uses standard stainless steel scalpel handle with same weight and feel – no purpose made handle to fit cartridge

- Can be used with preferred scalpel handle

- Meets OSHA needle stick and safety guidelines

- Provides the weight and feel of a traditional scalpel handle with the added safety features of a surgical safety scalpel. This is the first safety cartridge device that uses a standard scalpel handle that attaches directly to the surgical blade. This means that hospitals can convert with ease, as there is no requirement to purchase a purpose designed scalpel handle, resulting in the introduction of safety with significant cost savings

- Surgical Blade always visible
CHALLENGES YOU COULD FACE AND HOW TO OVERCOME THEM

- Cartridge self ejects off handle – blade not firmly attached to handle or poor quality handle or handle not manufactured to ISO standard. Test handle with an ISO standard surgical blade and check quality of fitment and ability to pull blade off the handle

- Handles used in the hospitals are old/worn, not manufactured to ISO 7740 Standard or have a thick nose – replace handles with MS+ SS Scalpel handle or well-known brand compatible with BMS

- Training Issues – use cartridge as if handling a standard scalpel blade (same principle applies). Review training manual

- Difficulty experienced in retracting Sheath – check position of thumb. Thumb must be positioned directly on the top part of the Sheath Clip (D)
The various Cartridge System brands on the market may be grouped by design features:

**CARTRIDGE ATTACHES TO A PURPOSE DESIGNED SCALPEL HANDLE**

**Design A.** Blade attaches directly to a purpose design handle.  
**Design B.** Blade is welded to a blade holder, which attaches to a purpose design handle.

Any one of these design variations may present with the following problems:

- Forward and backward movement of the blade
- The cartridge accidently ejects from the handle when sliding the protector forward to cover the blade
- Excessive blade flex, especially if the cartridge system is particularly long
- The cartridge system may not be ambidextrous
- The handle may have a coated surface which may flake off with normal use, and is not prescribed by the ISO 7740 specification

A purpose designed handle has to incorporate the features necessary to allow the cartridge system to function properly. A purpose designed handle is therefore ergonomically different to a traditional scalpel handle. The weight of the purpose designed handle may be similar to the traditional handle but the shape and general feel in the hand is not.

If a hospital wishes to implement one of these cartridge systems they must calculate the cost to purchase these purpose designed handles. Hospitals could find themselves trapped and committed to one cartridge system, as the purpose designed handles cannot be used with alternative brand cartridge systems.

**CARTRIDGE ATTACHES TO A STANDARD SCALPEL HANDLE**

**Design C.** Blade is welded to a blade holder, which attaches to a standard handle.  
The blade holder is particularly long, therefore the blade is likely to flex excessively.  
Placement of the hand and fingers on the cartridge may be relatively distant from the blade, causing diminished hand control when performing procedures.

**MS+ BMS design.** Blade attaches directly to a standard handle.  
The blade will perform with the same rigidity as a standard blade would on the handle.  
**THIS DESIGN CONCEPT IS PREFERABLE.**
The Medi-Safe Scalpel handle is manufactured in accordance with the requirements of the ISO 7740 standard. (Instruments for surgery – Scalpels with detachable blades – Fitting dimensions)
The advanced automated manufacturing process used assures that critical dimension tolerances and shape consistency are maintained throughout the manufactured batch.

GENERAL SPECIFICATION:

In accordance with the requirements of ISO 7153-1:1991
(Surgical Instruments – metallic materials Part 1– stainless steel)
Weight: 27-29 gram
THE BENEFITS OF REPLACING WORN/DAMAGED HANDLES WITH THE MS+ SCALPEL HANDLE

- The MS+ high quality scalpel handle is manufactured to the requirements of the ISO 7740 specification and will function perfectly with the MS+ BMS cartridge
- The MS+ scalpel handle is available to all our distributors and healthcare professionals
- The MS+ scalpel handle can be used as an alternative or replacement to any other scalpel handle in use by the healthcare facility
- The MS+ scalpel handle has a 5cm graduated ruler on the one side that may be used to indicate an approximate length

The Medi-Safe scalpel handle is a precision instrument and should be utilised only as per its intended use.

The MS+ scalpel handle must be cleaned and sterilised before use as per the hospitals’ standard protocols and procedures.
Handles should be cleaned in a solution of water and natural Ph(7) detergent, immediately after use. Blood and tissue should not be allowed to dry on the handle.

Medi-Safe recommends the following cleaning procedure:

**Ultrasonic Cleaning:**
The instrument should be processed in ultrasonic cleaner for 5-10 minutes. Stainless steel instruments should not be cleaned with instruments of other metal in the same cleaning cycle. Change solution frequently, according to the recommendation by the manufacturer.

**Manual Cleaning:**
If Ultrasonic cleaning is not available observe the following steps:
- Use stiff nylon cleaning brush
- Do not use abrasive brush
- Use cleaning pad or cleaner to clean the instruments
- Make sure all the instruments surfaces are perfectly cleaned
Method 1:
- For all instruments without other indications, steam autoclave sterilization with 270°F (130°C) for 15 minutes as recommended. Other temperatures and terms should be validated by the autoclave manufacturer. Sterilization temperatures should not exceed 280°F (137°C). The instructions of the autoclave manufacturer must be observed.

Method 2:
- Gamma Irradiation at 2.5 Mega Rad, follow validated process instructions.

NOTE
Contact the manufacturer of your Irradiator System to confirm appropriate sterilization parameters.

Method 3:
- Ethylene Oxide (ETO) Sterilization, follow validated process instructions.

NOTE
Contact the manufacturer of your ETO sterilizer to confirm appropriate sterilization parameters.

THE CLEANING AND STERILIZATION PROCEDURE CAN BE DOWNLOADED FROM THE MEDI-SAFE WEBSITE

http://www.medi-safe.net/
Medi-Safe Surgicals has a license agreement with Swann-Morton™ of Sheffield England. The license agreement allows Swann-Morton™ to manufacture and sell the MS+ cartridge design with surgical blades manufactured by Swann-Morton. The cartridge is sold by Swann-Morton™ under their brand, “KLEEN BMS cartridge™.”

Only Swann-Morton™ and Medi-Safe have the rights to manufacture the MS+ BMS Cartridge design, with Swann-Morton™ using their surgical blade and Medi-Safe using a high quality surgical blade manufactured in India.

The MS+ BMS Cartridge was designed and developed by Medi-Safe Surgicals. Numerous international patents protect the intellectual property rights.

All BMS Cartridges manufactured by Swann-Morton™ are identified by the MS+ logo on the device and all packaging.

**IMPORTANT TO NOTE**
The KLEEN BMS™ cartridge design is an adaptation of the MS+ cartridge design. The adaptation is necessary to accommodate the particularly thick blade attachment end of the Swann-Morton™ Scalpel handle. (Refer back to training manual notes)

The Medi-Safe MS+ BMS Cartridge cannot accommodate the Swann-Morton™ scalpel handle due to its particularly thick blade attachment end.
The KLEEN BMS™ Cartridge is a competitor device to the Medi-Safe MS+ BMS Cartridge.

Swann-Morton™ focuses on existing brand-loyal Swann-Morton™ customers worldwide, who already stock their scalpel handle.

Medi-Safe sells the Medi-Safe MS+ BMS Cartridge and focuses on those customers who require a safety cartridge with a high quality surgical blade at a more affordable price.

Swann-Morton™ is considered one of the world’s best surgical blade manufacturers with a large share of the surgical blade market through their loyal following. For this reason Medi-Safe agreed to license the BMS exclusively to Swann-Morton™. The license agreement underscores the fact that this is a high quality device and will be used by those clients loyal to Swann-Morton™, a market otherwise out of reach of the Medi-Safe MS+ BMS Cartridge.