schreiner MediPharm


# Small Needlestick — Large Risk

The Road to a Successful Directive 2010/32/EU Implementation:
Mitigating the Risk of Injuries from Sharp Instruments
in Hospitals and the Health Care Sector

## Table of Contents



# ABSTRACT

More than a million needlestick injuries occur in European hospitals and private medical practice every year[1]. Doctors, nurses, healthcare and cleaning personnel as well as laundry and kitchen workers are thus exposed to a higher risk of infection. The implementation of Directive 2010/32/EU to protect against injuries by sharp instruments into national law of the Member States as of May 11, 2013 aims to improve occupational health and safety. Employers have a duty to analyze the risk of infection by blood or other body fluids, to initiate appropriate actions and to use state-of-the-art technology to minimize potential risks. This includes the use of needle protection systems.

Directive 2010/32/EU recommends that hospital managers and responsible personnel in private medical practice conduct risk assessments in all situations where there is potential for injury or exposure to blood and other infectious material. Where such risks are identified, either processes or devices must be put in place to reduce or eliminate the risk, and measures taken have to be documented. First, the use of sharp instruments must be avoided and replaced by other devices and/or practices where possible. Generally, medical devices with integrated safety mechanisms must be used to the extent that technical solutions are currently available.

[1] *https://osha.europa.eu/de/sector/healthcare/prevention-sharp-injuries-workplace*

Training and the regular instruction as well as awareness raising of all employees are important. Furthermore, it should be communicated that needlestick injuries are primarily a question of working conditions and work techniques—and typically not the result of human error. If an injury has occurred, it must be reported immediately in order to initiate the required emergency treatment and follow-up medical checks. The faster the response, the better the chance of preventing an infection through post-exposure prophylaxis. In addition, reporting is essential to documenting needlestick injuries, as documentation is the only way to determine the incidence of needlestick injuries and reflect any changes that may have occurred in terms of numbers and frequency over time.

## Implementation of Integrated Safety Systems

The results of current research demonstrate that approximately 85% of all needlestick injuries may be avoided by using modern safety products[2, 3]. The EU Directive prescribes the use of safety systems if and when they are available, where they make it possible to achieve equivalent work results. With respect to the selection of suitable safety systems, it is particularly important to ensure an employee's acceptance of the safety system. Therefore, doctors and nurses should be involved in the decision. The key criterion for their acceptance is little to no impact to the product handling as they are accustomed to. The work area, must not be impaired in order to ensure that staff will continue to safely perform the injection to. Furthermore, the safety device should not injure the patient.

Safety systems are generally divided into active and passive systems. In the case of passive systems, the mechanism is automatically activated during handling. Active protection systems are activated by employees themselves. This technology provides the advantage that the user can personally or "actively" control the activation of the safety system. The Needle-Trap needle protection system designed and manufactured by Schreiner MediPharm is an active solution. Needle-Trap consists of a needle trap that is integrated into the syringe label, securing the blood-contaminated needle after injection. The system is activated in a controlled single handed method. When the needle locks in the trap, this is clearly audible. The activation of the needle protection may cause microscopic splatters, however these splatters do not pose any infection risk, as confirmed by a scientific study. The amounts of blood (0.0001 µl) and medication (0.00008 µl) are hardly detectable and thus pose no risk of blood borne disease infection. The needle protection system can be adapted to all conventionally used syringe dimensions, utilizing existing secondary packaging. Due to the simple design, Needle-Trap, like conventional labels, can be easily processed on commonly used labeling equipment with a few, minor modifications. A fast and easy integration into existing processes offers pharmaceutical manufacturers the possibility to quickly respond to the EU directive and the resulting requirements in the healthcare sector.

[2] *Müller-Barthelmeh R., Buchholz L., Nübling M., Häberle E.: Qualitätssicherung bei Nadelschutztechniken, Interventionsstudie zur Senkung der Nadelstichverletzungen durch Instrumente mit Nadelschutztechnik, Regierungspräsidium Stuttgart, Stuttgart 2005.*

[3] *Dale J., Pruett S, Maker M.: Accidental needle sticks in the phlebotomy service of the Department of Laboratory Medicine and Pathology at Mayo Clinic Rochester; Mayo Clin Proc 1998; 73: 611-5.*

# 1. Introduction

More than a million needlestick injuries occur in European hospitals and private medical practice every year[4]. They include injuries caused by needlestick cuts or scratches when using contaminated sharp devices. Experts, however, assume that a large number of unreported cases occur, estimating that each of the 21 million employees in the European healthcare sector sustains an injury caused by sharp medical instruments at least once a year.

To improve the protection of employees in hospitals and the healthcare sector, the Council of the European Union in May 2010 published the Directive 2010/32/EU. This specified rules and minimum requirements to be met to increase the prevention against sharps injuries for their employees. The EU Directive is in effect in all member states since May 11, 2013. Where necessary, it requires individual countries to amend their laws and regulations at national levels.

# 2. Needlestick Injuries: The Underrated Risk

Needlestick injuries are defined as all puncture, cut or scratch injuries caused by sharp instruments, such as tubes, lancets and scalpels, which may be contaminated with blood or other body fluids of the patient[5]. In addition, infection may be caused by exposure of non-intact skin and/or exposure of the mucous membranes of the eyes, mouth and nose to blood or other body fluids. Even the smallest injury harbors a risk of contracting a disease through exposure. For Hepatitis B the probability of infection is 30%, for Hepatitis C 3% and for HIV 0.3%[6]. Employees at risk are doctors and nurses, as well as personnel who may not be directly exposed to patients such as laundry and waste disposal, cleaning and kitchen personnel.

# 3. Overview of the Key Elements of Directive 2010/32/EU

The objective of Directive 2010/32/EU is to create a work environment that is as safe as possible by mitigating the risk of injuries attributed to sharp medical instruments in the hospital and healthcare sector. It is the employers' duty to mitigate the risk of injury by initiating appropriate actions and providing safety systems. To achieve this, the directive pursues an integrated approach with rules for risk assessment, risk prevention, education, instruction, information, and the development of risk awareness and monitoring programs.

## 3.1 Required Actions

To prevent sharps injuries, the Directive 2010/32/EU lists the following actions in descending order regarding their effectiveness:

**Most effective**

**Least effective**

- Avoidance of any unnecessary use of sharp instruments, e.g. elimination of unnecessary injections
- Definition and implementation of safe procedures for handling sharp instruments and contaminated waste as well as their disposal, e.g. through provision of medical devices with integrated safety mechanisms
- Definition of regulations and provision of training programs
- Observance of standard precautions, e.g. no recapping of used syringes
- Use of personal protective equipment such as gloves

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[4] *see footnote 1*
[5] *http://www.medterms.com/script/main/art.asp?articlekey=25492*
[6] *Hofmann, F., Berthold, H.: HBV-, HCV- und HIV-Übertragungsrisiko bei Verletzungen an gebrauchten Kanülen. In: Hallier E., Bünger J., (Hrsg): Dokumentationsband über die 38. Jahrestagung der DGAUM; Fulda 1998; 369-372.*

### 3.1.1 Risk Assessment

The definition of appropriate actions to prevent injuries and infections requires a risk assessment. Directive 2010/32/EU recommends that responsible personnel in hospitals and private medical practice initially analyze the situations in which employees are exposed to a risk of injury and where exposure to blood and other infectious material cannot be excluded. Generally, doctors are exposed to a higher risk than nurses which, among other things, can be attributed to differences in working hours and work in operating rooms. Working conditions and the techniques used are the key factors relating to injuries.

| **RISK** by amount of blood exposure per device | **FREQUENCY** of needlestick injuries in healthcare sector | | | |
|---|---|---|---|---|
| **Critical** | e.g. central-venous catheter | e.g. peripheral vein catheters | e.g. blood drawing needle | e.g. butterfly for blood drawing |
| **Serious** | | e.g. intra-muscular injection | e.g. porth catheter | e.g. scalpel blade |
| **Medium** | | | e.g. subcuta-neous injection | e.g. lancet, heparin injection |
| **Low** | e.g. accu-puncture | | | e.g. insulin injection |
| | **Rarely** | **Occasionally** | **Frequently** | **Very frequently** |

**LEGEND**

- Risk is not acceptable. Action to address the risk is very urgently required.
- Risk is not acceptable. Action to address the risk is required.
- Risk is acceptable. Standard precautions are appropriate.

*Source: Wittmann Andreas, Risk Assessment Matrix, University of Heidelberg, 2011*

### 3.1.2 Information and Education

To prevent needlestick injuries, it is necessary to heighten the awareness of all parties concerned and to point out the various risks. Therefore, regular instructions on the proper use of medical instruments, safe working procedures, correct disposal, importance of vaccinations as well as the relevant legal provisions are mandatory. This also includes training on the use of systems with integrated protection mechanisms.

Employees must also be aware of how to act in case of an injury and how to report incidents and accidents. The relevant reporting procedures are agreed between the employee representatives for safety and health protection in collaboration with employer and employee representatives. The reporting mechanisms shall include local, national and Europe-wide provisions.

### 3.1.3 Response and Follow-up Actions

Employers are expected to initiate the required steps to administer treatment including post-exposure prophylaxis and medical checks. In addition, they must investigate the causes and circumstances, document the accident and take appropriate actions to prevent future incidents. It must also be determined if rehabilitation actions are required, compensatory payments must be made or the continuation of employment is at risk.

## 4. Safety Systems

The result of current research confirms that approx. 85% of all needlestick injuries can be prevented through the use of modern safety systems[7]. The EU directive prescribes the use of safe systems if and when they are available and it is possible to achieve equivalent outcomes with them. Safety engineers recommend that safety systems have the following properties:

- The safety mechanism is a component of the system and compatible with other accessories.
- Its activation must be possible by using one hand.
- Its activation must be possible immediately after use.
- The safety product must not jeopardize the safety of the patient.
- The safety mechanism excludes its reusability.

[7] *see footnote 2,3*

- The safety product requires no change in the application technique.
- The safety mechanism must be marked by a clear, tactile or audible signal.

Other aspects play a role in the selection of suitable safety systems as well:

- Acceptance by employees: The less the application of the system differs from the handling to which the employee is accustomed, the higher the acceptance will be. Furthermore, it is important that the system does not impair the view of the injection area.
- Acceptance by patients: The system must not pose any health risks to the patient or cause anxiety.
- Acceptance by administration: Cost aspects are to be considered as well. Besides the purchasing price, they include costs for storage, particularly in the case of refrigerated products, and disposal.

The involvement of doctors and nurses in the decision is crucial to the successful use of the system. Only if employees are convinced of the product, can it be assured that the safety system will be correctly applied and used.

The standard to clearly mark safe instruments, ISO 23908-1 “Sharps Injury Protection” came into effect in October 2013. The standard provides requirements, test methods and protection systems for hypodermic single-use needles, for catheters and catheter introducers and needles used in blood sampling (ISO/DIS 23908-1:2009). Furthermore, the standard addresses the protection of hypodermic needles by both active and passive safety systems.

## 4.1 Active and Passive Systems

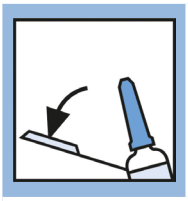
As the EU Directive only addresses employers in the healthcare sector, pharmaceutical manufacturers are principally not obligated to reduce the risk of needlestick injuries when designing their products. However, the pharmaceutical industry has already launched several products with passive or active safety systems.

In the case of passive systems, the safety mechanism is automatically activated in the course of the instrument’s normal operation, requiring no further action from the user. This form of activation, for example, is typically used with most of the safe permanent intravenous catheters in the case where the needle protection is automatically activated by removing the catheter guide. Active protection mechanisms are consciously activated by the employee. In this case, for instance, tubes are retracted into a protective sleeve, ejected or covered with a protective shield.

## 4.2 Needle-Trap: Label with Integrated Needle Protection

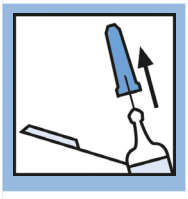
For protection against needlestick injuries, Schreiner MediPharm has developed a label that meets all legal and market requirements for prefilled syringes protection. Needle-Trap consists of a needle trap that is integrated in the label and secures the blood-contaminated needle after the injection. The system activation is performed by using one hand and is clearly audible. The system does notcover the syringe. Visual checks

through a transparent window are not impaired, thereby facilitating an administrator's visual inspection of the medication prior to administration. This system does not alter the handling of the syringe. The user merely has to move the needle trap aside, away from the needle before performing the injection.



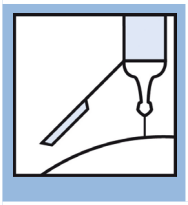
**Prepare.**

The trap is bent toward the side by approximately 90 degrees.



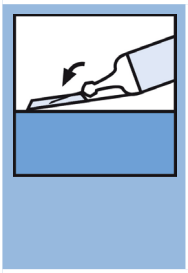
**Remove.**

The cap is removed.



**Inject.**

Healthcare staff performs the injection as usual.

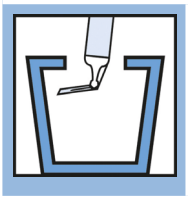


**Secure.**

The needle is secured by placing the trap against a hard, stable surface and then pressing it down. This activation can easily be performed using one hand.


**Snap.**

The user bends the trap until the needle audibly clicks into the plastic part.



**Dispose.**

The syringe with the secured needle can be disposed in the nearest Sharps Container.

The injection is administered without any risk of injury to the patient, contrary to automatic (passive) activation systems. The activation process to secure the needle can be controlled 100%. Furthermore, Needle-Trap may be activated at any time after administration, even when the syringe is only partially emptied.

Additional functions such as graduations or anti-counterfeiting features may be integrated into the label. Needle-Trap also allows reliable documentation of injections that have been administered. For this purpose, the label is equipped with peel-offs to facilitate documentation in the patient's medical file or vaccination card.


### 4.2.1 Easy Integration into Existing Production Processes

The number of stock keeping units does not increase due to Needle-Trap's two-in-one combination of a label and needle trap. Needle-Trap can be adapted to all standard syringe dimensions. Due to the simple design, this needle protection system, may be easily processed on all commonly used labeling equipment at the same speeds. Minor modifications to existing labeling equipment and processes are required. Qualification or re-qualification of the slightly modified manufacturing process provides needlestick safety with minimal capital investment. Due to the flexibility

of the Needle-Trap label's materials, there is no risk of the syringes breaking during the application process.

The fast and easy integration into existing processes offers pharmaceutical manufacturers the possibility to quickly respond to the EU directive and the resulting market requirements. The syringe label meets the requirements of the monitoring authorities for safety and quality and has been awarded 510(k) clearance by the Food and Drug Administration (FDA) for marketing in the United States. The prefilled syringe equipped with a Needle-Trap maintains the familiarity of the instrument (the prefilled syringe) in its original form, thereby ensuring continuity of the brand design and a high user-acceptance.

More information about Needle-Trap

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