Roncadelle Operations

NEEDLE-STICK INJURIES: A THREAT TO HEALTHCARE WORKERS AND PATIENTS

THE ADOPTION OF SAFETY SYRINGES AS A COST-EFFECTIVE MEASURE TO REDUCE THE RISK OF INFECTIONS

SUMMARY

Every day, **healthcare workers and patients are at risk of needle-stick injuries** (**NSIs**) which can lead to **dangerous and potentially life-threatening infections**, including hepatitis B, hepatitis C, and HIV.

The issue has become a priority topic:

1 million cases

In **EU countries** alone, **more than one million cases occur annually**[1] and at high cost to health systems and society.

72 million €

In **Italy**, the economic burden of NSIs is estimated **72 million €**, including only direct costs for diagnostics, prophylaxis, and post-exposure monitoring[6].

4 million £

In **UK**, the National Health Service spent more than **4 million £** for NSIs compensation between 2012 and 2017[7].

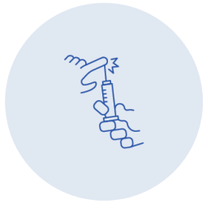
NSIs are mainly caused by the misuse of safety syringes, which means incorporating safety-engineered protection mechanisms that, after activation, provides a permanent barrier between the hands and the needle, until disposal.

Studies show that **80% of injuries could be prevented** by **shifting to the use of automatic safety syringes** and safety drug delivered systems for pre-filled syringes[8].

This would significantly decrease healthcare costs, reduce stress, increase workers' productivity, and improve the patient's experience.

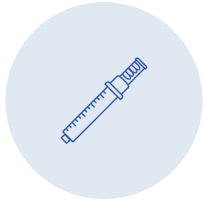
In many EU countries, despite the so-called "Sharps Directive" (Directive 2010/32/EU), there's still **suboptimal adoption of safety syringes**. A survey by HOSPEEM and EPSU investigated the concerns associated with poor compliance with the Directive.

Among them, the lack of adequate resources, training programs and effective data collection systems.



It is needed that institutions and healthcare organizations engage in facilitating consistent interpretation and widespread implementation of Directive 2010/32/EU as well as **ISO 23908 standard** which defines the safety requirements to be applied in the design and manufacture of devices to ensure compliance with the EU Regulation.

There are currently medical devices available on the market that guarantee full compliance with the quality and safety standards established by the Regulation. **Roncadelle Operations** syringes are **simple to use, require a minimal amount of force to activate** and **include automatic safety mechanism** to avoid any potentially dangerous intervention of the worker.



NEEDLE-STICK INJURIES: AN UNDERESTIMATED PUBLIC HEALTH PROBLEM

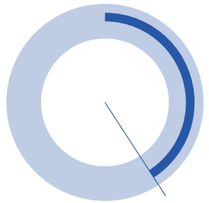
In Italy alone, about **100,000 percutaneous exposures occur each year**[3], although it has been estimated that **about 50% of injuries go unreported**, which can cause even greater impairment in the long term.

Sharps and needle-stick injuries represent the most common occupational injuries among healthcare workers, with an incidence of 41%[4].

Among these, accidental needle-stick incidents are the most significant and can occur during a wide range of procedures: blood sampling, suctioning, drugs' administration, placing catheters, handling clinical waste.

50%

of injuries go unreported



needle-stick injuries represent

41% of injuries among healthcare workers

Needle-stick injuries are suffered from **doctors**, **nurses**, **and support services personnel**, although more than two-thirds are faced by nurses[5].

For the injured worker, the **physical and emotional impact of the incident can be severe and long-lasting**: healthcare professionals and their families can experience months of anguish as they wait to discover whether they have contracted a dangerous infection.

Moreover, post-exposure prophylaxis following an occupational accident is associated with significant side effects.

A further problem is the **economic burden** of needle-stick injuries which is estimated about € 850 per event[6], **for a total of 72 million €** including only **direct healthcare costs** for diagnostics, prophylaxis, and post-exposure monitoring.

Indirect costs due to loss of productivity and workers' compensation are excluded.

In the United Kingdom, the outlay incurred by the health service for needle-stick injuries' compensation was quantified to be more than £4 million for the period 2012-2017[7].

NEEDLE-STICK INJURIES: A SERIOUS BUT AVOIDABLE RISK

Needle-stick injuries are mainly caused by the misuse of safety syringes, which means incorporating safety-engineered protection mechanisms that, after activation, provides a permanent barrier between the hands and the needle, until disposal.

Studies conducted in the EU have demonstrated **that the usage of safety devices with integrated protection mechanisms, together with training programmes for an appropriate education of the staff and the improvement of working conditions, could prevent 80% of injuries**[8]. This would significantly decrease healthcare costs, reduce stress, increase workers' productivity, and improve the patient's experience.

In the current healthcare scenario, characterized by the continuous growth in pharmaceutical innovation and the increase in chronic conditions such as diabetes, cardiovascular diseases, and autoimmune diseases, it is also important to consider the **growing role of pre-filled safety syringes for subcutaneous administration**.

The relevance of these devices is related to the use of new drugs that require special dosing accuracy and are frequently administered / self-administered at the patient's home.

One study estimated that by 2027, the worth of the **global market for pre-filled syringes** will surge from the current $5.9 billion to **about $9 billion**, at an annual growth rate of 9 percent.[9]

THE REGULATORY FRAMEWORK

In the last decade, the prevention from sharp injuries has become a high priority topic across the EU, which led to the adoption of the **Directive 2010/32/EU**[10] **on the prevention of sharps injuries in the hospital and healthcare sector**, whose aim is to provide "*the safest possible working environment through the prevention of injuries caused by all types of medical sharps devices*".

The Directive brought into law the framework Agreement negotiated by the sector's European social partners HOSPEEM (European Hospital and Healthcare Employers' Association)[11] and EPSU (European Federation of Public Services Union)[12].

In Italy, the Directive was transposed by **Legislative Decree No. 19 of February 19, 2014**[13], which amended Legislative Decree No. 81/2008 on the protection of health and safety in the workplace. The regulatory framework specifies minimum requirements the Member States must adopt to protect workers.

Measures concern: **risk assessment** (mapping of all the work areas and situations where potential for injuries exists); **adoption of appropriate preventive measures**, with particular attention to the use of medical devices with integrated safety and protective mechanisms, and the elimination of those at risk; **reporting** in case of accidents and injuries (to be taken seriously - today it is unobserved in 50% of cases); **information and training programmes** to raise awareness and provide practical instruction on the correct use of devices with integrated protective mechanisms.

STATE OF THE ART:
CRITICAL ISSUES AND POSSIBLE AREAS FOR ACTION

In February 2017, HOSPEEM and EPSU adopted a **Joint Work Program for the period 2017-2019**[14] with the aim of **monitoring the implementation of the Directive** in the EU Member States and, above all, **bringing to light the key challenges** in implementing the measures provided by the legislation.

A survey was addressed to HOSPEEM and EPSU national affiliates[15] to investigate the areas where the adoption of the Directive[16] has been proven beneficial in the prevention of sharp injuries and the existing problems in the implementation of the legislation, in order to identify ameliorative solutions to be applied in the different national contexts.

Among the most critical issues that emerged from the survey, there is the **suboptimal adoption of safety-engineered protection mechanism devices, which mainly affects Southern European countries** (Italy, Spain, and Greece).

The problem is linked to **the lack of sufficient financial resources**

39 % of hospital directors

44 % of nurses

39% of hospital directors and 44% of nurses surveyed for Italy stated that the problem is linked to **the lack of sufficient financial resources**, with the consequence - also shared by respondents from Spain and Norway - that many hospitals are still buying equipment without safety mechanisms, thus disregarding the regulatory provision. In these countries, hospitals' need to contain spending puts facilities at risk of incurring much higher costs for occupational incidents management.

A second challenge mentioned in the survey is linked to the **workforce that faces difficulties in accepting changes** in favor of more innovative devices (as reported by 68% of Italian nurses). Another problem is a **non-comprehensive coverage of training programmes** by all categories of staff potentially at risk. It refers especially to workers who are not permanently employed, such as trainees, students, and interns, as highlighted by respondents from Spain and Austria.

Moreover, **the lack of an effective system of data collection on percutaneous exposures at national level** does not allow to identify the causes and to put in place the appropriate corrective measures. The issue of underestimating the cases due to non-reporting sharps injuries emerged as particularly relevant in Italy, Spain, Germany, and Norway.

The problem is linked to the **workforce that faces difficulties in accepting changes**

68 % of nurses

The Working Group has drafted recommendations aimed at protecting healthcare personnel and patients from the risk of injury, thereby preventing the transmission of dangerous infectious diseases.

Allocation of **adequate resources for the purchase of quality medical devices and equipped with safety-engineered protection mechanism** as part of a broader strategy aimed at eliminating occupational risk, with a positive impact on healthcare facilities' budgets.

Adoption of common procedures for the procurement of medical devices and materials.

Revision of the national regulation on percutaneous exposures' reporting with the aim of reducing the number of unreported injuries and making it possible to share good practices at the European level.

Funding for training activities addressed to workers and focused on the use of the latest generation of medical devices.

SAFETY SYRINGES:
A SAFE AND EFFECTIVE WAY
TO REDUCE NEEDLE-STICK INJURIES

The World Health Organization (WHO) recommends the use of safety-engineered syringes with a re-use prevention feature[2] to eliminate or reduce as much as possible the risk of infection for workers and patients.

Promoting a safe working environment is a priority for healthcare systems today, even in view of the shortage of doctors and nurses registered in Italy as in the rest of Europe.

Syringe design and manufacturing requirements are defined by the International Organization for Standardization (ISO).

Specifically, **EN ISO 23908:2013** gives requirements and test methods for evaluating the performance parameters of sharps injury protection features, for medical devices containing hypodermic needles for single use, introducers for catheters and lancets, and other needles used in blood sampling.

As part of the European Commission's proposal for standardization of the Medical Devices Regulation 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices (IVDM) Regulation 2017/746, **EN ISO 23908:2013 is listed among the "existing harmonized standards to be revised" by May 27, 2024**, concerning "*technical solutions for safety mechanisms to be applied in the design and manufacture of devices to ensure compliance with Sections 11.1 and 22.2 of Chapter II of Annex I of Regulation (EU) 2017/745. The standard applies to devices intended to be used for the administration and/or extraction of body/blood fluids and/or medicinal substances*".

Considering the relevance of the issue of needlestick injuries, **there shouldn't be any gaps in the interpretation of MDR**, with regards to the general safety and performance requirements. This is crucial for manufacturers and to avoid uneven situations in protecting the safety of healthcare workers, patients, and community.

SAFETY SYRINGES:

1

should
be as simple as possible to use

should
require a minimal amount of force to activate

2

3

should
include an automatic safety mechanism
to avoid any potentially dangerous intervention of the worker.

Highlighting the real risk of uneven application of the regulation, the Spanish General Nurses Council and European Biosafety Network have published an **Interpretation Guide**[17] aimed at ensuring consistency in the implementation and interpretation of MDR about the requirements defined in Annex 1, Sections 11.1 and 22.2.

TECHNOLOGICAL INNOVATION FOR THE PREVENTION OF NEEDLE-STICK INJURIES

There are currently medical devices available on the market that guarantee full compliance with the quality and safety standards established by the regulations.

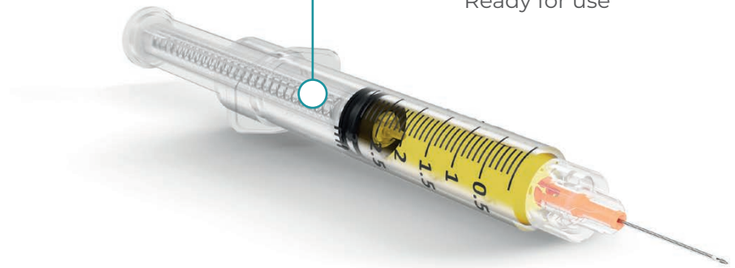
Roncadelle Operations is an Italian company that has been developing minimally invasive and safe devices for the administration/self-administration of drugs for more than two decades, making use of state-of-the-art technologies and production facilities.

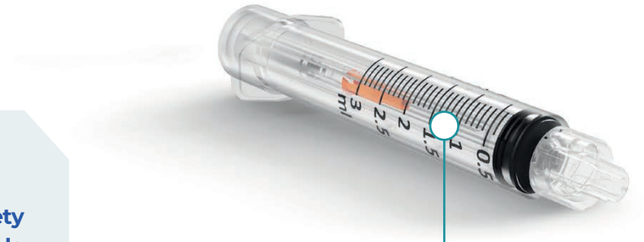
SAFER® SYRINGE

Passive safety syringe with retractable needle

Pre-injection

Ready for use





Post-injection

In safety mode

The **Safer® Passive Safety Syringe with Retractable Needle** has several safety features that ensure accurate dosing of the drug, allow the needle to **automatically** retract at the end of the injection, avoid the contact between the operator and the patient, and prevent the reuse of the device[18].

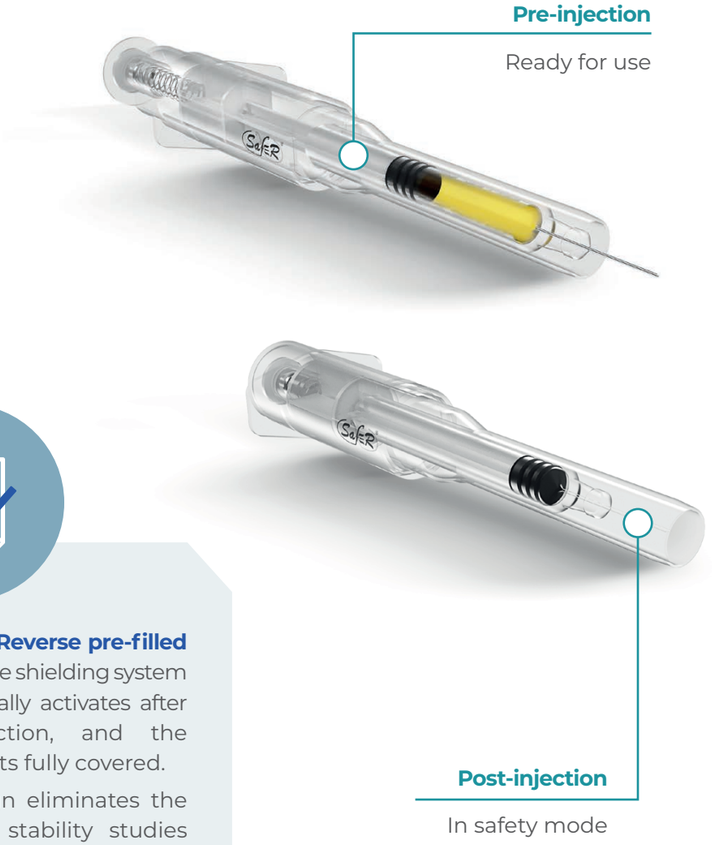
SAFER® SHIELD

Prefilled syringe

Similarly, in **Safer® Shield pre-filled syringes**, the needle gets fully covered by the shielding system on completion of the injection. In addition, since the drug only contacts the syringe during the entire shelf life, no need for drug stability studies is required[18].

SAFER® REVERSE PREFILLED SYRINGE

Retractable safety drug delivery system for pre-filled syringes



In **Safer® Reverse pre-filled Syringe** the shielding system automatically activates after the injection, and the needle gets fully covered.

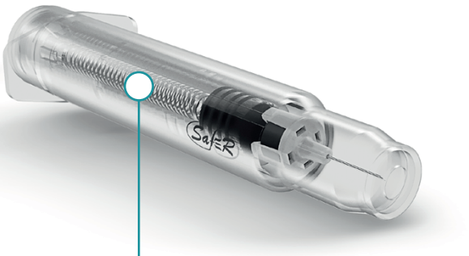
The design eliminates the need for stability studies since the drug doesn't contact anything but the syringe[18].

SAFER® CAR-GO

Retractable safety drug delivery system for pre-filled cartridges

Pre-injection

Ready for use



Post-injection

In safety mode

In **Safer® Car-GO Syringe** the entire cartridge and needle retract on completion of the injection.

Since the drug only touches the cartridge until injection, the syringe doesn't require drug stabilities studies[18].

CONCLUSIONS

To minimize the risk of needlestick injuries and protect healthcare workers and patients from potentially serious infections, the following are desirable:

1. **The consistent interpretation and universal implementation** of the Medical Sharps **Directive 2010/32/EU** and the **Medical Devices Regulation (EU) 2017/745**, as well as the **updated ISO 23908 standard** (by May 2024).

2. **The comprehensive use of safety syringe** and the elimination of unsafe devices.

3. **The introduction of nationwide surveillance** to guarantee the purchase and use of safety devices, monitor the phenomenon of accidental exposures and collects up-to-date data on needle-stick injuries.

References:

[1] Proposal for a Council Directive COM (2009) 577 Final, European Commission https://www.epsu.org/sites/default/files/article/files/COMM_PDF_COM_2009_0577_F_IT_PROPOSITION_DE_DIRECTIVE.pdf

[2] WHO, 2016: https://apps.who.int/iris/bitstream/handle/10665/250144/9789241549820-eng.pdf

[3] Puro V. et al. Aggiornamenti in tema di epidemiologia delle malattie infettive occupazionali trasmesse per via ematica. G Ital Med Lav Erg 2010: 32:3, 235,239.

[4] Survey conducted by the Italian Association of Local Health Authority Protection and Prevention Service Managers (AIRESPSA) 2002, 2004, 2006.

[5] Report by the Italian Study on Occupational Risk of HIV (SIROH), 1992 – 2010.

[6] Cazzaniga S., De Carli G., Sossai D., Mazzei L., Puro V. Il costo delle ferite accidentali da aghi e l'impatto dei dispositivi di sicurezza per la prevenzione dal rischio di punture accidentali. Mecosan n. 58, 2006.

[7] NHS Resolution. https://resolution.nhs.uk/wp-content/uploads/2017/05/NHS-Resolution-Preventing-needlestick-injuries-leaflet-final.pdf

[8] https://jahc.eu/jahc2003-002/

[9] https://www.marketresearchfuture.com/reports/prefilled-syringes-market-6167

[10] https://eur-lex.europa.eu/legal-content/IT/TXT/PDF/?uri=CELEX:32010L0032&from=DE

[11] HOSPEEM is the European Hospital and Healthcare Employers' Association. Established in 2005, it has members across the European Union, both in the state or regionally controlled hospital sector and in the private health sector.

[12] EPSU is the European Federation of Public Service Unions. It represents 8 million public service workers across Europe (including doctors, nurses, healthcare assistants, social workers, hospital cleaners) and actively intervenes in their defense on a wide range of issues.

[13] https://www.altalex.com/documents/leggi/2014/03/11/prevenzione-delle-ferite-da-taglio-o-da-punta-nel-settore-ospedaliero-e-sanitario

[14] HOSPEEM – EPSU. Follow-up on Directive 2010/32/EU. https://hospeem.org/wp-content/uploads/2019/09/HOSPEEM_EPSU_-Follow-up-Report-Directive-201032EU.pdf

[15] For Italy: ARAN-Agenzia Rappresentanza negoziale Pubbliche Amministrazioni; FIASO-Federazione Italiana Aziende Sanitarie e Ospedaliere; IRCCS Spallanzani

[16] Risk assessment – Elimination, prevention, and protection – Information and awareness raising – Training – Reporting – Response and Follow-up

[17] https://www.europeanbiosafetynetwork.eu/wp-content/uploads/2021/04/MDR-Sharps-Injuries-Guidance.pdf

[18] https://www.roncadelle-operations.com/solutions/

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