



Roncadelle
Operations

SAFEGUARD HEALTHCARE WORKERS FROM INFECTIONS!

DRIVING INNOVATION TO COUNTER
A GLOBAL PRESSING CHALLENGE

The use of innovative passive safety syringes
and needle protection systems in response
to a global healthcare challenge

INTRODUCTION

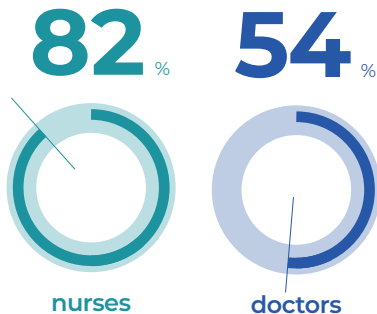
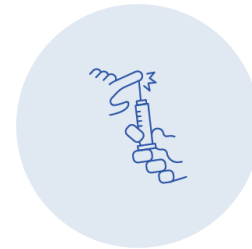
Healthcare Professionals face considerable risks stemming from blood-borne pathogens, a concern exacerbated by their frequent exposure to human blood. The multifaceted nature of human blood, harboring more than 20 diverse bacterial, viral, and fungal agents¹, underscores the potential hazards. Among the diseases spread through blood exposure, notable ones include AIDS, hepatitis B, and hepatitis C, heightening the urgency for robust mitigation strategies.

3
million

occupational
exposures
annually

Needle-stick injuries (NSIs) are the major cause of exposure to these diseases. According to the World Health Organization (WHO), an estimated **16 billion injections** are given to patients globally each year and approximately **3 million occupational exposures** occur among 35 million workers annually².

Blood-borne diseases contribute to multifaceted societal challenges, encompassing clinical, financial, and emotional dimensions. These challenges reverberate with far-reaching implications, impacting not only the well-being of patients but also the resilience of healthcare systems.



In **Europe** alone, there are **over 1 million** needle-stick injuries annually², and the situation has even worsened because of the **pandemic, with an estimated growth of 276,000 cases (23%)** in the year 2020³. In most countries, **nurses (82%)** and **doctors (54%)** have experienced the highest increase³.

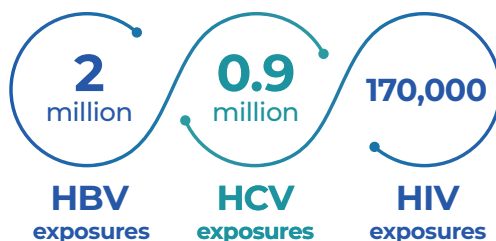
This Paper summarizes some of these burdens due to blood exposure and needlestick injuries, heightening the necessity for enhanced measures to safeguard against their transmission. The opportunity to prevent viral infections and their potential reduction by improving personal safety supports the wide adoption of safe and easy-to-use instruments.

OCCUPATIONAL HAZARDS AND ADHERENCE TO PROTECTIVE MEASURES AMONG HEALTHCARE WORKERS

The domain of healthcare services is spearheaded by a cohort of professionals ranging from nurses and physicians to laboratory technicians, all of whom are intricately linked to the provision of patient care. This diverse **workforce is regularly exposed to varying degrees of risk while carrying out their duties**, with potential hazards encompassing encounters with disease-causing agents such as Sars-CoV-2 (COVID-19), human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hepatitis B virus (HBV)^{4,5}. Additionally, the emergence of blood-borne pathogens like the Ebola virus during the 2013-2016 outbreak underscores the complexities of occupational hazards, with a staggering fatality rate among healthcare workers in Africa⁶.

The pathways of occupational exposure to pathogens are diverse, including percutaneous injuries and mucous membrane contact. Pertinently, a substantial **66-95%** of exposures to **blood-borne pathogens** in **hospital settings** manifest through **percutaneous injuries**, further emphasizing the necessity of safeguards against such incidents⁷.

Unfortunately, the global landscape concerning exposure to blood-borne pathogens remains mired in outdated information. A report from WHO estimated annual occurrences of **2 million HBV, 0.9 million HCV**, and **170,000 HIV exposures**, yielding an alarming incidence of infections coupled with subsequent **psychological distress, depression, and escalating management costs**^{8,9}.

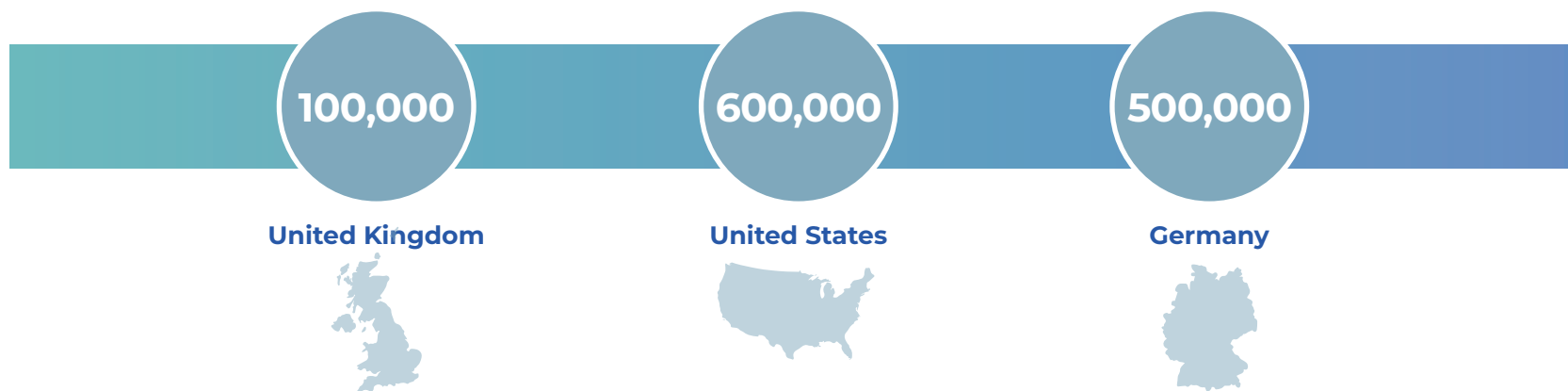


The spectrum of blood and body fluid exposures has been scrutinized across multiple nations. In the **United Kingdom**, the yearly exposure rate was quantified at **100,000**, while the **United States** reported a staggering **600,000** annual exposures^{10,11}.

Evidently, the challenge is not limited to these regions; **German hospitals account for 500,000** NSIs annually¹². Even as COVID-19 vaccinations are being diligently administered worldwide, the imperative of adhering to personal protective equipment remains unchanged⁵.

The **emergency department stands as a nexus of heightened risk**, marred by the confluence of blood and body fluid exposure and the ever-present peril of sharp object injuries¹³. The urgency, high workload, fatigue, and tension characteristic of this setting potentiate the occupational burden among emergency department personnel¹⁴.

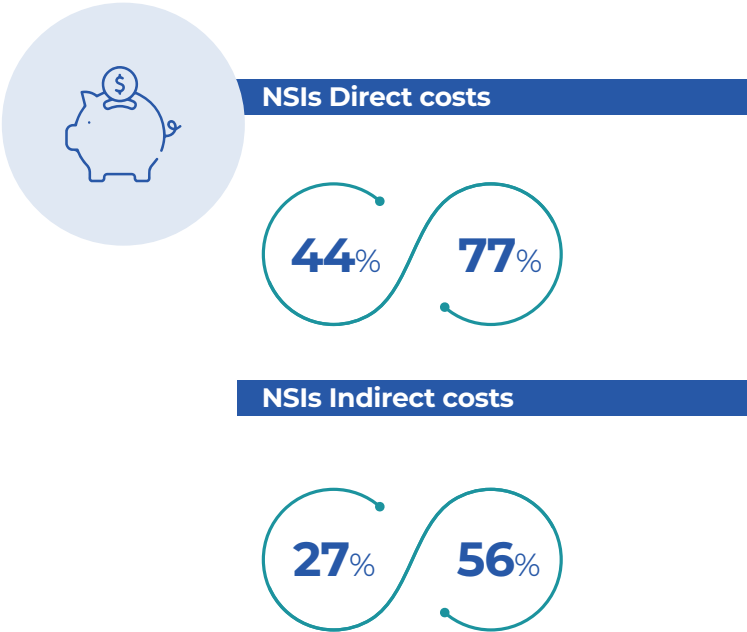
Yearly exposure rate :



The diversity of exposure patterns, strongly influenced by regional sociocultural and economic differences, underscores the importance of urgent action. The opportunity to prevent viral infections and their potential reduction by improving personal safety justifies the wide adoption of safe and easy-to-use instruments. In addition, the diverse characteristics of hospitals, from educational functions to patient loads, underscore the need for a tailored approach.

Roncadelle's passive safety syringes and needle protection systems, together with Roncadelle's customized training program, provide an effective and sustainable solution to protect healthcare workers while saving costs.

Studies detailing both direct and indirect costs reveal that **expenses attributed to NSIs** range between **44% and 77% of direct costs** and **23% to 56% of indirect costs**¹⁵. Among the direct costs, the primary cost drivers are post-exposure prophylaxis medications, accounting for 54% to 96% of average direct expenses. Individuals employed within the healthcare sector may encounter significant emotional and mental ramifications following a NSI, potentially leading to job loss and post-traumatic stress disorders (PTSD)¹⁵. The repercussions on individuals within the healthcare system and the psychological effects of NSIs in the United States and Europe are associated with a reduction in productivity and working hours¹⁵.



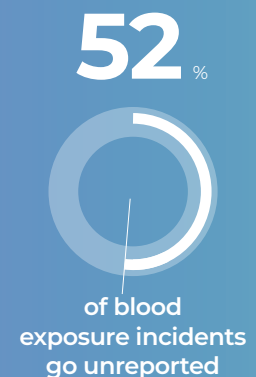
IMPLICATIONS AND STRATEGIES FOR MITIGATION

The heightened vulnerability associated with exposure to bloodborne pathogens underscores the necessity for enhanced measures to safeguard against their transmission. **This exposure encompasses risks that span clinical, economic, and emotional dimensions, warranting comprehensive attention and intervention.**

Clinically, the ramifications of bloodborne pathogen infections are particularly pronounced among healthcare professionals who encounter blood or mucocutaneous incidents. Among these, **nurses, medical students, and physicians are most vulnerable.** The potential for seroconversion following a singular percutaneous encounter with infected blood is quantified as follows: approximately 2% for hepatitis C, and 6–60% for hepatitis B. Similarly, the risk of seroconversion to HIV posts a single percutaneous exposure to HIV-infected blood stands between 0.1–0.3%².

Despite the established guidelines mandating personal protective equipment employment, **adherence remains suboptimal.** Empirical studies have underscored that compliance rates among healthcare professionals, encompassing nurses, nurse aides, and physicians, merely reached **67%** in 2012, although an improvement from previous records¹⁶.

Underreporting compounds the issue further. Research indicates that more than **52% of blood exposure incidents** have gone unreported as occupational accidents¹⁷. Economically, the costs associated with blood exposure incidents are heightened, particularly when ensuing infections necessitate treatment. The financial implications extend significantly to healthcare establishments and professionals. Beyond the fiscal impact, healthcare workers who encounter blood exposure are additionally burdened with emotional distress, fear, and anxiety stemming from the potential for seroconversion¹⁸.



NEEDLE-STICK INJURIES: A PREVALENT CONCERN

An elevated prevalence of needle-stick injuries underscores the need for addressing this occupational hazard. This issue is especially pertinent for medical practitioners, nurses, and medical/nursing students. Statistical evidence shows that **35%** of occupational exposures **occur during training**, with an additional **27%** affecting **experienced nurses**¹⁹.

The reporting of these injuries by healthcare workers varies, ranging from 9% to 38%. The incidence of NSIs is most prevalent among individuals engaged in close clinical interactions with patients or patient specimens²⁰.

Underreporting of these injuries is pervasive, with **38% of cases going unreported** to occupational health or emergency departments²¹.

Similar to blood exposure, the **emotional implications of needlestick injuries are substantial**. Up to 12% of medical professionals who endure needlestick injuries during their training exhibit signs of Post-Traumatic Stress Disorder (PTSD)⁸.

Elevated prevalence of needle-stick injuries for

**medical practitioners, nurses,
medical/nursing students.**

35 % during training



27 % experienced nurses



38 %



of cases go unreported

A STRATEGIC APPROACH: FOSTERING AWARENESS

The mitigation of needlestick injuries and blood exposure hinges on proactive education and heightened awareness. An optimal healthcare worker safety protocol, structured around three core components, strives to elevate safety standards, and reduce needlestick injuries. This comprehensive approach is designed to enhance overall safety within the healthcare environment.

- 1. Risk Recognition:** identification of potential hazards, risk assessment, and subsequent formulation of recommendations.
- 2. Utilization of Safety-Engineered Devices:** concurrent use of safety-engineered medical equipment coupled with thorough training.
- 3. Education and Training:** a focus on continuous learning and education.



The imperative of healthcare worker safety resonates as a collective concern, necessitating a concerted effort from all stakeholders to attenuate risks, enhance outcomes and alleviate burdens.

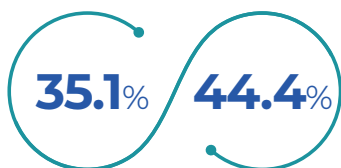
NEEDLE-STICK INJURIES: A ‘POPULATION’ OF HEALTHCARE WORKERS AT RISK

Needle-stick injuries’ incidence varies by healthcare setting and occupation.

In the **United States^a** between **35.1% and 44.4%** of the injuries occur in the **operating room**, mostly affecting physicians (up to 58%). Around **25%** is experimented by **workers other than the ‘original users’ of the device²²**; this suggests that the risk of injury is further extended during device disposal, impacting other professionals such as surgical technicians, environmental services, laundry, and sterile processing personnel. As in the US employment in healthcare occupations is expected to grow 15% from 2019 to 2029, adding about 2.4 million new jobs²³, a huge number of workers will be potentially at risk if adequate measures and safe devices are not adopted.

United States

injuries in the operating room



In **Germany**, about **50%** of NSIs occur **during the disposal** of the instruments after the invasive procedure²⁴.

A study in **Poland**²⁵ showed that **72.6%** of NSIs are recorded in hospitals, especially **among nurses**, as well as in **Italy** where more than two-thirds of injuries are faced by these workers²⁶.

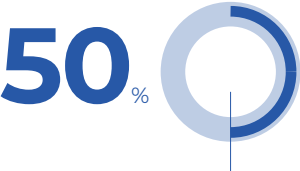
Globally, **35% of nursing students**²⁷ suffer from injuries, mainly taking place in clinical settings, for instance when administering injections or taking blood samples. 62.9% of them did not report their injuries.

Despite the high incidence, **underreporting** - estimated about **50%** of the injury events² - **is still a big issue that needs urgent addressing**. A study in Portugal detected a 45% underreporting of percutaneous injuries, whose main reasons were the underestimation of transmission risk (49%) and bureaucracy (41%)²⁸. Hence, it is crucial to promote awareness-raising among healthcare workers.

Because healthcare workers and their patients share the same physical environment, **protecting hospital personnel provides benefits to patients**.

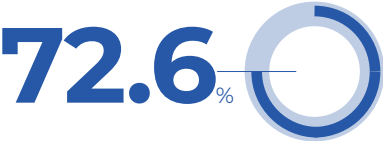
Germany

injuries during the disposal of the instruments



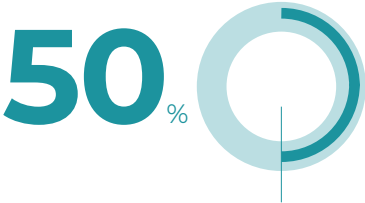
Poland

injuries among nurses



Globally

injuries among nursing students **unreported injuries**



ALSO BEYOND THE HOSPITAL SETTING

Health systems worldwide are coming under increased financial pressure, with healthcare expenditures - especially for hospital care - taking an ever-bigger chunk out of countries' GDPs. On the other hand, the aging population has resulted in a rise in chronic conditions such as diabetes, heart diseases and cancer, requiring for long-term care.

Healthcare is increasingly provided outside of hospitals, such as practitioners' offices, patient homes, rehabilitation centers, long-term care facilities, pharmacies.

40% of hospitals are expected to have shifted 20% of their beds to the patient's home by 2025²⁹. Today in the US, more than **two-fifths of nurses** are employed in **non-hospital settings**, and an estimated **7.5 billion syringes** are used in the **homecare environment** every year^{30,31}. This shift is expected to grow in the future, both across Europe and the US.

In Germany, 30% of all NSIs are caused by needles for subcutaneous injections and in **care facilities** the proportion is above **50%**²⁴.

nurses are employed in **non-hospital settings**



7.5

billion syringes
used in the homecare
environment annually

AT HIGH COST TO HEALTHCARE SYSTEMS AND SOCIETY

In the **United States**, needle-stick and sharp injuries affect more than 500,000 healthcare personnel annually, leading to over **\$1 billion in avoidable healthcare costs**³².

In **Germany**, according to a study held in a university hospital, the economic costs per NSIs varies from **€500 to €1,600**³³.

In the **UK** alone, around 1,200 successful incident claims for NSIs between 2012-2017 costed the NHS more than **£4 million** (about €4,602), equivalent to the annual salaries of 125 band 5 nurses (newly qualified nurses or staff nurses working in a hospital setting)^{34,35}. In the US, the Occupational Safety and Health Administration (OSHA) fines for the employers **more than \$13,260 per violation** (OSHA, 2018).

Regarding the testing costs for healthcare workers who had experienced a needle-stick injury, a Swedish study estimated an **annual cost offset of €850,000 with the introduction of safety-engineered needles** across the Swedish population³⁶.

850,000 €

annual cost offset with the introduction of safety-engineered needles

United States

1 billion \$
in avoidable healthcare costs

Germany

injuries in the operating room



13,260 \$
fines per violation

Costs of NSIs impact on a human and organizational level, both direct and indirect^{37,38}:

Direct costs



Laboratory testing for infection in the injured worker and, if known, the patient on whom the needle had been use.



Post-exposure prophylaxis to prevent or manage bloodborne virus transmission.



Short and long-term treatments of chronic bloodborne viral infections (e.g.: in the US, the initial cost of medications for HCV can be more than \$25,000)



Counselling for injured workers.



Absence of exposed workers and replacements.



Legal consequences (litigation and compensation claims).

Indirect costs

Side effects of antiviral drugs causing suffering to employees and their families.



Increased stress and post traumatic disorders that impact on social functioning.



Loss of productivity.



Reputational damage for healthcare facilities.



THE HIGHER THE SAFETY, THE LOWER THE RISK OF INFECTION AND THE HIGHER THE COST SAVINGS

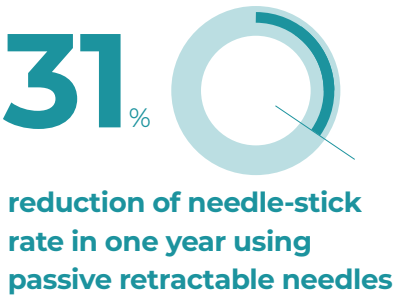
Switching from active syringes (which require the user to slide a shield over the needle after use) to passive needle safety devices (which do not require any active motion by the healthcare providers as the devices automatically and instantly retract the needle from the patient into the barrel of the syringe once the medication is delivered) demonstrated an effective strategy to generate cost avoidance.

This is the case of BJC Healthcare academic facilities (St. Louis, Missouri), where the existing active safety devices were removed and replaced with the same size passive retractable needles. The cost impact was immediate as the systemwide **needle-stick rate fell 31% in one year**³⁹. Cost saving was generated by avoiding laboratory tests and the analysis needed for both source patients and employees for up to 12 months depending on the nature of exposure; exposed employee hours for reporting and testing; HIV post-exposure medications, typically a 28-day regimen³⁹. During the 24-month pre-implementation period, 404 needlesticks with active devices were reported, with a rate of 0.58 injuries per 100,000 productive employee hours. During the 12-month implementation period, 160 needlesticks were reported for a rate of 0.46 injuries per 100,000 productive hours. It was calculated an **overall cost saving avoidance of \$11,000**³⁹.

Moreover, passive syringes facilitate waste management, as no special waste containers are needed and the syringes can be disposed of in the normal "household waste".

Not to mention the **priceless value of the absence of anxiety and fear** that can accompany exposure to a patient infected with a bloodborne pathogen, let alone subsequent seroconversion.

The higher the safety, the lower the risk of infection and the higher the cost savings.



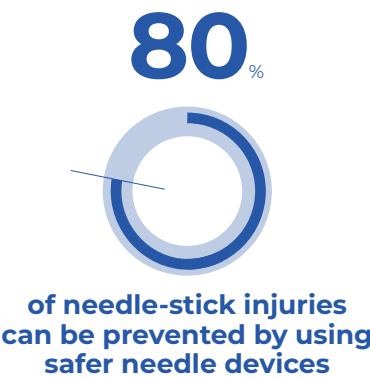
EXPOSURE TO NEEDLE-STICK INJURIES IS NOT “PART OF THE JOB”

One of the main causes of needle-stick injuries is not using safety syringes², which means incorporating safety-engineered protection mechanisms that, after activation, provides a permanent barrier between the hands and the needle, until disposal.

One study from 2007⁴⁰ reported a **93% reduction in relative risk of percutaneous injuries** in areas where safety syringes were used. According to the United States Occupational Safety and Health Administration (OSHA), **over 80% of needle-stick injuries can be prevented by using safer needle devices**, which, in conjunction with workers education and work practice controls, can reduce injuries by **over 90%**⁴¹. This would significantly decrease direct and indirect post-exposure medical costs, minimize litigation, reduce stress, increase workers' productivity, and improve the patient's experience.

Given to continuous growth in pharmaceutical innovation and the increase in chronic conditions such as diabetes, cardiovascular and autoimmune diseases, it is also important to consider the **rising role of pre-filled safety syringes for subcutaneous administration**⁴².

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%⁴³.



NEEDLE-STICK LEGISLATION: THE KEY ROLE OF SAFETY-ENGINEERED DEVICES

The **United States** have been the first nation-state to make a specific legislation to reduce percutaneous injuries. The **Needlestick Safety and Prevention Act (NSPA)**, approved at the end of the year 2000, revised the Occupational Safety and Health Administration (OSHA) bloodborne pathogens standard, requiring the implementation of a set of interventions, including healthcare facilities to provide safety-engineered devices (SEDs) to healthcare workers⁴⁴. The global effect was an immediate **drop of about 38%** in 2001 when the NSPA took effect⁴⁵.

A decline in the rate of NSIs due to the impact of legislation and consequent SEDs adoption is backed up by different researches^{46,47}, but they also found that a considerable proportion of injuries associated with these devices as the safety function in a majority of currently available SEDs is not passive.

Between 2010 and 2014, many countries, including the **European Union**, passed similar legislations that mandate health facilities to provide SEDs to workers to reduce the risk of NSIs. The **Directive 2010/32/EU**⁴⁸ on the “Prevention of sharps injuries in the hospital and healthcare sector”, was aimed to provide “the safest possible working environment through the prevention of injuries caused by all types of medical sharps devices”.

The Directive mandates the adoption of appropriate preventive measures, with particular attention to the **use of syringes (medical devices) with integrated safety and protective mechanisms, and the elimination of those at risk** (ISO 23908 standard defines the safety requirements to be applied in the design and manufacture of devices to ensure compliance with the EU Regulation⁴⁹).

Every country has applied the Directive, with varying degrees of compliance⁵⁰. The Directive have been fully implemented in the Netherlands and in Poland. In Spain, all the aspects of the Directive where transposed into national legislation; some Regions have legislated more rigorously than others. In Italy, all the Directive requirements were implemented, with, however, only a partial conversion from conventional devices to those integrating a safety mechanism⁵¹.

BARRIER TO IMPLEMENTATION: COST CONSTRAINTS AS AN ISSUE TO OVERCOME

Over the last years, intensive efforts have been invested to curb NSIs, but there's still a way to go. One of the main issues limiting the adoption of syringes with integrated safety and protective mechanisms, and the elimination of those at risk, is **the lack of financial resources**⁵⁰. Extensively in Europe, there is competition between cost and safety, as the swapping out the devices lead to an expenditure increase in the very short term (however, more than offset in the medium to long term by the decline in needle-stick rates³⁹).

To assess the level of implementation of the Directive, a national survey was conducted in **Italy** in 2017 and again in 2021, involving altogether 285 safety managers (SM) and 330 nurses from representative sample of 97 (2017) and 117 (2021) public hospitals⁵¹. In none of the investigations there was a total replacement of conventional devices with their safety counterpart: in 2017, conventional devices were totally replaced according to 48% of nurses and 42% of SM; in 2021, the corresponding figures were 47% and 59%, respectively, and 31% according to hospital pharmacists. As in other European studies⁵², **costs** were identified as one of the main reasons for not replacing conventional devices (pharmacists 29%, SM 25%). Furthermore, pharmacists and SM indicated difficulties in **ordering safety devices**. Device purchases are currently made through regional tenders, and safety features may not be included, or not be prioritized within the required characteristics, depending on the choices of the committee developing the tender. In 2021, the respondents also reported that they had **not received requests from hospital wards** (28% according to pharmacists, and 10% according to SM).

There's the need for a renewed commitment to guarantee that workers are offered an adequate level of protection, by ensuring the availability of the best and securest devices for the procedures being performed by healthcare for patients. At Roncadelle, we are committed to enhance patients' safety and provide healthcare professionals with advanced tools for precise and secure injections.

Conventional syringes' replacement in Italy

2017
42-48%



2021
47-59%

Reasons for not replacing conventional devices

- **costs**
- **ordering safety devices**

HEALTHCARE SAFETY: WHAT IS POSSIBLE?

The purchase of quality syringes and equipped with safety-engineered protection mechanism is a central part of the strategy aimed at eliminating occupational risk, with a positive impact on healthcare facilities' budgets.

Cost analysis



Consistent with this purpose, **selecting a safe device based exclusively on the lowest price is not appropriate**. As examined in the previous sections, the costs of NSIs to the healthcare facility and the personnel, direct and indirect, can be immense and the only way to mitigate these costs is through the prevention of injuries. **Safety-engineered syringes can reduce costs**.

Selection process

Safety syringes selection should meet the following criteria:

- Be as **simple as possible to use**.
- Require a **minimal amount of force to activate**.
- Include an **automatic safety mechanism** to avoid any potentially dangerous intervention of the worker.
- Ensure **patient's safety and comfort**.



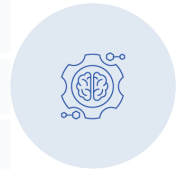
Mindset change

Support workers to accept changes in favor of the use of more innovative devices by:

Enhancing the **perception of risk** associated to needle-stick injuries.

Clarifying the **perceived benefit** of advanced tools.

Training on **how to use** the latest generation of medical devices.



To achieve this goals, **medical device manufacturers play a very important role** by developing innovative technologies with safety mechanisms as well as sustaining education and training on how to use them.



PRIORITIZING HEALTHCARE SAFETY: SAFER® SOLUTIONS

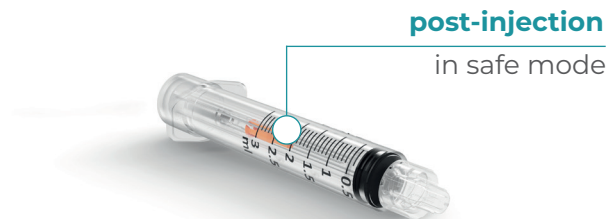
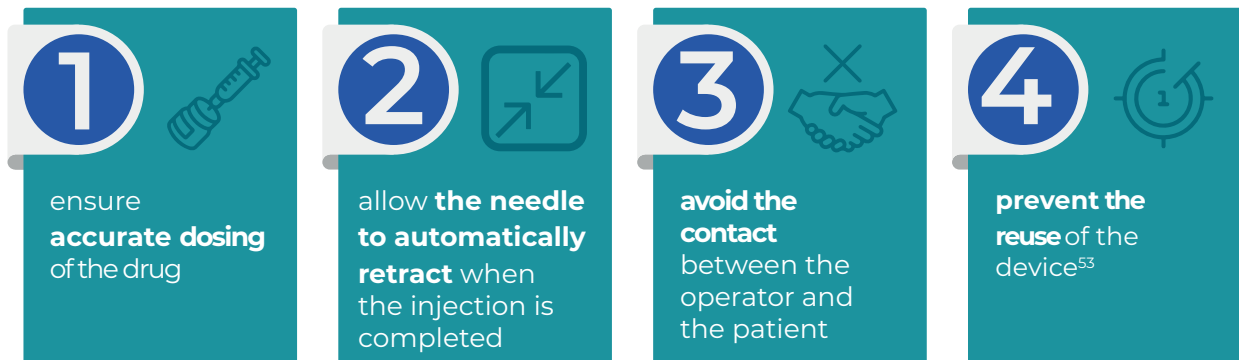
Roncadelle Operations' innovative solutions prioritize healthcare safety by providing professionals with advanced syringes for precise and secure injections, totally compliant with regulatory standards.

The company has been developing and manufacturing 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

Very easy to use, the **Safer® Passive Safety Syringe with Retractable Needle** works in just the same way as a classic syringe, but with one-click coaxial needle retraction, it automatically retracts the needle at the end of the injection.

Its safety features:



SAFER® SHIELD

Safer® Shield pre-filled Syringes is the innovative needle-shield system, specifically designed for pre-filled syringes. The needle gets fully covered by the shielding system on completion of the injection, minimizing the risk of needle-stick injuries during the administration of liquid medications for chronic diseases or vaccinations.

1



Since the drug only contacts the syringe during the entire shelf life, **no need for drug stability studies** is required.

2



With the needle-shield systems in place, users can experience **enhanced security and confidence** with every dose administered⁵³.

pre-injection
ready for use

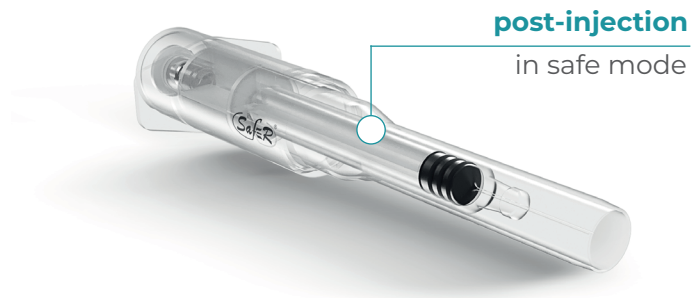


post-injection
in safe mode



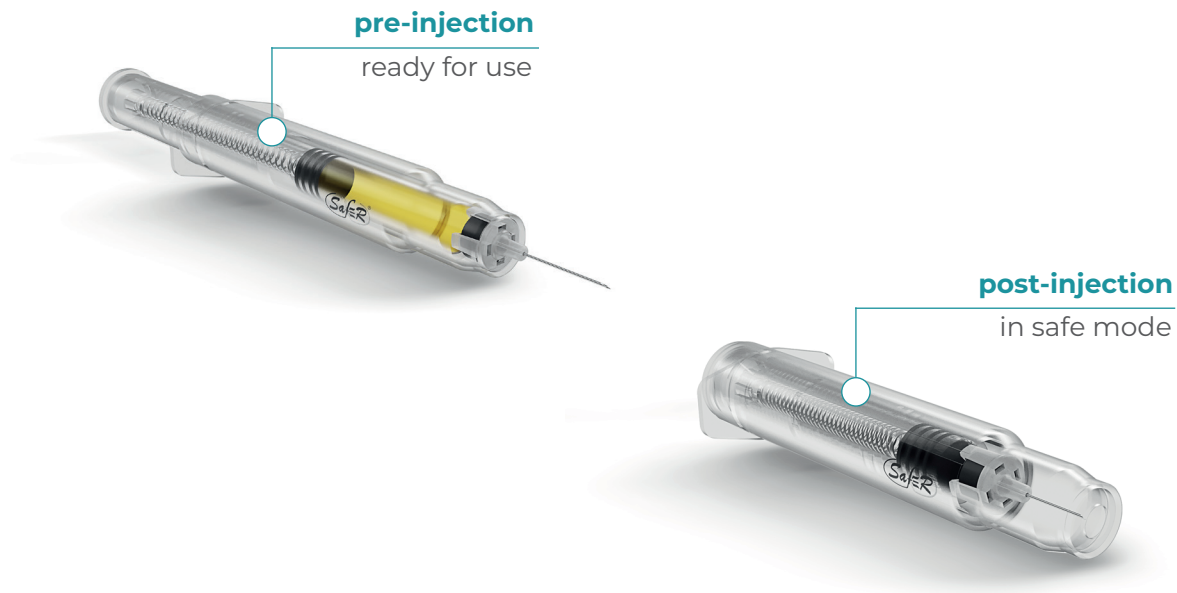
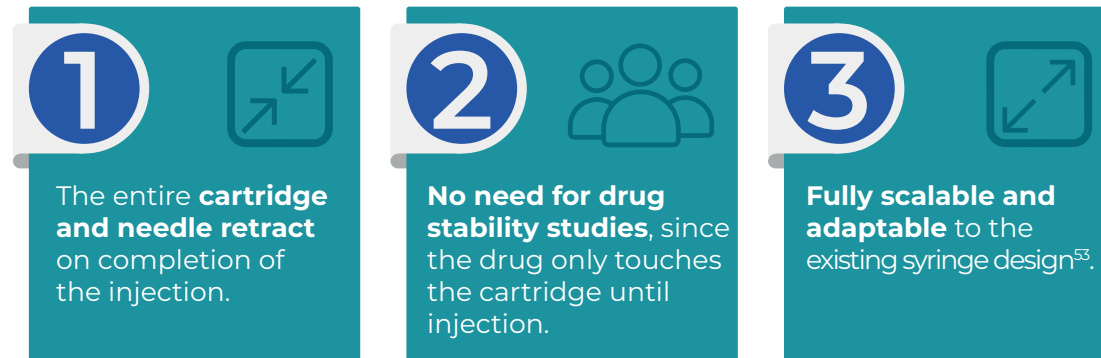
SAFER® REVERSE PREFILLED SYRINGE

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 syringe⁵³.



SAFER® CAR-GO

SafeR® Car-Go Syringe is the innovative medical safety secondary packaging design for use with drug-filled cartridges.







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