

# SAFETY ENGINEERED DEVICES IN THE HOSPITAL SETTING: THE ITALIAN MARKET



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## Background

As needles constitute a risk for healthcare workers, many safety engineered devices (SEDs) have been marketed in Italy over the past few years. However, marketing rules do not clearly state safety mechanism standards and there are no evidence based data demonstrating effectiveness between different protective mechanisms. Therefore, selection of SEDs for hospital introduction can be challenging for the pharmacist.

## Purpose

To analyse the Italian SED market.

## Material and methods

Technical information on SEDs was collected by research on a national database using a code that identified all medical devices (with or without safety mechanisms). When not available, documentation was obtained through direct contact with the manufacturers and web consultation.

Classification of medical devices according to medical procedure

Research on a national database (NSIS) using the CND code

Direct contact with manufacturers and healthcare workers



Figure 1. Material and methods

## Results

134 SEDs were divided according to medical procedure and different types of safety activation mechanisms: active, including toppling shield (TS), sliding protection (SP) or by button pushing (BP), and passive (P). For **venous blood sampling**, 17 butterfly needles were divided into 3 different safety activation mechanisms: TS (1 SED), SP (11 SEDs) and BP (5 SEDs); 6 syringes with needles: SP (3 SEDs) and BP (3 SEDs); and 7 hypodermic needles: TS (6 SEDs) and SP (1 SED). **Arterial blood sampling** (5 devices): TS (3 SEDs), SP (1 SED) and recapping mechanism (1 SED). **Capillary blood sampling** (12 lancets): P (12 SEDs). For **administration**, 18 butterfly needles: TS (1 SED), SP (12 SEDs) and BP (5 SEDs); 10 syringes with needles: SP (6 SEDs) and BP (4 SEDs); 7 hypodermic needles: TS (6 SEDs) and SP (1 SED); and 4 pen needles: P (4 SEDs). **Vascular catheterisation** (26 devices): SP (1 SED), BP (1 SED) and P (24 SEDs). **Central catheterisation** (10 Huber needles): SP activated with either one (3 SEDs) or two hands (7 SEDs). **Others** included 6 single use scalpels (6 SP) and 6 fistula needles (2 SP and 4 BP). Overall, passive mechanisms represented 31% of devices. The mechanism was not always clear (5% erroneously reported).

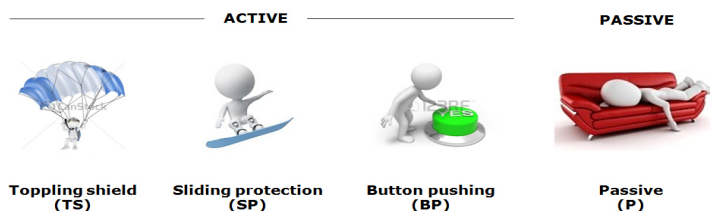


Figure 2. Different types of safety activation mechanisms



Figure 3. Examples of safety engineered devices

Medical Procedure	Device	Mechanism	Count	
Venous blood sampling	Butterfly needles	TS	1	
		SP	11	
		BP	5	
	Syringes with needles	TS	3	
		BP	3	
	Hypodermic needles	TS	6	
		SP	1	
	Arterial blood sampling	EGA syringes	TS	3
			SP	1
Recapping		1		
Capillary blood sampling	Lancets	P	12	
Central catheterisation	Huber needles	Activation with 1 hand	3	
		Activation with 2 hands	7	
Administration	Butterfly needles	TS	1	
		SP	12	
	Syringes with needles	SP	6	
		BP	4	
Hypodermic needles	TS	6		
	SP	1		
Pen needles	P	4		
	Vascular catheterisation	SP	1	
BP		1		
P		24		
Others	Single use scalpels	SP	6	
		SP	2	
	Fistula needles	BP	4	

Table 1. SEDs divided according to medical procedure and different types of safety activation mechanisms

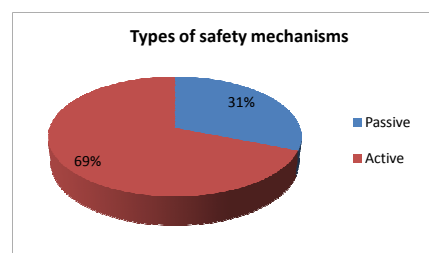


Figure 4. Percentage of active and passive safety activation mechanisms

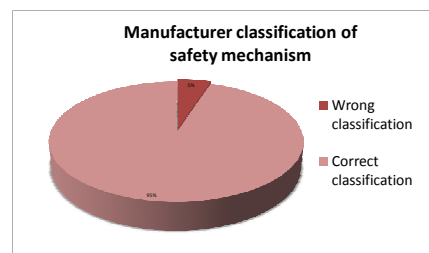


Figure 5. Percentage of erroneously reported safety activation mechanisms by manufacturers

## Conclusion

As many critical points were identified in the evaluation of SEDs, which could mislead the pharmacist in the choice of the device, a database has been built as a clear instrument to easily access all SED information.

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