

**Carefully Crafted**



## **K-Pack Surshield™**

Hypodermic needle with integrated  
passive sharps protection

# Passive and encapsulating sharps protection technology

**Dedicated to the pharmaceutical industry, K-Pack Surshield™ is a hypodermic needle with an integrated sharps protection feature for use with (pre)-filled syringes. The device geometry is designed to allow for automated manipulations during the packaging process, making it ideal for bundling and inclusion into the secondary packaging of parenteral medication by subcutaneous or intramuscular injection.**

Designed in particular for subcutaneous and intra-muscular injection applications, a route of administration for many parenteral pharmaceutical and biopharmaceutical drugs, K-Pack Surshield™ is a hypodermic needle with a passive actuated feature that aims for protection against accidental needlestick injury and hence reduced transmission risk for patient-associated pathogens from needlestick injuries.

The encapsulating protection feature is integrated with the needle and therefore the needle is never exposed, not before, during or after injection. As a truly passive system, the protection mechanism is 'armed' during needle insertion, thus the protection system cannot be bypassed. The needle fits to (pre)-filled syringes with standard 6 % luer slip and 6 % luer lock conical fittings.

With K-Pack Surshield™, Terumo offers the pharmaceutical industry a tailored technological solution to provide their customers and patients with injection equipment that includes features for the prevention of needlestick injuries. K-Pack Surshield™ has its own regulatory status as a medical device.

## Product features & benefits

### *User criteria and benefits*

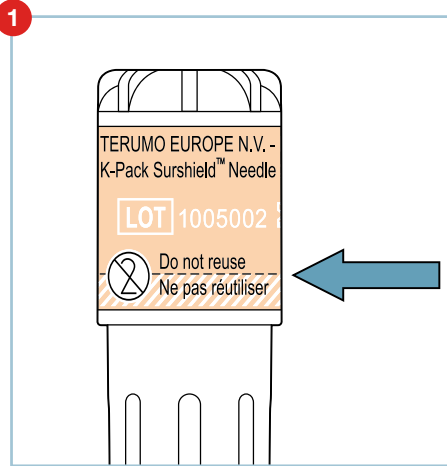
- Truly passive system; easy to use
- Efficient and permanent cover of the sharps
- Not possible to skip a crucial step to activate
- Needle sharps not exposed, before, during and after injection
- Does not require more time to use
- Clear view of syringe contents and access to syringe label
- Permanent and visual indication of activation
- Ergonomics appropriate for injection technique
- Terumo's T-Sharp™ needle technology aims to contribute to patient's comfort

### *Manufacturing perspective*

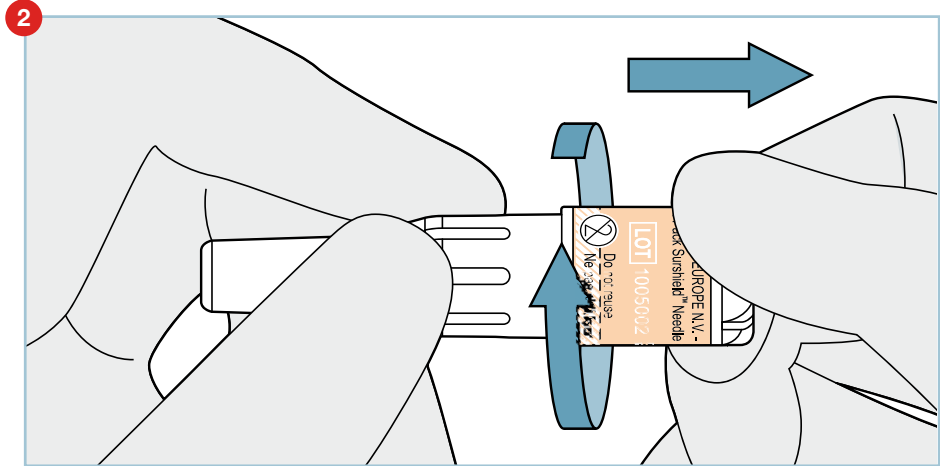
- Compact design, individually packed, requiring minimal space
- Product configuration suited for automated manipulations
- Colour coding on tamper-evident label, for in-line product detection by vision systems
- Does not require an additional assembly step
- Validation achievements by Terumo can help to reduce the efforts of our customers on own product and process validation works
- Own regulatory status as a medical device (time-to-market)
- Safety feature activation does not require interaction with the syringe; does not affect the syringe performance (e.g. dose accuracy)
- Provided by a global operating company with core competences in needle manufacturing

## Quick start

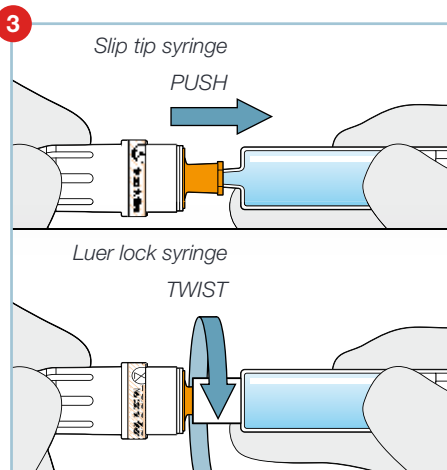
Six easy steps



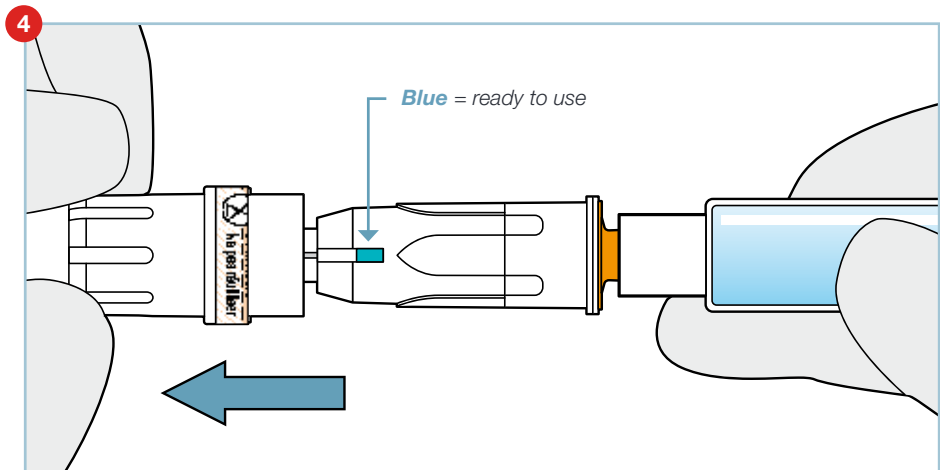
Verify tamper-evident label is sealed



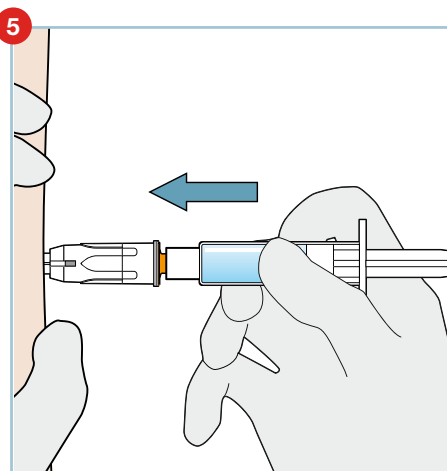
Remove cap



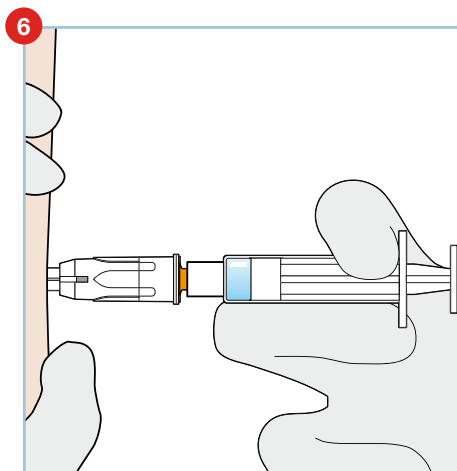
Attach syringe



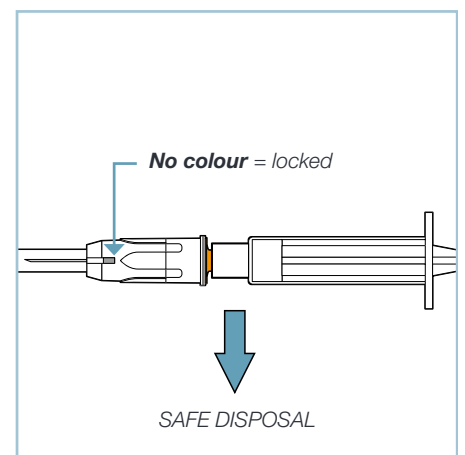
Remove case



Insert needle



Inject



No colour = locked

SAFE DISPOSAL

This Quick Start is provided on an "as is/as available" basis, it is not intended to be used as a comprehensive medical advice, but only for illustration purposes on the major information provided with the product and without the representation, warranty or liability of any Terumo entity. Images are of illustrative purpose only and might deviate from the final product. For more details, please refer to the instructions for use delivered with the products concerned.

## General Specifications

K-Pack Surshield™ is intended for subcutaneous and intra-muscular applications.

Specification	Description
Needle Point	Lancet point (3-bevel)
Cannulae	Stainless steel X5CrNi 18-10
Hub	Polypropylene
Conical fitting	ISO 594-1 (EN 20594-1) / ISO 594-2 (EN 1707) (named standards will be replaced by ISO 80369-7)
Individual packaging	Rigid packaging with tamper-evident label
Shipping carton	1500 pcs.
Method of sterilization	Ethylene Oxide
Shelf Life	5 years

K-Pack Surshield™ fulfils the requirements of:

- EN ISO 7864 Sterile hypodermic needles for single use
- ISO 23908 Sharps injury protection requirements and test methods: Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

**CE** 0197 *Devices have no components made of natural rubber latex or PVC.*

## Ordering Information

Depending on the intended use, please contact us for any specific requirements and needle sizes.

Product Code	Label color	Hub color	External diameter of the cannulae		Needle length
			Gauge	mm	mm
KN-S2516RB	Salmon 	Orange	25G	0.5	16
KN-S2713RB	Grey 	Grey	27G	0.4	12



Please note that some products may not be available in all regions, check with your local TERUMO Pharmaceutical Solutions contact for details.



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*Contact details are subject to change,  
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