

RAUMEDIC AG

RauSafe®: Award winning needle-safe prefilled syringe

THE CHALLENGE >

The EU Needle Safety Directive and USA Needlestick Act both came into force in order to protect healthcare workers from needlestick injury. Many existing drugs, particularly vaccines, had been supplied in staked-needle prefilled glass syringes. But as these did not meet the new needle safety legislation, pharmaceutical companies faced lengthy and costly processes to revalidate their drugs in new needle-safe primary pack delivery devices.

Raumedic AG recognised the need for a needle safety device that could be retro-fitted to existing primary packs, avoiding the need for revalidation and allowing pharma companies to avoid a costly gap in supply and revenues.

THE SOLUTION >

Raumedic AG and Cambridge Design Partnership developed a solution in just five months, so that when the EU regulation came into effect the new product was ready for use.

Working in partnership, we developed RauSafe; a novel needle safety device design for prefilled syringes. Our work included:

- Technology & IP landscaping
- Concept brainstorming & invention
- Mechanical CAD development
- Design for manufacture & assembly
- Tolerance & FEA testing
- Prototyping



RauSafe is activated after injection by the user pulling a telescopic active sleeve over the needle, thus protecting the user from needlestick injury. At all times the user has a clear view of the whole volume of drug and syringe label, and the high grip finger hold makes it easy to activate.

Rausafe has recently received the coveted DeviceMed award for most innovative medical device at Compamed 2014, the international trade fair for the medical engineering supply industry.



We were very impressed that together with Cambridge Design Partnership we could deliver such a neat and manufacturable solution so quickly, in time for the new regulations. Highly recommended.”

Dr Thomas Jakob, Director, Moulding / Pharma Solutions, Raumedic AG

BENEFIT TO THE CLIENT >

RauSafe can be customised to existing staked-needle prefilled glass syringes with slight modifications of the existing parts. This means it can be added to existing manufacturing lines, avoiding the time and cost that a lengthy revalidation process would take.

The product has been evaluated in a formative usability study, with excellent results. “The handling is good, it’s quick to use and it is safe,” (a nurse, Berlin usability study). RauSafe is currently available for license.

