



## SafeClick™ – Lyo

- SafeClick™ – Lyo is Future Injection Technology's (FIT's) single use auto-injector for lyophilized drugs.
- Designed from first principles for lyophilized formulations.
- Enables self-administration of subcutaneous (sc) and intramuscular (im) injections using any dual chamber cartridge.
- Automatic needle protection – fully needle safe device
- Pharmaceutical and Military application

## Key Features

- Delivery of any lyophilized drug in any type or size of dual chamber cartridge
- Robust design for use in healthcare and in the military for battlefield administration
- Unique proprietary mechanism allows reconstitution and administration in a single device
- Fully automatic needle protection inside the sturdy device with no need for a needle shield
- Entire therapeutic dose is delivered at correct needle depth
- Removes all air from the cartridge prior to injection
- Simple and fully automatic with simple three step activation
- Delivery time can be tailored from 1 second to 100s+
- Constant flow rate throughout the entire injection of the dose
- Design and the inclusion of additional safety features allow easy use by musculoskeltally impaired patients
- Audible clicks at beginning and end of injection
- Delivery of non-viscous and viscous reconstituted formulations
- Proprietary primary and secondary packaging ensures SafeClick™ functions perfectly only when required
- Huge time and cost savings in clinical development as SafeClick™ uses existing cartridges.

# SafeClick™ Lyo

## Requirement for auto-injectors

Primary healthcare costs can be reduced by up to 95% if patients can self-administer their injectable medicines as they no longer have to attend a clinic for administration of the injection by a healthcare professional. In addition, needle safe auto-injectors like SafeClick™ have been shown to reduce needle-stick injuries, estimated at 500 thousand to 1 million injuries per year in the US, by up to 85%.

## Novel design for lyophilized drugs in dual chamber cartridges

SafeClick™ was designed from first principles to deliver lyophilized formulations. It has many unique design features that protect the dual chamber cartridges from breakage while allowing effective drug reconstitution and easy needle safe administration.

## Use of existing and approved pre-filled dual chamber cartridges

SafeClick™ uses existing pre-filled dual chamber cartridges, which are already approved for therapeutic use. This means that additional clinical drug trials are not required and that the regulatory route to market is fast and low cost, usually via a 510k exemption or similar. SafeClick™ offers a fast and low cost solution for self-administration of lyophilized drugs as the pre-filled dual chamber cartridge is packaged within the SafeClick™ device as a single use disposable product.

## Regulatory needle-stick compliance

SafeClick™ has fully automatic needle protection with the needle retained inside the sturdy device before and after injection. It has been designed to comply with the emerging needle-stick regulations that are making needle safe devices mandatory.

## Protection of Pharmaceutical product franchises

The ability for patients to self-medicate with needle safe devices is a key market differentiator for injectable pharmaceuticals. Self-medication offers huge cost savings to healthcare providers and dramatic lifestyle benefits for patients. Where the delivery route is a key differentiator, access to a proprietary auto-injector such as SafeClick™ is essential from a patient, healthcare provider and business perspective.



## Fool-proof design – robust enough for military use on the battlefield

SafeClick™ is designed for fool-proof administration. The device is semi-automatic consisting of a reconstitution step followed by an administration step. The device cannot be fired to initiate the fully automatic injection cycle until the reconstitution step is complete. Administration is confirmed by audible clicks at the beginning and end of the injection cycle combined with a full length viewing window showing that the medication has been administered.

## High reliability

Proprietary primary and secondary packaging and automated safety features prevent misfiring caused by incorrect handling or abuse during transportation. The unique and proprietary mechanism protects the dual chamber cartridges from breakage and prevents the administration failures observed with other market offerings.

## Designed for musculoskeletally impaired patients e.g those lacking dexterity

The design is aimed at optimizing patient acceptance and affinity with the device. Activation is by depression of the reconstitution rod followed by removal of the ergonomically designed end-cap which is optimized for patients with impaired dexterity. SafeClick™ is activated by pushing the device against the skin.

## Huge development cost savings

SafeClick™ offers a low cost and fast route to market compared to alternative new, unapproved and high risk routes of delivery. Use of industry standard cartridges within the device precludes the need for additional large, expensive and time consuming clinical trials.

## Low cost manufacture

SafeClick™ is manufactured by existing and well proven injection moulding techniques on single or multi-cavity splits. The small number of highly robust components ensures low manufacturing and assembly costs.

## Partnering Opportunity

FIT is seeking partners with drugs on the market or in development to accelerate and diversify the use of SafeClick™ with new and existing lyophilized medicines. Key application areas include, proprietary biologics such as antibody based drugs, generic biosimilars, vaccines and in particular pandemic management and defense use for administration of battlefield medicines.

## Contact

Paul Whyte, Chief Executive Officer  
Future Injection Technologies Limited  
The Magdalen Centre  
Oxford, UK  
OX4 4GA

Web [www.futureinjection.com](http://www.futureinjection.com)  
Email [paul@futureinjection.com](mailto:paul@futureinjection.com)  
Tel +44 (0) 01865 784555  
Mob +44 (0) 7738 026 703  
Fax +44 (0) 01865 784004