



Elcam  
Drug Delivery Devices



# Product catalog



Wide Range  
Portfolio



Innovation



Customization



Manufacturing  
& Assembly



# About us

Elcam Drug Delivery Devices (E3D) is a subsidiary of Elcam Medical, an Israel-based group with 40 years of experience in development, manufacturing and global distribution of medical devices.

E3D is focused on design, development, manufacturing and supply of injectable drug delivery devices for self-administration and use in non-clinical environments. Its broad technology portfolio encompasses devices suitable for drugs in a range of primary containers - including auto-injectors, on-body delivery systems and smart devices with wireless connectivity.

With device manufacturing facilities in several countries, E3D works closely with customers from initial design phase to regulatory approval and commercial supply, providing innovative and differentiated solutions for delivery of injectable drugs.

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## Wide-Ranging Portfolio

E3D offers a wide-ranging portfolio of device platforms, suitable for biologic products, including biosimilars, and small molecule drugs. This offering ranges from disposable auto-injectors for drugs in prefilled syringes and vials for standard and high-viscosity drugs, to mechanical and electromechanical reusable auto-injectors for prefilled syringes and cartridges, as well as on-body delivery systems for bolus and continuous delivery profiles. E3D also offers a platform of On-Body Patch-Pumps for accurate changeable delivery rates or controlled rate bolus delivery, for small and large volumes.

Our range of device platforms, in combination with our experience in customization, provides solutions for a wide variety of injectable products, patient populations and primary container formats.

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# Flexi-Q PFS

Flexi-Q PFS 3-step Disposable Auto-injector for PFS



Flexi-Q PFS single-use auto-injector provides a fully-automated injection, with button activation and passive needle safety.

Flexi-Q PFS can differentiate new drug products and can be a lifecycle management tool for existing drugs.

## Pharmaceutical Company Advantages

### Differentiation

- Enables using a drug delivery device for drugs in prefilled syringes
- For drugs in 1mL "long" PFS - Fixed delivery volumes of 0.1 - 1.0 mL
- Compatible with low to medium drug viscosity
- Injection starts only after full needle penetration to intended injection depth
- Delivery of the entire dose – same dead space as with manual technique
- Color coding flexibility and other customization options

### Short regulatory path to market

- Proven technology platform; Compatible with standard glass PFS

## Patient Benefits

### Ease of use and convenience

- Fully automatic injection process
- Hidden needle and quiet injection to reduce anxiety and perceived pain
- Reduces needle phobia - by hiding the needle throughout the injection process

### Safety

- Passive needle safety to avoid needlestick injury
- Injection commences only when needle reaches intended depth
- Clear visual and audible confirmation throughout the injection process
- Skin sensor prevents inadvertent activation

Regulatory status - Device Master File was submitted to the FDA (# MAF-1638)



 [Video](#)

## User Steps



1. Inspect PFS and drug through Large Observation Window. Pull off Safety Cap.



2. Press device against injection site and press Button. Hold device in place until audible and visual signals indicate injection is completed.



3. Lift device from injection site\* and discard in appropriate container.

\* When the auto-injector is removed from the injection site, a Needle Guard automatically covers and locks over the needle for safe disposal of the auto-injector.



# Flexi-Q DV

Flexi-Q DV Disposable Auto-injector for liquid form drugs in vials



Flexi-Q DV represents a unique and enclosed solution for automated injection of drugs in vials. It is the only commercially available device that provides a unique and user friendly solution for self-administration of such drugs.

This single-use auto-injector allows simplified aspiration from conventional vials, features safety needle shielding throughout the process, provides life cycle management capabilities for new and existing drugs.

## Pharmaceutical Company Advantages

### Differentiation

- Provides a unique drug delivery solution for drugs in vials
- Vial Adaptor system minimizes risk of contamination during preparation
- Suitable for both fixed and patient-specific dosing
- Provides flexibility – the diluents may be contained in either vials or pre-filled in the injector (in a standard glass syringe)
- Optimizes drug extraction from vial - designed to optimize vial-drug removal and enhance dosing consistency
- Reduced local skin reactions – injection starts only after full needle penetration
- Vented vial adaptor, vial sizes, color coding flexibility and other customization options

### Short path to market

- Compatible with standard glass syringes and vials – no need to change drug container
- Regulatory path (depending on configuration) - 510(k), CE Mark

## Patient Benefits

### Ease of use and convenience

- Fully automatic injection process
- Quiet injection reduces patients' anxiety and perceived pain
- Reduces needle phobia - by hiding the needle throughout the entire reconstitution and injection process
- Easy titration and expelling of air bubbles using the long observation window

### Safety

- Prevents needle-stick injuries - needle is protected throughout the entire process of reconstitution and injection
- Reduced local skin reactions - injection starts only after full needle penetration into the correct depth (SC)
- Clear visual and audible confirmation of the injection progress from beginning to end
- Propriety feature prevents expensive drug spillage during reconstitution and injection
- Prevents false activation during all steps

Regulatory Status - FDA 510(k) cleared



 [Video](#)

## User Steps

-  **1. Attach Vial**
-  **2. Pull Plunger to aspirate drug into the autoinjector.\***
-  **3. Detach Vial Adaptor from the injector.**
-  **4. Press device against injection site and press Button. Hold device in place until audible and visual signals indicate injection is completed. Lift device from injection site and discard in appropriate container.\***

\* When the auto-injector is removed from the injection site, a Needle Guard automatically covers and locks over the needle for safe disposal of the auto-injector.



# Flexi-Q PVDR

Single-use auto-injector with reconstitution for lyophilized drugs in vials



Flexi-Q PVDR provides an integrated solution for reconstitution and automated injection of lyophilized drugs in vials.

This disposable auto-injector incorporates fully-enclosed and simple drug preparation, offering lifecycle management capabilities for both new and existing products.

## Pharmaceutical Company Advantages

### Differentiation

- Unique preparation & delivery solution for injectable drugs in vials
- Suitable for both fixed and patient-specific dosing
- Allows reconstitution of multiple vials for increased drug dosing/mixing
- Optimizes drug volume extraction from vial, enhancing dosing consistency
- Lifecycle management tool; enables transition from vial to self-injection device
- Can accommodate a range of vial sizes and configurations

### Short path to market

- Compatible with standard glass syringes and vials – no need to change drug container

## Patient Benefits

### Ease of use and convenience

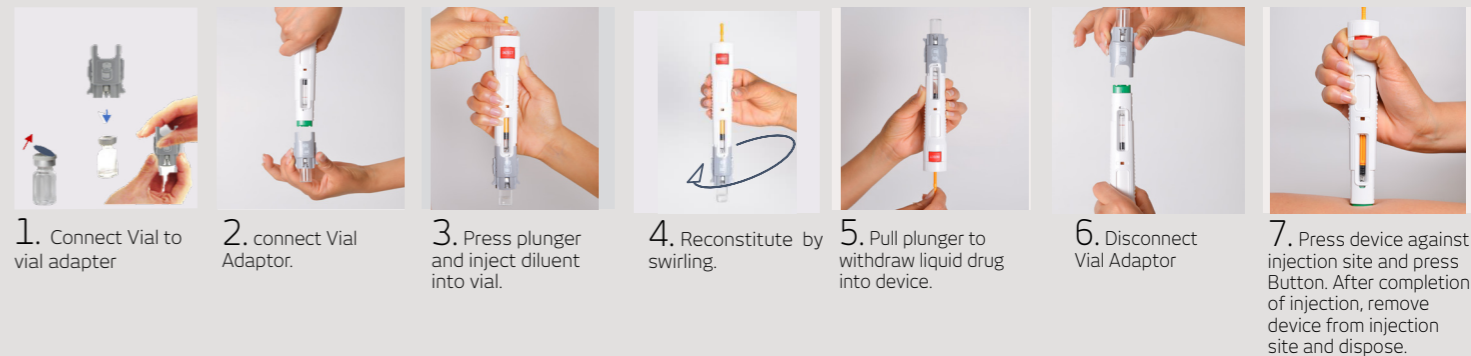
- Simple, intuitive reconstitution process
- Fully-automated injection
- Hidden needle reduces patient anxiety and discomfort
- Easy titration and expelling of air bubbles using the long observation window
- Large Observation Window enables dose titration and visual confirmation of reconstitution

### Safety

- Passive needle-safety features prevent needlestick injury
- Fully-enclosed Vial Adaptor minimizes risk of contamination during preparation
- Clear audible and visual confirmation of initiation and completion of injection
- Skin sensor prevents inadvertent activation



## User Steps



# Flexi-Q HV

Disposable Auto-injector for High Viscosity Drugs in PFS



Flexi-Q HV single-use auto-injector provides a fully-automated injection, with button activation and passive needle safety.

Flexi-Q HV incorporates a proprietary force-damping mechanism which allows the use of high spring force whilst protecting the glass PFS from mechanical damage.

It is the ultimate differentiating vehicle when considering the launch of a new drug or as a lifecycle management tool for an existing drug.

## Pharmaceutical Company Advantages

### Differentiation

- Fixed dose delivery of PFS fill volume: Configurable for 1mL or 2.25mL PFS
- Suitable for delivery of a wide range of drug viscosities, to 150cP according to injected volume and needle gauge
- Compatible with low to high drug viscosity
- Proprietary force-damping mechanism avoids damage to glass PFS, allowing use of elevated spring force for viscous drugs
- Passive needle safety to avoid needlestick injury
- Injection commences only when needle reaches intended depth
- Clear visual and audible confirmation throughout the injection process
- Skin sensor prevents inadvertent activation

### Short path to market

- Proven technology platform; Compatible with standard glass PFS

## Patient Benefits

### Ease of use and convenience

- Fully automatic injection process
- Hidden needle and quiet injection to reduce anxiety and perceived pain

### Safety

- Prevents needle-stick injuries - needle is protected throughout the injection process
- Reduced local skin reactions - Injects only into the correct depth (SC)
- Clear visual and audible confirmation of the injection progress from beginning to end
- Activation design options:
  - Trigger button and body sensing - prevents inadvertent activation
  - Activation by pressing against the skin - e.g. for emergency use



[▶ Video](#)

## User Steps



1. Inspect PFS and drug through the Large Observation Window. Pull off Safety Cap.



2. Press device against injection site and press Inject Button. Hold device in place until audible and visual signals indicate injection is completed.



3. Lift device from injection site and discard in appropriate container.

\* When the auto-injector is removed from the injection site, a Needle Guard automatically covers and locks over the needle for safe disposal of the auto-injector.

# Flexi-Q EAI

2-step Disposable Auto-injector  
for Emergency Use



Flexi-Q EAI is a 2-step, fully-disposable auto-injector, accommodating drugs in either 1mL "long" or 2.25mL pre-filled syringes (PFS).

This easy to use auto-injector is designed to meet requirements for use in case of life-threatening emergency situations.

## Pharmaceutical Company Advantages

### Differentiation

- Designed to meet the reliability requirements for emergency-use auto-injectors
- Fixed dose volumes:
  - Flexi-Q EAI 100 (for 1mL "long" PFS): 0.1mL - 1.0mL
  - Flexi-Q EAI 225 (for 2.25mL PFS): 0.1mL - 2.25mL
- Proprietary force damping mechanism prevents impact damage to glass PFS - allowing use of high-force power springs, enabling fast injection through layers of clothing:
  - a) for high-viscosity drugs
  - b) for fast injections required for emergency drugs
- Injection starts only after full needle penetration, delivering drug to target tissue depth
- Optional Observation Window – allows inspection of PFS and contents, as well as injection progress
- Easy and flexible customization options

### Short regulatory path to market

- Proven technology platform; Compatible with standard glass PFS; Manufacturing facilities established by E3D

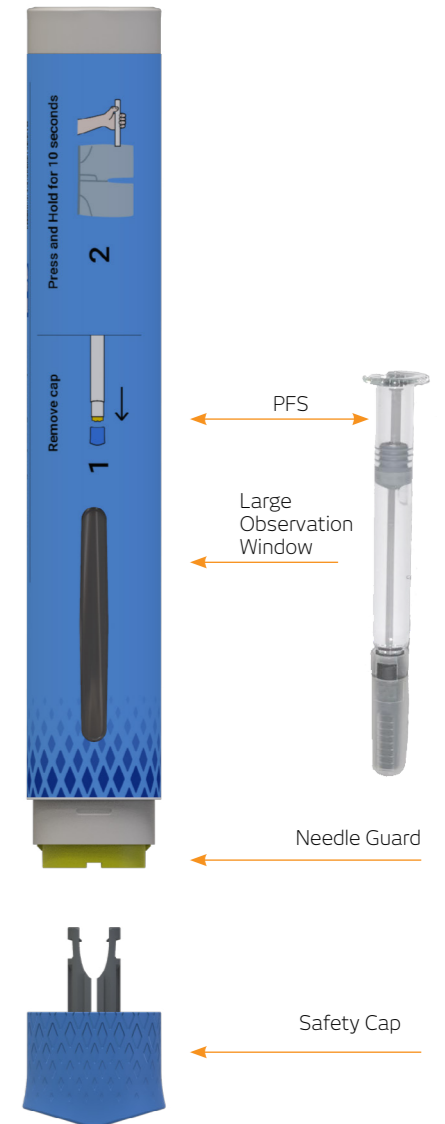
## Patient Benefits

### Ease of use convenience

- 2-step activation with fully automatic injection process
- Simple and intuitive operation
- Passive needle safety to avoid needlestick injury
- Injection commences only when needle reaches intended depth
- Clear visual and audible confirmation throughout the injection process

### Safety

- Prevents needle-stick injuries - Passive Needle safety throughout the injection process
- Reduced local skin reactions - injects only into the correct depth (IM / SC)
- Clear visual and audible confirmation of the injection progress from activation to completion
- Fast and simple activation design - Activation by pressing against the skin - e.g. for emergency use



 [Video](#)

## User Steps



1. Inspect PFS and drug through the Large Observation Window. Pull off Safety Cap.



2. Push device against injection site. Hold device in place until audible and visual signals indicate injection is completed.

\* When the auto-injector is removed from the injection site, a Needle Guard automatically covers and locks over the needle for safe disposal of the auto-injector.



# Flexi-Q CAI

2-step Disposable Auto-injector



Flexi-Q CAI is a 2-step disposable auto-injector platform for drugs in either 1 mL or 2.25 mL pre-filled syringes (PFS). This single-use auto-injector incorporates passive needle safety features and is designed to be intuitive and easy to use for patients with dexterity or motor-control challenges.

## Pharmaceutical Company Advantages

### Differentiation

- Configurable for intramuscular (IM) or subcutaneous (SC) injection
- Fixed dose volumes:  
Flexi-Q CAI 100 (for 1.0 mL "long" PFS): 0.1mL - 1.0mL  
Flexi-Q CAI 225 (for 2.25mL PFS): 0.1mL - 2.25mL
- Injection starts only after full needle penetration, delivering drug to target tissue depth
- Proprietary force damping mechanism prevents impact damage to glass PFS – allowing use of high-force power springs - enabling delivery of viscous drugs
- Observation Window – allows inspection of PFS and contents, as well as progress of injection
- Standardized device or configured according to pharmaceutical company's specific requirements.

### Shortened time to market

- Proven technology platform; Compatible with standard glass PFS; Manufacturing facilities established by E3D

## Patient Benefits

### Ease of use and convenience

- Simple, intuitive 2-step push-on-skin activation with fully automated injection process
- Clear visual and audible confirmation of the initiation and completion of injection
- Needle hidden throughout the injection process, reducing anxiety and needle aversion

### Safety

- Passive needle safety feature to prevent needlestick injury
- Clear visual and audible confirmation throughout the injection process



 Video

## User Steps



1. Inspect PFS and drug through Observation Window. Pull off Safety Cap.

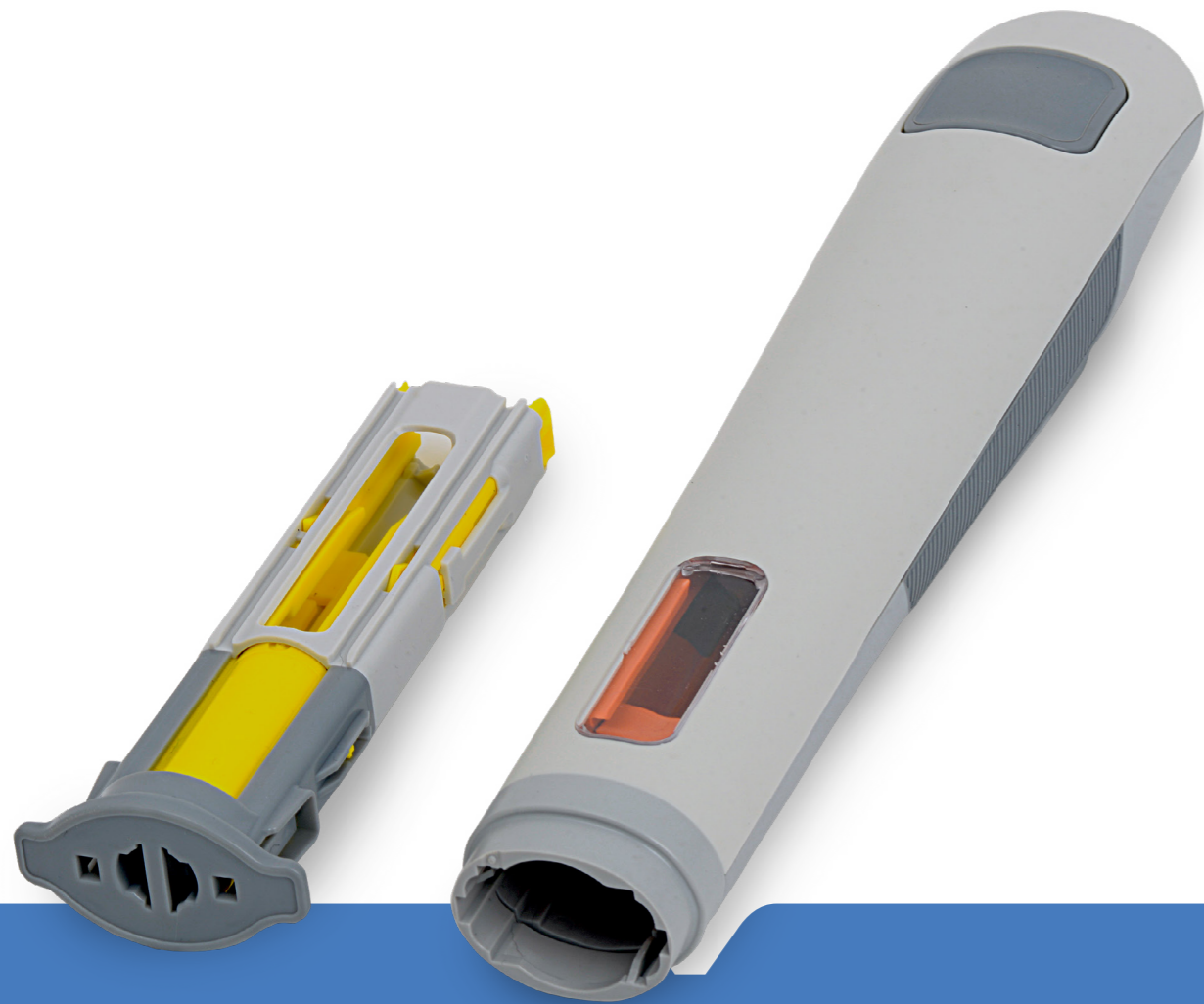


2. Push device against injection site. Hold device in place until audible and visual signals indicate injection is completed.

\*When the auto-injector is removed from the injection site, a Needle Guard automatically covers and locks over the needle for safe disposal of the device.

# Flexi-Q mMU

Mechanical Multi-Use Auto-Injector  
for Drugs in Pre-Filled Syringes



Flexi-Q mMU auto-injector consists of reusable Device and cost-effective, single-use Cassette (pre-loaded with PFS containing drug to be injected).

Flexi-Q mMU incorporates passive needle safety features and is designed to offer a cost-effective solution for patients whose treatment requires repeated injections, such as for chronic conditions. With a unique design and simple, 4-step operation, Flexi-Q mMU represents a significantly simpler self-injection device system than traditional reusable auto-injectors.

## Pharmaceutical Company Advantages

### Differentiation

- Cost-effective reusable Device and single-use Cassette
- Automatic needle insertion with pre-set needle penetration depth
- Automatic injection with pre-set injection duration
- Proprietary force damping mechanism prevents impact damage to glass PFS – allowing use of high-force power springs for viscous formulations
- Fixed delivery volumes of 0.1-1.0 mL, can be customized to 2.25 mL

### Selected customizable options of the disposable cassette

- Unique cassette design incorporating a standard glass PFS of different manufacturers
- Drug titration
- Color coding flexibility and other customization options
- Wireless transmission of injection data
- Drug recognition and safety improvement, using RFID technology

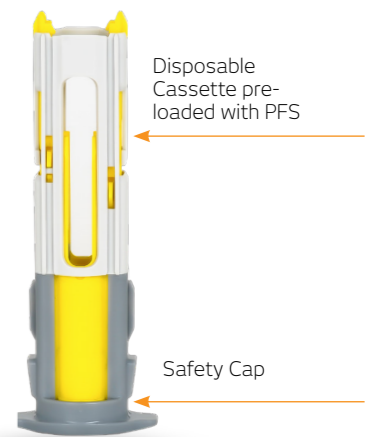
## Patient Benefits

### Ease of use and convenience

- Simple user interface – no complicated loading and re-assembly operations
- Fully automatic injection process
- Needle hidden throughout injection process, reducing anxiety and needle aversion
- Observation Window permits view of entire PFS fill volume and progress of injection

### Safety

- Passive needle safety feature to prevent needlestick injury
- Injection commences only when needle reaches intended injection depth



 [Video](#)

## User Steps



1. Push Cassette into Device.
2. Inspect PFS and drug through Observation Window. Pull off Safety Cap.
3. Press device against injection site and press Inject Button. Hold device in place until audible and visual signals indicate injection is completed.
4. Lift device from injection site. Eject cassette and discard in appropriate container.

\* When the device is removed from the injection site, a Needle Guard automatically covers and locks over the needle for safe disposal of the used cassette.

# Flexi-eMU-P

Electromechanical Multi-use Auto-injector for drugs in pre-filled syringes.  
Smart features and wireless data transmission



## Pharmaceutical Company Advantages:

### Functionality and Operation

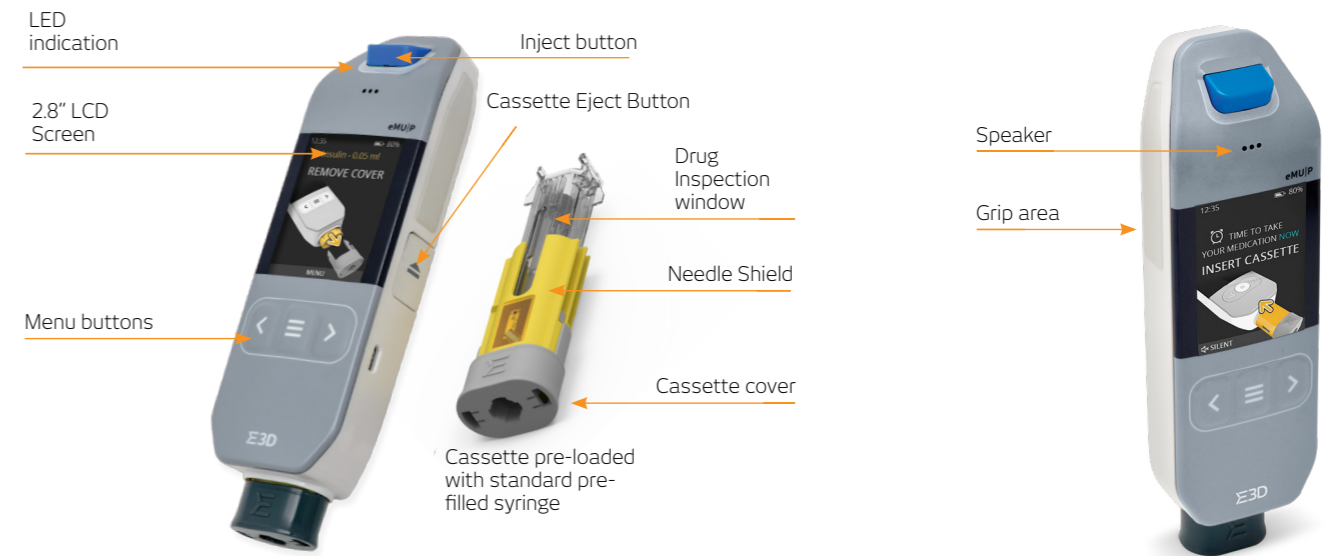
- Reusable, rechargeable electromechanical Device
- Single-use, disposable Cassette pre-loaded with PFS
- Fixed or variable delivery volumes (0.1 mL to 1 mL)
  - 2.25 mL PFS variant also available
- Automatic needle insertion, injection and needle retraction
  - Needle hidden at all times
  - Passive needle safety
  - Drug delivery begins only after full needle penetration
- Advanced user interface featuring LCD screen and functional keys, providing
  - Real-time user guidance and confirmation
  - Access to optional user control of injection parameters
  - Calendar settings and injection reminder alerts
- Skin sensor ensures appropriate contact with injection site before activation
- Suitable for injection of high-viscosity drugs

### Features

- Optional user controls
  - Injection time setting (3 - 100 seconds)
  - Needle penetration depth (6 - 12mm)
- Optional dose calculation (e.g. by body weight) and automated dose setting
- Temperature sensor ensures refrigerated drugs appropriately warmed before injection
- Drug/PFS validation and expiry check using RFID technology
- On-screen access to injection log
- Wireless transmission of injection data to remote storage

### Technical Information

- Smartphone design, suitable for pocket size
  - Length x Width x Height 120 x 60 x 20mm
- Rechargeable batteries: 30 injections per charge



Flexi-Q eMU-P system is comprised of a reusable Device and single-use Cassette pre-loaded with a standard pre-filled syringe (PFS). Flexi-Q eMU-P is particularly suitable for use in long-term therapies that require frequent injections, such as multiple sclerosis, autoimmune conditions and blood disorders. The reusable Flexi-Q eMU-P lowers cost per injection and reduces the volume of material for storage and disposal.

### User Steps





# Flexi-Q eMU-C

Electromechanical Multi-use Auto-injector for drugs in cartridges

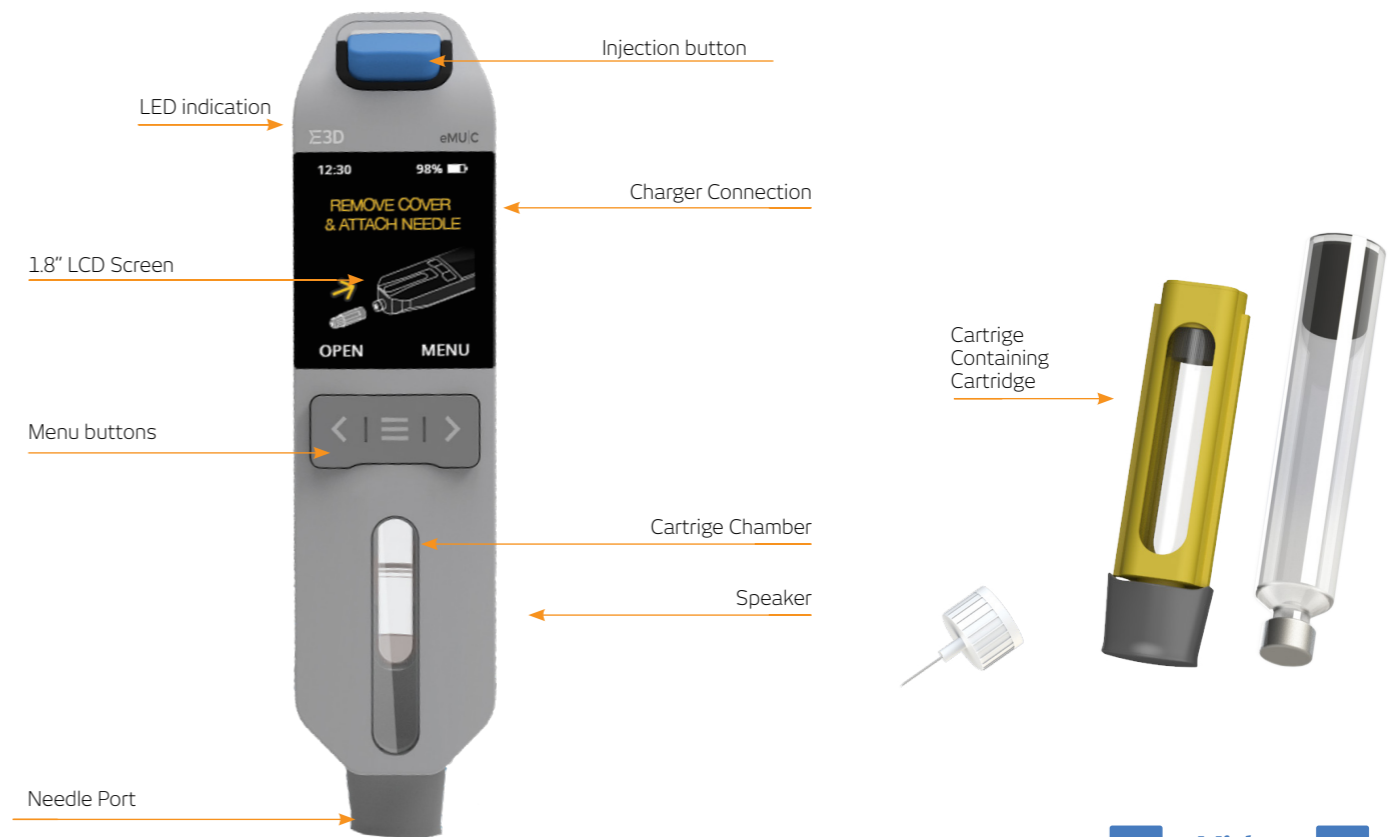


## Pharmaceutical Company Advantages

- Compatible with 1.5mL and 3mL cartridges; single and dual chamber formats. with standard 3 ml / 1.5 ml cartridge.
- Suitable for injection of high viscosity drugs.
- Enables injection of dosages as low as 0.005 ml with high accuracy.
- Allows reconstitution using dual chamber cartridge.
- Drug recognition and safety improvement, using RFID technology.

## Patient Benefits

- Advanced user interface with step-by-step, on-screen instructions.
- Injection-due reminders.
- Optional injection duration control - can be adjusted to reduce pain.
- Enables automatic priming for new cartridges.
- Injection data recording and on-board storage.
- Wireless data transfer to a remote data base.



Flexi-Q eMU-C system is comprised of a reusable Device and single-use Cassette, pre-loaded with a standard pre-filled cartridge.

Flexi-Q eMU-C is intended for use in chronic diseases that require frequent injections (e.g. multiple sclerosis, diabetes and others) and is configurable for both fixed and variable dose volumes. The reusable design of Flexi-Q eMU-C lowers the cost per injection and reduces the volume of material for storage and disposal.

## User steps



**1.** Insert Cassette into Device port

**2.** Remove Safety Cap Attach needle

**3.** Push Device against injection site and press Inject button

**Prime** (once for each new cartridge)

**4.** Eject Cassette Detach needle and dispose of in appropriate container.



# OBI-1 Wearable Injector

Bolus wearable Injector for subcutaneous administration of biologic drugs

## Pharmaceutical Company Advantages

### Differentiation

- Supplied pre-filled, sterile and ready to use
- Integrated needle and soft cannula insertion (only soft cannula remains in the SC tissue for the entire use duration)
- Programmable delayed activation
- Option for programmable delayed initiation of injection (with soft cannula for patient comfort during extended attachment of device)

## Patient Benefits

### Ease of use – better patient compliance

- Cost-effective device platform with minimal moving components
- Needle-safety features provide protection from injury before and after use
- Simple, intuitive operation
- Quiet operation
- Compact and lightweight

### Safety

- Incorporated safety features provide needle protection before insertion and after removal, and prevent needle-sticks injuries
- Soft cannula remains in SQ tissue



Video

The OBI-1 is a disposable wearable injector, compatible with biologics and other drugs requiring bolus subcutaneous administration. Due to its unique power source, OBI offers a compact, easy-to-use and cost-effective on-body injector solution.

# Patch Pump (eLVD)

Long duration subcutaneous administration of large dose volume biologics

## Pharmaceutical Company Advantages

### Differentiation

- Compatible with industry-standard vials
- Cost-effective design with reusable Driving Unit and disposable Injection Unit
- Automatic soft cannula insertion- cannula remains in the SC tissue for the entire use duration)
- Pre-programmable injection profile
- Minimum delivery rate of 0.25mL/hour
- Programmable flow rate sequence, by manufacturer

## Patient Benefits

### Ease of use and convenience

- Easy and straight forward installation and removal
- Simple user interface
- Adhesive patch for easy attachment and removal of device
- Simple operation
- Compact and lightweight
- Injection information communication to remote data storage

### Safety

- Incorporated safety features provide needle protection before insertion and after removal, and prevent needle-sticks injuries
- Soft cannula remains in SQ tissue



eLVD Patch Injector is comprised of a reusable Driving Unit and a disposable Injection Unit, compatible with drugs requiring longer duration subcutaneous administration.

# About Elcam Medical

Elcam Medical is a world class producer of disposable medical devices and components for the OEM market, and a provider of innovative solutions for specialized flow control needs.

Elcam Medical strives to provide the building blocks for safer and more effective fluid management in medical areas such as Intensive Care, Anesthesia, Dialysis, Interventional Cardiology & Radiology and Oncology.

As a worldwide leader of fundamentelements in fluid management systems such as stopcocks and manifolds in the OEM markets, Elcam maximizes efforts to provide customized solutions to our customers greatest needs and challenges.

With a commitment to provide an excellent customer experience, Elcam Medical global teams incorporate into all our services both professionalism and care in a way that exceeds industry standards.



## Solutions

Elcam's Solutions focus on enhancing patient and caregiver safety in four areas of clinical expertise. Our innovative solutions are designed to truly meet your customers' needs and provide you with differentiating advantages.



Intensive Care & Anesthesia



Dialysis



Interventional Cardiology & Radiology



Oncology

# The Elcam Medical Advantage

## Vast Product Range

Elcam Medical produces the widest range of high quality disposable medical devices for fluid control. We also provide specialized support with design and development, as well as process engineering, so that we can turn your idea into a reliable, working product. Elcam considers our team part of your team.

## State of the Art Design and Manufacturing Capabilities

Combining sophisticated equipment with superior facilities, our highly automated processes ensure production of consistently high quality products, at any quantity, large or small.

## Unparalleled Customer Experience

Our dedicated professionals – from our sales team and engineers to our customer service representatives and our managerial staff – communicate with each and every client throughout the entire development and manufacturing process.

## Quality Assurance

Elcam Medical is experienced in working under tight deadlines, without compromising quality. We operate in compliance with 21 CFR part 820 and ISO 13485 throughout the products life cycle. Elcam holds CE Mark for the European market and many of our products marketed in the US are 510(k) cleared devices.

## Global Presence

Elcam Medical currently has four manufacturing facilities, in Israel and Italy. We have offices and representatives in the US, Europe, Asia and South America.

## Clinical Know-How and Expertise

With more than 40 years in the medical device market, Elcam Medical expertly offers flexible solutions based on specific customer needs. We work in close cooperation with our OEM customers, key clinicians, and inventors, to explore market needs and trends.

## Business Philosophy and Structure



Incorporating and executing our mission throughout our sub-brands, Elcam Medical strives to balance quality with quantity so our customers may access the opportunities offered when value meets volume.

Your source of consistent quality and care

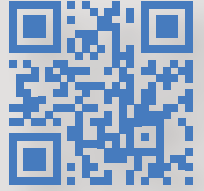


Elcam Devices Elcam Stopcocks Elcam Accessories





Elcam  
Drug Delivery Devices



REV-13 09/2023 ISO 13485

**WE FOCUS ON  
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