







Wide Range Portfolio



Innovation



Customization



Manufacturing & Assembly

About us

E3D specializes in developing and manufacturing auto-injectors and other drug delivery devices for conventional drugs, biologic products and biosimilar drugs. Our auto-injectors operate with injectable drugs in vials, prefilled syringes and cartridges. In addition, we offer disposable and reusable auto-injectors and a patch pump.

One of our major areas of expertise is customization of devices to meet the customer's exact needs.

E3D is a sister company of Elcam Medical, a world leader in OEM disposable medical devices.

Wide-Ranging Portfolio

E3D presents a wide-ranging portfolio suitable for conventional drugs, biological products and biosimilar drugs: from disposable auto-injectors for prefilled syringes and vials for standard and high-viscosity drugs, to mechanical and electronic reusable auto-injectors. E3D also offers an ePump (LVD), a patch pump with disposable and reusable parts.

This portfolio, in combination with our depth of experience in customization, gives pharmaceutical companies the flexibility to find the solutions that meet differentneeds – all within our broad product line.

Contact Details

_		\sim 1		
Tsa	chi	Sh	ake	-ח

Managing Director & Chief Business Officer

tsachi@elcam3d.com

T. 972-4-698-8881

F. 972-4-698-0777

Ilan Shopen

Marketing & Business Development Director

ilan@elcam3d.com

T. 972-77-256-8601 **F.** 972-4-698-0777

Table of Contents:

Products	Page
Flexi-Q PFS	4-5
Flexi-Q DV	6-7
Flexi-Q HV	8-9
Flexi-Q EAI	10-11
Flexi-Q CAI	12-13
Flexi-Q mMU	14-15
Flexi-Q eMU-P	16-17
Flexi-Q eMU-C	18-19
OBI-1	20
Patch Pump	21

Flexi-Q PFS

Fully Disposable Auto-Injector for Pre-Filled Syringes



The Flexi-Q PFS is a fully disposable auto-injector for Pre-Filled Syringes (PFS).

This single-use auto-injector features passive needle shielding, allows better patient safety and encourages patient compliance in self-injection. 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

- Enables using a drug delivery device for drugs in prefilled syringes
- Flexible delivery volumes, fixed dose:
 1.0 0.1 mL for the 1 mL version
 Can be customized to 2.25ml PFS
- Compatible with low to medium drug viscosity
- Reduced skin reactions injection starts only after full needle penetration
- Delivery of the entire dose same dead space as with manual technique
- Color coding flexibility and other customization options

Short regulatory path

• Compatible with standard glass syringes - no need to change drug container



Patient Benefits

Ease of use - better patient compliance

- Fully automatic injection process
- · Quiet injection reduces patients' anxiety and perceived pain
- Reduces needle phobia by hiding the needle throughout the injection process

Patient 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
- Prevents inadvertent activation allows activation only after pressing the injector against the patient's skin
- Clear distinction between injector ends prevents injection in wrong direction

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



See how easy it is to use:



1. Inspect drug integrity through window. Pull out the Safety Cover.



2. Press Injector against skin and press Inject Button.
Hold injector still for 10 seconds.
You will hear a click at the end of injection.
You may also observe the piston

reaching the end of the barrel.

3. Remove used auto-injector from skin and discard* properly.

^{*} 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

Fully Disposable Auto-Injector for Drugs in Vials



The Flexi-Q DV auto-injector is a fully disposable auto-injector for drugs in vials (in both lyophilized and liquid forms). 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 reconstitution and aspiration from conventional vials, features safety needle shielding throughout the process, provides life cycle management capabilities for new and existing drugs, encourages better patient compliance and improves safety in self-injection.



Pharmaceutical Company Advantages

Differentiation

- Enables using a unique drug delivery device for drugs in vials
- Compatible with drugs for both fixed and variable doses
- Provides flexibility the diluents may be contained in either vials or pre-filled in the injector (in a standard glass syringe)
- Allows reconstitution of multiple vials for increased drug dosing/mixing
- Optimizes drug extraction from vial designed to optimize vial-drug removal and enhance dosing consistency
- Facilitates reconstitution of hard to dissolve drugs allows swirling and time delays followed by user inspection, before performing the automatic injection
- Reduced local skin reactions injection starts only after full needle penetration
- Vented vial adaptor, vial sizes, color coding flexibility and other customization options

Short regulatory path

- 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 – better patient compliance

- 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

Patient 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

See how easy it is to use (reconstitution version):



1. Pull out Safety Cover. insert vial into the click Vial Adaptor onto the injector.



2. Press Plunger to inject the diluent into the vial, then pump mixed drug back into the auto Note: Should you need to mix more than one

> vial, replace the empty vial with a new one and repeat step 2.

Hold injector still for 10 seconds. You will hear a click at the end of injection. You may also observe the piston reaching the end



Syringe Plunger

^{3.} Detach Vial Adaptor from the injector. Press Injector against skin and press Inject Button.



^{*} When the auto-injector is removed from the injection site, a Needle Guard automatically

Flexi-Q HV

Fully Disposable Auto-Injector for **Low to High Viscosity** liquid drugs in Pre-Filled Syringes



The Flexi-Q HV is a fully disposable auto-injector for Low to High Viscosity liquid drugs in Pre-Filled Syringes (PFS).

This single-use auto-injector features passive needle shielding, allows better patient safety and encourages patient compliance in self-injection. 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

- Enables using a drug delivery device for drugs in pre-filled syringes
- Flexible delivery volumes, fixed dose:
 1.0 0.1 mL for the 1 mL version
 Can be customized to 2.25ml PFS
- Injection of 150 cP drug in less than 10 seconds (for 1 mL, depending on needle gauge and drug characteristics)
- Compatible with low to high drug viscosity
- New proprietary damping mechanism preventing impact on glass syringe, allowing use of extremely strong injection spring
- Reduced skin reactions injection starts only after full needle penetration
- Delivery of the entire dose same dead space as with manual techniques
- Easy and flexible customization options

Short regulatory path

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



Patient Benefits

Ease of use - better patient compliance

- Fully automatic injection process
- Quiet injection reduces patients' anxiety and perceived pain
- Reduces needle phobia by hiding the needle throughout the injection process

Patient 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

This product is under development

Drug Pre-Filled Syringe Long Observation Window Needle Guard



See how easy it is to use:



1. Inspect drug integrity through window. Pull out the Safety Cover.



2. Press Injector against skin and press Inject Button. Hold injector still for 10 seconds. You will hear a click at the end of injection. You may also observe the

piston reaching the end of



Remove used auto-injector from skin and discard* properly.

the barrel.
 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



The Flexi-Q EAI is a 2-step fully disposable auto-injector for drugs in 1 mL or 2.25 mL pre-filled syringes (PFS). This easy to use and single-use auto-injector features passive needle shielding and allows better patient safety.



Pharmaceutical Company Advantages

Differentiation

- Flexible delivery volumes, fixed dose:
 0.1 1.0 mL for the 1 mL Flexi-Q EAI 100 (for 1 mL PFS)
 0.1 2.25 mL for the 2.25 mL Flexi-Q EAI 225 (for 2.25 mL PFS)
- Compatible with Intramuscular (IM) and Subcutaneous (SC) injections
- Proprietary damping mechanism preventing impact on glass syringe -
- allowing use of extremely strong injection springs: a) for high-viscosity drugs
- b) for fast injections required for emergency drugs
- Reduced skin reactions injection starts only after full needle penetration
- Delivery of the entire dose same dead space as with manual techniques
- Optional large observation window allows view of the entire syringe fillvolume and injection progress
- Easy and flexible customization options

Short regulatory path

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



Patient Benefits

Ease of use

- 2-step activation with fully automatic injection process
- Simple and intuitive operation

Patient 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



11

See how easy it is to use:





1. Remove safety cap

Push against injection site

10

^{*} 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 motorcontrol challenges.



Pharmaceutical Company Advantages

Differentiation

- Configurable for both subcutaneous (SC) and intramuscular (IM) injection
- Range of delivery volumes: 0.1 - 1.0 mL for Flexi-Q CAI 100 (1 mL "long" PFS)
- 0.1 2.25 mL for Flexi-O CAI 225 (2.25 mL PFS)
- Proprietary force-damping mechanism allows use of high strength springs, whilst preventing excessive impact on glass PFS:
- enabling injection of high viscosity drugs
- Flexi-Q CAI platform can also be configured according to a pharmaceutical company's specific requirements

Shortened time to market

• Elcam E3D manufacturing and supply facilities established for standardized Flexi-Q CAI devices, reducing time to market



Patient Benefits

Ease of use

- Simple, intuitive 2-step push-on-skin activation with fully automated injection process
- Clear visual and audible confirmation of the initiation and completion
- Large observation window permits view of the entire PFS fill volume and progress of injection

Comfort and safety

- Needle hidden throughout the injection process, reducing anxiety and needle aversion
- Passive safety features prevent needlestick injuries





13

User Steps





1. Remove Safety Cap

2. Push device against injection site

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 and Vials



The Mechanical Multi-Use auto-injector features a reusable driving unit and a cost-effective, needle protection disposable cassette for use with standard pre-filled syringes and vials. For use in chronic diseases that require frequent injections (e.g. multiple sclerosis). The partially reusable design lowers the cost per injection and reduces the volume for storage and disposal.



Pharmaceutical Company Advantages

Differentiation

- Reusable driving unit and disposable cassette for use with standard pre-filled syringes
- Disposable cassette provides protection & safety to the glass pre-filled syringe
- Automatic needle insertion with preset needle penetration depth (exact depth TBD)
- Automatic injection with preset injection speed
- Fixed delivery volumes of 0.1-1.0 mL, can be customized to 2.25 mL
- Compatible with a wide range of drug viscosity (low and medium viscosity)
- Windows for visual inspection of the syringe content along the full length of the barrel

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 - better patient compliance

- Reduces needle phobia by hiding the needle throughout the entire injection process
- Simple user interface no complicated dismantling or unscrewing operations
- Quiet operation reduces patients' anxiety and perceived pain
- Controlled injection speed for increased comfort

Patient safety

- Delivery of the entire dose same dead space as with manual technique
- Reduced skin reactions injection starts only after full needle penetration
- Incorporated safety features provide needle protection before and after injection, preventing needle-sticks injuries

This product is under development





See how easy it is to use (pre-filled syringe version):



 Slide disposable cassette into the reusable device.



2. Remove Safety cover.



 Press Injector against skin and press Inject Button. Hold injector still for 10 seconds. You will hear a click at the end of injection. You may also observe the piston reaching the end of the barrel.



4. Lift autoinjector from skin, fully remove the cassette and discard* properly.

^{*} 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 used cassette.

Flexi-Q eMU-P

Electromechanical Multi-use Auto-injector for drugs in pre-filled syringes















Flexi-Q eMU-P is particularly suitable for use in long-term therapies that require frequent injections, such as growth hormone deficiency, multiple sclerosis, autoimmune conditions and blood disorders. The reusable design of Flexi-Q eMU-P lowers cost per injection and reduces amount of materials for storage and disposal.



The Flexi-Q eMU-P 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 12 mm)
- Optional dose calculation (e.g. by body weight) and automated dose setting
- Temperature sensor ensures refrigerated drugs are suitable 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 sizeg
- Length x Width x Height 120 x 60 x 20 mm
- Rechargeable batteries: 30 injections per charge





User Steps:









3. Push against injection site and press Inject button



4. Eject Cassette and dispose of in appropriate container

Flexi-Q eMU-C

Electrical Multi-Use Auto-Injector for biological drugs in cartridges.



This electrical Multi-Use auto-injector is comprised of a reusable driving unit and a disposable cartridge. Compatible with biological drugs in cartridges and suitable for variable dosing. The Flexi-Q eMU-C is intended for use in chronic diseases that require frequent injections (e.g. multiple sclerosis, diabetes and growth hormone disorders).

The reusable design lowers the cost per injection and reduces the volume for storage and disposal.

Pharmaceutical Company Advantages:

- Compatible 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 Step by step instructions on device screen.
- Injections data recording and logs.
- Wireless communication to a remote data base.
- · Calendar reminders.
- Injection time control can be adjusted to reduce pain.
- Enables automatic priming.





See how easy it is to use:







2. Attach a disposable



3. Prime (once for each new cartridge)



4. Insert needle and press Inject



5. Remove needle and discard properly

19

OBI-1 Wearable Injector

Bolus wearable Injector for subcutaneous administration of biologic drugs



Pharmaceutical Company Advantages

Differentiation

- Disposable wearable injector for use with prefilled syringes
- Automatic needle and soft cannula insertion (only soft cannula remains in the SQ tissue for the entire use duration)
- Drug delivery for extended periods of time
- Programmable delayed activation



Patient Benefits

Ease of use - better patient compliance

- Easy and straight forward installation and removal
- Simple user interface
- Intuitive operation, specially designed for self-administration
- Quiet operation
- Compact size

Patient safety

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

This product is under development



Patch Pump (eLVD)

Long duration subcutaneous administration of large dose volume biologics



Pharmaceutical Company Advantages

Differentiation

- Reusable driving unit and disposable unit for use with standard vials
- Automatic needle and soft cannula insertion (only soft cannula remains in the SQ tissue for the entire use duration)
- Large volume delivery for extended periods of time
- Pre programmable injection profile
- Minimum Flow administration: 0.25cc/hr
- Programmable flow rate sequence, by manufacturer
- Ability to sterilize in EtO



Patient Benefits

Ease of use - better patient compliance

- Easy and straight forward installation and removal
- Simple user interface
- Intuitive operation, specially designed for self-administration
- Quiet operation
- Compact size: 68x46x19.5 mm (L x W x D)
- · Communication to remote data base.

Patient safety

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

This product is under development



The OBI-1 is a disposable wearable injector, compatible with biologics and other drugs requiring bolus subcutaneous administration. One of the key advantages of the OBI-1 lies in its intuitive, easy-to-use and safe operation.

The E3D patch pump comprises of a reusable driving unit and a disposable unit, compatible with biologics and other drugs requiring long duration subcutaneous administration. One of the key advantages of the E3D Patch pump lies in its intuitive, easy-to-use and safe operation.

>0 >1



Elcam Medical is a world class producer of disposable medical devices for the OEM market, and a provider of innovative solutions for specialized flow control needs. Elcam Medical works with the medical industry's leading companies, with particular expertise in the areas of Fluid Management & IV Therapy, Vital Signs Monitoring and Drug Delivery.

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.

Global Presence

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

Quality Assurance

Elcam Medical is experienced in working under tight deadlines, without compromising quality. We operate in strict compliance with ISO 9001:2008 and ISO 13485:2003 standards. Most products are CE approved and 510(k) cleared.

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.

Clinical Know-How and Expertise

With more than 30 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.

E3D is a sister company of Elcam Medical



We focus on your needs





Our wide ranged auto-injectors portfolio, customization capabilities and in-house manufacturing & assembly, ensure your drug is delivered exactly as planned

