

Flexi-Q DV

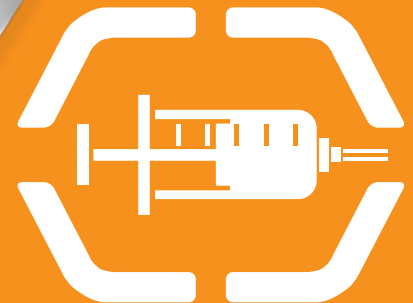
Fully Disposable Auto-Injector for Drugs in Vials

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.



I3D™

Injectable Drug Delivery Devices



 Elcam Stopcocks

 Lucomed Medical Products

 Injectech

Flexi-Q DV

Fully Disposable Auto-Injector for Drugs in Vials 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

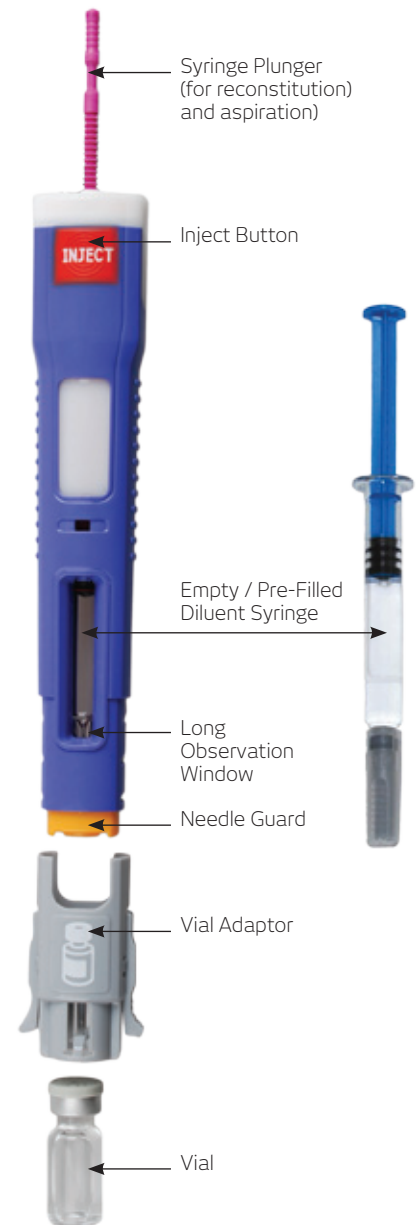
Ease of use – better patient compliance

- Fully automatic injection process
- Quite 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
- Proprietary feature prevents expensive drug spillage during reconstitution and injection
- Prevents false activation during all steps

Regulatory Status - FDA 510(k) cleared



REV-4 12/2012

See how Easy it is to Use (reconstitution version):



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



2 Press Plunger to inject the diluent into the vial, then pump mixed drug back into the auto injector.
Note: Should you need to mix more than one vial, replace the empty vial with a new one and repeat step 2.



3 Detach Vial Adaptor from the injector. 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 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.



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