SAFE AUTO-NEEDLES™

SAN™ PRODUCT FAMILY

Better injectors. Better compliance. Better care.

Addressing patient-centered challenges in injectable drug delivery

Compatible with:

- Prefilled syringes (luer and staked needle)
- Vials
- · Glass or Polymer
- Liquid, Iyo, powdered drugs





About DALI Medical Devices

DALI Medical Devices develops drug delivery technologies and devices - from product concept to commercialization - for pharmaceutical and medical device companies, physicians, hospitals and patients. One of the autoinjectors we invented and developed was launched in the market by a major pharma company.

We develop and customize products to meet specific end-user and high-volume manufacturing requirements. Our devices offer a value-added method to deliver and differentiate injectable drugs, but do not require drug manufacturers to alter their products or primary containers. For patients, our injectors reduce the perception of pain, lessen anxiety and improve adherence to treatment plans.

We have been active in the drug delivery arena for over 20 years. Our team of professionals specializes in plastics design and development, molding and testing - and has the ability to take medical and drug delivery devices from concept to registration and sales.

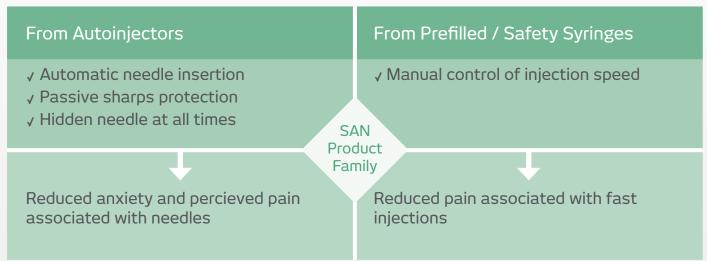
See a few examples and case studies from working with DALI on the back of the brochure.

Rapid Prototyping: **Both Niche and High-Volume Products:** From a general idea to High-value/high production capacity creative, products, as well as niche & small intuitive and effective designs, market-cap customized products to a fully-functional working prototype Competencies and **Technology Transfer: Product Design and** benefits working Development: Vast experience in technology with DALI transfer to CMOs both in Israel 3D modeling, FEAs, moldwhen we tailor our and internationally flows, tolerance analyses, devices to meet your statistics and Design-Of- Flexibility in production specific needs or design location / CMO according to Experiments (DOE), a custom product V&V testing client's preferences **Human Factors and Usability:** Quality Management System: Design and development Incorporation of human controls compliant with ISO 13485:2016 factors and usability testing and FDA OSR 21 CFR 820.30 through the whole project requirements cycle • Risk management and FMEAs in

compliance with EN ISO 14971

In order to minimize injection-related pain, a significant percentage of patients prefer to control injection speed whilst also benefiting from the features of autoinjectors.*

DALI's Safe Auto-Needle products offer a unique combination of features both from autoinjectors and prefilled/safety syringes:



^{*}Based on market research by DALI Medical Devices, presented at the Management Forum's Injectable Drug Delivery conference, March 2015

What our clients say about working with DALI:

"One thing that jumps out of the design review is that in general, clever and novel design approaches are evident throughout the product.... The product uses the minimum number of components to achieve the desired functionality, without undue component complexity..."

J.C., Founder of a major US-based engineering firm performing technical due-diligence for a major pharma client, for one of our autoinjector designs.

"DALI's staff is experienced and highly responsive. They adapt to changes with composure and professionalism. The latter are very important for any customized development.... When the need arise, we would very likely request another development project from DALI."

E.D., Innovative Formulations Project Coordinator, generic pharma client

"The products/prototypes we receive from DALI exceed my expectations.... DALI's technical and engineering support regarding new/customized products, project handling and corrective actions is excellent...."

T.S., Senior Director, Marketing & Business Development, medical device client

"Regarding the new prototype of the autoinjector, all of the people I have shown the device to have been really pleased with the outcome. As always, you have provided an exceptional amount of quality with your work. Thank you for all of your efforts."

C.B., PhD, Senior Biologic Project Manager, R&D, major U.S. pharma company

"DALI is a trustworthy partner to work with on development of new products. Staff is well trained and experienced and can successfully support the pharmaceutical business requirements...."

A.P., Direct Procurement Manager, EU generic pharma client

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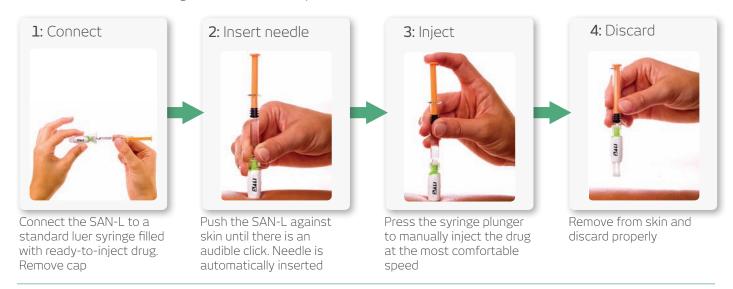
SAN-L™

for any type of luer syringe

SAN-L benefits:

- Compatible with any luer syringe
- Automatically inserts needle with an audible click
- Keeps needle hidden to reduce anxiety
- Allows patient to control injection speed
- Automatic (passive) needle shielding
- Customizable to drug manufacturer requirements



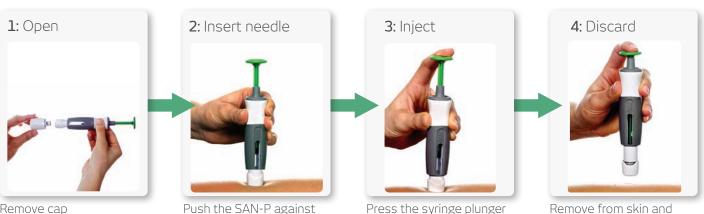


SAN-PTM

for staked-needle prefilled syringes

SAN-P benefits:

- Compatible with staked needle prefilled syringes
- Automatically inserts needle with an audible click
- Keeps needle hidden to reduce anxiety
- Allows patient to control injection speed
- Automatic (passive) needle shielding
- Large viewing window to verify drug clarity and integrity of prefilled syringe
- Customizable (multiple prefilled syringe sizes and drug manufacturer requirements)



Remove cap

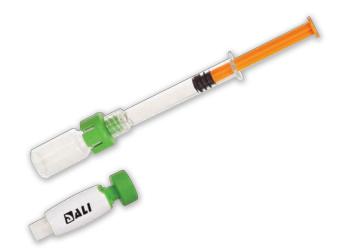
skin until there is an audible click. Needle is automatically inserted

to manually inject the drug at the most comfortable speed

Remove from skin and discard properly

SAN-DVTM

for drugs in vials



SAN-DV Pro™

for drugs in vials with integrated transfer system



SAN-DV & SAN-DV Pro benefits:

- Integrated vial adaptor and mixing system for easy reconstitution of lyophilized drugs
- Compatible with different vial sizes (13 mm and 20 mm neck) and with luer-lock prefilled syringes
- Automatically inserts needle with an audible click
- Keeps needle hidden to reduce anxiety
- Allows patient to control injection speed
- Automatic (passive) needle shielding
- Customizable to drug manufacturer requirements

SAN-DV



Press the SAN-DV on top of the drug vial and connect a luer syringe



Transfer / reconstitute the drug as needed.
Prepare for injection



Push the SAN-DV against skin until there is an audible click. Needle is automatically inserted



Press the syringe plunger to manually inject the drug at the most comfortable speed



Remove from skin and discard properly

SAN-DV Pro



Attach the drug vial into port 1, then connect the luer syringe into port 2



Transfer / reconstitute the drug as needed.
Prepare for injection



Push the SAN-DV Pro against skin until there is an audible click. Needle is automatically inserted



Press the syringe plunger to manually inject the drug at the most comfortable speed



Remove from skin and discard properly

SAN-Light™

Premium safety needles with passive needle protection for any type of luer syringe

The SAN-Light is a premium passive automatic safety needle, for use by healthcare professionals and self-injecting patients, to help prevent needlestick injuries.

SAN-Light benefits:

- Compatible with any type of luer/luer-lock syringe
- Automatic (passive) needle shielding reduces needlestick injuries
- Partially hidden needle prior to injection reduces patients' anxiety
- Exposed needle tip helps to prime and orient injector
- Customizable to meet drug manufacturer requirements (e.g., needle gauge and length for SC, IM, or ID injection)
- No change to common injection practice





Connect the SAN-Light to a standard luer syringe filled with drug. If required, remove airbubbles and adjust your dose



2: Insert needle*

Push the SAN-Light against skin until the needle guard fully retracts and stops

3: Inject*

Press the syringe plunger to manually inject the drug



Remove from skin. The needle guard will automatically lock over the needle for safe disposal

*Steps 2-4 are shown in self-injection. Healthcare professionals and caregivers may follow standard injection techniques when using SAN-Light for injecting patients or family members.

The SAN-Light can be incorporated in simplified versions of SAN-DV and SAN-DV Pro for use with drugs in vials





SAN-In™

Safety needle for integration with prefilled syringes

SAN-In benefits:

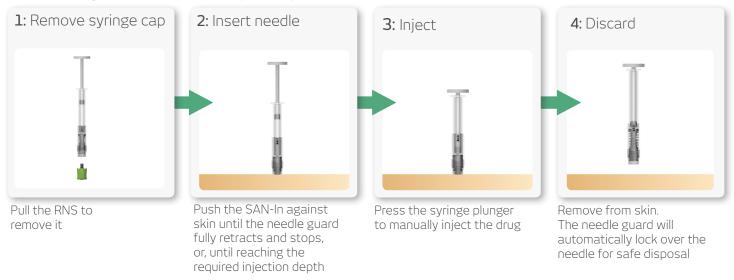
For the pharma company:

- For integration with COP/COC prefillable syringes
- Syringes delivered with the SAN-In safety needles in a nest and tub configuration, sterilized by ethylene oxide (EO) or Gamma - ready for filling on existing lines
- Proprietary safety mechanism prevents activation prior to RNS removal
- Requires small blister unit pack after filling
- Customizable e.g., needle gauge and length



For the user – HCP, caregiver or patient:

- Automatic (passive) needle shielding, unrelated to pushing plunger-rod all the way in or not reduces needlestick injuries
- Needle guard mechanism is inaccessible, lock is internal and cannot be easily reached
- RNS ergonomic external shape easy to grasp with intuitive pull for removal
- Needle bending impossible during RNS removal
- Partially exposed needle tip helps to prime and orient syringe against skin as requested by HCPs
- Partially hidden needle prior to injection reduces patients anxiety
- Clear visuality of plunger-stopper position at end of injection
- No change to common HCPs injection practice



OPTIONAL proprietary Finger-Grip & Sleeve™ eliminates fingers interference with needle shield movement during needle insertion



DALI's "DeviceBetter™" approach for Drug Delivery Devices

DALI Medical Devices brings over 20 years of experience in the development of innovative drug delivery devices. Our rigorous approach and procedures for design, engineering and project management enable us to not only develop exciting products but also ensure that they meet the user needs and comply with all relevant standards and regulations.

We always strive to develop a BETTER device -

- Better usability
- More intuitive & easier to use
- Device that the users want to use
- > a "DeviceBetter" shall provide a competitive advantage for generic/biosimilars as well as for innovative pharma companies.

Contact us to discuss how we can tailor our devices to meet your specific needs or design a custom product that meets your particular requirements.

Some project examples and case studies:

Autoinjector in the Market

One of the autoinjectors we invented and developed was launched in the market by a major pharma company. Other disposable and reusable autoinjectors are in development for other pharma clients

From Feasibility Project to Supply Agreement

4-5 months feasibility project for customized versions of two of the SAN products including rapidly production of fully-functional prototypes, formative usability/human factors study and bench testing.

Successful completion led to

supply agreement.

DALI is the Legal Manufacturer and CE mark holder

One of the SAN[™] products is customized for an EU pharma company for a generic drug treating endocrine diseases. Product is in late stage development.

Our extensive relationship with E3D, Elcam Drug Delivery Devices covers a variety of new generation autoinjectors for self-administration.

See the Flexi-Q range of autoinjectors at www.elcam3D.com



* The SAN product line is under development



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