

Dermal



CONVENIENT
FOR PATIENTS,
PROTECTIVE FOR
FORMULATIONS





Our airless and atmospheric delivery devices are suitable for RX and OTC medicines and are supported with comprehensive documentation packs for registration in regulated markets.

The dermal route is a convenient non-invasive way to administer liquid sprays, lotions, gels, or creams to the skin for **dermatological, transdermal local, and transdermal systemic** treatments.

Examples of dermatological therapeutic areas include acne, cold sore, eczema, alopecia, and psoriasis. Whilst transdermal local and systemic treatment routes are commonly used for anti-inflammatory and hormonal replacement therapy.

Dermal products

COMMERCIALLY
AVAILABLE

Sof'Bag®+

Sof'Bag®+ is an airless pouch-in-bottle packaging solution for prescription (Rx) and over-the-counter (OTC) formulations for dermal and transdermal application.



Sof'Airless XS+

Sof'Airless XS+ is a protective mini-airless system to deliver gel and creams for small dose applications and sampling.



Versatile atmospheric pumps

Our range of atmospheric pumps dispense formulations with different physicochemical properties, including viscosity, for regulated and low regulated markets.



IN DEVELOPMENT PLATFORM

Child Resistant Closure for Sof'Bag®+

The Child Resistant Closure for Sof'Bag®+ is a 'press and turn' concept developed to prevent unwanted opening by a child without compromising the ease of opening for adults.



A unique partner



Worldwide dermal
& transdermal
pharmaceutical
references



Fast time-to-market
& agility



Dedicated services
& customer
technical support

Sof'Bag®+

The airless solution for your sensitive formulations.

Sof'Bag®+ is an airless pouch-in-bottle packaging solution for prescription (Rx) and over-the-counter (OTC) formulations for dermal and transdermal application. Sof'Bag®+ is suitable for solutions, lotions, gels and creams, and even the most sensitive formulations.



High performance with different formulation types

- from fluid lotions, gels to thicker creams

Can be used in any position

- 360° formulation dispensing

Compliant device design and development

- According to the stringent pharmaceutical packaging component requirements and relevant sections of EU Medical Devices Regulation 2017/745

Protection against oxygen, light and moisture

- due to the pouch-in-bottle system

Very high restitution rate (>95%)

- minimal formulation waste

Precise delivery

- Sof'Bag®+ can be registered as a “metered dose system”

DIFFERENTIATE YOUR COMBINATION PRODUCT WITH CUSTOMIZED FEATURES

Our experts in User Design, User Experience and Human Factors can support your combination product customization. From the the color, shape, size or form of the cap and bottle, to dose counter and anti-tampering features.

* Sof'Bag®+ is a registered trademark of Nemera La Verpillière



POUCH-IN-BOTTLE TECHNOLOGY

Upon pump actuation, the formulation is dispensed out of a collapsing pouch encased inside a rigid bottle.

A STANDARD OFFER



Standard



B-shape*

Device is composed of 2 sub-assemblies: a pump and a pouch bottle.

SP943+ with a cap

- Available doses (μ l): 672*, 1000, 1420, 1500
- Fitment: Snap on
- Actuator included
- **Child Resistant Closure** in development



A laminated pouch inside a rigid bottle

Pouch-in-bottle+ sub-assembly

- Bottle sizes available (ml): 50, 100



**Not available for hormonal applications*

Sof'Airless XS+

The compact and transportable solution for local dermal treatments.

Sof'Airless XS+ is a protective mini-airless system for small dose applications and sampling.

It is the solution for trial sizes or local treatments with very little skin surface to cover. It targets Rx and OTC dermal gels and creams and is already used for a variety of sensitive actives for cold sore treatments and solar keratosis.

Can be used in any position

- 360° formulation dispensing

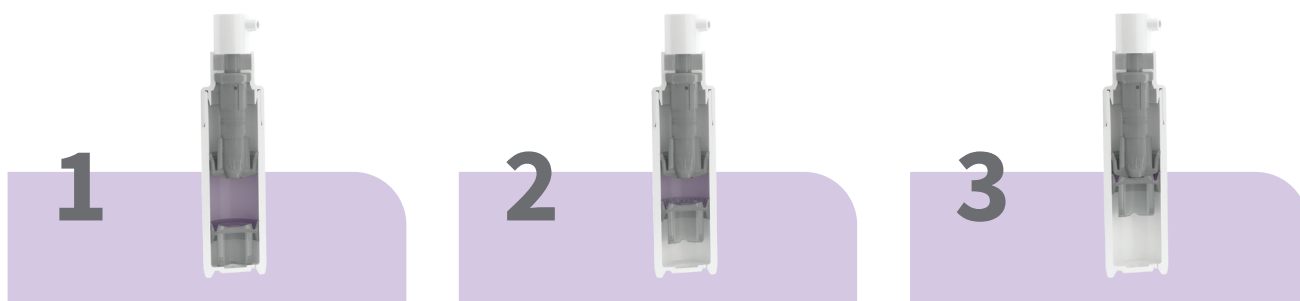
Compact and transportable

- 2ml size

Very high restitution rate (>95%)

- Almost no formulation waste





PISTON TECHNOLOGY

Upon pump actuation, the formulation is dispensed and the bottom piston rises.



Device is composed of 3 sub-assemblies: a pump, a piston bottle and a cap.

SP24A+ pump

- Pump volume (μl): 45, 80
- Fitment: Snap-on
- Actuator included



Piston-bottle

- Bottle volume (ml): 2



Cap

- Cap colours: white or transparent

Delivery solutions for dermal applications

Atmospheric pumps have been developed to deliver formulations with different physicochemical properties including viscosity. They are available with a comprehensive range of doses; suitable for topical drugs such as local anesthetics, anti-inflammatories, antibiotics, antifungals and transdermal drugs such as hormones.



Versatile atmospheric pumps

We have a range of solutions to deliver liquid formulations with different physicochemical properties, including viscosity, for regulated and low regulated markets.



Small doses,
regulated market

		Fitments		
	Doses (µl)	Crimp	Snap	Screw
Pumps				
SP270+	50, 70, 80, 90, 95, 100, 130, 140	FEA20	FEA20	DIN 18/10 GCM1 18/415
SP370+	180, 200			
Actuators				
		✓	✓	✓
9590D+				
		✓	✓	✓
5200+				

Small doses,
low regulated markets

		Fitments		
	Doses (µl)	Crimp	Snap	Screw
Pumps				
SP27	50, 70, 80, 90, 100, 130, 140	FEA20	FEA20	DIN 18/10 GCM1 18/415
SP37	180, 200			
Actuators				
		✓	✓	✓
9590				
		✓	✓	✓
5200				

Our integrated combination product services

ANALYTICAL SERVICES & DESIGN VERIFICATION

Our team of experts is dedicated to ensuring the safety, efficacy, and compliance of your combination product including:

- Comprehensive analytical services and design verification
- Advanced testing methods tailored to your formulation and active ingredients
- Testing method development, administration, and reporting
- Performance and integrity verification of your device and drug product
- Adherence to global standards throughout the process



HUMAN FACTORS & USER EXPERIENCE MANAGEMENT

We provide exceptional support for combination products across diverse regulatory pathways, device types, and patient populations for global markets including:

- Human Factors program strategy and risk management
- Formative/summative testing (design validation) administration
- Human Factors Engineering documentation for regulatory submissions
- Enhances safety, usability, and overall satisfaction of your combination product.
- Aligns with FDA Human Factors Engineering guidelines and ISO 62366 standards
- Extends beyond the device to include instructions for use, packaging, and training programs to optimize user adherence and engagement



REGULATORY STRATEGY & SUBMISSION AUTHORIZING

We provide tailored strategies and support for all stages of the regulatory process, including:

- Development of a comprehensive regulatory strategy including pre-market to post-market support
- Guidance on FDA regulations and international standards (ISO 14971, ISO 10993)
- Expert support in regional regulatory guidelines
- Assistance in authoring and compiling regulatory submissions, including: Premarket Approval (PMA), 510(k) submissions, CE marking documentation, and Notified body opinion support
- Accelerated submission processes drawing from our experience in over 54 markets



Our Dermal featured services

DOSE PERFORMANCE

Comprehensive tests range to characterize combination product performance with a specific formulation, leveraging Design Verification Testing know-how on standard deliverables



DEVICE USABILITY

Tailor-made test with adaptations based on user simulation approaches to characterize different parameters including actuation force, dimensional control, and cap disassembly force

FORMULATION CHARACTERIZATION STUDIES

A wide range of possible formulation characterization testing tailored to your specific needs of evaluation across various development phases and for registration purposes



