Nemera
we put patients first

Ear, Nose, Throat

MAKE EVERY
SPRAY COUNT

We provide a comprehensive range of pumps for Ear, Nose, Throat (ENT) route, suitable for regulated and low regulated markets.

Other than treating conditions locally, nasal delivery is an attractive option to also administer systemic therapies, by targeting the right optimal nasal region for drug deposition, which may vary from benign to serious health conditions.

To precisely address the exact part of the nasal cavity, the delivery device used within the drug combination product is a critical element and may vary depending on the therapeutic indications.

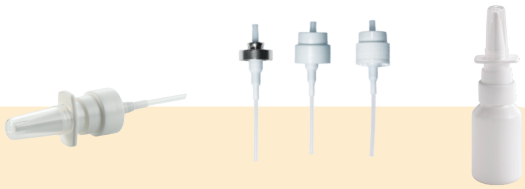
The nasal route offers many benefits:

- **Is not invasive and accessible for patients to self-administer their treatment with a rapid onset.**
- **Allows better bioavailability as drug administration via the nasal route avoids hepatic first-pass effect, unlike oral route.**

Specific expertise and a holistic approach are crucial in ENT device development to ensure optimal region targeting and drug deposition efficacy.

Our ENT products

COMMERCIALLY AVAILABLE



Multidose Spray Systems

We offer various technologies with a full range of pumps and actuators, for regulated and low-regulated markets including **In-Vitro BioEquivalence programs**:

- SP270+ and SP370+
- SP27 and SP37
- Child Resistant solutions

UniSpray

UniSpray delivers one accurate liquid dose, primarily for systemic-acting drug administration in emergency and crisis, including **In-Vitro BioEquivalence programs**

IN DEVELOPMENT PLATFORMS

Nasal Vaccine

Ideally used for respiratory infections prevention such as covid-19, influenza amongst others.

Electronic devices

Full range of services for design, development and manufacturing:

- Safe'n'Spray to manage overdosing
- Electronic Nasal device

A unique partner

Faster time to market thanks to our flexibility & agility

Worldwide Rx & OTC references including bioequivalence programs

Dedicated customer services & technical support

Multidose Spray Systems SP270+ and SP370+

Proven track record of our multidose spray pump platform for regulated markets

High quality standard
Reliable dosing throughout product shelf-life, suitable for liquid solution & suspension formulations

Materials compliant with combination product regulations

Robust, effective, and safe solutions for ear, nose, and throat application

Strong and close collaboration with CMOs to **accelerate time-to-market**

Regulatory expertise, fulfilled requirements and ready-tu-use data packages

Available off-the-shelf **bioequivalence programs** & in-house expertise

Quality and performance for ENT sprays in regulated markets.

Commercially Available

Pumps

	Stated Doses (µl)	Crimp	Snap	Screw
SP270+	50, 70, 80, 90, 100, 130, 140	FEA20	FEA20	DIN 18/10 GCMI 18/415
SP370+	180, 200			

Actuators

Nasal

	Crimp-on	Snap-on	Screw-on
4345+ 	✓	✗	✗
2371+ 	✓	✗	✗
9619+ 	✓	✓	✓
9620+ 	✓	✓	✓
4095+ 	✓	✗	✗

Available off-the-shelf **bioequivalence programs** *for nasal spray*

Buccal Auricular

	Crimp-on	Snap-on	Screw-on
9180+ 	✓	✓	✓
5860+ 	✓	✗	✗
1220+ 	✓	✗	✗
4325+ 	✓	✓	✓
9994+ 	✓	✓	✓

Others

	Crimp-on	Snap-on	Screw-on
9590+ 	✓	✓	✓

Accessories

Auricular cone #662+

Nasal cap #1033+ 

Other caps could be made available upon request.

SPRAY+LOCK™: Child-resistant closure

Lock your spray, keep it safe.

Our SP pump platforms are compatible with Roy+LeClair SPRAY+LOCK™, to offer a child resistant spray system for oral and nasal sprays.

Nemera we put patients first + Roy+LeClair Manufacturer of quality pharma packaging

CHILD RESISTANT ORAL SPRAY

CHILD RESISTANT NASAL SPRAY

Possible use: cannabinoid, nicotine, lidocaine, etc.

Key benefits:

Ergonomic and contempary design

Compact size

Easy Snap-on cap

Key features:

Doses available: 50, 70, 90, 95, 100, 130, 140, 180, 200 µl

Neck finish: Snap-on

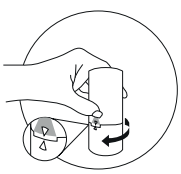
HDPE bottle available. Other material (PET, glass) upon request

20-60 ml regular and 20-30 NoWaste™ bottles

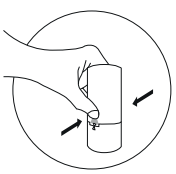
Cap color: White or natural available. Other colors upon request.

INSTRUCTIONS FOR USE

Cap removal instructions
Easy “align arrows and squeeze” removal

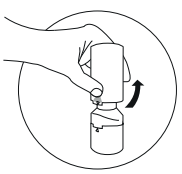


Align bottle and cap arrows

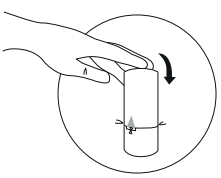


Squeeze ribs/textured area on both sides of the cap

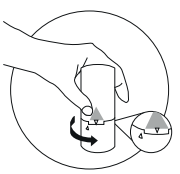
Closing instructions



Lift cap



Press on “cap snap-on”



Disalign arrows

spray+lock™ Patented Child Resistant Package -16 CFR 1700.20 COMPLIANT-

** NoWaste ™ and Spray+Lock ™ are trademarks of Roy+LeClair Emballage Inc.*

Multidose Spray Systems SP27 and SP37

Quality systems for low regulated markets.

	Stated Doses (µl)	Crimp	Snap	Screw
SP27	50, 70, 80, 90, 100, 130, 140	FEA20	FEA20	DIN 18/10 GCMI 18/415
SP37	180, 200			

Nasal

		Crimp-on	Snap-on	Screw-on
4345		✓	✗	✗
3959		✓	✓	✓
3960		✓	✓	✓
4095		✓	✗	✗

Buccal Auricular

		Crimp-on	Snap-on	Screw-on
9180		✓	✓	✓
5860		✓	✗	✗
1220		✓	✗	✗
4325		✓	✓	✓
9994		✓	✓	✓

Others

9590		✓	✓	✓

Accessories

Blue safety clip #1060
Snap on/Screw-on, Dose 100

Nasal cap #1033

Auricular cone #662

Other caps could be made available upon request.

UniSpray

Unit-dose system primarily for systemic-acting drug administration

UniSpray is a ready-to-use primeless device with single-metered liquid dose delivery. It offers one-handed activation with 360 functionality, used in emergency and crisis treatments. Thanks to its ergonomic design, it is intuitive and easy-to-use.

Key features:

- Ready-to-use, primeless device, with 360° functionality
- Compatible with existing primary drug container
- One accurate 100µL liquid metered-dose
- Compliant with regulatory requirements
- Possible spray performance adjustment
- For new, generics and repurposed drug

Available off-the-shelf **bioequivalence programs** *for nasal spray*

Key Benefits:

Reliable for rescue & emergency

- Safe and secured with no risk of accidental activation

Accelerates time-to-market

- Thanks to possible adaptations to conventional filling lines

Intuitive and robust device

- Ergonomic finger rest with two labelling surfaces
- A strong support on reliability management

Possible customization options

- Finger rest color, spray performance, etc

Equivalent utilization and performance

- For generics and bioequivalence programs

Nasal Vaccine

A nasal spray for vaccine administration

Our nasal vaccine concept device is currently under development, ideally used to prevent respiratory infections such as Covid-19, influenza, etc.

Key features:

- Designed to be compatible with commercially available luer lock syringe to administer liquid formulations
- May contain two doses for each nostril
- One-fit-all spray nozzle for both adults & pediatric patients
- Ergonomic nose rest allowing insertion depth control

Key Benefits:

Customizable administration volume

- dose volume adjustment depending on drug posology

Accelerates time-to-market

- thanks to possible adaptations to conventional filling lines

Assured sterile integrity

- thanks to its reliable sealing between syringe and spray nozzle

Reliable system

- prevent accidental actuation

Safe’n’Spray

Managing drug overdosing easily with a smart electronic concept device.

Safe’n’Spray, the new smart nasal spray with locking features, dramatically improves the existing way of administrating specific pain treatments, avoiding the risk of overdosing.

Key features:

Disposable unit “Spray”

- Nasal spray device
- Drug container
- System locked without the reusable part

Reusable unit “Safe”

- Electronic locking unit
- Patient-friendly interface
- Fingerprint sensor for patient identification
- Cloud connectivity with e-Nemera CS*

**e-Nemera CS is our cloud solution to store and share data generated by our electronic devices*

UNLOCKING: AUTHORIZED

- Touch fingerprint sensor to unlock
- ID check-in
- The dose is available for X min
- Fully administered dose
- Displays the number of remaining doses

UNLOCKING: UNAUTHORIZED

(Dose is not available for X hours)

- The patient tries to take a dose during the locking phase
- The device prohibits access to the patient

Electronic Nasal Device

Fostering patients' adherence with electronic nasal spray.

The smart electronic nasal concept add-on to enhance patient compliance.

Key features:

- Reminders
- Rechargeable
- Buzzer/Vibrator Shaking sensors
- On-device display
- Posology indication
- Dose counter

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 Enginering 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 AUTHORING

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 ENT featured services

IN-VITRO BIOEQUIVALENCE STUDY

Thanks to our lab test capabilities, we can support specific generic projects through a complete set of tests that meets the authority's prerequisite. This data generation will be statistically analyzed regarding USA and EU guidelines for eventual customers' IVBE dossier registration filing.

RELIABILITY REPORT FOR RESCUE AND EMERGENCY LIFE-SAVING TREATMENTS

A set of reliability testing and evaluation with customer's formulation for a specific combination product, particularly for emergency treatments, required by FDA, leveraging our know-how to navigate regulatory landscape.

SPRAY DEPOSITION STUDY

Simulation to characterize a deposition profile of a specific formulation using nasal casts testing expertise for optimum administration efficacy for various therapeutic areas and targeted zones.

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