



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 and direct CNS, Nose-to-Brain therapies, by targeting the right nasal region for drug deposition.

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:

- Non invasive and accessible for patients to self-administer treatment with a rapid onset.
- Potentially improved bioavailability as drug absorption and delivery via the nasal route avoids hepatic first-pass metabolism.

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 Pump Systems

We offer various technologies with a full range of pump and valve platforms, for regulated and low-regulated markets:

- SP270+ and SP370+
- Child Resistant solutions
- In-vitro Bioequivalence for nasal sprays, particularly dedicated to Corticosteroids & Combos molecules, e.g. mometasone, fluticasone propionate, azelastine fluticasone.

UniSpray



UniSpray delivers one accurate liquid dose, primarily for systemic-acting drug administration in emergency and crisis.

DuoSpray



DuoSpray delivers two-metered doses for seamless delivery of acute therapies.

IN DEVELOPMENT PLATFORMS

DriDose®

Nasal dry powder delivery platform designed for convenient and effective delivery.

Guided Stream Technology

An innovative non-invasive metered-dose device for direct nose-to-brain and CNS drug delivery.

A unique partner



Faster time to market thanks to our flexibility & agility



Worldwide Rx & OTC references including bioequivalence programs



Dedicated customer services & technical support

SP270+ and SP370+

Quality and performance for ENT sprays in regulated markets.



Pumps

	Stated Doses (µl)	Crimp	Snap	Screw
SP270+	50, 70, 80, 90, 95, 100, 130, 140	FEA20	FEA20	DIN 18/10 GCM1 18/415
SP370+	180, 200			

Actuators

Nasal

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

Buccal Auricular

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

Others

9590+	✓	✓	✓
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Spray+Lock™ child-resistant closures
compatible with the SP pump platforms
are available from Roy+LeClair.



Spray+Lock™ is a trademark of Roy+LeClair
Emballage Inc.

Accessories

Auricular cone #662+ Nasal cap #1033+

Other caps could be made available upon request.

Multidose Spray Systems SP27 and SP37

Quality systems for low regulated markets.



	Stated Doses (µl)	Crimp	Snap	Screw
SP27	50, 70, 80, 90, 95, 100, 130, 140	FEA20	FEA20	DIN 18/10 GCM1 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		✓	✗	✗
9994		✓	✓	✓

Others

9590		✓	✓	✓
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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

Unidose 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
- Threshold analysis available

Key Benefits:



Accurate dose delivery

- Primeless device single-metered dose volume 100 µL.

Safe and robust design

- Prevents risk of accidental activation. Once activated, device stays in final position. Compliant with reliability criteria for emergency use applications.

Accelerated market launch

- Thanks to possible adaptations to conventional filling lines. Regulatory expertise for swift dossier submission Industrial line ready.

Intuitive & user-friendly

- One-handed activation with 360° handling. Can be administered without HCP intervention. Ergonomic finger rest.

Customizable platform

- Finger rest color, spray performance, etc.

Unique Spray Expertise

- For generics and bioequivalence programs. Performance answers most stringent US and EU requirements.

DuoSpray

Bidose system primarily for systemic-acting drug administration

DuoSpray is a ready-to-use primeless device with double-metered liquid doses delivery. It offers one-handed activation with 360° handling, used in acute therapies. The device presents a visual dose indicator which provides clear confirmation of dose administration.

Key features:

- Ready-to-use, primeless device, with 360° handling
- Compatible with existing primary drug container
- 200 µL delivered as two 100 µL doses
- Compliant with regulatory requirements
- Possible spray performance adjustment
- For new, generics and repurposed drug

Key Benefits:



Accurate dose delivery

- Primeless device.

Safe and effective

- Robust design, compliant with regulatory requirement.

Accelerated market launch

- Thanks to possible adaptations to conventional filling lines. Regulatory expertise for swift dossier submission. Commercially ready.

Intuitive & user-friendly

- One-handed activation with 360° handling. Visual dose indicator.

Customizable platform

- Spray performance, etc.

Unique Spray Expertise

- For generics and bioequivalence programs. Performance answers most stringent US and EU requirements.

DriDose® Platform

Multidose reloadable and prefilled single dose devices for intranasal dry powder delivery

DriDose® platform provides high performance and flexibility for drug delivery for a range of target indications including emergency, acute and chronic indications.

Devices are suitable for local, systemic and nose-to-brain delivery and versatile for a wide range of formulations including small molecules, biologics and vaccines.

Key features:

- Breath-independent dose delivery
- High emitted dose and consistent delivered dose uniformity
- Propellant-free and suitable for preservative free formulations
- Simple to operate with no specialist training
- Flexible powder loading capacity
- Patent-protected technology designed for nasal powder delivery

Key benefits: DriDose® MultiDose reloadable device



Designed for efficiency and value

- Disposable prefilled component with drug candidate and reloadable propellant-free device
- Powder loading capacity up to 40 mg

Consistent and flexible dose delivery

- Highly consistent Delivered Dose Uniformity
- High Emitted Dose (> 95 %)
- Flexible dosing for daily, weekly or as needed use

Safe and hygienic

- No risk of powder build-up in disposable nozzle
- Visible dose actuation indicator

Available now for clinical trials

- DriDose platform technology has been evaluated in clinical studies

This design is for illustration purposes only

DriDose is a registered trademark of Nemera La Verpillière.

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

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 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.



