

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.

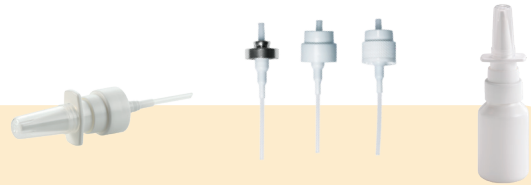
The nasal route offers many benefits:

- 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 Pump Systems

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

- SP270+ and SP370+
- SP27 and SP37
- In-vitro Bioequivalence for nasal sprays
- Child Resistant solutions

IN DEVELOPMENT PLATFORMS

UniSpray



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

Nasal Vaccine



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

RetroNose®



RetroNose® is an innovative concept device for nasal drug delivery through oral administration for better therapeutic efficacy and deposition.

Electronic devices



Full range of services for design, development and manufacturing:

- Safe'n'Spray
- Electronic Nasal device

Our services



**Integrated services
from device selection to
GMP manufacturing**



**Early-stage
Innovation**



**Testing services
for customer
formulations**

SP270+ and SP370+

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+ | ✓ | ✗ | ✗ |

Buccal Auricular

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

Others

| | | | |
|-------|---|---|---|
| 9590+ | ✓ | ✓ | ✓ |
|-------|---|---|---|

Accessories

Auricular cone #662+


Nasal cap #1033+

Other caps could be made available upon request.

In-vitro bioequivalence nasal for regulated markets

Accelerate your sprint to market with our Device Equivalence Program based on FDA or EU requirements.

We have developed off-the-shelf bioequivalent devices for some key nasal drug products.

| | Crimp-on |
|--|----------|
| 4290+  | ✓ |
| 32462+  | ✓ |
| 9130V+  | ✓ |

| Tests | Required by the FDA |
|---------------------------|---------------------|
| Dose delivery | ✓ |
| Droplet size distribution | ✓ |
| Spray pattern | ✓ |
| Plume geometry | ✓ |
| Priming / Repriming | ✓ |

Nemera can perform tests with customer formulations and support your registration process:

- In-vitro bioequivalence testing
- Different statistical calculations depending on regional needs



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.



Possible use: cannabinoid, nicotine, lidocaine, etc.

Key benefits:

Ergonomic and contemporary 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 or crimp-on available

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

15–20, 30ml regular and 15–20ml NoWaste™ bottles

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

CHILD RESISTANT ORAL SPRAY



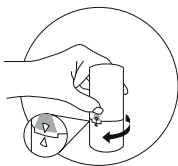
CHILD RESISTANT NASAL SPRAY



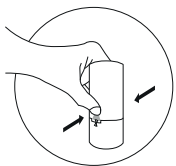
INSTRUCTIONS FOR USE

Cap removal instructions

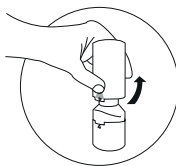
Easy “align arrows and squeeze” removal



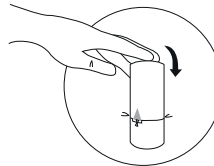
Align bottle and cap arrows



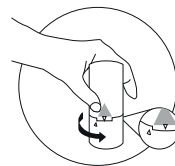
Squeeze ribs/textured area on both sides of the cap



Lift cap



Press on “cap snap-on”



Disalign arrows

Closing instructions

spray+lock

Patented Child Resistant Package
-16 CFR 1700.20 COMPLIANT-

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

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 GCM I 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

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

Key Benefits:



Safe, reliable 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

Possible customization options

- Finger rest color, spray performance, etc

Equivalent utilization and performance

- thanks to our in-vitro bioequivalence capability



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

RetroNose®

Better drug deposition to enhance therapeutic efficacy of nasal treatments.

RetroNose® is an innovative concept device for nasal drug delivery through oral administration. The principle of this concept is to deliver a spray through the oral cavity to deposit the drug in the nasal cavity from rear to front.



Key Benefits:

- Better treatment efficacy with lower drug amount* thanks to a fairly homogeneous deposition in the nasal cavities
- Low variability in terms of deposition distribution vs nasal pumps
- Opportunity of treating nose and throat in one-go
- Reduced patient-to-patient variability by avoiding the nasal valve passage

** To be verified with a clinical trial*

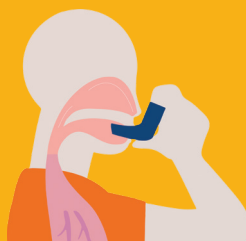
** RetroNose® is a registered trademark of LA DIFFUSION TECHNIQUE FRANCAISE and UNIVERSITE DE TOURS EPSCP*

How the device works:



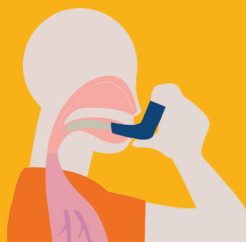
1.

Place the device in the mouth and inhale through the nose.



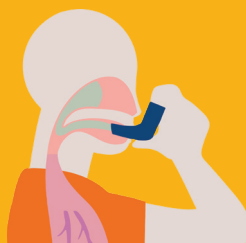
2.

Exhale through the nose.



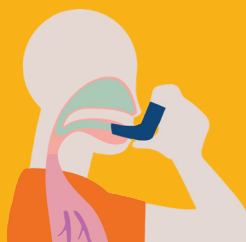
3.

The spray triggers automatically upon nasal expiration.



4.

Drug dispensing through the oropharynx and rhinopharynx.



5.

Homogenous deposition of the entire nasal cavity.

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”

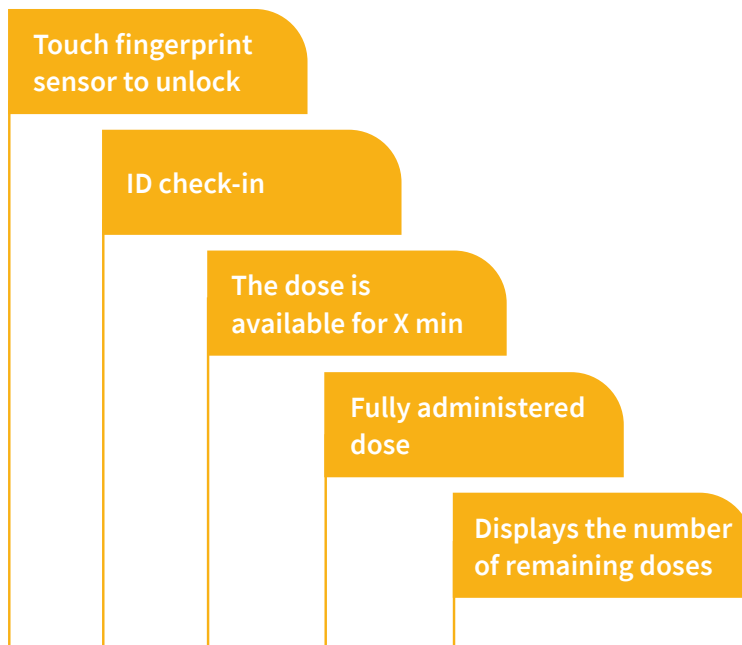
- Nasal spray device
- Drug container
- System locked without the reusable part

Reusable unit “Safe”

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

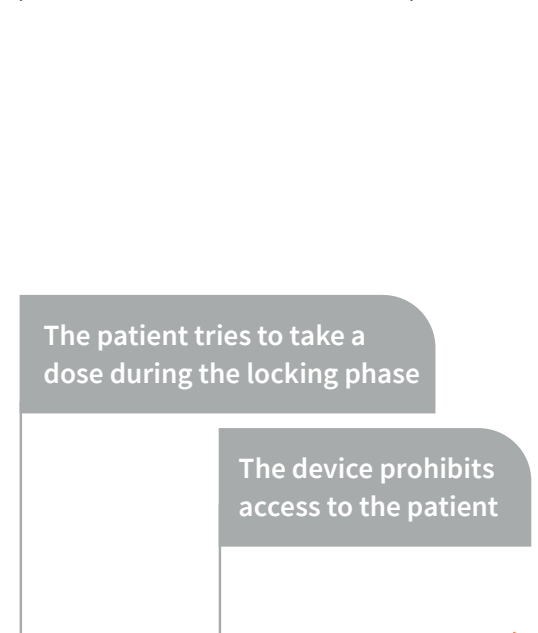
**e-Nemera CS is our cloud solution to store and share data generated by our electronic devices*

UNLOCKING: AUTHORIZED



UNLOCKING: UNAUTHORIZED

(Dose is not available for X hours)



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 services

INTEGRATED SERVICES

from device selection to GMP manufacturing

We have developed end-to-end services and expertise in ENT device development, and device consulting, to complement our diverse portfolio of products to help you through every step of the journey.



EARLY-STAGE INNOVATION

It is fundamental to integrate patients within the combination product development as early as possible. We provide a full understanding of the patient journey and recommend user-related activities to further optimize patients' experience for a specific drug/device combination product. Thanks to our extensive human factor capabilities, the pharma company could ensure that their selected device, in combination with their drug, is appropriate, safe and effective for the target population. Our support encompasses making a specific Instruction For Use (IFU) adapted to a certain target population, as well as supporting Human Factor activities in alignment with the pharma company's chosen regulatory path.



TESTING SERVICES FOR CUSTOMER FORMULATIONS

Thanks to our high-end laboratory facilities, we propose device plus formulation test services as well as test methods development for our customers' needs. In the case of establishing in-vitro bioequivalence (IVBE), following regulatory guidance is extremely crucial. 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.



Learn more about
our services at:
nemera.net/our-services

As a world-leading drug delivery device solutions provider, our purpose of putting patients first enables us to design and manufacture devices that maximize treatment efficacy.

We are a holistic partner and help our customers succeed in the sprint to market of their combination products. From early device strategy to state-of-the-art manufacturing, we're committed to the highest quality standards.

**Agile and open-minded,
we work with our
customers as colleagues.
Together, we go the extra
mile to fulfill our mission.**



Our broad offering

Offering a broad range of solutions in major delivery routes, we are the holistic development and manufacturing partner for your custom drug delivery device solution.

