



*injecting* new ideas

*Nemera*

we put  
patients  
First

# INJECTING NEW IDEAS

## Empower patients through good design...

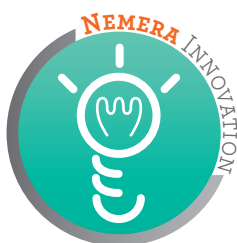
Parenteral administration of a drug exposes users (patients and healthcare professionals) to numerous hazards.

In designing a medical device, it is critical to consider the device failure and use-related hazards to ensure the product is safe to use and fits patients' needs. Through good design, patients are empowered with intuitive, easy-to-use, ergonomic and reliable medical devices.

## ...with Nemera's extensive experience in developing and manufacturing parenteral drug delivery devices

Nemera leverages **decades of manufacturing** and **development experience** in the parenteral device segment to offer patients premium products and customers a complete service. With the support of Nemera's global centre of expertise which is composed of more than 50 engineers and experts in **creative design** and **human factor activities**, Nemera is able to drive an idea from concept all the way to high scale manufacturing.

Nemera's balanced business model includes: **full proprietary product development**, **contract manufacturing** and **customized solutions**. This model gives flexibility to customers, being able to enter in the development & manufacturing process at any stage. Depending on their needs, pharmaceutical companies can leverage Nemera's know how and expertise to develop customized solutions based on either customers' or Nemera's intellectual property.



### Parenteral device portfolio

- Safe'n'Sound® passive safety device for prefilled syringes
- Safelia™ autoinjectors for 1ml & 2.25ml fluid or viscous formulations



### Customized solutions based on parenteral technologies

- Autoinjectors
- Implanters
- Other injection devices



### Large-scale industrial capabilities

- Insulin pens
- Autoinjectors
- Ready-to-fill plastic syringes

## Quality for patients

Nemera manufactures parenteral devices in best-in-class clean rooms. Manufacturing of devices at Nemera includes injection molding and complex assembly. All together our facilities have the following certifications:

- ISO 9001
- ISO 13485
- ISO 14001
- ISO 15378
- ISO 5001

We are committed to providing excellence in the quality of our products and services:

- Full traceability, 100% in-line controls
- Production according to 21CFR820/ GMP
- Manufacturing in ISO CLASS 5 to 8 clean rooms
- Datapack available

**Nemera**

## THE RIGHT PARTNER FOR SUCCESSFUL PARENTERAL PROGRAM MANAGEMENT

### CONCEPT GENERATION

IP Management, patients insights & creative design

Concept selection

Compliant structured stage gate progress

### DESIGN & PROTOTYPING

Human Factor Studies, DFSS and QBD

Detailed Design including Design For Manufacturing

Strong program management & governance  
Quality, Cost and Lead-time

### SCALE UP & PILOT

Final Design verification  
Process derisking & validation

Validated process & samples for clinical trials / stabilities

Sourcing & Supplier management  
Key partnerships  
equipment/molds

### INDUSTRIALIZATION

Validation according to GMP and FDA requirements

Validated commercial batches

Injection molding & high-speed assembly expertise

### REGULATORY

Facilitation of filling strategy

Long experience with EU & US authorities (FDA 510(k) / DMF / New Drug Applications)

Regulatory experts in-house



# Safe'n'Sound®

SAFE 'N' SOUND®

## THE FULLY PASSIVE SAFETY DEVICE FOR PREFILLED SYRINGES THAT PATIENTS CAN COUNT ON

### NEMERA'S SOLUTION TO NEEDLESTICK INJURIES

In the parenteral industry, needlestick injuries are a global concern. According to World Health Organization, over 3 million exposures to blood occur every year, resulting in health, psychological and cost issues.

Nemera has developed Safe'n'Sound®, a **fully passive safety device for prefilled syringes** to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needlesticks.

Not only does Safe'n'Sound® improve users safety and injection conditions, but also the device complies with the recommendations of the World Health Organization and the EU Council Directive 2010/32/EU .






Safe'n'Sound® platform for 1ml & 2.25ml syringes



Safe'n'Sound® Extended Finger Flanges portfolio of colors

### SAFE'N'SOUND® PLATFORM RANGE

	Off-the-shelf range		Customized	Development
	1 ml	2.25 ml	1 ml & 2.25 ml	0.5 ml
<b>Safe'n'Sound®</b>				
 Sub-Assembly	Cut/Round flange Small Round Flange Luer Lock	Small Round Flange Extra Small Round Flange Cut/Round Flange	Customers' specific syringes	Prototype
 Plunger Rod	White / Transparent	White / Transparent	Colored specific	White
<b>Option</b>				
 Add-on Extended Finger Flange	Portfolio of colors	Portfolio of colors	Colored specific	White



## KEY REASONS TO ADD SAFE'N'SOUND® (SnS) TO YOUR PREFILLED SYRINGE

### Activation extra force

Low extra force (<8N) required to activate the safety device of SnS

### Drop test

SnS protects against drops thanks to its design holding the syringe in every orientation

### Residual volume

SnS minimizes residual volume due to its efficient design

### Syringe unloading

Once the syringe is inserted into SnS safety device, the clips hold the syringe firmly

### Syringe loading

SnS requires low force to snap the syringe into the safety device, lowering the risks of potential syringe breakage during insertion.

### Override PUSH

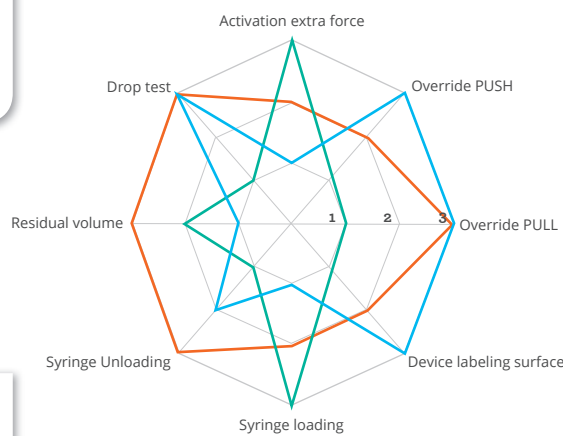
SnS requires high force (>100N) after the safety activation to break the safety feature by applying pressure on the plunger rod

### Override PULL

SnS requires high force (>100N) after the safety activation to disassemble the body and the sleeve

### Device labelling surface

Increased labelling surface thanks to SnS safety device and customizable plunger rod or extended finger flange



— Safe'n'Sound®  
 — Passive Safety device A (market sourced)  
 — Passive Safety device B (market sourced)



Safe'n'Sound®  
safety feature activated

Easy to use, convenient and ergonomic system

Reliable device ensuring safer injection

Robust & cost effective solution

Audible feedback to indicate safety feature final locking

Patented product / Freedom to Operate performed

510(k) cleared product/ On the market for Luer and Staked versions

Open platform of add-on safety devices compatible with syringes of different filling volume and flange type from multiple suppliers

## RIGID NEEDLE SHIELD REMOVAL CONCEPTS

Removing the rigid needle shield (RNS) of the syringe requires dexterity and minimum force. In order to facilitate device usage and overcome the issues of gripping or sticky RNS, Nemera has developed several solutions.

### Two options are available:

- **Integrated:** single use solution to remove the RNS pre-assembled to Safe'n'Sound® (1)
- **Stand-alone:** multiple use solution in which Safe'n'Sound® is inserted to remove the RNS (2)



(1) Integrated



(2) Stand-alone



(3) Subcutaneous



(4) Back-stop

## ONE-HANDED SUBCUTANEOUS INJECTIONS WITH ½ INCH NEEDLE

Performing a subcutaneous injection requires the user either to pinch the skin and inject at 90° or inject at 45°. As these steps are inconvenient, they can lead to injection in the wrong skin layer. With Nemera's solution for subcutaneous injections, only part of the needle is exposed, allowing:

- **One handed subcutaneous** injection (patient convenience)
- Drug delivery in the **right layer** (reduction of pain)
- Standard syringe usage while differentiating (cost & time to market/ no competition)

## BACK-STOP CONCEPT

In order to prevent accidental removal of the stopper or plunger rod, Nemera developed a back-stop feature: an add-on part (4) clipped at customer's facility after syringe insertion.

## BREAKTHROUGH TECHNOLOGY OF AUTOINJECTOR

SAFELIA™ - 2-STEP AUTOINJECTOR (AI) FOR 1ML AND 2.25 ML FLUID AND VISCOUS FORMULATIONS

Expected benefits	Standard AI	Safelia™ AI	Features
Creating possibilities for viscous injections with the same AI platform as for standard glass syringes	✗	✓	Injects fluid and viscous drugs up to 1000 cP
Risk of syringe breakage eliminated Possibility of using all (or no) syringe flanges	✗	✓	No stress on syringe flanges
Enables increased spring force and use of small gauge needles (less patient pain) without risk of glass breakage	✗	✓	No stress on syringe flanges
Reduction of pain at needle insertion	✗	✓	Adjust needle insertion speed
Reduction of pain during injection	✗	✓	No initial injection peak
Drug is delivered at the right depth	✗	✓	Needle insertion disconnected from injection





# NEMERA INJECTION DEVICES CONTRACT MANUFACTURING



## INSULIN PENS & AUTOINJECTORS

Nemera has proven expertise in managing **large-scale industrial projects**, manufacturing hundreds of millions of **insulin pens** and millions of **autoinjectors** every year.

## INJECTION DEVICES

With several decades of experience in manufacturing complex parenteral devices, Nemera offers its unique know-how in this field to its customers, along with premium service.

Over **5 million diabetics** rely every day on devices manufactured by Nemera

## IMPLANTERS

Sustained release parenteral drug formulations are delivered subcutaneously through implants in order to provide slow release of the drug. Since implants are **fragile**, insertion into the body requires caution.

Nemera has developed several devices to deliver implants with integrated anti-needlestick safety feature:

- A safety depot syringe with **telescopic plunger rod** (6)
- A safety retro injector for **soft implants** (7)



(6) Depot syringe

## Key product features

- Suitable for different implant sizes
- Can accommodate multiple implants, soft implants
- Implants easily loaded
- Integrated **safety feature**
- Little effort and pressure applied on implant
- **Retro-injection feature** allows deposit of implant at defined depth with multiple implants separated one from the other



(7) Retro injector

Nemera is a world leader in the design,  
development and manufacturing of drug delivery solutions.



**50<sup>+</sup>**

OVER 50  
ENGINEERS IN  
DEVELOPMENT

**30000+**

OVER 30,000  
SQM OF  
CLEAN ROOM  
MANUFACTURING

**47**

SALES IN  
47 COUNTRIES

**750**

OVER  
750 MILLION  
DEVICES  
PRODUCED YEARLY

**1300<sup>+</sup>**

OVER 1,300  
EMPLOYEES

## 4 PLANTS IN EUROPE & THE USA



- Neuenburg, Germany
- La Verpillière, France
- Le Tréport, France
- Buffalo Grove, IL, USA

## OUR PORTFOLIO



ear, nose,  
throat



pulmonary



dermal/  
transdermal



parenteral



ophthalmic



we put  
**patients**  
First

**Nemera**

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