Nemera
we put patients first

Parenteral

COMPLEX DEVICES,
SIMPLE CARE

State-of-the art parenteral device platforms to improve overall user's injection experience.

SELF-ADMINISTRATION

The growing prevalence of chronic diseases, coupled with the evolution of patient's lifestyles, is driving new ways of administrating parenteral drugs.

- Home-care therapy setting is clearly emerging as one of the major trend in the industry, reinforced by the switch from intravenous to subcutaneous injections.
- Self-administration at home therefore translates into a need for safer, easy-to-use, and ergonomic devices.
- Parenteral drug delivery devices are adapted in multiple ways to leverage the user's injection experience hence foster patient adherence.

PLATFORM APPROACH

Our platforms are designed strategically for a maximum possible range of potential therapeutic areas and patient populations.

- To meet both pharmaceutical company's and patients' needs, our platforms can be tailored and customized for your specific combination-product.

Our parenteral products

COMMERCIALLY AVAILABLE

Passive safety systems

Our premium passive safety device platform, Safe'n'Sound®, helps in preventing needlestick injuries and leveraging patients' injection experience.

- Safe'n'Sound® 1ml
- Safe'n'Sound® 2.25ml

Pen Platforms

Our comprehensive portfolio of pen injectors help customers to treat a wide range of pathologies.

- Reusable or disposable
- Manual or spring-assisted
- Variable or fixed dose

IN DEVELOPMENT

Wearables

Our smart on-body injector platform, Symbioze® , is tailored for reusable and large volume administration to foster patient adherence. It consists of a reusable main unit and a prefilled, preloaded disposable unit containing the drug.

Implanters

We developed a portfolio of devices to deliver implants with integrated needlestick protection. We can also support your projects and explore design attributes for new developments.

A unique partner

Proven track record of more than 2 decades with industrial capacity worldwide

Thorough development lifecycle from patient journey research, feasibility & usability testing to manufacturability evaluation

Broad expertise to support pharma partners in their journey to combination product

Safe’n’Sound®

SAFE’N’SOUND® 1 AND 2.25ML

Robust and ergonomic design to ensure a safe patient experience for self-injection at home.

Safe’n’Sound® 1ml and 2.25ml are highly customizable platforms of add-on passive safety devices for prefilled syringes. It helps in preventing needlestick injuries.

1ml Long Staked

2.25ml Long Staked

Key features

- Robust design
- Round shape
- Full transparency
- Ergonomic handling
- Versatile platform

Key benefits

- Commercially available and market-proven
- Fully compatible with ISO standard pre-filled syringes: glass or polymer based such as PLAJEX™
- Highly suitable for manual and automated assembly lines

** Plajex is a registered trademark of Terumo Corporation, TM Safe’n’Sound is a trademark of Nemera La Verpillière*

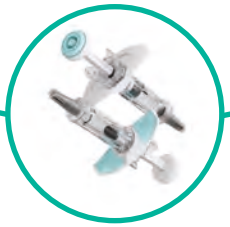
Safe’n’Sound® customization capabilities

Safe’n’Sound® is a highly customizable platform to meet both users and pharma needs.

Extended finger flanges

Colors: e.g., plunger rod and extended finger flanges

Specific design: e.g., thumb pad and finger flanges



Soft material: e.g., soft touch on thumb pad and extended finger flanges

Overcap: rigid needle shield removers

Pen injectors platforms

Designed for various therapies and applications.

Nemera offers 5 multi-dose pen platforms compatible with any drug in a cartridge container, designed to meet key user needs.

SIDE ACTIVATION

PENDURA AD

REUSABLE

Spring-assisted drug delivery

Low force & constant injection

PENONE

FIXED DOSE

Spring-assisted drug delivery

Dose counter

PUSH-BUTTON ACTIVATION

PENVARIO

VARIABLE DOSE

Manual drug delivery

Versatile platform

PENDIA

VARIABLE DOSE

Spring-assisted drug delivery

Suitable for GLP-1, insulin & novel drugs

PENSET

FIXED DOSE

Spring-assisted drug delivery

Suitable for novel drugs

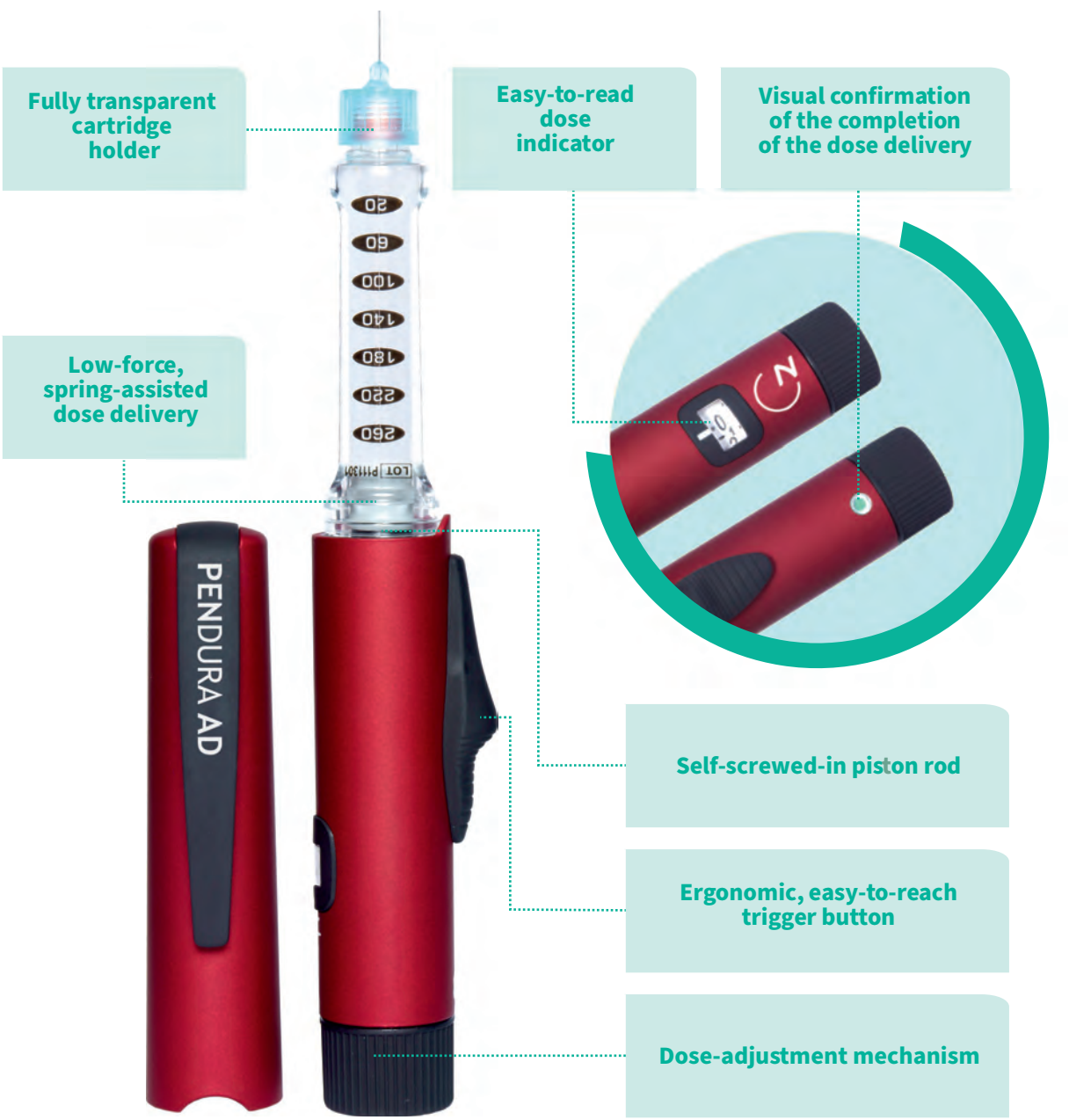
PENDURA AD

DURable because reusable

This reusable pen platform can accommodate insulins, systemic hormones and any other drug.

It enables a smooth injection with low force required and constant injection speed.

Ergonomic release button and clear indication at the end of injection provide a comfortable patients'experience.



PENONE

ONE fixed dose tailored to treatment regimen

This fixed dose pen platform is suitable for drugs not requiring variable dose, especially PTH and teriparatide.

It enables a smooth injection with low force required and no priming step of use.

Easy handling and dose counter to track drug intakes provide a comfortable patients'experience.

No priming needed

Low-force spring-assisted dose delivery

Ergonomic, easy-to-reach trigger button

Clear, unambiguous signalizations

Modern design

Simplicity of use

Client customised number of dose

Dose counter indicating doses left in the pen


PENVARIO

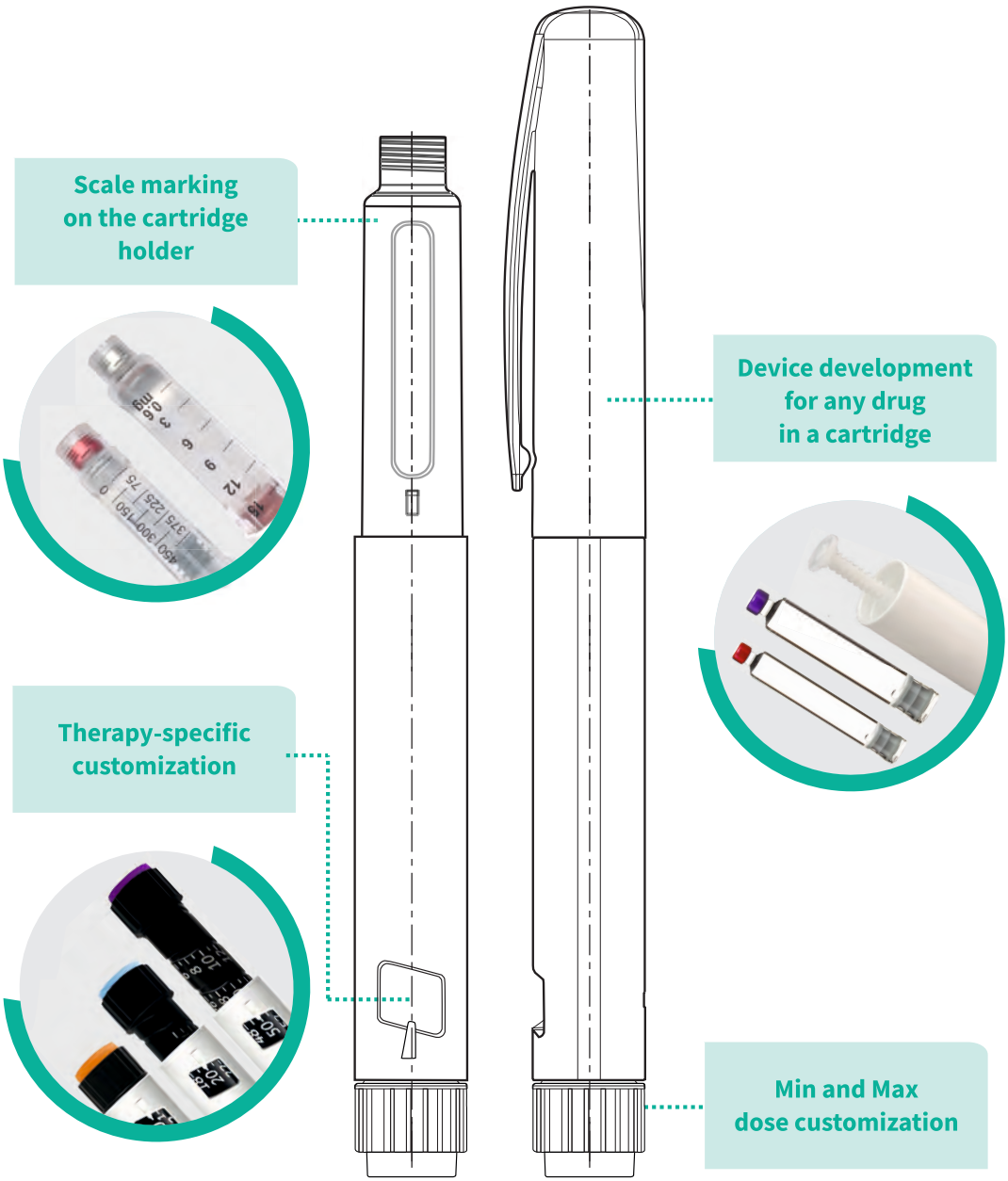
PENVARIO

Manual drug delivery and VARIable dOse

This variable dose pen platform can accommodate insulins, GLP-1, systemic hormones and any other drug.

It enables a reliable injection with low force required.

High capabilities of customization enable this platform to be very versatile.



PENDIA

Spring-assisted drug delivery, variable dose with DIAL back

This spring-assisted pen platform can accommodate insulins, GLP-1 and any other drug.
It enables a smooth injection with low force required and constant injection speed.

Ergonomic look & feel design provides a comfortable patient experience.

Integrated anti-roll function

Clear visualisation of the drug

Flexible cartridge volume

Clear, unambiguous signalizations

Soft dose setting-dial back button

Ergonomic non-extendable push button

Suitable for GLP-1 and novel drugs

Highly customisable

Comfortable patient experience

PENSET

Spring-assisted drug delivery with SET dose

This spring-assisted pen platform delivers a pre-set dose of drug.
The injection experience is very similar to an autoinjector one.

Use of predominantly soft surfaces creates a harmonious and calming visual experience.

Fluid contour conveying refinement

Ergonomic cartridge holder

Large and plane labeling space

Clear indication of fixed dose setting

Smooth use thanks to scallop grip surface

Suitable for novel drugs

Highly customisable

Close to an autoinjector

Symbioze®

Large volume and sustainable on-body injector platform to foster patient's adherence.

Nemera's smart patch-worn on-body injector platform, Symbioze®, is an innovative, user-friendly and sustainable solution to self-inject a medication at home. Its unique positioning consists of delivering large volume drugs (20ml), especially biologics, in combination with a multiple-use approach, thanks to its reusable and disposable parts.

READY TO USE
'clip, patch & go' patch worn, prefilled and preloaded

REUSABLE
Flexible for drug adjustment or multiple injections

SMART
Embedded and BT connectivity

PHARMA FRIENDLY
Compatible with Standard filling and assembly

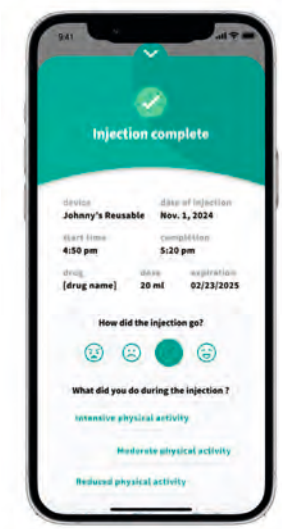
FLEXIBLE
Adjustable to different volumes, flowrates & viscosities

KEY BENEFITS

Flexible for drug types, volumes, viscosities and selected PDC

Ready-to-use for patients with reduced number of easy steps

Cost effective thanks to amortization of the reusable part



Connectivity feature to enhance patients' adherence to treatment and to preserve the connection with the team of healthcare professionals

Leveraging Insight by Nemera capabilities for developing mobile or embedded graphical user interface for a device or accessory: expertise in patient journey and UI/UX development

** Symbioze® is a trademark of Nemera La Verpillière*

Implanters

Solutions for sustained released formulations.

Implants are fragile and insertion into the body requires caution. Nemera developed a portfolio of devices to deliver implants with integrated needlestick protection. As implants can vary a lot, we support your projects and explore design attributes that will increase the user experience such as improved holding and priming, improved motion for implant insertion, etc.

SOLID IMPLANT DEPOT INJECTION DEVICE

- Implants easily loaded under the skin without risk of breakage
- Visible implant before application
- Prevent device reuse thanks to its clip mechanism
- Robust and simple system
- Customizable implant (needle size, shape...)
- Safety depot syringe with compact plunger rod

SAFETY RETRO INJECTOR FOR SOFT IMPLANTS

- Implants easily loaded under the skin without risk of breakage
- Prevent device reuse thanks to its clip mechanism
- Little effort and pressure applied on implant
- Automatic implant positioning thanks to its specific plunger rod
- Better control of implant positioning

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 Parenteral featured services

DEVICE VERIFICATION TESTING

Comprehensive tests range to ensure compliant and reliable drug-device combination, leveraging know-how on standard deliverables including robustness study, device performances, pre-conditioning.

COMPATIBILITY STUDIES WITH SPECIFIC PRELIMINARY DRUG CONTAINERS

Diversified activities to evaluate the compatibility between device platform and specific selected primary drug containers, to ensure combination product performances and regulatory dossier filing.

BIOLOGICAL RISK ASSESSMENT

Complete set of tests and evaluation to prove the biocompatibility of specific drug/device development process for regulatory dossier filing.

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