



# PRE-FILLABLE GLASS SYRINGES

FINE-TUNED TO MEET YOUR DRUG PRODUCT REQUIREMENTS



**NIPRO**  
PHARMAPACKAGING



## Continuous partnership...

Nipro PharmaPackaging is a long-standing and trusted partner of leading pharmaceutical companies for the development and manufacture of high-quality parenteral packaging. From early development throughout the entire life-cycle of your drug product, you will partner with a vertically integrated company with more than 60 years of experience.

- We advise you on the optimal raw material for your primary packaging and manufacture for you the glass tubing that meets your dimensional and cosmetic requirements.
- Upon finalizing the specifications of your primary packaging, our state of the art converting lines, equipped with the latest inspection technologies, manufacture with precision and adhere to the strict dimensional and cosmetic tolerances required of your primary container.
- For exceptional packaging challenges, our highly experienced laboratory service team will collaborate with you to analyze and find solutions.
- You can also choose from a range of accessories, which can be by-packed with your primary container to improve end-user comfort and ease of use.

**PACKAGING QUALITIES AND SERVICE LEVELS**  
fine-tuned to your drug product requirements!

# **...throughout the entire product life-cycle**

## **During drug product development**

- Extensive packaging range (ampoules, vials, cartridges, pre-fillable syringes)
- Cross-functional team of experts, advising on the most suitable packaging
- Quality Levels for structured and comprehensive packaging selection
- Provision of trial samples

## **During drug product approval**

- Fast request procedure for Letters of Authorization (LoA)
- Product registered at FDA, Canada Health, NMPA (Drug Master Files)

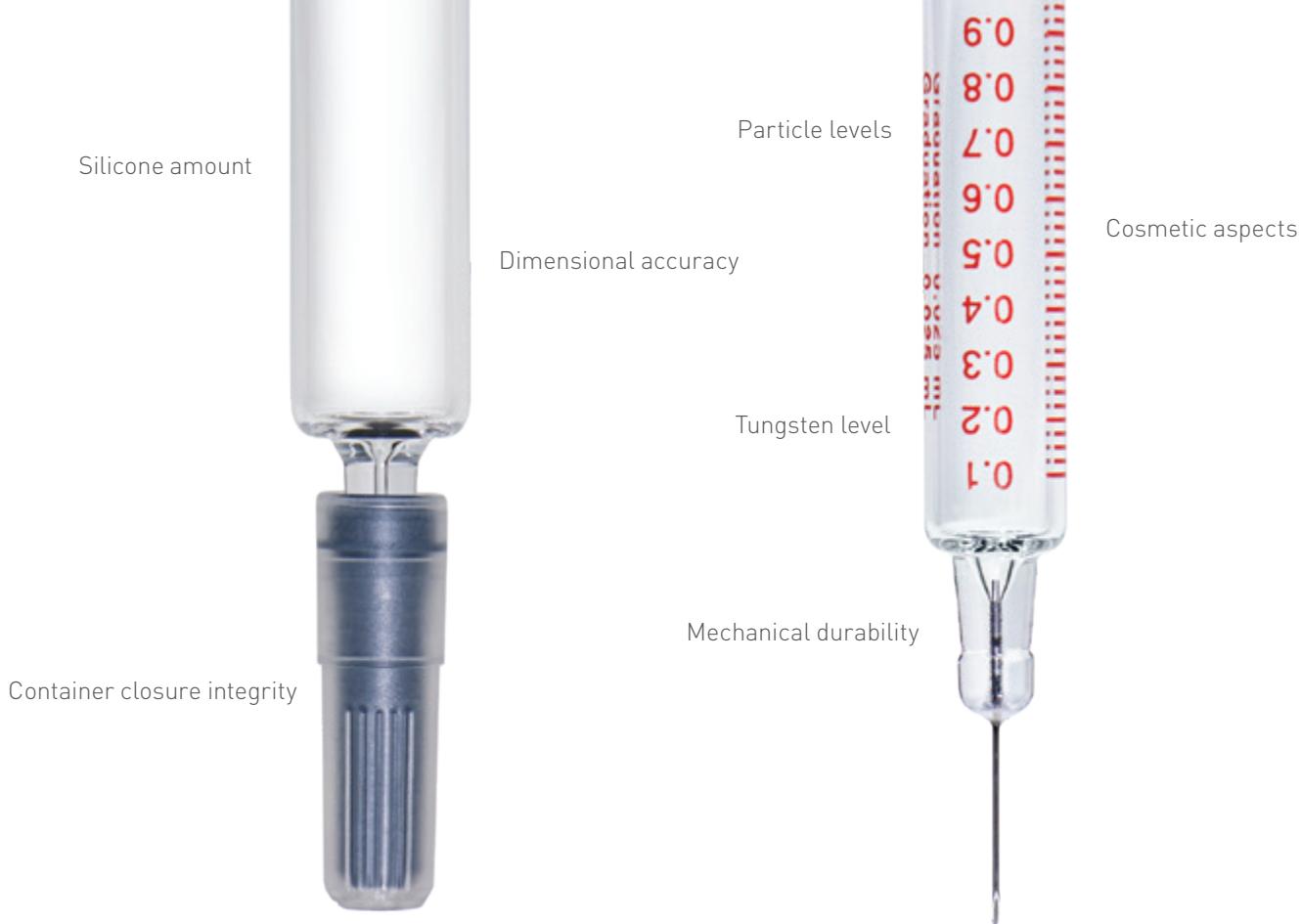
## **During commercial production**

- Large manufacturing network for continuous and ensured supply
- Switch from vials to syringes or cartridges while keeping the same supplier
- Laboratory services – Analytics for glass primary packaging
- Experienced technical service
- Specialized customer service
- Efficient complaint handling
- Dedicated sales

## **During product line extension**

- Adapted packaging solutions for generics/biosimilars
- Dedicated team to advise on optimal packaging solutions





## Solutions for a diverse market

Pharmaceutical companies are developing an increasing number of various drug products: from small molecules and biotechs to drugs for gene therapy. A substantial number are parenteral drugs, destined to be packed in pre-fillable syringes.

Each drug product has specific requirements that must be met by the primary packaging.

Some drug products require an economic packaging of standard quality, allowing a fast time to market and ensuring reliable processability of large quantities on high-speed filling lines.

Others are highly sensitive biotech drugs, requiring premium quality to minimize the risk of drug-container interactions, precise integration into auto-injection devices, and minimal drugs loss during fill-finish operations.

**NIPRO QUALITY LEVELS FORM THE PERFECT BASE**  
to capture and fine-tune your quality and service requirements.

# Quality Levels for pre-fillable syringes

At Nipro PharmaPackaging, we understand the diverse quality requirements of the pharmaceutical industry. Defining the right quality of primary packaging to meet your drug product requirements is a complex process.

**To facilitate this process, we offer three distinct quality levels:**

## **eNable:**

small molecule drugs, anticoagulants, diluents

## **eNhance:**

large molecule drugs, biotechs, ophthalmics, cosmetics, vaccines

## **eNgage:**

flexible solutions for exceptional drug products

## **Level of Customization & Product Complexity**

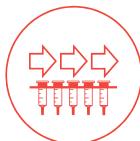




PRE-FILLABLE GLASS SYRINGES

## Meeting prevailing drug product requirements

FOR SMALL MOLECULES, ANTICOAGULANTS, DILUENTS



### Optimized processability for reduced total cost of ownership

Drug products packaged in pre-filled syringes are well established in the medical world and consumed in large quantities. Reliable processability on high-speed filling lines is particularly important for these drugs.

eNable syringes are controlled for specific attributes, such as reducing the risk of breakage, leakage, and rejections during final inspection.

#### Manufacturing & Inspections technologies | Benefits

|  |  |
|--|--|
| Tip dimensions and positioning of the needle shield      | Improved container closure integrity (CCI) |
| Inner diameter of the glass barrel<br>Flange restriction | Proper placement of plunger stopper        |
| Flange geometry  | Increased mechanical durability            |
| Nest & tub that is full and intact                       | Reliable processability                    |
| Nest & tub cleaned by ionized air                        | Reduced particle level                     |



## Standard data package for fast acceptance of goods

In order to register drug products and allow a seamless acceptance of in-bound goods, specific data from the packaging manufacturer is required. Nipro has foreseen this demand and supports customers by providing all necessary data.

### Data Support | Benefits

|  |   |
|--|---|
| Letters of Authorization (LoA)   |   |
| Drug Master Files (DMF) registered at the FDA, Canada Health, and NMPA                                   | Supporting your registration            |
| Certificate of Conformity (CoC)  | Efficient acceptance of delivered goods |
| Extended regulatory data, (compliance to pharmacopoeias, levels of sub-visible particles, risk analysis) | Additional quality assurance            |



## Designed for a safer and more reliable manual administration

Safeguarding patients and increasing their comfort while using syringes are principle objectives.

Our syringes are designed, manufactured, and inspected to contribute to a comfortable and safe administration.

### Manufacturing & Inspections technologies | Benefits

|   |   |
|---|---|
| Dive-in nozzle used for siliconization<br>Fixed silicone quantity per syringe                 | Consistent plunger performance                        |
| Needle angularity & point, needle siliconization, penetration force, and free cannula passage | Supports smooth punctures                             |
| Needle pull-out force<br>Sharp and accurate printing<br>Needle shield removal force           | Safer handling of the syringe during manual injection |

## Syringe type

| Volume<br>(mL) | O.D.<br>(mm) | Tip       |           |               | Flange |             |     | Shoulder |      |
|----------------|--------------|-----------|-----------|---------------|--------|-------------|-----|----------|------|
|                |              | luer slip | luer lock | staked needle | round  | small round | cut | round    | flat |
| 0.5            | 6.85         | •         | •         | •             | •      | •           | •   | •        |      |
| 1.0 long       | 8.15         | •         | •         | •             | •      | •           | •   | •        | •    |
| 1.0 std.       | 10.85        | •         | •         | •             | •      | •           | •   |          | •    |
| 1.25           | 10.85        | •         | •         | •             | •      | •           | •   |          | •    |
| 1.5            | 10.85        | •         | •         | •             | •      | •           | •   |          | •    |
| 2.25           | 10.85        | •         | •         | •             | •      | •           | •   |          | •    |
| 3.0            | 10.85        | •         | •         |               | •      | •           | •   |          | •    |

## Needle type

| Outer Ø<br>(G   mm) | Inner Ø<br>(mm) | Free length<br>(inch   mm) | Bevel   | Wall type |
|---------------------|-----------------|----------------------------|---------|-----------|
| 25   0.50           | 0.30            | 5/8   16.0                 | 3-Bevel | Regular   |
| 27   0.40           | 0.20            | 1/2   12.7                 | 5-Bevel | Regular   |
| 27   0.40           | 0.26            | 1/2   12.7                 | 5-Bevel | Thin      |

## Closures

| Staked needle       | Luer lock | Luer slip      |
|---------------------|-----------|----------------|
| Rigid needle shield | Tip cap   | Ribbed tip cap |
| Soft needle shield  |           |                |

## Components

| Plunger rod | Plunger stopper | Safety system |
|-------------|-----------------|---------------|
| Transparent | Standard        | Novaguard     |
|             | Coated          |               |

Suppliers: Aptar Stelmi, Datwyler, West, Nipro







# eN<sub>h</sub>ance..

PRE-FILLABLE GLASS SYRINGES

## Optimal choice for highly sensitive drugs

FOR LARGE MOLECULES, BIOTECHS, OPHTHALMICS, COSMETICS, VACCINES



### Improved drug-container compatibility

Highly sensitive drugs, due to their nature, run higher risks of interacting with primary container materials (e.g. pH shift, protein aggregation, delamination). Several syringe specifications are inspected during the production process to ensure drug-container compatibility.

#### Manufacturing & Inspections technologies

#### Benefits

Glass particles and foreign matter

Controlled particle levels

Low tungsten/tungsten-free

Low/No tungsten residuals/particles

Homogeneous silicone distribution  
Extra low silicone amount

Minimized risk of areas with excessive silicone



## Smooth integration into auto-injection devices

High drug viscosity, product differentiation, and end-user preference lead to an increased use of combination products. Several syringe parameters ensure reliable integration and a seamless functioning of auto-injection devices.

### Manufacturing & Inspections technologies | Benefits

|  |   |
|--|---|
| Rigid needle shield intact (camera and X-ray)  | Improved CCI reduces risk of unseen leakage   |
| Consistency of finger flange thickness   | Increased mechanical durability to withstand physical impact of injection mechanism |
| Precise dimensions of flange, barrel, and tip<br>Rigid needle shield concentricity and barrel bowing | Exact fit into device   |
| Pull-off force (POF) of rigid needle shield  | Reliable use of cap removers  |



## Optimized processability for minimal drug loss

When filling high value drug products, each unit counts. Controlling specific syringe attributes will contribute to smooth fill-finish operations, in terms of reducing the risk of breakage, leakage, and rejections during final inspection.

### Manufacturing & Inspections technologies | Benefits

|  |   |
|--|---|
| Highly precise tip dimensions and exact positioning of the needle shield         | Improved container closure integrity (CCI) reduces risk of leakage<br>Reduced filling volume thanks to optimized dead volume of syringe tip |
| Tightly controlled cosmetic aspects (especially effective on unprinted syringes) | Less risk of rejections of filled syringes at final inspection due to cosmetic aspects  |
| Consistency of finger flange thickness   | Stronger mechanical durability for less risk of breakage during the filling process   |
| Low silicone amount and tungsten level   | Minimized risk of rejections due to large molecule aggregates or sub-visible particles level  |

## Syringe type

| Volume<br>[mL] | O.D.<br>[mm] | Tip       |               | Flange |             |     | Shoulder |      |
|----------------|--------------|-----------|---------------|--------|-------------|-----|----------|------|
|                |              | luer lock | staked needle | round  | small round | cut | round    | flat |
| 0.5            | 6.85         | •         | •             | •      | •           | •   | •        |      |
| 1.0 long       | 8.15         | •         | •             | •      | •           | •   | •        |      |
| 1.0 std.       | 10.85        | •         | •             | •      | •           | •   |          | •    |
| 1.25           | 10.85        | •         |               | •      | •           | •   |          | •    |
| 1.5            | 10.85        | •         |               | •      | •           | •   |          | •    |
| 2.25           | 10.85        | •         | •             | •      | •           | •   |          | •    |
| 3.0            | 10.85        | •         |               | •      | •           | •   |          | •    |

## Needle type

| Outer Ø<br>(G   mm) | Inner Ø<br>(mm) | Free length<br>(inch   mm) | Bevel   | Wall type |
|---------------------|-----------------|----------------------------|---------|-----------|
| 25   0.50           | 0.30            | 5/8   16.0                 | 3-Bevel | Regular   |
| 27   0.40           | 0.20            | 1/2   12.7                 | 5-Bevel | Thin      |
| 29   0.33           | 0.19            | 1/2   12.7                 | 5-Bevel | Thin      |

## Closures

| Staked needle       | Luer lock | Plunger rod |
|---------------------|-----------|-------------|
| Rigid needle shield | LInC™     | Transparent |
|                     | V-OVS     | Color       |

## Components

| Plunger stopper | Safety system |
|-----------------|---------------|
| Standard        | Safe'n'Sound  |
| Coated          |               |

Suppliers: Aptar Stelmi, Datwyler, West, Nipro, Nemera, Vetter



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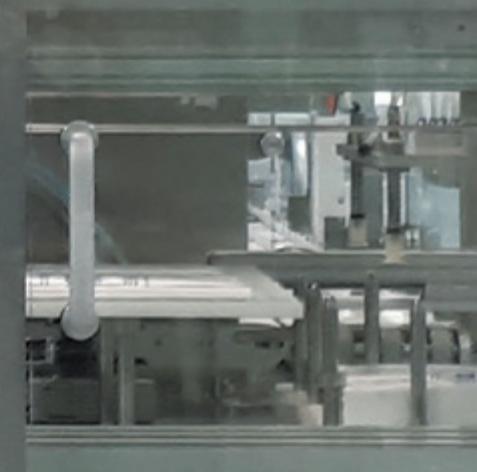


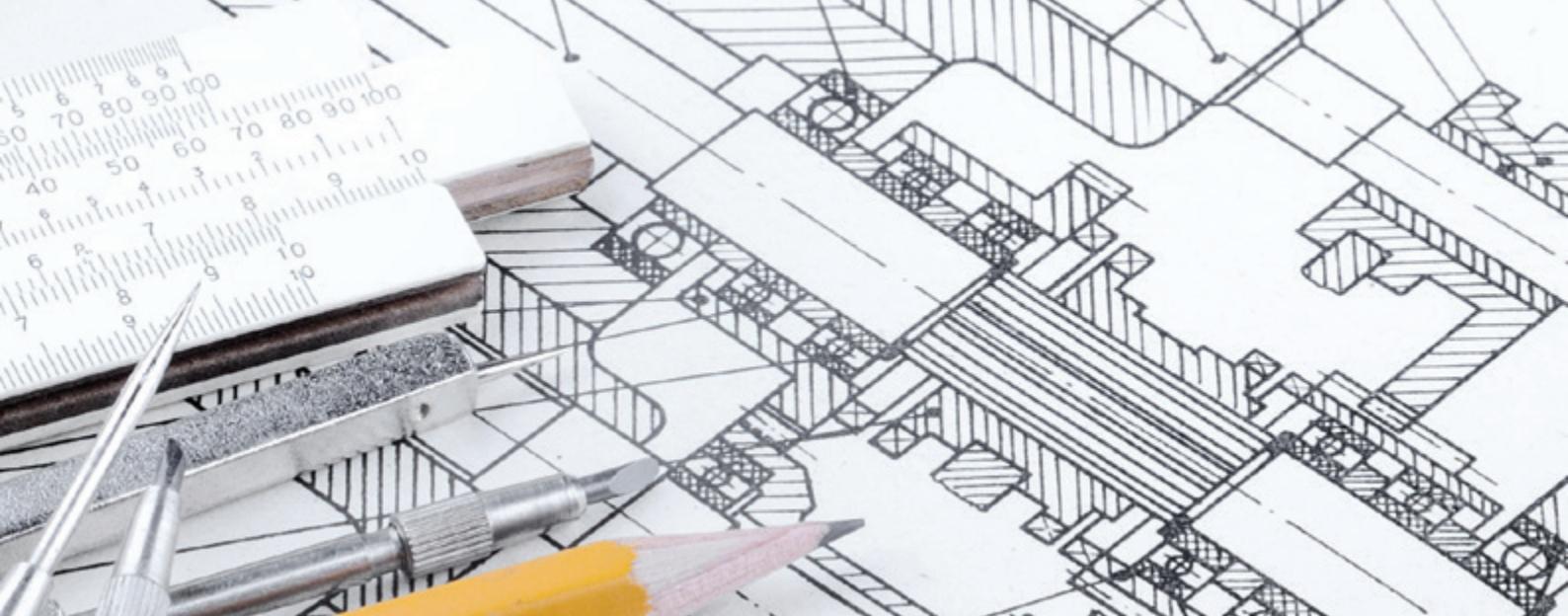
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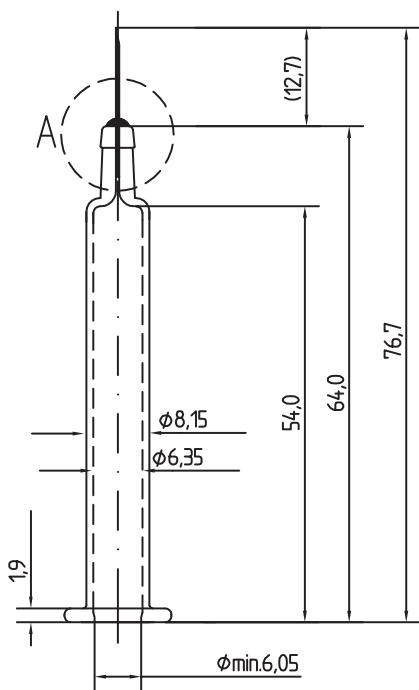


# eN<sub>g</sub>age...

PRE-FILLABLE GLASS SYRINGES

## For drug products with extraordinary packaging requirements

Customize your syringe specifications to meet your particular drug product requirements that surpass the eNhance quality level.



- Flange type
- Needle type
- Particle load
- Silicone level
- Cosmetic aspects
- Dimensional aspects

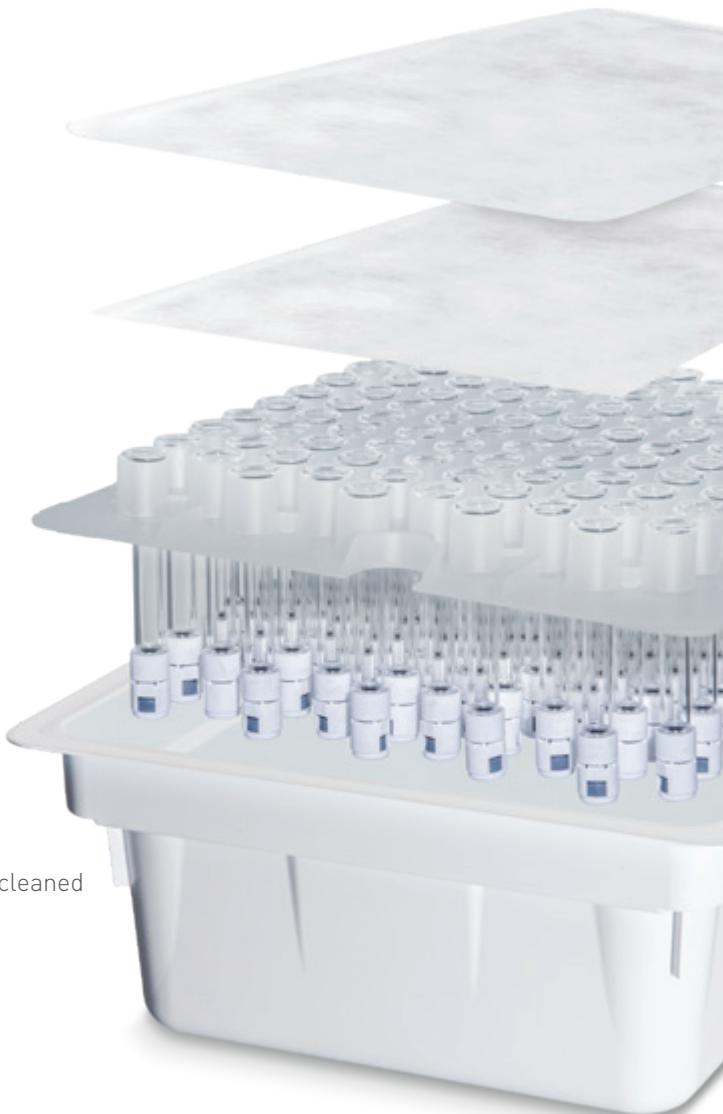
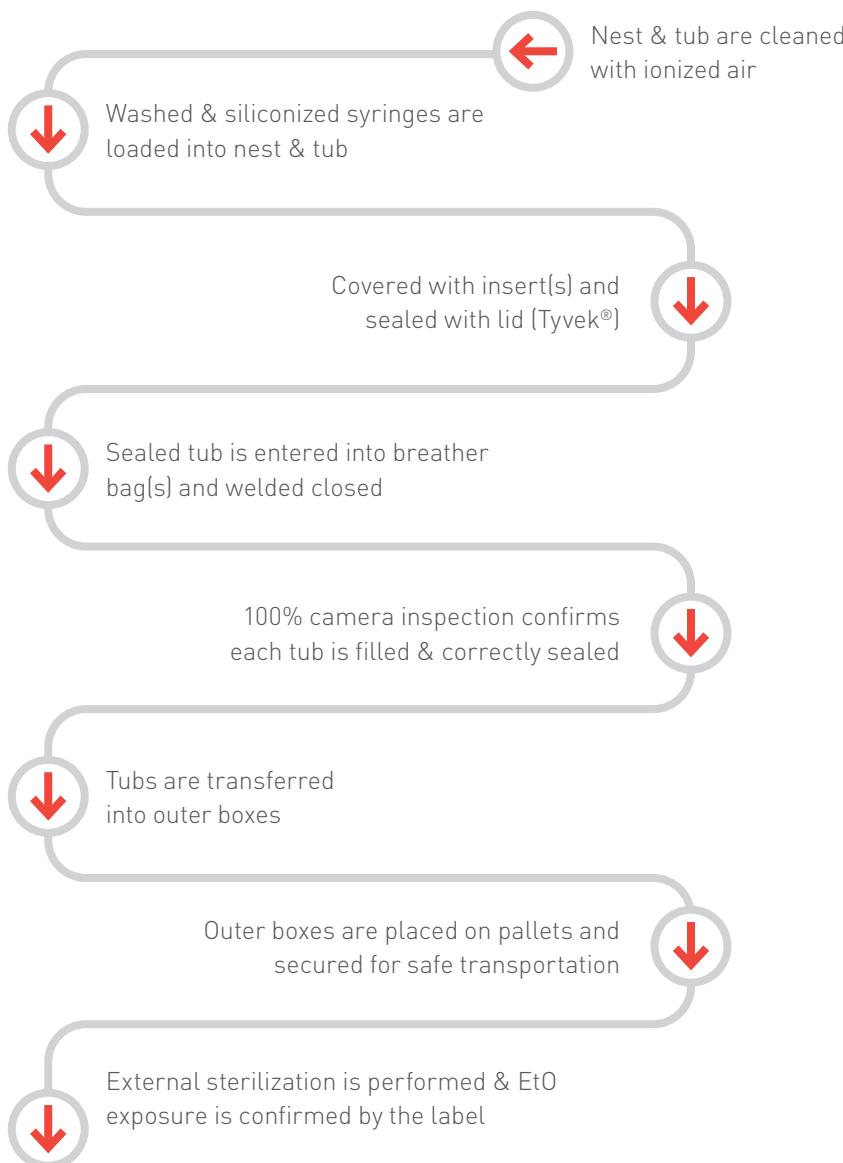


# Direct-To-Fill

## STERILE PACKAGING SOLUTIONS

Nipro PharmaPackaging manufactures D2F™ syringes in technologically advanced production sites that are certified according to ISO 9001, ISO 15378, ISO 14001, and ISO 50001.

Our fully automated cleaning and packaging process takes place in an ISO 7 / ISO 8 cleanroom with 100% monitoring under laminar air flow.



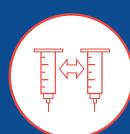
## Key Technologies



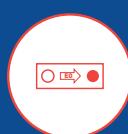
Cleaned with ionized air



100% in-line camera inspection



No glass-to-glass contact



EtO sensitive label

Nipro PharmaPackaging is specialized in developing and manufacturing advanced pharma packaging products and complete packaging solutions for early development drugs or the enhancement of packaging solutions for existing drugs.

With a worldwide manufacturing footprint of 14 plants, multiple sales offices, and internal lab services, Nipro PharmaPackaging offers an exceptional service platform. Through our personnel, products, and services, Nipro PharmaPackaging enables you to provide a safer and healthier administration to your customers.

Nipro PharmaPackaging is part of Nipro Corporation Japan, established in 1954. As a leading global healthcare company with over 29.000 employees worldwide, Nipro serves the Pharmaceutical, Medical Device, and Pharma Packaging industries.

