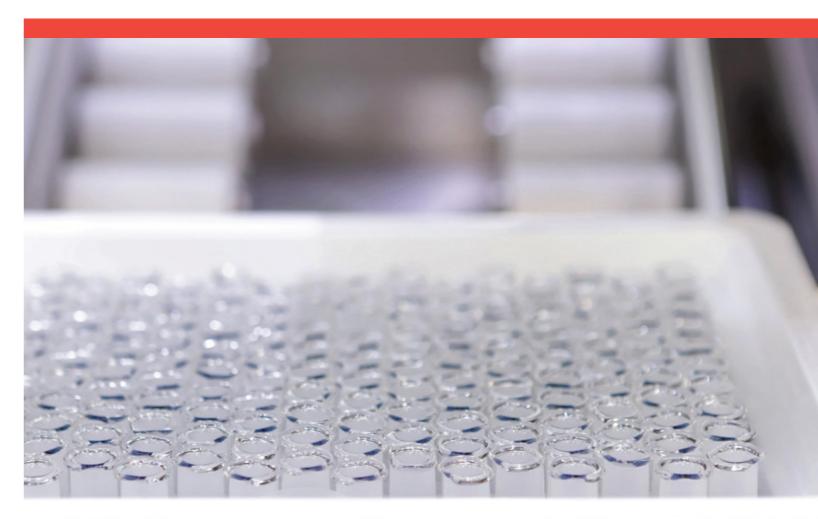


## D2F DIRECT-TO-FILL

## STERILIZED PACKAGING SOLUTIONS

PRE-FILLABLE GLASS SYRINGES





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 16 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 27,000 employees worldwide, Nipro serves the Pharmaceutical, Medical Device, and Pharmaceutical Packaging industries.





## D2F DIRECT-TO-FILL STERILIZED 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.



Nests and tubs are first cleaned with ionized air to minimize particle load.

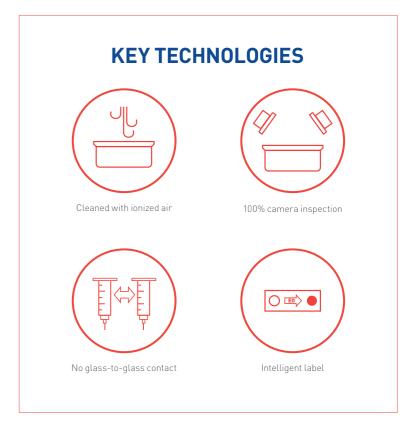
Robots then load the washed, siliconized, and final assembled pre-fillable syringes into nests and tubs. The tubs are covered with a Tyvek® insert, sealed with a corresponding Tyvek® lid, and then entered into a breather bag which is welded closed (double inserts & breather bags optional).

Our 100% in-line inspection systems allow for continuous quality monitoring as part of In Process Controls (IPC). This ensures that all pre-fillable syringes are foreseen with closures and that tubs are 100% filled and correctly sealed.

Afterwards, machines transfer the tubs to a station for final packing. Tubs are stacked and placed in outer boxes.

Outer boxes are placed on pallets, protective angle boards are applied, and fixation is ensured with PE-Bands. The total pallet is wrapped in plastic foil to ensure safe transportation.

Final packed pre-fillable syringes are then EO sterilized. Labels on the tubs and outer boxes are provided with a special EO indicator (a color change from blue to green after EO exposure). This allows for visual confirmation of EO sterilization and subsequent exposure.



Nipro's D2F packaging design is a smart, efficient choice. It prevents glass-to-glass contact while enabling immediate and direct use on the filling line. In essence, Direct-to-Fill.

<sup>2.</sup> Multiple pallet schemes are available.