LinC™

THE PERFECT LINC TO YOUR DRUG, FILL-FINISH, END-USER

NIPRO PHARMAPACKAGING

THE PERFECT UnC™ TO YOUR

Drug, Fill-Finish, End-user

Compatibility between drug and closure

The tip cap of the LInC is offered in a variety of carefully selected rubber formulations (FM27, FM30, 7025, 7028), allowing the selection of the rubber formulation most fitting to the drug requirements.

The LInC is assembled in an ISO 7 cleanroom (in an ISO 5 cleanroom for airborne particles) ensuring a reduction of the overall particle levels.

The LInC is suitable for EtO and terminal steam sterilization[1], and is apt for cold storage (-30°C).[2]

1 Steam Sterilization Test (II) as Part of Design Verification Test – D2F™ LInC Syringes | NPG QC | 09.08.2021
2 Cold-storage study – NPG TCS – 14-07-2021

Maintaining container closure integrity

Inherent to the LInC design is the highly accurate fit of the tip cap and the rigid cap to the Luer lock D2F glass syringes, thereby maintaining outstanding container closure integrity (CCI).[3]

Fast time to market

D2F-LInC is compatible with existing D2F nest and tub packaging solutions. Equivalent to the market standard for dimensional, cosmetic, and functional attributes.

3 Study concerning Accelerated / Realtime Aging – 3_QA_F_8_644_01 – NPG Quality – 19.03.2021

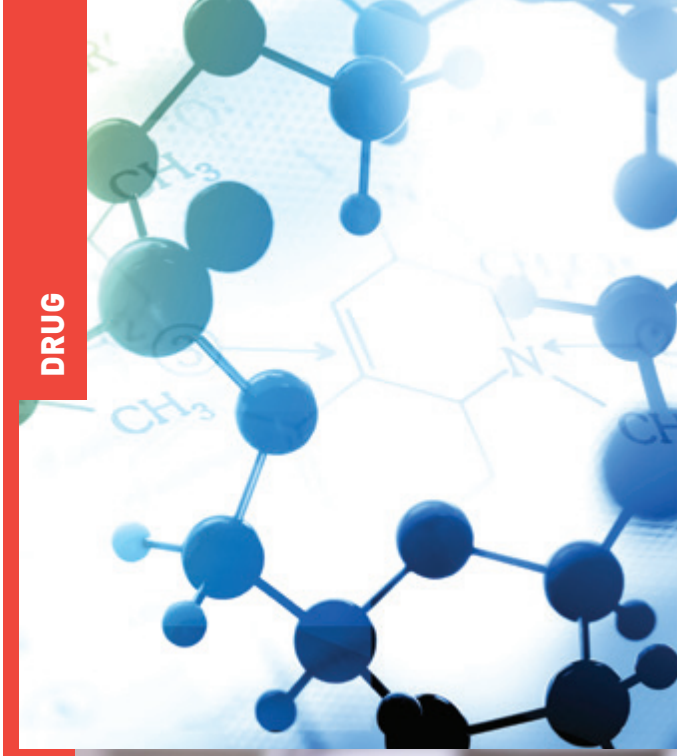
Offering an easy opening

A crucial link in the preparation and administration process thanks to an intuitive and easy opening.

Compatible with hypodermic needles

The Luer lock adapter is conform 11040-4 and compatible with hypodermic needles (compliant to ISO 80369-7). providing a secure connection.

DRUG



FILL-FINISH

END-USER

D2F™ PRE-FILLABLE GLASS SYRINGES WITH LInC

FINE-TUNED TO YOUR DRUG PRODUCT AND SERVICE REQUIREMENTS!

The process of defining the right quality and service requirements for your primary packaging is a complex one. Our Nipro "Quality Levels" form the perfect base to capture and fine-tune your requirements. You will be supported by an interdisciplinary team of experts throughout the entire process. The LInC closure is an option within all three Quality Levels to offer you a high degree of product customization.

Quality Levels for Pre-fillable Syringes

eNable	eNhance	eNgage
Meeting prevailing drug product requirements	**Optimal choice for highly sensitive drugs**	**Customized for unique drug requirements**
For anticoagulants, WFI, diluents, vaccines	For biotechs, vaccines	For drugs with custom requirements

LInC™

LInC Assembly Process

The LInC is produced in a 3-step assembly process on an advanced manufacturing line. Throughout the whole process, special attention is given to the careful handling of the rubber and plastic parts. The packaging and assembly process takes place in an ISO 7 cleanroom, incorporating an ISO 5 core cell under laminar airflow (LAF) for reduced particle generation.

The 100%, in-line inspection system controls each LInC for various quality aspects. Statistical process control (SPC) further ensures that all products comply to agreed quality specifications.

The Quality System is compliant to ISO 15378 and ISO 13485.

SPECIFICATIONS

Tip Cap (TC)
Rubber:
West: 7025/65 or 7028/55
Datwyler: FM27 or FM30

Rigid Cap (RC)
Polypropylene

Luer lock adapter (LLA)
Polycarbonate

Shelf-life (D2F syringes with LInC)
36 months

Sterilization (D2F syringes with LInC)
ETO sterilization, Steam sterilization

Part of the D2F™ portfolio

- Precisely fitting to our broad range of D2F syringes (1 to 3 ml)
- Fully compatible with our D2F tub & nest configurations
- 36-month shelf-life of D2F syringes with LInC

STANDARDS

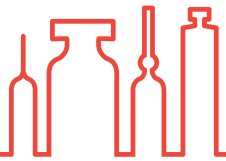
Standard*	Description
ISO 15378	Primary packaging materials for medicinal products
ISO 13485	Medical devices - Quality management systems
ISO 14971	Medical devices - Application of risk management to medical devices
IEC 62366-1	Medical devices
MDR	Medical Device Regulation
ISO 10993-1 -5 -7 -18	Biological evaluation of medical devices
ISO 80369-1 -7 -20	Small-bore connectors for liquids and gases in healthcare applications
ISO 11040-4 -7 -8	Pre-fillable syringes
ISO 11135	Sterilization of healthcare products - Ethylene oxide
ISO 8871-1 -2 -3 -4 -5	Elastomeric parts for parenterals and for devices for pharmaceutical use

*non-exclusive list

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 19 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 33.000 employees worldwide, Nipro serves the Pharmaceutical, Medical Device, and Pharma Packaging industries.



MM-1294 - Bro-D2F_LinC_-EN - 13.Oct.2021

NIPRO PHARMAPACKAGING

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