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NEST



Self-administration Solutions

www.cell-nestbio.com

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10600 m²

Class 100,000
Cleanshop

3600 m²

Class 10,000
Cleanshop

2300 m²

Pen Injector
Controlled
Workshop

20⁺

Professional
Certifications and
Honors



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Company Introduction

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2300 m²

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Professional
Certifications and
Honors



Compliance as the Foundation · Fully In-house Chain · Rapid Customization

—— NEST Pen Injector Manufacturing Overview

Since entering the medical device sector in 2018, Wuxi NEST Biotechnology Co., Ltd. ("NEST") has focused on pen injectors, gradually building end-to-end core capabilities from R&D to mass production.

NEST has obtained multiple authoritative certifications, including ISO 9001/13485/11137, FDA, and CE, and holds medical device licenses in several countries. Its production lines strictly follow GMP standards, with full-process third-party monitoring ensuring professional compliance at every step.

Leveraging a 2,300m² high-standard controlled workshop and two fully automated assembly lines, NEST has achieved fully automated, flexible production. From mold design to final packaging, all processes are independently managed in-house, enabling rapid response to customized user requirements.

Product Introduction

Safer, More Convenient, and More User-Friendly Self-Administration Solutions

NEST products are widely used with medications such as semaglutide, follicle-stimulating hormone (FSH), liraglutide, insulin, and growth hormone. NEST offers pen injectors, cost-effective disposable pen injectors (standard, SP, TSA and automatic types), ready-to-use components (cartridges, prefilled syringes), as well as assembly and press-fitting equipment, delivering safer, more convenient, and more user-friendly self-administration solutions for the biopharmaceutical industry.

Pen Injector Production Line & Supporting Products Overview



Product Advantages

1 Independent R&D and Mold Manufacturing Capability

Core structures and molds independently designed and manufactured.

2 Precise Injection Molding Process

High-precision dimensional control ensures product consistency.

3 Automated Product Assembly

Higher Efficiency, Lower Cost, Precise and Reliable.

4 Customizable Services

Appearance, color, dosage, and graduation markings can all be tailored to customer requirements.

5 Diverse Product Specifications

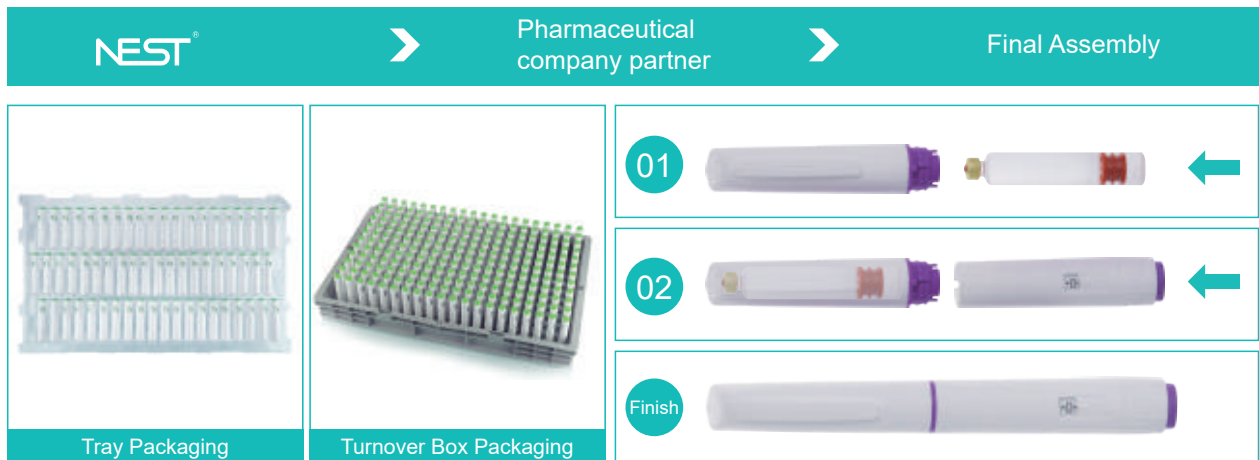
A full range of options is available to match different pen injector specifications with various drugs.

6 Product Validation & Patent Risk Mitigation

Full FTO analysis completed for China, the U.S., the U.K., and Europe; comprehensive product validation reports meeting international standards, with patent risk-mitigated designs.

Product Introduction

TSA Disposable Pen Injector



Comparison of External-Rotation vs. Internal-Rotation Pen Injectors

External-Rotation Type ▼



Rotating Pen Body Dose Selector with
Outward-Extending Component Structure

VS

Internal-Rotation Type ▼



After Rotation, No Outward-Extending
Components

Product Introduction

TSA Disposable Pen Injector

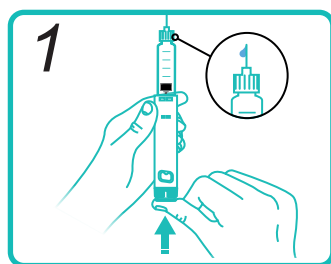
● Product Certifications

China CDE No.B20250000677

● Applicable Drugs

For injection of insulin, GLP-1 receptor agonists, follicle-stimulating hormone (FSH) and related medications, such as insulin degludec, semaglutide, liraglutide, and Gonal-F, mainly used for diabetes treatment, weight management, and assisted infertility therapy.

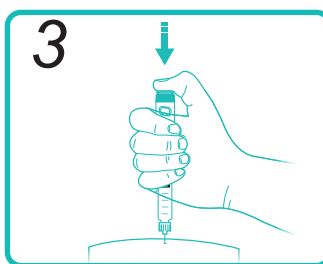
● Operating Instructions



Preparation



Dose Adjustment



Injection



Non-refillable: Discard the Entire Pen After Use

● Product Advantages

- ✓ Easy Operation: No professional guidance needed; simply press to administer the dose.
- ✓ Multiple Specifications: Available in 36/37/50/60/70/72/74/75/80 IU, with customization options.
- ✓ User Feedback: Visual and auditory cues during dose setting and injection enhance confidence.
- ✓ High Cleanliness: Injection molding, assembly, and packaging conducted in a 100,000-class cleanroom.
- ✓ Flexible Packaging: Options include bagged or tray packaging.
- ✓ Special Structural Design: Dose cannot exceed the remaining amount in the pen cartridge.
- ✓ FTO Analysis Completed: Covered China, the U.S., the U.K., and Europe.

● Dose Unit

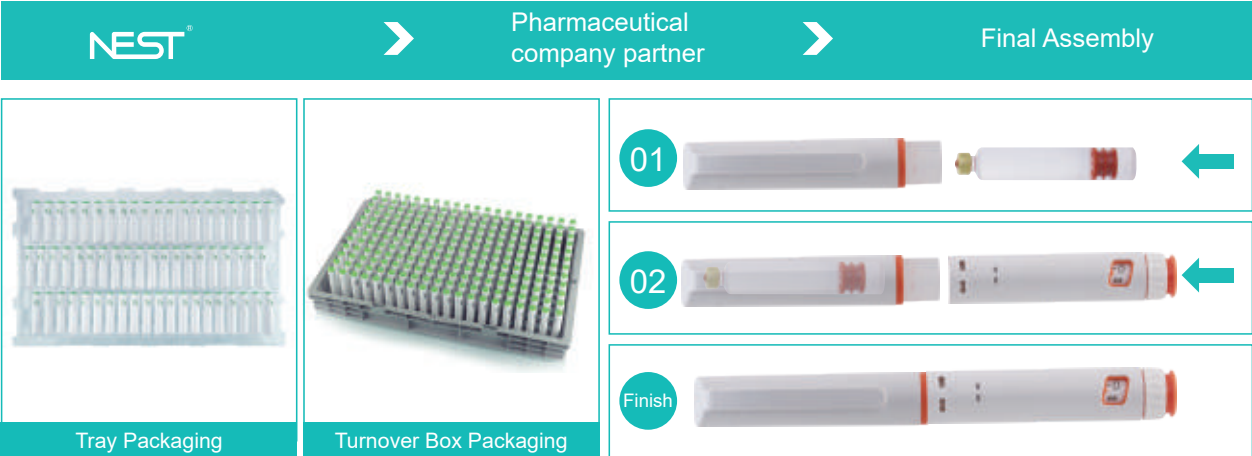
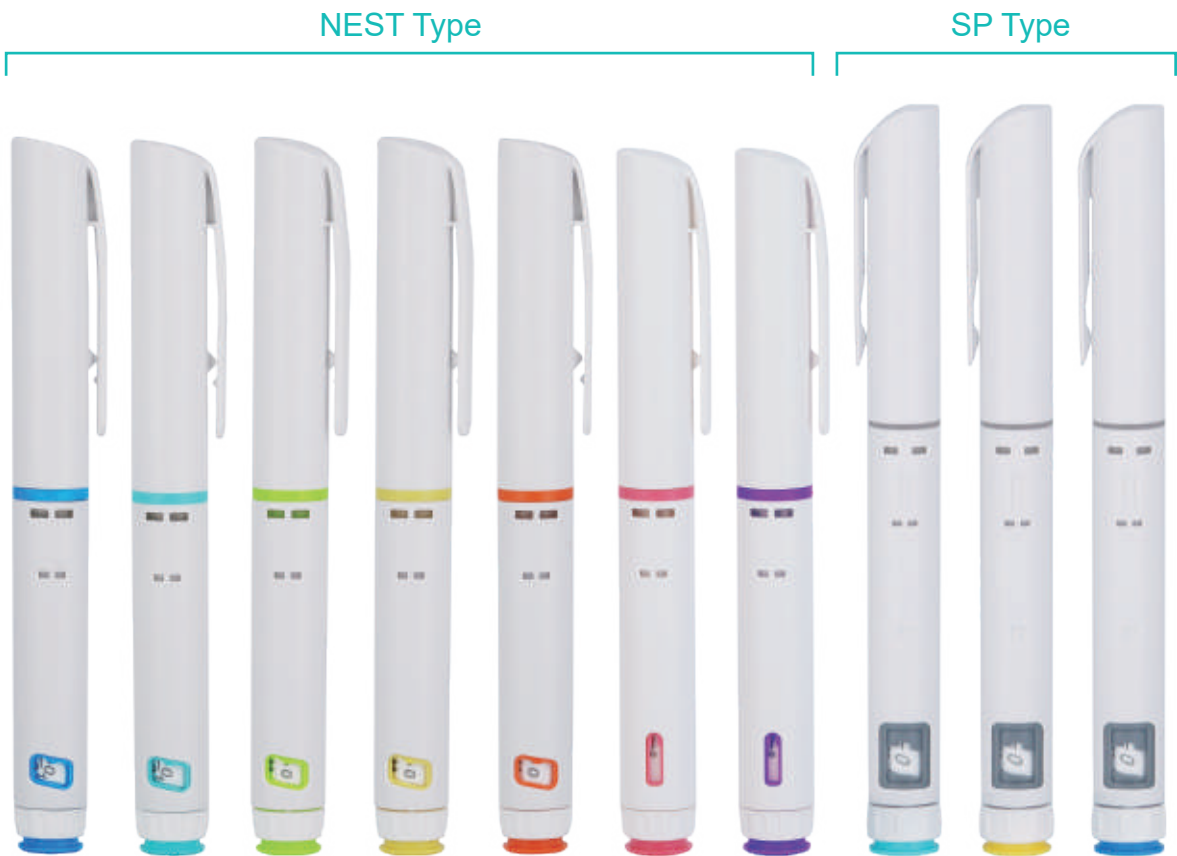
Dose Unit	Cartridge (Min. Dose)
36 Units	3.0 mL (0.02 mL)
37 Units	3.0 mL (0.01 mL)
50 Units	3.0 mL (0.01 mL)
60 Units	3.0 mL (0.01 mL)
70 Units	3.0 mL (0.01428 mL)
72 Units	3.0 mL (0.01 mL)
74 Units	3.0 mL (0.01 mL)
75 Units	3.0 mL (0.01 mL)
80 Units	3.0 mL (0.01 mL)

● Product Parameters

Injection Dose Range	0.01-1.0mL
Auditory Feedback	Auditory Feedback During Dose Adjustment
Viewing Window	Easy to Identify and Use
Injection Start Force	≤15N
Dose Accuracy	Professional Data Validation Available

Product Introduction

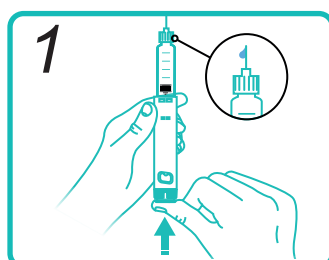
Disposable Pen Injector



Product Introduction

Disposable Pen Injector

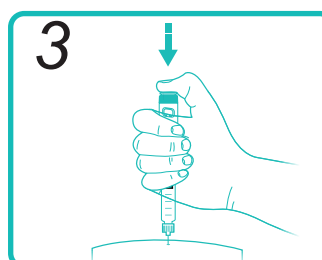
Operating Instructions



Preparation



Dose Adjustment



Injection



Non-refillable: Discard the Entire Pen After Use

Product Certifications

USA510(k) No.K240961

USA DMF NO.40744

Canada Medical Device License

Indonesia Medical Device Registration Certificate

MDSAP Five-Country Certification

China Class II Medical Device Certificate

NEST Type China CDE:B20230000891

SP Type China CDE: B20240000529

Product Advantages

- ✓ Highly customizable: appearance, color, dosage, scale lines customizable.
- ✓ Accurate dosage, professional R&D team and data validation support.
- ✓ Currently available in 36/ 37 /50 /60 /74 /75 /80 units, which can be customized for different indications.
- ✓ Applicable to liraglutide, simethicone, follicle stimulating hormone (FSH) drugs, insulin degludec and other drugs.
- ✓ FTO Analysis Completed: Covered China, the U.S., the U.K., and Europe.

Dose Unit

Dose Unit	Cartridge (Min. Dose)
8 Units	3.0 mL (0.01 mL)
	3.0 mL (0.005 mL)
19 Units	3.0 mL (0.01 mL)
30 Units	3.0 mL (0.01 mL)
36 Units	3.0 mL (0.0208 mL)
37 Units	3.0 mL (0.01 mL)
50 Units	3.0 mL (0.01 mL)
60 Units	3.0 mL (0.01 mL)
70 Units	3.0 mL (0.01428 mL)
72 Units	3.0mL (0.01 mL)
74 Units	3.0 mL (0.01 mL)
75 Units	3.0 mL (0.01 mL)
80 Units	3.0 mL (0.01 mL)

Product Parameters

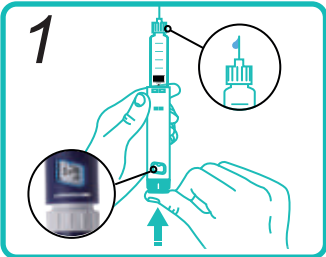
Injection Dose Range	0.005-1.0mL
Auditory Feedback	Auditory Feedback During Dose Adjustment
Viewing Window	Easy to Identify and Use
Injection Start Force	≤10 N for products up to 60 IU
Dose Accuracy	>10 N for products above 60 IU

Product Introduction

Self-locking Pen Injector (100 IU)



Operating Instructions



Preparation



Dose Adjustment



Pull Locking Mechanism



Automatically locks after injection; single-use only.

Product Advantages

- ✓ High Compatibility: Supports a maximum single injection volume of 1 mL, meeting the dosing requirements of multiple medications.
- ✓ Locking Mechanism: Automatically locks after injection for single-use only, ensuring safety and hygiene.
- ✓ FTO Analysis Completed: Covered China, the U.S., the U.K., and Europe.

Product Certifications

China CDE No.B20250000311

Dose Unit

Dose Unit	Cartridge (Min. Dose)
100 Units	3 mL (0.01 mL)

Disposable Fixed-dose Pen Injector



Applications: For human parathyroid hormone–related peptide analogs, such as teriparatide and abaloparatide injections, primarily used in patients with osteoporosis at high risk of fractures.

Product Advantages

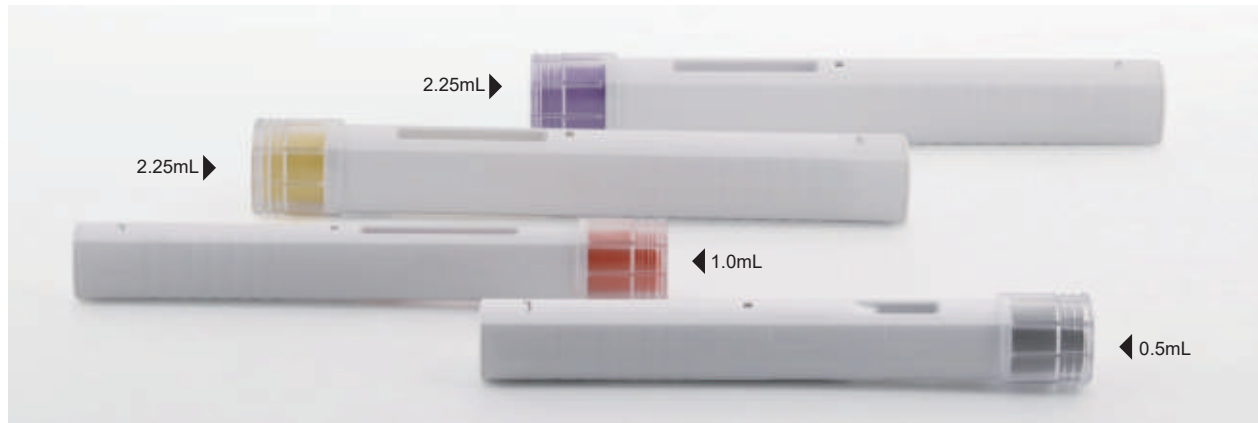
- ✓ Easy Operation: Tactile and auditory cues; push-button injection allows simple, safe, and reliable use.
- ✓ Accurate Dosing: Fixed injection dose minimizes errors, ensuring precise administration and patient safety.
- ✓ FTO Analysis Completed: Covered China, the U.S., the U.K., and Europe.

Dose Unit

Dose Unit	Cartridge (Min. Dose)
80 μ L	3.0 mL (80 μ L)
40 μ L	3.0 mL (40 μ L)

Product Introduction

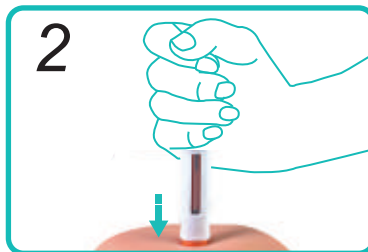
Prefilled Automatic Pen Injector (Two Step)



Two-Step Operation + Automatic Needle Insertion



Remove Pen Cap



Press Injection Site to Activate

Product Advantages

- ✓ Two-Step Operation: Simple and easy-to-use injection process.
- ✓ Square Anti-Roll Design: Ergonomic square body prevents accidental rolling.
- ✓ Hidden Needle: Needle remains fully concealed, reducing needle anxiety and improving injection success.
- ✓ Needle Safety Device: Protective cover automatically deploys and locks after injection to prevent needle-stick injuries.
- ✓ Large Viewing Window: Allows clear observation of medication and injection.
- ✓ Visual & Auditory Feedback: Dual cues enhance patient confidence in self-administration.
- ✓ FTO Analysis Completed: Covered China, the U.S., the U.K., and Europe.

Dose Unit

Dose Unit	Cartridge (Min. Dose)
0.5mL	1.0mL Long
1.0mL	1.0mL Long
2.25mL	2.25mL

Product Parameters

Built-in Container Specifications	1.0mL Long PFS/ 2.25mL PFS
Filling Volume	0.2-1.0mL(1.0mL Long PFS) / 0.4-2.25 mL(2.25mL PFS)
Needle Diameter	29 G TW or Larger
Dose Delivery Efficiency	≥96.5%
Injection Start Force	3-10N(0.5&1.0mL)/ 5-15N(2.25mL)
Injection Time	≤10s*
Needle Insertion Depth	6mm±2mm
Protective Locking Force	≥60N
Needle Safety Distance	≥4.5mm
Injection Feedback	Visual and Auditory Feedback

*Depend on the filling volum,ewiscosity,and needle diameter.

Product Introduction

Prefilled Automatic Pen Injector (Three Step)

● Product Certifications China CDE No.B20250000729



● Operating Instructions



● Dose Unit

Dose Unit	Cartridge (Min. Dose)
0.5mL	1.0mL Long
1.0mL	1.0mL Long

● Product Advantages

- ✓ Three-Step Operation: Locking mechanism effectively prevents accidental activation.
- ✓ Anti-Roll Design: Pen cap features a standable anti-roll structure for convenient placement.
- ✓ Hidden Needle: Needle remains fully concealed, reducing needle anxiety and improving injection success.
- ✓ Needle Safety Device: Protective cover automatically deploys and locks after injection to prevent needle-stick injuries.
- ✓ Large Viewing Window: Allows clear observation of medication and injection.
- ✓ Visual & Auditory Feedback: Dual cues enhance patient confidence in self-administration.
- ✓ FTO Analysis Completed: Covered China, the U.S., the U.K., and Europe.

● Product Parameters

Built-in Container Specifications	1.0mL Long PFS
Filling Volume	0.2-1.0mL
Needle Diameter	29 G TW or Larger
Dose Delivery Efficiency	≥96.5%
Injection Start Force	≤30N
Injection Time	≤10s
Needle Insertion Depth	6mm±2mm
Protective Locking Force	≥60N
Needle Safety Distance	≥4.5mm
Injection Feedback	Visual and Auditory Feedback

Product Introduction

Pen Injector

Product Certifications

Class II Medical Device Registration Certificate

USA 510(k) No.K240774

Canada MDL Licence

Indonesia Imported Medical Device

Registration Certificate

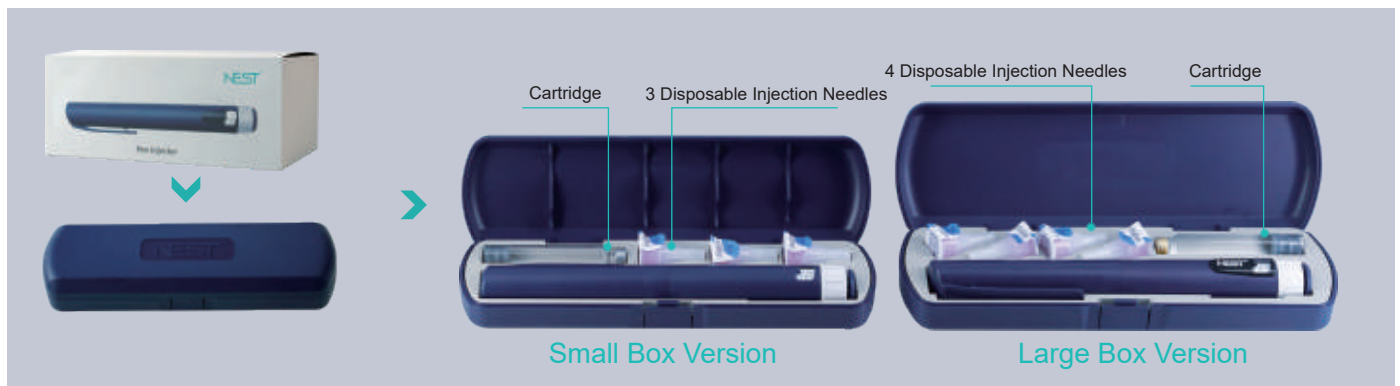
Malaysia Medical Device Registration

Brazil Medical Device Registration

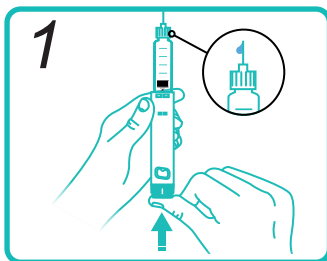
MDSAP Five-Country Certification



Product Packaging



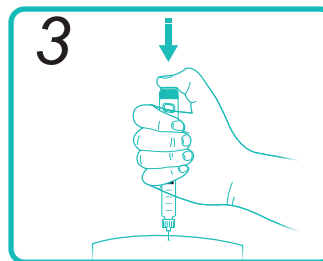
Perating Instructions



Preparation



Dose adjustment



Injection



Cartridge Replaceable, Reusable

Product Advantages

- ✓ Highly customizable: appearance, color, dosage, scale lines customizable.
- ✓ Customizable Dose Range: Minimum unit dose of 0.0075 mL; available in 8/48/50/60/70/75/80 IU, with indication-specific customization.
- ✓ Applicable Drugs: Suitable for long-term injectable therapies such as insulin aspart.
- ✓ FTO Analysis Completed: Covered China, the U.S., the U.K., and Europe.

Dose Unit

Dose Unit	Cartridge (Min. Dose)
8 Units	3.0 mL (0.01 mL)
48 Units	3.0 mL (0.01 mL)
50 Units	3.0 mL (0.01 mL)
60 Units	3.0 mL (0.01 mL)
	3.0 mL (0.0075 mL)
70 Units	3.0 mL (0.01428 mL)
75 Units	3.0 mL (0.01 mL)
80 Units	3.0 mL (0.01 mL)
	3.0 mL (0.0075 mL)
80 Units (Hidden Needle)	3.0 mL (0.0075 mL)

Product Parameters

Injection Dose Range	0.0075-1.0mL
Auditory Feedback	Auditory Feedback During Dose Adjustment
Viewing Window	Easy to Identify and Use
Injection Resistance	<20N

Product Customization

In-house Tooling & Flexible Customization

Scan to Complete
the Customization
Form Online



01

Pen Body Type



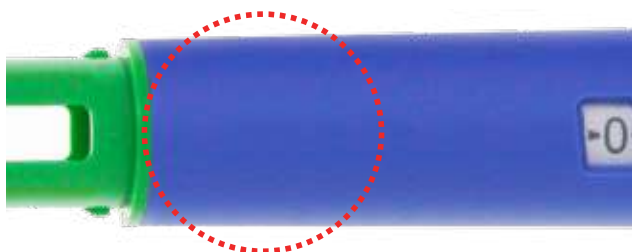
02

Exterior Color



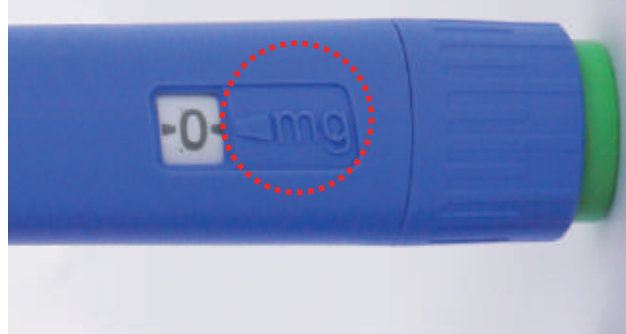
03

Logo Printing



04

Dose Units



05

Graduation
Marks



06

Packaging Options,
etc.



Product Validation

Pen Injector Validation Projects

Product Testing Summary

Pen Injector ● TSA Pen Injector ● AI Pen Injector ● Disposable Pen Injector ●

Product Performance Verification Tests	Periodic Monitoring Tests	Batch Release Tests
Injection Resistance (Start Force) ● ● ● ●	Appearance inspection ● ● ● ●	Periodic Performance Testing ● ● ● ●
Final dose accuracy testing ● ● ●	Cartridge chamber labeling inspection ● ● ● ●	
Free-fall dose accuracy testing ● ● ● ●	Injection dose labeling inspection ● ● ● ●	
Cool/Standard/Warm ambient environment dose accuracy testing ● ● ● ●	Injection dose knob stability testing ● ● ● ●	
Dry heat/Frozen atmospheric environment dose accuracy testing ● ● ● ●	Knob Performance / Torque Testing ● ● ● ●	
Hot and humid atmospheric environment dose accuracy testing ●	Dose accuracy testing ● ● ● ●	
Vibration test dose accuracy testing ● ● ● ●	Injection Resistance (Start Force) ● ● ● ●	
Cool/Standard/Warm ambient environment injection resistance, leakage check, and needle compatibility testing ● ● ● ●	Free-fall testing ● ● ● ●	
Dry heat/Frozen atmospheric environment injection resistance, leakage check, and needle compatibility testing ● ● ● ●	Pen Cap Removal Force Testing ● ● ● ●	
Hot and humid atmospheric environment injection resistance, leakage check, and needle compatibility testing ●	Needle Safety Device Activation and Locking Test ● ● ● ●	
Vibration test injection resistance, leakage check, and needle compatibility testing ● ● ● ●	Injection Time ● ● ● ●	
Lifecycle Testing ●	Leakage Testing ● ● ● ●	
Cyclic Testing ●		
Stability Verification Testing ● ● ● ●		
Knob Performance / Torque Testing ● ● ● ●		
Needle Compatibility Testing ● ● ● ●		
Pen Cap Removal Force Testing ● ● ● ●		
Needle Safety Device Activation and Locking Testing ●		
Needle Safety Distance and Insertion Depth Testing ●		
Injection Time ● ● ● ●		
Leakage Testing ● ● ● ●		

The tests in this chapter are performed in accordance with the national standard YY/T 1768.1 -2021 (ISO 11608- 1:2014, NEQ) and YY/T 1768.2-2021 (ISO 11608-2:2014, NEQ).

Product Performance Verification Tests

Injection Button Actuation Force Test:

Using purified water under cold/standard/warm/dry heat/frozen storage/humid heat conditions, injection resistance was <30 N with standard-selected needles and pen injectors. Actuation force meets applicable standards.

Final Dose Accuracy Test:

Using purified water with standard-selected needles and pen injectors, all other doses were expelled prior to testing the final dose (Vmin: 0.01 mL). Dose accuracy meets applicable standards.

Free-Fall Dose Accuracy Test:

Using purified water with standard-selected needles and pen injectors, the device was dropped freely from a height of 1000 mm onto the test surface. After the drop test, minimum, intermediate, and maximum dose injections were performed. Dose accuracy after free fall meets applicable standards.

Dose Accuracy Testing under Cold / Standard / Warm Atmospheric Conditions:

After conditioning in a cold atmospheric environment for 4 hours, testing was conducted using purified water with standard-selected needles and pen injectors. Minimum, intermediate, and maximum dose injections were performed, and dose accuracy met applicable standards. The same devices were then conditioned for 4 hours under standard atmospheric conditions and the tests were repeated, with dose accuracy meeting standards.

Subsequently, the same devices were conditioned for 4 hours under warm atmospheric conditions and the tests were repeated. Dose accuracy met applicable standards in all conditions.

Dose Accuracy Testing under Dry Heat / Frozen Storage Conditions:

After conditioning in a dry heat atmospheric environment for 96 hours, testing was performed using purified water with standard-selected needles and pen injectors. Minimum, intermediate, and maximum dose injections were conducted, and dose accuracy met applicable standards. The same devices were then conditioned for 96 hours under frozen storage conditions, and the tests were repeated. Dose accuracy met applicable standards.

Product Validation

Dose Accuracy Testing under Humid Heat Conditions:

After conditioning in a humid heat environment for 96 hours, tests were conducted using purified water with standard-selected needles and pen injectors. Minimum, intermediate, and maximum dose injections were performed, and dose accuracy met applicable standards.

Vibration test dose accuracy testing:

After vibration testing at alternating frequencies of 3–8 Hz and 8–300 Hz (four cycles per direction), dose accuracy was evaluated using purified water with standard-selected needles and pen injectors. Minimum, intermediate, and maximum dose injections were performed, and dose accuracy met applicable standards.

Cool/Standard/Warm ambient environment injection resistance, leakage check, and needle compatibility testing:

After conditioning in a cold atmospheric environment for 4 hours, tests were conducted using purified water with standard-selected needles and pen injectors. At the maximum displayed dose, the maximum start force and injection resistance were both <30 N. After testing, dose adjustment from minimum to maximum and back to zero showed needle leakage <0.01 mL. The needle assembly torque was 0.060–0.080 N·m, and dose accuracy was verified at alternating minimum and maximum doses. The needle seat removal torque was <0.100 N·m. All five tests met applicable standards. The same devices were then conditioned for 4 hours under standard atmospheric conditions and the same five tests were repeated; all met standards.

Subsequently, after 4 hours under warm atmospheric conditions, the five tests were repeated again; all met standards.

Dry heat/Frozen atmospheric environment injection resistance, leakage check, and needle compatibility testing:

After conditioning in a dry heat environment for 96 hours, tests were conducted using purified water with standard-selected needles and pen injectors. The five tests covering injection resistance, leakage inspection, and needle compatibility were repeated, and all met applicable standards. The same devices were then conditioned for 96 hours under frozen storage conditions, and the same five tests were repeated. All results met applicable standards.

Hot and humid atmospheric environment injection resistance, leakage check, and needle compatibility testing:

After conditioning in a humid heat environment for 96 hours, tests were conducted using purified water with standard-selected needles and pen injectors. The five tests covering injection resistance, leakage inspection, and needle compatibility were repeated, and all results met applicable standards.

Vibration test injection resistance, leakage check, and needle compatibility testing:

Vibration testing was conducted at alternating frequencies of 3–8 Hz and 8–300 Hz, with four cycles per direction. After the vibration test, using purified water with standard-selected needles and pen injectors, the five tests covering injection resistance, leakage inspection, and needle compatibility were repeated. All results met applicable standards.

Lifecycle Testing:

Three devices, previously tested for dose accuracy and injection resistance under cold, standard, and warm atmospheric conditions (using new cartridges), were selected. The pen injector mechanisms (excluding cap and needle attachment, and drug injection) were operated 4,500 times—1.5 times the expected lifespan. After this operation, dose accuracy and injection resistance tests under standard atmospheric conditions were repeated, and all results met applicable standards.

Cyclic Testing:

Pen injectors with cartridges were selected and subjected to alternating, low-temperature, high-temperature, and six-cycle testing according to GB/T 2423.4—2008. After this procedure, dose accuracy and injection resistance tests under standard atmospheric conditions were repeated, and all results met applicable standards.

Stability Verification Testing:

Pen injectors were selected according to standards and subjected to accelerated aging in an aging chamber for 28 days (1-year shelf life), 85 days (3-year shelf life), and 141 days (5-year shelf life). Verification was performed under each aging condition. Test items included: appearance, cartridge dose markings, injection dose markings, dose knob stability, dose accuracy under cold/standard/warm atmospheric conditions, injection resistance under cold/standard/warm/dry heat/frozen/humid conditions, free-fall testing, dry heat/frozen storage tests, humid heat testing, and leakage inspection—a total of ten tests. All results met applicable standards.

Knob Performance / Torque Testing:

Each full rotation of the dose knob produces a “click” sound. After setting the injection dose, dose readjustment is allowed. The torque range for clockwise and counterclockwise rotation of the knob is 0.05–0.25 N·m, meeting company standards.

Injection Start Force Test:

During injection, the start force is ≤15 N. The button can be fully pressed in a single motion, with smooth operation and no sticking, producing a clear “click” sound. Injection button actuation force meets company standards.

Product Validation

Needle Compatibility Testing:

Using standard-selected needles and pen injectors, the needle assembly torque was 0.060–0.080 N·m, and the needle seat removal torque was <0.100 N·m. Both tests met applicable standards.

Pen Cap Removal Force Testing:

Prefilled pen injectors were selected according to standards. The pen cap removal force met 4–45 N. After removal, the needle cap remained within the pen cap slot with no separation or cracking, and the needle safety cover was not activated. Meets company standards.

Needle Safety Device Activation and Locking Testing:

Prefilled pen injectors were selected according to standards and used to simulate subcutaneous injection. After injection, the injector was removed from the simulated tissue pad, and the needle safety cover automatically deployed and locked, with a protective locking force ≥ 60 N. Meets company standards.

Needle Safety Distance and Insertion Depth Testing:

Prefilled pen injectors were selected according to standards and used to simulate subcutaneous injection. After injection, the safety distance between the needle tip and the top edge of the needle safety cover was >4.5 mm. After resetting the needle safety cover, the distance was 6 ± 2 mm. Meets company standards.

Injection Start Force, Time, and Leakage Test:

Prefilled pen injectors were selected according to standards. During injection, the button pressed smoothly without sticking, with a start force of 10–30 N. Injection time was ≤ 10 s, and after the full 10 s injection, needle leakage was <0.002 mL. Meets company standards.

Dose Delivery Efficiency Test under Cold / Standard / Warm Atmospheric Conditions:

Prefilled pen injectors were selected according to standards. After 4 hours in a cold atmosphere, the devices did not activate unintentionally, and dose delivery efficiency met standards.

The test was repeated after 4 hours in standard and warm atmospheric conditions, with the same results: no unintended activation and dose delivery efficiency met standards.

Dose Delivery Efficiency Test under Dry Heat / Frozen Storage Conditions:

Prefilled pen injectors were selected according to standards. After 96 hours in a dry heat environment, the devices did not activate unintentionally, and dose delivery efficiency met standards.

The test was repeated after 96 hours in a frozen storage environment, with the same results: no unintended activation and dose delivery efficiency met standards.

Dose Delivery Efficiency Test – Vibration:

Prefilled pen injectors were selected according to standards and subjected to vibration testing at alternating frequencies of 3–8 Hz and 8–300 Hz, with four cycles per direction. After the test, the pen cap remained attached, the pen did not activate unintentionally, and dose delivery efficiency met standards.

Periodic Monitoring Tests

According to YY/T 1768.1-2021 (ISO 11608-1:2014, NEQ), annual periodic monitoring is required. Excluding stability tests, all other product performance verification tests are repeated.

Batch Release Tests

Appearance Inspection: According to the performance specifications for pen injectors, products were visually inspected. The surface was free of burrs, patterns, shrinkage, flow marks, scratches, or other appearance defects; the interior had no cracks; and printed markings were clear. Appearance inspection met standards.

Cartridge chamber labeling inspection: According to the performance specifications for pen injectors, a visual inspection of the cartridge chamber was conducted. The cartridge chamber displayed dose markings (IU); it was transparent, allowing visual confirmation of the administered dose and remaining volume. Inspection met standards.

Injection dose labeling inspection: According to the performance specifications for pen injectors, a visual inspection was conducted. The dose window allowed clear observation of the graduated scale and corresponding numbers; the scale lines were evenly spaced, with dose markings numbered as integers from 0 to 60. Inspection met standards.

Knob Performance / Torque Testing: According to the performance specifications for pen injectors, the dose-setting knob was inspected. Each full rotation of an integer increment produced a “click” sound, and dose readjustment was allowed after setting. Inspection met standards.

Sensory Feedback Inspection:

Visual Feedback: Prefilled pen injectors were selected according to standards, and the plunger status in the dose window was observed before, during, and after injection. Meets visual feedback requirements.

Auditory Feedback: A clear “click” sound was audible at the start and end of injection, with no extraneous noise during the process.

Tactile Feedback: When rotating the sleeve to the unlock/lock position, distinct resistance was felt, and the sleeve rotated smoothly without sticking.

Pen Injector Accessories

RTU Cartridges



Product Certifications

USA DMF No.42439

Cartridges serve as next-generation drug delivery containers. They function as standard pharmaceutical packaging during storage and are used with a pen injector and pen needle for drug administration. The drug is prefilled into the cartridge, which is then loaded into the pen injector. During injection, the injector advances the plunger, delivering the drug through the attached pen needle into the patient.

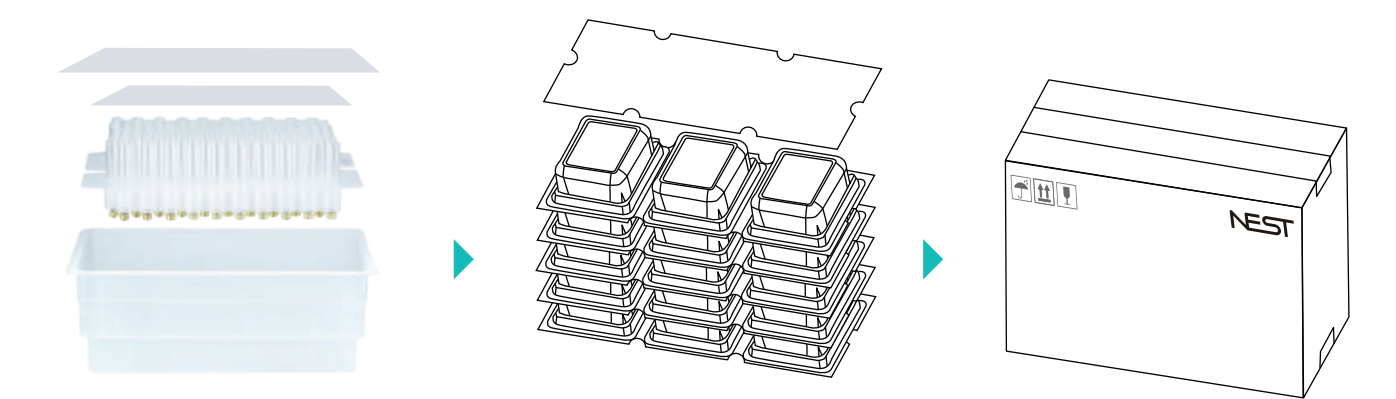
Operating Instructions

Widely used in pharmaceutical products such as insulin, GLP-1 therapies, hormones, and anesthetics.



RTU (Ready-to-Use) Packaging

Pre-washed, pre-sterilized, and non-pyrogenic, compatible with automated bag opening and filling. Nest-and-tub packaging minimizes vial-to-vial contact, reducing the risk of breakage.



RTU Cartridges

Specification	pcs/box	boxes/case	Cat.No.
3.0mL	100	15	217231
2.0mL	100	15	Coming soon
1.5mL	100	15	Coming soon

RTU Cartridge Accessories

Name	pcs/bag	bags/case
Piston	100	15
Piston	7000	1

*NEST offers products sterilized by either steam sterilization or ethylene oxide (EO).

Pen Injector Equipments

● Manufacturing Process



Among the first moist heat sterilized cartridges in China

Zero dead spots, Zero residue, Zero contaminants, Zero risk

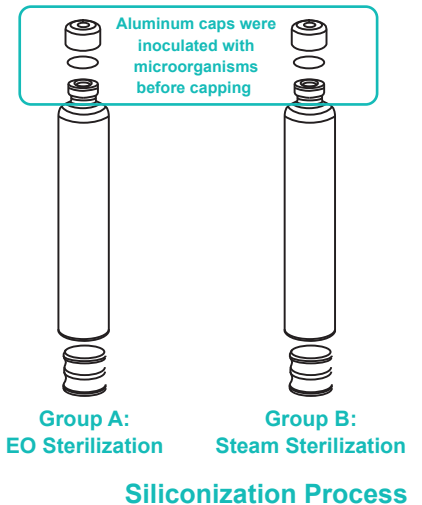
Microbial Challenge Test

Method: Aluminum caps were soaked in microorganisms before capping, then divided into two groups for ethylene oxide sterilization and moist heat sterilization. After removing the caps, sterility was tested for 14 consecutive days following the 2025 Chinese Pharmacopoeia, Volume IV, Section 1101 sterility test method.

Culture Days	Day1	Day2	Day3	Day4	Day5	Day6	Day7	Day8	Day9	Day10	Day11	Day12	Day13	Day14
EO Sterilization	-	+	+	+	+	+	+	+	+	+	+	+	+	+
Steam Sterilization	-	-	-	-	-	-	-	-	-	-	-	-	-	-

"-" indicates no colony growth; "+" indicates colony growth

Test Results: Ethylene oxide sterilization struggled to penetrate the aluminum caps and eliminate microorganisms in the gap between the cap and cartridge, while moist heat sterilization achieved more thorough microbial killing.



Cross-linked Siliconization

Cross-linked Siliconization | Performance Upgrade + Dual Effect of Pyrogen Removal

NEST cartridges use a proprietary cross-linked siliconization process. High-temperature baking converts free silicone oil molecules into a fixed state, forming a uniform and stable cross-linked silicon layer on the inner wall. This significantly enhances product performance while effectively removing pyrogens.

The cross-linked silicon layer provides four key benefits:

- **Enhanced safety:** Silicone oil is firmly bound through chemical bonds, greatly reducing shedding and particles, lowering drug contamination and patient risk.
- **Long-lasting performance:** Lubrication remains stable throughout the product's shelf life, ensuring consistent plunger feel and accurate dosing from the first to the last injection.
- **Improved compatibility:** Reduced free silicone oil makes it more suitable for high-value, sensitive protein and biologic drugs.
- **Low drug residue:** The smooth protective layer minimizes contact and adhesion between the drug and glass surface, significantly reducing residual liquid.

Advanced Forming Process



Advanced Forming Process

Stable cartridge dimensions, consistent quality

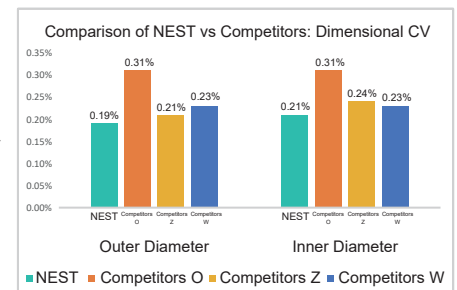
NEST selects high-quality international borosilicate glass tubes and uses advanced Italian Spami forming equipment and processes to ensure precise, consistent cartridge dimensions.

Dimensional Stability Comparison Test

Method: Thirty NEST cartridges and thirty cartridges from three competitors were measured for inner and outer diameters, and the coefficient of variation (CV) was calculated.

Evaluation: CV is the key indicator of dimensional stability—the smaller the CV, the better the consistency and stability.

Conclusion: NEST cartridges demonstrate superior dimensional stability compared with three similar domestic and international competitors.



※NEST offers products sterilized by either moist heat or ethylene oxide

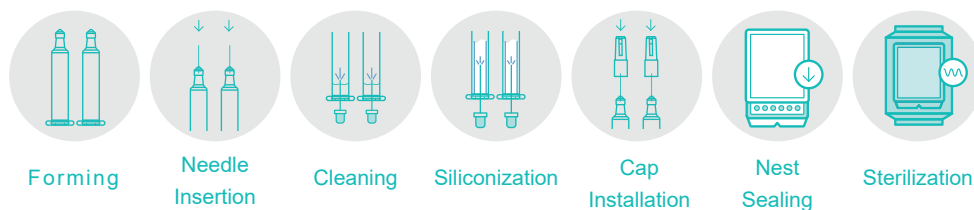
Pen Injector Equipments

Glass Prefilled Syringe Assembly

Prefilled syringes with needles are an integrated drug delivery system combining the medication, syringe, and needle in one unit, ready for immediate use upon opening without the need for drawing up the drug or changing the needle.

COMING
SOON

High-quality Controlled Manufacturing Process



Product Introduction

Product Applications



- Chemical drug formulations (antibiotics, anesthetics, emergency medications, etc.)
- Vaccines and standard biologics (inactivated vaccines, immunoglobulins, etc.)
- Ophthalmic and local drug formulations (intraocular injections, ophthalmic therapeutics, etc.)
- Peptide hormones, contrast agents, and diagnostic reagents

Product Advantages

Syringes

- Available in three sizes: 1.0 mL, 1.0 mL slim, and 2.25mL
- Made of imported borosilicate glass to ensure drug stability
- Ready-to-use design with pre-attached needle for low contamination
- Fully automated production with minimal particle load
- 100% final product inspection for consistent quality
- Full lifecycle validation for complete traceability



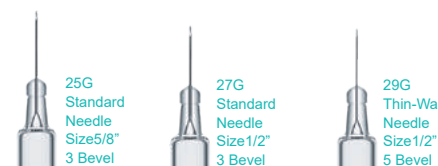
Needle Caps

- Made of rubber compliant with YBB00082004, ensuring needle cleanliness
- Available in hard and soft caps for effective sealing and protection



Needles

- Available in various lengths, diameters, and bevel types, made of stainless steel
- Standard and thin-wall options to meet different customer needs



Pen Injector Equipments

Automated Assembly System

We plan, procure, or develop customized systems to meet client-specific requirements, including automated assembly systems, automated testing systems, rotary table systems, vision systems, linear systems, robots for component insertion and removal, packaging systems, pre-production equipment, and drug assembly systems.



This equipment is designed to assemble the cartridge holder, pen cap, pen body, and cartridge into a complete prefilled pen injector.

•Highly flexible and efficient standardized module design.

Core: pre-designed, interchangeable standardized components that can be quickly and accurately configured to meet different product production needs, greatly enhancing production line adaptability and flexibility, while significantly reducing the time and cost required for product line change-overs.

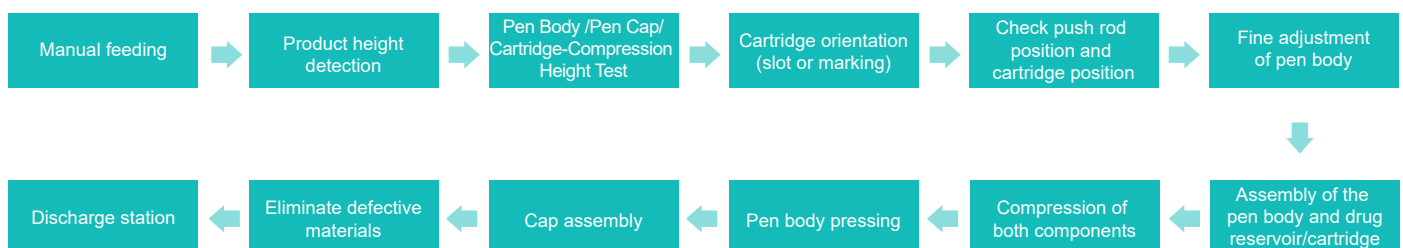
•Main driving force: cam-driven mechanism.

The cam structure is renowned for precise motion control and reliable synchronization, ensuring accuracy and efficiency during assembly. It helps minimize errors and scrap, improving overall production quality.

•Multiple inspection stations.

Ensure final product consistency through pressure, visual, and other inspection methods. Continuous quality monitoring and feedback help users promptly identify and address potential issues, preventing negative impacts on subsequent assembly steps or the final product.

● Flowchart



Pen Injector Accessories

Prefilled Automatic Pen Injector Assembly Press-Fitting Equipment



Scan to Watch the Operation Video



Designed for the precision assembly of prefilled automatic pen injector components, this system delivers efficient, accurate, and reliable assembly. It offers high throughput (6–10 units/min), excellent consistency, broad compatibility with various PFS specifications and leading autoinjector platforms, and comprehensive lifecycle technical support.

Product Parameters

Product Name	NEST Prefilled Automatic Pen Injector Assembly Press-Fitting Equipment
Dimensions (W × D × H)	594*508.5*587mm
Package	1 unit/case
Cat.No.	110201
Throughput	≥540 pcs/h
Rated Voltage	110V~230V
Power	800W
Weight	80 Kg

TSA Disposable Pen Injector Press-Fitting Equipment



Scan to Watch the Operation Video



Designed for the precision assembly of prefilled cartridges and TSA pen injectors, this system delivers an efficient and reliable solution for performance validation, clinical sample preparation, and small-batch production of combination products. It features two-hand safety activation, a bilingual touchscreen interface, a compact footprint, excellent assembly consistency, and comprehensive lifecycle technical support.

Product Parameters

Product Name	TSA Disposable Pen Injector Press-Fitting Equipment
Dimensions (W × D × H)	490*380*537mm
Package	1 unit/case
Cat.No.	110101
Throughput	≥480 pcs/h
Rated Voltage	110V~230V
Power	500W
Weight	55 Kg

Pen Injector Equipments

Disposable Pen Injector Press-Fit Fixture

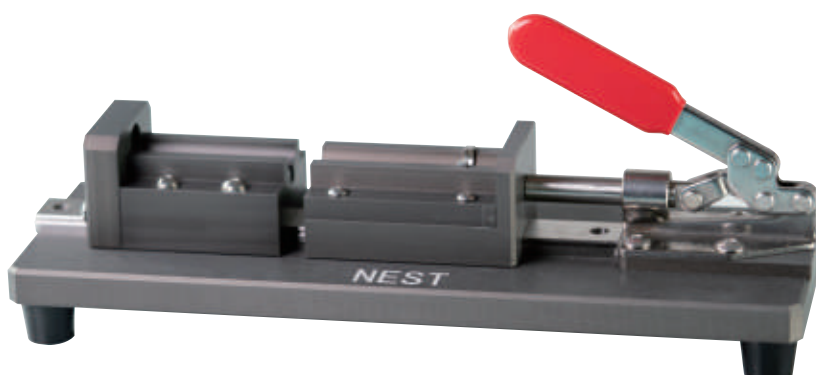


110191



110391

Scan to Watch the
Operation Video



110381

● Product Introduction

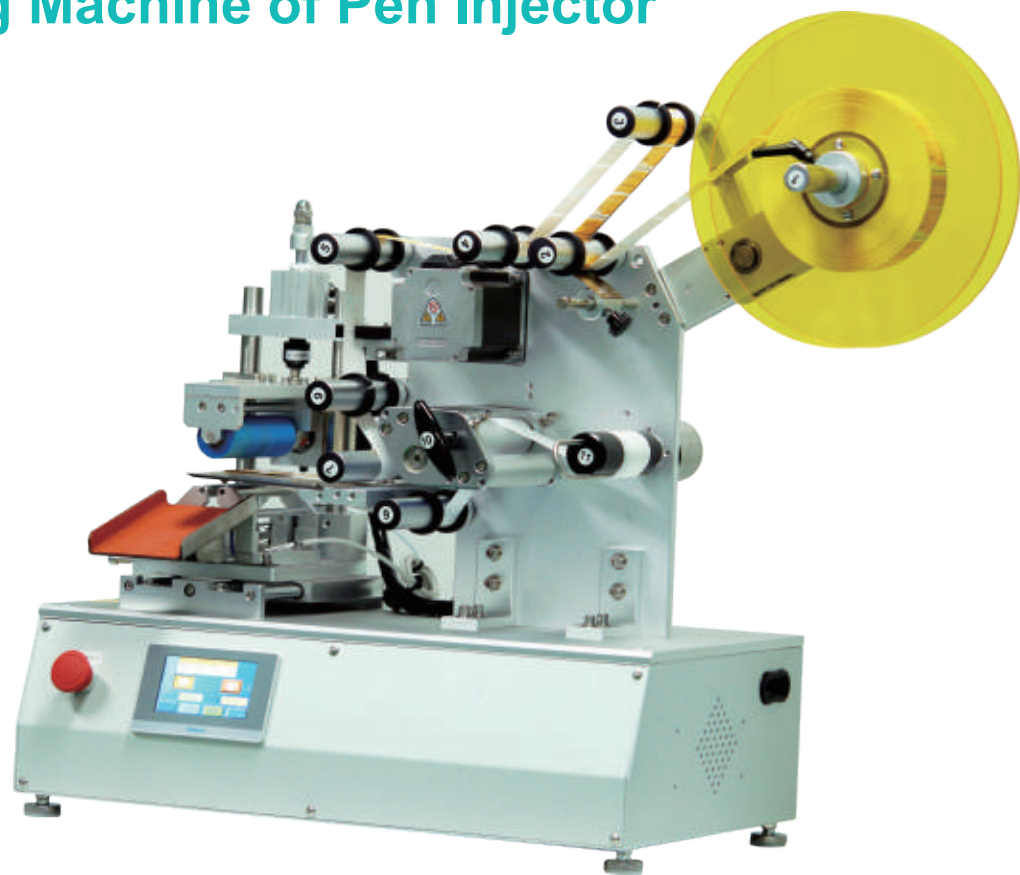
Designed for the precision assembly of disposable and TSA pen injectors with prefilled cartridges, this system delivers a safe, efficient, and reliable assembly solution for performance validation, clinical sample preparation, R&D, and small-batch production of combination products.

● Product Parameters

Product Description	Packaging	Dimension	Weight	Cat. No.
NEST TSA Disposable Pen Injector Press-Fit Fixture	1 unit/case	250 × 444 × 180mm	≈ 8 kg	110191
NEST Disposable Pen Injector Assembly Press-Fit Fixture	1 unit/case	250 × 444 × 180mm	≈ 8 kg	110391
NEST Disposable Pen Injector Assembly Press-Fit Fixture	1 unit/case	343 × 120 × 86 mm	≈ 3.6kg	110381

Pen Injector Accessories

Labeling Machine of Pen Injector



Scan to Watch the
Operation Video



● Product Introduction

Designed for pen injectors of various specifications, the labeling machine delivers precise and efficient wrap-around labeling. Featuring an adjustable fixture platform, it supports full-wrap, partial-wrap, inline coding, and inkjet marking for different product sizes. Ideal for R&D, small-batch, and large-scale production, it enhances labeling accuracy, production efficiency, and packaging integration.

● Product Parameters

Cat.No.	111101
Packaging	1 unit/case
Dimension	800 × 500 × 950 mm
Weight	≈ 53 kg
Rated Voltage	AC 220 V/50 Hz
Power	500 W
Compatible Label Size	(L) 6 mm ~ 250 mm, (W) 20 mm ~ 125 mm
Compatible Label Roll	OD φ280 mm, ID φ76 mm
Compatible Products	OD: φ 5 mm ~ φ 35 mm NEST Disposable Pen Injector NEST SP Disposable Pen Injector NEST TSA Disposable Pen Injector NEST Prefilled Automatic Pen Injector (Three-Step)
Speed	20 ~ 25 pcs/min
Labeling Accuracy	±0.5mm (excluding product and label tolerances)

Personnel and Quality Inspection Equipment

● Quality Team and R&D Team

1. Professional Team Structure

- The 76-person professional team is proficient in core quality tools such as APQP and FMEA, and has passed multiple system certifications
- A dedicated team is established to handle raw material analysis, product testing, and other processes

2. Full-Process Quality Control System

- Raw Material Testing: Physical and chemical analysis + component damage diagnostics
- Product Verification: Dual functionality testing for components and the complete unit
- Method Certification: Standardized verification of measuring equipment and testing processes

3. Standardization Certification System

- International Standards: ISO 9001/IATF 16949/ISO 13485 system certifications
- Professional Qualifications: All team members have undergone internal auditor training and are certified
- Testing Standards: Customized testing plans based on customer standards

4. Quality Closed-Loop Management

Test Data → Functional Testing Group Execution → Quality Engineer Evaluation → Final Review by Project Manager (Quality Engineering Department) (Based on the characteristics of the quality management system, the core elements are integrated, with a focus on professional division of labor and standardized processes.)

● Certification and Verification of Production Equipment, Processes, and Measuring Equipment

Experience with three-coordinate measuring system (Germany ZEISS, CONTURA 7/10/6RDS)

In practice, we extensively use three-coordinate measuring system for dimensional measurement of mold processed parts, fixtures, complex products, and experimental samples. The data is output and analyzed through a computer, ensuring high reliability. The coordinate measuring machine uses high-precision optical positioning technology and advanced data processing techniques, ensuring the reliability and stability of the measurement data.

Dimension Scanner (Japan Keyence, IM-8030)

Used for dimensional recognition and remodelling, the dimension scanner allows us to measure and analyze the surface dimensions of materials simply through computer processing. It enables fast, repeatable surface dimension measurements (e.g., measuring the same dimension across multiple holes) using the computer system.

Visual and Tactile Measurement Technology and Industrial Computed Tomography

The measurement laboratory equipped with modern measurement instruments ensures that precision mold inserts, injection molded parts, or assembly units can be measured with extreme accuracy. Complete component measurement data is recorded in the initial sample test report after measurement. These devices include various multi-sensor coordinate measuring machines for visual and tactile component measurement, universal measurement microscopes, and industrial computed tomography scanners for non-destructive measurement and testing of individual parts or entire assembly units.

Packaging Tear and Peel Strength Tester (YBB-03)

The YBB-03 Pharmaceutical Packaging Tear Strength Tester is mainly used for accurately measuring the pressing force and holding force of pen injectors, as well as conducting tensile, peel, opening force, puncture force, and breakage tests on pharmaceutical packaging materials such as rubber stoppers, combination caps, composite films, aluminum foil, and PVC sheets. It is also used for testing pre-filled syringes, ampoule breakage force, and sliding performance. It is suitable for research institutions, pharmaceutical companies, inspection and quarantine agencies, and other organizations.



Quality Assurance

Full Industry Chain Structure

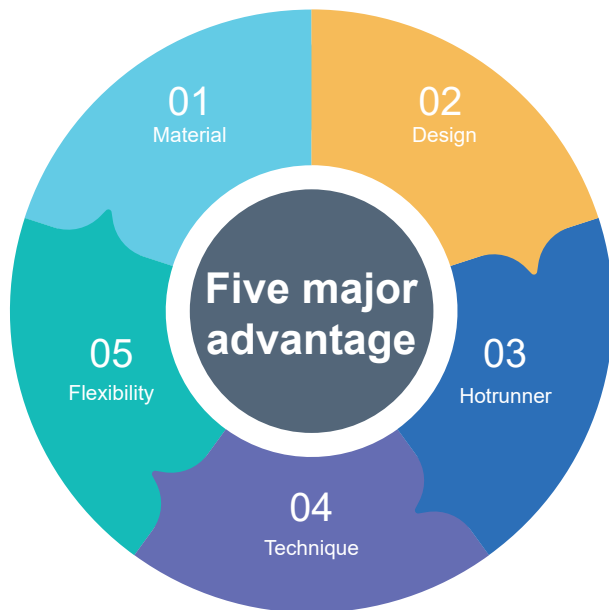
● R&D and Mould Manufacturing

Nest has the capability to independently design and develop molds. Based on your specific requirements, we can customize the development and optimize the injection molding layout for pen injectors. By embedding production process parameters during the development phase, we can significantly shorten the development cycle.

● Industry Experience and Achievements

- 30 years of technical accumulation: Over 300 precision molds delivered.
- Cross-industry applications: Covering fields with high precision requirements such as life sciences consumables and medical devices.
- 50-person maintenance team: 70% of members have more than 10 years of mold maintenance experience.

Their work ensures that our precision molds possess excellent high-repeatability accuracy, durability, and short molding cycles.



01 Material

Procurement of steel from Sweden, Germany, and Japan provides better mold polishing performance and higher product flatness

02 Design

Unique cooling and exhaust system

03 HotRunner

Select the most suitable hot runner system based on the product characteristics of thin walls, high transparency, multi-cavity, and short cycle times

04 Technique

Use professional analysis software Moldflow for analysis

05 Flexibility

Offer customized solutions for clients

● Raw Material Assurance

We focus on the research of polymer materials and have mastered modification techniques. We possess extensive experience in the performance and application of materials such as PP and PC. We also have rich application experience in the fields of environmentally-friendly plastics, medical-grade plastics, and specialty functional polymer materials.

Specific materials, physical and chemical analysis – Incoming material control

Nest implements strict control measures for supplier approval and raw material/packaging material approval. We conduct detailed material, physical, and chemical analysis on raw materials. Our laboratory staff possesses deep expertise, and the laboratory is well-equipped to perform physical and chemical analysis, such as viscosity, residual moisture, and density, to meet the personalized needs of our clients.

The company ensures that all raw materials/packaging materials meet product technical requirements through the following steps:

- Supplier questionnaire survey
- Supplier on-site audit
- Raw material/packaging material report review
- Raw material/packaging material performance validation
- Raw material/packaging material batch inspection

The implementation of these measures guarantees the stability of the supply chain and the quality of the products. This section will also list Nest's relevant statements on the control of raw materials and packaging materials:

Raw Material Compliance Statement (ROHS, REACH)

The raw material particles used in Nest's reusable pen injectors have relevant reports provided by the manufacturer, complying with ROHS and REACH regulations, including but not limited to ABS, PC, PP, etc.

ROHS: Nest strictly adheres to the European Union regulation "Directive on the restriction of certain hazardous substances in electrical and electronic equipment" (2011/65/EU) (ROHS). This standard controls the levels of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers in products.

REACH: Nest strictly follows the European Union regulation "Registration, Evaluation, Authorization, and Restriction of Chemicals" (2006/1907) (REACH) to control substances of very high concern (SVHC) in raw materials.

Global Warehousing and Logistics Capabilities

● Subsidiary Distribution

The company is committed to providing first-class products and services to global customers. We have established subsidiaries in the United States, the Netherlands, the UAE, and Japan to support our brand's expansion and development in international markets. Our U.S. subsidiary has been deeply engaged in the overseas market for over a decade. With the completion of a newly purchased warehouse in the western United States, we are now successfully providing integrated services for storage, transportation, and sales to our customers.

USA:

USA east: 3 Convery Blvd, Woodbridge, NJ 07095 USA

USA west: 641 S 53rd Ave, Phoenix, AZ 855043 USA

Europe:

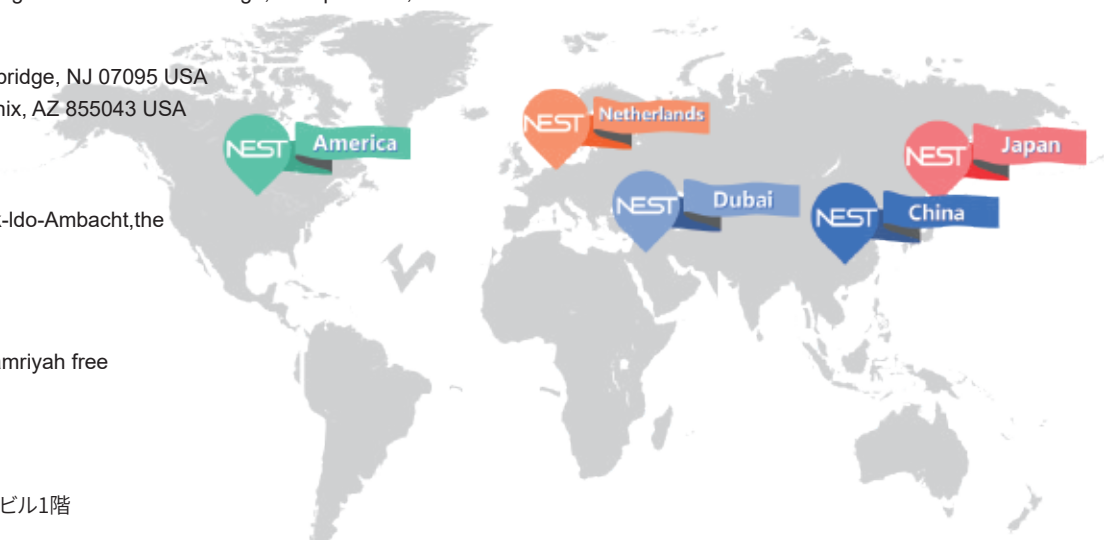
Ecologieweg 10, 3343LM Hendrik-Ido-Ambacht, the Netherlands

Middle east:

Warehouse LV-22D, phase 2 of hamriyah free zone, Sharjah, UAE

Japan:

横浜市都筑区池辺町3513番地B&Iビル1階



● Supply Chain Stability and Lead Time

To ensure supply stability and timely delivery, NEST manages the supply chain and lead time through the following measures:

- Long-Term Supply Contracts: Signing long-term supply contracts with customers to ensure stable supply over a defined period.
- Safety Stock: Maintaining a certain amount of safety stock during production to address unforeseen circumstances.
- Timely Scheduling: Adjusting production schedules based on customer orders and inventory status to ensure on-time delivery

● Traceability

NEST provides the following methods to trace the production and transportation process of products:

- Batch Information: Information for each product batch is recorded in the form of batch numbers, allowing traceability of key process inspection data and test results. Customers can trace the production status of the product using this information.
- Production Records: In NEST's production process, data from each process step, including raw materials, injection molding, and other product processing steps, are retained. This data can be used to trace the production status of the product.
- Sample Retention: A sample is retained from each batch of products, allowing customers to trace the production status of the product.
- Transportation Process Inspection: In addition to the production process, NEST also inspects the product during transportation to ensure that it has not been damaged or experienced quality issues during transit.

● Shelf Life

NEST determines the shelf life of its products by conducting accelerated aging tests according to YY/T 0681.1-2018 or ASTM F1980 standards. For specific details on the testing content, please refer to the shelf life testing section of the product tests. The shelf life is calculated from the time of product production, with the batch number specified in the COA/COC of the accompanying NEST product as the reference. The general shelf life of the product can typically be found in the COA/COC and the product technical documents on the official website.

Unless otherwise stated, the general storage conditions for NEST medical devices and pharmaceutical packaging materials are relative humidity not exceeding 80%, at room temperature (10-30°C), and in a light-protected environment. During transportation, the products should be protected from mechanical impact or contact with sharp objects, avoid direct sunlight and rain, and ensure the packaging remains intact and the product is not contaminated.



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NEST



ISO 9001



ISO 13485



ISO 11137



CE

