



Trusted partner for aseptic processing solutions



**Advanced aseptic filling
+ closing equipment**



Your **trusted partner**

AST, LLC has over 60 years of experience designing, manufacturing, and servicing flexible automated processing equipment. In 2006, AST leveraged its experience and close customer relationships to revolutionize the aseptic fill/finish industry with the launch of the ASEPTiCell®. The ASEPTiCell was the industry's first aseptic multi-format fill/finish machine capable of processing ready-to-use nested vials, syringes, and cartridges on the same line. Today, AST offers a range of products and services to support drug product development, clinical, and commercial fill/finish requirements.

Mission

AST develops intelligent, intuitive, and innovative solutions that minimize (and where possible eliminate) process, efficacy, and safety risks associated with drug product manufacturing.

We will consider all format applications including but not limited to vials, syringes, cartridges, infusion bags, inhalers, bottles, and devices.

Vision

AST strives to be one of our customers' most trusted partners for drug product manufacturing.

Purpose

The solutions AST delivers today enable life-changing therapies to reach more patients, in a race against time, where every day matters.



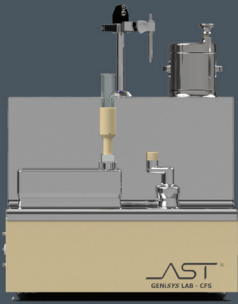
AST



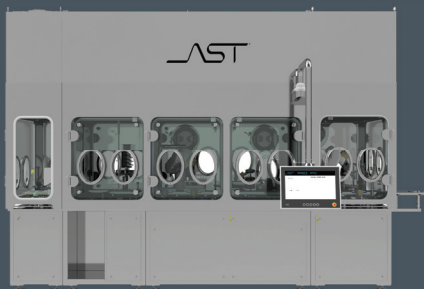


Start **small.** Scale **up.**

From discovery to treatment, we have solutions for every stage of the drug development process.



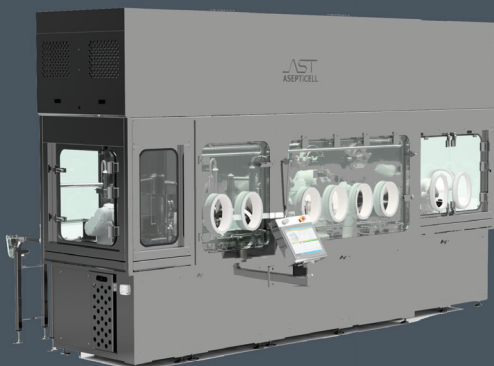
GENiSYS Labs



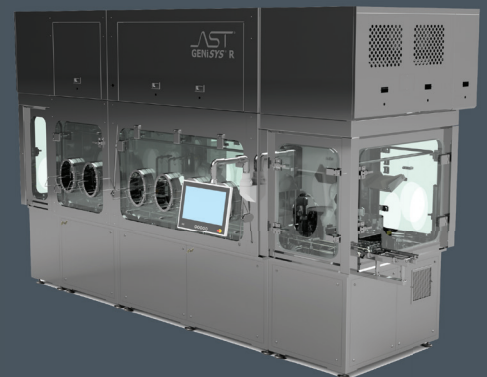
Isolated GENiSYS C



GENiSYS C



ASEPTiCell



GENiSYS R

AST[®]





GENiSYS[®] Lab

Benchtop automation

Compact

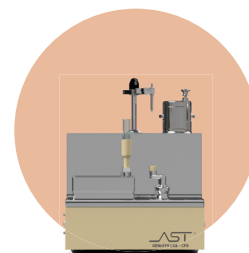
These benchtop machines come packed with features while taking up minimal space in your lab or cleanroom.

Simple

GENiSYS Lab machines feature easy, intuitive operation and direct technology transfer to larger-scale AST lines.

Precise

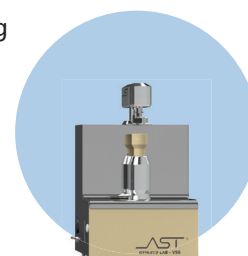
Automate the critical operations in filling and closing for precise control over all aspects of your process.



Container Filling System (CFS)



Container Closing System (CCS)



Vial Sealing System (VSS)

Applications

- Process development
- Clinical trials
- Small-scale commercial manufacturing

Barrier options

All GENiSYS Lab machines are compatible with our fully integrated, turn-key barrier systems:

- Bio-safety cabinet
- Laminar airflow hood
- Aseptic isolator

	CFS	CCS	VSS
Containers	<ul style="list-style-type: none">• Vials• Syringes• Cartridges	<ul style="list-style-type: none">• Syringes• Cartridges	<ul style="list-style-type: none">• Vials• Cartridges
Closing/sealing	<ul style="list-style-type: none">• Vial stopper placement• Press-fit cap application	<ul style="list-style-type: none">• Vacuum• Vent-tube• Combination vent-tube/vacuum	<ul style="list-style-type: none">• Spinning disc
Available options	<ul style="list-style-type: none">• Peristaltic or rotary piston pump filling• In-process fill weight verification (IPC)• Inert gas overlay• Electronic Batch Records (EBR)• Single-use fluid path	<ul style="list-style-type: none">• Inert gas overlay• Electronic Batch Records (EBR)• 2-up processing	<ul style="list-style-type: none">• Applied force monitoring• Electronic Batch Records (EBR)• Screw cap application
Dimensions (LxWxH)	Up to 840mm x 500mm x 800mm		



GENiSYS® C

Compact + flexible

Advanced

This system features the same options as larger scale filling lines to process nested ready-to-use (RTU) containers.

Flexible

GENiSYS C can be integrated with LAF hoods, RABS, and isolator systems to process vials, syringes, and cartridges with just a few change parts.

Reliable

Recipe-driven servos control every motion of filling and closing for repeatable results in every batch.



Applications

- Research and development
- Process development
- Engineering runs
- cGMP clinical trials
- Small-scale commercial manufacturing

Cart-Based Processing

AST's cart-based processing modules harness all the innovation and advancements of our larger line configurations into compact, robust aseptic processing solutions. Prioritizing cGMP processing at a smaller operational footprint, our cart-based processing modules are suitable for a wide range of facility areas, including decentralized operations like hospital or compounding pharmacy settings. Modules include:

- GENiSYS C fill / close module
- VSM C vial sealing module

Containers	<ul style="list-style-type: none">• All commercially available RTU nested vials, syringes, and cartridges• Custom formats available
Vial closing/sealing	<ul style="list-style-type: none">• Serum or lyo stoppers• Press-fit cap application• Crimp capping available
Syringe/cartridge closing	<ul style="list-style-type: none">• Vacuum• Vent-tube• Combination vent-tube/vacuum
Production rate	<ul style="list-style-type: none">• Up to 20 upm
Available options	<ul style="list-style-type: none">• In-process fill weight verification (IPC)• Viable, non-viable and total particulate monitoring (EM)• Electronic Batch Records (EBR)• Pre and post fill container gas purge• Integrated barrier systems and laminar airflow (LAF) hoods
Dimensions (LxWxH)	1800mm x 625mm x 1725mm





Isolated GENiSYS[®] C

Commercial small-batch flexibility

Flexible

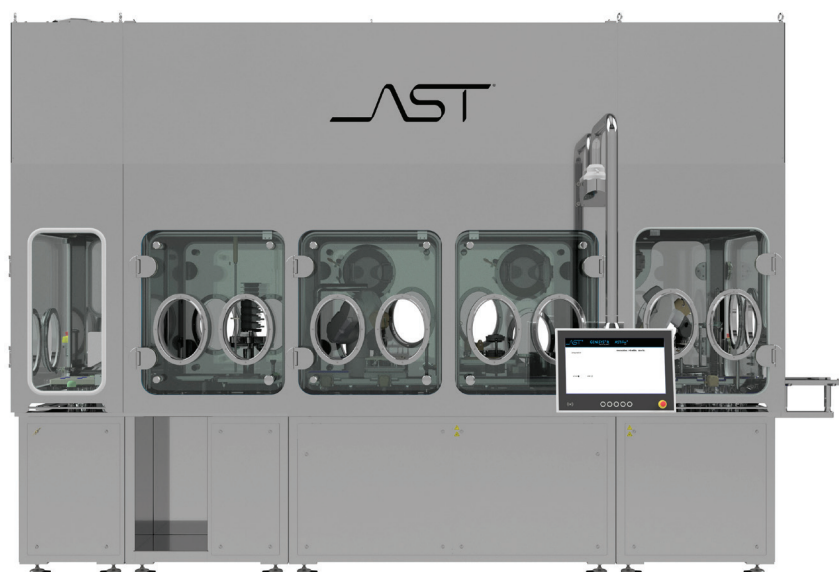
Process pre-sterilized nested vials, syringes and cartridges on a single machine, and close using any syringe closing or vial sealing process.

Simple

Minimal change parts, recipe-driven production process, and intuitive human-machine interface that unifies fill-finish machine, isolator, and decontamination system under a single interface.

Precise

Electronically driven for high repeatability of machine processes with non-destructive in-process fill weight verification (IPC)



Applications

- cGMP clinical trials
- Small-scale commercial manufacturing
- Cell & gene therapies
- Viral vector manufacturing
- Biologics manufacturing
- Regenerative medicine

Isolator Barrier System

Benefits of AST's latest isolator barrier technology include:

- Market-leading decontamination cycle times
- Made in the USA
- Double-wall construction for optimized airflow
- Full integration with aseptic filling line

Containers

- All commercially available RTU nested vials, syringes, and cartridges
- Trayed and custom formats available

Vial closing/sealing

- Serum or lyo stoppers
- Press-fit cap or crimp cap application

Syringe/cartridge closing

- Vacuum
- Vent-tube
- Combination vent-tube/vacuum

Production rate

- Up to 20 upm

Available options

- In-process fill weight verification (IPC) up to 100%
- Viable, non-viable and total particulate monitoring (EM)
- Electronic Batch Records (EBR)
- Pre- and post-fill container gas purge

Available machine modules

- Semi-automatic bag opener (SABO)
- Automatic bag opener (ABO)
- Manual tub opener (MTO)
- Automatic tub opener (ATO)
- Vial sealing module (VSM)

Dimensions (LxWxH)

Dependent on final configuration



GENiSYS[®] R

Precision + flexibility

Robotic

Robotic handling of nests and containers provides reliability, accuracy, and precision in your process.

Flexible

GENiSYS R is flexible enough to handle any of your process needs without requiring complicated changeovers between batches.

Precise

Robotic handling of containers allows you to prioritize process control without compromising process speed.



Applications

- Clinical and commercial production for small and medium batch drug manufacturing
- Biologics, proteins, and potent products
- Multi-product aseptic filling facilities
- Pilot-scale cGMP manufacturing

Barrier options

The GENiSYS R is designed for full integration with barrier systems including:

- Restricted access barrier systems (RABS)
- Aseptic isolators

Containers	<ul style="list-style-type: none">• All commercially available RTU nested and trayed vials, syringes, and cartridges• Custom formats available
Vial closing/sealing	<ul style="list-style-type: none">• Serum or lyo stoppers• Press-fit cap application• Crimp capping
Syringe/cartridge closing	<ul style="list-style-type: none">• Vacuum• Vent-tube• Combination vent-tube/vacuum
Production rate	Up to 20 upm
Available options	<ul style="list-style-type: none">• In-process fill weight verification (IPC) up to 100%• Viable, non-viable and total particulate monitoring (EM)• Electronic Batch Records (EBR)• Pre and post fill container gas purge
Available machine modules	<ul style="list-style-type: none">• Semi-automatic bag opener (SABO)• Automatic bag opener (ABO)• Manual tub opener (MTO)• Automatic tub opener (ATO)• Lyophilization integration• Vial sealing module (VSM)• Manual tray loader
Dimensions	Dependent on final configuration



ASEPTiCell®

Fully automatic + robotic

Robotic

Robotic handling from the moment a bagged tub enters the line until the final product is finished ensures the risk of human error is kept to a minimum.

Flexible

Simple, recipe-driven changeover streamlines processing of different products or containers on a single machine.

Advanced

Advanced features allow hands-off operation and ensure your product is filled precisely with the highest level of quality assurance.



Applications

- Clinical and commercial production for small and medium batch drug manufacturing
- Biologics, proteins, and potent products
- Filling of toxic and cytotoxic materials
- Multi-product aseptic filling facilities
- Pilot-scale cGMP manufacturing

Barrier options

The ASEPTiCell is designed for full integration with barrier systems including:

- Restricted access barrier systems (RABS)
- Aseptic isolators

Containers	<ul style="list-style-type: none">• All commercially available RTU nested vials, syringes, and cartridges• Custom formats available
Vial closing/sealing	<ul style="list-style-type: none">• Serum or lyo stoppers• Press-fit cap application• Crimp capping
Syringe/cartridge closing	<ul style="list-style-type: none">• Vacuum• Vent-tube• Combination vent-tube/vacuum
Production rate	Up to 100 upm
Available options	<ul style="list-style-type: none">• In-process fill weight verification (IPC) up to 100%• Viable, non-viable and total particulate monitoring (EM)• Electronic Batch Records (EBR)• Pre and post fill container gas purge
Available machine modules	<ul style="list-style-type: none">• Automatic bag opener (ABO)• Automatic tub opener (ATO)• Lyophilization integration• Vial sealing module (VSM)• Automatic tray loader
Dimensions	Dependent on final configuration

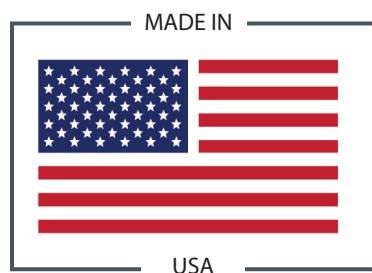


Atmos™ Isolator



USA design, manufacture, and service

A localized supply chain allows us to offer industry-leading delivery times and ensure quality at every step in the manufacturing process. All of our customers worldwide benefit from American ingenuity and streamlined manufacturing.



Technical Highlights

- 10ft ceiling height, with options for tech housing access from top or side
- Double-wall construction for optimized airflow
- Full bio-decontamination cycle in under 60 minutes
- Automated enhancements for maintenance and operations



A Turnkey Isolator Solution

Seamless integration and ergonomic design

The fill / finish equipment, isolator, and decontamination system are unified under ASTView, an intuitive human-machine interface, for a single point of information and control. AST's Atmos isolator eliminates common points of friction in barrier technology using advanced automation and ergonomic design.

Shield™ Wireless Glove Integrity Tester

AST's glove integrity testing solution features intelligently designed wireless glove testers and a docking cart that serves as a control center and wireless charging station. Benefits of this solution include:

- Full integration with filler / isolator control system, with unified batch report systems
- Pre-configured glove ports and test recipes, with automatic loading of recipes from the glove port ID
- High-definition touchscreen display
- Testing complete in as short as 10 minutes
- 21 CFR Part 11 compliant test reports



Industry-leading biodecontamination

AST has partnered with CURIS to integrate their 7000ei decontamination system with our isolator. The CURIS 7000ei ensures a rapid, consistent, and validated complete cycle in as little as 60 minutes (including aeration). Leveraging CURIS's federally approved low-concentration 7% hydrogen peroxide technology, the 7000ei offers the quickest cycle times with superior material compatibility and virtually no outgassing.





Customer Care

24/7 support throughout your filling journey

Support Services

We partner with our clients to ensure our equipment reliably meets their operational needs. We offer both onsite and remote options for:

- Standby support
- Training
- New recipe formulation
- New format configuration
- Preventative maintenance

New System Capabilities

As new opportunities and filling needs arise, our Customer Care team can help configure your AST machine to best suit your production goals.

Spare Parts Consultation

Our Customer Care team can help you determine the right amount of parts and materials to have in stock. We consider your machine and process to ensure a seamless operation.

Annual Maintenance

Regular servicing and preventative maintenance ensures your machine always operates at its optimal level. AST offers annual maintenance contracts to maximize your facility's uptime and ensure the best ROI on your machine.

Scale-Up Support

Thinking of moving to a higher capacity AST machine? Our team can help you assess the best options to meet your aseptic filling needs.

The AST Difference

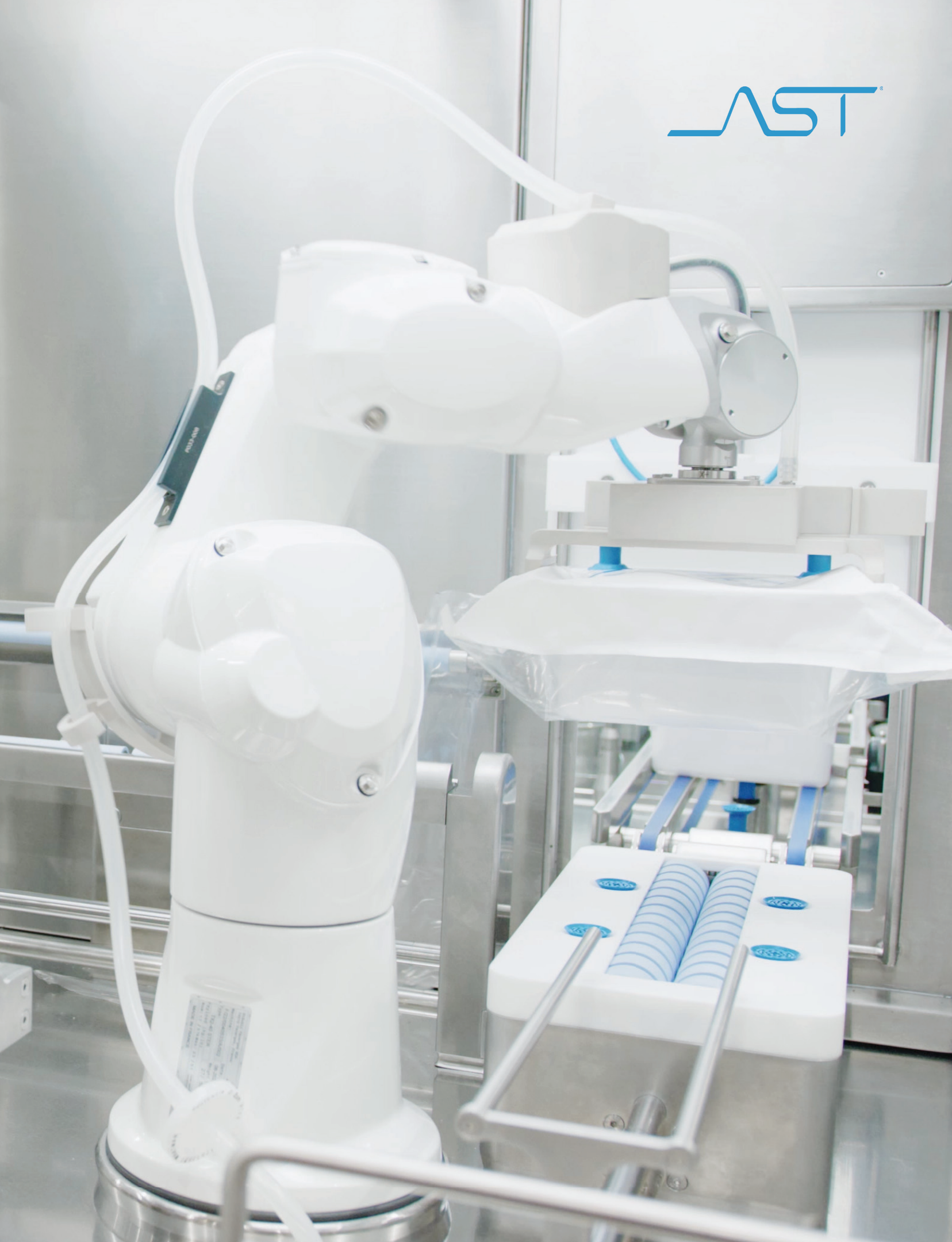
- US-based design and support team
- Quick response times 24/7
- Advanced remote support
- Dedicated field service engineers
- Comprehensive preventative maintenance and training plans



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AST[®]





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