Medical
Line

VARIOVAC
simpler faster better

PACKAGING TECHNOLOGY
THAT FORMS SAFETY!

MedicalLine

Safety Criteria | Requirements

Needle-free Vial Adapter

Infusion Bags

Pre-filled Syringe

Process and Material Safety

The VARIOVAC MedicalLine consistently meets the demanding requirements of sterile medical packaging. Our thermoforming packaging machines ensure maximum process stability and stand out with their efficiency – even when handling complex packaging solutions. Depending on the sterilization method, a wide variety of film types can be processed on our MedicalLine machines, including Tyvek®, medical paper, aluminum laminates, as well as semi-rigid and flexible films. This gives you maximum flexibility while maintaining consistently high quality and safety.

Regulations and Standards

Our MedicalLine thermoformers provide full validation capability, maximum process reliability, and uncompromised cleanroom suitability. They support medical device manufacturers in meeting regulatory requirements, particularly ISO 11607, EN 868, and the European Medical Device Regulation (MDR – EU 2017/745). Core processes such as forming, sealing, and marking can be validated according to IQ/OQ/PQ. All machines are designed for ISO Class 7 to 9 cleanrooms, offering a reliable foundation for safe, reproducible, and MDR-compliant packaging processes.

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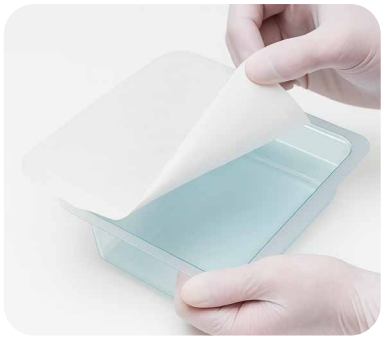
Requirements

Packaging for sterile medical devices must deliver more than protection alone. It is a decisive part of the Sterile Barrier System (SBS) – the defined packaging structure that ensures a reliable microbial barrier and guarantees sterility until the point of use. Our VARIOVAC MedicalLine thermoformers are designed specifically to implement this system in a reproducible, validatable, and user-friendly way.

Each MedicalLine machine is customized to your product – from packaging layout to the desired level of automation. Labeling also plays a key role: batch numbers, sterilization details, barcodes, and variable data must be applied clearly, durably, and in full compliance with applicable standards. We enable the integration of proven printing and labeling technologies with our machines – including thermal transfer, laser, inkjet, flexographic, and hot film printing. These systems can be used individually or in combination, and our in-house developed labeling units can be flexibly integrated into the packaging process.

Our solutions therefore contribute to traceability and product safety throughout the entire supply chain. The result is a validated packaging process that reliably unites functionality, patient safety, and regulatory compliance, providing optimal support for the SBS of your products.



Easy opening of sterile packaging

Standard-compliant package labeling

Key Requirements for Sterile Packaging

- **Sterility maintained until the package is opened**
- **Reliable protection against microbial contamination**
- **Resistance to mechanical damage**
- **Aseptic and user-friendly opening**
- **Compatibility with EO, gamma, and steam sterilization**
- **Easy and safe handling by medical personnel**
- **Reproducible and validatable production**
- **Standard-compliant labeling**

MedicalLine | Primus

Maximum Flexibility, Absolute Safety

The VARIOVAC Primus MedicalLine sets new benchmarks in sterile medical packaging. It delivers high-end technology for companies that demand the highest standards of precision, process safety, and flexibility. The proprietary VARIOVAC RAPID AIR SYSTEM ensures perfect film forming and reliable seal integrity, even with demanding materials. Precise film transport, stainless-steel sensor technology, and excellent visibility into the production area guarantee full process control.

Quick-change systems and modular format parts allow rapid changeovers between formats or batches. The intelligent control system with flexible recipe management and remote access supports efficient configuration changes and seamless integration of new products. The hygienic design, with foldable side panels, sloped surfaces, and open chain guides simplifies cleaning and ensures that production remains GMP-compliant and cleanroom-ready at all times.

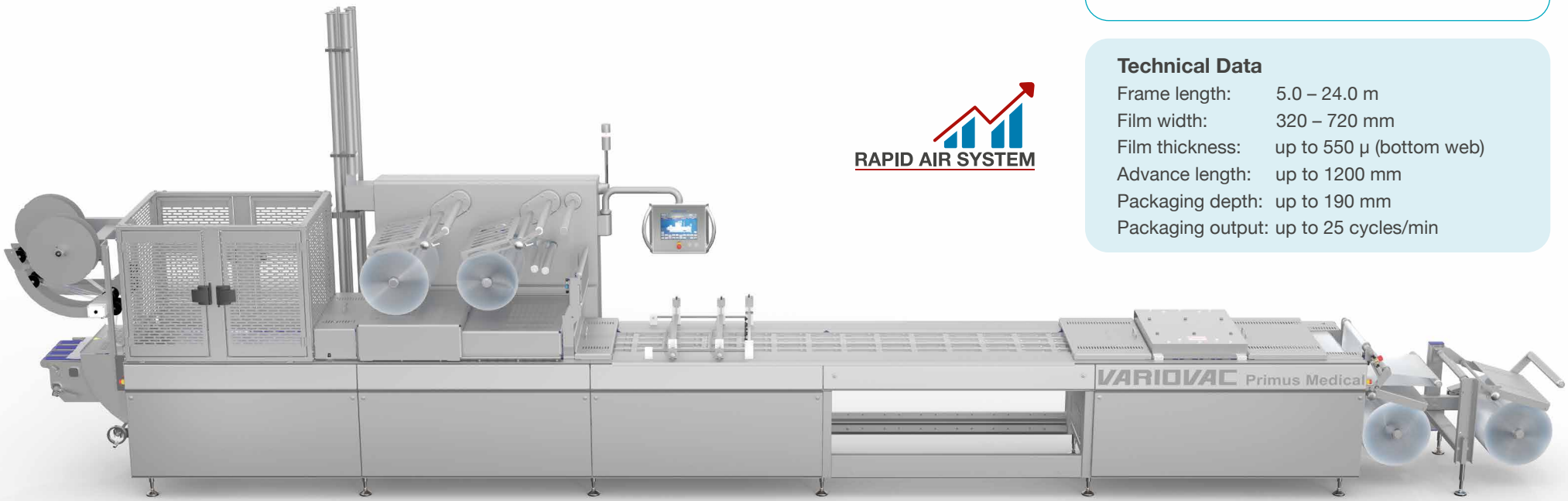
Key Benefits Primus

- **Premium solution for the highest demands in medical technology**
- **RAPID AIR SYSTEM for precise forming and consistent sealing quality**
- **Flexible adaptation to complex production requirements**
- **Intelligent control for efficient format changes**
- **Hygienic design for clean and safe processes**

Technical Data

Frame length:	5.0 – 24.0 m
Film width:	320 – 720 mm
Film thickness:	up to 550 µ (bottom web)
Advance length:	up to 1200 mm
Packaging depth:	up to 190 mm
Packaging output:	up to 25 cycles/min

RAPID AIR SYSTEM



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MedicalLine | Optimus

Efficiency and Performance in a Compact Design

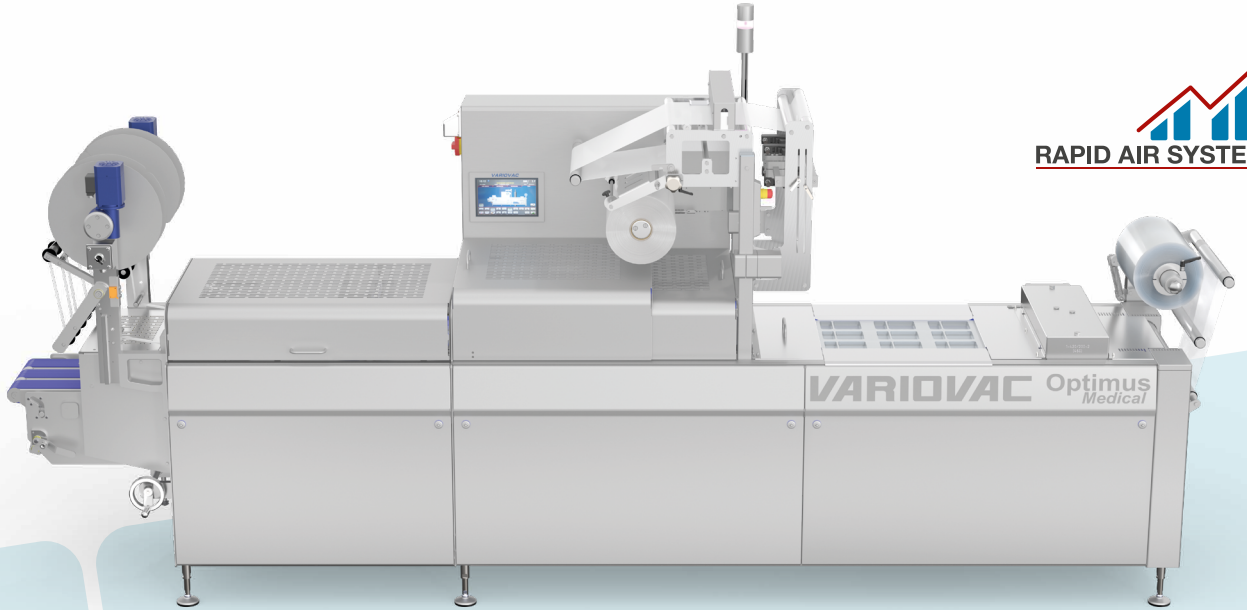
Key Benefits Optimus

- **Compact machine for efficient production processes**
- **RAPID AIR SYSTEM for precise forming and consistent sealing quality**
- **Ideal for varying pack formats, batch sizes, and environments**
- **User-friendly operation with clear workflows**
- **Hygienic design for clean and safe processes**

Technical Data

Frame length:	2.5 – 5.5 m (base machine)
	Extension modules: 1.0 – 3.5 m
Film width:	320 – 460 mm
Film thickness:	up to 550 µ (bottom web)
Advance length:	150 – 600 mm
Packaging depth:	up to 125 mm
Packaging output:	up to 12 cycles/min

The VARIOVAC Optimus MedicalLine is the perfect choice for an economical entry into automated sterile medical packaging. It combines a compact footprint with strong performance and fully meets all relevant hygiene and quality requirements. The proprietary VARIOVAC RAPID AIR SYSTEM enables precise forming and consistent seal quality, even with challenging materials. This ensures sterile packaging with maximum residual film thickness and consistently high quality. Its space-saving design, ease of operation, and wide range of options make the Optimus MedicalLine particularly suitable for smaller production areas, shorter batches, and varying packaging formats.
The hygienic machine design with easily accessible surfaces, foldable side panels, and open chain guides simplifies cleaning and prevents contamination buildup, making it ideal for safe cleanroom production.



RAPID AIR SYSTEM

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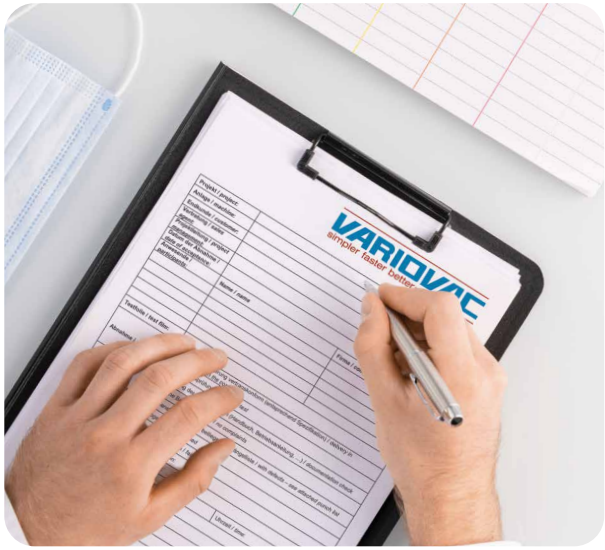
Documents | Documentation

Validated Processes

Optional Documentation Package

With our optional documentation packages, you receive all the necessary documents to qualify your VARIOVAC MedicalLine machine in compliance with international standards and to demonstrate its suitability for regulated production environments. Each documentation set is tailored to your machine and confirms compliance with ISO 11607, EN 868, MDR (EU 2017/745), and GMP guidelines. The package provides audit-ready, complete, and easily accessible information ensuring smooth qualification, successful audits, and long-term compliance.



Qualification and Validation Documents (optional)

- **IQ – Installation Qualification** – Proof of correct installation
- **OQ – Operational Qualification** – Proof of functionality according to specification
- **PQ – Performance Qualification** – Proof of performance under production conditions
- **FAT – Factory Acceptance Test** – Pre-delivery acceptance protocol
- **SAT – Site Acceptance Test** – On-site acceptance protocol

Specification Documents (optional)

- **FDS – Functional Design Specification** – Machine functionality description
- **HDS – Hardware Design Specification** – Technical details of installed hardware
- **SDS – Software Design Specification** – Description of control system and software features
- **Traceability Matrix** – Mapping of all requirements and their implementation
- **Calibration Certificates** – For all relevant sensors and measuring devices

Your Advantage

With the VARIOVAC documentation package, you can be sure that all audit-relevant documents are complete – clearly structured, readily available, and tailored to your MedicalLine machine.

MedicalLine

Standard | Optional Features

Cleanroom Compatibility

Cleanroom Compatibility

Sterile medical packaging requires the highest standards of cleanliness and hygiene. Our VARIOVAC MedicalLine thermoformers are specifically designed for cleanroom environments, with numerous construction details that minimize particle sources and ensure easy cleaning.

In-process Control


In-process Control

Maximum product safety starts with continuous monitoring of all critical process steps. Our inline control systems immediately detect deviations and guarantee consistent quality – without interrupting production.

Equipment – Optimus and Primus

Standard Features

- Hygienic design for particle minimization
- Suitable for ISO 14644 cleanroom classes
- Easy-to-clean materials, sloped surfaces, rounded edges and open design for quick access

Optional Features

- IP65 execution
- External control cabinet to reduce particle load
- Central process exhaust system
- Silencers with integrated particle separators
- Compressed air filters (e.g., sterile air filters)

In-process Control – Additional Functions

- Control for consistent sealing quality
- Detection of product, film, and positioning errors during production process
- Sensor-based quality inspection directly in the forming and sealing tools
- Automatic rejection of defective packs
- Complete documentation for full traceability

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More Information. More VARIOVAC.

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