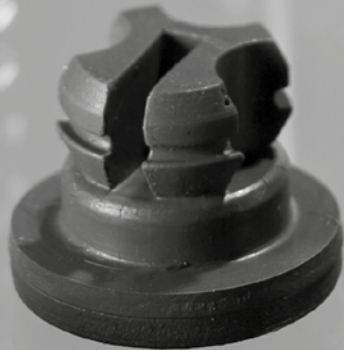




Aseptic Liquid Filling Solutions



Beyond Technology

The new business model from Romaco sets valuable incentives for meeting customer requirements. For the design of innovative solutions, Romaco relies on its unique knowledge portfolio.

With its diverse brands, Romaco focuses on important technological fields of competence. The single product lines offer the optimum

prerequisite for the development of comprehensive solutions.

Romaco promises its customers professional project handling, fast delivery times and a reliable service. Through this, Romaco provides its customers with a considerable boost to their earning and financial power.



Creating Value – best price/performance ratio

Romaco wins over its customers by offering an outstanding price/performance ratio over the entire life cycle of its products. In this way, customers can systematically optimise their cash flow. With efficient production and service management, Romaco prepares its customers for future long-term commercial success.

Delivering Solutions – high application expertise

Romaco offers integrated solutions for the growing markets of pharmaceuticals, cosmetics, food and industrial applications. Here, the customer benefits from the synergetic effects that result from the close collaboration of all the Romaco brands. This internal technology transfer imparts a considerable development potential and is the basis for comprehensive solutions.

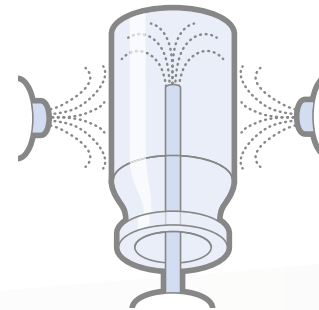
Exploiting Technologies – strong brands

Romaco is synonymous with European engineering on the highest level. With its seven brands, the company is widely recognised around the world. Continuity and progress are the keys to a strong positioning on the market. Romaco relies on the profound knowledge and the long-time experience of its employees.



» *Romaco provides you with the highest possible flexibility when it comes to configuring aseptic liquid filling solutions.*«

Nicola Magriotis, Sales Director, Romaco S.r.l.



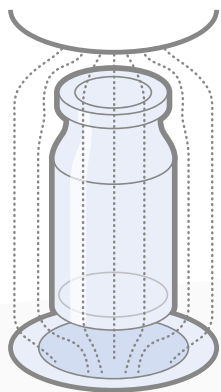
Delivering Solutions

Outstanding Expertise in Aseptic Liquid Filling

Sterility assurance first – all Romaco's aseptic liquid filling solutions conform to the rigorous current Good Manufacturing. These machines are ideal for filling injection vials and infusion bottles for applications in human and veterinary medicine. Our aseptic liquid fillers can be configured as integrated solutions, with selected upstream and downstream systems depending on the customer's requirements.

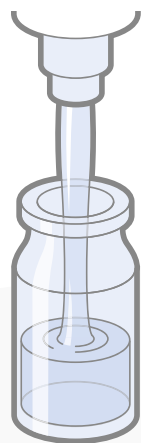
Vial Washing

- Glass vials cleaned on both the inside and the outside
- Suitable for cylindrical containers with different dimensions without holder change parts
- Vials washed with a set of special nozzles
- Complete washing cycle with nine stations



Vial Sterilisation

- Depyrogenation of glass vials and ampoules
- All vials pass through heating and cooling chambers
- Containers heated to a maximum of 340 °C
- Temperature and compressed air monitored continuously



Filling into Vials

- Optimised for filling sterile pharmaceutical liquids
- Suitable for filling glass vials
- Designed to handle containers 14 to 68 mm in diameter and 35 to 200 mm in height
- Variable filling volumes from 0,5 to 250 ml



Vial Stoppering

- Closing station either integrated in the liquid filler or available as a line component
- Standard closure with press-on rubber stopper
- Special closure types for subsequent freeze drying





Delivering Solutions

Sterile Processes are a Must

All Romaco solutions for filling sterile pharmaceutical liquids guarantee excellent sterility assurance levels (SAL). Conformity with rigorous hygienic requirements is a must, particularly in connection with liquid pharmaceutical products for parenteral administration.

The concentration of particles and micro-organisms has to be kept to a minimum throughout the entire process. At the same time, the operator must be protected against direct contact with toxic medications. First-class containment solutions are the answer.



High Barrier Protection

- RABS (Restricted Access Barrier System)
- Vertical laminar flow systems
- Glove boxes for controlled access
- Integrated CIP (Cleaning in Place) and SIP (Sterilisation in Place) systems

Efficient and Reliable

- Advanced level of automation provides absolute reproducibility
- Maximum flexibility through the use of servo technology
- Selected process analytical technologies (PAT) incorporated
- In-line check weighing system

Simple to Operate

- Ergonomic design for optimal access and ease of use
- Product and format changes completed in quickly and efficiently
- Simple control and monitoring of all processes on the HMI panel with intuitive navigation

Secondary Packaging Solutions

- Romaco Promatic PC 4000 continuous motion cartoner
- Romaco Promatic P 91 intermittent motion cartoner
- Romaco Promatic SM 2000 stretch bander
- Romaco Promatic PAK case packer





High Performance Ensures Precise and Smooth Handling

The automatic, intermittent motion washing machines in the Romaco Macofar WM 8000 series are known for their exceptionally high performance and flexibility. These machines are renowned for their ergonomic design and strict balcony architecture. The ultra-reliable transport system ensures precise and smooth handling of cylindrical containers, including those that are geometrically unstable. Flexible, programmable washing cycles contribute to a thorough cleaning process that is easy to validate.

Universal Transport Gripper

- Containers with different diameters are transported without having to change the format
- Even the most difficult containers are gripped gently and efficiently

Variable Washing Cycles

- Standard cleaning process with set of special nozzles
- Washing cycle can be customised on the control panel
- Eight or nine stations possible per washing cycle
- Self-draining washing circuits
- Additional wash, drying cycle or siliconising can be integrated on request

Technical Highlights

- Maximum output: 24,000 containers an hour
- Separate “white” and “grey” areas
- Washing principle allows combination of air and water
- Containers optionally pre-cleaned in an ultrasonic bath
- Cleaned vials are automatically discharged
- Washing circuit sterilised with free-flowing steam

Exploiting Technologies
Romaco Macofar WM 8000 Series



Vial loading



Vial washing



Universal grippers





Compliance with Strict Regulations

A pyrogen is a substance that induces fever. During the manufacture of parenteral pharmaceuticals these substances must be removed from the product and from all containers and stoppers. This process is known as depyrogenation. The Romaco Macofar T 600 and T 800 depyrogenation tunnels comply with even the strictest regulations.

Romaco Macofar T 600 and T 800

- Containers heated to a maximum of 340 °C using sterile air
- Sterilisation and depyrogenation with a unidirectional laminar flow
- Vials cooled to ambient temperature in the downstream cooling area
- Controlled environment conforms to ISO 14644-1 and ISO 5 over the entire tunnel length
- Sterilisation in the tunnel complies with even the strictest regulations
- Validation with LAL test

Technical Highlights

- Transport on a conveyor belt made of stainless steel wire mesh; no abrasion due to two anti-jam belts that advance with the containers
- Mesh belt sterilised by unidirectional, vertical laminar flows
- Integrity of the seal on the absolute filters assured by ceramic fibre gaskets
- Vacuum between upstream and downstream cleanroom areas eliminates infiltration of non-sterile air through the gaskets
- Adjustable walls inside the heating chambers ensure a constant laminar air flow velocity
- Cooling chambers sterilised with dry air

*Exploiting Technologies
Romaco Macofar T Series*





High Speed Aseptic Filling

The aseptic liquid fillers in the Romaco Macofar VF series combine top performance with completely reliable processes. These machines achieve a maximum output of 24,000 vials an hour with a filling volume of up to two millilitres. Users can choose from three different models with up to ten servo-controlled dosing syringes for continuously filling the vials with pharmaceutical liquids. Due to the linear positive transport principle, the vials are always guided safely. This is a great advantage, especially when unstable containers, such as those typically employed for freeze drying, are required. The VF series is the ideal solution for filling Small Parenteral Vials.

Slim Design

- Combination of balcony structure and table-top design
- Less than 600 mm between the front of the machine and the dosing station
- Large gap between the filling area and the machine's base plate
- Exceptionally compact machine
- Strict separation between the "white" and "grey" areas
- Through-wall installation available as an option

Sterile Cleanroom Environment

- No turbulent air movements in the vicinity of the open vials
- Can be equipped with RABS or isolator technology
- Designed with laminar flow systems
- Vials can be blown prior to flushing with nitrogen

Integral Precision

- Available with various dosing systems: peristaltic or rotary piston pump
- Very precise dosage of filling volumes with a tolerance as fine as 0,5 %
- Vials transported, weighed, filled and stoppered with the help of servo motors
- Linear configuration with positive transport system

Exploiting Technologies
Romaco Macofar VF Series



Vial infeed



In-line check weigher



Linear machine concept





Versatile System

The LF 200 ST liquid filler is the specifically designed aseptic model in the Romaco Macofar LF 200 series. With its unusually wide range of filling volumes from 0.5 to 500 millilitres it is ideal for injection vials and infusion bottles. Glass or plastic containers in a variety of formats can be handled with ease.

The technology is suited for applications in both human and veterinary medicine. The Macofar LF 200 ST achieves a maximum output of 12,000 vials an hour with a filling volume of up to five millilitres. The intermittent filling process with eight volumetric pumps combines all the benefits of efficient multiple dosing. LF 200 ST is the ideal solution to fill Large Parenteral Vials.

Sterile Design

- cGMP compliant balcony structure supports sterile processes
- Compact design saves space in the cleanroom
- Customised containment solutions and laminar flow systems
- Servo motors guarantee maximum flexibility and versatility
- Nitrogen flushing inhibits oxidation processes

Extremely Convenient

- Quick product and format changes
- Very ergonomic loading of stoppers
- Optimally accessible "grey" area
- Especially easy-to-clean surfaces in the "white" area

Reliable Processes

- Ergonomic HMI panel simplifies process control and monitoring
- Containers guided according to the linear positive transport principle
- Very precise dosing pumps driving mechanism

*Exploiting Technologies
Romaco Macofar LF 200 ST Series*



Rotary piston pumps



Vial transport system



HMI panel





Compact Design

The liquid fillers in the Macofar LVI series can be supplied in four different versions. These compact monobloc machines process sterile parenteral liquids in intermittent mode. The containers are transported to the dosing and closing stations by means of starwheels. The machine design meets all the requirements of cGMP and GAMP. Product and format changes are completed quickly and easily. The generously sized filling area is readily accessible and can be cleaned without any problems. Maximum productivity and minimal operating costs are the hallmarks of the Romaco Macofar LVI series. LVI can also be equipped to handle sterile ophthalmic bottles.

Flexible Machine Configurations

- Multiple dosing at 4 to 6 filling stations
- Equipped with volumetric or peristaltic pumps
- All machine groups are height adjustable
- Optional flushing with nitrogen before, during and after filling
- Vials can be blown as prior to filling
- Integration of one or two closing stations, ideal for eye drops

Wide Range of Container Types

- Able to fill glass or plastic bottles and vials
- Suitable for vials with a volume of 0.5 to 500 ml
- Reliable handling of unstable containers

Reliable Processes

- Micrometric adjustment of the filling volume either manually or on the HMI panel
- Positive closure positioning
- Automatic rejection of vials with misaligned or without stopper
- Can be combined with a vertical laminar flow system
- Electronic torque control (in case of eye drops bottles)

*Exploiting Technologies
Romaco Macofar LVI Series*



Filling station



Vial stoppering



Stoppering and capping station





The New Generation of Automatic Capping Machines

The capping machines in the Romaco Macofar CSP series integrate the most advanced technology for sealing cylindrical glass vials with aluminium, flip-off, press-on, screw or pilfer-proof caps. The machines comply with all established guidelines and regulations for aseptic filling.

Sealing with Stationary Guide

- Each container fed to the machine is instantly clamped from below
- Lifting and turning plate presses the container against a rigid plate
- Laterally mounted blade bends the cap bottom to seal the container

Sealing with Rotating Head

- Each container entering the machine is clamped between a stationary base plate and a rotating head
- Cap is positioned on the container, then tightly and securely fastened as the head rotates

Automation and Simple Operation

- Intuitive touch panel operation (HMI)
- Formulation management function
- Recording and management of production data
- Compliance with FDA 21 CFR Part 11 as an option

Ergonomic Design – Compact and Optimally Accessible

- Very small footprint
- Capping system design reduces contamination to a minimum
- Particle extraction system available as an option

- “White” and “grey” areas optimally accessible
- Machine cleaning time shortened
- All parts in contact with the cap can be changed quickly and easily
- Format changes completed in a few simple steps

Technical Highlights

- Minimum particles generation
- Highly suitable for laminar flow
- Automatic adjustment of capping pressure
- Collection in trays at the outlet
- Configured for installation of a RABS (Restricted Access Barrier System)
- Isolators can be supplied to protect the operator and the environment from hazardous substances

*Exploiting Technologies
Romaco Macofar CSP Series*



cGMP compliant capping process



Capping station



Capping with blade





Creating Value – Romaco generates added value for the customer across the entire life cycle of its solutions

- Romaco is interested in a long-term solution partnership with its customers
- Romaco is familiar with its customers' critical success factors throughout the different life cycle phases of our jointly developed solutions
- The range of services from Romaco is specifically designed for these phases and is delivered through the appropriate modular components
- Romaco optimises the internal processes so that the customer can benefit from more secure decisions within the time gained
- In April 2014 the new business unit Romaco Systems was founded within the Romaco Group: the aim of this unit is to integrate the offering of the Romaco Group into comprehensive solutions

We understand the business model of our customers and with a diverse portfolio we offer the best price/performance ratio for generating additional cash flow.

Benefit for the customer

Across the entire life cycle

- Minimal life cycle costs and low TCO guarantee fast amortisation of the financial investment
- The wide range of customer service products ensures sustainable value creation

In the investment phase (designing value)

- Professional consulting to increase decision-making security
- Short processing and delivery times give maximum scope for investment decision and thus optimum decision flexibility
- Customised solutions development for the optimum preparation of the implementation phases (ramp-up and production)
- Reliable and customer-orientated project management according to efficient milestone principles provides professional delivery

In the ramp-up phase (leveraging value)

- The production phase is reached more quickly due to shortening of ramp-up
- Transfer of expertise provides increased security to the customer in implementing production systems at the highest level
- Minimisation of ramp-up costs

In the production phase (harvesting value)

- Maintenance of the value stream due to quick customer service response times
- Best delivery times in service, format and spare parts
- Consulting on the optimisation of the OEE
- Continuous training of the customer team
- Extension of the life span

Creating Value

Creating Value describes our constant willingness to secure our customers' – and our own – financial success.



Comprehensive Range of Services from Initial Installation and Throughout the Operating Lifespan

Commissioning

- Installation: project planning and execution
- Commissioning and initial briefing of operators
- Process validation support
- Ramp-up support with shortened start-up phase

Maintenance

- Telephone advice available from Romaco experts
- Expert system guarantees coherent and efficient assistance
- Remote online support: prompt and reliable diagnostics using digital access
- On-site service: local emergency support provided where necessary
- Maintenance contracts: preventive maintenance reducing breakdowns to a minimum

Training

- Qualified training and seminars for machine operators and maintenance personnel
- FDA compliant training concepts with continuous performance reviews
- Provided on the customer's site or at the Romaco training centre

Production Optimisation

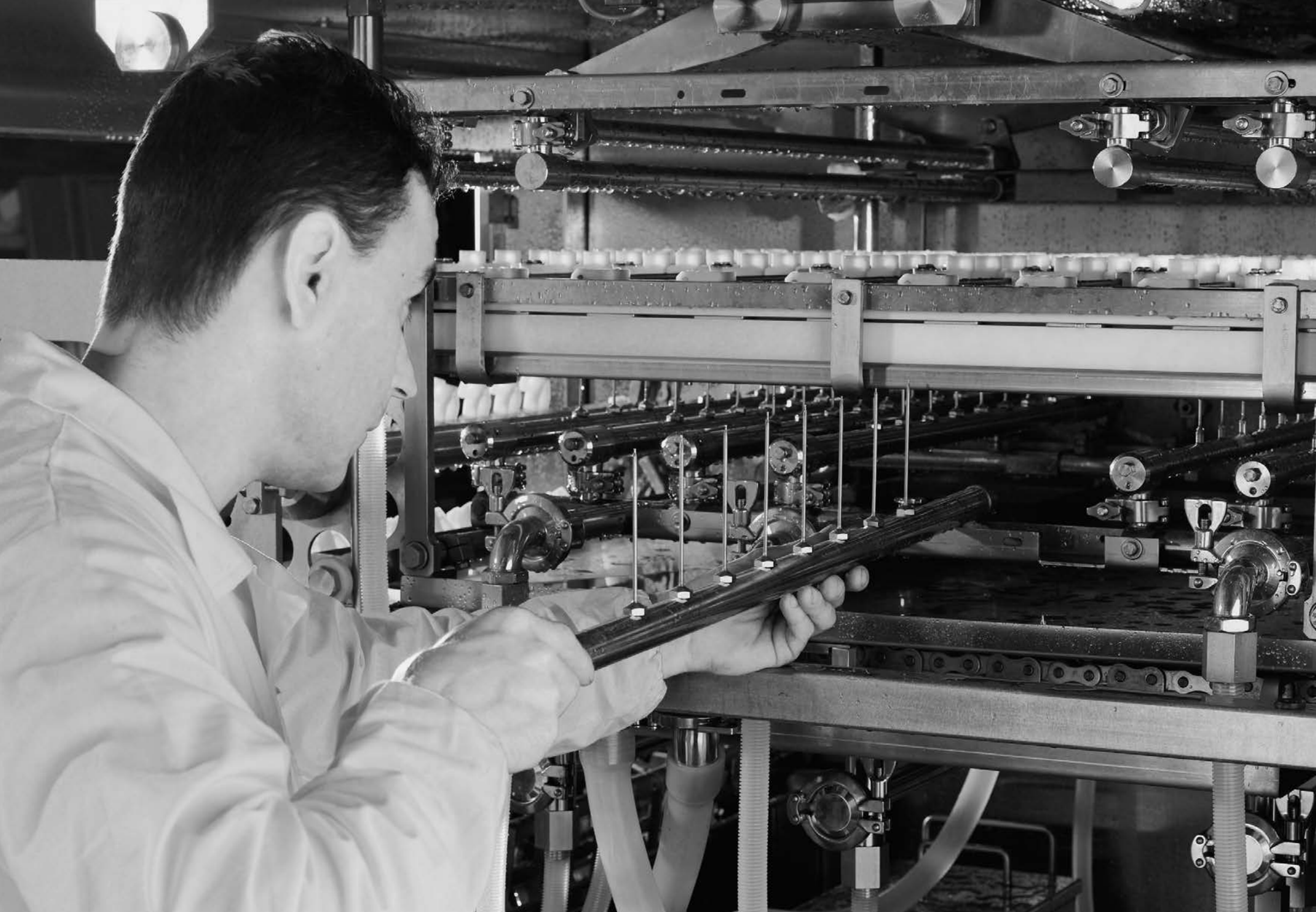
- Support for customers regarding the systematic optimisation of OEE values
- OEE audits on the customer's premises
- Detailed analyses of internal processes and downtime
- Combination of lean expertise and technical plant know-how

Retrofit, Expansion and Relocation

- Standard packages and customised solutions for machines in all series
- Special feed systems for complex products and specific layouts
- Plant relocation planning and execution

Original Parts

- Format sets compatible with all machines in the same series
- High-precision parts that fit exactly
- Format centre: each part is rigorously tested by Romaco before it leaves the factory
- Machine parameters and qualification documentation included in the scope of supply



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