ROMACO INNOJET

beyond technology

Herbert Hüttlin

Solutions for Drying, Granulating and Coating Small Particles

ROMACO
beyond technology

Delivering Solutions – Application Expertise

We are thoroughly familiar with your products and applications! Romaco specialises in engineering technologies for solid pharmaceutical dosage forms. Our concepts and system solutions are inspired by the rich experience and know-how of our 600-strong team of employees.

Creating Value – Enhanced Performance

Profit from Romaco's excellent value for money! We help you optimise your OEE balance systematically. With our efficient production and service management, we cut the running costs for your machines and increase your output in the long term.

Exploiting Technologies – Product Diversity

Our product diversity knows no bounds! The modular concept behind Romaco machines and equipment is the key to your success. With seven product lines, we are in a position to respond promptly and flexibly to changing market requirements. Together we are stronger!

ROMACO beyond technology INNOJET Herbert Hüttlin

» As an innovation leader for drying, granulation and coating, Romaco Innojet offers a range of high-efficiency processing solutions for the pharmaceutical, food and chemical industries«

Zeljko Pockaj, Managing Director Romaco Innojet

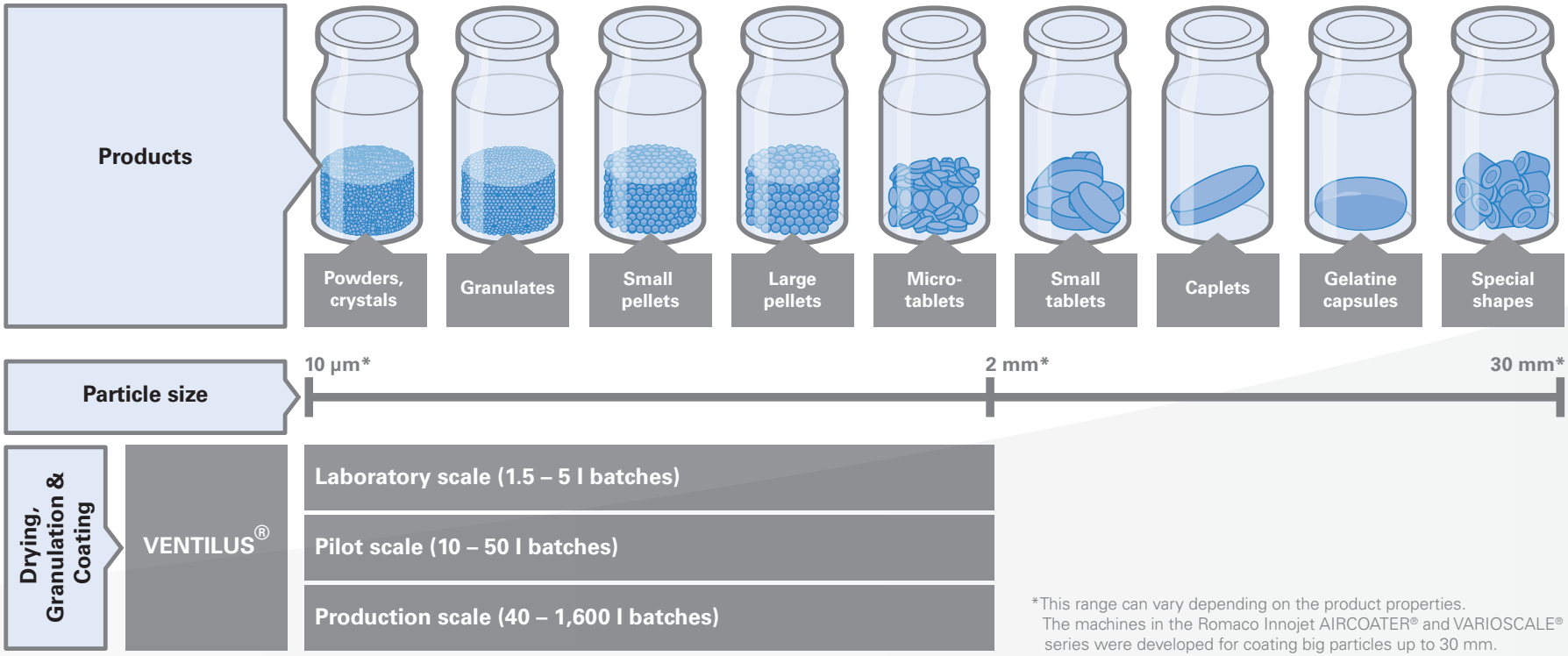
Delivering Solutions

We Improve your Return on Investment

The VENTILUS® technology was developed by Romaco Innojet for a broad array of applications involving small particles – from classic drying processes in combination with a high-shear mixer to innovative pellet or hot melt coating. Within these applications our customers acquire a standardised system solution which is simultaneously tailored to their individual needs. The superiority of the VENTILUS® technology in terms of product quality, scalability and processing time helps cut the costs for users in the long term and improves their return on investment.

One Step Ahead in Technology

- Better product quality and shorter processing times thanks to the air flow bed technology
- 3-in-1: drying, granulation and coating in a single batch process without having to retool the machine
- Extensive experience in the development and implementation of pellet and hot melt coating processes
- Numerous systems installed as laboratory, pilot or production scale solutions in Europe, Asia and the Americas
- Close to our customers worldwide: take advantage of the laboratory equipment and application consulting available from our Sales and Service Centres



*This range can vary depending on the product properties.
The machines in the Romaco Innojet AIRCOATER® and VARIOSCALE® series were developed for coating big particles up to 30 mm.

Granulation of Powdery Substances

- Improved flowability and dosing properties
- Preparation for tableting
- Dust binding
- Different raw materials combined without segregation
- Optimised release kinematics

Direct Applications for Granules

- Ready-to-use formulations (stick packs) for administration without water
- Instant beverages

VENTILUS®-Compatible Starter Materials

- Powders, crystals, granulate, pellets or micro-tablets
- All free-flowing bulk materials from 10 µm to 2 mm

Typical Substances

- Pharmaceutical carriers and APIs
- Acids, salts, sugar, aromas
- Minerals, vitamins and amino acids
- Probiotic bacteria
- Fertilisers
- Seeds

Coating in the Pharmaceutical, Food and Chemical Industries

- Improved stability and shelf life
- API coatings
- Controlled API release
- Taste masking
- Multilayer coatings
- Microencapsulation
- Moisture protection
- Enteric coatings
- Hot melt coatings

Delivering Solutions

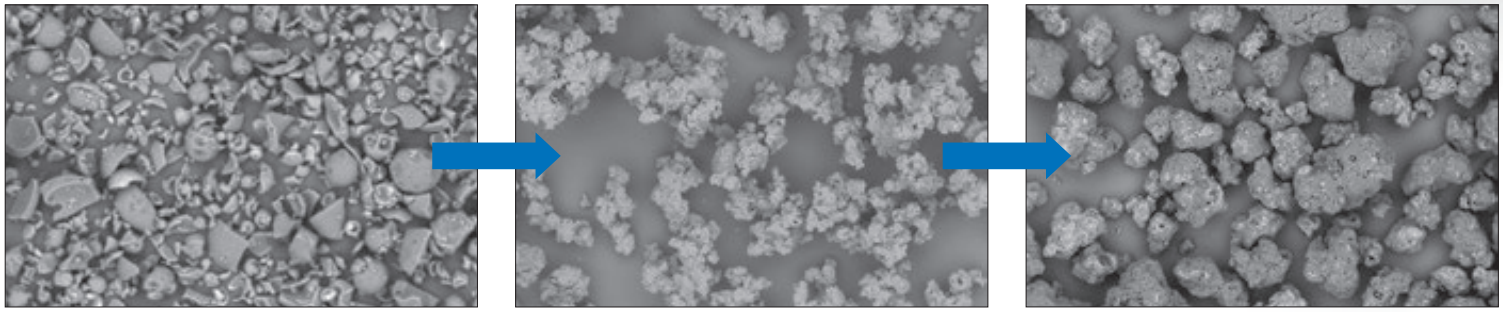
Air Flow Bed Technology

All Romaco Innojet solutions for drying, granulation and coating small particles are based on the air flow bed technology originally developed and internationally patented by Dr. h.c. Herbert Hüttlin. This method optimises the fluidisation of solid particles and creates flow conditions that enable extremely gentle intermixing of the product. The air flow bed technology provides significant benefits for our customers compared to granulation and coating systems based on a conventional fluidised bed.

Characteristics of the Air Flow Bed Technology

- Gentle product flow owing to the orbital, and hence controlled, flow of process air
- Particles float freely without any friction because the product hovers, resulting in rapid, and above all even, coating with the material
- Shorter processing times combined with excellent, reproducible product quality

Granulation and hot melt coating in the VENTILUS® V 400



Starter *Granulate* *Granulate with hot melt coating*

Shorter Batch Times

- Drying, granulation and coating combined in a single batch process (3-in-1)
- Multilayer coating: seamless sequence of individual spraying steps
- Drying times up to 25% shorter
- Higher productivity compared to conventional, conical product containers owing to the cylindrical container geometry

Optimised Process Control

- Efficient intermixing of the product with the innovative spraying system
- Large product surface facilitates the application of liquid coating or adhesive medium
- Cost efficient solution because spray loss is reduced to a minimum
- Reliable processing even of highly friable products
- Efficient coating of complex geometries as well as products and particles with a hollow structure

Scale-up

- Uniform flow conditions in the container owing to the cylindrical design
- Scalable spray rate because there is only one, central nozzle
- Nozzle designed with a spraying gap: the gap length can be varied proportionally but the geometry remains constant
- Stable droplet sizes regardless of the spray volume

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Applications by Industry

Pharmaceuticals

Granulate

Coated pellets

Coated micro-tablets

Food

Granulate

Hot melt coated granulate

Coated apple pieces

Chemicals

Coated seeds

Coated seeds

Coated fertiliser pellets

Laboratory Scale

VENTILUS® V 5 laboratory scale systems are specially designed for manufacturing small batches from 1,500 ml to 5,000 ml. They are excellent process development solutions for our customers in the pharmaceutical, food and chemical industries.

- Reliable scale-ups to the V 25 and V 50 pilot scale systems
- Process column made from stainless steel or glass
- Mobile housing mounted on castors
- Touch screen with gesture recognition and WiFi hotspot for remote control using any mobile device
- Optional: integral spray air heater for hot melt processes

Pilot Scale

The pilot scale systems in the Romaco Innojet VENTILUS® series are intended for batch sizes from 10 to 50 litres. They are ideal for clinical samples as well as for analysing and validating process parameters.

- Reliable scale-ups
- GMP design according to pharmaceutical regulations
- Product filled and discharged pneumatically
- Small batches or clinical samples
- Compact system design
- Mobile container solution also available

Product Trials Worldwide

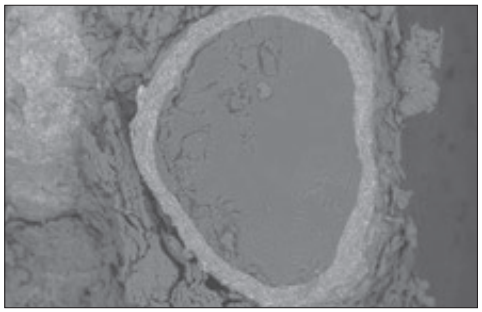
VENTILUS® laboratory equipment is installed at all our Sales and Service Centres in France, China, Brazil, Russia and the U.S. plus our Indonesian agent. Our customers can thus gain an insight into the benefits of the VENTILUS® technology "on their doorstep". The VENTILUS® laboratory and pilot scale systems in the test laboratory at our Steinen site enable us to provide professional process development support:

- Development of products and formulations
- Definition and optimisation of process parameters
- Test series with a variety of substances
- Full documentation of all experimental results

Exploiting Technologies

Lab Scale Series
V 5

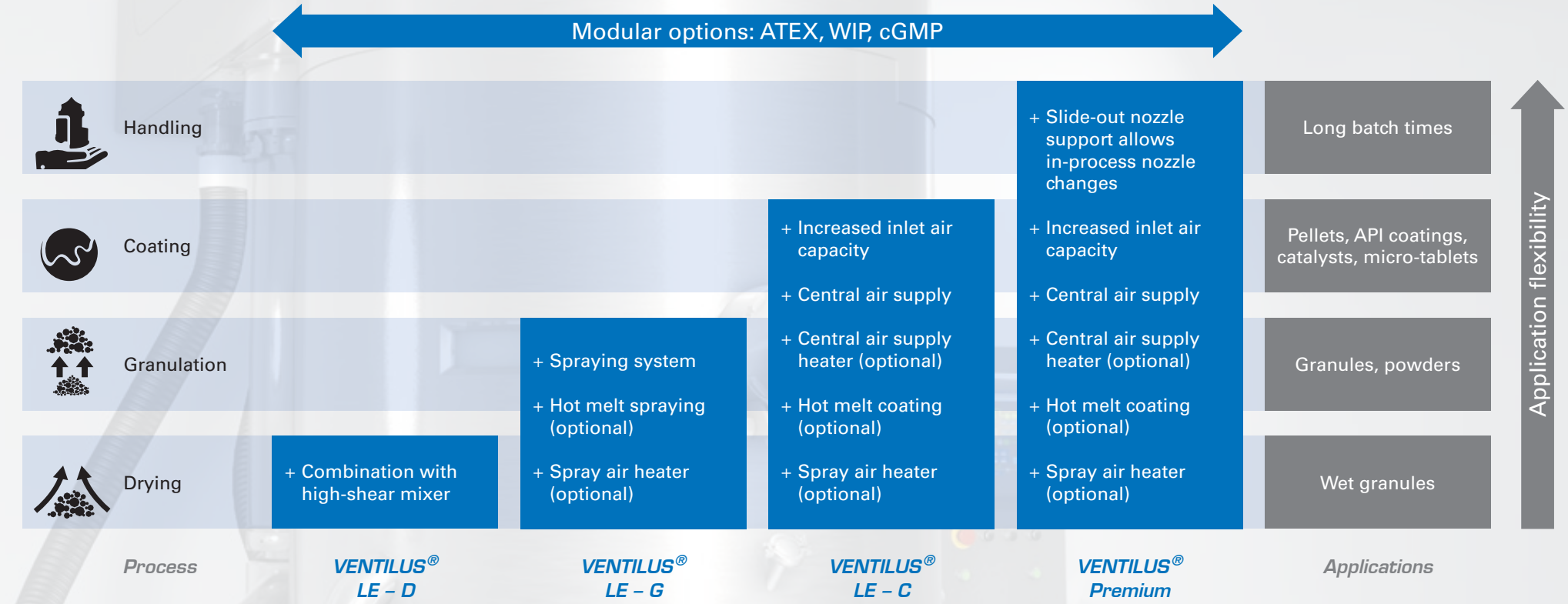
Pilot Scale Series
V 25
V 50



The VENTILUS® applies a homogeneous coating to an API pellet in a MUPS tablet

VENTILUS® V 25 and V 50 pilot scale systems

Laboratory equipment is at our customers' disposal locally


Modular options: ATEX, WIP, cGMP
Handling
Coating
Granulation
Drying
+ Combination with high-shear mixer
+ Spraying system
+ Hot melt spraying (optional)
+ Spray air heater (optional)
+ Increased inlet air capacity
+ Central air supply
+ Central air supply heater (optional)
+ Hot melt coating (optional)
+ Spray air heater (optional)
+ Slide-out nozzle support allows in-process nozzle changes
+ Increased inlet air capacity
+ Central air supply
+ Central air supply heater (optional)
+ Hot melt coating (optional)
+ Spray air heater (optional)
Long batch times
Pellets, API coatings, catalysts, micro-tablets
Granules, powders
Wet granules
Application flexibility
Process
VENTILUS® LE – D
VENTILUS® LE – G
VENTILUS® LE – C
VENTILUS® Premium
Applications

Production Scale

- Batch sizes from 40 to 1,600 litres
- Larger batch volumes or modifications on request
- Suitable for use in the pharmaceutical, food and chemical industries

Different LE (Light Edition) and Premium Versions Provide Application Flexibility

- VENTILUS® LE-D: for drying processes (optionally in combination with high-shear mixer)
- VENTILUS® LE-G: for granulation processes
- VENTILUS® LE-C: for granulation and coating processes
- VENTILUS® Premium: «all-in-one» system with slide-out nozzle support, allowing spray nozzle changes without interrupting the process
- Modular upgrade from a VENTILUS® LE-D dryer to a VENTILUS® LE-G granulator is a simple matter

GMP Granulation Line Concept

VENTILUS® systems can also be used as part of a multi-purpose wet granulation line in combination with a high-shear mixer. Owing to their application flexibility, they are ideal for contract manufacturing. The closed material transfer system has a built-in conical mill for wet and dry milling.

- Horizontal product flow with a compact design and small footprint in the cleanroom
- Discharge into different container sizes with a conical mill that is suitable for both wet and dry milling processes
- Ergonomic, integral cleaning of all complementary equipment
- Ex concept with interconnected process containers for fast and reliable transfer of intermediates

Optimised Cleaning

- WIP – washing in place: product-contacted parts inside the system are cleaned automatically
- Strictly hygienic design of the interior speeds up cleaning
- Special design of the ORBITER booster and the restriction to a single ROTOJET spray nozzle enable significantly shorter cleaning time after each batch
- Filters washed in place as part of pre-cleaning after the process
- Filters also available in a stainless steel CIP (cleaning in place) version
- Inner cores and seals of the complete process filter are cleaned during washing
- Small number of inflatable seals

Exploiting Technologies

Production Scale Series
V 100
V 200
V 300
V 400
V 600
V 800
V 1000
V 1200
V 1600

LE-D, LE-G, LE-C and Premium versions available

Larger batch volumes or modifications on request

VENTILUS® Premium: the spray nozzle can be changed without interrupting the process

VENTILUS® V 100 in the LE-C version

Romaco Innojet production scale WIP system

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SEPAJET

ROTOJET

ORBITER

ORBITER

ORBITER is the name given to the container bottom or booster through which process air is introduced. Its special design supports the formation of the orbital air flow bed. It consists of overlapping circular plates.

- Process air introduced between the circular plates
- Formation of the air flow bed by means of controlled air distribution with a precisely defined flow velocity
- Spiral, orbital movement guarantees gentle, uniform intermixing of the product
- Horizontal arrangement of the ORBITER's circular plates prevents the product from dropping through, even if the process air supply is interrupted

ROTOJET

All machines in the Romaco Innojet VENTILUS® series are equipped with a single, central ROTOJET spray nozzle. This nozzle enables rapid and homogeneous distribution of the spray liquid as well as perfect control of the process and is also suitable for hot melt applications no matter which size is used.

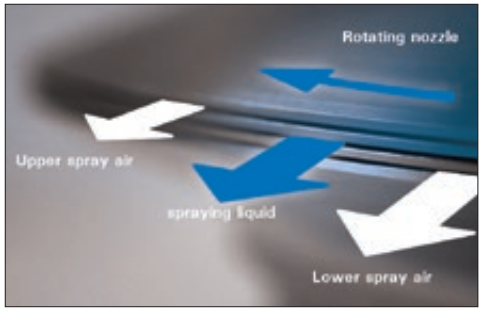
- Bottom spray principle directly onto the product
- Annular spraying gap: the diameter – and hence the size – of the gap increases the bigger the nozzle
- Dynamic spraying gap: the rotation of the spray head prevents any blockage
- Spraying and support air ensure precise control of the spraying direction
- Variable adjustment of the spraying gap allows the droplet size to be determined precisely

SEPAJET

The SEPAJET filter ensures that powdery particles are continuously returned to the process zone. Product loss is reduced to a minimum and a constant flow of process air is guaranteed.

- Larger filtering area in a smaller space because the filter bags are arranged in a star shape
- Filter bags cleaned by a blowing-air rotor with treated process air
- Inner cores of the filter are made from folded stainless steel and very easy to clean
- Simple handling because the inner cores are tightly welded in the filter plate
- Filter bags are individually fitted onto the inner cores and can also be individually changed

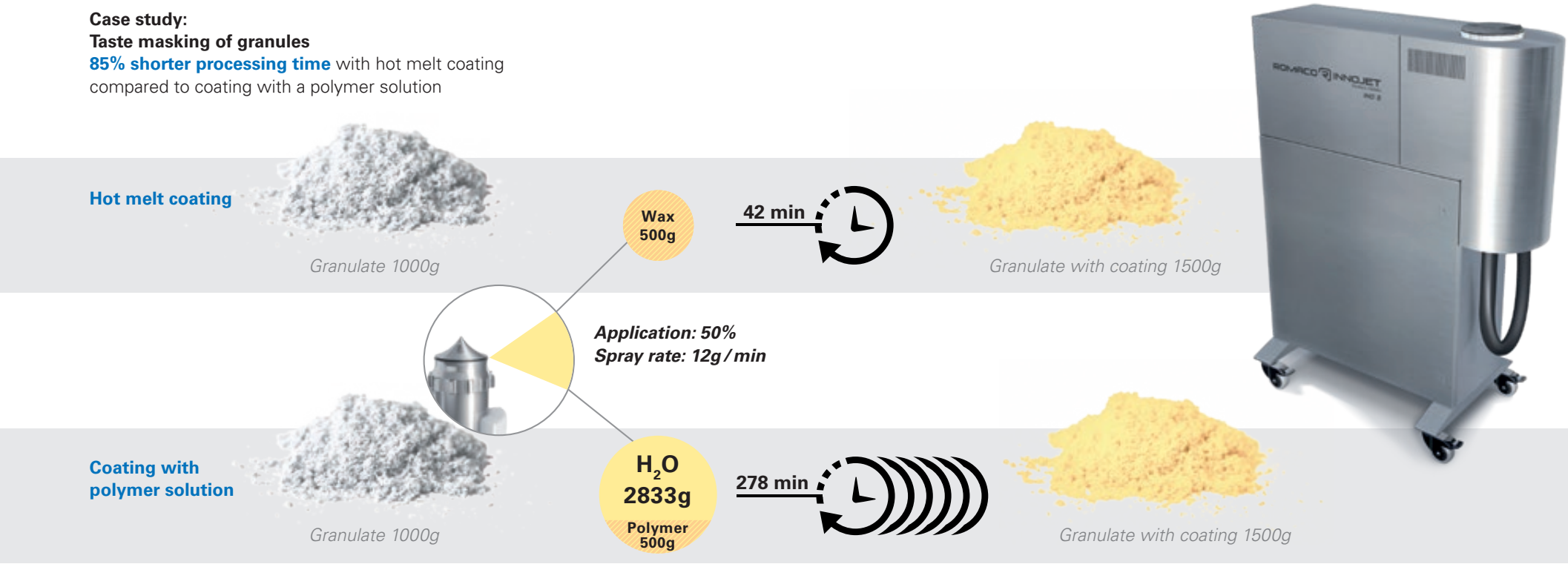
Easy-to-fit circular plates



Dynamic spraying gap with spraying air ducts

Simple fitting of the filter bags prior to the process

Case study:
Taste masking of granules
85% shorter processing time with hot melt coating compared to coating with a polymer solution



Exploiting Technologies

Technology Leader in the Hot Melt Sector

VENTILUS® systems are ideal for hot melt applications, in other words for granulation and coating with organic wax and hard fats.

- Particularly suited for moisture barriers and taste masks (e.g. for ready-to-use granules or in MUPS tablets)
- Process speeded up significantly because there is no evaporation
- Much better energy efficiency because there is no need to heat the process air

Romaco Innojet Hot Melt Device IHD 5

The Romaco Innojet Hot Melt Device impresses with its strictly GMP compliant design. Pulsation-free application of the melt is now a reality.

- Heating block with integral diaphragm valves guarantees a uniform temperature level
- Preheat function for the conveyor section to the spray nozzle
- Dosing piston with precision linear drive for optimal control of the dosing rate
- Heating block with CIP capable design and automatic cleaning function

Material Handling

VENTILUS® systems can be incorporated into any material transfer system. They are equipped with pneumatic filling and discharge as standard. However, gravimetric filling from silos or containers is also possible (all machine sizes), as is gravimetric discharge through a fold-out container bottom (size V 400 or larger).

- Discharge into standard drums or containers defined by the customer
- Material transfer from a high-shear mixer
- Easy integration of conical mills, product transfer systems, weighing stations and filling systems

Romaco Innojet TUBUS Monobloc

The Romaco Innojet TUBUS monobloc is used to treat the process air. The supply air technology is specially designed for use in the pharmaceutical industry.

- Integration of all available standard filter classes and filter elements
- Equipped with heating and cooling elements
- Cylindrical, double-walled, compact design
- Weatherproof and insulated for outdoor installation
- Hygienic design with no doors, covers, corners or edges
- Convenient access because the housing elements slide apart on rails

Romaco Innojet Control Systems

A modular and highly flexible control environment developed by Romaco Innojet can be supplied for VENTILUS® machines. This system provides precise process control and an advanced level of automation, meeting all the requirements of CFR 21 Part 11.

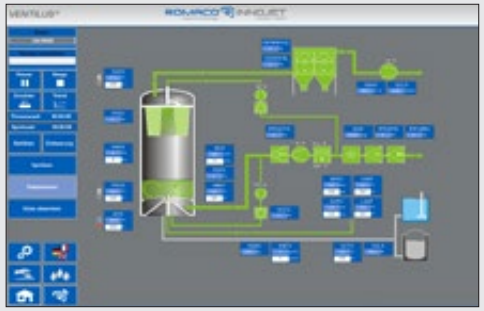
- Central control of formulations
- HMI panel with intuitive visualisation and navigation
- Client-server architecture: interconnection of production equipment
- Full documentation of all process data
- Automatic data back-ups
- Remote online support for users worldwide

Exploiting Technologies

Technical Accessories

Discharge into standard drums

TUBUS monobloc in operating (bottom) and maintenance mode (top)



Operation via a touch panel

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

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

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.

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

Maintenance
- Remote online support: prompt and reliable diagnostics using digital access
- Maintenance contracts: preventive maintenance reducing breakdowns to a minimum
- On-site service: local emergency support provided where necessary
- Quick inspection of patented parts on the Romaco Innojet premises

Consulting
- Telephone advice from experts on processing technologies, mechanical components and controls
- Technical support during scale-up tests and validations of new process parameters

Remote Service
- Telephone support for real-time assistance
- Expert hot-line connection for quick troubleshooting and problem solving
- Remote connection for online diagnostics and machine parameters control
- Call-4-service function for immediate assistance
- Smart-Glass allows our experts to be with you on the machine in real time

Training
- Individual training for the various HMI levels with certificate of attendance
- Qualified training and seminars for maintenance personnel with certificate of attendance
- Process training at the Romaco Innojet test laboratory

Retrofit, Expansion and Relocation
- Standard packages and customised solutions for machines in all series
- Customised adaptation of the educt and product flows, including planning and installation
- Individual adaptation of the system control
- Electronic and mechanical upgrades – depending on the specification
- Plant relocation planning and execution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