

MEDICAL

Machines for clean room production

world of innovation



WITTMANN BATTENFELD MEDICAL

For ultra-clean products

WITTMANN BATTENFELD injection molding machines are targeted to a minimal emission level as standard. Clamping units with lubrication-free tie-bars, encapsulated drive systems and an easy-to-clean mold space with smooth surfaces provide favorable conditions for contamination-free components production. For manufacturing in a controlled clean-room environment, these standards can be raised to meet the requirements for the clean room classes according to EN-ISO 14644 with specially adapted MEDICAL equipment upgrades.

These packages, based on many years of project partnership with renowned manufacturers of injection molded parts with highest standards of hygiene and freedom from foreign particles, are available for the *MicroPower*, *SmartPower* and *EcoPower* machine series. They are supplemented by a comprehensive range of matching WITTMANN robots and peripherals, with which the MEDICAL injection molding machines can be extended to form MEDICAL production cells.

It should also be noted that the MEDICAL machines meet all requirements for the production of microscopic to medium-sized electronic components or parts with complex surfaces under clean-room conditions.



Photo: Boehringer Ingelheim microParts GmbH



Meditechsys Co.



Photo: Greiner-BioOne



Photo: Micro Systems (UK) Ltd.



Photo: Greiner-BioOne

Always the right machine

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» **MicroPower MEDICAL**

All-electric injection molding machine in clamping force size of 15 t with shot volumes ranging from 1.2 to 6 cm³ (*)

The intended purpose is the production of micro parts with specified standards of cleanness. This includes medical components as well as parts for electronics, optical applications and fine tooling.

» **SmartPower MEDICAL**

Servo-hydraulic all-round injection molding machine in 18 clamping force sizes from 25 to 400 t with shot volumes ranging from 13.9 to 2128 cm³ (*)

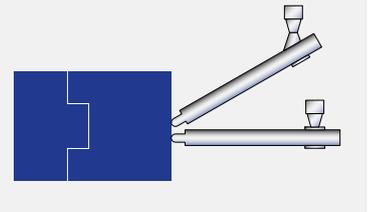
Multi-purpose machines for manufacturing small and medium-sized high-precision parts, especially expendable medical parts and devices, but also components of optical appliances or parts of housings with high-quality surfaces

» **EcoPower MEDICAL**

All-electric, high-precision injection molding machine in 11 clamping force sizes from 55 to 550 t with shot volumes ranging from 10.8 to 3012 cm³ (*)

Highly efficient machines for manufacturing ultra high-precision medical technology parts, such as pipette tips, implant or dialysis filter components and parts for electronic devices

(* calculated stroke volume)



COMBIMOULD

Multi-component machines can be obtained in all three series by combining at least two injection units.



SmartPower 25 – 400 t

MicroPower 15 t

EcoPower 55 – 550 t

MicroPower MEDICAL

Clean room micro injection molding

Facts and figures

- » Micro injection molding machine with all-in machine frame
- » For shot weights ranging from 0.05 to 4 g
- » Generous free mold space
- » Encapsulated 5-point toggle lever clamping system
- » Clamping unit in two sizes with 5 and 15 t clamping force
- » All movements directly electrical, powered by servo motors
- » Machine frame laid out for the integration of robots and quality inspection stations as standard
- » Available also as 2-component machine with a second injection unit and integrated rotary table

For technical details, see *MicroPower* brochure.



Photo: Micro Systems (UK) Ltd.



MicroPower MEDICAL

The system highlights

- » **Stand-alone clean room cell**
Through combination with an air filter and laminar flow unit, the machine frame cell of a *MicroPower* machine, which is closed on all sides, becomes a *MicroPower* clean room cell according to EN-ISO 14644 standard / class 9 to 7.
- » **Ample space for peripherals**
The closed cell of the *MicroPower* machines offers sufficient space for integrating optional equipment, such as a rotary table, robot, material dryer, temperature control technology and other product-specific options, and can thus be extended into an "all-in" production cell.
- » **Encapsulated drive system**
All modules of the all-electric drive systems are encapsulated with all their mechanical components in easy-to-clean housings.
- » **Finished parts depositing system (optional)**
The molded parts removed by a robot can be deposited separately according to cavities into containers inside the machine. The containers are combined with ionizers to neutralize static charges.
- » **Integrated quality inspection (optional)**
The clean room compartment inside the machine frame offers sufficient space for the integration of parts quality equipment for inspection and documentation within the controlled clean room environment.

SmartPower / EcoPower MEDICAL

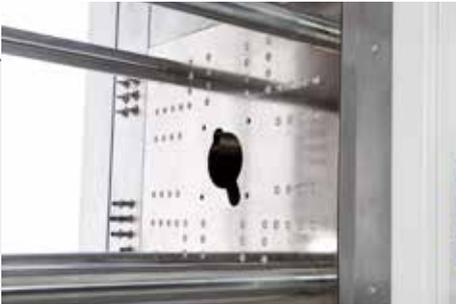
For high quality standards in medium-sized precision parts

Facts and figures

- » *SmartPower* and *EcoPower* are the medium-sized machine series from WITTMANN BATTENFELD, of which the former contains a hydraulic clamping unit combined with servo motor drive technology, and the latter combines all-electric drives with a 5-point toggle lever clamping unit.
- » The *SmartPower* machines are available in 18 clamping force sizes from 25 to 400 t clamping force and are a cost-efficient option for the production of clean parts in many areas thanks to their attractive price/performance ratio.
- » The *EcoPower* machines are available in 7 clamping force sizes ranging from 55 to 550 t and meet the highest standards in clean room production thanks to their ultimate precision combined with high speed (partly due to their facility for parallel operation of clamping and injection units) as well as low energy consumption.
- » Both series can be adapted perfectly to product-specific manufacturing requirements with the help of an extensive range of options.
- » The Kottlingbrunn plant is equipped with an in-house clean room facility for practical machine qualification and staff training.

Please see the *SmartPower* and *EcoPower* brochures for technical details.





SmartPower and EcoPower MEDICAL

The optional highlights

- » **Easy-to-clean mold space**
The mold platen drillings (EUROMAP) can be temporarily closed with plastic stoppers. The surroundings of the mold platens are lined with easy-to-clean stainless steel panels. If desired, the machine platens can be supplied with a reduced bore pattern.
- » **Controlled exhaust air disposal**
Undesirable disturbance variables in the clean room include the hot air and plastics vapor generated around the barrel during the injection process. Therefore the barrels on MEDICAL machines are covered by an encasement and equipped with a closed injection guard and detachable tray for the spray cake, as well as a suction flange. This enables both the hot air and the plastic vapors to be sucked off from a central point.
- » **Sliding laminar flow unit**
The air filter unit positioned above the mold space is mounted on linear guides. This allows it to be moved towards the clamping unit to provide an opening in the machine frame for mold change from the top.
- » **Total cleanness concept**
Additional stainless steel panels also cover the clearance spaces and components outside the mold space, thus providing an overall smooth, easy-to-clean machine environment.
- » **Safety through re-qualification at regular intervals**
Regular machine capability checks are carried out worldwide by expert engineers from WITTMANN BATTENFELD. All measuring devices used for recalibration comply with national measurement standards.

THE MOLD SPACE

A clean production center

A "clean" environment is not just a temporary issue for the moment of quality certification, but this state must be easy to maintain permanently. WITTMANN BATTENFELD offers the necessary detail solutions.

» Encapsulated media connections

All media connections are located at the rear of the machine next to the mold space. Fold-back covering panels form a housing to encapsulate the components for media supply and distribution.



» Lubrication-free tie-bar system

The moving platen of the machine travels on a carriage without coming into contact with the tie-bars. Within the clamping system, the tie-bars exclusively serve as force transmission elements without any guiding function. This keeps the mold space free of oil and grease.



» Encapsulated platen guides

Support and guiding of the moving platen is handled by two moving carriages sliding on linear bearings. The linear bearings on the machine frame are located outside the mold space. Telescopic covers prevent any potential contact between free falling molded parts and the linear guides.



MEDICAL MODULE SYSTEM

For clean room injection molding

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Since there is more than just "one" type of clean room production, a comprehensive range of equipment options and services is available for individual adaptation of the basic equipment to special needs.

» Equipment options according to EN-ISO 14644 classes 9 - 7

- Paint resistant to alcohol and disinfectants
- Nickel-plated clamping plates
- Drillings in the clamping plates with covers
- Easy-to-clean mold space
- Lubricants in H1 (NSF) quality
- Petek laminar flow module (LMP)
- Exhaust air suction device mounted on barrel
- Barrel insulation
- Enclosed water cooling system
- Good parts/rejects separation equipment
- Space-saving, encapsulated conveyor belt under the clamping unit
- Raised machine feet
- Machine qualification with manufacturer's calibration certificate



» Machine operation by remote control

The particle emissions of an injection molding machine can be effectively reduced by several different measures. This is more difficult where the "human" factor comes into play. Even with insulating protective clothing, humans remain one of the largest pollutants of clean room environments. To solve this problem, WITTMANN BATTENFELD offers a remote control function for the machine, which can be operated via a tablet computer. It is able to display every single page of the B8 control system without having to be close to the machine, which will reduce direct contact with the machine to a minimum.



» Qualification - the first step in process validation

An optimally validated production process starts with the machine manufacturer. WITTMANN BATTENFELD ensures this, for example, by the preparation of additional documentation in compliance with GMP/ISO-13485 standards.

- Master qualification plan
- Machine-specific qualification plan
- Risk analysis
- DQ (design qualification)
- IQ (installation qualification)
- OQ (operation qualification)
- QR (qualification report)
- FAT (factory acceptance test)
- SAT (site acceptance test)



WITTMANN 4.0

Communication in and with production cells

With its communication standard WITTMANN 4.0, the WITTMANN Group offers a uniform data transfer platform between injection molding machines and peripheral equipment from WITTMANN. For an appliance exchange, the correct operating software is loaded automatically via an update function according to the "plug & produce" principle.

Connection of peripherals via WITTMANN 4.0

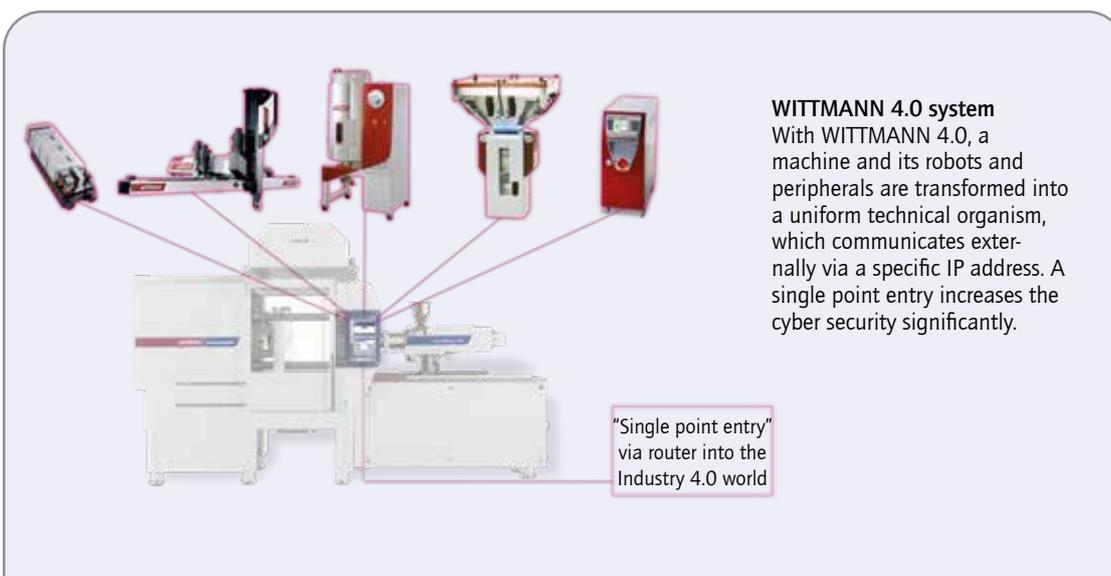
- » **WITTMANN FLOWCON plus water flow regulator, GRAVIMAX blenders and ATON dryers**
 - Units directly addressed and controlled via the machine's control system
 - Joint saving of data in the production cell, the machine and in the network via MES
- » **WITTMANN robots with R9 control system**
 - Operation of robots via the machine's monitor screen
 - High-speed communication between machine and robot to synchronize movements
 - Important machine movements can be set via the R9 robot control system
- » **WITTMANN TEMPRO plus D temperature controllers**
 - Setting and control of temperatures via the machine's control system possible
 - All functions can be operated either on the unit or via the machine's control system

Integration in MES system

The integration of machines and complete production cells in an MES system is a prerequisite for an efficient and transparent production facility according to the Industry 4.0 concept.

Depending on the customer's requirements, small and medium-sized companies are offered a compact MES solution based on TEMI+.

For large-scale and globally active companies, our cooperation partner is MPDV Microlab GmbH, a leading MES service provider. Due to the Windows® 10 IoT operating system, it is also possible to have selected status information from all connected machines on the production floor shown under *SmartMonitoring* on the display screen of every machine.



WITTMANN 4.0 system
With WITTMANN 4.0, a machine and its robots and peripherals are transformed into a uniform technical organism, which communicates externally via a specific IP address. A single point entry increases the cyber security significantly.

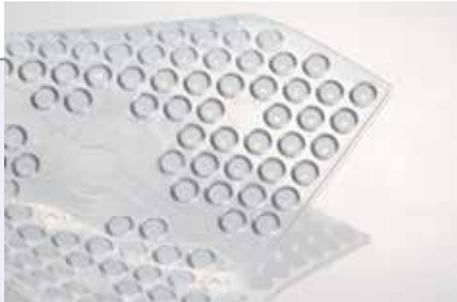
"Single point entry"
via router into the
Industry 4.0 world

APPLICATION TECHNOLOGY

Well above standard

Wittmann

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- » **LIM - Liquid Injection Molding**
LIM designates the injection molding process for making elastic parts from 2-component liquid silicone rubber (LSR). LIM micro parts are used for optical and medical applications and are mostly produced under clean room conditions.



- » **COMBIMOULD**
When two or more plastic materials in different colors or with different attributes must be combined into one part, the machines can be equipped with additional injection units.



Photo: Rohde & Schwarz

- » **High-precision micro parts**
In addition to standard plastics processing, the *MicroPower* injection unit is an ideal choice for manufacturing high-precision parts from engineering plastics such as POM, PEEK or PSU, without having to compromise on accuracy or production consistency.



Medtrachsys Co.

- » **Complex demolding**
Using core pulls to demold large undercuts is sometimes unavoidable even in clean room applications. However, this is easily done with the integrated, energy-efficient servo-hydraulic *EcoPower* and *SmartPower* aggregates.



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