

Mt

ALL ABOUT CLEANING

30 YEARS OF EXPERTISE IN CLEANING SOLUTIONS

IWT offers a complete range of cleaning solutions for the pharmaceutical, nutraceutical, cosmetic markets and related industries.

IWT specialises in the design, development, manufacture and installation of outstanding washing solutions. Our manufacturing base in Varese, just a few kilometers away from Milan Malpensa international airport, exceeds 12,000sqm (129,000sqft) of production areas, design studios, training and showroom facilities.

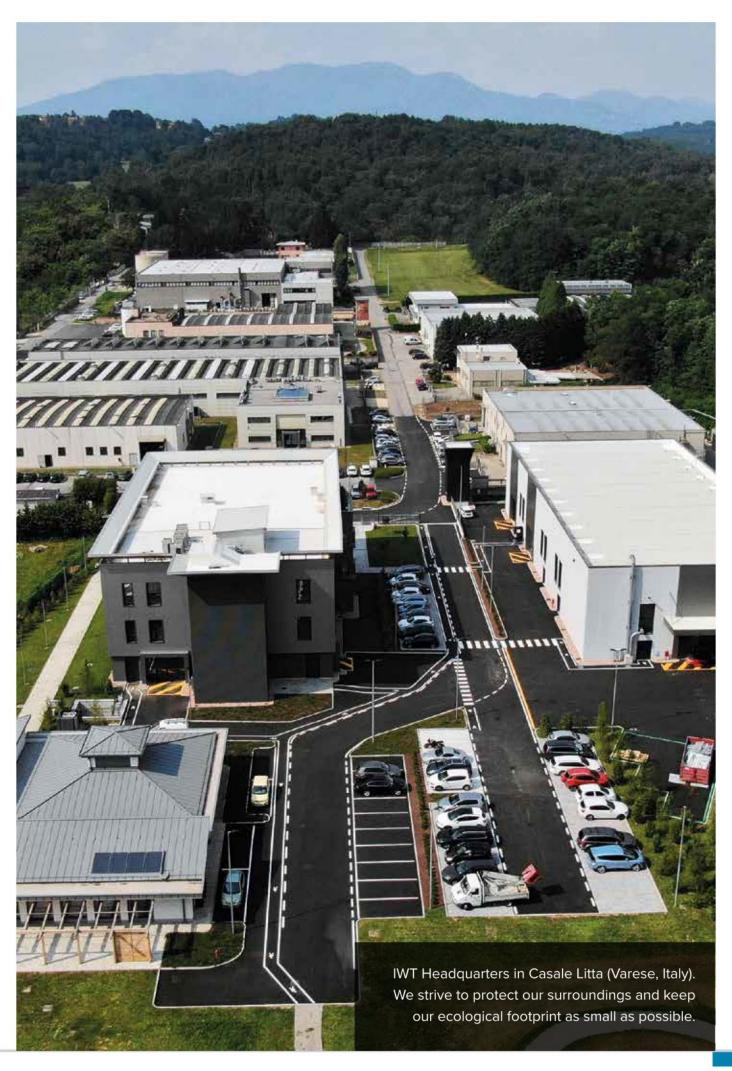
Our production departments are equipped with state-of-theart laser cutters, orbital welders and robots for processing pipes and tubular parts. The warehouse, fully automated

in alignment with the most stringent cGMP traceability requirements, features full overview and management of products and materials. IWT offers in-house advanced 3D design technology and software programming capabilities to ensure complete fulfillment, in terms of quality and flexibility, of any user requirements specifications.

Our comprehensive range of cleaning solutions include FULL cGMP product contact part washers, as well as high pressure washing systems either for bulk containers in cleaning-in-place applications or cabins for bulk parts and containers cleaning-out-of-place.

Our expertise in cold decontamination methods from material transfer through physical barriers mean the decon chambers and airlock systems complement our product range by ensuring complete compliance with cleanroom standards.

You are always welcome to visit our facilities, to feel IWT passion and commitment, to learn first-hand the quality and efficiency in our daily operations.



CONTACT PART

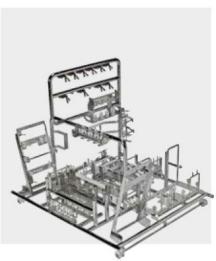
WASHERS

IWT cGMP Part Washers portfolio is engineered to perfectly clean pharmaceutical contact part products. The design is meant to minimize downtime of product lines, to eliminate any possibile cross-contamination between batches and to exceed the most stringent criteria as stated in the cleaning validation protocols.

A comprehensive set of baskets and racks, standardized or tailored made, are supporting the cleaning process to guarantee items are repeatably positioned for perfect surface coverage and complete drainability. Logistic trolleys, inclusive of lifting devices for egonomic handling, and storage racks are complementing the solutions to facilitate flows and minimize operational footprint requirements.







200 EVO

cGMP compact Part Washer

300

cGMP flexible Part Washer

RACKS & BASKETS

Standardized and tailored loading accessories



200 EVO

cGMP compact Part Washer

GAMP5	/
cGMP	/
ASME-BPE	/
ISPE baseline	/
FDA (including 21CFR part11)	✓
CE Marking	/
UL Listing	/

- ► Engineered to clean product contact parts from solid, semi-solid, liquid and aseptic manufacturing sites, from tableting machines to sterile filling lines
- ► Modular design in compliance with the industry standards to allow quick turnaround projects
- ▶ Compact solution to simplify installations in existing productions minimizing any impact on current operational flows
- ► Multiple configurations available such as electrical or steam heating, single or double door
- ➤ Three different sizes: 600, 1000, 1400 liters (160, 265, 370 gal) to maximize and optimize cleaning batches



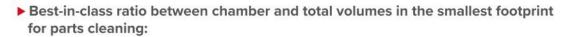


- ▶ Up to 30 fully customizable washing programs from pre-washing to drying and cooling
- ▶ PanelPC configuration for remote connectivity and INDUSTRY 4.0 integration for programs and batch data retrieval, audit trail and log files safe storage on the customer's network
- ➤ Cutting edge automation system GAMP5 compliant with ERES (21CFR Part11) and AUDIT TRAIL functions to guarantee full data traceability and storage



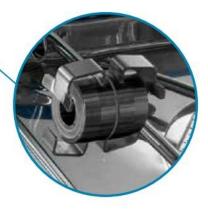


- Variable hydrodynamic control, high washing pressure and water flow tuned around every load need
- ▶ Product contact parts (chamber and piping) entirely made of AISI316L (1.4404), Ra \leq 0.51 μ m ASME-BPE compliant



200 EVO MODEL	060	100	140
Chamber Nominal Volume [m³ – ft³]	> 0.6 - 21.2	> 1.00 – 35.3	> 1.4 – 49.4
Footprint [m ² – ft ²]	~ 1.2 – 12.9	~ 1.8 – 19.4	~ 2.5 – 26.9
Unit height [mm - ft]	2500 - 8.2		
Unit total volume [m³ – ft³]	3 – 105.8	4.5 – 159.1	6.3 – 220.6
Ratio	20%	22%	22%

- ► HEPA filtered drying system featuring side channel compressor under inverter management for fast drying of parts, chamber and piping
- ► Multiple water inlet and chemical dosing systems with flow meter and conductivity control
- ➤ Single Pass Rinse feature via sterile compressed air booster with final conductivity control



- ➤ Full in-house design and manufacturing of customized racks connected via automatic quick-lock patented system
- ➤ Comprehensive set of handling solutions for manoeuvring, stocking and loading/unloading of custom racks, inclusive of height-adjustable trolleys to enhance operator's ergonomics

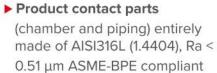
300

cGMP flexible Part Washer

GAMP5	/
cGMP	✓
ASME-BPE	/
ISPE baseline	/
FDA (including 21CFR part11)	✓
CE marking	/

- ► Engineered to clean product contact parts from solid, semi-solid, liquid and aseptic manufacturing sites, from tableting machines to sterile filling lines
- ▶ Modular design in compliance with the industry standards (cGMP – FDA – ASME-BPE – ISPE etc.) to allow quick turnaround projects
- ► Three different sizes: 400, 800, 1400 liters (160, 265, 370 gal) to maximize and optimize cleaning batches

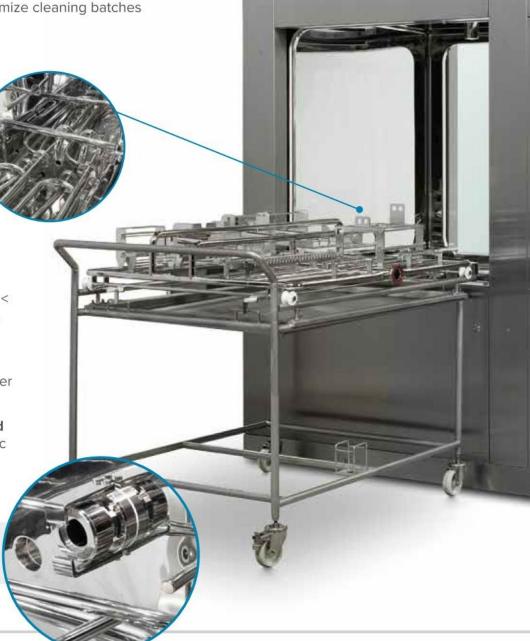




 Horizontally sliding doors design for easy operator access to the washing chamber

➤ Full in-house design and manufacturing of customized racks connected via automatic quick-lock system

► Quick-lock connection for customised rack



300 MODEL	025	050	100
Chamber Nominal Volume [m³ - ft³]	> 0.4 - 14.1	> 0.8 - 28.3	> 1.4 - 49.4
Footprint [m ² - ft ²]	~ 2 –21.5	~ 3 - 32.3	~ 4 - 43.1
Unit height [mm - ft]	2200 - 7.2	2400 - 7.9	
Unit total volume [m³ - ft³]	4.4 – 155.4	7.2 – 254.3	9.6 – 339
Ratio	9%	11%	14.5%

► Compatible with double bio-seal installations thanks to a full components accessibility for sampling, calibration and maintenance activities from side technical area



▶ PanelPC configuration for remote connectivity and INDUSTRY 4.0 integration for programs and batch data retrieval, audit trail and log files safe storage on the customer's network and SCADA system

- ► HEPA filtered drying unit for efficient drying of parts, chamber and piping
- Multiple water inlet and chemical dosing systems with flow meter and conductivity control
- ► Single Pass Rinse feature with final conductivity control and TOC monitoring
- Cutting edge automation system GAMP5 compliant with ERES (21CFR Part11) and AUDIT TRAIL functions to guarantee full data traceability and storage
- ► Comprehensive set of handling solutions for manoeuvring, stocking and loading/



► Constant monitoring of critical process parameters

RACKS & BASKETS

Standardized and tailored loading accessories



Ensuring an effective clean of a wide range of machine parts and miscellaneous items is essential to prevent the cross-contamination between production batches.

From drums to hoses, glasswares to plasticwares, filling needles to punch and dies - all components are meticulously studied to design and engineer the associated baskets and racks with the aim to achieve the optimal exposure and to optimize the load per cycle.

The drivers in developing our solutions, regardless of standardized or tailored ones, are:

- ▶ Easy and quick filling: intuitive 1-to-1 repeatable positioning of every critical item
- ▶ Full coverage and drainability
- ▶ Precise flushing of the smallest and hidden areas
- ▶ Perfect drying results of racks and related load

A comprehensive portfolio of accessories complete the logistics solutions thought to improve ergonomics in handling racks and parts minimizing the operational footprint requirements.

Transport trolleys, inclusive of lifting systems, enhances accessibility for operator's ease of loading/unloading as well as warehouse systems for efficient baskets storaging.

SOME OF THE APPLICATIONS:



Sterile filling needles



Hoses



QC glasswares/plasticwares



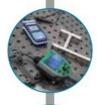
3D SCANNING for custom parts and MEASUREMENTS CHECKS for standardized components

3D PARTS MODELING AND POSITIONING, **BATCH OPTIMIZATION STUDIES** AND FLUIDODYNAMIC COVERAGE SIMULATIONS





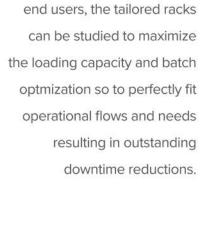
SHOP-DRAWINGS ELABORATION AND RELATED MANUFACTURING STEPS inclusive of mandatory traceability and quality controls



RACK INTERNAL COMMISSIONING AND CUSTOMER'S APPROVAL AT FAT



ON-SITE CLEANING VALIDATION with actual final load



Via a tight collaboration with



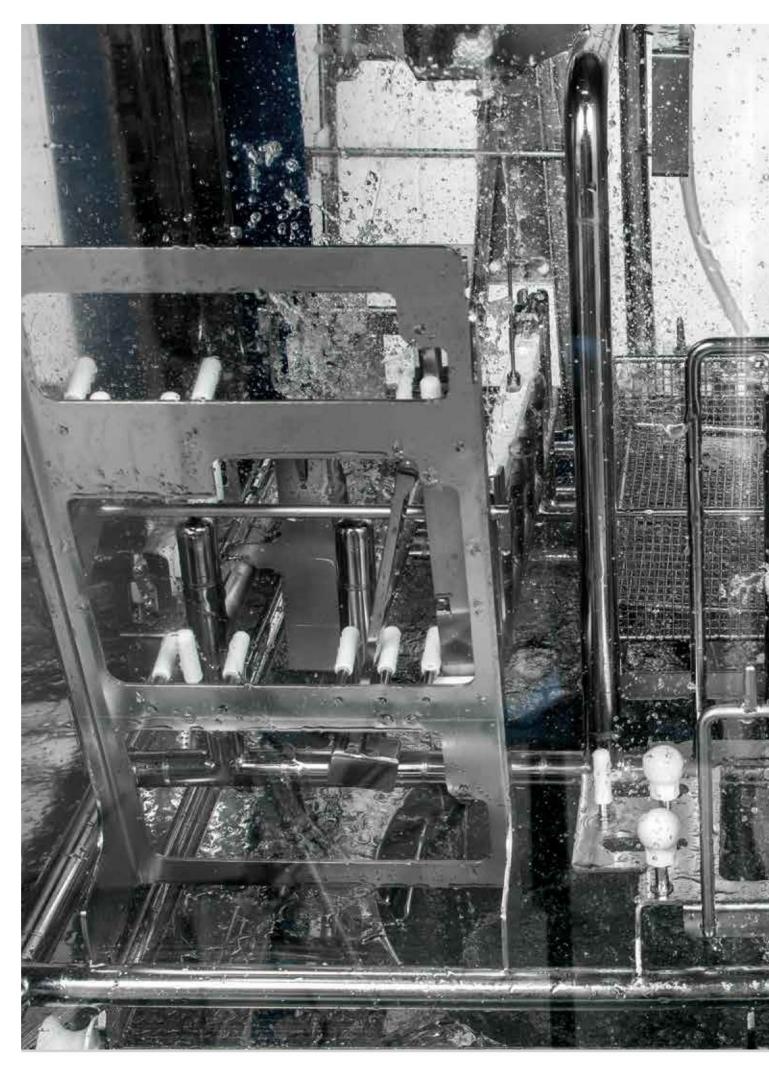
Tableting machine

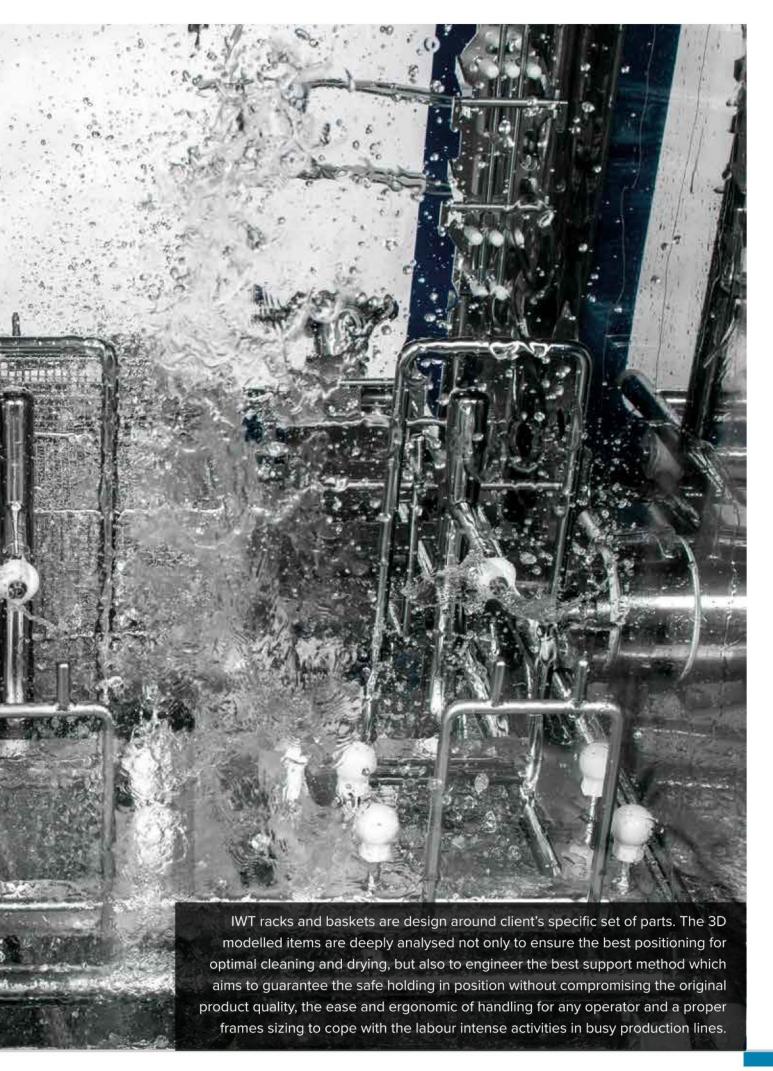


Punch & Die sets



Drums





WE OPERATE LOCALLY. WORLDWIDE.





IWT Headquarters and production site



Group Subsidiaries and commercial offices



Dealers/Agents

Being a global company, as part of the Tecniplast Group, means we are well aware of the challenges the world is facing.

Our worldwide network of Subsidiaries, Dealers and Agents allows us to understand different cultures, languages and needs, thus perfectly responding to regional expectations.



DESIGNING RESULTS



COMPANY WITH QUALITY SYSTEM CERTIFIED BY DNV GL

HEADQUARTERS IWT s.r.l. | Tel. +39 0332.96701 www.iwtpharma.com • E-mail: info@iwtpharma.com CONTACT US TO FIND YOUR LOCAL DISTRIBUTOR