

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.



CONTACT PART

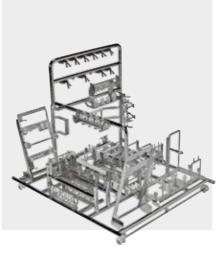
WASHERS

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

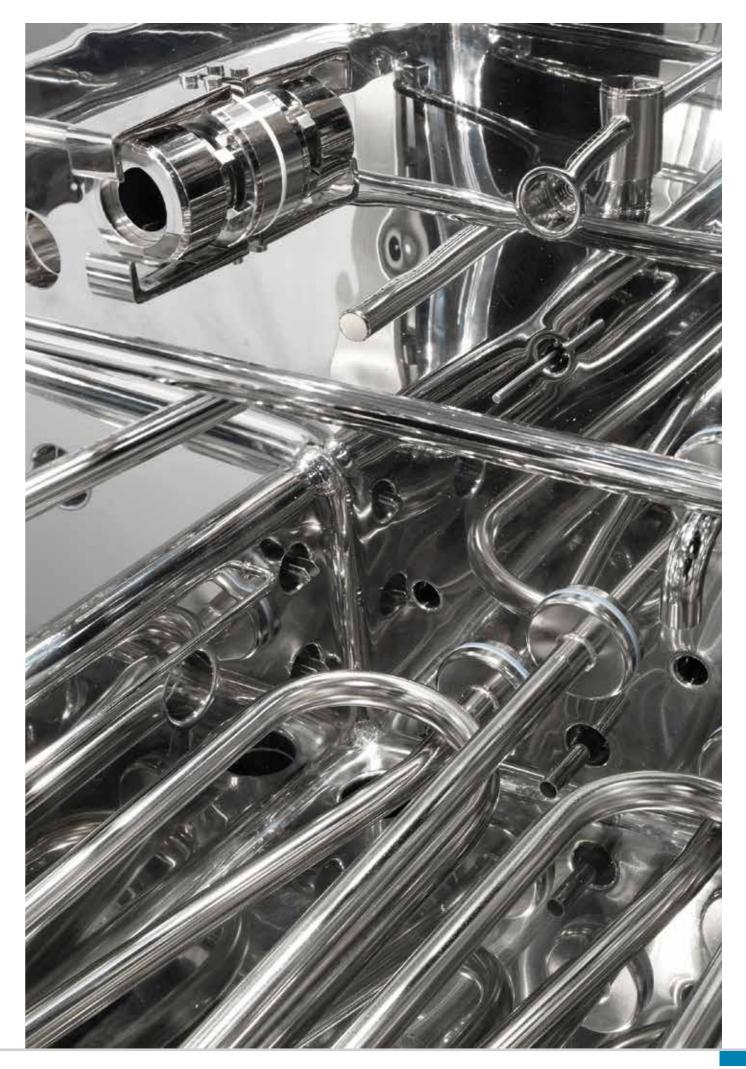
cGMP compact Part Washer

300

cGMP flexible Part Washer

RACKS & BASKETS

Standardized and tailored loading accessories



200 EVO

cGMP compact Part Washer

Engineered to clean product contact parts
from solid, semi-solid, liquid and aseptic
manufacturing sites, from tableting machines to
sterile filling lines

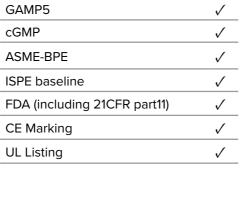
- ▶ Modular design in compliance with the industry standards to allow quick turnaround projects
- ▶ Compact solution to simplify installations in existing productions minimizing any impact on current operational flows
- ▶ Multiple configurations available such as electrical or steam heating, single or double door
- ▶ Three different sizes: 600, 1000, 1400 liters (160, 265, 370 gal) to maximize and optimize cleaning batches





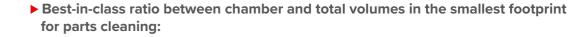
- ▶ Up to 30 fully customizable washing programs from pre-washing to drying and cooling
- ▶ PanelPC configuration for remote connectivity and INDUSTRY 4.0 integration for programs and batch data retrieval, audit trail and log files safe storage on the customer's network
- ► Cutting edge automation system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

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



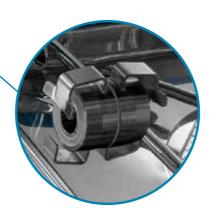


- ▶ Variable hydrodynamic control, high washing pressure and water flow tuned around every load
- ► Product contact parts (chamber and piping) entirely made of AISI316L (1.4404), Ra \leq 0.51 μm ASME-BPE compliant



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	✓

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

- ► 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



- ► Product contact parts (chamber and piping) entirely made of AISI316L (1.4404), Ra < 0.51 µm ASME-BPE compliant
- ► 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



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

DESIGNED AROUND CUSTOMER'S LOAD TO GRANT PERFECT CLEANING RESULTS

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.

Via a tight collaboration with end users, the tailored racks can be studied to maximize the loading capacity and batch optmization so to perfectly fit operational flows and needs resulting in outstanding downtime reductions.



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



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



CUSTOMER'S APPROVAL of the detailed proposal design



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

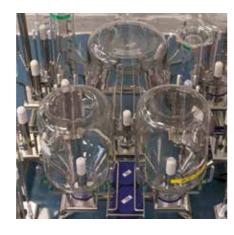
SOME OF THE APPLICATIONS:



Sterile filling needles



Hoses



QC glasswares/plasticwares



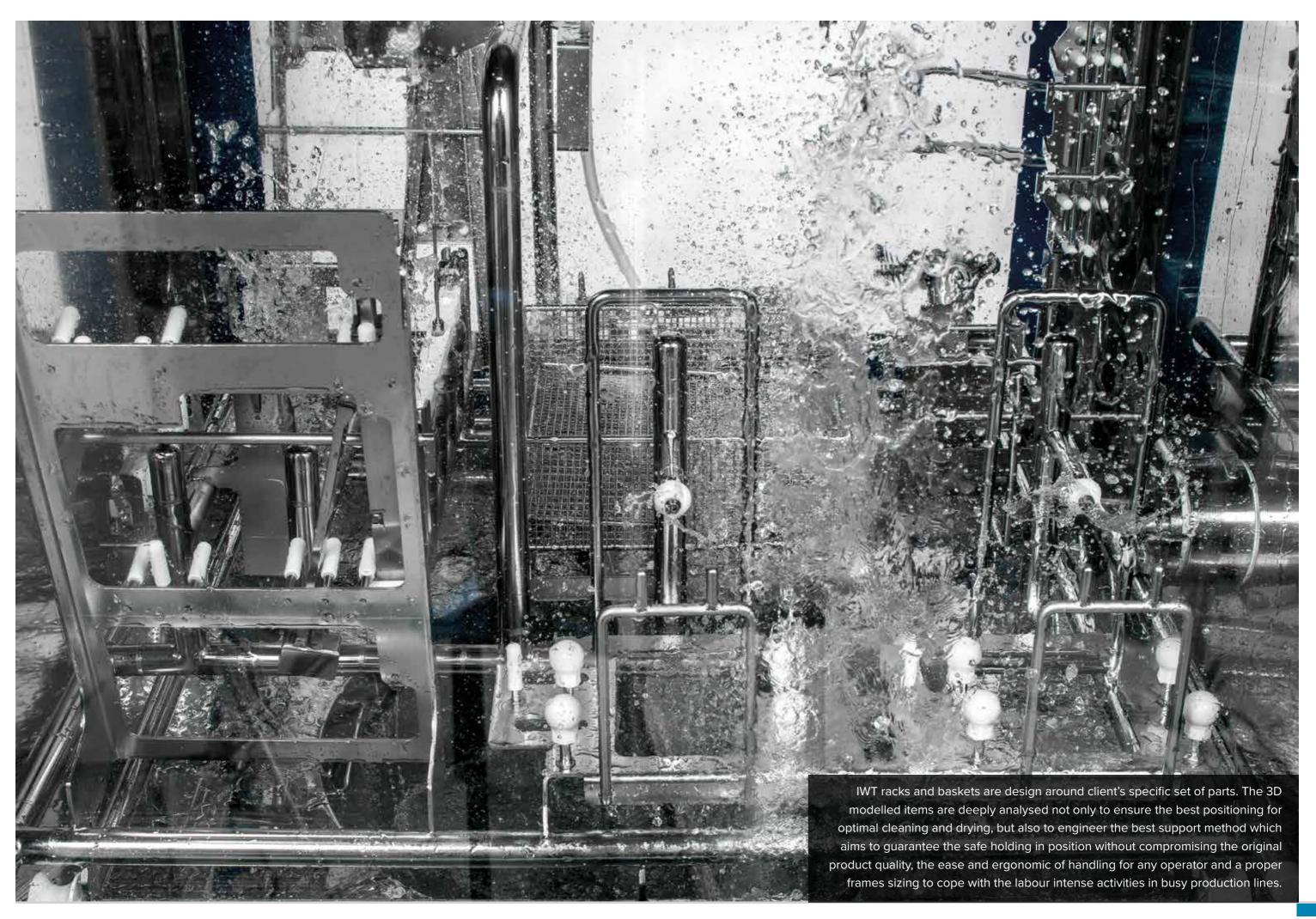
Tableting machine



Punch & Die sets



Drums

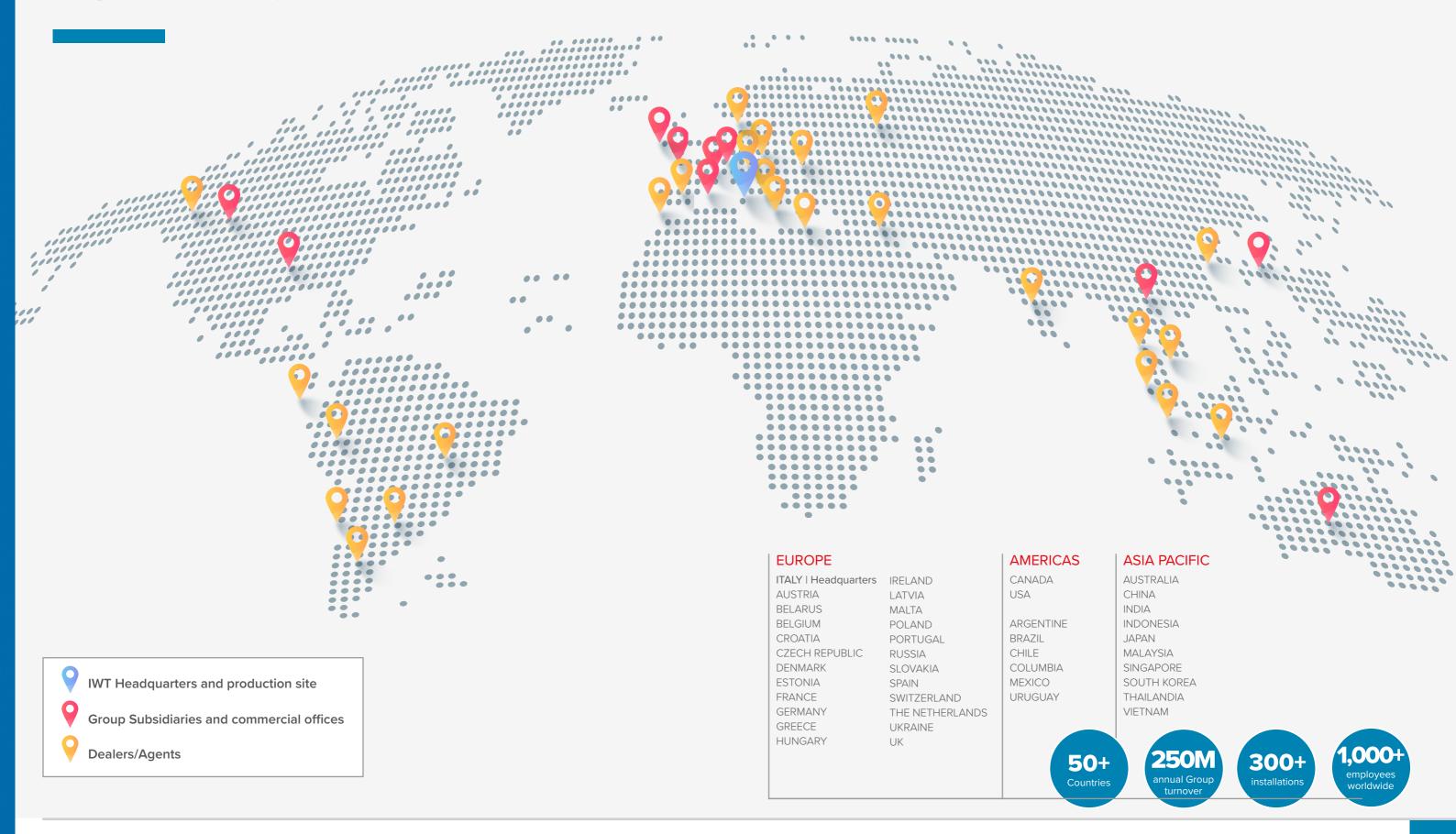


WE OPERATE LOCALLY.

WORLDWIDE.

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

contact: pharma@tecniplast.com.au