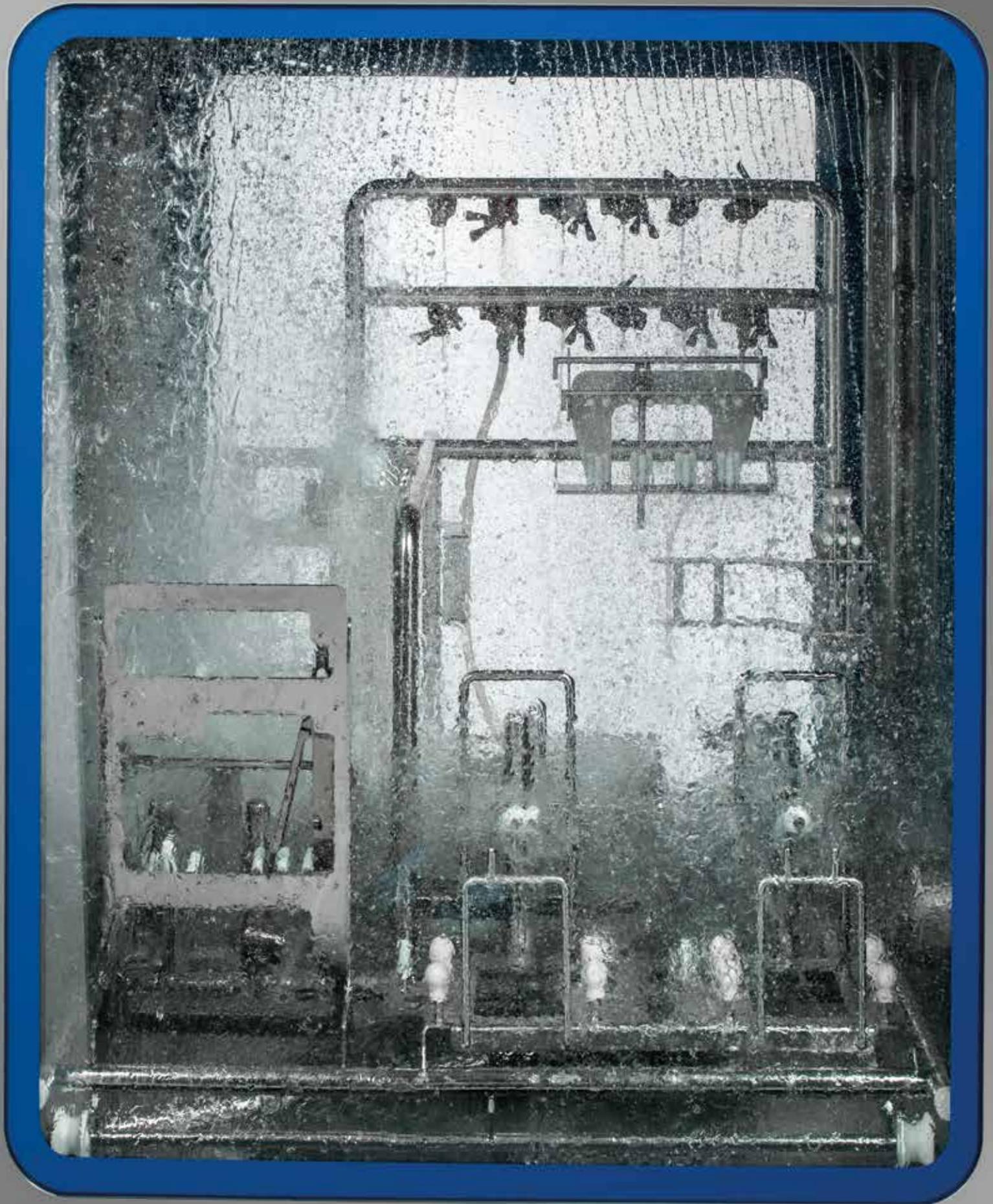




WASHING
SOLUTIONS



 CLEANING





EXPLORE IWT'S COMPLETE RANGE OF WASHING SOLUTIONS FOR THE PHARMACEUTICAL, NUTRACEUTICAL, COSMETIC MARKETS AND RELATED INDUSTRIES

SINCE IT WAS FOUNDED IN 1991, IWT HAS BEEN A PIONEER IN THE DESIGN, DEVELOPMENT AND INDUSTRIALIZATION OF INDUSTRY STANDARD AUTOMATED WASHING EQUIPMENT. OUR ENGINEERING EMBRACES ADVANCED TECHNIQUES ENCOMPASSING:

- FULLY VALIDATED PROCESSES INCLUSIVE OF CRITICAL PARAMETERS MONITORING AND TRACKING
- COMPLETE PREVENTION OF CROSS CONTAMINATION
- IMPROVED OPERATORS' SAFETY
- HIGH THROUGHPUT RESULTING IN MINIMAL PRODUCTION DOWNTIME.

IWT SOLUTIONS INCLUDE FULL cGMP PRODUCTS 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 EXPERIENCE IN CLEANING, COMBINED WITH PROVEN SPECIFIC SKILLS AND KNOW-HOW, ARE AT YOUR DISPOSAL TO DEFINE TOGETHER THE MOST SUITABLE AND EFFICIENT SOLUTIONS INCLUSIVE OF RELATED SERVICES (CALIBRATION, QUALIFICATION AND VALIDATION) TO MEET YOUR SPECIFIC NEEDS.

INDEX

4 OUR CAPABILITIES

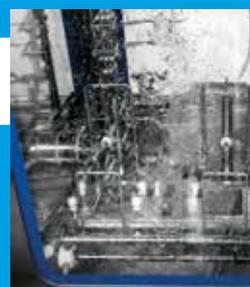


9 HIGH PRESSURE WASHERS

- 12 • M-LINE
- 14 • C-LINE
- 15 • S-LINE

CONTACT PART WASHERS 17

- 20 • 200
- 20 • 300
- 22 • BASKETS



25 CABINET WASHERS

- 26 • 650C
- 26 • 900C



OUR CAPABILITIES: COMPLIANCE, VALIDATION, ENGINEERING & SERVICE

Cleaning procedures have become more and more important in the pharmaceutical manufacturing environments and they have been recognized as critical steps in the improvement of the final product quality.

IWT's daily mission is to deliver the finest equipment in one of the highest regulated environment's existing. Our absolute focus is to achieve regulatory compliance, to accomplish the validation of both systems and processes, to install quality in every engineering phases and to exceed any safety standards.

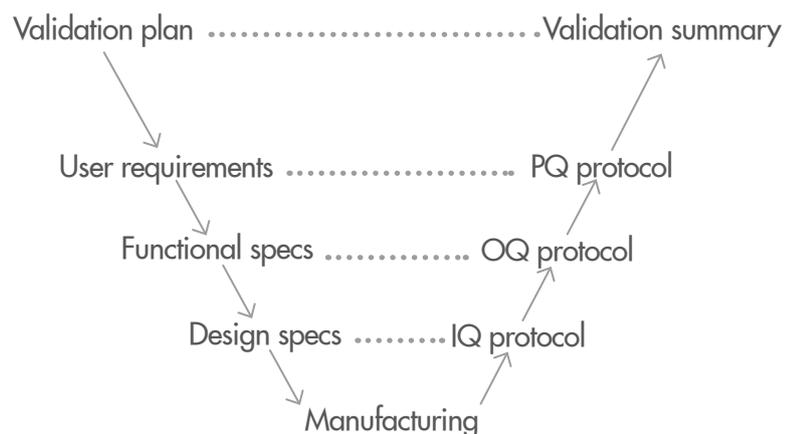


IWT cleaning systems are developed following worldwide standards and guidelines:

- ISO9001
- EU GMP (Annex 11 and 15 above all)
- FDA 21CFR part 11 for software and part 210-211 (GMP)
- ASME – BPE
- GAMP5
- ISPE Baseline
- Ph.Eur and USP

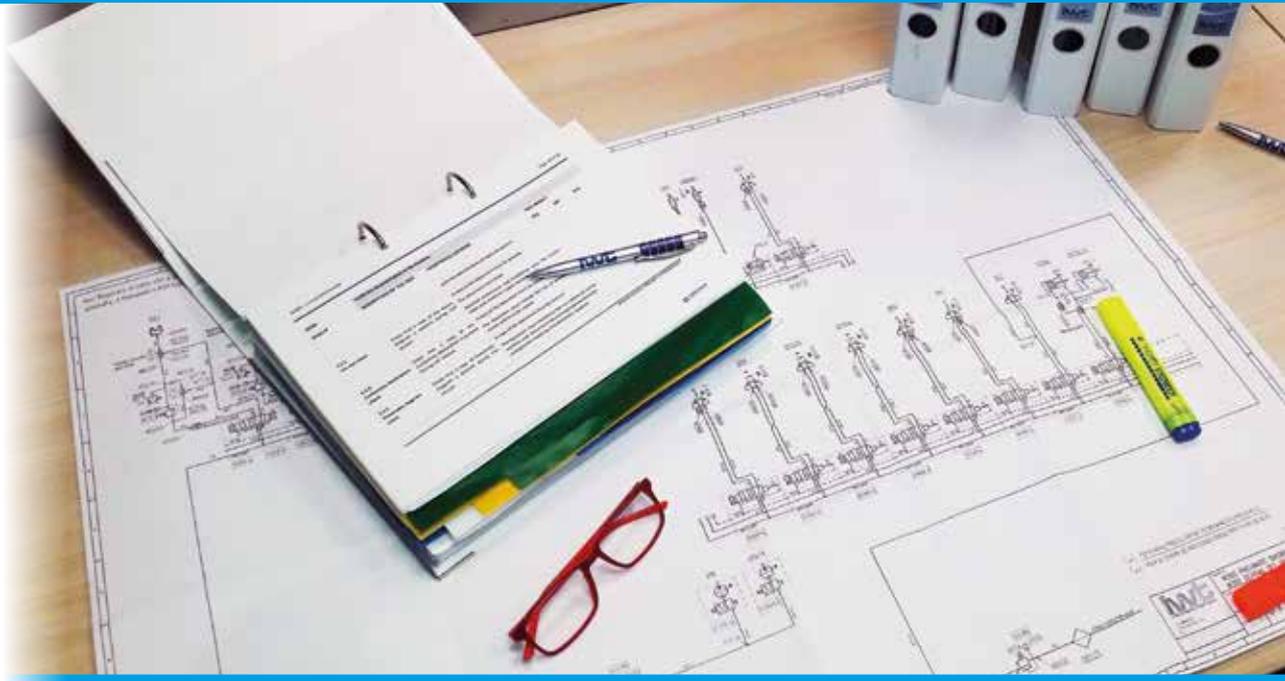
IWT products meet the EU requirements (CE marking) as well as UL/CSA standards.

VALIDATION APPROACH (GAMP 5)



COMPLIANCE

VALIDATION



The final goal of any validation is to assure the equipment under testing is not only suitable for the intended purposes but that it is also built according to the user's requirement specifications - meeting, if not exceeding, guidelines and industry standards.

At IWT we strongly believe that communication with our clients is the key for a successful partnership. Several protocols and documents are shared upfront in order to set clear and definitive project targets, which will constitute the bases for designing and manufacturing phases as well as benchmarks for all the commissioning activities.

Our comprehensive documentation includes:

- QPP Quality project plan
- FDS – HDS – SDS normally provided and commonly agreed
- FAT, SAT IQ/OQ and OQ Alarms
- WPS-WPQR certifications
- RX analysis of the welding
- Calibration SOPs and certificates
- Materials and components traceability matrix
- Change control system whenever required

Once the on-site handover is accomplished, our team of highly skilled technicians will always be available to support any PQ and/or cleaning validation activities you might require as part of your specific quality insurance protocols.

Validation and calibration:
IWT always there for you!

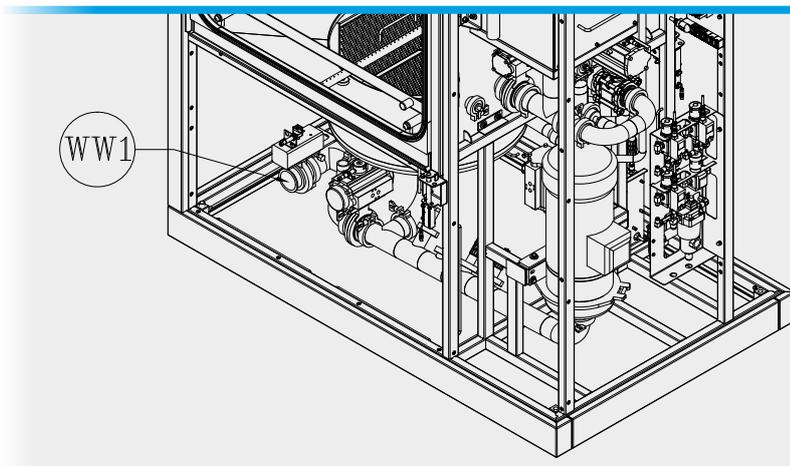
ENGINEERING

The design of the washing equipment and relevant accessories has an enormous impact on time, efficiency and throughput of the cleaning processes. Proper engineering also influences how easily and ergonomically material can be circulated from production lines and washing areas or for CIP applications how quick and effective the in-place setup will be. In order to minimize the downtime between your production batches, IWT always applies a risk based approach in the evaluation of your needs, layouts and working procedures with the aim to release quality products with a perfect blend of performance, timing and cost.

Years of experience and multiple complex projects managed for multinational companies result in a solid knowledge and understanding of the cleaning dynamics. These are the cornerstones of IWT expertise to deliver different level of custom solutions to match your unique application to process:

- Product contact parts
- Format parts
- Tanks, drums and bins
- Glassware
- Trays
- ...and many more

All units manufactured feature premium quality components selected from top brands and long term durability.



Mechanical design according to the industry standards and guidelines is then complemented by a user friendly control system that is GAMP5 and 21 CFR Part 11 compliant and by a PLC code based on a Siemens platform. All the software is developed in house by our team of dedicated engineers to guarantee the full responsibility on analysis and validation of the code itself, this combined with a complete code handover to clients are meant to speed-up and simplify both maintenance and troubleshooting activities.

The human machine interface (HMI) provides a simple gateway for users to build the most suitable cleaning cycle according to the different loads.

Different user access levels (4 available as standard) grant full protection of the systems against unauthorized logins. An embedded Ethernet connectivity allows integration of the washers with SCADA systems to manage (for example) electronic transfer of the batch reports, setting and troubleshooting from a remote location, as well as date and time synchronization with the company network.



SERVICE

All IWT systems are designed with safety in mind for both operator and process. A full risk analysis and consequent HAZOP is part of the early engineering phases to provide equipment capable to deliver safe, repeatable and reliable cleaning results.



SENSORS CALIBRATION

Calibrated probes, sensors and specific controls are embedded to guarantee a real time monitoring of critical parameters and accurate process diagnostics.

A safe process ensures not only a clean load exceeding the QA acceptance criteria but also prevents any possible cross contamination between product batches and any microbial growth during inoperative phases. To do so all the washing machines are designed for full drainability and cleanability of chamber, pumps and piping.

The bio-seal separation and door interlocking system which allows the unload door to be open only when the cycle is duly accomplished, permits a perfect separation between loading and unloading areas when different levels of classification are necessary.



HIGH PRESSURE WASHERS



M-LINE

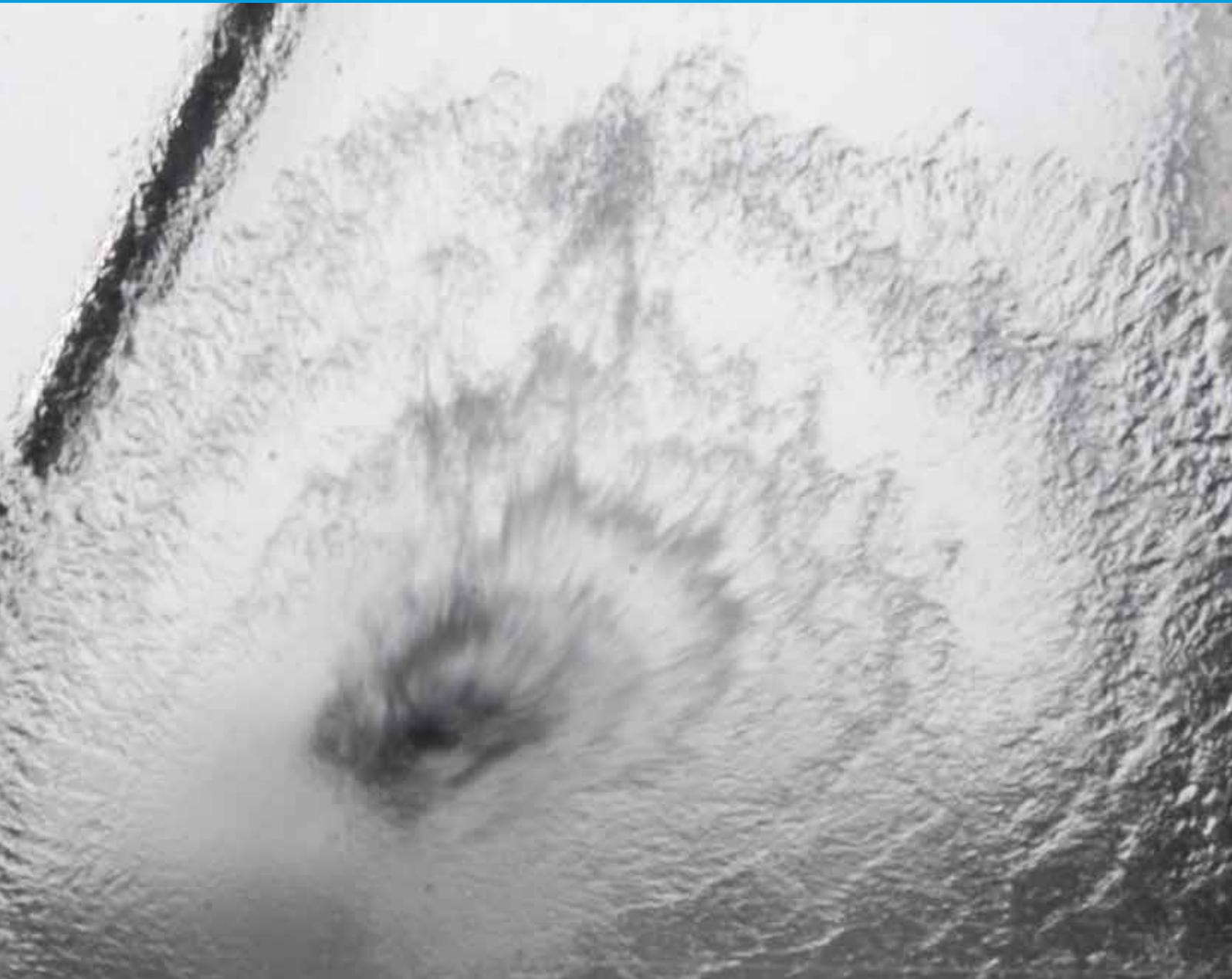


C-LINE



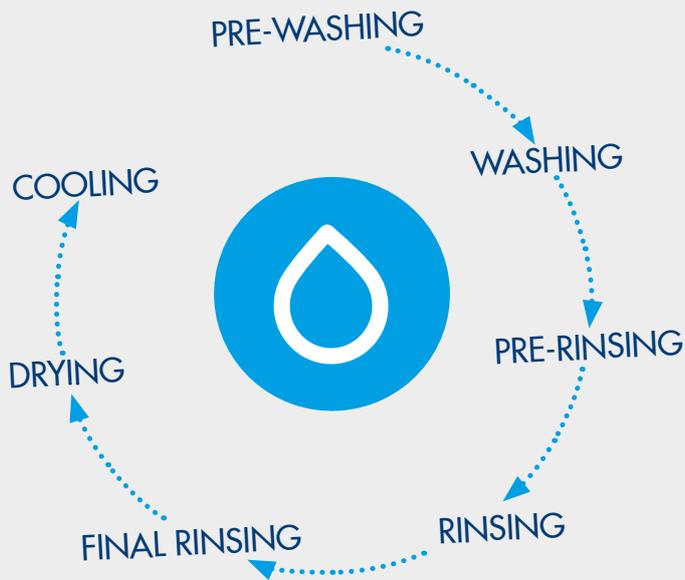
S-LINE

FOR BINS, TANKS, BULK CONTAINERS
AND PROCESSING EQUIPMENT.
IWT HIGH PRESSURE SYSTEMS
PROVIDE TOP CLEANING
PERFORMANCE THANKS TO THE
EXTRAORDINARY MECHANICAL
ACTION OF HIGH PRESSURE
(70 BAR/1015 PSI) COMBINED WITH A
LOW WATER FLOW RATE OF 40 L/MIN
(9 GAL/MIN) FOR REDUCED WATER
CONSUMPTION.



- Once-through working principle: loads are processed with fresh water without recirculation, a guarantee against risk of any cross contaminations
- Units are managed by a PLC with software compliant with GAMP5 guidelines. The operators, through an user-friendly interface, can select among 30 different customizable washing programs
- High pressure cleaning equipment can be coupled to different accessories such as cleaning heads and high efficiency hydrokinetic lances for a 360° coverage
- At the end of each cleaning cycle, the piping is dried using micro-filtered compressed air to eliminate water residues and prevent microbiological contamination growth





Create the cleaning process that better suits your needs!

PICK YOUR CYCLE PHASES AND PROGRAM FOR EACH OF THEM:

- WATER TYPE
- TEMPERATURE
- DETERGENT, IF REQUIRED
- CONDUCTIVITY
- DRAIN OUTPUT

HIGH PRESSURE SYSTEMS MAIN FEATURES

- High-pressure pump with SS AISI316L (1.4404) head and a flow rate of 40 l/min (9 gal/min) at 70 bar (1015 PSI)
- Critical process parameters constantly monitored
- Siemens PLC controller and multicolor HMI touch screen
- Data transfer of batch report in electronic format via USB port and/or integrated printer



C-LINE OVERVIEW AND TOUCH SCREEN CONTROL PANEL



High Pressure Cleaning - a proven solution to reduce utilities and labour

When an automatic High Pressure cleaning system is used, a significant reduction can be achieved in terms of water and detergent consumption, and in man power requirements. The major time savings can be identified in the washing cycle time itself, but also in the mandatory process quality checks.

STAINLESS STEEL BIN (1500 LITERS/396 GAL)
WITH RESIDUAL OF POWDER
STRONGLY STUCK ON THE SURFACES*

	Manual Cleaning	Automatic M-Line Cleaning
Cycle Time (drying excluded)	15 minutes	90 seconds
PW consumption	140 liters/37 gal	63 liters (no detergents)/16.5 gal
CQ samples	After each cycle	Monthly based

STAINLESS STEEL BLENDER (6000 LITERS/1585 GAL)
WITH RESIDUAL OF POWDER
STRONGLY STUCK ON THE SURFACES*

	Manual Cleaning	Automatic M-Line Cleaning
Cycle Time (drying excluded)	4 hours	7 minutes
PW consumption	2000 liters/525 gal	300 liters/79 gal
CQ samples	After each cycle	Monthly based

* The data in the tables must be considered as general indications.





360° orbital spray patterns for complete coverage

M-LINE

High Pressure Mobile solution

Built in compliance with the main regulatory guidelines, the M-line can be easily moved and connected to various washing stations.

The machine can be coupled to a wide range of cleaning heads and to hydrokinetic lances to obtain a 360° coverage of all the surfaces in a 1.5 m (60 in) radius. Containers can be installed with the washing heads through dedicated/custom fittings.

M-Line additional features

- Wheel mounted ABS crash-proof covers
- Quick lock connections for hydrokinetic lances.....
- Different water quality inlets
- Detergent dosing stations available
- On-board electrical cabinet
- Final rinse water conductivity control





C-LINE

High Pressure IBC washing solution

The C-line has been engineered in compliance with the main regulatory guidelines, with the aim to erase any variability of cleaning processes involving containers of different sizes and shapes.

The operator positions the load in the cabin and once the cycle starts a movable head enters the container itself from the top granting a direct and perfect coverage of areas in contact with the product.

The hydrokinetic head on chamber floor, together with four oscillating arms, completes the cleaning of external surfaces and bottom valve. If needed, a drying unit concludes the cycle exposing the load to hot HEPA filtered air.



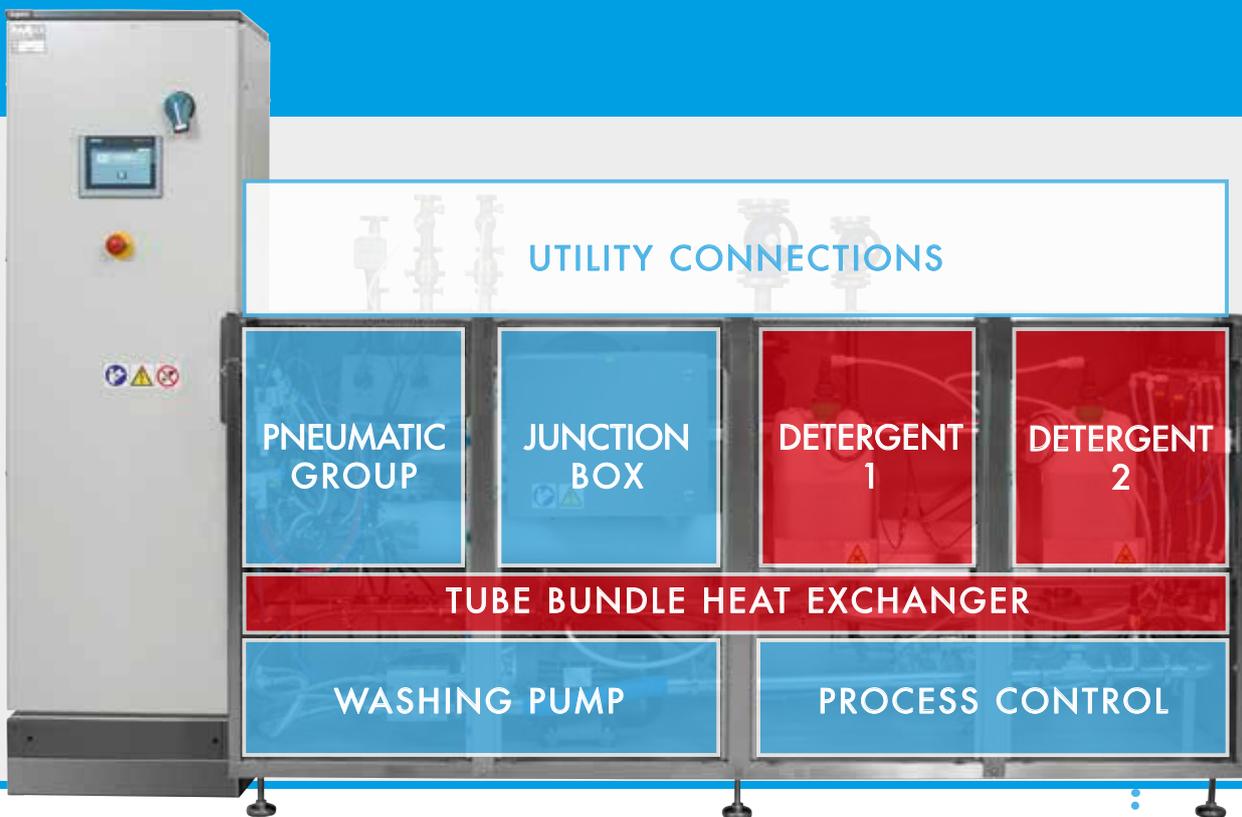
C-Line is composed by:

- A washing chamber entirely made of AISI 316L (1.4404), roughness lower than $0.5 \mu\text{m}$ with full thermal and acoustic insulation
- High pressure water handling unit
- High efficiency air handling unit with HEPA filter for effective drying of the load.

Extra features include:

- Single or double door for pass-through application
- Quick lock connections for supplementary washing devices (e.g. loading trolley for drums)
- Air cooling system allows faster unloading reducing cycle time
- TOC and conductivity monitoring of the final rinse water
- Modular design allows installation of the chamber in classified areas whilst the technical components can be remoted

HYDROKINETIC HEAD INSTALLED IN CHAMBER FLOOR



S-LINE

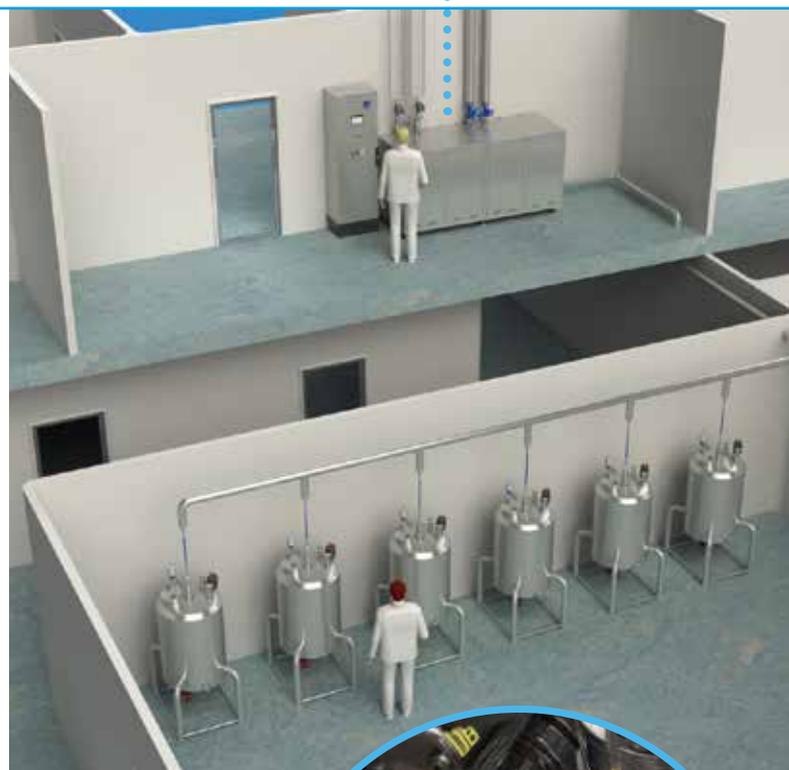
High Pressure Cleaning-In-Place solution

S-Line consists of a modular technical compartment installed in an appointed plant area from which, via distribution manifolds, multiple stationary loads can be connected (e.g. bulk preparation tanks).

S-Line provides the core hardware for the cleaning process while the end effector is then tailored around the specific application. Consult our experts to evaluate capabilities and flexibilities of this advanced cleaning solution.

Additional modules that can be provided:

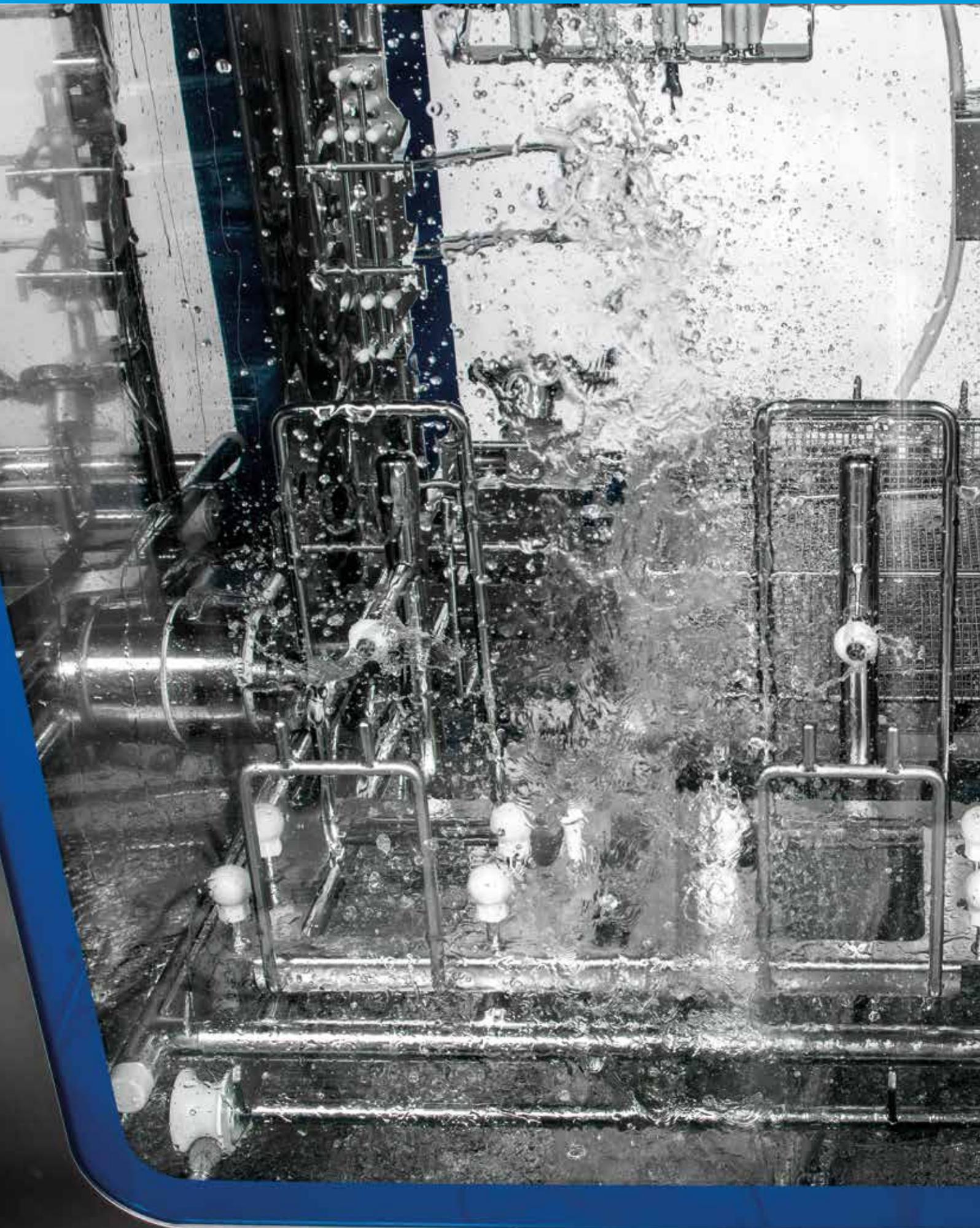
- Air handling unit with HEPA filter for effective drying of the load
- Tube bundle heat exchanger for water heating
- Chemical dosing system



BIN WASHING STATION



FLOW, HYDROKINETIC HEAD AND PRESSURE METERS

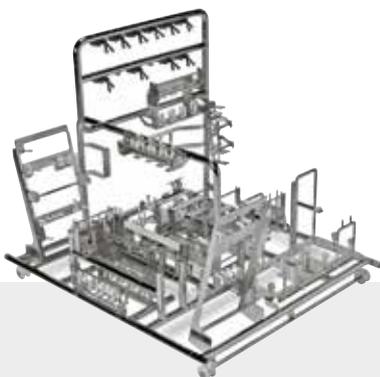




200



300

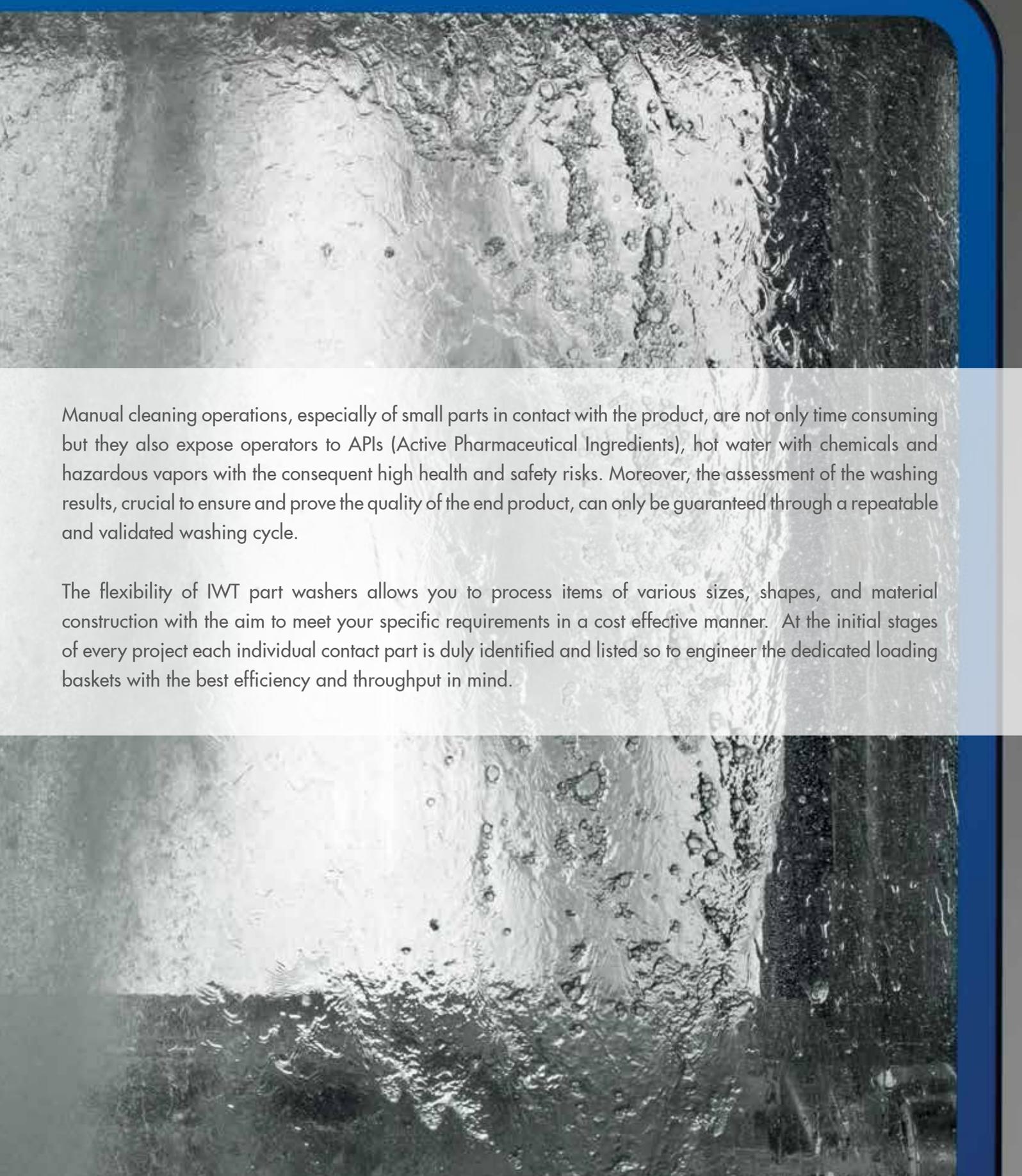


BASKETS

CONTACT PARTS WASHERS

IWT cGMP WASHERS FOR PROVEN CLEANING OF PRODUCTS CONTACT PARTS TO MINIMIZE DOWNTIME OF PRODUCTION LINES AND TO ELIMINATE ANY POSSIBLE CROSS-CONTAMINATION BETWEEN BATCHES.

CUSTOM ACCESSORIES, IN-HOUSE DESIGNED AND MANUFACTURED, ENSURE PERFECT PROCESSING OF THE SPECIFIC MIX OF ITEMS.



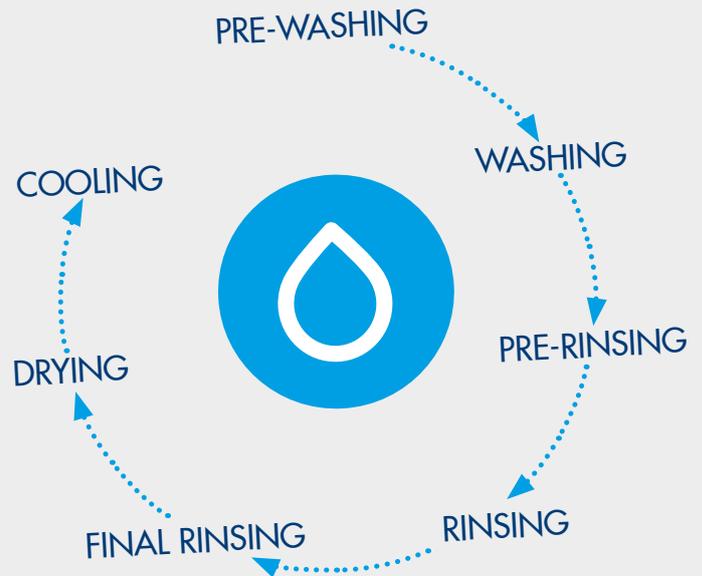
Manual cleaning operations, especially of small parts in contact with the product, are not only time consuming but they also expose operators to APIs (Active Pharmaceutical Ingredients), hot water with chemicals and hazardous vapors with the consequent high health and safety risks. Moreover, the assessment of the washing results, crucial to ensure and prove the quality of the end product, can only be guaranteed through a repeatable and validated washing cycle.

The flexibility of IWT part washers allows you to process items of various sizes, shapes, and material construction with the aim to meet your specific requirements in a cost effective manner. At the initial stages of every project each individual contact part is duly identified and listed so to engineer the dedicated loading baskets with the best efficiency and throughput in mind.

PICK YOUR CYCLE PHASES
AND PROGRAM FOR EACH OF THEM:

- WATER TYPE
- TEMPERATURE
- DETERGENT, IF REQUIRED
- CONDUCTIVITY
- DRAIN OUTPUT

Create the cleaning
process that better suits
your needs!

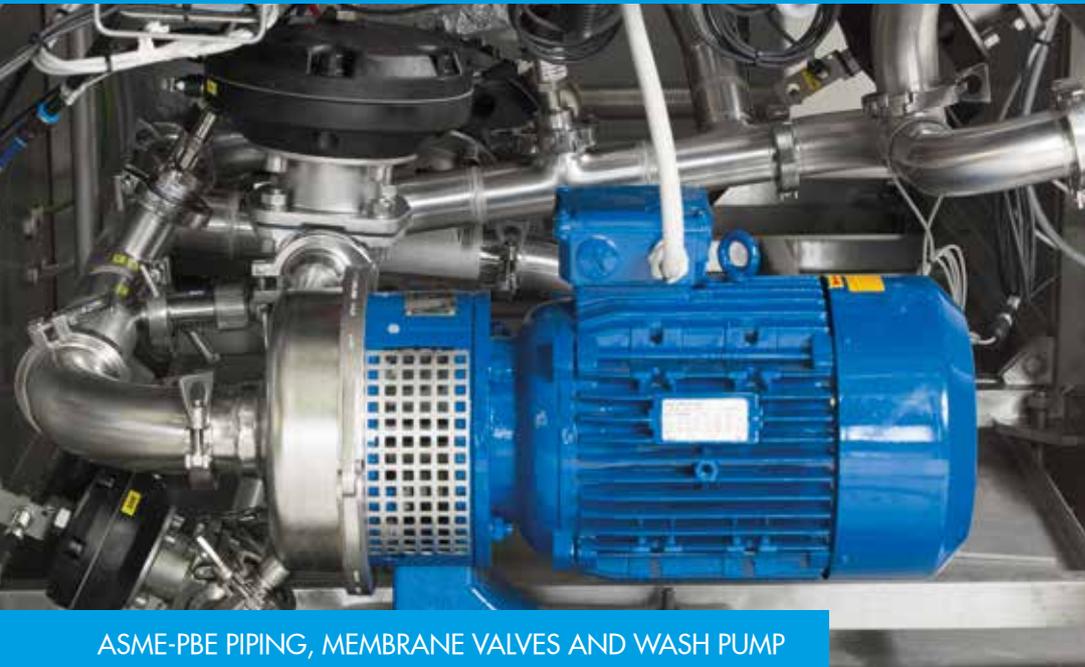


IWT has many years of experience from successful installations all around the world where we have been able to provide customers with real tangible benefits associated to the automation of their cleaning procedures:

- TIME SAVINGS – thanks to parts ready to be re-used immediately with substantial reductions in downtime of production lines
- VALIDATED PROCESSES - thanks to the achievement of the pre-determined acceptance criteria over and over again granted through a full process control of cleaning and drying phases
- INCREASED SAFETY AND REDUCED HANDLING – thanks to the automatic washing of contaminated parts properly presented over tailored designed accessories which are meant to simplify and minimize tasks
- RAPID RETURN ON INVESTMENTS (ROI) - thanks to each of the points above where optimization of labor and running costs are merged with proven quality procedures in a better working environment
- NO CROSS CONTAMINATION – thanks to interlocking doors and bio-seal separation featured on facilities where a physical barrier is in place to separate flows of incoming polluted components and outgoing clean ones

IWT's team of experts are available to evaluate, engineer and qualify the most suitable solution to match your operational requirements.





ASME-BPE PIPING, MEMBRANE VALVES AND WASH PUMP

200 and 300 series are developed to meet the highest cleaning requirements and exceed industry standards and guidelines (GAMP5, cGMP, ASME-BPE, ISPE baseline; FDA including 21CFR part11).

200 and 300 main features:

- Single or double doors made of multilayer tempered glass
- Steam or electrical heating with PT100 temperature probes
- Washing chamber entirely made of AISI316L (1.4404), roughness <math>< 0.5 \mu\text{m}</math>
- Piping entirely made of AISI316L (1.4404) ASME-BPE compliant
- Orbital weldings featuring tri-clamp connections for diaphragm or ball valves
- Polymer materials made of FDA compliant PTFE and/or EPDM
- Siemens PLC and operator touch screen interface
 - Batch reports data transfer via USB and/or ethernet ports, as well as integration with SCADA systems
 - Up to 30 fully customizable washing programs from pre-washing to cooling and drying
 - Constant monitoring of critical process parameters
 - Exhaust fan for vapour extraction
 - Up to 2 different drain lines
 - Inflatable gasket made of silicon FDA compliant.

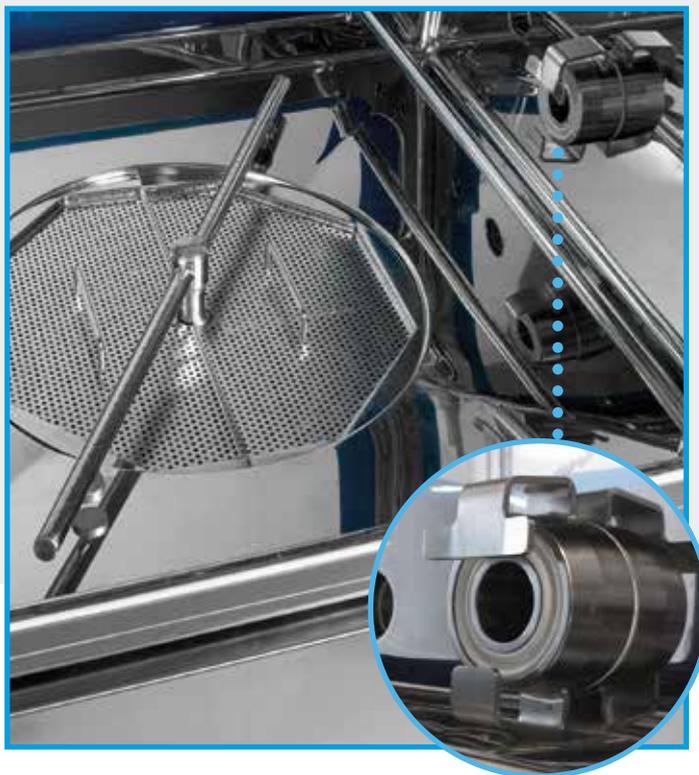
Optionals include:

- Drying unit with pre-filter and HEPA filter on the air inlet
- Water conductivity and/or TOC monitoring for final rinsing





AISI 316L (1.4404) MIRROR FINISHING WITH ROUNDED CORNERS • PERFECT DRAINING OF TANKS AND LINES

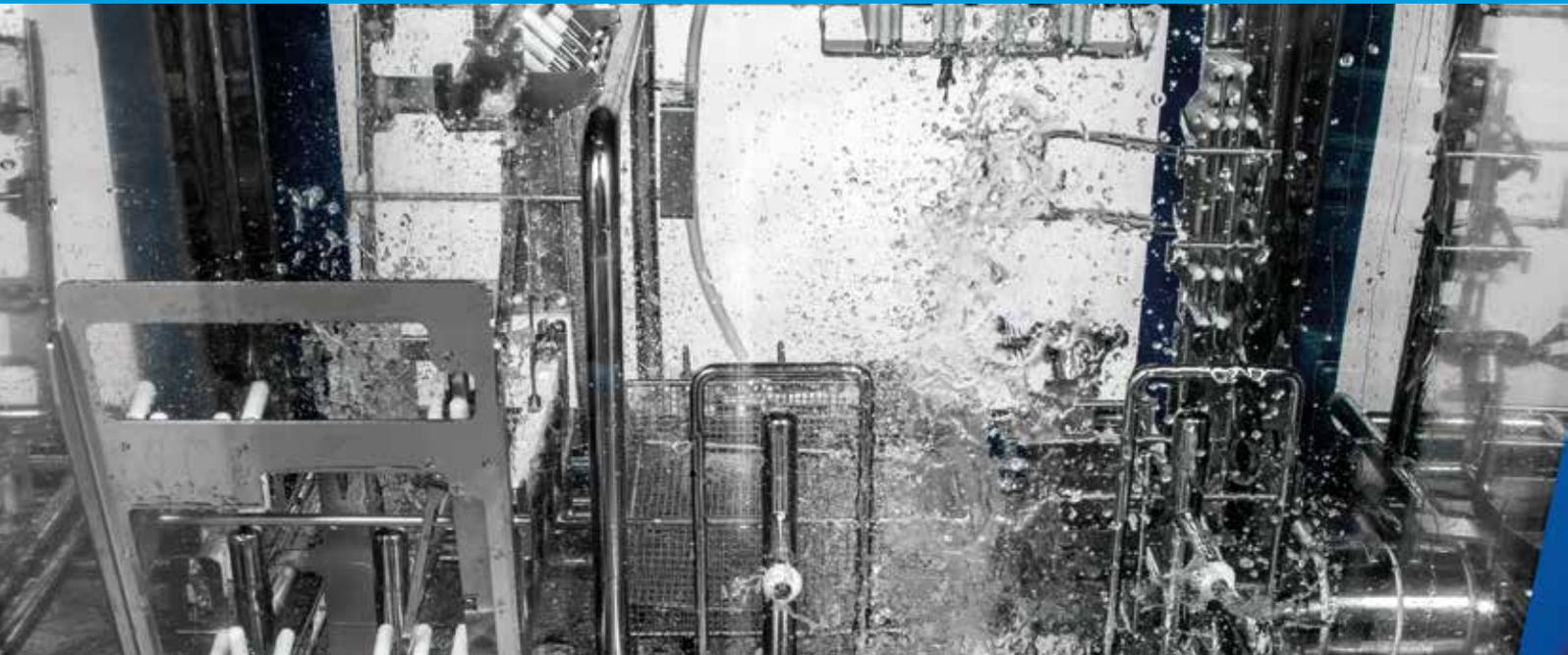


200

- Three different chamber sizes: 400, 800 and 2000 liters/14, 28 and 70 cu.ft
- Patented quick-lock connection with inflatable gasket
- Up to 2 different water supplies
- Multiple water supplies and chemical dosing systems
- Compact footprint

300

- Three different chamber sizes: 250, 500 and 1000 liters/9, 18 and 35 cu.ft
- 3 different water supplies
- GMP WFI rinse facility
- Multiple water supplies and chemical dosing systems

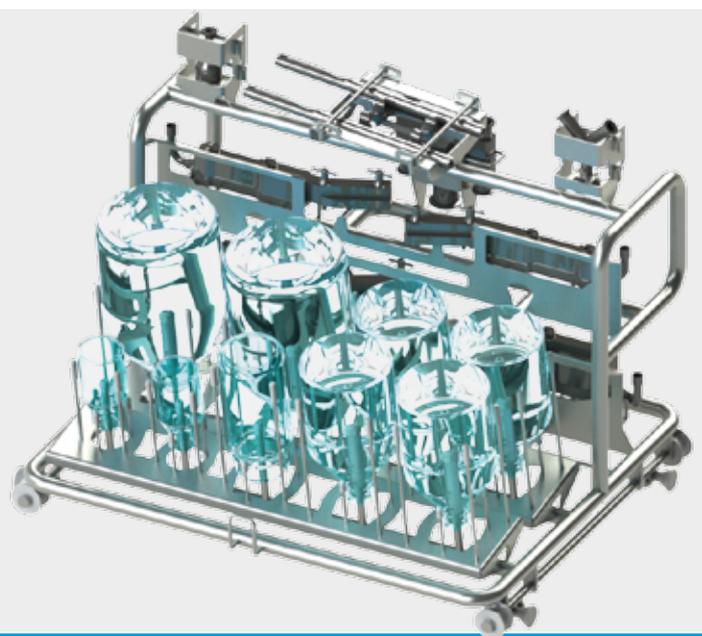
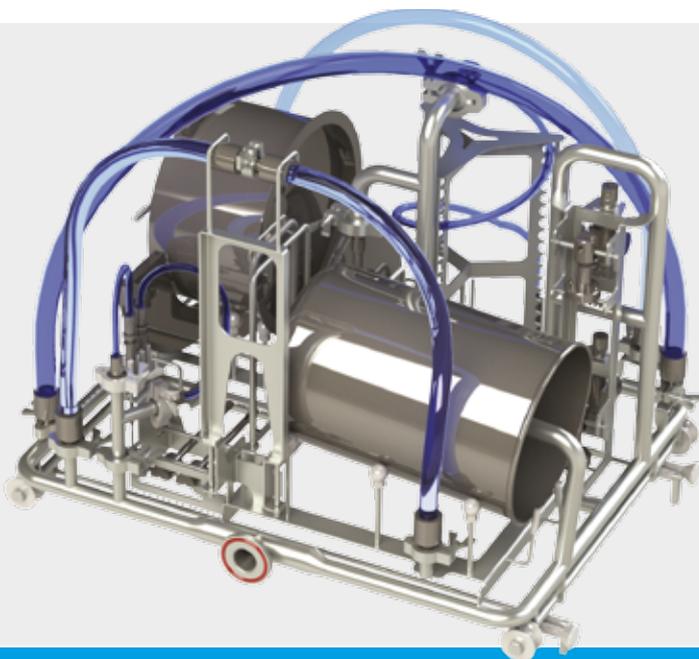


CUSTOMIZED LOADING BASKETS

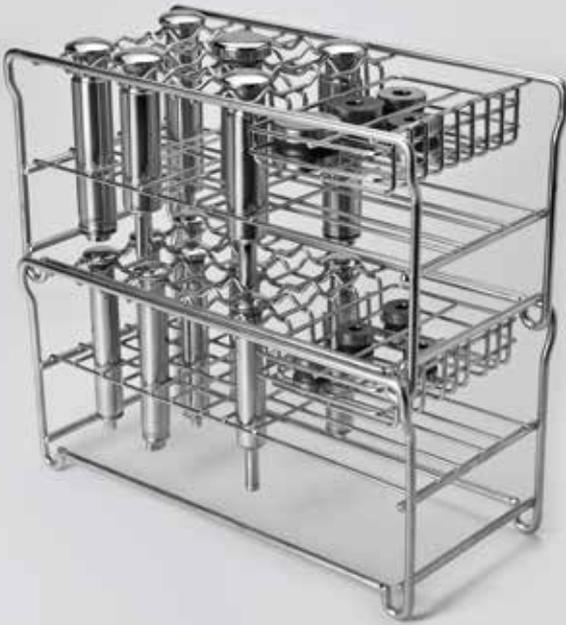
In order to guarantee no cross-contamination between production batches, a proper cleaning of the wide range of machine parts involved in the specific application is mandatory. The correct exposure of the loads is crucial to ensure efficacy and repeatability of the automatic washing process. From drums to hoses; and filling needles to punches and dies - all components are studied to design and engineer the associated basket with the aim to achieve the optimal exposure and maximize the load per cycle.

The drivers in developing our custom loading baskets are to give you:

- Easy and quick filling: intuitive 1-to-1 positioning of every critical item
- Full coverage and drainability
- Precise flushing of the smallest and hidden areas.



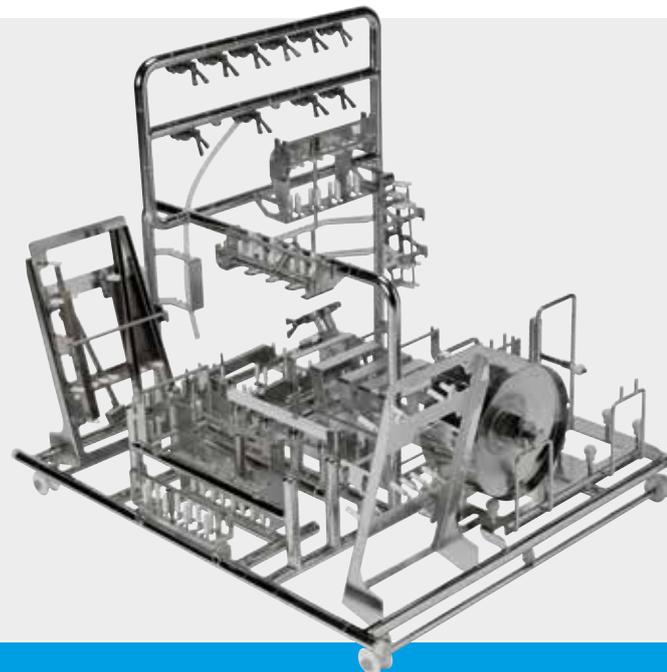
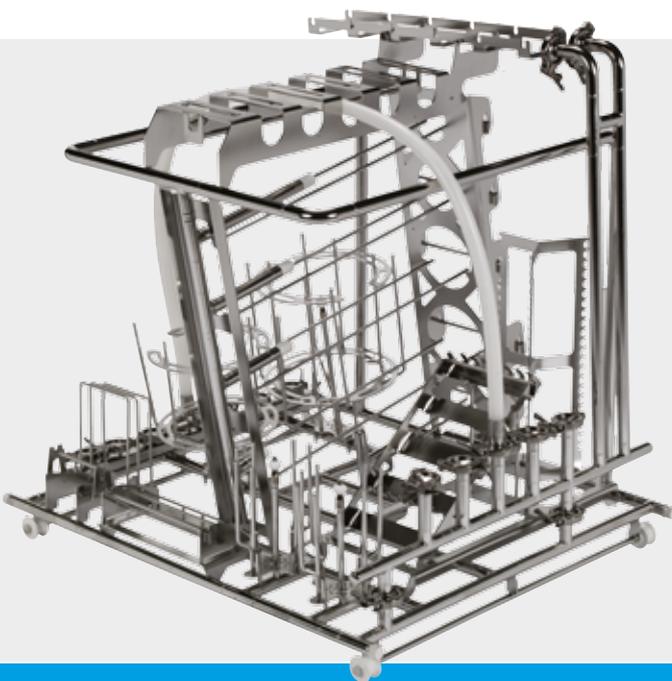
FROM 3D CONCEPT DESIGNS...



A digital simulation of the flushing path combined with a risk analysis study are the last steps of the engineering process. Modeling and simulation allow to truly verify and proof the final design to meet the most stringent acceptance criteria before the actual production.

Loading baskets are made in AISI 316L (1.4404) with ASME-BPE fully welded piping to distribute the washing solution on the load; the connection is done by means of a quick-lock between the loading basket and the contact part washers circuits.

*What do you need to clean?
Consider it done!*



...TO FINISH PRODUCTS!



CABINET WASHERS



650C



900C

IWT CABINET WASHERS ARE THE IDEAL SOLUTION FOR THE AUTOMATION OF CLEANING PROCEDURES IN THE COSMETIC, NUTRACEUTICAL AND UNCLASSIFIED PHARMACEUTICAL AREAS.

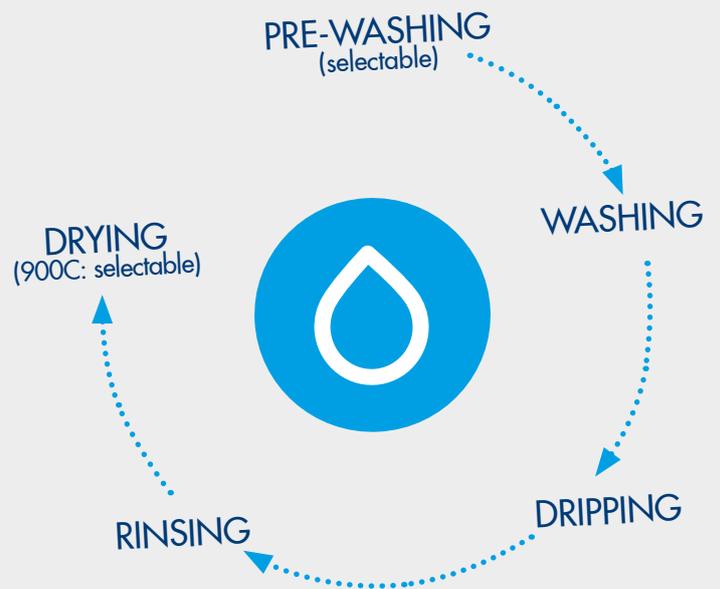
Thanks to their compact dimensions, IWT 650C and 900C can easily be installed either in new or in existing facilities.

Dismountable components, re-used between production batches, must be cleaned and sanitized. IWT cabinet washers, through an automatic cleaning procedure, bring the following benefits:

- Operator safety
- Process repeatability
- Monitoring and traceability of sensitive parameters
- Optimization of time and running costs

650C and 900C main features:

- Complete separate circuits for washing and rinsing
- Steam or electrical heating
- Single or double interlocking doors for loading and unloading
- Process pump made of AISI316L
- Fan for vapor extraction
- Fully controlled and validated process
- Multicolour 7" touch screen and PLC
- Data transfer of batch report in electronic format via USB port
- Easy access to the technical compartment via front hinged door
- Up to 2 detergent tanks duly housed inside the technical area



Create the cleaning process that better suits your needs!

PICK YOUR CYCLE PHASES AND PROGRAM FOR EACH OF THEM:

- WATER TYPE
- TEMPERATURE
- DETERGENT, IF REQUIRED



STANDARD AND CUSTOMIZED LOADING KITS





WASHING CHAMBERS ENTIRELY MADE OF STAINLESS STEEL WITH OSCILLATING ARMS TECHNOLOGY

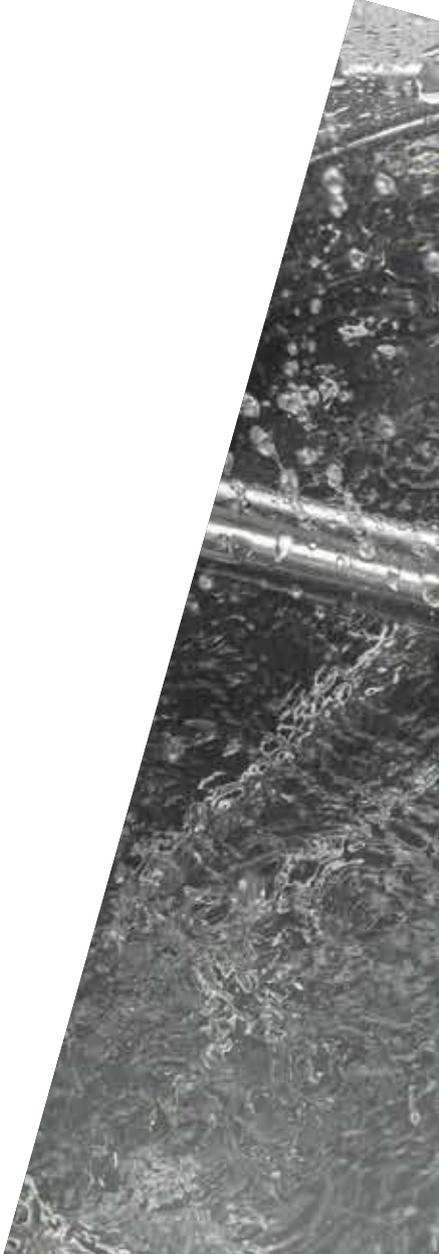


650C

- For small/medium sized parts from compressing and filling lines
- Interchangeable customized loading systems
- Removable static mesh filters for the water tank
- Roll-out electrical cabinet to allow wall-to-wall installations
- Loading capacity of over 1 m³ in a reduced footprint

900C

- Quick lock device to connect custom made baskets for critical components
- Multiple water connections
- Loading capacity of over 4 m³
- Ideal for large parts such as pallets, drums and buckets
- High productivity on repetitive loads
- Drying for load and chamber
- Sanitization cycle by means of clean steam injection
- Slanted floor to enhance water dripping from flat surfaces
- Self cleaning in-line filter



HEADQUARTERS IWT s.r.l. | Tel. +39 0332.96701
www.iwtpharma.com · E-mail: info@iwtpharma.com

