Your partner for the design
and manufacture of sterile
Rapid Transfer Systems

castus®

Flexibility when it counts.
Customized solutions for isolator technology

COMPONENT **PROCESSING SYSTEM** (CPS)

About castus Group companies

castus GmbH & Co. KG

Headquartered in Ochsenhausen, Germany, castus has become one of the world's leading manufacturers of sterile transfer solutions since 2011. The company provides its customers in the pharmaceutical and medical industry with alpha Ports and beta Containment systems for contamination-free loading and unloading of components into and out of isolators.

castus sterile systems GmbH & Co. KG

As a subsidiary of the castus Group, castus sterile systems GmbH & Co. KG has been supporting the sales activities of HANAG Steriltechnik AG in the field of CPS since 2019. Following the acquisition of HANAG in 2021, it today bundles the production of the CPS within the castus Group in order to strengthen its position as a systems provider.

HANAG Steriltechnik AG

Founded in Basel in 1956, HANAG has developed into one of Switzerland's leading suppliers in the field of vessel manufacturing and sterile process equipment over the past 60 years. It joined the castus Group in 2021 as a supplier to castus sterile GmbH & Co. KG and brings its extensive expertise to the manufacture of pressure vessels, magnetic agitators and machines.

Component Processing System (CPS)

Sterile cap and stopper treatment for the transfer process to the filling line

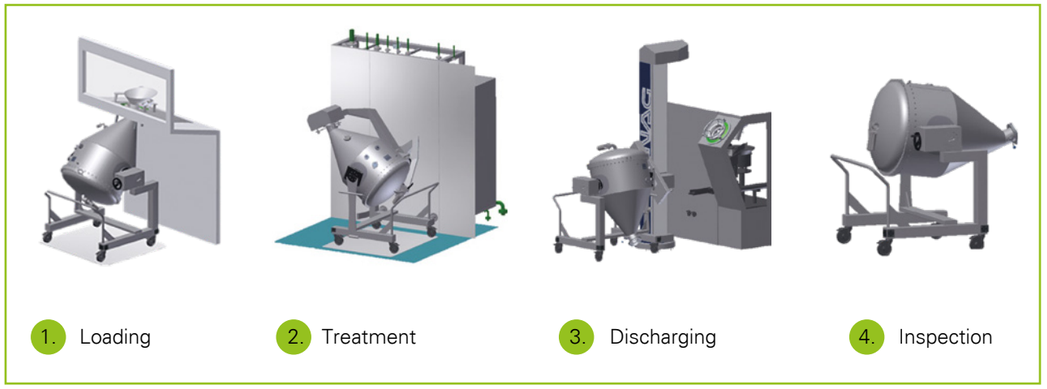
CPS provides cleaned, sterilized and dried components and closures for pharmaceutical primary packaging.

Possible treatment objects are
Lined seals, plugs, components and closures of all common types,
optionally passing through the following steps at the treatment station,
with 100 % CIP/SIP including the ring of concern:

1. Washing step(s) (with or without detergent) ⇢ Reduction of particles and endotoxins
2. Rinsing ⇢ Removal of detergent residues
3. Siliconization (optional) ⇢ Prevention of clumping, assurance of smooth transfer
4. Sterilization ⇢ Sterilization of the treatment objects
5. Drying ⇢ Maintenance of the desired residual moisture value
6. Cooling ⇢ Reduction of temperature

During these steps, the castus-specific smooth treatment prevents any deformation of the closures.

Overview – Stages involved in the process



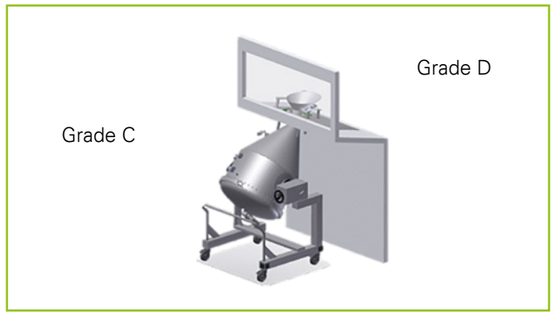
1. Loading 2. Treatment 3. Discharging 4. Inspection

1. Loading station

For the filling of the vessel, two options can be selected:

a) **Filling in the cleanroom**
The vessel can be opened manually or by using the castus alpha port.

b) **Aseptic loading**
The vessel is located in room class C, the filling happens in room class D.
castus alpha Port provides room grade, ensures process safety and contamination-free loading.

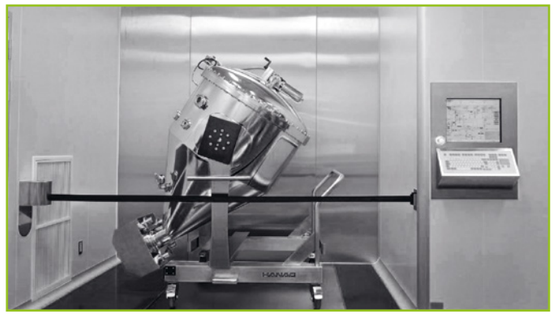


Equipment like a platform with stairs or the filling cone without physical vessel contact are helpful to get the filling material into the vessel. Elevating devices like lifts are also realizable to support the operator.

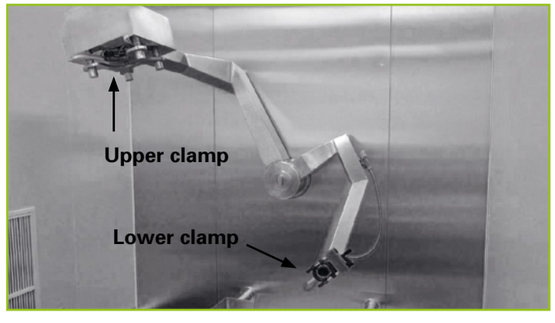
2. Treatment station

Min. required space in **cleanroom**
(H x W x D): 2700 mm x 3400 mm x 1800 mm

First step on the treatment station is the connection of the vessel to the station.
The vessel itself remains on the trolley during the whole time.



Media are distributed from the technical room to the process vessel through the clamp systems. The lower clamp system is closed manually, the upper clamp system (+ opening of the beta flange) is automated.

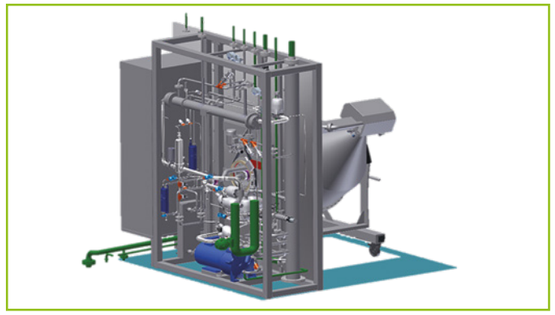


Process steps
Pressure test
Vacuum test

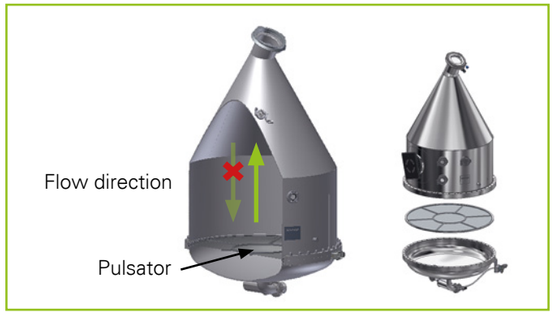
Washing step(s) (with or without detergent)
Rinsing
Siliconization (optional)
Sterilization
Drying
Cooling

Pressure overlay

Min. required space in **technical area**
(H x W x D): 2700 mm x 3400 mm x 800 mm



Skid
- The Skid ensures the supply with all required media for the treatment
- Sampling points for all pure media are possible
- Technical area with very compact design, access to all components is ensured
- Skid is self-draining
- Hygienic design is standard, process connection can be selected in accordance to customers specifications (e.g. ISO 2852 (DIN 32676), DIN 11864)
- Process time < 5 h



Vessel
- Vessel material for wetted parts is 316 L
- Vessel capacity is available from 100 l to 350 l treatment volume
- The goods are located within the vessel carrying out the required processes
- Connections and sight glasses for the process observation and validation are included
- No back contamination possible thanks to the flow direction from bottom to top
- Special designed pulsator ensures safe process and consistent results thanks to smooth washing
- High cleanability thanks to dismountability of pulsator and dished bottom plate

3. Discharge station

Discharge with **Stationary Lift**

- Typically based at an isolator
- For discharge, the vessel requires overpressure (min. 30 mbar overpressure), to provide sterility
- Docking and lifting of the vessel is an automatic process. Locking and 90° rotation are manual steps

Discharge with **Lifting Trolley**

+ Lifting function is included in the moveable trolley
+ Space saving at the discharge positions with identical functions compared to the Stationary Lift
+ Less interfering contours in the cleanroom
+ No weight at ceiling to beware of
+ Movement at the discharge station is completely automated
+ Trolley with loaded vessel is operable by one person
+ Trolley weight is at about 200 kg
+ Safety systems ensure human and process safety

4. Inspection

Lifting Trolley while in stand-alone position

The **Inspection** is the process step where the vessel is examined from the inner side.
It is done in order to check if there is any mechanical damage or any stopper left inside the vessel from the previous batch. It can be carried out with the vessel on the trolley as the vessel can be rotated in its trolley while in stand-alone position.

References

- NIPRO Pharma Vietnam, Hai Phong, Vietnam
- NIPRO Pharma Odate, Odate, Japan
- NIPRO Pharma ISE, Ise, Japan
- Sanofi Deutschland GmbH, Frankfurt, Germany
- GlaxoSmithKline Biologicals SA, Wavre, Belgium
- Merckle Biotec GmbH, Blaubeuren, Germany
- Novartis Pharma AG, Stein, Switzerland
- Bayer Schering AG, Berlin, Germany
- Roche Basel, Switzerland

Checklist

We want to prepare a target-oriented, technical quotation for you. Therefore, we kindly ask you to provide us with some basic information that we listed in the following questionnaire.

Please provide the following information:

- ☐ User Requirement Specification (URS) available
- ☐ Automation requirements

Components

- ☐ Quantity of caps and stoppers
- ☐ Diameter of caps and stoppers

Treatment steps

- ☐ Washing with detergent
- ☐ Washing without detergent
- ☐ Rinsing
- ☐ Siliconization (optional)
- ☐ Sterilization
- ☐ Drying
- ☐ Cooling

Filling products

- ☐ Freeze-dried product
- ☐ Liquid product

Components finishes

- ☐ Ready to wash (rtw) stoppers (washing required)
- ☐ Ready to sterilize (rts) stoppers

Premises

- ☐ Available space / Layout of the premises
- ☐ Number of lines and vessels
- ☐ Desired batch quantities

Loading

- ☐ in cleanroom
- ☐ aspetic loading (contamination-free loading)

Further specifications

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