HIGH CONTAINMENT STERISPLIT: technical characteristics

- Valve body in AISI 316L.
- Disc in AISI 316L.
- Gasket in silicone, EPDM, FKM (viton®) (FDA CFR § 177.2600).
- PTFE bushings.
- Handle and the top plate in AISI 304.
- Rotary pneumatic actuator.

HIGH CONTAINMENT STERISPLIT

The **SteriSplit** provides perfect sealing during emptying and filling operations and satisfies the most stringent hygienic and safety requirements for product and operator protection. The system is composed by two parts: the active valve so named for its components that command the whole system. Its body is endowed of four flared holes on its surface, which are necessary to hold the passive valve. The passive valve has four spotting pins containing notches, which are necessary to enable the coupling of the two parts to be tightened and secured by a bayonet that runs through them.

The passive valve has a mechanical lock to avoid accidental opening of the passive part without the active unit connected. Both the active and the passive valve have their own butterfly and gasket (in silicone, viton, EPDM of pharmaceutical grade FDA CFR § 177.2600) which guarantees that the whole valve is perfectly sealed when it is in lock position. The valve has two stainless steel cylinders placed on the side of the valve that actuate the bayonet that lock the active and passive valves together (1° lock system). Two other cylinders in stainless steel will be needed to lock the two half vane together (2° lock system).

1. Connection occurs once the two valves are on the same vertical axis. A particular device on the active valve allows it to carry out the operation despite a ± 5 mm non-alignment.
2. Tightening is made possible by the bayonet with the use of a pneumatic actuator.

hanningfield

VEGA ENVIRONMENTAL CONSULTANTS LTD.

CERTIFICATE OF CONFORMANCE

When tested as a 'Single Point Transfer System' in accordance with Protocol No.1 of the International Society of Pharmaceutical Engineering (ISPE) Standardised Measurement for Equipment Particulate Airborne Concentration (SMEPAC) Good Practice Guide 'Assessing the Particulate Containment Performance of Pharmaceutical Equipment', the equipment (as detailed below) achieved to the following containment performance:

Manufacturer: SteriValves srl, Lucca, Italy
Equipment: SteriSplit Automated ND100 Split Butterfly Valve
Containment Achieved: 0.37 µg.m^{-3}

The displayed value relates to personal exposure data and is the 95 % Upper Confidence Limit of the dataset. For information, the Geometric Mean of the results was 0.037 µg.m^{-3} and the number of samples was 3.

Vega Report/ Project No.: ENV/08/2117
Date of Test: 21 May 2008

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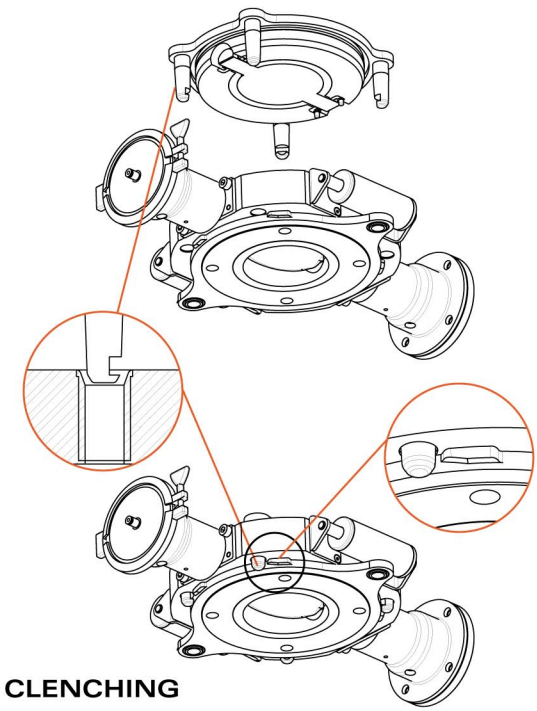
Authorised Signatory:

Duncan George Smith BSc (Hons) CertOH LFOH
Licentiate of the BOHS Faculty of Occupational Hygiene

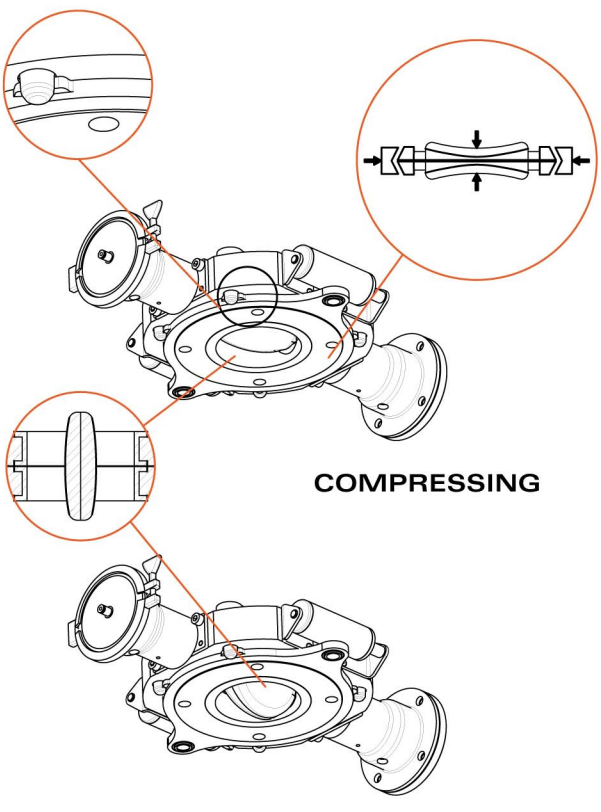
H.C. STERISPLIT APPLICATION

- Active substances;
- Hormones;
- Antibiotics;
- Injectable;
- Toxic products;
- Sensitive products (baby food);
- Whenever there is a need to avoid cross contamination.

DOCKING



CLENCHING



COMPRESSING

OPENING

H.C. STERISPLIT OPTIONAL

AIR PURGE

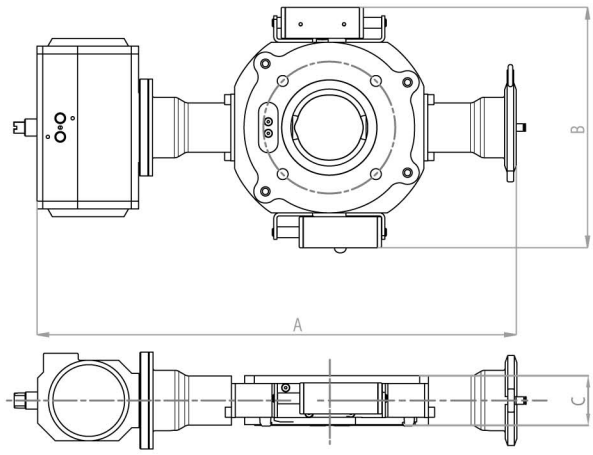
Upon request, an air vacuum system will be provided (as well as a water purge) to clean the system before splitting is completed.

1. After having emptied the product and re-connecting the two butterflies, the valves will be detached and separated about 4 mm. This will create a hermetical chamber between the two valves. Compressed air (or nitrogen) will be injected through the pipes. A whirlpool will be introduced inside the chamber which will be sucked from the second pipes while air tight.
2. In alternative water will be sprayed, which will flood the chamber. On the other side the water will be vacuumed.
Afterwards it will be dried with hot air.
3. At the end of the cleaning cycle the two valves will be completely separated.

Dust emission level (OEL) guaranteed is 0,37µg/m^3.

H.C. STERISPLIT DIMENSIONS

ND	A	B	C
100	618	310	64
150	668	355	64
200	736	425	84
250	790	498	94



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