



InterApp **IA**[®]

No contamination !



BIANCA *pharma*

FLUIDS UNDER CONTROL

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This high-quality shut-off and control butterfly valve has been developed specifically for sterile process control. The emphasis is on avoiding contamination by bacteria during the fermentation process. The shut-off chambers through which steam flows effectively prevent ingress of non-sterile ambient air. The body of the butterfly valve is made either of solid material 1.4435, AISI 316L with a ferrite content of < 1 % or of casted stainless steel 1.4435, AISI 316L. The butterfly valve is a sealing unit together with the flange. The O-ring recess on the body has been relocated as far to the outside as possible in order to avoid clearance volumes. The material of the polished disc is made of DIN 1.4435, AISI 316L with a ferrite content of < 1 % and features a surface quality $R_a < 0,8 \mu$. A PFA-coated disc may be used as an option. The advantage of **BIANCA *pharma*** of solid material body also relates to the fine outer surface and the option of matching the body to various requirements (see overleaf).

Leakage test:

The **BIANCA *pharma*** is a shut-off butterfly valve, developed by InterApp which can be sterilised under saturated steam conditions. Special-purpose seals in the upper and lower shaft zone separate an area which can be subjected to steam off from the product chamber (steam seal).

The **Fraunhofer Institut für Grenzflächen- und Bioverfahrenstechnik (Fraunhofer Institute for Interfacial Engineering and Biotechnology – Fraunhofer IGB)** was commissioned to investigate the performance of the seal of the steam chamber. In order to investigate the leakage of dynamic and static seals, the Fraunhofer IGB developed a quantitative method in which the fluorescein Na used as „leakage indicator“ can still be reliably detected in concentrations of 1.2×10^{-5} mg/ml using fluorescence spectrometry.



Results of the leakage test:

The **BIANCA *pharma*** butterfly valve was subjected to steam at a temperature of 121 °C for a total of 244 hours in two consecutive tests. This involved the butterfly valve disc switching a total of 4,320 times. The measurements of fluorescein transfer which were conducted afterwards (subject to a pressure loading of 3 bar abs.) indicated that it was not yet possible to detect the presence of fluorescein.

This means that the leakage flow rate was below the limit of 7.6×10^{-5} µl/h, the limit which can still be determined analytically. This detection limit corresponds to a fluid quantity of 0.7 µl were we able to collect the leakage flow over a period of one year.

Bacteriological test:

The results of the bacteriological test were published after conclusion of the extensive test runs.

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Sterility thanks to steam seal:

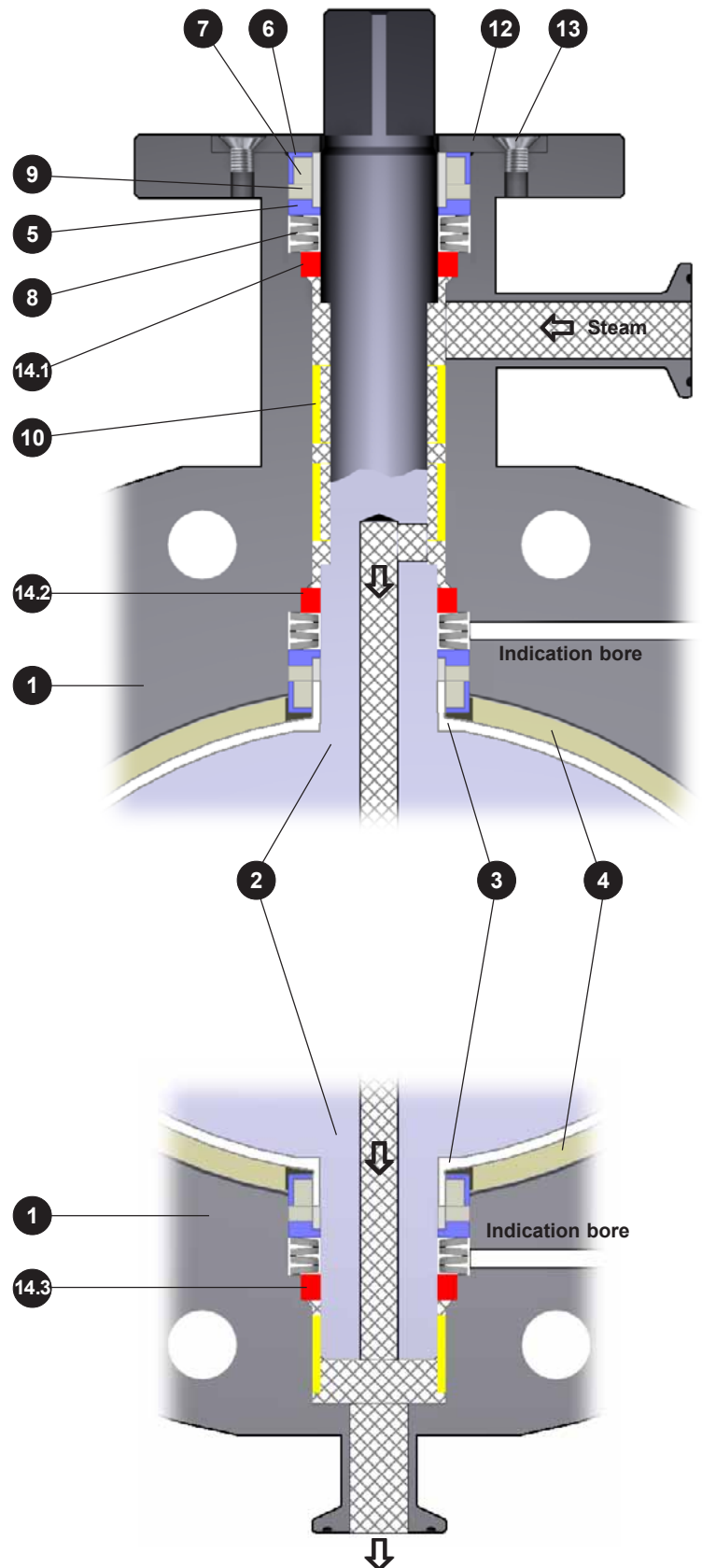
The steam entering through the upper steam port fills the upper steam shut-off chamber (between steam seal 14.1 and 14.2) and then flows through the shaft-disc bore into the lower steam shut-off chamber.

The steam seals 14.2 + 14.3 thus seal off the medium area to the outside.

In the event of medium escaping nevertheless through the upper or lower indication bore, it must be assumed that there is a defect at the sealing point between disc-shaft unit 2 and PTFE seal 3. By contrast, if steam condensate escapes at the indication bores, it must be assumed that there is a defect in the steam seal 14.2 or 14.3.

This ensures constant sterility monitoring.

Item	Qty.	Designation	Material
1	1	Body, 2-section - solid material	1.4435, AISI 316L, Fe < 1%
		or - casted stainless steel	1.4435, AISI 316L
2	1	Disc polished <0,8µ optional	1.4435, AISI 316L, Fe < 1% PFA coated
3	1	Seal	PTFE (FDA-compliant)
4	2	Support	Silicone (MVQ)
5	3	Packing ring	1.4435, AISI 316L, Fe < 1%
6	3	Packing bushing	1.4435, AISI 316L, Fe < 1%
7	3	Inner seal	EPDM (FDA-compliant)
8	12	Disc spring	1.4310
9	3	Outer seal	EPDM (FDA-compliant)
10	3	Sliding bearing	CuSn8
11	2	Screw	DIN 912 /A4
12	1	Cover	1.4435, AISI 316L, Fe < 1%
13	4	Screw	DIN 7991 / A4
14	3	Steam seal	HNBR (Therban), (FDA-compliant)



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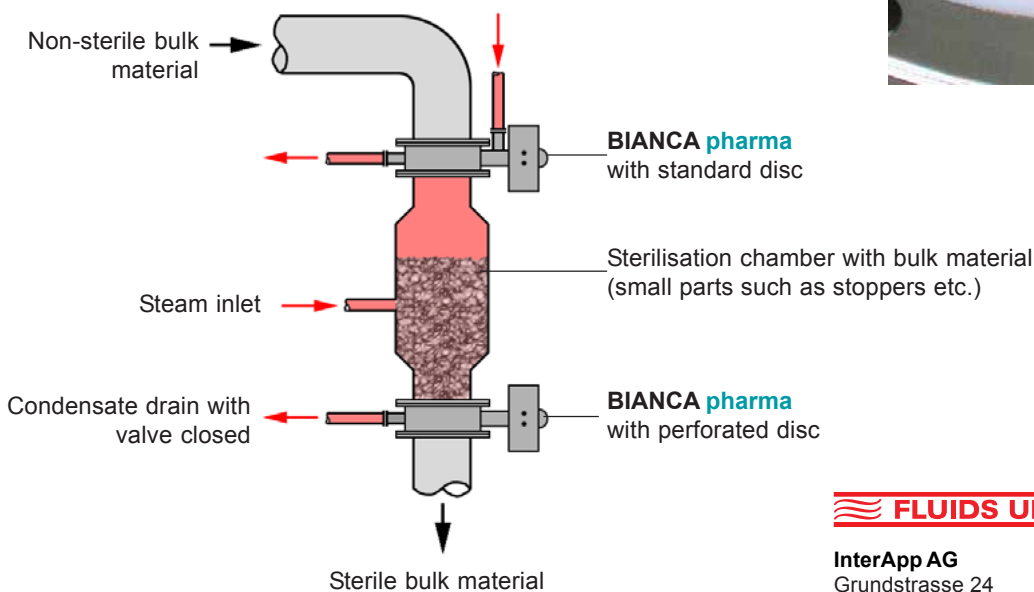
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Special versions:

The user of these special-purpose butterfly valves produces large quantities of disposable medical components which must be sterilised as effectively as possible after the production process and prior to filling. The shut-off butterfly valves must ensure optimum condensate drainage after steam sterilisation in horizontal position without opening of the butterfly valve disc so as to perform time-saving sterilisation after each filling or emptying operation. The precisely defined arrangement of the bores allows the condensate to be transferred to the outside quickly and reliably from the disc via the shaft. Using this principle, the operator saves a tremendous amount of time and can sterilise, fill and pack small parts far more quickly.



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