

Custom-manufactured multi-port valves in stainless steel can be used as a base for filter housings.

#### **Process description**

For process engineering reasons, additional process valves, fittings or connections are required in aseptic production plants upstream and downstream of any existing filters, one reason being to supply sterile steam and drain condensate in order to sterilize the filter or perform filter integration tests as required by official bodies.

These process valves or fittings are generally welded onto the filter base itself (see image on the right) either individually or in prefabricated subassemblies. It is advisable to manufacture the entire filter unit, comprising filter base, valves, fittings and connections, from a block material – namely stainless steel block. This minimizes the installation space and removes the need for time-consuming welding work.

For the most varied applications, GEMÜ develops custom filter bases, tailored to customer requirements, e.g. for bioreactors.

Configuring filter bases this way makes PUPSIT filter tests (Pre-Use Post Sterilization Integrity Test) easier to perform.



Conventional construction of a filter base with process valves welded on



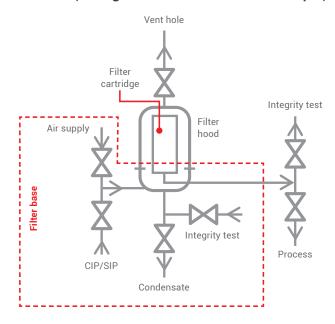
# Construction of a multi-port valve as filter base

The valve seats of the process valve are integrated into the valve block. This results in a space-saving construction and substantially less dead space between the valves.

To make installation easier, all process connections are integrated directly into the block on the basis of DIN11864

(aseptic connections). The subsequent pipes are fitted with the appropriate counterpart so they can be easily screwed onto the housing with an additional O-ring gasket. Alternatively, butt weld spigots or other process connections could be incorporated.

### Flow chart (taking sterile air filter as an example)

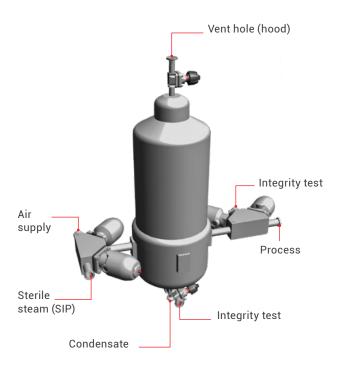




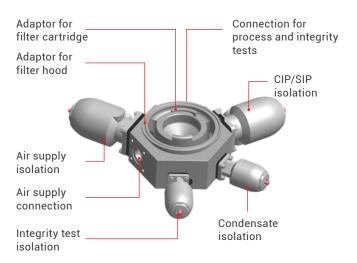
The filter hood and cartridge and the venting valve attached on top are to be viewed separately.

The adaptor for the filter cartridge and hood can be integrated directly into the block on a case by case basis for the application in question.

### Conventional design



## Design as multi-port valve block



## Multi-port valve block - detailed view



# Integrity test

FDA and GMP directives stipulate that sterile filters must be subject to integrity tests for the pharmaceutical production of drugs and medical products. The integrity test must prove that the filter is fully functioning before and after a production cycle. There are essentially three different methods of testing this – the bubble point test, the diffusion test (forward flow test) and the water intrusion test (water flow test).

PUPSIT filter tests are conducted in installed condition (i.e. in situ).



Custom-manufactured filter base with filter cartridge inserted

# Why GEMÜ?

For several decades, GEMÜ has been developing and producing high-quality multi-port valve bodies in stainless steel for use in the most varied of industrial sectors. GEMÜ has established itself as a global market leader in this field. GEMÜ M-block valves, which are usually customized, are the first choice for any applications requiring product reliability, compact and flexible design, sophisticated processes and minimal dead space, particularly those that involve specific customer needs.

