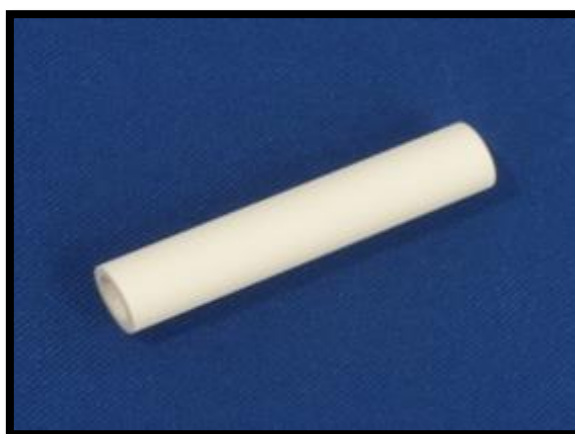


FISP® Ceramic Membrane Data Sheet

PRODUCT DESCRIPTION

FISP® ceramic membranes are designed for in-situ, microfiltered sampling of bioprocessing vessels and chemical reactors. The durable construction and inert nature of the membrane material allows the membrane to withstand a wide range of operating temperatures, pressures, viscosities, shear forces and chemicals. The ceramic membrane requires no pre-treatment and is compatible with steam-in-place (SIP) and clean-in-place (CIP) use. The hydrophilic nature of the membrane material makes it ideal for bacterial, fungal and cell culture applications.



QUALITY CONTROL

Every lot of membranes undergoes extensive physical and performance testing before release. A Certificate of Conformance is issued with each released batch to ensure adherence to specifications and for lot traceability. A Certificate of Conformance is provided upon request.

ANIMAL DERIVED COMPONENT FREE (ADCF)

No animal derived components or materials are used in the membrane manufacturing process. The membranes are considered safe for use in pharmaceutical, biopharmaceutical, food and beverage applications.

CERAMIC MEMBRANE CYTOTOXICITY TESTING

FISP ceramic membranes are tested for cytotoxicity in accordance with ISO 10993: Biological Evaluation of Medical Devices - Part 5: Tests for *In Vitro* Cytotoxicity. The purpose of the cytotoxicity test is to determine if extracts of the test material are toxic to mammalian cells.

CYTOTOXICITY TEST RESULTS		
TEST METHOD	SAMPLES TESTED	RESULT
ISO 10993-5:2009 Cytotoxicity Elution Test (MEM Extract)	Three FISP Ceramic Membranes	No cytotoxic effect after 48 hours of testing.

FISP ceramic membranes meet the non-cytotoxicity requirements of ISO 10993-5:2009.

CERAMIC MEMBRANE SPECIFICATIONS

FISP ceramic membranes can be used as a multi-use or single-use filtration device, depending on the end-user's process application. The following table provides specifications for standard ceramic membranes.

MEMBRANE DATA	
PARAMETER	VALUE
Membrane Part Number	A-MR-01
Membrane Material	Ceramic
Length*	1.85 inches (47 mm)
Diameter (OD)*	0.375 inches (9.53 mm)
Pore Size*	0.2 um
Operating Flow Rate**	0.2 – 2.0 ml/minute
Maximum Flow Rate**	5.0 ml/minute
Maximum Operating Pressure	70 psi (2.7 bar)
Operating Temperature Range	0 – 121°C (32 – 250°F)
Sterilization Method	Autoclave or SIP
Sterilization Temperature Range	121 – 135° C (250 – 275°F)
Membrane Lifecycle***	10 cycles

*Values are for standard membrane specifications. Custom dimensions and pore sizes available. Contact Flownamics for availability and pricing.

**Flow rates are for typical bioprocessing applications. Flow rates are dependent on application and use.

***The membrane can be used up to 10 times if the prescribed cleaning procedure is utilized after each use. However, the membrane lifecycle is dependent on the vessel's internal environment and vessel operating conditions while the membrane is employed.