

SEFAR MEDIFAB® Fabrics are Low Protein Binding (LPB)

Protein adsorption to surfaces in medical devices may be critical. Therefore, the SEFAR MEDIFAB® polyester and polyamide product line was evaluated for protein adsorption.

Following qualitative pre-studies, a quantitative study for the protein binding capacity of SEFAR MEDIFAB®

fabrics was conducted. Selected, representative fabrics were submerged in a BSA solution – Bovine Serum Albumin is a lead protein in blood – and the adsorption of protein was determined. The results of this study show that the fabrics do not adsorb protein (BSA) in detectable amounts.

Conclusion

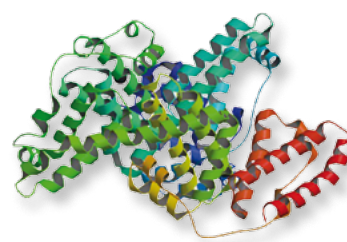
SEFAR MEDIFAB® fabrics can be considered as Low Protein Binding (LPB).

Low protein binding

The Sefar healthcare brochure «Safety Filters & Spreading Media» references this study in section «SEFAR MEDIFAB® Tests» on the last page.



Available online
<http://healthcare.sefar.com>



Bovine Serum Albumin (BSA) adsorption tests prove that SEFAR MEDIFAB® fabrics adsorb BSA at non-detectable levels.

SEFAR MEDIFAB® – Tests

The document «SEFAR® MEDIFAB – Tests» references the low protein binding properties in the chapter non-recurring tests.

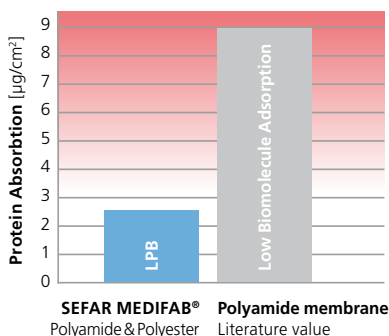


Available on request
Sefar internal document

SEFAR MEDIFAB® – TESTS			
Test	Reference	Release criteria	Limit/Control
Tests for efficiency of filter for blood and fluid	ISO 11634-2:2004 (E)	above limit	efficiency > 99%
Biocompatibility	EN ISO 10993-1:2009 A	none	
Protein binding capacity	SEFAR	none	Bovine Adsorption Limit < 2.5 µg/cm²

Lowest protein adsorption

The results of the study on SEFAR MEDIFAB® fabrics can be compared to test results of commercial polyamide membranes which are marketed as low biomolecule binding.



Background

Protein adsorption to surfaces may have following negative effects:

- Fouling: Formation of bio films
- Dose reduction: Non-specific binding of proteins from drugs
- Loss of proteins from circulating blood

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