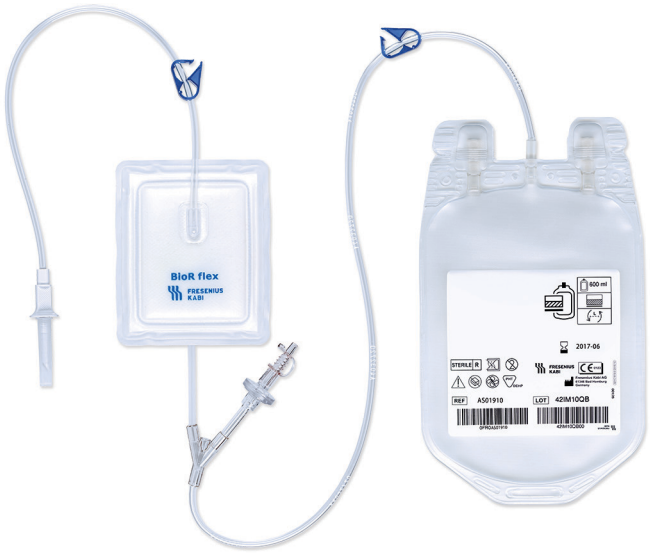
FRESENIUS KABI

BioR flex Filter

Leukocyte Depletion for Red Cell Concentrates

A flexible filter that provides high filtration efficiency and stable performance, excellent recovery and easy to use for a reduced filtration time

- BioR flex filter is intended for the filtration on demand of red cell concentrates
- BioR flex filter provides convenient handling with an integrated pre-filter, no priming needed, vertical flow filtration and automatic filter emptying by self-collapsing
- BioR flex filter offers a 'one size fits all' approach that is suitable for both buffy-coat and platelet rich plasma procedures



System Description:

- Indication: Leukocyte depletion of 1 unit of red cell concentrate
- Single use
- Spike for bag connection
- PVC/DEHP tube compatible with sterile connection
- Soft, squared filter – direct priming
- Full traceability by laser marking on perimeter
- Blood catcher for air removal ensuring system intergity after use
- Printed tube for sampling
- PVC/DEHP foil with an internal diamond structure
- Label: tamper proof PVC material,
  - symbol label design according to ISO norm

Filter Specifications:

- Filter: BioR flex
- Filter made by melt-blown, non-woven, surface treated polyester material
- Neutral charge coated fiber surface
- Excellent wetting characteristic
- High biocompatibility
- Flexible, transparent housing with laser printed batch number
- Filter tested by 100% in-process control
- Performance (based on available data):
  - Leukocyte depletion: consistently averaging less than 0.5 x 10^5 residual leukocytes [1]
  - RBC recovery: averaging >90% [2]
  - Filtration time: consistently averaging less than 12 min [1-2]

Ordering information

For more information such as technical details and manuals, please contact your local sales representative. A variety of other configurations are available.

Article code	Product name	Storage Bag	Packaging	Special feature
AW00911	BioR flex BS PF	-	25 pcs/box	Bed side use
AS01910	BioR flex BBS	600 ml DEHP-PVC	25 pcs/box	Blood bank use
AS01912	BioR flex BBS BP	600 ml DEHP-PVC	25 pcs/box	Blood bank use and Bypass

Performance (based on available data)

- The Fresenius Kabi BioR flex filter has been tested with RCC from different production and storage conditions
- The validation results represented here are from eight different centers. In this validation 450/470/500 ml donated whole blood was processed with three most representative blood working conditions:
  - RCC from BC (CPD/SAG-M) stored 0-30 days before filtration
  - RCC from PRP (CPD/SAGM) stored 0-14 days before filtration.
  - RCC from PRP (CPDA-1) stored 0-14 days before filtration
- Overall data showed a capable leukocyte depletion efficiency irrespective of blood processing conditions. Statistical analysis confirmed a > 96% conformance with the European regulatory limit of 1 x 10^6/U (EDQM 20th ed., 2020)
- The mean filtration time is below 22 min. irrespective of working procedure for blood bank use products.
- This study has shown that RCC leukodepletion can be performed with Fresenius Kabi's RCC filter, BioR flex without any restrictions in pre-filtration conditions.

Overall validation results by working procedure

Procedure		BC (CPD/SAGM) (1)	PRP (CPD/SAGM) (2)	PRP (CPDA-1) (3)
		n = 126	n = 83	n = 34
PRE-FILTRATION				
Volume	(ml)	292 ± 24.7	355 ± 30.8	239 ± 23.8
Total Hb	(g/U)	60 ± 9.4	65 ± 7.4	57 ± 5.8
HCT	(%)	60 ± 4.4	55 ± 2.8	73 ± 3.6
Total WBC	(x 10^6/U)	867 ± 604	2256 ± 1025	1776 ± 599
Total PLT	(x 10^9/U)	7.6 ± 11.86	21.0 ± 16.72	17.3 ± 9.71
AT FILTRATION				
RCC age range	(days)	0 - 30	0 - 14	0 - 14
RCC unit Temp. range	(°C)	10 - 27	11 - 24	12 - 24
Filtration time	(mm.ss)	08.50 ± 03.54	10.38 ± 05.43	21.34 ± 12.20
POST-FILTRATION				
Volume	(ml)	258 ± 24.6	325 ± 30.9	207 ± 23.9
Total Hb	(g/U)	53 ± 9.0	60 ± 7.5	49 ± 5.4
HCT	(%)	60 ± 4.5	56 ± 5.8	74 ± 3.5
Total WBC (4)	(x 10^6/U)	0.02 ± 0.016 (79/106)	0.17 ± 0.179 (24)	0.12 ± 0.164 (7)
Total PLT (4)	(x 10^9/U)	2.3 ± 3.70 (94)	1.4 ± 0.81 (59)	2.4 ± 5.50 (27)
RBC Recovery	(% by weight)	88 ± 1.4	91 ± 1.9	87 ± 2.7

Data are reported as mean ± s.d.
(1) RCC from BC removal procedure (CPD/SAG-M)
(2) RCC from PRP procedure (CPD-SAG-M)
(3) RCC from PRP procedure (CPDA-1)
(4) Number of non-detects are reported within brackets

It is recommended to avoid bedside filtration when the patients are under treatment with ACE inhibitors, since they are more exposed to the risk of hypothensive reaction.

This product contains DEHP (Bis(2-ethylhexyl) phthalate), a plasticizer suspected to be toxic for reproduction. Repeated or prolonged treatment with this or other DEHP-containing products of children, pregnant or nursing women should, if possible, be avoided. Medical practitioners must assess the benefit of use against foreseeable risks.

This marking reflects compliance with the applicable CE Marking requirements for medical devices. CE 0123

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