FRESENIUS KABI
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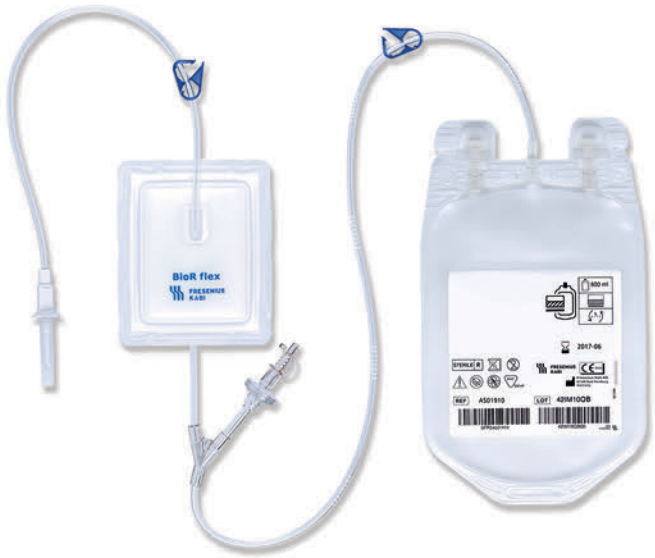
BioR flex Filter

Leucocyte 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
- DEHP-PVC 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:
  - Leukocyte depletion: consistently averaging less than 0.5 x 10^5 residual leukocytes [2]
  - RBC recovery: averaging >90%[3]
  - Filtration time: consistently averaging less than 12 min [4-5]

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
AW00910	BioR flex BS	-	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 data

- The new Fresenius Kabi BioR flex filter has been tested at different actual 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 (CPDA-1) stored 0-14 days before filtration and RCC from PRP (CPD/SAGM) stored 0-14 days before filtration.
- Overall data showed a capable leucodepletion efficiency irrespective of blood processing conditions. Statistical analysis confirmed a > 96% conformance with the European regulatory limit of 1 x 10^6/U.
- The mean filtration time is below 22 min irrespective of working procedure.
- This study has shown that RCC production by all conditions 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)	PRP (CPDA-1)	PRP (CPD/SAGM)
		n = 126	n = 34	n = 83
PRE-FILTRATION				
Volume	(ml)	292 ± 24.7	239 ± 23.8	355 ± 30.8
Total Hb	(g/U)	60 ± 9.4	57 ± 5.8	65 ± 7.4
HCT	(%)	60 ± 4.4	73 ± 3.6	55 ± 2.8
Total WBC	(x 10^6/U)	867 ± 604	1776 ± 599	2256 ± 1025
Total PLT	(x 10^9/U)	7.6 ± 11.86	17.3 ± 9.71	21.0 ± 16.72
AT FILTRATION				
RCC age range	(days)	0 - 30	0 - 14	0 - 14
RCC unit Temp. range	(°C)	10 - 27	12 - 24	11 - 24
Filtration time	(mm.ss)	08.50 ± 03.54 (4)	21.34 ± 12.20	10.38 ± 05.43 (5)
POST-FILTRATION				
Volume	(ml)	258 ± 24.6	207 ± 23.9	325 ± 30.9
Total Hb	(g/U)	53 ± 9.0	49 ± 5.4	60 ± 7.5
HCT	(%)	60 ± 4.5	74 ± 3.5	56 ± 5.8
Total WBC(1)	(x 10^6/U)	0.02 (2) ± 0.016 (79)	0.12 ± 0.164 (7)	0.17 ± 0.179 (24)
Total PLT(1)	(x 10^9/U)	2.3 ± 3.70 (94)	2.4 ± 5.50 (27)	1.4 ± 0.81 (59)
RBC Recovery	(% by weight)	88 ± 1.4	87 ± 2.7	91 ± 1.9 (3)

Data are reported as mean ± s.d.
(1) Number of non-detects are reported within brackets
(2) n = 106 & Post-filtration total WBC for BC (CPD/SAGM)
(3) RBC recovery for PRP (CPD/SAGM)
(4) Filtration time for BC (CPD/SAGM)
(5) Filtration time for PRP (CPD/SAGM)

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