

P-CAPT™

PRION CAPTURE FILTER FOR LEUCODEPLETED RED CELL CONCENTRATES



Globally, over 90 million blood units are collected annually and MacoPharma is committed to providing solutions that safeguard this blood supply.

The P-Capt™ Prion Capture Filter is a new innovative dockable filter for the removal of prions from leucodepleted red cell concentrates (RCC) to reduce the risk of transmission of variant Creutzfeldt-Jakob disease (vCJD) through blood transfusion.

vCJD and Bovine Spongiform Encephalopathy (BSE) are both part of a family of diseases called Transmissible Spongiform Encephalopathies (TSE). vCJD was initially transmitted to humans by the consumption of BSE contaminated meat, but a secondary route of transmission by the transfusion of blood units from asymptomatic vCJD individuals threatens to increase the prevalence of this fatal disease. Transmission of TSE infections through blood transfusion from asymptomatic blood donors has been demonstrated in animals and several suspected cases of transmission of vCJD by blood transfusion from blood donors incubating vCJD have recently been reported in humans. Leucodepletion has been shown to remove only 42% of the total TSE infectivity¹.

Thus, while leucodepletion is necessary to remove the infectivity associated with WBCs (cell associated) there is a necessity to remove the remaining non-cell associated infectivity.

EFFICACY OF PRION REMOVAL

The prion removal ability of the P-Capt™ Prion Capture Filter is:

- > 99.9 % [$> 3 \log_{10}$] reduction of exogenous brain spike infectivity in red blood cell concentrates²
- > 90% [$> 1.2 \log_{10}$] reduction of endogenous whole blood infectivity (to the limit of detection of the hamster bioassay model)³.

QUALITY OF RED CELL COMPONENTS

- Red cell units stored in SAGM and CPD/plasma have been treated using the P-Capt™ Prion Capture Filter and stored to outdate.
- RBC quality was maintained following 42 day storage of RBC in SAGM and 28 day storage of RBC in CPD/plasma⁴.
- The results were within the UK "Red Book"⁵ and Council of Europe Guidelines⁶. No effect on complement or coagulation factor activation has been observed and no platelet activation identified.
- Prion binding capacity is not affected by different anticoagulants and additive solutions; CPD, ACD-A, CPD-50, Adsol, SAGM.

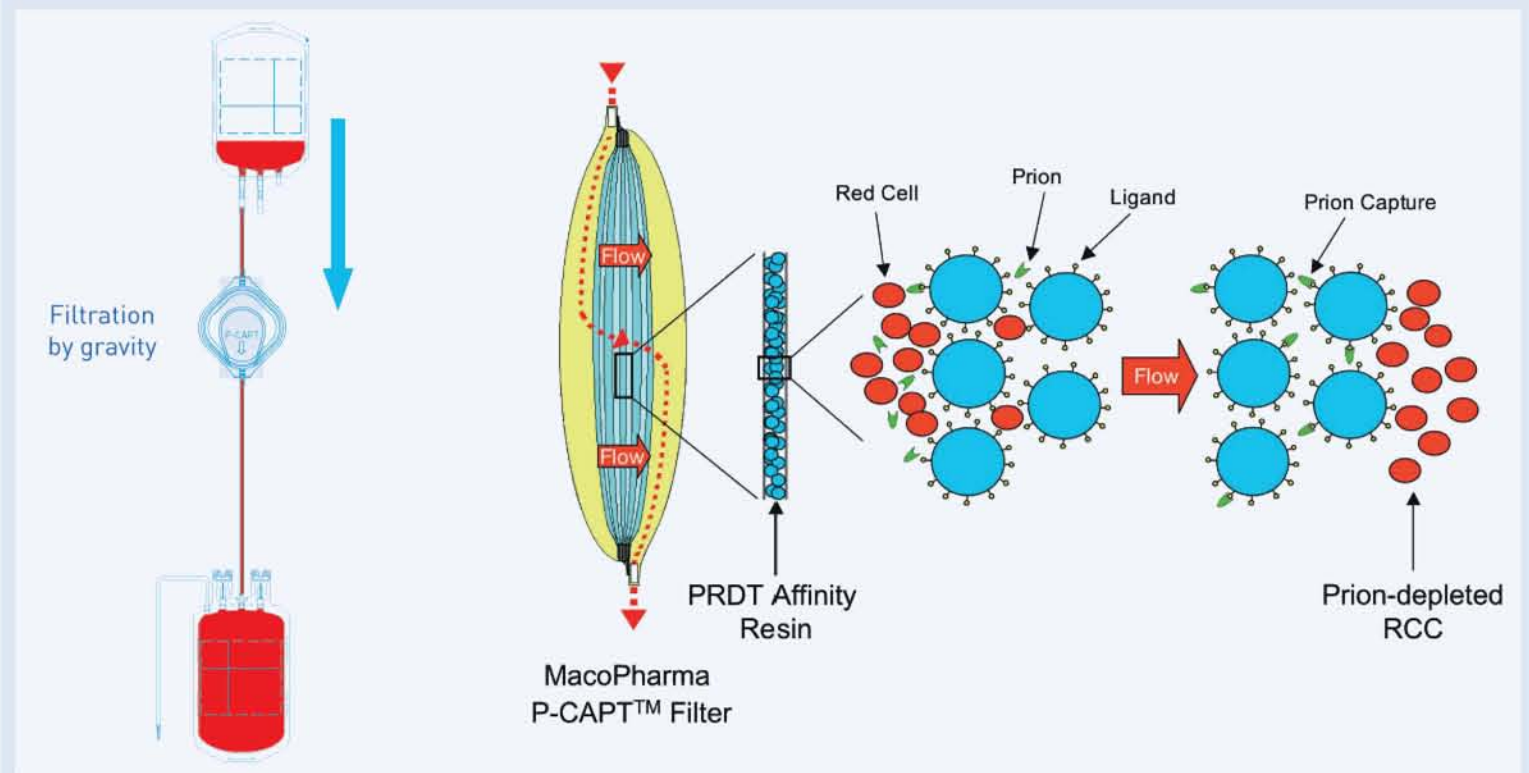
PRINCIPLE

The P-Capt™ Prion Capture Filter is a prion specific filter incorporating PRDT * patented ligand technology for the selective adsorption of prions in leucodepleted red cell concentrates suspended in additive solution or plasma.

The filter is a wet filter containing 40ml SAGM for optimal filter performance.

- Ligands specific for prion are covalently attached to resin
- The resin is in turn incorporated between nonwoven media
- The media is integrated and placed in an outer PVC housing to form the P-Capt™ filter
- Blood is passed through the filter resulting in prion removal.

* Pathogen Removal and Diagnostic Technologies





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TRACEABILITY

By producing the complete prion reduction system (both bags and filters), MacoPharma can ensure:

- Maximal traceability on each system
- Optimal filter traceability in each batch of packs
- Individual traceability on each filter through a unique number.



FLEXIBILITY

MacoPharma offers maximum flexibility:

- **Flexible housing**
The unique MacoPharma PVC flexible housing is the ideal material for dockable red cell prion filtration:
 - Single step sterilisation of the complete system (bags and filters)
 - Absolute integrity of the filter after steam sterilisation guaranteed
 - Ease of use during processing.
- **Flexible process conditions:**
 - Prion filtration is carried out at ambient temperature after leucodepletion on Day 0 or Day 1 after overnight hold at +4°C.
- **Compatibility:**
 - Compatible with sterile connection systems.

BIBLIOGRAPHY

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4. Manuscript in preparation. Poster presentation during the 24th BBTS Annual Scientific Meeting in Bournemouth, 21-23 September 2006.
5. Guidelines for the Blood Transfusion Services in the United Kingdom "Red Book". 7th Edition, October 2005. Published by TSO.
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www.macopharma.com

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