**Selective Plasma Exchange with Evaclio™ EC-4C**

~Reduced loss of coagulation factors~

**ANCA-associated Vasculitis**

**Myasthenia Gravis**

**Drug Toxication**

**Toxic Epidermal Necrolysis**

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**Specification**

<table>
<thead>
<tr>
<th>Plasma Separator Evaclio</th>
<th>EC-4C20</th>
<th>EC-4C10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hollow fiber</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>Ethylene-vinyl alcohol co-polymer</td>
<td></td>
</tr>
<tr>
<td>Inner diameter</td>
<td>175 µm</td>
<td></td>
</tr>
<tr>
<td>Wall thickness</td>
<td>40 µm</td>
<td></td>
</tr>
<tr>
<td><strong>Housing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>Polycarbonate</td>
<td></td>
</tr>
<tr>
<td>Membrane surface area</td>
<td>2.0 mL</td>
<td>1.0 mL</td>
</tr>
<tr>
<td>Outer dimension</td>
<td>57 φ x 280 L mm</td>
<td>45 φ x 280 L mm</td>
</tr>
<tr>
<td>Priming volume</td>
<td>Approx. 150 mL</td>
<td>Approx. 82 mL</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Gamma-ray irradiation</td>
<td></td>
</tr>
</tbody>
</table>

**Note**

- Please read instructions carefully before using the product.
- Evaclio™ is a trademark of KAWASUMI LABORATORIES, INC.
**What is Evaclio?** Membrane plasma separator with unique permeability

Evaclio is a membrane separator with smaller pore size than conventional plasma separators. It allows small and medium molecular weight proteins to be removed, while retaining large molecular weight proteins.

**Molecular weight**

- **Small**
  - Polymers
  - Urea (60kDa)
  - Creatinine (113kDa)
  - Cytokines (4,000-30,000)
- **Large**
  - Complement (176kDa)
  - Fibrinogen (340kDa)
  - IgG (90kDa)
  - Immune complex (90kDa)
  - LDL cholesterol (35nm)

**Evaclio™ EC-4C**

**Sieving Coefficient**

Evaclio EC-4C has sieving coefficient “0” for fibrinogen. It can remove IgG and lower weight molecules, while retaining fibrinogen in patients’ blood.

**Flow diagram & setting (example)**

**Operating procedure**

- Treatment volume: 1-1.5 plasma volume
- Setting of TMP alarm: 150mmHg
- QB: 80-1000mL/min
- QF < QB x 30%

**Potential indications**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Target substance</th>
<th>Molecular weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgG antibody related autoimmune disorders (e.g. ANCA-associated Vasculitis / Myasthenia Gravis / Pemphigus Vulgaris / Bullous Pemphigoid)</td>
<td>IgG antibody, Cytokines</td>
<td>160,000, 8,000 – 30,000</td>
</tr>
<tr>
<td>Toxic Epidermal Necrolysis (Steven-Johnson syndrome)</td>
<td>soluble Fas-ligand, Cytokines</td>
<td>26,000 (in trimer), 8,000 – 30,000</td>
</tr>
<tr>
<td>Recurrent Focal Segmental Glomerulosclerosis</td>
<td>Causative Factors</td>
<td>30,000 – 50,000</td>
</tr>
<tr>
<td>Drug Toxication</td>
<td>Causative drug (with molecular weight smaller than albumin)</td>
<td>&lt;66,000</td>
</tr>
</tbody>
</table>

**Selective Plasma Exchange (Selective PE)**

Selective Plasma Exchange using the Evaclio EC-4C retains more coagulation factors than conventional plasma exchange, therefore the use of FFP is unlikely to be required. The potential problems with conventional plasma exchange as shown below can be eliminated by using selective PE.

**Problems**

- Risk of infection or allergic reaction,
- High dose of acid citrate,
- Loss of coagulation factors and other useful substances

**Clinical effectiveness**

Selective PE was performed for 17 patients with MPO-ANCA associated vasculitis.

- (2 times/week, average 3.6 times/patient)
- MPO-ANCA level decreased an average of 81% (Fig.1).
- Reduction of fibrinogen was less than DFPP or IAPP (Fig.2).
- Selective PE can be performed with albumin solution for substitution fluid.
- Selective PE may be a safe and effective treatment taking into consideration of the risk of infection or bleeding tendency.