HDx THERAPY ENABLED BY THERANOVA

The new HDx therapy (expanded HD) is the next evolution in hemodialysis, as it effectively targets the removal of large middle molecules. Indeed, many of them are linked to the development of inflammation, cardiovascular disease, and other co-morbidities in dialysis patients. Not only can HDx therapy provide HDF performance and beyond in the removal of middle and larger middle molecules, it does so using regular HD workflow and infrastructure.

The HDx therapy is enabled by the THERANOVA* dialyzer featuring an innovative membrane that combines a higher permeability than regular high-flux dialyzers with effective selectivity for large proteins.

HDF PERFORMANCE AND BEYOND, AS SIMPLE AS HD³

- Markedly greater clearances and intradialytic reduction ratios for middle molecules than regular HD — at ordinary blood flow rates
- Equivalent removal of small and conventional middle molecules to high-volume HDF — Greater removal possible for larger middle molecules
- Albumin removal limited to between 1 and 4 grams
- Compatible with any HD monitor and with standard dialysis fluid quality

SIEVING PROFILE CLOSER TO THE NATURAL KIDNEY

An innovative membrane and dialyzer design that combines:

- High permeability to middle molecules
- Effective selectivity by size exclusion
- Augmented internal filtration
- Similar retention of endotoxins as other dialysis membranes of the same material

TYPICAL PATIENT PROFILE: PATIENTS BELIEVED TO BENEFIT FROM GREATER REMOVAL OF LARGER UREMIC TOXINS

* Do not use THERANOVA dialyzers in HDF or HF mode
The theranova® Dialyzer

COMPONENTS | MATERIALS
---|---
Membrane | Polyarylethersulfone / Polyvinylpyrrolidone
Potting | PUR
Housing, Header | Polycarbonate
Gasket | Silicon rubber
Protection Cap | Polypropylene

MEMBRANE

Membrane design | Asymmetric wall, 3-layer finger structure
Before blood exposure* |
MWCO (cut-off) [kDa] | 56 +/- 3
MWRO (reversal onset) [kDa] | 9.4 +/- 0.2
Effective Membrane Area [m²] | 2.0
Fiber Dimension | – Inner diameter [µm] 180
– Wall thickness [µm] 35
Sterilizing Agent | STEAM
Sterile Barrier | Medical Grade Paper

BLOOD COMPARTMENT

Blood Compartment Volume [ml] | 105
Residual Blood Volume [ml] | <1

DIALYSIS FLUID QUALITY REQUIREMENTS

Minimum Requirements | Standard Dialysis Fluid Quality
ISO 11663:2014 or ANSI/AAMI RD62 standard

PERFORMANCES*

UF-Coefficient [ml/(h*mmHg)] | 59
Pressure Drop – Blood Compartment [mmHg] |
Qb=200 | ≤ 80
Qb=300 | ≤ 120
Qb=400 | ≤ 160
Qb=500 | ≤ 200
Qb=600 | ≤ 240
Pressure Drop – Dialysate Compartment [mmHg] |
Qd=300 | ≤ 15
Qd=500 | ≤ 25
Qd=800 | ≤ 40

Sieving Coefficients* (%) |
Inulin (5.2 kDa) | 100
β-2-microglobulin (11.8 kDa) | 100
Myoglobin (17 kDa) | 90
Albumin (66.4 kDa) | 0.8

LIMITS FOR USE

Maximum TMP [mmHg] | 600
Operating blood flow range [ml/min] | 200-600
Operating dialysate flow range [ml/min] | 300-800

IN-VITRO CLEARANCES (at UF = 0 ml/min)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Qb/Qd</th>
<th>Ob/Od</th>
<th>ml/min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urea (60 Da)</td>
<td>200/500</td>
<td>199</td>
<td></td>
</tr>
<tr>
<td>Phosphate (95 Da)</td>
<td>400/800</td>
<td>381</td>
<td></td>
</tr>
<tr>
<td>Creatinine (113 Da)</td>
<td>400/800</td>
<td>365</td>
<td></td>
</tr>
<tr>
<td>Vitamin B12 (1.4 kDa)</td>
<td>200/500</td>
<td>169</td>
<td></td>
</tr>
<tr>
<td>Insulin (5.2 kDa)</td>
<td>200/500</td>
<td>139</td>
<td></td>
</tr>
<tr>
<td>Cytochrome C (12 kDa)</td>
<td>400/500</td>
<td>193</td>
<td></td>
</tr>
<tr>
<td>Myoglobin (17 kDa)</td>
<td>400/500</td>
<td>147</td>
<td></td>
</tr>
</tbody>
</table>

STORAGE CONDITIONS

Storage conditions | <30 °C; <86 °F


Do not use THERANOVA dialyzers in HDF or HF mode

For further information visit hdxtheranova.com