

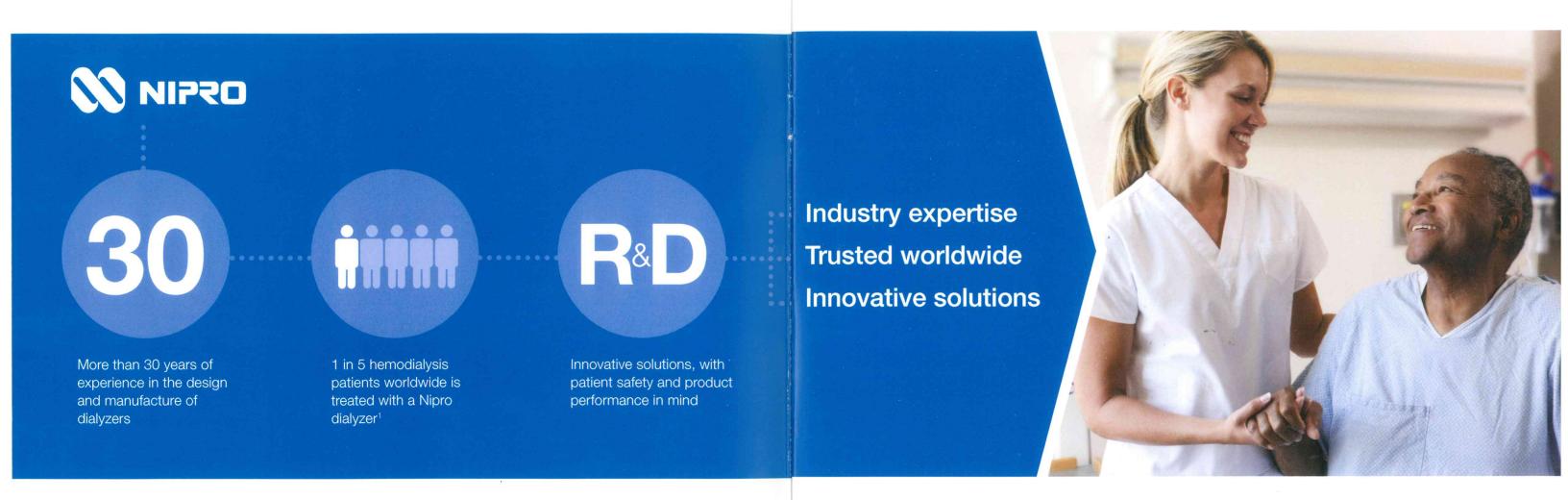


# Cellentia<sup>™</sup>-H

Cellulose triacetate, single-use, hollow-fiber, high-flux hemodialyzer Tree Max. True Box Parit Donne MIPZO

# Confidence

## from the inside out



Best known for its signature line of high-performance Elisio<sup>™</sup>-H dialyzers, Nipro also offers the Cellentia<sup>™</sup>-H single-use cellulose triacetate (CTA) dialyzer for hemodialysis patients with acute or chronic renal failure when standard therapy is judged to be inadequate.

### **Patient safety**

Nipro offers the only dialyzers in the U.S. market that are made without BPA and DEHP in any of the product components. This ensures patients receive treatment with a dialyzer that is safe and gentle while limiting the exposure to these well-known endocrine disruptors.<sup>2</sup>

In addition, the Nipro Cellentia dialyzer is designed with a CTA membrane, which offers a solution for treating patients who have difficulty tolerating standard hemodialysis filters made with polysulfone, polyethersulfone, or polyarylethersulfone.<sup>3</sup>

### **Proven performance**

Dialyzer membranes are important in the success of hemodialysis therapies and adequacy. Matching dialyzer performance to the patient needs is critical in meeting the prescribed clearance goals.<sup>4</sup>

As part of Nipro's commitment to quality, all of its dialyzers are designed to meet high performance membrane (HPM) standards. The HPM classification system is used to identify hollow-fiber dialyzers that deliver an advanced level of performance.<sup>5</sup>

# **Cellentia-H**

Every detail of the Cellentia dialyzer is designed to inspire confidence, from its internal membrane construction to its external housing.



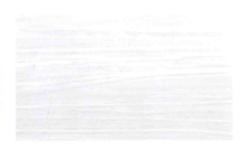
### Smooth mirror-like surface

Mirror finish on both ends of the hollow fibers optimizes blood rinse-back.6



#### **CTA** membrane

Cellulose triacetate is a thinner semisynthetic membrane material, which allows for optimized clearances.



#### Moire fiber structure

Crimp fiber allows homogeneous flow of dialysate, which enhances transmembrane solute passage.6



CTA membrane and housing are not made with BPA or DEHP, minimizing patient risk of endocrine disruption and related health issues.2



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BPA DEHP

## **NIPZO** CELLULOSE TRIACETATE HEMODIALYZER









1.5m<sup>2</sup> / Max.TMP 66kPa (500mmHg)

### **Excellent** biocompatibility

CTA membrane biocompatibility optimizes transmembrane solute passage and minimizes potential for adverse reaction in patients.7

### Dry gamma sterilization

Process optimized to reduce free radicals and enhance product safety.

### Four dialyzer sizes

Available in 15H, 17H, 19H, and 21H sizes to enable treatments tailored to patient needs while providing cost efficiencies.

### Specifications and in-vitro data

|  | Cellentia-15H          |            | Cellentia-17H                 |            | Cellentia-19H          |            | Cellentia-21H          |            |
|--|------------------------|------------|-------------------------------|------------|------------------------|------------|------------------------|------------|
| Product code                                     | DD+CT-C-15H            |            | DD+CT-C-17H                   |            | DD+CT-C-19H            |            | DD+CT-C-21H            |            |
| Surface area (m²)                                | 1.5                    |            | 1.7                           |            | 1.9                    |            | 2.1                    |            |
| CLEARANCE (mL/min) Blood (mL/min)                | 200 300 400 500        |            | 200 300 400 500               |            | 200 300 400 500        |            | 200 300 400 500        |            |
| Dialysate(mL/min)                                |                        |            |                               |            |                        |            |                        |            |
| Urea 500<br>800                                  | 195 265 315<br>338 383 |            | 198 273 326<br>353 402        |            | 198 277 337<br>364 417 |            | 199 281 344<br>372 430 |            |
| Creatinine 500<br>800                            | 187 246 280<br>307 335 |            | 191 258 294<br>323 358        |            | 193 266 306<br>336 374 |            | 195 273 315<br>345 390 |            |
| Vitamin B12 500<br>800                           | 133 150 163<br>174 183 |            | 142 162 177<br>190 201        |            | 149 175 190<br>205 218 |            | 154 184 203<br>218 234 |            |
| Phosphate 500<br>800                             | 183 224 252<br>273 301 |            | 186 234 264<br>289 319        |            | 189 242 277<br>303 335 |            | 192 250 285<br>316 350 |            |
| Ultrafiltration coefficient (mL/hr/mmHg)         | 41                     |            | 45                            |            | 48                     |            | 52                     |            |
| Priming volume (mL)                              | 87                     |            | 98                            |            | 110                    |            | 122                    |            |
| PRESSURE DROP  Blood (mL/min)  Dialysate(mL/min) | 200<br>500             | 500<br>800 | 200<br>500                    | 500<br>800 | 200<br>500             | 500<br>800 | 200<br>500             | 500<br>800 |
| Blood compartment (mmHg)                         | 65                     | 155        | 64                            | 152        | 63                     | 149        | 62                     | 145        |
| Dialysate compartment (mmHg)                     | 14                     | 22         | 15                            | 24         | 14                     | 22         | 14                     | 22         |
| Maximum blood flow rates (mL/min)                | 500                    |            | 500                           |            | 500                    |            | 500                    |            |
| Maximum dialysate flow rates (mL/min)            | 800                    |            | 800                           |            | 800                    |            | 800                    |            |
| Sieving coefficient (tested substances)          |                        |            | Urea<br>Creatinine<br>Albumin |            | 1.00<br>1.00<br><0.01  |            |                        |            |

### **Technical information**

Membrane polymer: Cellulose triacetate

Inner diameter: 200 microns
Membrane thickness: 15 microns
Maximum TMP: 500 mmHg
Header: Polypropylene
Housing: Polypropylene

**Potting compound:** Polyurethane **Sterilization:** Gamma irradiation

### In-vitro test conditions

Testing was performed in compliance with the evaluation standard for dialyzer performance called for by ANSI/AAMI ISO 8637.

- 1. Test solution temperature: 37° C
  Ultrafiltration rate: 10 mL/min
- 2. Ultrafiltration rate test solution: Bovine blood Hematocrit: 32%
- Priming volume (blood compartment) test solution: Water

- 4. Pressure drop: 50 mmHg transmembrane pressure
- Maximum blood flow: 500 mL/minMaximum dialysate flow: 800 mL/min
- Minimum blood flow: 200 mL/minMinimum dialysate flow: 500 mL/min

#### Sources

- 1 Data on file.
- 2 Manikkam M, Tracey R, Guerrero-Bosagna C, Skinner MK. Plastics Derived Endocrine Disruptors (BPA, DEHP and DBP) Induce Epigenetic Transgenerational Inheritance of Obesity, Reproductive Disease and Sperm Epimutations. PLOS ONE, 2013;8(1):e55387.
- 3 Sánchez-Villanueva R, González E, Quirce S, et al. Hypersensitivity reactions to synthetic haemodialysis membranes. Nefrología, 2014;34(4):520-525.
- 4 Azar, AT. Modelling and Control of Dialysis Systems: Dialyzer Performance Parameters. Springer Berlin Heidelberg, 2013;1:379-425.
- 5 National Kidney Foundation. A Clinical Update on Dialyzer Membranes: State-of-the-Art Considerations for Optimal Care in Hemodialysis. Clinical Bulletin, 2014.
- 6 Sunohara T, Masuda T. Cellulose triacetate as a high-performance membrane. Contrib Nephrol, 2011;173:156-63.
- 7 Liu S, Shi W, Liang X, et al. Cellulose Triacetate Dialyzer Reduces Platelet Loss during Continuous Veno-Venous Hemofiltration. Blood Puri, 2010;29:375-382.



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