



Prismaflex HF20 Set

Emergency Use Authorization for the United States

The Prismaflex HF20 Set has been Authorized by the FDA to provide continuous renal replacement therapy (CRRT) to treat low weight (8-20 kg) and low blood volume patients or patients who have acute renal failure, fluid overload, or both, and who cannot tolerate a larger extracorporeal circuit volume in an acute care environment during the Coronavirus Disease 2019 (COVID-19) pandemic.

The Prismaflex HF20 Set has neither been cleared or approved to provide CRRT in an acute care environment.

The Prismaflex HF20 Set has been authorized by FDA under EUA201769.

The Prismaflex HF20 Set is Authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the Prismaflex HF20 Set under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Intended Use for Patients

The Prismaflex HF20 Set is indicated for use only with the Prismaflex control unit or with the PrisMax control unit in providing continuous fluid management and renal replacement therapies in an acute care environment during the Coronavirus Disease 2019 (COVID-19) pandemic. The system is intended for patients with low weight (8-20 kg) and low blood volume or who cannot tolerate a larger extracorporeal circuit volume who have acute renal failure, fluid overload, or both.

Relative contraindications (individual risk/benefit to be determined by treating physician) for the use of Prismaflex HF20 Sets include:

- The inability to establish vascular access
- Severe hemodynamic instability
- Known hypersensitivity to any component of the Prismaflex HF20 Set

This set is intended for use in the following veno-venous therapies: Slow Continuous Ultrafiltration (SCUF); Continuous Veno-Venous Hemofiltration (CVVH); Continuous Veno-Venous Hemodialysis (CVVHD); Continuous Veno-Venous Hemodiafiltration (CVVHDF).

All treatments administered with the Prismaflex HF20 Set must be prescribed by a physician. The size, weight, metabolic and fluid balance, cardiac status, and general clinical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

Additional Product Information for the United States

To access COVID-19 Resources, product details, product use information, and the comprehensive Prismaflex Control Unit Operator's Manual and PrisMax Control Unit Operator's Manual that are also authorized to be used with the Prismaflex HF20 please visit the Baxter Healthcare Acute Therapies website at <http://www.renalacute.com>