FRESENIUS MEDICAL CARE

Press Release

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Fresenius Medical Care Brings Kidney Care Innovation to Critical Care Patients with U.S. Launch of multiFiltratePRO™

- Expands access to Fresenius Medical Care's globally established portfolio of advanced kidney replacement therapies in the U.S.
- FDA clearance of multiFiltratePRO and approval of dedicated solutions expand continuous kidney replacement therapy options for U.S. patients requiring treatment for acute kidney injury
- Integrated technology helps hospital intensive care teams deliver complex treatment simply and efficiently

Bad Homburg (October 21, 2026) – Fresenius Medical Care, the world's leading provider of products and services for people with kidney disease, today announced the U.S. launch of the multiFiltratePRO System for critically ill patients with acute kidney injury (AKI). multiFiltratePRO's integrated technology eliminates the need for separate citrate and calcium pumps, and automatically adjusts as treatment conditions change, making complex treatment easier for hospital intensive care teams to manage.

On October 19, 2026, the U.S. Food and Drug Administration (FDA) cleared the multiFiltratePRO System and approved Cienby™ (sodium citrate solution) and Calrezdy™ (calcium chloride solution) as the first continuous kidney replacement therapy (CKRT, also known as continuous renal replacement therapy, CRRT) system and dedicated solutions package available in the United States for on-label regional citrate anticoagulation (RCA) using the Ci-Ca Protocol. Cienby is an anticoagulant indicated for regional citrate anticoagulation (RCA) during continuous venovenous hemodialysis (CVVHD) or continuous venovenous hemodiafiltration (CVVHDF) in adults and pediatric patients weighing greater than or equal to 40 kg and Calrezdy is a source of calcium indicated for calcium substitution for regional citrate anticoagulation (RCA) during continuous venovenous hemodialysis

(CVVHD) or continuous venovenous hemodiafiltration (CVVHDF) in adults and pediatric patients weighing greater than or equal to 40 kg. The system is designed to support intensive care teams treating critically ill patients with acute kidney injury (AKI), a serious condition in which the kidneys lose their ability to filter waste from the blood.

The launch reflects Fresenius Medical Care's longstanding ability to identify, develop and scale innovative therapies across global markets. Most recently, the company introduced the 5008X™ CAREsystem in the United States, helping bring hemodiafiltration (HDF) to American patients, currently the standard of care in many parts of Europe and Asia-Pacific. With the introduction of multiFiltratePRO enabled with the Ci-Ca Protocol, Fresenius Medical Care is once again bringing a treatment approach already used in other parts of the world to healthcare providers and patients in the United States.

The multiFiltratePRO System features integrated citrate and calcium pumps that work with the Ci-Ca protocol to deliver RCA without the need for separate external infusion pumps. With the Ci-Ca protocol, citrate and calcium infusion rates automatically adjust to changes in blood and effluent flow, helping clinicians maintain protocol-defined ratios throughout therapy. For ICU teams, minimizing clotting during CKRT is an important part of delivering effective treatment. A multicenter randomized controlled trial reported that among critically ill patients with AKI receiving CKRT, anticoagulation with regional citrate, compared with systemic heparin anticoagulation, increased filter life span. The study was underpowered to draw definitive conclusions regarding mortality.[1]

"Fresenius Medical Care has a long history of bringing innovative kidney care solutions to patients around the world and making them available in new markets where they can have an even greater impact," said Joe Turk, Chief Executive Officer of Care Enablement at Fresenius Medical Care. "The introduction of multiFiltratePRO enabled with the Ci-Ca Protocol is another example of that commitment. As the first FDA-cleared continuous kidney replacement therapy (CKRT) system, designed to support regional citrate anticoagulation (RCA) during CVVHD and CVVHDF on-label use in the United States, it expands the options available to critical care teams while reinforcing our leadership in advancing kidney care innovation."

multiFiltratePRO will be showcased during ASN Kidney Week 2026 in Denver, where attendees can visit Booth 571 to view the system firsthand, engage with product experts and learn more about its role in supporting critically ill patients with acute kidney injury.

The U.S. launch will begin as a controlled rollout and move quickly to full availability.

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[1] Zarbock A, et al. JAMA. 2020;324(16):1629-1639. doi:10.1001/jama.2020.18618

INDICATION

CIENBY (sodium citrate solution) for extracorporeal use is an anticoagulant indicated for regional citrate anticoagulation (RCA) during continuous venovenous hemodialysis (CVVHD) or continuous venovenous hemodiafiltration (CVVHDF) in adults and pediatric patients weighing greater than or equal to 40 kg.

CONTRAINDICATIONS

CIENBY is contraindicated in patients with:

• known hypersensitivity to active substance

• severely impaired citrate metabolism.

IMPORTANT SAFETY INFORMATION

Hypocalcemia/Hypercalcemia

Due to its mechanism of action, CIENBY causes hypocalcemia. Severe hypocalcemia can lead to serious and life-threatening consequences including arrhythmia, cardiac arrest, seizure, and coma. Correct pre-existing hypocalcemia before initiating treatment with CIENBY to reduce the risk of clinically relevant hypocalcemia.

To prevent depletion of the patient's calcium stores due to calcium loss in the continuous kidney replacement therapy (CKRT) effluent fluid, a separate infusion of calcium in the post-filter (return) bloodline of the extracorporeal circuit is required during CKRT with CIENBY.

Hypercalcemia can occur in patients treated with CIENBY and calcium replacement infusion. Adjust calcium replacement infusion rates and CKRT settings as clinically indicated to maintain electrolytes within target ranges.

In patients undergoing prolonged RCA-CKRT, a decrease in calcium infusion requirements may indicate bone demineralization and parathyroid hormone (PTH) levels and bone turnover markers should be monitored to prevent spontaneous fractures.

Hypernatremia

CIENBY can cause hypernatremia. Use in combination with low-sodium fluids and monitor serum sodium concentrations regularly during and after use of CIENBY.

For patients with pre-existing severe hypo/hypernatremia, slowly correct serum sodium concentration according to physician discretion prior to treatment with CIENBY and consider an anticoagulation method other than RCA.

Hypomagnesemia

CIENBY chelates magnesium ions which can cause hypomagnesemia. Patients with pre-existing magnesium deficiency or those receiving medications known to lower magnesium levels (e.g., proton pump inhibitors) may be at increased risk for hypomagnesemia

with CIENBY. Monitor serum magnesium levels regularly during and after use of CIENBY. Supplementation with magnesium may be necessary.

Metabolic and Acid-Base Disturbances, including Citrate Accumulation

CIENBY can cause metabolic alkalosis or metabolic acidosis, depending on citrate accumulation or citrate insufficiency.

Metabolic Acidosis

In patients with hepatic impairment, shock, or other conditions associated with reduced citrate metabolism, citrate accumulation may occur, which can present as a progressive increase in the ratio of total calcium to ionized calcium, accompanied by metabolic acidosis and ionized hypocalcemia. Monitor acid-base status and calcium parameters frequently during CIENBY administration, especially in patients with hepatic impairment, shock, or other conditions associated with reduced citrate metabolism. Use the total calcium to ionized calcium ratio as a surrogate marker for citrate accumulation. Adjust citrate infusion rates and CKRT settings as clinically indicated based on ongoing monitoring.

Metabolic Alkalosis

Metabolic alkalosis may result from excessive conversion of citrate to bicarbonate in the liver. Use CIENBY in combination with low-bicarbonate fluids.

Drug Interactions

Avoid administration of calcium-containing solutions upstream of the filter as they may reduce the effect of CIENBY.

Overdosage

Excessive infusion causes acute hypocalcemia that may expose the patient to neurological and cardiac complications. In addition, metabolic alkalosis and hypernatremia could also occur due to an excessive amount of CIENBY. Immediately discontinue or lower the dose of CIENBY and administer intravenous calcium in patients with an overdosage.

The safety and effectiveness of CIENBY have not been established for RCA during CVVHD or CVVHDF in pediatric patients weighing less than 40 kg.

Elderly patients may be at risk of impaired citrate metabolism. Frequent monitoring to detect citrate accumulation is recommended.

The most common adverse reactions with CIENBY (incidence > 5%) are hypercalcemia, hypernatremia, hypocalcemia, and metabolic alkalosis.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Medical Care Renal Therapies Group, LLC at 1-800-323-5188 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information.

Dosage forms and Strengths: CIENBY 40 g/L sodium citrate (136 mmol/L citrate) is provided in bag with 1,500 mL clear, colorless solution.

INDICATION

CALREZDY (calcium chloride solution), for extracorporeal use is a source of Calcium indicated for calcium substitution for regional citrate anticoagulation (RCA) during continuous venovenous hemodialysis (CVVHD) or continuous venovenous hemodiafiltration (CVVHDF) in adults and pediatric patients weighing greater than or equal to 40 kg.

IMPORTANT SAFETY INFORMATION

Hyper/Hypocalcemia

Hypocalcemia and hypercalcemia can occur in patients receiving CALREZDY for RCA during continuous kidney replacement therapy (CKRT). Excess dosing with CALREZDY may result in hypercalcemia and insufficient dosing may result in hypocalcemia.

Hypocalcemia should be corrected prior to starting treatment. Patients with hypercalcemia prior to starting treatment should be initiated on a lower starting dose of CALREZDY and monitored closely.

During CALREZDY infusion, regularly check the systemic ionized calcium concentration and increase or decrease the dose as required.

The full effect of calcium dose changes, including calcium released from calcium-citrate chelate complexes, can lead to ionized hypercalcemia up to 12 hours or longer after treatment.
In patients with comorbidities affecting calcium metabolism or excretion (such as but not limited to nephrocalcinosis, hypercalciuria and overdose of vitamin D), monitor blood calcium levels more closely before, during, and after treatment.

Arrythmia and Hypotension

CALREZDY infusion during RCA may cause cardiac arrhythmias and decreased blood pressure. Electrocardiogram (ECG) monitoring during administration with CALREZDY is recommended. Synergistic arrhythmias may also occur if calcium and cardiac glycosides are administered together.

Local Clotting of Extracorporeal Circuit

When infused into the extracorporeal circuit, the site of CALREZDY infusion must regularly be inspected for signs of locally developing clotting. If observed, consider changing the extracorporeal circuit.

Drug Interactions

Cardiac Glycosides

Avoid coadministration of CALREZDY in patients receiving cardiac glycosides. Synergistic arrhythmias may occur with concomitant use. The use of calcium chloride may result in hypercalcemia which increases the risk of digoxin toxicity. If concomitant use is unavoidable, monitor ECG closely during administration of CALREZDY.

Calcium Channel Blockers

Administration of calcium may reduce the response to calcium channel blockers.

Drugs That Increase the Risk of Hypercalcemia

Increase frequency of monitoring of calcium concentrations in patients taking concomitant drugs that increase the risk of hypercalcemia (e.g., calcipotriene, estrogen, teriparatide, Vitamin A, and Vitamin D).

The safety and effectiveness of CALREZDY have not been established for calcium substitution in pediatric patients weighing less than 40 kg undergoing CVVHD or CVVHDF with RCA.

OVERDOSAGE

Overdosage of CALREZDY may lead to hypercalcemia. Symptoms of hypercalcemia typically develop when the total serum calcium concentration is > 3 mmol/L [12 mg/dL] or ionized calcium > 1.2 mmol/L [4.8 mg/dL], and include shortening of QT interval, bradycardia, hypertension, anorexia, nausea, vomiting, bowel hypomotility and constipation, muscle weakness, bone pain, decreased concentration, depression, weakness, fatigue, confusion, hallucinations, disorientation, hypotonicity, seizures, and coma. Hypercalcemia effects on kidney include diminished ability to concentrate urine and diuresis.

In the event of overdosage, promptly discontinue CALREZDY, and institute appropriate countermeasures.

The most common adverse reactions with RCA (incidence > 5%) are hypercalcemia, hypernatremia, hypocalcemia, and metabolic alkalosis.

Please see the full Prescribing Information.

Dosage Forms and Strengths: CALREZDY 14.7 g/L calcium chloride dihydrate (100 mmol/L calcium) is provided in a bag with 1,500 mL ready-to-use solution.

Indication for use

The multiFiltratePRO System is indicated for the following use: Continuous Renal Replacement Therapy (CRRT) with and without integrated regional anticoagulation for patients weighing 40 kilograms or more with acute renal failure with or without fluid overload. All treatments administered by the multiFiltratePRO System must be prescribed by a physician.

About Fresenius Medical Care:
Fresenius Medical Care is the world's leading provider of products and services for individuals with renal diseases of which around 4.5 million patients worldwide regularly undergo dialysis treatment. Through its network of 3,513 dialysis clinics, Fresenius Medical Care provides dialysis treatments for approx. 290,000 patients around the globe. Fresenius Medical Care is also the leading provider of dialysis products such as dialysis machines or dialyzers. Fresenius Medical Care is listed on the Frankfurt Stock Exchange (FME) and on the New York Stock Exchange (FMS).

For more information visit the company’s website at www.freseniusmedicalcare.com.

Disclaimer:
This release contains forward-looking statements that are subject to various risks and uncertainties. Actual results could differ materially from those described in these forward-looking statements due to various factors, including, but not limited to, changes in business, economic and competitive conditions, legal changes, regulatory approvals, results of clinical studies, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. These and other risks and uncertainties are detailed in Fresenius Medical Care's reports filed with the U.S. Securities and Exchange Commission. Fresenius Medical Care does not undertake any responsibility to update the forward-looking statements in this release.

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