July 30, 2026
NIPRO CORPORATION

NIPRO CORPORATION Receives FDA 510(k) Clearance for ELISIO™-HX, Introducing HDs to the United States

New medium-cutoff Dialyzer with a super high-flux membrane brings NIPRO's approach to expanded hemodialysis to United States healthcare providers.

Osaka, Japan – [July 30, 2026] — NIPRO CORPORATION has been granted 510(k) clearance for the ELISIO-HX dialyzer by the United States Food and Drug Administration (FDA), effective July 28, 2026. The clearance enables the introduction of HDs (Hemodialysis powered by super high-flux membrane) in the United States. HDs is NIPRO's approach within expanded hemodialysis (Expanded HD), providing healthcare professionals with a practical way to enhance hemodialysis while using existing dialysis infrastructure and established clinical workflows.

Expanded hemodialysis (Expanded HD) is an approach to hemodialysis designed to extend the removal of larger middle molecules beyond conventional high-flux dialysis. HDs combines the ELISIO-HX dialyzer with NIPRO's proprietary membrane technology, enabling enhanced middle molecule removal while remaining fully compatible with routine hemodialysis practice.

Hemodialysis remains the cornerstone of treatment for patients with end-stage kidney disease in the United States. Although treatment standards continue to evolve, there remains an ongoing need to improve the removal of a broader range of uremic toxins, including larger middle molecules that have been associated with chronic complications of kidney disease. ELISIO-HX has been developed to address this need through an approach designed for broad patient eligibility and straightforward integration into routine dialysis care.

Making expanded hemodialysis more accessible

At the core of HDs is the ELISIO-HX dialyzer, featuring NIPRO's proprietary super high-flux membrane technology. The membrane incorporates a highly controlled and precisely engineered pore structure that extends the removal profile of larger middle molecules while maintaining albumin retention, an important consideration in preserving patients' nutritional status.

This precision-engineered membrane design enables healthcare professionals to enhance dialysis treatment while remaining fully compatible with conventional hemodialysis systems. Because ELISIO-HX integrates into existing hemodialysis infrastructure and established clinical workflows, providers can adopt HDs without investing in new dialysis machines or fundamentally changing the way dialysis is delivered.

"Innovation creates its greatest value when it becomes accessible in everyday clinical practice," said Tsuyoshi Yamazaki, President & CEO of NIPRO CORPORATION. "Our ambition is to broaden the number of patients who can benefit from enhanced hemodialysis. With HDs, enabled by ELISIO-HX and our proprietary super high-flux membrane technology, healthcare professionals can enhance hemodialysis using the infrastructure and expertise they already have. FDA clearance represents an important milestone in bringing this approach to patients across the United States."

Building on global experience

The introduction of HDs to the United States market builds on clinical and real-world experience with ELISIO-HX across Japan, Europe and Latin America, demonstrating its applicability in a variety of healthcare settings.

"Our experience across multiple regions has shown that HDs can be successfully integrated into routine dialysis care," said Goichi Miyazumi, President of NIPRO's Medical Business Global Division. "Introducing ELISIO-HX in the United States represents another important step in making advanced dialysis technologies available to more patients while supporting healthcare professionals in delivering high-quality care."

Helping more patients benefit from expanded hemodialysis

The United States is home to one of the world's largest populations of patients receiving maintenance hemodialysis. FDA clearance of ELISIO-HX enables NIPRO to introduce HDs to this important market, providing dialysis providers with an additional approach within expanded hemodialysis that integrates seamlessly into existing models of care.

By combining proprietary membrane engineering with broad patient eligibility and compatibility across conventional hemodialysis systems, HDs enables healthcare providers to extend the benefits of expanded hemodialysis across a wide spectrum of patients without adding complexity to routine clinical practice.

With the 510(k) clearance, NIPRO will begin the commercialization of ELISIO-HX in the United States immediately. NIPRO will work closely with healthcare providers to support the successful introduction of HDs into routine clinical practice.

This milestone reflects NIPRO's commitment to developing practical solutions that help healthcare professionals deliver better care to more patients. By making enhanced dialysis care more accessible, we continue to contribute to our promise of helping people live longer and better lives.

Media Contacts:

Annick Somers / Global Marketing & Communications

Annick.Somers@nipro-group.com

David Reese / Americas Marketing & Communications

DavidRe@nipromed.com

News Release

NIPRO

This news release is meant to provide information on NIPRO's corporate activities and an overview of our initiatives to not only the press but also our many stakeholders, including shareholders and investors in a fair and timely manner.
The information about NIPRO products and services included in this release is not intended for use in attracting customers or as medical advice.