



Lyka[®] PORT Needle-Free Access Device for Hemodialysis

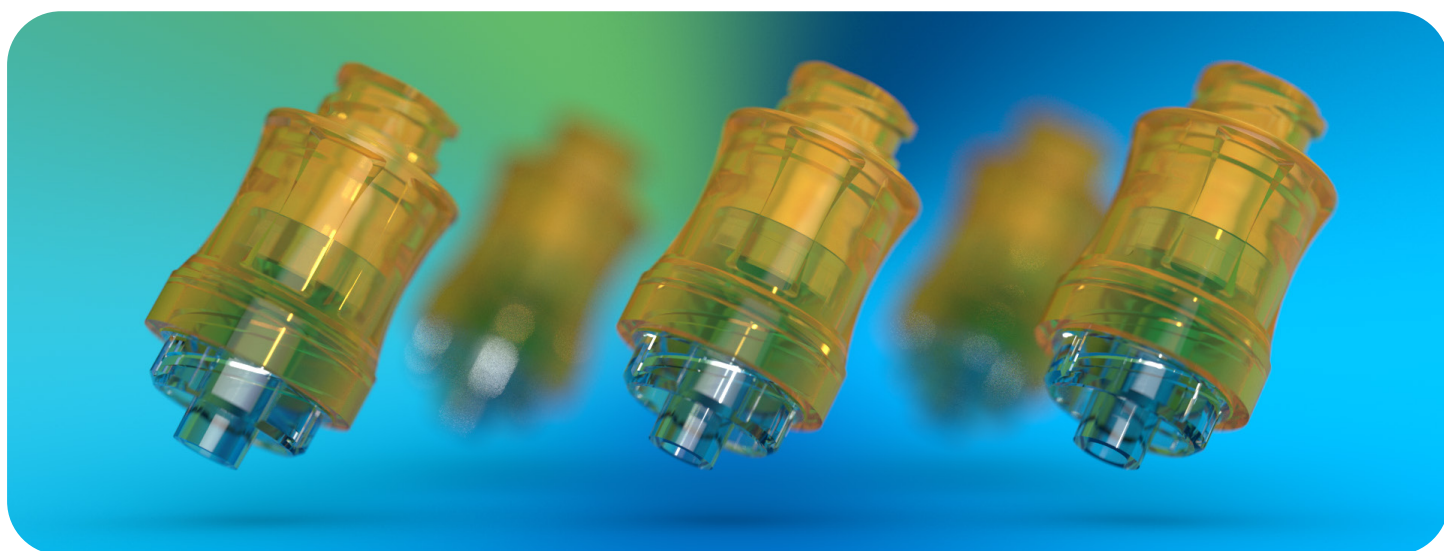
A NEW STANDARD IN PATIENT SAFETY
AND PERFORMANCE

Lyka® PORT Needle-Free Access Device for Hemodialysis:

A New Standard in Patient Safety and Performance

Introduction:

Vascular access is a critical component of hemodialysis therapy. The Lyka® PORT needle-free access device by Quest Medical, a Nordson MEDICAL company, is redefining standards in hemodialysis care.¹ Engineered for safety, durability, and clinical efficiency, the Lyka® PORT needle-free connector offers a robust alternative to traditional connectors like the Tego®. Validated for 7 days of continuous use with superior material compatibility and leak resistance, the Lyka® PORT needle-free access device is designed to meet the evolving needs of hemodialysis providers and patients. The Lyka® PORT addresses long-standing challenges in infection control, fluid dynamics, and device compatibility. Developed by Quest Medical, a Nordson MEDICAL company, a leader in medical device innovation for over 40 years, the Lyka® PORT needle-free access device is FDA 510(k) cleared and purpose-built for hemodialysis.



Key Features and Benefits:

Key features and benefits of the Lyka® PORT needle-free access device include:

- **High flow rate:** up to 600 mL/min for efficient hemodialysis.²
- **Straight fluid path:** reduces turbulence and improves flow consistency.
- **Approved for up to 7 days of continuous use:** validated for extended use without compromising safety.³
- **Low dead space:** minimizes clotting and residual medication.
- **Fully flushable:** enhances infection control by clearing the entire fluid path.
- **Translucent housing:** allows quick and easy visual checks.
- **Microbiological barrier:** provides protection against contamination.⁴
- **Needle-free access:** enables safe, needleless connection to hemodialysis lines, reducing the risk of needlestick injuries for healthcare workers and improving overall clinic safety.

Advantages of the Lyka® PORT Needle-Free Access Device

MATERIAL COMPATIBILITY

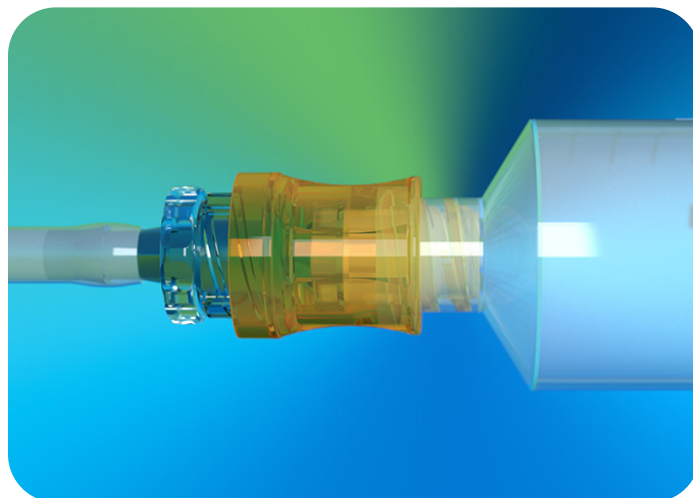
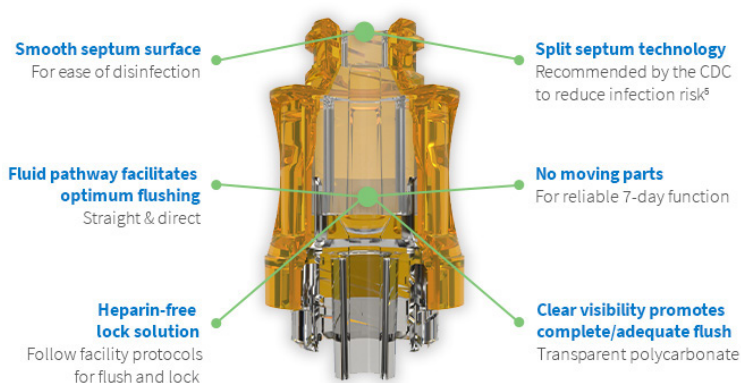
The Lyka® PORT needle-free access device is constructed from a hard, chemically resistant plastic that maintains its integrity after repeated disinfection. Unlike some connectors that become tacky or degrade over time, the Lyka® PORT needle-free connector retains its smooth surface.

RESISTANCE TO LEAKAGE

The rigid plastic body of the Lyka® PORT needle-free access device provides a secure and sealed fluid path, minimizing the risk of leakage and external contamination—an essential feature for infection prevention in high-risk hemodialysis environments. While competitor valves include soft outer sheaths that can tear, allowing leaks and breaching the integrity of the fluid path, the Lyka® PORT needle-free connector's hard plastic body protects the fluid path for the duration of treatment.

ROBUST CONNECTION

The Lyka® PORT needle-free connector features a fully-threaded, durable luer connection design that ensures a secure connection with vascular access devices. This robust threading reduces the risk of cross-threading or accidental disconnection during treatment.



Advantages of the Lyka® PORT Needle-Free Access Device *(continued)*

VALIDATED FOR HEMODIALYSIS DURATION

The Lyka® PORT needle-free access device is validated for use as a physical and microbial barrier for up to 7 days, eliminating the need for replacement after every treatment. The Lyka® PORT's long duration of use represents a critical advantage for hemodialysis patients who require consistent, long-term vascular access.

NEEDLE-FREE ACCESS

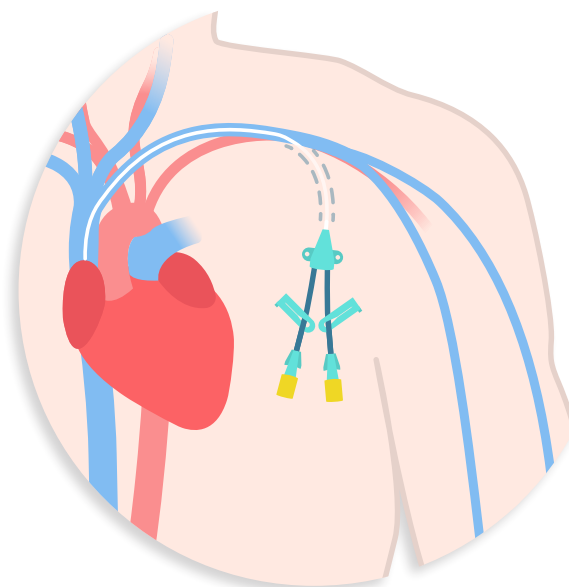
The Lyka® PORT enables safe, needle-free connection to hemodialysis lines, significantly reducing the risk of needlestick injuries for healthcare workers and improving overall clinic safety.

INFECTION CONTROL

The Lyka® PORT needle-free access device utilizes split septum technology with low dead space, and is fully flushable to reduce infection risk. The CDC recommends split septum valves over mechanical valves in needleless systems to reduce infection risk. The Lyka® PORT features a split septum with low dead space and an open fluid path, delivering ultra-high flow rates and enhanced safety for hemodialysis patients⁵. This design is clinically preferred over alternative valve designs, which have been associated with higher infection rates. The septum is securely contained in the body of the connector, preventing problematic leaks and occlusions due to mobility issues seen in competitor valves. By minimizing internal complexity and allowing full flushability, the Lyka® PORT needle-free access device supports best practices in infection prevention.

SUMMARY

The Lyka® PORT needle-free access device offers a clinically validated, high-performance alternative to traditional connectors like the Tego®. With its superior material durability, infection control features, needle-free access, and compatibility with standard disinfecting caps, the Lyka® PORT needle-free access device is engineered to support safer, more effective hemodialysis care.



References

1. FDA 510(k) Cleared for use with vascular access devices in hemodialysis
2. Data on file.
3. Data on file.
4. Data on file.
5. O'Grady et al., CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011.