kpNext® MDR1

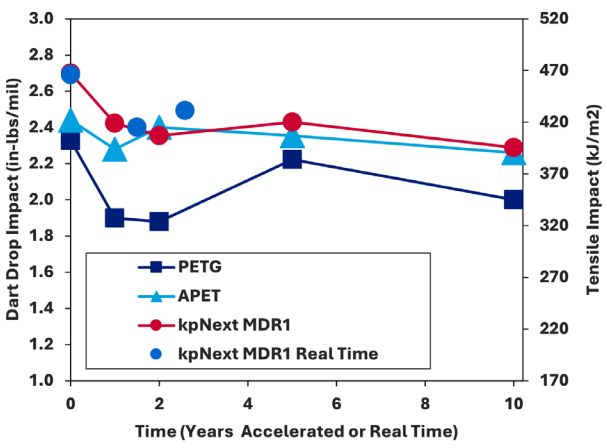
The Next Generation of Medical Device Packaging

kpNext® MDR1 is a copolyester sheet designed to offer medical device manufacturers exceptional protection, optical clarity, and processing performance while being compatible with the RIC #1 PET recycling stream. To enhance supply chain reliability, kpNext® MDR1 is produced using dual-sourced, highly available resins and is supported by multiple manufacturing sites. This redundancy ensures consistent material availability, reducing the risk of supply chain disruptions and promoting uninterrupted production continuity, ultimately supporting improved patient outcomes and greater accessibility to quality healthcare.

- **Processing:** Engineered as a drop-in alternative to traditional materials.
- **Mechanical Properties:** Excellent impact resistance characteristics.
- **Sterilization:** Compatible with EO, E-Beam, Gamma methods.
- **Clarity:** Outstanding clarity, equivalent to traditional materials.
- **Sustainability:** Designed to be recycled in the RIC #1 recycling stream.

Equivalent Protection and Performance

kpNext® MDR1 matches or exceeds traditional materials in key performance areas such as thermoformability, impact resistance, shelf stability, clarity, sterilization compatibility, and sealability to coated Tyvek® lidding. It is specifically designed for recyclability in the RIC #1 stream, supporting sustainability without compromising performance.

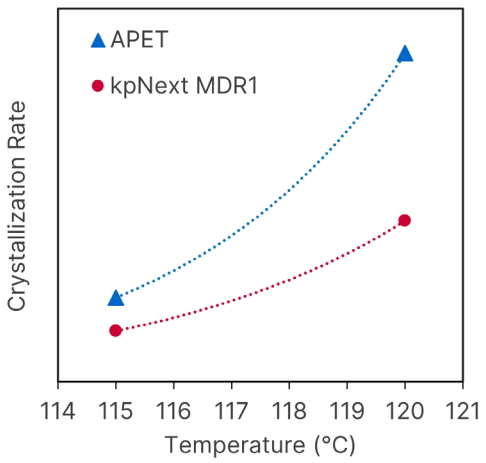


Graph 1. Aging performed in accordance with ASTM F-1980 at 50°C, ambient humidity. Tests performed on 20mil film.

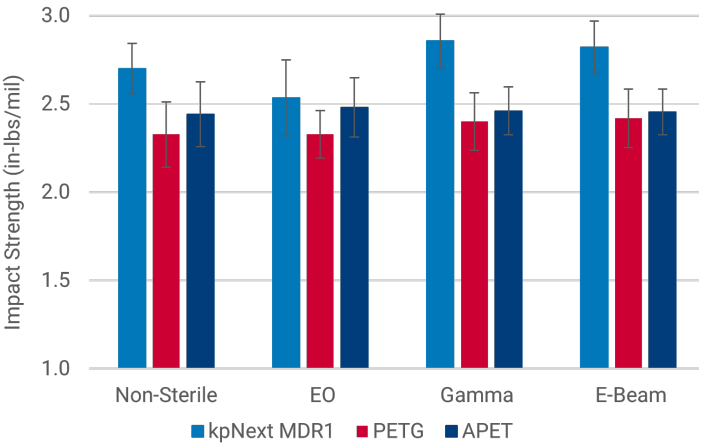
kpNext® MDR1 has undergone rigorous testing under both standard ISO protocols and real-world conditions to ensure a seamless transition to sustainable packaging. Complying with ISO 11607-1 for terminally sterilized medical packaging and ISO 10993-5 for biocompatibility, it meets the stringent demands of medical device packaging.

A key advantage of kpNext® MDR1 is its optimized crystallization rate. Although crystallization at elevated temperatures is necessary for APET recycling, kpNext® MDR1's reduced crystallization rate provides a wider thermoforming window, minimizes brittleness from overheating, and reduces scrap rates. This leads to

greater temperature control flexibility, increased productivity, and less waste compared to standard APET.



Graph 2. Data generated by isothermal Differential Scanning Calorimetry (DSC).



Graph 3. Dart-drop impact resistance characteristics pre- and post-sterilization methods.

kpNext® MDR1 has undergone thorough testing for long-term packaging stability, including pre- and post-sterilization evaluations of impact strength, color, haze, and seal performance. Across common sterilization methods—Ethylene Oxide (EtO), Gamma, and E-Beam — kpNext® MDR1 retains its mechanical properties and optical clarity, with no significant degradation. Accelerated aging studies per ASTM F-1980 confirm kpNext® MDR1's ability to maintain its impact resistance, color stability, and seal strength over time, meeting ISO 11607-1 requirements for maintenance of sterile barrier in medical packaging.

Critical Properties for Rigid Medical Packaging				
Property	**Method**	**Pentamed® APET**	**Pentamed® PETG**	**kpNext® MDR1**
Forming Range	DMA	105-125°C	105-135°C	105-130°C
Impact Resistance	ASTM D1790	2.4 in-lbs/mil	2.3 in-lbs/mil	2.6 in-lbs/mil
Elastic Modulus	ASTM D882	2399 MPa	2083 MPa	2069 MPa
Haze	ASTM D1003	3%	3%	3%
Sealability (Coated Tyvek)	ASTM F-88	4 N/m^2	4 N/m^2	4 N/m^2
Sterilization Compatibility	ISO 11607-1	EtO, Gamma, e-Beam	EtO, Gamma, e-Beam	EtO, Gamma, e-Beam
Sustainability	ASTM D-7611	RIC #1 Compatible	--	RIC #1 Compatible

Comprehensive Medical Compliance

The reliability of packaging for medical device manufacturers and its direct impact on patient outcomes, particularly in ensuring long-term maintenance of the sterile barrier, are critical considerations in the design and validation of kpNext® MDR1. This medical packaging solution has undergone extensive testing to meet the stringent requirements outlined in ISO 11607 and ISO 10993, ensuring compliance in key areas such as shelf life stability, cytotoxicity, and biocompatibility.

kpNext® MDR1 is manufactured using FDA food-contact compliant materials and is registered in the FDA Medical Device Master File (MAF #240), reflecting Klöckner Pentaplast's dedication to regulatory compliance and product safety. In line with Klöckner Pentaplast's commitment to providing high-quality, reliable, and processable materials, kpNext® MDR1 represents the latest advancement in the Pentamed® medical packaging portfolio, combining best-in-class performance with a forward-looking focus on sustainability for next-generation medical packaging solutions.

Pentamed® Medical Packaging Portfolio				
Medical Standards and Support	**kpNext® MDR1**	**Pentamed® PETG**	**Pentamed® APET**	**Compliance**
Packaging for terminally sterilized medical devices (ISO 11607-1)	✓	✓	✓	Products comply with all applicable sections of ISO 11607-1
Biological evaluation of medical devices (ISO 10993-5)	✓	✓	✓	Products comply with and have been tested for compliance with ISO 10993-5 for in-vitro cytotoxicity.
Quality systems and GMP	✓	✓	✓	KP Quality systems comply with cGMP and ISO 9001 requirements for the design, development, manufacture, and supply of polymers.
U.S. FDA Drug Master Files (DMF)	✓	✓	✓	Products are registered with the FDA in the Klockner Pentaplast Medical Device Master File. (MAF #240)
U.S. FDA Food Contact Compliant	✓	✓	✓	All raw materials used to manufacture products are FDA compliant and suitable for food contact.

Maximizing Sustainability and Recyclability in Medical Packaging

kpNext® MDR1 was developed with a strong focus on both sustainability and performance. It is fully compatible with the RIC #1 recycling stream, and has been certified with a Class A recyclability rating by RecyClass®. By eliminating materials of concern and adhering to widely recognized recyclability guidelines (American Society for Testing and Materials (ASTM) and the Association of Plastic Recyclers (APR), kpNext® MDR1 supports the industry's sustainability goals while delivering optimal packaging performance.

Recyclability is determined by a material's chemical composition and thermal properties, which must be compatible with established mechanical recycling processes. These processes include sortation, granulation, washing, sink/float separation, crystallization, and solid-state polymerization, among others. Each of these steps is necessary to ensure the material's successful reintegration into the polymer supply chain without loss of functionality.

kpNext® MDR1 represents a significant step forward in medical device packaging, providing manufacturers with a high-performance, sustainable alternative that meets the most stringent regulatory standards while ensuring supply chain continuity.