KYDEX® THERMOPLASTICS FOR MEDICAL DEVICES, DIAGNOSTIC EQUIPMENT, AND MEDICAL FURNITURE



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INTRODUCTION

The Affordable Healthcare Act has compelled acute care hospitals to change the way they operate. Reimbursements are now based upon patient outcomes, infection prevention, and patient satisfaction. With more challenging requirements and tighter budgets, products need to last longer. KYDEX® sheet lives up to the demanding needs that medical care facilities face with medical devices, diagnostic equipment, and medical furniture. In addition to changing regulatory requirements, patient expectations have evolved as well.

Patients expect to receive care in a clean, warm, and welcoming environment. Medical facilities are challenged to source materials that are aesthetically pleasing and able to withstand daily wear and cleaning requirements. KYDEX® Thermoplastics meet or exceed regulatory compliance and safety standards and are ideal for medical devices, diagnostic equipment, and furniture used in medical environments.

This material guide highlights the benefits of the following materials in medical environments:

- KYDEX® T is a general purpose material with great impact resistance, UL 94 V-0, chemical resistance, and bio-compatibility.
- KYDEX® 100 has similar characteristics as KYDEX® T, but provides higher impact resistance and may offer improved UV stability.
- KYDEX® 110 is primarily used for aesthetic accents. It shares many of the same properties as KYDEX® T, but offers a "metallic" finish and lower impact resistance than KYDEX® T.
- KYDEX® 430 is used when IEC 60695-10-2 Ball Pressure testing is a requirement.

KYDEX® T SHEET

KYDEX® T is a proprietary thermoplastic sheet that is a substitute for ABS/PVC (FR-ABS) with competitive pricing offering superior performance. KYDEX® T offers significantly greater resistance to chemicals and cleaning solutions. It has superior impact strength, with more uniform forming, less wall-thinning, and does not require pre-drying. KYDEX® T meets the UL 94 Std for V-0 and 5V in all thicknesses and is perfect for medical products and equipment housings.





KYDEX® T is available in many different colors and textures for all of your medical equipment needs.

KYDEX® 100 SHEET

KYDEX® 100 is a super tough and durable proprietary PVC/Acrylic thermoplastic sheet designed for medical products and equipment housings. It is available in a wide range of custom colors, textures, and sheet sizes. KYDEX® 100 meets UL Std 94 V-0, 5V and has 961 J/m (18 ft-lbs/in) notched izod impact resistance. No matter the part geometry KYDEX® 100 sheet is good for deep or hard to form parts and will form beautifully offering design flexibility.





KYDEX® 100 is similar to KYDEX® T but offers higher impact resistance.

KYDEX® 110 METALLIC SHEET

KYDEX® 110 metallic fire-rated sheet is a tough alloy sheet offering outstanding formability, rigidity, chemical resistance, and fire retardancy. It is available in a wide range of metallic colors including silver, copper, bronze, and others to replace metal housings and meets the UL 94 Std for V-0 and 5V in all thicknesses. KYDEX® 110 is ideal for deep or hard to form parts where good finished detail is required.





KYDEX[®] 110 is available in a variety of metallic colors to replace metal housings.

KYDEX® 110 Liquid Metals



Fire-rated sheet for thermoforming and membrane pressing.

KYDEX® 430

KYDEX® 430 is an ABS/PVC proprietary thermoplastic sheet designed specifically for medical device housing applications. It is available in a wide range of colors and textures. KYDEX® 430 meets the UL 94 Std for V-0 and 5V in all colors and thicknesses. KYDEX® 430 passes the IEC 60695-10-2 ball pressure test and the ISO 10993 Bio-compatibility test.





KYDEX® 430 is a proprietary ABS/PVC blend developed specifically for medical device housing applications.

KYDEX® 430 for Medical Device Enclosures



KYDEX® 430 is available not only in this color palette developed for the medical device industry, but in any color you need.

KYDEX® SHEET MEDICAL APPLICATIONS

KYDEX® Thermoplastics are ideal for these medical applications:

- · Diagnostic Imaging MRI, MRA, CT, Nuclear & Molecular Imaging, Ultrasound
- Patient Monitoring Anesthesia Machines, Operating Tables
- · Medical Equipment Housings
- · Mobile Carts
- · Patient Beds, Footboards, Headboards
- · Orthotics and Prosthetics
- Table and Tray Furniture
- · Ceiling Panels
- Protective Wall Coverings
- · Blood Analyzers
- · Laboratory Equipment Liquid Assay Systems, Genome Sequencers
- · Autoclave Equipment
- · Patient Headwall Systems
- Overbed Tables
- Stretchers
- · Surgical Robots
- Lifts
- Syringe Collection Boxes
- Examination and Dental Chair Trays and Backs
- · Drawer and Door Fascias

Table 1. KYDEX® Thermoplastics for Medical Device Applications Comparison

Product	Thickness	Textures	Fabrication Methods	Meets UL Std 94 V-0,5V (in all thicknesses)	Meets IEC 60695-10-2 (Ball Pressure Test)	ISO 10993 Bio-Compatible
KYDEX® T High-impact fire-rated sheet, alternative to ABS	.028"400" (.7mm - 10.2mm)	P1, P3, PK, P8, PA, PC, PE	Thermoform Membrane Press Flat Lamination	√	-	Certified
KYDEX® 100 High-impact fire-rated sheet	.028"400" (.7mm - 10.2mm)	P1, P3, P8, PC, PE	Thermoform Membrane Press Flat Lamination	√	-	Certified
KYDEX® 110 Metallic fire-rated sheet with excellent durability, can replace metal housings	.028"250" (.7mm - 6.4mm)	P3, PK, P8, PE	Thermoform Membrane Press Flat Lamination	√	-	Compliant
KYDEX® 430 ABS/PVC blend specifically for medical device housing applications with special medical color palette	.028"400" (.7mm - 10.2mm)	P1, P3, P8, PC, PE	Thermoform	√	✓	Certified

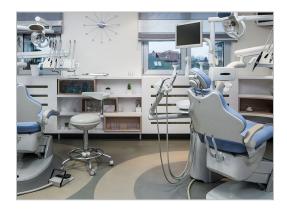
Note: Pearlescent (KYDEX® XD03) and Woodgrain (KYDEX® XDWG material options are also available.

KYDEX® Thermoplastic sheet is an excellent choice for applications where appearance, toughness, and chemical resistance is required.

DISINFECTANTS AND CHEMICAL REAGENTS

SEKISUI KYDEX, manufacturers of KYDEX® Thermoplastics support the medical device industry by providing products that stand up to the daily rigors of medical facilities, strong disinfectant cleaners and harsh chemicals. In today's medical environment, the use of aggressive cleaning agents and disinfectants is critical in eliminating surface bacteria and viruses to reduce the risk of infection. These chemical reagents have been known to have an adverse effect on materials, causing discoloration, brittleness, and/or product failure. KYDEX® Thermoplastics are made from a robust blend of polymers that stand up to harsh disinfectants and cleaners.

SEKISUI KYDEX has conducted testing on KYDEX® T, KYDEX® 100, and KYDEX® 430 using the ASTM D543 standards. These stringent tests include: stressed tensile bar, submersion, continuous contact and wipe downs. KYDEX® T, KYDEX® 100, and KYDEX® 430 have been shown to meet or exceed the test requirements for evaluating the resistance of plastics to chemical reagents. Test results are shown in Table 2. Disinfectants and Chemical Reagents Testing.





KYDEX® Thermoplastics stand up to many disinfectants and chemical reagents.

Table 2. Disinfectants and Chemical Reagents Testing

Cleaner	Manufacturer	Active Technology	
CIDEZYME® GI Enzymatic Detergent	Advanced Sterilization Products	Subtilisin (proteolytic enzymes)	
ENZOL® Enzymatic Detergent	Advanced Sterilization Products	Subtilisin (proteolytic enzymes)	
Ball-Phene	Ball	Phenolic	
Clorox® Disinfecting Spray	The Clorox Company	Quaternary ammonium compounds	
Dispatch® Hosptial Cleaner Disinfectant Towels with Bleach	The Clorox Company	Sodium hypochlorite	
Sporicidin Disinfectant Solution	The Clorox Company	Buffered phenol	
Sporicidin Disinfectant Towelette	Contec	Buffered phenol	
Citrusolve Cleaner Degreaser	Lawrason Inc.	d'Limonene	
MediClean EZ™	Medivators	Subtilisin (proteolytic enzymes)	
Rapicide™	Medivators	Glutaraldehyde	
Rapicide PA®	Medivators	Peracetic acid	
CaviCide™ AF	Metrex Research, LLC	Quaternary ammonium compounds	
CaviWipes™ Bleach	Metrex Research, LLC	Sodium hypochlorite	
Caviwipes™	Metrex Research, LLC	Quaternary ammonium compounds	
Caviwipes1 [™]	Metrex Research, LLC	Quaternary ammonium compounds	
PDI Sani-Cloth AF3 Germicidal Disposable Wipe	Professional Disposables International, Inc.	Quaternary ammonium compounds	
Lysol® Brand Disinfectant Concentrate	Reckitt Benckiser, LLC	o-Benzyl-p-chlorophenol	
Professional Lysol® Brand Disinfectant Spray	Reckitt Benckiser, LLC	Quaternary ammonium compounds	
Hepacide Quat II	Spartan Chemical Company, Inc.	Quaternary ammonium compounds	
CIP 100®	Steris Corporation	Potassium hydroxide (alkaline-based)	
CIP 200®	Steris Corporation	Phosphoric acid/citric acid (acid-based)	
CIP 220®	Steris Corporation	Glycolic acid (acid-based)	
Coverage Plus NPD	Steris Corporation	Quaternary ammonium compounds	
Environ® LpH® st	Steris Corporation	Phenolic	
LpH® se	Steris Corporation	Phenolic	
Spor-Klenz®	Steris Corporation	Hydrogen peroxide/ peroxyancetic acid	
Vesphene II SE	Steris Corporation	Alkaline phenolic	
DECON-CYCLE	Veltek Associates, Inc.	Phenolic	
DECON-PHENE	Veltek Associates, Inc.	Phenolic	

Results: The results of the testing confirmed that KYDEX® T, KYDEX® 100, and KYDEX® 430 are not affected by any of these cleaners and disinfectants.

Conclusion: SEKISUI KYDEX, LLC's KYDEX® Thermoplastics stand up to a range of hospital-grade disinfectants and cleaners without loss of surface finish, color fastness, or degradation of mechanical and physical properties

Source: SEKISUI KYDEX

ANTI-FUNGAL AND ANTI-MICROBIAL PROPERTIES

KYDEX® sheet resists bacteriological and fungal growth, which makes it ideal for use in medical facilities and medical device housings. KYDEX® sheet contains no plasticizers, which are additives found in most plastics that provides a nutrient source for microbial growth. Since it does not contain a nutrient source, KYDEX® sheet performs very well in bacterial and fungal growth tests.

KYDEX® sheet was subjected to fungus resistance testing in accordance with ASTM G-21. A combination of 5 common fungi were cultured for 18 days, combined and incubated on KYDEX® sheet samples for 28 days. After 28 days, the KYDEX® sheet samples showed no fungal growth.

ASTM G-22 bacterial resistance testing, procedure B was performed on KYDEX® sheet. KYDEX® sheet was subject to a common bacterium (ATCC 13388) for 21 days. KYDEX® sheet allowed no bacterial growth.

These test results show that KYDEX® sheet has exceptional performance when exposed to bacteria and fungus without the addition of an anti-microbial additive. For additional test information see TB-120-C.

DURABILITY

KYDEX® sheet is highly durable to resist impact from moving hospital beds, equipment, and gurneys. KYDEX® 430 passes the IEC 60695-10-2 ball pressure test and its durability works well in equipment housings as well as wall covering and countertops. Figure 1 shows notched izod impact data for KYDEX® T and Std. FR-ABS.

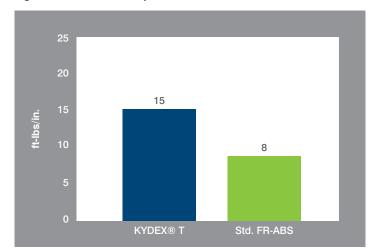


Figure 1. Notched Izod Impact Resistance of KYDEX T® and Std. FR-ABS

Source: SEKISUI KYDEX

THERMOFORMING

KYDEX® sheet is a highly thermoformable plastic sheet which can be used to duplicate intricate part geometries usually seen only in injection molding. It has excellent forming properties, which results in uniform wall thicknesses and crisp detail. KYDEX® sheet forms to deep draws with low forces when heated to the upper end of the forming temperature range and forms more consistently than other thermoplastics resulting in fewer rejected parts. KYDEX® sheet can be drape, vacuum, and pressure formed. These methods result in increased levels of detail.





KYDEX® Thermoplastics form easily into intricate geometries.

COLOR

KYDEX® T is available in a large range of colors and textures. The KYDEX® 430 color palette was designed specifically for the medical device industry and KYDEX® 110 is available in a metallic palette to mimic traditionally used metal housings. Pearlescent (KYDEX® XD03) and woodgrain (KYDEX® XDWG) material options are also available. SEKISUI KYDEX also offers designLab® which can formulate almost any color needed.

Most manufacturers of plastic sheet require large minimums or even truckload quantities for custom colors. SEKISUI KYDEX can make most custom colors with a minimum production run of just 600 pounds; and since they formulate their colors in-house, they have short lead times.

In addition to a wide variety of colors, KYDEX® sheet is available in eight different surface textures. The surface textures pared with color throughout the thickness of each sheet help hide scratches due to wear and tear on medical devices and equipment at busy facilities.

Infused Imaging™ is a new technology that was recently developed by SEKISUI KYDEX where custom images are imbedded into the polymer. Unlike printing, which creates images on the top surface of a sheet material, Infused Imaging™ technology penetrates deeply into the surface, which results in extremely durable, abrasion-resistant graphics. Virtually any image that you can imagine can be infused into KYDEX® sheet.





KYDEX® sheet is available in many different colors and textures with color consistent throughout the thickness of each sheet. Custom colors can be easily produced with low minimum orders and short lead times.

RoHS DIRECTIVE

The RoHS directive is often referred to as "lead-free" legislation. The proper name for RoHS is Directive 2002/95/EC (RoHS1), 2011/65/EU (RoHS2) and 2015/863 (RoHS3), which are Restrictions of Certain Hazardous Substances in Electrical and Electronic Equipment. SEKISUI KYDEX does not utilize any of the substances listed in this directive, KYDEX® sheet products are in compliance. The RoHS Directive is a European Union directive.

SUMMARY

For medical device, diagnostic equipment, and medical furniture manufacturers looking for material solutions that can withstand the daily rigors of busy medical facilities, this line of KYDEX® thermoplastic products is your answer. These materials are durable, chemical resistant, and provide a wide range of design and forming options with the availability of virtually any color and texture.

For more information on KYDEX® Thermoplastics or to obtain color and texture samples, contact Curbell Plastics at 1-888-287-2355.

ABOUT THE AUTHOR

Liz Grimes is a Senior Business Development Manager for Curbell Plastics, Inc. She has a Bachelor of Science Degree in Chemistry and over 30 years of experience in the plastics industry. Liz has expertise with a wide variety of polymer materials including acrylic, polycarbonate, and KYDEX® Thermoplastics. Her work at Curbell involves collaborating with customers to solve technical problems and develop new plastic part applications.

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TECHNICAL EXPERTISE

Curbell white papers are intended to provide engineers and designers with basic information about the engineering polymers available as sheet, rod, tube, and film stock from Curbell Plastics. We invite you to contact Curbell to discuss applications in detail.

ABOUT CURBELL PLASTICS

For over 75 years, Curbell Plastics has been one of the nation's leading providers of plastic sheets, rods, tubes, and films, as well as fabricated parts, adhesives, and prototyping materials. Our customers range from small local businesses to large Fortune 500 companies and government agencies. We partner with organizations in dozens of industries, including aerospace, pharmaceutical, machinery manufacturers and sign fabricators. At Curbell, we understand the unique demands of each market and we have the expertise to help you meet your business needs. Whether your objective is to reduce manufacturing costs, improve productivity, or increase product reliability, Curbell can help.

OUR CAPABILITIES

Our branch network includes sales and warehouse locations throughout the United States. We offer a number of value-added services including custom cutting, fabrication, packaging, and kitting, as well as warehousing for just-in-time delivery. With Curbell, you get the plastics you want and the peace of mind you need, from technical support and design assistance at the earliest stages of product design, through production and aftersale support for each product we sell.

PUT US TO WORK FOR YOU

At Curbell, we are committed to providing the highest level of service to our customers. We recognize the urgency of customer needs, and we pride ourselves on providing quick and proactive solutions. Our tag line says it all – we appreciate the opportunity to earn your business and we invite you to "Put us to work for you."

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