EASTMAN

Designing for manufacturability, cleanability, and serviceability

Early engagement with Eastman accelerates commercialization of your projects.

WHAT TO ASK

Key questions for design phase

- **What bar of disinfection will be required?**
  Based on the expected use of this device, (e.g., is *C. diff* a risk? If so, it needs to stand up to bleach.)
- **What is the anticipated life of the device?**
- **During that time, how often is it likely to be cleaned/disinfected?**
  Multiple times a day? Weekly? Monthly?
- **Are there materials available that are more durable to repeated exposure to disinfectants?**
  Test those materials.
- **What is the cost of repairs/replacement vs. incremental material/design costs** to enable easy cleaning and disinfection?

Natus housing features easy-to-clean curved edges and touchscreen panel.

WHAT TO AVOID

Design element choices may hinder the cleaning and disinfecting process.

- **Sharp edges**
  A torn glove can be life threatening!
- **Grooves**
- **Places where disinfectants can pool**
- **Very thin parts**
- **Knobs/buttons that protrude**
  Touchscreens and membrane keypads are preferred.
- **Texture**
  Some surface texture improves grip, but too much holds bacteria and is hard to clean.
- **Paint**
  Paint gets damaged over time and starts to look bad.
- **Hard-to-clean designs**
  Think about how the part will be cleaned before finalizing the design—then try to clean the prototype yourself.

Eastman Design Services assistance

- Part design critiques
- Mold design assistance
- End-use testing
- Failure analysis
- Secondary operations
- Mold-filling simulation (Moldflow®)
- 3D design (SolidWorks)
- Structural finite element analysis (SolidWorks-Cosmos)
- Material characterization/specialized testing

Contact info

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Pantone Color of the Year 2018 | PANTONE Ultra Violet
Ultra Violet communicates originality, ingenuity, and visionary thinking that points us toward the future.

4-step test results

Materials	Control (joules)	DISINFECTANTS						
		Diversey Virex® TB (ether, benzyl quat)	Clorox Healthcare® Bleach Germicidal Wipes (germicidal hypochlorite)	Clorox Healthcare® Multi-Surface (IPA quat)	Clorox Healthcare® Hydrogen Peroxide (H_2O_2 cleaner)	PDI Sani-Cloth® AFIII (benzyl quat, DPG ether)	PDI Super Sani-Cloth® (IPA quat)	PDI Sani-Cloth® Plus (IPA benzyl quat)
		% RETENTION OF IMPACT ENERGY TO BREAK						
Eastman Tritan™ MX711 copolyester	4.3	75 ± 26	89 ± 1	92 ± 4	95 ± 5	109 ± 3	101 ± 3	114 ± 1
Eastman Tritan™ MX731 copolyester	4.3	65 ± 24	96 ± 5	98 ± 5	99 ± 5	104 ± 2	100 ± 2	116 ± 1
Eastman MXF221 copolyester	5.2	94 ± 2	95 ± 2	92 ± 3	98 ± 1	93 ± 4	83 ± 1	96 ± 3
PC/PBT	5.3	8 ± 3	98 ± 2	57 ± 45	94 ± 2	9 ± 2	91 ± 8	16 ± 2
PC/polyester	5.5	6 ± 1	6 ± 2	91 ± 12	23 ± 1	5 ± 0	75 ± 28	8 ± 2
PC/ABS 1	6.8	15 ± 1	70 ± 21	84 ± 13	97 ± 2	20 ± 3	16 ± 1	71 ± 22
PC/ABS 2	6.6	Break on jig	102 ± 1	64 ± 21	69 ± 32	6 ± 1	42 ± 37	5 ± 0
PVC	4.5	19 ± 2	19 ± 0	45 ± 36	56 ± 32	46 ± 36	18 ± 2	100 ± 0

% Retention

≥ 80% ≥ 60% < 60%

EASTMAN

The results of **insight**™

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It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

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