EASTMAN

Health care-associated infections (HAIs) and chemical resistance

How they impact design and performance of medical devices

Medical devices must not only keep pace with advances in technology—they must adapt to the increased use of aggressive disinfectants.

A medical device only safeguards patients and saves lives if it works.

In today's health care environment, it is becoming more common to see medical devices that don't work satisfactorily. They are unable to do their job—or fail prematurely—because of environmental stress cracking (ESC) or other defects resulting from exposure to disinfectants and other chemicals.

With a focus on patient safety, today's health care is more motivated than ever to prevent HAIs. This trend drives not only hospitals but also the growing number of ambulatory and outpatient settings. Reduced reimbursements for patients who are readmitted because of HAIs provides even more motivation to use stronger disinfectants—and use them more often.

The good news: HAI control efforts are achieving positive results. Thanks to improved hygiene and aggressive disinfection and sterilization protocols, the Centers for Disease Control and Prevention (CDC) HAI Progress Report describes significant reductions for nearly all infections.[1]

The bad news: These aggressive disinfectants, disinfectant wipes, and sterilization take a high toll on devices molded with traditional polymers. Brand owners are addressing this challenge by using polymers with a higher level of chemical resistance. The selection of these high-performance materials early in the design process is one of the most critical considerations for the future of patient safety.[2]

See inside …

What are HAIs?

A health care-associated infection (HAI) is a patient infection that is not present or incubating at the time of admission. It often includes infections that appear after the discharge date.

These infections occur during treatment either in a hospital or another health care setting—and can occur either in a patient or a health care worker. Nonhospital settings include:

- Outpatient settings such as ambulatory surgical centers or dialysis facilities
- Long-term care settings such as nursing homes, rehabilitation centers, or home health care

The most serious HAIs involve "superbugs," such as methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), and *Clostridium difficile (C. diff).*

[1] "Healthcare-associated Infections (HAI) Progress Report." Centers for Disease Control and Prevention. Website. Updated 23 Mar. 2015. Available at http://www.cdc.gov/HAI/progress-report/index.html. Accessed 22 July 2015.

[2] "Devices Safeguard Patient Safety Only When They Work." Web blog post. *Medical Design Technology.* 16 Mar. 2015. Available at http://www.mdtmag.com/blogs/2015/03/devices-safeguard-patient-safety-only-when-they-work. Accessed 31 July 2015.

How HAIs increase the cost of medical care

In addition to the value of patient safety and the cost in human lives, HAIs add costs to the health care industry through:

- Increased mortality and morbidity
- Longer hospital stays
- Reduced reimbursements for hospitals with excess readmissions—which are considered hospital mistakes

In 2009, Medicare (through the Centers for Medicare and Medicaid Services [CMS]) began refusing to pay for some readmissions resulting from HAIs. Beginning in 2012 as part of the Affordable Care Act, CMS's readmissions reduction program has been lowering reimbursements to hospitals with excess readmissions, including HAIs. Beginning October 1, 2014, hospitals face an additional 1% reduction in Medicare reimbursement payments if their HAI-related readmission rate is within the top quartile (25%) of all applicable hospitals relative to the national average.[3]

The need for more powerful disinfectants

In collaboration with the CDC, CMS concluded that five types of HAIs are preventable when proper disinfection and aseptic clinical protocols are followed. They are:

- Catheter-associated urinary tract infections (CAUTI)
- Surgical site infections (SSI)
- Central line-associated bloodstream infections (CLABSI)
- *Clostridium difficile (C. diff)* infections (CDI)
- Ventilator-associated pneumonia (VAP)

The top CDC recommendations to prevent HAIs are available in a fact sheet at http://www.cdc.gov/HAI/pdfs/hai/top-cdc-recs-factsheet.pdf.[4]

Hospitals are preventing these infections through diligent environmental cleaning and sterile protocols. Often, they rely on frequent use of isopropyl alcohol (IPA), IPA + chlorhexidine, bleach, and other aggressive chemical disinfectants. Many applications require sterilization with ethylene oxide (EtO) or gamma irradiation, especially to control pathogens that are resistant to traditional disinfectants.

The increased use of chemicals creates opportunities for them to attack the appearance, performance, and life cycle of many classes of medical devices.

[3]42 CFR Parts 405, 412, 413, etc. Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS). *Fed Reg.* 79:163 (22 Aug 2014) p. 49864.

[4]Healthcare-Associated Infections (HAIs): Top CDC Recommendations to Prevent Healthcare-Associated Infections. Website page. Available at http://www.cdc.gov/HAI/prevent/top-cdc-recs-prevent-hai.html. Accessed 24 Aug 2015.

Chemical resistance at work—medical infusion devices

Medical infusion devices provide good examples of the wide range of ways chemical resistance can protect aesthetics, clarity, performance, and life cycle of the device.

- They must withstand constant exposure to blood and lipids.
- Multiuse devices are repeatedly cleaned with aggressive disinfectants.
- Catheter hubs and connectors that have near-patient or skin contact are frequently disinfected, which can lead to cracking or clouding.
- Device housings are exposed to the stresses of repeated handling—especially multiport devices.

Device housings are soaked with disinfectants, which dull device finishes and break down the protective housing, leading to shorter useful lives for pumps and monitors and lower quality perceptions from patients and health care purchasing.

- Infusion devices are exposed to an increasing number of harsh oncology drugs and their carrier solvents.
- In devices requiring assembly or secondary operations, chemical compatibility with bonding solvents and adhesives is important.
- A premium is placed on devices that do not shift color or lose functionality following sterilization with EtO or gamma irradiation.

Testing polymers for chemical resistance

Engineered polymers have gained popularity by offering many advantages over other material options, including design and color flexibility, aesthetic appeal, lightweight and portability, toughness, corrosion resistance, and clarity.

When determining which polymer offers the properties you need, consider chemical resistance as a function of three factors:

1. The polymer used in the device
2. The chemical(s) contacting the device
3. The stress applied to the device

Polymers that have a low level of compatibility with a chemical can become brittle prematurely, exhibit ESC, and fail under stress.

Tables 1, 2, and 3 present the results of three studies comparing the chemical resistance of common clear polymers. Each study uses a three-step testing method, illustrated at right, where flex bars molded from different polymers were exposed to various disinfectants for 24 hours while being held under 1.5% strain. After exposure, the flex bars were impacted with a pendulum hammer to measure the energy required to break them.

Comparisons of impact property retention for clear parts when exposed to chemical disinfectants (Table 1) and common disinfectant wipes (Table 2) follow.

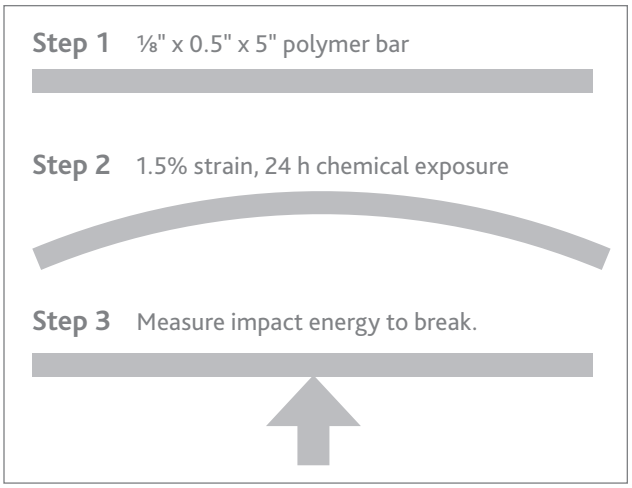

Table 1— Residual property evaluation: *Impact properties vs. chemical disinfectants*

Chemical	Control (joules)	Povidone-iodine 10% (iodine)	Wonder Woman (IPA)	Envirocide (IPA, EG ether)	CaviCide (IPA, EG ether)	SPOR-KLENZ (hydrogen peroxide)
		% Retention of impact energy to break				
Eastman Tritan™ copolyester MX711 (standard)	4.3	103	103	110	108	96
Tritan MX731 (high flow)	4.3	91	101	100	106	101
PC (high flow)	5.3	113	78	55	53	104
PC (standard)	5.4	114	31	7	32	103
PC (lipid resistant)	5.5	116	79	76	78	108
Impact modified styrenic	4.3	66	42	110	89	90

■ > 80% retention ■ > 60% retention ■ < 60% retention

Table 2— Residual property evaluation: *Impact properties vs. chemical disinfectant wipes*

Chemical	Control (Joules)	Sani-Cloth AF III (benzyl quat, DPG ether)	Sani-Cloth HB (benzyl quat)	Virex TB (benzyl quat, DEG ether)	Vesphene II SE (phenolics)	Decon disinfectant (phenolics)
		% Retention of impact energy to break				
Eastman Tritan™ copolyester MX711 (standard)	4.3	109	112	75	47	14
Tritan MX731 (high flow)	4.3	104	109	65	37	21
PC (high flow)	5.3	4	65	All broke on jig.	All broke on jig.	All broke on jig.
PC (standard)	5.4	3	34	All broke on jig.	All broke on jig.	All broke on jig.
PC (lipid resistant)	5.5	3	99	79	All broke on jig.	All broke on jig.
Impact modified styrenic	4.3	29	109	16	53	7

■ > 80% retention ■ > 60% retention ■ < 60% retention

Studies also compared popular opaque polymers used in many medical device housings. Table 3 shows the results against medical disinfectants.

Table 3—Residual property evaluation: *Tritan MXF121 and competitive opaque materials against medical disinfectants*

Chemical	Control (joules)	CaviCide (IPA, EG ether)	Envirocide (IPA, EG ether)	Sani-Cloth AF III (benzyl quat, DPG ether)	Sani-Cloth HB (benzyl quat)	Wonder Woman (IPA)
		% Retention of impact energy to break				
Eastman Tritan™ copolyester MXF121	4.8	103	105	103	105	104
PC/ABS 1	6.1	12	10	10	16	12
PC/ABS 2	6.2	8	6	6	11	6

> 80% retention > 60% retention < 60% retention

Results show that Eastman Tritan™ copolyesters have overall high chemical resistance under stress. Both the clear and opaque formulations exhibit excellent retention of impact properties when tested against chemical and medical disinfectants. Tritan copolyesters also exhibited high or medium compatibility with all screened chemical wipes, with the exception of the phenolic chemicals—and higher chemical resistance than competitive polymers tested.

For additional results of tests comparing compatibility with oncology drugs and carrier solvents or color shifting after sterilization with EtO or gamma irradiation, contact 844-4-TRITAN.

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