

FACTS ABOUT BPA

Role of Polycarbonates in Health Care and Medical Devices Must Be Preserved

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Polycarbonate plastic, which is manufactured using the well-studied, building-block chemistry known as Bisphenol A, or BPA, plays a critical role in health care and medical devices, particularly in hospitals, neonatal units, and surgical facilities, due to its unique combination of strong durability, transparency, heat resistance, and easy sterilization, among others.

In many medical applications, polycarbonate is the [best-in-class material](#) and particularly difficult to substitute in life-saving and safety-enhancing applications. From surgical instruments to equipment housings and patient-care devices and tools, polycarbonate plays an indispensable role in patient and staff safety, infection control, and the overall efficiency of many medical procedures.

In order to safeguard polycarbonate's critical role in the medical field, as well as general industry, government authorities need to base regulations on sound science. Initiatives based on incomplete assessments of the weight of the evidence, such as the [recent EFSA opinion](#), could threaten health and safety by potentially limiting the use of well-studied materials that are used in life-saving applications. Regulations must have a robust and sturdy scientific foundation to protect public health and safety and keep the public's confidence. In fact, [government and scientific bodies around the globe](#) have extensively evaluated the weight of scientific evidence on BPA and have confirmed its safety, including in materials that come into contact with food.

The [CLARITY Core Study](#), a two year guideline-compliant study on the toxicity of BPA conducted by the FDA, thoroughly examined these potential health effects. What's more, an expert panel from the National Toxicology Program (NTP) put the CLARITY Core Study

FACTS ABOUT BPA

through a rigorous peer review to ensure that the results and conclusions were presented fully and clearly. The peer review panel supported the CLARITY Core Study's bottom-line conclusion: BPA has little potential to cause health effects, including cancer.

It's therefore important to acknowledge how critical polycarbonate is to our health care institutions and professionals. One of the primary reasons polycarbonate is favored in medical settings is its outstanding durability and strength. Medical devices and equipment must withstand rigorous daily use, frequent cleaning, and sterilization procedures without compromising their structural integrity. Polycarbonate's inherent toughness and impact resistance allows devices to remain intact and functional over extended periods, reducing the risk of breakage or malfunction during critical medical procedures.

The optical clarity of polycarbonate is another crucial attribute that enhances its utility in healthcare environments. Many medical devices and equipment components, such as incubators, infusion pumps, and protective eyewear, require transparent materials to allow for clear visibility and monitoring of patients or internal mechanisms. Polycarbonate's high transparency enables healthcare professionals to observe and assess conditions accurately, facilitating timely interventions and patient care.

Furthermore, maintaining a sterile environment is paramount in healthcare settings to prevent infections and the spread of disease and to promote patient safety. Polycarbonate is uniquely compatible with various sterilization methods, including autoclaving, gamma radiation, and ethylene oxide (EtO) gas sterilization. Its ability to withstand these processes makes it ideal for manufacturing reusable medical instruments and equipment that require frequent sterilization cycles.

Polycarbonate is also inherently biocompatible, meaning it is well-tolerated by the human body and does not elicit adverse reactions or tissue responses. This property makes it suitable for applications such as [surgical instruments, implants, and devices](#) used in invasive

FACTS ABOUT BPA

procedures where patient safety and compatibility are paramount concerns.

It should be noted as well that compliance with stringent regulatory standards is imperative in the healthcare industry to protect patient safety and product efficacy. Polycarbonate materials used in medical devices are [regulated by the U.S. Food & Drug Administration](#) and must undergo extensive testing to meet rigorous quality assurance criteria and regulatory requirements, including biocompatibility testing, sterilization validation, and material compatibility assessments. Manufacturers adhere to these standards to achieve regulatory approval and certification, demonstrating the reliability and safety of polycarbonate-based medical products.

As technological advancements and healthcare demands continue to evolve, the polycarbonate industry remains at the forefront of innovation, supporting the development of safe, reliable, and sustainable medical solutions for the benefit of patients and healthcare providers worldwide.