The E-Beam Alternative
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The last step for many medical and orthopedic products before shipping is sterilization—the complete eradication of microorganisms such as bacteria from the products. Historically, there have been challenges in implementing this necessary step. It must be done by a proven process that can be guaranteed to work in every case, because the products can’t be physically inspected after the sterilization procedure without risking recontamination. The sterilization process must also be able to eradicate contaminants without adversely affecting the product itself—ruling out heat or chemicals, for example, as sterilizing methods for the numerous products whose structures are vulnerable to one or both of those processes. And it’s not only

Electron beam use in medical sterilization and materials modification has come of age.

Packaged medical products being conveyed to the e-beam generator for sterilization at lotron.

the products themselves that must remain unharmed—the workplace, workers, and surrounding environment must be kept safe as well.

Radiation sterilization, as a physical “cold” process, avoids the issue of heat or chemical damage to a product, and has been widely used in the medical manufacturing industry for years. The most common method has been gamma irradiation,

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with the source of gamma rays being a radioactive cobalt isotope—although the storage, transport, and disposal of such radioactive material calls for the greatest care and has been a cause for environmental concern. As we’ll see, the same set of concerns is in play when considering safe and effective methods of materials modification in the industry.

Manufacturers, packaging companies and value-added resellers and distributors in the medical and orthopedic production industries are today taking a new look at another irradiation method—electron-beam processes. Electron-beam sterilization, bioburden reduction, and materials modification processes have recently emerged as viable alternatives.

With environmental concerns and safety issues impacting traditional sterilization and materials modification processes, electron-beam alternatives—particularly at the high beam energy level of 10 MeV (million electron volts)—present themselves as cost-effective, green and strategic non-cobalt and non-chemical solutions. Electron-beam (or “e-beam”) offers the medical device and disposable industries solid efficiencies in product turnaround, broad flexibility in the number of products and markets served, and a high degree of commercial reliability.

Electron-beam applications in the medical device industry

Typical applications for electron beam in the medical device industry include strategic materials modification (cross-linking for orthopedic applications) in the medical manufacturing industry as well as sterilization services for a variety of medical products, including single-use disposables such as catheters, tubing and syringes.

With the key processing parameters, including energy, scan profile and dose controlled to a high degree of precision, electron-beam irradiation in industrial applications offers a cost-effective and strategic alternative for processing medical devices and products in the high-volume and low-value categories (e.g., syringes) or the low-volume, high-value categories (e.g., specialized medical equipment).

Commercial e-beam generation produces electron beams entirely through an electrical process, and uses no radioactive products or harmful chemicals. When the accelerator system shuts off, so does the electron beam—with no residual radiation or lingering chemical hazard. The electron-beam accelerator does produce certain levels of ozone, but this ozone is safely exhausted away from the processing facility and quickly dissipated naturally.

Electron beam accelerators produce ionizing radiation through a focused beam of electrons. No radioactive materials are used, which negates any later safety or waste disposal challenges. Iotron’s Impela technology uses an L-band, on-axis-coupled, standing wave cavity system for accelerating the electrons. This technology combines the best features of pulsed and continuous-wave machines (used by other electron-beam processors) by operating in a long-pulse mode.

Sterilization and materials modification

Many products deployed in an e-beam process typically pass through accelerators producing beams in the 3 MeV (or lower) to 12 MeV range. When the product is subjected to the electron beam it absorbs energy from the high-speed electrons. By absorbing this energy, the product either undergoes a chemical modification or organisms/bio materials are subjected to DNA destruction. In the case of chemical modifica-
tion at the molecular level, the material is strengthened and/or hardened for longer and more effective industrial use. The later process effectively sterilizes materials.

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Advances in electron beam technology today make the e-beam process a viable sterilization alternative in the medical device and medical disposable industries. The high penetration capacity at 10 MeV provides a high degree of bio elimination. Products can be prepackaged and addressed for delivery prior to being subjected to the electron-beam sterilization process. Once sterilized, these prepackaged products emerge from the accelerator beam ready to be immediately shipped, thus providing significant value-added service through just-in-time (JIT) distribution capacity without any potential quarantine issues.

The electron-beam process produces many of the positive attributes of cobalt-based radiation processing without the safety or waste disposal factors sometimes associated with isotope-based treatments. Both electron-beam and gamma processing produce similar reactions and results: products exposed to electrons produced by either process undergo changes in chemical or molecular bonds. Destruction of DNA or forced changes in microorganism reproductive processes produces the desired degree of sterilization in the electron-beam application model.

Many medical and healthcare products require higher energies to adequately penetrate and fully sterilize the packaged product (such as the loron 10 MeV model), which produces a beam capable of deep penetration. High-energy beam accelerators also have the capacity to be modified to produce X-rays, which increases the facilities capacity to sterilize a variety of other metal and high-density medical device products.

Material modification using electron-beam technology such as cross-linking or chain scission is used in polymer-based products to improve mechanical, thermal, chemical and other properties. When the electron beam cross-links polymers—such as the polymers used in orthopedic manufacturing—the product typically increases in tensile strength and resistance to abrasions.

As noted by various sources, polymers which are commonly subjected to crosslinking or chain scission using an advanced 21st century electron-beam irradiation process include polyvinyl chloride (PVC), thermoplastic polyurethanes and elastomers (TPUs), polybutylene terephthalate (PBT), polyamides/nylon (PA66, PA6, PA11, PA12), polyvinilidene fluoride (PVDF), polymethylpentene (PMP), polyethylenes (LLDPE, MDPE, HDPE, UHMWPE), and ethylene copolymers such as ethylene-vinyl acetate (EVA), ethylene tetrafluoroethylene (ETFE) and Polytetrafluoroethylene (PTFE).

As noted by the industry, an electron beam is most frequently used for the crosslinking of polyethylene and polyvinyl chloride products, which are common in the orthopedic OEM market. A growing amount of electron-beam crosslinking or chain scission of fluoropolymers has been a recent trend. This includes ETFE in molded parts.

Conversion to e-beam

In today’s competitive environment, medical device manufacturers must carefully consider the costs and associated issues in fulfilling their sterilization and materials modification requirements in the long-term.

Medical device and disposable manufacturers rightly possess concerns about core production capacity, “make or buy” issues and outsourcing non-core processes. Independent electron-beam processing facilities offer cost-effective and strategic resources to OEMs, particularly when they can partner (like the Canadian and US facilities of lotron) on inventory control and storage, just-in-time production and product availability, ease of logistical access and delivery, and other valued-added services. Current and promising research and product development for electron-beam resistant RFID passive chips is well underway, which will add additional value in fulfilling traceability requirements for medical devices, parts and supporting products.

Meeting new FDA and other regulatory or industry standards with electron beam represents few challenges in today’s market. Many electron-beam processing companies, including lotron, have access to research and conversion support through expert resources, and can help prospective clients effectively address critical conversion and regulatory issues in a timely and cost-effective manner.

Simply put, like any other major consideration or venture, adoption of/or conversion to electron-beam processing in any given application requires careful thought, planning and testing.

Many new applications for electron-beam usage are being developed at the university level and in direct industry applications. When viewed over the long-term, conversion costs are immaterial, particularly when the major advantages of cost-savings, higher efficiencies, JIT inventory control, ease of adoption and safe technology are factored in.