



Endomechanical Products – Environmental Considerations for the RFP/RFI Process

The environmental considerations for this category are covered by the 13 Standardized Environmental Questions for Medical Products. Additional suggested questions are provided that would pertain to any electronic equipment provided in this contract.

#	Question	Preferred Response	Definition	Rationale	
Standardized Environmental Questions for Medical Products					
Natural Resources	1.	Does this product contain postconsumer recycled content (excluding steel)? (Yes/No) If yes, what percentage by weight?	Yes, highest %	<p>Postconsumer recycled content material is a material or finished product that has served its intended use and has been diverted or recovered from waste destined for disposal, having completed its life as a consumer item.ⁱ Basically, it is the material collected from recycling programs. It is calculated as a percentage of total weight of the product. Steel is excluded from consideration as it commonly contains recycled content. This does not include preconsumer (sometimes referred to as postindustrial) recycled content which are recovered materials obtained from manufacturers.ⁱⁱ</p>	Buying recycled-content products ensures that the materials collected in recycling programs will be used again in the manufacture of new products. According to EPA, recommending postconsumer recycled content levels for items will have the most positive impact on reducing the amount of solid waste requiring disposal. ⁱⁱⁱ Purchasers should prefer products with the highest postconsumer recycled content that also meet other considerations. Use of postconsumer recycled content supports closing the loop in the recycling process, and, based on EPA's ReCon Tool , helps avoid generating greenhouse gas emissions.
	2.	Is this product recyclable? (Yes/No)	Yes	Recyclable, according to the FTC Green Guides , means the product can be collected, separated, or otherwise recovered from the solid waste stream for reuse, or in the manufacture or assembly of another package or product, through an established recycling program. Any claims of recyclability indicates the supplier can demonstrate that at least 60% of the hospitals in the U.S., or in the product distribution area, have access to an established recycling program for this item, or there is an existing take-back program by the vendor of the manufacturer that has been in operation at least one year and covers the indicated percentage of hospitals and will recycle the	Recyclable products, those that are recyclable in communities in the U.S., reduce materials going to the waste stream and their associated costs. Although FTC has not finalized definitions to prove this claim, we are utilizing the FTC draft definition for 'substantial majority' to mean at least 60% and adding what it means to the health care community to ensure the needs of facilities who strive to divert materials from their waste stream.

				product.	
3.	Does the product's primary packaging contain postconsumer recycled content? (Yes/No) If yes, what percentage?	Yes, highest %	The primary packaging surrounds the product. For example the paper wrap surrounding a roll of toilet paper is primary packaging. (Secondary packaging surrounds a group of products, such as the box containing rolls of toilet paper.) Postconsumer recycled content material is a material or finished product that has served its intended use and has been diverted or recovered from waste destined for disposal, having completed its life as a consumer item. ^{iv} Basically, it is the material collected from recycling programs. It is calculated as a percentage of the total weight of the product.	Buying recycled-content products ensures that the materials collected in recycling programs will be used again in the manufacture of new products. According to EPA, recommending postconsumer recycled content levels for items will have the most positive impact on reducing the amount of solid waste requiring disposal. ^v Purchasers should prefer products with the highest postconsumer recycled content that also meet other considerations. Use of postconsumer recycled content is fundamental to closing the loop in the recycling process, using fewer natural resources, and based on EPA's ReCon Tool , can reduce greenhouse gas emissions. There are exceptions to the use of postconsumer recycled content in sterile barrier packaging (ISO 11607-1).	
4.	Is this product packaged without polystyrene? (Yes/No)	Yes	Polystyrene (CAS 9003-53-6) is a plastic polymer from the monomer styrene. It comes in many forms: sheet, expanded or extruded foam, or as oriented polystyrene. What is commonly known as Styrofoam™ refers only to the extruded form of polystyrene. Packaging refers to all materials (primary, secondary, etc) used to transport and protect a product from damage. Alternatives to polystyrene packaging are available.	Also referred to as 'PS' with the SPI (Society of the Plastics Industry) resin code 6, polystyrene is difficult for hospitals to recycle and there are alternatives. Polystyrene is made with styrene. ^{vi} The International Agency for Research on Cancer (IARC) classifies styrene as a possible carcinogen. ^{vii} Foam blowing agents (called hydrochlorofluorocarbons, HCFCs) used to make polystyrene foam are compounds that have an ozone depletion potential ^{viii} .	
5.	Is this product sold as a multi-use product or device (not single patient use)? (Yes/No)	Yes, with exceptions	A multi-use product or device is sold as a product that can be used on more than one patient. In Sec 201 [21 U.S.C. 321] , the FDA defines the term "single-use device" to mean a device that is intended for one use, or on a single patient during a single procedure. This question does <u>not</u> include products that can be reprocessed.	Products that can be used more than once reduce waste (and associated costs) and conserve natural resources. There are case studies that demonstrate the cost and environmental benefits of multi-use devices. There are exceptions; not all medical products should be multi-use.	

Chemicals

6.	Is this product free of intentionally added polyvinyl chloride (PVC)? (Yes/No)	Yes	Polyvinyl chloride (PVC) shall be defined as a plastic polymer used in a wide array of products. It is the third most widely produced plastic. Intentionally added means a substance is deliberately added in the production of the product.	Production and incineration of PVC releases dioxins and other harmful chemicals. Dioxins are widely distributed throughout the environment in low concentrations and are persistent, bioaccumulative and toxic (PBT). Dioxins are potent toxicants with many health impacts even at low exposure levels.
7.	Is this product free of intentionally added phthalates: DEHP, BBP, DnHP, DIDP, and DBP? (Yes/No) If no, please specify the phthalate(s)	Yes	Phthalates are esters of phthalic acid mainly used as plasticizers (substances added to plastics to increase their flexibility, transparency, durability, and longevity). They are used primarily to soften polyvinyl chloride (PVC). Di-2-ethyl hexyl phthalate (DEHP) CAS 117-81-7, Benzylbutylphthalate (BBP) CAS 85-68-7, Di-n-hexyl phthalate (DnHP) CAS 84-75-3, Di-isodecyl phthalate (DIDP) CAS 68515-49-1 or 26761-40-0, Dibutyl phthalate (DBP) CAS 84-74-2	People can be exposed through the use of products containing these chemicals. In 2002, the FDA issued a Public Health Notification for PVC devices containing DEHP. DEHP is also listed as a carcinogen on the Prop 65 list. The National Research Council has also noted the importance of looking at cumulative exposure from multiple phthalates. These five phthalates are listed as reproductive toxicants by Prop 65.
8.	Is this product free of intentionally added Bisphenol A (BPA) or BPA derived plastics (such as polycarbonate plastic and resins)? (Yes/No)	Yes	Bis(4-hydroxyphenyl)propane, or Bisphenol A (BPA), is an organic compound used to make polycarbonate plastic, epoxy resins and for other applications. Polycarbonate plastic is derived from BPA. Resin derived from BPA is used to line metal food containers and in thermal paper for impact printing purposes. Intentionally added means a substance is deliberately added in the production of the product.	People can be exposed through the use of products containing these chemicals. BPA is one of the highest volume chemicals produced worldwide. Laboratory studies have shown widespread health effects, at least in part through endocrine disruption mechanisms. The National Toxicology Program has some concern for the effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to Bisphenol A.
9.	Does this product contain less than 1000 ppm halogenated organic flame retardants by weight of homogenous material? (Yes/No)	Yes	Halogenated organic flame retardants are intended to inhibit ignition and the spread of flames. Halogenated chemicals are chemicals that contain bromine, chlorine, fluorine or iodine bonded to a carbon atom. Homogeneous means uniform composition throughout, such as individual types of plastics or paper. Homogenous material, as defined by RoHS, is a unit that cannot be mechanically disjointed into single materials, or any material that is not mechanically divisible (disassembled, cut or ground) into separate material constituents. Mechanically disjointed means the materials can be, in principle, separated by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes. ^{ix} Guidance for suppliers on testing is available.	Halogenated organic flame retardants and/or their breakdown products tend to be persistent bioaccumulative and toxic (PBT) in the environment. They are widely found in the environment and in humans with Americans having some of the highest levels of them in their bodies. Some halogenated organic flame retardants are carcinogenic. These compounds are used in foams (for furniture and mattresses), textiles, paints and coatings, electronics, and plastics in health care. Alternatives exist that reduce the concern for environmental and human health effects. The European Union has a ban on some brominated flame retardants. In Europe, the Restriction of Hazardous Substances Directive (RoHS) restricts the use of PBDE's and PBB's in electronic equipment. Examples include, but are not

					limited to: Tetrabromobisphenol-A (CAS 79-94-7), Hexabromocyclododecane (CAS 25637-99-4), Deca-BDE (1163-19-5), Octa-BDE (CAS 32536-52-0), Penta-BDE (CAS 32534-81-9), Tris (2- chloroisopropyl phosphate) (TCPP) (CAS 13674-84-5), Tris(2-chloroethyl) phosphate (TCEP) (CAS 115-96-8), TDCP (Tris (1,3-dichloro-2-propyl) phosphate (CAS 13674-87-8)
	10.	Is this product free of intentionally added mercury? (Yes/No)	Yes	Mercury is a naturally occurring element that is found in air, water and soil. It exists in several forms: elemental or metallic mercury, inorganic mercury compounds, and organic mercury compounds. Intentionally added means a substance is deliberately added in the production of the product.	Medical facilities use a large variety of mercury-containing equipment and products. ^x Mercury is persistent bioaccumulative and toxic (PBT) and is found in thermometers, sphygmomanometers, dental amalgam, lab reagents, cleaners, electrical switches, and other scientific apparatus. Mercury is a potent neurotoxicant that can affect the brain, spinal cord, and peripheral nerves. It is also toxic to the kidneys. Efforts in health care are intended to reduce exposure to patients and staff, address workplace safety, and safely handle products at the end of life.
	11.	Is this product free of intentionally added latex? (Yes/No)	Yes	Latex is natural rubber latex that comes from a liquid found in tropical rubber trees. Intentionally added means a substance is deliberately added in the production of the product.	Liquid latex is processed to make many medical and dental supplies, including gloves, blood pressure cuffs, urinary catheters, dental dams and material used to fill root canals, as well as tourniquets and equipment for resuscitation. Non-latex substitutes (synthetic latex) can be found for all of these latex-containing items. The protein in rubber can cause an allergic reaction in some people. This reaction can range from sneezing to anaphylactic shock, which is a serious condition that requires immediate medical attention.

	12.	Will this product be classified (on its own or when aggregated) as non-hazardous waste according to EPA's RCRA when disposed? (under 40 CFR 261.31-33)? (Yes/No)	Yes	<p>Hazardous wastes are those determined by EPA to be hazardous including those classified as hazardous and if products exhibit one of the four characteristics (defined in 40 CFR Part 261.21-24). Hazardous wastes are divided into listed wastes, characteristic wastes, universal wastes, and mixed wastes. Specific procedures determine how waste is identified, classified, listed, and delisted. The Resource Conservation and Control Act (RCRA) mandates strict controls over disposal of hazardous waste. These listed wastes are divided into three categories: K-list, F-list, and the P and U-Lists. Characteristic wastes include wastes that exhibit ignitability, corrosivity, reactivity or toxicity. Universal wastes include batteries, pesticides, mercury-containing products and lamps. Examples include computer equipment, lead-containing products, and applicable cleaning chemicals.</p>	<p>Note: products that contain lead in the tape would become a hazardous waste when aggregated.</p> <p>Purchasers should know when products may become hazardous waste at the end of product use so that facilities can comply with EPA and RCRA regulations regarding the handling of hazardous waste or to seek alternatives during the procurement process. Reducing hazardous waste generation lessens the environmental impact and the expenses associated with disposal. Suppliers should seek alternative technologies to the greatest extent possible. Many state regulations may be more stringent than federal requirements. Consult the HERC State Hazardous Waste Locator to find more information on an individual state's hazardous waste regulations. For more information on EPA listed wastes: http://www.epa.gov/osw/hazard/wastetypes/index.htm.</p>
	13.	Does this product contain carcinogens or reproductive toxicants, as listed under the California Safe Drinking Water and Toxic Enforcement Act of 1986, Proposition 65, below Prop 65 Safe harbor levels ? (Yes/No)	Yes	<p>Note: tape for sterility products may contain lead; alternatives are available.</p> <p>California's Prop 65, The Safe Drinking Water and Toxic Enforcement Act, enacted in 1986, requires the state to publish a list of chemicals known to cause cancer or reproductive harm. Prop 65 applies to suppliers who sell products in the state if their products exceed safe harbor levels established in Prop 65. Safe harbor levels establish thresholds for no significant risk levels (NSRLs) for carcinogens and maximum allowable dose levels (MADLs) for chemicals that cause reproductive toxicity.</p>	<p>The California Proposition 65 list is an authoritative government list of carcinogens <i>and</i> reproductive toxicants that health care facilities may wish to avoid. All suppliers who do business in California must comply with this law. As such, this law already applies to many suppliers in the health care sector. Since this list is updated at least once a year, suppliers must provide up-to-date information for procurement contracts.</p>

Additional Considerations – Electronics

14.	Is this product compliant with RoHS? (Yes/No)	Yes	<p>RoHS restricts mercury and cadmium at no more than 100ppm, and hexavalent chromium and lead at 1000ppm. Although RoHS does not apply to electronic medical products until 2014, responsible suppliers should manufacture equipment free of intentionally added heavy metals to prevent exposure.</p>	<p>Heavy metals are persistent bioaccumulative and toxic. Heavy metals may enter the human body through food, water, air, or absorption through the skin when they come in contact with humans in agriculture and in manufacturing, pharmaceutical, industrial, or residential settings. They may build up in biological systems and become a significant health hazard. Cadmium is an extremely toxic metal.^{xi} Lead accounts for most of the cases of pediatric heavy metal poisoning (Roberts 1999)^{xii}.</p>
15.	(a) Does the supplier offer a Take-Back Program that will reuse or recycle the product? (Yes/No)	Yes	<p>Product take-back programs offer potential business benefits that are significant - fostering a stronger bond with customers, reducing manufacturing and waste expenses, and reusing resources are a few. Product take-backs are a part of Extended Producer Responsibility (EPR), or Product Stewardship, means whoever designs, produces, sells or uses a product takes primary responsibility for minimizing its environmental impact through all stages of the product's life cycle. And the producer, having the greatest ability to minimize impacts, has the most responsibility.</p>	<p>Electronic products contain many toxic chemicals and materials of concern including mercury, lead, polyvinyl chloride and brominated flame retardants. Therefore it is essential that electronic products are properly disposed of at the end of their useful life. One strategy is to support product stewardship through manufacturer take-back programs. In Europe, the waste electronic and electrical equipment (WEEE) directive was passed in 2006 to force manufacturers of electronics to mitigate these risks by taking back and recycling used product in order to divert it from landfills, illegal dumps and unsafe disassembly practices.</p>
15.	(b) If yes to #13(a), will this product be recycled by a certified electronics recycler to recycle in an environmentally responsible manner equal to or greater than requirements by e-Stewards certified recyclers? (Yes/No)	Yes	<p>e-Stewards certified recyclers must meet stringent environmental and corporate environmental responsibility requirements.</p>	<p>All of these electronics become obsolete or unwanted, often within 2-3 years of purchase. This global mountain of waste is expected to continue growing 8% per year, indefinitely (BCC Research). Electronic waste isn't just waste, it contains some very toxic substances, such as mercury, lead, cadmium, arsenic, beryllium and brominated flame retardants. When the latter are burned at low temperatures they create additional toxins, such as halogenated dioxins and furans – some of the most toxic substances known to humankind. The toxic materials in electronics can cause cancer, reproductive disorders, endocrine disruption, and many other health problems if this waste stream is not properly managed. An estimated 70-80% of the e-waste that's given to recyclers is exported to less developed countries. Once there, primitive technologies such as open air burning and riverside acid baths are used to extract a few materials. The rest of the toxic materials are usually dumped.^{xiii}</p>

	16.	If this product uses batteries, is there a Takeback Program for battery recycling? (Yes/No)	Yes	Many states require that manufacturers and marketers of rechargeable battery and rechargeable battery powered products sold implement a unit management system. The unit management system should clearly inform consumers of the disposal prohibition, ensure batteries and products are labeled to show electrolyte and disposal options, and provide a program to properly collect, transport, and recycle or dispose of the batteries and products.	Several types of batteries contain mercury and may also contain other heavy metals such as lead and cadmium. These metals may be a potential threat to human health and the environment if improperly disposed. In landfills, the heavy metals have the potential to leach slowly into soil, ground water, and surface water. When incinerated, metals such as cadmium and lead can concentrate in the ash produced by combustion and enter the atmosphere through incinerator smokestack emissions. For more information, see Guide to Batteries in Health Care (member log in required)
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ⁱ Glossary, Comprehensive Procurement Guidelines, U.S. Environmental Protection Agency, <http://www.epa.gov/epawaste/conservation/tools/cpg/glossary.htm> viewed September 2011

ⁱⁱ Reusable Vocabulary, U.S. EPA, <http://www.epa.gov/osw/wycd/catbook/you.htm> viewed September, 2011

ⁱⁱⁱ Background Document for the Final Comprehensive Procurement Guideline (CPG) III and Final Recovered Materials Advisory Notice (RMAN) III, U.S. EPA, September 1999, EPA530-R-00-002

^{iv} Glossary, Comprehensive Procurement Guidelines, U.S. Environmental Protection Agency, <http://www.epa.gov/epawaste/conservation/tools/cpg/glossary.htm> viewed September 2011

^v Background Document for the Final Comprehensive Procurement Guideline (CPG) III and Final Recovered Materials Advisory Notice (RMAN) III, U.S. EPA, September 1999, EPA530-R-00-002

^{vi} U.S. Environmental Protection Agency, "Air Toxics- Styrene," <http://www.epa.gov/ttnatw01/hlthef/styrene.html>, website viewed June 2011

^{vii} Ibid

^{viii} *Phaseout of HCFCs, Ozone Layer Depletion*, U.S. EPA, <http://www.epa.gov/ozone/title6/phaseout/class2two.html> viewed September 2011

^{ix} RoHS Producer Support Booklet, National Measurement Office, 2010, pg 6, <http://www.bis.gov.uk/assets/bispartners/nmo/docs/rohs/support-literature/producer-support-booklet.pdf>

^x EPA: Information for Health Care Providers, <http://www.epa.gov/hg/healthcare.htm#facilities>, viewed August 30, 2011

^{xi} OSHA, <http://www.osha.gov/SLTC/metalsheavy/index.html>

^{xii} <http://www.lef.org/protocols/prtcl-156.shtml#comm>

^{xiii} The e-waste crisis introduction, E-Stewards website, <http://e-stewards.org/the-e-waste-crisis/> Accessed February 2012