Enhancing patient experience and improving safety

DySIS Medical chooses Eastar™ copolyester MN058 for its new system for advanced detection of cervical cancer.

To assist in earlier and more accurate detection of cervical cancer, DySIS Medical Ltd. created a unique medical device that uses advanced biophotonic technology implemented in the form of a colposcope (an instrument designed to view the patient's cervix to identify abnormalities) and a bespoke speculum.

DySIS™ uses proprietary technology called Dynamic Spectral Imaging that automatically takes measurements of a patient's cervix during the examination. The patented method measures the response of the cervical epithelium to a standard biomarker. The results are then summarized on a color map known as a DySISmap™, which helps the clinician identify possible abnormalities.

"There have been multiple published clinical trials that demonstrate more disease is identified when the DySISmap is included as part of a patient's examination," said Alastair Atkinson, chief executive officer at DySIS Medical. "The DySIS instrument requires the use of an advanced speculum. In testing existing products on the market, we were surprised to find many plastic speculums shattered under pressure and therefore represent a significant safety hazard to patients."

DySIS Medical chose Eastar™ MN058 copolyester as the material for the DySIS vaginal speculum to enhance the patient experience and improve safety. Eastar is a BPA-free medical grade base material that provides exceptional clarity, high-impact strength, and chemical resistance.

Eastar MN058 was developed specifically for medical devices, so it is chemical resistant to most solvents, has superior clarity, smooth touch, is strong against impact and has a low shrinkage rate. And it doesn't contain a mold release or ultraviolet stabilizer.

"When designing the speculum, our key requirement was safety," said Atkinson. "We looked for a material that met the strict regulatory standards. It needed to be susceptible to sterilization and have the mechanical properties to prevent dangerous breakages. We chose Eastar based on the material's characteristics and ultimately formed a great relationship with the Eastman team. Our collaboration was a success because of both teams' expertise."

For more information on DySIS, visit www.dysismedical.com or its Twitter page. For more information on Eastman, visit www.eastman.com.

EASTMAN

The results of **insight**™

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Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

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.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

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