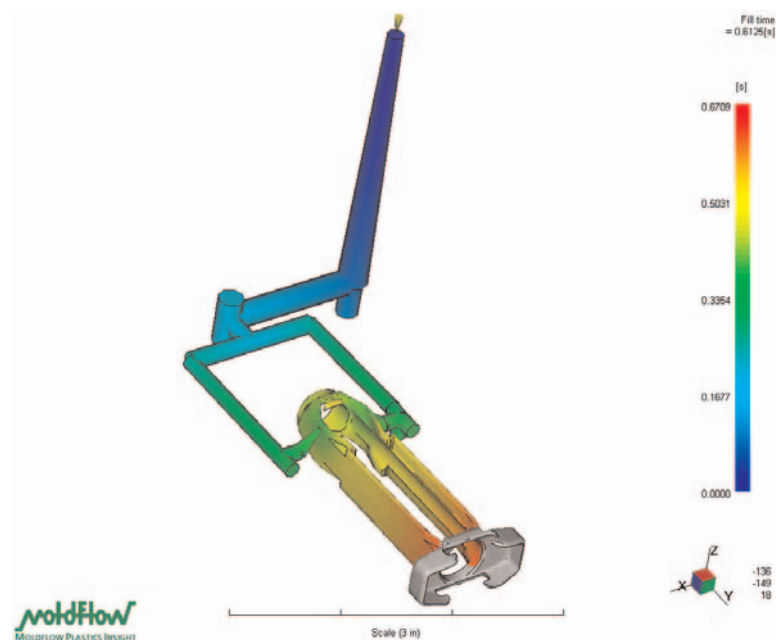


The Material Difference™ In Medical Applications

From Design Concept to Production Part Capabilities in Injection Molding Design

Eastman Injection Molding Design Services Group

- Material Selection
- Part Design Reviews
- Tooling Reviews
- Mold Filling Simulation
- Secondary Operations Advice



Safety Syringes, Inc. worked with Eastman to design a safer easy-to-use anti-needlestick device using a combination of winning materials that enhance the form and function of its innovative product line.

From Design Concept to Production Part Capabilities in Injection Molding Design

Transforming a concept for an injection-molded medical device into a successful, functional part requires careful design and planning.

The medical device development process is typically initiated when the medical OEM identifies a need for a particular device. A conceptual part design is then produced, with the primary objectives being functionality and aesthetics. Another key element of successful part development, which is sometimes overlooked during the initial concept phase of a project, is optimizing the design so that the part can be manufactured in the most efficient manner.

For more than 20 years, the Eastman Injection Molding Design Services Group has assisted customers in the development of component medical parts that meet the functional and aesthetic requirements of a medical device. The group works with customers to optimize production of the part with the selected *Eastman* medical grade plastic. Customers can count on the Design Services Group to help them design for good manufacturability. And when *Eastman* plastics are teamed up with the proper part design, suitable mold design, and recommended processing parameters, designers and molders can achieve efficient production of quality medical parts.

Following are some of the services Eastman can provide to assist in the medical device development process:

- **Material Selection**—Recommending the *Eastman* medical grade plastic to meet processing and physical performance requirements of the device.
- **Part Design Reviews**—Reviewing the initial part design for uniform wall thickness, adding radius to sharp corners to improve part strength, and ensuring unique part features such as snap fits, bosses, and joints are properly designed.
- **Tooling Reviews**—Reviewing tooling design features such as the type of feed system (hot or cold runner), gate design (hot or cold gates), cooling line arrangement, venting, and ejection systems to ensure these features are properly designed for the selected *Eastman* plastic.

- **Mold Filling Simulation**—Using Moldflow Corporation's *Moldflow* mold filling simulation software to model the injection molding process. Eastman has the ability to simulate all phases of the molding process, including filling, packing, cooling, and warping. The primary outputs of these simulation studies include gate location optimization, fill pattern analysis to identify any problem areas such as air traps or weld lines, overall fill pressure requirements for the proposed part geometry and selected *Eastman* plastic, verification of the runner system dimensions, evaluation of the proposed cooling line layout, and many more mold filling attributes.
- **Secondary Operations**—Providing specific design advice on secondary operations such as adhesive bonding, solvent bonding, various welding processes (ultrasonic, laser, hot plate, vibration, etc.), mechanical fastening, snap fits, press fits, and post molding cold forming operations.

Early involvement of the Eastman Injection Molding Design Services Group is one of the keys to success in the medical product development process, and offers several advantages:

- Part and tooling designs can be optimized for the selected *Eastman* plastic.
- Product development cycles are often reduced.
- Production interruptions and scrap rates are lowered after initial startup, and throughout the program life.

All of these advantages add up to a win-win situation for the OEM and Eastman.

Call Eastman today to find out more about how our capabilities in injection molding design can help make The Material Difference™ in your medical application.

Transforming the Concept . . .

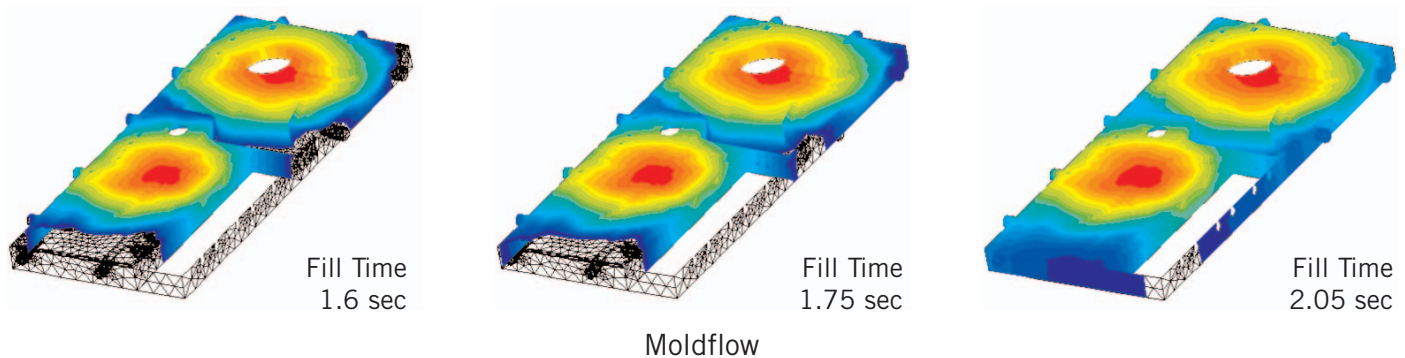
Gambro BCT, Lakewood, Colorado, molded their *Trima* Cassette in *Eastman* MN211 plastic using a two-cavity cold runner system. Investigating their options to build a hot runner tool to eliminate “scrap” material, Gambro asked the Eastman Injection Molding Design Services Group to evaluate a conceptual design for a two-cavity tool for each half of the cassette, each with a hot runner system with two valve gates. Eastman evaluated the design for required fill pattern and pressure, and completed a mold filling simulation. Results suggested Gambro’s conceptual design yielded a reasonable fill pattern and relatively low fill pressure. Based on these results, Eastman suggested that a single gate on each cavity would significantly reduce mold complexity and cost. In addition to eliminating a knit line where the two flow fronts come together, which can represent a potential weak point of the part, the single-gate design

simulation indicated a reasonable fill pattern with relatively low fill pressure.

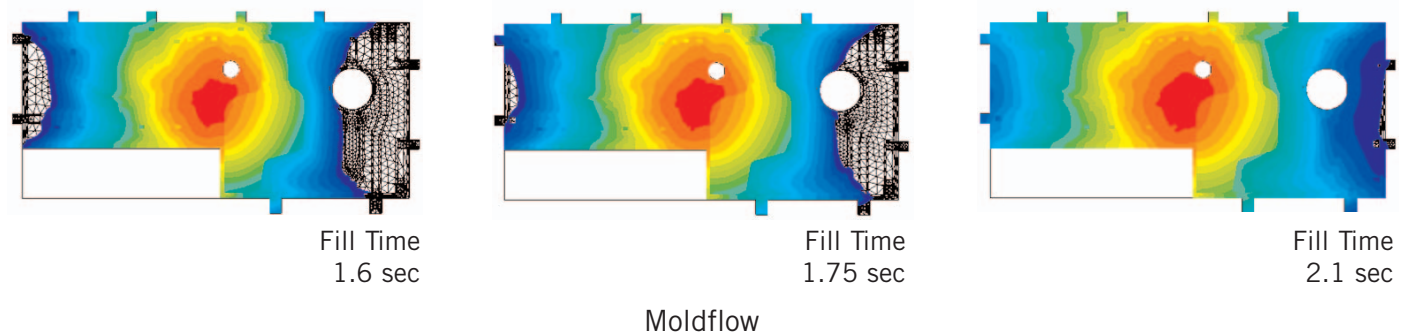
The images below model plastic filling the mold over time per second for a two-gate tool design and a single-gate tool design. The red to dark blue color scale indicates the temperature of the plastic as it flows from the gate location (red) throughout the mold (orange, yellow, green, aqua, and blue) as it fills the mold and cools.

Gambro’s tooling was constructed with a single gate on each cavity at the locations suggested by Eastman Design Services. Additional suggestions regarding temperature control were also incorporated into the tooling design. Tooling was started up and has been in production for six years with no production issues.

Two-Gate Tool Design Moldflow Simulation



Single-Gate Tool Design Moldflow Simulation



EASTMAN

NORTH AMERICA

Eastman Chemical Company Corporate Headquarters

P.O. Box 431
Kingsport, TN 37662-5280 U.S.A.

Telephone:
U.S.A. and Canada, 800-EASTMAN (800-327-8626)
Other Locations, (1) 423-229-2000
Fax: (1) 423-229-1193
www.eastman.com/medical

LATIN AMERICA

Eastman Chemical Latin America

9155 South Dadeland Blvd.
Suite 1116
Miami, FL 33156 U.S.A.

Telephone: (1) 305-671-2800
Fax: (1) 305-671-2805

EUROPE / MIDDLE EAST / AFRICA

Eastman Chemical B.V.

Fascinatio Boulevard 602-614
2909 VA Capelle aan den IJssel
The Netherlands

Telephone: (31) 10 2402 111
Fax: (31) 10 2402 100

ASIA PACIFIC

Eastman Chemical Commercial Co., Ltd. Jingan Branch

1206, CITIC Square
No. 1168 Nanjing Road (W)
Shanghai 200041, P.R. China

Telephone: (86) 21 6120-8700
Fax: (86) 21 5213-5255

Eastman Chemical Japan Ltd.

AIG Aoyama Building 5F
2-11-16 Minami Aoyama
Minato-ku, Tokyo 107-0062 Japan

Telephone: (81) 3-3475-9510
Fax: (81) 3-3475-9515

Eastman Chemical Asia Pacific Pte. Ltd.

#05-04 Winsland House
3 Killiney Road
Singapore 239519

Telephone: (65) 6831-3100
Fax: (65) 6732-4930

Material 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 in order 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 (sub-acute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available upon 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 upon 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.

Eastar and Eastman are trademarks of Eastman Chemical Company.

© Eastman Chemical Company, 2006.