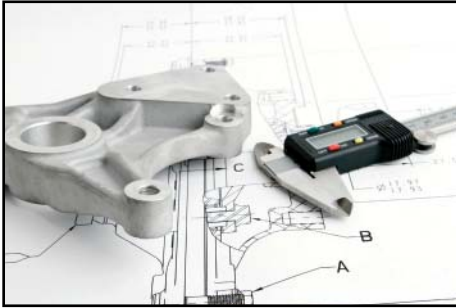


Epic Medical Concepts & Innovations

*Medical Device Solutions for the 21st Century*

## Creative, High-Quality Solutions

We continually think about how our products can be improved, how we can advance the technology of medical devices already on the market, and how we can introduce new solutions to existing needs and challenges faced by medical professionals.



### About Us

We are the premier medical device solutions firm in the Midwestern United States.

With more than 25 years of medical device expertise, we are up to any challenge. From concept to reality, we are with you every step of the way.

We specialize in new product development, both internally and in partnering with doctors, surgeons, and other medical professionals to develop procedure-enhancing medical devices. Our products range from simple hand-held tools to sophisticated electronic and electro-mechanical devices.

By close collaboration with those who know best, we are able to turn their expertise and ours into game-changing innovations that move the medical profession steadily forward for the benefit of many.

### Design & Engineering

We take our product (or yours) through our comprehensive design process, from product requirements planning to regulatory approvals, including PMA's and 510(k)s.

### First-Class Manufacturing & Service

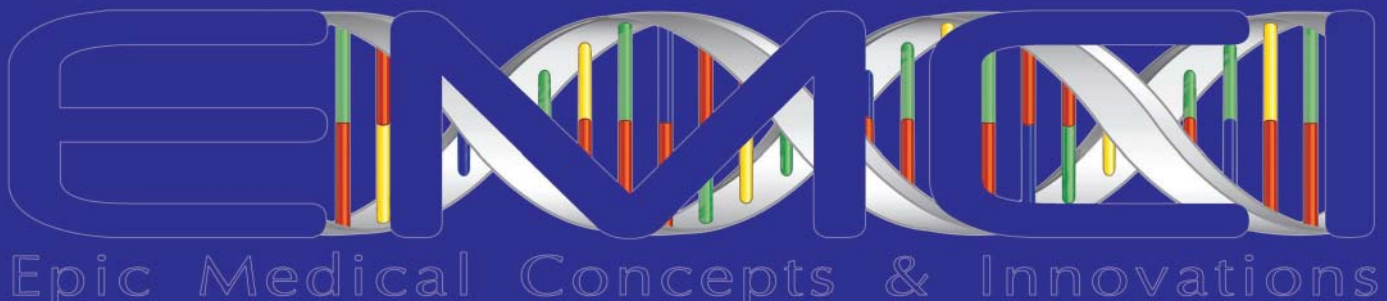
We manufacture to the highest standards, and only use suppliers and vendors who do the same. We also are expert in after-sales service, handling all customer and end-user issues.

### Seamless Supply Chain

In addition to our own distribution, EMCI works with some of the largest distribution companies in the world, with well-established sales networks in dozens of countries. Our distributors have existing relationships with doctors, hospitals, and medical offices, and can introduce new products effectively with minimal time and effort. When EMCI introduces a new product, it is immediately integrated into this global supply chain.

### Uncompromising Quality

We believe that "Quality" means a well-designed and administered quality system and more - uncompromising quality as a *mindset*, a firm belief in excellence and a conviction that it will be achieved.



# Letter from the President



We just called ourselves “premier.” Easy to say, but what does that mean?

It means that we’re in this field to make a difference. We intend to stand out because we’re excellent at what we do – in the way we think (“Concepts”), create (“Innovations”), design, engineer, manufacture, service, and distribute. We believe that ethics and performance go hand-in-hand. We’re not in this field just to have something to do or to make money.

We’re premier because we take excellence and quality seriously. We believe that everything that we (or others) are doing can be improved. We listen to our customers and those who actually use our products. We don’t cut corners. We’re proud to be FDA registered, with a strong record of cooperation with it and other regulatory bodies. And we’ve summarized our seriousness with our ISO certifications.

We’re also premier because we work in multiple areas that allow us to benefit those we serve in numerous ways, and to cross-fertilize what we do, unlike most organizations that work in only one or two areas. We have our own *proprietary products*, recognized as the best in class. We carry out *product development*, both with our own innovations and with licensed technology. We enjoy *partnering* with doctors and other medical professionals, innovators of all stripes, and other medical device manufacturers and distributors. And for high-quality organizations, we’re delighted to provide *world-class outsourcing*.

We invite you to see what we can do for you. We think it will be worth it – now, and for a long time to come.

James R. Lucas, Ph.D., P.E.  
President & CEO



## Certifications

EMCI is proud to be certified to the highest standards of quality and excellence in medical device manufacturing. These certifications include ISO 9001:2008 and ISO 13485:2003.

In addition to ISO, EMCI is also FDA registered and in compliance with all FDA QSR requirements.

## Quality Policy

The objective of Epic Medical Concepts & Innovations is to provide quality products that meet or exceed the needs and expectations of our customers, partners, regulatory bodies and other interested parties. We are committed to meeting all applicable requirements and continually improving the effectiveness of the Quality Management System.

## About James R. Lucas

James R. Lucas began his career in management working in managerial and executive positions for such companies as Black & Veatch Consulting Engineers, Hallmark Cards, and VF Corporation. He has worked in the medical device field since 1983, serving as president of EPIC Corporation, the forerunner of EMCI.

Jim received his education in leadership, business, economics, and engineering at the University of Missouri (Columbia & Rolla), where he received his Ph.D. (h.c.). He has also taught at Rockhurst University. Jim is past president of the Academy of Engineering Management, a member of the American Society of Engineering Management, a senior member of the Society of Manufacturing Engineers, and a registered professional engineer in Missouri and Kansas. Jim has been honored with continuous listings in Who’s Who in Finance & Industry (1989-2009).

## Design Process

Design reviews are carried out at appropriate stages in accordance with the design project plan. The purpose of the design review is to evaluate the ability of the design to meet input requirements, identify any problems, and propose necessary actions.

Participants in design reviews include representatives of functions concerned with the design stage being reviewed, as well as other specialists and an independent reviewer that has no prior involvement in the development activities that led to the particular review.

Design verification is the next step. The purpose is to ensure that design outputs have met the design input requirements, and that the resulting device is capable of meeting the requirements for specified application and intended use.

Design Validation is the next step. The objective of design validation is to ensure the production equivalent device functions in its intended use or simulated use. Design validation may be performed with either bench or clinical testing.

## Proprietary Products

At EMCI, we have a long history of providing high-quality products to medical professionals. Since 1991, EMCI has specialized in design, development, manufacturing, distribution, and servicing of active and non-active surgical instruments for reconstructive and plastic surgery. We have operated as the proprietary manufacturer of such products as our advanced line of electrical and pneumatic dermatomes, upper hands, and areola markers.

Using our design experience and quality trending, these products have been honed over the years to be the industry choice of professionals around the world. We are constantly adding innovative new features and upgrades to these devices and components to keep EMCI and our users, customers, and distributors at the "top of the pile."

### *EMCI Proprietary Product Principles:*

- Forecasting accurately to serve an unbroken supply chain
- Producing to high, not just "acceptable," standards
- Improving products and features relentlessly
- Standing behind our workmanship with no excuses



# Product Development

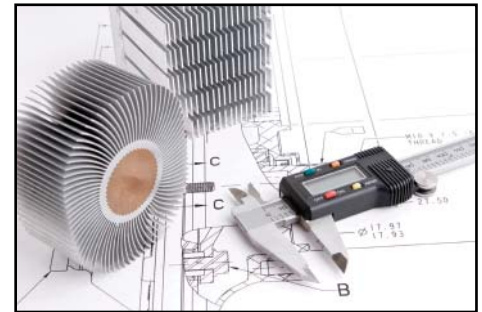
We have two methods for new product development: internal innovation and licensed technology. Both of these lead to medical devices that are truly different - and *make* a difference. Our expert design and manufacturing engineers bring new concepts through prototyping, while our quality department carefully guides the regulatory process.

## Internal Innovation

The first new product development method is fostering our own concepts. Our creative staff listens to the ideas, challenges, and complaints of medical professionals and designs new products to fill the need.

## Licensed Technology

The second method is through licensing new inventions that have not yet been developed. EMCI licenses the rights to develop the inventor's medical concept (usually patented or patentable) and produce it. Licensed technology products are also serviced by our in-house, after-sales service department.



## *EMCI Internal Innovation Principles:*

- Generating & garnering ideas
- Incubating & evaluating ideas
- Gatekeeping & filtering ideas
- Resourcing & implementing ideas

## *EMCI Licensed Technology Principles:*

- Working with serious inventors and professionals
- Creating mutually beneficial relationships
- Recognizing & honoring creative contributors



# Our Founder

James E. Petersen founded EPIC Manufacturing, the forerunner of EMCI, in 1959 after serving in the Navy during World War II and then working for Bendix Corporation. Petersen was the first person to graduate from Bendix Corporation's apprenticeship program in 1956.

In his role as an inventor and engineer, Petersen held a pioneering role in the development of plastics technology. He developed numerous patented medical devices which are still in production today. EPIC was also one of the first companies to offer teflon coatings on its products.

Petersen's inventions have saved countless lives during the past 50 years. Epic Medical Concepts & Innovations was named to honor the history and heritage of EPIC Manufacturing and James E. Petersen.

## Partnerships

Things that are valuable usually come with challenges, and partnerships are no exception. But if you want an ethical, performance-oriented partner, you've found one with EMCI.



We are able to work behind the scenes, take the lead, or share the responsibilities. Too many ideas *stay* ideas without a partner who brings design, development, engineering, production, and quality capabilities to the effort. We can help you turn those ideas into reality.

### EMCI Partnering Principles:

- Making compatibility a first priority
- Focusing together on benefits to users and patients
- Setting, and committing to, common objectives and goals
- Developing a win-win integration plan
- Addressing differences with honesty and humility

### After-Sales Service

Once the product is being used in the field, EMCI has a fully operational service and repair department specifically trained to work on our products. All servicing is handled directly by EMCI.

We handle all regulatory paperwork, the actual servicing, record-keeping, and shipping/receiving for devices needing repairs or preventative maintenance.

### How We Work

We know that medical professionals are experts at the procedures they perform. However, they rarely have the time to become experts in design, engineering, regulatory approvals, production, servicing, and quality.

That's where we come in. We utilize the expertise of the inventor and combine it with our prototyping, regulatory, and production expertise to get those great ideas into hands that need them.



Epic Medical Concepts & Innovations

# World-Class Outsourcing

Backlogged? Need an excellent manufacturing outlet to support your efforts? Want better pricing without sacrificing quality standards or service? Looking for integrated component production?

We produce your product, systems, modules, or components with unwavering quality. And because we're lean, we can usually do it at significantly reduced cost. We are masters at lightening your burdens.

## EMCI Outsourcing Principles:

- Selling reliability and flexibility as well as products
- Delivering product on or ahead of schedule
- Pricing our work to lower your costs
- Providing quality throughout our supply chain
- Suggesting improvements to enhance your product

## Engineering Capabilities

EMCI provides in-house engineering services that are both cutting edge and practical. Our full service department can take your product from sketch through prototype to production with ease.

- CAD
- Mechanical Engineering
- Electrical Engineering
- Prototyping
- Product Development
- Advanced Testing
- Manufacturing Engineering
- Proof-of-Concept Testing
- Packaging Design
- Reverse Engineering

## Manufacturing Capabilities

EMCI's manufacturing system turns out sophisticated mechanical and electro-mechanical devices every day. In addition to the capabilities listed below, we have well-established partners specializing in a variety of other support processes.

- Machining
- Welding
- Bending
- Overmolding
- Soldering
- Laser Engraving
- Special Finishing
- Mechanical Assembly
- Electrical Assembly
- Servicing & Troubleshooting

## Inventory Management

EMCI can manage your product and allow you to enjoy total peace of mind while we work directly with end users in your name. Our experience takes you out of the day-to-day hassle of managing inventory and service.

- Custom Labeling
- Custom Packaging
- Bar Coding
- Drop Shipping
- Inventory Management
- RMA (Return Merchandise Authorizations)
- Warranty Service



## Supplier Quality

We hold our suppliers and vendors to the same high standards that we adhere to ourselves.

EMCI regularly evaluates its suppliers and purchases only from those who can satisfy our demanding quality requirements. Our quality department conducts strict supplier evaluations that weed out all but the best. EMCI continually monitors supplier quality performance. Suppliers whose performance is found to be inadequate are requested to implement corrective actions. If the corrective actions are not implemented or are not effective, the supplier is immediately removed from the approved supplier list.

EMCI maintains an approved supplier list which is periodically reviewed by the Director of Quality for accuracy and completeness. Orders for materials, components, and subcontracted services are only placed with vendors that are on the list. It's tough to get on, or stay on, our list.



Proprietary Products

Product Development

Partnerships

World-Class Outsourcing

**Epic Medical Concepts & Innovations**

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