



# Raising the standards for **product quality**

Ethicon places surgeons and patients front and center throughout our entire process.

**ETHICON**  
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Shaping  
the future  
of surgery

# Going above and beyond Every step of the way

Surgeons demand quality. Patients depend on it. Ethicon delivers it. How? We identify opportunities in a fast-changing world. Then quickly respond and adapt to deliver quality solutions.

One core component of this process: Our comprehensive Quality Management System (QMS). It guides a product from design to marketplace with the goal of surpassing compliance at every phase and achieving continuous product improvement.



# Product design and development: High standards start here

Every product starts with our dedicated New Medical Device group, which includes design, reliability, manufacturing, and quality assurance engineers. These qualified professionals place the patient and surgeon at the center of the product design and development process. This includes developing preclinical design models and partnering with healthcare professionals to focus our process on improving patient outcomes.

To carry out our commitment to quality, Ethicon invests millions of dollars in developing each new product. This includes rigorous testing to ensure our products meet the needs of the surgeon and evolving surgical challenges. Ethicon focuses on meaningful innovation to help advance patient care.



## One product, thousands of hours

The new product development process for HARMONIC® HD 1000i Shears included a significant investment of time and effort to ensure the highest quality design:

- Roughly **92,610** design/development hours
- **663** rigorous tests against design requirements over the product's development life
- **27,624** engineering calculations



## Product stewardship and sustainability

As hospitals reach for new sustainability goals, Ethicon also is embracing environmentally friendly practices. Ethicon participates in the Johnson & Johnson Earthwards® program, which is dedicated to designing more sustainable products. In order to earn Earthwards® recognition, a product must show at least three sustainability improvements across seven impact areas, including materials, waste reduction, packaging, energy and water use, innovation, and social impact.

An Earthwards® success story: The product team for Surgicel® Absorbable Hemostat, a fabric designed to absorb bleeding during surgery, discovered that folding the material instead of rolling it saved so much space that it reduced packaging materials by almost 60%. In addition, Ethicon facilities in the United States, Scotland, Germany, Puerto Rico, and Mexico are independently certified to ISO 14001, an international standard for environmental management systems.

# Product manufacturing and testing: Delivering excellence, every time

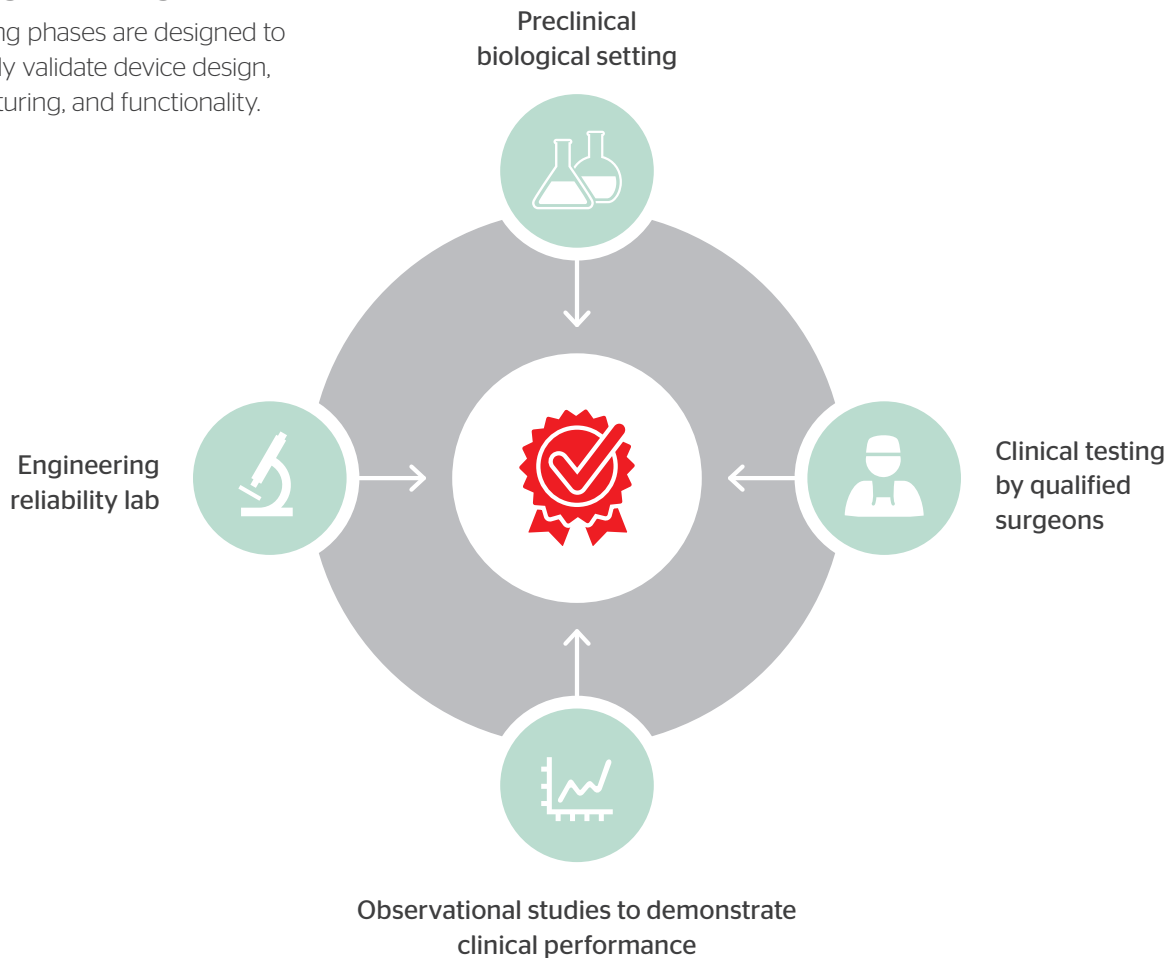


Manufacturing is a critical step in delivering device safety and reliability. We approach product manufacturing with care, craftsmanship, precision, and high-quality components. Our rigorous, state-of-the-art process maintains product traceability and consistent quality.

In fact, international registrars have certified 21 Ethicon facilities in eight countries for maintaining compliance to ISO 13485, an international standard for quality management systems in the medical devices field. Our products also conform to many other international standards as applicable. These include IEC 60601-1, requirements for basic safety and essential performance of medical electrical equipment; ISO 14630, requirements for non-active surgical implants; and others.

## 360-degree testing

Our testing phases are designed to statistically validate device design, manufacturing, and functionality.





## Passing the toughest tests

Ethicon products are put through their paces during the manufacturing process. Our tests and inspections include:

### All devices

- Hours of rigorous quality inspections assure products meet requirements in our production facilities, including device performance, packaging, and label integrity
- Finished goods quality assurance is conducted by highly trained staff

### Surgical stapling

- Every endocutter and circular stapling device is test fired prior to shipment
- Automated vision systems verify staple presence in each cartridge staple pocket

### Energy sealing and dissection

- 100% inspection for features critical to device performance:
  - Acoustic system parameters
  - Clamp force
  - Button activation
  - Closure profile

### Wound closure

- Ethicon needles are qualified to penetrate and carry suture through tissue with minimal resistance while being rigid to resist bending and breakage
- Each Ethicon suture lot is evaluated to confirm appropriate needle attachment and suture tensile strength

### Adjunctive hemostats

- Biosurgery devices and biologic products are designed and manufactured to comply with comprehensive quality requirements and to consistently meet the needs of our customers

# Customer feedback and post-market surveillance: Always listening, always improving

The voices of our customers matter. We encourage surgeons to report any issues with Ethicon products directly to us. This provides valuable information for our continuous product improvement efforts, and we

have dedicated personnel to investigate all reported issues. For Ethicon, every investigation represents an opportunity to optimize device performance for better patient outcomes.

## Rigorous customer response process

Surgeon or hospital reports a **product issue**.



We gather **as much information as possible** from surgeons and other operating room personnel to learn more about the reported event.



Every reported adverse event is investigated by a **cross functional team** that includes Quality Engineering, Medical Professionals, Research and Development, Customer Quality, and Post-Market Surveillance.

Customers receive a **detailed analysis** of each investigation and free product replacement by request.

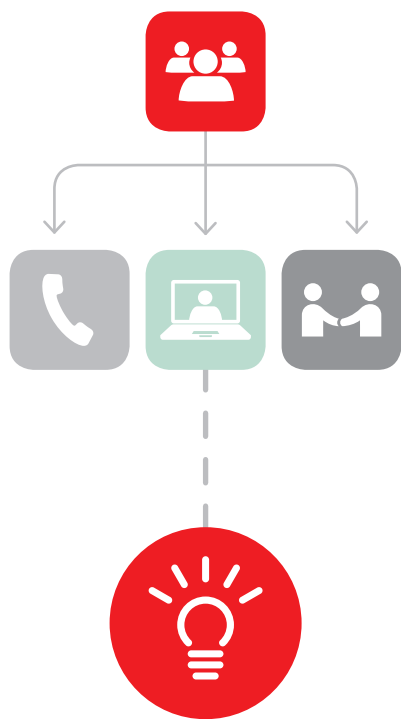


Returned devices are analyzed by a customer quality engineer in an attempt to **determine the root cause** of the issue experienced.



Prepaid return packaging is provided.

A cross functional rapid-response team is also available to address product quality concerns by **phone, video conferencing, and on-site visits**. This cross functional team includes representatives from Research and Development, Quality Engineering, Medical, Customer Quality, Post-Market Surveillance, and Marketing.



Global complaint information is routinely monitored to identify potential product issues and shape **continuous product improvement**.



### Proactive safety monitoring

Global complaint information is routinely monitored using statistically validated methods of quality. In addition to reported events, Ethicon routinely reviews each product family using both internal data sets, such as reported events and manufacturing data, as well as proactive data sources, such as clinical literature reviews and user surveys. This data is used to identify potential product issues and influences future product design, helping us achieve continuous product improvement.



### Better training for optimized device performance

Ethicon offers quality-focused training sessions to support optimized device performance. Our training programs and other tools are influenced by complaint data. We proactively train Ethicon sales staff and hospital clinical staff to reduce product issues potentially associated with use error.



# A commitment to quality A commitment to customers

We're committed to raising the standards of quality because it's the right thing to do. For surgeons. For patients. For customers.

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