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From the Blog

Process Control, Traceability, and Industrialization in Healthcare Product Assembly

March 23rd 2026

Healthcare products are rarely delivered to hospitals as isolated components. Instead, they are increasingly provided as pre-configured procedural kits containing multiple sterile or non-sterile components required for a specific clinical intervention. These kits may include implants, single-use devices, pharmaceuticals, accessories, and protective materials assembled into a single validated packaging system.

As medical device and pharmaceutical companies transition products from development into industrial-scale manufacturing and distribution, the complexity of kit assembly increases significantly. Ensuring that each kit is assembled correctly, maintains sterility where required, and remains fully traceable requires controlled processes aligned with regulatory expectations.

Surgical kit packing and manufacturing services therefore represent a specialized operational discipline combining logistics, quality management, sterile processing, and validated packaging systems. When performed within a regulated environment, these services enable manufacturers to industrialize product assembly while maintaining compliance with international regulatory frameworks.

The Role of Surgical Kit Manufacturing in Healthcare Supply Chains

Procedural kits have become a key component of modern healthcare supply chains because they simplify hospital logistics and reduce preparation time in clinical environments. Typical kits may contain:

- Implantable devices
- Disposable surgical instruments
- Sterile consumables
- Pharmaceuticals or injectables
- Packaging accessories and documentation

Instead of hospitals sourcing each item individually, kits allow all required components to arrive assembled, documented, and ready for use.

However, assembling these kits introduces significant operational challenges:

- Multi-component traceability requirements
- Lot and serial number management
- Sterility maintenance across multiple materials
- Packaging validation and sterile barrier integrity
- Quality inspection and release procedures

For this reason, many manufacturers rely on specialized contract partners capable of performing kit assembly under ISO 13485-compliant quality systems and controlled manufacturing environments.

Process Architecture of Surgical Kit Packing

Industrial surgical kit manufacturing follows a structured process architecture designed to ensure repeatability, traceability, and compliance.

1. Component Reception and Incoming Control

Kit manufacturing begins with the controlled reception of components supplied by the manufacturer or multiple suppliers. Incoming processes typically include:

- Verification of delivery documentation
- Lot and serial number registration
- Visual inspection for transport damage
- Environmental control verification (when applicable)

All materials are entered into a controlled inventory system where full traceability is established before assembly begins.

2. Controlled Storage and Inventory Management

Following reception, components are stored under defined conditions depending on their characteristics. Storage may involve:

- Ambient warehouse environments



Regulatory Framework Governing Kit Assembly

Surgical kit manufacturing must operate within the broader regulatory frameworks governing medical devices and pharmaceutical products.

Key regulatory standards typically include:

- ISO 13485 – Quality management systems for medical devices
- ISO 11607 – Packaging for terminally sterilized medical devices
- ISO 11135 / ISO 17665 – Sterilization process standards (EO and steam)
- EU MDR (Regulation (EU) 2017/745)
- FDA Quality System Regulation (21 CFR Part 820)

These frameworks require that manufacturers demonstrate:

- Controlled assembly processes
- Traceability of all components
- Validation of packaging systems
- Documented inspection and release procedures

Traceability and Documentation

One of the most critical aspects of surgical kit manufacturing is the ability to maintain full traceability across all components and manufacturing steps.

Traceability systems typically record:

- Component supplier and batch numbers
- Assembly operators and timestamps
- Packaging configuration data
- Sterilization batch information
- Final release documentation

These records ensure that manufacturers can demonstrate compliance during regulatory audits.

Distribution and Logistics Integration

After final inspection and release, surgical kits must be prepared for distribution.

Distribution processes may include:

- Final packaging verification
- Labeling and regulatory marking
- Export documentation preparation
- Palletization and shipping coordination

Integrated pick, packing, and shipping solutions allow manufacturers to streamline the transition from manufacturing to distribution.



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- Temperature-controlled storage
- Segregated areas for sterile and non-sterile components

Inventory systems maintain detailed records of:

- Lot numbers
- Storage duration
- Supplier information
- Expiration dates

These controls ensure that only approved components are released to the kit assembly process.

3. Pick and Pack Operations

Once a kit order is released for production, components are retrieved from storage through controlled pick and pack procedures. This stage typically includes:

- Digital work instructions defining kit composition
- Barcode-based component verification
- Sequential assembly steps
- Operator verification checkpoints

Each kit configuration is assembled according to a predefined Bill of Materials (BOM) and controlled assembly protocol. Modern systems increasingly integrate digital manufacturing tools to minimize assembly errors and ensure that the correct components are included in each kit.

4. Kit Assembly and Packaging

During assembly, components are placed into the designated packaging system according to validated instructions. Packaging configurations may include:

- Thermoformed trays
- Pouches
- Multi-layer sterile barrier systems
- Protective packaging for fragile components

Packaging systems must comply with ISO 11607 requirements, ensuring that they can maintain sterility throughout the product lifecycle. Assembly processes are typically performed in controlled environments designed to protect sterile components and maintain product integrity.

5. Integration of Sterilization Processes

For kits that require terminal sterilization, assembly is followed by sterilization processing.

Common sterilization modalities include:

- EO sterilization for temperature-sensitive products
- Steam sterilization for heat-resistant materials

Facilities capable of performing both assembly and sterilization within an integrated operational environment can reduce transport risks and improve efficiency & process control.

Medistri, for example, operates integrated sterilization services within its infrastructure in Switzerland and Hungary, allowing kit assembly to be combined with validated sterilization workflows.

To learn more about Medistri's Manufacturing services, visit our website [here](#) or contact our team at contact@medistri.com.

– The Medistri Team

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For global healthcare supply chains, this integration helps reduce lead times and ensures that kits arrive at hospitals or distributors in a ready-to-use configuration.

Industrialization and Scalability

As healthcare products transition from clinical development to commercial production, kit manufacturing processes must scale while maintaining quality control. Industrialization typically involves:

- Process validation
- Assembly line standardization
- Digital manufacturing instructions
- Inventory planning and logistics integration

Contract manufacturing partners capable of supporting both early-stage assembly and high-volume production can provide continuity throughout the product lifecycle.

With dual operational infrastructure in Switzerland and Hungary, Medistri supports manufacturers across multiple development stages, from small pre-clinical kit preparation to large-scale industrial assembly combined with sterilization and laboratory validation services.