



Engineered Medical Packaging Solutions

SIX SIGMA Ltd.

Sterilization-Ready

ISO 13485 Certified QMS

Production-Scalable

What We Do

We support medical device manufacturers from concept to mass production, delivering engineered packaging systems designed for safety, compliance, and scalable production.



Packaging engineering & custom cavity design



Medical-grade material selection



Process validation support (IQ/OQ/PQ)



Tyvek® and sterile barrier system integration



Prototype sampling & production ramp-up



Validation-ready sterile barrier systems

Packaging Validation & Regulatory Compliance

We design sterile barrier systems in alignment with international medical packaging standards and regulatory expectations.



Designed to support ISO 11607 sterile barrier system requirements



Seal strength & peel performance validation support



Accelerated & real-time aging study support



Transportation testing support (ISTA protocols)



Sterilization compatibility (EO, Gamma, E-beam)



Cleanroom manufacturing options



Documentation support for EU MDR Technical Documentation



Packaging Development Process

Structured development from concept to validated production:



Our Packaging Solutions



Rigid Packaging

Designed for disposable and sterile medical devices requiring stable protection and precise cavity control



Tyvek® Wrap & Cover

Tyvek®-based cover materials providing reliable microbial barrier and compatibility with common sterilization processes



Flexible Packaging

Flexible sterilization packaging solutions suitable for disposable medical devices and cost-sensitive applications



Integrated Supply

We deliver integrated plastic and metal medical components, mechanical sub-assemblies, and custom packaging solutions under one ISO 13485-certified manufacturing framework.

Our coordinated engineering approach ensures compatibility, scalability, and production stability - with single-source accountability.

Rigid Packaging Solutions

Rigid Packaging Overview



Strong protection for precision medical components

Designed in alignment with ISO 11607 requirements

Suitable for sterile and non-sterile medical applications

Engineered to withstand sterilization, transportation and aging conditions

Custom cavity design and material options available based on device requirements

Packaging for Sharp & Puncture Medical Devices



Secure cavity design for sharp and puncture instruments to limit movement and reduce damage risk

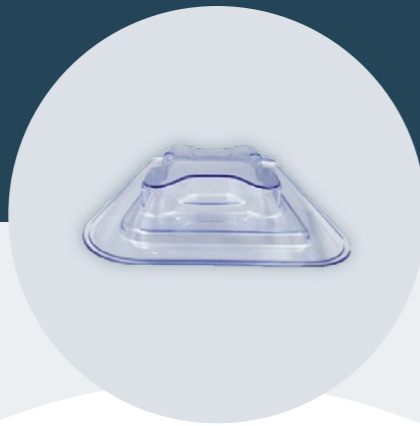
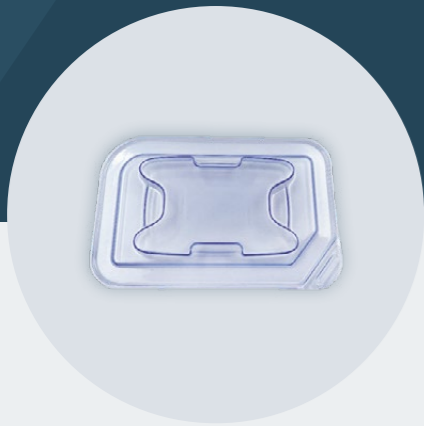
Secure fixation to reduce risk of sterile barrier compromise.

Material options compliant with medical-grade requirements.

Designed with consideration for EO or Gamma sterilization, depending on material and structure selection

Material options include PETG, APET, PET, PS, PP, and PVC, selected according to application needs

Disposable Laryngoscope Packaging



Stable fixation for disposable laryngoscopes

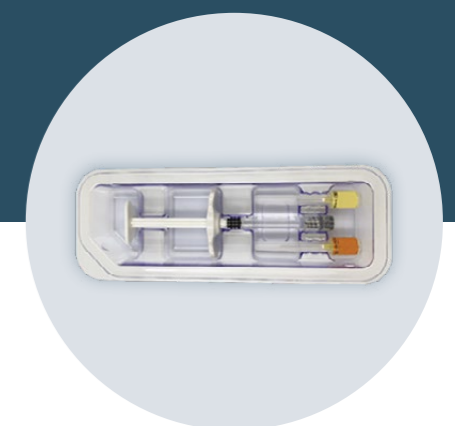
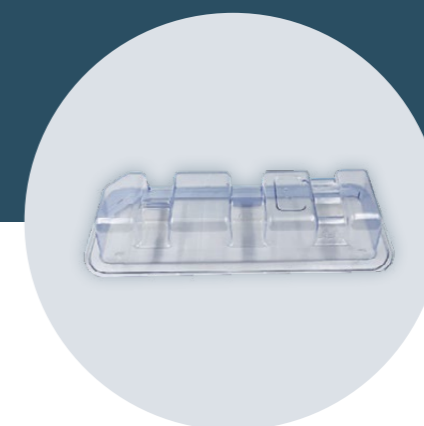
Clear packaging structure for visual inspection of the product

Designed for single-use medical applications

Designed to maintain sterile barrier integrity

Optimized for clinical handling

Aesthetic Injection Device Packaging



Clinically appropriate appearance for medical devices

Protects precision injection components during handling and transportation

Compatible with sterile barrier sealing systems

Designed for controlled peel performance

Suitable for sterile applications based on packaging structure and material selection

Custom blister shapes and structures available

Tyvek® Material Solutions

Tyvek® Material Overview

Microbial Barrier

Provides reliable protection against microbial contamination

Breathability

Optimized breathability to support EO sterilization processes

Peel Performance

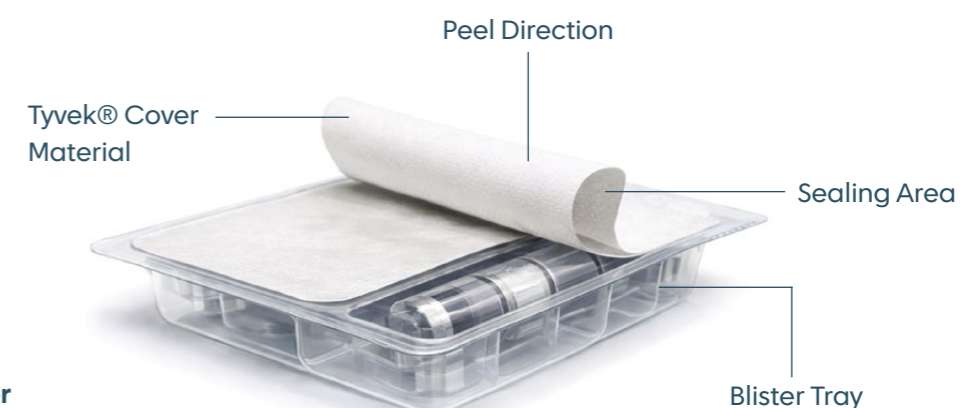
Designed for consistent sealing strength and clean opening

Tyvek® Material Selection Guide

How to Choose the Right Tyvek® Coating for Your Application

Type	Key Feature	Application
Water-based Coating	Clean sealing, eco-friendly	Stable peel performance
Hot-melt Adhesive	Strong sealing strength	High-speed packaging lines
Water-resistant Coating	Moisture resistance	Automatic packaging machines

Typical Blister Sealing Structure



Tyvek® 1073B Water-based Coating System



High breathability suitable for EO sterilization processes

Clean and smooth peel performance

Suitable for blister packaging cover applications

Widely applied in disposable medical device packaging

Tyvek® 1059B Hot Coating System



Strong and consistent sealing strength

Designed for high-speed automatic packaging operations

Stable performance during sterilization processes

Ideal for mass production environments

Tyvek® Roll Materials



Available in multiple Tyvek® grades

Suitable for automatic sealing equipment (FFS)

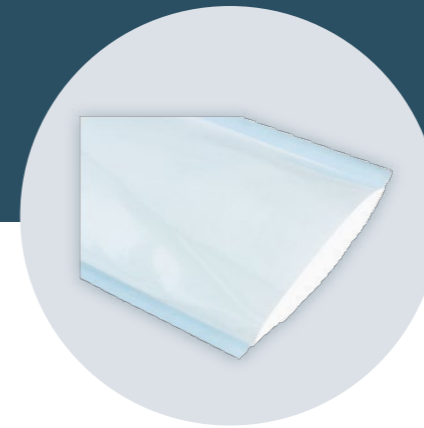
Consistent quality and performance

Custom width and roll length available

Controlled basis weight and consistent porosity

Flexible Packaging Solutions

Flexible Packaging Overview



Suitable for EO sterilization processes

Breathable and protective packaging structures for disposable medical devices

Cost-effective solutions for volume production

Custom size and material combinations available

Designed for validated sterile barrier systems

Tyvek® Sterilization Bags

Paper-Plastic Sterilization Bags



Reliable microbial barrier performance

Peel strength performance control

Seal integrity validation support

Designed for EO or Gamma sterilization, depending on material structure

Clean opening and consistent sealing performance

Available in standard and custom sizes

Medical-grade paper compliant with EN 868

Reliable breathability for sterilization

Transparent film for product visibility

Widely used for disposable medical devices

Cost-efficient packaging solution

Medical Grade Sterilization Paper Packaging

Special Flexible Packaging



Designed specifically for EO sterilization

High breathability and safety performance

Stable sealing strength

Suitable for medical consumables

Self-Adhesive

Adhesive-free closure design

Paper-Aluminum

Composite bags for moisture and light protection

Customized

Tailored structures for unique medical device needs

Quality & Compliance

Manufacturing under an ISO 13485-certified QMS, with sterile barrier validation support and European regulatory experience



Your Integrated Medical Manufacturing Partner

Precision Components

- ✓ Plastic & Metal Medical Parts
- ✓ Mechanical Sub-Assemblies

Engineered Packaging

- ✓ Custom Blister Systems
- ✓ Sterile & Non-Sterile Solutions

Single-Source Manufacturing

- ✓ Scalable Production
- ✓ ISO 13485-Certified QMS

Let's build your next medical device together.

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