



SIGMA[®]

a subsidiary of BenQ Materials



Passion for
Better Protection

SIGSeal™

Tyvek® Coating Technology

Features

- In-house eco-friendly water-based adhesive
- Combines breathability with excellent sealing properties
- Offers superior humidity and condensation resistance
- Remains free from yellowing over time

Core Strengths



Exceptional
air permeability



Uniform
heat sealing



Consistent
seal quality



Even adhesive
application

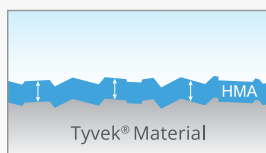


Resistance
to yellowing



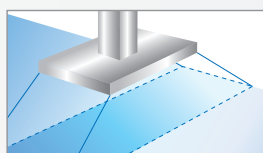
Long-lasting
seal strength

Advantages



Non-Contact Coating

Introduction of Non-Contact Coating
for even adhesive application.



Precision Thickness Control

Ensures impeccable and precise
adhesive control.



AOI Process

Real-time monitoring of coating
defects during the AOI process.

Performance Data

| Properties | Test Method | Units | Tyvek® 2FS | Tyvek® 1059B |
|-----------------------|-------------|-----------|---------------------------|------------------------|
| Basis Weight | ASTM D3776 | g/m2 | 59.5 | 64.4 |
| Coat Weight | ASTM-F2217 | g/m2 | 18 | 18 |
| Coated Base Weight | ASTM D3776 | g/m2 | 77.5 | 82.4 |
| Tensile Strength (MD) | EN ISO 1924 | N/15mm | 92 | 99 |
| Tensile Strength (CD) | EN ISO 1924 | N/15mm | 93 | 103 |
| Elmendorf Tear (MD) | ASTM D1424 | N | 2.8 | 3 |
| Elmendorf Tear (CD) | ASTM D1424 | N | 3.7 | 3.2 |
| Gurley Hill Porosity | ISO-5636-5 | sec/100cc | 82 | 87 |
| Thickness | ASTM F2251 | um | 170 | 185 |
| Dye Penetration | ASTM F1929 | - | Pass | Pass |
| Sealing Strength | ASTM F88 | N/15mm | 3.1N (Base on PE Film) | 3.9N (Base on PETG) |

Medical Device Manufacturers (MDM) Use

Header Bags (3 Layers)



Features

- Tight sealing and puncture resistance to support and suitable for packaging the sharp surgical devices.
- High moisture resistance and microbial barrier make it suitable for packaging of high dollar value implantable medical devices.
- Tyvek® enables effective sterilization of surgical materials and ensures the sterile barrier system. Sterility inside the bag.
- With Tyvek® printing technology, ink printed on Tyvek is precise and settled.

Applications

- Disposable surgical gown packaging
- Breastfeeding medical device products packaging
- Cardiac catheter tube and stent packaging
- Eustachian tube balloon dilation catheter



| Top web | Bottom web | | Specifications | | Sterilization methods |
|-------------------|------------|----------------|----------------|-------------|------------------------|
| Model number | Structure | Thickness (um) | Width (mm) | Length (mm) | |
| 2FS (Laminated) | PE | 75 & 100 | 150~800 | 200~800 | E.O Plasma Gamma |
| 1059B (Laminated) | | | | | |
| 1073B (Laminated) | | | | | |

CUSTOMER'S SIZE, SUPPLIED UPON REQUEST.

Reinforced Header Bags (4 Layers)



Features

- Larger capacity than Header Bags (Standard) make it suitable for larger and heavier medical devices.
- Tight sealing and puncture resistance feature to support and suitable for sharp surgical devices. High moisture resistance and microbial barrier makes it suitable for high dollar value implantable medical devices.
- Tyvek® enables effective sterilization of surgical materials and ensures the sterile barrier system.
- With Tyvek® printing technology, ink printed on Tyvek is precise and settled.

Applications

- Disposable surgical drape packs and equipment cover
- Large surgical supplies packaging
- Breastfeeding medical device products packaging
- Large surgical sets packaging



| Top web | Bottom web | | Specifications | | Sterilization methods |
|-------------------|------------|----------------|----------------|-------------|------------------------|
| Model number | Structure | Thickness (um) | Width (mm) | Length (mm) | |
| 2FS (Laminated) | PE | 75 & 100 | 150~800 | 200~800 | E.O Plasma Gamma |
| 1059B (Laminated) | | | | | |
| 1073B (Laminated) | | | | | |

CUSTOMER'S SIZE, SUPPLIED UPON REQUEST.

Aluminum Foil Bag



Features

- Excellent light-shielding properties are suitable for products that need to be protected from light.
- Higher water and oxygen resistance, can be used for anti-oxidation, water and moisture resistance.

Applications

- Surgical blade packaging
- Electrode pad patch packaging
- Surgical suture packaging
- Hemostatic dressing and cotton packaging
- Packaging for temporary anchorage device and reconstruction plate



| Top web | | Bottom web | | Specifications | | Sterilization methods |
|-------------------------|----------------|-----------------------------|----------------|----------------|-------------|-----------------------|
| Structure | Thickness (um) | Structure | Thickness (um) | Width (mm) | Length (mm) | |
| Easy-Peel Aluminum Foil | 90 | Non-Easy-Peel Aluminum Foil | 90 | 30~800 | 50~1000 | Gamma |
| | | PET/ PE | 52 & 72 | | | |

CUSTOMER'S SIZE, SUPPLIED UPON REQUEST.

Easy-Peel Pouches/ Film Pouches

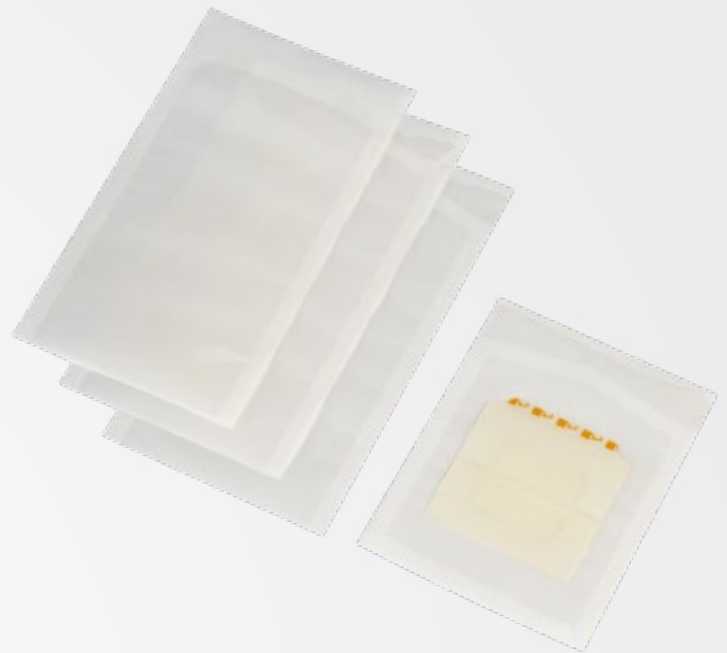


Features

- High-strength sealant and puncture resistance, suitable for storing medical products with sharp edges.
- Customized multi-layer film is available.
- Both webs of Easy-Peel Pouches are transparent, allowing users to see the contents of the products clearly.
- The medical film has excellent antibiotic properties and can be sterilized effectively and remain the sterile barrier system.

Applications

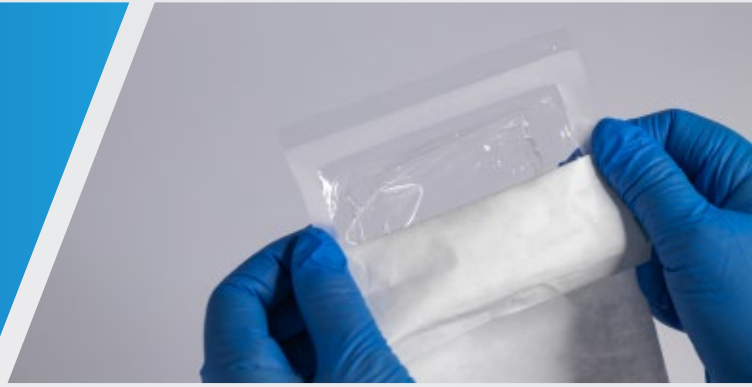
- Various types of gloves
- Packaging for temporary anchorage devices and reconstruction plates
- Disposable medical instruments (Cell Culture Tubes)
- Ideal breathable packaging for wound care products



| Top web | | | Bottom web | | Specifications | | Sterilization methods |
|-------------------|-----------------------------------|----------------|------------|----------------|----------------|-------------|-----------------------|
| | Structure | Thickness (um) | Structure | Thickness (um) | Width (mm) | Length (mm) | |
| Easy-Peel Pouches | Milky white easy-peel film | 65 | PET/PE | 52 & 72 | 30~800 | 50~1000 | Gamma |
| | Polyester and easy-peel polyester | 52 & 72 | PET/PE | 52 & 72 | | | |
| Film Pouches | PET/PE | 52 | PET/PE | 52 | 30~800 | 50~1000 | Gamma |

CUSTOMER'S SIZE, SUPPLIED UPON REQUEST.

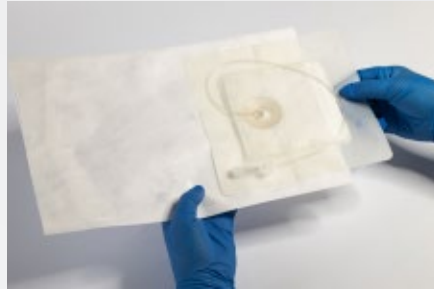
Multi-Layer Medical Films



PP-Laminated Film



PE-Laminated Film



Blister Film

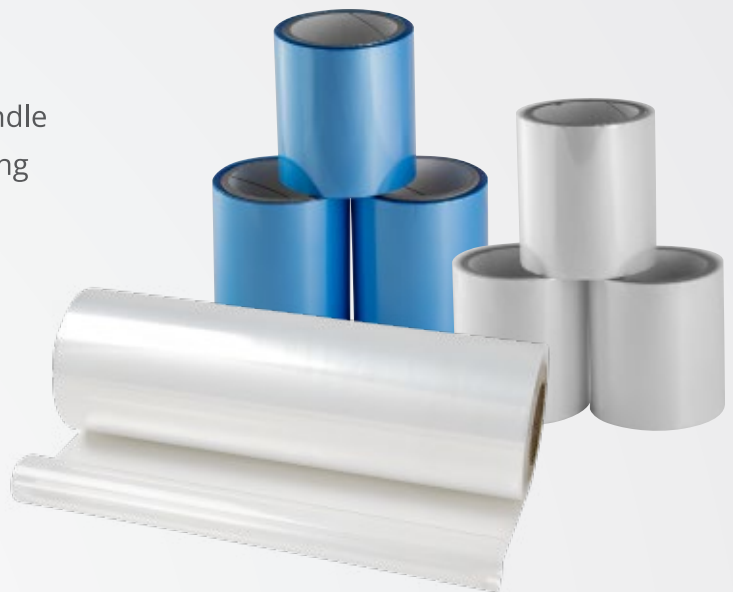


Features

- Enhanced firmness and tensile strength
- Excellent heat-sealing ability and easy to handle
- Customized puncture resistance for packaging heavy or sharp medical devices

Applications

- General medical device packaging
- Surgical glove packaging
- Disposable needles
- Intravenous catheters
- Disposable medical devices/consumables



| Type | Structure | Application | Thickness (um) | Width (mm) | Length (M) | Color |
|-------------------|---------------------------------------|--------------------------------------------------------|----------------|------------|------------|--------------------------|
| PP-laminated film | PET/PP | Steam sterilization for medical devices | 42, 52, 62 | 400~1,250 | 500~3,000 | Blue, green, transparent |
| PE-laminated film | PET/PE | EO, Plasma, and Gamma for medical devices | 52, 72 | 400~1,250 | 500~3,000 | Transparent |
| Blister film | PA co-extrusion / Non-PA co-extrusion | Medical device packaging with flexibility requirements | 40~200 | 400~1,250 | 500~3,000 | Transparent |

Medical Paper Rolls



Features

- Various coated or printed paper is available.
- Both high and low temperature medical paper, can be sterilized effectively and antibacterial.
- With good heat-sealing strength, it can remain sterile barrier system after sealing with film.
- With Tyvek® printing technology, ink printed on Tyvek is precise and settled.
- Special water-based/hot-melt glue with precision coating technology to increase the ease of the sealing process.

Applications

- Suitable for all medical-grade sterilization packaging (medication packs, gauze, medical plaster patches, medical swabs, cotton patches, syringes, sputum suction tubes, dialysis tubing bags, etc.)
- Commonly applied in sealed bags or FFS (Form-Fill-Seal) machines



| Porous Materials | Gram | Coating* | Sterilization |
|------------------------|---------------------|----------|----------------------|
| High-temperature paper | 60 & 70 | N | Steam / E.O / Plasma |
| Low-temperature paper | 60, 70, 80, 83 & 90 | Y or N | E.O / Plasma |
| Tyvek® | 2FS, 1059B, 1073B | Y or N | E.O / Plasma / Gamma |

Self/Heat-Sealing Pouches



Features

- Multi-Sealing Lines : Reduce fiber peel and the risk of damage of sealing-integrity while loading, stocking and transporting.
- Non-Polluted Printing : Printing is located at the sealing area / outside packing areas with water-based ink to avoid contamination on packed items during sterilization.
- Assured Sterility : Followed by ISO standards and CDC infection control guidelines.

Specifications

- Medical grade paper is available in both 60gsm & 70gsm & 80gsm & 90gsm.
- Film is available with tinted-blue standard film and tinted-green film and transparent film.
- Products are available with 60gsm medical paper & 52um tinted-blue standard film and 70gsm medical paper & 52um tinted-green film.
- With 2 indicators for Steam & E.O. Gas sterilization.



| Self-sealing Sterilization Pouches | | | Heat-sealing Sterilization Pouches | | |
|------------------------------------|-----------|---------|------------------------------------|-----------|---------|
| SIZES | BOXES/CTN | PCS/CTN | SIZES | BOXES/CTN | PCS/CTN |
| 57mm x 133mm | 90 | 18000 | 75mm x 200mm | 12 | 9600 |
| 90mm x 162mm | 30 | 6000 | 75mm x 300mm | 8 | 6400 |
| 70mm x 257mm | 40 | 8000 | 100mm x 200mm | 8 | 6400 |
| 90mm x 257mm | 30 | 6000 | 100mm x 300mm | 6 | 4800 |
| 135mm x 283mm | 20 | 4000 | 150mm x 300mm | 4 | 3200 |
| 180mm x 335mm | 15 | 3000 | 200mm x 400mm | 4 | 1600 |
| 190mm x 358mm | 10 | 2000 | 250mm x 450mm | 4 | 1600 |
| 300mm x 380mm | 5 | 1000 | 300mm x 500mm | 3 | 1200 |
| 300mm x 474mm | 5 | 1000 | | | |

CUSTOMER'S SIZE, SUPPLIED UPON REQUEST.

Flat/Gusseted Roll



Features

- Multi-Sealing Lines : Reduce fiber peel and the risk of damage of sealing-integrity while loading, stocking and transporting.
- Non-Polluted Printing : Printing is located at the sealing area / outside packing areas with water-based ink to avoid contamination on packed items during sterilization.
- Assured Sterility : Followed by ISO standards and CDC infection control guidelines.

Specifications

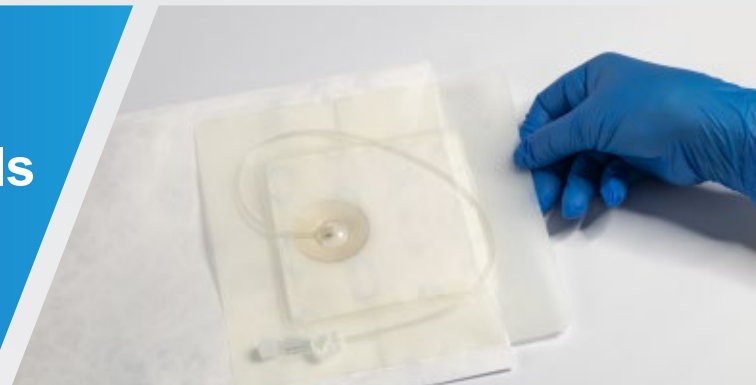
- Medical grade paper is available in both 60gsm & 70gsm & 80gsm & 90gsm.
- Film is available with tinted-blue standard film and tinted-green film and transparent film.
- Products are available with 60gsm medical paper & 52um tinted-blue standard film and 70gsm medical paper & 52um tinted-green film.
- With 2 indicators for Steam & E.O. Gas sterilization.



| Flat Sterilization Rolls | | Gusseted Sterilization Rolls | |
|--------------------------|-------|------------------------------|-------|
| SIZES | R/CTN | SIZES | R/CTN |
| 50mm x 200M | 16 | 75mm x 100M | 10 |
| 75mm x 200M | 10 | 100mm x 100M | 8 |
| 100mm x 200M | 8 | 150mm x 100M | 8 |
| 150mm x 200M | 6 | 200mm x 100M | 4 |
| 200mm x 200M | 4 | 250mm x 100M | 4 |
| 250mm x 200M | 2 | 300mm x 100M | 4 |
| 300mm x 200M | 2 | 350mm x 100M | 4 |
| 350mm x 200M | 2 | 400mm x 100M | 2 |
| 400mm x 200M | 2 | | |

CUSTOMER'S SIZE, SUPPLIED UPON REQUEST.

Tyvek / Film Sterilization Rolls & Heat-Sealing Pouches



Features

- Provides an effective sterile barrier and prevents medical devices from cross infection.
- Tyvek® paper with air permeability, anti-bacterial, waterproof, and leakproof.
- Applies non-toxic ink and de-ink prevention technology.
- Transparent film makes it easy for users to identify the contents within the packaging.
- Strong sealing edge prevents bursting after the sterilization and maintains the integrity of the sealing.

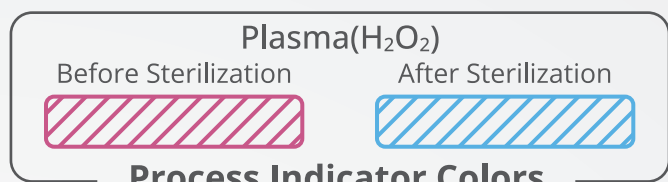
Applications

- Suitable for low-temperature and ultra-low-temperature surgical instrument packaging.
- Medical surgical consumables and special material packaging.
- Sterilization bags for endoscopes.
- Tyvek® Flat Heat-Sealing Pouches are used for packing flat and small-sized instruments.
- Tyvek® Gusseted Heat-Sealing Pouches are used to pack stereoscopic and large-sized instruments





- Durable / Tear Resistant / Lightweight & Flexible / Water-resistant & Breathable / Unique Balance of Strength & Softness.
- **Sterilization methods** : Hydrogen Peroxide (Plasma), E.O. Gas, Gamma and Electron-beam Sterilization.
- **Non-polluted printing** : All of printings are placed at sealing areas with water-based ink to avoid contamination.



*Plasma(H₂O₂) indicator is available upon request.

*OEM & ODM are welcome.

| Top web | | Bottom web | | Specifications | | Sterilization methods |
|-------------------------------------|--------------|------------|----------------|----------------|-------------|------------------------|
| | Model number | Structure | Thickness (um) | Width (mm) | Length (mm) | |
| Tyvek® Flat Sterilization Rolls | 2FS | PET/ PE | 52 & 72 | 50~6000 | 70~200 | E.O Plasma Gamma |
| | 1059B | | | | | |
| | 1073B | | | | | |
| Tyvek® Gusseted Sterilization Rolls | 2FS | PET/ PE | 52 & 72 | 30~800 | 50~1000 | E.O Plasma Gamma |
| | 1059B | | | | | |
| | 1073B | | | | | |

CUSTOMER'S SIZE , SUPPLIED UPON REQUEST.

SIGMA is a associated converter of Dupont.



Medical Sealer



Features

- High-speed sealing
- Reproducible sealing process
- Space-saving allocation
- One-stop shopping experience for medical sterilization packaging materials and sealers
- Material selection recommendations for sterilization packaging materials provided, along with optimization of heat sealing parameters for medical sealers

Specification

- Sealing speed: 10m/min
- Sealing seam width: 12mm
- Sealing temperature: max. 220°C
- With conductor monitoring sealing temperature, pressure, and speed
- Main connection/frequency: 115/230V50/60 Hz
- Power: 390W
- Dimension: 505*255*145mm
- Weight: 12kg

Applications

- Suitable for sealing medical pouch/reel

| Model | Sealing speed | Sealing seam width | Sealing Temperature |
|---------------------------|---------------|--------------------|---------------------|
| Medical Sealer | 10 m/min | 12mm | Max. 220°C |
| Main connection/Frequency | Power | Dimension | Weight |
| 115/230V 50/60 Hz | 390 W | 505*255*145 mm | 12kg |

Certifications

Product certification and production process validation in compliance with ISO 11607.

Certified by the
Taiwan Food and Drug
Administration (TFDA)

Medical sterilization packaging design and manufacturing process has received the TFDA QMS (formerly GMP).

ISO 13485:2016
Medical Devices -
Quality Management
System

Medical sterilization packaging design and manufacturing process passed the ISO 13485 certification in 2016.

ISO14644-1
Cleanrooms
Standards

Medical packaging manufacturing environments are in accordance to the FED-209E, ISO 14644-1, and EU CGMP environmental certifications which specify the maximum allowable concentration of particles above 0.5-micron.

USA

Medical products and devices comply with 21 CFR Part 820 - Quality System Regulation.

EU

In accordance with EU MDR Regulations for Medical Products and Devices.





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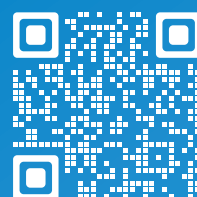
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