

Disposable and Surgical Isolation Gowns

Inngen

Inngen Products
2020



ISO 9001:2015 ISO 14001:2015 ISO 113485:2016 OHSAS 18001:2007 ISO 26000:2010 ISO 22301:2014 ISO 27001:2013

FDA

Protective materials

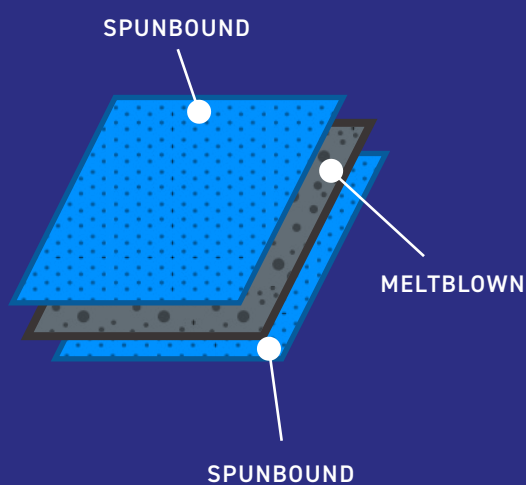
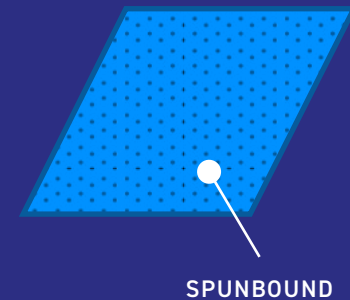
Product range and materials descriptions

In-001

SPUNBOND POLYPROPYLENE

Standard, cost-effective and comfortable

For basic infection control, this non-woven fabric bonds fibers together to form a single layer that is appropriate only for very minimal fluid exposure.



In-002

SMS MATERIAL

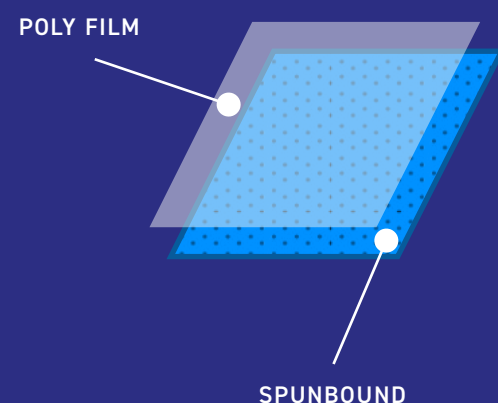
Balanced mix of protection and comfort

Strong and breathable, Spunbond/Meltblown/ Spunbond (SMS) is a multi-layer fabric composed of inner layers of meltblown polypropylene between outer layers of spunbond polypropylene that is ideal for extended wear. Light/medium weight SMS is appropriate for low amounts of fluid and heavy weight SMS maybe appropriate for moderate contact with fluids.

In-003

COATED POLYPROPYLENE

Soft, spunbond polypropylene is coated with a layer of polyethylene (plastic) film.



IN-001

Isolation Gown Light Weight PP



Meets AAMI level 1 requirements



Light PP fabric



Natural rubber latex-free



Anti-static treated fabric



Our products provide high protection and great comfort

Compliance with
EN ISO 13485:2016
EN 14971:2012
EN ISO 15223-1:2016



Personal Protective Equipment (PPE) is a two-way street. Originally developed to protect the healthcare worker, PPE when used properly can also represent the first line of defense against contact transfer of pathogens like MRSA and viruses like Covid-19.

Isolation gown

IN-001

Basic spunbond polypropylene gown. Comfort and protection for use in very minimal fluid settings. Generously sized for greater coverage and flexibility.

Knit cuffs, ties at the neck and waist, breathable back

Size

S to XL



Neck Hook & Loop Fastening

For ease of adjustment and fit.

Ultrasonically bonded sleeves

Maximum protection in critical areas

Flexible cuffs

Reduces chance of skin debris being transferred to patient while maintaining dexterity

Anti-alcohol and anti-static treatment

Enhances safety and clinical comfort

Side fastening

Support clinical protocols of gown donning

Suitable for health care workers and visitors, helps to prevent contamination with particulates.

IN-002

Isolation Gown Medium Weight SMS



Meets AAMI level 2 requirements



Medium Weight SMS



Natural rubber latex-free



Anti-static treated fabric

Compliance with
EN13795
EN ISO 13485:2016
EN 14971:2012
EN ISO 15223-1:2016



Our products provide high protection and great comfort

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Using the latest advancements in SMS technology, gown offer outstanding softness and enhanced breathability. This lightweight line has great moisture evaporation, leaving the wearer cool and dry.

Isolation gown

IN-002

Fluid Resistant, Isolation Gown -
Medium Weight, SMS Suitable
for procedures with moderate
risks of exposure to
nonbiological fluids.

Knit cuffs, ties at the neck and
waist, breathable back

Size

S to XL



Neck Hook & Loop Fastening

For ease of adjustment
and fit.

Ultrasonically bonded sleeves

Maximum protection in
critical areas

Flexible cuffs

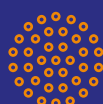
Reduces chance of skin
debris being transferred to
patient while maintaining
dexterity

Anti-alcohol and anti-static treatment

Enhances safety and
clinical comfort

Side fastening

Support clinical protocols
of gown donning



Class 3 Resistance

penetration by contaminated
solid particles
EN ISO 22612 per EN 14126



Class 6 Resistance

bacterial penetration
EN ISO 22610 per EN 14126



Resistance

liquid penetration
>200 cmH₂O

IN-003

Surgical Laminated Gown SMS 45 GSM



Meets AAMI level 3 requirements



SMS 45 GSM



Natural rubber latex-free



Anti-static treated fabric

Compliance with
EN13795
EN ISO 13485:2016
EN 14971:2012
EN ISO 15223-1:2016



Our products provide high protection and great comfort

High performance gown with microporous film technology, this surgical gown offers a superb combination of protection and comfort. Gown blocks fluids while still allowing moisture vapour to escape, keeping the wearer dry and comfortable.

Surgical laminated gown

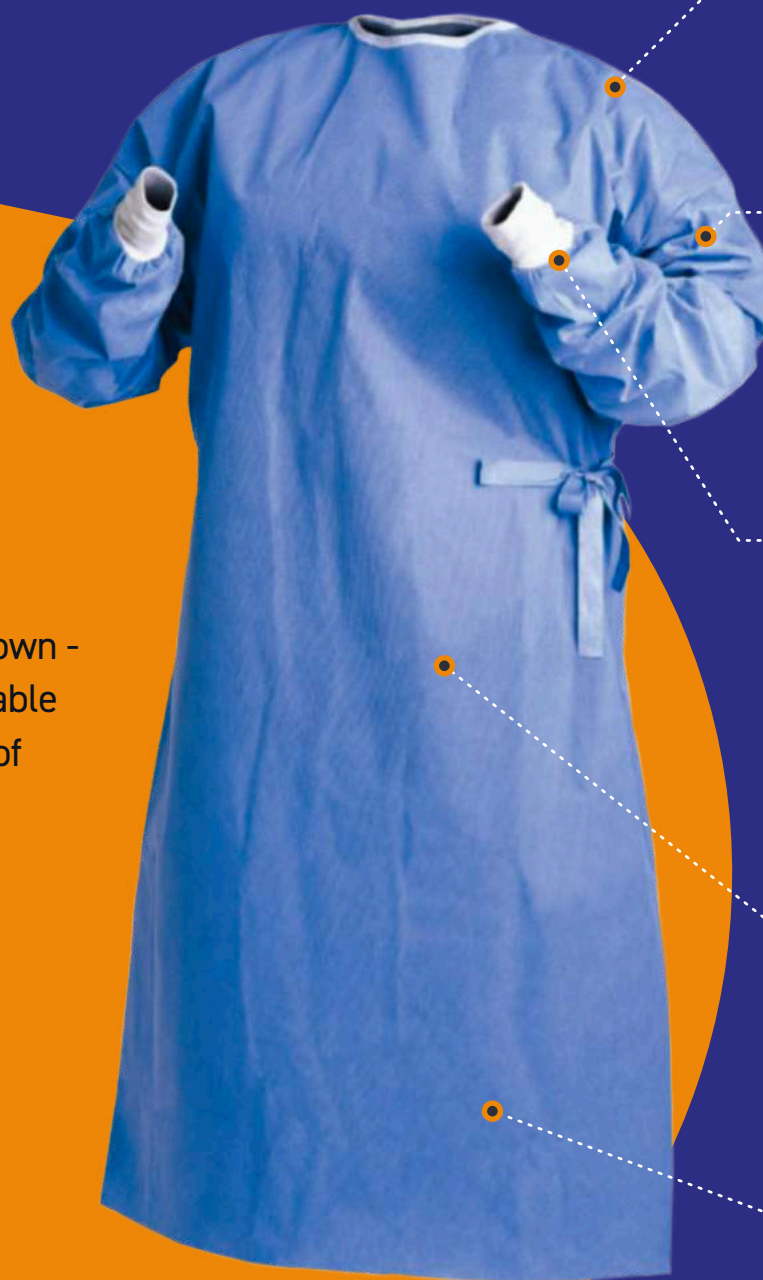
IN-003

Surgical Laminated Isolation Gown -
SMS 45 GSM Microporous Suitable
for procedures with high risks of
exposure to fluids.

Knit cuffs, ties at the neck and
waist, breathable back

Size

S to XL



Neck Hook & Loop Fastening

For ease of adjustment
and fit.

Ultrasonically bonded sleeves

Maximum protection in
critical areas

Flexible cuffs

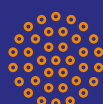
Reduces chance of skin
debris being transferred to
patient while maintaining
dexterity

Anti-alcohol and anti-static treatment

Enhances safety and
clinical comfort

Side fastening

Support clinical protocols
of gown donning



Class 3 Resistance

penetration by contaminated
solid particles
EN ISO 22612 per EN 14126



Class 6 Resistance

bacterial penetration
EN ISO 22610 per EN 14126



Resistance

liquid penetration
>500 cm H₂O

IN-004

Surgical Laminated Gown Height Weight PP+PE Lamination



Meets AAMI level 4 requirements



Height weight PP+PE



Natural rubber latex-free



Anti-static treated fabric

Compliance with
EN13795
EN ISO 13485:2016
EN 14971:2012
EN ISO 15223-1:2016



Our products provide high protection and great comfort

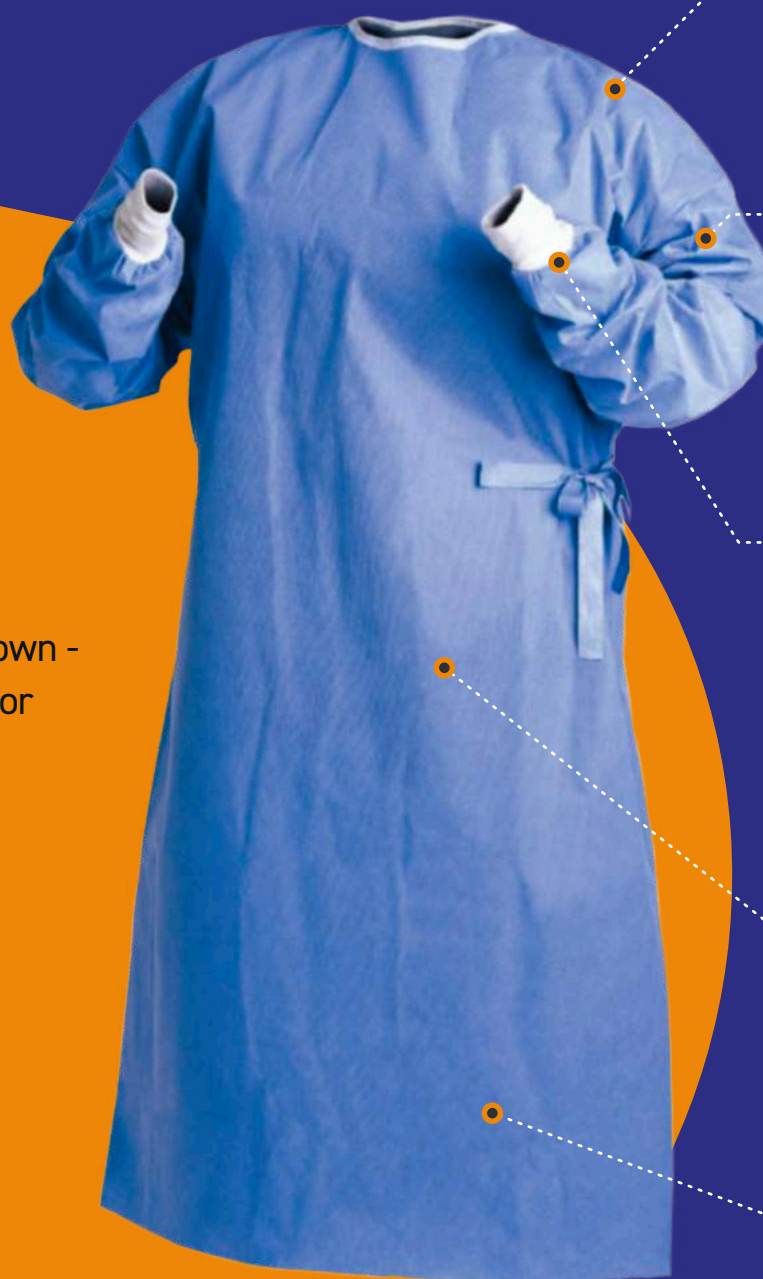
High performance gown with microporous film technology, this surgical gown offers a superb combination of protection and comfort. Gown blocks fluids while still allowing moisture vapour to escape, keeping the wearer dry and comfortable.

Surgical laminated gown **IN-004**

Surgical Laminated Isolation Gown -
PP + PE Microporous Suitable for
procedures with high risks of
exposure to fluids.

Knit cuffs, ties at the neck and
waist, breathable back

Size
S to XL



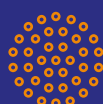
**Neck Hook & Loop
Fastening**
For ease of adjustment
and fit.

**Ultrasonically bonded
sleeves**
Maximum protection in
critical areas

Flexible cuffs
Reduces chance of skin
debris being transferred to
patient while maintaining
dexterity

**Anti-alcohol and
anti-static treatment**
Enhances safety and
clinical comfort

Side fastening
Support clinical protocols
of gown donning



Class 3 Resistance
penetration by contaminated
solid particles
EN ISO 22612 per EN 14126



Class 6 Resistance
bacterial penetration
EN ISO 22610 per EN 14126



Resistance
liquid penetration
>500 cm H₂O

USA Levels of Barrier Protection Standards

AAMI (The Association for the Advancement of Medical Instrumentation®) PB70 guidelines

| Level 1 | Level 2 | Level 3 | Level 4 |
|---|---|---|---|
| Minimal fluid levels | Low fluid levels | Moderate fluid levels | Hight fluid levels |
| <div>AATCC 42</div> <div>Impact penetration</div> <div>Measures the resistance of fabrics to the liquid penetration of water by impact.</div> <div>< 4.5 g</div> | <div>AATCC 42</div> <div>Impact penetration</div> <div>Measures the resistance of fabrics to the liquid penetration of water by impact.</div> <div>< 1.0 g</div> <div>AATCC 127</div> <div>Hydrostatic pressure</div> <div>Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.</div> <div>> 20 cm</div> | <div>AATCC 42</div> <div>Impact penetration</div> <div>Measures the resistance of fabrics to the liquid penetration of water by impact.</div> <div>< 1.0 g</div> <div>AATCC 127</div> <div>Hydrostatic pressure</div> <div>Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.</div> <div>> 50 cm</div> | <div>ASTM F1671</div> <div>Viral penetration</div> <div>Measures the resistance of materials used in protective penetration by blood borne pathogens using a surrogate microbe under conditions of continuous liquid contact.</div> <div>Impervious</div> |

Association for the Advancement of Medical Instrumentation. Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for use in Health Care Facilities. ANSI/AAMI PB70:2012. Arlington, VA: AAMI.

EU performance requirements and performance levels for surgical gowns EN 13795

Performance requirements for surgical gowns

| Characteristic | Standard performance | | Hight performance | |
|--|----------------------|---------------------|-----------------------|---------------------|
| | Critical area | Less critical area | Critical area | Less critical area |
| Resistance To Microbial Penetration – Dry <i>Log₁₀ (CFU)</i> | N/A | ≤ 2 ^{a, c} | N/A | ≤ 2 ^{a, c} |
| Resistance To Microbial Penetration – Wet <i>BI</i> | ≥ 2,8 ^b | N/A | ≥ 6,0 ^{b, d} | N/A |
| Cleanliness – Microbial <i>Log₁₀ (CFU/dm²)</i> | ≤ 2 ^c | ≤ 2 ^c | ≤ 2 ^c | ≤ 2 ^c |
| Cleanliness – Particulate Matter <i>IPM</i> | ≤ 3,5 | ≤ 3,5 | ≤ 3,5 | ≤ 3,5 |
| Linting <i>Log₁₀ (5m count)</i> | ≤ 4,0 | ≤ 4,0 | ≤ 4,0 | ≤ 4,0 |
| Resistance to Liquid Penetration <i>cm H₂O</i> | ≥ 20 | ≥ 10 | ≥ 100 | ≥ 10 |
| Bursting Strength – Dry <i>kPa</i> | ≥ 40 | ≥ 40 | ≥ 40 | ≥ 40 |
| Bursting Strength – Wet <i>kPa</i> | ≥ 40 | N/A | ≥ 40 | N/A |
| Tensile Strength – Dry <i>N</i> | ≥ 20 | ≥ 20 | ≥ 20 | ≥ 20 |
| Tensile Strength – Wet <i>N</i> | ≥ 20 | N/A | ≥ 20 | N/A |



















^a Test conditions: challenge concentration 108 CFU/g talc, and 30 minutes vibration time.

^b The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. This means materials varying by up to 0,98 BI are probably not different; materials varying by more than 0,98 BI probably are different. (The 95% confidence level means that an observer would be correct 19 times out of 20 to accept these alternatives).

^c For the purpose of this standard, log1 0 CFU² 2 means maximum 300 CFU.

^d BI = 6,0 for the purpose of this standard means: no penetration. BI = 6,0 is the maximum achievable value.

Packaging details

| | | | | |
|--|---------|--|--|--|
|  0.73 cm | 1.16 cm |  80 CARTON QUANTITY |  10/11 WEIGHT |  40-60-40 DIMENSION |
|  0.75 cm | 1.18 cm |  80 CARTON QUANTITY |  10/11 WEIGHT |  40-60-40 DIMENSION |
|  0.77 cm | 1.20 cm |  80 CARTON QUANTITY |  10/11 WEIGHT |  40-60-40 DIMENSION |
|  0.79 cm | 1.22 cm |  80 CARTON QUANTITY |  10/11 WEIGHT |  40-60-40 DIMENSION |