

COVID-19 Infection Prevention and Control

Guide for correct sterile surgical gown selection

Purpose

The Agency for Clinical Innovation and Clinical Excellence Commission have partnered with clinicians to develop this guide to assist health workers to select the most appropriate gown for each surgery or aseptic procedure and minimise the risk of exposure to blood, body and irrigation fluids/substances. This guide contains gown recommendations for both routine surgery (Table 1), and surgery for patients with suspected/probable/confirmed COVID-19 (Table 2).

NSW Health has implemented a state-wide strategy to ensure all staff have products needed to protect them at work. This strategy includes sourcing substitute products from alternative suppliers where sufficient quantities of usual products are not available. These substitute products may look different from the one's clinicians are familiar with, however, they meet the necessary recommendations and/or approvals in accordance with the Therapeutic Goods Administration.

The aim of this guide is to facilitate easy identification of an appropriate surgical gown for surgical/aseptic procedures.

Gown levels

The Association of the Advancement of Medical Instrumentation (AAMI) is a recognised and collaborative organisation that develops international standards, information and guidance to achieve safe use of medical devices^{1,2}. The AAMI has established a classification system for *minimum requirements for healthcare protective apparel and drapes based on their liquid barrier performance* in their standard^{1,2}. Surgical gowns with a level 1 classification provide the lowest level of protection and level 4 provide the highest level of protection². Some common procedures are provided as examples in the tables below, to guide sterile gown selection based on the AAMI standard.

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Risk assessment and gown selection

Penetration of a sterile gown by any fluid places both health worker at risk of microbial exposure^{1,2}. Risk assessment considers the anticipated risk of exposure to blood, body fluids/substances and irrigation fluid, the procedure itself, and the patient. Regardless of gown level, once fluid has penetrated the gown, the integrity of the protective barrier and sterility is compromised. It is recommended the gown is then changed¹.

When selecting the most suitable sterile gown, consider:

- Does the surgery/aseptic procedure require a sterile gown?
- What level of exposure to staff is anticipated during the procedure? Note, not all clinicians will have the same level of exposure and therefore may not require the same level of gown.
- What is the anticipated risk of exposure and estimated level of blood, body substances and irrigation fluid?
- How much fluid will be used during the procedure for irrigation?
- Are there measures in place to control blood, body substances and irrigation fluid exposure e.g. a collection pouch, tourniquet?

The examples provided are not inclusive of all procedures or specialties. This guide is not a substitute for clinical judgement.

Table 1: Sterile surgical gown selection routine surgery

Examples of procedures drawn from industry supplier ³ <i>This list is not exhaustive</i>	Barrier Performance ⁴	Risk of exposure ⁴	Description ⁴
<ul style="list-style-type: none"> Regional anaesthesia (Epidural/Spinal) Biopsies, Excision of superficial lesions Minor gynaecological procedures (e.g., Dilation and Curettage) Minor orthopaedic surgery (e.g. Carpal tunnel, wedge resection toenails) Ophthalmic surgery Insertion of Central Venous Access Devices Minor Ears, Nose and Throat Surgery Scalp leads – foetal monitoring Lumbar puncture 	<p>Level 1 Use sterile level 2 gowns if level 1 gowns are not available</p>	<p>Minimal fluid</p>	<p>Used for situations where risk of exposure to blood, body fluids/substances or irrigation fluids is MINIMAL</p> <p>Provides a barrier to small volumes of fluid</p> <p>Single test of water impacting the surface of the gown material is conducted to assess barrier protection performance.</p>
<ul style="list-style-type: none"> Minimally invasive surgery (e.g. Laparoscopic, endoscopic) Hernia repair Breast reduction/Plastic/Cosmetic surgery Orthopaedic arthroscopy (ankle) Open reduction internal fixation (ORIF) Dental surgery Chest drain insertion Interventional radiology Cardiac catheterisation lab Maxillofacial surgery 	<p>Level 2</p>	<p>Low fluid</p>	<p>Used for situations where risk of exposure to blood, body substances or irrigation fluids is LOW</p> <p>Provides a barrier to larger amounts of fluid penetration through splatter and some fluid exposure through soaking</p> <p>Two tests are conducted to assess barrier protection performance:</p> <ul style="list-style-type: none"> Water impacting the surface of the gown material Pressurising the material
<ul style="list-style-type: none"> Mastectomy Urological procedures (e.g. TURP) and Hysteroscopy Laparoscopic assisted Hysterectomy / Bowel resection Joint replacement surgery Neurosurgery & Vascular Surgery Orthopaedic arthroscopy (shoulder/knees) Burns Spinal surgery Suturing vaginal tears 	<p>Level 3</p>	<p>Moderate fluid</p>	<p>Used for situations where risk of exposure to blood, body substances or irrigation fluids is MODERATE</p> <p>Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2</p> <p>Two tests are conducted to test barrier protection performance:</p> <ul style="list-style-type: none"> Water impacting the surface of the gown material Pressurising the material
<ul style="list-style-type: none"> Major trauma Knee/shoulder reconstruction Lower Segment Caesarean Section (LSCS) Cardiac/thoracic – open procedures <p>Where surgeon hands/arms are in a body cavity throughout the procedure.</p>	<p>Level 4</p>	<p>Highest fluid and microbial barrier</p>	<p>Used for situations where risk of exposure to blood, body substances or irrigation fluids is HIGH</p> <p>Provides a barrier to large volumes of fluid penetration and greater resistance to fluid soaking than Level 3</p> <p>In addition to the other tests conducted under levels 1-3, barrier level performance is tested with a simulated blood containing a virus – if no virus is found at the end of the test, the gown passes</p>

Note; not all clinicians will have the same level of exposure and therefore may not require the same level of gown.

SARS-CoV-2 is transmitted largely via the droplet route. The highest risk of transmission of respiratory viruses is during aerosol-generating procedures (AGPs) of the respiratory tract.

The table below outlines gown selection for patients who have suspected, probable or confirmed COVID-19 where the surgical gown rating level is changed to reflect the risk of transmission via the airborne route.

Table 2: Sterile surgical gown selection for patients with suspected, probable or confirmed COVID-19

Examples of Procedures <i>This list is not exhaustive</i>	Barrier Performance ⁴	Risk of exposure ⁴	Description ⁴
<ul style="list-style-type: none"> • Nose and Throat surgery (e.g. tonsillectomy/adenoidectomy/Endoscopic sinus surgery, laryngectomy, tracheostomy) • Dental • Chest drain insertion • Maxillofacial surgery 	Level 3	Moderate fluid	<p>Used where risk of exposure to blood, body fluids/substances or irrigation fluids is MODERATE</p> <p>Provides a barrier to larger amounts of fluid through splatter and more fluid exposure through soaking than Level 2</p>

Note; not all clinicians will have the same level of exposure and therefore may not require the same level of gown.

This guide has been developed by the Clinical Excellence Commission in consultation with the Agency for Clinical Innovation

References:

1. Australian College of Perioperative Nurses Ltd (ACORN). (2018). Standards for Perioperative Nursing in Australia 15th ed. Adelaide, South Australia, Australia.
2. Centre for Disease Control and Prevention. ANSI/AAMI PB 70:12 classification of barrier performance of surgical gowns, other protective apparel, surgical drapes and drape accessories. Sourced May 28, 2020. <https://wwwn.cdc.gov/PPEInfo/Standards/Info/ANSI/AAMIPB70Class3>
3. Recommended procedures from Cardinal Health (Industry supplier) <https://www.cardinalhealth.com.au/content/dam/corp/web/documents/whitepaper/cardinal-health-surgical-gowns-best-practices-in-use-and-purchasing-white-paper.pdf>
4. Extracted from Standard ANSI/AAMI PB 70:12 and ASTM F1670 / F1670M.