

# Isolation Gown FAQs



## 1. What is an isolation gown?

Isolation gowns are intended to help protect health professionals and prevent the transfer of microorganisms.

In 2004, the FDA recognized the consensus standard American National Standards Institute/Association of the Advancement of Medical Instrumentation (ANSI/AAMI) PB70:2003, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.<sup>1</sup>

According to the FDA an isolation gown must:

- Meet a minimum barrier performance of AAMI level 1 at its fabric, ties and seams
- Provide 360 degrees of coverage
- Be clearly labeled as an isolation gown with the AAMI level and serial number

Check with your vendor partner to ensure your gowns meet all the above requirements. Gowns that do not meet the requirements provide less protection and should not be used in an isolation setting. These gowns should be categorized differently (e.g. cover gown or protective gowns).

**Note:** Barrier coats cannot be AAMI level rated as they are not a medical device and don't provide 360-degree coverage.

## 2. What AAMI level isolation gown do I need for COVID-19?

For both reusables and disposables, according to the CDC, both AAMI level 1 and level 2 isolation gowns are recommended for routine care of patients suspected or confirmed to be infected by COVID-19.\*\*

## 3. How do I wash reusable isolation gowns?

Reusable isolation gowns do not need to be sterilized and are washed at high heat in an industrial laundry machine. Instructions for use (IFU) should always be available with directions on how to clean isolation gowns.\*\*

## 4. What is carbon used for in an isolation gown?

Carbon fiber helps to dissipate static electricity. This can improve comfort in dry environments and protect sensitive instrumentation.

## 5. What is the difference between an AAMI level 1 and AAMI level 2 reusable isolation gown?

Per the FDA:

- Level 1: Minimal risk, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit
- Level 2: Low risk, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab<sup>2</sup>

### Medline AAMI level 1 reusable gowns

Item no.	Size	Color
MDT011207	One size fits most	Yellow
MDT011205	One size fits most	Gray
MDT011201L	Large	Yellow
MDT011201XL	Extra large	Yellow
MDTISO3AHY	One size fits most	Yellow
MDTISO3AHG	One size fits most	Gray

**\*\*Disclaimer:** Healthcare facilities are responsible for determining the appropriate level of protection for personal protective equipment (PPE) when performing specific tasks and how their PPE is processed. Information provided is only guidance supported by the FDA and CDC.

**References:** 1. <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns#g5> 2. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpCD/classification.cfm?id=2869> 3. <https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers>