VitaLife International Inc.

Disposable Isolation Gowns

Level 3

Technical Data Sheet

Gowns are examples of personal protective equipment used in health care settings. They are used to protect the wearer from the spread of infection or illness if the wearer comes in contact with potentially infectious liquid and solid material. They may also be used to help prevent the gown wearer from transferring microorganisms that could harm vulnerable patients, such as those with weakened immune systems. Gowns are one part of an overall infection-control strategy.

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." New terminology in the standard describes the barrier protection levels of gowns and other protective apparel intended for use in health care facilities and specifies test methods and performance results necessary to verify and validate that the gown provides the newly defined levels of protection.

Level 1: Minimal risk
Level 2: Low risk
Level 3: Moderate risk
Level 4: High risk

Materials

Level 3 Isolation gowns are made of:

- PP
- PP+PE
- SMS

Use For

- Used in MODERATE risk situations
- Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soakin than Level 2
- Arterial blood draw, Inserting an IV, Emergency Room, Trauma
- Always follow User Instructions and use in manners as indicated

Do Not Use for

- DO NOT use in industrial settings
- DO NOT use in case of liquid and fluid contact.
- DO NOT use in any manner not indicated in the User Instructions

Approvals and Standards

- FDA
- CE
- ISO 13485

Style

Elastic cuff

Knitted cuff

Velcro

With tie

Fitting Instructions
Must be followed each time Isolation gown is worn. Before fitting, ensure hands and cloths are clean.
See Figures below

Figure 1:
1. Begin by placing your arms in the sleeves with thumbs in thumb loops
2. Pull the gown over your head
3. Tie in back at the waist

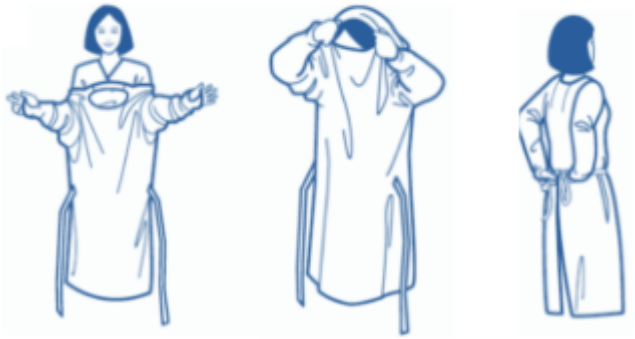

Figure 2:
1. Pull the gown forward with hands breaking away from the back, neck andwaist, continue to roll down the body into a ball and discard after removal.
2. Pull gown at chest or waist level with arms slightly bent. Repeat removal at waist level if chest breaks away first. Contunue to roll down the body into a ball and discard after removal. With no nek ties to undo, you reduce the chance for cross contamination from gloves to the hair or back of the neck.

Warnings and Use Limitations

Always be sure that the complete product is:
- Suitable for the application;
- Worn during all periods of exposure;
- Replaced when necessary.

• It is recommended that fit testing be conducted before assigning a Isolation gown to an individual. If you cannot achieve a proper fit then do not enter contaminated area. See your supervisor.
• Inspect the gown before each use to ensure it is in good working condition. Examine all parts for signs of damage
• Leave the contaminated area immediately and contact supervisor irritation or other distress occurs.
• Dispose of used product in accordance with applicable regulations.
• All Isolation gowns should be used in accordance with local regulations.
• Do not alter, repair, wash, and abuse or misuse the gown.
• TheIsolation gown is designed for occupational/professional use by adults who are properly trained in it's use and limitations. Is not designed to be used by children.
• Maximum Operating Temperature: +50 degrees Celsius.

Storage and Transportation
Shelf life of the unopened product is five (5) years from date of manufacture when stored within temperature range of -20°C to +30°C and at less than 80% relative humidity. End of shelf life date is marked on the product packaging. Before initial use, always check that the product is within the stated shelf life. When storing or transporting this product use original packaging provided.

Warning
The use of the Vitalife product described within this document assumes that the user has previous experience of this type of product and that it will be used by a competent professional. Before any use of this product it is recommended to complete some trials to validate the performance of the product within its expected application. All information and specification details contained within this document are inherent to this specific vitalife product and would not be applied to other products or environment. Any action or usage of this product made in violation of this document is at the risk of the user. Compliance to the information and specification relative to the vitalife product contained within this document does not exempt the user from compliance with additional guidelines (safety rules, procedures). Compliance to operational requirements especially in respect to the environment and usage of tools with this product must be observed. The Vitalife group (which cannot verify or control those elements) would not be held responsible for the consequences of any violation of these rules which remain external to its decision and control.