

EN 13795 - weak spot testing

Created: 17 November 2020

Last Updated: 04 December 2020

The BS EN ISO 13795-1 stipulates that "*testing shall include potential weak spots*" and "*in particular, all types of joints in critical areas such as e.g. seams in sleeves of surgical gowns*".

SMTL's Policy on gown testing therefore is to use the following sampling plan when testing the critical areas (area where direct contact with blood and body fluids is most likely to occur) of surgical gowns and drapes. **It may not be possible to test across seams for some products due to their method of construction.**

Surgeons Gowns

- 3 x chest (Figure 1 area A)
- 1 x lower sleeve (Figure 1 area B)
- 1 x lower sleeve seam (Figure 1 area B)

Note 1: Samples will exclude cuffs, hems and bindings

Note 2: For tensile testing, the seams will only be tested with the seam horizontal to the grips, as testing the seam vertically to the grips is not a potential weak spot.

Note 3: Dry microbial penetration testing is performed on 10 samples from the gown non-critical area. Where possible the laboratory will attempt to include 2 samples taken across the non-critical area upper arm seam.

Note 4: Some gown designs may be constructed of a homogenous material for critical and less critical areas (see Figure 2). For such products SMTL will consult with the client and may only test the critical area of the gown (area A and B) and report these results for both critical and less critical areas.

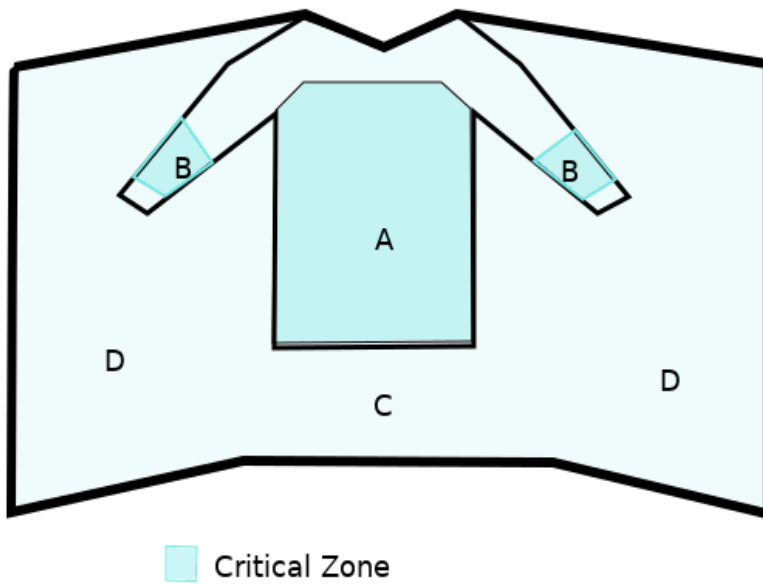


Figure 1 - Surgical Gown

A: Critical Zone - Front

B: Critical zone - Sleeve

C: Front

D: Back

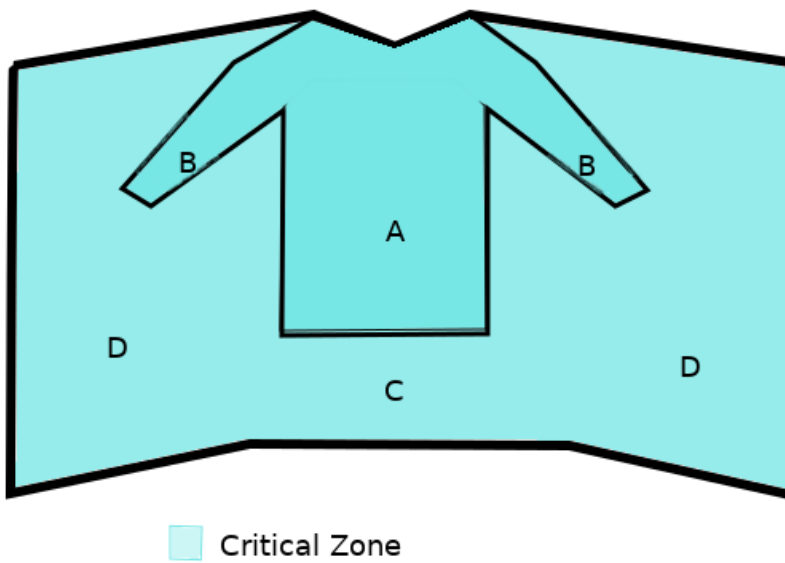


Figure 2 - Surgical gown of homogenous design.

Surgical Drapes

- 4 x centre of the drape, around any fenestrations or openings (Figure 3 Area A)
- 1 x seam of two protective areas (Figure 3 joining between areas A and B)

Note 1: For tensile testing, the seams will only be tested with the seam horizontal to the grips, as testing the seam vertically to the grips is not a potential weak spot.

Note 2: Some drape designs may be constructed of a homogenous material for critical and less critical areas. For such products SMTL will consult with the client and may only test the critical area of the drape and report these results for both critical and less critical areas.

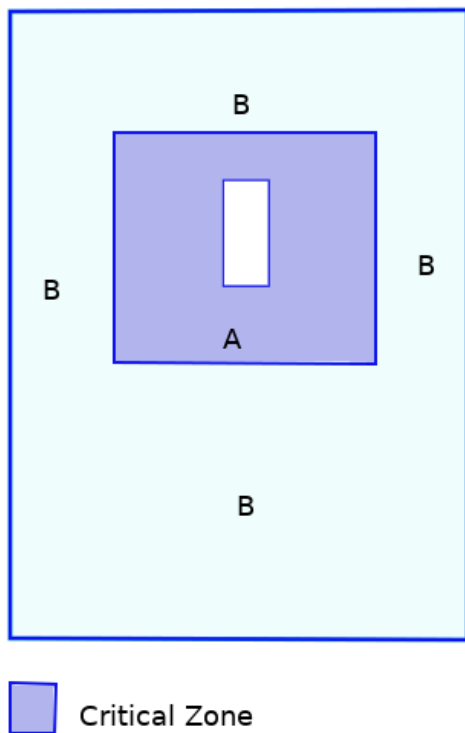


Figure 3 - Surgical Drape