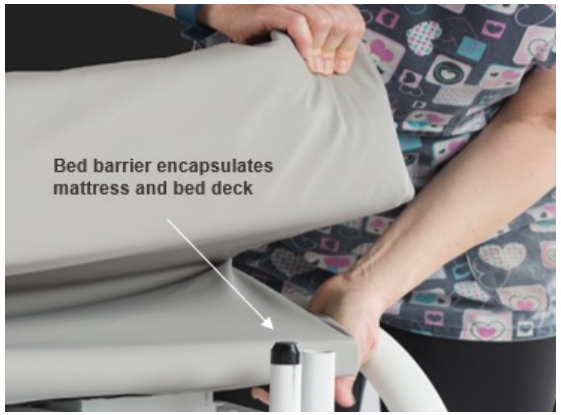
WHAT IS THE DIFFERENCE BETWEEN A SOTERIA BED BARRIER AND A MATTRESS COVER- OUR RESULTS SPEAK FOR THEMSELVES

Criteria	Soteria Bed Barrier - Product Code - QTV	Mattress Cover – Product Code -FMW
Principle of operation	Protects Mattress and bed deck from patient fluids & reduces contaminates	Intended for medical purposes & used to protect a mattress
Resistance of Penetration to Liquid	Pass- AATCC Method 42, AATCC Test Method 127	Unknown
Tensile Testing	ASTM-D5034	Unknown
Flammability	16CFR Part 10, Class 1	Unknown
Biocompatibility	Biocompatible per ISO 10993-1	Unknown
Seam Strength	ASTMD7571	Unknown
Tear Strength	ASTM D5587	Unknown
	Testing to Surgical Drape Performance Characteristic: All Pass at End of Life- 150 launderings	Mattress Cover Does Not meet Surgical Drape Characteristics
Water Resistance	AATCC42 Water Resistance Impact Penetration Test	N/A
Hydrostatic Pressure Test	ASTM F 2407	N/A
Standard Test for Breaking Strength (ASTMD5034)	ASTM2407	N/A
Standard Test Method for Tearing Strength (ASTMD5587)	ASTM F2407	N/A
Standard Test Method for Coated Fabrics	ASTMD751	N/A
Standard for Flammability of Clothing Textiles 16CRF Part 1610	ASTM F2407	N/A

SOTERIA BED BARRIER



- Soteria is applied over the existing mattress,
- Soteria has no side zipper seams and is completely RF welded.
- Pocket design allows barrier to slip over mattress allowing for fitted sheet use
- Laundry process washes out stains

TYPICAL HOSPITAL MATTRESS COVER

- Mattress covers and most mattresses are 510-K Class 1 exempt devices and have had little FDA oversight
- Many mattresses / toppers can not be opened for inspection
- Those that can be opened have side zipper seams that are difficult to clean and can leak, many that are sewn
- Performance testing criteria is left to the manufacturer of the device
- Cleaning performed by manual wipe processes and often relies on disinfectant manufacturer off label claims

CRITERIA	SOTERIA-CLEANING/LAUNDERING VALIDATION	MATTRESS COVER -
Cleaning Validation*	Can be laundered 150 times Residual Protein < 6.4ug/cm2; Residual hemoglobin < 2.2ug/cm2	Required to meet non-critical medical device standards per Re-processing Guidance
Laundering Validation*	99.9999% reduction Escherichia coli ATCC 11229,Pseudomonas aeruginosa ATCC 15442, MRSA ATCC33592, Klebsiella pneumoniae ATCC 10031; Mycobacterium ATCC15755, C.Diff Spores ATCC43598diby wash off.	

* Cleaning and laundering validation performed at beginning and end of life