

SORBAVIEW® ULTIMATE

TECHNICAL MONOGRAPH



PRODUCT DESCRIPTION

SorbaView Ultimate is a highly permeable, transparent film dressing that uses an innovative multi-layer construction.

First, an absorbent, non-adherent pad helps prevent moisture build-up by wicking away moisture from the skin into the fibrous pad; where it then continues to breathe through the upper film and film/fabric layers. This highly absorbent pad material is fenestrated to form a “window” in the dressing.

Second, this polyurethane film membrane covers and surrounds the fenestrated pad. This thin, semi-permeable film is a strong protective barrier to external contaminants and liquids, and is visually clear, thus ideally suited for use in the care of intravenous catheter sites.

The adhesive non-woven fabric layer on top completes the dressing. This outer border of fabric adds strength to the dressing, conforms comfortably to patients’ skin and is comfortable to the touch.

SorbaView Ultimate can be worn for up to 7 days because it continuously prevents the build up of moisture from under the dressing.

INTENDED USE

SorbaView Ultimate is classified as a TSM (transparent semi-permeable membrane) dressing and was designed for covering and securing the insertion sites of peripherally inserted central catheters (PICCs), central venous catheters (CVCs), internal jugular central venous catheters (IJ CVCs), dialysis procedures and epidural catheters. It is ideally suited for a range of catheter access devices.

DESIGN FEATURES

- Integrated pad wicks away moisture, keeping site dry
- Easy to apply
- Stays securely in place for up to 7 days
- Easy to remove
- Exceptionally high Moisture Vapor Transmission Rate (MVTR)
- Non-cytotoxic adhesive is also non-irritating and non-sensitizing
- Transparent window allows continuous site visibility
- Multi-layer construction is protective, breathable and comfortable to patients’ skin
- Creates an occlusive barrier against bacteria, viruses and other contaminants, but not to moisture vapor or other normal gases such as CO₂ and O₂
- Conforms and responds to body contours
- Latex free
- Available in individual sterile packages, or in custom procedure trays
- U.S. Patent Nos. 6,841,715; 7,025,749; 7,232,427; 7,294,751; 7,294,752

DESIGN RATIONALE

The anatomy and physiology of human skin, as the breathable protective barrier that allows the body to survive in a contaminant-filled environment, is what inspired the combination of different material layers in the design of SorbaView Ultimate.

Skin is composed of multiple layers. The thin outer layer, or epidermis, is composed of cells which are continuously eroding while new replacement cells are multiplying to provide a protective barrier. Beneath this is the dermis, which is comprised mostly of connective fibrous tissues which create the anchoring adhesive to underlying tissues and provide for proper control of moisture and temperature.

SorbaView Ultimate mimics skin in its innovative multi-layer construction. Its unique design utilizes a breathable outermost layer, a protective and strong lower layer which controls moisture, and a conforming adhesive layer to anchor it all securely.

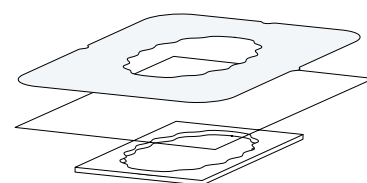
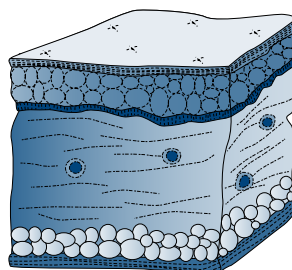
ADVANCED MATERIALS & METHODS

The select medical-grade adhesive used in SorbaView Ultimate has a unique combination of aggressive tack coupled with moderate peel strength, which is particularly advantageous in medical applications. This adhesive performs well in a wide range of ambient seasonal humidity and temperature environments.

The adhesive coating on the film is applied in a unique pattern that prevents any blockage of the film's permeability, allowing the dressing to be more breathable, highly moisture vapor permeable and to hold securely for extended time periods – even beyond seven days. The high moisture permeability of the film used in SorbaView Ultimate creates an occlusive barrier to micro-sized contaminants and liquids, while allowing for the free exchange of gases enabling the skin to breathe normally.

Both the film and the non-woven fabric have an “omni-directional” stretch characteristic much like human skin. The needle-punched fabric moves with the skin in any direction and conforms securely to the skin surface or intravenous access device with a breathable seal. It allows the skin and the clear polyurethane film barrier to be joined with a minimum amount of adhesive and remain intact and comfortably worn to lock out contaminants. The patient benefits from this gentle, protective, net-like layer while wearing the dressing and also during its removal, which is thus made less traumatic. In addition, the added physical strength of the fabric on top of the film helps SorbaView Ultimate to remain intact for extended periods.

The non-adherent pad under the film is lint free and highly absorbent. This pad material is cut with scalloped shaped interior edges that increase the fibrous surface area. This is designed to help keep the catheter exit site dry by wicking away gaseous moisture from under the film center into the pad, where it then continues to breathe up through the film and film/fabric layers. The pad also adds internal strength to the dressing, making it easier to apply and remove.



The cross section of skin can be compared to the multiple layers of materials that combine to create SorbaView Ultimate

The dressing is designed to have a layered quality like that of skin, and to be able to transpire moisture from the lower inside barrier film layer to the outside top surface. The exposed fabric can and will get wet by showering and precaution should be taken to avoid saturating the dressing while bathing.* The Centers for Disease Control and Prevention (CDC) guidelines recommend changing dressings should they become damp, loosened or soiled. However, with the protective film layer below the fabric, a fully intact dressing (closed around all edges) will always keep the site sealed. Liquids are shut out, but gases are allowed to move freely as they do in normal function of the skin. This dressing is unique in its designs and has been granted five US Patents.

*Normal drying time (c. 20 minutes) may be accelerated by blotting with dry cloth; do not rub.

PRODUCT PROFILE

Liner: Silicone treated paper

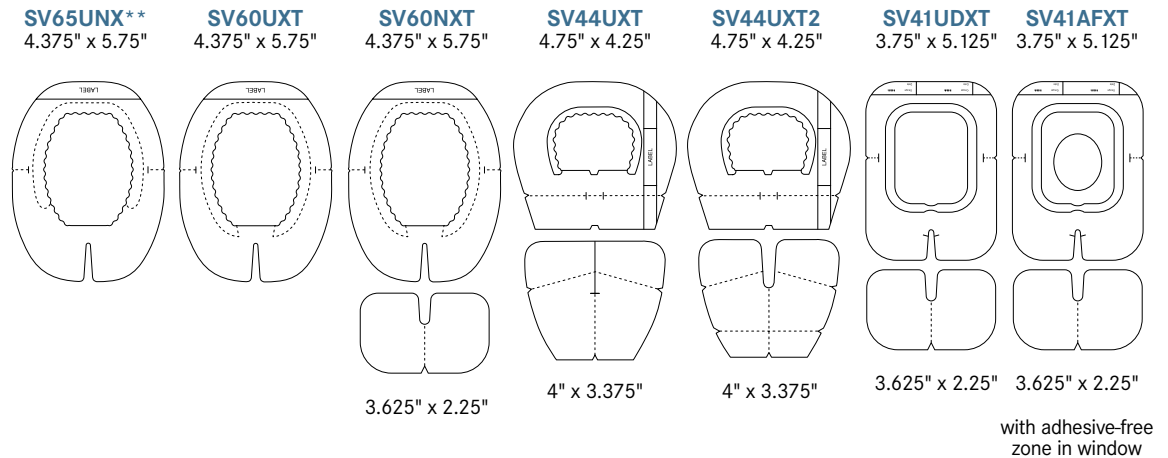
Pad: Absorbent Lyocell pad – solvent-spun cellulose, 70 mil.

Adhesive: Acrylic based adhesive (biocompatible, skin contact grade)

Film: Polyurethane film, 1 mil.

Fabric: Dupont 8010 Sontara™ non-woven fabric, 10 mil.

ILLUSTRATED DRESSING SIZES



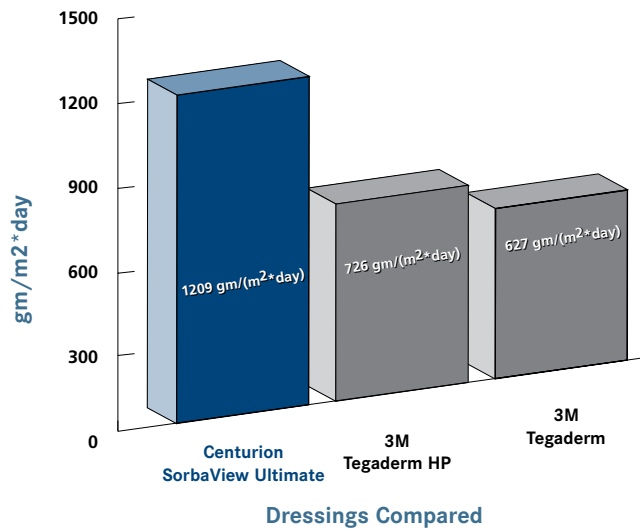
Other dressing sizes and styles may be available; check with your representative for details

** Available only as part of PICC Security System™

MOISTURE VAPOR TRANSMISSION RATE

Test Method: ASTM F1249*

Testing performed by MOCON Consulting and Testing Services, Minneapolis, MN



SorbaView Ultimate was tested to measure the Moisture Vapor Transmission Rate in accordance with ASTM F1249. This is the standard test method for determining the rate of water vapor transmission through flexible barrier materials using a modulated infrared sensor. This test was performed on a Mocon 3/31 instrument.

SorbaView Ultimate showed a Moisture Vapor Transmission Rate of 1209 gm/m²*day.

VIRAL BARRIER EFFECTIVENESS

Test Method: ASTM F 1671 *

Testing performed by Nelson Laboratories, Inc., Salt Lake City, UT

SorbaView Ultimate was tested for viral barrier effectiveness in accordance with ASTM F 1671, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System." This test method is used to measure the resistance of materials to penetration by blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact. The test method is designed to model the viral penetration of Hepatitis (B and C) and HIV transmitted in blood and other potentially infectious body fluids. Pass/fail determinations are based on the detection of viral penetration.

SorbaView Ultimate passed the testing criteria; no viral penetration was detected.

The test results show that SorbaView Ultimate dressings are resistant to viral penetration and behave as viral barriers. The tested Phi-X 174 bacteriophage is one of the smallest known viruses. Therefore, by inference, the test provides indirect evidence to suggest that SorbaView Ultimate dressings would behave as a barrier to other, larger viral and bacterial contaminants.

BLOOD BARRIER EFFECTIVENESS

Test Method: ASTM F 1670-98 *

Testing performed by Nelson Laboratories, Inc., Salt Lake City, UT

SorbaView Ultimate was tested for blood barrier effectiveness in accordance with ASTM F 1670-98, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood." This test method is used to measure the resistance of materials to penetration by synthetic blood under conditions of continuous liquid contact. The test method helps assess the effectiveness of materials for protecting against contact with body fluids that potentially contain blood-borne pathogens. Pass/fail determinations are based on visual detection of synthetic blood penetration.

SorbaView Ultimate passed the testing criteria; no synthetic blood penetration was detected.

The test results show that SorbaView Ultimate dressings are resistant to blood penetration and behave as liquid barriers.

Test results on file.

CENTURION
MEDICAL PRODUCTS

100 CENTURION WAY | P.O. BOX 510 | WILLIAMSTON | MICHIGAN | 48895
517.546.5400 | 800.248.4058 | fax 517.546.9388 | www.centurionmp.com

©2010 Centurion Medical Products Corporation LIT071V3