

SORBAVIEW® 2000

TECHNICAL MONOGRAPH



PRODUCT DESCRIPTION

SorbaView 2000 is a highly permeable, transparent film dressing that uses an innovative multi-layer construction and medical grade skin contact adhesive.

First, an absorbent, non-adherent pad helps keep the catheter exit site dry by wicking away moisture from the skin to the fibrous pad, and then displacing it to the exterior non-woven fabric border. This highly absorbent pad material is fenestrated to form a “window” in the dressing, plus it serves as a protective blanket under bulky catheters to make patients feel more comfortable.

Second, a 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, fenestrated, non-woven fabric layer completes the materials in this unique multi-layer dressing. This conformable outer border of fabric is ideal for protecting catheter exit site wounds and securing access devices to patients' skin.

INTENDED USE

SorbaView 2000 is classified as a TSM (transparent semi-permeable membrane) dressing and can be used in the treatment of central venous catheter (CVC), peripherally inserted central catheter (PICC), and peripheral intravenous site management; dialysis procedures; implanted port access; epidural catheter securement; and to cover and protect superficial wounds, skin tears, and abrasions. SorbaView 2000 can be worn for long periods of time (up to seven days) because it continuously prevents the build up of moisture from under the dressing.

DESIGN FEATURES

- Integrated pad wicks away moisture, keeping site dry
- Easy to apply
- Stays securely in place with easy peel removal
- Designed to be used in seven day dressing change protocols
- High Moisture Vapor Transmission Rate (MVTR)
- Non-cytotoxic adhesive is 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 contaminants
- Various sizes accommodate a wide range of access devices
- Conforms and responds to body contours
- Latex free
- Available in individual sterile packages, or in custom procedure trays
- U.S. Patent No. 6,841,715

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 2000.

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 2000's innovative multi-layer construction 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

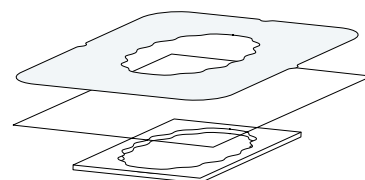
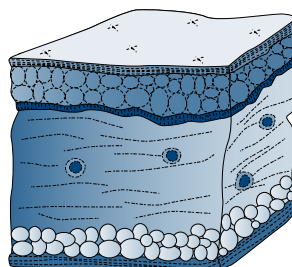
The select medical grade adhesive used in SorbaView 2000 has a unique combination of aggressive tack coupled with moderate peel strength, which is particularly advantageous in medical applications. This adhesive performs well in a wide range of ambient seasonal humidity and temperature environments.

The adhesive coating on the film is applied in a unique pattern, allowing the dressing to be more breathable, highly moisture vapor permeable and to hold securely for up to seven days. The high moisture permeability of the polyurethane film used in SorbaView 2000 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 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 2000 to remain intact.

The non-adherent pad under the film is lint free and highly absorbent. This is designed to help keep the catheter exit site dry by wicking away exudate or moisture from under the film center, into the pad, and displacing it to the exterior region of the dressing’s nonwoven fabric border. The pad also adds a very small amount of stiffness to the dressing to keep the dressing from crumpling and sticking to itself, thus making it very easy to apply and remove.

The dressing is designed to have a layered quality like that of skin, and be able to “transpire” moisture from the lower inside barrier film layer to the outer surface area of the fabric. 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, the site will always be sealed. Liquids are shut out, but gases are allowed to move freely as they do in normal function of the skin. This dressing’s unique design is patented.



The cross section of skin can be compared to the multiple layers of materials that combine to create SorbaView 2000

PRODUCT PROFILE

Liner: Silicone treated paper

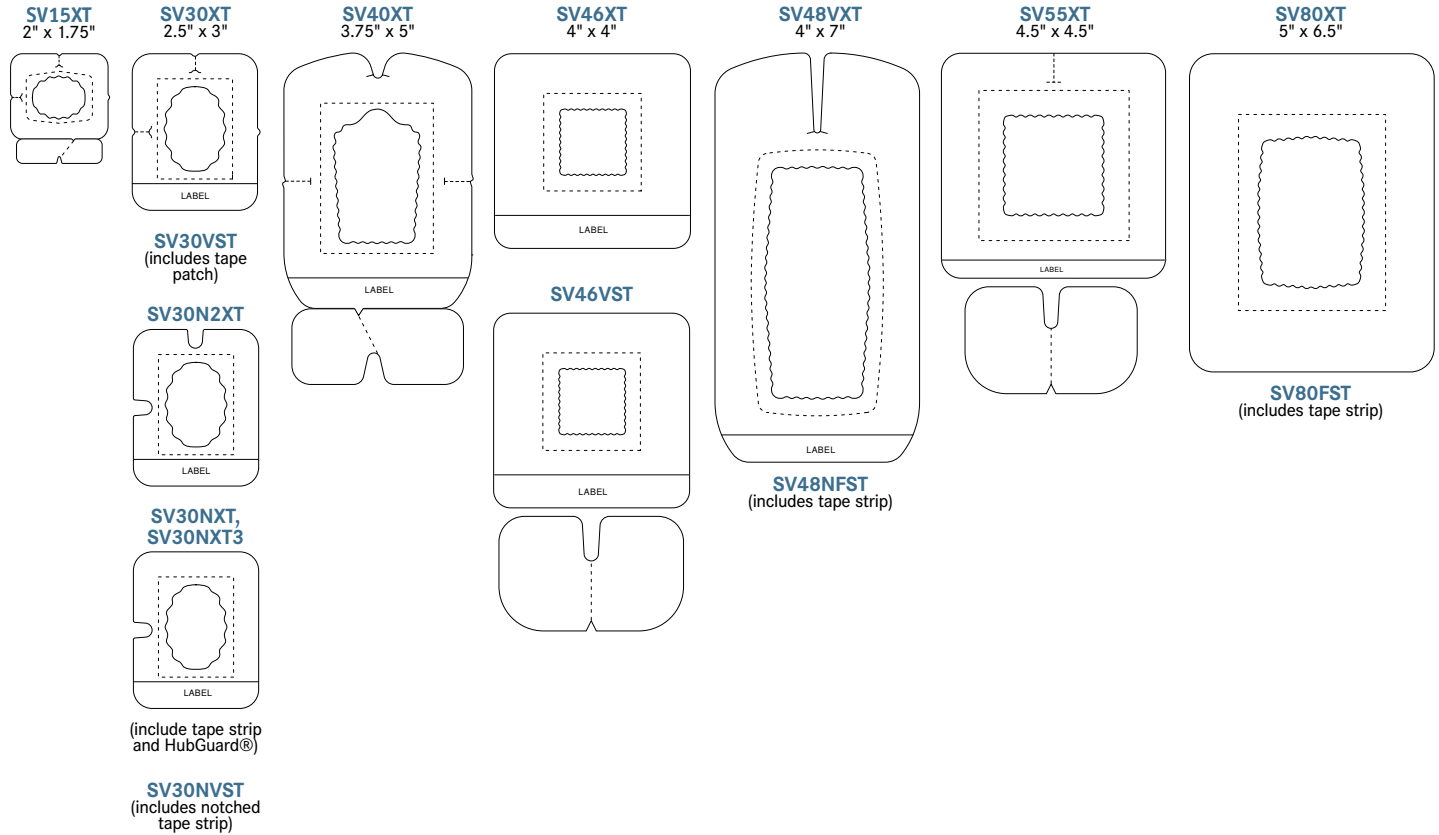
Pad: Absorbent Lyocell pad – solvent-spun cellulose, 70 mil.

Adhesive: Polyacrylate adhesive (non-sensitizing)

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.

BLOOD BARRIER EFFECTIVENESS

Test Method: ASTM F 1670-98*

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

SorbaView 2000 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 2000 passed the testing criteria; no synthetic blood penetration was detected.

The test results show that SorbaView 2000 dressings are resistant to blood penetration and behave as liquid barriers.

VIRAL BARRIER EFFECTIVENESS

Test Method: ASTM F 1671-97b*

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

SorbaView 2000 was tested for viral barrier effectiveness in accordance with ASTM F 1671-97b, "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 2000 passed the testing criteria; no viral penetration was detected.

The test results show that SorbaView 2000 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 2000 dressings would behave as a barrier to other, larger viral and bacterial contaminants.

PEEL ADHESION (ADHERENCE)

Test Method: (PSTC-1) 180° Peel Adhesion*

Averages as tested on stainless steel after 20<30 mins.

Testing performed by DermaMed Coatings Company, Tallmadge, OH

SorbaView 2000 was tested in accordance with PSTC-1. This test method is used to measure the adherence of the dressing (when peeled at 180° angle, to a standard steel panel).

SorbaView 2000 showed an average peel force of 871.3 gm.

MOISTURE VAPOR TRANSMISSION RATE

Test Method: ASTM F1249*

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

SorbaView 2000 was tested to measure the Moisture Vapor Transmission Rate in accordance with ASTM F1249. This test method is used to measure the rate of evaporation of moisture away from the skin through the dressing.

SorbaView 2000 showed a Moisture Vapor Transmission Rate of 556 gm/meters²/24 hrs.

*Test results on file.

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