3M™ Cavilon™ Advanced Skin Protectant for IAD
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01 Value Summary
3M™ Cavilon™ Advanced Skin Protectant
Incontinence-associated dermatitis (IAD) occurs frequently, is time-consuming, costly to manage, and painful for patients

**Definition**
- Incontinence-associated dermatitis (IAD) is skin damage associated with urine and/or fecal exposure.

**Burden of IAD**
- IAD is common, resource intensive and costly.
- IAD is associated with pain and discomfort, with downstream impact on patient’s quality of life, and perceived quality of care.
- IAD is a known risk factor for pressure ulcers and secondary fungal infections.

**Prevention and Management of IAD**
- Prevention is aimed at avoiding or minimizing exposure to urine or stool combined with a structured skin care regimen.
- For management of IAD, the skin care regimen should protect the skin from further exposure to irritants, establish a healing environment, and eradicate any cutaneous infection.

**IAD challenges**
- Lack of a clinically effective and patient and clinician friendly product for moderate to severe IAD and high risk patients.
- Evidence suggests that IAD persists despite the use of current skin care regimens.
- Current products can be time-consuming for clinicians, requiring frequent application and removal.
- Current products can interfere with absorbent products that are used in the management of IAD.
- The frequent removal and reapplication of current products is painful for the patient.

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2. Plante, Association for Advancement of Wound Care. Atlanta, Ga.;1996.
5. Junkin, Nursing 2008;38(11 Suppl):56n1-10
6. CMS HCAPS
7. Demarre, J Adv Nurs 2014; Aug 19
Evidence suggests that IAD persists despite the use of standardized skin care regimens\(^1\)

**Critically Ill Adults\(^1\)**

81% of patients still had IAD at discharge from the ICU (median time in ICU = 7 days)

81% at 7 days

In a study of critically ill patients (n=45) across 3 surgical/trauma critical care units in urban US hospitals, the median time to onset was 4 days (1-6 days) and 81% of ICU patients still had IAD at discharge (median of 7 days) with the median time to IAD healing of 11 days (range, 1-19 days).

\(^1\)Bliss D, J WOCN 2011;38(4):433-445
Cavilon Advanced Skin Protectant is an effective barrier that helps in prevention and management of moderate to severe IAD

Adheres to wet, weepy tissue

Cavilon Advanced Skin Protectant adheres to wet, weepy tissue, creating an effective barrier to caustic irritants and allowing skin to heal in the most extreme cases.

Durable

Cavilon Advanced Skin Protectant reduces frequency of applications to 2-3 times per week and reduces nursing time.

Reduces pain associated with IAD care

Cavilon Advanced Skin Protectant can reduce patient’s pain associated with IAD, improving quality of life and the patient’s experience.

1Brennan MR et al. JWOCN. Accepted for publication 2016.
02 Incontinence Associated Dermatitis (IAD) Landscape Overview
Incontinence-associated dermatitis (IAD) can range in severity from erythema to partial-thickness skin loss and infection\(^1\)

\(^1\)Beekman et al, Wounds international 2015.

Incontinence-associated dermatitis (IAD) is a skin damage associated with urine and/or fecal exposure

**Category 1** (Mild IAD)
- Erythema +/- edema
- Affected skin is red* but intact

**Category 2** (Moderate-to-Severe IAD)
- Erythema +/- edema; +/- vesicles/bullae/skin erosion; +/- denudation of skin; +/- skin infection
- Affected skin is red* with skin breakdown

*Or paler, darker, purple, dark red or yellow in patients with darker skin tones

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High risk patients are those with fecal incontinence, especially where loose stool is present

high risk population
All patients or residents with incontinence are at risk but those with mixed incontinence are the most vulnerable especially when stools are liquid or diarrhea is present

Type of incontinence

- Urine
- Formed feces +/- urine
- Liquid feces +/- urine

Liquid stool increases the risk and severity of IAD

Severe-to-moderate IAD occurs in ~35% of cases

Beekman et al, Wounds international 2015; Gray M and Baros S. Presented at the 23rd Annual Meeting of the Wound Healing Society; SAWC Spring/WHS Joint Meeting, Denver, CO May 1-5, 2013.

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IAD is a risk factor for pressure injury (ulcer) development\textsuperscript{1-3}

<table>
<thead>
<tr>
<th>The risk of developing pressure ulcers has been found to increase as the severity score for IAD increases\textsuperscript{2}</th>
<th>Patients with IAD are at a significantly higher risk of superficial sacral pressure ulcers\textsuperscript{1}</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.9</strong> odds ratio</td>
<td><strong>44%</strong> Superficial sacral pressure ulcers developed in 44.4% of patients who had IAD versus 12.2% of patients who did not have IAD (n=610)\textsuperscript{1}</td>
</tr>
<tr>
<td>The likelihood of developing a pressure ulcer increases by a ratio of <strong>1.9 for every 1-point increase in IAD severity score</strong> (odds ratio = 1.9, 95% CI = 1.237-2.917)\textsuperscript{2}</td>
<td><strong>2.99</strong> odds ratio Patients with IAD are at an increased risk of superficial sacral pressure ulcers with an odds ratio of 2.99 (CI: 1.20-7.52, p=0.19)\textsuperscript{1}</td>
</tr>
</tbody>
</table>

\textsuperscript{1}Demarre, J Adv Nurs 2014;Aug 19; \textsuperscript{2}Park KH, J WOCN 2014;41(5):424-29; \textsuperscript{3}Beeckman, Wounds International 2015
IAD is associated with pain, discomfort, depression, and poor quality of life\(^1\)

Pain associated with IAD can have a negative impact on patients’ health and well-being\(^{1-3}\)

“You have to manage time, as well as the patient’s pain and discomfort. And then there is this anguish that starts because we see it very clearly. The patients are on a respirator, so we feel it right away, the machines ring loudly, the cardiac rhythm increases, the pressure increases... they dread it. Before we have even touched them.”\(^4\)

-Nurse responding to impact of diarrhea on nurses’ everyday work

\(^{1}\)Beeckman, Wounds International 2015; \(^{2}\)Junkin, Nursing 2008;38(11 Suppl):56hn1-10; \(^{3}\)CMS HCAHPS; \(^{4}\)Guillemin, Int J Nurs Pract. 2015 May 1;21(S2):38-45
Skin integrity and pain management are recognized as key indicators of quality of care\textsuperscript{1,3}

Quality

Joint Commission for Accreditation of Health Care Organizations and the Centers for Medicare and Medicaid Services (CMS) recognize skin breakdown as a key indicator for quality of care\textsuperscript{4}

Pain management is one of nine key topics reported in the Centers for Medicare and Medicaid Services (CMS) Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores\textsuperscript{1}

Pain Management Questions

<table>
<thead>
<tr>
<th>How often was your pain well controlled? How often did the hospital staff do everything they could to help you with your pain?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never + Sometimes</td>
</tr>
<tr>
<td>(7%)</td>
</tr>
</tbody>
</table>

Represents over 3 Million patients discharged from 4,136 hospitals between July 2013 and June 2014\textsuperscript{2}

\textsuperscript{1}CMS HCAHPS; \textsuperscript{2}CMS HCAHPS Hospital Characteristic Chart; \textsuperscript{3}Meraviglia, Adv Skin Wound Care 2002;15(1):24-9; \textsuperscript{4}https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r8som.pdf
02 Incontinence Associated Dermatitis (IAD) Landscape

Burden of Illness
IAD is a common problem

Although IAD is known to be a common problem, wide variation in reported IAD prevalence and incidence exists. This is likely due to differences across care settings and the diagnosis of IAD.

<table>
<thead>
<tr>
<th>Setting</th>
<th>Prevalence</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTAC</td>
<td>22.8%</td>
<td></td>
</tr>
<tr>
<td>Critical care setting</td>
<td>36%</td>
<td></td>
</tr>
<tr>
<td>Acute care setting</td>
<td>41%</td>
<td></td>
</tr>
<tr>
<td>Hospital setting</td>
<td>50%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Nursing home setting</td>
<td>50%</td>
<td>5.6%</td>
</tr>
<tr>
<td>LTAC</td>
<td>42%</td>
<td>3.4%</td>
</tr>
</tbody>
</table>

IAD = Incontinence

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Incontinence Associated Dermatitis (IAD) is a frequent complication of urinary and/or fecal incontinence\textsuperscript{13}

Prevalence of incontinence in acute care settings

<table>
<thead>
<tr>
<th>Type of Incontinence</th>
<th>Prevalence range reported in the literature</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary Incontinence</td>
<td>22% to 46%</td>
<td>1, 4</td>
</tr>
<tr>
<td>Fecal Incontinence</td>
<td>7% to 42%</td>
<td>4-7</td>
</tr>
<tr>
<td>Double (fecal and urinary) Incontinence</td>
<td>20% to 33%</td>
<td>8-12</td>
</tr>
</tbody>
</table>

IAD is time-consuming to manage

“Fifty percent (50%) of nurses reported that the management of a patient with diarrhea caused them to work overtime once a month, while for 17% of nursing aides and 5% of nurses this happened once a week.”

Above calculation was based on a questionnaire completed and returned by 146 of the 204 ICU caregivers, corresponding to 75% of answers among nurses and 73% among nursing aides in Switzerland.†

† Two nurses are the standard of care to clean and position a patient.

Another survey of 962 questionnaires completed by nurses (60%), physicians (29%) and pharmacists or purchasing personnel (11%) in Germany (n=94), Italy (n=165), Spain (n=144) and the UK (n=127) estimated that one patient experiencing five episodes of fecal incontinence would consume 3.75 hours of nursing time.³
### IAD is costly to manage

<table>
<thead>
<tr>
<th><strong>Nursing time</strong></th>
<th><strong>Barrier + cleanser cost</strong></th>
<th><strong>Total Cost</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.86 hours/day *2 nurses x 17.5 min x 6 episodes</td>
<td>$25.81 per hour Blend of RN &amp; CNA</td>
<td>6 episodes/day * mid $0.27-0.45 midpoint of $0.36</td>
</tr>
<tr>
<td>$697.39/wk.</td>
<td>$15.12/wk.</td>
<td>~$713 per week / IAD patient</td>
</tr>
</tbody>
</table>

Solid data on the cost of IAD is lacking, however, available estimates confirm that IAD can be costly to manage:

- Total estimated cost of IAD in the US in 1995 was **$136.3 million** in nursing home residents with urinary incontinence.
- In a separate study, Wilson et al. estimated the 1995 **cost of moderate-to-severe IAD at $69-$504 per episode** for the institutionalized elderly.
- A more recent study conducted in 2014 estimated the **weekly cost of managing IAD at $127.19** in Canada. This included the cost of products (assumed to be petroleum-based creams) and nursing time.

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03 Cavilon Advanced Skin Protectant for moderate to severe IAD

Product Description
Cavilon Advanced Skin Protectant is a novel barrier used for patients with, or at risk of moderate-to-severe IAD

Product Description:

- The protective barrier creates an environment that allows healing\(^1,2\)
  - In a case series evaluating Cavilon Advanced Skin Protectant for management of severe IAD, a WOC Nurse described the performance of the product as “miraculous” when she observed the rapid improvement in skin condition.
- The product is durable requiring reapplication only 2-3 times per week\(^1\)
- The product adheres to, and forms a barrier on wet, weeping tissue\(^1,2\)
- The product forms a barrier that helps to control minor bleeding and weeping of serous fluid\(^2\)
- The liquid is non-stinging and comfortable during application, wear and cleansing\(^1\)
- The protective film coating reduces pain associated with Incontinence Associated Dermatitis (IAD)\(^1\)
- The product attaches to the skin and does not require removal\(^1\)
- The product allows easy cleansing - stool and other soil can be easily removed without disturbing the film\(^1\)
- The product is transparent allowing visualization of the underlying skin\(^1\)
- The product is a single use device minimizing the risk of cross-contamination\(^1\)

\(^1\)Brennan, Accepted for publication in JWOCN 2016
\(^2\)Been R. Accepted for publication in Wound Repair & Regeneration. DOI: 10.1111/wrr.12455. (In an animal model – translations to humans not shown.)
Cavilon Advanced Skin Protectant was designed to be the ideal barrier product to prevent and manage IAD per best practice recommendations.

**Characteristics of Ideal Products**

- Clinically proven to prevent and/or treat IAD
- Low irritant potential/hypoallergenic
- Does not sting on application
- Transparent or can be easily removed for skin inspection
- Removal/cleansing considers caregiver time and patient comfort
- Does not increase skin damage
- Does not interfere with the absorption or function of incontinence management products
- Compatible with other products used (e.g. adhesive dressings)
- Acceptable to patients, clinicians and caregivers
- Minimizes number of products, resources and time required to complete skin care regimen
- Cost-effective

\(^1\)Beeckman, Wounds International 2015. Available to download from www.woundsinternational.com

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03 Cavilon Advanced Skin Protectant for moderate to severe IAD

Clinical Value
Cavilon Advanced Skin Protectant adheres to wet, weepy tissue, protecting the skin from irritants and creating an environment to allow healing\(^1\)

Proven to adhere to wet, weepy tissue; creating a healing environment

Cavilon Advanced Skin Protectant showed significant (p=0.013) improvement for patients with severe IAD (n=16); 4 of the 12 patients with epidermal skin loss had complete re-epithelialization with 4-6 applications of the product.\(^1\)

Untreated wounds produced 1.9 times more fluid (4.328 g) compared to wounds treated with Cavilon Advanced Skin Protectant (2.231 g) (N=6, preclinical)\(^2\)

18.3% greater re-epithelization (p=0.003, 95% CI= 9.2%-27.5%) was seen in wounds covered with Cavilon Advanced Skin Protectant compared to untreated wounds (N=7)\(^2\)

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\(^1\) Brennan, Accepted for publication in JWOCN 2016

\(^2\) Been R. Accepted for publication in Wound Repair & Regeneration. DOI: 10.1111/wrr.12455. (In an animal model – translations to humans not shown.)
Cavilon Advanced Skin Protectant has been shown to significantly improve severe cases of IAD even in the presence of continued incontinence\(^1\)

### Results from 16 patients with severe IAD from two facilities providing nursing care 24h/day\(^1\)

- The IAD score improved in 13 of 16 patients with severe IAD
- The median percent improvement in IAD score was 96\%, significantly different from zero, \(p=0.013\) by Wilcoxon Signed-Rank test
- Four of the 12 patients with epidermal skin loss had complete re-epithelialization with 4-6 applications of the product

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\*IAD Score: Sum of 6 zones scored using the 3M Skin Assessment Tool

\(^1\)Brennan, MR. Accepted for publication in JWOCN 2016

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Cavilon Advanced Skin Protectant protects skin even in the presence of a caustic irritant

In a pre-clinical animal model, a single application of Cavilon Advanced Skin Protectant prevented skin breakdown from simulated incontinence fluid and provided protection for at least 48 hours.

The average normalized irritation score was 0.2 for Cavilon Advanced Skin Protectant protected wounds and 1.7 for untreated wounds.

Untreated sites had 8.5 times more irritation compared to sites treated with Cavilon Advanced Skin Protectant.

### Mean skin irritation scores at 48 hours after caustic challenge in guinea pig intact skin model (n=24)

<table>
<thead>
<tr>
<th>Score</th>
<th>Clinician Erythema Assessment scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Clear skin with no signs of erythema</td>
</tr>
<tr>
<td>1</td>
<td>Almost clear; slight redness</td>
</tr>
<tr>
<td>2</td>
<td>Mild erythema, definite redness</td>
</tr>
<tr>
<td>3</td>
<td>Moderate erythema; marked redness</td>
</tr>
<tr>
<td>4</td>
<td>Severe erythema; fiery redness</td>
</tr>
</tbody>
</table>

P < 0.001


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Cavilon Advanced Skin Protectant

Untreated control

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Mean skin irritation scores at 48 hours after caustic challenge in guinea pig intact skin model (n=24)
Cavilon Advanced Skin Protectant provides an environment for re-epithelization even in the presence of a caustic irritant\(^1\)

In a pre-clinical animal model, 18.3% greater re-epithelization (\(p=0.003\), 95% CI= 9.2%-27.5%) was seen in partial thickness wounds covered with Cavilon Advanced Skin Protectant compared to untreated wounds

**Untreated sites had 8.5 times more irritation** compared to sites treated with Cavilon Advanced Skin Protectant

“The unique characteristics of the new skin protectant, along with the environment it provided for skin protection, resulted in a greater degree of re-epithelialization despite the continued presence of a simulated caustic fluid.”

![Mean percent wound re-epithelialization at 96 hours in porcine partial-thickness wound model](attachment:graph.png)

<table>
<thead>
<tr>
<th>Mean % wound re-epithelialization</th>
<th>Cavilon Advanced Skin Protectant</th>
<th>Untreated</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>70</td>
<td>65</td>
</tr>
<tr>
<td>P = 0.003</td>
<td>80.6%</td>
<td>62.2%</td>
</tr>
</tbody>
</table>
Cavilon Advanced Skin Protectant significantly reduced the amount of weeping exudate\(^1\)

In a pre-clinical animal model, there was a significant (p=0.001) reduction in the amount of exudate weeping from partial thickness wounds over 96 hours following a single application of Cavilon Advanced Skin Protectant.

**Untreated wounds produced 1.9 times more fluid** (4.328 g) compared to wounds treated with Cavilon Advanced Skin Protectant (2.231 g).

"The results indicate that the formulation helped reduce the amount of minor bleeding and weeping from wounds compared to untreated wounds, and that this effect could last at least 96 hours."

<table>
<thead>
<tr>
<th></th>
<th>Fluid Absorbed (g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavilon Advanced Skin Protectant</td>
<td>0.083 2.231</td>
</tr>
<tr>
<td>Untreated control</td>
<td>0.238 4.328</td>
</tr>
</tbody>
</table>

**Mean weight of fluid absorbed with gauze immediately and 96 hours after wound creation** in porcine partial-thickness wound.

\(^1\) Been R. Accepted for publication in Wound Repair & Regeneration. DOI: 10.1111/wrr.12455 (http://onlinelibrary.wiley.com/doi/10.1111/wrr.12455/abstract). (In an animal model – translations to humans not shown.)
Cavilon Advanced Skin Protectant has proven durability, requiring less frequent applications and reducing nursing time required to prevent and manage IAD.

A durable product¹ that eliminates the need for frequent applications.

Cavilon Advanced Skin Protectant need only be applied 2-3 times per week.

Cavilon Advanced Skin Protectant

- Adheres to wet, weepy tissue
- Reduces pain associated with IAD care
- Durable
Cavilon Advanced Skin Protectant is highly durable which reduces frequent applications.

Many products require application with every episode of incontinence…
Assumes 6 episodes/day¹ x 7 days

~42 applications / week

Cavilon Advanced Skin Protectant is highly durable, requiring application 2 to 3 times per week, instead of with every cleansing²

2-3 applications / week

Minimizing frequent contact with damaged skin may help promote healing and reduce patient discomfort associated with IAD and IAD care

¹Bliss et al. J WOCN 2007;34(2):143-152. ²Brennan, Accepted for publication in JWOCN 2016.
Cavilon Advanced Skin Protectant can **help reduce patient’s pain** associated with IAD and IAD care

Adheres to wet, weepy tissue

Durable

**Eliminates difficult cleansing and does not require product removal minimizing irritating and frequent contact with damaged skin**

Cavilon Advanced Skin Protectant is easy to cleanse, does not require removal and is applied 2-3 times per week

**100% of patients** who reported IAD-associated pain on Day 1 (n=9), **saw a reduction in pain** with the use of Cavilon Advanced Skin Protectant

Better patient comfort can improve patient experience and perceived quality of care

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1Brennan, Accepted for publication in JWOCN 2016
Cavilon Advanced Skin Protectant can help reduce patient’s pain\(^1\) associated with IAD and IAD care

100% of patients reporting pain on Day 1 saw a reduction in pain with the use of Cavilon Advanced Skin Protectant, with baseline pain scores of 7-10 reduced to 0-3.

\(^{1}\)Brennan, Accepted for publication in JWOCN 2016

*Study enrolled 16 patients with severe IAD. 4 patients were unresponsive or paraplegic and 2 patients (No. 1 and 10) reported no pain throughout the study. 1 patient's pain score were missing.
Cavilon Advanced Skin Protectant does not need to be removed and can help reduce patient pain and discomfort\(^1\) associated with IAD and IAD care.

Many paste/ointment products require removal during cleansing in order to inspect the wound.

Assumes 6 episodes per day\(^2\) x 7 days.

Cavilon Advanced Skin Protectant does not require removal and is transparent, allowing inspection of damaged skin.

Minimizing frequent contact with damaged skin can reduce patients’ pain and discomfort associated with IAD and IAD care.

\(^1\)Brennan, Accepted for publication in JWOCN 2016  
\(^2\)Bliss et al. J WOCN 2007;34(2):143-152
03 Cavilon Advanced Skin Protectant for moderate to severe IAD

Economic Value
Cavilon Advanced Skin Protectant can reduce nursing time to manage IAD

Application Time: 1 min 01 sec
Cleansing Time: 13 mins 32 sec

Potential savings of 16.5 hours per week per average IAD patient

Cavilon Advanced Skin Protectant

Application Time*: 0 min 45 sec
Cleansing Time: 2 mins

What could you accomplish with more time?

6 episodes per day
for an average case of urinary and fecal incontinence

20.4 hours per week per average IAD patient

Cleansing Time: 2 mins

zinc oxide paste

2 nurses†

2 nurses†

3.9 hours per week per average IAD patient**

* Time reported as per application
* 3 applications per week
† Two nurses are the standard of care to clean and position a patient

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1 Bliss D. JWOCN 2007; 34(2):143-152
2 Heidegger CP. International J of Nursing Studies. 2016 Jul 31; 59:163-8
4 Brennan MR. Accepted for publication in JWOCN 2016

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Cavilon Advanced Skin Protectant can reduce nursing time to manage IAD

**zinc oxide paste**

- **Application Time**: 1 min 01 sec
- **Cleansing Time**: 13 mins 32 sec
- **50.9 hours per week per average IAD patient**

Potential savings of **41.3 hours** per week for a **severe** IAD patient

15 episodes per day for a **severe** case of fecal incontinence

What could you accomplish with more time?

**Cavilon Advanced Skin Protectant**

- **Application Time**: 0 min 45 sec
- **Cleansing Time**: 2 mins
- **9.6 hours per week per average IAD patient**

**Potential savings of 41.3 hours per week per severe IAD patient**

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* Time reported as per application
* 3 applications per week
† Two nurses are the standard of care to clean and position a patient

1. Bliss D. JWOCN 2007; 34(2):143-152
4. Brennan MR. Accepted for publication in JWOCN 2016
Cavilon Advanced Skin Protectant can reduce total overall cost

6 episodes per day for an average case of urinary and fecal incontinence

Cavilon Advanced Skin Protectant

Zinc oxide paste

2 nurses†

20.4 hours per week

$33.23 per hour

$677 per week

6 times per day

$0.29 per application

$12 per week

Potential savings of $533 per week per IAD patient

Cavilon Advanced Skin Protectant

2 nurses†

3.9 hours per week

$33.23 per hour

$129 per week

3 times per week

$9.00 per application

$27 per week

† Two nurses are the standard of care to clean and position a patient

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