Section 1: Application Summary

Name of Product	**3M™ Cavilon™ Advanced Skin Protectant**
Australian launch date	**October 2017**
Products used in (please select)	✔ diagnosis ✔ prevention ✔ treatment ✔ management
Contact details	As below

Your details

Name	**Julia Stafford**	Position	**Out of Hospital Care Setting Leader**
Email	jstafford@mmm.com	Phone	**+64274982539**
Name of Company	**3M**	ABN	**90 000 100 096**

Executive Summary: [200 words max.] NB Executive Summary must be suitable for use in Award promotion

Healthcare-acquired skin damage represents negative clinical outcomes resulting in potential complications such as infection, pain and suffering, longer hospital stays, and a poor patient experience. In addition, skin damage increases the work and cost of care. Exposure over time to factors such as irritants, moisture, friction, shear and adhesives can lead to conditions of skin breakdown, including: Moisture-Associated Skin Damage (MASD), Pressure Injury and Medical Adhesive-Related Skin Injury (MARSI).

Featuring 3M's revolutionary polymer-cyanoacrylate technology, 3M™ Cavilon™ Advanced Skin Protectant is designed to help manage moderate to severe skin damage and protect at-risk skin.[1,3] The ultra-thin yet highly durable barrier is able to attach to wet, weepy surfaces and create a protective environment that repels irritants and supports healing.[1,2,3] It delivers complete protection and prevention – even in the most challenging circumstances.

Cavilon Advanced Skin Protectant addresses a significant unmet need in that it can treat cases of severe healthcare-acquired skin damage. Additionally, it can prevent this skin damage from occurring in the first place.

Section 2: Product Details

Describe the technology [300 words max.]

3M™ Cavilon™ Advanced Skin Protectant is a polymeric-cyanoacrylate solution intended for the protection of intact or damaged skin. Upon application to skin, the liquid dries rapidly to form a highly durable, long-lasting waterproof film barrier. It represents a revolutionary technology for management of skin damage and protection of at-risk skin. Its formulation is unlike any other skin protectant or moisture barrier. The following is an explanation of the technology, and what makes it so different;

- **Unique, elastomeric polymer**
  The polymer forms a coating that can elongate and conform, avoiding the cracking seen with other moisture barriers. This assures greater barrier integrity, durability and protection against challenging irritants such as liquid stool and gastric fluid.[1,2,3]

- **Revolutionary polymercyanoacrylate system**
  The cyanoacrylate enables attachment of the skin protectant to damaged skin that is wet and weeping. Once on the skin, the protective coating creates an environment that repels irritants and supports healing and comfort.[1,2,3.] Note: if a moisture barrier product cannot reliably attach to the underlying skin, it's not capable of reliable protection.
- **Non-stinging solvent**
  The polymer-cyanoacrylate system is delivered onto the skin by a non-stinging solvent.[1,3]

Cavilon Advanced Skin Protectant is also breathable, allowing for moisture-vapour transmission that helps keep skin comfortable. Plus, it doesn't require removal, and the surface is easily cleansed – making wear easier for patients and care easier for staff.

What health problem is the technology addressing and how does it address the problem? [300 words max.]

Healthcare-acquired skin damage represents negative clinical outcomes resulting in potential complications such as infection, pain and suffering, longer hospital stays, and a poor patient experience. In addition, skin damage increases the work and cost of care. Exposure over time to factors such as irritants, moisture, friction, shear and adhesives can lead to conditions of skin breakdown, including: Moisture-Associated Skin Damage (MASD), Pressure Injury and Medical Adhesive-Related Skin Injury (MARSI).

3M™ Cavilon™ Advanced Skin Protectant may be used to protect skin from stool, urine, and other caustic body fluids such as gastric fluid. Primary uses include: incontinence skin protection, peristomal and peritube skin protection. It is intended for use by healthcare professionals in settings such as critical care, medical surgical, cardiovascular, orthopaedic, long-term acute care, long-term care and hospice.

Cavilon Advanced Skin Protectant addresses these problems and provides a product that;

- Attaches to wet, weepy, damaged skin[1,3]
- Provides an effective barrier, which has been shown to reduce the pain of managing Incontinence-Associated Dermatitis (IAD)[1,3*]
- Comes in a single-use applicator that reduces the potential for cross-contamination
- Is durable. Unlike traditional pastes and creams, which need to be removed and reapplied after every incontinence episode, Cavilon Advanced Skin Protectant only needs to be applied every 2-3 days. In some applications, it can last up to 7 days[3]. This creates a significant savings in nursing time, and also improves the overall healthcare experience for the patient.
- Does not require removal. This means that the skin is left undisturbed. And, as result, the damaged skin is protected, enabling healing to occur.
- Helps control minor bleeding and weeping of serous fluid.[1]

What other products are currently available to address this issue and how does this technology differ from and/or improve on existing technology? [300 words max.]

Moisture barrier creams, ointments and pastes have long been the standard of care for skin protection, but often these products have limitations:

- Aren't effective for preventing and managing skin damage
- Don't last as long as you need them to, with many needing to be removed and reapplied after every incontinent episode.
- Don't adhere to wet, weepy, damaged skin. If a moisture barrier product cannot reliably attach to the underlying skin, it's not capable of reliable protection.
- May interfere with healing
- Cause discomfort upon application, during wear and cleansing
- Don't stay in place on the skin - so when the patient slips down in the bed, the cream or paste slips off where it needs to be

- Are difficult to clean and remove, and may cause additional skin damage
- Difficult incontinence cleansing consumes significant nursing time, up to 20 minutes for 2 nurses, per episode of incontinence[7]
- Interfere with skin assessment, as pastes are opaque, preventing observation of the affected area, and must be removed completely to facilitate skin assessment
- Are not suitable around an ostomy or fistula

Results from clinical studies;

- 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 new 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)[2]
- 18.3% greater re-epithelialization (p=0.003, 95% CI= 9.2%-27.5%) was seen in wounds covered with Cavilon Advanced Skin Protectant compared to untreated wounds[2]
- 100% of patients who reported pain associated with IAD on Day 1 (n=9) experienced a reduction in pain resulting from the protective barrier provided by Cavilon Advanced Skin Protectant[1]

Having regard to the consumer's quality of life, does the product provide a balance between invasiveness and efficacy? [300 words max.]

Yes. Invasiveness is reduced, and efficacy is improved.

For patients, 3M™ Cavilon™ Advanced Skin Protectant provides an effective barrier, which can help:

- Reduce the pain associated with IAD[1,3,*].
- Eliminate the need for frequent reapplication – this reduces invasiveness for the patient
- Prevent skin injury and maintain skin integrity[1,3]
- Protect against caustic, corrosive body fluids including liquid stool and gastric fluid[1,2,3]
- Create an environment that supports healing[1,2,3]
- Improve the overall healthcare experience
- Reduce the potential for the cross-contamination that's possible with traditional multi-use products
- Lead to improved patient and resident outcomes

* Cavilon Advanced Skin Protectant is not an analgesic

Health economic assessment

With Cavilon Advanced Skin Protectant, a healthcare facility could potentially save **17.5 hours** of nursing time per IAD patient per week. This would equate to savings of **$618** per IAD patient per week. **

** Based on six episodes per day[4], two nurses at 2.9 hours/week at $37.13/hour[5] each; application/cleansing time of 45 sec/2 min[1,6]; three applications per week. Compared to use of a traditional zinc oxide paste.

Include scientific evidence to support the claims. This may include published data, unpublished scientific data, results of clinical trials and/or patient feedback. Photographs may be submitted. Product samples will not be accepted.

Attachments:

- 3M™ Cavilon™ Advanced Skin Protectant Summary of Clinical Evidence
- 3M™ Cavilon™ Advanced Skin Protectant Case Studies

Patient Photos:

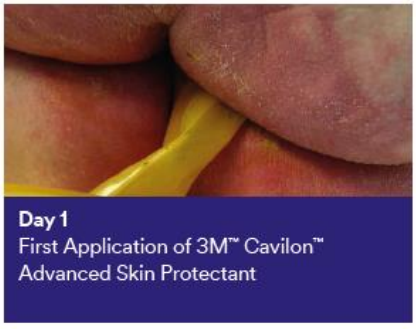
Case 1: Treatment of severe Incontinence Associated Dermatitis (IAD) in an acute and community setting

12 December 2017
Presentation to Tissue Viability Service and first application of Cavilon Advanced (in hospital)

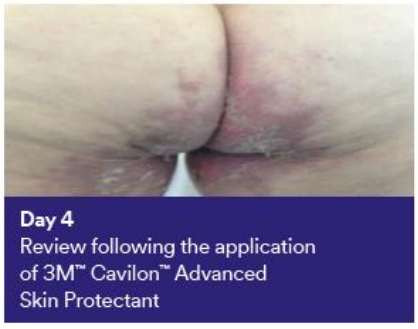
15 December 2017
Second application of Cavilon Advanced (in hospital)

18 December 2017
Third application of Cavilon Advanced (discharged home)

Case Two – Treatment of severe incontinence associated dermatitis for an acutely unwell patient with antibiotic related diarrhoea in an intensive care setting



Day 1
First Application of 3M™ Cavilon™ Advanced Skin Protectant



Day 4
Review following the application of 3M™ Cavilon™ Advanced Skin Protectant

Case Three - Rectovaginal fistula

Picture 1: **7 August 2017**

Picture 2: **10 August 2017**

Picture 3: **14 August 2017**

Picture 4: **17 August 2017**

Case Four - Leaking gastrostomy

Picture 1: **9 February 2018**

Picture 2: **12 February 2018**

Case Five - High output enterocutaneus fistula

Picture 1: **18 December 2017**

Picture 2: **22 December 2017**

Case Six - Incontinence associated dermatitis in a large acute trust

Application day 1

Application day 2

Application day 3

Application day 4

For full details of these patients, please see the attached Case Studies booklet.

References:

1. Brennan, Mary R.; Milne, Catherine T.; Agrell-Kann, Marie; Ekholm, Bruce P. Clinical Evaluation of a Skin Protectant for the Management of Incontinence Associated Dermatitis: An Open-Label, Nonrandomized, Prospective Study. J of Wound, Ostomy & Continence Nursing. 2017. 44(2):172-180.
2. Been RA et al. In vivo methods to evaluate a new skin protectant for loss of skin integrity. Wound Repair and Regen. 2016: 24: 851-859
3. 3M data on file. EM-05-01 3924.
4. Bliss DZ, Zehrer C, Savik K, Smith G, Hedblom E. An economic evaluation of four skin damage prevention regimens in nursing home residents with incontinence. J WOCN 2007;34(2):143-52.
5. Nurses and Midwives (Queensland Health and Department of Education and Training) Certified Agreement (EB9) 2016, RN – Grade 5, band 3. Accessed on 8/8/2018.
6. http://www.qirc.qld.gov.au/qirc/resources/pdf/certified_agreements/cert_agreements/2016/ca32_2016.pdfHeidegger CP; Graf S; Perneger T; Genton L; Oshima T; Pichard C. The burden of diarrhea in the intensive care unit (ICU-BD). A survey and observational study of the caregivers' opinions and workload. Int J Nurs Stud. 2016 Jul;59:163-8.
7. Heidegger CP, Graf S, Perneger T, Genton L, Oshima T, Pichard C. The burden of diarrhea in the intensive care unit (ICU-BD). A survey and observational study of the caregivers' opinions and workload. Int J Nurs Stud. 2016 Jul;59:163-8.

Section 3: Declaration

I certify that the information provided in this application is accurate and that the company accepts the Rules of the Award. Representative/s of the company will participate in promotional activities relating to the Award.

Name: Justin Lawrence _ *Position: Marketing Manager, 3M Medical Solutions Division, Australia and New Zealand*

Signature of the CEO/Authorised Representative: _____

Date: 2/ 8 / 19

Please send your application to MTAA Secretariat – Kerrin Rennie Award

CLOSING DATE: **2 AUGUST 2019**