

# Evaluating an incontinence cleanser and skin protectant ointment for managing incontinence-associated dermatitis

Incontinence-associated dermatitis (IAD) relates to skin breakdown from exposure to urine or faeces, and its management involves implementation of structured skin care regimens that incorporate use of appropriate skin barrier products to protect the skin from exposure to moisture and irritants. Medi Derma-Pro Foam & Spray Cleanser and Medi Derma-Pro Skin Protectant Ointment are recent additions to the Total Barrier Protection™ (Medicareplus International) range indicated for management of moderate-to-severe IAD and other moisture-associated skin damage. This article discusses a series of case studies and product evaluations performed to determine clinical outcomes and clinician feedback based on use of the Medi Derma-Pro skin barrier products to manage IAD. Results showed improvements to patients' skin condition following use of Medi Derma-Pro, and the cleanser and skin protectant ointment were considered better than or the same as the most equivalent products on the market.

## KEY WORDS

- » Dermatitis
- » Incontinence
- » Medi Derma-Pro
- » Skin ointment

Moisture-associated skin damage (MASD) occurs when there is prolonged exposure of the skin to excessive amounts of moisture from incontinence, wound exudate or perspiration. Incontinence-associated dermatitis (IAD) relates specifically to skin breakdown from faecal and/or urinary incontinence (Beekman et al, 2009), and has been defined as erythema and oedema of the skin surface, which may be accompanied by bullae with serous exudate, erosion or secondary cutaneous infection (Gray et al, 2012). IAD may also be referred to as a moisture lesion, moisture ulcer, perineal dermatitis or diaper dermatitis (Ousey, 2012). The effects of ageing on the skin are known to affect skin integrity, as is the underdeveloped nature of very young skin; as such, elderly patients and neonates are particularly vulnerable to damage from moisture (Voegeli, 2007).

The increase in moisture resulting from episodes of incontinence is exacerbated due to bacterial and enzymatic activity associated with urine and faeces, particularly when both are present, which leads to an increase in skin pH alongside over-hydration of the skin surface. This damages the natural protection of the acid

mantle, the skin's naturally acidic pH, which is an important defence mechanism against external irritants and microorganisms. This damage leads to the breakdown of vulnerable skin and increased susceptibility to secondary infection (Beekman et al, 2009).

It has become well recognised that presence of IAD greatly increases the likelihood of pressure ulcer development, since over-hydrated skin is much more susceptible to damage by extrinsic factors such as pressure, friction and shear as compared with normal skin (Clarke et al, 2010). While it is important to firstly understand that pressure and moisture damage are separate aetiologies and, secondly, be able to recognise the clinical differences in presentation, one of the factors to consider for prevention of pressure ulcers is minimising exposure to moisture/incontinence.

Another important consideration with IAD is the effect on the patient. IAD can be painful and debilitating, and has been associated with reduced quality of life. It can also be time-consuming and expensive to treat, which has an impact on clinical resources and financial implications (Doughty et al, 2012). IAD is known to impact on direct

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costs, such as through increased nursing time and cost of products and treatments, through linen and laundry costs and the increased risk of complications like secondary infection and pressure ulceration (Morris, 2011; Gray, 2014). One acute Trust during an audit estimated direct care costs of £93,417.69 per year for managing 37 patients with moisture lesions (Morris, 2011). A considerable amount is also known to be spent annually purely on skin protectant products, with the UK spend in the community alone being documented at £43,510,209 (NHS Business Service Authority, 2015). Therefore, appropriate management of IAD is critical to maintain high standards of care, promote good patient outcomes and to reduce financial burden in an already struggling NHS.

## MANAGING IAD

The foundation of prevention and management for IAD is a consistent and structured approach to skin care. The main factors to consider are thorough and regular skin inspection, management of incontinence (through identification and rectification of the root cause where possible, use of appropriate continence aids and involvement of specialist teams, as indicated) alongside appropriate cleansing, hydration and protection of the skin (Beeckman et al, 2015).

### Cleansing

There has been a move away from traditional cleansing with soap and water in recent times, with the acknowledgement that this can exacerbate skin damage, especially in patients with vulnerable or fragile skin (Beeckman et al, 2015). Soaps are usually alkaline substances that upset the skin's protective acidic pH and can also remove lipids from within the skin, impacting barrier function and increasing dryness (Beeckman et al, 2009). Aggressive cleansing with harsh washcloths should also be avoided to prevent damage to the skin from increased friction and abrasion (Beeckman et al, 2011).

For these reasons, guidelines relating to IAD management advocate skin cleansing with specific perineal cleansers labelled for incontinence, which are pH-balanced so they do not affect the normal skin pH (Beeckman et al, 2011; Beeckman

et al, 2015). These cleansers also often contain ingredients with additional protection and/or moisturising properties, and are designed to be non-rinse, reducing the need to rub or dry the skin and thus exposure to additional friction forces. For practical purposes, many incontinence cleansers convert into a foam, which remains on the skin allowing for easier cleansing of difficult areas and minimising the risk of splashback. The need to use wash basins, a practice that has been identified as an infection control hazard, is also eliminated (Johnson et al, 2009).

### Protection

To prevent and manage IAD, skin must not come into contact with moisture and irritants associated with urine and faeces. Skin barrier products place a protective, waterproof layer onto the skin to prevent exposure to urine and faeces, which either maintains or allows recovery of the natural barrier function and subsequent skin integrity. NICE (2014) recommends that skin barrier preparations are considered for adults and children (including neonates) who have been assessed as being incontinent or at a high risk of developing MASD or IAD, such as those with oedema, dry or inflamed skin.

There are various skin barrier products available on the market with differing ingredients and properties. It is important to be aware of the potential impact on efficacy of other necessary devices when choosing a suitable skin barrier product; for example, possible reduction of absorbency of incontinence pads, which could be detrimental to treatment outcomes.

Modern skin barrier products containing silicone to form a protective film on the skin are commonly available as a cream, a film foam applicator or a film spray. A recent development within the silicone barrier product market is skin protectants that contain bioadhesives; these give the ointment a tacky consistency, so it adheres to even very moist and damaged skin surfaces, making it ideal for severe presentations of IAD. Choosing the correct type of barrier product is an important factor to maximise outcomes for the patient and usually depends on the level of existing skin damage and the amount of moisture the skin is being exposed to.

### IMPLEMENTING STRUCTURED SKIN CARE REGIMENS

While 'good skin care' seems a simple solution for prevention and management of IAD and other forms of MASD, research — while limited — shows that correct implementation of national and local skin care protocols is often inconsistent or does not occur at all (Nix, 2000). One proposed reason for these inconsistencies is the wide and diverse choice of available products, with differing indications and usage guidelines, with clinicians finding choosing the right product for the level of skin damage confusing (Doughty et al, 2012; Hughes, 2016). This can also lead to overuse or misuse of products, both of which can have implications for optimal patient outcomes and costs.

A moisture damage treatment strategy has been devised to aid care providers at all levels to manage patients using the most appropriate product at a given time. Total Barrier Protection (Medicareplus International) provides a single range of products with clear guidance and rationale for use based on the type and severity of moisture exposure and degree of skin damage, enabling the strategy to be tailored to individual patient needs. By introducing a simple and consistent approach to skin protection, implementation of Total Barrier Protection should help prevent product misuse and in doing so drive cost savings by way of improving efficiency.

A recent introduction to the Total Barrier Protection range is Medi Derma-Pro, which sits alongside Medi Derma-S Barrier Cream & Film and Lifteez Medical Adhesive Remover. Medi Derma-Pro is a skin protection system that incorporates a pH-balanced Foam & Spray Incontinence Cleanser and a Skin Protectant Ointment. Medi Derma-Pro Skin Protectant Ointment contains dimethicone and bioadhesives, which provides the tacky consistency making it suitable for use on severe skin damage. The Medi Derma-Pro Foam & Spray Cleanser is a pH-balanced, non-sting, non-rinse formulation and thus meets requirements for an appropriate and effective incontinence cleanser. The cleanser easily and effectively cleanses skin and removes adherent bodily fluids while minimising the need

for unnecessary rubbing. It contains ingredients that help protect the skin and promote a soft, non-sticky skin feel to enhance patient comfort.

Guidelines for similar products advocate usage across the complete scale of skin damage from intact to severe. Conversely, within the Total Barrier Protection system, users are encouraged to be more selective and introduce Medi Derma-Pro only for skin damage at the more severe end of the spectrum, where maximum barrier protection is required and patients will reap the most benefit. In this manner, use of more expensive products that are not clinically indicated could be reduced.

A series of clinical evaluations were conducted across the UK to gain clinical evidence on the efficacy of Medi Derma-Pro Foam & Spray Incontinence Cleanser and Skin Protectant Ointment for management of IAD, and to gather clinical opinion regarding outcomes and ease of use compared with previously used barrier products.

### METHOD

Clinical evaluations were conducted across seven UK centres, five in the acute sector and two in the community. Two acute trusts performed short clinical evaluations to gain clinician feedback on product performance, with the remaining centres performing a series of case studies evaluating more in-depth treatment outcomes, such as assessment of incontinence and specific changes in skin condition and level of skin damage, alongside product feedback.

Fifty patients with IAD who required protection with a skin barrier product were included in the study and followed for a period of up to 2 weeks. The existing skin barrier product was replaced with Medi Derma-Pro Skin Protectant Ointment in all cases, with use of Medi Derma-Pro Foam & Spray Cleanser left to clinician choice. Lead clinicians were informed of the intended focus for Medi Derma-Pro products to manage moderate-to-severe skin damage, and product training was provided to relevant staff where requested prior to commencement of the evaluations.

Case study data were collected using standardised evaluation forms, with local feedback forms used for the short product

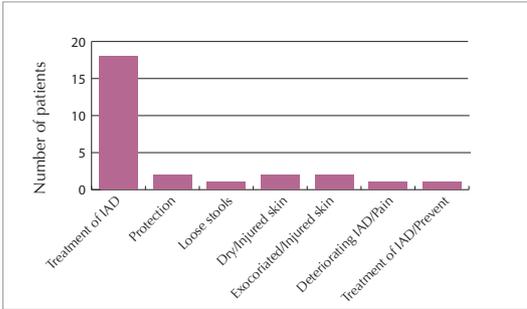


Figure 1. Main indication for use

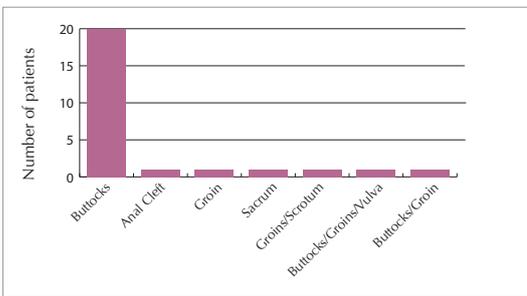


Figure 2. Location of skin damage

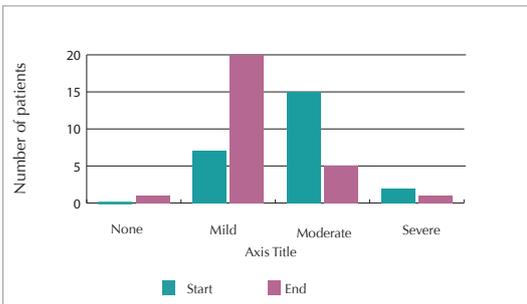


Figure 3. Overall change in skin damage frequency

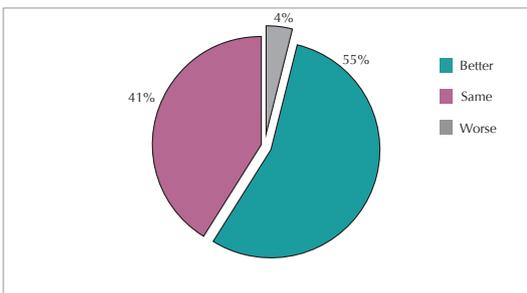


Figure 4. Assessment of change in level of skin damage

performance evaluations. All data were amalgamated and analysed descriptively.

**RESULTS**

Fifty patients with varying degrees of IAD were treated with Medi Derma-Pro: 29 as part of the case series and a further 21 as part of the short product performance evaluations. Clinical outcomes with the case series group will be discussed first and then results of the clinician feedback on the products for the overall sample.

**Case series**

Twenty-nine patients (17 male and 10 female; average age: 81.2 years) were treated with Medi Derma-Pro Skin Protectant Ointment, 28 in conjunction with Medi Derma-Pro Foam & Spray Cleanser, for an average duration of 9.6 days. All patients were incontinent (urine: 57.7%; faeces: 19.2%; urine and faeces: 23.1%) with mild-to-severe skin damage, except for one patient who was normally continent but was experiencing an acute episode of loose stools.

Figure 1 illustrates the main reasons for using Medi Derma-Pro as described by the treating clinicians, which is predominantly treatment for IAD or associated conditions. The main area treated was the buttocks, with some patients also experiencing IAD to the groin, scrotum and vulva (Figure 2). The average product application frequency was 16.9 times over the average 9.6 day evaluation duration, so approximately twice daily on average — although the majority of documented

application frequency was ‘as required’ followed by twice daily and then daily.

Medi Derma-Pro Skin Protectant Ointment replaced Proshield (H&R Healthcare) as the skin barrier product in 20 (69%) cases, Medi Derma-S Barrier Cream or Film in eight cases (28%), and Cavilon Barrier Cream (3M) in one case. Medi Derma-Pro Foam & Spray Cleanser again replaced Proshield Foam & Spray Cleanser (H&R Healthcare) as the current cleansing product in the majority of cases (63%, *n*=18), with soap & water (17%, *n*=5), foam cleanser (7%, *n*=2) and wet wipes (3%, *n*=1) also being used. Three patients were not using a cleansing product previously (10%).

On commencement of the evaluation, the majority of patients were assessed as having a moderate level of skin damage (59%, *n*=17), three as having severe skin damage (10%) and nine as having mild damage (31%). Figure 3 indicates the changes in level of skin damage from evaluation start to end of the study period, demonstrating the trend towards improvement, with decreasing numbers of moderate and severe cases, and an increasing number of mild cases. Figure 4 shows the overall change in skin damage as better, the same or worse, illustrating improvements or unchanged levels in the assessed severity of skin damage for 28 patients. Only 1 patient, for whom multiple barrier products had been unsuccessfully tried previously, was assessed as having a worse level of skin damage following the evaluation.

Changes in individual skin conditions (for example, erythema, excoriation, maceration) again showed a trend towards improvement, with reduction in the frequency of erythema, excoriation and dryness and a large increase in the number of patients assessed as having healthy skin (Figure 5). There was one case of a patient developing maceration during the evaluation (the same patient where the level of skin damage was considered to have worsened).

Not all patients were able to have their pain assessed during the evaluation — of the 16 where pain assessment was possible, all patients reported decreased pain following commencement of Medi Derma-Pro, with Figure 6 illustrating the overall changes in frequency for each pain score.

**Product evaluations**

Twenty-one patients underwent short product evaluations to gain clinician feedback on product performance and ease of use. These patients were treated with Medi Derma-Pro for an average of 2.7 days, 10 with both the cleanser and skin protectant ointment in combination and 10 with just the skin protectant ointment.

When analysed as a single group of 50 patients, 38 patients received both Medi Derma-Pro products and 11 the skin protectant ointment alone.

Figure 7 demonstrates clinician feedback when comparing Medi Derma-Pro Foam & Spray Incontinence Cleanser with the previously used cleanser, indicating the majority considered Medi Derma-Pro cleanser to be better (68%). Only one clinician assessed the cleanser as being worse than the previous cleanser (wet wipes) (the same patient who was recorded as having the worse skin condition, as discussed previously). All clinicians recorded the cleanser was effective and easy to use in foam and/or spray mode. Pain/stinging on application of the cleanser was recorded for 33 patients, only one of which reported mild stinging. This did not necessitate discontinuation of the cleanser and overall reports indicated the cleanser was still better than the previous product.

Directly comparing the patients who had been previously using Proshield Foam & Spray Incontinence Cleanser ( $n=28$ ), the most similar cleanser to Medi Derma-Pro, 18 clinicians rated Medi Derma-Pro Foam & Spray Cleanser as better (64%) and 10 the same as (36%) Proshield (one missing response).

With regards to Medi Derma-Pro Skin Protectant Ointment, all clinicians reported that the product effectively adhered to skin with no pain or stinging on application. In two cases, Medi Derma-Pro ointment was effectively applied in conjunction with a fungal treatment with good outcomes.

Figure 8 depicts clinician responses with regards to ease of use, patient opinion and change in clinical condition using Medi Derma-Pro ointment compared with the previous barrier product used, with the majority considering Medi Derma-Pro to be excellent or better, followed by

the same, as the previously used product. As before, one case was recorded as worse for patient opinion and clinical condition. For overall performance, 76% ( $n=37$ ) rated Medi Derma-Pro as excellent or better than the previously used product and 22% ( $n=11$ ) the same as.

Again, directly comparing the patients who had previously been using Proshield Skin Protectant ( $n=30$ ), the most comparable product to Medi Derma-Pro, Medi Derma-Pro was rated excellent or better than for ease of use ( $n=18$ , 60%), patient opinion ( $n=17$ , 63%), clinical condition ( $n=19$ , 63%) and overall performance ( $n=18$ , 60%). The remaining clinicians rated it the same as their previous product, with no assessment of it being worse.

**DISCUSSION**

The patients included in the case series were indicative of the general picture for IAD: a condition more often found in an ageing population where incontinence itself is more prevalent and skin integrity is more vulnerable to compromise. The trend towards improvement in overall skin condition, incorporating level of skin damage and individual skin conditions such as erythema and excoriation, indicates the products were effective at providing skin barrier protection for patients experiencing varying degrees of IAD and thus are suitable for use as part of a structured skin care regimen as recommended for IAD prevention and management.

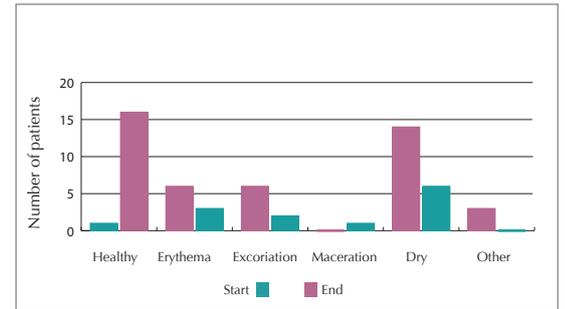


Figure 5. Changes in skin condition

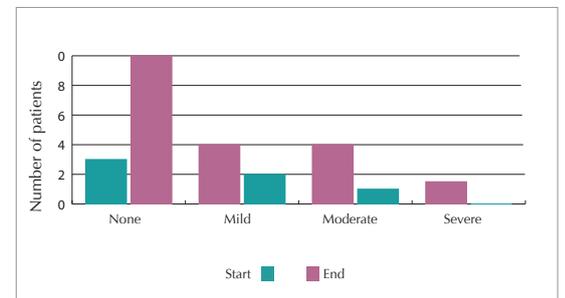


Figure 6. Changes in pain score

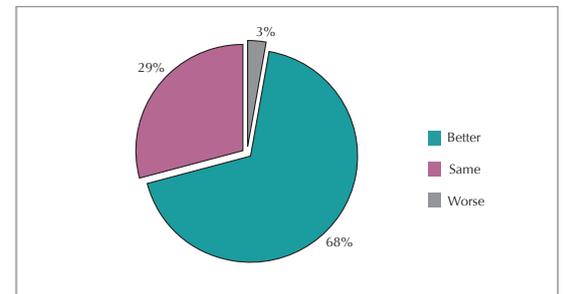


Figure 7. Comparison to previous cleanser

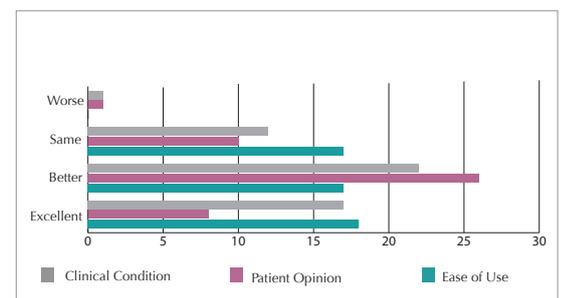


Figure 8. Comparison to previous barrier product

Where the overall grade of damage (mild, moderate, severe) was unchanged, improvements were seen in the individual assessments of skin condition, demonstrated by a 750% increase in the frequency of healthy skin documented and decreased frequency of erythema, excoriation and dryness. This indicates that overall skin condition improved with the use of the Medi Derma-Pro cleanser and skin protectant ointment.

Another positive outcome from the case series was that all patients assessed for pain recorded a decreased pain rating during the evaluation, an important consideration with the known pain and discomfort associated with IAD. This demonstrates further that the products were cleansing and protecting the skin appropriately to prevent the soreness associated with continued exposure of vulnerable skin to the products of incontinence and the subsequent damage they cause. It also reiterates the importance of the non-sting formulations of the evaluation products and the clinician feedback regarding ease of use; particularly, the need for a gentle, non-rinse cleanser that does not necessitate undue rubbing of the skin to remove irritants and an adherent skin protectant ointment that allows for easy application without the need for rubbing in, thus minimising patient discomfort as well as reducing friction.

With regards to the patient whose skin condition was considered to worsen, the exact reasons for this were unknown — multiple skin barrier products had been tried previously with no improvement, which could potentially indicate that the skin damage was occurring due to multiple problems, rather than being a reflection of the products themselves. Feedback from the treating clinician suggested the issue could be due to the tackiness of the skin protectant ointment causing the incontinence pad to stick to the skin, but this was not otherwise reported throughout the case series and wider evaluations. A study conducted with Medi Derma-Pro to assess the potential of the product to block absorbency of incontinence pads found that product transfer from the skin to the pad was not of any significance as to cause absorbency problems (Dykes and Bradbury, 2016), which could suggest that in this case the product was applied too liberally. This further highlights the need for continued education with regards to correct usage of skin barrier products.

The very positive clinician feedback received for both products overall provides further support for the efficacy of the products in clinical practice, especially where they were found to be better than or at least the same as comparable products available on the market at this time. This provides clinicians with a degree of choice when choosing this type of cleansing and barrier product, and allows for consideration of other important factors, such as unit cost, while still maintaining confidence in achieving good patient outcomes with good quality products.

The successful use of Medi Derma-Pro Skin Protectant Ointment in association with fungal treatments also provided useful and clinically relevant information to support use of the products in this way. A 2015 Best Practice Statement 'Incontinence-Associated Dermatitis: Moving Prevention Forward' advocates topical treatment of fungal infections/candidiasis in association with appropriate skin protectants once a diagnosis has been confirmed — while many skin barrier creams are not appropriate for use in this manner due to their moisturisation properties, these evaluation results suggest that Medi Derma-Pro Skin Protectant Ointment will provide the suitable barrier protection required to prevent further exposure to moisture and irritants exacerbating any secondary infection, while not donating excessive moisture to the skin from the product itself.

One consideration that should be taken away from this case series evaluation is the need for further education and training regarding appropriate usage of skin barrier products, an outcome which supports the clinical need for an easy-to-implement, moisture damage treatment strategy like Total Barrier Protection. Within this strategy, Medi Derma-Pro is indicated for moderate-to-severe moisture-related skin damage; the product is designed to address the problems with managing this degree of damage specifically and not with the aim of replacing simpler and more cost-effective barrier products, such as creams and films, when they are clinically suitable. Despite discussions with lead clinicians and provision of some product training before commencement of the evaluations, Medi Derma-Pro was still used on nine patients with mild skin damage. There may have been clinical reasons for use of Medi

Derma-Pro in these cases — three patients only had mild skin damage but were assessed as having a moderate severity of incontinence, therefore, Medi Derma-Pro may have been instigated to prevent further deterioration in patients being regularly exposed to urine and/or faeces. A further patient was experiencing an acute episode of loose stools that was beginning to damage the skin, hence Medi Derma-Pro was commenced in the short term to prevent further breakdown until the diarrhoea resolved. For the remaining 5 patients with mild skin damage and mild incontinence, while the benefit to the patient would be no less for treatment with Medi Derma-Pro, a simpler skin barrier cream such as Medi Derma-S may have proved sufficient and less costly. This may have been a case of the treating clinician supplementing the existing barrier product with Medi Derma-Pro without due consideration to the clinical need dictated by the existing or potential severity of the IAD, or could indicate gaps in the provision of product training. These evaluations were not intended to research implementation of Total Barrier Protection as a strategy involving the complete Medi product range, and therefore the full educational programme available to support the strategy was not provided as part of the methodology — however, outcomes support the recognition that education and training on a wider scale is required to support the most appropriate product selection for patients on an individual basis.

## CONCLUSION

This case series evaluation provides good supporting evidence for the use of Medi Derma-Pro Foam & Spray Cleanser and Skin Protectant Ointment for managing IAD, reflecting the reality of clinical practice. Providing clinicians with product choice for managing varying levels of skin damage is important to ensure that IAD and other moisture-related skin damage is managed appropriately and prevented where possible, promoting improved quality of life for patients and reducing the prevalence and incidence of such problems while offering financial savings. This could also impact on prevalence, incidence and consequences of pressure injuries, due to the accepted association. When used as part of the Total Barrier Protection moisture-damage

treatment strategy, where product choice is simplified with focused indications for use, the Medi Derma-Pro Skin Protection System could effectively prevent further deterioration of IAD while reducing overuse of expensive products when they are not clinically necessary, and enable all levels of care provider to consistently implement a standardised regime. WUK

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