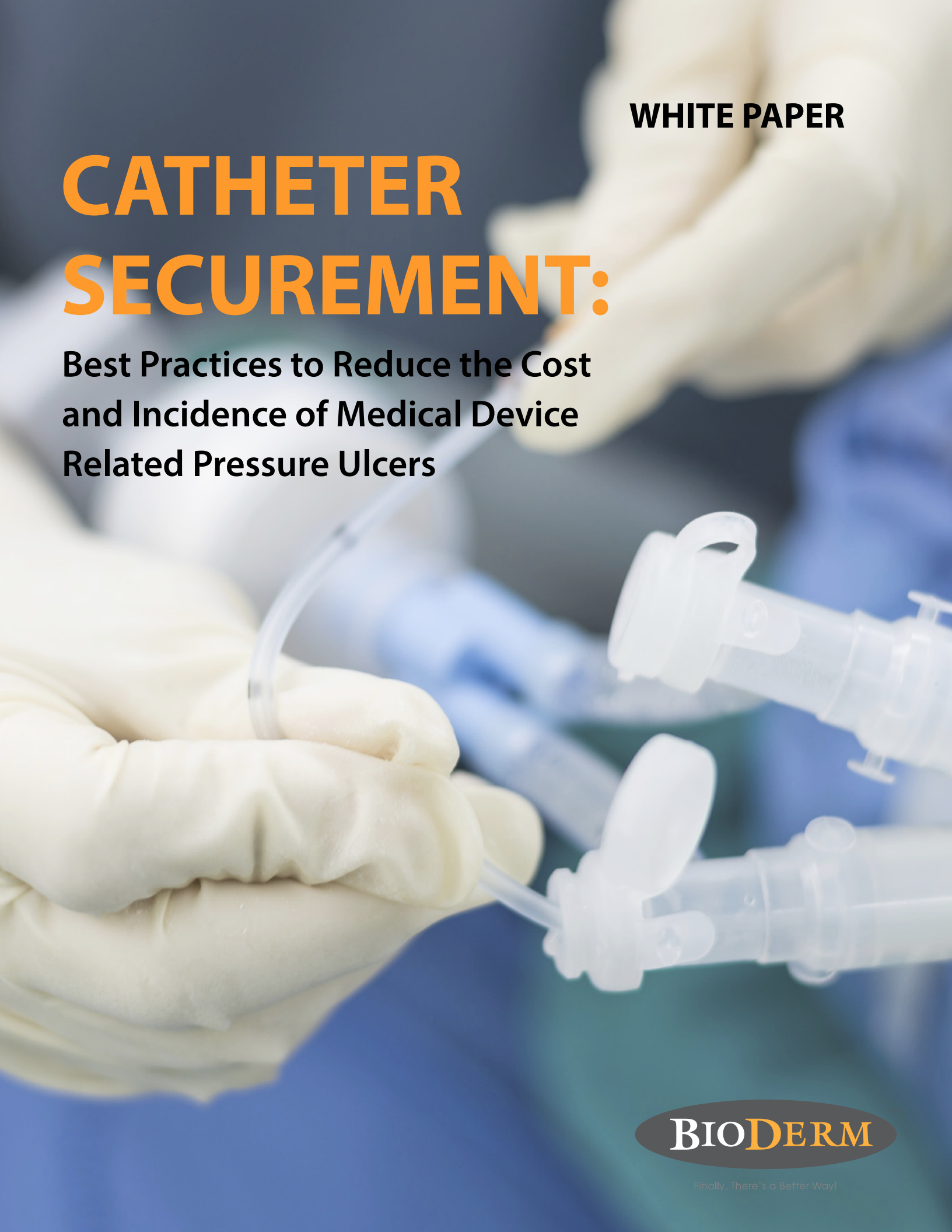


WHITE PAPER

CATHETER SECUREMENT:

Best Practices to Reduce the Cost and Incidence of Medical Device Related Pressure Ulcers

BIODERM

Finally, There's a Better Way!

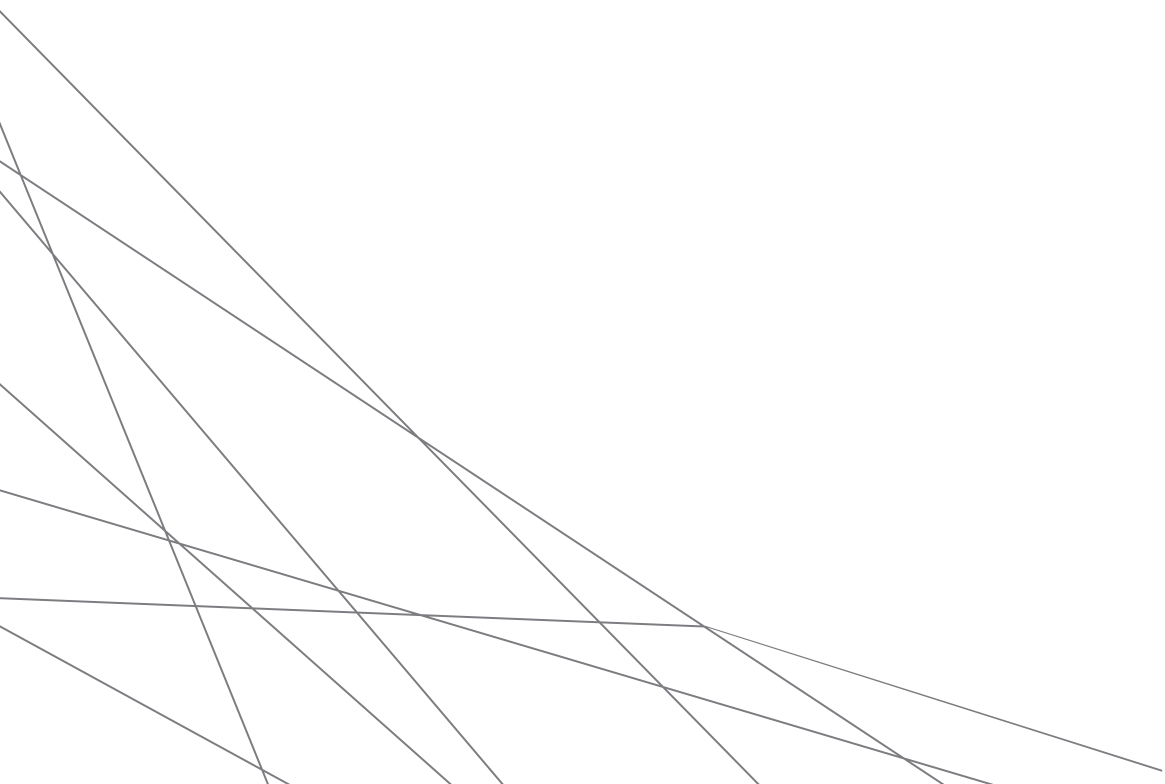


Table of Contents

Executive Summary

Pressure ulcers cost the US healthcare system more than $11 billion dollars annually. With over 1/3 of those costs associated with medical device usage, clinicians, manufacturers and purchasing have a unique opportunity to implement a coordinated strategy to reduce or eliminate these ulcerations.

Medical device related pressure ulcers (MDR-PU) are unique due to their development away from the traditional bony prominences seen with other pressure ulcers. In addition, they are much more likely to be identified at a later stage of development (74%)[2], increasing treatment costs (Avg: $10,700)[11] and length of stay (adding 4-10 days excess LOS)[5].

In order to assist acute care facilities in reducing the clinical and financial burden of these events, we have identified the key components of a risk mitigation protocol. This includes interventions from clinicians, modifications of purchasing processes and partnerships with medical device manufacturers to build in risk mitigation from the outset. Implementation of these protocols may help reduce the cost and incidence of medical device related ulcers.

Introduction

The scourge of medical device related pressure ulcers (MDR-PU) in acute care facilities is a pressing challenge for today's clinicians. While strides in medical device development in the preceding decades have extended life spans and drastically improved patients' quality of life, their use has undoubtedly had unintended consequences.

Medical device related pressure ulcers create a significant clinical and financial burden on patients, caregivers and acute care facilities. This burden has grown unsustainably over the previous two decades, emerging as one of the largest single financial challenges to the current healthcare system.

A plethora of research has defined the scope of the issue:

- A patient with a medical device in place is 2.4 times more likely to develop a pressure ulcer than a non-device patient.[1]
- The average incident costs more than $10,000 to treat, a total cost of more than $3.8 billion dollars annually in the United States[1,2,4]
- Patients with pressure ulcers spend an average of 4-10 extra days in hospital and see an corresponding increase in their risk of nosocomial infections, complications and the associated morbidities.[5]

Effective, October 1, 2012, hospitals now face a strong financial incentive to eliminate device related ulcers as they fall squarely within the 'never events' identified by the Center for Medicare and Medicaid Services.6 Failure by facilities to prevent these ulcers will have a dramatic impact on patient satisfaction scores, quality scores and ultimately, reimbursement.

The overwhelming medical evidence indicates that while all ulcerations are not preventable, a vast majority can be prevented through the implementation and maintenance of clinical best practices.[8] These best practices include the use of manufactured securement devices – to date there are many on the market which do not currently meet this need. Additional support is needed for clinical partners and manufacturers to assist in the development and implementation of securement devices that target the prevention and reduction of medical device related pressure ulcers.

The Role of Medical Devices

Distinguishing Medical Device Related Ulcers

Pressure ulcers are defined as "a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure or pressure in combination with shear."[3] It is estimated that pressure ulcers occur in 5.4% of hospitalized patients[1,14]; this is the equivalent of an estimated 1.9 million people per year. Of these, 24.1% (456,518 people) were related to the use of a medical device.[1,14]

The key distinguishing factor between generalized pressure ulcer development and those associated with medical devices is location. While the vast majority of pressure ulcers occur over bony prominences, medical devices related ulcers often occur elsewhere, proximate to the device and unrelated to any bony prominence[1]. For example, the prevalence of device related pressure ulcers on the head, face and neck are often linked to the use of ET tubes, nasal cannulas and other tubes. Analysis of multiple population groups has estimated that 34.5% of all hospital acquired pressure ulcers are related to the use of a medical device.[1]

The most common locations for a medical device related ulcer were ears, lower legs and heels. By comparison, most non-device related ulcers occurred on the sacrum-coccyx, heels and buttocks.[2]

Pressure Ulcer Location	Device Related PU	Non-Device Related PU
Head/Face/Neck	70.3%	7.8%
Other/Multiple	21.9%	5.8%
Heal/Ankle/Foot	20.3%	16.9%
Coccyx/Buttocks	7.8%	67.5%
Sacrum	1.6%	16.9%

2. Apold, J., "Preventing Device Related Pressure Ulcers", J Nurs Care Qual, Vol. 27, No. 1, pp. 28-34.

Medical devices are commonly placed to monitor or treat a patient's condition. Within ICU and critical care units, most patients will have multiple medical devices in place during their hospital stay[6]. These patients are already at a heightened risk of injury due to their ill health and decreased mobility. However, among population level studies there were no statistically significant population differences to determine which patients when admitted were more or less likely to develop a medical device related ulcer.[1]

Unique Risk Factors

In addition to population level risk factors among hospitalized patients, medical devices can introduce new risk factors.

Common factors that increase the risk of a medical device related ulcer include:

- The device itself can create pressure on the skin, even when sized and applied correctly. The pressure can be significantly higher if the device is not correctly sized or if the patient develops edema.
- Friction can be caused by the device against the skin, particularly in mobile or semi-mobile patients.
- Humidity and heat can develop between the device and the skin. This can negatively impact the microclimate of the skin and reduce skin's barrier function. Studies have established that the presence of moisture against the skin can enhance the negative effects of friction more than fivefold[1].
- Medical devices must often be tightly secured to the skin which can create additional pressure in unusual locations not associated with bony prominences.
- The materials used in most medical devices, including securement devices, do not allow for regular inspection of the skin beneath the device. This may increase both the absolute risk of an ulcer developing as well as the likelihood that the ulcer will not be discovered until a later stage in its development (Stage III or IV).[1] This delay in diagnosis has significant implications for severity and cost of treatment. The exception to this statement is the CathGrip securement device which has an opaque adhesive to allow for continuous skin visibility.

Stage at Discovery	Device Related PU	Non-Device Related PU
Stage 1	5.4%	20.1%
Stage 2	20.3%	26.0%
Stage 3	20.3%	11.8%
Stage 4	1.4%	0.6%
Unstageable	52.7%	41.4%

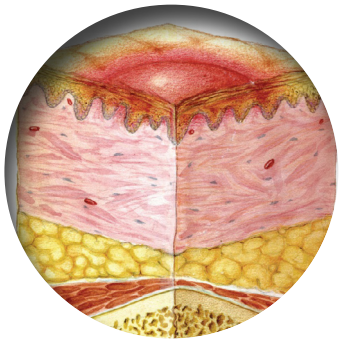
2. Apold, J., "Preventing Device Related Pressure Ulcers", J Nurs Care Qual, Vol. 27, No. 1, pp. 28-34.

Current best practices for pressure ulcer prevention have focused largely on nursing interventions and monitoring of high risk locations. Under these protocols, it is possible to understand how a medical device related ulcer developing elsewhere, obscured by a device might be missed until it had developed to a full thickness ulceration.

Therefore, new protocols are needed to target the development of medical device related ulcers. This new approach necessitates the support of clinicians, purchasing and medical device manufacturers to reduce device risks, improve product selection and ensure compliance with best practice.

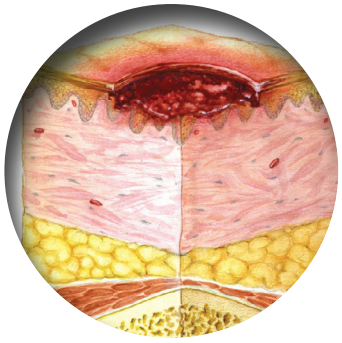
PRESSURE ULCER STAGES

According to the National Pressure Ulcer Advisory Panel (NPUAP), there are currently four stages of a pressure ulcer, regardless of cause. There are also two alternatives stages to denote unstageable or otherwise unidentifiable deep tissue injuries. These definitions have been reprinted below for your reference.



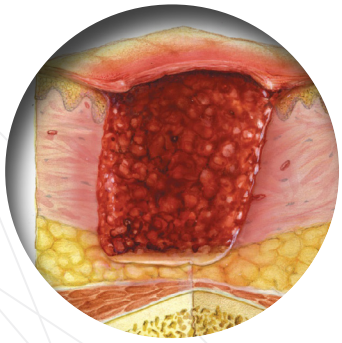
Stage 1

Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area. The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" persons.



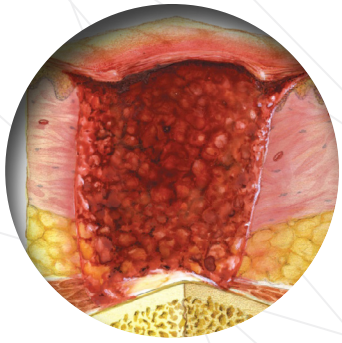
Stage 2

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled or sero-sanginous filled blister.Presents as a shiny or dry shallow ulcer without slough or bruising*. This category should not be used to describe skin tears, tape burns, incontinence associated dermatitis, maceration or excoriation.*Bruising indicates deep tissue injury.



Stage 3

Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling. The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

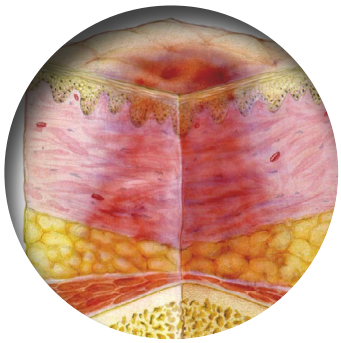


Stage 4

Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often includes undermining and tunneling. The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/muscle is visible or directly palpable.

Unstageable

Full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either a Category/Stage III or IV. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as "the body's natural (biological) cover" and should not be removed.



Deep Tissue Injury

Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment.

The vast majority of all pressure ulcers in the acute care setting as identified while still in Stage I or Stage II, making treatment easier and lower cost.[2] However, due to the unique risk factors identified earlier, medical device related ulcers are unlikely to be caught until Stage III or Stage IV.[2]

According to analysis of Minnesota's mandatory statewide reporting system, between 2003 and 2010, indicated that 74% of medical device related pressure ulcers are not discovered until Stage III, Stage IV or unstageable, compared to 54% of non-device related ulcers.[2]

Financial Impact

This late stage identification is a missed clinical opportunity with huge financial penalties. The US Healthcare system spends an estimated $11.6 billion dollars to treat pressure ulcers annually, according to the Agency for Healthcare Research & Quality.[10]

Based on our earlier analysis, we can determine that medical device related uclers at 27% more likely to be discovered at Stage 3 or 4 than non-medical device related ulcers. In addition, we know that 34.5% of all ulcerations are directly attributed to medical devices. Therefore, we can assess a total cost to the healthcare system for MDR-PU of of $3.8 billion or more annually.[1,10]

Because treatments costs vary by location and severity of the ulceration, prevention and early identification are key to reducing the overall financial burden. A Stage I ulcer costs just over $2000 per ulcer, but a Stage IV ulcer can cost as much as $21,140 per ulcer.[12] The Society of Actuaries estimates the average cost of treating pressure ulcers at $10,700 per ulcer.[11] None of these costs reflect any soft costs, including increased nursing time, specialty products, medications or surgical debridement.

Reimbursement, Penalties & Quallity Scores

Effective October 1, 2012, the Center for Medicare and Medicaid Services have deemed pressure ulcers as a "never event" with monetary penalties for hospitals where they occur.[8]

This was strengthened considerably in October 2014 as part of the Patient Protection and Affordable Care Act. This legislation requires the Department of Health and Human Services to ranks hospitals by performance and implements a 1% reduction in reimbursement for all Medicare patients for hospitals in the highest quartile of HAPU incidence.[5]

One percent of Medicare reimbursement can make or break a hospital's financial standing. Of the 724 hospitals penalized in 2015, the total reduction in reimbursement was more than $373 million.[9]

Additional financial incentives are expected to be implemented within the next 5-7 years as patient satisfaction scores begin to play a larger role in reimbursement decisions.

Therefore, implementation of a prevention and early identification program for medical device related pressure ulcers can yield both direct and indirect cost savings.

PREVENTION: The average cost, as identified by the Society of Actuaries, for treating a pressure ulcer is $10,700.[11] If a 200 bed hospital with 12,000 admissions a year can reduce their rate of pressure ulcers by just half a percent, they could save $1.2 million annually.

EARLY IDENTIFICATION: The cost to treat a pressure increases as it becomes deeper. If that same 200 bed hospital, could identify 50% of all ulcers by Stage II (up from 26%), they could reduce their average expenditure by more than $500,000 per year.

For a full breakdown of the cost analysis, please see the cost analysis below. These calculations include three seperate components: first, the cost the treat based on existing incidence data; second, the anticipated cost to treat assuming a half percent reduction in incidence in the nuymber of patients at each stage; and third, the anticipated cost to treat assuming an improvement in the early detection rate of MDR-PU with 50% of ulcerations being discovered during Stage I or Stage II.

Cost of Pressure Ulcers

Beds	200	**Percent % Assoc w/MD**	34.50%
Admissions Per Year	12,000	**Reduced PU Rate**	0.65%
Current PU Rate	1.30%		

	Cost	% of ALL MDR-PU[2]	# of Patients with MDR-PU @ 1.3%[1]	Cost to Treat @ 1.3%
Stage 1	$ 2,159.07	5.40%	8.42	$ 18,188.01
Stage 2	$ 8,932.55	20.30%	31.67	$ 282,875.99
Stage 3	$ 14,839.56	20.30%	31.67	$ 469,939.19
Stage 4	$ 21,410.12	1.40%	2.18	$ 46,759.70
Unstageable	$ 18,731.47	52.70%	82.21	$ 1,539,951.61
		100%		**$ 2,357,714.50**

	Cost	% of ALL MDR-PU[2]	# of Patients with MDR-PU @ 0.65%	Cost to Treat @0.65%
Stage 1	$ 2,159.07	5.40%	4.21	$ 9,094.00
Stage 2	$ 8,932.55	20.30%	15.83	$ 141,438.00
Stage 3	$ 14,839.56	20.30%	15.83	$ 234,969.59
Stage 4	$ 21,410.12	1.40%	1.09	$ 23,379.85
Unstageable	$ 18,731.47	52.70%	41.11	$ 769,975.81
		100%		**$ 1,178,857.25**

	Cost	If They ID MDR-PU by Stage II, 50% of the time	# of Patients with MDR-PU	Cost to Treat
Stage 1	$ 2,159.07	15.0%	23.4	$ 50,522.24
Stage 2	$ 8,932.55	35.0%	54.6	$ 487,717.23
Stage 3	$ 14,839.56	25.0%	39	$ 578,742.84
Stage 4	$ 21,410.12	1.0%	1.56	$ 33,399.79
Unstageable	$ 18,731.47	24.0%	37.44	$ 701,306.24
		100.0%		**$ 1,851,688.33**

Expected Savings Through .5% Reduction of MDR-PU Rates	**$ 1,178,857.25**
Expected Savings By Improving Early Identification of MDR-PU	**$ 506,026.17**

BEST PRACTICES

In light of the continuous stream of new medical devices coming to market, product evaluations are part of daily life for many nurses and techs in the acute care space. These range from high risk products used in surgical procedures to low-risk commodities like catheter securement. Evaluations traditionally focus on usability, cost, patient safety and nursing preference – all necessary components of a well rounded evaluation.

However, it is helpful to ask yourself, ahead of a potential evaluation – ***"what problem am I looking to solve?"*** and then address that problem as part of your evaluation. The source of medical device pressure ulcers can include both the device and it's method of securement. So how can this product help me prevent or reduce this?

To ensure that you get the data you need from your securement product evaluation, be sure to examine the following key characteristics:

1. Does this product contain any hard plastic/metal parts that could cause chaffing, shear or skin trauma?
2. Does the device avoid skin injury when stretched, such as during edema?
3. What impact does the adhesive (if applicable) have on the patient's skin?
4. Is this device opaque or removable to allow nurses to inspect the skin?
5. Is this securement repositionable?
6. How long is the device supposed to remain in place?
7. What are the removal procedures and how do they affect that patient's skin?
8. What complications am I currently seeing? What is the cost to treat these?

A sample evaluation form can be found on the next page.

It is also available for download here at: www.bioderminc.com/eval-form

• UniGrip™ •
• Product Evaluation •

Type of Catheter Secured

_____

Date and Time Applied: _____ **Date and Time Removed:** _____

Please specify your satisfaction level for the attributes identified below.

	1 - Very Unsatisfied	2 - Unsatisfied	3 - Neutral	4 - Satisfied	5 - Very Satisfied
Held tubing securely					
Skin integrity at application site					
Wear Time					
Prevention of tube dislodgement					
Ability to reposition tube					
Ease of use					
Patient Comfort/Satisfaction					
Skin condition upon removal					

Please specify your preference between the products listed for each feature identified below.

	CathGrip®	Current Securement Device
Secure on skin		
Easy to use		
Holds tube securely		
Durable for repeat positioning		
Patient Preference/Comfort		
Wear Time		
Gentleness of Tube Securement Clasp		

Additional comments:

_____

_____

Available Securement Options

There are dozens of securement options currently on the market. They fall into three main categories:

1. Adhesive Securement Devices
2. Tape
3. Sutures

Securement Manufacturers:

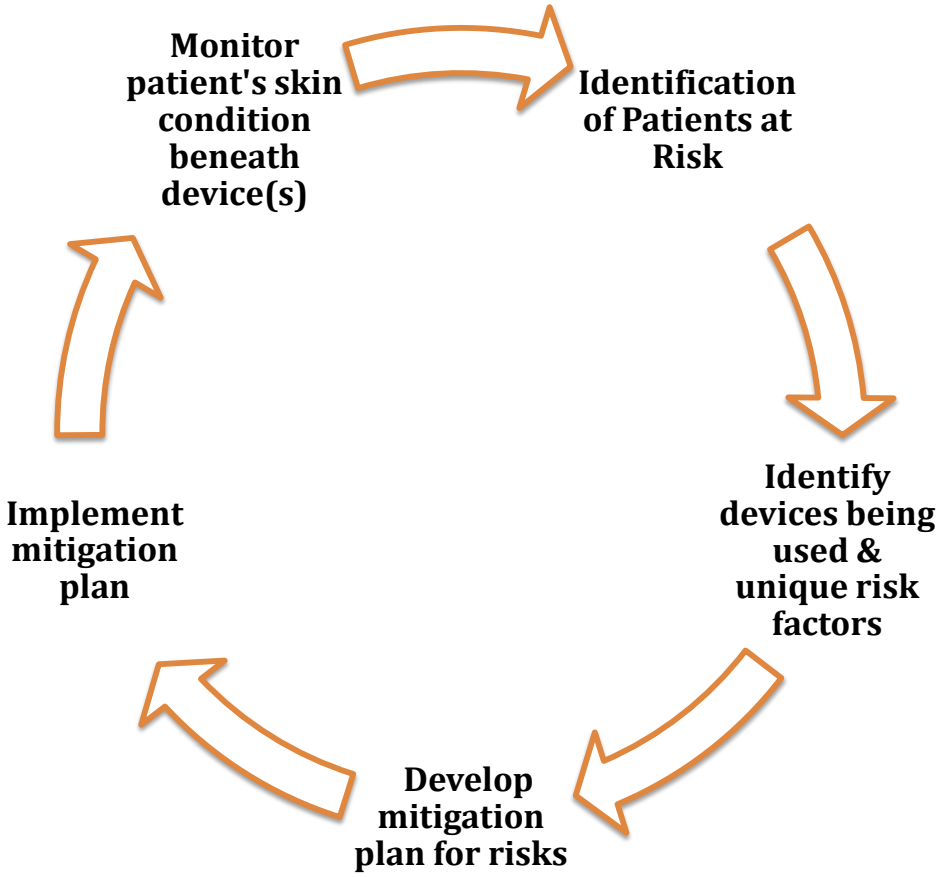
CR Bard®
Hollister®
Centurion®
ConvaTec®
Merit Medical®
BioDerm, Inc.®
3M Healthcare®

Each category has positives and negatives and more than one may be appropriate for each type of tube you are looking to secure and is not intended to be all inclusive.

Brand	Pros	Cons
Flexi-Trak	• Low Cost • Easy to Apply • Repositionable	• Short wear time • Acrylic adhesive • Ease of catheter movement • Cannot monitor skin condition beneath device
StayFix	• Insertion site securement • Repositionable	• Higher cost • Short wear time • Dislodges when patients sweat • Cannot monitor skin condition beneath device
StatLock	• Widely available • Repositionable • Included with most kits • Established market leader	• Hard plastic parts • Acrylic adhesive • Catheter not secure in both directions • Associated with skin tears • Cannot monitor skin condition beneath device
CathGrip	• Skin friendly hydrocolloid adhesive • Made with soft, no-slip grips • Intuitive design • One-size fits all (secures 2-47 Fr) • Opaque adhesive keeps skin condition visible. • Repositionable	• Currently not included with kits • Requires application to clean, dry skin
Tape	• Low cost • Readily available • Easy to use	• Dislodges easily • Short wear time • Associated with skin tears • Cannot monitor skin condition beneath device
Sutures	• Low cost • Preference of some physicians for high risk tubes • Can be combined with sutureless securement	• Patient discomfort • Risk of infection • Requires physician intervention

Key Components of a Nursing Protocol to Reduce MDR-PU

To achieve lasting results, device selection can only be one component of a multi-pronged strategy for the prevention and reduction of medical device related pressure ulcers. A MDR-PU focused protocol should include the following components:



Common components of a mitigation plan could include:

- Use of pressure relief devices
- Repositioning patients every 2 hours
- Regularly scheduled removal of securement and repositioning of medical devices and tubes.
- Flag the patient as high risk in charts
- Consider the prophylactic use of wound dressings beneath devices to promote skin integrity
- Evaluate use of alternative securement and other devices to reduce risks
- Extensive staff training on the unique aspects of medical device related pressure ulcers and the importance of early identification.

For Example...

For example, the mitigation strategy of a 500 bed teaching hospital in the Northeast dealing with a rise in pressure ulcers on the thigh might focus on the use of a well known foley securement devices with hard plastic components.

An ideal mitigation strategy could include:

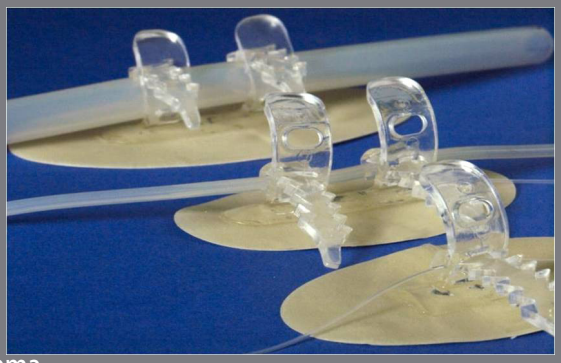
- Staff training on the correct placement location for Foley securement, i.e. top of thigh, not towards the inside
- Addition of tube repositioning to the check list for each shift
- Evaluation of alternative Foley securement devices that do not have the same hard plastic parts as a StatLock
- Monitoring fecal management of patients to reduce potential for moisture
- Use of skin barrier prep wipes (such as BioPlus+) beneath the securement device
- Establish target reduction level and monitor staff progress towards goal

CASE STUDY

Product Info

CathGrip is a hydrocolloid catheter securement product that was introduced in 2013. It utilizes BioDerm's proprietary hydrocolloid formulation to deliver long lasting securement with skin friendly results. The CathGrip has been shown to reduce traction on tubes and reduced potential for tube migration.[15]

Each CathGrip securement device includes:



- BioPlus+ Skin Barrier Prep Wipe
- 100% hydrocolloid adhesive
- Latex free
- Hypoallergenic
- Polyurethane coating to stretch with the skin during edema
- Opaque coloring for skin visibility
- Soft, no slip grips that secure tubes from 2-47 Fr
- Durable for repeat catheter repositioning

The CathGrip line contains thirteen (13) SKUs in three product families: UniGrip for universal securement, Grip & Seal for insertion site securement and Hold Me for low profile securement.

Product Evaluation

In 2015, it was evaluated by clinicians in a 600 bed hospital in the Northeast. Following their evaluation, the UniGrip device was introduced hospital-wide in July of 2015. Additional evaluation and data collection on MDR-PU and other key performance indicators is expected over the following months.

Clinical Champion: WOCN & Interventional Radiology

Units Participating: MICU, ICU(s)

Duration: two weeks

SKU Evaluated: 51300NS, UniGrip Large

Tube Secured: Foley Catheter

Results[13]:

In each evaluation, the skin condition of the patients was monitored before, during and after using the CathGrip device. In 100% of evaluations, the skin condition after using CathGrip was the same or better than prior to application of the securement device. No adverse events, including skin tears or pressure ulcers were reported. All respondents agreed that the CathGrip provided reliable securement of the Foley catheter, effectively limiting any movement in/out of the urinary meatus.

In addition:

- 79% of respondents indicated that CathGrip met or exceeded their securement expectations
- 89% of nurses said CathGrip was easy to apply
- 90% said the device adhered well and remained secure on the patient for the full expected wear time.

CathGrip & MDR-PU

Prevention is the best medicine. CathGrip can help facilities prevent MDR-PU by managing the risks of medical device securement and making a robust monitoring program easier to implement and maintain.

CathGrip has all the key features we've identified in the preceding pages:

- Hydrocolloid base, similar to many wound dressings
- Repositionable
- Maintain skin visibility
- Eliminate hard, plastic parts
- Eliminate acrylic adhesives
- Maintain skin integrity during edema
- Includes skin barrier wipe

If you are interested in evaluating the benefits of CathGrip at your facility, please visit us online at www.BioDermInc.com or email: CustomerCare@BioDermInc.com

CONCLUSION

Medical device related pressure ulcers are a major financial and clinical burden on today's healthcare system. Fortunately, it is a fixable problem. Hospitals have a growing financial incentive to invest in preventative care and risk mitigation strategies to reduce the rates of all CMS identified never events, most especially pressure ulcers.

Hospitals can achieve real term financial savings and improve patient satisfaction rating by taking a multi-pronged, evidence based approach to prevention and early identification of medical device related pressure ulcers. These strategies must include risk identification, utilization of alternative technologies and better education and support for clinical staff.

Current devices and securement option do not always meet the unique clinical needs for prevention of medical device related pressure ulcers. The introduction of alternative devices, such as CathGrip and others, can support the reduction medical device related ulcers and delivery better care at lower overall costs.

Long term change is dependent on an ongoing partnership between clinicians, medical device manufacturers and purchasing departments. These changes have the opportunity to improve reimbursement & patient satisfaction in addition to delivering six figure savings.

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SAMPLE REQUESTS

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