Product Trial

Australian Sheepskin Products

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EXECUTIVE SUMMARY

With an estimated cost of $US3.6 billion in the USA to teat pressure ulcers and a product that has proven to reduce them by 68% compared to standard practice, health care givers have requested an assessment and evaluation of sheepskin products. Research has shown that 1 in 14 patients are susceptible to pressure ulcers acquired during hospital stays. Occupational Therapists are acutely aware of these health issues that occur and are supportive of a product or process that helps these individuals.

The product trial proved the product claims of helping these individuals and the personal testimonies to a speedy recovery from pre-existing conditions. One of the nine original individuals refused to use the products, while others outside of the nine were asking for them before the trial was completed. Overall resident acceptance was excellent. The only product that failed to show promise was the wheelchair covers as they were not designed to fit the many variations of wheelchairs.

Though the processing of the sheepskin products required some changes, they were not outside the general demands to provide a sanitized product for infection control requirements. Investing in a moisture censor control for the dryers would increase the turn-around-time. The laundry can expect to see more efficiencies in wash costs and drying times.

The initial investment in product is expensive and the recovery was distributed over 75 washes to match the manufacturer's guarantee. The standard flat rate pricing as used on basic linens provided by the laundry service was changed to a charge per processing to ensure recovery of the initial investment. This cost was then broken down to a cost per day for each product based on the turn over experience.

It is recommended that this product can be provided at a reasonable cost to health care providers with an optimistic expectation to improve conditions for patients suffering from pressure ulcers and those that are at-risk to developing them.

INTRODUCTION

Skin care programs need to be tailored to individual need. General practices of repositioning residence, regular skin inspection and assessing skin damage is important. There is a need for simple cost effective devices and even more expensive devices for high-risk residences. Pressure ulcers continually challenge the health care professional. It is estimated to cost $3.6 billion per year to treat these ulcers in the American healthcare system.(see: Appendices B)

Leslie Sommerfeld with Nordon Medical & Drug Supply Ltd reported to the Canadian Paraplegic Association that chronic care patients pay between $1,800 and $2,000 per month for wound care dressings. Silver dressings which require a cover dressing can cost $200 per pack of ten and foam dressings $45 per pack of five, which doesn't cover the cost of the cover dressing or nursing time.

The Australian medical sheepskin products have been acclaimed in a number of studies as a medical device that prevents bedsores and improves healing time. The Laundry received a number of individual testimonies to this.(Appendices: D) The Linen Standardization/Quality Assurance Committee received a request from a group of Occupational Therapists to provide these products as a regular service.

The initial product cost and special handling requirements were deterrents. The central laundry process develops efficiencies and cost-effectiveness by bulk purchasing and processing large volumes of common items. Annual linen replacement costs are offset in the charge rate. With new developing technologies in fabrics and health care demands the Laundry is challenged to stay current while at the same time to remain cost effective.

In the past, the Laundry developed products and services in the Battleford plant that processes personal laundry services for residence of the Prairie North Health Region. In recent years, a linen control system was installed to track items. With these resources in place, a product trial was proposed to report resident acceptance, results, processing requirements, and costs.

THE PRODUCT

Prior to 1997, sheepskin standards in Australia for health care products were unsatisfactory to users and promoters of quality products. Due to poor test procedures, counterfeit products and loss market position, a new measurable standard had to be developed. The standard had to include a long product life and perform well in use and processing.

Label

In 1997, the Commonwealth Scientific and Industrial Research Organization **(**CSIRO), Division of Wool Technology, the Meat Research Corporation partnered with Australian tanners to develop a reliable health care product that could meet these demands. The product had to be urine resistant, able to be processed at 80^{o}C on a regular basis where the wool type, length and finish were vital factors to maximize pressure relief and provide comfort in a health care environment.

The Australian Standard 4480.1-1998 was established based on this research and development. (Appendices E)

Sores result from tissue break down due to pressure on the tissue that reduces the capillary blood flow between the body's surface and skeletal parts. Friction and shear forces at these points, and moisture buildup, contribute to the condition. High-density wool creates a cushion for the body distributing the pressure with low friction. Wool fiber also dissipates the moisture and is able to absorb 34% of its dry weight. The Australian Standard identifies the optimum wool pile properties and wool type.

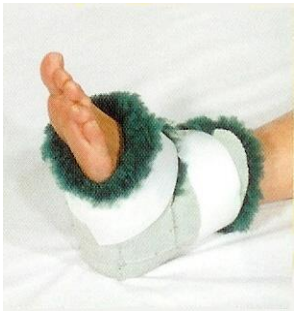
Research trials revealed:

a) comfort and support increased with increased pile length (30mm)
b) increased comfort after ten washings even with decreased fiber diameter
c) sheepskins were more comfortable than lambskins
d) laundering enables the wool and leather to relax
e) laundering does not significantly affect the appearance or characteristics (50 washes)

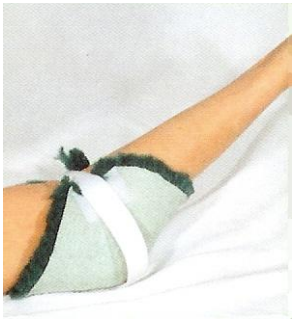
Basic bedsore prevention products consist of bed pads of various sizes and wheelchair covers. Other products to help the healing process are heel, palm and elbow protectors and a variety of footwear products (boots, slippers and inner soles). The product line also includes coccyx pads for inside incontinence garments.

Bed Pad

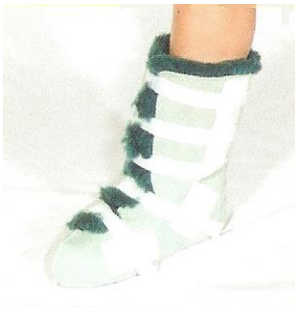
30”x60”
30”x48”



Heel Protector

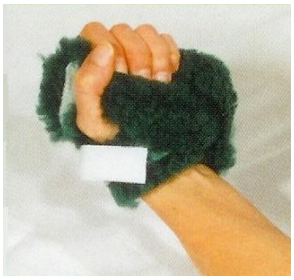


Elbow Protector

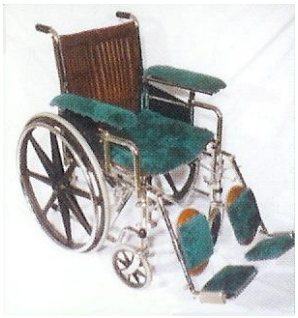


Long boot

Adjustable Slipper



Palm Protector



Wheelchair Cover

THE SCENARIO

The Battleford District Care Center (BDCC) identified nine residences with a variety of skin conditions. The BDCC is a level 4, long-term care facility. It serves 117 fulltime residences with 7 respite beds for the Prairie North Health Region. Products were assigned based on the individual situation and each resident was graded on the Braden scale (Appendices: F):

Resident	Braden Scale	Pre-Condition	Product
A	11	Ulcer on elbow (Stage 4)	Elbow pad
B	9	Skin redness	Bed pad
C	9	Hand sores Skin redness	Palm protector Bed pad
D	17	Leg abrasions Skin redness	Boots Bed pad
E	9	Skin redness	Coccyx pad Bed pad
F	13	Hands Back area	Palm protector Bed pad
G	14	Ulcers on heels (stage 4)	Adjustable slippers
H	11	Ulcer on elbow From wheelchair	Wheelchair protectors
I	15	Coccyx	Coccyx pads

The pre-conditions of each resident were documented by unit nursing coordinators and monitored through out the trial. Adjustments were made as conditions or circumstances changed. Schaan Health-care Products representative worked with the unit to demonstrate the proper application of the products. The initial instructions were to apply the sheepskin's wool directly on the area of treatment and discontinue the current wound care protocol.

THE PROCESS

All the sheepskin products were processed at the Battleford plant. The needs of the nine residences were assessed and product purchased to ensure continuous uninterrupted service for the 8-week period. Each piece was labeled with a bar code to track usage, quality inspection, and inventory levels.

The most remarkable characteristic is the ability to withstand the 80°C temperature on a regular cycle. At this temperature the product is disinfected and sanitized. Alkalis, hydrogen peroxide, phosphates, bleaches and enzymes are not used. A bacteria stat rinse was used to enhance sanitization. With multi-resistant organisms being identified today this will become an important practice. The wash formula was:

Operation	Water Level	Temp °C	Time (min)	Chemical
Wash	High	45	3	Non-ionic detergent 5 ml/kilogram
Rinse	High	45	2	
Wash	High	60	4	Non-ionic detergent 5ml/kilogram
Rinse	High	60	2	
Thermal	High	72	8	
Rinse	High	60	2	
Rinse	High	45	2	Bacteria stat 2 ml/kilogram
Extract			8	

As the dryers only had time and temperature controls with no moisture censors, it was decided that product would be rack dried which took from 24 to 36 hours. Over drying any product is detrimental to the product life. The pre-trial sample tests were dried at 60°C. Some samples showed signs of stiffening, but were flexed and the leather softness returned. The softness and appearance were not affected. Two of the test samples were imitation synthetic sheepskin that did not survive the pre-test temperatures.

All the products were provided with the regular deliveries on an-as-required bases. Each individual piece was recorded in and out of the laundry facility with an inspection of the quality. Throughout the trial inventory levels were monitored and processing costs documented.

THE RESULTS

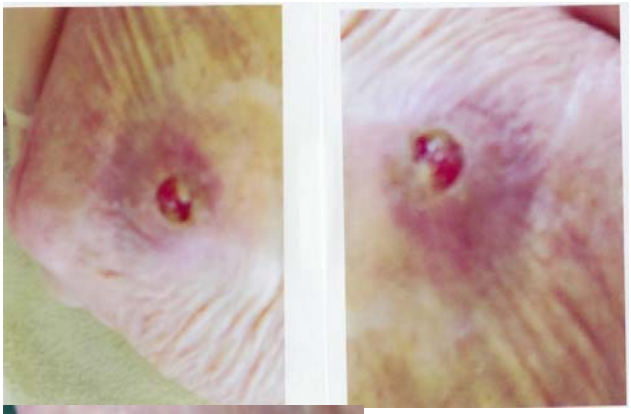
The Nursing Home Perspective

Results from acute care trials in Australia reported a 68% reduction in bedsores. (see: (Appendices B) The trial was designed to record current skin conditions and the impact of the sheepskin product. The facility report the cost charged to the individual for wound treatment.

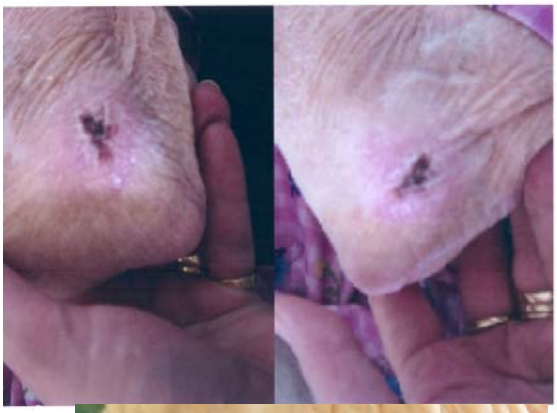
Resident A

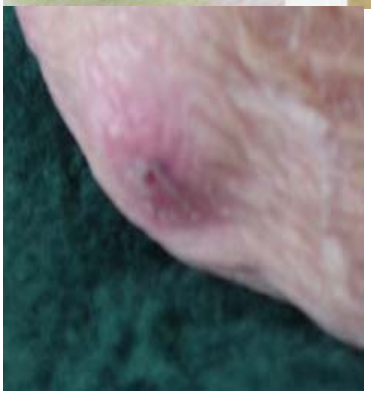
The resident had a pre-existing ulcer (Stage 4) for six months with daily wound care at $28 per month (not including nursing time). The Braden risk of developing ulcers was 11. The condition of the ulcer had somewhat improved during the six months. By the third week of the trial the ulcer had scabbed over, but was inflamed. Parsing the area was being considered but cleared within a couple of days. Usage of elbow pads per week was 1 at a cost of $1.496/week or 21.4¢ per day. By the sixth week the scab had diminished and disappeared by the eighth week with no scaring. Pink skin condition indicated better blood circulation.

Pre-condition



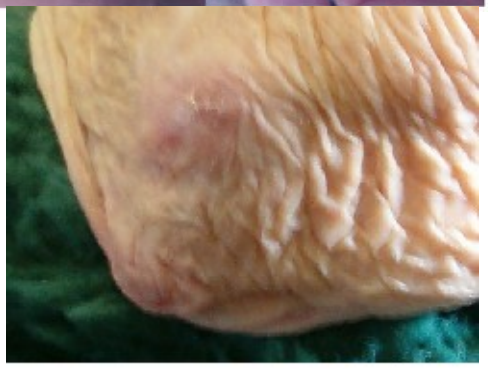
3 weeks





6 weeks

9 weeks



The original resident refused the use of a collar and bed pad. Another resident was assigned the bed pad (30x60) as a preventative measure. This resident was graded 9 on the Braden Scale, but had stage 1 existing on the buttocks area. The skin condition was reddened with small blisters. The usage was 1 pad per week at $9.446/week or $1.349 per day). Within 3 weeks there was a marked improvement and by the sixth week had disappeared. Skin showed good blood circulation.

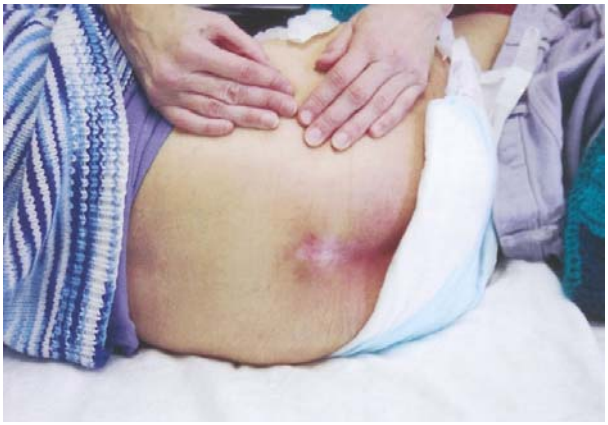
Resident C

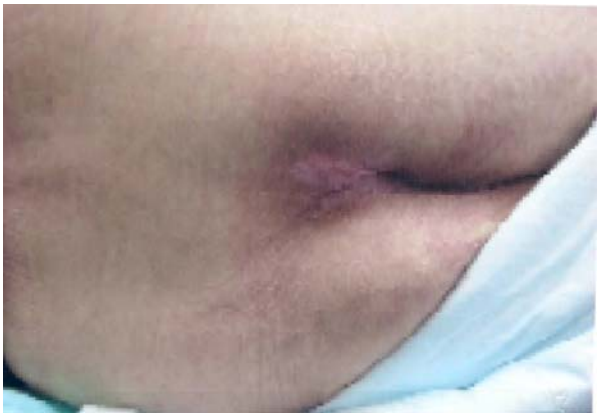
This resident had contracted arms and hands as a pre-existing condition and was scaled at 9 on the Braden Scale. A full arm covering was designed, but was too long and irritated the crease at the elbow. Further use was discontinued until the redness disappeared. Palm protectors were used to relieve contracted hands. The legs had signs of discoloring from poor blood circulation. The bed pad (30x48) improved leg color by the third week. Usage was 1 bed pad per week $7.765/week or $1.09 per day and 1 pair of palm protectors at 13¢ per day. In the sixth week the hands could be opened with out discomfort to the resident. The skin color of the legs had gone from white to pink.

Resident D

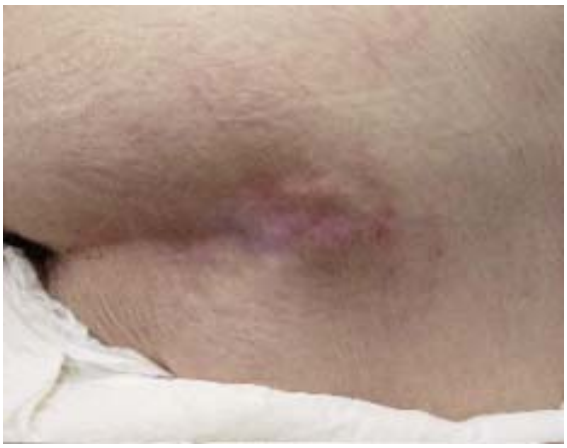
This resident had reddened and darkened skin (Stage 1) with abrasions on the legs due to thrashing. On the Braden Scale was graded at 17. Boots and a 30x48 bed pad were assigned. The usage was 1 pad/week at $7.765 or $1.09 per day and 1 pair of boots per week at $5.489 per week or 78.4¢ per day. Previous treatment had been $26/month. By the third week the redness had disappeared in the buttocks area and by the sixth week the abrasions to the legs had disappeared with no scaring. The Braden Scale was improved to 15.

Pre-condition **3 weeks**

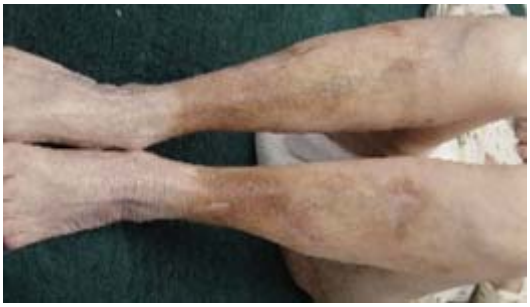




This resident showed signs of reddening of the skin and was graded at 9 on the Braden Scale. Coccyx pads and a bed pad were assigned. All the rednss had disappeared by the third week. The bed pad was changed once a week in the three-week period at a cost of $7.65 or $1.09 per day with a daily average usage of 2.3 coccyx pads at a cost of 57.3¢ per day. By the sixth week no signs of the pre conditions remained.



6 weeks



This resident had abrasions on the legs from thrashing. Boots were used to protect from contact with wheelchair and bed railings. All the nicks and cuts healed within the 6 weeks with no additional ones.

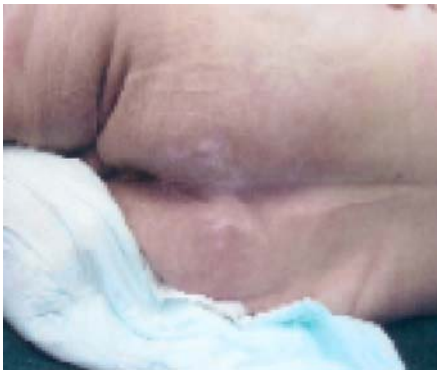
Resident E

This resident was graded 9 on the Braden scale with redness of the skin on the hips and coccyx area. The resident was assigned a bed pad (30x48) and coccyx pads. Within the first

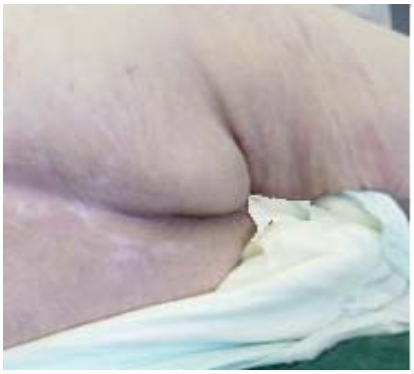
three weeks the redness disappeared and continued to show improvement in skin condition though out the trial. The sheepskin costs were $1.09 per day for the pad and 57.3¢ per day for the coccyx pads.

Resident F

This individual was graded 13 on the Braden Scale. Buttocks had reddened skin surface.A catheter was being used. The palms were also contracted. Palm protectors and a 30x60 bed pad were assigned. The products were changed weekly at a cost of $9.446/week or $1.349 per day for a bed pad and 12.6¢ per day for palm protectors. Previous treatment had been $26/month. In the third week the skin showed a marked improvement. By the sixth week the catheter was discontinued. The resident did not have any discomfort in the hands.



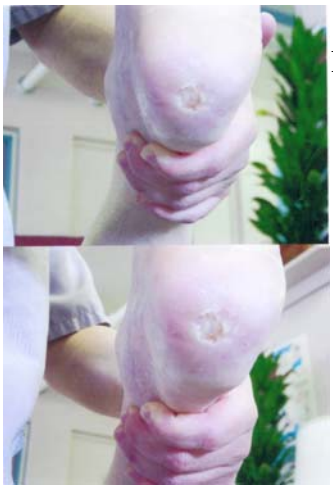
3 weeks



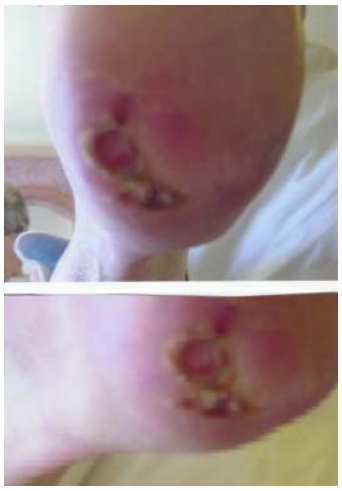
6 weeks

Resident G

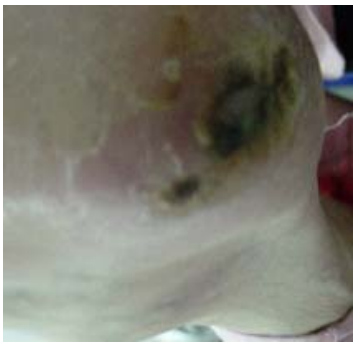
This resident suffered with heel ulcers (Stage 3) that persistently reappeared over a period of two years. Poor blood circulation left the heels white. Overall risk of developing ulcers was assessed at 14 on the Braden Scale. Slippers were assigned and changed weekly. Within a very short time the blood circulation had improved and the skin turned pink. In the third week the healing had started from the center of the ulcer and scab formed on the edges. The resident could walk without pain. The slippers cost $4.378/week or 62.5¢ per day. Previous treatment was $27.20 per month. By the sixth week scab had formed over the area.



Pre-existing

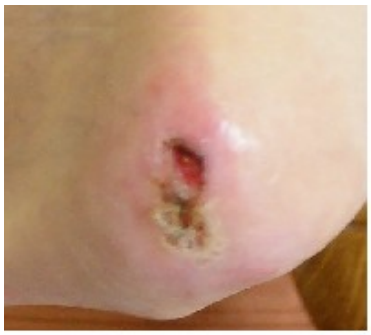


3 weeks



6 weeks

The scab formed over the area. In the 8th week the scab had shrunk noticeably.



9 weeks

Resident H

This resident had an ulcer from long periods of sitting in a wheelchair. The Braden Scale assessment was 11. The wheelchair pad did not fit properly as the chair was a special modification with a curved back. The circumstance were discussed and it was suggested that in the future a customized pad could be patterned by Australian Sheepskin Apparel (ASA) and tracked through the system to meet special need. ASA agreed that this would be a service they could provide. However, a seat pad was used and within 3 weeks all redness had disappeared.

Resident I

This resident was incontinent with reddened skin surface in the coccyx area. The Braden Scale was 15. The redness had disappeared by the third week. The average use was 2.3 pads

per day at a cost of 57.3¢ per day. Previous treatment had cost $20 per month with little sign of improvement.

The Laundry Perspective

Assumptions and Cost Factors

The standard guarantee for the sheepskin product is 50 washes. During the trial period, Australian Sheepskin Apparel representative examined the processed product delivered by the Laundry and increased the guarantee to 75 washes. This reduced the capital recovery projection in determining a per-use-cost. Other laundries are reporting 100 washes and better in use. (see: Appendices C) If these same results are achieved then there will be significant reductions in the cost-per-use. All construction work was guaranteed at 100%.

At no time during the trial was a washer capacity achieved due to the small volume of the trial. Chemical concentration and water levels are important in achieving cost effectiveness. With increased volumes the Laundry could expect a decrease in the cost-per-use.

Labor costs were measured based on the portions of wash, shipping and delivery that are experienced with the processing of personal linens on a per pound base. The average hourly rate is $15.15 with an 18% benefit cost.

To improve turn around time at the Laundry a moisture censing processor would need to installed in the dryers to ensure that product would not be over dried. Utility costs would increase marginally ($.08/pound).

Costing Results

An initial inventory was established at 9 pieces per product per resident according to the assignment. Sixty coccyx pads were included for one incontinent resident. An on-site inventory of 3 pieces per resident and 20 coccyx pads prior to June 1 was delivered. The trial began June 4, 2004. The experience showed that the inventory 9:1 ratio was not required. A more realistic ratio would be 3:1. This will reduce the initial investment required by the Laundry to set up the services. An incontinent resident would require a higher ratio.

Processing and replacement costs per-use were determined:

		Processing Costs			Replacement Costs	
	weight (lbs)	labor	wash	total	75 washes	100 washes
Elbow Pad	0.301	0.203	0.032	0.235	0.513	0.385
Collar 3"	0.333	0.225	0.035	0.260	0.865	0.649
Bed Pad 48"	3.94	2.660	0.413	3.073	4.692	3.519
Bed Pad 60"	4.68	3.159	0.490	3.649	5.797	4.348
Palm Protector	0.01	0.007	0.001	0.008	0.433	0.325
Long Boots	1.75	1.181	0.183	1.364	1.380	1.035
Slippers	1.44	0.972	0.151	1.123	1.066	0.800
Wheelchair Pad	0.875	0.591	0.092	0.683	3.525	2.644
Arm Rest	0.167	0.113	0.017	0.130	0.880	0.660
Calf Cover	0.292	0.197	0.031	0.228	0.817	0.613
Sole Rest	0.208	0.140	0.022	0.162	0.608	0.456
Coccyx Pads	0.075	0.051	0.008	0.059	0.190	0.143

These highlighted results were used to determine the cost-per-use. The cost after 100 washes was also determined and listed below.

Elbow Pad	0.748	0.620
Collar 3"	1.125	0.909
Bed Pad 48"	7.765	6.592
Bed Pad 60"	9.446	7.997
Palm Protector	0.441	0.333
Long Boots	2.744	2.399
Slippers	2.189	1.922
Wheelchair Pad	4.208	3.327
Arm Rest	1.010	0.790
Calf Cover	1.045	0.841
Sole Rest	0.770	0.618
Coccyx Pads	0.249	0.202

The linen tracking system monitored the turn over of product and calculated the weekly usage and cost per day of each product for each resident.

	Average Usage Per Resident	Daily Cost	Daily Cost (100 Washes)
Elbow Pad	1set/week	0.214	0.177
Collar 3"	n/a		

Bed Pad 48"	1/week	1.109	0.942
Bed Pad 60"	1/week	1.349	1.142
Palm Protector	1set/week	0.126	0.095
Long Boots	1set/week	0.784	0.686
Slippers	1set/week	0.625	0.549
Wheelchair Pad	.3/week	0.401	0.317
Arm Rest	.3/week	0.096	0.075
Calf Cover	.3/week	0.100	0.080
Sole Rest	.3/week	0.073	0.059
Coccyx Pads	2.3/day	0.573	0.464

Conclusion

The trial proved that the product is effective both as a preventative measure against pressure ulcers and as a healing device in treating existing conditions. All the residence saw improvements in skin condition and wound treatment. An important factor is that none of the issues reappeared during the eight-week period.

The cost to residence of pre-existing conditions was reported. The cost did not take into account nursing time. This was compared to a monthly cost (multiplied by 30) for the sheepskin products.

Cost Comparison	Pre-trial	Sheepskin
A Elbow Pad	28	6.41
B Bed Pad 60"		40.48
C Bed Pad 48"		33.28
Palm Protector		3.78
D Bed Pad 48"		33.28
Long Boots	26	23.52
E Bed Pad 48”		33.28
Coccyx Pads		17.19
F Bed Pad 60"		40.48
Palm Protector	26	3.78
G Slippers	27	18.76
H Wheelchair Pad		
I Coccyx Pads	20	17.19

Treatment was both effective and cost effective. Cost of other prevention devices (air mattresses, cushions, special pillows, etc) were not considered against the cost of pads.

However given the cost of treating chronic conditions rental is very feasible.

APPENDICES

A	Acknowledgements
B	Australian Medical Journal, 5 April 2004
C	National Launderer – Stericlean Linen Services
D	Letters of Testimonials
E	Australian Standard – 4480.1-1998
F	Wound Assessment & The Braden Scale

APPENDIX A

ACKNOWLEDGEMENTS

A special thank you to the staff and residence
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APPENDIX B

Preventing pressure ulcers with the Australian Medical Sheepskin: an open-label randomised controlled trial

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ABSTRACT

Objective: To estimate the effectiveness of a new high-performance Australian medical sheepskin (meeting Australian Standard 4480.1-1998) in preventing pressure ulcers in a general hospital population at low to moderate risk of these ulcers.

Design: Open-label randomised controlled clinical trial.

Setting: A large metropolitan teaching hospital in Melbourne, Victoria, in 2000.

Participants: 441 patients aged over 18 years admitted between 12 June and 30 November 2000, with expected length of stay over 2 days and assessed as at low to moderate risk of developing pressure ulcers.

Intervention: Patients were randomly allocated to receive a sheepskin mattress overlay for the duration of their hospital stay (218 patients) or usual treatment, as determined by ward staff (referent group, 223 patients).

Main outcome measures: Incidence rate and cumulative incidence of pressure ulcers, assessed daily throughout hospital stay.

Results: 58 patients developed pressure ulcers (sheepskin group, 21; referent group, 37). Cumulative incidence risk was 9.6% in the sheepskin group (95% CI, 6.1%–14.3%) versus 16.6% in the referent group (95% CI, 12.0%–22.1%). Patients in the sheepskin group developed new pressure ulcers at a rate less than half that of referent patients (rate ratio, 0.42; 95% CI, 0.26–0.67).

Conclusions: The Australian Medical Sheepskin is effective in reducing the incidence of pressure ulcers in general hospital inpatients at low to moderate risk of these ulcers.

MJA 2004; 180: 324–327

PRESSURE ULCERS are preventable adverse events that are both common and costly. A national survey in the United States reported a prevalence of 14.8% across 365 acute hospitals.[1] A pressure ulcer of Stage 2 or higher has been calculated to increase patients' costs by a factor of 2.7,[2] while the annual cost of pressure ulcers to the American healthcare system is estimated at $US3.6 billion.[3]

Many types of pressure-relieving support surfaces are available,[4,5] but a Cochrane systematic review found that the only surfaces that consistently outperformed the standard hospital mattress in reducing the incidence of pressure ulcers were high-specification foam mattresses.[4] However, the review also stated that most interventional studies of pressure-relieving support surfaces were seriously underpowered or had other methodological flaws.[4]

In the 1960s and 1970s, sheepskins were reported to help prevent pressure ulcers,[6–10] but recent reviews have found inconclusive evidence to support their use.[4,5,11,12] In 1998, the CSIRO (Commonwealth Scientific and Industrial Research Organisation) introduced a new high-performance medical sheepskin, the Australian Medical Sheepskin. This has a denser and higher wool pile and can withstand multiple washes at 80°C, representing a significant advance in leather technology.[13] A recent randomised controlled trial found that use of this sheepskin reduced the incidence of pressure ulcers by 68% (95% CI, 54%–84%) compared with standard practice in 297 elderly orthopaedic patients.[14]

To extrapolate these findings to a broader hospital population, we conducted an open-label randomised controlled clinical trial of the effectiveness, relative to usual nursing care, of the Australian Medical Sheepskin in reducing the incidence of pressure ulcers in general hospital inpatients.

For editorial comment, see page 316

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METHODS

The trial was conducted at the Royal Melbourne Hospital, a general teaching hospital with about 360 inpatient beds in Melbourne, Victoria. The trial was approved by the Clinical Research and Ethics Committee of the Royal Melbourne Hospital Research Foundation.

Participants

All patients who were admitted to the hospital between 12 June and 30 November 2000 were eligible for the trial if they

1: Classification of pressure ulcers[11]

Stage 1: Persistent non-blanching erythema; epidermis remains intact.

Stage 2: Partial thickness loss of skin layers involving the epidermis and possibly penetrating into, but not through, dermis. The ulcer is superficial and presents clinically as an abrasion, blister or shallow crater. The wound base is moist, pink and free of necrotic tissue.

Stage 3: Full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, the underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

Stage 4: Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures. Undermining and sinus tract may also be present.

were at low to moderate risk of developing a pressure ulcer on the Braden Pressure Ulcer Risk Assessment Scale.[15] This validated scale is based on mobility, activity, sensory perception, nutrition, exposure to moisture, shear and friction.

Patients were excluded from the trial if they:

- were assessed as at "no risk" (requiring no intervention) or "high risk" (requiring more complex interventions);
- had any pre-existing pressure ulcer;
- were less than 18 years of age;
- had an expected length of stay less than 48 hours; or
- had darkly pigmented skin, making a Stage 1 pressure ulcer difficult to detect.

Recruitment and randomisation

Participants were recruited by one of five clinical nurse specialists employed as research nurses. These nurses attended the emergency department two to three times daily during morning and afternoon shifts on weekdays and morning shifts on weekends, and recruited as many patients as possible during these hours. The nurses also assessed patients attending pre-admission clinics for targeting on admission.

All patients were assessed for risk of pressure ulcers within 24 hours of admission using the Braden scale.[15] Formal informed consent was obtained from patients for participation in the trial.

Immediately after risk assessment, patients were randomly allocated to receive either the sheepskin or standard treatment, using numbered cards in individually sealed opaque envelopes; blocks of 16 envelopes (eight of each group) were shuffled before use.

Intervention

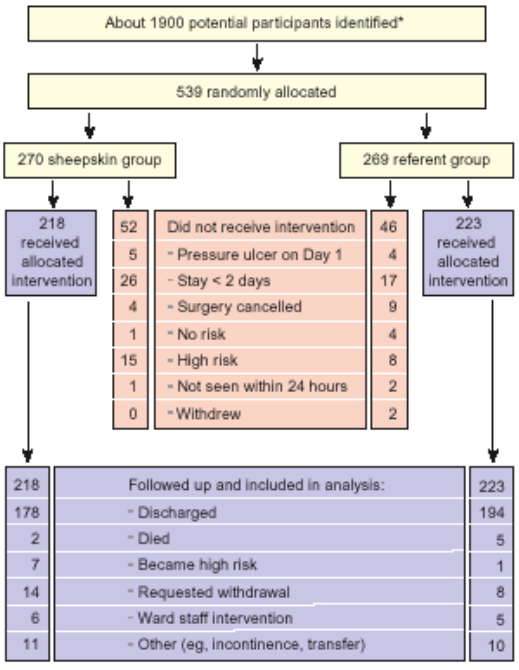
The Australian Medical Sheepskin is a leather-backed sheepskin with a dense, uniform, 25 mm natural wool pile. The sheepskin is used without covering as a partial mattress overlay and is specifically designed to reduce pressure, minimise shear and friction and absorb moisture.[13] It meets Australian Standard AS4480.1-1998.[16]

A sheepskin overlay was fitted to the patient's bed immediately after allocation to the sheepskin group, and a sheepskin remained in place until the patient was discharged. Sheepskins were changed on Mondays, Wednesdays and Fridays or when soiled, and were laundered to the specifications of Australian Standard AS4480.1-1998 to achieve thermal disinfection.[16] Pressure points not covered by the sheepskin were protected with a second sheepskin or specific sheepskin elbow and heel protectors. Patients in the sheepskin group received usual nursing care, including repositioning, as determined by ward staff.

The referent group used any other pressure-relieving device or prevention strategy deemed appropriate by ward nursing staff, comprising standard hospital mattress and sheet, with or without other low-technology constant-pressure-relieving devices and repositioning as determined by nursing staff.

As it was logistically impossible to blind patients, ward staff and research nurses to the treatment group, this was an open-label, unblinded trial.

2: Flow of participants



* About 1300 potential participants either were not approached or did not meet inclusion criteria.

Assessment

Research nurses assessed each participant daily for pressure-ulcer risk as described previously, and for skin integrity. Any patient whose risk increased to "high" (Braden score < 12) for 48 hours was no longer followed up for pressure-ulcer endpoints for this trial.

Patients were assessed for new ulcers using a standardised protocol and the operational definitions of the US Agency for Health Care Policy and Research (Box 1).[12] A Stage 1 ulcer was diagnosed if non-blanching erythema (using finger-point pressure) was still present after 30 minutes of pressure relief to the affected area.[14] Suspected ulcers were assessed by a second research nurse. Research nurses notified ward staff if a pressure ulcer was observed.

Interobserver reliability was measured using blinded observation on 45 patients in pairs with four clinical nurses. For total Braden score, the intraclass correlation estimate was *r*, 0.89

3: Baseline characteristics of 441 patients at entry

	Sheepskin (n=218)	Referent (n=223)
Mean age (range)	63.2 (18–97)	61.1 (18–99)
Sex (% female)	49%	52%
Emergency admission	51%	43%
Medical specialty		
General surgery	12%	13%
Orthopaedics	19%	17%
Neurosurgery	21%	24%
General medical	22%	17%
Other surgical*	13%	19%
Other medical†	13%	10%
Mean score for pressure-ulcer risk (range)‡	15.7 (13–18)	15.9 (13–18)

* Including plastic, cardiothoracic, vascular, renal and urological surgery.
† Including oncology, endocrinology, rheumatology, cardiology and gastroenterology.
‡ Braden score for pressure-ulcer risk: high risk (< 12); moderate risk (13–14); low risk (15–18).[15]

(95% CI, 0.82–0.96). During the trial, agreement between paired observers recording erythema or Stage 1 ulcers was 94% (32/34 pairs) with weighted $\kappa = 0.90$.

Statistical analysis

We calculated pressure-ulcer incidence rates in each group as the ratio of the number of new pressure ulcers to the number of bed-days observed. Confidence intervals were inferred around each point estimate using Poisson probability distribution.[17] The efficacy of the sheepskin relative to usual care was assessed by the ratio of incidence rates.

Kaplan–Meier survival functions were used to describe time in days to development of first ulcer, and relative ulcer-free survival was estimated using Cox regression methods.[17] Patients were censored on discharge or progression to high risk status.

A previous Australian survey in a general hospital population reported an ulcer incidence rate of 50 per 2500 patient-days, or 2% per day.[18] We postulated that a twofold reduction in pressure ulcer incidence was feasible and cost-effective. For a test at a significance level of 5% to distinguish between expected incidence rates of 2% per day and 1% per day with 80% power, at least 70 new pressure ulcers (across both groups) are required.[19] No interim analysis was planned or performed. After 3289 bed-days of observation, we had recorded 85 new pressure ulcers and ceased recruiting.

RESULTS

The flow of participants through each stage of the trial is shown in Box 2; 539 of 1900 potential participants were randomly allocated. Of these, 441 received the allocated intervention. All 441 were followed up to the endpoints of discharge, death, withdrawal based on clinical decision by ward staff, change in pressure-ulcer risk status to high risk, or patient request.

Baseline demographic and clinical characteristics of the 441 patients are shown in Box 3. The sheepskin and referent groups differed substantially only by admission type, as there were more emergency admissions in the sheepskin group.

Outcomes

Primary outcome measures are shown in Box 4. The crude incidence rate of pressure ulcers in the sheepskin group was 0.42 times that in the referent group (95% CI, 0.26–0.67), implying a reduction in pressure-ulcer risk of more than 50%. A consistent, but not statistically significant, result was obtained by restricting analysis to Stage 2 ulcers, for which the crude incidence rate ratio was 0.54 (95% CI, 0.24–1.16). No Stage 3 or 4 ulcers were seen in either group.

Results showed that the sheepskin may prevent, on average, one new Stage 1 or 2 ulcer every 46 bed-days of use (attributable risk, 3.7 – 1.6 = 2.15 per 100 bed-days; therefore, number of bed-days needed to treat to prevent one ulcer = 100/2.15 = 46.4). The difference in cumulative incidence risk between the sheepskin and referent groups was 6.9%, giving an estimated average number of patients needed to treat of 14.4 to prevent the development of pressure ulcers in one patient.

Kaplan–Meier survival curves for time to onset of first ulcer (Box 5) show separation between the sheepskin and referent groups ($P < 0.001$, log-rank test). A hazard ratio of 0.39 (95% CI, 0.22–0.69), estimated using Cox proportional hazards regression, confirmed the magnitude and direction of the rate ratio of crude incidence rates. After 20 days, few patients remained in either group, invalidating further comparison.

Seven patients died during follow-up (2 sheepskin, 5 referent), and a further eight progressed to "high risk" for pressure ulcers for more than 48 hours while under observation (7 sheepskin, 1 referent). After review, none of these events was considered attributable to the intervention. Ten patients in the sheepskin group complained about its comfort ("too hot", 6; sensitive to the wool surface, 2; "uncomfortable", 2) and requested its removal.

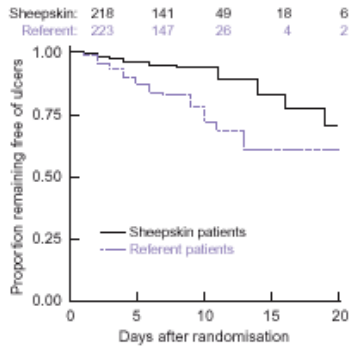
DISCUSSION

We found that use of the Australian Medical Sheepskin as a mattress overlay reduced the incidence of Stage 1 or 2

4: Outcomes in 441 patients randomly allocated to sheepskin or standard (referent) treatment

Outcome	Sheepskin (n=218)	Referent (n=223)
Total bed-days observed	1728	1561
Mean bed-days observed/participant	7.9	7.0
Number of participants with ulcer(s)	21	37
Total number of ulcers	27	58
Cumulative incidence risk (%) (95% CI)	9.6% (6.1%–14.3%)	16.6% (12.0%–22.1%)
Risk ratio (95% CI)	0.58 (0.35–0.96)	1.0
Incidence rate per 100 bed-days (95% CI)	1.6 (1.0–2.3)	3.7 (2.8–4.8)
Incidence rate ratio (95% CI)	0.42 (0.26–0.67)	1.0
Number of Stage 2 ulcers (% of all ulcers)	12 (44%)	20 (34%)
Odds ratio of Stage 2 v Stage 1 ulcer (95% CI)	1.52 (0.54–4.3)	1.0

5: Kaplan–Meier survival curves for time to onset of first ulcer



pressure ulcers by 58% (1.6, compared with 3.7 pressure ulcers per 100 bed-days) compared to standard nursing care in general hospital inpatients at low to moderate risk of developing a pressure ulcer. However, comparing incidence rates alone is not sufficient to establish effectiveness of the sheepskin, as some patients developed multiple ulcers. For individual patients, the risk of developing a pressure ulcer in the sheepskin group was 40% less than the risk in the referent group (9.6%, compared with 16.6%).

As this study was an open-label, unblinded trial, it had potential biases. Most prominent is observer bias in diagnosing pressure ulcers, particularly Stage 1 ulcers, which are notoriously difficult to diagnose. However, the research nurses followed a strict protocol in diagnosing these ulcers, and their actions were recorded on the data collection charts and checked. Furthermore, an analysis of Stage 2 ulcers alone also found a reduction of 46% in their incidence in the sheepskin group relative to the referent group.

There was also potential for observer bias in assessing patient risk. Indeed, the number of patients who were assessed as high risk immediately after randomisation and failed to receive the allocated intervention was greater in the sheepskin group than in the referent group (15 versus 8). However, risk was assessed with an objective reliable instrument,[15] so that bias was unlikely. Although more patients in the sheepskin group were excluded during the trial after they became "high risk" (7 versus 1 in the referent group), all ulcers observed up to the time of exclusion were included in the analysis (3 in the sheepskin and 1 in the referent group). On balance, the total number of exclusions was small and unlikely to have influenced incidence rate ratios.

As well as observer bias, nursing care may have differed between the two groups, with patients in the sheepskin group receiving either additional care (because of a perception that they were "at risk") or, alternatively, less pressure-relief care (because they already had a therapeutic device *in situ*). Either possibility is difficult to confirm or disprove. The length of the study (25 weeks) and number of clinical units involved (14) might be expected to minimise any differences in nursing care between the two groups.

The results of this study extend the previous findings in an elderly orthopaedic population[14] to the general adult hospital population. The Royal Melbourne Hospital is a general adult teaching hospital that serves a broad population. We believe our sample is representative of the general adult population found in most tertiary hospitals,[20] and that our results can be generalised to most similar hospitals across Australia.

The results suggest that an Australian Medical Sheepskin pressure-relieving support surface may prevent one new Stage 1 or 2 ulcer every 46 bed-days of use in general hospital patients at low to moderate risk. The estimated number of patients needed to treat to prevent ulcers in one patient was 14.4, similar to the number found in orthopaedic patients.[14]

Our results apply when the sheepskin is used for prophylaxis from the time of admission. We did not investigate the efficacy of the sheepskin in the presence of pre-existing pressure ulcers. Although the sheepskin may initially add to the cost of patient care, it has the potential to reduce the incidence of pressure ulcers in general hospital patients.

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Funding for this study was provided by a project grant from the National Health and Medical Research Council of Australia, and by the CSIRO Textile and Fibre Technology, Leather Research Centre.

COMPETING INTERESTS

KCM and MBH are employees of CSIRO Textile and Fibre Technology, Leather Research Centre, which coordinated the development of the Australian Standard 4480.1-1998 for the Australian Medical Sheepskin.

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APPENDIX C

Shirley Naylor, Editor

NATIONAL LAUNDERER

LAUNDERING of the new *Australian Medical Sheepskins*

Part 1: Case Study ~ Stericlean Linen Services

Mark Hickey and Ken Montgomery, CSIRO Textile and Fibre Technology, Leather Research Centre

The Australian Medical Sheepskin is a new high performance health-care product that has been clinically proven to prevent pressure ulcers (bed sores). It is fully specified by a new Australian Standard (AS4480.1-1998). This robust product is vastly superior to previous sheepskin products utilised in the hospital system, as it is now more durable to washing and drying, and is capable of withstanding high level thermal disinfection at 80°C. It is an Australian manufactured product made from the unique Australian merino-cross woolskins.

A comprehensive six-month clinical trial has recently been conducted at The Royal Melbourne Hospital (RMH), further evaluating the efficacy of the sheepskins in the prevention of hospital acquired pressure ulcers. Stericlean Linen Services were contracted to the hospital and provided the commercial laundering of the new sheepskin products as specified in the Australian Standard.

The high level of co-operation and commitment extended by Guy Reeves and his professional team at Stericlean enabled the six-month long study to run without incident. Stericlean were able to facilitate the additional new sheepskin stream, which required separate washing from normal hospital linen. On completion of the trial, Stericlean will continue to launder the medical sheepskins and sheepskin components as part of their ongoing contract with The Royal Melbourne Hospital.

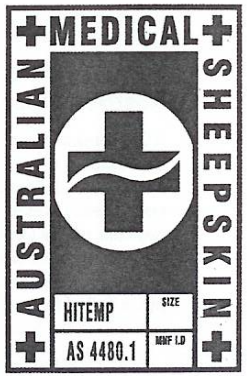


Figure 1: Australian Medical Sheepskin Stamp stating compliance to AS4480.1 and identification of the manufacturer.

Overcoming Pre-Existing Perceptions

Many laundries have had experience with earlier sheepskin products and are aware of the potential problems with laundering – most notably due to shrinkage and associated hardening of the leather. Sheepskins have been used in the hospital system since the early 1960's and unfortunately, due to the influx of some poor quality products into the market, commercial laundries are apprehensive about the durability of these products to extended laundering.

The Australian Medical Sheepskin

The new product, marketed as the **Australian Medical Sheepskin**, was a result of several years of research and development at CSIRO's Leather Research Centre in collaboration with the tanning industry, supported by extensive testing in hospitals and laundries. The new product is superior to previous sheepskin products, and trials conducted by CSIRO have demonstrated that the Hitemp **Australian Medical Sheepskin** could withstand more than 100 wash and dry cycles while still retaining its softness and pressure relieving properties.

Product fully specified by a new Australian Standard

All sheepskin products claiming compliance to the Standard must have the **Australian Medical Sheepskin** label (Figure 1 on previous page) permanently bonded to the leather backing. The presence of this label indicates that samples of the product have undergone independent testing in an authorised testing laboratory and has passed all of the product specifications as outlined in the Standard.

There are two product types specified in the Australian Standard:

Hitemp Medical Sheepskin:

- Wool colour green.
- Capable of withstanding thermal disinfection at 80°C
- Designed for hospital use

Regtemp Medical sheepskin:

- Wool colour blue.
- Capable of withstanding washing at 60°C
- Suited for home and nursing home use where risk of cross-infection is low

Both products are capable of withstanding tumble drying.

* For effective washing and chemical disinfection, use a suitable non-ionic liquid detergent containing a bacteriostat.

** The drying time of 120min at 60°C is based upon extensive laboratory trials. However, higher temperatures over a shorter time period have been used successfully in commercial laundries fitted with humidity controlled heating. Any variation from the recommended drying temperatures should be tested to ensure there is no deterioration of the sheepskins.

Acetic acid was added to steps 1, 5 & 9 to aid dye fastness properties (pH controlled to 3.8 - 4.2). This modification will be proposed at the next review of AS4480.1.

Clinically Proven Health-Care Product

The results from the clinical trial at RMH, with a broad patient population, are currently being analysed (funded by the National Health and Medical Research Council). This follows a highly successful study in Western Australia's Fremantle and Hollywood hospitals that proved unequivocally that medical sheepskins are a valuable healthcare product for the prevention of hospital acquired pressure ulcers in elderly orthopaedic patients. Both trials were run by a multidisciplinary team of investigators comprising of physicians and nurses specialising in wound-care management, epidemiologists and scientists.

It is anticipated that as the results from both of the recent clinical trials become available to the healthcare network, the demand for the **Australian Medical Sheepskin** will increase. As hospitals begin to increase the usage of medical sheepskins, it will be important for the laundries to introduce the Standard washing procedure to ensure prolonged durability of the product.

Case-Study: Stericlean Linen Service

Stericlean successfully integrated the separate sheepskin stream into their normal laundry production.

To minimise the risk of sheepskins being laundered with the normal hospital linen, a

Figure 2: Hitemp Laundering Procedure

Washing instructions for Hitemp Medical Sheepskins to meet thermal disinfection requirements. The washing machine should be loaded to half capacity.

	Operation	Water Level	Temperature °C	Time, min	Washing Agent
1	Wash	High	Cold	3	Detergent* 3.5-4.5 mL/kg of sheepskin
2	Drain	–	–	1	
3	Rinse	High	40	2	
4	Drain	–	–	1	
5	Wash	High	60	4	Detergent* 3.5-4.5 mL/kg of sheepskin
6	Drain	–	–	1	
7	Rinse	High	60	2	
8	Drain	–	–	1	
9	Thermal	High	80	8	
10	Drain	–	–	1	
11	Rinse	High	Cold	2	
12	Drain	–	–	1	
13	Extract			9	
14	Dry**	–	60 max.	120	

system was put in place that allowed the sheepskins to be segregated at the ward level in the soiled linen room prior to dispensing down the laundry chutes. The use of a distinctive coloured (orange) linen bag for soiled sheepskins and the unique green colour of Hitemp sheepskins minimised the sorting time at the laundry and greatly reduced the risk of the sheepskins following the regular linen stream.

To ensure that the supply of medical sheepskins and components were maintained at ward levels, it was necessary to have a streamlined process for dispatching soiled skins and the replenishment of freshly laundered skins in a tight time frame (*Figure 3, page 32*). The Stericlean linen room at RMH co-ordinated the delivery of freshly laundered medical sheepskins to the research team for use in the clinical study.

Advice for Laundering of Australian Medical sheepskins

Sheepskins consist of the natural wool attached to the tanned leather backing. The sheepskin must be carefully laundered to ensure that the leather is not damaged. There is a temperature at which leather will shrink irreversibly and this temperature must never be exceeded. Some laundry chemicals destabilise the leather structure and should not be used.

There have been no instances of the Hitemp medical sheepskin failing due to shrinkage when the correct laundering procedure has been followed.

The two greatest risks to the medical sheepskin during laundering are:

× **exposure to excessively high temperatures**

Hitemp Sheepskins: water temperature must never exceed 80°C.

Regtemp Sheepskins: water temperature must never exceed 60°C

× **laundering with incorrect chemicals**

Laundering chemicals that are known to be detrimental to the leather and must not be used:

- Enzymes
- Phosphates
- Peroxide
- Alkali
- Bleach
- Triethanolamine
- Sequestering Agents
- Phosphoric acid

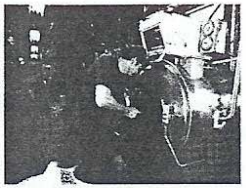
Further recommendations for successful laundering:

✔ Soiled (urine) sheepskins are ideally rinsed in cold water as soon as possible

✔ Separate sheepskins from regular linen at hospital ward level by using distinctive linen bags

✔ Track wash numbers per sheepskin and invoicing with the use of a transponder system (refer Part 2: Use of Identipak Transponder System in the April 2001 issue of the 'National".)

Figure 3: Stericlean Sheepskin Flow Path



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- Guy Reeves and staff at Stericlean Linen Services for the outstanding co-operation throughout the clinical study at RMH
- Ray Mair (Identipak) for his assistance with the Datamars transponder system for monitoring the number of washes for each medical sheepskin and component
- Hugh Grimm and Ecolab for their technical support
- Project staff at RMH and Jacinta Wassenberg (CSIRO)

Thanks to **Mayall Australia** and **Fleececraft Industries** for the supply of Australian Medical Sheepskins and heel and elbow components.

Further Information

Further information about **Australian Medical Sheepskins** and details of the clinical trials can be obtained from:

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CSIRO Textile and Fibre Technology
Leather Research Centre
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Clayton, VIC 3169
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http://www.tft.csiro.au/leather/amedskins.html

APPENDIX D

Nicky Samuel, RN
Home Care
Phone: (403) 820-6005
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Cell: (403) 820-4207

Hi Steve

Sorry it took so long to get this to you. I needed to get permission from the clients and my boss to email the pictures, the next thing I knew it was Christmas etc.

The first set of photos of the ankle were taken in May, 2003. Physio had already been working with her since February, 2003. I took over in September 2003 and the first time I used the sheepskin was November 20, 2003. To say the least I am very impressed with your product as are my clients. The ankle ulcer was approximately 1 cm deep when I first took over, and since the use of the sheepskin, it has completely filled in.

I hope the explanation for the ankle was okay. I saw that client this afternoon, January 12, 2003, and took another picture. Her ankle has scabbed over and I feel that the scab will just slough off as the open area had completely filled in. Her daughter is so pleased she is having her wear the sheepskin protector 24 hours a day. See Photos 1 – 5.

As for the stump protector, the fellow isn't willing at this time to purchase and we are doing everything we can to convince him this would improve his quality of life. I will get in touch if he changes his mind.

The buttocks are of a fellow who started to have skin breakdown because he mainly sits all day. We had him on a roho cushion which really did nothing. The week after I met you at the conference I saw him and he had started to break down. You can see about a 1-cm area that is open. One week later, he was healed with only the sheepskin patch applied to the wound. We were thrilled! He has not broken down since (see photos 6 – 7). His family think I am a miracle worker, but I had to give your product the credit. Thanks again.

Thanks. Please keep in touch

Nicky Samuels, RN
Drumheller Health Centre

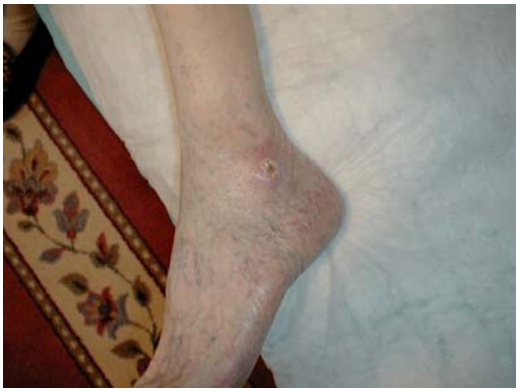

Photo 1

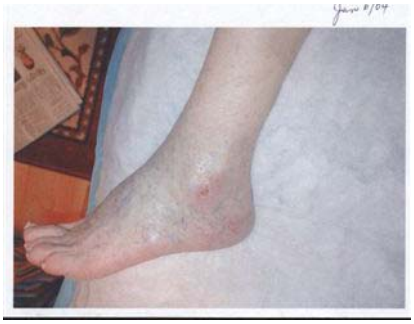

Photo 5

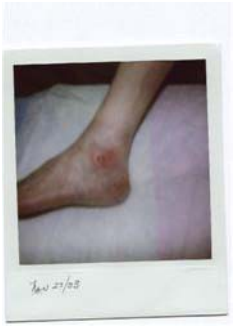

Photo 2

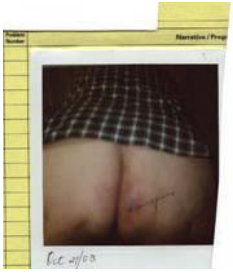

Photo 6

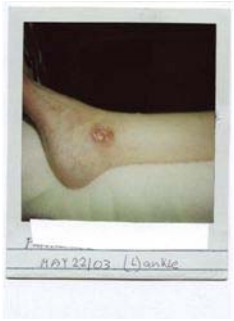

Photo 3

Photo 7

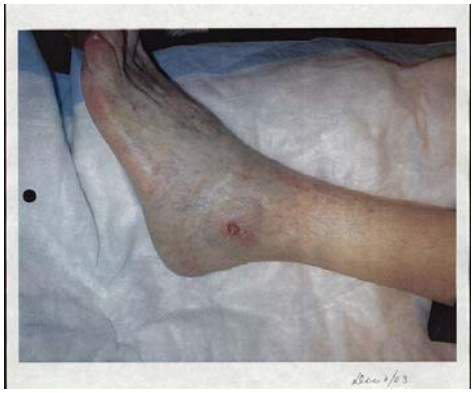

Photo 4

October 9, 2003

Congdon's Aids to Daily Living
Att: Rick Jackson
15830 – 100 A. Ave.
Edmonton, AB. T5P-0L8

Dear Rick,

Thank you for giving me the opportunity to trial the Australian Sheepskin. I am happy to inform you that I believe it was helpful in the expediency toward the healing of a Stage 2 coccyx pressure ulcer.

The trial was done on a thirty-two year old patient with Multiple Sclerosis that was bed and wheelchair bound. The trial commenced September 5, 2003, using the Australian Sheepskin on the bed at all times while the patient was in bed, and lining the wheelchair seat while the patient was sitting in the chair. The Stage 2 coccyx pressure ulcer presented as a crack in the skin involving the dermis measuring 3 cm. x 0.5 cm. The pressure ulcer was dressed with an alginate over the ulcer and covered with a hydrocolloid. By September 9 2003 the ulcer measured 2 cm. x 0.2 cm. At that time, the only change in wound care was deleting the calcium alginate and covering the ulcer with a hydrocolloid. On September 15, 2003, the ulcer had completely healed.

Again, many thanks for the opportunity to trial the Australian Sheepskin.

Sincerely,

Shelley Sluser
Wound/ Ostomy Nurse
Sturgeon Community Hospital

SASKATOON DISTRICT HEALTH
ROYAL UNIVERSITY HOSPITAL
SURGERY 5000/ BURN UNIT

September 17, 1998

Australian Sheepskin
221 Nahanni Drive
Saskatoon, Saskatchewan
S7K 3Z7

Dear Mr. Playford,

I would like to express my appreciation for the opportunity to trial the Australian Medical Sheepskin in recent months. It was used on several of our patients who had lengthy hospitalization stays and who were immobilized with nutritional deficits. These patients were indeed high risk candidates for skin breakdown.

As we all know, hospital beds are not the most comfortable surfaces. The sheepskin proved to be most effective in terms of patient comfort as evidenced by verbal feedback and the clients ' reluctance to give up the sheepskin.

The second benefit of notice was the thick sheepskins' ability to absorb moisture from the patient to keep them cleaner and drier. The thickness and softness of the sheepskin would appear to reduce the pressure between the patient's skin and the surface of the bed. These properties certainly help to minimize skin breakdown.

Another nice feature of the product was its ability to maintain softness , thickness, and shape after many laundering processes.

After trailing this product, we have decided to purchase several more sheepskins so that more of our acutely ill patients will benefit from the usage. I would recommend the Australian Medical Sheepskin for purchase by any long term or acute care facility.

Sincerely,

Lilah Weinberger
MON, Surgery 5000

SASKATOON DISTRICT HEALTH

ALVIN BUCKWOLD CHILD DEVELOPMENT PROGRAM

Kinsmen Children's Centre
1319 Colony Street
Saskatoon, Saskatchewan Canada S7N 2Z1
TEL 306-655-1070 FAX 306-655-1449

UNIVERSITY OF SASKATCHEWAN
DEPARTMENT OF PEDIATRICS
COLLEGE OF MEDICINE

PARTNERS WITH

Alvin Buckwold Early Childhood Intervention Program

Bruns-al School/ KCC

Prairie Hills Early Childhood Intervention Program

Saskatchewan Institute on Prevention of Handicaps

Communities

Families

December 1, 1997

Australian Medical Sheepskin
221 Nahanni Drive
Saskatoon, Sask.
S7K 3Z7

Dear Mr. Playford,

I would like to thank you for the sheepskin that you so kindly donated to the Multi-Handicapped Team. The sheepskin has been used by a seventeen year old male who has a diagnosis of cerebral palsy. This particular young man is a spastic quadriplegic and is very immobile. He also has a great many feeding challenges due to his condition and is quite under weight. This lack of body fat has led to concerns with his skin because of bony prominences.

The family decided to use the sheepskin on a 30 day trial basis. At our first appointment, the client had a total of five pressure ulcers located on his scapula, coccyx and hip. Four of the five pressure ulcers rated at stage II according to the Braden Assessment Scale. It was evident that the other ulcer was forming from a shearing action due to a brace. This last area was well on it's way to becoming a Stage II ulcer as well. The family had been trying to control the skin's condition with hydrocolloid products which were costing as least $25.00 per week.

After thirty days of sheepskin use, four of the five ulcers had healed. The physical therapist involved decided to cut the brace back rather than use a small piece of sheepskin I am confident that using a small piece of sheepskin to relieve the pressure would have been more cost effective, made less travelling for the family, and decreased the amount of stress on the individual

The parents have commented on the fact that their son seems to sleep better, is definitely more comfortable and is much happier since the introduction of the sheepskin. The benefits have been enormous to this person. I also believe that we have saved the taxpayers money. In the long run , a lot of funds would have been spent on hydrocolloid products. Due to the successful use of the sheepskin, this family requires reduced hours of professional time

SASKATOON DISTRICT HEALTH

ALVIN BUCKWOLD CHILD DEVELOPMENT PROGRAM

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Bruno Bilodeau School, KCC

Prairie Hills Early Childhood Intervention Program

Saskatchewan Institute on Prevention of Handicaps

Communities

Families

In closing, we appreciate your efforts and have had an extremely positive experience with your product. It would be beneficial, I believe, to have the Australian Medical Sheepskin available to those who are at great risk for skin breakdown.

Yours sincerely,

Janine L. Koroluk

Janine Koroluk, R.N.
Nurse Clinician

TISDALE HOSPITAL

Box 1630
Tisdale, Saskatchewan S0E 1T0
Phone: 873-2621 Fax: 873-5994

A Division of PASQUIA HEALTH DISTRICT

April 24, 1998

To: Playzad Import-Export Ltd
Steve Playford, Joanne Zadorozny
2212 Nahanni Dr. Saskatoon, Sask. S7K 3Z7
Phone: 934-7119 Fax: 934-1597

From: Nancy Carter
Community Health Manager, Tisdale

Re: Evaluation of Sheepskin blanket

Our staff at the long term care facility in Tisdale has used the sheepskin provided by your company for one resident over a number of weeks. As compared to previously used products, this sheepskin has remained softer, with no pilling or hardening so it is expected that the life expectancy would be longer than previous products.

The resident did display an improvement to a pre-existing hip wound but of course it is difficult to attribute this to any one cause. The sheepskin is being re-assigned to another resident who is experiencing skin breakdown to further evaluate the product.

The Tisdale Hospital has received one of your sheepskins through a donation to the facility based on the recommendation of the hospital Director of Nursing who liaisons with the long term care facility Director of Care.

Thank you very much for the opportunity to test this product.

APPENDIX E

Australian Standard™

Textiles for health care facilities and institutions—Medical sheepskins

Part 1: Product specification and testing

STANDARDS AUSTRALIA

This Australian Standard was prepared by Committee TX/15, Textiles for Health Care Facilities and Institutions. It was approved on behalf of the Council of Standards Australia on 27 February 1998 and published on 5 May 1998.

The following interests are represented on Committee TX/15:

Australian Chamber of Commerce and Industry

Australian Linen Services Executive

Australian Wool Research and Promotion Organisation

Australian Wool Testing Authority

Council of Textile and Fashion Industries of Australia

Federation of Sterilising Research and Advisory Councils of Australia

Hospital Laundry Managers Association of Australia

N.S.W. Health Department

Textile Distributors Association

Textile Rental Laundry Association

Victorian Institutional Laundries Association

This Standard was issued in draft form for comment as DR 97015.

Australian Standard™

Textiles for health care facilities and institutions—Medical sheepskins

Part 1: Product specification and testing

First published as AS 4480.1—1998.

Published by Standards Australia
(Standards Association of Australia)
1 The Crescent, Homebush, NSW 2140

ISBN 0 7337 1913 9

PREFACE

This Standard was prepared by the Standards Australia Committee TX/15, Textiles for Health Care Facilities and Institutions.

The objective of this Standard is to provide manufacturers and suppliers of medical sheepskins with a set of requirements for product specification and testing.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix to which they apply. A 'normative' appendix is an integral part of a Standard, whereas an 'informative' appendix is only for information and guidance.

CONTENTS

STANDARDS AUSTRALIA

Australian Standard

Textiles for health care facilities and institutions—Medical sheepskins

Part 1: Product specification and testing

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE This Standard specifies requirements for woolskins (tanned sheepskins and lambskins) for health care, medical and institutional uses. These are used to minimize the incidence, severity and duration of pressure ulcers by decreasing friction, pressure and humidity at the points of contact between a patient and the support surface (e.g. bed or chair).

1.2 REFERENCED DOCUMENTS The following documents are referred to in this Standard:

AS	
4146	Laundry practice
IWS	
TM 5	Method of test for determining colourfastness to light
TM 165	Method for assessing colourfastness to rubbing of textile materials and dyed sheepskins
TM 174	Method for assessing the colourfastness of textile materials in a damp alkaline environment
TM 175	Colourfastness in an acidic environment
TM 250	Colourfastness to hand washing
SLP	
2 (1965)	Sampling
18 (1965)	Shrinkage temperature measurement

1.3 DEFINITIONS For the purposes of this Standard, the following definitions apply.

1.3.1 Crimp—the waves, folds and corrugations of wool fibres within a wool staple.

1.3.2 Fatliquors—emulsified oils applied to leather to soften the leather's fibrous structure and prevent the fibres sticking together on drying after washing.

1.3.3 Flesh—the muscle tissue and fat adhering to the inner layer of a freshly flayed skin which can be removed by a fleshing machine.

1.3.4 Hitemp medical skins—tanned skins which can be washed and disinfected in an industrial washing machine at temperatures not exceeding 80°C and dried at temperatures not exceeding 60°C.

NOTE: Restrictions on additives to the wash formulae. (See Table A9.4).

1.3.5 Initial wool finishing stage—the processing stage after dry cleaning and prior to the final wet processing which is the stage in the process where the wool is combed, ironed and clipped to the final finished length (see Clause 2.7).

1.3.6 Kemp—coarse and medullated wool fibres, often found in the britch areas of sheep and lambs.

1.3.7 Leather—skin with its original fibre structure more or less intact, tanned so as to be imputrescible.

1.3.8 Medical sheepskin—lambskin or sheepskin tanned and shorn to a uniform wool pile height for use as a bed or chair underlay to distribute and relieve pressure so as to prevent the onset of pressure ulcers (decubitus ulcers or bed sores).

1.3.9 Pilling Small balls/tufts of wool which form on woolskins above the main wool pile due to mechanical action and washing of the wool pile—the tufts may be attached to the wool tips.

1.3.10 Regtemp medical skins—tanned sheepskins which can be washed and disinfected in an industrial washing machine at temperatures not exceeding 60°C and dried at temperatures not exceeding 60°C.

NOTE: Restrictions on additives to wash formula (Table A9.3).

1.3.11 Seed scar—healed damaged skin tissue formed after a grass seed has penetrated the skin.

1.3.12 Tanning—the processing of perishable raw hides and skins by the use of tanning materials into the permanent and imputrescible form of leather.

NOTE: A rationale is provided in Appendix A to clarify terms and procedures which have special significance when used in the processing of sheepskins.

1.3.13 Urine resistant (UR)—a type of medical sheepskin which has had additional treatment to enhance the resistance to urine provided by other tanning agents.

1.3.14 Wool pile height—the vertical distance between the leather grain surface and the shorn wool tips, measured at right angles to the leather grain.

1.4 DESIGNATION OF SHEEPSKINS Each skin's designation is comprised of components as indicated in Tables 1.4(A) and (B).

TABLE 1.4(A)

TYPE DESIGNATION OF MEDICAL SHEEPSKIN

Type	Regtemp	Hitemp
Standard	R1	H1
Urine resistant	R2	H2

TABLE 1.4(B)

SIZE DESIGNATION OF MEDICAL SHEEPSKIN

Code	Minimum length cm	Minimum width cm	Area dm^2	
			Minimum	Maximum
S (small)	83	56	46	54
M (medium)	87	60	55	63
L (large)	92	63	64	72
XL (extra large)	100	70	73	80 +

1.5 TEST SAMPLES

1.5.1 Selection

1.5.1.1 *Samples for shrinkage temperature test* When testing for compliance with this Standard, a neck cutting from three separate skins shall be supplied and marked and identified (as in Appendix B) for determination of the mean shrinkage temperature value (T_s). The testing authority will take two samples from each cutting of approximately 28 × 4 mm, one parallel and perpendicular to the backbone line of the sample skin.

1.5.1.2 *Samples for colourfastness* Samples shall be taken within mirror image positions on either side of the backbone line of the test skin, as shown in Appendix B, and tested as per Table 2.12. The sample size shall be as required by the test.

1.5.2 Identification The samples shall be marked on the flesh side of the skin with a label durable to water, which includes the information required by Appendix C.

1.5.3 Accompanying information The following information shall accompany each test sample:

(a) Supplier's name and identification code, and manufacturer's identifier.

(b) Size code in accordance with Table 1.4(B).

(c) Wool-pile height (refer to Clause 2.7).

(d) Designation code as per Table 1.4(A).

1.6 MANUFACTURER'S LABELLING The following information shall be shown on the flesh side of each skin on a label which complies with one of the examples given in Figure C1. The label shall be permanent and durable to liquids. The label shall remain legible for the life of the product. The following information shall appear on the label:

(a) Manufacturer's identification code.

(b) Skin size in accordance with Table 1.4(B).

(c) Whether the product has been specially treated for increased urine resistance (by marking it 'UR').

(d) The skin designation as per Table 1.4(A).

(e) Reference to this Australian Standard, i.e. AS 4480.1 if compliance is being claimed.

NOTE: Manufacturers making a statement of compliance with this Australian Standard on a product, packaging or promotional material related to that product are advised to ensure that such a compliance is capable of being verified.

1.7 SUPPLIER'S LABEL The supplier's lable shall comply to Appendix C.

SECTION 2 MANUFACTURING REQUIREMENTS

2.1 GENERAL The product shall be a tanned sheepskin or lambskin, well trimmed with the pre-washed finish (see Paragraph A1).

2.2 WOOL The wool pile shall be homogeneous and of uniform length, and density with a well-defined staple and crimp, straight to light curl in appearance, free from pilling and from kemp fibre and vegetable matter, with belly wool density similar to the fleece. The wool shall not be felted.

2.3 LEATHER The leather shall be free from excessive natural fat and grease, clean-fleshed (but not necessarily buffed to remove all flesh) and free of faults such as large holes and cuts (no more than two holes per skin and hole diameter no greater than 5 mm). Seed scar is permissible but seed is not. The leather shall be symmetrical with respect to the backbone line of the skin. There shall be no separation of grain and corium (double hiding).

The leather may be further processed to give increased urine resistance and labelled accordingly. The leather shall not give off any pungent or rancid odour.

2.4 DIMENSIONS The pre-washed and pre-shrunk skin (see Paragraph A1) shall be of natural shape and greater than or equal to the dimensions in Table 1.4(B).

2.5 WOOL COLOUR FOR AUSTRALIAN INSTITUTIONAL USE Wool colour for Australian institutional use shall be as follows:

(a) **Regtemp**—Medical Blue (approximated by Pantone Matching System (PMS) 540.

(b) **Hitemp**—Medical Green (approximated by PMS 562).

2.6 WOOL FIBRE DIAMETER The mean wool fibre diameter shall be 26 to 34 μm in the mid-side position (approximated to a wool count of 50 s–58 s) e.g. measured by a recognized procedure, e.g. CSIRO Sirolan-Laserscan.

2.7 WOOL PILE HEIGHT

2.7.1 Initial stage In order to achieve the specified wool pile height in the finished skin (see Clause 2.7.2) the wool pile shall be clipped to no less than 30 mm from the top surface of the skin. Refer to Paragragh A1.

2.7.2 Final stage The wool pile height shall be a minimum of 25 mm in the final finished state. Refer to Paragraph A1.

2.7.3 For medical accessories When a skin is to be cut up for use as other medical accessories, elbow and heel pads and the like, the wool pile height shall be a minimum of 20 mm for the final finished state.

2.8 SOFTNESS/DRAPE Initially, and after five standard wash/dry cycles appropriate to the product, the dry product shall hang with sides parallel when suspended (lengthwise along the backbone line, or widthwise across the centre-line perpendicular to the backbone) on a round bar of 19 mm diameter (see Paragraph A7).

2.9 FLATNESS At all times, the product should lie flat on a horizontal surface with minimal curling around the edges.

2.10 DEGREE OF TANNAGE The degree of tannage is measured by the hydrothermal shrinkage temperature (T_s) of the sheepskin or lambskin leather *in water*. The leather shall be fully finished by the tannery and should be tested within one month of completion of wet processing. Prior to the measurement of T_s, the leather shall be rehydrated (wetted) in accordance with SLP 18 (refer to Clause A8) with the exception that the immersion period of one hour be increased to 18–24 h.

The end use of the product shall determine the degree of tannage required as follows:

(a) **Regtemp**—T_s minimum 100°C (Paragraph A8).

(b) **Hitemp**—T_s minimum 110°C (Paragraph A8).

2.11 MAINTENANCE OF SHRINKAGE TEMPERATURE After five standard wash and dry cycles of a whole skin at the standard wash temperature of the designated skin, the shrinkage temperature shall not decrease by more than 5°C.

2.12 COLOURFASTNESS The colourfastness of the Regtemp and Hitemp skins shall comply with each of the colourfastness tests described in the following Table:

TABLE 2.12

COLOURFASTNESS

Property	Substrate	IWS test method	Test	Pass level Minimum
Washing	Wool	TM 250 July 1996	Change Staining wool Staining cotton	3 3 3
Alkaline perspiration	Wool	TM 174* July 1996	Change Staining wool Staining cotton Staining nylon	3–4 2–3 2–3 2–3
Acid perspiration	Wool	TM 175* August 1993	Change Staining wool Staining cotton Staining nylon	3–4 2–3 2–3 2–3
Rubbing	Wool	TM 165 July 1996	Dry Wet	3–4 3–4
Rubbing	Leather	TM 165 July 1996	Dry Wet	3 3
Light	Wool	TM 5 July 1996	> ⅓ SD < ⅓ SD	4 3

* Dyes regarded as particularly suitable to produce the Regtemp Blue and Hitemp Green colours may possibly cause staining of bedwear, in certain cases of prolonged contact with coloured wool, when exposed to heavy perspiration. This is especially the case with nylon fabrics the use of which should be avoided.

The minimum pass levels specified for staining of wool, cotton and nylon are consequently lower than would normally be for bed underlay materials in recognition of this factor.

However, on the basis of extensive practical experience with comparable sheepskin products, dyed with such dyes, staining of bedwear should not be a problem, especially when 100% cotton or cotton/polyester fabrics are used.

2.13 REPORT The following shall be reported:

(a) Designation of woolskins (see Table 1.4A).

(b) Dimensions (see Table 1.4B).

(c) Wool colour (see Clause 2.5).

(d) Wool fibre diameter (see Clause 2.6).

(e) Wool pile height (see Clause 2.7).

(f) Softness/drape (see Clause 2.8).

(g) Flatness (see Clause 2.9).

(h) Degree of tannage (see Clause 2.10).

(i) Maintenance of shrinkage temperature (see Clause 2.11).

(j) Colourfastness (see Clause 2.12).

(k) Reference to this Standard, i.e. AS/NZS 4480.1.

APPENDIX A
RATIONALE
(Informative)

A1 THE PRE-WASH FINISH Previously, for the service life of a medical sheepskin the product was considered to be in a 'new' (at point-of-sale) condition prior to the first wash only. The 'new' point of sale condition was created by the tannery's finishing process, which produced a homogeneous ironed finish. Laundering allowed the wool fibres to relax, similarly the leather fibres relaxed and shrinkage occurred in the first wash. Further laundering did not significantly change the product appearance.

To eliminate this change from the new to the washed state the product should be fully finished at the initial wool finishing stage (see Clause 1.3.5) and prior to subsequent wet processing. It is only necessary to clip wispy wool fibres from the wool tips during final wool finishing.

A2 TANNAGE To obtain the required shrinkage temperatures (see Clause 2.10) it is recommended that the skins be chromium tanned.

A3 DEGREASING Lambskins and sheepskins contain natural grease within their structure. The grease is best removed by solvent degreasing since it is offensive and would constitute a health hazard in a medical sheepskin. The solvents in common use are hydrocarbons such as white spirit and chlorinated hydrocarbons such as perchlorethylene. These solvents are removed from the skin during processing.

The solvent may remove some fatliquor from the skin structure—it is advisable to replace the fatliquor following degreasing (dry-cleaning).

A4 AREA Skins are sold on the basis of area, measured by a machine to the nearest square decimetre.

A5 URINE RESISTANT LEATHER Glutaraldehyde can be used in conjunction with the main tanning agent in the production of sheepskins because it offers some increased resistance to urine and perspiration. Urine resistant skins are identified by the words 'urine resistant' or 'UR' on the permanent label.

A6 MEDICAL BLUE AND MEDICAL GREEN DYEING Regtemp skins should be dyed the Medical Blue shade to identify this product. Dyeing formulations are readily available from dyestuff supply companies.

Hitemp skins should be dyed the Medical Green shade to identify this product.

A7 SIMPLE DRAPE TEST The minimum acceptable skin softness is determined by a simple drape test. From the air equilibrated state, skins are conditioned for at least 24 h at 20°C and 65% RH prior to testing (refer to Clause 2.8).

A8 SHRINKAGE TEMPERATURE MEASUREMENTS For measurement of shrinkage temperature up to and including 100°C, refer to Society of Leather Trades Chemists, Official Methods of Analysis, SLP 18 (1965). For measurement of shrinkage temperature above 100°C, refer to Bavinton J, American Leather Chemists Association Journal 1969, **64**, 96. For tannery quality control purposes only (and *not* for compliance to AS 4480.1) the shrinkage temperature above 100°C can be measured in a mixture of glycerol/water (75%/25% V/V) using SLP 18 apparatus and techniques. The values obtained in glycerol/water are at least 5°C higher than in water under pressure.

A9 STANDARD WASH AND DRY CYCLES

A9.1 General The following chemicals should not be used in any of the processes covered in this Paragraph: bleach, enzymes, phosphates, alkali, peroxides, or cold water detergents.

CAUTION: DETERGENTS CONTAINING ENZYMES, PHOSPHATES, PEROXIDE, ALKALI OR BLEACH CAN CAUSE IRREVERSIBLE DAMAGE TO LEATHER. USE A SUITABLE NON-IONIC LIQUID DETERGENT CONTAINING A BACTERIOSTAT (E.G. QUATERNARY AMMONIUM COMPOUND).

A9.2 Staining If the skin has been heavily soiled or stained with urine, it should be rinsed immediately in cold to lukewarm water.

A9.3 Regtemp sheepskins Sheepskin should be laundered in accordance with the wash formulae specified in Table A9.3 which achieves low level chemical disfection to AS 4146. The machine should be loaded to half-capacity.

A9.4 Hitemp sheepskins Sheepskin should be laundered in accordance with the wash formulae specified in Table A9.4 which achieves high level thermal disfection to AS 4146. The machine should be loaded to half-capacity.

TABLE A9.3

REGTEMP AUSTRALIAN MEDICAL SHEEPSKINS (BLUE COLOUR) COMMERCIAL LAUNDERING INSTRUCTIONS

Operation	Water level	Temperature, °C	Time, min	Washing agent
1 Wash	High	Cold	3	Detergent* (3.5–4.5 mL/kg of sheepskin)
2 Drain	—	—	1	
3 Rinse	High	40	2	
4 Drain	—	—	1	
5 Wash	High	60	8	Detergent* (3.5–4.5 mL/kg of sheepskin)
6 Drain	—	—	1	
7 Rinse	High	50	2	
8 Drain	—	—	1	
9 Rinse	High	30	2	
10 Drain	—	—	1	
11 Rinse	High	20	2	
12 Drain	—	—	1	
13 Extract	—	—	9	
14 Dry	—	60 max.	120	

* See Paragraph A9.

TABLE A9.4

HITEMP AUSTRALIAN MEDICAL SHEEPSKINS
(GREEN COLOUR)
COMMERCIAL LAUNDERING INSTRUCTIONS

Operation	Dip	Temperature, °C	Time, min	Washing agent
1 Wash	High	Cold	3	Detergent*
2 Drain	—	—	1	(3.5–4.5 mL/kg of sheepskin)
3 Rinse	High	40	2	
4 Drain	—	—	1	
5 Wash	High	60	4	Detergent*
6 Drain	—	—	1	(3.5–4.5 mL/kg of sheepskin)
7 Rinse	High	60	2	
8 Drain	—	—	1	
9 Thermal	High	80	8	
10 Drain	—	—	1	
11 Rinse	High	Cold	2	
12 Drain	—	—	1	
13 Extract	—	—	9	
14 Dry	—	60 max.	120	

* See Paragraph A9.

A10 REGTEMP AUSTRALIAN MEDICAL SHEEPSKINS (BLUE COLOUR) DOMESTIC LAUNDERING INSTRUCTIONS

- A soiled skin should be immediately rinsed in cold water.
- Machine wash the Regtemp Medical Sheepskin on gentle cycle, for 10 minutes in hot water up to 60°C.
- For effective washing and chemical disinfection, use a suitable *non ionic liquid detergent* containing a *bacteriostat*, which has no enzymes, phosphates, peroxide, alkali or bleach, as these chemicals may cause irreversible damage to the leather.
- Use approximately 10 mLs detergent if washing one skin only. Use 5 mLs detergent, per skin, if washing two or more skins.
- Drain and rinse for 3 minutes with warm water at 30–40°C.
- Repeat, drain and rinse cycles twice.
- Spin off excess water.
- Drying: Tumble dry on warm setting – do not exceed 60°C. Avoid over-drying.
- Alternatively, hang dry in shade away from direct heat. Flex skin vigorously to restore leather softness.

A11 HITEMP AUSTRALIAN MEDICAL SHEEPSKINS (GREEN COLOUR) DOMESTIC LAUNDERING INSTRUCTIONS

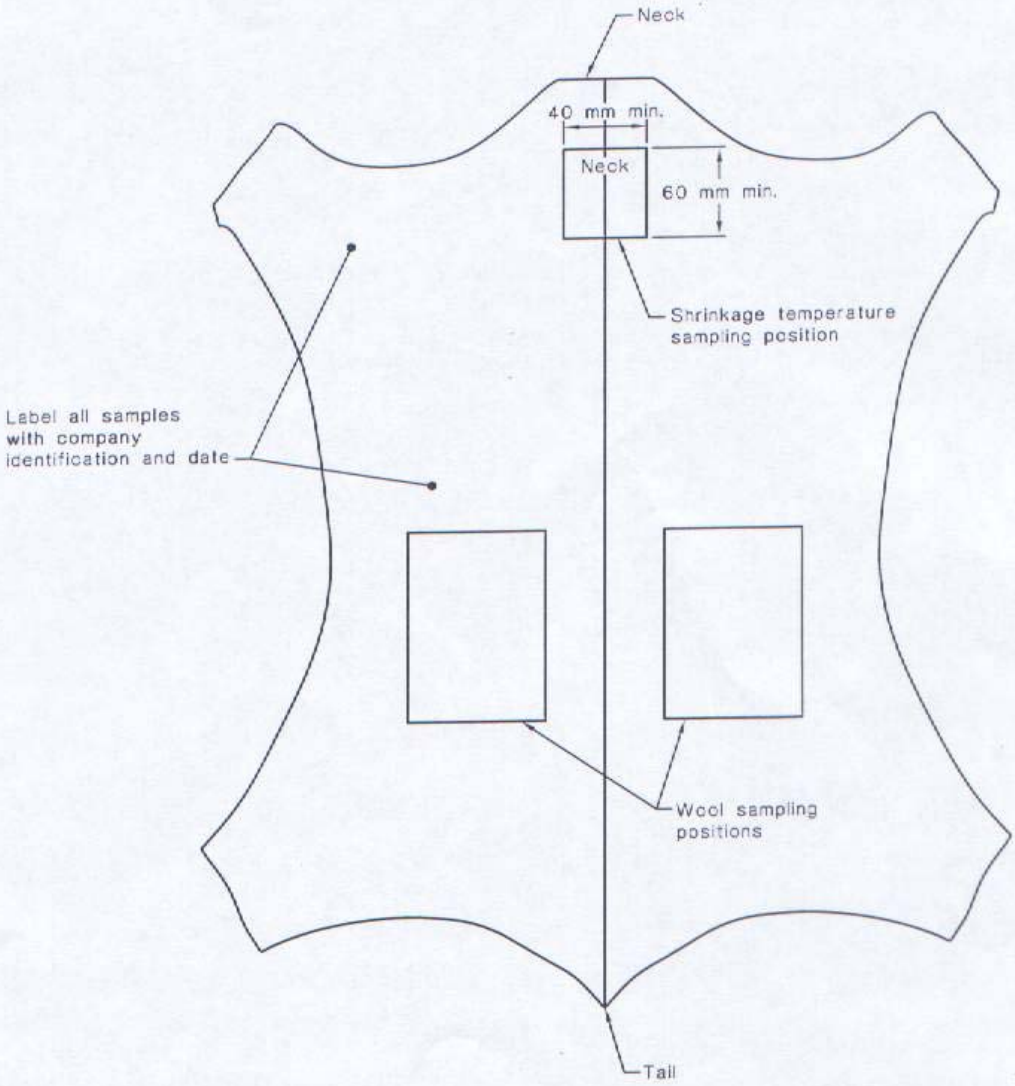
- A soiled skin should be immediately rinsed in cold water.
- Machine wash the Hitemp Medical Sheepskin on gentle cycle, for 10 minutes in hot water up to 60°C.
- For effective washing and chemical disinfection, use a suitable *non ionic liquid detergent* containing a *bacteriostat*, which has no enzymes, phosphates, peroxide, alkali or bleach, as these chemicals may cause irreversible damage to the leather.
- Use approximately 10 mLs detergent if washing one skin only. Use 5 mLs detergent, per skin, if washing two or more skins.
- Drain.
- Rinse for 3 minutes with warm water at 30–40°C.
- To achieve high leval thermal disinfection, wash the skin in water for 8 minutes at 80°C. Do not add detergent to the 80°C wash.
- Drain.
- Rinse for 3 minutes in cold water.
- Spin off excess water.
- Drying: Tumble dry on warm setting – do not exceed 60°C. Avoid over-drying.
- Alternatively, hang dry in shade away from direct heat. Flex skin vigorously to restore leather softness.

A12 HAND WASH Alternatively, the skin can be hand washed in warm water using a non ionic detergent. Rinse and squeeze to remove excess moisture. Hang dry in shade away from direct heat.

Before leather is fully dry flex skin to restore leather softness.

A13 FREQUENCY OF LAUNDRY AND PATIENT COMFORT Advice is given in Appendix D with regard to patient comfort frequency of laundering.

APPENDIX B
SELECTION OF TEST SAMPLES
(Normative)



APPENDIX C
SUPPLIER'S LABEL
(Normative)

The supplier's label (see Figure C1) shall contain the following information:

(a) Supplier's name.

(b) Commercial laundry instructions shall be in accordance with AS 4180.1. Labels shall include the following statements:

  (i) No enzymes, phosphates, bleach, peroxides, or alkalis to be used.

  (ii) Regtemp wash, ≤60°C.

  (iii) Hitemp wash, ≤80°C.

(c) Domestic laundry instructions shall be stated as per Paragraphs A10; A11 and A12. Domestic instructions may be abbreviated.

(d) The label shall clearly state that the product is made from genuine woolskin with real leather. It is recommended that the International leather symbol be used.

(e) Any other information required by state or federal legislation.

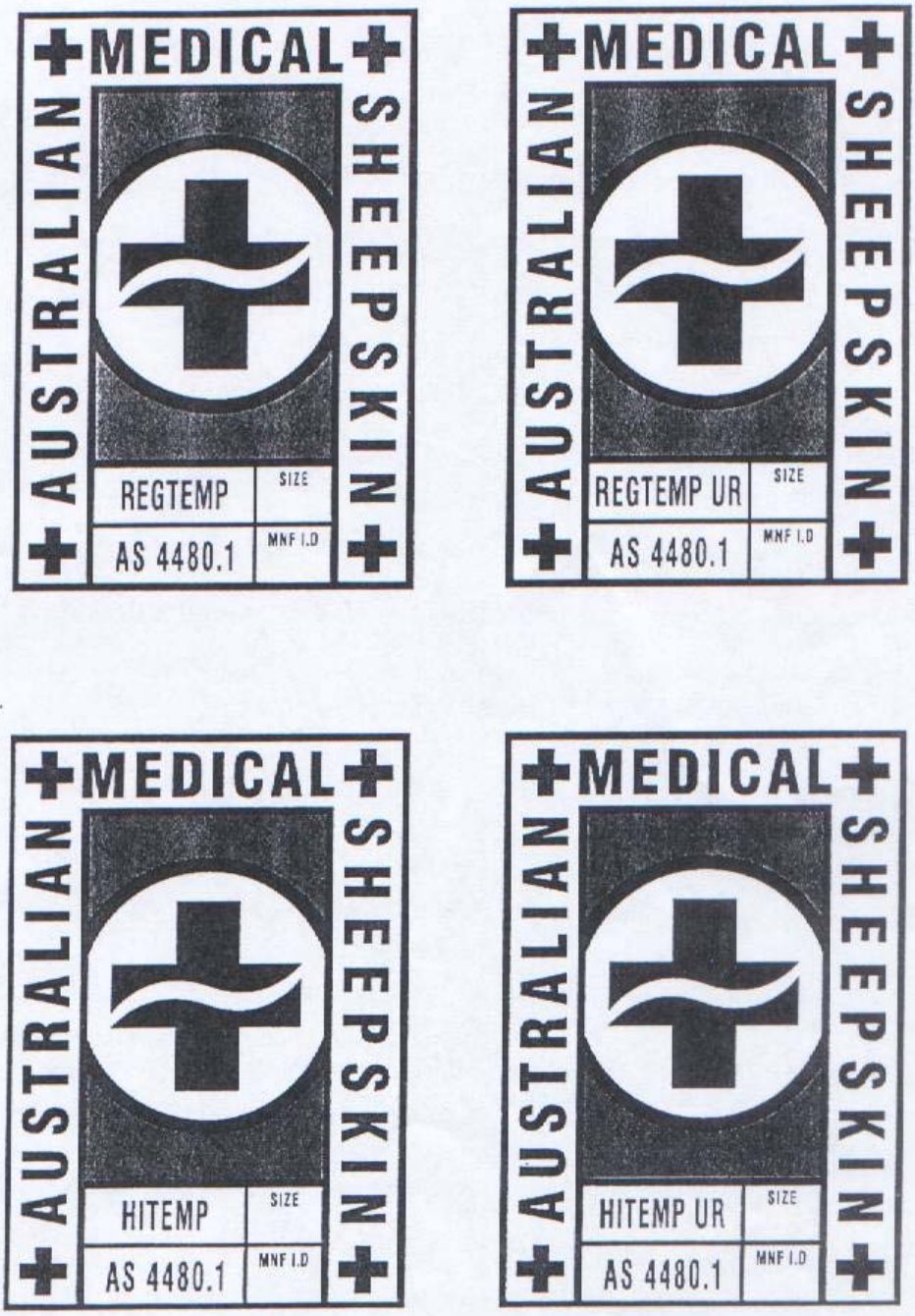


FIGURE C1 SUPPLIER'S LABEL

APPENDIX D

USER'S GUIDE FOR REGTEMP AND HITEMP SHEEPSKINS

(Informative)

D1 SCOPE This Appendix gives recommendations for optimal use of medical sheepskins and for prolongation of their effectiveness in the prevention of pressure ulcers.

D2 GENERAL The use of medical sheepskins to reduce pressure, friction and moisture problems is well documented. These factors contribute to the development, severity and duration of pressure ulcers for patients confined to bed or chair. The previous decline in the use of skins was largely due to inadequately tanned or poorly selected skins and the use of incorrect washing procedures.

D3 SPECIFIC CONSIDERATIONS Sheepskins are supplied as follows:

(a) **Regtemp**—labelled 'L3/L4: to be washed and dried at temperatures not exceeding 60°C'.

(b) **Hitemp**—labelled 'L1/L2: to be washed at temperatures not exceeding 80°C and dried at temperatures not exceeding 60°C'.

Both types can be supplied with increased urine resistance which is identified by the letters 'UR' on the permanent label.

To gain maximum advantage from the sheepskin the following procedures should be observed:

(i) The sheepskin appropriate for the patient should be selected. If urinary incontinence is anticipated, a urine resistant type should be used.

(ii) The sheepskin should be laid flat over the bottom sheet, drawsheet or seat with the wool layer uppermost.

(iii) The patient should be positioned so that, where possible, the patient's skin is in direct contact with the wool.

(iv) Prolonged compaction of the wool fibres reduces its effectiveness. For maximum cushioning the sheepskin should be replaced after a few days continuous use then relaundered and disinfected. This is sufficient to restore the pile and resilience of the wool.

D4 SEGREGATION PRIOR TO LAUNDERING Sheepskins, whether Regtemp or Hitemp, require specialized laundering and handling. Therefore they should be segregated from other bed linen. On removal from the patient's bed or chair they should be placed in the correct sheepskin laundry bag (Regtemp or Hitemp). They should be further sorted at the laundry according to washing temperature required.

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APPENDIX F

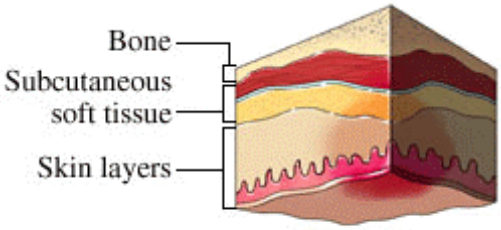
Wound Assessment

Pressure Sore Data Collection Questionnaire

Attached is a tool for documenting the presence of pressure ulcers. Documentation has key benefits

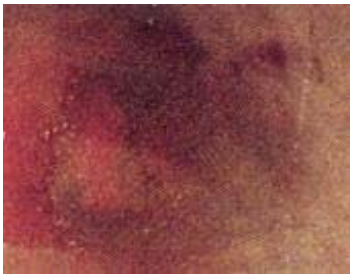
- Elicits information on every bony prominence
- Useful for documentation of outcomes
- Useful for quality assurance studies

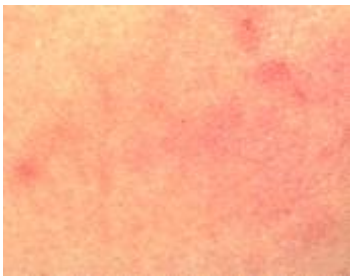
Stage I



Stage 1

This stage is characterized by a surface reddening of the skin. The skin is unbroken and the wound is superficial. This would be a light sunburn or a first degree burn as well as a beginning Decubitus ulcer. The burn heals spontaneously or the Decubitus ulcer quickly fades when pressure is relieved on the area.

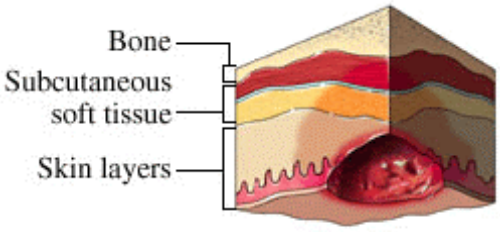




The key factors to consider in a Stage I wound is what was the cause of the wound and how to alleviate pressure on the area to prevent it from worsening. Improved nutritional status of the individual should also be considered early to prevent wound worsening. The presence of a Stage I wound is an indication or early warning of a problem and a signal to take preventive action.

Treatment consists of turning or alleviating pressure in some form or avoiding more exposure to the cause of the injury as well as covering, protecting, and cushioning the area. Soft protective pads and cushions are often used for this purpose. An increase in vitamin C, proteins, and fluids is recommended. Increased nutrition is part of prevention.

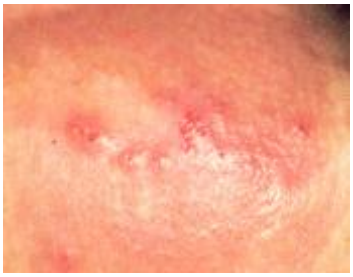
Stage II



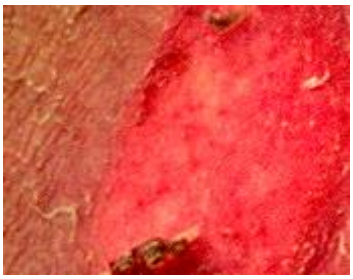
Stage 2

This stage is characterized by a blister either broken or unbroken. A partial layer of the skin is now injured. Involvement is no longer superficial.

The goal of care is to cover, protect, and clean the area. Coverings designed to insulate and absorb as well as protect are used. There is a wide variety of items for this purpose.

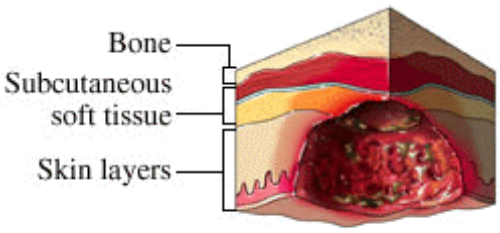


Skin lotions or emollients are used to hydrate surrounding tissues and prevent the wound form worsening. Additional padding and protective substances to decrease the pressure on the area are important. Close attention to prevention, protection, nutrition, and hydration is important also. With quick attention, a stage II wound can heal very rapidly.



A wound can appear to be a Stage I wound upon initial evaluation, and actually be reevaluated as a Stage II wound during the course of care. Quick attention to a Stage I Decubitus ulcer or pressure wound will prevent the development of a Stage III Decubitus ulcer or pressure wound. Generally Decubitus ulcers or pressure wounds developing beyond Stage II is from lack of aggressive intervention when first noted as a Stage I.

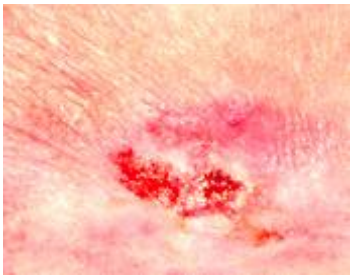
Stage III



Stage 3

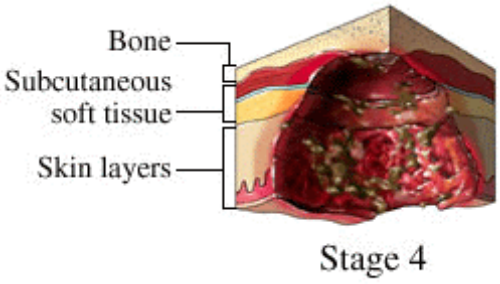
The wound extends through all of the layers of the skin. It is a primary site for a serious infection to occur.

The goals and treatments of alleviating pressure and covering and protecting the wound still apply as well as an increased emphasis on nutrition and hydration.



Medical care is necessary to promote healing and to treat and prevent infection. This type of wound will progress very rapidly if left unattended. Infection is of grave concern.

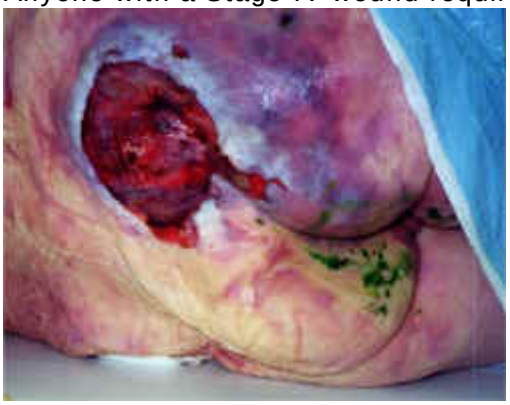
Stage IV



Stage 4

A Stage IV wound extends through the skin and involves underlying muscle, tendons and bone. The diameter of the wound is not as important as the depth. This is very serious and can produce a life threatening infection, especially if not aggressively treated. All of the goals of protecting, cleaning and alleviation of pressure on the area still apply. Nutrition and hydration is now critical. Without adequate nutrition, this wound will not heal.

Anyone with a Stage IV wound requires medical care by someone skilled in wound care.



Surgical removal of the necrotic or decayed tissue is often used on wounds of larger diameter. A skilled wound care physician, physical therapist or nurse can sometimes successfully treat a smaller diameter wound without the necessity of surgery. Surgery is the usual course of treatment. Amputation may be necessary in some situations.

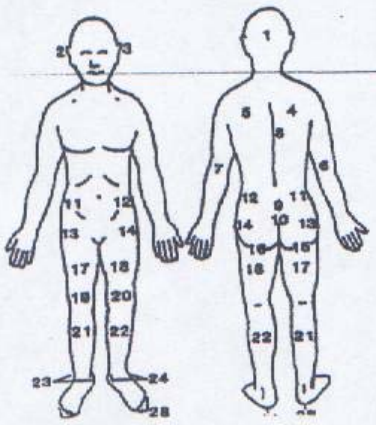
PRESSURE SORE DATA COLLECTION QUESTIONNAIRE
SKIN ASSESSMENT TOOL (NURSE II)

Name _____ ID Number _____

DATE OF OBSERVATION: _____ _____
Month Day Year

ASSESSMENT SITE*	SKIN CONDITION		
	Size	Depth	Stage
1) Back of head			
2) Right ear			
3) Left ear			
4) Right scapula			
5) Left scapula			
6) Right elbow			
7) Left elbow			
8) Vertebrae (upper-mid)			
9) Sacrum			
10) Coccyx			
11) Right iliac crest			
12) Left iliac crest			
13) Right trochanter (hip)			
14) Left trochanter (hip)			
15) Right ischial tuberosity			
16) Left ischial tuberosity			
17) Right thigh			
18) Left thigh			
19) Right knee			
20) Left knee			
21) Right lower leg			
22) Left lower leg			
23) Right ankle (inner/outer)			
24) Left ankle (inner/outer)			
25) Right heel			
26) Left heel			
27) Right toe(s)			
28) Left toe(s)			
29) Other (specify)			

*Assess and record each site each observation time. Mark site(s) on figure below.



Stage Key

Stage 0 No redness or breakdown
Stage 1 Erythema only: redness does not disappear for 24 hours after pressure is relieved
Stage 2 Break in skin such as blisters or abrasions
Stage 3 Break in skin exposing subcutaneous tissue
Stage 4 Break in skin extending through tissue and subcutaneous layers, exposing muscle or bone
Stage 9 Dark necrotic tissue. (Use this rating until tissue sloughs, then continue staging.)

Revised 3/2/89

The Braden Scale

The Braden Scale is a summated rating scale made up of six subscales scored from 1-3 or 4, for total scores that range from 6-23. The subscales measure functional capabilities of the patient that contribute to either higher intensity and duration of pressure or lower tissue tolerance for pressure. A lower Braden Scale Score indicates lower levels of functioning and, therefore, higher levers of risk for pressure ulcer development.

The Braden Scale for Predicting Pressure Sore Risk© is a clinically validated tool that allows nurses and other health care providers to reliably score a patient/client's level of risk for developing pressure ulcers.

Key Benefits

- Assists nurses with varied experience and judgment to consistently identify patients at risk and to quantify the severity of risk.
- Reminds busy nursing staff to attend to this aspect of patient assessment and care with the consistency necessary to influence outcomes.
- Directs the attention of the nurse to six specific risk factors so that preventive care can be appropriately prescribed.

Institutions that have used the Braden Scale and simple protocols keyed to level of risk in a program of prevention have been able to:

- reduce the incidence of nosocomial pressure ulcers by 40-60%.
- reduce the severity of nosocomial pressure ulcers
- reduce the cost of care by decreasing the inappropriate use of specialty beds
- reduce the cost of care by avoiding the excess hospital days associated with the complication of nosocomial pressure ulcers

Protocols By Level of Risk

AT RISK (15-18)*

TURN, TURN, TURN
MAXIMAL REMOBILIZATION
PROTECT HEELS
MANAGE MOISTURE, NUTRITION AND FRICTION AND SHEAR
PRESSURE REDUCTION SUPPORT SURFACE
IF BED- OR CHAIR-BOUND
* If other major risk factors are present (advanced age, fever, poor dietary intake of protein, diastolic pressure below 60, hemodynamic instability)
advance to next level of risk

MODERATE RISK (13-14)*

TURNING SCHEDULE
WITH 30° RULE
PRESSURE REDUCTION SUPPORT SURFACE
MAXIMAL REMOBILIZATION
PROTECT HEELS
MANAGE MOISTURE, NUTRITION AND FRICTION AND SHEAR
* If other major risk factors present, advance to next level of risk

HIGH RISK (10-12)

PRESSURE REDUCTION SUPPORT SURFACE
INCREASE FREQUENCY OF TURNING
30° WITH FOAM WEDGES
SUPPLEMENT WITH SMALL SHIFTS
MAXIMAL REMOBILIZATION
PROTECT HEELS
MANAGE MOISTURE, NUTRITION AND FRICTION AND SHEAR

BRADEN SCALE FOR PREDICTING PRESSURE SORE RISK

Patient's Name:		Evaluator's Name:		DATE OF ASSESSMENT:				
Sensory perception Ability to respond meaningfully to pressure-related discomfort	**1. Completely limited:** Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation, OR Limited ability to feel pain over most of body surface	**2. Very limited:** Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness, OR Has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body.	**3. Slightly limited.** Responds to verbal commands but cannot always communicate discomfort or need to be turned, OR Has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	**4. No impairment:** Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.				
Moisture Degree to which skin is exposed to moisture	**1. Constantly moist:** Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned.	**2. Moist:** Skin is often but not always moist. Linen must be changed at least once a shift.	**3. Occasionally moist:** Skin is occasionally moist, requiring an extra linen change approximately once a day.	**4. Rarely moist:** Skin is usually dry; linen requires changing only at routine intervals.				
Activity Degree of physical activity	**1. Bedfast:** Confined to bed.	**2. Chairfast:** Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair.	**3. Walks occasionally:** Walks occasionally during day but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.	**4. Walks frequently:** Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours.				
Mobility Ability to change and control body position	**1. Completely immobile:** Does not make even slight changes in body or extremity position without assistance.	**2. Very limited:** Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	**3. Slightly limited:** Makes frequent though slight changes in body extremity position independently.	**4. No limitations:** Makes major and frequent changes in position without assistance.				
Nutrition Usual food intake pattern	**1. Very poor:** Never eats a complete meal. Rarely eats more than ⅓ of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement, OR Is NPO[1] and/or maintained on clear liquids or IV[2] for more than 5 days.	**2. Probably inadequate:** Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement, OR Receives less than optimum amount of liquid diet or tube feeding.	**3. Adequate:** Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products) each day. Occasionally will refuse a meal, but will usually take a supplement of offered, OR Is on a tube feeding or TPN[3] regimen, which probably meets most of nutritional needs.	**4. Excellent:** Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation.				
Friction and Shear	**1. Problem:** Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequent slides down in bed or chair, requiring frequent repositioning with maximum assistance. Spasticity, contractures, or agitation leads to almost constant friction.	**2. Potential problem:** Moves feebly or requires minimum assistance. During a move, skin probably slides to some extent against sheets, chair, restraints, or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	**3. No apparent problem:** Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in be or chair at all times.					
ADOPTED 1997				TOTAL SCORE:				

[1] Nothing by mouth
[2] Intravenously
[3] Total Parenteral Nutrition