Using a new lipidocolloid dressing in paediatric wounds: results of French and German clinical studies

Letouze A, Voinchet V, Hoecht B, Muenter KC, Vives F, Bohbot S

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In this article, the authors note that the contact layer dressing was left in place for up to eight days in some cases. The interval between dressing changes beyond seven days is not recommended by Hollister Wound Care LLC, and has not been cleared by the FDA.

Warnings and Precautions: Do not re-use the dressing. Restore Contact Layer Dressing tends to stick to latex gloves. Moisten latex gloves with normal sterile saline prior to use. Store the dressing flat and at room temperature.

Contraindications: Restore Contact Layer Dressing should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or one of its components.

- * The product cited in this article – Urgotul® (Laboratoires URGO, Dijon, France) – is marketed in the U.S. by Hollister Wound Care LLC as **Restore**® Contact Layer Dressing with TRIACT™ Technology. (In the United States, lipidocolloid technology is known as TRIACT Technology.)
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Using a new lipidocolloid dressing in paediatric wounds: results of French and German clinical studies

A. Letouze, MD, Surgical Paediatric Unit and Burn Unit, Clocheville Hospital, University of Tours, France;
V. Voinchet, MD, Paediatric Surgical Unit and Burn Unit, North Hospital, University of Marseille, France;
B. Hoecht, MD, Paediatric Surgical Unit, University of Wuersburg, Germany;
K.C. Muenter, MD, Specialist for General Medicine, Leiter Klinische Prüfung, Hamburg, Germany;
F. Vives, MSc, Clinical Study Manager, Laboratoires Urgo, Chenôve, France;
S. Bohbot, MD, Medical Director, Laboratoires Urgo, Chenôve, France
Email: a.letouze@ clocheville.chu-tours.fr

Using a new lipidocolloid dressing in paediatric wounds: results of French and German clinical studies

- **Objective:** To evaluate the efficacy, tolerance and acceptability of a lipidocolloid dressing, Urgotul (Laboratoires Urgo), in the local treatment of acute and chronic paediatric wounds.
- **Method:** Two non-comparative multicentre prospective clinical studies were conducted using the same protocol in France and Germany. A total of 100 patients were recruited from 16 centres (11 in France and five in Germany), and followed up for four weeks. Seventy wounds (55 burns and 15 other wounds) from France and 30 from Germany (22 burns and eight other wounds) were evaluated by nursing staff at every dressing change and by the medical investigator on a weekly basis.
- **Results:** In the French study population, 86% of the burns (superficial and deep partial-thickness) and 53% of the other wounds healed completely within the four weeks. Figures for the German study population were 100% and 88% respectively. Pain was evaluated using pain scales adapted to the patient's age (objective pain scale, faces scale for pain and a visual analogue scale) at each dressing change. Dressing removal was non-traumatic, inducing very limited pain. Minor local adverse events were reported in four children.
- **Conclusion:** Urgotul is not only efficacious, but also well-tolerated and accepted by children with acute and chronic wounds. The dressing, therefore, might be an appropriate and highly promising alternative to conventional dressings.
- **Declaration of interest:** This study was sponsored by Laboratoires Urgo.

paediatric wound care; dressing removal; pain; burns

Most wounds in surgical paediatric wards are acute (mainly burns) and are treated with neutral or impregnated vaseline gauze or an equivalent. These can cause pain on removal, with sociopsychological consequences.[1-3]

As pain in children is influenced by age and anticipation of pain,[4,5] assessment is difficult. Therefore, pharmacologic and non-pharmacologic interventions should be combined to manage pain.[6]

Even though the efficacy of tulle-gras dressings has not been proven, they have long been used on wounds,[7] particularly burns, surgical wounds and chronic wounds at the granulation and re-epithelialisation stages of healing. They need to be changed daily to avoid adherence to the wound bed and painful removal.

Hydrocolloid dressings contain carboxymethylcellulose, which maintains a moist environment at the wound surface, accelerating the healing process.[8-10] Their efficacy has been demonstrated in controlled clinical trials involving patients with chronic wounds such as leg ulcers,[11,12] pressure ulcers[13,14] and acute wounds.[15,16]

Recently, lipidocolloid technology has been developed.[7,17] Hydrocolloid particles within the dressing hydrate on contact with exudate. Combined with petroleum, they form a lipidocolloid interface, which does not adhere to the wound surface, enabling non-traumatic, pain-free removal.

The primary aim of this study was to evaluate the efficacy of a new lipidocolloid dressing, Urgotul (Laboratoires Urgo), in children with burns or other acute and chronic wounds. The secondary aims were to evaluate tolerance to and acceptability of the dressing, particularly at dressing removal.

Materials and method

Study design

Two open multicentre non-randomised prospective clinical studies were conducted: one in France (11 centres) and one in Germany (five centres).

Inclusion criteria

- Children (in- or outpatients) aged one to 12 years
- Acute or chronic wounds less than 200cm^2. If more than one wound was present, a single lesion was chosen for the study.

Exclusion criteria

- Cancerous lesions
- Donor sites for skin grafting
- Wounds with necrotic plaque
- Wounds with clinical signs of infection
- Hypersensitivity to the test dressing
- Previous inclusion in a clinical study.

A. Letouze, MD, Surgical Paediatric Unit and Burn Unit, Clocheville Hospital, University of Tours, France;
V. Voinchet, MD, Paediatric Surgical Unit and Burn Unit, North Hospital, University of Marseille, France;
B. Hoecht, MD, Paediatric Surgical Unit, University of Wuersburg, Germany;
K.C. Muenter, MD, Specialist for General Medicine, Leiter Klinische Prüfung, Hamburg, Germany;
F. Vives, MSc, Clinical Study Manager, Laboratoires Urgo, Chenôve, France;
S. Bohbot, MD, Medical Director, Laboratoires Urgo, Chenôve, France
Email: a.letouze@clocheville.chu-tours.fr

Table 1. Baseline characteristics of the studies' populations

	France (n=70)		Germany (n=30)	
	Burns (n=55)	Other wounds (n=15)	Burns (n=22)	Other wounds (n=8)
Sex				
Male	35 (64%)	9 (60%)	9 (41%)	5 (63%)
Female	20 (36%)	6 (40%)	13 (59%)	3 (37%)
Age				
3 years	38 (69%)	4 (27%)	12 (55%)	1 (13%)
4–6 years	9 (16%)	2 (13%)	5 (23%)	2 (25%)
>6 years	8 (15%)	9 (60%)	5 (23%)	5 (63%)
Body weight (kg)	16.9 ±10.5	31.2 ±18.7	18.0 ±10.3	31.3 ±13.7
Minimum; maximum	6.0; 69.0	7.0; 63.0	8.0; 48.0	10.0; 50.0
Height (cm)	98.1 ±21.2	129.3 ± 32.8	104.5 ±26.9	135.1±26.8
Minimum; maximum	76.0; 166.0	70.0; 182.0	72.0; 158.0	80.0; 165.0
Wound duration (days)	3.8 ±5.7	15.4 ±21.1	1.7 ±1.3	13.3 ±20.8
Minimum; maximum	0.0; 28.0	0.0; 70.0	0.04; 5.0	0.04 ; 56.0
Location				
Face	5 (9%)	1 (7%)		
Hand	12 (22%)	1 (7%)	1 (5%)	4 (50%)
Superior limb	19 (35%)	2 (13%)	9 (41%)	1 (13%)
Lower limb	7 (13%)	8 (53%)	5 (23%)	1 (13%)
Other	12 (22%)	3 (20%)	7 (32%)	2 (25%)
Previous treatment				
None	20 (36%)	2 (13%)	2 (9%)	3 (38%)
Greasy dressing	22 (40%)	11 (73%)	14 (64%)	3 (38%)
Other	13 (24%)	2 (13%)	8 (36%)	2 (25%)

Table 2. Wound characteristics

	France (n=70)		Germany (n=30)	
	No.	(%)	No.	(%)
Burns	**55**	**(79)**	**22**	**(73)**
• Superficial partial thickness	15	(27)	7	(32)
• Deep partial thickness	40	(77)	15	(68)
• Thermal origin	53	(96)	22	(100)
Other wounds	**15**	**(21)**	**8**	**(27)**
Acute wounds				
• Post-surgery	4		1	
• Traumatic	4		5	
• Recent pressure under plaster	1		–	
• Post-surgery necrosis	1		–	
Chronic wounds				
• Burn sequelae	5		1	
• Other	–		1	

Ethics

Approval was obtained from the University of Nantes national ethic committee in France and the local ethic committees of each investigation centre in Germany. The studies were conducted according to European regulations under Good Clinical Practice.[18] Written informed consent was obtained from parents or guardians before enrolment.

Treatment and follow-up

The children's medical and surgical histories, and the origin, duration and characteristics of their wounds were recorded at inclusion.

Wounds were cleaned with saline, and the Urgotul dressing was then applied directly to them. A secondary dressing (gauze pad) was secured with adhesive tape. No other interventions were undertaken, unless manual debridement was indicated.

Dressing change frequency was decided by the investigator, based on clinical need. Use of analgesics was permitted before dressing change, again according to the investigator's practice. Less than 20% received this, mainly as paracetamol. The fact that this may have reduced pain levels at dressing changes was considered when evaluating the results on the level and character of pain.

Clinical evaluation, wound-area tracing and photographic follow-up were performed weekly until healing occurred or for a maximum of four weeks.

Wound area was traced using transparent film in line with a protocol provided by the sponsor.

Nurses evaluated dressing acceptability at each dressing removal. This included ease of application and removal, odour, bleeding, dressing conformability and adherence to the wound bed. Nurses were trained by the lead investigator at the site on the use of the various pain scales and on how to assess dressing acceptability.

Pain was assessed using one of two paediatric pain assessment scales, depending on the child's age:[19-23]

- The faces scale, which is designed to assess pain in children aged over three years — children choose one of a range of faces, 'smiling', 'indifferent', 'weeping' or 'sobbing', to reflect the intensity of their pain
- A visual analogue scale (VAS) for children aged over six years — this is a 100mm non-hatched line where 0 = no pain and 100 = worst imaginable pain.

In addition, the investigators and/or nurses evaluated pain in children aged one to six years. This involved using the objective pain scale, which has four items (crying, motion, restlessness and verbal and non-verbal expression) scored 0–2 for each parameter. The VAS was also used (same as above).

The investigators and nurses evaluated pain in the younger children to get an objective view as very young patients may have difficulty communicating their scores. Nurses evaluated the pain level at each dressing change using different scales, depending on the patient's age. The investigator evaluated this at their weekly assessments.

Local adverse events were also monitored at each assessment.

References

1 Goldman, A., Lloyd-Thomas, A.R. Pain management in children. Br Med Bull 1991; 47: 3, 676-89.

2 Chalkiadis, G.A. Management of chronic pain in children. Med J Aust 2001; 175: 9, 476-479.

3 Chambliss, C.R., Heggen, J., Copelan, D.N., Pettignano, R. The assessment and management of chronic pain in children. Paediatr Drugs 2002; 4: 11, 737-746.

4 Bhatt-Mehta, V. Current guidelines for the treatment of acute pain in children. Drugs 1996; 51: 5, 760-776.

5 American Academy of Paediatrics. Committee on Psychosocial Aspects of Child and Family Health. Task Force on Pain in Infants, Children, and Adolescents. The assessment and management of acute pain in infants, children, and adolescents. Paediatrics 2001; 108: 3, 793-797.

Data processing and statistical analysis

Efficacy and tolerance (occurrence of local adverse events) were analysed on the intent-to-treat population (all patients recruited).

The primary outcome measure was predefined as the number of children with full wound healing (100% re-epithelialisation).

Categorical variables were described using frequencies and percentages. Continuous variables were summarised using frequencies, means, standard deviation, medians and extremes. No statistical tests were performed, and the results were calculated separately for each clinical study.

Collected data were analysed using SAS 6.12.

Results

Patients and wounds

Seventy children were enrolled in 11 centres in France between May 2000 and July 2001 and 30 children in five centres in Germany between September 2002 and May 2003. Baseline characteristics of patients and wounds are given in Tables 1 and 2.

Efficacy results: the French study

•-Burns Forty-seven out of 55 burns (86%) healed during -the study (range: four to 28 days; median: 12 days). Mean time to healing was shorter in superficial partial-thickness burns than in deep partial-thickness wounds (9.5 ±4.2 days versus 13.8 ±5.6 days).

One burn was grafted after the third week of follow-up. Two burns had not completely re-epithelialised at week four. Overgranulation occurred in three patients, who were withdrawn from the study. Two patients were lost to follow-up.

•-Other wounds Eight out of 15 children (53%) healed within seven to 21 days (median: 13 days; mean: 13.3 ±4.2 days). In six patients the wound had not healed completely at week four.

An adverse event (infection of the wound bed) caused one child to be withdrawn from the study and another child's investigation to be stopped prematurely.

Efficacy results: the German study

•-Burns All 22 burns (100%) healed within seven to 28 days (mean: 13 days). Mean time to healing was shorter in superficial partial-thickness burns than in deep partial-thickness wounds (10.6 ±3.0 days versus 16.1 ±6.7 days).

•-Other wounds Seven out of eight children (88%) healed within 13–26 days (median: 21 days; mean: 19.7 ±4.2 days). One patient's wound had not healed at week four.

Healing rates reported here are the same as reported for Urgotul in the literature.[17] Table 3 gives differences in wound surface area in wounds at inclusion and after four weeks.

Table 3. Wound surface area (cm^2) at inclusion and four weeks

	France		Germany	
	Burns (n=55)	Other wounds (n=15)	Burns (n=22)	Other wounds (n=8)
Surface area (cm^2) at inclusion	41.9	9.15 ±10.93	46.0 ±59.9	8.2 ±13.4
Minimum; maximum	5; 170	1.70 ±37.30	1.3; 226.7	1.2; 28.3
Surface area (cm^2) after four weeks	–	1.59 ±2.21	–	0.3 ±0.8
Minimum; maximum		0; 7.11		0; 2.4

Table 4. Dressing acceptability*

	France (355 changes)		Germany (174 changes)	
	Burns (n=262)	Other wounds (n=93)	Burns (n=120)	Other wounds (n= 54)
Dressing application				
No. of changes	237	67	117	53
Easy or very easy	208 (88%)	67 (100%)	115 (98%)	50 (94%)
Difficult or very difficult	29 (12%)	0 (0%)	2 (2%)	3 (6%)
Dressing removal				
No. of changes	261	74	120	51
Easy or very easy	252 (97%)	74 (100%)	113 (94%)	50 (98%)
Difficult or very difficult	9 (3%)	0 (0%)	7 (6%)	1 (2%)
Odour				
No. of changes	260	74	120	52
None or moderate	250 (96%)	71 (96%)	120 (100%)	52 (100%)
Important or nauseating	10 (4%)	3 (4%)	0 (0%)	0 (0%)
Bleeding				
No. of changes	261	74	120	52
None or slight	247 (95%)	72 (97%)	119 (99%)	52 (100%)
Moderate or important	14 (5%)	2 (3%)	1 (1%)	0 (0%)
Dressing conformability				
No. of changes	222	67	117	53
Good or very good	198 (89%)	61 (91%)	115 (98%)	37 (70%)
Poor or very poor	24 (11%)	6 (9%)	2 (2%)	16 (30%)
Adherence to wound bed				
No. of changes	258	74	119	52
None or slight	246 (95%)	74 (100%)	112 (94%)	52 (100%)
Moderate or important	12 (5%)	0 (0%)	7 (6%)	0 (0%)

*Results of nurse assessment. In the French study, certain data were not complete because the initial dressing application may have been made by the investigator on the visit at inclusion

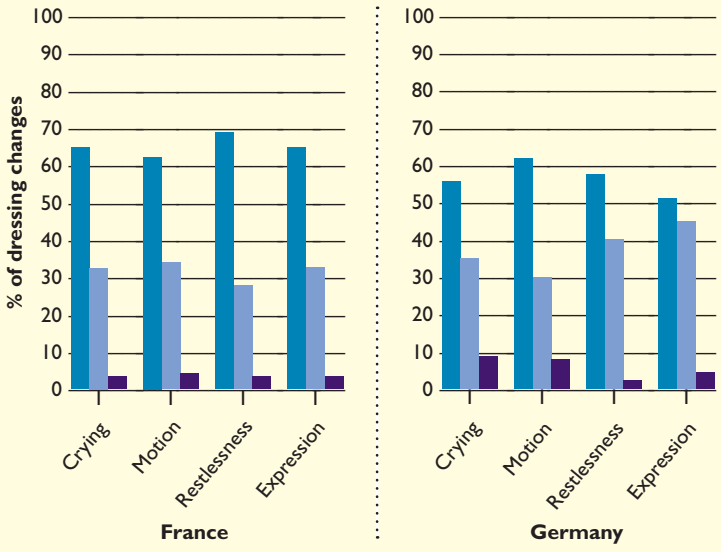
Dressing-change frequencies

Mean time between dressing changes for burns was 2.7 days (range: one to eight days) and 2.6 days (range: one to seven days) in the French and German studies respectively. For other wounds, this was 2.8 days (range: one to seven days) and 3.1 days (range: one to eight days) in France and Germany

6 Senecal, S.J. Pain management of wound care. Nurs Clin North Am 1999; 34: 4, 847-860.

7 Benbow, M. Urgotul: alternative to conventional non-adherence dressings. Br J Nurs 2002;11: 2, 135-138. ▶

Fig 1. Objective pain scale (children from one to six years)



Crying	None Child crying but may be consoled Child crying and inconsolable
Motion	None Intermittent Continuous
Restlessness	None Intermittent, moderate Continuous
Verbal or non-verbal expression	Peaceful or sleeping child Moderate disturbance, restless Immoderate and intense disturbance, may hurt him/herself

Dressing acceptability

Nurses documented 355 dressing changes in France and 174 in Germany. Results are given in Table 4.

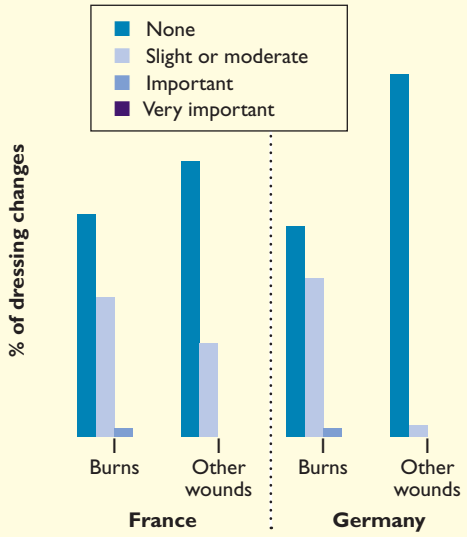
Pain evaluation during nursing care

•-Assessment by the children The faces scale, used by children aged over three to demonstrate the level of pain, was completed at 61 dressing changes in the French study and in 92 dressing changes in the German one. In the French study 60% of the children with burns and 73% of those with other wounds selected smiling faces. In the German study this was 35% and 80% respectively.

The VAS scale, used by children aged over six years, was completed at 96 dressing changes in France and at 58 dressing changes in Germany.

•-Assessment by the investigator and nurses In France the objective pain scale was used during 235 dressing changes for burns and 35 for other wound types. In Germany this was 104 and 16 respectively. (There were significantly more burns than other wound types.) Results are in Fig 1.

Fig 2. Pain (qualitative evaluation by investigators)



Nurses completed 352 VASs for both burns and other wound types after dressing changes in France and 122 in Germany in children aged over six. Again, numbers reflect sample sizes. Results are in Table 5.

Pain was considered totally absent in 60% (burns) and 74% (other wounds) of the dressing changes in France, and in 57% and 97% respectively in Germany. Results are in Fig 2.

Prescription of analgesia

In France analgesia was given before 27% of dressing changes. Of children under six years, 96% received non-morphine analgesia and 56% morphine.

In Germany only 16% of burns and 1.6% of other wounds received analgesia before dressing changes. Morphine was used in less than 1% of changes.

Local tolerance

Four local adverse events were reported in France and warranted withdrawal from the study: three wounds overgranulated (burns) and there was one local infection (other wound). These were not attributed to the dressing as they are caused by a wide range of factors.

No local adverse events were noted in Germany.

Patient outcomes

In the French study treatment was discontinued in seven patients before the four-week follow-up for reasons other than healing. Six of these patients had burns: causes of discontinuation were overgranulation (n=3); skin grafting (n=1) and being lost to follow-up (n=2). The seventh patient, who had another wound type, had a local wound infection.

No patients were withdrawn in Germany.

Discussion

The efficacy of Urgotul has been demonstrated in adult outpatients with leg ulcers, traumatic wounds, second-degree burns[17] and epidermolysis bullosa.[24]

8 Meaume, S., Senet, P. Les pansements hydrocolloïdes. J des Plaies et Cicatris-ation 1998; 11: 27-33.

9 Winter, G.D. Formation of the scab and rate of re-epithelialization of superficial wounds in the skin of the young domestic pig. Nature, 1962; 193: 293-294.

10 Winter, G.D. Effect of air drying and dressings on the surface of wounds. Nature 1963; 197: 91-93.

11 Brandup, F., Menne, T., Agren, M.A randomized trial of two occlusive dressings in the treatment of leg ulcers. Acta Derm Venereol (Stockh) 1990; 70: 231-235.

12 Friedman, S.J., Daniel, S.U. Management of leg ulcers with hydrocolloid occlusive dressing. Arch Derm 1984; 120: 1329-1336.

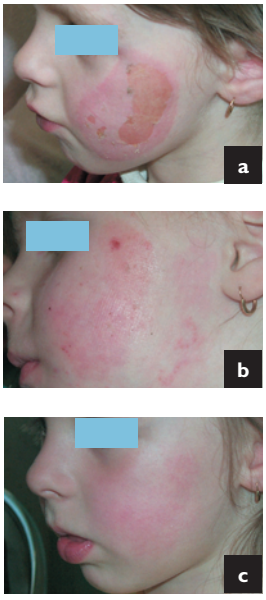


Fig 1. Young girl with cheek burn: at day 0 (A), day 14 (B) and after three months (C)

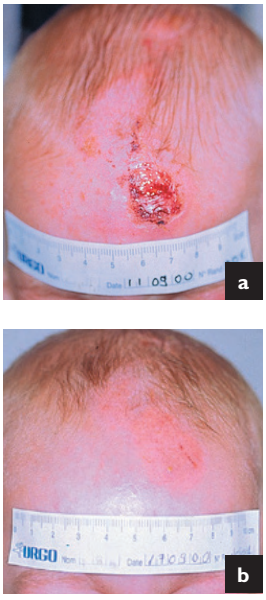


Fig 2. Young boy with forehead wound: day 0 (A) and at day 14 (B)

Table 5. Pain assessment using the VAS

	France		Germany	
	Burns	**Other wounds**	**Burns**	**Other wounds**
Children				
No. of changes	50	46	25	33
Mean	8.5	3.3	10.1	0.9
Minimum; maximum*	0.0; 50.0	0.0; 45.0	0.0; 45.0	0.0; 15.0
Nurses				
No. of changes	271	81	60	62
Mean	6.7	4.0	6.0	1.1
Minimum; maximum*	0.0; 69.0	0.0; 37.0	0.0; 52.0	0.0; 28.0

*0 = no pain, 100 = maximum pain

In the last study, in the 20 patients studied (nine children and 11 adults), healing was observed in a mean time of 8.7 days without adherence or bleeding at dressing removal (more than 200 documented dressing changes), with no apprehension apparent in the paediatric population.[24]

In the present studies, baseline characteristics of the populations and their wounds were very similar: burns represented the great majority of wounds (78% and 73%), particularly in children under three.

The study appears to confirm Urgotul's efficacy as 86% and 100% of the burns and 53% and 88% of the other wounds healed completely in the French and German studies respectively.

The efficacy of non-adherent dressings has been studied in children.[25-28] However, these studies had selected populations (paediatric scalds or skin-graft donor sites). The present study includes children with wounds of any origin.

Acceptability parameters reported by the nurses show that Urgotul is easy to apply and remove, and is conformable and non-adherent. Moreover, attention was paid to pain at dressing change. All the assessments, both by children and practitioners, were concordant and showed either no pain or minor pain requiring little analgesia. However, children with burn injuries did require analgesia, confirming that these wounds are the most painful.[29]

Finally, reported data confirm that Urgotul can be left in place for several days. The mean time between two dressing changes was almost three days in the two studies, with a maximum of eight days. In both studies the wounds showed no signs of maceration or odour when changed at this frequency. Reducing the number of dressing changes is cost-effective — neutral-type tulle-gras dressings often need to be changed daily.

Urgotul's pain-free removal could result in significant time savings and decrease the need for analgesia. Less time was needed to remove the dressing from the wound bed, and less than 20% of the children needed analgesia, principally paracetamol.

The two studies confirm the efficacy and safety of Urgotul, which offers patient comfort and clinical benefits, enhancing both concordance and parental satisfaction. ■

13 Alm, A., Hornmark, A.M., Fall, P.A. Care of pressure sores: a controlled study of the use of hydrocolloid dressing compared with wet saline gauze compresses. Acta Dermatol Venereol 1989; 149: (suppl), 1-10.

14 Gorse, G.J., Messner, R.L. Improved pressure sore healing with hydrocolloid dressings. Arch Dermatol 1987; 123: 766-771.

15 Thomas, S.S., Lawrence, J.C. Evaluation of hydrocolloids and topical medication in minor burns. J Wound Care 1995; 4: 5: 218-220.

16 Brotherston, T.M., Lawrence, J.C. Dressings for donor sites. J Wound Care 1993; 2: 2, 84-88.

17 Meaume, S., Senet, P., Dumas, R. et al. Urgotul: a novel non-adherent lipido-colloid dressing. Br J Nurs 2002; 11: 16 (Suppl), S42-50.

18 Directive 2001/20/EC. Implementation of Good Clinical Practice. European Parliament & Council, 2001.

19 Maio, R.F., Garrison, H.G., Spaite, D.W. et al. Emergency Medical Services Outcomes Project (EMSOP) IV: pain measurement in out-of-hospital outcomes research. Ann Emerg Med 2002; 40: 2, 172-179.

20 Kelly, A.M. Setting the benchmark for research in the management of acute pain in emergency departments. Emerg Med (Fremantle) 2001; 13: 1, 57-60.

21 Rossato, L.M., Angelo, M. Using tools for pain perception assessment in hospitalized pre-school children undergoing painful procedures. Rev Esc Enferm USP 1999; 33: 3, 236-249.

22 Agency for Health Care Policy and Research. Acute pain management: operative or medical procedures and trauma, Part 2. Clin Pharm 1992; 11: 5, 391-414.

23 Wilson, G.A., Doyle, E. Validation of three paediatric pain scores for use by parents. Anaesthesia 1996; 51: 11, 1005-1007.

24 Blanchet-Bardon, C., Bohbot, S. Urgotul in the management of skin lesions of epidermolysis bullosa. Results of a clinical study. J des Plaies et Cica-trisations 2002; 6: 32, 1-4.

25 Gotschall, C.S., Morrison, M.I., Eichelberger, M.R. Prospective, randomized study of the efficacy of Mepitel on children with partial-thickness scalds. J Burn Care Rehabil 1998; 19: 4, 279-283.

26 Barret, J.P., Dziewulski, P., Ramzy, P.I. et al. Biobrane versus 1% silver sulfadiazine in second-degree paediatric burns. Plast Reconstr Surg 2000; 105: 1, 62-65.

27 Ou, L.F., Lee, S.Y., Chen, Y.C. et al. Use of Biobrane in paediatric scald burns—experience in 106 children. Burns 1998; 24: 1, 49-53.

28 Bishop, J.F. Paediatric considerations in the use of Biobrane in burn wound management. J Burn Care Rehabil. 1995; 16: 3 (Pt 1), 331-3; discussion 333-334.

29 Palmieri, T.L., Greenhalgh, D.G. Topical treatment of paediatric patients with burns: a practical guide. Am J Clin Dermatol 2002; 3: 8, 529-534.

Restore Contact Layer with TRIACT technology,
Non-Adherent Dressing

DESCRIPTION
Restore Contact Layer is a non-adhesive, non-occlusive wound contact dressing composed of a polyester mesh impregnated with a matrix comprising of hydrocolloid particles (carboxymethyl cellulose), petrolatum and cohesion polymers.

INDICATIONS FOR USE
Restore Contact Layer is indicated in low to moderate exuding partial and full thickness wounds including:
- minor abrasions
- lacerations
- minor cuts, scalds and burns
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- diabetic ulcers
- pressure ulcers/sores (partial & full thickness)
- surgical wounds (left to heal by secondary intention, donor sites, and dermatological surgery)
- second degree burns
- traumatic wounds
- skin tears

The dressing may be used on infected wounds only under the care of a healthcare professional.

MECHANISM OF ACTION
The proprietary TRIACT technology specificity lies in the presence of a polymer matrix which ensures cohesion of hydrocolloid particles and petrolatum on a polyester mesh.

In contact with wound exudates, the hydrocolloid particles combine with the matrix to form a lipido-colloidal gel, providing a moist environment that promotes healing.
Being non-adhesive, removal of **Restore Contact Layer** is virtually pain-free and helps minimize damage to newly formed surrounding skin. It is ideal for use on wounds with fragile surrounding skin.

DIRECTIONS FOR USE
- Clean the wound using sterile saline solution.
- Choose a dressing size which ensures that the dressing will cover the entire wound.
- Remove the protective tabs from the dressing
- Apply the dressing directly to wound.
- Cover it with a secondary dressing and hold in place using a fixing bandage.
- **Restore Contact Layer** should be changed depending on the wound and the healing progression or after a maximum of seven days.

WARNINGS AND PRECAUTIONS
- **Restore Contact Layer** tends to stick to latex gloves. Moisten latex gloves with normal sterile saline prior to use.
- Do not re-use the dressing.
- Store the dressing flat and at room temperature.

CONTRAINDICATIONS
Restore Contact Layer should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or one of its components.

HOW SUPPLIED
Restore Contact Layer is supplied in 2 sizes:
4”x 5” (10 cm x 12 cm) and 6”x 8” (15 cm x 20 cm).
Each box contains 10 dressings.
Each dressing is individually packed in a sterile pouch.
Sterilized by radiation. Sterility is guaranteed unless a package is damaged or opened.
Single Use Only.

REF.: 509338: 4”x 5” (10 cm x 12 cm)
509339: 6”x 8” (15 cm x 20 cm)

Graphical Symbols
Symboles graphiques
Simbolos Gráficos


Attention: see instructions for use.
Attention: voir le mode d’emploi.
Atención: Vea las instrucciones de uso.


Single Use.
Usage unique.
No los use más de una vez.


Keep dry.
Conserver au sec.
Consérvelos secos.

USA: 1-800-323-4060
FAX Order: 847-680-1017
CANADA: 1-800-263-7400
FAX Order: 1-800-432-8846

ETATS-UNIS: 1-800-323-4060
Commande par télécopieur: 847-680-1017
CANADA: 1-800-263-7400
Commande par télécopieur: 1-800-432-8846

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Restore
TRIACT

INSTRUCTIONS/MODE D’EMPLOI/INSTRUCCIONES

Contact Layer,
Non-Adherent Dressing

Interface,
Pansement non-adhérent

Capa de contacto,
Apósito no adherente

STERILE
STÉRILE
ESTÉRIL

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Restore Interface avec la Technologie TRIACT,

Pansement non-adhésif

DESCRIPTION

L'interface Restore est un pansement non-adhésif, non-occlusif constitué d'une trame polyester imprégnée de particules hydrocolloides (carboxymethyl-cellulose), de polymères et de vaseline.

INDICATIONS

L'interface Restore est indiquée dans le traitement des plaies aiguës et chroniques, faiblement à modérément exsudatives, incluant :

- coupures superficielles
- dermabrasions
- ulcères veineux, artériels et mixtes
- ulcères du pied diabétique
- escarres
- plaies chirurgicales (site donneur de greffes, chirurgie dermatologique)
- brûlures du 2ème degré
- plaies traumatiques

Le pansement peut être utilisé sur des plaies infectées sous la surveillance d'un professionnel de la santé.

MODE D'ACTION

La spécificité de la technologie TRIACT réside dans la présence d'une matrice polymérique qui assure la cohésion des particules hydrocolloides et de la vaseline sur une trame polyester.

Au contact des exsudats, les particules hydrocolloïdes se gélifient et forment un gel lipido-colloïde, qui créé un environnement humide et favorise le processus cicatriciel. Le retrait de **l'interface Restore** est indolore et n'endommage pas les tissus néoformés. Ce pansement est recommandé dans le traitement des plaies présentant une peau péri-lésionnelle fragile.

MODE D'EMPLOI

- Nettoyer la plaie avec du sérum physiologique.
- Choisir une taille appropriée afin que le pansement recouvre toute la plaie.
- Retirer les ailettes de protection du pansement.
- Appliquer directement le pansement sur la plaie.
- Recouvrir avec un pansement secondaire et maintenir en place avec une bande de fixation.
- Renouveler **l'interface Restore** en fonction de la plaie traitée et de son évolution ou après 7 jours maximum.

MISES EN GARDE ET PRECAUTIONS D'EMPLOI

- **L'interface Restore** risque d'adhérer aux gants chirurgicaux (latex et vinyl). Il est recommandé d'humidifier les gants avec du sérum physiologique avant de le manipuler.
- Ne pas réutiliser le pansement.
- Stocker le pansement à plat et à température ambiante.

CONTRE-INDICATIONS

L'interface Restore ne doit pas être utilisée sur des personnes qui sont sensibles ou qui ont eu une réaction allergique au pansement ou à un de ses composants.

PRESENTATION

L'interface Restore est disponible dans deux tailles :
4"x 5" (10 cm x 12 cm) et 6"x 8" (15 cm x 20 cm).
Chaque boîte contient 10 interfaces.
Chaque pansement est conditionné individuellement sous sachet stérile.
Stérilisation par radiation. Le contenu est stérile sauf si l'emballage est ouvert ou endommagé.
Usage unique.

REF.: 509338 : 4"x 5" (10 cm x 12 cm)
509339 : 6"x 8" (15 cm x 20 cm)

Restore Capa de contacto con la Tecnologia TRIACT,

Apósito no adherente

DESCRIPCIÓN

Restore Capa de contacto es un apósito no adherente, no-oclusivo, compuesto por partículas de hidrocoloides (carboximetilcelulosa), de vaselina y de polímeros dispersas en una red de poliéster.

INDICACIONES

Restore Capa de contacto está indicado en heridas con poca a moderada exudación, incluyendo :

- cortes y abrasiones
- úlceras de pierna
- úlceras diabéticas
- úlceras por presión
- quirúrgica heridas (quirúrgica dermatológica)
- quemadura de segundo grado
- heridas traumáticas

El apósito se puede usar en las heridas infectadas, con un control de los profesionales de salud.

MODO DE ACCIÓN

La tecnología TRIACT consiste en asociar una matriz polimérica que garantiza la cohesión de las partículas hidrocoloides con una trama de poliéster impregnada de vaselina.
Las partículas hidrocoloides (CMC), al entrar en contacto con los exudados, forman un gel y forman, gracias a la matriz, una capa de contacto que crea las condiciones favorables para el proceso de cicatrización (cicatrización en medio húmedo).

Los cambios del **Restore Capa de contacto** no son dolorosos ni traumáticos. Está particularmente más indicado para heridas con piel alterada.

INSTRUCCIONES DE USO

- Limpiar la herida con suero fisiológico.
- Seleccionar un tamaño adaptado para que el apósito cubra toda la herida.
- Retirar las láminas protectoras del apósito.
- Aplicar directamente los apósitos sobre la lesión en una sola capa.
- Cubrir con un apósito secundario: compresas estériles sujetas con una venda de fijación.
- Los cambios de **Restore Capa de contacto** se realizarán cada 3 o 4 días, en función de la herida a tratar, de su evolución y de los signos clínicos o después 7 días.

PRECAUCIONES DE USO

- **Restore Capa de contacto** se adhiere a los guantes quirúrgicos (látex vinilo), así pues se recomienda humedecer los guantes con suero fisiológico para facilitar la manipulación.
- No uso el apósito de nuevo.
- Conservar el apósito en posición horizontal, a temperatura ambiente.

CONTRAINDICACIONES

- La trama **Restore Capa de contacto** no se debe utilizar en personas sensibles o que tienen reacciones alérgicas al soporte o a algunos de sus componentes.

PRESENTACIONES

Restore Capa de contacto está disponible en dos tamaños:
4" x 5" (10 cm x 12 cm) y 6" x 8" (15 cm x 20 cm)
Una caja contiene 10 apósitos.
Cada apósito esta acondicionado individualmente en sobre estéril.
Esterilizado por radiación. La esterilidad queda garantizada salvo si el paquete esta dañado o abierto.
Uso único.

REF.: 509338: 4"x 5" (10 cm x 12 cm)
509339: 6"x 8" (15 cm x 20 cm)