

Urgotul[®]: a novel non-adherent lipidocolloid dressing

Meaume S, Senet P, Dumas R, Carsin H, Pannier M, Bohbot S

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The enclosed peer-reviewed journal article is provided in the interest of free exchange of truthful scientific information. **Restore**[®] wound care dressings* are intended for single use in the management of partial- and full-thickness wounds.

In this article, the authors note that the contact layer dressing was left in place in some cases for five to 10 days. 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.)
- The Instructions for Use (IFU) is attached. The full IFU – written in English, French and Spanish – is available at: www.hollisterwoundcare.com/products/ifus.html

Urgotul[®]: a novel non-adherent lipidocolloid dressing

S Meaume, P Senet, R Dumas, H Carsin, M Pannier, S Bohbot

Dressing selection should have the main objectives of promoting and maintaining a favourable environment to facilitate healing (Eaglstain and Falanga, 1997). Most of the published clinical data support the use of dressings that promote microenvironmental factors, such as optimal oxygen tension, pH and humidity, which stimulate more rapid wound healing, in particular those that support a moist wound environment. In addition, the choice of dressing will be influenced by clinical factors, such as the type of wound, position, presence of debris or infection, level of exudate and patient comfort.

Further, an optimal wound dressing should meet the following criteria:

- Maintain a moist environment at the wound/dressing interface
- Remove excess exudate
- Have thermal insulation properties
- Allow gaseous exchange
- Be impermeable to bacteria, in and out of the wound environment
- Be free of particles and toxic wound contaminants
- Permit trauma and pain-free removal (Dealey, 1993).

Taking into account the fact that wound healing takes place in three phases (inflammation, tissue formation, and tissue remodelling) that overlap in time, it is unlikely that any one dressing will have an optimal performance for all of these stages (Singer and Clark, 1999).

The categories of modern wound dressings broadly include films, foams, hydrocolloids and alginates. Foams and alginates are generally appropriate for wounds with a significant amount of exudate (Morgan, 1996; Schultze et al, 2001). Hydrocolloids are designed for wounds with mild to moderate drainage. Films are used in superficial wounds with minimal drainage (Choucair and Phillips, 1998; Bradley et al, 1999; Briggs, 2000).

When granulation tissue is present, exudate levels low, and re-epithelization of wound underway these dressings may not be totally appropriate. In this instance, non-adherent silicone or perforated plastic film dressings, or petrolatum gauze are often used (Williams, 1995; Thomas, 1997; Dealey, 2000).

Such gauzes are regarded as hypoallergenic dressings; they act as interfaces that cling and conform to the wound without adherence. However, in practice this is not always the case (Thomas, 1990; Moody, 1995); because of the physiologically inert nature of petrolatum they can be used on any wound, acute or chronic.

Abstract

Urgotul[®] belongs to a new class of non-adherent dressings: the lipidocolloid dressings. It is composed of an open weave polyester mesh impregnated with hydrocolloid polymers dispersed within petrolatum. The first clinical trial data are presented. Efficacy and safety were evaluated in a multicentre non-comparative trial involving 92 patients treated to healing or up to 4 weeks. Adult outpatients with acute wounds (n=34), leg ulcers (n=24), other chronic wounds (n=14) or with second-degree burns (n=20) were included. Results showed 32.4% (n=11) of the acute wounds, 12.5% (n=3) of the leg ulcers and 14.3% (n=2) of the other chronic wounds completely healed before 4 weeks. Surface areas decreased on average by 76.4%, 63.5% and 44.2% at study endpoint respectively. For burns, 19 patients healed (95%) within 5–19 days.

A total of 771 dressing changes were performed during the course of the study. Dressing application was considered as easy or very easy in 90% or more of the changes and there was no difficulty in removing the dressing in about 95% of the cases. Safety was good with five reports of a transitory local adverse event, probably dressing-related, being observed. Two patients (2.2%) prematurely stopped treatment because of moderate periwound erythema. Urgotul[®] is a highly promising new dressing which is currently undergoing further, comparative, clinical evaluations.

Nevertheless, owing to their non-existent absorbency, secondary absorbent dressings may be required. Currently, such impregnated gauze dressings are widely used in burns therapy and acute wounds, and to a lesser extent in the treatment of chronic wounds (Lawrence, 1993; Moody, 1995; Williams, 1995; Dealey, 2000).

In order to combine desirable properties of hydrocolloids with those of petrolatum gauze, a new generation of dressing has been developed, the lipidocolloid dressings. The first representative of this new class of dressing is Urgotul[®]

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(Urgo, France). The characteristics of this material appear to be particularly adapted to the treatment of the granulation and re-epithelization stages of the healing process, both in acute and chronic wounds (Benbow, 2002; Dumas and Meaume, 2000; Pannier et al, 2000).

Urgotul®: a new non-adherent petrolatum and hydrocolloid impregnated dressing

Urgotul® is composed of a 100% polyester crosswise open weave impregnated with hydrocolloid polymers dispersed within a petrolatum impregnated mesh. Its macroscopic aspect is that of a non-greasy light and soft gauze which adapts itself easily to wound shape (*Figures 1a* and *1b*). Urgotul® will not fray, so no microfibrils will be released into the wound.

In contact with exudate, hydrocolloid polymers are hydrated and constitute with the petrolatum part of the dressing, a lipidocolloid interface which is designed to reduce adhesion to the wound surface. Urgotul® has an appreciable fluid absorbent capacity.

The lipidocolloid interface is very cohesive, preventing release of petrolatum on to the wound surface and facilitating dressing removal. In addition, the open weave of the polyester is non-deformable and maintains the 500µm size when impregnated, thus reducing the growth of granulation tissue growing through and the consequent risk of trauma on removal. This dressing maintains a pH of 6.5–7.5, according to the wound environment.

Urgotul® is indicated for the treatment of superficial acute or chronic exuding wounds at the granulation and re-epithelization stages of the healing process. It is a non-adherent primary wound contact layer that should usually be changed every 2–3 days, but can be left in place for longer (6 days) on low or lightly exuding wounds. As a result of the low adherence to the wound, painfree and non-traumatic (no bleeding) removal are to be expected (Moody, 1992; Hollinworth, 1995; Williams, 1996). In practice, this has been found to be the case (Benbow, 2002)

Clinical experience with Urgotul®

Methods

The efficacy and safety of Urgotul® were evaluated in a multicentre non-controlled clinical trial involving a total of 92 patients followed up to healing or up to 4 weeks. This trial was approved by the relevant ethics committees and written agreement obtained before the start of treatment.

Patients aged 18 years or over, with acute (duration of wound \leq 28 days) or chronic (duration >28 days) wounds were included by 20 centres in France. Only clean/debrided wounds of surface area less than 100cm², without signs of infection, and of any aetiology except cancerous lesions, were included.

At the inclusion visit, a complete patient history was recorded, clinical evaluation of the wound performed, including photograph and planimetry measurement, and the first Urgotul® dressing was applied after cleansing the wound with physiological saline.

Thereafter, patients were seen at least once per week for evaluation or more often for dressing changes, as required. At

Figure 1a. Microscopic view of the Urgotul® weave showing fibres coated with lipidocolloid.

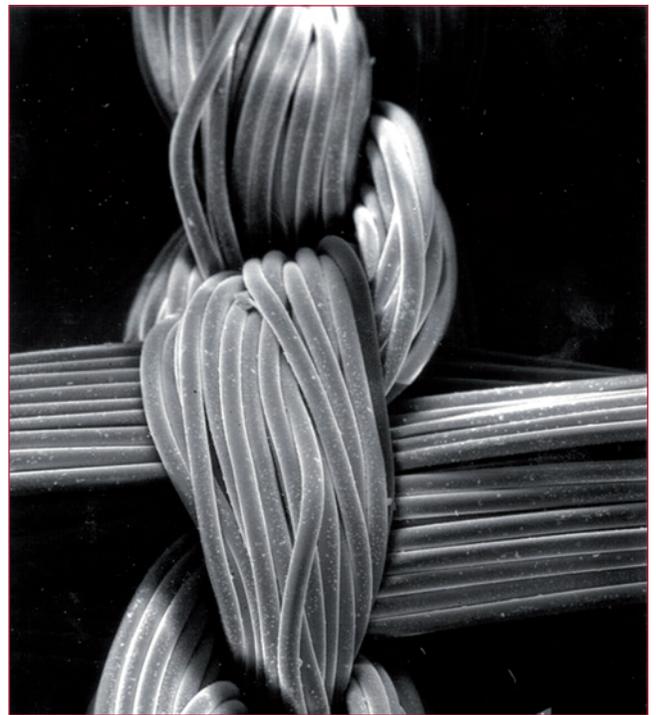


Figure 1b. Microscopic view of a typical paraffin gauze showing absence of ordered fibres.



each evaluation the general appearance of the wound, surface area and dressing tolerability (i.e. signs of local erythema, pain, maceration, malodour, bleeding, infection) were recorded.

After the inclusion of 72 patients with acute or chronic wounds, the trial was extended to include partial-thickness burns. Seven burn units participated in the extension of this study. Patients with clean, non-infected second-degree burns of less than 200cm² area, and any origin or location, were enrolled.

At the inclusion visit the general appearance of the lesion and planimetry were recorded. Urgotul® was applied after usual lesion cleansing (*Figure 2*). Patients were then seen on a

Figure 2. Urgotul® dressing in position on leg wound showing dressing texture and conformability.



weekly basis up to healing or up to 4 weeks for evaluations or more often, as required, for dressing changes. At each visit, surface area and dressing conformability, adhesion and tolerability were recorded.

Data from all 92 patients enrolled were included in the descriptive analysis. The progress of wound surface area over the 4-week follow-up period (digitized from the tracings by planimetry) was calculated with the last observed value carried over. Tolerability and local or general adverse events were descriptively reported. No statistical tests were performed. Results are presented as means or percentages.

Results

Patients

Seventy-two patients with acute or chronic wounds (excluding burns) were enrolled in the first part of the trial (Table 1). The main baseline characteristics of these subjects are presented in Table 1. Fifty-four per cent ($n=39$) of the patients were females. The mean age of the population ranged 68–73 years. Thirty-four wounds were acute with a mean duration of 10.2 days; these were mainly of a traumatic or postoperative aetiology and were located on the lower limbs in most cases. Their mean baseline surface area was $19.1 \pm (\text{SD}) 21.0 \text{cm}^2$.

Among the 38 chronic wounds, 24 were leg ulcers (venous or arterial; mean baseline area: $19.1 \pm 35.5 \text{cm}^2$) and were present for 9.6 months on average (in one case a 2-day-old recurrent venous ulcer was classified as a chronic wound). The other 14 chronic wounds (mean duration of 3.2 months, mean baseline surface area $10.3 \pm 7.2 \text{cm}^2$) were principally pressure ulcers (five cases) or amputation stump wounds (four cases). On inclusion 25% and 50% of acute and chronic wounds were in turn completely covered with granulation tissue.

In the series of burned patients (Table 2), 20 subjects with partial-thickness second-degree burns were included. Their mean age was 39.5 years. They were seen on average 2.3 days after the injury. The site of the burn was mainly the lower limbs and the hands.

Drop-outs

Fifteen patients (20.8%) out of the 72 first included patients dropped out (Table 3). Main reasons for this were hospitalization (four cases) and need for skin grafting (four cases). The remainder dropped out for other unrelated reasons. Occurrence of a local adverse event or wound deterioration were reported in two and three patients respectively. One dropout was reported in the 20 burned patients. In this patient a partial necrotic zone appeared at treatment day 20 and the continued use of Urgotul® was regarded as clinically inappropriate.

Healing rate

In the first part of the study, 16 wounds (22.2%) healed before the end of the 4-week follow-up period. The percentage of patients who healed in this period was 32.4%, 12.5% and 14.3% respectively in the acute wounds, leg ulcers and other chronic wounds (see Table 3).

Compared with baseline values, surface areas decreased on average by 76.4%, 63.5% and 44.2% respectively at study end point in the acute, leg ulcers and chronic lesions.

Regarding the burned lesions, 19 patients healed (95.0%) during the course of the study. Complete healing was obtained within 5–19 days (11.0 ± 4.5 days on average).

Dressing changes

In the first part of the study, 771 dressing changes were performed (Table 4); this was approximately 11 changes per wound. Urgotul® was changed every 2–2.3 days on average but was left in place in some cases from 5–10 days. Dressing application was considered as ‘easy’ or ‘very easy’ in over 90% of the changes and no instance of ‘difficult to remove’ recorded. Dressing changes were generally painless and maceration not observed. The conformability of the dressing to the wound shape was considered as appropriate in almost all of the acute wounds and less often in chronic wounds (poor conformability noted in 11% and 14% of the changes respectively). No or slight adhesion of the dressing was observed in more than 90% of dressing changes.

In the burns group, 97 dressing changes were conducted. Dressing application and removal were considered as ‘easy’ or ‘very easy’ in 81% and 79% respectively of the changes. The wear time ranged from 2–5 days (mean 2.5 days). As

Table 1. Baseline patients' characteristics (72 first inclusions)

	Acute wounds (n=34)	Chronic wounds (n=38) Leg ulcers (n=24)	Others (n=14)
Sex (F/M)	50.0%/50.0%	62.5%/37.5%	50.0%/50.0%
Age (mean years)	73	72	68
Body weight (kg; mean)	68	71	67
Duration of the wound (means and extremes)	10.2 days (0–28 days)	9.6 months (2 days–36 months)	3.2 months (1–8 months)
Type of wounds and frequency			
Postoperative wound	20	–	–
Traumatic wound	11	–	2
Pressure ulcer	2	–	5
Leg ulcer	–	24	–
Amputation stump	1	–	4
Burn sequelae	–	–	3
Wound sites (number of patients)			
Abdominal	5	0	0
Pelvic girdle	0	0	3
Upper limbs	1	0	1
Lower limbs	22	23	7
Heel	3	1	3
Other	2	0	0
Mean wound surface area (cm ²) (mean ± SD and extremes)	19.1±21.1 (0.6–103.9)	19.1±35.5 (0.2–170.5)	10.3±7.2 (0.6–30.4)
Granulation tissue over whole surface (% of wounds)	50%	25%	43%
Previous dressing (% of wounds)			
None	29%	–	–
Petrolatum dressings	29%	48%	57%
Hydrocolloids	12%	13%	14%
Alginates	15%	17%	21%
Others	15%	22%	7%

anticipated, dressing changes were less frequently reported as painless compared with the acute and chronic wounds. Conformability was considered 'very good' in 62% of the cases (the remaining 38% where conformability was less were especially burns located on the fingers). No adherence of the dressing to the wound was noticed in 67% of the cases.

Local tolerability

In ulcers, acute and chronic wounds, a total of seven local adverse events (Table 5) were recorded in seven patients (7.6% of the total population). Three of these patients were treated for an acute wound. In two cases only, the occurrence of periwound erythema was the reason to stop the study dressing. In chronic wounds, one extension of ulceration of the wound edges was observed in a patient treated for an amputation stump wound, and a transitory overgranulation was noted in a post-traumatic wound. For the other events there was no causal relation to Urgotul®.

In two patients (10.0%) out of the 20 treated for second-degree burns, a local adverse event was reported, considered by the investigators as 'probably' related to the dressing. This was a slightly painful and transitory inflammatory reaction in one case and a painful removal of the dressing on one occasion in the other. Otherwise, these two events did not justify the stopping of Urgotul® application.

Discussion and Conclusions

It is vitally important that the delicate newlyformed tissues that appear in wounds undergoing granulation and re-epithelization are protected from trauma. Since the development of tulle gras in the early 20th century there have been many dressing developments for superficial or partial-thickness wounds. Not all of these have been successful as non-adherent and painfree products (Williams, 1996; Schultze et al, 2001).

Table 2. Baseline patients' characteristics (burns)

Patient characteristics	Burns (n=20)
Sex (F/M)	45.0%/55.0%
Age (years)	39.5 (extremes 19–83)
Body weight (kg)	70.0 (extremes 49–100)
Delay between burn and first care with Urgotul®	2.3 days (extremes 0.5 hours– 15 days)
Wound sites	Number of patients
Hands	6
Thorax	2
Abdomen	1
Upper limbs	4
Lower limbs	7

	Acute wounds (n=34)	Chronic wounds (n=38) Leg ulcers (n=24)	Others (n=14)	Total wounds (n=72)	Burns (n=20)
Healed before 4 weeks	11 (32.4%)	3 (12.5%)	2 (14.3%)	16 (22.2%)	19 (95.0%)
4-week study completers	15 (44.1%)	16 (66.7%)	10 (71.4%)	41 (56.9%)	–
Drop-outs	7 (20.6%)	6 (25.0%)	2 (14.3%)	15 (20.8%)	1 (5.0%)
Local adverse event	2 (5.9%)	0 (0.0%)	0 (0.0%)	2 (2.7%)	–
Skin grafting	2 (5.9%)	2 (8.3%)	0 (0.0%)	4 (5.6%)	–
Wound deterioration	0 (0.0%)	1 (4.2%)	2 (14.3%)	3 (4.2%)	1 (5.0%)
Osteitis	0 (0.0%)	1 (4.2%)	0 (0.0%)	1 (1.4%)	–
Death	1 (2.9%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	–
Hospitalization	2 (5.9%)	2 (8.3%)	0 (0.0%)	4 (5.6%)	–

Acute	Leg wounds	Chronic ulcers	wounds	Burns
Number of documented dressing changes	363	247	161	97
Mean wear times (days)	2.0	2.3	2.3	2.5
(mean and extremes)	(1–6)	(1–10)	(1–5)	(2–5)
Numbers (%) of changes with the following characteristics				
Very easy or easy dressing application	352 (96.9)	198 (80.2)	145 (90.0)	79 (81.4)
Very easy or easy dressing removal	349 (96.1)	242 (97.9)	159 (98.8)	78 (80.4)
No pain at dressing removal	283 (77.9)	188 (76.1)	127 (78.9)	71 (73.2)
No smell	330 (90.9)	217 (87.9)	127 (78.9)	93 (95.9)
No bleeding at dressing removal	301 (82.9)	227 (91.9)	135 (83.9)	88 (90.7)
No or minimal maceration	305 (84.0)	202 (81.8)	108 (67.1)	87 (89.7)
Very good or good conformability to the wound shape	359 (98.9)	221 (89.5)	138 (85.7)	59 (60.8)
No or slight adhesion to the wound	330 (90.9)	233 (94.3)	156 (96.9)	65 (67.0)

There is a need for a dressing that can remain in place, without adhering, and be painfree and non-traumatic on removal in the treatment of burns, fixation of grafts, abrasions, and chronic wounds. Urgotul® is the first of a new generation of wound dressing, the lipidocolloid dressings. It is an interface (wound contact layer) dressing well designed to treat acute or chronic wounds at their granulation and re-epithelization stages.

This clinical study was aimed at evaluating the tolerability of this new material in various types of wounds and anatomical location. A total of 92 patients were treated over 4 weeks for second-degree burns, acute wounds, and leg ulcers or other chronic wounds. A total of 868 dressing

changes were conducted. Ease of dressing application and removal were rated as 'excellent' in most of the cases; the dressing did not promote maceration, bleeding or pain. Its conformability to the shape of the wounds was generally good and inappropriate adhesion of the dressing was regarded as a problem in only a single instance.

While this study was not designed to evaluate healing rate, the data collected over a 4-week treatment period are nonetheless encouraging. Urgotul® constitutes a highly promising new generation of dressing which merits further clinical evaluations.

BJN

Benbow M (2002) Urgotul: an alternative to conventional non-adherence dressings. *Br J Nurs* 11(2): 135–8

Bradley M, Cullum N, Nelson EA, Petticrew M, Sheldon T, Torgerson D (1999) Systematic reviews of wound care management: (2) Dressing and topical agents used in the healing of chronic wounds. *Health Technol Assess* 3(17; part 2): 1–35

Briggs MN (2000) Topical agents or dressings for pain in venous leg ulcers. *Cochrane Database of Systematic Reviews* 2: CD001177

Choucair M, Phillips T (1998) A review of wound healing and dressing materials. *Skin and Ageing* June(Suppl): 37–43

Dealey C (1993) Role of hydrocolloids in wound management. *Br J Nurs* 2(7): 358–64

Dealey C (2000) *The Care of Wounds*. Blackwell Science, London

Dumas R, Meaume S (2000) Clinical evaluation of a very new wound dressing, in the local treatment of acute and chronic wounds. Kongress der Deutschen Gesellschaft für Wundheilung und Wundbehandlung, 29 June–1 July, Würzburg, Germany

	Acute wounds	Leg ulcers	Chronic wounds	Burns
Peri wound erythema	2			
Peri wound ulceration			1	
Overgranulation			1	
Bleeding	1			
Pain and inflammatory reaction				1
Pain to dressing removal (adhesiveness)				1

-
- Eaglstein WH, Falanga V (1997) Chronic wounds. *Surg Clin N Am* **77**: 689–700
- Hollinworth H (1995) Nurses' assessment and management of pain at dressing changes. *J Wound Care* **4**(2): 77–83
- Lawrence JC (1993) Medicated tulle dressings. *J Wound Care* **2**(4): 240–3
- Moody M (1995) Principles of wound management. In: Bennett G, Moody M, eds. *Wound Care for Health Professionals*. Chapman & Hall, London
- Moody M (1992) Looking for non-adherence. *Nurs Times* **88**(19): 65–6
- Moody M (1995) Wound dressings. In: Bennett G, Moody M, eds. *Wound Care for Health Professionals*. Chapman & Hall, London: 49–64
- Morgan D (1996) Alginate dressings. *J Tissue Viabil* **7**(1): 4–14
- Pannier M, Meaume S, LeFourn B, Bohbot S (2000) Evaluation clinique d'un nouveau pansement original URGO dans le traitement des pertes de substance aiguës ou chroniques. 4th Conférence Plaies et Cicatrisations, 16–18 Janvier, Paris, France
- Schultze HJ, Lane C, Charles H, Ballard K, Hampton S, Moll I (2001) Evaluating a superabsorbent hydropolymer dressing for exuding venous leg ulcers. *J Wound Care* **10**(1): 511–18
- Singer AJ, Clark RAF (1999) Cutaneous wound healing. *N Engl J Med* **341**(10): 738–46
- Thomas S (1997) A guide to dressing selection. *J Wound Care* **6**(10): 479–82
- Thomas S (1990) *Wound Management and Dressings*. The Pharmaceutical Press, London
- Williams C (1995) Mepitel. *Br J Nurs* **4**(1): 51–5
- Williams C (1996) Painful dressings. *J Tissue Viabil* **6**(3): 69–70

KEY POINTS

- Urgotul® is a new lipidocolloid dressing for use on acute and chronic wounds.
- Preliminary clinical trial data show Urgotul® to be safe and effective on partial-thickness burns, and a variety of acute and chronic wounds.
- The combination of hydrocolloid polymers and petrolatum gives the dressing its specific properties and represents an alternative to conventional or modern wound dressings.
- Further comparative clinical trials are underway to establish the relative effects of the Urgotul® dressing on the healing process.

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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.

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Restore



INSTRUCCIONES/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 hydrocolloïdes (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 hydrocolloïdes et de la vaseline sur une trame polyester.

Au contact des exsudats, les particules hydrocolloïdes se gélifient et forment un gel lipido-colloïde, qui crée 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 Tecnología TRIACT, Apósito no adherente

DESCRIPCIÓN

Restore Capa de contacto es un apósito no adherente, no-occlusivo, 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)