

The importance of pain reduction through dressing selection in routine wound management: the MAPP study

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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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The importance of pain reduction through dressing selection in routine wound management: the MAPP study

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The importance of pain reduction through dressing selection in routine wound management: the MAPP study

- **Objective:** To discover the incidence of pain in patients with acute or chronic wounds of various causes during dressing removal, and the effect of switching to a non-adherent dressing.
- **Method:** A total of 656 primary care physicians reported the relevant details of all acute or chronic wounds observed during routine visits throughout the study period. The pain experienced during dressing changes was systematically evaluated. In patients with moderate to severe pain, a more extensive evaluation was performed and they were invited to complete a self-evaluation questionnaire. If the patients were seen at a subsequent visit, a new evaluation was performed.
- **Results:** In total 5850 patients were seen: 2914 with acute wounds and 2936 with chronic wounds. During dressing changes, a similar number of patients with acute and chronic wounds reported 'moderate to severe' pain during the medical screening visit (79.9% and 79.7%) and 'very severe' pain in their self-evaluation questionnaire completed at home (47% and 59% respectively). Dressing removal was most painful when there was adherence to the wound bed. Switching to a new, non-adherent dressing reduced pain during dressing changes in 88% of patients with chronic wounds and 95% of patients with acute wounds.
- **Conclusion:** This study demonstrates that similar problems with patient acceptability arise irrespective of wound aetiology. Pain is a major problem and is most often related to dressing selection. Selecting a suitable, non-adherent dressing improves patient acceptability.
- **Declaration of interest:** This study was sponsored by Laboratoires Urgo.

dressing removal; wound bed adherence; pain; non-adherent dressing

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Successful wound management includes local and general therapeutic interventions such as pressure off-loading, compression therapy, appropriate debridement, management of exudate^{1,2} and selection of the appropriate dressing for the particular phase of healing.³

However, other factors that may affect wound healing have been less exhaustively evaluated. Pain is one of the most common complaints made by patients with acute wounds, yet it remains largely unrecognised in chronic wound management.⁴

As many as 80% of patients with pressure ulcers have experienced severe and constant pain, as have patients with venous leg ulcers, with dressing removal being one of the most painful local care procedures.⁵⁻⁹ Furthermore, while the importance of administering local analgesics has been evaluated, the role of dressings in pain management is largely unknown.¹⁰

To evaluate the extent and importance of wound pain during dressing removal, a prospective cohort survey was conducted.

Method

The principal objective of the study was to determine the proportion of patients with chronic and acute wounds experiencing 'moderate to severe' pain during dressing change.

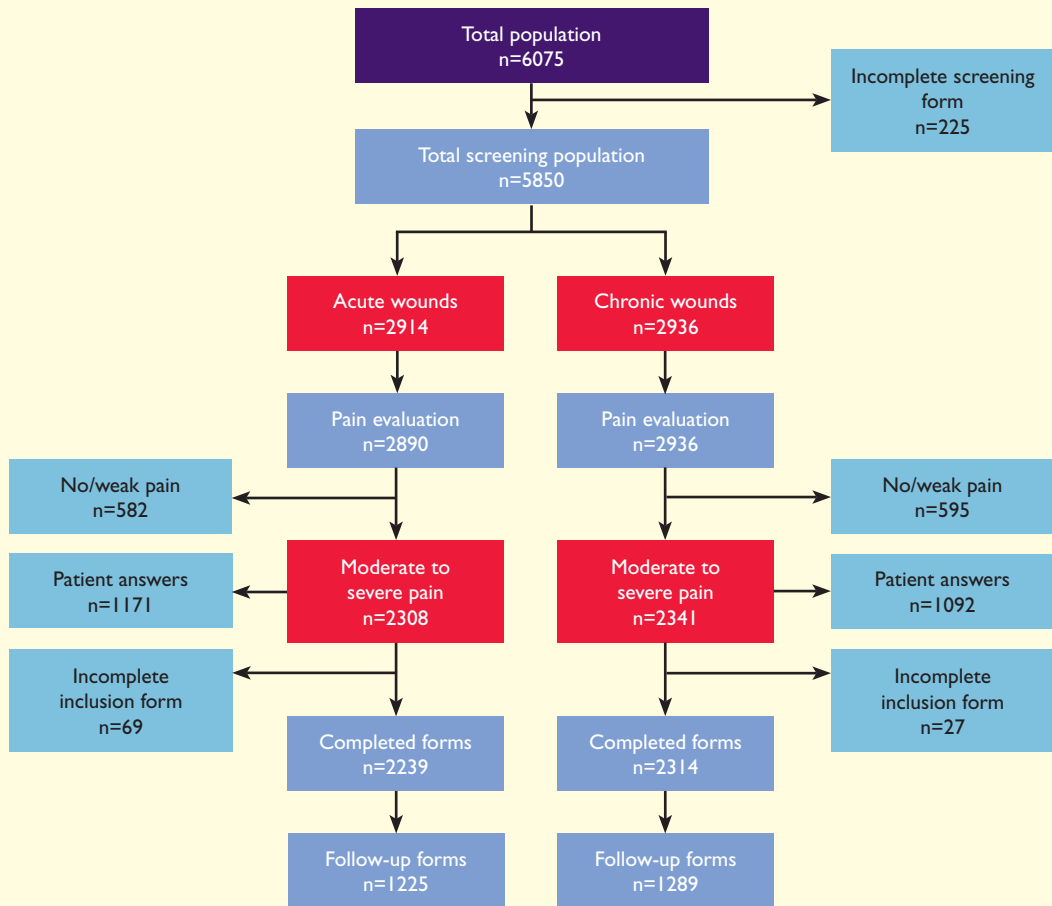
The following were recorded for each patient:

- Age
- Gender
- Wound aetiology
- Wound location (the largest wound when more than one lesion was present)
- Type of dressing last applied.

At their routine visits to their primary care physician for the treatment of the chronic or acute wound, all patients were asked to score the intensity of the pain they had experienced during the dressing change on a subjective four-point scale: none, minor, moderate or severe. When moderate or severe pain was reported, additional parameters were recorded, namely wound duration, largest and smallest wound axes and appearance.

A more extensive pain questionnaire documented the presence and intensity of spontaneous pain and the most painful local wound-care procedures.

Fig 1. Patient flow chart



References

- 1 Cullum, N., Nelson, E.A., Flemming, K., Sheldon, T. Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy. *Health Technol Assess* 2001; 5: 9, 1-221.
- 2 O'Meara, S., Cullum, N., Majid, M., Sheldon, T. Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration. *Health Technol Assess* 2000; 4: 21, 1-237.
- 3 Bradley, M., Cullum, N., Nelson, E.A. et al. Systematic reviews of wound care management: (2). Dressings and topical agents used in the healing of chronic wounds. *Health Technol Assess* 1999; 3: 17 (part 2), 1-35.
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Any local care procedures performed during the visit were noted along with the type of dressing selected. Two questionnaires were then completed. Patients completed one at home (and posted it to the coordinating centre) after 15 days of regular local care for acute wounds or 30 days for chronic wounds. This questionnaire asked patients to:

- Report who was responsible at home for their wound care
- Evaluate any difficulties encountered during local care procedures and report the pain intensity (no pain or always weak, moderate most of the time, severe most of the time, always very severe) and compare it with their experience before the last medical visit
- Score any apprehension experienced while receiving wound care
- Document the usual attitude adopted by health professionals if they complained of pain during local care procedures
- Specify whether or not they would agree to continue with the latest dressing prescribed.

The second questionnaire was completed (and sent to the coordinating centre) by the health professional managing the patient's wound. It comprised questions about the practitioner's usual

approach to the management of a painful wound.

Corresponding investigator and patient questionnaires were identified with the same pre-printed number. Each investigator screened patients until 10 painful wounds had been evaluated or, if none of the wounds met the selection criteria, until 30 wounds had been screened.

If the patients were seen at a subsequent visit, a follow-up form was completed to report the wound outcome.

Investigator and patient questionnaires were sent to a coordinating centre (VERTICAL, Paris, France). All data were entered using Microsoft Access software and analysed by Unistat 5.0 (Unistat, England). Results are presented as means (± SD) or percentages with a 95% confidence interval (95% CI). Continuous variables were compared using the Student's t-test. Categorical variables were compared using the chi-square test.

Results

From February to August 2002, 656 investigators spread evenly throughout France reported on a total of 6075 wounds and completed a screening form for 5826 (patients included in the analysis): 2890 acute and 2936 chronic wounds (Fig 1).

- The acute wound population was predominantly male (56.4%) and generally younger (mean age: 45.8 years) than the chronic wound population
- The chronic wound population was mainly female (66.2%)
- Irrespective of wound aetiology, female patients were older (mean age: 64.8 years)
- Fifty-seven per cent of acute wounds were secondary to injury, 30% were burns and 13% were of 'another' cause (mainly secondary to a surgical procedure)
- A total of 66% of chronic wounds (out of 2936) were leg ulcers (of these, 66% were venous, 18% arterial, 16% post-phlebotic), 16% were pressure ulcers, 8% were diabetic foot ulcers and 11% (308 wounds) were classed as 'other' — these corresponded mainly to chronic post-traumatic or post-surgical wounds
- More than 23% of the study population had more than one chronic wound.

The following dressings were used at the screening visit:

- Simple wet or dry gauze was used (alone or in combination with another dressing) to treat 48% of acute and 19% of chronic wounds
- Paraffin gauze was used to treat 34% of acute and 27% of chronic wounds
- Hydrocolloid and foam dressings were applied on 12% of acute wounds and 41% of chronic wounds. Other dressing types were used respectively in 12% and 21% of cases. More than one type of dressing was sometimes used on individual wounds.

The prevalences of painful dressing changes were as follows:

- A total of 79.9% (95% CI: 78–81%) of patients with acute wounds and 79.7% (95% CI: 78–81%) of patients with chronic wounds reported when interviewed by their physician at the screening visit that their dressing change had been either moderately or severely painful
- The proportion of painful dressing changes was similar for pressure ulcers, leg ulcers, burns and traumatic wounds (Fig 2)
- The least painful wounds were those classified as 'other' and diabetic ulcers.

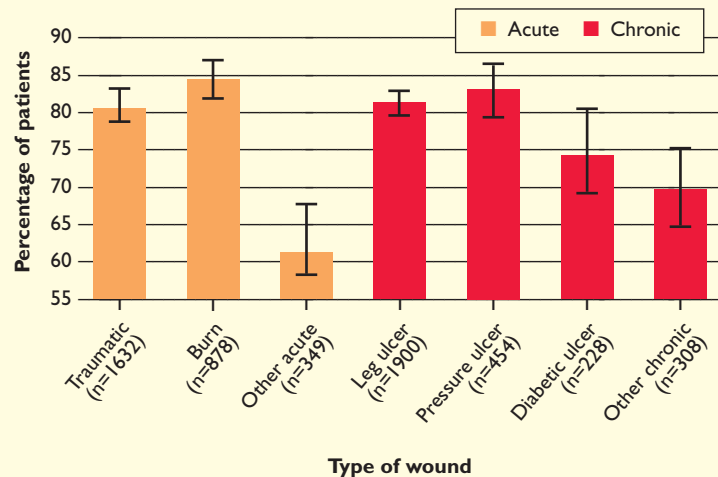
Patients with acute wounds reporting severe pain were:

- Slightly younger on average than those with moderate pain (42.2 ±19.5 versus 46.1 ±20.8 years; $p < 0.001$)
- Seen sooner after the injury (4.1 ±3.9 versus 5.6 ±7.8 days; $p < 0.001$)
- Had larger wounds across their longest dimension (7.2 ±5.0 versus 5.7 ±3.9cm; $p < 0.001$).

Patients with chronic wounds:

- Showed no differences for age when the population was stratified according to pain severity (72.5 ±1.03 versus 72.1 ±12.7 years for severe and moder-

Fig 2. Percentage (and 95% CIs) of screened patients with moderate to severe pain at dressing changes



- Had a similar wound duration (6.0 ±10.0 versus 6.1 ±11.5 months; $p = 0.874$)
- Had a slightly longer main wound axis on average when severe pain was reported at the latest dressing change (5.5 ±4.1 versus 4.8 ±3.4cm; $p < 0.001$).

Characteristics of the pain reported

Eighty-three per cent of patients with acute wounds who reported pain at dressing changes also experienced spontaneous pain. This was continuous in 16% of traumatic wounds and up to 24% of burns. In chronic wounds these figures were 77% and 10–13% respectively. This pain was scored as often 'very severe' in 7–11% and 11–15% respectively and was responsible for nocturnal awakenings in 42–58% and 46–53% of the cases, depending on the wound origin.

Moderate to severe pain at dressing change was reported at all changes in 56% of acute and 46% of chronic wounds. Dressing removal was the most painful operation during local care in acute wounds for 85% of the patients. In chronic wounds, wound cleansing was reported as frequently painful (97% versus 98% of the patients). Pain at dressing removal was scored by patients as 'sometimes' or often 'very severe' in 47% and 59% of the cases with acute and chronic wounds respectively. The most painful dressing-related event was adherence to the wound surface, which was reported in 55% of the acute wounds and 38% of the chronic wounds.

There was a trend for patients who experienced severe pain at dressing changes to report spontaneous pain more frequently than those had moderate pain (90% versus 80% for acute wounds and 90% versus 72% for chronic wounds).

Prescription of analgesia

Few patients (3–5%) suffering from wound-induced pain received local analgesics (Emla cream, Astra-Zeneca) during their care. Oral analgesics were prescribed for 42% of patients with acute wounds and 45% with chronic wounds.

Local and/or oral analgesics were more frequently prescribed when patients reported severe pain than moderate pain (74% versus 49% of patients with chronic wounds and 57% versus 39% of patients with acute wounds).

Follow-up visits

Some 1225 patients with acute wounds and 1289 patients with chronic wounds who reported moderate to severe pain during the dressing change were seen at a routine follow-up visit. In 1023 acute wounds and 856 chronic wounds the original dressing was replaced by Urgotul (Laboratoires Urgo, France) to reduce pain during dressing change.

Urgotul is a non-adherent, non-occlusive hydrocolloid dressing comprising a polyester net impregnated with hydrocolloid particles dispersed in a petroleum jelly matrix. Upon contact with wound exudate, it forms a lipidocolloid interface that creates a moist environment and allows painless and non-traumatic removal in adults and children.^{11–15}

Results with Urgotul

Switching to the new dressing decreased complaints of pain — the dressing was less painful or not at all painful in 95% of the acute group and 88% of the chronic group.

Patients with acute wounds were followed up for a median of 10 days post-screening and those with chronic wounds for a median of 23 days. Of the patients with acute wounds, 99.1% healed or improved. The corresponding figure for chronic wounds was 85.3%.

Sixty-nine per cent of patients with leg ulcers received compression bandaging and 64% of diabetic ulcers were off-loaded.

The investigators asked patients about pain on dressing removal. During treatment with Urgotul, the prevalence of pain fell to 18% in acute wounds and 17% in chronic wounds.

The number of dressings adhering to the wound surface ranged from 1.4% (burns and leg ulcers) to 3.7% (diabetic ulcers). In chronic wounds the prevalence of dressing changes noted as 'no more' or 'less' painful was 69.2%, even when wound status was unchanged or worse (n=117). Dressing removal was painless in 70.6% of these patients.

This was confirmed independently by patient replies to the questionnaire provided at screening. When compared with the period prior to the dressing switch, 95% of the patients with acute wounds reported 'no more' or 'less pain' during dressing

changes. This reached 88% for chronic wounds. Some 11% of patients with acute and 12% with chronic wounds reported pain during all dressing changes in the follow-up period. A total of 83% of patients reported that since switching dressings they were substantially less anxious before wound treatment. Finally, when asked whether they would agree to continue with the same dressing, 80% in the acute group and 71% in the chronic group answered 'certainly yes'.

Nurses' opinion

The nurses responsible for regular local wound management were issued with a questionnaire. A total of 707 nurses completed it. Of these:

- Pain was considered a major problem during wound-care procedures, irrespective of the nature of the wound, in 502 cases (70.1%)
- Dressing removal and wound cleansing were considered the most painful steps in the local care of acute wounds in 558 cases (79%) compared with 445 (63%) for chronic wounds
- Forty-nine (11%) stated that they never used analgesics when dressing wounds
- Sixty-two (14%) systematically used analgesics
- When patients complained of pain, 417 (59%) used analgesics
- If pain was severe, 262 (37%) used analgesics only
- A total of 113 (16%) often used analgesics depending on the nature of the wound.

Discussion

It should be noted that this was only an observational study, with no inclusion criteria except the presence of pain during care. However, the results show that most of the wounds, acute or chronic, are painful in outpatients and underestimated by physicians.

MAPP (Médecine Ambulatoire Plaies et Pansements, or Ambulatory Medicine Wounds and Dressings) is one of the largest prospective surveys of an unselected patient population to evaluate the prevalence of pain in acute and chronic wounds to be published.

Patients were involved in order to obtain the best perceptions about the pain intensity experienced during local wound care for both acute and chronic wounds. Patients' opinions were recorded during medical visits and independently at home.

The study population's characteristics accurately reflect the patient population routinely seen at surgeries for the management of acute and chronic wounds. It is impossible to assess how representative the participating investigators were — they were selected solely on the basis of their potential to encounter chronic wounds. That said, they were evenly distributed throughout France in an attempt to avoid bias.

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One of the most striking results was the very high prevalence of pain during dressing changes. While burns were the most painful lesions, pain prevalence was not substantially different for leg ulcers or pressure ulcers. The high prevalence of pain in patients with diabetic ulcers was surprising, but the investigators often classified any diabetic patient's lesion (neuropathic or not) as a diabetic ulcer.

Despite this, analgesics were prescribed infrequently, although the rate for patients complaining of severe pain was higher. Nonetheless, 26% of patients with chronic wounds and 43% with acute wounds were not prescribed analgesics.

Dressing removal appeared to be the most painful procedure and was responsible for very severe discomfort in around half the patients. This was clearly related to the infrequent use of 'modern' dressings in this population. In fact, most of the patients were treated with simple gauze or simple paraffin gauze (tulle) dressings, irrespective of the type of wound and volume of exudate, and many of these dressings adhered to the wound. These dressings were used because French physicians do not receive education on wound management and they are cheaper than modern wound dressings.

Switching to the new dressing resulted in fewer complaints of pain among the study subjects — the dressing was less painful or not at all painful in 95% of the acute group (95% and 86% in healed/improved wounds and in unchanged/aggravated wounds respectively) and in 88% of the chronic group (91% and 69% in healed/improved wounds and unchanged/aggravated wounds respectively).

While improvements in wound status may partly explain this change, a similar trend was observed in the sub-sample made up of persistent or deteriorating wounds. This was reflected in the 'high' patient satisfaction score established at home independently of any investigator influence.

Conclusion

This survey confirms that pain is a major problem in wound management, irrespective of the aetiology of the wound, or whether it is acute or chronic.

All patients should be considered for appropriate analgesia during wound treatment. The rational selection of adequate dressings should be vigorously promoted through active educational programmes for health-care professionals and, perhaps, for patients themselves. ■

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
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ETATS-UNIS: 1-800-323-4060
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Restore



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 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)