**Evaluation of a new silver foam dressing in patients with critically colonised venous leg ulcers**

Lazareth I, Ourabah Z, Senet P, Cartier H, Sauvadet A, Bohbot S

*Journal of Wound Care*  
March 2007, 16(3)

The enclosed peer-reviewed journal article is provided in the interest of free exchange of truthful scientific information. The barrier functions of the Restore® Foam Dressing with Silver® may help reduce infection in moderately to high exuding partial- and full-thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, donor and graft sites. Restore wound care dressings are intended for single use.

In this article, the authors note that the foam dressing was left in place for an average of 2.66 ±1.93 days (range 1-13). The interval between dressing changes beyond three to four 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. Store the dressing flat and at room temperature.

**Contraindications**: Restore Foam Dressing Silver, Non-Adhesive with TRIACT Technology 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 – UrgoCell® Silver (Laboratoires URGO, Dijon, France) – is marketed in the U.S. by Hollister Wound Care LLC as Restore® Foam Dressing Silver, Non-Adhesive with TRIACT™ Technology. (In the United States, lipidocolloid technology is known as TRIACT Technology.)
- This device is restricted to sale by or on the order of a physician or licensed healthcare professional.
- 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](http://www.hollisterwoundcare.com/products/ifus.html)
Evaluation of a new silver foam dressing in patients with critically colonised venous leg ulcers

Objective: To evaluate the performance (efficacy and safety) of an absorbent dressing impregnated with silver salts (UrgoCell Silver) in the management of leg ulcers with clinical signs of critical colonisation.

Method: This was a prospective multicentre non-comparative phase III clinical trial. Patients were assessed weekly for up to four weeks. Assessment included clinical assessment of critical colonisation (severe spontaneous pain between dressing changes, erythema, oedema, malodour and heavy exudate), wound area tracing and photography. Acceptability was documented by the nursing staff when dressings were changed between two weekly evaluations.

Results: Forty-five leg ulcers were included. At baseline the mean number of clinical signs of critical colonisation per ulcer was 3.6 ± 0.7, which decreased to 1.2 ± 1.2 at the end of the fourth week of follow-up (an average reduction of 2.3 ± 1.3, p < 0.001). Oedema, malodour, erythema and spontaneous pain disappeared at the fourth week in 80%, 70%, 69% and 65% of the treated ulcers respectively. Compared with baseline, the mean reduction in ulcer area was 35.0 ± 58.0% (median 33%, p < 0.001) after the four weeks treatment. Granulation tissue covered a mean 77% of the ulcer surface area at four weeks, compared with 41% at baseline. Only three local events were documented: contact dermatitis, a burning sensation and erythema.

Conclusion: The results suggest that the test dressing had a favourable influence on the wound prognosis, and was well tolerated and accepted in the treatment of venous leg ulcers with clinical signs of critical colonisation.

Declaration of interest: This study was sponsored by Laboratoires Urgo, Chenôve, France.
References

1 Bowler, P.G., Duender, B.L., Armstrong, D.G. Wound microbiology and associated approaches to wound management. Clin Microbiol Rev 2001; 14: 2, 244-269.

Table 1. Baseline patient and leg ulcer characteristics

<table>
<thead>
<tr>
<th>Patient characteristics (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (M/F)</td>
</tr>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>Body weight (kg)</td>
</tr>
</tbody>
</table>

Patient history and associated diseases:

| High blood pressure | 31 (69%) |
| Heart disease       | 15 (33%) |
| Diabetes            | 10 (22%) |
| Cigarette smokers   | 10 (22%) |
| History of allergy  | 5 (11%) |
| Other history       | 16 (36%) |

Venous history:

| Venous thrombosis         | 19 (42%) |
| Superficial venous surgery| 15 (33%) |
| Sclerotherapy             | 20 (44%) |
| Family history of venous disease | 34 (76%) |

Target ulcer characteristics

| Leg ulcer duration         | 15.2 ± 18.5 (1-96) |
| Recurrent leg ulcer        | 24 (53%) |
| Surface area (cm²)         | 12.6 ± 10.0 (2.6-48) |
| Altered perilesional skin  | 39 (87%) |

Wound aspect (% of wound surface)

| Sloughy tissue             | 58.3 ± 29.4 (10-100) |
| Granulation tissue         | 41.3 ± 29.4 (0-90) |
| Necrotic tissue            | 0.4 ± 1.8 (0-10) |

more than one pathology may be present

| ABPI | 0.95 ± 0.12 (0.70-1.20) |

Selection of these signs was based on a EWMA position document and our own clinical experience.

Additional inclusion criteria were:

- Ulcer area between 5cm² and 40cm²
- Ulcer duration between three and 24 months
- Ankle brachial pressure index greater than 0.7
- Ability to wear compression therapy and the test dressing.

The main exclusion criteria were:

- Patients receiving systemic antibiotics at the time of enrolment or in the previous week
- Patients who had had deep venous thrombosis in the three previous weeks
- Ulcers with clinical signs of infection or erysipelas of the lower limb such as cellulitis, green exudate and inflammation of the surrounding skin and that required systemic antibiotics, according to the investigating physician.

Method

Efficacy — the primary study endpoint — was judged by the physician at each weekly visit based on an assessment of each of the five selected signs of critical colonisation. The dressing was considered effective if there was a significant reduction in these signs and in the wound surface area.

Secondary endpoints — tolerance (occurrence of local adverse events) and acceptability of the dressing — were also assessed.

At baseline, after gaining the patients’ written consent to participate, the patient’s general characteristics were recorded, the test leg ulcer was fully described, wound-area tracing and photography were performed, and the dressing was applied.

Participants were seen weekly for four weeks by the investigating physician. Full study documentation and recommendations for dressing use were provided, along with a nurse case-report form to document the dressing-change characteristics at each dressing removal.

The nurse in charge of the patient performed dressing changes in the patient’s home between the weekly clinical evaluations. Wounds were cleansed with normal saline only. The frequency of dressing change was at the investigating physician’s discretion, based on the state of the wound.

All study participants were offered compression therapy in combination with the test dressing.

The test dressing

UrgoCell Silver is composed of three layers:

- A lipoidocolloid dressing (Urgotul) impregnated with silver salts (contact)
- A highly absorbent polyurethane foam (intermediate)
- A polyurethane film (outer).

This silver dressing is indicated for moderately to highly exudating chronic wounds that are at high
risk of clinical infection. The manufacturer recommends that the dressing be changed every two to three days.20-24

Statistical analysis
Data analyses were performed with the SAS 9.0 for Windows. A descriptive statistical analysis was performed on all patients included in the trial. The statistical analysis was performed on the basis of intention-to-treat (ITT) for all endpoints, and all patients who received at least one care operation with the test dressing after their inclusion were included in the efficacy and tolerance analyses. No patients were withdrawn before the first week of treatment. If a patient withdrew before the end of the treatment period, the analysis took account of the last evaluation (last observation carried forward, LOCF).

Continuous data were described by sample size, mean, standard deviation, median and range. The following statistical methods were used for changes with respect to inclusion:
- MacNemar test for binary variables
- Signed ranks test (Wilcoxon) for the clinical score
- Student's paired t-test for continuous variables.

Ethics
The study protocol was approved by the Medical Ethics Committee of Versailles (France), and the clinical trial was then conducted in compliance with good clinical practice and the principles of the Declaration of Helsinki.

All patients gave written consent to participate after having received full written information about the study objectives and conduct.

Results
Baseline characteristics: patients and leg ulcers
Forty-five patients were included in the study between February and September 2005 by the 12 investigating centres. Table 1 outlines the baseline patient and ulcer characteristics. Perilesional skin was documented as ‘healthy’ in only six of the 45 patients (13%).

Table 2 outlines the clinical indicators of critical colonisation, as defined for the purposes of this study, and the number of patients who demonstrated one or more of them at baseline. All ulcers had at least three clinical signs at baseline, and 80% (n=36) had four to five signs.

Study participants had previously been treated by the investigating physicians. Treatments had included paraffin gauze, foam or alginate. At baseline, 73% (n=32) of the study ulcers were considered to be stagnant or deteriorating.

Forty-one patients (91%) had received compression bandaging before inclusion in the study: 62% monolayer bandaging, 22% multilayer bandaging and 16% compression hosiery.

Nine patients (20%) did not wear their compression therapy on each day of the four-week follow-up period; the remainder (80%) were concordant throughout.

Efficacy
All patients included were included in the efficacy analysis, and none were lost to follow-up despite the outpatient nature of this clinical trial.

At baseline, as stated above, all wounds had between three and five of the indicators for critical colonisation. By week 4, 36% (n=16) ulcers had no indicators remaining, while 22% (n=10) still had three to four. No study ulcers had all five indicators by the study end compared with 13% at baseline.

Table 2 shows the mean number of indicators from study start to completion. The reduction in number was highly significant (p<0.001).

Clinical-indicator percentages at baseline and study end are shown in Fig 1. The physicians documented the perilesional skin as ‘healthy’ in 17 patients (38% versus 13% at baseline). By the fourth week of treatment, mean ulcer surface area of grana-
Discussion
The aim of this study was to evaluate the efficacy and safety of UrgoCell Silver in the management of venous or mixed leg ulcers with indicators of critical colonisation. The indicators studied are congruent with heavy bacterial colonisation.7

The total number of indicators significantly decreased during the four-week treatment period with the test dressing. This simple clinical score was shown to be sensitive to wound evolution, with an apparently limited inter-observer variability as reflected by the low variance of its distribution: the score decreased with the disappearance of the local clinical signs.

Indicators that appeared to be particularly responsive to the test dressing were malodour, wound pain and erythema, which is in line with other silver-dressing studies.9,23

Wound surface area reduction was noted in 35% of ulcers after four weeks of treatment. As this was not a controlled trial, it is difficult to compare these efficacy results with those of other silver dressings, as the leg ulcers in this trial will not always have the same characteristics as those in other clinical trials.3,5,10,20,22

Wounds at risk of infection are characterised by a high heterogeneity in their clinical characteristics and aetiology. Therefore, even with a very large sample size, the influence of confounding factors cannot be ruled out, despite randomisation.20

Only three dressing-related local events were documented. All are often observed in leg ulcer management.26,27

The test dressing improved the perilesional skin: nearly 40% of the ulcers showed a healthy surrounding skin at the end of the treatment period compared with an ‘altered’ state in 87% of patients at baseline.

The acceptability of the dressing (ease of application and removal) to health-care professionals was good. Patients appreciated the painless dressing removal, which supports previous studies undertaken with neutral UrgoCell.28

The investigating physicians considered that the wounds improved (or healed) in nearly 78% of patients after four weeks of treatment, despite their poor prognosis27 and considering the mean initial surface area (12.6cm²) and ulcer duration (15.2 months).

These results suggest UrgoCell Silver had a favourable influence on the wound prognosis, and was well tolerated and well accepted in the treatment of venous leg ulcers with clinical signs of critical colonisation. However, a randomised clinical evaluation is required to confirm these encouraging clinical results.

Days (range 1–13). It was left in place for two days or more in 76% of cases. The nurses considered it easy to use and apply, and that it conformed well to the wound bed.

Local tolerance (safety)
Three local adverse events, considered to be dressing related, were reported by the investigators:

- One patient developed ‘moderate’ contact dermatitis during the fourth week of treatment and was withdrawn from the study. This patient had a lesion at inclusion
- One patient experienced a burning sensation on the wound on the first day of treatment. The test dressing was discontinued and an alginate dressing applied. However, he was included in the analysis as the erythema disappeared after a few days.
- One patient developed ‘moderate’ contact dermatitis beneath the test dressing after one week of treatment. The wound on the first day of treatment. The test dressing was discontinued and an alginate dressing applied. However, he was included in the analysis as the erythema disappeared after a few days.

Dressing changes
In all, 470 care episodes were documented, representing 1250 cumulated days of treatment.

The studied dressing was removed every 2.66 ± 1.93 days (range 1–13). It was left in place for two days or more in 76% of cases. The nurses considered it easy to use and apply, and that it conformed well to the wound bed.
**Restore**

**INSTRUCTIONS/MODE D'EMPLOI/INSTRUCCIONES**

Silver sulfate: 3.22 mg/mg.l

Sulphate d’Argent: 3.22 mg/mg.l

Sulfato de Plata: 3.22 mg/mg.l cuadrada

---

**Foam Dressing Silver, Non-Adhesive with Non-Adhesive Contact Layer, Antimicrobial**

**Pansement hydrocolloïdale Argent**, non adhésif avec interface non-adhésive, antibactérien.

**Apósito hidrocoloidal con Plata, No adhésivo con capa de contacto no adherente, antimicrobiano**

**STÉRILE**

**ESTÉRIL**

Couvercle Federal: restitue la qualité de la base en ouvrant le pansement pour le patient de la façon suivante:

- Ouvrir le couvercle de la base en ouvrant le pansement pour le patient.

---

**Restore pansement hydrocolloïdale Argent avec la Technologie TRACT**

**Traité antimicrobien non-adhésif avec contact latéral non-adhésif**

**DESCRIPTION**

Le pansement hydrocolloïdal Argent Restore non-adhésif est le premier dans sa catégorie à posséder un traitement antimicrobien. Il est conçu pour aider à réduire la quantité de microorganismes sur la plaie. Le pansement hydrocolloïdal Argent Restore non-adhésif est indiqué pour la couverture des plaies non infectées et les plaies infectées, y compris celles qui nécessitent une gestion de l'infection.
Restore Foam Dressing Silver with TRIACT Technology, Antimicrobial, Non-Adhesive with Non-Adherent Contact Layer.

**DESCRIPTION**
Restore Foam Dressing Silver Non-Adhesive is non-adhesive, non-evaporation, antimicrobial absorbed dressing, composed of Silver.
- It contains a silver polypeptide matrix which releases silver ions from the dressing matrix.
- Non-adhesive, non-evaporation, antimicrobial absorbed dressing.

**INDICATIONS FOR USE**
The barrier function of Restore Foam Dressing Silver Non-Adhesive may reduce bacterial invasion, help to keep wounds clean and dry, provide a barrier to prevent bacterial penetration.

**MECHANISM OF ACTION**
The proprietary TRIACT technology specifically targets the presence of a polypeptide matrix which releases silver ions from the dressing matrix, reducing bacterial invasion and helping to keep wounds clean and dry.

**HOT STIRL STEREL**
Cautions: Federal and state laws restrict this device to the use by or on the order of a physician or licensed health care professional. Please refer to the site specific use of this device for professional use. For prescription only, one prescription is necessary for each device.

**PRECAUTIONS**
Restore Foam Dressing Silver Non-Adhesive is not recommended for use with compression bandaging due to the ability of the dressing to resist removal.

**DIRECTIONS FOR USE**
- Clean the wound using sterile saline solution.
- Choose a dressing size which ensures that the dressing will cover the entire wound.
- Place the dressing over the wound.
- Apply the dressing directly to the wound.
- Use it with or without a free border. Use a compression bandage when prescribed.
- Change Restore Foam Dressing Silver Non-Adhesive dressing every 1 - 3 days, depending on the wound and the healing progress.
- Duration of treatment determined by the physician and dependent on wound type and conditions.

**CONTRAINDICATIONS**
- Known sensitivity to silver and/or other dressing components.
- Allergic reaction to the dressing components.

**HOW SUPPLIED**
Restor Foam Dressing Silver Non-Adhesive is supplied in sizes 4" x 4" (10 cm x 10 cm) and 4" x 8" (10 cm x 20 cm).

**EXAMPLES**
- 1020404: 4" x 4" (10 cm x 10 cm)
- 5001041: 4" x 8" (10 cm x 20 cm)

**Restor pansement hydraté Argent avec la Technologie TRIACT**, Antimicrobial, non-adhésif avec contact non-adhésif.

**DESCRIPTION**
Le pansement hydroalcoolique Argent Restor non-adhésif est un pansement hydroalcoolique, non-adhésif à contact non-adhésif avec lequel le liquide se retrouve en contact étroit avec la peau du patient.
- Il est composé d'une matrice polyméthacrylate qui libère du silicium et d'argent à l'intérieur de la matrice.
- Le pansement hydroalcoolique Argent Restor non-adhésif est un pansement hydroalcoolique, non-adhésif, absorbant, absorbant, constituant de 3 couches.
- Il est livré sous une couche de papier absorbant et une couche de viscosité.

**MOOT D'ACCTION**
Le pansement hydroalcoolique Argent Restor non-adhésif est utilisé pour stopper le saignement et maintenir la zone de lésion propre.

**INDICATIONS**
Le pansement hydroalcoolique Argent Restor non-adhésif est utilisé dans les zones qui nécessitent une couche hydroalcoolique, non-adhésive, absorbante.

**DISCRIPTION**
Le pansement hydroalcoolique Argent Restor non-adhésif est un pansement hydroalcoolique, non-adhésif, absorbant, absorbant, constituant de 3 couches.
- Il est livré sous une couche de papier absorbant et une couche de viscosité.

**MOOT D'ACCTION**
Le pansement hydroalcoolique Argent Restor non-adhésif est utilisé pour stopper le saignement et maintenir la zone de lésion propre.

**INDICATIONS**
Le pansement hydroalcoolique Argent Restor non-adhésif est utilisé dans les zones qui nécessitent une couche hydroalcoolique, non-adhésive, absorbante.

**DISCRIPTION**
Le pansement hydroalcoolique Argent Restor non-adhésif est un pansement hydroalcoolique, non-adhésif, absorbant, absorbant, constituant de 3 couches.
- Il est livré sous une couche de papier absorbant et une couche de viscosité.

**MOOT D'ACCTION**
Le pansement hydroalcoholique Argent Restor non-adhésif est utilisé pour stopper le saignement et maintenir la zone de lésion propre.

**INDICATIONS**
Le pansement hydroalcoholique Argent Restor non-adhésif est utilisé dans les zones qui nécessitent une couche hydroalcoholique, non-adhésive, absorbante.

**DISCRIPTION**
Le pansement hydroalcoholique Argent Restor non-adhésif est un pansement hydroalcoholique, non-adhésif, absorbant, absorbant, constituant de 3 couches.
- Il est livré sous une couche de papier absorbant et une couche de viscosité.

**MOOT D'ACCTION**
Le pansement hydroalcoholique Argent Restor non-adhésif est utilisé pour stopper le saignement et maintenir la zone de lésion propre.

**INDICATIONS**
Le pansement hydroalcoholique Argent Restor non-adhésif est utilisé dans les zones qui nécessitent une couche hydroalcoholique, non-adhésive, absorbante.

**DISCRIPTION**
Le pansement hydroalcoholique Argent Restor non-adhésif est un pansement hydroalcoholique, non-adhésif, absorbant, absorbant, constituant de 3 couches.
- Il est livré sous une couche de papier absorbant et une couche de viscosité.

**MOOT D'ACCTION**
Le pansement hydroalcoholique Argent Restor non-adhésif est utilisé pour stopper le saignement et maintenir la zone de lésion propre.

**INDICATIONS**
Le pansement hydroalcoholique Argent Restor non-adhésif est utilisé dans les zones qui nécessitent une couche hydroalcoholique, non-adhésive, absorbante.

**DISCRIPTION**
Le pansement hydroalcoholique Argent Restor non-adhésif est un pansement hydroalcoholique, non-adhésif, absorbant, absorbant, constituant de 3 couches.
- Il est livré sous une couche de papier absorbant et une couche de viscosité.