



# Clinical Evaluation of a New Contact Layer Dressing for the Local Management of Acute and Chronic Wounds

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## Objectives:

1. To provide clinical experience in reducing patient pain using a contact layer\* in acute and chronic wounds.
2. To provide clinical experience in clinical assessment of wound healing in acute and chronic wounds treated with a contact layer\*.

## Statement of the Problem

Contact layer dressings are commonly used for chronic and acute, partial- and full-thickness wounds. When choosing an appropriate contact layer dressing, the potential for wound healing and pain reduction must be considered. Non-adherence, ease of application, and ease of removal of the dressing are all features that may contribute to these outcomes.

## Methodology

This was an open-label, non-randomized product evaluation of a contact layer\* newly introduced into the U.S. The study was conducted at 9 sites. Study subjects were selected from

the general population of patients with acute and chronic wounds, for which a contact layer dressing would be appropriate. Specific questions were asked to obtain the clinicians' perception of performance characteristics of the product.

## Results

Thirty-one wounds had the contact layer\* applied (27 chronic, 4 acute). Clinician perception of the ease of application, adherence to wound, and pain during removal of the contact layer was assessed.

## Conclusion

The new contact layer\* was easily applied and removed with minimal to no adhesion to the wound bed. This may decrease patient pain during dressing removal and help promote the wound healing process in the chronic and acute wounds observed in this product evaluation.

\* Product used was Urgotul (Laboratoires URGO, Dijon, France) marketed in the U.S. as **Restore** Contact Layer Dressing with TRIACT Technology by Hollister Wound Care LLC.

## Study Objectives

- The primary objective of this product evaluation was to obtain the perception of the users about characteristics of the contact layer featuring Technology Lipido Colloid (TLC—known in the U.S. as TRIACT Technology), specifically with the following parameters:
  - Ease of application of the dressing
  - Adherence of the dressing to the wound
  - Pain during removal of the dressing
- The secondary objective was to obtain an overall impression of time and resources required to use the contact layer

## Study Design

- Open-label, non-randomized, uncontrolled product evaluation
- 9 sites—between 3 and 13 subjects with acute or chronic wounds were recruited at each site
- The contact layer dressing was applied following the institution's practice, and product instructions
- Subjects were followed until one of the following occurred:
  - Use of the contact layer was no longer appropriate
  - Wound healed
  - Four weeks had passed
- Specific questions were asked in order to obtain each clinician's perception of the performance characteristics of the contact layer dressing

## Results

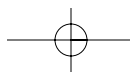
A total of thirty-one (31) wounds were treated.

**Table 1.** Subject Demographics

	<b>N</b>	<b>Age, yrs (SD)</b>	<b>Chronic Wound</b>	<b>Acute Wound</b>
<b>Total</b>	31	62 (17.2)	27	4
<b>Female</b>	15	66.5 (15.7)	14	1
<b>Male</b>	16	57.8 (17.9)	13	3

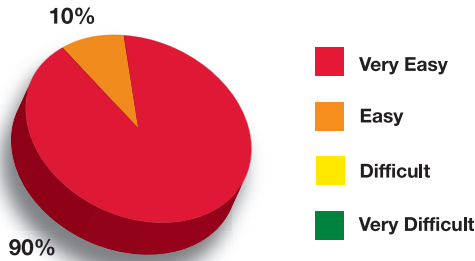
## Types of Wounds Treated with the Contact Layer

- 1 Diabetic Foot Ulcer
- 1 Atypical Venous Ulcer
- 8 Pressure Ulcers
  - 7 Stage II ulcers
  - 1 superficial slough
- 7 Venous Ulcers
- 5 Traumatic
  - 4 chronic
  - 1 acute
- 6 Postoperative
  - 4 chronic
  - 2 acute
- 1 Skin Tear
- 1 Tape Tear
- 1 Necrotizing Fasciitis (Post-Debridement)



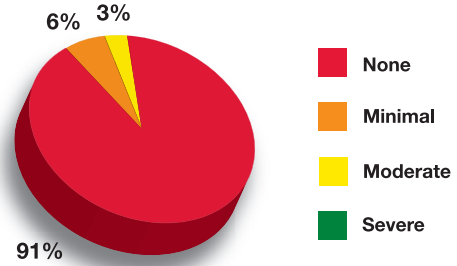
**Figure 1.** Clinician perception of the ease of application of the contact layer.

**Ease of Application of the Contact Layer**



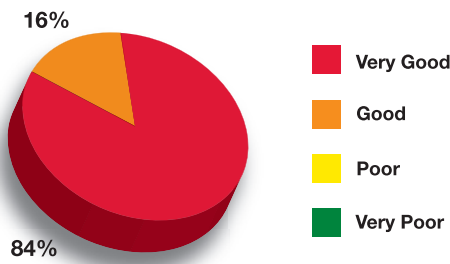
**Figure 4.** Clinician perception on the adherence of the contact layer to the wound.

**Adherence of Contact Layer to Wound**



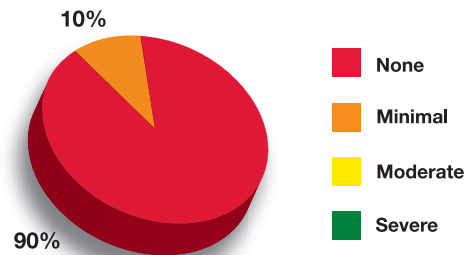
**Figure 2.** Clinician perception of the conformability of the contact layer to the wound.

**Conformability of the Contact Layer to the Wound**



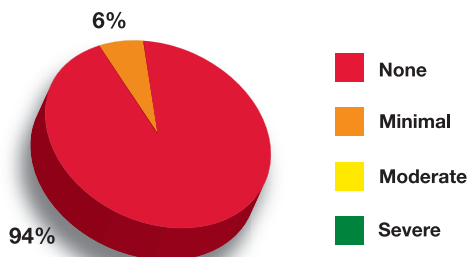
**Figure 5.** Clinician assessment of maceration present associated with use of the contact layer.

**Maceration Associated with Contact Layer Use, N = 29**



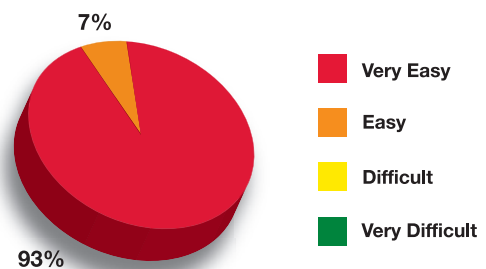
**Figure 3.** Clinician perception on the amount of bleeding present with the removal of the contact layer.

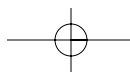
**Bleeding Upon Removal of the Contact Layer**



**Figure 6.** Clinician perception of the ease of contact layer removal.

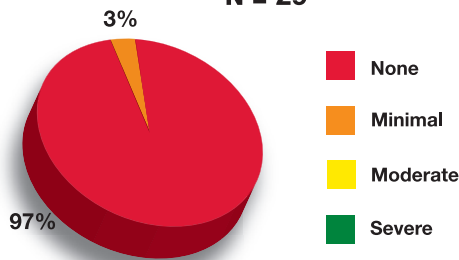
**Ease of Contact Layer Removal, N = 29**





**Figure 7.** Perceived pain associated with contact layer removal.

**Pain Associated with Contact Layer Removal,  
N = 29**

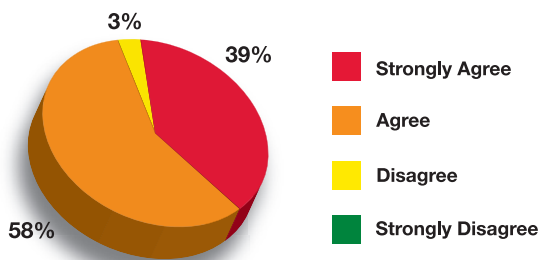


**Conclusion**

The new contact layer\* conformed well and was easily applied. Removal was performed with minimal to no bleeding of the wound bed. These attributes are thought to decrease patient pain during dressing removal and may promote the healing process in the chronic and acute wounds observed in this product evaluation.

**Figure 8.** Clinician overall recommendation to use the contact layer.

**Clinician Recommends Use of Contact Layer**



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