Use of a Novel Foam Dressing With Negative Pressure Wound Therapy and Instillation: Recommendations and Clinical Experience

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Abstract: A new reticulated open-cell foam dressing with through holes (ROCF-CC) has been introduced to assist with wound cleansing by removing thick wound exudate and infectious materials during negative pressure wound therapy with instillation. Due to the limited published evidence supporting use of ROCF-CC dressings with negative pressure wound therapy with instillation and dwell time (NPWTi-d), clinicians have been relying on practical application experience to gain proficiency with the dressing and NPWTi-d. To help provide general guidelines for safe and efficient use of ROCF-CC dressings with NPWTi-d, a multidisciplinary expert panel of clinicians was convened from September 28 to 29, 2017. Principal aims of the meeting were to develop recommendations based on panel members' experience and limited published results for use of ROCF-CC dressings, appropriate wound and patient characteristics for use, application settings, and clinical techniques to optimize outcomes. An algorithm to guide use of ROCF-CC dressings with NPWTi-d was also created. Panelists recommended the following goals for using ROCF-CC dressings: cleanse wounds when areas of slough or nonviable tissue remain on the wound surface, remove thick exudate, remove infectious materials, promote granulation tissue formation, and help provide a bridge to a defined endpoint. Negative pressure wound therapy with instillation and dwell time with ROCF-CC dressings may be an appropriate adjunct therapy for wound cleansing, especially in cases when sharp excisional debridement is not available or appropriate. All panel members agreed that controlled clinical and scientific studies of NPWTi-d with ROCF-CC are needed to further elucidate best practices and effectiveness in various wound types.

Key words: instillation of topical wound solution, negative pressure wound therapy, NPWTi-d, reticulated open-cell foam dressing with through holes, ROCF-CC, wound cleansing

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Introduction

Wound cleansing, or the process of washing a wound with a solution, has long been recognized as a cornerstone of wound management to help remove cellular debris and surface pathogens contained in wound exudates. Debridement, the removal of devitalized tissue or foreign material impeding normal tissue growth, is well-established in national and international guidelines as an important step in the process of wound healing. Although there are a variety of debridement strategies available (eg, mechanical, biologic, autolytic, enzymatic, and surgical methods), excisional sharp debridement remains the mainstay treatment for infected and/or nonviable tissue in tandem with application of topical antimicrobial agents, such as silver sulfadiazine, mafenide acetate, cadexomer iodine, or hypochlorous acid solutions, to help lower bacterial burden. Combined with debridement, cleansing is a critical step in facilitating progression from the inflammatory to proliferative phase of wound healing by removing debris that can inhibit the healing process. A primary goal of cleansing is to clean the wound while avoiding trauma to the wound bed and minimizing the risk of driving bacteria further into the wound bed.

A challenge in wound healing today is that in some circumstances, surgical excisional debridement may not be appropriate or accessible for wound treatment. In cases where there are high risks to the patient associated with sharp excisional debridement and anesthesia, when the patient does not consent, or when access to the operating room is delayed or limited, alternative methods for wound cleansing may be
Use of Foam Dressing With NPWTi-d

Table 1. Comparative characteristics\(^1\) of ROCF-CC, ROCF-V, and ROCF dressings (adapted from Téot et al\(^9\))

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>ROCF-CC Dressing</th>
<th>ROCF-V Dressing</th>
<th>ROCF Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foam size</td>
<td>Wound contact layer: 18.0 cm x 12.5 cm x 0.8 cm</td>
<td>17.0 cm x 15.0 cm x 1.8 cm (2 pieces/package)</td>
<td>18.0 cm x 12.5 cm x 3.3 cm (medium)</td>
</tr>
<tr>
<td>Thin cover layer:</td>
<td>18.0 cm x 12.5 cm x 0.8 cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thick cover layer:</td>
<td>18.0 cm x 12.5 cm x 1.6 cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holes size</td>
<td>1.0 cm circular</td>
<td>No holes</td>
<td>No holes</td>
</tr>
<tr>
<td>Spacing between holes</td>
<td>0.5 cm between</td>
<td>No holes</td>
<td>No holes</td>
</tr>
<tr>
<td>Pore size</td>
<td>400–600 microns on contact surface of dressing</td>
<td>400–600 microns</td>
<td>400–600 microns</td>
</tr>
<tr>
<td>Tensile/tear strength wet</td>
<td>Substantially greater than ROCF-V and ROCF</td>
<td>Lower than ROCF-CC but greater than ROCF</td>
<td>Lowest tear strength compared to ROCF-V and ROCF-CC</td>
</tr>
<tr>
<td>Relative hydrophobicity</td>
<td>Less hydrophobic (more absorptive) than ROCF and ROCF-V</td>
<td>Less hydrophobic (more absorptive) than ROCF, but more hydrophobic than ROCF-CC</td>
<td>Most hydrophobic</td>
</tr>
</tbody>
</table>

1. ROCF-CC: reticulated open-cell foam dressing with through holes (V.A.C. VERAFLO CLEANSE CHOICE Dressing; KCI, an Acelity Company); ROCF-V: V.A.C. VERAFLO Dressing (KCI); ROCF: V.A.C. GRANUFLOAM Dressing (KCI). KCI website: http://www.kci-medical.sg/SG-ENG/vaculta

required. With negative pressure wound therapy with instillation and dwell time (NPWTi-d; V.A.C. VERAFLO Therapy; KCI, an Acelity Company, San Antonio, TX), the combination of instilling a topical solution over the wound bed, soaking the wound in the solution, compressing and decompressing the foam under cycles of negative pressure, and removing the exudate via negative pressure wound therapy (NPWTi-d) is a gentle method of cleansing that appears to minimize risk of cross-contamination\(^7\) and help decrease bacterial bioburden in the wound bed.\(^6\) However, historically, NPWTi-d systems have been limited in their ability to remove large amounts of thick exudate and slough through the foam dressing. Recently, a wound interface dressing containing an array of through holes has been developed that may be an important evolutionary concept to advance the use of NPWTi-d.

This new reticulated open-cell foam dressing with through holes (ROCF-CC; V.A.C. VERAFLO CLEANSE CHOICE Dressing; KCI, an Acelity Company) is intended to assist with wound cleansing by removing thick wound exudate and infectious materials. Used with NPWTi-d, the dressing can be a tool to mechanically extract sloughy debris from wounds that are covered with devitalized tissue. The dressing also may extend the possibilities of early use of NPWTi-d to facilitate the softening, solubilizing, and degrading of viscous exudate, fibrin, wet slough, and other infectious materials\(^9\) prior to excisional sharp debridement, after excisional sharp debridement, or in cases when complete excisional surgical debridement is not an option. Although standard facility NPWTi-d usage protocols require proper debridement prior to use, NPWTi-d with the ROCF-CC dressings may be well suited in intervals between debridements to help cleanse and temporize the wound to prepare for the next step in the wound healing process.\(^9\)

Purpose: The ROCF-CC dressing has only been commercially available since 2015; therefore, there is little evidence to support its use. Despite this, clinicians continue to use NPWTi-d with ROCF-CC, optimizing application through trial and error. Although considered the lowest level of evidence, expert opinion may be beneficial in providing general guidelines for safe and efficient use of ROCF-CC dressings with NPWTi-d in the interim. At the least, it provides an informed starting point and initial direction for clinicians in using NPWTi-d with ROCF-CC.

The principal aims of these expert recommendations are to address the following: (1) goals for use of ROCF-CC dressings; (2) appropriate wound and patient characteristics for use of ROCF-CC dressings; (3) suggested NPWTi-d settings for use with ROCF-CC, including topical instillation solution, volume and dwell time, NPWT phase, and pressure settings; (4) clinical techniques that may optimize use of NPWTi-d with ROCF-CC; and (5) creation of an algorithm to guide optimal use of ROCF-CC dressings with NPWTi-d.

Methods

Advisory panel meeting. Panelists were selected by the sponsor based on publication experience on the topic of ROCF-CC and level of clinical experience with NPWTi-d using ROCF-CC. An attempt was made to include panelists from a range of specialties to capture diverse practice patterns for discussion and case study presentations. A total of 5 nurses and nurse practitioners and 8 physicians were invited to attend the advisory panel meeting. Panelists were selected from the United States and France and encompassed the specialties of general surgery, plastic surgery, nursing, wound care, and podiatric surgery. All panelists who attended had extensive experience with use of ROCF-CC dressings; 3 physicians who were invited but could not attend the meeting agreed to contribute as authors to this publication. Recommendations were formulated using a multistep process.

The advisory panel convened from September 28 to 29, 2017, in Charlotte, NC. The sessions were directed by 2 comoderators (authors PK and
LT) and organized into the following topics: (1) basic science of NPWTi-d mechanisms, (2) literature review of clinical use, (3) discussion and development of clinical recommendations, (4) clinical techniques for dressing application, (5) development of an algorithm to guide optimal use, and (6) attendee presentations of clinical experience and case studies. No conclusive statements were finalized during the meeting; the meeting was tape-recorded for follow-up.

**Literature search and dissemination of studies.** A selection of relevant research literature was compiled by the co-moderators for panel members to review prior to the face-to-face meeting. A list of 61 articles was identified through a PubMed literature search using the terms cleanse choice negative pressure, NPWT-CC, and negative pressure wound therapy instillation. Articles were selected from this list for review if they focused on NPWT-CC or NPWTi-d clinical recommendations, were written in English, included US Food and Drug Administration (FDA)-cleared applications, and were published in 2013 and after. Eight peer-reviewed US or international publications fit these criteria and were e-mailed to panel participants. Copies of 4 previously presented ROCF-CC-related posters also were disseminated with the articles.

**Post-meeting follow-up.** A detailed outline, including the expert recommendations and algorithm, was distributed via e-mail to panelists subsequent to the meeting for review and response. Edits were collected from all panel members and incorporated by the medical writer into the final submitted document. All content in this manuscript was approved by all authors.

**Results**

**Mechanisms of action of NPWTi-d with ROCF-CC.** Limited available data suggest that the new ROCF-CC with through holes dressing appears to assist wound cleansing by enhancing the efficiency of slough and fibrinous tissue removal with NPWTi-d in complex wounds.\(^9\) The foam dressing consists of a contact layer with 1-cm diameter through holes spaced 0.5 cm apart and 2 cover layers (0.8-cm and 1.6-cm thickness) without holes. The foam cover layers are meant to be placed completely over the contact layer and to fill up the wound cavity; they are made of the same foam but come in 2 thicknesses to address different wound depths. Depending on the depth of the wound, either layer, or both layers on top of each other can be used to fill the wound cavity. Whether the effects of the therapy vary with different thicknesses of cover layer foam is unknown.

The foam material for the ROCF-CC dressing is essentially the same as the ROCF-V dressing (V.A.C. VERAFLÖ Dressing; KCI, an Acelity Company), which is standard to the NPWTi-d system, but looks and feels slightly different due to processing that gives it a much higher tear strength. Both foam dressings are less hydrophobic than the ROCF-CC dressings. The less hydrophobic and more absorptive nature of the ROCF-CC dressing allows a more even distribution of instilled fluid throughout the foam. Comparative characteristics of ROCF-CC, ROCF-V, and ROCF dressings are listed in Table 1.

Previous studies\(^{10-12}\) suggest 2 major mechanisms are at work with NPWT using ROCF dressings: macrostrain and microstrain. Macrostrain, or a visible stretch, occurs with the application of NPWT to ROCF\(^10\); it draws wound edges together, provides direct wound bed contact, evenly distributes negative pressure, and assists with wound cleansing by removing exudate. Microstrain is the microdeformation of the wound surface induced by NPWT and a ROCF dressing that has pore sizes between 400 µm and 600 µm, which, at the cellular level, stimulates cell proliferation that helps promote wound healing.\(^11\) The level of strain induced by NPWT is hypothesized to proactively cause cell proliferation in a process similar to external and soft tissue expansion.\(^12\) Although

![](image1.png)

**Figure 1.** Reticulated open-cell foam dressing with through holes (ROCF-CC) and development of macro-columns. (A) The ROCF-CC contact layer in wound; (B) cover layer applied over contact layer; (C) side view of macrocolumns formed within the holes of the dressing; and (D) top view of macrocolumns.
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Figure 1.Proposed mechanisms of action of reticulated open-cell foam dressing with through holes (ROCF-CC) combined with negative pressure wound therapy with instillation and dwell time. (A) Noncompressed ROCF-CC dressing with no negative pressure applied; (B) compressed ROCF-CC dressing with negative pressure applied; (C) instillation of topical solution with no negative pressure applied; and (D) wound bed with macrocolumns after dressing removal.

Corresponding to the shapes of the holes in the ROCF-CC contact layer are usually present on the wound surface upon removal of the ROCF-CC dressing (Figure 1).

Panel members postulated that when negative pressure is applied, air within the ROCF-CC dressing space is evacuated and the dressing compresses, drawing wound edges together (macrostrain-induced macrodeformation of the wound surface). This appears to induce wound bed compression that pulls tissue into the dressing through the holes, creating an undulating wound surface and potentially creating a strain profile that is uniquely different from dressings without holes. This type of macrodeformation appears to have a disruption effect on a wound bed that contains thick fibrinous exudate and slough. The physical changes to the wound bed are on a centimeter scale, and these deformations may add to the well-characterized microstrain induced by the micron-scale dressing pores.

Cyclic delivery of the topical solution, as well as dwell time and removal of the solution, is hypothesized to produce a mechanical hydrodynamic force on the stressed wound bed, disrupting and helping to soften and solubilize thick exudate and loosen wound debris for removal during NPWT (Figure 2).13,14 The presence of larger openings or through holes in the dressing may then accommodate easier passage of thick, fibrinous materials away from the wound bed. In addition, at dressing changes, many wounds with slough tend to show some residual slough on the tops of the macrocolumns, versus the base of the wound bed. One of the panel members (LT) proposed during the meeting that numerous physical forces (such as vertical, horizontal, etc.) may likely play a role in the mechanisms of action, but far more research is needed to definitively describe the mechanical effects of the therapy.

Figure 2. Proposed mechanisms of action of reticulated open-cell foam dressing with through holes (ROCF-CC) combined with negative pressure wound therapy with instillation and dwell time. (A) Noncompressed ROCF-CC dressing with no negative pressure applied; (B) compressed ROCF-CC dressing with negative pressure applied; (C) instillation of topical solution with no negative pressure applied; and (D) wound bed with macrocolumns after dressing removal.

the characteristics of different ROCF dressings vary, panel members suspect similar previously described mechanisms of macrostrain and microstrain are at work with NPWTi-d using ROCF-CC dressings, except the macrostrain manifests in a different type of deformation in the wound bed.

Authors of an in vitro study11 found that a histologic cross-section of NPWT-treated wounds showed a marked increase in rolling contour with protrusions and indentations corresponding to the geometry of ROCF contact with the wound. Similarly, macrocolumns of granulation tissue corresponding to the shapes of the holes in the ROCF-CC contact layer are usually present on the wound surface upon removal of the ROCF-CC dressing (Figure 1).

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Figure 2. Proposed mechanisms of action of reticulated open-cell foam dressing with through holes (ROCF-CC) combined with negative pressure wound therapy with instillation and dwell time. (A) Noncompressed ROCF-CC dressing with no negative pressure applied; (B) compressed ROCF-CC dressing with negative pressure applied; (C) instillation of topical solution with no negative pressure applied; and (D) wound bed with macrocolumns after dressing removal.
Literature review. To date, there is only 1 published peer-reviewed study that describes outcomes with the use of NPWTi-d with ROCF-CC. In this study, medical records were retrospectively reviewed from 21 patients with 21 large complex wounds with the majority being pressure ulcers that contained substantial areas of devitalized tissue and/or yellow fibrinous slough and received treatment with NPWTi-d using ROCF-CC in an acute care setting. The wounds included a range of clinical situations including difficult wounds with devitalized and/or fibrinous tissue on the wound surface. Surgical debridement was performed on 11 out of 21 wounds prior to application of NPWTi-d with ROCF-CC. In the remaining 10 wounds, a superficial layer of nonviable tissue or at least 60% fibrin cover was present when NPWTi-d with ROCF-CC was applied for the first time. Negative pressure wound therapy with instillation and dwell time with ROCF-CC was delivered by instilling normal saline with a 10-minute dwell time, followed by 3.5 hours of NPWT at -125 mm Hg. The mean number of dressing changes was 2.9, and mean duration of therapy was 8.7 days. The NPWTi-d with ROCF-CC assisted in loosening, solubilizing, and detaching viscous exudate, dry fibrin, wet slough, and other infectious materials.

Wound management required an average of 1 to 3 ROCF-CC dressing applications (3–9 days of NPWTi-d), after which 18 (85.7%) out of 21 wounds had ≤ 10% surface area with black nonviable tissue remaining and 15 (71.4%) out of 21 wounds had ≤ 20% surface area with yellow fibrinous slough remaining. Of 21 wounds, 20 (95.2%) displayed enhanced granulation tissue formation and reduction in wound volume during use of ROCF-CC dressings with NPWTi-d. Authors concluded that the adjunctive use of NPWTi-d with ROCF-CC may be suitable for wound cleansing in chronic, complex wounds when complete surgical debridement is not possible or appropriate and areas of nonviable tissue are still present on the wound surface.

Recommendation statements. The recommendation statements agreed upon by the members of the expert panel are presented herein to provide general guidelines and not absolute principles.

1. The ROCF-CC dressing should be used in combination with NPWTi-d.

According to the FDA 510K summary, “The V.A.C. VERAFLO CLEANSE CHOICE™ Dressing System is intended for use with the V.A.C. ULTA™ Negative Pressure Wound Therapy System.” All testing has been performed with ROCF-CC used in conjunction with NPWTi-d devices; outcomes with tandem use of ROCF-CC and other devices are unknown. The ROCF-CC manufacturer’s instructions for use state that ROCF-CC also can be used when transitioning from NPWTi-d to standard NPWT in the acute care setting.

2. Panel suggests the following goals for using ROCF-CC dressings:
   (1) cleanse wounds when areas of slough or nonviable tissue remain present on the wound surface, (2) remove thick exudate, (3) remove infectious materials, (4) promote granulation tissue formation, and (5) help provide a bridge to a defined endpoint for a clinical plan of care.

The panel’s suggestions for clinical goals for use of ROCF-CC dressings are based on observed outcomes with the dressings over time as well as limited published evidence. Such goals should be made prior to the start of treatment and reevaluated at each dressing change. At first, the goal may be palliative, but as wound characteristics change, the goal might be altered to achieve a new endpoint. Negative pressure wound therapy with instillation and dwell time with ROCF-CC may be used to temporize a wound, so that it can be treated conservatively. Similar to the treatment of wounds with NPWTi-d and standard...
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ROCF-V dressings, use of ROCF-CC may convert an unmanageable wound to a manageable wound with respect to viable tissue. A maximal amount of slough or non-viable tissue acceptable for use of this dressing was not set by panel members, but several cases presented during the meeting showed large areas of slough reduction during use of NPWTi-d with ROCF-CC in wounds that initially presented with 90% to 100% slough cover. Likewise, of the 21 wounds treated with NPWTi-d and ROCF-CC in the Téot et al’s study, 9 wounds initially contained 60% to 100% surface area of nonviable/yellow fibroin tissue. With the exception of 1 wound that was discontinued from the study, percent surface area of devitalized tissue was reduced and percent area of granulation tissue was increased in the remaining 8 wounds during use of NPWTi-d with ROCF-CC. Panel presentations indicated that the degree of devitalized tissue, versus the amount, seemed to play an important role in the success of the therapy. In these presentations, the therapy was more successful in wounds with wet versus dry slough.

Compared to characteristics observed with previous NPWTi-d foam dressings, panel members have observed distinctly different wound bed characteristics at dressing changes with the ROCF-CC dressings. Macrocolumns of granulation tissue typically form within the holes of the dressing, protruding from the base of the wound when the dressing is removed. The base area of the wound bed that is in contact with the ROCF-CC contact layer typically contains brighter red granulation tissue than on the tops of the macrocolumns, which may be covered with fibroin tissue spots.

The ROCF-CC dressing was designed to assist in loosening, detaching, and removing viscous exudate, dry fibrin, wet slough, and other infectious materials from the wound bed when combined with NPWTi-d.16 Wet slough and loose, nonviable tissue may be collected into the exudate canister or may be attached to the wound contact layer dressing at removal. These observations are consistent with the study by Téot et al’s which showed the majority of the devitalized tissue and/or yellow fibroin slough originally present in 21 large complex wounds was removed at the first dressing change after 3 days of NPWTi-d with ROCF-CC.

<table>
<thead>
<tr>
<th>Table 2. Solutions indicated for topical wound treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Solution Class</td>
</tr>
<tr>
<td>------------------------</td>
</tr>
<tr>
<td>Sodium hypochlorite solutions</td>
</tr>
<tr>
<td>Hypochlorous acid (HCl) solutions</td>
</tr>
<tr>
<td>Oxidized water/sodium hypochlorite/ hypochlorous acid solutions</td>
</tr>
<tr>
<td>Sulfur-based solutions (sulfonamides)</td>
</tr>
<tr>
<td>Biguanides (polyhexanides)</td>
</tr>
<tr>
<td>Lidocaine HCl</td>
</tr>
<tr>
<td>Isotonic solutions</td>
</tr>
<tr>
<td>Acetic acid</td>
</tr>
</tbody>
</table>

¹ SteadMed Medical, Fort Worth, TX
² Innovacyn, Inc, Rialto, CA
³ NovaBay Pharmaceuticals, Inc, Emeryville, CA
⁴ Sonoma Pharmaceuticals, Petaluma, CA
⁵ Mylan Bertek Pharmaceuticals, Inc, Sugar Land, TX
⁶ B. Braun Medical, Inc, Bethlehem, PA
⁷ Available through KCI (Part Number: 400230; San Antonio, TX)
⁸ KCI

NPWTi-d: negative pressure wound therapy with instillation and dwell time.
addition of an instilled topical solution has been shown to help facilitate wound cleansing via exudate removal, enhancing healing time of wounds compared with standard NPWT alone, but panel members agreed that the ROCF-CC dressing appears to allow passage of thick exudate more easily through this foam dressing compared versus previous NPWTi-d dressings. More published research is needed to support these observations.

Panel members have observed that the removal of debris and devitalized tissue allows for a more accurate assessment of the dimensions and status of the wound bed, demarcating viable tissue and isolating areas of nonviable tissue. Panel members also have noted greater lateral contraction of the wound size with ROCF-CC versus other NPWT dressings, but future controlled studies are needed to make accurate comparisons.

3. The ROCF-CC dressings may be an appropriate adjunct therapy after adequate wound treatment and evaluation for all wound types indicated for NPWTi-d, such as (1) wounds with exposed bone; (2) wounds with treated, underlying osteomyelitis; (3) wounds with intact mesh; (4) extensive hematoma cavity with confirmed hemostasis; (5) wounds in the presence of orthopedic fixation hardware; and (6) wounds being prepared for definitive closure or coverage (eg, split-thickness skin graft [STSG], full-thickness skin graft [FTSG], or flap).

Wound types indicated for use of ROCF-CC dressings are the same wound types that are indicated for all dressings used with NPWTi-d. Indicated wound types include chronic, acute, traumatic, sub-acute, and dehisced wounds; partial-thickness burns; ulcers, such as diabetic, pressure, and venous insufficiency; and flaps. More specifically, the ROCF-CC dressing should be considered in indicated wounds that contain exudate that may be difficult to remove by either NPWT or NPWTi-d with ROCF-V.

Negative pressure wound therapy with instillation and dwell time with ROCF-CC reticulated open-cell foam dressing with through holes (V.A.C. VERAFLÖ CLEANSE CHOICE Dressing; KCI, an Acelity Company; San Antonio, TX; ROCF-V: V.A.C. VERAFLÖ Dressing [KCI])

Fill Assist is part of V.A.C. VERAFLÖ Therapy (KCI)

Table 3. Recommended NPWTi-d therapy settings

<table>
<thead>
<tr>
<th>Available range for therapy unit</th>
<th>Dwell Time</th>
<th>Negative Pressure Time Phase</th>
<th>Negative Pressure</th>
<th>Topical Solution Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 sec–30 min</td>
<td>3 min–12 h</td>
<td>-50 to -200 mmHg</td>
<td>6–500mL</td>
<td></td>
</tr>
<tr>
<td>Default setting for therapy unit</td>
<td>10 min</td>
<td>3.5 h</td>
<td>-125mmHg</td>
<td></td>
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<tr>
<td>Manufacturer’s guidelines for topical solution volume for ROCF-CC</td>
<td>Fill Assist set point range for medium dressing: 85–160mL (1.6cm cover layer); 42–80mL (0.8cm cover layer); 24–46mL (0.8cm wound contact layer)</td>
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<tr>
<td>2015 published panel recommendations: review of evidence and recommendations for NPWTi-d with ROCF-V</td>
<td>Fill Assist tool recommended; volume should be modified based on amount of foam dressing and wound topography, including tunneling and undermining</td>
<td></td>
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</tr>
<tr>
<td>Panel-recommended range for ROCF-CC</td>
<td>2–20 min</td>
<td>30 min–3.5 h</td>
<td>-125mmHg and -150mmHg</td>
<td>Underfilling using Fill Assist is recommended. Consider filling just to the point when dressing foam starts to swell; stop just before the solution reaches the drape around the perimeter of the dressing. Or fill to halfway mark with Fill Assist, then empty; run test cycle and watch dressing for 3–5 min to make sure seal is maintained.</td>
</tr>
<tr>
<td>Consider increasing respective setting if:</td>
<td>Goal is removal of fibrinous debris (≥10 min).</td>
<td>Goal is removal of fibrinous debris (more cycles: 1 h).</td>
<td>Wound is edematous/wet.</td>
<td>Wound volume is larger.</td>
</tr>
<tr>
<td>Consider decreasing respective setting if:</td>
<td>Goal is granulation tissue (1–5 min). Wound is edematous and/or highly exudating.</td>
<td>Goal is granulation tissue or wound is edematous/wet (fewer cycles: 2–3 h).</td>
<td>Wound size volume is smaller. Wound is edematous/wet. If leaks during therapy.</td>
<td>Wound is edematous/wet.</td>
</tr>
</tbody>
</table>

NPWTi-d: negative pressure wound therapy with instillation and dwell time; ROCF-CC: reticulated open-cell foam dressing with through holes V.A.C. VERAFLÖ CLEANSE CHOICE Dressing (KCI, an Acelity Company; San Antonio, TX); ROCF-V: V.A.C. VERAFLÖ Dressing (KCI)

Fill Assist is part of V.A.C. VERAFLÖ Therapy (KCI)

Dressing; KCI, an Acelity Company; San Antonio, TX; ROCF-V: V.A.C. VERAFLÖ Dressing (KCI)

Fill Assist is part of V.A.C. VERAFLÖ Therapy (KCI)
use of NPWTi-d, a thorough wound assessment should be conducted for all wound types, addressing the underlying wound etiology. Confounding elements may include immune/protein deficiencies, coagulopathies, arterial/venous compromise, medical comorbidities, peripheral neuropathic states, infectious conditions, and biomechanical abnormalities. Fundamental principles of wound treatment apply, including appropriate antibiotic therapy, debridement, proper offloading of pressure, good local wound care, and hardware/implant removal, if necessary. At every dressing change, it is important to reevaluate the status of the wound.

**Osteomyelitis.** Osteomyelitis must be treated prior to initiating NPWTi-d with ROCF-CC. Consideration should be given to thorough debridement of infected bone and appropriate antibiotic therapy. Once osteomyelitis is treated and bone fragments are eliminated, the ROCF-CC dressing may be used.

**Hemostasis.** Use of NPWTi-d with ROCF-CC may allow for less aggressive methods of debridement, which can help with hemostasis. However, extreme caution should be taken with anticoagulated patients. Confirmed hemostasis is necessary prior to use of ROCF-CC dressings, and especially in cases of immediate, postsurgical application.

**Intact mesh.** Efficient use of NPWTi-d has been reported for abdominal wound dehiscence with mesh exposure and in an infected wound after laparotomy for abdominal hernia reconstruction with mesh placement. However, according to the manufacturer’s instructions for use, instilling topical solutions with NPWTi-d is contraindicated in the thoracic or abdominal cavity due to the potential risk to alter core body temperature and the potential for fluid retention within the cavity.

In parallel with the manufacturer’s guidelines, panel members recommended use of ROCF-CC directly over mesh, if mesh is intact, extracavitary, and does not involve contact with neurovascular or exposed vessels or exposed visceral organs, including bowel. The ROCF-CC dressing may be used directly over synthetic mesh. Negative pressure wound therapy with instillation and dwell time is not intended for use with cellular or acellular bioengineered tissue.

**Skin grafting.** In cases of STSG or FTSG closure, in the experience of panel members, a STSG can be applied directly over developed macrocolumns with no detrimental aesthetic or clinical effects. In cases presented during the meeting where standard NPWT was applied over the STSG, macrocolumns did not persist under the STSG (Figure 3).

4. **Appropriate patients for NPWTi-d with ROCF-CC are patients with wounds that contain nonviable tissue, including (1) operative candidates when surgical debridement is not available, (2) operative candidates who refuse surgical debridement, (3) patients who have undergone excisional sharp debridement but nonviable tissue remains in the wound bed, and (4) nonoperative candidates when surgical debridement is not appropriate.**

While a wound may require temporizing to prepare for the next step in wound healing, surgical debridement may not be a manageable option for many reasons. In facilities with limited resources, such as rural clinics or community hospitals, surgical suites and qualified surgeons may not be available to perform complete surgical debridement. Certain patients may be unable to safely undergo anesthesia, particularly in cases of elderly patients with multiple comorbidities. In the presence of pre-existing conditions, such as diabetes, paraplegia, severe infection, renal failure or devascularization, surgeons often avoid or patients refuse anesthesia and surgical debridement, opting instead for nonsurgical alternatives.

Partial or complete surgical debridement may not be an option when there is a high risk of hemorrhage, deep undermining is present, or a less invasive procedure is required. In a 2013 document, the European Wound Management Association recommended that alternate methods of debridement should be considered if nonviable tissue demarcation does not extend deeper than the deep dermal layer or the wound bed is covered by fibrin or slough, as these situations may require more gentle methods of debridement to avoid excess wound damage.

In cases where complete surgical debridement is not feasible or appropriate, NPWTi-d with ROCF-CC can provide an active mechanism to assist wound cleansing by removing fibrinous slough from the wound bed and prepare the wound for the next step in wound closure. The therapy also may be beneficial in patients who have previously undergone surgical debridement or other types of debridement yet fibrinous tissue remains in the wound bed.

5. **Appropriate wounds for NPWTi-d with ROCF-CC contain a majority area of slough/fibrinous tissue and (1) have heavy bioburden and/or (2) are difficult to granulate.**

Based on the literature, the manufacturer’s guidelines, and panel members’ experience, NPWTi-d with ROCF-CC is not recommended for clean wounds or wounds with small areas of devitalized tissue. Wounds should be large enough to allow adequate cover of the base of the wound with a contact layer that contains at least 2 through holes. Negative pressure wound therapy with instillation and dwell time maintains a closed system of controlled wound irrigation, which may assist in removing infectious materials and promoting granulation tissue formation.

Infection should be appropriately managed with systemic antibiotics, using NPWTi-d with ROCF-CC adjunctively. The manufacturer’s instructions for use recommend careful monitoring of infected wounds during treatment with NPWTi-d and close physician involvement when signs of systemic infection or advancing infection at the wound site are present. Negative pressure wound therapy
<table>
<thead>
<tr>
<th>Prior to Application of ROCF-CC Dressings</th>
<th>Application of ROCF-CC Dressings</th>
<th>During Use of ROCF-CC Dressings</th>
<th>Removal of ROCF-CC Dressings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protect skin edges; window pane completely around wound with stoma adhesive, cohesive seal, or ostomy strip paste.</td>
<td>Ensure contact layer is in contact with entire base of wound, including into creases.</td>
<td>May need to increase pressure based on exudate.</td>
<td>Use dressing soak feature on device prior to removal.</td>
</tr>
<tr>
<td>When determining solution volume, slightly underfill; typically needs less volume than with standard NPWTi-d.</td>
<td>Completely fill wound cavity without overfilling with remaining cover dressings.</td>
<td>When applicable, consider educating patients about basic therapy functions and alarms, so patients can help alert clinicians to alarms and/or leaks.</td>
<td>Gently peel back the drape and release the periwound barrier dressing from the periwound skin.</td>
</tr>
<tr>
<td>May need less solution volume in wounds that contain greater amounts of thin exudate.</td>
<td>Topography of the wound bed should be considered to allow the contact layer to interface with entire architecture of the wound.</td>
<td>Support nursing staff, including providing troubleshooting tips.</td>
<td>Peel off the foam contact layer in a slow, fluid motion.</td>
</tr>
<tr>
<td></td>
<td>In undermined areas, try to use just 1 piece or as few pieces as possible of contact layer dressing.</td>
<td>Educate hospital-wide on use of therapy.</td>
<td>May use forceps and normal saline to help release dressing.</td>
</tr>
<tr>
<td></td>
<td>Cut contact layer foam when needed to fit undermined area. Smooth contact layer over base of undermined area to eliminate wrinkles and prevent contact layer from folding over onto itself.</td>
<td></td>
<td>Take greater care to gently remove dressing in cases of sensitive anatomic locations and/or with deep macro-columns.</td>
</tr>
<tr>
<td></td>
<td>Holes in the contact layer dressing do not need to line up with successive dressings.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tubing set should be placed to account for gravity, patient’s activity level, future repositioning, and to avoid pressure points.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Larger wounds may require 2 tubing sets.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Minimize number of wrinkles created with the drape, as wrinkles can cause leaks.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ROCF-CC: reticulated open-cell foam dressing with through holes; NPWTi-d: negative pressure wound therapy with instillation and dwell time.
with instillation and dwell time with ROCF-CC was not recommended by panel members in cases of 100% surface area coverage with dry intact eschar as well as in the presence of abscesses.

6. The ROCF-CC dressing can be used with caution in cases of (1) patients at an increased risk of bleeding complications, (2) signs of systemic infection or advancing infection at the wound site, (3) exposed structures, (4) explored tunnels, or (5) explored undermining.

Panel members agreed on the following precautionary measures, based on the manufacturer’s instructions for use of NPWTi-d, in treating difficult-to-heal wounds in patients with complex chronic diseases.

**Explored wounds.** A comprehensive wound assessment should be performed to determine wound size (length, width, and depth), presence of infection, undermining, tunneling sinus tracts, exudates, and necrotic tissue, as well as granulation tissue status and epithelialization. If indicated, imaging modalities, including plain film radiographs, computed tomography, and/or magnetic resonance imaging, may be necessary to identify fluid collections or tunnels.

**Increased risk of bleeding.** All exposed organs in or around the wound must be completely covered and protected prior to administering NPWTi-d with ROCF-CC. Extreme caution should be used when NPWTi-d with ROCF-CC is applied near infected or potentially infected blood vessels, as they are at risk of complications including bleeding. It also is necessary to protect against dislodging nonsutured hemostatic agents (ie, bone wax, absorbable gelatin sponge, or spray wound sealant), if used.

If active bleeding develops suddenly or in large amounts during NPWTi-d with ROCF-CC, or if blood is seen in the tubing or exudate canister, therapy should be stopped immediately and measures should be taken immediately to stop the bleeding. Negative pressure wound therapy with instillation and dwell time with ROCF-CC should not be used to prevent, minimize, or stop vascular bleeding.

**Exposed structures.** Careful consideration should be made to protect exposed deep structures (eg, tendons, ligaments, and nerves) when using NPWTi-d with ROCF-CC.

**Systemic infection.** Negative pressure wound therapy with instillation and dwell time with ROCF-CC is not intended to replace the use of systemic therapy or other infection treatment regimens.

7. The topical solutions that have been recommended for instilling during standard NPWTi-d also are recommended when using the ROCF-CC dressing. However, more research is needed to determine optimal topical solutions to best address various types of bioburden and wound characteristics.

The topical wound solutions that are compatible with NPWTi-d with ROCF-CC are listed in Table 2.

Panel members recommended starting NPWTi-d with saline, and, if appropriate, switching to an appropriate topical antimicrobial or antiseptic solution. When signs of infection are no longer present, the topical solution may be switched back to saline.

In addition, topical solutions can be used to help control pain or odor. Instillation of a topical anesthetic with NPWTi-d has been reported to effectively minimize wound pain that may be associated with the therapy or a combination of factors. Hypochlorous acid solutions may work well with malodorous wounds. Negative pressure wound therapy with instillation and dwell time with ROCF-CC should not be used with Octenisept (schülke inc, Norderstedt, Germany), hydrogen peroxide, or solutions that
are alcohol-based or contain alcohol. There also have been cases of material degradation in bench testing with use of higher concentrations (>0.125%) of sodium hypochlorite solutions. However, panel members reported good outcomes and no material degradation with use of higher concentration hypochlorous acid wound cleansing solution.

The cassette that delivers the topical solution in the NPWTi-d device is for single-patient use. The cassette should be changed if the instillation solution is changed, if the volume of instillation solution exceeds 11 250 mL, or if the cassette assembly is compromised. Individual organizational policies may dictate specific frequencies for changing the cassette. Panel members discussed that a change in instillation solution from one wound cleansing product to another should prompt a cassette change to negate any possibility of reactive precipitate formation, solution inactivation, or an unforeseen reaction with a system component. Also, it is recommended that any time a topical solution for instillation, other than saline, is changed, that the dressing assembly is changed; a residual solution could potentially react to the new solution. Changing the dressing assembly and the cassette when a topical solution is changed ensures that the 2 solutions will not interact. Currently, no evidence exists to support the use of additional topical agents including enzymatic debridement agents, collagenase, and honey-based products with NPWTi-d. Although panel members have used these topical agents in various clinical situations, none of the panel members recommended use of these agents during NPWTi-d.

8. Based on minimal experience, the following range of NPWTi-d settings are suggested for use with ROCF-CC: (1) dwell time of 1 to 20 minutes, (2) negative pressure time phase of 30 minutes to 3.5 hours, (3) negative pressure of -125 or -150 mm Hg, and (4) topical solution volume will greatly vary between wounds.

**Figure 5. Algorithm to guide use of ROCF-CC with NPWTi-d.**

TSA: total surface area; OR: operating room; NPWTi-d: negative pressure wound therapy with instillation and dwell time; ROCF-CC: reticulated open-cell foam dressing with through holes.
A wide range of NPWTi-d settings are available for use with any of the available foam dressings (Table 3). Selecting the appropriate setting can depend on a variety of factors, including wound location, mobility of patient, goal of therapy, patient condition, wound type, and wound size. There is currently no published evidence that suggests optimal ranges of NPWTi-d settings for ROCF-CC dressings. Prior clinician recommendations based on trial and error suggested an optimal range of 10-minute to 20-minute dwell time followed by 1 to 2.5 hours of negative pressure for each cycle for NPWTi-d with ROCF-V. These recommendations continue to be refined to address specific patient circumstances or wound status.

There was no strong consensus among current panel members to change prior recommendations for NPWTi-d settings with ROCF-CC, since information is lacking. However, successful cases that were presented during the meeting reported dwell times between 2 and 20 minutes and NPWT phases of 30 minutes to 3.5 hours per cycle.

Compared with NPWTi-d with ROCF-V, panel members recommended more frequent cycles and longer dwell times with the ROCF-CC dressing in general, and especially when the goal is wound cleansing via the removal of thick, fibrinous debris. The manufacturer’s recommended dressing change frequency for ROCF-CC dressings is once every 2 to 3 days, similar to all other NPWTi-d dressings. More frequent dressing changes...

Figure 6. Venous stasis ulcer management. (A) Venous stasis ulcer measured 22cm x 16cm and 85% fibrinous; (B) wound after 10 days of negative pressure wound therapy with instillation and dwell time using normal saline with 3-minute dwell time followed by 2 hours of negative pressure; (C) on treatment day 10, patient was switched to standard negative pressure wound therapy (NPWT); and (D, E) at week 4, split-thickness skin grafts on right and left leg ulcers after 5 days of NPWT bolster.
were recommended during periods of rapid granulation tissue formation to reduce adherence of the granulation tissue to the foam dressing.

As with NPWTi-d and ROCF-V dressings, less frequent cycles and shorter dwell times were recommended in cases of edematous wounds, primarily to avoid leaks in the dressing. It is important to recognize that large wounds treated with frequent cycles of instillation can lead to frequent solution exchange, filling and emptying of canisters, and placement of new solution containers — all of which needs to be managed proactively and cost-effectively within facility guidelines.

9. The clinical evidence of effectiveness of NPWTi-d with ROCF-CC needs to be further explored.

Many questions remain regarding the mechanisms of action and clinical efficacy of NPWTi-d with ROCF-CC dressings. The observed effects of this dressing differ from other foam dressings used with NPWTi-d, but how ROCF-CC compares to other dressings used with NPWTi-d has not been investigated. Panel members suggested numerous experimental designs that would add to the current limited body of knowledge regarding use of this dressing.
The need for a clinical study comparing outcomes of wounds treated with NPWT with ROCF, versus NPWTi-d with ROCF-V, NPWTi-d with ROCF-CC, and enzymatic debridement topped the list. Specifically, comparing the ability to remove nonviable tissue, rate of granulation tissue formation, cost and patient length of stay between these study groups for specific wound types would aid clinical decision making. A scientific study explaining perfusion and macro/microdeformation effects of the ROCF-CC dressing with NPWTi-d on the wound bed also could guide appropriate use of the therapy.

Clinical techniques for ROCF-CC dressing application

Application of the ROCF-CC dressing is similar in most ways to previous NPWTi-d dressings. The addition of the ROCF-CC dressing’s wound contact layer with through holes does appear to impact wound healing in a manner different from the ROCF-V dressing, although this has yet to be quantified in a controlled setting. Panel members recommended several techniques in applying the ROCF-CC dressing to help optimize outcomes (Table 4).

Clinical considerations for pressure ulcer/injury management with NPWTi-d and ROCF-CC

Panel members recommended use of NPWTi-d with ROCF-CC for cleansing, particularly in cases of unstageable or stage 4 pressure ulcers/injuries. Pressure ulcers/injuries were a predominant wound type represented in case study presentations during the panel meeting. Patients with pressure ulcers/injuries often have severely compromised health and multiple comorbidities that make them poor candidates for sharp excisional debridement.

Clinicians are sometimes limited in current treatment options for pressure ulcers/injuries. Because these wounds can be complex and time consuming to dress, they may benefit from the relatively long time (2–3 days) between dressing changes when using NPWTi-d with ROCF-CC. Quick negative pressure therapy cycles of 1 to 2 hours were recommended to encourage numerous applications of macrostrain to the wound bed and active cleansing. Shorter dwell times, as well as turning and repositioning during a negative pressure phase versus instillation phase, may be helpful in reducing risk of leaks. Figure 4 shows

**Figure 8.** Flap donor site wound management. (A) Flap donor site wound at presentation; (B) wound after bedside debridement.
demarcation of a stage 4 sacral pressure ulcer/injury during use of NPWTi-d with ROCF-CC.

Algorithm to guide optimal use of ROCF-CC dressings with NPWTi-d

An algorithm formulated by panel members to help clarify how and when ROCF-CC dressing use with NPWTi-d may fit into a clinical treatment approach for patients who present with a wound covered with slough and other devitalized tissue is displayed in Figure 5.

Case Examples

Case 1: bilateral venous stasis ulcers. A 65-year-old woman with a history of type 1 diabetes, chronic lymphedema, and chronic venous ulceration presented with right and left venous leg ulcers. The ulcers had persisted for 1 year and were nonresponsive to compression. The left leg ulcer measured 22 cm x 16 cm and was 85% covered with fibrinous, devitalized tissue (Figure 6A). Wound cultures were positive for methicillin-sensitive Staphylococcus, Pseudomonas, and Klebsiella. Prior treatment included intravenous antibiotics, hyperbaric oxygen therapy, and debridement via surgery and ultrasonic mist therapy. Negative pressure wound therapy with instillation and dwell time was initiated with ROCF-CC. With each cycle, 50 cc of normal saline was instilled with a 3-minute dwell time followed by 2 hours of -125 mm Hg negative pressure. At 10 days, the therapy goal of decreased fibrinous debris and bioburden was achieved; the cellulitis surrounding the wound improved as well (Figure 6B). Treatment was changed to standard NPWT and compression (Figure 6C). At 4 weeks, the wounds were granulated and ready for skin grafts. Split-thickness skin grafts were applied and bolstered with NPWT for 5 days; there was 100% graft take over both wounds (Figure 6D, 6E). The patient was fitted for compression stockings and instructed to wear them; she also was referred to a lymphedema center for lymphatic massage and education. The skin grafts remained intact and healed during the 6-month follow-up period, after which she moved away and was lost to follow-up.
Case 2: dehisced midline abdominal wound. A 75-year-old woman diagnosed with stage IV endometrial cancer with peritoneal carcinomatosis presented to the hospital from a medical rehabilitation center after she was found to have progressive shortness of breath and acute kidney injury with decreased urine output. The patient had a medical history of obstructive sleep apnea, type 2 diabetes with hyperglycemia, hypothyroidism, hypertension, and anemia. The patient’s surgical history consisted of an exploratory laparotomy for tumor debulking and staging, and total abdominal hysterectomy with bilateral salpingo-oophorectomy. On postoperative day 25, surgical skin dehiscence of the midline incision resulted in a wound measuring 13.2 cm x 4.1 cm x 4 cm. Antibiotics were administered to treat pneumonia. Standard NPWT was initiated on day 3 after presentation (Figure 7A), and the wound was reassessed on day 7 (Figure 7B). Treatment was changed to NPWTi-d with ROCF-CC dressings (Figure 7C, 7D) with goals of decreasing nonviable tissue and promoting granulation tissue formation. With each cycle, 16 mL of normal saline was instilled with a 10-minute dwell time, followed by 30 minutes of NPWT. Therapy continued for 8 days with dressing changes every 48 to 72 hours (Figure 7E). After 8 days of NPWTi-d with ROCF-CC, the wound exhibited decreased nonviable tissue and increased beefy red granulation tissue (Figure 7F). At no time was collagenase used in conjunction with NPWTi-d; however, after the patient was discharged, collagenase ointment was used as an adjunctive therapy with NPWT.

Case 3: infected donor site wound after harvest of gracilis flap. A 55-year-old woman presented with a donor site wound that failed to close after 38 days following harvest of a gracilis flap (Figure 8A). The patient’s medical history included hypertension, chronic pain, hepatitis, gastrointestinal reflux disease, and osteoporosis; her surgical history consisted of bilateral hemiarthroplasty on both hips, open reduction internal fixation of bilateral ankles, and a muscle flap over the right ankle. Failed closure of the flap donor site resulted in multiple hospital admissions, several surgical debridements, and infection of the donor site. Following bedside debridement with intravenous morphine, the wound measured 22 cm x 9.7 cm x 6.1 cm (Figure 8B). Negative pressure wound therapy with instillation and dwell time was initiated with an ROCF-CC dressing; 44 mL of 0.125% sodium hypochlorite solution was instilled with a 3-minute dwell time, followed by 2 hours of -125 mm Hg NPWT (Figure 8C). The goal of therapy was to progress the wound toward closure. The wound was reassessed the next day, and negative pressure was increased to -150 mm Hg. After 5 days of NPWTi-d with ROCF-CC, wound size was noticeably smaller, measuring 16.5 cm x 8.5 cm x 5.3 cm after removal of dressing (Figure 8D). Edema and erythema were visibly reduced. Therapy was switched to standard NPWT, and the patient was discharged to a skilled nursing facility.

Conclusions

Used in conjunction with NPWTi-d, intermittent instillation of saline, topical wound cleansers, or appropriate topical antimicrobial and antiseptic solutions has provided the added benefit of wound cleansing and solubilizing exudate for easier removal of infectious material and other devitalized tissue. Several published studies have described NPWTi-d as an adjunctive therapy for contaminated or infected complex wounds and successful use has been described in open fractures, breast reconstruction, necrotizing fasciitis, upper and lower extremity wounds, pressure ulcers/injuries, venous leg ulcers, diabetic foot ulcers, and other complex wounds requiring surgical debridement. With the introduction of the ROCF-CC dressing, NPWTi-d may be an appropriate adjunct therapy for wound cleansing in cases when debridement is not available or appropriate. Although no conclusive statements were finalized at the meeting, the panel recommendations and algorithm on the use of NPWTi-d with ROCF-CC can serve as a guide for clinicians until more studies are published. All panel members agreed that large, controlled clinical studies will be necessary to determine the optimal therapy settings and greatest effectiveness for the use of NPWTi-d with ROCF-CC.

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References


