

**STERILE FOAM DRESSING**  
**RFI: VA119-14-I-0194**  
**Attachment 1.1**



**PRODUCT DESCRIPTION**  
**DEPARTMENT OF VETERANS AFFAIRS**  
**OFFICE OF PROCUREMENT AND LOGISTICS**  
**MEDICAL COMMODITIES PROGRAM EXECUTIVE OFFICE**

**Foam Dressings**  
**Date: March 11, 2014**

**SAC-13-10964**

**Version 3.0**

## PRODUCT DESCRIPTION

### 1. REQUIREMENTS:

The Department of Veterans Affairs (VA), Veterans Health Administration (VHA) National Standardization Wound Care Integrated Product Team (IPT) identified foam dressings as a candidate item for standardization. Foam Dressings shall be provided in the following three categories: (1) Sterile Bordered Foam Dressing (no contact layer); (2) Sterile Bordered Foam Dressing (with contact layer); and (3) Sterile Foam Dressing (non-bordered). These dressings can be used as primary or secondary dressings and will be used in wound care for highly effective absorption of wound exudate in partial or full thickness wounds with minimal to moderate drainage.

The product characteristics applicable to the items identified under this requirement are described in the Minimum Technical Requirements (MTRs) specified below:

Contract Line Item Number (CLIN) 0001	<b>Product Description: Sterile Bordered Foam Dressing (<u>no contact layer</u>)</b> — a sterile, bordered foam dressing with <b><u>NO contact layer</u></b> for use in wound care for highly effective absorption of wound exudate in partial or full thickness wounds with minimal to moderate drainage. For purposes of this Request for Information, “ <b><u>contact layer</u></b> ” is defined as a wound contact layer containing either silicone gel adhesive or soft silicone.
<b>Minimum Technical Requirements (MTRs)</b>	
MTR1	“Not made with natural rubber latex” (based on 3/11/13 FDA Guidance Document or similar notation indicating the product and product packaging can be used safely in a latex-allergic patient)
MTR2	Sterile
MTR3	Semi-occlusive
MTR4	Composition: Polyurethane foam or Hydro polymer
MTR5	Adhesive border
MTR6	Outer film of dressing will be vapor permeable and waterproof to act as a bacterial barrier
MTR7	Indelible or embossed imprinted expiration date and lot on smallest individual dispensing unit (peel & stick labels are considered unacceptable)
MTR8	Moldable to and adherent to body part
MTR9	Provides a moist wound environment

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MTR10	Instructions for use included as package insert, printed on box or printed on smallest individual dispensing unit.
MTR11	Adhesive does not leave residue on skin when dressing is removed after 6 hours of wear time
MTR12	Required size: smaller than 4 inch x 4 inch but no less than 3 inch x 3 inch
MTR13	Required size: 4 inch ( $\pm 1$ inch) x 4 inch ( $\pm 1$ inch)
MTR14	Required size: larger than 4 inch x 4 inch but no greater than 7 inch x 7 inch (excludes sacral shapes).
MTR15	Sacral-shaped dressing
MTR16	Must not have a contact layer (Silicon gel adhesive or soft silicon)
MTR17	Fluid handling capacity is $\geq 20$ g/ 10cm <sup>2</sup> /24hrs: Reference: Must submit documentation referencing value using EN 13726 or Edana Method 442.1-99. (Vendor must submit a certified document, which includes: 1. Testing method utilized 2. Name of laboratory utilized for testing 3. Testing results in g/10 sq. cm/24 hrs. [no other units are acceptable, conversions will not be performed by evaluators] 4. Name and signature of laboratory scientist/technician performing the test 5. Date testing was performed/completed <b>*Restatement of the value will be considered unacceptable.)*</b>
<b>INTENDED USE:</b> An adhesive, bordered dressing to be used as a primary or secondary dressing in the management of partial and full-thickness wounds with light to moderate exudate.	

Contract Line Item Number (CLIN) 0002	<b>Product Description: Sterile Bordered Foam Dressing (with contact layer) — a sterile, bordered foam dressing <u>with a contact layer</u> for use in wound care for highly effective absorption of wound exudate in partial or full thickness wounds with minimal to moderate drainage. For purposes of this Request for Information, “contact layer” is defined as a wound contact layer containing either silicone gel adhesive or soft silicone.</b>
<b>Minimum Technical Requirements (MTRs)</b>	
MTR1	“Not made with natural rubber latex” (based on 3/11/13 FDA Guidance Document or similar notation indicating the product and product packaging can be used safely in a latex-allergic patient)
MTR2	Sterile
MTR3	Semi-occlusive
MTR4	Composition: Polyurethane foam or Hydropolymer
MTR5	Adhesive border
MTR6	Outer film of dressing will be vapor permeable and waterproof to act as a bacterial barrier

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MTR7	Indelible or embossed imprinted expiration date and lot on smallest individual dispensing unit (peel & stick labels are considered unacceptable)
MTR8	Moldable to and adherent to body part
MTR9	Provides a moist wound environment
MTR10	Instructions for use included as package insert, printed on box or printed on smallest individual dispensing unit
MTR11	Adhesive does not leave residue on skin when dressing is removed after 6 hours of wear time
MTR12	Required size 4 inches ( $\pm 1$ inch) x 4 inches ( $\pm 1$ inch)
MTR13	Required size: one additional size smaller than 4 inch x 4 inch, but no less than 3 inch x 3 inch
MTR14	Required size: one additional size larger than 4 inch x 4 inch, but no greater than 7 inch x 7 inch (excludes sacral-shaped)
MTR15	Sacral-shaped dressing
MTR16	Contact layer (Silicon gel adhesive or soft silicon)
MTR17	Atraumatic removal
MTR18	<p>Fluid handling capacity is <math>\geq 20</math> g/ 10cm<sup>2</sup>/24hrs: Reference: Shall submit documentation referencing value using EN 13726-1 or Edana Method 442.1-99 in portable document format (PDF).</p> <p><i>(Vendor shall submit a certified document, which includes:</i></p> <ol style="list-style-type: none"> <li>1. <i>Testing method utilized (identify either EN 13726-1 or Edana Method 442.1-99)</i></li> <li>2. <i>Name of laboratory utilized for testing</i></li> <li>3. <i>Testing results in g/10 sq cm/24 hrs <b><u>[No other units are acceptable. Conversions will not be performed by evaluators.]</u></b></i></li> <li>4. <i>Name and signature of laboratory scientist/technician performing the test</i></li> <li>5. <i>Date testing was performed/completed</i></li> </ol> <p><i>*Restatement of the value will be considered unacceptable.)</i></p>
<p><b>INTENDED USE:</b> An adhesive, bordered dressing to be used as a primary or secondary dressing in the management of partial and full-thickness wounds with light to moderate exudate.</p>	

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Contract Line Item Number (CLIN) 0003	<b>Product Description: Sterile Foam Dressing (<i>non-bordered</i>)</b> — a sterile, foam dressing for use in wound care for highly effective absorption of wound exudate in partial or full thickness wounds with minimal to moderate drainage.
<b>Minimum Technical Requirements (MTRs)</b>	
MTR1	Sterile
MTR2	“Not made with natural rubber latex” (based on 3/11/13 FDA Guidance Document or similar notation indicating the product and product packaging can be used safely in a latex-allergic patient)
MTR3	Semi-occlusive
MTR4	Composition: Polyurethane foam or Hydropolymer
MTR5	Outer film of dressing will be vapor permeable and waterproof to act as a bacterial barrier.
MTR6	Indelible or embossed imprinted expiration date and lot on smallest individual dispensing unit (peel & stick labels are considered unacceptable)
MTR7	Provides a moist wound environment
MTR8	Required size 4 inches (± 1 inch) x 4 inches (± 1 inch)
MTR9	Required size: 6 inch(± 1 inch) x 6 inch (± 1 inch)
MTR10	Instructions for use included as package insert, printed on box or printed on smallest individual dispensing unit
MTR11	Promotes autolytic debridement
MTR12	<p>Fluid handling capacity is <math>\geq 23 \text{ g/10cm}^2/24\text{hrs}</math>: Reference: Shall submit documentation referencing value using EN 13726-1 or Edana Method 442.1-99 in portable document format (PDF).</p> <p><i>(Vendor shall submit a certified document, which includes:</i></p> <ol style="list-style-type: none"> <li><i>1. Testing method utilized (identify either EN 13726-1 or Edana Method 442.1-99)</i></li> <li><i>2. Name of laboratory utilized for testing</i></li> <li><i>3. Testing results in g/10 sq cm/24 hrs [No other units are acceptable. Conversions will not be performed by evaluators.]</i></li> <li><i>4. Name and signature of laboratory scientist/technician performing the test</i></li> <li><i>5. Date testing was performed/completed</i></li> </ol> <p><i>*Restatement of the value will be considered unacceptable.)</i></p>
	<b>INTENDED USE:</b> A <i>non-bordered</i> dressing to be used as a primary or secondary dressing in the management of partial and full-thickness wounds with light to moderate exudate.

**Note:** The physical inspection will include the submission of samples, which shall be

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destroyed upon completion of the evaluation or returned to the customer upon, or at their request (**IAW FAR 52.212-1)(d)**).

## **2. PURPOSE AND OBJECTIVES**

The purpose of this procurement is to establish a five year, or 60 months period, Blanket Purchase Agreement (BPA), for the purchase of Foam Dressings. The BPA will be established with a Federal Supply Schedule (FSS) contractor that shall be able to provide a supply for this item on an as needed bases. The actual needs under this product will be specified by the issuance of individual BPA Orders by the Government based on patients needs as determined by the ordering VA Medical Facility.

**Contract Effective Date:** The effective date of the BPA shall be date signed by the Contracting Officer (or upon mutual agreement) after the date of award.

## **3. EXTENT OF OBLIGATION**

a. **Government Participants** – The Contractor shall provide delivery of United States Food and Drug Administration (FDA) approved Foam Dressings, as specified in the BPA, directly to VA Medical Centers (VAMC) throughout the United States and Puerto Rico at the prices awarded herein and under the terms and conditions set forth in the BPA upon receipt of a properly executed Order signed by a person with purchasing authority on behalf of a VAMC. Individual VAMCs shall issue Orders to the contractor which shall indicate the specific items ordered, item quantities, and all necessary delivery and payment procedures.

b. **Delivery Requirements** –

- 1) The products are available on FSS. The selected contractor must be able to deliver to any VA medical facility enterprise-wide.
- 2) Delivery shall be made to VA facilities (which may include outpatient facilities).

c. **Inspection and Acceptance** – The provisions **IAW FAR 52.212-4** are incorporated and made a part of this requirement. The Government inspection of commercial items will not prejudice its other rights under the acceptance paragraph.

- d. **Warranty** – The Government's post award rights contained **IAW FAR 52.212-4(o)** are the implied warranty of merchantability, the implied warranty of fitness for particular purpose and the remedies contained in the acceptance paragraph.

#### **4. SCHEDULE FOR DELIVERABLES**

The following provisions apply to all shipments:

**Inspection:** Destination

**Acceptance:** Destination

**Special Shipping Instructions:**

Prior to shipping, the contractor shall notify site point of contact, which will be specified under each BPA Order, by telephone and email, of all incoming deliveries including line-by-line details for review of requirements. All shipments, either single or multiple container deliveries, will bear the VA Order number on external shipping labels and associated manifests or packing lists. In the case of multiple container deliveries, a readable statement near the VA Order number will indicate total number of containers for the complete shipment (e.g., "Package 1 of 2"), clearly readable on manifests and external shipping labels.

**Packing Slips/Labels and Lists shall include the following:**

IFCAP PO # \_\_\_\_\_ (i.e., 166-E11234)

Total number of Containers: Package \_\_\_\_ of \_\_\_\_\_. (e.g., Package 1 of 3)