

## Appendix 3

### Framework Agreement Specification Advanced Wound Care

#### 1. Introduction

1.1 The Framework Agreement is for the supply of dressings and wound care products intended for use by clinicians in both the acute and community sectors to aid the management of wound healing process.

1.2 The Framework Agreement is for the following Lots:

Lot Number	Lot Title
<b>1.0</b>	<b>Products with Testing Requirements</b>
1.1	Gelling Fibres and Alginates
1.2	Super Absorbent Dressings
1.3	Foam Dressings
1.4	Non-Woven Island Dressings
1.5	Film and Film Island Dressings
<b>2.0</b>	<b>Products without testing requirements</b>
2.1	Hydrogels
2.2	Wound Contact Layers
2.3	Dressing Pads
2.4	Hydrocolloid Dressings
2.5	IV Dressings
2.6	Burns and Scar Management
2.7	Speciality Wound Care
2.8	Wound Irrigation
2.9	Debridement
2.10	Adhesive Removers
2.11	Barrier Creams & Films
2.12	Compression Bandages
2.13	Medical Adhesive Tapes

1.3 Full technical specifications of the product lines awarded to the Framework Agreement (each a “**Technical Specification**” and together the “**Technical Specifications**”) must be made available to NHS Supply Chain on request during the term of the Framework Agreement.

1.4 Applicants must notify NHS Supply Chain immediately about any proposed changes to the Technical Specifications throughout the term of the Framework Agreement.

1.5 If changes to the Technical Specification of any product line awarded to the Framework Agreement mean that the product line no longer meets the minimum requirements outlined in the Specification, NHS Supply Chain reserves the right to exclude that product line from the Framework Agreement.

1.6 NHS Supply Chain reserves the right to request evidence of compliance with the Specification throughout the term of the Framework Agreement.

1.7 This Framework Agreement Specification makes reference to a number of standards and legislation. The list of standards and legislation is not intended to be exhaustive and any

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relevant standards and legislation which applies to the Framework Agreement (even if not stated) must be complied with by Applicants (together with those listed in this Framework Agreement Specification the “**Standards and Legislation**”).

- 1.8 Product lines must comply with the Standards and Legislation (as amended, extended or re-enacted from time to time).
- 1.9 Evidence of compliance to the Standards and Legislation must be provided by Applicants awarded to the Framework Agreement (“**Suppliers**”) to NHS Supply Chain on request during the term of the Framework Agreement; in the event that sufficient evidence is not provided by Suppliers NHS Supply Chain reserves the right to suspend product lines until such evidence is provided by Suppliers.

2. **Criteria applicable across all product lines**

2.1 2.1 Standards and Legislation

STANDARD AND LEGISLATION	
<b>BS EN ISO 9001-2015</b>	Quality Management Systems. Requirements
<b>BS EN ISO 13485:2016</b>	Medical Devices. Quality management systems. Requirements for regulatory purposes
<b>Medical Devices Directive 93/42/EEC / EU MDR (EU) 2017/745 (replaces 93/42EEC introduced 25/5/17 with 3-year transition to full implementation 26/5/20)</b>	<p><u>EC Declaration of conformity to the Medical Devices Directive 93/42/EEC to be provided with your Tender response.</u></p> <p><u>Additional documentation may be requested in support of the EC declaration, for example, CE certification, technical agreements with manufacturers etc. Such information must be provided to NHS Supply Chain on request during the term of the Framework Agreement.</u></p> <p>Declaration of conformity to the Medical Devices Directive 93/42/EEC to be provided with your tender submission. <u>Class I Sterile, Class I measuring, Class IIa, Class IIb and Class III</u></p> <p><b>Where not Applicable</b> Provide a statement confirming why this Directive does not apply to your product(s) submitted for a product line. You will need to do this for each product line where this Directive is not applicable to your product(s)</p>
<b>CE Marking for Class I MHRA products and above.</b>	CE certificate from a notified body (or self-certified conformity if Class I non-sterile) to be provided with your tender submission. All products must have their CE marking clearly evident on the product and/or packaging.
<b>EN ISO 15223-1:2016 (Harmonised standard)</b>	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

- 2.2 On request Applicants must provide NHS Supply Chain with Safety Data Sheets (SDS) for all products that fall under REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) 2007 –more specifically, an SDS must be provided if a substance or a mixture supplied is classified as hazardous under the CLP Regulation (EC) No 1272/2008.
- 2.3 Any product line classed as a cosmetic must meet the requirements of Regulation (EC) 1223/2009.

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- 2.4 If a product line contains phthalates this must be indicated on the packaging of that product line in accordance with Directive 2007/47/EC (amending Directives 90/385/EEC and 93/42/EEC).
- 2.5 Electrical product lines must comply with the requirements of the Directive on waste electrical and electronic equipment (WEEE Directive 2012/19/EU) and the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2 Directive 2011/65/EU).
- 2.6 All product lines and packaging should be latex free where possible. If a product line or any packaging contains latex this must be labelled on the product line or packaging (as applicable) to inform the user.
- 2.7 During the term of the Framework Agreement Applicants must make NHS Supply Chain aware of any awarded product line that is classed by the MHRA as a Medicinal Product.
- 2.8 All product line(s) must be supplied with a minimum 12-month shelf life.
- 2.9 All product lines must be delivered free of charge to a location as directed by either NHS Supply Chain or the customer.
- 2.10 For clarity, unless otherwise stated absorbency refers to Total Fluid Handling Capacity as per **BS EN 13726-1 2002/ BS EN 13726-1 2023 Test methods for primary wound dressings. Aspects of absorbency.**
  - 2.10.1 For the purposes of this specification, and by extension Framework, the absorbency values are defined by NHS Supply Chain below:
    - Low 0.01 - 4.99 g/10cm<sup>2</sup>.**
    - Moderate 5.00 - 14.99 g/10cm<sup>2</sup>.**
    - High 15.00 - 24.99 g/10cm<sup>2</sup>.**
    - Ultra-High 25.00 + g/10cm<sup>2</sup>.**
- 2.11 Suppliers must have available instructions for safe use in English or pictograms which must be provided to NHSSC on request.
- 2.12 The expiry date and lot number must be stated on the individual product packaging.
- 2.13 Training at launch/switch and updates annually must be available from the supplier to all types of organisations. Dates, times, and other details are to be agreed with the end user.

### 3. **Lot 1 Products with Testing Requirements**

#### 4. **Lot 1.1 Gelling Fibres and Alginates**

Gelling fibre dressings and Alginate Dressings are used for moderate to highly exuding wounds and can be used for a wide variety of flat and cavity wounds. The dressings absorb exudate in their solid form, forming a gel, encouraging autolytic debridement promoting tissue granulation, and the maintenance of a moist wound environment.

- 4.1 Be supplied sterile, individually wrapped and in packaging marked for single use only.
- 4.2 Enable an aseptic, no-touch application technique (ANTT).

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- 4.3 The dressing must be composed of solid fibres that form a cohesive gel on contact with wound exudate.
- 4.4 Must be intended for use in the management of at least moderate amounts of exudate applicants must be able to demonstrate compliance with independent lab/in house testing for 'free swell' fluid handling capacity.
- 4.5 Dressing removal must be atraumatic, minimising pain to the patient and trauma to the wound bed and peri-wound skin.
- 4.6 Applicants must be able to demonstrate compliance with independent lab/in house testing for dispersion characteristics.
- 4.7 Must be available in sheet or rope form.
- 4.8 Must state at least 7 days wear time.
- 4.9 All antimicrobials must provide evidence of invitro reduction of bacterial load.
- 4.10 Suppliers must have available instructions for safe use in English or pictograms and be provided to NHSSC on request.
- 4.11 Products containing known allergens such as chitosan must be clearly labelled.
- 4.12 **Additional Properties**  
Products in this lot must be listed with one of the following additional properties:
  - 4.12.1 **Alginates**  
Must be composed of natural materials.  
Must be suitable for use as a haemostatic aid.
  - 4.12.2 **Further Additional Properties**  
Products in this lot may be listed with the following additional properties:
    - 4.12.2.1 **Antimicrobial Alginates**  
All antimicrobials must provide evidence of invitro reduction of bacterial load.
  - 4.12.3 **Gelling Fibres**  
Must be composed of synthetic or and mixture of synthetic and natural materials.
  - 4.12.4 **Further Additional Properties**  
Products in this lot may be listed with the following additional properties:
    - 4.12.4.1 **Antimicrobial Gelling Fibres**  
All antimicrobials must provide evidence of invitro reduction of bacterial load.

**5. Lot 1.2 Super Absorbent Dressings**

Super Absorbent Dressings are pad dressings with a highly absorbent hydrophilic core that can absorb and hold exudate without adhering to the wound bed. Backed super absorbent dressings within this Lot are to be provided without an adhesive border, intended for use as a primary dressing on heavily exuding wounds.

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- 5.1 Be supplied sterile, individually wrapped and in packaging marked for single use only.
- 5.2 Enable an aseptic, no-touch application technique (ANTT).
- 5.3 Must be intended for use in the management of at least high amounts of exudate. Applicants must be able to demonstrate compliance with Independent Lab/in house testing for Free Swell Absorbency.
- 5.4 Be flexible, allowing it to conform to body contours and natural orifices.
- 5.5 Be able to ensure that absorbed exudate is held within the dressing without causing the dressing to stiffen, lose shape or integrity.
- 5.6 Remain intact in use and not leave particles in the wound bed.
- 5.7 Must be suitable for use under compression.
- 5.8 Must state at least 7 days wear time.
- 5.9 Suppliers must have available instructions for safe use in English or pictograms and be provided to NHSSC on request.

5.10 **Additional Properties**

Products in this Lot may be listed with the following additional properties:

5.10.1 **Backed Super Absorbent Dressings**

The outer side of the dressing (side away from the wound bed) must have a surface layer that prevents the exudate from leaking from the core and transferring to any secondary bandage, bed linen or patient clothing.

5.10.2 **Non-Sterile Super Absorbents**

Suppliers may submit an additional non-sterile product which is exempt from criteria 5.1. and 5.2.

5.10.1 **Bordered Super Absorbent Dressings**

Must include an adhesive border, of adequate width to secure the dressing, along the full perimeter. Adhesive must aid with dressing removal which is atraumatic, minimising pain to the patient and trauma to the wound bed and peri-wound skin.

5.10.2 **Silicone Super Absorbent Dressings**

5.10.2.1 Must have a Silicone wound contact layer. This can be extended across the border if there is a border on the product.

5.10.2.2 Where products have a border, it must use a silicone-based adhesive.

5.10.3 **Antimicrobial Super Absorbent Dressings**

All antimicrobials must provide evidence of invitro reduction of bacterial load.

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## 6. Lot 1.3 Foam Dressings

Foam Dressings are designed to aid wound healing by providing a moist healing environment while effectively managing exudate.

- 6.1 Be supplied sterile, individually wrapped and in packaging marked for single use only.
- 6.2 Enable an aseptic, no-touch application technique (ANTT).
- 6.3 Must be intended for use in the management of at least moderate amounts of exudate. Applicants must be able to demonstrate compliance with Independent Lab/in house testing for fluid handling capacity.
- 6.4 Be flexible, allowing it to conform to body contours and natural orifices.
- 6.5 Be able to ensure that absorbed exudate is held within the dressing without causing the dressing to stiffen, lose shape or integrity.
- 6.6 Remain intact in use and not leave particles in the wound bed.
- 6.7 Must state at least 7 days wear time.
- 6.8 Must be permeable to moisture vapour.
- 6.9 Foam dressings must protect the peri-wound skin by sealing the wound edges and minimising the risk of maceration.
- 6.10 Have a multilayer construction to allow for exudate management. Layers must include:
  - 6.10.1 A low-adhering wound contact layer.
  - 6.10.2 Absorbing foam pad made of either polyurethane (PU) or polyvinyl acetate (PVA), or equivalent.
  - 6.10.3 Backing material must be a moisture vapour permeable polyurethane (PU).
- 6.11 **Additional Properties**  
Products in this Lot may be listed with the following additional properties:
  - 6.11.1 **Bordered Foams**  
Must include an adhesive border, of adequate width to secure the dressing, along the full perimeter. Adhesive must aid with dressing removal which is atraumatic, minimising pain to the patient and trauma to the wound bed and peri-wound skin.
  - 6.11.2 **Silicone Foams**
    - 6.11.2.1 Must have a Silicone wound contact layer. This can be extended across the border if there is a border on the product.
    - 6.11.2.2 Where products have a border, it must use a silicone-based adhesive.

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6.11.3 **Lite Foams**

6.11.3.1 Must be able to manage at least low amounts of exudate.

6.11.3.2 Must have a depth profile of no greater than 4mm.

6.11.4 **Tracheostomy Foams**

6.11.4.1 Must be able to be safely fitted between the skin and the flange/back plate of the tracheostomy cannula.

6.11.4.2 Must be of a 'keyhole' design with an opening between the aperture and one edge of the dressing.

6.11.5 **Antimicrobial**

All antimicrobials must also provide evidence of invitro reduction of bacterial load.

6.11.6 **Non-Sterile Foams**

Suppliers may submit an additional non-sterile product exempt from criteria 6.1 and 6.2.

6.11.7 **Enhanced Foam Dressings**

Enhanced dressings must be able to demonstrate additional properties which provide a clinical advantage through direct interaction with aspects of the biochemical process of wound healing, this should be supported by published peer reviewed scientific evidence. Additional properties could be in the form of, but shall not be limited to:

6.11.7.1 Protease management.

6.11.7.2 Accelerated debridement.

6.11.7.3 Additional layer, which interact with the wound such as a gelling fibre or superabsorbent.

6.11.7.4 Unique modes of action around the wound bed.

7. **Lot 1.4 Non - Woven Island Dressings**

Non-Woven Island Dressings are an adhesive dressing with an absorbent pad for use as an initial dressing on wounds, with low or no exudate and to also provide a covering for surgical wounds and/or wounds healing by secondary intention.

7.1 Be supplied sterile, individually wrapped and in packaging marked for single use only.

7.2 Enable an aseptic, no-touch application technique (ANTT).

7.3 Have a fixed absorbent pad applied centrally to the back of the dressing.

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- 7.4 Must be intended for use in the management of at least low amounts of exudate. Applicants must be able to demonstrate compliance with Independent Lab/in house testing for fluid handling capacity.
- 7.5 Be non-linting.
- 7.6 Be Latex free.
- 7.7 Must be showerproof or water resistant.
- 7.8 Must state at least 3 days wear time.
- 7.9 Suppliers must have available instructions for safe use in English or pictograms and be provided to NHSSC on request.

**8. Lot 1.5 Film and Film Island Dressings**

Film & Film Island Dressings are vapour-permeable films and membranes, which allow the passage of water vapour and air but are impermeable to liquid water and micro-organisms (Film Dressings) with or without an absorbative 'island' pad. They are for use as a primary dressing.

- 8.1 Must be composed of a polyurethane film, coated with synthetic adhesive mass; fully transparent (to be visually able to see the skin after application).
- 8.2 Be supplied sterile, individually wrapped and in packaging marked for single use only.
- 8.3 Enable an aseptic, no-touch application technique (ANTT).
- 8.4 Be Latex Free
- 8.5 Must be permeable to moisture vapour.
- 8.6 Be showerproof/wipeable or waterproof.
- 8.7 Be intended to minimise pain and trauma on removal.
- 8.8 Must state at least 5 days wear time.
- 8.9 Suppliers must have available instructions for safe use in English or pictograms and be provided to NHSSC on request.

**8.10 Additional Properties**

Products in this Lot may be listed with the following additional properties:

- 8.10.1 **Antimicrobials**  
All antimicrobials must also provide evidence of invitro reduction of bacterial load.

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9. **Lot 2 Products without testing requirements**

10. **Lot 2.1 Hydrogels**

Hydrogels are suited to the management of dry wounds but can be used for a wide variety of flat and cavity wounds. They are used in a sheet and gel form as well as impregnated into dressing materials. Hydrogels promote a moist healing environment, rehydrate the wound and facilitate autolysis and will debride a wound.

- 10.1 Be supplied sterile, individually wrapped and in packaging marked for single use only.
- 10.2 Enable an aseptic, no-touch application technique (ANTT).
- 10.3 Hydrogels must have a high-water content, greater than 51%, which provides moisture to the wound.
- 10.4 Multi-layered dressings must incorporate the hydrogel component as the wound contact layer.
- 10.5 Hydrogels must not contain propylene glycol.
- 10.6 Suppliers must have available instructions for safe use in English or pictograms and be provided to NHSSC on request.
- 10.7 **Additional Properties**  
Products in this lot may be listed with the following additional properties
  - 10.7.1 **Antimicrobial Hydrogels**  
All antimicrobials must provide evidence of invitro reduction of bacterial load.

11. **Lot 2.2 Wound Contact Layers**

Wound Contact Layers (WCL) are low or non-adherent primary dressings traditionally used to manage acute and chronic wounds at the proliferative stage of healing. They are often used as a primary dressing on low exuding or granulating wounds. Wound contact layers have recently been used alongside negative pressure wound therapy to protect the wound bed from trauma associated with the use of negative pressure.

- 11.1 Be supplied sterile, individually wrapped and in packaging marked for single use only.
- 11.2 Enable an aseptic, no-touch application technique (ANTT).
- 11.3 Must be permeable to moisture vapour.
- 11.4 The dressing must allow the passage of exudate away from the wound bed.
- 11.5 Be flexible, allowing it to conform to body contours and around natural orifices.
- 11.6 Dressing removal must be atraumatic, minimising pain to the patient and trauma to the wound bed and peri-wound skin.
- 11.7 Must state at least 3 days wear time.
- 11.8 Suppliers must have available instructions for safe use in English or pictograms and be provided to NHSSC on request.

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11.9 **Additional Properties**  
Products in this lot may be listed with the following additional properties:

11.9.1 **Silicone Wound Contact Layers**

11.9.1.1 Silicone WCL must be non-adherent.

11.9.1.2 Silicone WCL must be compatible with Negative Pressure Therapy.

11.9.1.3 Must state at least 14 days wear time.

11.9.2 **Antimicrobial Wound Contact Layers**

11.9.2.1 All antimicrobials must provide evidence of invitro reduction of bacterial load.

12. **Lot 2.3 Dressing Pads**

Dressing Pads for are simple absorbent dressings intended for managing exudate in conjunction with other wound care products, dressing pads may be supplied as sterile or non-sterile.

12.1 Be supplied sterile, individually wrapped and in packaging marked for single use only.

12.2 Enable an aseptic, no-touch application technique (ANTT).

12.3 Be non or low linting.

12.4 Be flexible, allowing it to conform to body contours and natural orifices.

12.5 Suppliers must have available instructions for safe use in English or pictograms and be provided to NHSSC on request.

12.6 **Additional Properties**  
Products in this Lot may be listed with the following additional properties:

12.6.1 **Antimicrobial Dressing Pads**

All antimicrobials must provide evidence of invitro reduction of bacterial load.

12.7.2 **Non-Sterile Dressing Pads**

Suppliers may submit and additional non-sterile product exempt from criteria 12.1 and 12.2.

13. **Lot 2.4 Hydrocolloid Dressings**

Hydrocolloid Dressings provide a moist wound environment promoting autolysis. They can be used as a primary wound dressing suitable for light to moderate exuding wounds and are often used on superficial burns and pressure ulcers.

13.1 Be supplied sterile, individually wrapped and in packaging marked for single use only.

13.2 Enable an aseptic, no-touch application technique (ANTT).

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- 13.3 Must be a wafer type dressing that contains gel-forming agents in an adhesive compound laminated onto a flexible, water-resistant outer layer.
- 13.4 Must be occlusive and able to be cut into shapes and sizes for specific body areas such as sacrum, elbows and heels.
- 13.5 Edges of dressing should be designed to deter them from rolling up when worn.
- 13.6 All products must include IFU (Instructions for Use). in English or pictograms and be provided to NHSSC on request.

**Additional Properties**

Products in this Lot may be listed with the following additional properties:

**13.6.1 Antimicrobial Hydrocolloid Dressings**

All antimicrobials must provide evidence of invitro reduction of bacterial load.

**14. Lot 2.5 IV Dressings**

IV Dressings are vapour-permeable films and membranes, which allow the passage of water vapour and air but are impermeable to liquid water and micro-organisms with or without a section of non-woven material. The primary intended use must be to retain an IV access device, as securement device or a fixation device.

- 14.1 IV Dressings All Peripheral IV dressings, Securement and Fixation Devices within this Lot must
- 14.2 Must be supplied sterile, where possible
- 14.3 Be individually wrapped and in packaging marked for single use only.
- 14.4 Enable an aseptic, no-touch application technique (ANTT).
- 14.5 Be Latex Free
- 14.6 The primary intended use must be to retain an IV access device, as securement device or a fixation device.
- 14.7 Must be permeable to moisture vapour.
- 14.8 Be showerproof/wipeable or waterproof.
- 14.9 Be designed to minimise pain and trauma on removal.
- 14.10 Must state at least 5 days wear time.
- 14.11 Suppliers must have available instructions for safe use in English or pictograms and be provided to NHSSC on request.
- 14.11 **Additional Properties**  
Products in this Lot may be listed with the following additional properties:

**14.11.1 Antimicrobials**

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All antimicrobials must also provide evidence of invitro reduction of bacterial load.

## 15. Lot 2.6 Burns and Scar Management

Burns and Scar and Skin Management must be designed to support treatment of burns, scar tissue or recently healed wounds, actively encourage healthy skin healing and minimise the discomfort or pain to the patient.

- 15.1 Must provide immediate treatment for burns.
- 15.2 Scar and skin management products are specifically designed to support the treatment of scar tissue or recently healed wounds.
- 15.3 Can be supplied in different forms including:
  - 15.3.1 Dermatology garments.
  - 15.3.2 Dermatology creams.
  - 15.3.3 Dermatology ointments.
  - 15.3.4 Scar management dressings.
- 15.4 **Additional Properties**  
Products in this Lot may be listed with the following additional properties:
  - 15.4.1 **Antimicrobials**  
All antimicrobials must also provide evidence of invitro reduction of bacterial load.

## 16. Lot 2.7 Speciality Wound Care

Speciality Wound Care This Lot is to ensure provision for products that do not fall within Lots 1.1 – 2.7. To promote, or as an adjunct to healing by secondary intention, under the advice and guidance of a Wound Care Specialist.

- 16.1 Must be supplied sterile, where possible.
- 16.2 Must be individually wrapped, where possible.
- 16.3 Enable an aseptic, no-touch application technique (ANTT).
- 16.4 Products can include:
  - 16.4.1 Protease modulator dressings.
  - 16.4.2 Wound measurement devices.
  - 16.4.3 Capillary action dressings.
  - 16.4.4 Odour control standard dressings.
  - 16.4.5 Acrylic dressings.
  - 16.4.6 Hydrobalance bio cellulose dressings.

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- 16.4.7 Topical haemoglobin sprays.
- 16.4.8 Sterile absorbent cellulose dressings with fluid repellent backing.
- 16.4.9 Collagen dressings.
- 16.4.10 Wound cycloidal vibration accessories.
- 16.4.11 Hydroactive colloid gels.
- 16.4.12 Polymeric Membrane dressings with surfactant.
- 16.4.13 Non-adhesive Analgesic dressings.
- 16.4.14 Adhesive analgesic dressings.
- 16.4.15 Topical oxygen wound therapy.
- 16.4.16 Electrostimulation Wound Therapy.
- 16.4.17 Wearable Dressing Retention Systems
- 16.4.18 Speciality Lotions, Oils, Ointments and Gels
- 16.4.19 Temporary Matrix Dressings
  - 16.4.19.1 Must not require special licences for handling associated with Human Tissues Act, Animal By-Products Act etc
  - 16.4.19.2 Must not require surgical implantation or removal must be intended to be removed or absorbed in its entirety.

16.5 **Additional Properties**

Products in this Lot may be listed with the following additional properties:

- 16.5.1 **Antimicrobials**  
All antimicrobials must also provide evidence of invitro reduction of bacterial load.

17. **Lot 2.8 Wound Irrigation and Cleansing**

Wound Irrigation and Cleansing is the steady flow of a solution across an open wound surface to achieve wound hydration, to remove deeper debris, and to assist with the visual examination and aid wound healing.

- 17.1 Contents must be supplied sterile.
- 17.2 Can be supplied in different forms including:
  - 17.2.1 Spray.
  - 17.2.2 Bottles.
  - 17.2.3 Sachets.
  - 17.2.4 Pods.

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**18. Lot 2.9 Debridement**

Debridement - Products design to assist with the removal of necrotic material, scabs, devitalized tissues, dried serous fluid, infected tissues, biofilm, stratified epidermis, pus, hematomas, foreign bodies, bone fragments and other impurities whose presence delays wound healing.

- 18.1 Consumables must be individually wrapped and in packaging marked for single use only.
- 18.2 Debridement must be administered in a short discrete procedure.
- 18.3 Product should not remain in the wound bed after use.
- 18.4 All products must include IFU (Instructions for Use).

**19. Lot 2.10 Adhesive Removers**

Adhesive Removers are required to support the removal of adhesive dressing by dissolving the adhesives, which secure the dressings to the skin. Minimising the discomfort or pain to the patient. Adhesive removers are required in various formats depending on the need of the clinician including, liquids, wipes, sprays, and foams.

- 19.1 Must be latex and fragrance free.
- 19.2 Must be alcohol free.
- 19.3 All products must include IFU (Instructions for Use).

**20. Lot 2.11 Barrier Creams & Films**

Barrier Creams & Films (Skin Protectants) are products designed to provide protection for human skin (including peri wound skin) from external irritants and also prevent moisture contact damage. For the avoidance of doubt this Lot does not include products intended for direct application to wound sites.

- 20.1 Adhere to sterility by either; being put through a sterilization process post manufacture; or produced sterile by exacting manufacture techniques.
- 20.2 Provide a barrier between the skin and external irritants including faeces, urine, exudate, other bodily fluids and moisture, and act as a repellent to such irritants.
- 20.3 Be suitable for a range of skin types and patient age groups.
- 20.4 Be suitable for use on healthy and damaged/compromised skin and safe for use near to mucus membranes.
- 20.5 Be permeable to moisture vapour.
- 20.6 Must not adversely affect skin pH levels.
- 20.7 Have minimal odour and not create strong or offensive smells when dry.
- 20.8 Designed to minimise pain and/or discomfort during application, reapplication or removal.
- 20.9 Be ready to use and not require mixing or preparation.

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- 20.10 Must include instructions for safe use in English or pictograms and be provided to NHSSC on request, including frequency of application and contraindications.
- 20.11 The volume of liquid contained in the packaging is printed (in ml) - in order to understand the contents of the product.
- 20.12 **Additional Properties**  
Products in this Lot may be listed with the following additional properties:
  - 20.12.1 **Barrier Creams**
    - 20.12.1.1 Must not be particular or granular in consistency and must be sufficiently viscous to prevent dripping and fluid flow.
    - 20.12.1.2 Must not bond and/or stick to skin or surrounding surfaces such as bandages, clothing and bed linen or other foreign objects and must be non-staining.
  - 20.12.2 **Barrier Films**
    - 20.12.2.1 Must be transparent with no added colour.
    - 20.12.2.2 Must dry within 40 seconds of application.
- 20.13 Where applied to pump action spray bottles, shrink-wrapped (tamper-proof) packaging should be marked for opening - to ease the opening process.
- 20.14 Pump action spray bottles and aerosol bottles must have a lid that can be replaced and maintained.
- 20.15 Foam applicator packaging to have a marked 'tear line', or a tab to enable ease of opening, indicating the correct place to open.

**21. Lot 2.12 – Compression Bandages**

Compression Bandages are intended for use in the applicant of even, graduated compression therapy to the limbs. Compression bandages should only be applied by a clinician with a suitable level of education and experience.

- 21.1 All compression bandages should conform to British Standard BS 7505:1995 Specification for the elastic properties of flat, non- adhesive, extensible fabric bandages.
- 21.2 Compression bandages may be supplied as single items or as part of a multi-layer kit in the following categories:
  - 21.2.1 Compression Bandages.
  - 21.2.2 Type 2 Support Bandages.
  - 21.2.3 Type 3A Support Bandages.
  - 21.2.4 Type 3B Support Bandages.
  - 21.2.5 Type 3C Support Bandages.
  - 21.2.6 Type 3D Support Bandages.

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- 21.2.7 Short Stretch Bandages.
- 21.2.8 Cohesive bandages.
- 21.2.9 Single Layer Compression Bandage.
- 21.3 All products must include IFU (Instructions for Use) to include contraindications.
- 21.4 To ensure the application of compression bandaging is undertaken effectively, a programme of initial and continued education and guidance on the application of compression bandaging will be made available. The scope of the training will be agreed with each trust on a case-by-case basis. In house training, training materials and product information (both printed and electronic suitable for clinicians and patients) are required to be supplied free of charge and on request by the customer.

**22. Lot 2.13 – Medical Adhesive Tapes**

Medical Adhesive Tapes are supplied in a variety of widths and lengths.

- 22.1 Products within this Lot include:
  - 22.1.1 Cloth.
  - 22.1.2 Foam.
  - 22.1.3 Paper.
  - 22.1.4 Plastic impermeable.
  - 22.1.5 Plastic perforated.
  - 22.1.6 Silicone.
  - 22.1.7 Silk.
  - 22.1.8 Zinc oxide.

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