

# Clinical review

## Gelling Fibre Dressings

Version 2 – January 2018



## Contents

1. Introduction .....	4
2. Clinical Context .....	5
2.1 Clinical Definition and Scope.....	5
2.2 Intended Clinical Use .....	5
2.3 Clinical Practice .....	6
2.4 Clinical Impact.....	6
2.5 Other Clinical Considerations.....	6
3. Pathway Methods for Gelling Fibre Dressings .....	7
3.1 Intelligence Gathering .....	7
3.1.1. Literature search .....	7
3.1.2. National procurement provider specification .....	8
3.1.3. National and international safety and quality standards .....	8
3.1.4. Product suppliers and manufacturers .....	8
3.1.5. Quality of evidence .....	8
4. NHS Clinical Engagement .....	10
4.1 Clinical Conversations .....	11
4.2 Clinical Criteria.....	11
4.2.1. Criteria explanation- Inclusion (Gelling Fibre Dressings) .....	13
4.2.2. Criteria explanation- Exclusion (Gelling Fibre Dressings) .....	15
4.3 Product Assessment Results- Laboratory.....	15
4.4 Product Evaluation .....	16
5. Product Assessment Results.....	19
6. Further Considerations and Recommendations .....	24
6.1 Future recommendations .....	24
6.2 Barcodes.....	25
7. Disclaimer .....	26
8. Acknowledgements.....	27
9. Authors and NHS Clinical Evaluation Team Information.....	28

## Guidance for use

This clinical evaluation report is aimed primarily at the NHS and all those working to support patient care. If you would like to talk through how this report can be used in your setting, please contact us at: [clinical.evaluationteam@nhs.net](mailto:clinical.evaluationteam@nhs.net)

Please note that the product assessment results should only be read and used in conjunction with the full text of this clinical review.

### Version Two – Published January 2018

This version has been updated from the original gelling fibres report published in February 2017 to include results from laboratory testing of the gelling fibres that were originally evaluated in the first report. It now includes information on the following to assist clinician selection:

- Absorptive capacity ( $\text{g/cm}^2$ )
- Rope strength when wet (N)
- Dispersion characteristics
- Shrinkage of dressing when wet (%)

New sections have also been included:

4.2.1 Criteria explanation- inclusion

4.2.2 Criteria explanation- exclusion

These have been added to provide guidance as to the rationale for the inclusion and exclusion of the clinical criteria featured in this gelling fibre report.

4.3 Laboratory results

Provides guidance to interpret the findings associated with the laboratory results, and relate them to practice.

## 1. Introduction

The NHS Clinical Evaluation Team was established in April 2016. The team's remit is to add independent clinical review to 'everyday healthcare consumables' used by the NHS.

Everyday healthcare consumables are products that are found in the majority of wards, clinics, health centres, treatment rooms and district nurses' bags across the NHS. The purpose of this report is two-fold: firstly, to provide a clinical assessment of the usability and requirements from the NHS for gelling fibre dressings that are available to the NHS from the national procurement provider and secondly, to provide a clinical statement of desired functions and properties that the clinicians in the NHS require of gelling fibres for use in future procurement activities.

It is clear from the evidence that gelling fibre dressings, featured in this report, are everyday healthcare consumables that are found in most clinics or ward settings and would certainly be items included in any stock list to set up a new clinical service. On that basis, the project was approved by the Clinical Reference Board in June 2016, culminating in the production of this report for their approval in December 2016.

Based on 2015 data supplied by NHS Supply Chain, in the NHS, Trusts are purchasing nearly 3.5 million gelling fibre dressings annually, with an increase in 500,000 from the previous year, continuing a trend of consistent increased usage over the past 8 years. This leads to an annual spend in excess of £8 million through the national distributor. We are aware that this route of purchase makes up only a percentage of total products purchased (approximately 40%) although with wound care products, this market share may be significantly lower. Community services being a major purchaser of wound care products; with direct purchase and FP10 (prescription) being a predominant route for dressing procurement. There are many different gelling fibre dressings on the market, with products regularly being launched to the UK market, however the scope of this evaluation is to include only those products listed on the national distributors framework at the time of the evaluation. This report covers the range of products available as of August 2016.

Intelligence on gelling fibre dressings was gathered from a variety of sources to provide background information on the current evidence available to support the way in which the devices are designed and clinically evaluated.

Following this, clinical engagement sessions were held with the aim of identifying important clinical criteria for gelling fibres from frontline NHS clinicians. This information was used to develop clinical criteria for these dressings, against which all brands available from the national procurement provider were reviewed.

Findings from these clinical reviews are collated into a product assessment report to allow users to identify products and see how they performed against the agreed clinical criteria.

A more detailed description of the team and our pathway approach can be found in the NHS Clinical Evaluation Team operating manual which can be found on our website at: [www.nhsbsa.nhs.uk/cet](http://www.nhsbsa.nhs.uk/cet).



## 2. Clinical Context

### 2.1 Clinical Definition and Scope

Gelling fibre dressings, also known as hydrofibers, or hydrocolloid-fibrous dressings are synthetic fibrous dressings designed for moderate to highly exuding wounds. They absorb exudate in their fibres forming a gel, encouraging autolytic debridement, promoting tissue granulation, and the maintenance of a moist wound environment.

- Gelling fibre dressings are an everyday clinical product, in the 12 months to December 2015; the national provider estimates it sold nearly 3.5 million products.
- Gelling fibre dressings can be located in most health centres / treatment rooms, ward and clinic environments, as well as in theatres along with community services and in patients own homes.
- Gelling fibre dressings have a clinical and patient impact; they are applied routinely on patients, as the volume of sales figures from national provider support.
- The composition of fluid handling capacity, tensile strength, and adhesion to wound may vary amongst products which can have key impact upon the patient experience and outcomes.

#### **Antimicrobial gelling fibres**

For the purposes of this evaluation antimicrobial gelling fibres have been removed, as the mode of action and delivery of antimicrobial agents would be best compared to other antimicrobials rather than against other gelling fibre dressings.

### 2.2 Intended Clinical Use

Gelling fibre dressings provide a plethora of functions in the healthcare setting. As previously mentioned; they manage fluid exudate, both serous and haemoserous; they aid autolytic debridement of debris, necrotic tissue and slough (not on dry wounds); and they enhance the maintenance of a moist wound environment.

Exudate management is often a key feature in the frequency of dressing changes: Good management may increase dressing wear time, and reduce frequency of dressing changes, resulting in less pain to patient, greater maintenance of wound temperature and reduction in exposure to external environment.

Gelling fibre dressings are principally used as a primary wound dressing for all wounds, including shallow and deep tissue/cavity, though some now have adhesive borders allowing them to be primary and secondary dressing for shallower wounds.

This report has two main sections. The first will provide the product assessment matrix showing all products and their scores against the defined clinical criteria, designed to aid clinicians in selecting the product that will best meet their population needs. The second section will focus around recommendations for future product development and initiatives.

## **2.3 Clinical Practice**

Gelling fibre dressings are primary dressings, they are applied to make direct contact with wound bed. They come in flat sheet form, for shallow wounds, and rope for deeper cavities, or indurating wounds, and can be used in combination i.e. rope and flat sheet.

Some gelling fibres feature adhesive waterproof outer dressing, meaning they are primary and secondary dressings combined.

## **2.4 Clinical Impact**

Selection of suitable product for intended clinical purpose can result in; reduced risk of infection from external environment, prolonged maintenance of moist warm clean wound environment to optimise wound healing, improve patient experience from frequency of dressing changes, to pain on dressing changes, and potentially reduce clinical workload on healthcare professionals.

## **2.5 Other Clinical Considerations**

It must be recognised that, the clinical understanding of wound care and knowledge of product(s) will vary amongst healthcare professionals in any given clinical environment.

## 3. Pathway Methods for Gelling Fibre Dressings

### 3.1 Intelligence Gathering

In preparation of the criteria, account has been taken of academic and related clinical evidence, known guidance and nationally recognised publications as further described in this Section 3.

#### 3.1.1. Literature search

A literature search has been undertaken to establish what current academic knowledge exists on the products for evaluation. It should be noted that the team have not conducted a comprehensive or systematic review of literature. However, the team have interrogated the information to look for common themes which supported the development of the clinical criteria.

Initially an evidence search was performed across the NICE databases. This provided a recently published national article highlighting the lack of robust clinical evidence on the performance of complex/advanced wound care products, in aiding wound progression in comparison to basic products. The document concluded that the expected performance of these advanced products was not the issue, but the lack of robust evidence was a concern.

The search terms used (see figure 1, below) generated many returns however, data gleaned supported the earlier opinion from the NICE paper. Many of these reports provided case studies, posters, and examples of performance and delivery of advanced wound care products, however many were open to bias, i.e. funded by manufacturer, without a defined methodology, without a clear control, and often included subjective opinion from clinicians using these products. This information was of value, but difficult to quantify and qualify.

Search criteria	Databases searched
<ul style="list-style-type: none"><li>• Gelling fibre dressings</li><li>• Hydrofiber dressings</li><li>• Hydrocolloid fiborous dressings</li><li>• Protease modulators</li><li>• Adhesive gelling fibre dressings</li><li>• Variants on spelling of fibre/fiber</li></ul>	<ul style="list-style-type: none"><li>• <b>NICE website Evidence search</b> <a href="https://www.evidence.nhs.uk/">https://www.evidence.nhs.uk/</a></li><li>• <b>NICE website journals and databases</b> <a href="https://www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases">https://www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases</a> (using Healthcare databases advanced search tool – Ovid, Medline, CINAHL, databases searched)</li></ul>

Figure 1 Literature and other sources searches – Gelling Fibre Dressings

### **3.1.2. National procurement provider specification**

As the national procurement provider, NHS Supply Chain manages a framework of suppliers who are then listed in the national catalogue. The framework covers a wider selection of products than just gelling fibre dressings.

The specification used by the national provider (NHS Supply Chain) has been reviewed to understand what has previously been asked of suppliers of these products.

The specification, as used by the NHS national procurement provider (NHS Supply Chain, 2016), provides limited detail relating to the clinical criteria relevant for gelling fibre dressings, but are considered in the process for the development of such criteria.

### **3.1.3. National and international safety and quality standards**

Account has also been taken of appropriate international and other standards as they pertain to the devices (e.g. ISO, EN and/or BSI).

The Medicines & Healthcare products Regulatory Agency (MHRA) website (<https://www.gov.uk/drug-device-alerts>) returned no product alerts relating to this product category against the search terms previously described.

### **3.1.4. Product suppliers and manufacturers**

Requests for information were sent to all suppliers listed on the national procurement provider framework. All suppliers provided some level of information from product brochure through to technical datasheets and compliance with standards.

Additionally laboratory testing, clinical trials, and case studies were submitted by some of these suppliers.

### **3.1.5. Quality of evidence**

Hierarchy of evidence

Levels of evidence sometimes referred to as hierarchy of evidence are assigned to studies based on the methodological quality of their design, validity, and applicability to patient care.



Hierarchy ranking	Description
Level 1	A systematic review of all relevant randomised controlled trials (RCT) or evidence-based clinical practice guidelines based on systematic reviews of RCT evidence
Level 2	Evidence from at least one well designed RCT
Level 3	Evidence from well-designed controlled trials; non-randomised, quasi experimental
Level 4	Well-designed case control & cohort studies
Level 5	Systematic reviews of descriptive and qualitative studies
Level 6	Evidence from a single, descriptive or qualitative study
Level 7	Evidence from the opinion of authorities and/or reports of expert committees

Figure 2 – Hierarchy ranking: Evidence based practice in nursing & healthcare: a guide to best practice” (B.M. Melnyk & E. Fineout-Overholt; 2005; p10)

## 4. NHS Clinical Engagement

In order to develop a shared vision of what gelling fibre dressings should offer several methods of engagement were used. These engagement events were used to formulate thoughts, ideas and needs from differing clinicians familiar with these products; identifying their own expectation(s) of the product for their given patient group, and intended patient outcome, being used in a variety of differing clinical environments.

Mapping exercises were undertaken to determine personnel that should be involved and/or consulted regarding these products. This stage of the report focused on clinical staff that are:

- a) recognised as subject experts, and/or
- b) recognised regular users of the devices in their clinical practice

Various methods of engagement were undertaken to ensure these clinical opinions were robust, and validated by peers from around the country, options of engagement included:

Regional and national face-to-face events with NHS clinical colleagues

Focussed visits to NHS clinicians regional and national face-to-face events

Website subscription

Attendance at specialist network events

Attendance at NHS Business Services Authority events

Web-based surveys and e-engagement tools (e.g. email, WebEx, portal based surveys).

## 4.1 Clinical Conversations

To build a broad caucus of attendees at our events letters were sent inviting Trusts to nominate clinical colleagues to attend a series of regional group events. These were hosted by NHS organisations throughout England to enable the widest possible access for all invited. This ensured to set aside any pre-existing regional variance.

Details of the discussion outcomes were recorded from the open events, then used together with the evidence gathered at the previous project stage to inform a list of clinical criteria against which the product(s) are measured against.

Much of these national clinical conversations featured opinions by generalist health care professionals, and allied health professionals. For the purpose of wound care products, ratification and validation was sought of the proposed criteria by tissue viability specialists. Engagement at regional tissue viability networks took place to obtain this validation. Furthermore these events were used to gain consent from these specialist clinicians to provide valuable feedback on the performance of products being used in their own clinical environment against the proposed criteria.

## 4.2 Clinical Criteria

The data received from all the NHS clinical conversation events, alongside the data collected from individual experts, was assimilated into a series of clinical criteria.

A clinical criterion is defined for the purposes of this report as a principle or standard by which products may be evaluated. It is a statement which describes the clinician's requirements for the product.

The proposed criteria were validated by workshop attendees and all other clinical experts engaged in the development process. In addition, other clinical experts who are likely to add further useful insight were also included, leading to the finalised clinical criteria listed below.

## Clinical Criteria – Gelling Fibre dressings

### PACKAGING

The product category is clearly visible on the box packaging

The product category is clearly visible on the dressing packaging

The size of the dressing is clearly visible on the box packaging

The dressing size and shape is visible without opening the individual packaging

The lot number, expiry date and CE marking are clear on the packaging

Product information including application is located within the packaging

Instructions for dressings application is located on the individual packaging

The instructions are clear and easy to follow

### OPENING & PREPERATION FOR USE

The dressing can be opened maintaining product sterility

How easy would you rate opening of packaging and maintaining product sterility

Conformability of the flat dressing to a wound bed

Ease of application of flat dressing to wound

Ease of application of rope to cavity

### CLINICAL USE

Wear time

Fluid management

Conformability

Tensile strength when wet

Shrinkage of product when wet

Figure 4 – NHS Clinical Criteria gelling fibre dressings; October 2016

Clinical criteria are published online at [www.nhsbsa.nhs.uk/CET](http://www.nhsbsa.nhs.uk/CET) .

#### 4.2.1. Criteria explanation- Inclusion (Gelling Fibre Dressings)

To enhance the readers understanding of this report, and to provide value to the results, an explanation for the defined clinical criteria is captured.

Packaging Criteria	Explanation
The product category is clearly visible on the box packaging (Gelling fibre/Hydrofiber)	Displaying the product category clearly ensures health professionals know that the product being selected is a gelling fibre dressing
The product category is clearly visible on the individual packaging (Gelling fibre)	As in some working environments ( district nurses/ clinic rooms) products are removed from external box packaging, thus the individual packaging will be the only form of product identification
The size of the dressing is clearly displayed on the box packaging	Wastage of clinical time- clear visibility of size reduces time taken for a health professional to select the correct product first time (this will also reduce wastage of opening wrong size product)
The dressing size and shape is visible without opening the individual packaging	As previous to reduce wastage of time and error of product size/shape- which can also lead to longer dressing time, greater risk of compromising sterile field, reduce patient confidence in health professional and reduce concordance in dressing and health education
The lot number, expiry date and CE marking are clear on the packaging	As medical devices, these products may be recorded in medical/nursing records, as such need to be present and easily accessible
Product information including application is located within the packaging	Information regarding product is important for health professionals to familiarise themselves with products prior to application
Instructions for dressings application is located on the individual packaging	As mentioned previously products are not always kept in original outer packaging, thus information may only be available on individual dressing packaging
The instructions are clear and easy to follow	As for rationale to dressing size and shape visibility



<b>Opening and Preparation Criteria</b>	<b>Explanation</b>
The dressing packaging can be opened maintaining product sterility	Aseptic technique and maintaining a sterile field is required for many wound care procedures
How easy would you rate opening of packaging and maintaining product sterility	Being able to open a product aseptically is a fundamental, however the ease at which this can be achieved is also important for patient experience, health professional credibility, and reducing wastage- both time and product
Conformability of the flat dressing to a wound bed	Primary dressings function by making direct contact with the wound bed, the greater the percentage of wound bed surface area in direct contact with the primary dressing, the greater the efficacy of the dressing
Ease of application of flat dressing to wound	Ease of application may reduce product wastage from mis application, it may also reduce duration of dressing change, which may reduce; risk of infection; temperature/moisture loss from wound bed, and enhance patient experience, promote patient confidence and concordance in health professional knowledge and ability
Ease of application of rope to cavity	Ease of applying rope mirrors rationale for ease of applying flat sheet, additionally it may enhance the efficacy of the dressing ( see conformability section) and may enhance probability of successful wound packing, encouraging healing from wound bed up

<b>Clinical Use Criteria</b>	<b>Explanation</b>
Wear time- Manufacturers guidance	Optimising wound environment, is a key feature of dressing, a factor inconsideration is the wear time for the dressing, clear information on this and manages expectations of both patient and other health professional on dressing duration
Fluid management	Gelling fibre dressings absorb wound exudate and gel, encouraging autolytic debridement and maintenance of moist wound environment. Fluid management and capacity may impact this, and may impact wear time of the dressing which may affect the optimised wound environment and heal rate
Conformability	See conformability in opening and preparation
Tensile strength when wet	Gelling fibre dressings as previously mentioned are synthetic products, they are non-biodegradable as such need to be fully removed from body, for shallow wounds this concern is less as the force to remove dressing is less and visibility to observe for remaining dressing is present, in cavity wounds the force to remove the packing is greater and the visibility to confirm all product removal may not be possible- strength of the product gives indication as risk of product breaking up within a cavity
Shrinkage of product when wet	As with conformability the greater the percentage of wound bed surface area in direct contact with the primary dressing, the greater the efficacy of the dressing, shrinkage of dressing may reduce this surface area, for cavity wounds it may also reduce contact with product on the wound bed, which may impact efficacy and healing from wound bed up

#### 4.2.2. Criteria explanation- Exclusion (Gelling Fibre Dressings)

To capture true representation of clinical opinion, this report also aims to capture criteria that were raised, but not included as final criteria when the evaluation of these dressings took place.

Proposed Criteria	Explanation for exclusion
Tensile Strength when dry	Whilst tensile strength when wet has been included in the criteria, tensile strength when dry has not, the rationale behind this, is that the dressing should not be removed if dry: It would suggest either too short a duration in-situ or not suitable for the type of wound (dry)
Disposal of product	Whilst disposal of product is of concern to clinicians, the disposal is often governed by: a the clinical environment where the product is being used/disposed of i.e. acute setting or patients own home, and b: the patient factors associated with their dressing i.e. infection risk

### 4.3 Product Assessment Results- Laboratory

Laboratory results provide numerical results against the defined criteria; for the gelling fibre dressings these include:

- Absorptive capacity- looking at the volume of fluid the gelling fibre products can absorb, captured in grams per centimetre square ( $\text{g}/\text{cm}^2$ )
- Tensile strength when wet (of the rope) rope gelling fibre products may be packed into sinuses and cavities, removal of these products once activated (i.e. when wet and gel like) is required, this test captures the force required in Newtons (N) to break the wet rope product(s), also captured in Newtons per centimetre square ( $\text{N}/\text{cm}^2$ )
- Dispersion characteristics- looks at the structure and formation of the product to observe for integrity when activated, thus highlighting those product(s) which may separate when activated and those that remain intact
- Shrinkage of product when wet, as the gelling fibres manage exudate their physical structure alters as they “gel” this may lead to some shrinkage or contraction of product, having insight into shrinkage enables clinicians to consider degree of border they may wish to allow for when applying dressings if shrinkage is known, captured as percentage of total area lost (% area loss)

## 4.4 Product Evaluation

Evaluation methodologies are defined for each and every clinical criterion. They reflect a simulated clinical environment; actual clinical environment, or a laboratory test environment.

Wherever possible, products were supplied in a 'ward ready' unit of issue as would be found by clinical staff on accessing a store area in their clinical environment. Where this has not been possible it was acknowledged as part of the product assessment results matrix.

The tests were formulated to move through the key aspects of product use using the NHS Clinical Evaluation Team product cycle:

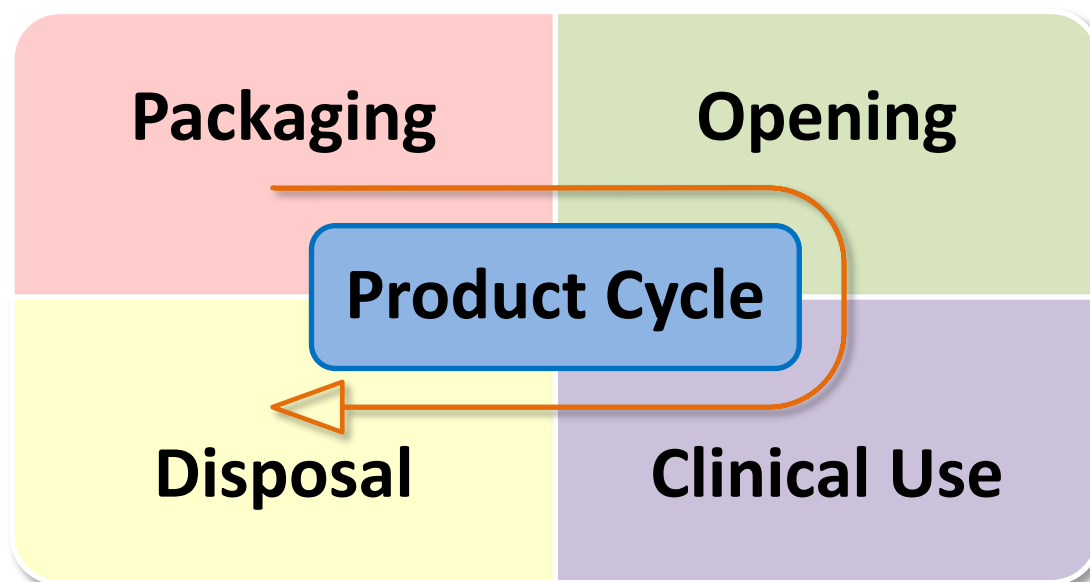


Figure 4 – NHS Clinical Evaluation Team Product Cycle

The evaluation product was ordered and picked from the NHS distribution centres. Products evaluated have been stored post evaluation for a period of three months after publication of this review.

Practicing NHS clinical staff were invited to review the products in accordance with the developed criteria. It was not possible to 'blind' the evaluations; in the sense that the evaluators were aware of the product brand; however, the product to be evaluated was independently picked in accordance with the product selection criteria in Section 2 and prepared for evaluation by colleagues who were not otherwise involved in the process.

Each clinical evaluator entered data independently and without inter-rater comparison into their own workbook. These were then collated, reviewed and summarised by the clinical specialist lead for the project.

As part of the evaluation preparation, each evaluator was given a more detailed and product specific definition for each of the scores

The defined criteria either prompted a 'yes/no' answer, represented with a ✓/X, or a score was given between 0 and 2, or 0 and 3 as follows:

Score	Meaning
0	This does not meet the criteria
1	This partially meets the criteria
2	This meets the criteria
3	This exceeds the criteria

Figure 5 – NHS Clinical Evaluation Team scoring methods

These numerical scores across all evaluators were totalled and a mean value determined. This mean value has then been converted into a star rating (see matrix below).

The mean values convert to a star rating in accordance with the following table:

Point scored	Star value
0 to 0.99	0 Stars
1 to 1.24	1 Star
1.25 to 1.74	1.5 Stars
1.75 to 2.24	2 Stars
2.25 to 2.74	2.5 Stars
2.75 to 3	3 Stars

Figure 6 – conversion of mean scores to star rating

The above scoring mechanisms will not be followed where the criterion identified by the CET cannot reasonably exceed expectations. For example, if the clinical criterion was whether the removal of an adhesive dressing was atraumatic and with the individual patient reporting no pain or skin damage, then it cannot reasonably be expected that a product could exceed that criteria. Therefore, in such circumstances, the relevant criteria will be based on the scoring regime of:

- a. If the criterion is a Yes/No response, the responses will be converted into aggregate percentages and then star ratings as follows:

Percentages (Yes)	Star value
0% to 24.99%	0 star
25% to 49.99%	1 star
50% to 74.99%	1.5 stars
75% to 100%	2 stars

Figure 7 – Percentage scores to star rating

- b. For other subjective criteria, the responses will be converted into mean scores and then star ratings as follows:

Point scored	Star value
0 to 0.49	0 star
0.5 to 0.99	1 star
1 to 1.49	1.5 stars
1.5 to 2	2 stars

Figure 8 – Points scores to star rating

On the basis that clinical evaluators will be providing scores as follows:

- 0 stars – Does not meet the criteria
- 1 star – Partially meets the criteria
- 2 stars – Meets the criteria

All supplemental products used in the evaluation are in use in the NHS and available through the national catalogue (e.g. clinical waste containers, gloves, drug labels and syringes).

Evaluators were also encouraged to record comments where they felt it necessary to provide rationale for their scoring and answers.

The results obtained have been validated by the NHS Clinical Evaluation Team moderation committee for consistency of scoring and interpretation. These results are presented in the product assessment reports herein.



## 5. Product Assessment Results

The following product assessment results pages show the tested clinical criteria listed horizontally on the left-hand side of the page with the tested device found vertically across the top of the matrix. The accompanying photographs were taken during evaluation. These photographs are of sample products provided for evaluation. Lot numbers were recorded and samples have been retained in storage following the completion of evaluation.

The products represented are the range of suppliers and brands available through the NHS national procurement provider's framework as of August 2016.

Results can be seen within the product matrix. Each clinical product has been given a star rating and the evaluator's collated comments are included in the matrix.

The product assessment results have been divided into three sub-categories; gelling fibre sheet, gelling fibre rope and combination gelling fibre and adhesive border.

Product Assessment Cycle	CLINICAL CRITERIA	Aquafiber	Aquacel Extra (flat)	Aquacel Foam non-adhesive	Durafiber	Kerrafiber	Urgoclean
	GELLING FIBRES						
PACKAGING AND STORAGE:	The product category is clearly visible on the box packaging	✓	✓	✓	✓	✓	✗
	The product category is clearly visible on the individual dressing	✓	✓	✓	✓	✓	✗
	The size of the dressing is clearly visible on the box packaging	✓	✓	✓	✓	✓	✓
	The dressing size and shape is visible without opening the individual packaging	✓	✓	✓	✓	✗	✓
	The lot number expiry date and CE mark are visible on the packaging	✓	✓	✓	✓	✓	✓
	Product information including application is located within the packaging	✓	✓	✓	✓	✓	✓
	Instructions for dressings application is located on the individual packaging	✗	✓	✓	✗	✗	✗
	The instructions are clear and easy to follow	★★★☆☆ (2.00)	★★★☆☆ (2.00)	★★★☆☆ (2.00)	★★★☆☆ (2.00)	★★★☆☆ (1.70)	★★★☆☆ (1.70)
OPENING AND PREPARATION:	The dressing can be opened maintaining product sterility	✓	✓	✓	✓	✓	✓
	Ease of opening packaging and maintaining product sterility	★★★☆☆ (2.00)	★★★★☆ (2.30)	★★★★☆ (2.30)	★★★☆☆ (2.00)	★★☆☆☆ (1.00)	★★★☆☆ (1.70)
	Conformability of the flat dressing to the wound bed on application	★★★☆☆ (2.30)	★★★☆☆ (2.30)	★★★☆☆ (2.30)	★★★☆☆ (2.00)	★★★☆☆ (2.00)	★★★☆☆ (2.00)
	Ease of applying flat dressing as primary dressing to a wound	★★★☆☆ (2.30)	★★★☆☆ (2.00)	★★★☆☆ (2.00)	★★★☆☆ (1.70)	★★★☆☆ (2.00)	★★★★☆ (2.30)
	Ease of application of rope into cavity	N/A	N/A	N/A	N/A	NA	NA
CLINICAL USE:	Wear Time	7 days	14 days	7 days	7 days	7 days	7 days
	Fluid management simulated testing	38.25mls (24 hrs)	38.5mls (24 hrs)	50mls (24 hrs)	41mls (24 hrs)	50mls (24 hrs)	40.38mls (24 hrs)
		39mls (48 hrs)	39mls (48 hrs)	76mls (48 hrs)	42.5mls (48 hrs)	66mls (48 hrs)	43mls (48 hrs)
	Absorptive capacity in g/cm2	23.93 (SD 0.6)	21.07 (SD 0.6)	N/A combination gelling fibre/foam	26.17 (SD 1.1)	45.55 (SD 2.1)	20.22 (SD 1.2)
	Tensile Strength when wet (N)	N/A	N/A	N/A	N/A	N/A	N/A
	Dispersion characteristics - Product remains intact when wet	✓	✓	✓	✓	✗	✓

Product Assessment Cycle	CLINICAL CRITERIA		Aquafiber Ribbon		Aquacel Ribbon		Durafiber Ribbon		Urgoclean Rope	
	GELLING FIBRES									
PACKAGING AND STORAGE:	The product category is clearly visible on the box packaging		✓		✓		✓		✓	
	The product category is clearly visible on the individual dressing		✓		✓		✓		✓	
	The size of the dressing is clearly visible on the box packaging		✓		✓		✓		✓	
	The dressing size and shape is visible without opening the individual packaging		✓		✓		✓		✓	
	The lot number expiry date and CE mark are visible on the packaging		✓		✓		✓		✓	
	Product information including application is located within the packaging		✓		✓		✓		✓	
	Instructions for dressings application is located on the individual packaging		✗		✗		✓		✗	
	The instructions are clear and easy to follow		★★★★ (2.50)		★★★★ (2.00)		★★★★ (2.75)		★★★★ (2.50)	
OPENING AND PREPARATION:	The dressing can be opened maintaining product sterility		✓		✓		✓		✓	
	Ease of opening packaging and maintaining product sterility		★★★★ (2.75)		★★★★ (2.25)		★★★★ (2.00)		★★★★ (2.75)	
	Conformability of the flat dressing to the wound bed on application		N/A		N/A		N/A		N/A	
	Ease of applying flat dressing as primary dressing to a wound		N/A		N/A		N/A		N/A	
	Ease of application of rope into cavity		★★★★ (2.75)		★★★★ (2.50)		★★★★ (2.00)		★★★★ (2.75)	
CLINICAL USE:	Wear Time		7 days		14 days		7 days		7 days	
	Fluid management simulated testing		N/A (24 hrs)		N/A (24 hrs)		N/A (24 hrs)		N/A (24 hrs)	
			N/A (48 hrs)		N/A (48 hrs)		N/A (48 hrs)		N/A (48 hrs)	
	Absorptive capacity g/cm2		25.09 (SD 1.3)		13.71 (SD 0.5)		14.18 (SD 1.7)		17.28 (SD 1)	
	Tensile Strength when wet		★★★★ (2.67)		★★★★ (3.00)		★★★★ (3.00)		★★★★ (3.00)	
	Lab test rope breakage when wet maximum load (N)	Maximum load per mm (N/mm)	3.42 (SD 1.2)	0.17 (SD 0.1)	18.48 (SD 1.6)	0.92 (SD 0.1)	3.7 (SD 0.9)	0.19 (SD 0)	6.11 ( SD 0.4)	0.24 (SD 0)
	Shrinkage of product when wet- captured as % area loss		21.6% (SD 8.64)		37.1% (SD 1.0)		21.7% (SD 7.56)		6.7% (SD 5.4)	

Product Assessment Cycle	CLINICAL CRITERIA	Aquacel Foam adhesive	Aquacel Surgical
	GELLING FIBRES		
PACKAGING AND STORAGE:	The product category is clearly visible on the box packaging	✓	✓
	The product category is clearly visible on the individual dressing	✓	✓
	The size of the dressing is clearly visible on the box packaging	✓	✓
	The dressing size and shape is visible without opening the individual packaging	✓	✓
	The lot number expiry date and CE mark are visible on the packaging	✓	✓
	Product information including application is located within the packaging	✓	✓
	Instructions for dressings application is located on the individual packaging	✓	✓
	The instructions are clear and easy to follow	★★★☆☆ (2.00)	★★★☆☆ (2.25)
OPENING AND PREPARATION:	The dressing can be opened maintaining product sterility	✓	✓
	Ease of opening packaging and maintaining product sterility	★★★☆☆ (2.50)	★★★☆☆ (2.50)
	Conformability of the flat dressing to the wound bed on application	★★★☆☆ (2.00)	★★★☆☆ (2.50)
	Ease of applying flat dressing as primary dressing to a wound	★★★☆☆ (2.25)	★★★☆☆ (2.50)
	Ease of application of rope into cavity	N/A	N/A
CLINICAL USE:	Wear Time	7 days	7 days
	Fluid management simulated testing	50mls (24 hrs)	43mls (24 hrs)
		68.25mls (48 hrs)	45.75mls (48 hrs)
	Fluid management lab testing	N/A combination product	N/A combination product
	Tensile Strength when wet	N/A	N/A
	Dispersion Characteristics	N/A combination product	N/A combination product

## **Using the Product Assessment Results Matrix**

The clinical criteria displayed are designed to capture key clinical elements that health professionals may wish to consider when reviewing/selecting products for their own clinical practice. The report is intended as a guidance tool to aid product selection and is not intended to be a universal determination of the clinical effectiveness of any particular product. Each clinical practitioner should therefore make their own assessments taking into account all relevant considerations for their particular situation.

Not all clinical criteria cited in the report will be relevant or important in all environments,

### **i.e. Wear time in an acute environment where dressings are removed routinely for medical review**

Likewise not all clinical criteria will be relevant or important for all patient groups;

### **i.e. Tensile strength when wet, if being used on patients with superficial venous leg ulcers in a leg ulcer clinic**

Clinicians may identify the criteria that most represent their clinical environment and patient demographic, and may choose to build their own hierarchy of importance to aid product(s) selection for patient outcome goals using the matrix presented in this report, their own clinical knowledge, as well as any other resources (including publications) to provide informed choice and transparency of their decision for product(s) being used.



## 6. Further Considerations and Recommendations

### 6.1 Future recommendations

There is an expanding range of gelling fibre dressings to the market, and expanding portfolio currently available via the national provider (NHSSC).

This report recognises that no one product will suit all individuals, nor does one product suit the differing clinical applications and requirements, this will not only be dependent on the individual, but on the clinical environment these products are being used in.

Whilst it is not reasonable or sensible to provide an extensive range of gelling fibre dressings within any given health care setting, consideration should be given to the primary use of these products for the majority of their patient group, within a Trust/Health organisation, with recognition and identification to some of the other options of gelling fibre dressing for particular individuals/circumstances.

Having clearer knowledge of clinical needs allows the clinician better insight into which product(s) may best meet their needs.

This report for future product development recommends and advocates that a products performance threshold is inherently linked to the knowledge of the clinician using it. To potentially optimise this, the Clinical Evaluation Team would recommend suppliers consider a standardisation for colour coding products by group/classification. Consideration again must be given to the primary function/wound contact layer of the dressing to best represent its group.

Product Group	Colour Coding
Hydrogels	Blue
Hydrocolloids	Yellow
Gelling Fibres	Orange
Films	Red
Non-adherent wound contact layers	Black
Foams	Light Orange
Antimicrobials	Green
Absorbents	Light Purple
Super absorbents	Dark Purple

Figure 7. -Clinical Evaluation Team colour coding of dressing groups

Additional recommendations would be to clearly display maximum wear time of product, and to clearly capture fluid capacity handling of these products. Currently there is no guide as to what constitutes low, medium and high fluid capacity handling for gelling fibre dressings. This will aid clinical and patient experience in managing expectations and performance of the products being applied.

## 6.2 Barcodes

The CET are aware of the Scan4Safety project and are aligned with the ambitions of the programme, which will deliver significant benefits in terms of patient safety and efficiency, to the NHS. The adoption of standards, driven by Scan4Safety, enables patient, product and location identification and traceability from the supply chain to the patient.

Adoption of these standards has also been shown to improve the quality of care by minimising the risk of human error.

The CET will be considering the inclusion of an evaluation criteria relating to the presence of GS1 compliant barcodes in future reports, as following our clinical conversations we have seen clinical staff asking for it to be included, but further information will be issued by the CET on this to stakeholders in advance.

## 7. Disclaimer

Reports published by the NHS Clinical Evaluation Team represent general guidance and the team's opinions on products are based on the clinical evaluations undertaken, using the information and clinical criteria generated from extensive stakeholder engagement in line with the team's requirements and evaluation pathway. Reports will be reviewed and updated at the team's discretion as deemed appropriate to reflect any changes.

You should make your own assessment and not take or rely on the opinions expressed by the NHS Clinical Evaluation Team, as contained in the reports, as recommendations or advice to buy or not buy (as the case may be) particular products.

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Reports are accurate at the time of publication, any recommendations or best practice guidance should be checked for updates.

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**‘Quality, safety and value are at the heart of our work and it’s important that we use our clinical experience to deliver high standards of care while reducing cost and waste in the NHS.’**

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