NHS
Business Services Authority

Clinical review

Film and Film Island Dressings

NHS Clinical Evaluation Team
by the NHS, for the NHS

Contents

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 three-fold: firstly to identify and quantify the clinical criteria for film and film island dressings in respect of wound care; secondly to provide clinical assessment of the usability and performance of film and film island dressings available from the national procurement provider against this defined criteria; and thirdly to provide a clinical statement of desired functions and properties that the NHS requires of film and film island dressings in wound care for use in future product development and procurement activities.

Based on 2015 data supplied by NHS Supply Chain, NHS Trusts are using nearly 9 million vapour permeable film dressings, and over 11 million film dressings with pad. This leads to an annual spend in excess of £10 million. There are 30 different film and film island products in the category supplied. This report covers the range of products available as at August 2016.

Intelligence on film and film island dressings was collated from a variety of sources. This provided background information on current and historic evidence available on these products, considering rationale for use, methods of application, function of product, and contraindications/limitations to use. This information informed the initial development of the clinical criteria for this product category.

Following this, clinical engagement sessions were held with the aim of identifying important clinical criteria for film and film island dressings from frontline NHS clinicians, identifying what was important, and what was unnecessary, together with additional factors that can truly only be identified by clinicians using these products in everyday practice. A review of the initial/former criteria was also examined and evolved with these clinicians. With each national engagement session this clinical criteria was further reviewed, developed and refined to reflect the synthesised national opinion.

The national clinical engagement events provided a lot of rich information from generalists, and specialists from diverse clinical roles. It was recognised that for wound care products tissue viability specialist opinion should be sought to validate this proposed criteria, to ensure the criteria would capture the performance aspects of the dressing that specialists would want. Further engagement events took place with tissue viability networks to obtain this validation.

This information was used to develop clinical criteria for film and film island dressings, against which all brands available from the national procurement provider were reviewed.

Findings from the clinical review are collated into a series of product reports to allow users to identify products, which did not meet criteria, partially met, fully met or exceeded the clinical criteria. Further consideration and recommendations are also made at the end of this report.

A more detailed description of the team and our pathway approach can be found in the NHS Clinical Evaluation Team operating manual, which is available on our website at: www.nhsbsa.nhs.uk/CET.

Clinical review

Clinical definition and scope

Vapour permeable adhesive film dressings, more commonly referred to as “film dressings” are *thin transparent polymeric films, with one side coated in a continuous adhesive layer*. They are commonly used for wound management, skin protection and to secure external devices to the skin.

Vapour permeable film island dressings, have the same principles as film dressings in composition with the added element of a “low adherence” central pad to manage low levels of exudate from wounds to the skin.

- Film and film island dressings are an everyday clinical product, in the 12-months to December 2015; the national provider estimates it sold nearly 20 million products.
- Film and film island dressings can be located in most health centres / treatment rooms, and ward and clinic environments, as well as in theatres and with community services and in patients’ own homes.
- Film and film island dressings have a clinical and patient impact; they are applied routinely on patients, as the volume of sales figures supports. The composition of adhesive, application and removal vary amongst products which can have key impact upon the patient experience and outcomes.

For the purposes of this evaluation film dressings are being evaluated from a wound management perspective, as such all films with an alternative primary purpose have been excluded in this evaluation i.e. intravenous cannulation fixation films.

Intended clinical use

Film dressings provide a plethora of functions in the healthcare setting; they provide a physical barrier from dirt, debris, and bacteria entering the wound; and they enhance the maintenance of a moist warm clean wound. The standard film dressings provide visual access to the wound bed without removal of the dressing, with the island dressings designed to provide greater fluid management capacity of low exuding wound, potentially increasing “wear time of the product”. They can be used as a primary wound dressing for superficial wounds, and/or wounds closed by primary intention, and can be applied as secondary dressings to secure a primary dressing in place.

This report will have two main sections. The first will provide the matrix showing all products and their scores against the defined clinical criteria. The second section will focus around recommendations for future product development and initiatives.

Pathway methods

Intelligence gathering

Information from a number of sources was gathered to provide a basis for clinical discussions regarding film and film island dressings.

In writing this report, account has been taken of academic and related clinical evidence and known guidance and nationally recognised publications.

All suppliers listed within the national frameworks were invited to submit clinically relevant evidence of their own.

A review of MHRA alerts has also been performed.

Finally the specification used by the national provider (NHS Supply Chain) has been reviewed to understand and confirm the regulatory and technical requirements that suppliers are required to meet. It was further reviewed for any clinical criteria or evaluative phase that may already exist.

This evidence has then been used as a basis, alongside supplier submitted evidence to help form initial ideas on product use, performance and requirements. This contributed to the development of the initial clinical criteria for film and film island dressings, which was then taken to frontline staff at national engagement events.

Literature search

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, although 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
• Film dressings • Vapour permeable film dressings • Vapour films • Film dressings wounds • Primary film dressings • Secondary film dressings • Film with pad dressings • Film island dressings	• **NICE website evidence search** **https://www.evidence.nhs.uk/** • **NICE website journals and databases** **https://www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases** (using Healthcare databases advanced search tool – Ovid, Medline, CINAHL, databases searched)

Figure 1 Literature and other sources searches – **Film and Film Island Dressings**

Additionally, a literature search was carried out on clinical performance of film and film island dressings. This yielded little relevant information, case studies and isolated clinical reports were not considered due to the volume, variance, and lack of clear reliability and validity in these studies. An independent report published in 2016 from the National Institute for Health and Care Excellence (NICE) surmised that there was insufficient evidence on the performance of advanced dressings.

Product suppliers and manufacturers

Request for information were sent to all suppliers on framework. A limited amount of information was received back from this request.

Quality of evidence

In “Evidence based practice in nursing & healthcare: a guide to best practice” (B.M. Melnyk & E. Fineout-Overholt; 2005; p10) the evidence hierarchy is demonstrated within the table below.

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

The full review of evidence shows a lack of high quality information, supporting the view of the NICE publication.

NHS clinical engagement – Building the clinical criteria

In order to develop a clear vision of what is required from film and film island dressings several methods of engagement with frontline clinicians were used.

There are several stages to the clinical engagement process starting with a mapping exercise to determine who should be involved. At this stage of the report focus was placed on clinical staff who are either a) recognised as subject experts, or b) recognised regular users of the products in their clinical practice.

Approaches included:

- regional and national face-to-face events with NHS clinical colleagues
- focussed visits to NHS clinicians
- attendance at specialist regional and national tissue viability network events
- web based surveys and e-engagement tools (e.g. email, WebEx, portal based surveys)

To build a broad spectrum of attendees at our events, communications were distributed inviting Trusts to nominate clinical colleagues to attend a series of regional group events; these were hosted by NHS organisations around England to enable the widest possible access. This was aimed at ensuring the opinions generated were reflective of national opinion and not subject to regional and / or local potential bias.

Details of the information gathered were recorded in booklet form, transcribed and then used together with the evidence gathered at the previous project stage to inform a list of clinical criteria against which the product has been tested.

NHS clinician colleagues were asked to score the importance of each of the clinical criteria's developed following the information gathering exercise that took place prior to these events. Clinicians were asked to score each of the proposed criteria, on a

scale of 0-10, where a score of 0 was having no importance and 10 as having critical importance. Space was also available for comments to add additional clinical observations, proposed criteria or testing.

Information from each of these clinical engagement events along with the intelligence gathered was reviewed and collated and used to inform the development of the NHS clinical criteria for film and film island dressings. Feedback opportunities with the evolving criteria were shared with the clinicians who had attended events.

Clinical criteria

The method of evaluation against each of the criteria was developed by the clinical specialist lead, and ratified by clinicians and the NHS Clinical Evaluation Team.

As much of the national clinical engagement had featured generalist health care professionals, for the purpose of wound care products ratification and validation by tissue viability specialists nationally was sought to ensure the proposed criteria met their professional needs as well as the needs of the generalist populations. 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.

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

For continuity of evaluation and to maximise clinical opinion the criteria followed a "product cycle" considering how clinicians use the products, from identifying them, to opening them applying them and disposal.

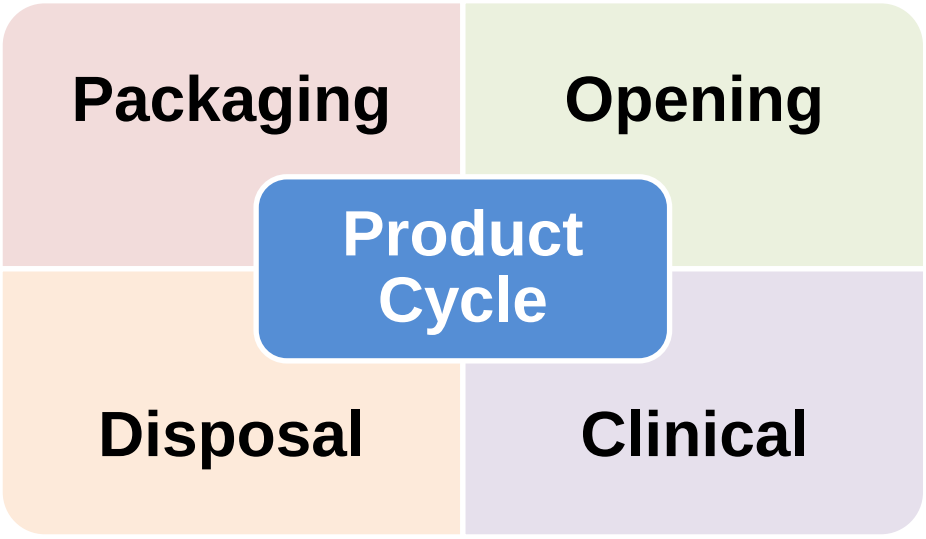


Figure 3 – NHS CET Product Cycle

Clinical Criteria – Film and film island 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
For film island dressings the size and shape of the wound contact pad 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
OPENING & PREPERATION FOR USE
The dressing can be opened maintaining product sterility
How easy would you rate opening of packaging and maintaining product sterility
Ease of preparing the dressing for application
CLINICAL USE
Conformability
Skin stripping on removal
Vapour permeability
Not contra-indicated for Paediatric use
Not contra-indicated for Neonatal use
Adherence of island (film island dressings only)

Figure 4 – NHS Clinical Criteria film and film island dressings; October 2016

It was noted from the engagement events, and validated by regional tissue viability networks that there were no clinical requirements relating to product disposal.

Product evaluation

Product inclusion criteria

As previously discussed, products for inclusion in the evaluation were required to be in the NHS Supply Chain catalogue, and currently available at the commencement of the evaluation in August 2016. Further caveats were placed on wound care products, as the clarity of product information, and/or function could be difficult to define, a mantra was applied that a product whose primary function or whose wound contact layer was that of a film or film island dressing would be included in evaluation.

Methodology

Evaluation methodologies are defined for each and every clinical criterion. They reflect a simulated clinical environment, undertaken by team members, institution clinical opinion, obtained by polling specialist nurses, and independent laboratory testing.

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

The evaluation product was ordered and picked from NHS distribution centres so we were reviewing LOT numbers in use across the NHS. Products evaluated will be stored post evaluation for a period after publication of this review.

Practicing NHS clinical staff were invited to review NHS Supply Chain product in accordance with the developed criteria. It was not possible to "blind test" the evaluations, as the packaging of products contributed to the evaluation; however the product to be evaluated was independently picked 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.

A subjective score was given against each of the defined criteria from 0-3 as below.

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

Figure 5 – NHS CET Scoring Methods

These numerical scores from all evaluators were totalled and a mean value determined. This mean value has then been converted into a star rating against the individual product compliance per each criterion (see reports below).

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

Point scored	Star value
0 to 0.99	0 star
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

For criteria that generated a defined answer i.e. Yes/No this would be represented with a √/ X

Evaluators were encouraged to also make comments where they felt 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.

Testing was split into three distinct modes:

- **Simulated testing**, where members of the NHS Clinical Evaluation Team +/- observing clinicians would conduct table-top evaluation of products following a test methodology against the defined criterion
- **In situation testing**, where specialist clinicians would evaluate products used in their clinical environment against the defined criterion
- **Laboratory testing**, where technical performance of products would be conducted in an independent laboratory

These three modes of evaluation were selected to aim to achieve a robust evaluation toolkit, where table top testing would form a simple test environment to establish products performance against clinical criteria, and act as a control methodology for the evaluations being conducted by clinicians in their own clinical field. The laboratory testing was felt necessary to establish the extent and detail of the performance of some products against specific criteria.

As part of the criteria focused around the packaging instructions and guidance on application, products were not blinded in the simulated evaluation. This also mirrored the testing that would be undertaken by specialist clinicians who would be evaluating products they use regularly in a similar manner, and again non-blinded.

Simulated testing: Each evaluator tested the products in a table top setting against each criterion following a defined methodology. This was conducted without peer to peer discussion so as to avoid any potential contagion of opinion. Data was entered by each evaluator into their own Excel spreadsheet, again to avoid contamination of results.

On completion, each evaluator forwarded their completed spread sheet to the evaluation lead (clinical specialist lead), who then amalgamated, interrogated and summarised the findings for use within the final report.

In-situation testing: Surveys were sent out to specialist tissue viability nurses through the regional networks. Clinicians were asked to disclose the products they were using and to evaluate against the defined criteria. The numerical scoring was removed from the survey to enhance clarity of question and answer, the criteria remained:

- Does not meet criteria
- Partially meets criteria
- Fully meets criteria
- Exceeds criteria

This criteria rating was reverted to a numerical value as outlined previously and given star rating using the tool described.

For criteria that generated a defined answer i.e. Yes/No this would again be represented with a √/ X

Laboratory testing: For criteria which required technical testing, these tests were commissioned by the clinical evaluation team and conducted in an independent laboratory.

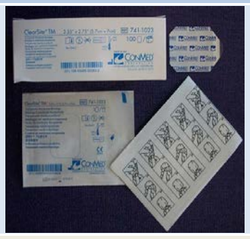
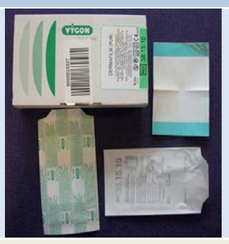
For criteria that generated an independent value, i.e. vapour permeability, the actual result value would be recorded.

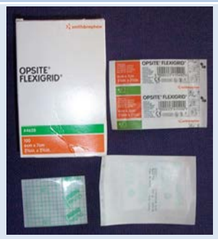
Product assessment results

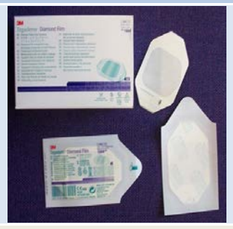
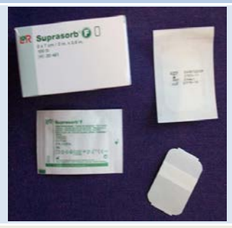
The below product assessment results summary pages show the tested clinical criteria listed vertically down the left hand side of the page with the tested device found horizontally across the top of the matrix. The accompanying photographs were taken during evaluation. This is a photograph of the sample product provided for evaluation. Lot numbers were recorded and samples have been retained in storage following the completion of evaluation.

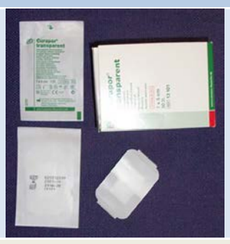
The products represented are the range of suppliers and brands available through the NHS national procurement provider's framework as of August 2016.

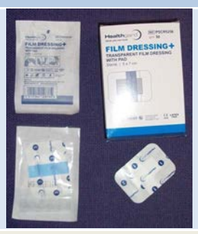
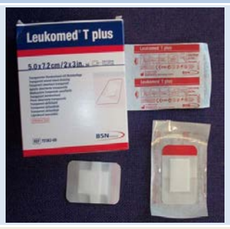
Product Assessment Cycle	CLINICAL CRITERIA	365 Healthcare TOTAL	Bioclusive Plus	C View	ClearFilm
	FILM DRESSING				
PACKAGING AND STORAGE:	The product category is clearly visible on the box packaging	✓	✓	✓	✓
	The product category is clearly visible on the dressing packaging	✓	✓	✓	✓
	The size of the dressing is clearly visible on the box packaging	✓	✓	✓	✓
	The dressing size and shape is visible without opening the individual packaging	✓	✓	✓	✓
	For Film Island dressings the size and shape of the wound contact pad is visible without opening the individual packaging	N/A	N/A	N/A	N/A
	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	✗	✓	✓	✓
OPENING AND PREPARATION FOR CLINICAL USE:	The dressing can be opened maintaining product sterility	✓	✓	✓	✓
	Ease of opening dressing maintaining product sterility	★★☆ (2.00)	★★☆ (2.00)	★★½ (1.50)	★★☆ (2.00)
	Preparing dressing for application-Clarity & simplicity of instructions	★☆☆ (1.00)	★★½ (2.50)	★★½ (2.50)	★★☆ (2.00)
	Preparing dressing for application-Ease of removal of dressing backing	★★½ (1.50)	★★★ (2.75)	★★½ (2.50)	★★☆ (2.00)
	Preparing dressing for application-Wastage of dressing	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
CLINICAL USE:	Conformability-Ease of application to "flat" area of body	★★☆ (2.00)	★★½ (2.25)	★★☆ (2.00)	★★☆ (2.00)
	Conformability-Ease of backing layer removal to "flat" area of body	★★½ (1.25)	★★½ (2.25)	★★½ (2.50)	★★½ (1.60)
	Conformability-Wear time on evaluation "flat" area (up to 7 days)	7 days	7 days	2 days	7 days
	Conformability-Ease of application to "joint" area of body	★★☆ (2.00)	★★☆ (2.00)	★★½ (2.50)	★★½ (1.30)
	Conformability-Ease of backing layer removal to "joint" area of body	★☆☆ (1.00)	★★☆ (2.00)	★★☆ (2.00)	★★½ (1.30)
	Conformability-Wear time on evaluation "joint" area (up to 7 days)	7 days	7 days	5 days	2 days
	Conformability- Ability to reposition	✗	✗	✗	✗
	Conformability- Manufacturers licensed wear time	7 days	7 days	Several days	7 days
	Conformability- Shear affect of dressing whilst insitu on skin	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Skin stripping on removal-Pain & Trauma	★★☆ (2.00)	★★☆ (2.00)	★☆☆ (1.00)	★★☆ (2.00)
	Skin stripping on removal-Skin condition post removal	★★☆ (2.00)	★☆☆ (1.00)	★☆☆ (1.00)	★★☆ (2.00)
	Vapour permeability- Waterproofness	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Vapour permeability- Moisture vapour transmission rate	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Contra-indicated for Paediatric use	✓	✓	✓	✓
	Contra- indicated for Neonatal use	✓	✓	✓	✓
	Adherence of island- To wound bed	n/a	n/a	n/a	n/a
	Adherence of island-Ease of removal of pad	n/a	n/a	n/a	n/a
	Adherence of island-Atrauma to wound bed	n/a	n/a	n/a	n/a
SAFE DISPOSAL IN THE CLINICAL ENVIRONMENT:	6.2 ✗				

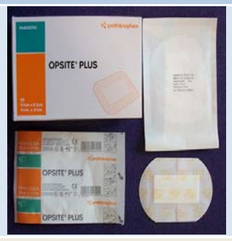
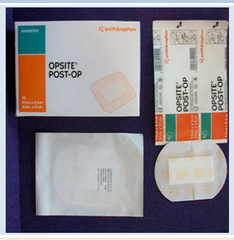
Product Assessment Cycle	CLINICAL CRITERIA	ClearSite	Dermafilm	Healthgard	Hydrofilm
	FILM DRESSING				
PACKAGING AND STORAGE:	The product category is clearly visible on the box packaging	✗	✓	✓	✓
	The product category is clearly visible on the dressing packaging	✗	✓	✓	✓
	The size of the dressing is clearly visible on the box packaging	✓	✓	✓	✓
	The dressing size and shape is visible without opening the individual packaging	✗	✗	✓	✓
	For Film Island dressings the size and shape of the wound contact pad is visible without opening the individual packaging	N/A	N/A	N/A	N/A
	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	✓	✗	✓	✓
OPENING AND PREPARATION FOR CLINICAL USE:	The dressing can be opened maintaining product sterility	✗	✗	✓	✓
	Ease of opening dressing maintaining product sterility	(0.60)	(0.70)	(2.00)	(2.00)
	Preparing dressing for application-Clarity & simplicity of instructions	(0.70)	(0.30)	(2.30)	(2.70)
	Preparing dressing for application-Ease of removal of dressing backing	(0.70)	(0.30)	(2.30)	(2.30)
	Preparing dressing for application-Wastage of dressing	(0.30)	(0.30)	(2.30)	(2.00)
CLINICAL USE:	Conformability-Ease of application to "flat" area of body	(1.30)	(0.30)	(2.30)	(2.60)
	Conformability-Ease of backing layer removal to "flat" area of body	(1.00)	(0.70)	(2.30)	(2.70)
	Conformability-Wear time on evaluation "flat" area (up to 7 days)	7 days	4 days	3 days	4 days
	Conformability-Ease of application to "joint" area of body	(0.70)	(0.30)	(2.00)	(2.30)
	Conformability-Ease of backing layer removal to "joint" area of body	(0.70)	(0.30)	(2.00)	(2.70)
	Conformability-Wear time on evaluation "joint" area (up to 7 days)	7 days	3 days	7 days	3 days
	Conformability- Ability to reposition	✗	✗	✗	✗
	Conformability- Manufacturers licensed wear time	Not stated	Not stated	7 days	6 days
	Conformability- Shear affect of dressing whilst insitu on skin	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Skin stripping on removal-Pain & Trauma	(2.00)	(2.00)	(1.00)	(2.00)
	Skin stripping on removal-Skin condition post removal	(2.00)	(1.00)	(1.00)	(2.00)
	Vapour permeability- Waterproofness	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Vapour permeability- Moisture vapour transmission rate	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Contra-indicated for Paediatric use	✓	✓	✓	✓
	Contra- indicated for Neonatal use	✓	✓	✓	✓
	Adherence of island- To wound bed	n/a	n/a	n/a	n/a
	Adherence of island-Ease of removal of pad	n/a	n/a	n/a	n/a
	Adherence of island-Atrauma to wound bed	n/a	n/a	n/a	n/a
SAFE DISPOSAL IN THE CLINICAL ENVIRONMENT:	6.2 ✗				

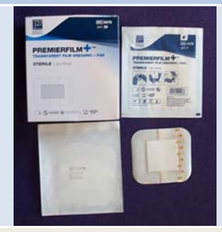
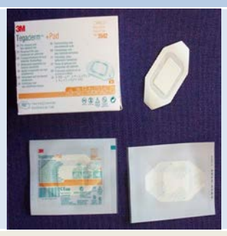
Product Assessment Cycle	CLINICAL CRITERIA	Leukomed T	Mepitel Film	Mepore Film	Opsite Flexigrid
	FILM DRESSING				
PACKAGING AND STORAGE:	The product category is clearly visible on the box packaging	✓	✓	✓	✓
	The product category is clearly visible on the dressing packaging	✗	✓	✓	✓
	The size of the dressing is clearly visible on the box packaging	✓	✓	✓	✓
	The dressing size and shape is visible without opening the individual packaging	✓	✓	✓	✗
	For Film Island dressings the size and shape of the wound contact pad is visible without opening the individual packaging	N/A	N/A	N/A	N/A
	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	✓	✓	✓	✓
OPENING AND PREPARATION FOR CLINICAL USE:	The dressing can be opened maintaining product sterility	✓	✓	✓	✓
	Ease of opening dressing maintaining product sterility	★★☆ (2.00)	★★☆ (1.60)	★★☆ (1.25)	★★☆ (1.70)
	Preparing dressing for application-Clarity & simplicity of instructions	★★☆ (1.30)	★★☆ (2.00)	★★☆ (2.00)	★★★ (2.30)
	Preparing dressing for application-Ease of removal of dressing backing	★★☆ (1.60)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Preparing dressing for application-Wastage of dressing	★★☆ (1.60)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (1.70)
CLINICAL USE:	Conformability-Ease of application to "flat" area of body	★★☆ (2.00)	★★☆ (2.00)	★★☆ (1.25)	★★★ (2.30)
	Conformability-Ease of backing layer removal to "flat" area of body	★★★ (2.30)	★★☆ (2.00)	★★☆ (1.75)	★★☆ (1.30)
	Conformability-Wear time on evaluation "flat" area (up to 7 days)	7 days	7 days	2 days	7 days
	Conformability-Ease of application to "joint" area of body	★★☆ (1.70)	★★☆ (2.00)	★★☆ (1.25)	★★☆ (2.00)
	Conformability-Ease of backing layer removal to "joint" area of body	★★☆ (1.70)	★★☆ (2.00)	★★☆ (1.25)	★★☆ (1.30)
	Conformability-Wear time on evaluation "joint" area (up to 7 days)	7 days	6 days	2 days	7 days
	Conformability- Ability to reposition	✗	✓	✗	✗
	Conformability- Manufacturers licensed wear time	7 days	7 days	Not stated	14 days
	Conformability- Shear affect of dressing whilst insitu on skin	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Skin stripping on removal-Pain & Trauma	★★☆ (2.00)	★★★ (3.00)	★☆☆ (1.00)	★★☆ (2.00)
	Skin stripping on removal-Skin condition post removal	★★☆ (2.00)	★★★ (3.00)	★☆☆ (1.00)	★★☆ (2.00)
	Vapour permeability- Waterproofness	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Vapour permeability- Moisture vapour transmission rate	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Contra-indicated for Paediatric use	✓	✓	✓	✓
	Contra- indicated for Neonatal use	✓	✓	✓	✓
	Adherence of island- To wound bed	n/a	n/a	n/a	n/a
	Adherence of island-Ease of removal of pad	n/a	n/a	n/a	n/a
	Adherence of island-Atrauma to wound bed	n/a	n/a	n/a	n/a
SAFE DISPOSAL IN THE CLINICAL ENVIRONMENT:	6.2 ✗				

Product Assessment Cycle	CLINICAL CRITERIA	Tegaderm Diamond	Premierfilm	Suprasorb F	Tegaderm
	FILM DRESSING				
PACKAGING AND STORAGE:	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	✓	×	×	✓
	For Film Island dressings the size and shape of the wound contact pad is visible without opening the individual packaging	N/A	N/A	N/A	N/A
	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	✓	✓	×	✓
OPENING AND PREPARATION FOR CLINICAL USE:	The dressing can be opened maintaining product sterility	✓	✓	✓	✓
	Ease of opening dressing maintaining product sterility	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Preparing dressing for application-Clarity & simplicity of instructions	★★☆ (2.00)	★★☆ (2.00)	★☆☆ (1.00)	★★½ (2.30)
	Preparing dressing for application-Ease of removal of dressing backing	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Preparing dressing for application-Wastage of dressing	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★½☆ (1.70)
CLINICAL USE:	Conformability-Ease of application to "flat" area of body	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★½☆ (1.70)
	Conformability-Ease of backing layer removal to "flat" area of body	★★☆ (2.00)	★★☆ (2.00)	★½☆ (1.70)	★½☆ (1.30)
	Conformability-Wear time on evaluation "flat" area (up to 7 days)	2 days	5 days	4 days	5 days
	Conformability-Ease of application to "joint" area of body	★★☆ (2.00)	★★☆ (2.00)	★½☆ (1.70)	★½☆ (1.30)
	Conformability-Ease of backing layer removal to "joint" area of body	★★☆ (2.00)	★★☆ (2.00)	★½☆ (1.70)	★☆☆ (1.00)
	Conformability-Wear time on evaluation "joint" area (up to 7 days)	4 days	6 days	6 days	2 days
	Conformability- Ability to reposition	×	×	×	×
	Conformability- Manufacturers licensed wear time	Not stated	7 days	5-7 days	Not stated
	Conformability- Shear affect of dressing whilst insitu on skin	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Skin stripping on removal-Pain & Trauma	★☆☆ (1.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Skin stripping on removal-Skin condition post removal	★☆☆ (1.00)	★★☆ (2.00)	★☆☆ (1.00)	★★☆ (2.00)
	Vapour permeability- Waterproofness	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Vapour permeability- Moisture vapour transmission rate	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Contra-indicated for Paediatric use	✓	✓	✓	✓
	Contra- indicated for Neonatal use	✓	✓	✓	✓
	Adherence of island- To wound bed	n/a	n/a	n/a	n/a
	Adherence of island-Ease of removal of pad	n/a	n/a	n/a	n/a
	Adherence of island-Atrauma to wound bed	n/a	n/a	n/a	n/a
SAFE DISPOSAL IN THE CLINICAL ENVIRONMENT:	6.2 ×				

Product Assessment Cycle	CLINICAL CRITERIA	365 Healthcare+Pad	C-View Post-Op	Clearpore	Curapor Transparent
	FILM DRESSING				
PACKAGING AND STORAGE:	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	✓	✓	✓	✗
	For Film Island dressings the size and shape of the wound contact pad 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	✗	✓	✓	✗
OPENING AND PREPARATION FOR CLINICAL USE:	The dressing can be opened maintaining product sterility	✓	✓	✓	✓
	Ease of opening dressing maintaining product sterility	★½☆ (1.30)	★½☆ (1.30)	☆☆☆ (0.60)	★★☆ (2.00)
	Preparing dressing for application-Clarity & simplicity of instructions	☆☆☆ (0.60)	★★½ (2.30)	★½☆ (1.30)	★½☆ (1.50)
	Preparing dressing for application-Ease of removal of dressing backing	★½☆ (1.60)	★★½ (2.30)	★★☆ (2.00)	★★½ (2.50)
	Preparing dressing for application-Wastage of dressing	★½☆ (1.60)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
CLINICAL USE:	Conformability-Ease of application to "flat" area of body	★½☆ (1.60)	★★½ (2.30)	★★☆ (2.00)	★★½ (2.50)
	Conformability-Ease of backing layer removal to "flat" area of body	★½☆ (1.30)	★★½ (2.30)	★☆☆ (1.00)	★★☆ (2.00)
	Conformability-Wear time on evaluation "flat" area (up to 7 days)	7 days	4 days	3 days	7 days
	Conformability-Ease of application to "joint" area of body	★½☆ (1.60)	★½☆ (1.60)	★½☆ (1.30)	★★☆ (2.00)
	Conformability-Ease of backing layer removal to "joint" area of body	★½☆ (1.30)	★½☆ (1.60)	★½☆ (1.30)	★★☆ (2.00)
	Conformability-Wear time on evaluation "joint" area (up to 7 days)	7 days	2 days	1 day	3 days
	Conformability- Ability to reposition	✗	✗	✗	✗
	Conformability- Manufacturers licensed wear time	7 days	7 days	Not stated	Not stated
	Conformability- Shear affect of dressing whilst insitu on skin	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Skin stripping on removal-Pain & Trauma	★★☆ (2.00)	★★☆ (2.00)	☆☆☆ (0.00)	★★☆ (2.00)
	Skin stripping on removal-Skin condition post removal	★★☆ (2.00)	★★☆ (2.00)	★☆☆ (1.00)	★☆☆ (1.00)
	Vapour permeability- Waterproofness	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Vapour permeability- Moisture vapour transmission rate	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Contra-indicated for Paediatric use	✓	✓	✓	✓
	Contra- indicated for Neonatal use	✓	✓	✓	✓
	Adherence of island- To wound bed	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Adherence of island-Ease of removal of pad	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Adherence of island-Atrauma to wound bed	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
SAFE DISPOSAL IN THE CLINICAL ENVIRONMENT:	6.2 ✗				

Product Assessment Cycle	CLINICAL CRITERIA	Healthgard Plus	Hydrofilm Plus	Leukomed Control	Leukomed T Plus
	FILM DRESSING				
PACKAGING AND STORAGE:	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	✓	✓	✗	✓
	For Film Island dressings the size and shape of the wound contact pad 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	✓	✓	✗	✓
OPENING AND PREPARATION FOR CLINICAL USE:	The dressing can be opened maintaining product sterility	✓	✓	✓	✓
	Ease of opening dressing maintaining product sterility	★★☆ (2.00)	★★☆ (2.00)	★½☆ (1.50)	★★☆ (2.00)
	Preparing dressing for application-Clarity & simplicity of instructions	★★½ (2.30)	★★½ (2.70)	★★½ (2.50)	★½☆ (1.60)
	Preparing dressing for application-Ease of removal of dressing backing	★★½ (2.30)	★★½ (2.30)	★★★ (2.75)	★★½ (2.60)
	Preparing dressing for application-Wastage of dressing	★★½ (2.30)	★★½ (2.30)	★★☆ (2.00)	★★½ (2.60)
CLINICAL USE:	Conformability-Ease of application to "flat" area of body	★★½ (2.30)	★★½ (2.30)	★★★ (2.75)	★★½ (2.30)
	Conformability-Ease of backing layer removal to "flat" area of body	★★½ (2.30)	★★½ (2.30)	★★★ (2.75)	★★½ (2.30)
	Conformability-Wear time on evaluation "flat" area (up to 7 days)	3 days	7 days	7 days	7 days
	Conformability-Ease of application to "joint" area of body	★★½ (2.30)	★★½ (2.30)	★★☆ (2.00)	★★☆ (2.00)
	Conformability-Ease of backing layer removal to "joint" area of body	★★½ (2.30)	★★½ (2.30)	★★☆ (2.00)	★★☆ (2.00)
	Conformability-Wear time on evaluation "joint" area (up to 7 days)	7 days	5 days	7 days	7 days
	Conformability- Ability to reposition	✗	✗	✗	✗
	Conformability- Manufacturers licensed wear time	7 days	6 days	7 days	7 days
	Conformability- Shear affect of dressing whilst insitu on skin	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Skin stripping on removal-Pain & Trauma	★☆☆ (1.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Skin stripping on removal-Skin condition post removal	★☆☆ (1.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Vapour permeability- Waterproofness	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Vapour permeability- Moisture vapour transmission rate	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Contra-indicated for Paediatric use	✓	✓	✓	✓
	Contra- indicated for Neonatal use	✓	✓	✓	✓
	Adherence of island- To wound bed	★★☆ (2.00)	★★☆ (2.00)	★★★ (3.00)	★★☆ (2.00)
	Adherence of island-Ease of removal of pad	★★☆ (2.00)	★★☆ (2.00)	★★★ (3.00)	★★★ (3.00)
	Adherence of island-Atrauma to wound bed	★★☆ (2.00)	★★☆ (2.00)	★★★ (3.00)	★★☆ (2.00)
SAFE DISPOSAL IN THE CLINICAL ENVIRONMENT:	6.2 ✗				

Product Assessment Cycle	CLINICAL CRITERIA	Mepore Film & Pad	Opsite Plus	OpSite Post Op Visible	OpSite Post Op
	FILM DRESSING				
PACKAGING AND STORAGE:	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	✗	✗	✓	✓
	For Film Island dressings the size and shape of the wound contact pad 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	✓	✓	✓	✓
OPENING AND PREPARATION FOR CLINICAL USE:	The dressing can be opened maintaining product sterility	✓	✓	✓	✓
	Ease of opening dressing maintaining product sterility	★½☆ (1.25)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Preparing dressing for application-Clarity & simplicity of instructions	★★☆ (2.00)	★★½ (2.30)	★★½ (2.30)	★★½ (2.30)
	Preparing dressing for application-Ease of removal of dressing backing	★★☆ (2.00)	★★½ (2.30)	★★☆ (2.00)	★★☆ (2.00)
	Preparing dressing for application-Wastage of dressing	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
CLINICAL USE:	Conformability-Ease of application to "flat" area of body	★½☆ (1.25)	★★½ (2.30)	★★☆ (2.00)	★★½ (2.30)
	Conformability-Ease of backing layer removal to "flat" area of body	★★☆ (2.00)	★★½ (2.30)	★★☆ (2.00)	★★☆ (2.00)
	Conformability-Wear time on evaluation "flat" area (up to 7 days)	4 days	4 days	6 days	6 days
	Conformability-Ease of application to "joint" area of body	★★☆ (2.00)	★★☆ (2.00)	★★½ (2.30)	★★½ (2.30)
	Conformability-Ease of backing layer removal to "joint" area of body	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Conformability-Wear time on evaluation "joint" area (up to 7 days)	2 days	6 days	4 days	5 days
	Conformability- Ability to reposition	✗	✗	✗	✗
	Conformability- Manufacturers licensed wear time	Not stated	Not stated	Not stated	Not stated
	Conformability- Shear affect of dressing whilst insitu on skin	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Skin stripping on removal-Pain & Trauma	★☆☆ (1.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Skin stripping on removal-Skin condition post removal	★☆☆ (1.00)	★★☆ (2.00)	★★☆ (2.00)	★★☆ (2.00)
	Vapour permeability- Waterproofness	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Vapour permeability- Moisture vapour transmission rate	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17	Awaiting lab results April 17
	Contra-indicated for Paediatric use	✓	✓	✓	✓
	Contra- indicated for Neonatal use	✓	✓	✓	✓
	Adherence of island- To wound bed	★★★ (3.00)	★★★ (3.00)	★★★ (3.00)	★★☆ (2.00)
	Adherence of island-Ease of removal of pad	★★☆ (2.00)	★★☆ (2.00)	★★★ (3.00)	★★★ (3.00)
	Adherence of island-Atrauma to wound bed	★★★ (3.00)	★★☆ (2.00)	★★★ (3.00)	★★☆ (2.00)
SAFE DISPOSAL IN THE CLINICAL ENVIRONMENT:	6.2 ✗				

Product Assessment Cycle	CLINICAL CRITERIA	Premierfilm+Pad	Tegaderm +Pad
	FILM DRESSING		
PACKAGING AND STORAGE:	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	✗	✓
	For Film Island dressings the size and shape of the wound contact pad 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	✓	✓
OPENING AND PREPARATION FOR CLINICAL USE:	The dressing can be opened maintaining product sterility	✓	✓
	Ease of opening dressing maintaining product sterility	★★☆ (2.00)	★★☆ (2.00)
	Preparing dressing for application-Clarity & simplicity of instructions	★★☆ (2.00)	★½☆ (1.70)
	Preparing dressing for application-Ease of removal of dressing backing	★★½ (2.30)	★★½ (2.30)
	Preparing dressing for application-Wastage of dressing	★★☆ (2.00)	★★☆ (2.00)
CLINICAL USE:	Conformability-Ease of application to "flat" area of body	★★½ (2.30)	★★½ (2.30)
	Conformability-Ease of backing layer removal to "flat" area of body	★½☆ (1.70)	★½☆ (1.70)
	Conformability-Wear time on evaluation "flat" area (up to 7 days)	5 days	6 days
	Conformability-Ease of application to "joint" area of body	★★½ (2.30)	★★☆ (2.00)
	Conformability-Ease of backing layer removal to "joint" area of body	★★☆ (2.00)	★★☆ (2.00)
	Conformability-Wear time on evaluation "joint" area (up to 7 days)	2 days	3 days
	Conformability- Ability to reposition	✗	✗
	Conformability- Manufacturers licensed wear time	7 days	Not stated
	Conformability- Shear affect of dressing whilst insitu on skin	Awaiting lab results April 17	Awaiting lab results April 17
	Skin stripping on removal-Pain & Trauma	★★☆ (2.00)	★★☆ (2.00)
	Skin stripping on removal-Skin condition post removal	★★☆ (2.00)	★★☆ (2.00)
	Vapour permeability- Waterproofness	Awaiting lab results April 17	Awaiting lab results April 17
	Vapour permeability- Moisture vapour transmission rate	Awaiting lab results April 17	Awaiting lab results April 17
	Contra-indicated for Paediatric use	✓	✓
	Contra- indicated for Neonatal use	✓	✓
	Adherence of island- To wound bed	★★☆ (2.00)	★★☆ (2.00)
	Adherence of island-Ease of removal of pad	★★☆ (2.00)	★★☆ (2.00)
	Adherence of island-Atrauma to wound bed	★★☆ (2.00)	★★☆ (2.00)
SAFE DISPOSAL IN THE CLINICAL ENVIRONMENT:	6.2 ✗		

Recommendations for the future

There is a large range of film dressings currently available via the current national provider.

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 in which these products are being used. Whilst it is not reasonable or sensible to provide an extensive range of film and film island dressings within any given health care setting; consideration should be given to the primary use and objectives of these products given the patient demographics, within a Trust or Health organisation. Recognition and identification to some of the other properties of film dressing for particular individuals/circumstances, will enable patient centric care and optimise outcome.

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 NHS 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	
Hydrocolloids	
Gelling Fibres	
Films	
Non-adherent wound contact layers	
Foams	
Antimicrobials	
Absorbents	
Super absorbents	

Figure 7. – NHS Clinical Evaluation Team colour coding of dressing groups

An additional recommendation would be to clearly display maximum wear time of product to aid clinical and patient experience in managing expectations and performance of the products being applied.

“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 encourages suppliers to add GS1 compliant barcodes to their products before the published deadlines. 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.”

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.

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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.'

Mandie Sunderland
Chair, Clinical Reference Board
(Governing body of the NHS Clinical Evaluation Team)