

**National Institute for Health and Care Excellence
Medical Technologies Evaluation Programme**

**MT192 – The Debrisoft monofilament debridement pad for use in acute or chronic wounds
Consultation Comments table
MTAC date: 18th October 2013**

There were 26 consultation comments from 6 consultees (2 NHS professionals, 2 specialist societies, 1 patient organisation and 1 manufacturer (topic sponsor)). The comments are reproduced in full, arranged in guidance section order.

Table 1

Com. no.	Consultee number and organisation	Sec. no.	Comments	Response
1	2.Sponsor	1.2	The data indicate that the device is particularly effective for chronic sloughy wounds and hyperkeratotic skin.	Thank you for your comment. The Committee decided to change section 1.2 to read ‘The data show that the device is particularly effective for chronic sloughy wounds and hyperkeratotic skin around acute or chronic wounds.’
2	3. Specialist Society	2.1	Should read “on or around acute and chronic wounds”. (hyperkeratotic skin is found around a wound)	Thank you for your comment. The Committee decided to change this sentence in section 2.1 to clarify that hyperkeratotic skin is found around a wound.
3	2. Sponsor	2.2	The Debrisoft pad is moistened with tap water, sterile water or saline and using the soft fleecy side, wiped across the wound with gentle pressure.	Thank you for your comment. This comment and comment 24 both suggest including tap water. The manufacturer’s instructions for use states that the ‘soft fleecy side’ of the Debrisoft pad should be moistened with tap water (or saline) and wiped across the wound with gentle pressure.

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				The Committee decided to change the first sentence of section 2.2 to read ‘The Debrisoft pad is moistened with tap water, sterile water or saline, folded, and then using the soft fleecy side, wiped across the wound with gentle pressure.’
4	2. Sponsor	2.2	A new pad is needed for each separate area of skin or wound to be treated.	Thank you for your comment. The Committee decided to change section 1.2 to state that a new pad is normally needed for each separate wound to be treated.
5	3. Specialist Society	2.2	Should read “slough, necrotic tissue” not slough (necrotic) tissue. they are two different things	Thank you for your comment. The Committee decided to remove ‘necrotic’ as experts advised that these terms would be used interchangeably in clinical practice.
6	2. Sponsor	2.3	The cost of 1 Debrisoft monofilament debridement pad stated in the sponsor’s submission is £6.19 (excluding VAT). <i>This price has been increased to £6.27 due to an annual drug tariff price increase.</i>	Thank you for your comment. This comment and comment 7 both refer to the price of the technology. The list price of the technology used in the evaluation is provided by the sponsor in its submission. This is stated in section 2.3. The Committee decided to change section 2.3 to clarify the difference between the submission price and the price at the time of the publication of the guidance. The Committee was also informed by the External Assessment Centre that it had re-run the cost analyses at the increased cost for Debrisoft and that the results did not change significantly. Section 5.14 of the guidance has been changed to include this information.
7	3. Specialist Society	2.3	Should add that the price is correct at time of publication or something to that effect.	Thank you for your comment. Please refer to the response to comment 6.
8	2. Sponsor	2.5	In the community these are likely to include mechanical (gauze swabs), autolytic (amorphous	Thank you for your comment.

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			hydrogels, dressings or compression to support wound healing.	The Committee decided to update section 2.5 to clarify the types of comparators used in the community.
9	3. Specialist Society	2.5	Should read “dressings to support moist wound healing...” Remove hydrogels as they come under the healing of autolytic debridement and compression bandaging as whilst they can indirectly support autolytic debridement, their main function is to aid venous return.	Thank you for your comment. Please refer to the response to comment 9.
10	3. Specialist Society	2.8	Should read “negative pressure wound therapy”	Thank you for your comment. The Committee decided to change section 2.8 of the guidance to include the additional word ‘wound’.
11	2. Sponsor	3.2	Time to healing may be shortened by reducing the time taken to de-slough, debride and clear the skin or wound of debris that may obscure assessment.	Thank you for your comment. This comment and comment 12 both refer to key clinical outcomes. The Committee considered this comment and decided not to change the guidance because no specific evidence was presented on time to healing.
12	2. Sponsor	3.2	Device-related adverse events, including non-selective trauma to healthy surrounding tissue or bleeding that may occur as a result of using a scalpel or scrubbing brush.	Thank you for your comment. Please refer to the response to comment 11.
13	3. Specialist Society	4.3	The number of applications of hydrogel to debride a wound will vary significantly from patient to patient depending on wound aetiology, size of wound, depth and adherence of slough etc. To say that hydrogels take up to 10 applications is rather misleading.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance because the Committee’s consideration on the number of applications needed is based on estimates by expert advisers and is clearly stated as such.
14	2. Sponsor	5.16	Expert advice to the Committee was that the	Thank you for your comment.

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			Debrisoft pad was not suitable for wounds with black necrotic tissue or hard eschar. The manufacturer's guidance states that in some cases hard necrosis or thick tenacious slough may benefit from prior softening with a hydrogel before using Debrisoft.	The Committee considered this comment and decided not to change the guidance because the consideration of using hydrogel before Debrisoft is outside the scope.
15	3. Specialist Society	8	<p>The Royal College of Nursing submitted comments on the draft scope, but appear to be missing in the list of contributors.</p> <p>Ms Cathie Bree-Aslan - clinical expert, appears to be inadvertently listed as being ratified by the Royal College of Nursing.</p>	<p>Thank you for your comment. This comment and comment 18 both refer to the ratification of an expert adviser.</p> <p>The Royal College of Nursing's input is acknowledged on pages 11 and 12 of the scope.</p> <p>NICE apologises for the error in reporting the ratifying body and has updated the assessment report overview and the medical technologies consultation document to state that the expert adviser was ratified by the Tissue Viability Society.</p>
16	1.NHS Professional	General	<p>I use the Debrisoft for removal of hyperkeratotic skin around venous ulcers, particularly if there is a large build up under compression bandaging. I think that it is very effective and potentially cost effective, particularly in a community setting where it would reduce the time needed by district nurses to soften the skin with emollients and then remove this skin with forceps.</p> <p>I have limited use of it in debridement of the wound bed as I have undergone specific training/further study in sharp debridement and tend to use this at my clinics. As it is a requirement for nurses to undertake specific training in sharp debridement, this quick and cheap method of debridement is not always an option. The use of debrisoft in these instances can be more cost effective when you consider</p>	Thank you for your comment.

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			how quick the debridement effects are on the wound. This can be measured against the cost of repeated applications of hydro gels/honey to aid autolytic debridement over many weeks.	
17	2. Sponsor	General	The consultation document is well set out with clear information on the technology and the evidence that supports debridement with this method.	Thank you for your comment.
18	3. Specialist Society	General	<p>I was just going through the above consultation document and noticed the following listed as being ratified by the Royal College of Nursing</p> <ul style="list-style-type: none"> Ms Cathie Bree–Aslan, ratified by Royal College of Nursing – clinical expert <p>I had a look at our records and could not find the ratifying information from our end. Could you please send me the relevant information from the RCN, confirming this? Thank you.</p>	<p>Thank you for your comment.</p> <p>Please refer to the response to comment 15.</p>
19	3. Specialist Society	General	We need to be mindful that debridement rarely takes place in 1 or 2 isolated events. Nowadays we adopt the process of ‘maintenance debridement’ where the clinician repeatedly debrides the wound where slough or non viable tissue returns to the wound bed. This must be considered when looking at cost.	<p>Thank you for your comment.</p> <p>The Committee considered this comment and decided not to change the guidance because it discussed this issue when considering the economic modelling and noted in section 5.17 that there is no available data to inform a cost analysis of this scenario. The economic model considered by the Committee was based on a time to debridement outcome.</p>
20	3. Specialist Society	General	In view of the current evidence and the suggested improvement in patient comfort, more effective debridement in some categories of wounds and the potential for faster wound healing, the RCN welcome the suggestion to use Debrisoft in the community. However there is a need to ensure that all the categories of nurses who may use this	<p>Thank you for your comment.</p> <p>The Committee carefully considered this comment and decided to add section 4.5 to state that nurses and other healthcare professionals should only use Debrisoft after appropriate training in its indications and safe application.’</p>

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			product receive training to ensure that they do not damage new tissue and the need for really effective infection control techniques. This must include nurses in care homes, practice nurses as well as community nurses.	
21	Specialist Society		As the evidence base is still limited, further evaluation should be undertaken to clarify where its use would be most effective	The Committee considered this comment and decided not to change the guidance because Section 3.19 describes the Committee wish to 'encourage the collection of better quality comparative evidence to improve decision-making in the debridement of acute or chronic wounds.'
22	4. Specialist Society	General	The experts rightly pointed out that the absence or presence of slough does not point to whether the wound will heal or not.	Thank you for your comment.
23	4. Specialist Society	General	Debrisoft may be helpful for the grossly hyperkeratotic skin of lymphovenous disease, but should not replace the use of regular emollients.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance because the consideration of replacing regular emollients is outside of the scope of this evaluation.
24	4. Specialist Society	General	The report comments on using sterile water or normal saline prior to use – there is enough evidence to say that tap water is safe for all wounds (except in the immunosuppressed, where caution is necessary).	Thank you for your comment. Please refer to the response to comment 3.
25	5. Patient organisation	General	We have reviewed the draft guidance and recommendations upon the use of Debrisoft and have no comments to make reflecting our agreement with the content of the document.	Thank you for your comment.
26	6. DH	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation	Thank you for your comment.

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