NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

The Debrisoft monofilament debridement pad for use in acute and chronic wounds

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the sponsor's submission of evidence and with the EAC report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations
- Appendix D: External Assessment Centre correspondence
- Appendix E: Sponsor's factual check of the assessment report and the External Assessment Centre's responses

1 The technology

The Debrisoft monofilament debridement pad (Activa Healthcare) is a sterile, single-use pad for nurses and other healthcare professionals to use on adults and children to remove devitalised tissue, debris, and hyperkeratotic skin caused by chronic and acute wounds. The Debrisoft monofilament debridement pad (referred to in the remainder of this document as the Debrisoft pad) is used to ensure the wound bed is not obscured, aiding full assessment and further treatment if needed.

The Debrisoft pad is 10×10 cm and is made of monofilament polyester fibres with a reverse side of polyacrylate. The monofilament fibres are cut with angled tips designed to penetrate irregularly shaped areas and remove devitalised skin and wound debris.

To use, the Debrisoft pad is moistened with sterile water or saline and then folded and wiped across the wound with an appropriate amount of pressure. Cellular debris, slough (necrotic tissue), exudate and hyperkeratotic tissue become integrated into the monofilaments and are therefore removed from the wound site. The Debrisoft pad is intended for use without analgesia, and the process takes, on average, 2–4 minutes. A new Debrisoft pad is needed for each separate area of skin being treated. For large areas, more than 1 pad may be needed. Expert advisers stated that the Debrisoft pad should be used only after a registered healthcare professional has made a clinical assessment.

2 Proposed use of the technology

2.1 Disease or condition

The types of chronic wounds that may be relevant for debridement include pressure ulcers, leg ulcers and diabetic foot ulcers and skin conditions associated with lymphoedema. The types of acute wounds that may be relevant include burns, surgical dehiscences and haematomas.

Approximately half a million people in the UK develop at least 1 pressure ulcer in any given year. These are usually people with an underlying health condition. Leg ulcers affect 1 in 500 people, although this rises sharply with age to 1 in 50 in those over the age of 80. In the UK, the annual incidence of foot ulcers among people with diabetes is 2–5%, with 0.25–1.8% needing amputation. Approximately 10% of all leg ulcers are caused by arterial insufficiency. In the UK lymphoedema occurs in 1 in 10,000 people, with primary lymphoedema affecting approximately 100,000 people. Skin and tissue problems in lymphoedema include hyperkeratosis (thickened scaly areas).

Acute wounds can be surgical or traumatic and they need management to prevent infection and promote healing. Subacute wounds are those that have reached a stage of healing characterised by new growth of connective tissue and capillaries, usually between days 4 and 21 of healing.

Burn wounds are estimated to cause hospital admission in 0.29 per 1000 people with burn or smoke inhalation. In the UK, it is estimated that each year about 250,000 people with burn injuries present to primary care.

Approximately 4.2 million surgical procedures are carried out each year in England. Dehiscence is the opening of surgical wounds. Mortality rates of 14–50% have been reported with surgical wound dehiscence. Wound haematomas are a relatively common complication of surgical procedures. Haematomas delay healing in acute traumatic wounds and can cause infection.

2.2 Patient group

The Debrisoft pad can be used on adults and children with devitalised tissue caused by chronic and acute wounds in any healthcare setting.

For this assessment the Debrisoft pad was evaluated in patients needing debridement of an acute or chronic wound by a healthcare professional (most likely to be a nurse) in a community-based setting.

Two potential subgroups were identified; people with closed acute or chronic wounds where the skin is intact and people with open acute or chronic wounds where the skin is not intact.

2.3 Current management

Debridement is the removal of dead, damaged tissue or haematoma from the wound, helping it to repair. This process occurs naturally (autolytic debridement) but can take time. Several techniques are used to debride wounds, depending on the type of wound. The techniques that are likely to be used in the community include:

- mechanical debridement
  - gauze swabs
- autolytic debridement
  - dressings to support wound healing – moisture retention dressing.
  - hydrogels and compression bandages
- biosurgical debridement
  - larvae.

Debridement can be carried out under general or local anaesthetic, and with or without analgesia depending on the degree of wound pain, the site, size and severity of the wound as well as the patient's needs.

Pressure ulcer management (NICE clinical guideline 29) states that standard practice in the management of chronic wounds should include wound debridement to remove dead tissue and that clinicians should recognise the positive potential benefit of debridement in the management of pressure ulcers. NICE includes debridement in the pressure ulcer management pathway.

Diabetic foot problems (NICE clinical guideline 119) recommends that diabetic foot ulcers are managed by a multidisciplinary foot care team and new ulcers are assessed by an appropriately trained health professional within 24 hours

of them developing. Choice of dressings and therapy depends on the site and size of the ulcer, patient preference, clinical circumstances and experience as well as dressing costs. The guideline states that debridement should be performed only by healthcare professionals from the multidisciplinary foot care team, using the technique that best matches their specialist expertise, clinical experience, patient preference, and the site of the ulcer.

The clinical pathway for people with burns or dehisced wounds is not well defined and varies by wound type. All types of burns may need medical attention. Deep partial-thickness and full-thickness burns may need wound care. Treatment for dehisced wounds may include antibiotics, wound packing, and negative pressure therapy.

Haematomas with overlying necrotic skin can be treated conservatively using autolytic, larvae or honey debridement. If the haematoma is very large, surgical debridement may be needed depending on depth, severity, size, position and patient-related factors.

2.4 Proposed management with new technology

The scope of this assessment is the use of the Debrisoft pad as an alternative to existing methods of debridement of an acute or chronic wound by a healthcare professional in adults or children in a community-based setting.

The use of the the Debrisoft pad in a secondary care setting is not included in this evaluation.

2.5 Equality issues

No equality issues were identified.

Groups covered by the Equality Act 2010 include patients with chronic wounds and diabetes. The Debrisoft pad may have particular advantages for people who have foot ulcers as a result of chronic wounds or diabetes. The Debrisoft pad would not restrict the access to treatment for these groups of people.

3 Issues for consideration by the Committee

3.1 Claimed benefits

The benefits to patients claimed by the sponsor are:

- Reduction in pain associated with debridement with no analgesia required in most cases.
- Improved acceptability to patients with reduced fear and anxiety associated with treatment.
- Faster treatment and healing with reduced frequency and total episodes of care.
    - Reduced risks of trauma to healthy tissue, and of bleeding.

The benefits to the health system claimed by the sponsor are:

- Reduced time and resources associated with debridement and reduced overall time to healing.
- Use by nurses and other healthcare professionals in the community leading to lower costs and shorter waiting times for treatment.
- More effective debridement facilitating initial assessment with the possibility of reduced referrals, hospital administration and inappropriate treatment through misdiagnosis.
    - Improved patient concordance with reduced costs of analgesia often required with other forms of debridement.
    - Avoidance of ongoing costs relating to specialist methods of debridement and treatment that require additional consumables.

4 The evidence

4.1 Summary of evidence of clinical benefit

The sponsor's submission presented 5 peer-reviewed journal papers, 29 poster presentations and 11 non peer-reviewed single patient case studies as relevant to the scope. It was unclear whether the posters had been peer-

reviewed; these consisted of 18 multiple-case series, 8 single-case series, 1 description of the technology and 2 in vitro studies. The External Assessment Centre considered that the following 7 of the 45 papers presented by the sponsor were relevant to the scope because they included appropriate comparators and outcomes: Bahr et al. 2011 (paper); Callaghan and Stephen-Haynes, 2012 (poster); Collarte et al. 2011 (poster); Johnson et al. 2012 (paper); Mustafi et al. 2011 (poster); Pietroletti et al. 2012 (poster); and Wiser et al. 2012 (poster). All were comparative multiple-patient case series except Callaghan and Stephen-Haynes (2012), which does not mention a comparator but presents a result, for 'reduction in wound care visits'. Two of the papers accepted by the External Assessment Centre (Bahr et al. 2011; Mustafi et al. 2011) present results from the same study.

The following 8 multiple-patient case series were considered by the External Assessment Centre not to be directly relevant to the scope: Alblas 2012 (poster); Dam 2012 (poster); Gray et al. 2011 (paper); Hammerle et al. 2011 (paper); Johnson 2012 (poster); Reike 2012 (poster); and Skovgaard-Holm and Simonsens, 2012 (poster); Stephen-Haynes and Callaghan 2012 (paper and poster).

Table 1 Summary of clinical evidence (adapted from table 3 page 19 in the External Assessment Centre report). All are multiple case series and presented in author alphabetical order.

Study	Country	Study design	Population	Intervention	Comparator	Outcomes considered
Bahr et al. (2011) and Mustafi et al. (2011) – same study	Germany, Austria, Italy (company sponsored)	Multiple-patient case series: with retrospective controls from same centres, not matched	N=60 enrolled, 57 evaluated. 54 had 1 wound, 3 had 2 wounds, acute and chronic combined. Lymphoedema – acute and chronic wounds, 42 women, 18 men.	Debrisoft monofilament debridement pad	N=not clear Retrospective data from database • autolytic with hydrogel • mechanical with wet gauze • surgical	All three comparators were compared against Debrisoft for: • efficacy • pain and discomfort for the patient when debriding the wound • user satisfaction. The hydrogel was compared against Debrisoft for time-to-complete debridement.
Callaghan and Stephen-Haynes (2012)	United Kingdom (company sponsored)	Poster: multiple-patient case series	N=12 Pressure ulcers	Debrisoft monofilament debridement pad	None used	• Pain and discomfort for the patient • Time-to-complete debridement • Number of nurse visits • Number of debridements required
Collarte et al. (2011)	England (company sponsored)	Poster: multiple-patient case series with a comparison, not matched	N=10 Chronic wounds	Debrisoft monofilament debridement pad	N=not clear Standard best practice (variety of methods not specified but including autolytic)	• Pain and discomfort for the patient • Time-to-complete debridement • Duration of nurse visits for each patient
Johnson et	United	Multiple-	Hospital and	Debrisoft	N=16	• Debrisoft efficacy

Study	Country	Study design	Population	Intervention	Comparator	Outcomes considered
al. (2012)	Kingdom (NG)	patient case series: historical comparison on same patients	community, N=20; 10 chronic leg ulcers, 10 chronic wounds including diabetic, ischaemic, leg ulcers	monofilament debridement pad	Other debridement methods but not clear which ones.	• Skin condition compared with previous hyperkeratotic method • Pain and discomfort for the patient • Time-to-complete debridement
Pietroletti et al. (2012)	Italy (company sponsored)	Poster: multiple-patient case series, retrospective comparison, non-matched	N=27 Wound bed coated with fibrin and slough or skin around the wound with keratosis and/or exudate	Debrisoft monofilament debridement pad	N=25 Autolytic (hydrogel) or enzymatic'	• Percentage of wound debrided after first use • Time-to-complete debridement
Wiser et al. (2012)	France (company sponsored)	Poster: multiple-patient case series with retrospective comparison of 'similar patient group' non-matched	15 patients with venous leg ulcers or diabetic foot ulcers	Debrisoft monofilament debridement pad	N=not clear Saline soaks	• Pain and discomfort for the patient • Device-related adverse events including non-selective trauma to healthy surrounding tissue or bleeding

Table 2 Summary of clinical evidence considered not to be relevant to the scope by the External Assessment Centre (appendix 2, page 80 in the External Assessment Centre report). All are multiple case series and are presented in author alphabetical order.

Study	Country	Study design	Population	Intervention	Comparator	Outcomes considered
Albas (2012)	Amsterdam	Poster: Multiple-patient case series	N=10 Trauma wounds and bites	Debrisoft monofilament debridement pad	None used	• Debrisoft efficacy • Pain and discomfort for the patient • Time-to-complete debridement • Number of debridements required • Device-related adverse events
Dam (2012)	Denmark	Poster: multiple-patient case series	N=29 Chronic wounds	Debrisoft monofilament debridement pad	None used	• Debrisoft efficacy • Pain and discomfort for the patient • Number of debridements required
Gray et al. (2011)	United Kingdom	Multiple-patient case series	N=18 Hyperkeratotic, haematomas and soft slough wounds.	Debrisoft monofilament debridement pad	None used	• Debrisoft efficacy • Pain and discomfort for the patient • Time-to-complete debridement
Hammerle et al. (2011)	Austria and Germany	Multiple-patient case series	N=11 The need for debridement, regardless of wound	Debrisoft monofilament debridement pad	All non-surgical debridement	• Debrisoft efficacy • Pain and discomfort for the patient • Device-related adverse events.
Johnson (2012)	England	Poster: multiple-patient case-series	N=10 Various ulcers	Debrisoft monofilament debridement pad	None used	• Pain and discomfort for the patient • Time-to-complete debridement • Time-to-healing

Study	Country	Study design	Population	Intervention	Comparator	Outcomes considered
Reike (2012)	Amsterdam	Poster: observational, multiple-patient study	N=25 Diabetic foot ulcers	Debrisoft monofilament debridement pad	None used	• Time-to-complete debridement • Time-to-healing • Number and frequency of healthcare professional visits • Number of debridements required • Need to escalate to other debridement methods.
Skovgaard-Holm and Simonsens (2012)	Denmark	Poster: multiple-patient case series	N=10 Various wounds	Debrisoft monofilament debridement pad	None used	• Efficacy of Debrisoft • Pain and discomfort for the patient • Time-to-complete debridement • Number and frequency of healthcare professional visits • Number of debridements required
Stephen-Haynes and Callaghan (2012)	England	Multiple-patient case series: reported as a journal paper and a poster	N=40 tissue viability nurses assessing wounds. Various wounds and hyperkarotosis	Debrisoft monofilament debridement pad	None used	• Debrisoft efficacy • Pain and discomfort for the patient • Time to debridement

Summary of results from multiple-patient case series (considered by the External Assessment Centre to be relevant to the scope)

Bahr et al. (2011)

A prospective, observational case series by Bahr et al. (2011) evaluated the wound debridement efficacy of the Debrisoft pad. The Debrisoft pad was used over a 6-month period on 60 patients, with chronic wounds, from 11 wound healing centres. Standardised clinical digital photographs were taken before and after debridement and the condition of each wound bed was categorised as:

- Class A – wound bed is covered in slough and has some necrotic tissue
- Class B – wound bed is covered in slough and has no necrotic tissue and
- Class C – the wound is clean with less than 20% slough.

Debrisoft was used at 4-day intervals for a total of 3 debridement sessions per wound for a 12-day evaluation period. A total of 164 visits were documented by 57 clinicians (20 physicians and 37 nurses) and 152 procedures were performed.

Results from the study showed a significant improvement in wound bed condition after 3 debridement sessions: After 1 session, 60% of wounds (n=34) were categorised as class A, 28% (n=16) as class B and 12% (n=7) class C. After 3 sessions, 47% (n=27) were class A, 25% (n=14) class B, 7% (n=4) class C and 21% (n=12) had re-epithelialised. Clinicians reported that the test product removed debris, slough, dried exudate and crusts efficiently, without damaging the fragile skin surrounding the wound and photographic analysis confirmed this. Debridement was effective in 93.4% (142/152) of the sessions, and the Debrisoft pad remained intact in 95.4% (145/152). Its shape changed slightly in 3.3% (5/152) of sessions, and in 1.3% (2/152) of sessions a small number of fibres were loosened. The overall mean time for each debridement session was 2.51 (SD±0.57) minutes for Debrisoft, 7 (±2.08)

minutes for hydrogel, 5 (±1.60) minutes for gauze and 9 (±2.64) minutes for surgical debridement.

During the debridement procedure 45% (n=26) of patients reported that they experienced no pain, 50.4% (n=29) reported slight discomfort of short duration (mean 2 minutes) and 4.6% (n=2) reported moderate pain of short duration (mean 2.4 minutes). When patients were asked about irritation, allergies and pain after the procedure, 98.2% (n=56) reported that they experienced no side effects. The convenience and ease of use of Debrisoft was rated 'very good' by its users, with a mean score of 2.29 (±0.57) on a 6-point scale (1=excellent, 2=very good, 3=good, 4=poor, 5=very poor, 6=inadequate). Wet gauze had a similar result with a mean score of 2.49 (±0.67). Debrisoft users rated its debridement efficacy as 'very good', giving a mean score of 1.98 (±0.68). Hydrogel debridement (local best practice) scored 2.54 (±0.72; very good/good). The average time to complete debridement was about 20 days with enzymes or hydrogel. Debrisoft was shown to be faster, with 77% (n=44) achieving complete debridement by 12 days compared with 20 days when using enzymes and hydrogel. No serious adverse events or adverse events were reported.

Callaghan and Stephen-Haynes (2012)

Callaghan and Stephen-Haynes (2012) described a case series of 12 patients with pressure ulcers. The study investigated if the Debrisoft pad caused any pain during the debridement process and if rapid debridement led to an improved visualisation of the wound bed. The time to achieve debridement was 0–5 minutes in all 12 patients. Four patients experienced pain during the procedure (visual analogue scale [VAS]: 1, 1, 6, 4) and the first 3 of these patients experienced pain before treatment commenced (VAS: 1, 1, 7). No patients reported pain after the treatment. There was improved visualisation of the wound bed in 92% (11/12) of the patients. The treatment using the Debrisoft pad reduced the wound care visits in 92% (11/12) of the patients. The treatment helped assess the category of the pressure ulcer in all 12 patients.

Collarte et al (2011

Collarte et al. (2011) evaluated the use of the Debrisoft monofilament debridement pad against standard best practice in a non-specialist setting. Ten patients completed the study. No statistical results were provided in the overall results. It was reported that the Debrisoft was easy to use and removed devitalised tissue and hyperkeratosis more quickly than the standard treatment. The time to treat was decreased and patients found the treatment comfortable. One patient, who had a venous leg ulcer was debrided in 4 minutes using the Debrisoft pad, and the patient reported no pain or discomfort while the wound was being cleansed. The patient had the leg ulcer for 3 years and over the last 2 years, nurses had attempted to debride the wound with various types of debridement, including autolytic and larvae therapy, but with limited success.

Johnson et al. (2012)

Johnson et al. (2012) described a 2-centre observational study that examined the effectiveness of the Debrisoft pad against other debridement methods (not specified) for the removal of hyperkeratosis and/or the debridement of devitalised tissue within the wound bed. One centre was a hospital-based wound care clinic and 1 was a community-based leg ulcer clinic; 10 patients were recruited from each centre. Treatment was considered to be the removal of slough and soft necrotic tissue or hyperkeratotic skin or both. It is not stated but it appears from the results that each wound was treated using the Debrisoft pad once. Patients found the treatment very acceptable with minimal pain reported in 95% of cases. The authors noted that giving patients the chance to touch the monofilament fibre pad helped dispel anxiety about the procedure. The reported time to debridement was 2–4 minutes for 10 patients, 5–7 minutes for 5 patients and more than 7 minutes for 5 patients. The efficacy of the Debrisoft pad and the resulting skin condition were rated by the clinician who used it. It is not clear how many clinicians were involved in the ratings. The skin condition after the Debrisoft pad compared with a previous hyperkeratosis method was rated for 8 patients and was ‘much better’ for

6 patients, ‘good’ for 1 patient and ‘very good’ for 1 patient. The debridement performance compared with a previous method was rated for 16 patients by the clinician and was ‘much better’ for 8 patients, ‘good’ for 5 and ‘very good’ for 3.

Pietrolettti et al. (2012)

Pietroletti et al. (2012) assessed the efficacy of the Debrisoft pad in a case series of 27 patients. The data were retrospectively compared with a group of 25 patients who had used an autolytic debridement method of either hydrogel or enzymes (it was not clear in what percentage of patients they were used). The wound condition in both groups was wound bed coated with fibrin and slough or skin around the wound with keratosis and/or exudate. The maximum area of the wounds was 60 cm^2. Results showed that 92% of patients had their wound debrided after 1 application of the Debrisoft pad. This involved 1 visit, whereas 38.4% of patients had debrided wounds after 1 application of the autolytic or enzymatic debridement, which involved 2 visits. The author concluded that based on these results, autolytic debridement would need to be used 8-10 times to give the same results as the Debrisoft pad.

Wiser et al. (2012)

Wiser et al. (2012) assessed the Debrisoft pad in 15 patients who had venous leg ulcers or diabetic foot ulcers with a sloughy wound bed. The results of debridement with the Debrisoft pad were retrospectively compared with the results obtained with saline soaks used in a similar patient group. No quantitative results were reported. The Debrisoft pad was shown to deliver effective and fast debridement but it was reported to be somewhat rigid when used on toes or cavity wounds. Patient-reported pain during the procedure was less than for those treated with saline soaks, especially for the patients with arterial ulcers. The slight discomfort reported with the Debrisoft pad seemed to be better tolerated than debridement using saline soaks. Use of the product did not cause damage to the fragile skin surrounding the wound.

Multiple-patient case series (not considered by the External Assessment Centre to be relevant to the scope)

These studies were not considered by the External Assessment Centre to be directly relevant to the scope (mainly because they are not of comparative design), so the results have not been critically appraised. They are included here for completeness, because they provide information about clinical use of the Debrisoft pad and because the clinical evidence is otherwise limited in quantity. The External Assessment Centre's consideration of the relevance of the findings to the scope is in appendix 2 of their report.

Albas (2012)

Albas (2012) evaluated the Debrisoft pad in 10 patients with trauma wounds and bites. Debridement was considered effective in all patients because visible debris and slough were successfully removed. A mean of 2.1 sessions (SD±0.83; range: 1–3) was needed to obtain a clean wound bed. In all the sessions, the product remained intact. The mean time for the debridement sessions was 2.57 minutes (SD±0.04; range 2–4). Patients reported slight discomfort for a short duration (2 minutes on average) in 35% of cases and no discomfort in 65% of cases. No secondary infections were reported.

Dam (2012)

Dam (2012) evaluated the Debrisoft pad in 29 patients with chronic wounds. The percentage of wound bed covered by fibrin was evaluated before debridement. Wound pain was measured using a VAS and the need for a topical analgesic was determined. Debridement was performed once using the pad for 2–4 minutes. On average, fibrin was reduced by 30%. It was reported that thin and soft layers of fibrin were easier to remove than thick fibrin and necrotic tissue. The Debrisoft pad was not able to remove fibrin that firmly adhered to the wound bed. Eleven patients had debridement with a topical analgesic, 8 patients reported no change in pain level and 10 patients reported increased pain during debridement. Keratosis was present in 21 patients and this was removed by using the Debrisoft pad in all 21 patients.

Gray et al. (2011)

Gray et al. (2011) described a case series of 18 patients that evaluated which types of slough and necrotic tissue benefit the most from mechanical debridement with the Debrisoft pad. No local anaesthetic was used. Seventeen patients found the treatment acceptable, 1 was unable to tolerate the use of the pads. The following results were reported for 10 patients only, not all 18. Three types of wounds were assessed: hyperkeratotic; haematomas and soft slough. Two patients had the hyperkeratotic skin removed on their lower limb in less than 2 minutes. One patient's hyperkeratotic skin was not removed by the Debrisoft pad, but it was thought that this was because an emollient was applied before the treatment. Two patients had their wound beds cleared of any haematoma after it had been debrided for less than 5 minutes. One patient had most (but not specified how much) of their haematoma cleared from the wound bed. Two patients with pressure wounds on the heel had partially successful debridement (not clear how successful). Two patients presented with sloughy leg ulcers, which were fully debrided. The authors noted that where dry, black necrosis or slough had adhered to the wound bed, it was found that the Debrisoft pad did not remove the devitalised tissue.

Hammerle et al. (2011)

Hammerle et al. (2011) described a case series of 11 patients from 2 hospitals with chronic wounds. The clinical efficacy of debridement using the Debrisoft pad was assessed using a health professional's global assessment and a blind efficacy ranking by a surgeon. Pain during the procedure, as rated by the patients, as well as the safety and tolerability of the product and procedure were also assessed. There was no pre-debridement pain medication used. The Debrisoft pad was also compared against all existing types of non-surgical debridement and ranked from 1–5 with 1=very good and 5=very poor. Debrisoft was able to remove most of the coatings in exudating, seropurulent wounds with highly viscous yellow slough (indicating local infection) after only a single use. Most of the material removed by the debridement became

attached to the pad. In dry wounds with serocrusts between the new vital granulation and epithelial tissue, the Debrisoft pad was able to remove the crusts without affecting the new healthy tissue. In wounds with necrotic layers, hyperkeratotic debris and crusts of dried exudate, the Debrisoft pad removed the necrotic layers after a single use and revealed the skin of the lower extremity, showing an almost normal epidermis. For both types of wounds, the Debrisoft pad was able to debride without affecting the new healthy tissue and no healthy tissue was disturbed by the debridement process.

The global assessment showed that the use of the Debrisoft pad was easy, fast and efficient. Patients did not report any adverse symptoms, in particular pain, during the debridement process. A surgeon carried out a blind assessment of the quality of the Debrisoft pad by analysing pictures taken of 9 wounds before and after debridement. From the pictures taken before debridement, all wounds except 1were defined as having no need for surgical debridement. After the debridement procedure with the Debrisoft pad, he ranked the debridement of the wound formerly defined as needing surgical debridement as equally effective to surgery. He ranked the debridement results of all the other wounds in the best category.

Johnson (2012)

Johnson (2012) described a case series of 10 patients who were treated using the Debrisoft pad. The Debrisoft pad facilitated healing in all 10 patients. It was stated that pain scores remained low during debridement, with most patients scoring the same before, during and after the procedure. There were no details on what pain scale was used. It was not clear how many times the Debrisoft pad was used to debride each wound during the evaluation. The average time spent on debridement was 4 minutes (range 2-10). The time to complete healing was recorded. Venous leg ulcers in 2 patients healed within 2 weeks. A neuropathic foot ulcer in 1 patient healed within 3 weeks. A neuro-ischaemic ulcer in 1 patient healed within 6 weeks. Two patients with mixed aetiology healed within 6 weeks. One patient treated before a below knee

amputation healed with no complications but it is not stated how long it took. Two other wounds are ongoing and 1 was lost to follow-up.

Rieke (2012)

A poster by Rieke (2012) reported the results of an observational study of 25 patients in which the Debrisoft pad was used on diabetic foot ulcers. Patients had weekly visits for 4 weeks and then up to 16 weeks if needed. The Debrisoft pad was wetted with polyhexanide and used to debride the wound. Debridement was effective in all of the sessions and visible debris, slough, hyperkeratosis and scabs were successfully removed. In 8 cases additional surgical debridement was performed to remove the thick callus at the edges. The mean time for each debridement session was 2.59 minutes (±SD 0.06). Eighteen of the 25 ulcers healed within 16 weeks, 2 required surgery and 5 had not healed at the end of 16 weeks.

Skovgaard-Holm and Simonsens (2012)

Skovgaard-Holm and Simonsens (2012) described a study of 10 patients that was completed by homecare nurses. Debridement using the Debrisoft pad was performed 3 times a week over a 2-week period. A visual analogue score was used to assess any patient pain. The efficacy rate of the Debrisoft pad was found to depend on the thickness and adherence of the slough and the thickness of the hyperkeratotic layer. The debridement reduced the area of thin slough by an average of 24% in 3 patients. In 6 patients, an adherence layer of slough was reduced by an average of 7%. The Debrisoft pad reduced a thick soft layer of slough by 10% in 1 patient. Three patients did not feel increased pain during treatment, but 3 patients experienced severe pain (scores of 8, 7 and 6). The pain level decreased immediately after treatment to the level at the starting point. The nurses felt that 4 patients could have benefitted from local anaesthesia before treatment.

Stephen-Haynes and Callaghan (2012)

The sponsor submitted a multiple-patient case series in the form of a peer-reviewed paper and a poster, both by Stephen-Haynes and Callaghan,

(2012). Forty tissue viability nurses used the Debrisoft pad on a wound or hyperkeratosis to evaluate the effectiveness of the debridement and the condition of the wound bed. The assessment took 12 weeks. Debrisoft was used for debridement by 25 nurses (62.5%), for hyperkeratosis by 4 nurses (10%), and for both by 11 nurses (27.5%). Thirty-eight (95%) of the nurses said that patients' skin condition improved, whereas 2 (5%) said that it remained the same. Thirty-two of the nurses (80%) reported a positive impact of the wound bed using a clinical visual assessment. Thirty-four (85%) nurses reported that after debridement, there was clearer visibility of the wound bed and surrounding skin due to the removal of debris, slough or hyperkeratosis, so they were able to identify clearer wound management objectives. Six out of 40 (15%) said there was no improvement. The time taken to carry out debridement using Debrisoft was 0–2 minutes in 8 patients (20%); 3-5 minutes in 21 patients (52.5%) and 6–10 minutes in 9 patients (22.5%). The overall performance of Debrisoft was rated as 'very good' by 24 (60%) nurses, 'good' by 10 nurses (25%), 'fairly good' by 5 nurses (12.5%) and 'poor' by 1 nurse (2.5%).

Adverse events

The sponsor found no adverse event reports relating to the Debrisoft pad in a search of the Medicines and Healthcare products Regulatory Agency (MHRA) database.

4.2 Advice from experts and patient organisations

Expert adviser questionnaires were completed by 12 experts at the briefing note stage. No further questionnaires were completed during the evaluation stage. All 12 questionnaires are summarised in appendix B.

NICE's Public Involvement Programme received 1 response from 1 patient organisation about this technology. This was the Limbless Association and the questionnaire is summarised in appendix C.

4.3 Summary of economic evidence

The sponsor conducted a search for published economic evaluations with an intervention of autolytic, larval or mechanical debridement and considered 16 studies relevant to the scope. The External Assessment Centre judged that 10 of these studies were relevant to the scope (see assessment report pages 35–38); 8 were cost studies and the results are summarised in table 8 (see assessment report page 39); 2 other papers (Gilead et al. 2012; Milne et al. 2010) reported information on resource use to debride wounds.

None of the published studies contain cost information relating to the Debrisoft pad. The Soares (2009) study, which reported results from the VenUS II trial, was used to provide clinical-effectiveness information for the comparators in the cost analysis. The VenUS II trial was a UK-based randomised controlled trial funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme, which compared the effectiveness and cost-effectiveness of bagged larvae, loose larvae and hydrogel in patients with venous or mixed venous and arterial leg ulcers. The External Assessment Centre considered it to be a well-conducted study and noted that resource outcomes were prospectively collected.

Sponsor's de novo analysis

The sponsor submitted a de novo cost analysis that estimated the costs and resource-consequences of using the Debrisoft pad in a community setting compared against hydrogel, gauze and larvae. A community setting was defined as patients treated by a district nurse at home (including residential or nursing home), or in a community-based clinic.

The patient groups were adults and children needing debridement of an acute or chronic wound. A single cost analysis was provided in the sponsor's submission to account for all debridement; no distinction was made between adults and children, or between acute and chronic wounds. Because the clinical evidence used in the cost analysis was from the debridement of chronic wounds in adult populations the External Assessment Centre

considered the cost analysis to reflect the debridement of chronic wounds in adults.

In the cost analysis the sponsor considered biosurgical debridement as a comparator in addition to the use of hydrogel or gauze as specified in the scope. Biosurgical debridement involves the use of either bagged or loose larvae. The sponsor stated that this was an appropriate comparator for the Debrisoft pad for sloughy wounds, because larvae are used in the UK by nurses in the community. Expert advice to the External Assessment Centre was that bagged larvae are used in clinical practice in the UK, therefore it considered larvae an appropriate comparator for cost modelling.

Model structure

The cost analysis was provided as a cost model using Microsoft Excel. Separate analyses were conducted for debridement applications in the home and in the community-based clinic setting. The same comparators were used for both settings.

The clinical pathway included in the analysis involved an assessment of the skin and wound by a district nurse, followed by the ordering of the debridement agent if not available. Once available, the wound was debrided using the debridement agent by a district nurse. The wound was then reassessed at the next visit. Further applications could be done, if required, until debridement was judged to be complete. The External Assessment Centre considered this general illustration of the pathway of care to be appropriate.

The time horizon of the analysis was the time to complete debridement of the wound. The External Assessment Centre considered this to be appropriate if only concerned with debridement, but noted that time to wound healing would have been preferred as a more appropriate time horizon to judge the costs and resource-consequences of the products. The Centre stated that this

would have been a more meaningful outcome for patients and would take into account any multiple debridements needed.

Clinical parameters and variables

Clinical effectiveness information for each product was used to inform the 'number of applications to complete debridement' parameter (see table 3). The effectiveness estimate for the Debrisoft pad was derived from the Bahr et al. (2011) study. Data from the VenUS II trial (Soares et al. 2009) was used to represent the effectiveness of larvae and hydrogel. The effectiveness of gauze was based on the sponsor's assumptions, based on clinical opinion. The External Assessment Centre did not comment on whether this was appropriate.

The cost analysis assumed a 'stopping rule' for the Debrisoft pad. If a wound was not completely debrided after a maximum of 3 applications, patients were switched to hydrogel. Switching to alternative debridement products was not considered for the 3 comparators. This assumption reflected the design of the Bahr et al. (2011) study, which limited the number of applications of the Debrisoft pad to 3.

Other assumptions relating to parameters in the sponsor's cost analysis included: all treatments were provided by a district nurse; each visit took 15 minutes; the number of nurse visits per application depended on the product and its availability; no adverse events were considered. Full details of these assumptions are described on page 43 of the assessment report.

The sponsor estimated all the clinical model parameters and inputs based on published literature and the clinical opinion of 4 experienced tissue viability nurses with knowledge of using the Debrisoft pad and other methods of debridement used in a community setting in the NHS. A summary of the key parameters, the value and source is shown in table 3. The External Assessment Centre expressed concerns about a number of parameters (see

pages 50–52 of the assessment report) and presented revised base-case results (see table 5) and sensitivity analysis.

Costs and benefits

Costs were modelled from an NHS and personal social services perspective. The costs of all the debridement products were obtained from the 'British national formulary' (BNF) 2013. A median cost was used in the sponsor's analysis if more than 1 product was listed. The unit costs of larvae were not listed in the BNF; the cost was obtained directly from a supplier. The External Assessment Centre checked the costs used and agreed they were correct.

The costs used in the sponsor's model are detailed in tables C5, C6 and C7 of the sponsor's submission, pages 121–128. Key costs and parameters used in the analysis are presented in table 3:

Table 3 Key parameters in sponsor's base-case model (adapted from section 9.1.6 and tables C5, C6 and C7 in the sponsor's submission). All costs are excluding VAT.

Variable		Value	Source
Number of applications to complete debridement	Debrisoft	3.0 (probability Debrisoft will 77% of patients)	Bahr S (2011)
	Hydrogel	9.2	VenUS II trial
	Saline and gauze	12.0	Sponsor estimate
	Larvae	1.45	VenUS II trial
The cost per application (1 debridement product for a wound size of 10×10 cm or less)	Debrisoft	£6.19	British national formulary
	Hydrogel	£2.03	
	Saline and gauze	£0.39	
	Larvae	£295.00 (bagged) £175.00 (loose)	Manufacturer (Biomonde) list price
The number of nurse contacts (visits) per application	Debrisoft (clinic)	1st application=1 visit Subsequent=1 visit	Sponsor estimate based on clinical opinion
	Debrisoft (home)	1st application=2 visits Subsequent=1visit	
	Hydrogel (clinic)	1st application=2 visits Subsequent=1 visit.	
	Hydrogel (home)	1st application=3 visits Subsequent=1 visit	

Variable		Value	Source
	Saline and gauze (clinic and home)	1st application=2 visits Subsequent=1	
	Larvae (clinical and home)	1st application=3 Subsequent=2	
Total number of nurse visits required for complete debridement	Debrisoft (home)	4	Sponsor estimate based on clinical opinion
	Debrisoft (clinic)	3	
	Hydrogel (home)	11.2	
	Hydrogel (clinic)	10.2	
	Gauze	13	
	Larvae	3.9	
Cost per nurse contact (assuming a 15 minute appointment)	Clinic visit	£12.75	Personal and Social Services Research Unit Costs of Health and Social Care
	Home visit: (includes an additional cost for travel time)	£24.25	
Secondary (cover) dressings when needed	Absorbent dressing pad	£0.17 (for 1)	British national formulary
	Dressing pack	£0.60 (for 1)	
	semi-permeable adhesive film	£1.02 (for 1)	

Sensitivity analysis

The sponsor's submission explored the uncertainty around the model parameters and the effect this had on the incremental cost of the Debrisoft pad using deterministic sensitivity analysis. Because there was no consistent information about the likely variation in mean values, qne-way sensitivity analysis was performed on model parameters and unit costs based on an increase and decrease of 20%. Two-way scenario analysis was conducted varying the probability that the Debrisoft pad will debride after 3 applications and varying the number of nurse visits associated with hydrogel in a clinic setting.

Results

Base-case analysis results

Results from the sponsor's base-case analysis are presented in tables 14 and 15 in the assessment report on page 56. The External Assessment Centre

noted an error in the implementation of the switching after 3 Debrisoft applications, which slightly increased the cost of the Debrisoft pad (details on page 58–59 of the assessment report). The corrected base-case analysis results are shown in table 4.

Table 4 Base-case analysis results (corrected by the External Assessment Centre)

	Clinic visits				Home visits			
Intervention	Debrisoft	Hydrogel	Gauze	Larvae	Debrisoft	Hydrogel	Gauze	Larvae
Mean cost per patient (£)	97	165	180	306	189	308	330	351
Debrisoft incremental cost (£)		−68	−84	−210		−120	−141	−162

Sensitivity analysis results

The External Assessment Centre identified some errors in the implementation of the sponsor's model, which also affected the results of the sensitivity analysis: the cost of the Debrisoft pad in the proportion of patients who switched (details on page 59 of the assessment report); the number of nurse visits varied in line with the number of applications in sensitivity analyses (details on page 60 of the assessment report). The results of the corrected sensitivity analyses (tables 20 and 21 of the assessment report) showed that the Debrisoft pad remained cost saving for clinic and home visits in all scenarios tested. The key drivers of the cost savings associated with the Debrisoft pad were the fewer nurse visits needed compared with hydrogel and gauze and the cheaper product costs compared with larvae.

Subgroup analysis

The sponsor did not provide an analysis of the subgroups with open and closed wounds as specified in the scope. The External Assessment Centre noted the key consideration for this subgroup analysis would be whether the number of applications differed for open compared with closed wounds. They considered that the available clinical evidence could not provide reliable estimates of the treatment effect for subgroup analysis.

Additional cost analysis by the External Assessment Centre

Revised base-case cost analysis

The External Assessment Centre considered that some assumptions and estimates in the sponsor cost model were incorrect or unlikely (details are listed on pages 50–52 and 63–64 of the assessment report) and they modified them by:

- using bagged, rather than loose, larvae (£295 compared with £175 per pack)
- basing the unit cost of a district nurse on the hourly rate of a community nurse with the relevant qualifications: £58 in a clinic and £70 for a home visit
- changing the length of a district nurse visit from 15 to 22 minutes in the clinic setting and from 15 to 40 minutes in the home setting
- considering that film and absorbent dressings would not be needed at the first appointment if the debridement product had to be ordered
- considering the cheapest option for the cost of hydrogel, gauze and dressings rather than the median price as opted for by the sponsor

Results from the revised cost analysis are presented in table 22 (page 65 of the assessment report) which detailed the individual and cumulative impact of the External Assessment Centre revisions. The cumulative results (table 5) indicated a cost saving for the Debrisoft pad of £99, £152 and £375 compared against hydrogel, gauze and larvae respectively, when used at a clinic. There was a cost saving for the Debrisoft pad of £211, £288 and £280 compared against hydrogel, gauze and larvae respectively, when used at home. These results showed that the Debrisoft pad was more cost saving in the revised External Assessment Centre's base case than in the sponsor's base-case. The External Assessment Centre noted that this was mainly due to the longer length of nurse visits and the higher cost of bagged larvae.

Table 5 Revised base-case analysis results

	Clinic visits				Home visits			
Intervention	Debrisoft	Hydrogel	Gauze	Larvae	Debrisoft	Hydrogel	Gauze	Larvae
Mean cost per patient (£)	139	238	291	514	333	544	621	613
Debrisoft incremental cost (£)		−99	−152	−375		−211	−288	−280

Revised sensitivity analysis

The External Assessment Centre re-ran the sponsor's sensitivity and scenario analyses using the revised costs analysis described above (tables 23 and 24 of the assessment report (pages 67and 68). Additional variations were included: duration of nurse visits and in the scenario analysis the number of nurse home visits needed to use hydrogel. The Debrisoft pad remained cost saving in all scenarios except:

- when compared with hydrogel and when the probability that the Debrisoft pad would debride the wound is 77% and when only 5 nurse visits are required for hydrogel in the home (additional cost £22)
- when compared with hydrogel and when the probability that the Debrisoft pad would debride the wound is 50% and when only 5 or 7 nurse visits are required for hydrogel in both the clinic and home settings (additional costs £26 [5 visits] and £3 [7 visits] for the clinic setting and £87 [5 visits] and £38 [7 visits] for the home setting).

The sponsor's analysis assumed that all patients would switch to hydrogel if the Debrisoft pad had not fully debrided the wound after 3 applications. The External Assessment Centre conducted additional exploratory analyses to assess the possible impact of switching to bagged larvae or to gauze if the Debrisoft pad did not completely debride the wound after 3 applications (see section 3.5, page 69 of the assessment report). These patients were then assumed to receive the same number of applications of gauze or larvae as for patients treated with them initially. Results are presented in tables 25 and 26 of the assessment report (pages 69 and 70). These results suggested that the

Debrisoft pad also remained cost saving when patients, after 3 unsuccessful applications, were switched to a more expensive comparator than hydrogel.

Threshold analysis

The External Assessment Centre conducted a threshold analysis to identify the number of Debrisoft pad applications needed to make it more expensive than hydrogel in 2 different scenarios:

- switching to hydrogel after a given number of Debrisoft pad applications (applying the stopping rule)
- applying the Debrisoft pad until the wound is completely debrided.

Results of these analyses are reported in tables 27and 28 in the assessment report on pages 70 and 71. Results from the first scenario showed that the Debrisoft pad is no longer cost saving in both the home and clinical settings if the wound is not completely debrided after 7 applications and the patient has to be switched to hydrogel. In the second scenario, when the Debrisoft pad alone is used, results showed it was no longer cost saving in the clinic setting if more than 9 applications are needed per patient and in the home setting if more than 10 applications are needed per patient.

5 Issues for consideration by Committee

Clinical evidence

Lack of comparative evidence

The clinical evidence for the Debrisoft pad is limited in both quantity and quality. There are no published randomised controlled trials and few of the available multiple-patient case series reported comparative information. Most studies report the efficacy of the Debrisoft pad, the pain and discomfort for the patient when debriding the wound, the time to debridement (not necessarily complete healing) and the number of debridements needed, but reporting of

the number, frequency and duration of healthcare professional visits for each patient was incomplete.

The External Assessment Centre considered that the lack of comparative outcomes and the limited time to healing evidence are significant limitations. Although it assessed some studies that included comparative statements or numerical results, the timing and exact nature of the comparator technology was, in many cases, unclear. The External Assessment Centre judged that the most convincing evidence was Bahr et al. (2010) which gave some results for debridement efficacy and patient acceptability of the Debrisoft pad compared with gauze, autolytic and sharp/surgical debridement.

The sponsor stated that the time horizon reflects the time necessary to complete debridement of the wound, not time to healing; therefore, it varies between comparators. The sponsor acknowledged the weakness in the evidence, but considered that a number of trends emerge about the use of the Debrisoft pad from the available evidence (sponsor's submission page 77–78) including: it has been used in a wide variety of chronic and acute wounds; it does not require the intervention of a specialist wound care practitioner; thin slough may be removed by the Debrisoft pad in a single application whereas tenacious slough may not; the Debrisoft pad appears to remove hyperkeratotic debris within 1 or 2 applications. Information on time to debride a wound ranged from 2 to a maximum of 20 minutes and the effect of the Debrisoft pad on patients' experience of pain during debridement appears contradictory. The sponsor considered that these trends require exploration in future controlled trials. However, it also noted that a strength of the evidence was the growing volume of clinical evaluations since the product was launched in 2011.

Lack of a standard care pathway

Community-based wound care is driven by many factors including the variation in wounds being treated, patient characteristics and the training and experience of healthcare professionals. The External Assessment Centre

noted that despite recent guidelines (the European Wound Management Association [EMWA] debridement consensus 2013), summarised in the assessment report table 1 page 10), there were no good data on current practice or adherence to the recommendations. It sought clinical expert advice, but was unable to conclude which methods of debridement are used most often in the community. The lack of an accepted standard clinical pathway increases the uncertainty in the evaluation.

Economic evidence

Focus on debridement efficiency

In their conclusions (assessment report page 73) the External Assessment Centre considered that the cost analysis showed that if the decision is only concerned with debridement efficiency, the Debrisoft pad may be cheaper overall compared with larvae, hydrogel and gauze. However, the cost analysis did not consider adverse events, hospital visits and only included a short time horizon relating to time to complete debridement. The External Assessment Centre also noted that results from the VenUS II trial, which evaluated larvae and hydrogel, indicated significant differences in time to debridement but no difference in time to healing.

Lack of comparative data

The External Assessment Centre agreed with the sponsor's comment that the lack of comparative evidence directly comparing gauze, hydrogel, larvae and the Debrisoft pad is a key weakness. It also considered that the lack of comparative results for the Debrisoft pad with any comparators makes an assessment of the resource implications difficult because it depends on the relative effectiveness and the number of applications needed for each product.

Relevance of a maximum of 3 applications of Debrisoft ('stopping rule') to clinical practice

The sponsor's cost analysis assumed a 'stopping rule' for the Debrisoft pad: if a wound was not completely debrided after a maximum of 3 applications, patients were switched to hydrogel. The External Assessment Centre explored the impact of switching to the other comparators and found that the Debrisoft pad was still cost saving. A threshold analysis conducted by the External Assessment Centre demonstrated that the Debrisoft pad became cost neutral if 7 applications were used before switching to hydrogel. It also found that if the Debrisoft pad was used with no switching, 9 or 10 applications were needed for complete debridement before it became cost neutral.

Clinical evidence from the Bahr et al. (2011) study showed that 77% of the wounds in 60 patients were completely debrided within 3 applications. Most of the other clinical evidence reported results for a variety of wounds only considered 1–3 applications of Debrisoft for complete debridement.

Robustness of cost analysis results

The Debrisoft pad was selected because it was considered that an improvement in clinical outcomes associated with its use for the debridement of acute and chronic wounds may contribute to overall cost savings compared with current practice. The cost savings were considered to have likely come from a reduction in the number, length and frequency of nurse visits. It would appear from the cost model that the key drivers of the cost savings associated with the Debrisoft pad were the fewer nurse visits needed compared with hydrogel and gauze and from the cheaper product costs compared with larvae. The sponsor had the model inputs validated by 4 clinical experts. However, the variation in practice and the lack of good quality comparative evidence means that assumptions and parameter values in the model have inherent uncertainty.

6 Ongoing research

Information on 1 ongoing randomised controlled trial (Clark and Young) was included in the sponsor's submission. This was described as a prospective, exploratory study to compare the debridement of sloughy venous leg ulcers using the Debrisoft pad against autolytic debridements. It is not clear when the results of this will be published because it has been delayed to allow more patients to be recruited.

The External Assessment Centre considered that a randomised controlled trial of the Debrisoft pad compared with current clinical practice would be useful. It suggested that outcomes could include wound infection, costs and quality of life. They also stated that an audit of current debridement practice would be helpful.

7 Authors

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NICE Medical Technologies Evaluation Programme

October 2013

Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment report:

- Meads C, Lovato E, Longworth L. Debrisoft monofilament debridement pad for the debridement of acute and chronic wounds. September, 2013

B Submissions from the following sponsors:

- Activa Healthcare Ltd.

C Related NICE guidance

- Diabetic foot: inpatient management of people with diabetic foot ulcers and infection. NICE clinical guideline 119 (2011).
- MIST Therapy system for the promotion of wound healing in chronic and acute wounds. NICE medical technologies guidance 5 (2011).
- MoorLDI2 Burns Imager a laser Doppler blood flow imager for the assessment of burn wounds, NICE medical technologies guidance 2 (2011).
- Negative pressure wound therapy for the open abdomen. NICE interventional procedure guidance 322 (2009).
- Prevention and treatment of surgical site infection. NICE clinical guideline 74 (2008).
- Pressure ulcers: The management of pressure ulcers in primary and secondary care. NICE clinical guideline 29 (2005).
- Type 2 diabetes: prevention and management of foot problems. NICE clinical guideline 10 (2004).

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Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

Ms Cathie Bree–Aslan
Tissue Viability Clinician and Head of Governance, Royal College of Nursing

Mr Steven John Boom
Vascular surgeon, Vascular Society of Great Britain and Ireland

Dr Louis Fligelstone
General and Vascular surgeon, Vascular Society of Great Britain and Ireland

Ms Sian Fumarola
Senior Clinical Nurse Specialist Tissue Viability, Tissue Viability Society

Ms Sylvie Hampton
Tissue Viability Nurse Consultant, Royal College of Nursing

Mr Jonathan Hossain
Expert Vascular Surgery Consultant, Vascular Society of Great Britain and Ireland

Ms Sue Johnson
Clinical Nurse Specialist, Vascular Society of Great Britain and Ireland

Dr Douglas Orr
Consultant Vascular Surgeon, Vascular Society of Great Britain and Ireland

Mr Duncan S W Stang
Consultant Podiatrist, Society of Chiropodists and Podiatrists (Feet for Life)

Mr Paul Tisi
Consultant Vascular Surgeon, Vascular Society of Great Britain and Ireland

Ms Kathryn Vowden

Nurse Consultant Wound Care, European Wound Management Association

Professor Peter Vowden

Consultant Vascular Surgeon and Professor of Wound Healing Research, Vascular Society of Great Britain and Ireland

- Expert advice was received from 11 people from 5 societies at the scope stage. The summary of these questionnaire is:
- Clinical Indication: The main clinical indication for the technology is for the removal of sloughy or dead tissue from wounds including burns, ulcers, trauma wounds, granulated wounds, haematomas and for treatment of hyperkeratotic skin requiring debridement. The product is also useful for removing accumulated cellular debris, emollients from the skin, preparing skin for amputation, stimulating cell activity in a static wound and hyperkeratosis.
- Comparators: There were differing opinions on the comparator. Three experts stated that there was no comparator for the product while the other experts considered a range of debriding techniques as suitable comparators including cleansing the wound with water and emollient, debridement with water or as an indirect comparison debridement with dressings or a scalpel. Surgical scrub brushes were also suggested as a comparator although not as gentle as Debrisoft monofilament debridement pad with local anaesthetic required. Larvae and wound dressings or autolytic debridement were also thought to be suitable comparators although both these techniques are time consuming. Surgical debridement could be a comparator but this must be carried out by a specialist and often requires a hospital or specialist clinic appointment.
- Possible benefits for patients: A majority (10/11) experts considered Debrisoft monofilament debridement pad to be a more rapid, more effective, less abrasive technique than current treatments with benefits such as reduction in wound slough and reduction in hyperkeratosis being measured. This enables accurate assessment of the wound and

surrounding skin, reducing clinical episodes and surgical operations. Other patient benefits include reduced need for topical steroid preparations, less malodour from the wound, reduced patient discomfort and a reduction in the risk of infection. The device is also safe to use in the community setting.

- Possible benefits for the healthcare system: The consensus of the experts was that this device could produce faster healing potentially increasing cost effectiveness with a reduction in required dressings, hospital days and surgical and other wound healing procedures. Little education is required for use of Debrisoft monofilament debridement pad by experts or non-experts and no additional equipment is required keeping costs low.
- Facilities, training and functioning: All experts considered minimal or no training would be required with Debrisoft monofilament debridement pad. The technology could be used at clinics by district nurses and could be introduced via the established Tissue Viability Nursing structure.
- Costs: The device was considered to be more cost effective than some techniques such as maggot larvae, Versajet and autolytic debriders although Debrisoft monofilament debridement pad could be higher in price than gauze although the longer term costs could be reduced. The technology is thought to be of minimal cost compared to the benefits of improved wound healing. Cost of the product could be minimal although its simplicity could result in overuse and additional cost for the NHS.
- General advice: Although Debrisoft monofilament debridement pad is indicated for use in the treatment of dry skin conditions one expert thought practitioners may be unsure when to use the device to provide greatest benefit to patients. Some clinicians may also perceive that the technology may cause trauma to wounds although the expert considered this to be an unfounded belief. All the experts agreed that NICE guidance on the technology would be extremely useful.

Appendix C: Comments from patient organisations

Advice and information was sought from patient and carer organisations. The following patient and carer organisations responded:

Limbless Association

- Possible benefits for patients: Debrisoft appears to remove all the flaky skin without much effort or pain and the device should be suitable for anyone who is experiencing this problem.
- Disadvantages for the patient: There may be an issue with spreading infection such as gangrene and this could make the patient's state worsen.
- Equalities issues: There would be no equality issues with Debrisoft.
- Usefulness of NICE guidance: If NICE did not produce guidance on Debrisoft it is unlikely to affect access to the technology.

The following patient organisations were contacted and no response was received.

- British Skin Foundation
- Burned Children's Club
- Changing Faces
- Children's Burn Trust (CBT)
- Counsel and Care
- Dan's Fund for Burns
- Diabetes Research & Wellness Foundation
- Diabetes UK
- Disability Rights UK
- Disabled Living Foundation
- Eczema Voice
- Ethnic Health Foundation
- Foot in Diabetes UK
- Insulin Dependent Diabetes Trust

- Let's Face It
- Lindsay Leg Club Foundation
- Lymphoedema support network
- Multiple Sclerosis Resource Centre
- Multiple Sclerosis Society
- Multiple Sclerosis Trust
- Muscular Dystrophy Campaign
- Psoriasis and Psoriatic Arthritis Alliance (PAPAA)
- Psoriasis Association
- Shine
- Skin Care Campaign
- Spinal Injuries Association
- Surya Foundation
- Talkeczema
    - The National Eczema Society

Appendix D: External Assessment Centre correspondence

National Institute for Health and Care Excellence

External Assessment Centre correspondence

Debrisoft

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission.

Submission Document Section/Sub-section number	**Question / Request** Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.	**Response** Attach additional documents provided in response as Appendices and reference in relevant cells below.	**Action / Impact / Other comments**
General	Email form Catherine Meads to 8 NICE clinical experts (26/06/2013): Your names have been forwarded to me by NICE Medical Technologies Evaluation Programme with regard to the evaluation of Debrisoft (MT192) that will be starting shortly (main timetable 23rd July to 19th September). So I would like to take the opportunity to introduce myself. Also, being a systematic reviewer with little recent clinical	Responses from: **1.** *Steven Boom (27/06):* As a clinician I agree with you that debridement is the removal of devitalised tissue, but suspect that the definition used by the manufacturers of Debrisoft also includes the removal of slough. Whilst infection/bacterial proliferation/biofilm do inhibit healing I am not certain that	General knowledge about debridement. No further action required

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	experience, I know very little about recent theories to do with wound debridement, which I understand is the main use of Debrisoft. So if anyone could explain why clinical staff are now removing the surface layer of wounds instead of leaving them alone, I would be very grateful. In particular I am after the evidence that shows that wound debridement results in quicker and better wound healing than no wound debridement. Very many thanks for your help	devitalised tissue per se is always detrimental. Healing can occur happily beneath a dry escar of devitalised skin as long as there is no infection beneath it. Sometimes it is better to leave it intact rather than remove it as it can provide an effective barrier to infection for some time. Unfortunately I do not have any published evidence to support this to hand! **2.** *Peter Vowden (27/06):* Debridement is defined as: Debridement is the removal of dead, non-viable/devitalised tissue, infected or foreign material from the wound bed and surrounding skin. This definition fits with both the role of the podiatrist where removal of callus is considered as debridement, the management of acute wounds where tissue contamination may be an issue and the concept of	

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		maintenance debridement put forward by Vincint Fallanga and others when considering wound bed preparation. Debrisoft as a product is not designed to deal with hard eschar and functions as an agent used for the managements of adherent slough/soft necrotic debris and accumulated fibrinous exudate. Why do we deride a wound? To allow full assessment of the extent of the wound, to remove a potential source of infection and to allow the more rapid promotion of healthy granulation tissue. The decision to debride should only be taken as part of the overall management strategy and is the first stage in the process of moist wound healing. Some wounds the aim is to mumify the wound area whilst in others the margins between healthy tissue and non-viable tissue have not been	

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		defined and in these cases deridement should be avoided or delayed. **3.** *Sylvie Hampton (27/06):* You would be most welcome to come to our Wound Healing Centre in Eastbourne to observe debridement in action should you wish. The most important thing is to remove devitalised tissue (which delays wound healing and is a focci for infection) and to remove biofilms (which recently have been shown to have a detrimental affect on healing). The word 'debridement' is misunderstood by different clinicians. It is the removal of devitalised tissue. Some clinicians view that as removal of all dead tissue, including slough and others see it as the removal of necrotic (black) tissue through sharp or surgical debridement. TVN Kath	

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		Vowden would be able to lead you on the rationale for debridement. **4.** *Jonathan Hossain (28/06/13):* I would agree with the view expressed by Peter Vowden. There is not always evidence for things at that are common sence and custom and practice.	
General	Visit to wound care centre Eastbourne hosted by S Hampton (NICE clinical expert)	Visit occurred (29/07/2013), Debrisoft and other wound debridement techniques observed	General knowledge about debridement and to see Debrisoft being used. No further action required
General	Email from Catherine Meads to 8 NICE clinical experts (13/08/2013) We are struggling to find several sorts of evidence: 1. A comparative evaluation of Debrisoft compared to the comparators listed in the NICE scope,	Response from: **1.** *Peter Vowden (13/08/13):* Not sure that there is any data available for the first two questions but this may be helpful for the third.	General knowledge about debridement. Papers sent had already been sent in sponsor's submission or had

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	specifically hydrogel or other autolytic dressing, or cleansing with gauze, preferably with numerical results such as time to wound healing 2. A good (relatively large) study of what is currently used in the community NHS services for wound debridement (if anything) without debrisoft being available. An audit would do. 3. A systematic review of RCTs of debridement compared to no debridement to demonstrate that debridement per se is a good thing. Do any of you have anything that might help with any of these? Also, I have been to see trained wound care specialists using debrisoft and they are using the hem of the pad as well as the fluffy bit. Is this normally done?	Journal article sent about large cohort study from USA showing more frequent debridement results in faster wound healing **2.** *Peter Vowden (14/08/13):* From my clinical experience in hospital Debrisoft will be less painful than larvae or cleaning with gauze, is likely to be neutral or more effective in reducing healing time as debridement is likely to be more effective and will reduce or be neutral in wound infection. The enclosed paper may be helpful. It is a review but does point to some areas of community debridement research. "Community debridement" paper sent. **3.** *Sylvie Hampton (14/08/13):* There are no side effects that I know of and pain is less with this product	been found previously. No further action required

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		than others that are commonly used. We use a spatula to scrape the wound and canot always undertake it if the wound is painful. Therefore, Debrisoft causes less pain. I would also be happy to look at debridement generally. There is an excellent article written in America about Debridement that may be helpful. I will ask if I can pass that on to NICE **4.** *Sue Johnson (15/08/13):* I do not believe there has been a comparative evaluation of Debrisoft compared to other debriders. I also do not know of any up to date large studies with regard to debriding agents. With regard to the practicalities re the use of the debrisoft I do not personally use the edge of the dressing for debriding as it is only the monofilament fibres	

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		that are suggested for debridement of wounds. It may be that staff are using the edge of the dressing to remove hyperkeratotic skin from intact skin. With regard to pain I have found that in all patients there has been a reduction in pain plus the actual procedure of debridement is relatively pain free especially compared to cleansing with guaze. The publication I am sending you(see email you sent dated today) will also outline my findings re infection and healing rates. Publications related to side effects sent 5. *Jonathan Hossain (16/08/13):* This is all my vascular nurse could find. There is a UK consensus statement, also a debrisoft lit review, Peter Vodwen is an author	

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		and is on our group: four documents sent **6.** *Sylvie Hampton (21/08/13):* Please find attached some useful articles on debridement. The most important being that of Jim Wilcox who undertook and enormous study on the benefits of debridement across America of 312,744 wounds where debridement was undertaken two weekly. The outcome clearly demonstrated that wounds debrided every two weeks healed almost twice as quickly as those with less debridement. This paper was accepted for publication in Journal of the American Medical Association (JAMA) and is the first paper written by a nurse to be accepted in that journal. Therefore, it is a very credible piece of work. The work was undertaken in the	

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		Wound Care Centres by doctors. Therefore, we cannot ask District or Practice Nurses to undertake the same procedure without a great deal of education and competency training. The simplest method, in order to achieve similar results, is one that does not involve curettes. This gives Debrisoft an important future if similar results can be shown using that product. Therefore, would it not be an idea to test Debrisoft against standard treatment in whichever area is being used for the study. Ie. If District Nurses are using gauze, then that is standard treatment. If a specialist unit uses curettes to debride, that would be standard treatment. It would certainly throw up some very interesting results.	

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	Email from Catherine Meads to Jeanette Muldoon (13/08/2013): Comparative clinical evidence; Recommended Debrisoft practice	Email from Jeanette Muldoon (Sponsor) to Catherine Meads (13/08/2013): Additional poster and Manufacturer's instruction sent	Poster treated as additional information of part of sponsor's submission. No further action required
	Email from Catherine Meads to Jeanette Muldoon (14/08/2013): Email addresses for some poster authors	Email from Pierina Andersoon and Clare Morris (Sponsor) to Catherine Meads (14/08/2013): Email addresses sent	Emails sent to poster authors requesting further information on their studies (see next entry).
	Email from Catherine Meads to Poster authors (15/08/2013): I am conducting an evaluation of Debrisoft on behalf of the UK National Institute for Health and Care Excellence. Your poster was submitted as	Response from: 1. *Anneke Andriessen* (15/08/2013): Please find enclosed the preliminary report on the case	Additional information referred to in clinical evidence sections. No additional action

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	part of this project (Evaluation of a new polyester monofilament debridement pad* from both patients and homecare nurses point of view). However the poster has few details about the patients you evaluated so I was wondering whether you might have written up the project more completely, for example for an internal audit or a dissertation? If you have any further details about this project I would be very grateful if you could send them to me	series. The section on discussion is not yet finalised and there is still more data to come. The person involved in this is on holyday until the end of September. The case series included 60 patients who together underwent 120 debridement procedures. From our clinical experience we noted that the debridement product is useful for this patient category. Their treated takes place mainly in the community where skilled nurses or physicians are not always available to perform the procedures. Important is to note that all the included patients received compression with rigid bandages and skin care using moisturizers, as is standard procedure for these patients in The Netherlands. This also supported an improvement of	required

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		their skin condition. Before the debridement product was available the clinicians used tweezers to remove debris and scales. The procedure took them on average 28 minutes per session. In the Netherlands we do not soak oedematous legs (as is done in the UK) because of risk of infection and maceration. Because of the time investment required in practice debridement of the skin was often omitted, resulting in delayed healing. 2. *Sewell David (20/08/13):* Unfortunately I do not have much in the way of information as I passed the details straight to Activa for use in the poster. I have enclosed the information I recorded at the time. 3. *Helen Skovgaard-Holm (24/08/13):* I am sorry for this late answer !	

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		Thank You very much for Your mail an interest for our poster and work with the debridement pad. I am very pleased, that our evaluation has interest for You and may be other wound specialists. We and most of our patients "love" Debrisoft because of the effectiveness of debridement - especially used for the infected wounds to provide using antibiotics! We must provide MRSA! We made an abstract in english too, I will attach it to this mail as a file. The project was only written in danish and we published an article about it too in the danish wound journal called "Sår" (=wounds). I am not sure, that You want these works in danish? I am quite busy these days, but I would like to translate the article and the description of the project for You - perhaps next week? It takes some	

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		time for me, I am 54 years old and it was decades since I went to school and learned english :) 4. *Wilja Yvonne Dam Eskildsen (29/08/13):* All I have in english is this Abstract for EWMA Lohmann & Rauscher Satellite Symposium, May, 2013, Copenhagen. This abstract was presented by Karsten Fogh, MD, DMSci, Department of Dermatology, Aarhus University Hospital, Denmark. I hope this will be enough for you. 5. *Rieke Francisca (14/09/2013):* We stopped the study due to organisational reasons. I am no longer involved with this project and further data are not available through our group.	
	Submission memory stick included more references than referred to in submission	Memory stick received	Assessed additional references

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General	Email from Catherine Meads to 8 clinical advisors 22/08/2013 1. What might be the reason behind the choice of using a different type of second dressing ('cover dressing') after having used hydrogel (film) compared to using 'secondary dressing' when using gauze, debrisoft and larvae? 2. Why would an evaluation only use a surrogate outcome namely debridement, when clinically speaking we would have thought that wound healing would be much more useful? For example, Wilcox et al JAMA Dermatol 2013 on a cohort study of 312,744 wounds reported wound healing as the main outcome measure and in the VENUS1 trial (Soares BMJ 2009), they used ulcer-free days and time to healing. Do you agree? 3. Why would it be assumed that if Debrisoft does not completely debride the wound after 3 applications only, the patient will be	Email from Sue Johnson (NICE clinical expert) to Catherine Meads 22/08/2013 1. Hydrogel dressings are not film dressings. They consist of starch and water and require a secondary dressing which is usually a film dressing when debriding a dry wound or a foam dressing if the wound is wet(exudating). Debrisoft is not a dressing it is a mechanical debridement tool therefore an appropriate dressing should be placed on the wound after this procedure has been done. This can be a one piece or two piece dressing. Guaze is a debriding tool and therefore after it has been used an appropriate dressing should be applied. With larvae a retention dressing is required to keep the larvae in contact with the wound and an absorptive dressing is	Answers informed critical appraisal of cost model. No additional action required

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	switched to hydrogel dressing and will then incur the total cost of hydrogel debridement as well? Whereas for hydrogel the model describes trying for 9.2 applications then assumes the wound is completely debrided and doesn't switch. 4. Would you switch to larvae or gauze if debrisoft doesn't work? If not, what would you switch to? 5. With regard to the number of clinic and home visits - in the clinic, they have assumed that debrisoft will be available in the clinic so 1 visit only is required, whereas for gauze, they have assumed that the first application will require 2 visits. Is this reasonable? Its just that we would have expected any clinic to have gauze in the cupboard. They may well have a hydrogel dressing in the cupboard as according to the BNF, each dressing costs £1.50-2.00. Is this the case in practice? Similarly, for home visits, I would have expected a district nurse to have gauze in his/her bag. Similarly, why	required to handle the increased exudate. 2. We are looking at a particular event within the wound healing continuum I.e debridement which is only required to ensure a clean granulating wound bed. Once this is achieved further debridement is not required therefore to put full healing, and by this I assume you mean complete epithelialisation, is not an acceptable outcome for this evaluation. 3. I think both assumptions are wrong as it is dependent on the type of wound, position of wound and reason for debriding the wound. I have one patient who attends regularly and I debride regularly with Debrisoft because he has a longstanding chronic wound which I am convinced develops a biofilm. I would not use any of the other	

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	3 visits for hydrogel home application and larvae application, as the first visit would be to assess then the next visit would be to apply the dressing or the larvae? Would you need three visits? 6. Are loose larvae used in the community in the UK rather than bagged? 7. The model has used 15 minutes as duration of nurse time for each visit? Is this reasonable? Would you have the same duration for each intervention, because in Bahr et al Journal of Wound Care 2010 it gives estimates of debridement time of 2.5 for debrisoft, 7 for hydrogel and 5 for gauze. So one would expect a different nurse time for each type of debridement. Also the duration of visits from the Venus 1 trial (Soares et BMJ 2009) gives 22mins for clinic visit and 40 for home visits? Is this reasonable in practice? 8. Would a standard community nurse use gauze for debriding a wound or just for cleaning it? What would be the difference	debriding agents on this type of wound but do see a difference using Debrisoft. Most anecdotal evidence would suggest to debride a hard eschar would take 10 +days with a hydrogel but only 2-3 applications of the Debrisoft whereas a sloughy (rehydrated necrotic tissue) would take 3-5 days with a hydrogel but only 1 application with Debrisoft. 4. Difficult to say what you would swap to as that is totally dependent on your wound assessment but I personally would never use guaze. 5. Not sure what you want here. On our clinic we keep a large variety of dressings so always have debrisoft and hydrogels etc available. As previously stated I would not use guaze to debride a wound. District Nurses do not always carry supplies with them but do have access to the	

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	between the two?	main staples of wound care i.e. dressing packs, hydrogels, foams, films, hydrocolloids and alginates. If specific dressings are required these will need to be prescribed and delivered and this is dependent on whether they are in stock at the chemist. With regard to larvae this also needs to be prescribed. 6. I believe the bagged larvae are the larvae of choice in the UK. 7. I believe 15 mins is the average time but believe your second and third figure are more accurate. 8. District nurses(and in fact most nurses) use quaze to cleanse a wound, they would never use it to debride a wound. Guaze is still used in the States(USA) though not as much now to debride a wound but this is in the form of applying wet guaze to a wound allowing it to dry and then ripping it off taking the	

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		non viable tissue with it. A barbaric practice. *Email from Peter Vowden to Catherine Meads 08/09/2013* 1. The choice of dressing is often defined by other factors than debridement alone. Dressing selection will also be defined by exudate level, possible infection, odour and pain as well as the condition of the surrounding skin. 2. Wound debridement aims to provide a wound bed suitable for healing. At this stage actual healing may be achieved in a number of ways - plastic surgical procedure (flap, or graft), the use of a biological skin substitute or by secondary healing. In addition healing may not be an option for all wounds and debridement in these patients is used to reduce odour or infective load.	

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		Given this then both are necessary end points 3. Debrisoft is used as an addition to autolytic debridement in all cases - The act of covering a wound with any moist wound healing dressing encourages autolytic debridement 4. Decision on how to debride an individual wound is dependent upon the nature of the tissue to be removed. Hard eschar requires either sharp/surgical debridement or softening by hydration before other techniques including larval therapy can be successfully applied. Wound exudate levels (larvae will drown) or wound position will also define debridement technique (larvae may get crushed). As Debrisoft works most effectively on moist slough I would generally simply continue with autolytic debridement if Debrisoft was ineffective.	

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		5. Gauze debridement is usually used as part of "wet-to-dry" debridement. The gauze is applied moist to the wound and left in situ until the next dressing change when the dry gauze is removed along with any adherent slough or necrotic tissue. Gauze can also be used to cleanse (scrub) the wound but this is not general practice. For larvae the process has to be completed by removing and disposing of the larvae - assess and order/apply/remove, dispose of biological waste and reassess = 3 visits 6. Don't know - in general we try to use the bagged larvae 7. The use of Debrisoft adds about 2-3 minutes to the dressing time and therefore to the nursing visit time. Gauze when used to cleanse the wound will add more time (5 minutes). Both techniques would be combined with a dressing change. Hydrogel	

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		autolytic debridement will simply be the dressing time with no additional time. The dressing times quoted are reasonable. 8. Gauze is used - cleansing is a gentle washing of the wound, without rubbing to remove eschar and slough, and periwound area. When debriding more vigorous rubbing of the wound bed is used.	
General	Email from Catherine Meads to 8 NICE clinical advisors 28/08/2013 Is an average wound size of 10cm by 10cm reasonable? Presumably wounds come in many shapes and sizes, what are other common wound sizes? And how may larvae would be required to treat them per application? Are larvae obtained directly from the suppliers to the clinics? Is any form of prescription required? How does this process work?	Email from Peter Vowden to Catherine Meads 08/09/2013 Wounds can be of any size, the majority are small and under 10x10cm The enclosed file gives an indication of the recommended larvae to wound size for free range maggots. Bags are ordered as appropriate for the wound size Ordering process will vary across trusts. We order ward supplies through a special order through pharmacy but	Answers informed critical appraisal of cost model.

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	We have re-presented the information around the number of visits anticipated for each treatment in the table below. Please could you comment on the assumptions and if they seem reasonable? - It assumes that larvae must be ordered for use in both home or clinic, and that hydrogel must be first ordered for home use. - For gauze, it is assumed that this will be readily available, but that a return visit will be needed to assess treatment success. - A return visit to reassess the wound is not considered necessary for Debrisoft. Rather an assessment is made immediately after application as to whether the patient will require an additional application at a later date.	this is not by prescription. As far as I am aware the GP has to authorise an order. Process outlined in the chart seems OK. Remember that the goal is to achieve a healthy wound bed and maintain it. Debridement is rarely a one off event and even after successful debridement the process my need to be reapplied if further necrotic tissue develops.	

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<tr><th>Submission Document
Section/Sub-section number</th><th>Question / Request
Please indicate who was contacted. If an Expert Adviser, only include significant correspondence and include clinical area of expertise.</th><th>Response
Attach additional documents provided in response as Appendices and reference in relevant cells below.</th><th>Action / Impact / Other comments</th></tr>
<tr><td></td><td>Number of nurse visits per application
<table>
<tr><th>Treatment</th><th>Location</th><th>First application</th><th>Subsequent applications</th></tr>
<tr><td>Larvae</td><td>Home</td><td><u>3 visits</u>

1. Assess and order treatment
2. Apply treatment
3. Re-assess and reorder if needed</td><td><u>2 visits</u>

1. Apply treatment
2. Re-assess and reorder if needed</td></tr>
</table></td><td></td><td></td></tr>
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	Larvae	Clinic	**<u>3 visits</u>** 1. Assess and order treatment 2. Apply treatment 3. Re-assess and reorder if needed	**<u>2 visits</u>** 1. Apply treatment 2. Re-assess and reorder if needed		
	Hydrogel	Home	**<u>3 visits</u>** 1. Assess and order treatment	**<u>1 visit</u>** 1. Reassess		

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			2. Apply treatment 3. Re-assess and reorder if needed	and reapply		
	Hydrogel	Clinic	**2 visits** 1. Assess and apply treatment 3. Re-assess and reapply if needed	**1 visit** 1. Reassess and reapply		

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	Gauze	Home	**2 visits** 1. Assess and apply treatment 3. Re-assess and reapply if needed	**1 visit** 1. Reassess and reapply		
	Gauze	Clinic	**2 visits** 1. Assess and apply treatment 3. Re-assess and	**1 visit** 1. Reassess and reapply		

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			reapply if needed			
	Debrisoft	Home	**1 visit** 1. Assess and apply treatment. Re-assess debridement	**1 visit** 1. Reassess and reapply		
	Debrisoft	Clinic	**1 visit** 1. Assess and apply treatment. Re-assess	**1 visit** 1. Reassess and reapply		

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	debridement		
Economic analysis	Email from Catherine Meads to Dawn Ashby 22/08/2013 to request advice to several questions: 1. What is the reason behind the choice of using a different type of second dressing ('cover dressing') after you have used hydrogel (film) compared to using 'secondary dressing' when using gauze, debrisoft and larvae? 2. Why use the median and not the mean as the unit cost in the cost model? The two are close together so it doesn't look like a skewed distribution. 3. In tables C7(A) and C7(B) and economic model: the cost of debriding with Debrisoft should be calculated for 100% of patients not just 77% as all patients get debrisoft at first, and 77% are completely debrided after 3 treatment but 23% are not, but they still have all had debrisoft used on them?	Email from Dawn Ashby (Sponsor) to Catherine Meads 30/08/2013: 1. Presumably because the hydrogel is a dressing with a debridement action, whereas the other method are debridement products used then and there with either successful outcomes or not. If a successful outcome following gauze, Debrisoft or larvae a different dressing with other characteristics and effect would be used. Hydrogels and larvae both require secondary dressings to hold them in place for the number of days whilst treatment is taking place to debride the tissue. Hydrogels also dry out if left uncovered and this adds to the costs.	Conducted an analysis to correct cost model in MS

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	4. In table C11: there is a discrepancy in the results of the incremental cost for Debrisoft compared with Hydrogel and Larvae of £1 each (from Excel the cost is fine, but the report table costs do not add up) – eg £134 + £12 does not add to £147. 5. Why have you only used a surrogate outcome in the model namely debridement, when clinically speaking wound healing would be much more useful? For example, Wilcox et al JAMA Dermatol 2013 on a cohort study of 312,744 wounds reported wound healing as the main outcome measure and in the VENUS1 trial (Soares BMJ 2009), they used ulcer-free days and time to healing. 6. Why have you assumed that if Debrisoft does not completely debride the wound after 3 applications only, the patient will be switched to hydrogel dressing and will then incur the total cost of hydrogel debridement as well? Whereas for hydrogel you try for 9.2 applications then assume the wound is	2. The complete healing outcome would bring in all sorts of confounding variables and the comparison of the benefits between debriding alternatives would be I suspect lost in the impact of the variables to complete wound healing i.e. physiology of the patient, background disease, effect of arterial status etc. 3. Gauze seen as largely ineffective, but was an old paradigm debridement method of treatment, now seen as very painful and probably unacceptable to nurses. 4. Gauze requires 2 visits, one to apply and one to remove. Debrisoft can be used and assessed at one visit. Maggots take 1 visit to assess and order, then 2nd to apply and a 3rd to remove. 5. Was it a mistake that was based on using the cheaper version I	

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	completely debrided and don't switch. 7. Why not switch to larvae or gauze if debrisoft doesn't work? 8. On p116-7 you list the number of visits. In the clinic, why do you assume that debrisoft will be available in the clinic so 1 visit only is required, whereas for gauze, the first application will require 2 visits. I would have expected any clinic to have gauze in the cupboard. They may well have a hydrogel dressing in the cupboard as according to the BNF, each dressing costs £1.50-2.00. Similarly, for home visits, I would have expected a district nurse to have gauze in his/her bag. Similarly, why 3 visits for hydrogel home application and larvae application as the first visit would be to assess then the next visit would be to apply the dressing or the larvae? 9. Why have you gone for loose larvae rather than bagged as there is a considerable yuck factor for loose larvae. What evidence do you have that loose larvae are used in the	suspect? Healing is not always the end point; when using Debrisoft and any other method of debridement the outcome should be complete debridement that may lead to better healing outcomes in terms of reduced overall management time. 6 and 7. The type of debridement method depends on the type of tissue and there may be cases where very necrotic and firmly fixed tissue may need to be softened first with a hydrogel followed by rapid removal with Debrisoft. In this case although the hydrogel was useful initially the total debridement process with a hydrogel would have taken longer than initial hydrogel and Debrisoft. Hydrogels also have the disadvantage of creating extra fluid that may lead to maceration due to poor fluid handling. Gauze carried a risk of contamination	

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	community in the UK rather than bagged? 10. Why have you used 15 minutes as duration of nurse time for each visit? What is this based on? Why have you used the same duration for each intervention, because in Bahr et al Journal of Wound Care 2010 it gives estimates of debridement time of 2.5 for debrisoft, 7 for hydrogel and 5 for gauze. So one would expect a different nurse time for each type of debridement. Why do you not use the duration of visits from the Venus 1 trial (Soares et BMJ 2009) which gives 22mins for clinic visit and 40 for home visits and gives separate results for hydrogel and larvae?	when the gauze is passed from one side of the wound to the other. Debrisoft locks the bacteria within the fibres to prevent this from occurring. 9. (from Biomonde). 90% of larvae sold are Bio bags and 10% loose, free range. The following answers are from our external economic advisor :- A detailed response to each of NICE's questions are attached 'Answers to NICE questions'. The calculations of expected cost of Debrisoft debridement (Q3) has been reworked to show the analysis and all of the sensitivity analysis. This is now incorporated into the revised Excel cost model and a revised version of the submission is attached.	

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		We are still awaiting to hear from our International colleagues in respect of some of your questions which will be sent to you as soon as possible.	
	Email from Catherine Meads to Jeanette Muldoon 28/08/2013 to request advice to several questions: 1. The economic model includes the % of people whose wounds had completely debrided by 12 days (77%; n=44). This statistic is noted in the discussion section of the paper by Bahr et al, but not in the Results section. Please can you confirm whether this outcome was a primary outcome and whether it was pre-specified? How does it relate to the data reported in the Results – debridement efficacy section about the proportions of each class of wound? 2. Are the costs of posting and packaging included within the unit costs of larvae? 3. Is VAT included in any of the costs of any of	Email from Dawn Ashby (sponsor) to Catherine Meads 30/08/2013: 1. Awaiting response 2. Larvae costs do include post and packing, 3. VAT is not included in any of the costs. 4. See attached table 5. Sent	Answers informed critical appraisal of cost model. No further action required

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	the treatments? 4. Please can you provide baseline characteristics of patients included in the study by Bahr et al. Preferably including • Gender (% male) • Age (Mean, median, SD) • Area of wound (mean, median, SD, range) • Duration of wound. 5. Please can you supply the trial protocol for the ongoing study of Debrisoft referred to within the submission.		
	Email to Prof Lesley Curtis of PSSRU 30/8/13 Dear Prof Curtis I have a query regarding one of the figures in the latest version of the PSSRU Unit costs. It relates to the unit costs of a Community Nurse	Response from Prof Lesley Curtis 3/9/13 The £61 refers to the cost per hour of home visiting (with travel but without qualifications) and the £70 is the cost per hour with travel and qualifications.	Conducted an analysis to correct cost model in MS

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	(Section 10.1, p175). At the bottom of the table it states Unit costs available 2011/2012 (costs including qualifications given in brackets) £42 (£48) per hour; £61 (£70) per hour of home visiting (including travel); £51 (£58) per hour of patient-related work Please can you confirm that the £61 refers to the cost per hour, including travel, of a Community Nurse without qualifications and that the £70 refers to the cost per hour, including travel, of a Community Nurse with qualifications? Or whether the £61 refers to the cost per hour of a Community Nurse without travel included and that the £70 refers to the cost per hour of a Community Nurse with travel included?		
	Email from Catherine Meads to Dawn Ashby 04/09/2013 :	Email from Dawn Ashby (sponsor) to Catherine Meads 06/09/2013: Please find attached the paper that you	Paper referred to in report. No further action required

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	We notice in the systematic review of economic studies that there was one publication that was excluded because it was not in English. Please can you forward to us the reference to this paper? If you have the paper itself, that would be very useful.	requested. Also, in response to your email from August 28th question 1 the reply is: Bahr et al, the primary endpoint is debridement efficacy (at day 0 [session 1], at 4±1 days [session 2], and at 8±1 days [session 3]). Result section reported data related to proportion of patients achieving debridement until 8 days (i.e. after 3 sessions) which accounts for only 28% of patients (re-epithelialised patients: 21% and per-wound skin is clean, with less than <20% slough in the wound bed: 7%). However, discussion section reported complete debridement of 77% patients after 12 days which was not indicated as the study endpoint in the methodology section. The two parameters, “complete debridement” and “proportion of each class of	

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		wound" could not be correlated to difference in their endpoint.	
	From Louise Longworth: On behalf of the EAC looking at Debrisoft for the NICE review, I would like to clarify whether the study by Bahr et al (2011) contains the same patients as the study by Mustafi (2011) since the patients' characteristics are not reported in the latter. Could you please confirm whether the two studies are the same? Also, you kindly sent us the preliminary report on the case series. Could you please confirm whether the case series referred to is Bahr et al (2011), or Mustafi (2011) or A van den Wijngaard?	From sponsor: I can confirm that the Bahr study and the Mustafi reference are from the same patient population. The van den Winjingaard poster relates to a separate patient. As the following article may have been a translation by Anneke Andriessen of the work by Mustafi and Bahr it may well relate to patients within the Bahr study. If you need to have this confirmed I can contact Dr Martin Abel at L&R. Clinical efficacy of a monofilament fiber debridement product evaluated in patients with skin lesions, scales, rhagades and hyperkeratosis; case series; A Andriessen; 8/15/2013	

Appendix E: Sponsor's factual check of the assessment report and the External Assessment Centre's responses.

Debrisoft monofilament debridement pad for use in acute and chronic wounds

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
None of the studies mention that they were conducted in a community based setting Page 5	The studies included management in hospital and community settings	See references 1, 5, 8 that clearly indicate community settings in clinics and nursing homes. New and as yet un-submitted evidence is emerging to show patient care at home delivered by district nurses	We have change this statement to: "None of the comparative studies mention that they were conducted solely in a community based setting"

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
The effectiveness of gauze was based on assumptions Page 5	Although anecdotally gauze is used by some practitioners, no studies have been published to confirm this practice	This is not just an assumption by the sponsor. 3 studies cited in the EWMA debridement document focused on gauze to debride surgical wounds Ref 3	We have changed this statement to: "The number of applications of gauze to achieve debridement is based on assumptions"

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Wound healing rather than time to debridement would be a more meaningful measure Page 6	Debridement is now seen as a clinical goal as part of the wound management process.	This is in accordance with the new debridement guidelines that have been published (EWMA 2012) Ref.3	This is not a factual error since it is an opinion of the EAC

4 Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Most relevant studies are unpublished conference posters or testimonials Page 7	Conference posters, unpublished data and testimonials are included as this is a new therapy area and new technology in this field.	The lack of RCTs and advanced level evidence was discussed with NICE and we were reassured that posters and single case studies would be acceptable for new technology according to the new rules by NICE. E-mails sent on 3.6.2013 and 26.7.2013	There is not a factual error

5 Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
There is no conclusive evidence to demonstrate that debridement is more likely to	Effective debridement has been shown to be associated with reduced exudate, reduction in odour and the appearance of	Although there are no clinical studies to prove healing with effective debridement, it is	The EAC considers that “reduced exudate, reduction in odour and the appearance of granulation tissue in

result in wound healing Page 7	granulation tissue in the wound bed (Vowden and Vowden 2011) Debrisoft is effective in debriding wounds in preparation for wound healing	stated and well documented as good clinical practice The positioning of Debrisoft within wound management was always to demonstrate debridement to the point of granulation and an aid to assessment of the wound or skin, and not end point healing	the wound bed" is not wound healing

6 Description of factual inaccuracy	**Description of proposed amendment**	**Justification for amendment**	**EAC response**
Breakdown of total cost of hydrogel (clinic visit) on page 54. Total cost described as £165.68 (£165.25 visit cost + £18.68 application cost)	Total cost of hydrogel (clinic visit) in original model is £165.25 (£146.57 visit cost + £18.68 application cost).	The total cost number does not add up based on the individual cost components reported.	Thank you. We have corrected this statement.

7 Description of factual inaccuracy	**Description of proposed amendment**	**Justification for amendment**	**EAC response**
It is suggested in submission that debridement is carried by a multidisciplinary team, not	Debridement may be carried out by any member of the multidisciplinary team	Anecdotal and case study evidence shows debridement by lymphoedema specialists, doctors, podiatrists, patients and	The EAC is not aware of any factual inaccuracies. The statement in the EAC report is a direct quote from the

just nurses Page 12		nurses	manufacturer's submission.

8 Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
On page 42, the EAC notes that a more appropriate perspective for the economic model should have been time to wound healing rather than time to debridement.	The perspective of time to debridement was adopted due to the availability of data. Had time to wound healing data been available this perspective would have been adopted.	The model made best use of available data. There was very limited data around time to wound healing which would imply developing an economic model with less robust data than used currently.	This is not a factual error since it is an opinion of the EAC

9 Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
On page 42 and 46, the EAC state the model did not include a switching component to hydrogel, gauze, and larvae.	The model did not include a switching component for the alternatives to Debrisoft in order to provide a conservative estimate of the cost-savings. It was assumed in the model hydrogel, gauze, and larvae were effective in wound debridement. In any scenario where these methods were not fully effective would make the potential cost savings of Debrisoft greater.	The cost model used conservative assumptions where possible. The purpose of using conservative estimates was to provide evidence that even in ideal scenarios where other alternatives are always effective in debriding wounds – Debrisoft still generates costs savings.	This not a factual error.