

# The Juxta CURES adjustable compression system for treating venous leg ulcers

Medtech innovation briefing

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## Summary

The Juxta CURES system provides adjustable compression management of venous leg ulcers and is designed to be easier to use for both clinicians and patients than standard compression bandages. Small noncomparative studies suggest that using Juxta CURES is associated with a reduction in wound size, improved healing or improved quality of life. Juxta CURES costs £151.50 and each system is designed to last for 6 months.

<p><b>Product summary and likely place in therapy</b></p> <ul style="list-style-type: none"><li>• The Juxta CURES is an adjustable wrap-around compression system for use in patients with venous leg ulcers in whom compression therapy is otherwise indicated.</li><li>• It would be used as an alternative to standard compression bandages, with the same patient selection considerations and with minimal changes to the current care pathway.</li></ul>	<p><b>Effectiveness and safety</b></p> <ul style="list-style-type: none"><li>• Nine studies, comprising small published case reports, abstracts and poster presentations, were identified. Of these, 1 (Oates 2013) did not specify the number of included patients, and the other 8 involved 51 patients in total.</li><li>• All 9 studies reported reduction in wound size, improved healing or improved quality of life in patients using the Juxta CURES. None of the studies were comparative; it is therefore unclear if other compression systems would have achieved similar results.</li><li>• No safety concerns were raised in any study.</li></ul>
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Technical factors	Cost and resource use
<ul style="list-style-type: none"> <li>• Initial fitting of the Juxta CURES should be done by a trained clinician with experience in compression therapy.</li> <li>• The device is designed to be easier to apply than standard compression bandages and to be adjustable by a clinician, patient or carer. The level of pressure applied is measurable and adjustable due to the trademarked 'built-in pressure system'.</li> </ul>	<ul style="list-style-type: none"> <li>• A single Juxta CURES pack costs £151.50 excluding VAT.</li> <li>• The Juxta CURES is guaranteed for 6 months of daily use and can be prescribed using an FP10 prescription.</li> <li>• Harris (2013) (n=14) reported a cost saving after 12 weeks of Juxta CURES to replace compression bandaging. After 6 months of use there was a cost saving of £2141 per patient.</li> <li>• Bianchi et al. (2013) (n=17) reported that using the Juxta CURES instead of compression bandages would realise a cost saving of £4806 per patient over 6 months. This saving was attributed to a reduction in the use of dressings, bandages and clinician time.</li> <li>• Elson (2012) (n=17) reported savings of £282.82 per patient over 6 months, based on reduced use of dressings, compression bandages and associated nursing costs.</li> <li>• As with standard compression bandages, regular clinician-led appointments are required to monitor initial progress.</li> </ul>

## Introduction

Venous leg ulcers (VLUs) are the most common type of leg ulcer, accounting for over 90% of all leg ulcers. VLUs often develop after a minor injury to an area of the leg where persistently high blood pressure in the veins has already damaged the skin. Affecting an estimated 1 in 500 people in the UK, VLUs become more common with increasing age and approximately 1 in 50 people older than 80 years are estimated to have a VLU (NHS Choices, 2014). They are more common in people with varicose veins and in those with poor mobility, such as people with paralysis, osteoarthritis, leg

fractures, and those who are obese or have had recent leg operations such as a hip or knee replacement. About 200,000 people in the UK have an open leg ulcer at any time (Posnett and Franks 2008).

One study estimated that 50% of venous ulcers did not heal within 9 months, 20% were unhealed after 2 years and 8% were still open at 5 years (Douglas 1995). With good management most VLUs will heal within 3–4 months, but the rate of recurrence is high. Some VLUs do not heal for many years and a small number never heal. Chronic wounds, such as VLUs, are often painful and up to 65% of people with a leg ulcer have severe or continuous pain (Briggs 2012), which can be worsened by wound dressing changes. Chronic wounds can cause reduced mobility, sleep loss, and wound odour and exudate. These all have a highly adverse effect on quality of life, often leading to social isolation and reduced work productivity (Persoon et al. 2004; Vowden and Vowden 2009).

VLUs are a significant cost and resource issue for the NHS. Ashby (2014) estimated a mean annual cost of £1795.30 per patient with a VLU treated with compression bandages, and £1492.90 per patient treated with compression hosiery, including health care consultation costs.

## Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

### *About the technology*

#### CE marking

CircAid Medical Products was awarded a CE-mark for the Juxta CURES in September 2012 as a class I medical device. Under this CE-mark the Juxta CURES is described by the Universal Medical Device Nomenclature System (UMDNS) as 'bandages compression support'. The Juxta CURES device, liners and compression anklets are included within the certification. CircAid Medical Products was acquired in 2012 by medi UK, which currently holds the CE certification for the device.

## Description

The Juxta CURES is an adjustable, wrap-around compression system made of breathable inelastic fabric. It is designed to be applied over conventional wound dressings, for the treatment of VLUs as an alternative to compression bandaging. The Juxta CURES pack includes:

- 1 Juxta CURES device (body and spine)
- 2 comfort leg liners
- 2 comfort compression anklets
- 1 built-in pressure system (BPS) card
- 1 disposable paper measuring tape
- 6 Velcro stays
- 2 sets of instructions for use (1 for the clinician and 1 for the patient).

An instructional video is available online the [MediUK website](#).

The leg liner is fitted over the leg and any dressings on the VLU. The Juxta CURES device is made up of 2 fabric pieces: a 'body' and a 'spine'. The body is a large piece of fabric that wraps around the lower leg; it has measurements marked along the top and bottom edges showing different ankle and calf circumference measurements. The spine of the device is fitted to the body by lining it up with the correct ankle and calf measurements for each patient, allowing the Juxta CURES to be adapted to fit a wide range of leg sizes. The spine attaches to the body using Velcro, and additional separate Velcro stays can be used to improve adhesion. Once the spine is in the correct position, excess fabric from the body can be cut off.

Once the Juxta CURES has been initially adjusted to fit the patient it should be put on over the leg liner. The Juxta CURES should be loosely secured using the 4 attached Velcro-lined straps to ensure it is in the correct position before adjusting it to the correct pressure using the BPS card.

The pressure applied by the Juxta CURES is managed via 3 Velcro straps that can be tightened or loosened to achieve the pressure prescribed by the clinician. The pressure is determined using the 5-sided BPS card, each side of which has markings corresponding to a different range of ankle circumferences. For each range, marks on the card correspond to different pressure levels. These marks are aligned to parallel lines on the Velcro straps to measure and apply the prescribed pressure, of either 20, 30, 40 or 50 mmHg. The 3 Velcro straps are each tightened (or loosened) to

align the appropriate marks on the BPS card with the parallel lines on each strap and achieve the correct pressure. The BPS card can be used by the patient at home to ensure that the correct pressure is achieved whenever the Juxta CURES is applied, and throughout the day, to allow for any reduction in swelling or for improved comfort.

The comfort compression anklet is applied after the Juxta CURES has been fitted. It applies light pressure to the foot and ankle, to prevent and control oedema. Two anklets can be applied together if additional compression is needed.

The Juxta CURES is available in 3 lengths: short (28 cm), standard (33 cm) and long (38 cm) and will fit patients with an ankle circumference of up to 42 cm and maximum calf circumference of 64 cm. The length of the Juxta CURES is chosen depending on the patient's ankle to knee crease measurement. The comfort compression anklet is available in 2 sizes: standard and large. The Juxta CURES is guaranteed for 6 months, is machine washable and can be tumble dried on a cool setting. The comfort compression anklet is not covered by the warranty and will not be replaced unless defective.

It is important that all Velcro straps are securely applied to prevent the risk of falls. This is particularly important when patients are wearing Juxta CURES on both legs.

## Intended use

The Juxta CURES is a compression device intended to be used over primary dressings for the treatment of open VLU. The manufacturer's indications for use are: venous insufficiency, venous stasis ulcers, post-thrombotic syndrome and dependent oedema.

The manufacturer states that the Juxta CURES should not be used for people with the following conditions:

- severe peripheral arterial disease
- decompensated congestive heart failure
- septic phlebitis
- phlegmasia cerulea dolens
- decreased or absent sensation in the leg
- allergy to compression materials

- moderate peripheral arterial disease
- infection in the leg.

## Setting and intended user

After the initial fitting, the Juxta CURES can be used in any setting including in the community and at home, and it can be applied and adjusted by patients, carers or clinicians. The BPS guide card allows the user to maintain the prescribed pressure. Follow-up appointments with a clinician are needed to allow for any subsequent adjustments to ensure that the Juxta CURES fits correctly. Adjustments may be needed because of reduced swelling in the leg. If the reduction is significant, the spine of the device can be readjusted by the clinician until the swelling settles.

The clinician and patient instruction leaflets give advice on applying the device and day-to-day use and maintenance. Patients can carry on their usual activities while wearing the Juxta CURES, and can remove and reapply it as needed to change dressings and bathe. It is safe to be used day and night, and if the patient has discomfort while lying down they can reduce the pressure. As it allows users to wear everyday shoes, the Juxta CURES is safe to use while driving. The ability to adjust the device as swelling reduces ensures that the correct pressure is maintained between clinician visits.

The Juxta CURES is can be prescribed on an FP10 prescription and may be fitted and adjusted by a trained clinician.

The Scottish Intercollegiate Guideline Network (SIGN) guideline on the management of chronic venous leg ulcers specifies that compression therapy should only be applied by staff with appropriate training. It also recommends that specialist leg ulcer clinics are the best place for community treatment of venous leg ulcers. Assessment by a clinician with suitable training and experience will still be needed to ensure compression therapy is appropriate and to decide the correct level of compression.

## Current NHS options

The NICE clinical knowledge summary on [venous leg ulcers](#) advises uncomplicated ulcers should be treated by cleaning and dressing the ulcer, applying compression therapy and providing appropriate follow-up care and lifestyle advice. For patients with persistent VLU, specialist referral should be considered and compression therapy choices and lifestyle advice should be reviewed with the patient.

This advice states that wounds should be cleaned with warm tap water or saline. Dressings should be simple (not, for example, alginate dressings, hydrocolloids, hydrogels or foams), have low adherence to prevent damage to the wound bed and be acceptable to the patient. Current national guidelines suggest that there is insufficient evidence to endorse the use of any specific type of dressing (Royal College of Nursing [RCN] 2006, SIGN 2010), therefore the dressings used should be low cost. For patients who do not need frequent bandage changes, the choice of dressings should be determined by their ability to stay in place for up to a week.

The RCN recommendations (2006) advise that the most important treatment for uncomplicated venous ulcers is the application of high compression using a stocking or bandage. It recommends that multi-layer bandaging with adequate padding should be applied at the highest-tolerated compression, and that the bandaging should be capable of maintaining compression for at least 1 week. In patients with an ankle brachial pressure index of less than 0.8 and in those with diabetes, compression should be used only under specialist advice and close monitoring. Compression should be applied only by trained staff.

The following standards have been suggested for compression: mild (less than 20 mmHg), moderate (20–40 mmHg or less), strong (40–60 mmHg or more) and very strong (more than 60 mmHg). Pressures of 40 mmHg or more are generally recommended for the treatment of VLUs, although this may not be appropriate for some patients due to factors including arterial insufficiency, neuropathy or cardiac failure (Partsch 2008).

SIGN's guideline on the management of chronic VLUs advises that the following should be taken into account when considering which type of compression to use for VLUs:

- practitioner level of expertise
- frequency of application needed – this can be determined by several factors including levels of exudate, bandage slippage and swelling in the leg
- leg size and shape
- patient preference, lifestyle and likely concordance.

NICE is not aware of other devices available in the NHS that have a similar function to the Juxta CURES.

## *Costs and use of the technology*

The Juxta CURES is listed on the NHS Drug Tariff, February 2015 at a cost of £151.50 per pack (excluding VAT). Additional comfort leg liners are available at a cost of £13.19 for 2 and comfort compression anklets are available at a cost of £11.16 for 2.

Juxta CURES can also be purchased directly from the manufacturer at a cost of £181.80 including VAT.

The NICE clinical knowledge summary on [venous leg ulcers](#) advises that, for people who are immobile, 4-layer or 3-layer bandaging is more suitable, whereas in those who are mobile, 2-layer bandaging is more suitable. The Juxta CURES can be used for both mobile and immobile patients.

Illustrative examples of prices for conventional compression bandages and wadding, of which numerous alternatives are available, taken from the British National Formulary (December 2014), are listed below.

Sub-compression wadding bandage:

- Padding: 3.5 m unstretched 10 cm, £0.47 Flexi-Ban (Activa).
- Padding: 10 cm×3.5 cm unstretched, £0.37 Ortho-Band Plus (Steraid).

Multi-layer compression bandages, 2-layer systems:

- Multi-layer compression bandaging kit: 2-layer system (latex-free, foam bandage and cohesive compression bandage) 1 size, £8.08; Coban2 Lite (reduced compression) 1 size, £8.08. Coban2 (3M).
- Multi-layer compression bandaging kit: 2-layer system, size 0 (short), £6.55; 18–25 cm ankle circumference 8 cm, £7.32; 10 cm, £7.76; 12 cm, £9.78; 25–32 cm ankle circumference 8 cm, £7.96; 10 cm, £8.48; 12 cm, £10.69. K-Two (Urgo).

Multi-layer compression bandaging, 4-layer systems:

- Multi-layer compression bandaging kit: 4-layer system for ankle circumference up to 18 cm, £6.73; 18–25 cm, £6.44; 25–30 cm, £6.44; above 30 cm, £8.87; reduced compression 18 cm and above, £4.21. K-Four (Urgo).

- Multi-layer compression bandaging kit: 4-layer system for ankle circumference 18–25 cm, £7.46. System 4 (Mölnlycke).
- Using the Juxta CURES will also incur additional cost as a trained clinician needs to assess the patient to ensure that compression therapy is appropriate before the system is initially used.

### *Likely place in therapy*

It could be offered to most patients with VLUs, and may be particularly useful for patients who are unable or not willing to use traditional compression techniques. As it can be applied without specialist training it is suitable for GP prescribing, although a trained clinician will still need to assess the patient to ensure that compression therapy is appropriate.

### *Specialist commentator comments*

One specialist commentator noted that, although the outcomes from the studies of the Juxta CURES were favourable, the numbers of patients involved in these studies made the data unreliable. They added that, in the context of the overall number of patients with venous leg ulcers, larger trials are warranted. This commentator felt that, although there is currently a lack of conclusive evidence, the Juxta CURES shows potential for both patients and clinicians in view of the recognised challenges of applying traditional compression bandages.

One specialist commentator reflected that the Juxta CURES could easily fit into the current patient pathway. Another commentator noted that current research suggests consistent delivery of correct care is an important factor to promote healing of VLUs. They commented that compression bandages are often applied at a lower pressure than advised, and that this results in reduced healing rates. Use of the BPS ensures compression is applied at the correct level.

The same commentator remarked that the Juxta CURES may help to ensure that compression therapy starts sooner and is applied at the correct pressure, as patients don't have to wait for a leg ulcer clinic appointment and more nurses could be trained to use the Juxta CURES. As less nursing time is needed to apply the Juxta CURES compared to standard compression therapy, this may increase the capacity of GP surgeries to provide compression therapy.

Three specialist commentators noted the benefit to patients (or carers) of being able to apply their own compression therapy and felt that there was potential for reduced clinician input. One felt that this could lead to significant cost savings and another noted this was safer than patients applying their own standard compression bandaging systems. There may also be a benefit in involving patients in their own care, with a positive impact on compliance and clinical outcomes.

Two specialist commentators noted the differences in costs and cost savings between the published studies and felt it would not be possible to make an informed decision on the cost benefits based on the examples given. One commentator felt that GPs may be deterred from prescribing the device due to its relatively high initial cost compared to other compression systems.

## *Equality considerations*

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief, in the way we produce our guidance (these are protected characteristics under the Equality Act 2010).

Age and disability are protected characteristics under the Equality Act 2010. Factors that increase the risk of developing venous leg ulcers include reduced mobility; previous deep vein thrombosis; injury or surgery to the leg; obesity and increased age. Appropriate treatment of venous leg ulcers may reduce healing times, control associated symptoms and improve quality of life for those affected.

## **Evidence review**

### *Clinical and technical evidence*

#### **Regulatory bodies**

A search of the Medicines and Healthcare Products Regulatory Agency (MHRA) website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this equipment. No reports of adverse events were identified from searches of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

#### **Clinical evidence**

Thirty one studies were identified for this briefing, however 21 were excluded as they did not meet the inclusion criteria, while 1 study was excluded as it did not contain any quantitative data. Therefore 9 studies have been included in this briefing. Four of these are published case studies of

1–3 patients (Bianchi et al. 2013; Dowsett and Elson 2013; Lawrence 2014a; Nugent et al.2013). Two publications also report cost savings (Bianchi et al. 2013; Nugent et al.2013). Four of the studies were only available as poster presentations; the case report by Davies (2013) and the 3 case series by Elson (2012), Harris (2013) and Oates et al. (2013). Of these, Elson et al. (2012) also reported cost savings. Finally, 1 case series was available as an abstract only (Lurie et al. 2012). The details and results of these studies are reported in tables 1–9.

One study by Harris (2013) reported that 3 of the 14 patients in this study decided to change to an alternative compression bandaging system. Their reasons were cited as preference, management of lymphoedema, and a fall. It is unclear if these events were device related.

**Table 1 Summary of the Bianchi et al. (2013) case reports**

Study component	Description
Objectives/ hypotheses	To illustrate effective management using the Juxta CURES compression system.
Study design	Retrospective descriptive case reports on 3 patients.
Setting	Hospital, GP and community setting in the UK. Patients treated with the Juxta CURES 2012–13.
Inclusion/ exclusion criteria	Venous disease of the lower limb.
Primary outcomes	Not applicable
Statistical methods	Not applicable

<p>Participants</p>	<p>Case 1: a 42-year-old female with a 4-year history of leg ulcers. The patient was not compliant with compression therapy and preventative hosiery, resulting in frequent ulcer recurrence often resulting in hospitalisation due to cellulitis. The patient was clinically obese and had type 2 diabetes and epilepsy. Her job required her to stand for long periods with no facility to sit or elevate her leg. She had normal ABPI, with a wound measuring 7.5 cm × 5.5 cm completely covered in slough. She was reluctant to use compression bandages due to the negative impact on body image, inability to wear attractive shoes, uncontrolled exudate and bandage bulk and slippage.</p> <p>Case 2: a 48-year-old male with a 12-month history of non-healing VLU (size of wound not stated). This is likely to be the same patient as described by Nugent (2013; table 8).</p> <p>Case 3: a 65-year-old female with recurrent leg ulcers since her late 40s. She had worsening, extremely painful, continuous non-healing ulcers on both lower legs for the last 5 years. She had type 2 diabetes, hypertension and hyperthyroidism and needed a knee replacement. Allergy to cetearyl alcohol prevented use of numerous topical creams. Difficulties with compression therapy caused uncontrolled venous hypertension leading to lymphovenous disease.</p>
<p>Description</p>	<p>Case 1: The patient and practice nurses were trained in the use of the Juxta CURES.</p> <p>Case 2: The Juxta CURES was applied at a pressure of 40 mmHg.</p> <p>Case 3: The patient was admitted to hospital for 10 weeks of intensive wound management, including 4 weeks of intravenous antibiotics and multi-layer lymphoedema bandaging. Ulcers were dressed with 7, 15 cm × 15 cm Aquacel dressings every other day, with 9 bandages applied at each dressing change. Oramorph was taken prior to dressing changes as analgesia, but she was comfortable between dressing changes and her legs improved rapidly. The Juxta CURES was prescribed to allow self-management on holidays while providing continued effective compression.</p>

<p><b>Results</b></p>	<p>Case 1: Clinic appointments were reduced from alternate days to twice weekly. After 3 weeks the wound reduced in size to 5 cm × 3.5 cm and after a further 3 weeks was 3.5 cm × 1.2 cm with the wound bed showing 50% slough and 50% granulation. A further few weeks showed the wound had almost closed. The patient and practice nurse found the device easy to use, and compliance was no longer an issue.</p> <p>Case 2: The wound had decreased in size by 50% by the fifth week, and the wound area to the lateral and posterior aspects had healed. By week 10 there was further healing in wound size with 3 remaining wounds to the anterior aspect. The patient found the Juxta CURES very comfortable to wear and the ability to wear shoes was a bonus. The treatment regime also showed a significant cost saving.</p> <p>Case 3: The patient reported that she had stopped taking painkillers and had an improved quality of life. She could bathe, shower and dress her own legs. The patient reported that the Juxta CURES felt light to wear, unlike bandages which used to weigh her legs down; she was also able to wear her own shoes. The Juxta CURES was reported to be easy to apply and took 30 minutes to apply, whereas conventional bandages had taken 1 hour.</p>
<p><b>Conclusions</b></p>	<p>Clinical experience using the Juxta CURES on less demanding ulcers has shown accelerated healing rates due to consistent compression. This is facilitated by a degree of self-management from the patients.</p>
<p>Abbreviations: ABPI, ankle brachial pressure index; VLU, venous leg ulcer.</p>	

**Table 2 Summary of the Davies (2013) case report**

<p><b>Study component</b></p>	<p><b>Description</b></p>
<p>Objectives/ hypotheses</p>	<p>To evaluate the treatment of a painful leg ulcer with a novel compression device.</p>
<p>Study design</p>	<p>Retrospective descriptive case report.</p>
<p>Setting</p>	<p>Not stated. Patient treatment with the Juxta CURES commenced in 2013.</p>

Inclusion/exclusion criteria	Not applicable
Primary outcomes	Not applicable
Statistical methods	Not applicable
Participants	73-year-old male with a VLU on the left leg that had not healed in 18 months. Medical assessment and ABPI indicated the wound was suitable for compression bandaging therapy. Multi-layer compression started in September 2011 but discontinued in October 2012 at patient request due to pain and sleep disturbance. The patient had a pain score of 10 at night (0=no pain, 10=worst pain) and was taking strong opiate analgesia and antidepressants.
Description	The VLU was treated with the Juxta CURES, with pressure adjusted, if not tolerated, by the patient and could be removed at night when the pain was severe.
Results	<p>After 4 days the patient reported the device was comfortable and allowed him to sleep through the night. Oedema had reduced by 9 cm at the ankle and 6.5 cm at the calf. The wound appeared unchanged.</p> <p>After 14 days the patient stated the treatment had transformed his life. The patient reported minimal pain levels (score 1–2) and no longer required regular analgesia; antidepressants were also discontinued. Reduced pressure was maintained through the night. At 8-week follow-up, the wound had healed.</p>
Conclusions	This simple adjustable self-management compression device maintained the therapeutic levels of compression necessary day and night for the healing of venous leg ulcers thereby improving patient quality of life.
Abbreviations: ABPI, ankle brachial pressure index; VLU, venous leg ulcer.	

**Table 3 Summary of the Dowsett and Elson (2013) case reports**

Study component	Description
Objectives/hypotheses	To assess whether quality-of-life issues could be addressed by treatment with the Juxta CURES.

Study design	Retrospective descriptive case reports on 2 patients.
Setting	Patients treated with Juxta CURES in a UK community setting between 2010 and 2012.
Inclusion/exclusion criteria	Not applicable
Primary outcomes	Not applicable
Statistical methods	Not applicable
Participants	<p>Case 1: a 47-year-old male with a 10-year history of bilateral VLUs. A variety of compression systems had been used on his legs but he admitted non-compliance due to the impact on his employment caused by the need to take unpaid leave to attend clinic appointments. He was experiencing malodour, extreme pain and depression. When at home he spent his time lying on the bed elevating his legs as instructed by his nurse.</p> <p>Case 2: a 63-year-old woman with a 42-year history of VLUs. A variety of compression systems had been used and all of those required daily treatment due to bandage slippage or high exudate levels. Her 'inverted champagne bottle' shaped leg, with a large calf and a relatively small ankle circumference, proved complex to manage. The patient's quality of life was severely affected due to high levels of exudate and repeat episodes of cellulitis resulting in her becoming housebound. Her 30-year-old son left full-time employment to become her carer.</p>
Description	<p>Case 1: Patient applied the Juxta CURES, checked by the nurse at appropriate intervals.</p> <p>Case 2: The Juxta CURES initially applied to the right leg and then also to the left leg with dressings changed once or twice a week as needed.</p>

Results	<p>Case 1: After 8 months use of the Juxta CURES, the ulcer was completely healed. The patient's quality of life dramatically improved, his pain and depression disappeared and he resumed normal work.</p> <p>Case 2: The Juxta CURES was applied to the patient's right leg as this was the least severely affected. The patient was pleased to be able to wear non-orthotic shoes. Swelling reduced and there were signs of improvement to the wound, and the patient asked for a second device for her left leg. Both legs continued to heal. Nursing time was reduced from 90 minutes per week to 20 minutes per week. The patient's condition improved to the point where she no longer needed a carer and her son could plan a return to work.</p>
Conclusions	The Juxta CURES assisted in improving patient wellbeing while still maintaining therapeutic levels of compression.
Abbreviations: VLU, venous leg ulcer.	

**Table 4 Summary of the Elson (2012) case series**

Study component	Description
Objectives/hypotheses	To compare the costs of treating venous ulcers with compression bandages compared with the Juxta CURES.
Study design	A multicentre, prospective case series (17 patients).
Setting	UK Healthcare centres.
Inclusion/exclusion criteria	Not reported
Primary outcomes	Not reported
Statistical methods	Not applicable
Participants	17 patients, average length of time ulcer present = 7 years.

Description	<p>Each clinician recorded 6 months of data of standard compression therapy and 6 months of Juxta CURES use including:</p> <ul style="list-style-type: none"> <li>• number of nurse visits</li> <li>• patient quality of life</li> <li>• type and number of wound dressings used</li> <li>• compression bandaging type and number used.</li> </ul> <p>During 6 months of treatment with standard care before testing the new device, all ulcers remained static or deteriorated.</p> <p>Where the patient had not used the compression garment for 6 months an estimate was made. This data was used to calculate and compare the costs of the 2 treatment options.</p>
Results	<p>After 6 months of treatment with the Juxta CURES all patients showed improvement in the condition of their leg ulcers. Patients and clinicians all gave positive feedback. Other results are summarised in the 'published cost studies' section.</p>
Conclusions	<p>The Juxta CURES proved cost effective when compared to standard compression bandaging, with improved leg ulcer condition at significantly lower cost.</p>

**Table 5 Summary of the Harris (2013) case series**

Study component	Description
Objectives/hypotheses	<p>Using the Juxta CURES can eliminate issues associated with leg ulceration and provide the clinician with an easy alternative. It can improve quality of healthcare and reduce costs.</p>
Study design	<p>Retrospective descriptive case series of 14 non-consecutive patients.</p>
Setting	<p>Community setting – 7 patients seen in the leg ulcer clinic, 7 patients seen at home.</p>

Inclusion/exclusion criteria	Not reported
Primary outcomes	Not reported
Statistical methods	Not applicable
Participants	n=14 9 patients with venous leg ulcers, 5 patients with leg ulcers of mixed aetiology (one patient had ulcers on both legs). Duration of leg ulceration ranged from new onset to 2.5 years.
Description	A mix of new patient referrals and patients already having conventional compression therapy. All patients were offered the Juxta CURES with compression levels ranging from 20 mmHg to 40 mmHg as suited to their ABPI and clinical presentation.
Results	<p>All patients experienced improvements in their wounds and in skin integrity. The system was tolerated by 11 patients at the same or higher compression than previously used and 3 patients changed to alternative compression systems. Five patients' wounds progressed to healing in the 10-week study period, and 4 were able to self-manage, resulting in reduced nursing time. Three chose to keep using the Juxta CURES after healing.</p> <p>Clinicians particularly valued being able to accurately measure the compression levels through the built-in pressure measurement system. 96% of clinicians reported the fit, ease of application, application time and use of the built-in pressure system as very good or excellent. Clinicians reported reduced nurse time applying the Juxta CURES compared to conventional compression bandaging. A cost saving was realised after 12 weeks use of Juxta CURES in replacement of compression bandaging. Over 6 months use there was a cost saving of £2141 per patient.</p>
Conclusions	Improved quality of life and wound healing was seen in 12 out of 14 patients. The Juxta CURES provided patients and clinicians with solutions to the problems associated with conventional compression therapy. Use of the Juxta CURES promoted self-care and resulted in financial savings compared to conventional compression bandaging, and a reduction in materials (for example, bandaging), nurse time and clinical waste.

Abbreviations: ABPI, ankle brachial pressure index; n, number of patients.

**Table 6 Summary of the Lawrence (2014a) case reports**

Study component	Description
Objectives/ hypotheses	To illustrate how finding a compression regime that individuals can adopt without discomfort while being able to wear their usual footwear is important for many patients, and this can help maintain mobility and improve concordance.
Study design	Retrospective descriptive case reports on 3 patients.
Setting	Community setting in the UK.
Inclusion/ exclusion criteria	Not applicable
Primary outcomes	Not reported
Statistical methods	Not applicable
Participants	<p>n=3</p> <p>Case 1: a 52-year-old woman with a 10-year on-off history of VLUs and normal ABPI. She had self-treated for almost 2 years before referral with a VLU measuring 8 cm x 5 cm.</p> <p>Case 2: a 33-year-old morbidly obese man with a 6-month ulcer history and normal ABPI. On examination, venous disease and associated oedema were present. Initial ulcer measurement was 12 cm x 10 cm; the ulcer was superficial with a low exudate level.</p> <p>Case 3: an 82-year-old man with bilateral weeping oedematous legs and feet and 2 ulcers on his left leg. The patient also had type 2 diabetes and poor mobility caused by osteoarthritis and previous ankle injury and exacerbated by pain from leg ulcers. He also suffered peripheral vascular disease, foot neuropathy and reduced ABPI: 0.64 (left leg) and 0.75 (right leg).</p>

<p>Description</p>	<p>Case 1: 4-layer compression bandaging at 40 mmHg was applied for approximately 1 month, during which time the patient was unable to wear footwear suitable for her employment and lost her job. New work commitments meant she became unable to attend clinics and the ulcer remained static. Therefore the Juxta CURES was considered as the patient could learn how to change her own dressings and reduce clinic visits. It was used after dressing with Aquacel foam and Cavalon No Sting Barrier was used to protect the periulcer area.</p> <p>Case 2: Bandages were applied, but proved difficult due to leg shape. 4-layer and 2-layer methods were trialled but removed by the patient due to slippage and discomfort. These bandages also made wearing a suit and dress shoes difficult and bandage slippage was embarrassing to the patient. The patient also reported malodour which he attributed to infrequency of dressing changes. The limb was too large for compression hosiery and the Juxta CURES was used to provide compression with Atrauman dressings.</p> <p>Case 3: Reduced compression was prescribed but was painful, especially over the left ankle which had metal implants following a previous injury. Even highly absorbent dressings became saturated with exudate within a day and needed changing. Compression was stopped and replaced with the Juxta CURES at 20 mmHg with Aquacel dressings which the patient was able to tolerate.</p>
<p>Results</p>	<p>Case 1: The patient was able to self-manage the Juxta CURES bandages whilst still working and attended clinics when possible. The wound reduced in size to 2 cm x 2 cm (time period not stated).</p> <p>Case 2: The patients' ulcer responded well, healed completely and had remained healed at 12 months follow-up. Off-the-shelf standard compression stockings were provided for maintenance.</p> <p>Case 3: The Juxta CURES required frequent readjustment over the first 2 days to maintain a good fit whilst the oedema reduced rapidly. The ulcers still remained at the time of reporting, but oedema and wetness had resolved. The patient tried to use compression hosiery on his right leg again but weeping resumed so he continued with the Juxta CURES to maintain skin integrity.</p>

<b>Conclusions</b>	The Juxta CURES is useful for patients with large lower limbs and narrow ankles who struggle with bandage and hosiery slippage. It is beneficial for patients who wish to self-treat or are unable to attend regular clinic appointments. It provides and maintains therapeutic compression at the desired, measurable level. Patients find it comfortable to wear and it could help improve compliance with treatment.
Abbreviations: ABPI, ankle brachial pressure index; n, number of patients; VLU, venous leg ulcer.	

**Table 7 Summary of the Lurie et al. (2012) case series**

<b>Study component</b>	<b>Description</b>
Objectives/ hypotheses	To determine the suitability of the Juxta CURES as a compression device for the treatment of VLUs.
Study design	Retrospective descriptive case series of 10 non-consecutive patients.
Setting	Vein Clinic, Hawaii.
Inclusion/ exclusion criteria	Not reported
Primary outcomes	Clinician and patient satisfaction and therapeutic effectiveness.
Statistical methods	Not applicable
Participants	n=10 8 male, 2 female patients aged between 26 and 92 years.
Description	Patients wore the Juxta CURES over an appropriate wound dressing and a sock liner in combination with a compression anklet for the foot. Regular check-ups and wound dressing changes were undertaken. 8 patients wore the device all day every day; 2 patients wore the system continuously for 1 week and then for 12 hours during the day, every day thereafter.

Results	2 patients withdrew due to unrelated causes. The ulcers of the remaining 8 patients all healed in an average of 66 days after starting use of the Juxta CURES.
Conclusions	Clinicians found the Juxta CURES easy and quick to fit and remarked that it provided a good fit. Patients reported it was comfortable to wear, controlled swelling and allowed maintenance of hygiene. Clinicians evaluated the change in patients' oedema and skin, patient compliance and overall ulcer healing as excellent.
Abbreviations: n, number of patients; VLU, venous leg ulcer.	

**Table 8 Summary of the Nugent (2013) case report**

Study component	Description
Objectives/ hypotheses	To demonstrate how the Juxta CURES has had a positive impact on the patient's quality of life.
Study design	Retrospective descriptive case report.
Setting	Community setting in the UK.
Inclusion/ exclusion criteria	Not applicable
Primary outcomes	Positive impact on patient quality of life.
Statistical methods	Not applicable
Participants	n=1 A 48-year-old man with a 12-month history of a non-healing ulcer 20 cm × 10 cm which, although extensive, was fairly superficial. The patient was classed as non-concordant as he declined to attend appointments because they clashed with his work schedule. This is likely to be the same patient as described in the study by Bianchi (2013).

Description	<p>The patient started self-managing his wound care in November 2012. Initially he used a 2-layer compression system. This was changed to the Juxta CURES in November 2012, as the tissue viability nurse had concerns about the correct level of compression being reached at each application. The Juxta CURES was used in combination with a skin care and dressing regime comprising of Cetraben emollient cream and DryMax EXTRA. The patient was shown how to apply the Juxta CURES and use the built-in pressure system to ensure the correct level of compression (40 mmHg) was maintained throughout the week between appointments.</p>
Results	<p>After 1 week the patient reported that the device was comfortable and easy to use. After 3 weeks wound size had reduced significantly, although there were signs of overgranulation. By week 5 the wound size had decreased by 50%, the wound area to the lateral and posterior aspects had healed and the overgranulation had settled. At week 7, 4 superficial granulating areas remained. Further improvement was seen at week 10, when just 3 superficial granulating areas remained and these measured 3 cm × 2.8 cm, 1.4 cm × 1.6 cm and 2.9 cm × 1.9 cm.</p> <p>The patient enjoyed being in control of the wound management process and knowing that, if there was odour from the wound, he could shower and change the dressing. The ability to wear his own shoes was a bonus.</p>
Conclusions	<p>Use of the Juxta CURES had a positive impact on the patient, and he found using the device a positive experience.</p>
<p>Abbreviations: n, number of patients.</p>	

**Table 9 Summary of the Oates et al. (2013) case series**

Study component	Description
Objectives/hypotheses	<p>To enable patients to continue gold standard compression therapy treatment while allowing a higher degree of independence.</p>
Study design	<p>Case series (unclear if prospective or retrospective).</p>
Setting	<p>Community setting.</p>

Inclusion/exclusion criteria	Not reported
Primary outcomes	Not reported
Statistical methods	Not applicable
Participants	n = not reported Patients with venous leg ulceration currently being treated with compression bandages were invited to change to the Juxta CURES.
Results	The study reported a measurable reduction in wound size and leg oedema, improved patient concordance and wellbeing and a heightened sense of achievement for the nurses managing the patient. Costs and nursing time were noticeably reduced. Patient concordance was found to be much higher with the Juxta CURES than with comparable bandaging systems. Ease of use, the ability to reduce the pressure at night and to remove the device to take a shower being among the perceived benefits. The enhanced possibilities for patient self-management also resulted in a lower number of district nurse visits being needed, bringing further reductions in cost.
Description	No methods stated.
Conclusions	The use of the device delivered significant benefits for both patients and staff in terms of better concordance, clinical effectiveness and cost reduction.
Abbreviations: n, number of patients.	

## Recent and ongoing studies

A UK study of 36 patients treated with the Juxta CURES has recently been completed. This data is expected to be published in May 2015.

## Costs and resource consequences

In 2014 approximately 3,000 Juxta CURES devices were dispensed on prescription, with 86% of these prescribed by primary care clinicians and 14% by secondary care clinicians. The device has been used in approximately 15 locations across the NHS in England and is also used in leg clubs in

Wales. The use of the Juxta CURES would not require any change to existing NHS facilities and would fit into the current care pathways, and can be prescribed on an FP10 prescription.

Current guidelines advise that standard compression therapy should only be applied by staff with appropriate training (RCN 2006; SIGN 2010), but the level of training needed is not specified. A standard pathway for prescribing compression therapy is also not specified.

Although the device has a higher acquisition cost than traditional compression bandages, it is anticipated that over the 6-month minimum life-span of the product, cost savings may be seen in the reduction of clinician time (reduced numbers of home or clinic visits and shorter visits), reduced amount of dressings and bandages needed and a resultant reduction in clinical waste.

## Published cost studies

A case report on 3 patients (Bianchi et al. 2013) reported cost savings with the Juxta CURES compared with conventional bandaging over a 6-month period. This was based on an evaluation of 17 patients and illustrated costs in 3 areas:

- dressings: average saving of £753 per patient
- bandages: average saving of £881 per patient
- clinician time: average saving of £3172 per patient.

This would equal a total average saving of £4806 per patient. The study suggests that the use of the Juxta CURES results in reduced exudate, meaning that expensive extra-absorbent dressings are not needed. Its use also appears to be cheaper than repeat bandaging and reduces clinical waste. The reduction in clinician time arises from faster application during clinic visits and a reduction in the number of clinic and home visits as the patient is encouraged to self-manage their care. The timeframe for this saving is not specified but is assumed to be over the course of 6 months. The source of these costs savings is not specified.

A poster presentation by Elson (2012) contained a product evaluation to compare the cost of treating venous ulcers with compression bandages with the Juxta CURES. Clinicians treating 17 patients recorded 6 months of data using standard compression therapy and 6 months using the Juxta CURES. Where the patient had not used the compression garment for 6 months an estimate was made. The data recorded included:

- number of nurse visits

- patient quality of life
- type and number of wound dressings used
- compression bandaging type and number used.

The data were used to calculate and compare the costs of the 2 treatment options. These costs are detailed below in table 10.

**Table 10 Summary of the cost evaluation from Elson (2012)**

Costs associated with the care of 17 leg ulcer patients	
Treatment	Average cost
Dressings under compression	
Standard compression treatment	£826
Treatment with the Juxta CURES	£72
Compression treatment	
Standard compression treatment	£1073
Treatment with the Juxta CURES	£193
Associated nursing costs	
Standard compression treatment	£4671
Treatment with the Juxta CURES	£1497

Using these calculations, total included costs for standard care are £6570 and £1762 for the Juxta CURES. This would provide an average saving of £4808 for the 17 patients equating to £282.82 per patient. The timeframe for this saving is not specified but is assumed to be over a 6-month period. The sources of costing prices are not specified.

Harris (2013) reported that a positive cost saving was realised at week 12 after the initial outlay to purchase the Juxta CURES.

A case report by Nugent (2013) detailed treatment of a patient treated with the Juxta CURES, whose ulcer was previously treated unsuccessfully with compression bandages. The cost of the previous 12-months' treatment before assessment prior to use with the Juxta CURES was calculated at over £3300 with no healing of the ulcer. After reassessment and commencement of

the Juxta CURES, the ulcer reached an almost-healed state before reporting at an estimated cost of £732. The time period for this estimated cost is not stated but is assumed to be for the 10 weeks during which the patient was treated with the Juxta CURES.

### *Strengths and limitations of the evidence*

The identified evidence for the clinical effectiveness of the Juxta CURES was very limited in both quantity and quality, and comprised published case reports, abstracts and poster presentations. No large-scale studies, or robust comparative data were identified.

All of the included studies involved small numbers of patients (the maximum specified was 17). Five studies (Bianchi et al. 2013; Davies 2013; Dowsett and Elson 2013; Lawrence 2014a; Nugent et al. 2013) are case studies of 3 patients or fewer, and therefore it can be assumed that the outcomes of these studies should not be generalised.

It is unclear whether patients in the identified studies were enrolled consecutively; this raises concerns about selection and attrition bias. Five studies are not reported in full, and are available only as posters or abstracts and have not undergone peer review. This includes the 4 case series (Elson 2012, Harris 2013, Lurie et al. 2012 and Oates et al. 2013). Inclusion and exclusion criteria are not clearly stated for these case series, and only Lurie et al. (2012) state primary outcomes. The lack of available detail means that these results should be treated with caution.

It is highly likely that the patient reported by Nugent (2013) is the same as 1 patient reported in the Bianchi et al. (2013) paper, of which Nugent is a co-author.

Seven of the 9 studies contain acknowledgements to medi UK or have authors employed by medi UK or CircAid.

Economic reporting is limited and the sources of the costs and assumptions made are not specified, therefore it is not possible to assess their appropriateness. Variability of the cost saving between each study suggests that these results may not be generalisable. However all reports suggest the device is cost saving compared to compression bandaging.

### **Relevance to NICE guidance programmes**

NICE has issued the following guidance:

- [Pressure ulcers: prevention and management of pressure ulcers \(2014\) NICE guideline CG179](#). Date for review: June 2016.
- [Varicose veins in the legs: The diagnosis and management of varicose veins \(2013\) NICE guideline CG168](#). Date for review: September 2015.
- [Diabetic foot problems: Inpatient management of diabetic foot problems \(2011\) NICE guideline CG11](#). Date for review: to be confirmed.
- [Surgical site infection: Prevention and treatment of surgical site infection \(2008\) NICE guideline CG74](#). Date for review: December 2016.
- [Type 2 diabetes foot problems: Prevention and management of foot problems \(2004\) NICE guideline CG10](#). Date for review: currently under review.

NICE has also issued the following evidence summaries:

- [Wound care products \(2015\) NICE key therapeutic topic 14](#).
- [Leg ulcer – venous \(2012\) NICE clinical knowledge summary](#).

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## Search strategy and evidence selection

### *Search strategy*

The following search strategy was used to search Ovid MEDLINE (R) 1946 to November week 1:

1 A fresh way to treat venous leg.m\_titl.

2 Comparison of elastic versus nonelastic.m\_titl.

3 Meeting the challenges of delivering leg ulcer services.m\_titl.

4 Juxta CURES: compression for healing venous leg ulcers.m\_titl.

5 (Compression therapy in mixed ulcers increases venous output and arterial perfusion).m\_titl.

6 Juxta CURES: An innovative.m\_titl.

7 Juxta CURES: compression.m\_titl.

8 or/1-7

9 exp Compression Bandages/

10 Varicose Ulcer/th [Therapy]

11 9 and 10

12 juxta cures.tw.

13 (compression adj5 venous adj3 ulcer\*).tw.

14 (compression adj5 varicose adj3 ulcer\*).tw.

15 11 or 12 or 13 or 14

16 8 and 15

Similar search strategies were adapted for Medline in Process, Embase, PsycInfo, Cochrane Library (all components), Pubmed, HEED, NHS Evidence and Web of Science. The searches returned a total of 669 references after duplicate removal.

## *Evidence selection*

Retrieved results were independently sifted by 2 researchers using the selection criteria below, and disagreements discussed and resolved.

- Population: Patients with venous stasis ulcers; venous insufficiency; post thrombotic syndrome; dependent oedema.
- Intervention: Juxta CURES.
- Comparator: Compression therapy.
- Outcomes:
  - change in wound size
  - time to healing
  - patient tolerability/acceptability
  - patient compliance
  - clinician assessment
  - quality of life
  - frequency of dressing changes

- treatment costs
- maceration of surrounding areas
- adverse events
- pain
- infection rates.

Following the first sift 654 records were removed based on the following criteria:

- non-English language studies
- not relevant to selection criteria
- animal studies
- review articles and protocols.

Full articles were retrieved for the remaining 15 studies. Several articles were known to be published in Wounds UK which is not indexed in the databases; therefore Google Scholar was used to search for Juxta Cures in Wounds UK resulting in 1 additional paper. The grey literature also resulted in one additional paper. Additionally 19 articles and conference posters were provided by the manufacturer or were available on their website. At this stage a total of 31 references were available to consider for inclusion. Due to the paucity of data all studies meeting the selection criteria were considered for inclusion. Ultimately 9 references met the criteria and were included in this briefing. Four of these are full text papers (Bianchi et al. 2013; Dowsett and Elson 2013; Lawrence 2014a and Nugent et al. 2013); 4 are poster presentations (Davies 2013; Elson 2012; Harris 2013; Oates et al. 2013) and 1 an abstract (Lurie et al. 2012). A tenth study (Lawrence 2014b) also met the selection criteria but did not contain any quantitative data and was therefore excluded.

## About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

## *Development of this briefing*

This briefing was developed for NICE by Cedar. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

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