

# Innovative Medical Technology Overview: Number 011/2018

This IMTO summarises the evidence relating to a technology submitted for assessment by the manufacturer. This IMTO offers an impartial review of the strengths and weaknesses of the technology to contribute to local decision-making by NHS health professionals, managers and procurement colleagues. IMTOs do not make recommendations and should be considered alongside existing guidance applicable to NHSScotland.

## Juxta Range of Products (Juxtacures, Juxtalite, Juxtafit)



## Summary

### Technology

The Juxta range of products are inelastic reusable wraparound garments that are used to apply measurable compression to limbs. Juxtacures provides below the knee compression and is used in the management of venous leg ulcers (VLUs) when oedema is present. Juxtalite also provides below the knee compression, and is suitable where there is no oedema and for the prevention of recurrence. Juxtafit products are used for lymphoedema, and come in a variety of styles to provide arm or leg compression as required.

## Comparator(s) and use in pathway of care:

The indications for which the Juxta range are suitable treatment options may present in acute or primary care, with the majority of patients treated in a community setting.

Multi-layered compression bandaging is the current recommended treatment for VLUs, but patients are reliant on a healthcare professional for their application, adjustment and removal. The level of compression applied with bandaging is also dependent on the skill of the healthcare professional applying the bandage. Across the Juxta range, a proprietary pressure measurement card (Built-In-Pressure system [BPS]) allows the compression pressure to be measured and monitored to apply optimum compression. Hence, self-adjustment of the Velcro wraps in the Juxta range of products are intended to provide a safe and consistent level of compression.

The use of the Juxta range is an alternative to the traditional bandaging used for VLUs and lymphoedema; patients have the potential to promote self-care in the community and reduce nursing time and resources without the need to markedly change current care pathways.

## Product performance

The evidence relating to the Juxta range of products is variable. The evidence-base for Juxtacures is limited to a small number of non-comparative case series, case reports and poster presentations, generally reporting reduction in wound size, improved healing or improved quality of life for patients. The evidence for Juxtalite is lacking, with one case study submitted by the manufacturer reporting fast healing and a significant reduction in exudate in one patient. Based on this low quality and non-comparative evidence it is not possible to determine how these products compare with traditional multilayer bandages in their effectiveness at healing leg ulcers.

For Juxtafit, the evidence is more developed, with two randomised controlled trials (RCTs) demonstrating that Juxtafit achieves a significantly better short-term reduction in leg volume compared to traditional multi-layered compression bandages in patients with moderate to severe lymphoedema and chronic venous oedema. The trials had a very short follow-up (24h and 7 days), small sample sizes, and the demonstrated reduction in wound volume does not necessarily equate to healing – an issue noted by clinical experts.

## Economic considerations

The unit cost of Juxta products is higher than traditional bandages. However, when taking into account the re-usability of the products (traditional bandages need to be changed on each application, which can be up to several times a week) and also considering the impact on clinician time associated with self-management, the introduction of the Juxta range as an alternative to traditional compression bandages could be associated with resource savings as reported in several analyses.

## Safety

No safety concerns were raised in any of the studies included in the evidence base and no safety reports were identified in a high level literature review. The BPS card included in the Juxta range, which provides an objective measure of the pressure applied, could potentially reduce the risks associated with compression therapy that is too tight (such as skin damage and restricted arterial flow).

## Organisational and patient issues

Juxtacures and Juxtalite are guaranteed by the manufacturer to provide effective daily compression for 6 months, whilst Juxtafit is guaranteed for 12 months. If the products fail within this timeframe they will be replaced by the manufacturer free of charge, assuming they have been fitted, used and maintained in line with the instructions of use. All of the Juxta range of products are available on the Drug Tariff in Scotland.

Patient testimonials were also included as part of the manufacturer's submission. Compared to traditional compression bandages, Juxta products were noted to offer: increased independence and ability to self-care; a reduction in the amount of time waiting for community nursing visits; and improved aesthetic appearance providing the opportunity for people to wear their preferred choice of clothes and footwear.

## Overview of technology

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The Juxta range of products are inelastic reusable wraparound garments that are used to apply measurable compression to the leg for the following:

- Juxtacures – suitable for VLUs where oedema is present
- Juxtalite – suitable for VLUs where there is no oedema and for the prevention of recurrence
- Juxtafit – suitable for effective control of leg ulcers including reduction and maintenance of lymphoedema.

The Juxta products are CE marked Class 1 medical devices, registered under Part 2 of the Scottish Drug Tariff and therefore a mechanism is in place for prescription of the products. After initial fitting by a trained clinician, Juxta products can be adjusted and reapplied by a clinician, patient or carer – the level of pressure applied is measurable and adjustable using the pressure measurement card (i.e. BPS).

Juxtacures and Juxtalite use the same material, fastening and pressure checking system. Juxtacures can be reduced in circumference to match the reduction in size of the limb as venous oedema subsides and exudate dries up. Juxtalite is a sized version for use where there is no change in limb volume expected, for example in patients with thin legs.

VLUs affect an estimated 1% of the population in any one year, therefore there are 55,000 potential users of this technology in Scotland. The Scottish Intercollegiate Guidelines Network (SIGN) Guideline 120 offers guidance on the management of VLUs and recommends compression therapy with high compression multicomponent bandages – Juxtacures and Juxtalite offer an alternative to traditional compression therapy.

Juxtafit is a firmer garment that provides effective compression for the management of lymphoedema. There are an estimated 7,000 patients with lymphoedema in Scotland<sup>1</sup>.

## Comparator(s) and use in pathway of care

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Multi-layered compression bandaging is the traditional treatment for VLUs and has been considered the gold standard since the mid-1980s. However, patients are reliant on a healthcare professional for their application, adjustment and removal. Bandages are normally fitted for 3 or 4 days at a time and it is not uncommon for patients to experience a degree of slippage during that period. The level of compression applied with bandaging is dependent on the skill of the healthcare professional applying the bandage. With the Juxtacures and Juxtalite devices, the BPS allows pressure to be measured and monitored to apply the optimum compression. Hence, self-adjustment of the Velcro wraps in the Juxta range of products is intended to provide a safe and consistent level of compression, having the potential to promote self-care in the community and reduce nursing time and resources.

Similarly, with lymphoedema patients, Juxtafit and the BPS can be used to apply the optimum pressure during the reduction (when lymphoedema is reduced) and maintenance phases of treatment. This may lead to self-management by the patient where appropriate.

The use of the Juxta range is an alternative to the traditional bandaging used for VLUs and lymphoedema patients. Current care pathways are simply designed to apply compression. This is the mode of action of the Juxta range, and the manufacturer proposes it has the added benefits of measurable compression and ease of application. The use of Juxta products would not require any change to existing NHS facilities and would fit into the current care pathways<sup>2</sup>. Juxta products may also have the potential to increase patient well-being, by supporting self-management of a chronic condition.

The view of NHS experts contacted as part of this review was mixed, with some suggesting that the Juxta range would replace traditional compressions bandages, while others were of the opinion that they would not replace any products currently used in clinical practice but would add an extra management option which is potentially more patient friendly. Experts also noted these products are reliant on patient dexterity, eyesight (to adjust the straps), reliability and willingness. According to one clinical expert, these products are suitable for patients with mild-moderate oedema who can self-care, and may not be safe for patients with some degree of learning disability. One clinical expert advised that for lymphoedema patients whose limbs have become distorted in shape, off the shelf garments may not be large enough and custom fitted garments would increase the cost significantly; and so in this patient group the first choice of treatment may still be the multi-compression bandages.

The technology is currently being introduced to, and adopted by, the NHS in England, Wales, Scotland and Northern Ireland. It is unclear if there is a wide variation in use of the technology across Scotland, although the technology is currently being used within NHSScotland:

- as an adjuvant to standard compression therapy for specific group of patients who can self-manage;
- in primary care leg ulcer clinics.

There is an on-going assessment of this range of products in NHS Greater Glasgow and Clyde (GGC). NHS GGC have also developed protocol/guidance for use of compression wraps, and the intention is to include Juxta products on the GGC compression formulary pending the on-going assessment.

## Product performance

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The published evidence relating to product performance that was submitted by the manufacturer comprises of the National Institute for Health and Care Excellence (NICE) advice, two RCTs, case series, and case study reports. Additionally, a search of the published literature was conducted by Healthcare Improvement Scotland which yielded an additional five

publications. The evidence base is summarised in Table 1, and is described in more detail thereafter.

*Table 1: Summary of evidence base included in this technology overview*

	Study design	Device	Comments/findings
<b><u>Manufacturer Submission</u></b>			
<b>NICE MIB25<sup>2</sup></b>	Technology review	Juxtacures	<p>Nine studies included, comprising small published case reports, abstracts and poster presentations.</p> <p>All studies included reported reduction in wound size, improved healing or improved quality of life.</p> <p>Juxtacures led to average cost savings estimates ranging from £2,141 to £4,808 per patient over a 6 months period - associated with reduction in standard bandages and dressings, clinician time, clinic and home visits.</p>
<b>Damstra et al. (2013)<sup>3</sup></b>	RCT (n=30)	Juxtafit	<p>Compares juxtafit with traditional bandages in the initial treatment of lymphoedema.</p> <p>Significant reduction in the volume of affected leg at 24 hours follow-up.</p>
<b>Mosti et al. (2015)<sup>4</sup></b>	RCT (n=40)	Juxtafit	<p>Compares Juxtafit with traditional bandages but for venous leg oedema (indication for Juxtacures).</p> <p>Significant reduction in volume at 7 days follow-up.</p>
<b>Wicks (2015)<sup>5</sup></b>	Case series (n=16)	Juxtacures Juxtafit	<p>Effective healing reported with Juxtacures/Juxtalite in mixed population. Lower pain scores compared to traditional bandages.</p> <p>Includes resource impact analysis: £417 and £217 cost savings per week in two cases.</p>
<b>Elvin (2015)<sup>6</sup></b>	Case series (n=26)	Juxtacures	<p>Skin condition, wound size, satisfaction were recorded but not reported.</p> <p>Includes resource impact analysis: £767 cost saving per patient over 6 months associated to compressions and dressings; overall nursing time saving of 32h and 26m over 6 months.</p>
<b>Freeman et al. (2016)<sup>7</sup></b>	Case series (n=16)	Juxtacures	<p>Data collected in 9 patients but not reported. Average visit time was also reduced from 40 minutes with bandages to 19 minutes with Juxtacures.</p>

<b>Bradley <i>et al.</i> (2017)<sup>8</sup></b>	Case series (n=10)	Juxtacures	Effective healing rates were reported by week 3 and 4.  Includes resource impact analysis: £1240 savings per patient over 12 weeks associated to compressions and bandages.
<b>Tickle <i>et al.</i> (2017)<sup>9</sup>, Lawrence (2014a)<sup>10</sup>, Lawrence (2014b)<sup>11</sup></b>	Case reports (n=7)	Juxtacures	Case reports including a total of seven case studies, reporting good healing rates.
<b>Smith (2017)<sup>12</sup></b>	Case report (n=1)	Juxtalite	Improvement in the size of the ulcers and significant reduction in exudate was observed but no clinical data were reported.
<b>Patullo <i>et al.</i> (2017)<sup>13</sup>, Mullings <i>et al.</i> (2012)<sup>14</sup></b>	Case reports (n=2)	Juxtafit	Two case reports reporting on the healing process of two patients with lymphoedema using Juxtafit.
<b><u>Healthcare Improvement Scotland search</u></b>			
<b>Freeman (2015)<sup>15</sup></b>	Case report (n=2)	Juxtacures	Regular reviews showed juxtacures improved healing, and reduced oedema. There was full acceptance of the treatment from patients who were non-compliant with traditional bandage therapy.
<b>Hampton <i>et al.</i> (2016)<sup>16</sup></b>	Technology report	Juxtafit ReadyWrap JOBST FarrowWrap	Report comparing the functionality of three different compression wraps, including Juxtafit, but not reporting any clinical outcomes.
<b>Partsch <i>et al.</i> (2015)<sup>17</sup></b>	Review on the use of compression therapy in leg ulcers	Various devices	Juxtacures is mentioned but no clinical outcomes or comparison is reported.
<b>O'Meara <i>et al.</i> (2012)<sup>18</sup></b>	Systematic review	Adjustable compression boot (Velcro wraps and elastic anklets produced by Medi; no reference to juxta range)	Evaluates the effects of compression bandages and stockings on venous ulcer healing. Includes two RCTs comparing 'adjustable compression boots' with compression bandages. The authors state: 'Two RCTs found no evidence of a difference in healing between adjustable compression boots and compression bandage systems. Both trials were small with high (DePalma 1999) and unclear (Blcken 2005) risk of bias. The compression boot may be a less costly option (DePalma 1999).'

## Juxtacures

Juxtacures was reviewed by NICE in a 2015 Medtech Innovation Briefing (MIB25)<sup>2</sup> which looked at the clinical and cost saving benefits of Juxtacures as an alternative to standard compression bandages in patients with VLUs. Nine studies were identified, comprising small published case reports, abstracts and poster presentations. There were 51 patients included across eight of these studies, while one study did not report the number of patients included. All nine studies reported reductions in wound size, improved healing or improved quality of life in patients using Juxtacures. However, none of the studies were comparative and it is therefore unclear if the Juxta compression products themselves led to the improved outcomes. In one case series, three of the 14 patients participating in the study decided to change to an alternative compression bandaging system. The reasons cited were personal preference, management of lymphoedema, and a fall, but it is unclear whether these events were device-related.

A recent case report by Tickle *et al.* (2017)<sup>9</sup>, which included four case studies, found the use of Juxtacures enabled patients to self-care; which increased adherence to treatment and helped promote healing, leading to a decrease in ulcer size at follow-up in all cases. Similar findings are reported in the two case reports by Lawrence<sup>10, 11</sup>, also covered by the NICE MIB25, and in one further case report<sup>15</sup>.

Wicks (2015)<sup>5</sup> evaluated the use of Juxtacures and Juxtafit in a mixed population of 16 patients requiring compression therapy for VLUs with/without chronic oedema/lymphoedema. All patients had a leg ulcer and were already undergoing compression bandaging as part of their plan of care. Ankle and calf circumference decreased during follow-up, which is indicative of the ulcers healing. However, in the absence of comparative data, it is not possible to determine how the healing process compares with standard compression bandages. Patients generally reported higher pain scores associated with bandages compared with Juxtacures. The study also investigated the potential savings in the community nursing team, both financially and in terms of reduced nursing time, which are reported in the economic considerations section.

Another case series (Elvin, 2015)<sup>6</sup> evaluated the use of Juxtacures in 26 patients who had their wounds cleaned with UCS™ (a disposable, single-use debridement cloth that cleanses and hydrates the skin, Medi UK Ltd) in preparation for compression therapy. Skin condition, wound size, ankle and calf measurements, patient response, and level of satisfaction with product use were recorded at each visit, although no quantitative data were reported. The study also analysed treatment costs, nursing time and number of visits required for Juxtacures compared to the previous compression and dressing regimen. Again, these findings are reported in the economic considerations section.

Freeman *et al.* (2016)<sup>7</sup> report on another case series of 16 patients fitted with Juxtacures. Of these, data were available for analysis in nine patients but no quantitative results are reported on the clinical effectiveness of the device. Two of the nine patients were subsequently discharged as they were able to manage their adjustable compression device independently. Six of the nine patients found the devices comfortable and were keen to continue with the treatment. Of the remaining three, one returned to using bandages as they were not able to wash and care for the device, while two others asked to be returned to their previous regimens. During the project there was an overall reduction in nursing visits by seven per week across all nine patients. The average visit time was also reduced from 40 minutes with bandages to 19 minutes with Juxtacures, leading to an estimated 4 hours and 40 minutes of nursing time saved per week.

Bradley *et al.* (2017)<sup>8</sup> evaluated the use of Juxtacures over a 12 week period in 10 patients whom had been using compression bandages for more than 5 months. All eligible patients were informed about the products available and were offered the choice to switch to Juxtacures and participate in the study. Patients were reviewed three times a week for the first 2 weeks (weekly thereafter) and the size of patients' wounds were measured at each visit. Between weeks one and three, a reduction was noted in nine out of ten patients' wound size and depth and an increase in exudate levels, followed by an improvement by 1-2mm in wound depth and diameter immediately following this. The study also looked at costs and resource use which are reported in the economic considerations section.

NCT02790593 is an upcoming RCT which aims to determine whether the Juxtacures device provides at least equivalent ulcer healing for patients with venous ulceration compared to bandaging. Secondary outcome measures include whether the Juxtacures device improves patient compliance and quality of life compared to bandaging, and whether the Juxtacures device is cost-effective compared to bandaging. The estimated completion date for the RCT is December 2018.

### **Juxtalite**

Evidence surrounding the use of Juxtalite is lacking.

A case report (Smith, 2017)<sup>12</sup> submitted by the manufacturer and authored by one of manufacturer's clinical trainers describes the effects of Juxtalite applied to one patient with bilateral leg ulcers with minimal oedema and slim legs. A 'dramatic improvement in the size of the ulcers and significant reduction in exudate' was observed, with the first ulcer healing in 3.5 months after 20 years of having to live with ulcers. It is not clear what treatment, if any, the patient was receiving before.

### **Juxtafit**

The effectiveness of adjustable compression Velcro wraps (i.e. Juxtafit) versus inelastic multicomponent compression bandages (IMC) in the initial treatment of lymphedema was compared in an RCT (Damstra *et al.*, 2013)<sup>3</sup>. The study included 30 hospitalised patients admitted to a single centre due to moderate to severe lymphedema (stages 2-3) of the leg, randomised (using sealed envelopes) into two groups of 15 patients: group A treated with

Juxtafit and group B treated with a three-component Trico IMC bandaging system (BSN Medical GmbH). The primary outcome measures in both groups were reduction in volume of the affected leg (measured by water-displacement device) and interface pressure after 2 and 24 hours. Despite randomisation, patients in group A were younger (mean age 54.5 vs 59.9), had a lower primary-to-secondary lymphedema ratio (6:9 vs 9:6), a longer duration of lymphedema at the time of the study (16.6 vs 11.0 years), and a higher mean leg volume (3609mL vs 3314mL and 53mmHg). Results showed that there was a higher reduction in median volume in group A both at 2 hours (109mL vs 75mL, Mann-Whitney  $p>0.05$ ) and at 24 hours (339mL vs 190mL, Mann-Whitney  $p<0.05$ ). The interface pressure dropped significantly after 2 and 24 hours in group B (-50% and -6%), but significantly less in group A (-26% and -44%), mainly due to self-adjustment. These findings illustrate that Juxtafit achieves a significantly more pronounced volume reduction after 24 hours than IMC bandages in the initial treatment of patients with moderate to severe lymphedema. However, the very short study period makes it unclear whether Juxtafit is associated with more effective healing in the long-term maintenance phase. Other weaknesses are a small sample size and the differences in sample characteristics between groups A and B.

Another RCT (Mosti *et al.*, 2015)<sup>4</sup> compared the effectiveness and comfort of Juxtafit with inelastic bandages (IBs) in reducing venous leg oedema in the initial treatment phase. Presence of lymphoedema, which is the intended indication for Juxtafit, was an exclusion criteria in this study and the device was used to reduce leg oedema which is the intended use of Juxtacures. Forty legs from 36 patients were randomised to two groups using a list randomiser: IBs (n=20) and Juxtafit (n=20). Both compression devices remained in place on the leg day and night and were reviewed after 1 day. Patients in the Juxtafit group were asked to adjust the device as needed. The main outcomes observed at baseline (T0), after 1 day (T1) and after 7 days (T7) were leg volume (calculated using the truncated cone formula), interface pressure (measured by an air filled probe), and static stiffness. Patient comfort was also measured by grading sign and symptoms on a visual analogue scale. At T1, the median percent volume reduction was 13% for the IB group versus 19% for the Juxtafit group; at T7 it was 19% versus 26% respectively ( $p<0.001$ ). The pressure in the IB group was significantly higher compared with the Juxtafit group at T0 (63 vs 43 mmHg) but dropped by >50% over time, while it remained unchanged with Juxtafit owing to the periodic readjustment by the patients. Comfort was reported to be similar with the two compression devices. The results show juxtafit - with a resting pressure of around 40mmHg - is more effective short-term in reducing chronic venous oedema than IBs with a resting pressure of around 60mmHg. However, as with the other RCT, weaknesses include a small sample size and short follow-up.

A reduction in leg circumference and increase in satisfaction was also reported in two case reports that included a total of three patients diagnosed with lymphoedema.<sup>13, 14</sup>

## Safety

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No safety concerns were raised in any of the studies included in the evidence base already presented. A search of the Medicines and Healthcare Products Regulatory Agency (MHRA)

website revealed no manufacturer Field Safety Notice on Medical Devices 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).

Compression therapy does have potential risks. High pressures may cause pressure damage to skin particularly in patients with impaired arterial supply who make up 20% of patients with leg ulcers. The use of compression in patients with an ankle brachial pressure index (ABPI) less than 0.8 should only be initiated under specialist advice and requires very close monitoring and review.<sup>21</sup> Compression should also be used with caution in patients with diabetes, who may have unreliable ABPIs due to arterial calcification as well as an underlying sensory neuropathy.<sup>21</sup>

The highest risk for a patient who is undergoing compression therapy is that it is applied too tight, restricting the arterial flow. All Juxta devices have hook and loop fastenings on each strap which allows for instant adjustment of the device to maintain the prescribed level of compression and for simple removal in the unlikely event of any safety concerns being expressed. The manufacturer claims that the BPS card offers an accurate reading of the pressure applied by each band and thus can actually be safer than conventional multi-layer bandages. Application training is very simple, unlike traditional leg ulcer bandaging which requires specialist training and regular revision.

## Strengths and limitations of the evidence

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The research evidence for the use of adjustable compression wrap devices from the Juxta range of products in people with lymphoedema, chronic oedema, and venous ulceration is fairly limited. Most of the evidence is in the form of descriptive papers, case studies, or relatively small research studies that were undertaken over a short period of time, and do not reflect the long term nature of these chronic conditions and their treatment. There are two RCTs<sup>3,4</sup> comparing Juxtafit with traditional bandages which demonstrated significant reduction in leg size; however, it is not clear whether this is equivalent to healing and the follow-up periods and sample sizes were small. The clinical data in the rest of the studies were generally poorly reported or not reported at all. Despite the weaknesses in the evidence, the early results are promising, and some expert reviewers are positive about the technology, and so further research is encouraged.

## Economic considerations

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Currently cost of compression therapy in Scotland is approximately £4m per annum and the incidence of chronic venous insufficiency and VLU is expected to rise due to ageing population and patient lifestyle. NHS GGC annual cost for compression bandages is approximately £1.3m,

not including cost of clinician time or opportunity cost to the patient who must be available for treatment during working hours.

The unit cost of this device is higher than standard therapy bandages. While the average use of multi-layered bandages is associated with a cost of approximately £8-10 (based on Scottish Drug Tariff for multi-layer compression bandages), the Scottish Drug Tariff (section 2) lists the following prices for the Juxta range of adjustable compression wraps:

- Juxtacures Compression System (pack contains Juxtacures, 2 standard anklets and 2 liners): £155.01
- Juxtalite Compression system (pack contains Juxtalite, 2 standard anklets and 2 liners): £96.97
- Juxtafit
  - Lower Legging: £135.85
  - Upper Leg with Knee Piece (Right, Left): £143.77
  - Ankle Foot Wrap, Interlocking/Closed heel: £38.04

However, Juxta wraps can be used for up to 6 months (12 months for Juxtafit) and are machine washable, whereas replacement bandages are required on each application. Applications can average twice weekly and are dependent on the level of oedema and condition of ulcer based on expert opinion. Although these devices have a higher acquisition cost than traditional compression bandages, it is anticipated that over the 6 month minimum life-span of the products, 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. Assuming continuous use of traditional bandages with two applications a week at an average cost of £8, there would be a £416 cost associated with traditional bandages over a 6 months period. It should be noted that two sets of garments might be required for patients that need to wear a set while washing the other. Also, clinical experts pointed out that some degree of staff training may be required initially.

The published evidence on costs and resource implications in relation to Juxtacures was assessed in NICE MIB25<sup>2</sup>. Substantial cost savings associated with the use of Juxtacures compared to conventional compressions bandages was reported in three studies included in this review. The estimates ranged from £2,141 to £4,808 average cost saving per patient over a 6 months period. These savings were attributed to a reduction in the use of dressings, bandages, or clinician time arising from faster application and a reduction in the number of clinic and home visits as the patient is encouraged to self-manage their care. These studies appear to be of poor methodological quality with very small sample sizes, with the timeframe and sources of costing prices not being specified.

Savings were also reported in the case reports submitted by the manufacturer and summarised in the product performance section. Sources for the costing calculations were not specified in these studies either. Below is a summary of the findings:

- Elvin (2015)<sup>6</sup> compared costs associated with dressings and compression for 26 patients for 6 months before and after a trial regimen of Juxtacures. Results showed a cost

saving of £560 in compression and £207 in dressings per patient over the 6 months period. There was also an overall nursing time saving of 32 hours and 26 minutes over the 6 months (75 minutes per patient).

- Bradley *et al.* (2017)<sup>8</sup> estimated savings related to Juxtacures for 10 patients of £4,000 on primary dressing costs (£400 per patient) and £8,400 on traditional bandaging (£840 per patient) over the 12-week evaluation period.
- Wicks (2015)<sup>5</sup> reported cost savings in two case reports of £417 per week and £253 per week respectively based on a reduction from a daily application of bandages and nurse visits before the evaluation with Juxtacures to one or twice a week visits.

Williams (2017)<sup>22</sup> reported similar potential savings for one patient of £340 per week for dressings and bandages and £116 associated to staff time, while for a second patient a saving of £11 and £12 respectively was observed. The first patient had experienced multiple episodes of ulceration over a number of years, while the second patient's leg ulcer had been present for over a year.

## Organisational and patient issues

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All of the Juxta range are available on the Drug Tariff in Scotland. They are deemed suitable for GP prescribing on GP10 and are also available for direct purchase in the acute sector. Use of the Juxta range is supported by four Medi team members in Scotland, one Clinical Trainer and three Account Managers. Training and support is provided free of charge.

Juxtacures and Juxtalite are guaranteed by the manufacturer to provide effective daily compression for 6 months, Juxtafit for 12 months. If the products fail within this timeframe they will be replaced by the manufacturer free of charge, assuming they have been fitted, used and maintained in line with the instructions of use.

Patient testimonials were also included as part of the manufacturer's submission. From a patient issues perspective, the Juxta products were noted to offer:

- Increased independence and ability to self-care
- A reduction in the amount of time waiting for community nursing visits
- Improved aesthetic appearance providing the opportunity for patients to wear their preferred choice of clothes and footwear.

## Conclusions

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The clinical evidence surrounding the use of the Juxta range is fairly limited – and for the Juxtalite product is lacking. The long-term effectiveness of the technology versus traditional bandages is also unclear. However, there are data to show that Juxta products may lead to reduction in wound size as a proxy for healing, a reduction in nurse resource required to

reapply compression, and therefore there is potential for resource savings to be gained from use of the devices. Assuming they are at least equally effective as traditional compression bandages at healing VLU with/without oedema/lymphoedema, it seems they would offer good value for money for NHSScotland through the savings realised on traditional dressings and clinician time. Further studies should investigate their medium and longer-term effectiveness.

### **What is an IMTO?**

Innovative Medical Technology Overviews (IMTOs) summarise the evidence relating to an individual technology that has been submitted by the manufacturer of the technology.

The purpose of IMTOs is to provide information that will contribute to local decision-making by NHS health professionals, NHS managers, and procurement colleagues.

IMTOs do not contain recommendations for NHSScotland and should be considered alongside existing guidance applicable to NHSScotland.

### **Chair**

### **Scottish Health Technologies Group**

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