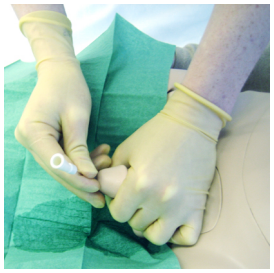
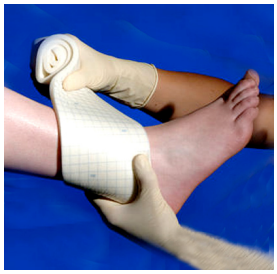
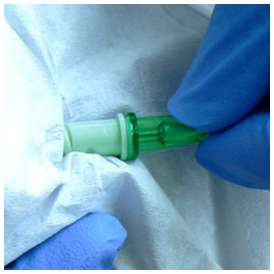
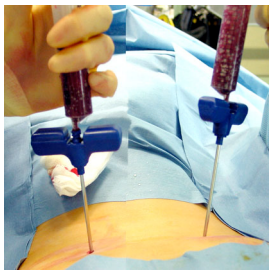
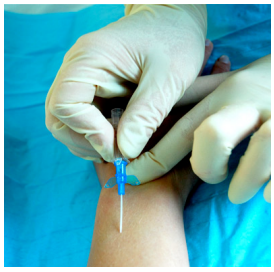
The-ASAP Product Evaluation Programme (PEP)




Connecting best products with best practice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Product Evaluation Programme (PEP): Evaluation of ASep Healthcare Tournistrip® single use disposable tourniquet

Report completed 5th August, 2013

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1.0 Aims of the PEP

In the spirit of aiming to improve patient care and outcomes, support effective aseptic practice and support the reduction of healthcare associated infection (HAI), the aims of the PEP are:

- To help link medical products that support ANTT® principles so as to promote best practice aseptic technique.
- To develop independent and objective non-biased and non-exclusive working relationships with manufacturers of high calibre medical products and medical devices in the hope of improving practice standards and reducing HAI.

2.0 The scope of the PEP

- Products will be endorsed if they are designed and manufactured to integrate with accepted best practice and help facilitate safe and efficient aseptic technique, as considered and defined by The-ASAP.
- The-ASAP/ANTT product evaluations are not exclusive.
- The-ASAP/ANTT does not recommend or market medical products or devices, nor have vested commercial interest in products it evaluates.

3.0 Background

It is widely acknowledged that aseptic technique is the most common critical competency used for invasive clinical procedures, and, failures in aseptic technique are generally thought to be one of the biggest causes of preventable healthcare-associated infection (HAI). Contributing to this is a confused historical literature base and a lack of gold standard evidence (NICE 2012).

It has been shown that the effectiveness of aseptic technique can be significantly improved by improving education, training and standardisation of practice with ANTT® (Rowley & Clare 2009, Pike 2009, White 2010). Variances in the procedure and process of aseptic technique and the maintenance of invasive medical devices can also be improved by medical equipment and supplies, especially equipment and supplies that are designed to negate or reduce 'human factors' and better protect (what ANTT terms) Key-Parts and Key-Sites through direct or indirect Key-Part and Key-Site Protection.

3.1 The benefits of a universal language for aseptic technique

ANTT® is evolving into a universal standard for aseptic technique. One of the primary purposes of ANTT® was to originate a 'fresh' and explicitly defined practice language that would address historical ambiguities with practice terms and terminology. ANTT® originated and defined the terms, 'Key-Parts' and 'Key-Sites' as part of the fundamental ANTT® concept of Key-Part and Key-Site Protection. The benefits for patient safety, healthcare organisations and industry in having a common practice language for aseptic technique are obvious and immense. Many of the recommendations in this PEP will relate to using this standard practice language in educational and marketing literature. This is likely to better connect products with clinical practice for the benefit of patients.

4.0 Product Evaluation

4.1 Manufacturing technical information

According to ASep Healthcare technical information, Tournistrip® (W/O/N20350) is a single use disposable tourniquet supplied as a box (NHS FWJ030) of 200 hundred tourniquets (boxed presentation reviewed). The product is CE marked and conforms to 93/42/EEC specification as a class 1 medical device. The device(s) present as a multi-dispensing roll of tourniquets within a sealed laminated paper box. Each Tournistrip® brand tourniquet is a 49cm bonded laminated strip with a cut away notch (approx. 6mm) allowing the strip to be threaded back across itself like a belt. The device is secured by removing a peel away section (approx. 80mm) of adhesive material. The adhesive strip allows the tourniquet to be attached to itself, removed, and re-attached several times before compromising adhesion. The device is marked as a single use only product.

4.2 Evaluation method 1

Video practice analysis

This evaluation examines the conventional use of the Tournistrip®. The use of the device was video recorded in a controlled environment. Slow motion video analysis is used to aid accurate evaluation of practice utilisation and identification of potential issues.

4.2.1 Findings

Packaging/Product:

The packaging box thoughtfully serves as a Tournistrip® dispenser and this was easy to handle as intended. It was straightforward to pull out one device and detach it with little potential to contaminate other devices. It was straightforward to peal away the panel protecting the adhesive component. Tournistrip® was easy to handle and manipulate as a typical tourniquet.

Tournistrip® in use:

Standard-ANTT

The tourniquet was examined using a Standard-ANTT approach. The device had good surface-to-surface adhesion and formed a strong and reliable fixation once appropriately applied. The device was appropriately used from a main General Aseptic Field without issue. The ease of application was considered to contribute indirectly to an effective non-touch technique because users are less likely to experience difficulties physically deploying the device. We were able to attach the device without touching the patient, although in practice this is not likely to be the norm.

It was clear from comparative video analysis of Tournistrip® and another commonly used device type (a ‘tie around strip of rubber’), that the Tournistrip® was quicker to apply, easier to adjust, and less abrasive to the skin (possibly reducing the disturbance and distribution of patient skin flora).

Surgical-ANTT

Like other tourniquets, the Tournistrip® is not particularly suitable for a Surgical-ANTT approach because it cannot be safely included and managed on a main Critical Aseptic Field as it is not terminally sterilised. That said, it can be used 'alongside' a Surgical-ANTT approach (e.g. PICC insertion) as long as the operator can adjust it using a barrier method or have a second assistant to do so.

4.3 Evaluation method 2

Assessment of Synergy between the Tournistrip® and the ANTT® Foundation Principles and Safeguards:

Clinical Practice

Principle 1
ANTT® is designed to protect patients from infection for all invasive clinical procedures including maintenance of invasive devices; the aim is always asepsis.

- The Tournistrip® maintains the asepsis of Key-Sites and Key-Parts in normal use (Asepsis is defined as the absence of pathogenic microorganisms in sufficient quantity to cause an infection). The device is packaged in a 'clean' environment and its package presentation facilitates 'hygienic' storage. Like other non sterile clinical products, as long as the device has been correctly stored, a low and safe burden of microorganisms will be presumed by users.

- The device adheres to itself well and provides a secure anchoring point for intravenous venepuncture and cannulation activities, promoting a safe and efficient aseptic technique that will help promote asepsis.

  - The single use, disposable nature of the device significantly reduces the risk of microorganism transference and cross infection as associated with re-usable medical devices (MHRA 2006, Kane 2011, Hassan & Dixon 2012). It is noted, that unlike most, if not all other disposable tourniquets, Tournistrip® virtually guarantees single usage only – as removal of it renders it virtually unusable. Other disposable tourniquets made from rubber materials can easily be re-used. This is a particularly strong design future and provides the device a possibly unique selling point.

Principle 2
Asepsis is achieved by protecting Key-Parts and Key-Sites from microorganisms transferred from the healthcare worker and the immediate environment (Key-Part and Key-Site Protection).

The Tournistrip® protects Key-Parts and Key-Sites by:

- Indirectly by promoting Non-Touch Technique (See Safeguard 3)

- The in-built securement features of the device help prevent premature detachment reducing the risk of procedure breakdowns in asepsis and failed vascular access.

- The single use nature of the device reduces the risk of procedure contamination from a previously contaminated tourniquet.

Principle 3
ANTT® needs to be efficient as well as safe; therefore, Surgical-ANTT is used for complicated procedures and Standard-ANTT for uncomplicated procedures – 'From Surgery to Community Care'.

As explained above, Tournistrip® is mostly suitable for Standard-ANTT but can be utilised alongside Surgical-ANTT with specific precautions.

Principle 4
Choice of Surgical or Standard-ANTT is based on ANTT® Risk-Assessment – according to the technical difficulty of ensuring Key-Part and Key-Site asepsis.

N/A. Tourniquet choice is not significant in determining type of aseptic technique.

ANTT Safeguards

Safeguard 1
Basic infective precautions such as hand cleaning & the disinfecting of medical devices significantly reduce the risk of healthcare worker and environmental contamination of Key-Parts and Key-Sites.

Compliance with hand cleaning and other basic infective precautions is a critical component of effective aseptic technique. Consequently, as with other clinical equipment, the effective aseptic manipulation and application of Tournistrip® (and other medical products) is naturally dependant upon healthcare worker (HCW) compliance to basic infective precautions.

In this light, The-ASAP recommends that instructional and educational materials should highlight the critical importance of basic infective precautions prior to and during the use of Tournistrip®. Such essential pre-requisites are rarely stressed by manufacturers in product literature and we suggest doing so would promote best practice, provide hospitals with improved quality assurance and reflect well on ASep Healthcare.

Safeguard 2
Identification and protection of Key-Part & Key-Sites

- Through easy access and manipulation, the Tournistrip® device promotes effective non-touch technique (See Safeguard 3). This indirectly helps to protect the Key-Parts and Key-Site (insertion site) of invasive IV venepuncture and cannulation procedures from HCW contamination.

- Non-disposable tourniquets represent a higher risk of indirectly contaminating the Key-Parts and Key-Site with microorganisms. So as previously stated, Key-Parts and Key-Sites are protected by the single use nature of the device.

Safeguard 3
Non-touch technique is a critical skill that protects Key-Parts & Key Sites from the Healthcare worker and the immediate working environment – for both Surgical and Standard-ANTT

Standard-ANTT

- Prior to use, Tournistrip® is protected from inadvertent touch contamination from HCWs and from the immediate physical and air environment due to the enclosed product design, and 'one-at-time' presentation from the packaging box.

- During use, the strong attachment and securement of Tournistrip® helps minimise the potential for repeated tourniquet manipulation, thus reducing the risk of indirect touch contamination of Key-Parts and Key-Sites.

- Correct application of Tournistrip® effectively limits HCW to patient skin contact as it can be applied with very little, or even no, touching of the patient's skin directly.

Safeguard 4
Aseptic fields protect Key-Parts and Key-Sites from the immediate environment. Surgical and Standard-ANTT involve very different aseptic field management.

- The utilisation of Tournistrip® in Surgical and Standard-ANTT is explained in 4.2.1.

4.4 Evaluation method 3

User feedback

It is noted that Tournistrip® is already used quite widely. For the purpose of this report, samples of Tournistrip® tourniquets were disseminated for evaluation to nursing staff experienced with intravenous therapy, venepuncture and cannulation. Users evaluating the Tournistrip® device reported on the tourniquets' function and utility.

- All users agreed that Tournistrip® was easy to access (packaging) and use.

- All users expressed that Tournistrip® attached well to itself and had strong adhesion.

- Two users commented on the devices application with bariatric patients, and the facility to connect multiple Tournistrips® was thought to be innovative and useful; moreover, there was no noted compromise in adhesion or the ability to gain and maintain a suitable compression on a patient's extremity.

- A few users initially said they didn't like using the product but interestingly, grew to like it and recognised its infection prevention benefits quite quickly. We noticed that this phenomena was related to the type of tourniquet they were already using.

- Users reported that Tournistrips® were held in place very securely, and yet despite this, repositioning the device was reported as easy by all reviewers.

- No problems were reported with application and removal of the device.

- Users reported that the Tournistrip® was comfortable whilst insitu in the vast majority of circumstances. Where the tourniquet was required to be especially tight, a few users noted some slight patient discomfort. How this compares to other disposable tourniquets is unknown and possibly warrants some further enquiry.

- The tourniquet was able to be applied with very little, and sometimes no touching of the patient's skin directly.

  Users considered the novel single use design to be advantageous in preventing cross infection.

5.0 Overall Summary

The Tournistrip® promotes asepsis of Key-Parts and Key-Sites:

- Facilitation of effective Key-Site and Key-Part protection by limiting the potential number of microorganisms on the patients' skin commonly associated with medical devices inappropriately reused. Non-disposable or reusable tourniquets have been associated with increased risk of microbial contamination (Kane 2011, Hassan 2012).

- By design, the packaging of the device protects the tourniquet from contamination during storage.

- The single unit dispenser design of the packaging box is simple but seems likely to be effective when compared with the storage and presentation of other tourniquets.

- Supports non-touch technique; e.g. it is possible to apply the device without the need to touch the patient's skin during the attachment or repositioning process.

- Promotion of genuine single use; e.g. whilst the device is easily repositioned during a procedure it is impractical to re-use the device on a subsequent patient. This is a unique selling point.

6.0 Conclusion

Tournistrip® is evaluated to be a medical device designed to help promote efficient and safe aseptic technique. The packaging and single unit dispenser design helps protects unused devices from contamination. The simple application and good fixation of the device promotes uninterrupted aseptic technique. Tournistrip® design virtually guarantees a single-use utilisation only.

7.0 Recommendations

All the recommendations below relate to marketing materials supplied by ASep Healthcare and the above practical evaluation. Most of the recommendations below aim to better explain, in product literature, how the product is best utilised in aseptic technique. This is rarely done well, and doing this well is likely to reflect well on the product and its manufacturer.

1. The-ASAP recommends that instructional and educational materials should highlight the critical importance of basic infective precautions prior to and during common device use and / or manipulation.

2. The ANTT® originated clinical practice language of 'Key-Part' protection (originated as both concept and method of teaching and articulating aseptic technique) is, as far as practicable, used in practice and the

literature throughout. It is advised that incorporating Key-Part, Key-Part Protection and other ANTT® terminology into marketing and instruction material will help to promote safe aseptic technique by aligning ASep Healthcare generally, and Tournistrip® specifically, with the most common international standard for aseptic technique (ANTT).

3. Regarding non-touch technique (NTT), instructional and technical data sheet(s) should 'spell out' its importance and specifically how it is performed using this product; e.g. the product can be applied without the HCW directly touching the skin.

4. Marketing and instructional materials should state how the product supports and is utilised in Standard & Surgical-ANTT.

5. Instructional and technical materials should explain how aseptic field management and how the product is handled and manipulated using Standard & Surgical-ANTT. The-ASAP is happy to advise further on these issues.

6. Marketing materials should better highlight the unique practice and selling points of Tournistrip® regards infection prevention. Namely, the dispenser design of the packaging box and the guaranteed by design single utilisation of the product.

8.0 Disclaimer/Limitations

This PEP is based on a structured but informal appraisal of the product literature, medical literature, user feedback; consideration of the products design and usage with regards aseptic technique and synergy with ANTT® principles. This evaluation is provided in good faith without any representations or warranties express or implied. The-ASAP and ANTT® assume, accept or imply no liability, responsibility or accountability for any clinical failures or other problems indirectly or directly related to the ASep Healthcare and Tournistrip®.

9.0 References

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