NHS
Business Services Authority

# Clinical review

## Syringes – hypodermic luer slip

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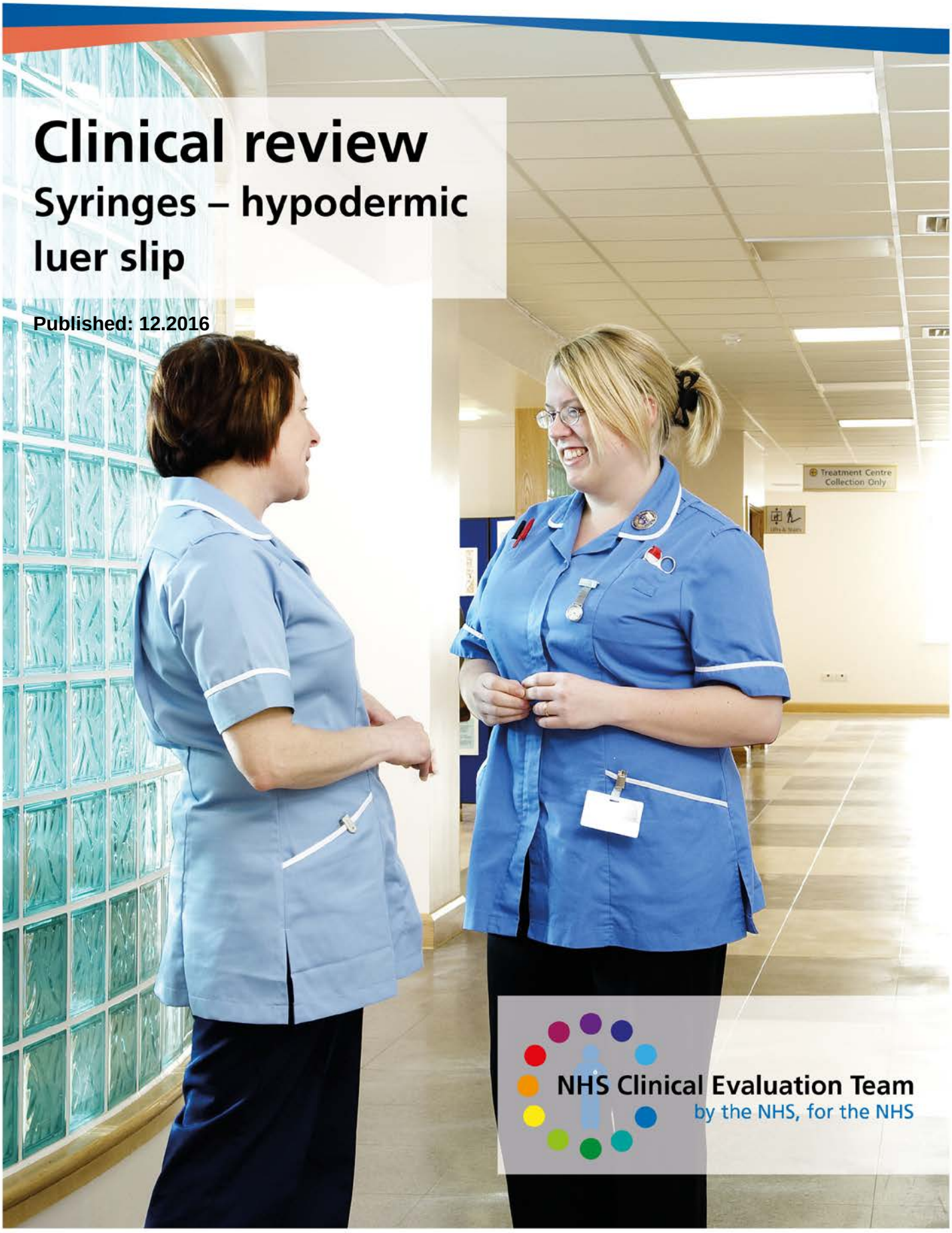


NHS Clinical Evaluation Team
by the NHS, for the NHS

## Contents



### Guidance for use

This clinical evaluation report is aimed primarily at the NHS and all those working to support patient care. If you would like to talk through how this report can be used in your setting, please contact the team by emailing: clinical.evaluation@nhs.net

Please note that the product assessment results should only be read and used in conjunction with the full text of this clinical review.

## Introduction

The NHS Clinical Evaluation Team was established in April 2016. The team's remit is to add independent clinical review to 'everyday healthcare consumables' used by the NHS.

Everyday healthcare consumables are products that are found in the majority of wards, clinics, health centres, treatment rooms and district nurses' bags across the NHS. The purpose of this report is two-fold; firstly to provide a clinical assessment of the usability and requirements from the NHS for hypodermic luer slip syringes that are available to the NHS from the national procurement provider. Secondly, to provide a clinical statement of desired functions and properties that the clinicians in the NHS require of hypodermic luer slip syringes for use in future procurement activities.

It is clear from the evidence that hypodermic luer slip syringes featured in this report are everyday healthcare consumables that are found in most clinics or ward settings and would certainly be items included in any stock list to set up a new clinical service. On that basis, the project was approved by the Clinical Reference Board in June 2016, culminating in the production of this report for their approval in November 2016.

Based on 2015 data supplied by NHS Supply Chain, in the NHS, 290 different Trusts are using over 150 million luer slip syringes annually with total spends approaching £8million. There are 42 different product codes in the category supplied via 4 different suppliers. The presentation of syringes is either in 2 or 3 piece designs, however 2 piece syringes represents less than 2% of total usage across the NHS and so this report covers the range of 3 piece luer slip syringes available as at August 2016. This accounts for 33 product codes and a range of sizes from 1ml-60ml.

Intelligence was gathered from a variety of sources to provide background information on the current evidence available to support the way in which the devices are designed and clinically evaluated.

Following this, clinical engagement sessions were held with the aim of identifying important clinical criteria from frontline NHS clinicians. This information was used to develop clinical criteria against which all brands available from the national procurement provider were reviewed.

Findings from these clinical reviews are collated into a series of product assessment reports to allow users to identify products and see how they rated against the agreed clinical criteria.

A more detailed description of the team and our pathway approach can be found in the NHS Clinical Evaluation Team operating manual which can be found on our website at: www.nhsbsa.nhs.uk/cet.

## Clinical review

## Clinical definition and scope

Hypodermic luer slip single use syringes have been used extensively in the NHS for many years and have been in use in healthcare since the late 1960s.

A luer slip syringe is used for general purpose injection or bolus infusion via IV access and aspiration of fluids from vials, ampoules and parts of the body below the surface of the skin and allows for a push fit of a luer compatible needle to the tip.

A luer slip syringe is supplied with either a concentric or eccentric tip; this refers to the location of the tip in relation to the body of the syringe. A concentric syringe has the tip located centrally and an eccentric syringe tip is offset towards the edge of the body.

This report has only reviewed luer slip syringes and has excluded luer lock which allows fixation by screw fitting along with catheter tip and insulin syringes which are also excluded.

Suppliers were invited to submit relevant evidence, product information and testing data to help support the review where necessary.

## Intended clinical use

The intended use of a hypodermic luer slip syringe is for parenteral administration of small solutions either through subcutaneous, intramuscular or intravenous bolus infusion (Bouwman, 2015).

A luer lock syringe allows fixation by screw and thus is a more secure fixation. Luer lock syringes are more commonly used for extended IV infusion using a syringe pump or in areas such as chemotherapy infusion where a secure connection is essential (Dougherty et al, 2015).

Professional guidance and a literature review have been completed as part of the review to support the development of criteria along with establishing best practice standards to compare against.

## Product technical design

A sterile, disposable, three-piece luer slip syringe consists of a polypropylene barrel and piston, polyisoprene stopper and a tip. The inner surface of the barrel is siliconised to allow for smooth movement of the plunger. The tip design indicates the type of syringe.

The design and development of hypodermic luer slip syringes are governed by a number of ISO standards including EN ISO 7886-1:1997 Sterile Hypodermic Syringes for Single Use and EN ISO 594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. All suppliers to the NHS in England are required to meet these standards.

Syringes are supplied with a concentric and eccentric tip with the requirement of the ISO standard that up to 5ml is concentric and greater than 5ml either concentric or eccentrically. These standards govern a number of design requirements for labelling, graduation, plunger and clinical use.

## Clinical practice

The NHS clinical criteria developed for this review can be linked in part to the requirements of the ISO standards particularly EN ISO 7886-1:1997 Sterile Hypodermic Syringes for Single Use; however, the focus has been on criteria for use in clinical practice and requirements for clinicians using these products.

## Clinical impact

It is widely expected that changes in clinical practice will have an impact on how we select and use luer slip syringes, this is being driven by the need to meet both legislative requirements e.g. safer sharps, a move in IV infusion therapy to use luer lock for more secure connections and the revision of a number of ISO standards to minimise incorrect connections and this may impact on total volume in use in the future.

The choice of size of syringe is made according to the volume of medication to be administered in practice so it is important to choose the smallest syringe possible to ensure accuracy (Downie et al 2003).

A review of luer slip syringe size by volume shows a high percentage use in 2, 5, 10 and 20ml with smaller volumes in 1, 30 and 60ml.

| Volume % by Size | |
|---|---|
| Syringe Hypodermic 1ml luer slip | 0% |
| Syringe Hypodermic 2ml luer slip | 16% |
| Syringe Hypodermic 3ml luer slip | 3% |
| Syringe Hypodermic 5ml luer slip | 20% |
| Syringe Hypodermic 10ml luer slip | 42% |
| Syringe Hypodermic 20ml luer slip | 18% |
| Syringe Hypodermic 30ml luer slip | 0% |
| Syringe Hypodermic 50/60ml luer slip | 1% |
| Figure 1 Syringe volume by size - Nov 16 | |

Whilst there are no clear recommendations in the literature on when to use a luer slip vs. a luer lock syringe, the engagement with clinicians across the NHS indicates that practice is being reviewed and adapted.

# Pathway methods

## Intelligence gathering

In writing this report, account has been taken of academic and related clinical evidence and known guidance and nationally recognised publications.

All suppliers listed within the national frameworks have also been invited to submit clinically relevant evidence of their own. All suppliers provided some level of information from product brochure through to technical datasheets and compliance with standards.

Account has also been taken of appropriate International and other standards as they pertain to the devices (e.g. ISO, EN and/or BSI). A review of MHRA alerts has also been performed.

Finally the specification used by the national provider (NHS Supply Chain) has been reviewed to understand what has previously been asked of suppliers of these devices.

This evidence has then been used as a basis to help form initial ideas around suitable clinically based statements of what clinical staff require of a hypodermic luer slip syringe and how it should best perform in order to satisfy those clinical requirements.

## Literature search

A literature search was completed using the NICE Evidence services:

https://www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases

| Search criteria | Databases searched |
|---|---|
| • Hypodermic luer slip syringe<br>• Luer slip syringe | • **NICE website Evidence search https://www.evidence.nhs.uk/**<br><br>• **NICE website journals and databases https://www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases** (using Healthcare databases advanced search tool – AMED, EMBASE, HMIC, BNI, Medline, PsycInfo, CINAHL, HEALTH BUSINESS ELITE databases searched) |
| **Date Range** | **Since 1975** |
| **Language** | **English** |

The search returned two results which are summarised below:

| | |
|---|---|
| **1. Failures of luer slip syringes.**<br>**Source:** Anaesthesia; May 2007; vol. 62 (no. 5); p. 532-3; author reply 533<br>**Publication Date:** May 2007<br>**Publication Type(s):** Letter<br>**PubMedID:** 17448078<br>**Author(s):** McVey FK; Jayasheela N<br>Available in full text at Anaesthesia - from John Wiley and Sons<br>Available in full text at Anaesthesia - from Wiley Online Library Free Content NHS Collection<br>**Database:** PubMed | This was a letter to the Journal highlighting in practice usage issues with a range of syringes in 2005 when introduced in practice that they had reported to the supplier. The supplier also responded to the letter concerning its investigation & vigilance work and the matter was closed. |
| **2. Is it true that best practice for administering IV flushes/boluses is via a Luer lock syringe as opposed to a Luer slip?**<br>**Source:** Nursing times; 2009; vol. 105 (no. 39); p. 19<br>**Publication Date:** 2009 | This was a practice based question regarding the type of syringe for IV flush & bolus. The author summarised that there was no clear evidence or recommendations for this type of activity however luer slip were |

| | |
|---|---|
| **Publication Type(s):** Journal Article<br>**PubMedID:** 19863029<br>**Author(s):** Dougherty L<br>**Database:** PubMed | commonly used for subcutaneous and intramuscular injection. |

A review of the Royal Marsden manual of nursing procedures highlighted the use of luer slip syringes for subcutaneous and intramuscular injection.

The Royal College of Nursing Standards for Infusion Therapy (4th Edition, 2016) and the Journal of Infusion Nursing Infusion Therapy Standards of Practice (Jan/Feb 2016) were reviewed with no specific guidance to the use of a luer slip syringe identified.

NHS Scotland had published a good practice statement for the preparation of injections in near patient areas, including clinical and home environments in 2002. This highlighted a number of practice statements regarding protection of sterility to syringes prior to use. It stated that clinical staff should peel wrappers from needles and syringes – do not push through wrappers as this will result in heavy particulate contamination.

A search of the NHS Central Alerting System (CAS) returned 27 results for the keyword syringe but none were related to the specific use of luer slip syringes.

## National procurement provider specification

Hypodermic luer slip syringes are available in a range of sizes from 1ml-50/60ml with main volume usage in 2ml, 5ml, 10ml and 20ml.

The current National procurement provider's (NHS Supply Chain) framework specification allows for suppliers to submit either a 2-piece or 3 piece luer slip design for consideration and at present two suppliers provide a 2-piece syringe to the NHS. 2-Piece syringes consist of a barrel and plunger and use an alternative lubricant usually of fatty acid amides to help with plunger movement. Volumes of 2-piece syringe usage are low in the NHS with it accounting for less than 2% of the national volume. We were unable to identify through the literature or clinical engagement a reason to use 2-piece or 3 piece syringes but on the basis of NHS consumption we have excluded 2-piece syringes from this report and these will be reviewed separately if required.

### Product suppliers and manufacturers

Request for information were sent to all suppliers on framework.  All suppliers provided some level of information from product brochure through to technical datasheets and compliance with standards.

### Best practice guidelines

The existing specification was reviewed to confirm the regulatory and technical requirements that suppliers are required to meet as part of the specification and confirmation from the national provider that these were in place.

We could not identify any particular recommendations for use of concentric or eccentric tip other than this was different by supplier but in line with the required standard.
This along with information from a number of sources was gathered to provide a basis for clinical discussions about the use of luer slip syringes with the NHS.

## NHS clinical engagement

In order to develop a shared vision of what a hypodermic luer slip syringe should offer, several methods of engagement were used.

There are several stages to the clinical engagement process starting with a mapping exercise to determine who should be involved. For our purposes in this stage of the report we focused on clinical staff who are either a) recognised as subject experts, and / or b) recognised regular users of the devices in their clinical practice.

These are some of the approaches we have used:

- regional and national face-to-face events with NHS clinical colleagues
- focussed visits to NHS clinicians regional and national face to face events
- website subscription
- attendance at specialist network events
- attendance at NHS Business Services Authority events
- web based surveys and e-engagement tools (e.g. email, WebEx, portal based surveys)

To build a broad caucus of attendees at our events communications were distributed inviting Trusts to nominate clinical colleagues to attend a series of regional group events; these were hosted by NHS organisations around England to enable the widest possible access. This enabled any pre-existing regional variance to be set aside.

Details of the information gathered were recorded in booklet form from the open events, transcribed and then used together with the evidence gathered at the previous project stage to inform a list of clinical criteria against which the product has been tested.

The questions used to stimulate discussion and further information gathering were developed following a questionnaire sent to the clinical procurement specialist network which represents nurses and other clinicians working in procurement roles at NHS Trusts, regional procurement hubs and NHS Supply Chain.

Examples of the evidence gathering criteria questions posed for hypodermic luer slip syringes are shown in the table below. NHS clinician colleagues were also asked to score the importance of each criteria, with 0 as having no important and 10 as having critical importance.

| Syringes Hypodermic Luer Slip Criteria / questions |
|---|
| Any specific packaging requirements for this product? |
| Any specific issues with how we open and prepare this product for clinical use? |
| How important are the markings and grading? |
| How important is it that you can still attach a label, whilst still seeing the markings? |
| How important is a smooth plunger action? |
| How important is it that you can be confident in the accuracy of dosing? |
| How important is it that you can attach a range of needles safely and securely? |
| How important is secure universal fitting with needle-free access devices? |
| How important is the feel, shape and size of the wings and plunger top to enable accurate single handed use? |
| How important is it that you can operate the syringe with a gloved hand? |
| Does/would a ridged or textured plunger top make a difference? |
| Does/would a slightly indented plunger top make a difference? |
| Any specific disposal criteria for this product? |
| What would make a “perfect” product if you could design your own based on your clinical experience and knowledge?<br><br>What features would it have? |

**Figure 2 - Examples of the evidence gathering criteria questions posed for Hypodermic Luer Slip Syringes**

## Clinical criteria

The data received from all the NHS clinical engagement events, alongside the data collected from individual experts, was assimilated into a series of clinical criteria. A clinical criterion is defined as a principle or standard by which products may be evaluated. It is an objective statement which describes the clinician's requirements for the product.

The synthesised criteria were then validated by clinical engagement workshop attendees and clinical experts as likely to produce useful outcomes.

| CLINICAL CRITERIA – Syringes hypodermic luer slip |
|---|
| **Packaging** |
| The product type, size, lot number and expiry date is simple for staff to identify on the external packaging |
| The external packaging is of a robust construction for storage and simple to access for removal of products |
| The product type, size, lot number and expiry date is simple to identify on the syringe wrapper |
| The syringe wrapper should give a clear indication of how to open |
| **Opening and Preparation for Clinical Use** |
| The syringe can be opened quickly whilst protecting any sterility requirements |
| **Clinical Use** |
| The volume numbers and measured graduation lines are clear, visible and easy to read for clinical staff |
| There is space to apply a drug label in certain clinical situations without compromising the visibility of graduations - This will only be a criteria for 2ml/5ml/10ml/20ml sizes in Luer Slip |
| The design should enable staff to use the syringe with a one-handed technique |
| The syringe should easily draw up and dispense a range of solutions commonly used in clinical practice |
| The syringe should accept a range of hypodermic, blunt and filter drawing up needles |
| The plunger should not easily be accidentally removed when drawing up a solution |
| The handling and use of the syringe should not be affected by wearing of medical gloves |
| **Disposal after use** |
| A range of hypodermic, filter & blunt drawing up needles that are secured to a luer slip syringe can be removed safely using a sharps container needle remover lid. |

Figure 3 – NHS Clinical Criteria Luer Slip Syringes October 2016

## Product evaluation

Evaluation methodologies are defined for each and every clinical criteria. They reflect a simulated clinical environment.

All products were supplied in a 'ward ready' unit of issue as would be found by clinical staff on accessing a store area in their clinical environment. The tests were formulated to move through the key aspects of product use using the NHS Clinical Evaluation Team product cycle:

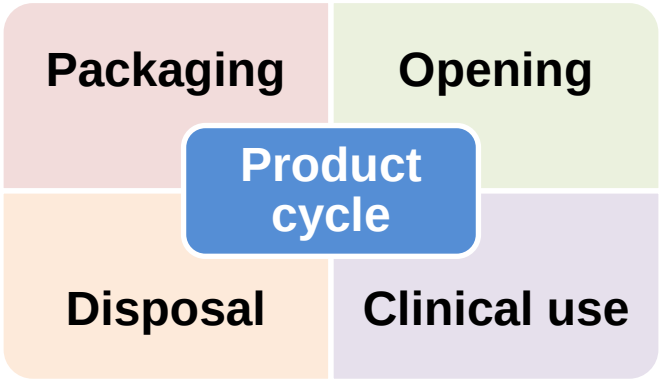


Figure 4 – NHS Clinical Evaluation Team product cycle

The evaluation product was ordered and picked from NHS distribution centres so we were reviewing lot numbers in use across the NHS. Products evaluated have been stored post evaluation for a period of three months after publication of this review.

Practicing NHS clinical staff were invited to review NHS Supply Chain product in accordance with the developed criteria. It was not possible to "blind" the evaluations; however the product to be evaluated was independently picked and prepared for evaluation by colleagues who were not otherwise involved in the process.

**Each clinical evaluator entered data independently and without inter-rater comparison into their own workbook. These were then collated, reviewed and summarised by the clinical specialist lead for the project.**

A subjective score was given against each of the defined criteria from 0-3 as follows:

| Score | Meaning |
|---|---|
| **0** | This does not meet the criteria |
| **1** | This partially meets the criteria |
| **2** | This meets the criteria |
| **3** | This exceeds the criteria |

Figure 5 – NHS Clinical Evaluation Team scoring methods

These numerical scores across all evaluators were totalled and a mean value determined. This mean value has then been converted into a star rating against the individual compliance against the criteria (see matrix below).

The mean values convert to a start rating in accordance with the following table:

| Point scored | Star value |
|---|---|
| **0 to 0.99** | 0 star |
| **1 to 1.24** | 1 star |
| **1.25 to 1.74** | 1.5 stars |
| **1.75 to 2.24** | 2 stars |
| **2.25 to 2.74** | 2.5 stars |
| **2.75 to 3** | 3 stars |

Figure 6 – conversion of mean scores to star rating

All supplemental products used in the evaluation are in use in the NHS and available through the national catalogue (e.g. clinical waste containers, gloves, drug labels and syringes).

Evaluators were encouraged to also make comments where they felt necessary to provide rationale for their scoring and answers.

The results obtained have been validated by the team's moderation committee for consistency of scoring and interpretation. These results are presented in the product assessment results matrices below.

## Product assessment results

The below product assessment results pages show the tested clinical criteria listed vertically down the left hand side of the page with the tested device found horizontally across the top of the reports. The accompanying photographs were taken during evaluation. This is a photograph of the sample product provided for evaluation. Lot numbers were recorded and samples have been retained in storage following the completion of evaluation.

The products represented are the range of suppliers and brands available through the NHS national procurement provider's framework as of August 2016.

## Supplier Name - Terumo

| Product Code & Description | FWC531<br>Syringe Hypodermic<br>Tuberculin<br>1ml 100 Graduations at<br>0.01ml Increments Luer Slip<br>Terumo | FWC407<br>Syringe hypodermic<br>concentric luer slip<br>2 to 2.5ml<br>Terumo<br>SS02S1 | FWC102<br>Syringe hypodermic<br>concentric luer slip<br>5ml with 0.2ml graduations<br>Terumo<br>SS05S1 | FWC103<br>Syringe hypodermic<br>eccentric luer slip<br>10ml<br>Terumo<br>SS10ES1 | FWC104<br>Syringe hypodermic<br>eccentric luer slip<br>20ml<br>Terumo<br>SS20ES1 | FWC539<br>Syringe hypodermic<br>eccentric luer slip<br>30ml<br>Terumo<br>SS30ESE1 | FWC421<br>Syringe hypodermic<br>eccentric luer slip<br>50ml<br>Terumo<br>SS50ES1 |
|---|---|---|---|---|---|---|---|
| **Score** / **Meaning**<br>**0** This does not meet the criteria<br>**1** The partially meets the criteria<br>**2** This meets the criteria<br>**3** This exceeds the criteria<br>**Scoring Matrix** |  |  |  |  |  |  |  |
| **Unit of issue** | Box 100 | Box 100 | Box 100 | Box 100 | Box 50 | Box 50 | Box 25 |
| **Graduation lines measured in** | 0.01ml | 0.1ml | 0.2ml | 0.2ml | 1ml | 1ml | 1ml |

| CLINICAL CRITERIA - IV Luer Slip 3 Piece Syringes | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating |
|---|---|---|---|---|---|---|---|
| **The product type, size, lot number and expiry date is simple for staff to identify on the external packaging** | (1.8) | (1.8) | (1.8) | (1.8) | (1.8) | (1.8) | (1.8) |
| **The external packaging is of a robust construction for storage and simple to access for removal of products** | (2.0) | (1.8) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |
| **The product type, size, lot number and expiry date is simple to identify on the syringe wrapper** | (1.6) | (1.6) | (1.6) | (1.6) | (1.6) | (1.4) | (1.6) |
| **The syringe wrapper should give a clear indication of how to open** | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) |
| **The syringe can be opened quickly whilst protecting any sterility requirements** | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) |
| **The volume numbers and measured graduation lines are clear, visible and easy to read for clinical staff** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |
| **There is space to apply a drug label in certain clinical situations without compromising the visibility of graduations - This will only be a criteria for 2ml/5ml/10ml/20ml sizes in luer slip** | **Not Applicable** | (2.0) | (2.0) | (2.0) | (2.0) | **Not Applicable** | **Not Applicable** |
| **The design should enable staff to use the syringe with a one-handed technique** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |
| **The syringe should easily draw up and dispense a range of solutions commonly used in clinical practice** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |
| **The syringe should accept a range of hypodermic, blunt and filter drawing up needles** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (1.8) | (2.0) |
| **The plunger should not easily be accidentally removed when drawing up a solution** | (2.2) | (2.2) | (2.0) | (2.2) | (2.2) | (2.2) | (2.0) |
| **The handling and use of the syringe should not be affected by wearing of medical gloves** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |
| **A range of hypodermic, filter & blunt drawing up needles that are secured to a luer slip syringe can be removed safely using a sharps container needle remover lid.** | (1.6) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |

## Supplier Name - Medicina

| Product Code & Description | FWC345<br>Syringe hypodermic concentric luer slip<br>1ml<br>Medicina<br>IVS01 | FWC346<br>Syringe hypodermic concentric luer slip<br>3ml<br>Medicina<br>IVS03 | FWC347<br>Syringe hypodermic concentric luer slip<br>5ml<br>Medicina<br>IVS05 | FWC348<br>Syringe hypodermic concentric luer slip<br>10ml<br>Medicina<br>IVS10 | FWC409<br>Syringe hypodermic eccentric luer slip<br>10ml with eccentric tip<br>Medicina Ltd<br>IVS10E | FWC349<br>Syringe hypodermic eccentric luer slip<br>20ml<br>Medicina<br>IVS20 | FWC351<br>Syringe hypodermic eccentric luer slip<br>30ml<br>Medicina<br>IVS30 | FWC436<br>Syringe Hypodermic Eccentric Luer Slip<br>60ml<br>Medicina<br>IVS60 |
|---|---|---|---|---|---|---|---|---|
| |  |  |  |  |  |  |  |  |
| **Unit of issue** | Box 100 | Box 100 | Box 100 | Box 100 | Box 100 | Box 50 | Box 30 | Box 30 |
| **Graduation lines measured in** | 0.01ml | 0.1ml | 0.2ml | 0.2ml | 0.2ml | 1ml | 1ml | 1ml |

| Score | Meaning |
|---|---|
| 0 | This does not meet the criteria |
| 1 | The partially meets the criteria |
| 2 | This meets the criteria |
| 3 | This exceeds the criteria |

**NHS CET Scoring Matrix**

| CLINICAL CRITERIA - IV Luer Slip 3 Piece Syringes | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating |
|---|---|---|---|---|---|---|---|---|
| **The product type, size, lot number and expiry date is simple for staff to identify on the external packaging** | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) | (2.2) |
| **The external packaging is of a robust construction for storage and simple to access for removal of products** | (2.4) | (2.4) | (2.4) | (2.4) | (2.4) | (2.4) | (2.2) | (2.4) |
| **The product type, size, lot number and expiry date is simple to identify on the syringe wrapper** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |
| **The syringe wrapper should give a clear indication of how to open**** | ** | ** | ** | ** | ** | ** | ** | ** |
| **The syringe can be opened quickly whilst protecting any sterility requirements**** | ** | ** | ** | ** | ** | ** | ** | ** |
| **The volume numbers and measured graduation lines are clear, visible and easy to read for clinical staff** | (1.4) | (2.0) | (2.0) | (1.8) | (2.0) | (2.0) | (2.0) | (2.0) |
| **There is space to apply a drug label in certain clinical situations without compromising the visibility of graduations - This will only be a criteria for 2ml/5ml/10ml/20ml sizes in luer slip** | **Not applicable** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | **Not applicable** | **Not applicable** |
| **The design should enable staff to use the syringe with a one-handed technique** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (1.8) |
| **The syringe should easily draw up and dispense a range of solutions commonly used in clinical practice** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |
| **The syringe should accept a range of hypodermic, blunt and filter drawing up needles** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |
| **The plunger should not easily be accidentally removed when drawing up a solution** | (1.8) | (2.0) | (1.8) | (1.8) | (1.8) | (1.8) | (1.8) | (1.8) |
| **The handling and use of the syringe should not be affected by wearing of medical gloves** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |
| **A range of hypodermic, filter & blunt drawing up needles that are secured to a luer slip syringe can be removed safely using a sharps container needle remover lid.** | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) | (2.0) |

**** Awaiting updated packaging for review**

## Supplier Name - BD Emerald

| Product Code & Description | FWC253<br>Syringe hypodermic general purpose<br>2ml luer slip concentric 3-piece<br>BD Emerald<br>307727 | FWC254<br>Syringe hypodermic general purpose<br>5ml luer slip concentric 3-piece<br>BD Emerald<br>307731 | FWC255<br>Syringe hypodermic general purpose<br>10ml luer slip concentric 3-piece<br>BD Emerald<br>307736 |
|---|---|---|---|
| |  |  |  |
| **Unit of issue** | Box 100 | Box 100 | Box 100 |
| **Graduation lines measured in** | 0.1ml | 0.2ml | 0.2ml |

| Score | Meaning |
|---|---|
| 0 | This does not meet the criteria |
| 1 | The partially meets the criteria |
| 2 | This meets the criteria |
| 3 | This exceeds the criteria |

**NHS CET Scoring Matrix**

| CLINICAL CRITERIA - IV Luer Slip 3 Piece Syringes | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating |
|---|---|---|---|
| **The product type, size, lot number and expiry date is simple for staff to identify on the external packaging** | (1.8) | (1.8) | (1.8) |
| **The external packaging is of a robust construction for storage and simple to access for removal of products** | (1.6) | (1.6) | (1.6) |
| **The product type, size, lot number and expiry date is simple to identify on the syringe wrapper** | (2.0) | (2.0) | (2.0) |
| **The syringe wrapper should give a clear indication of how to open** | (1.2) | (1.2) | (1.2) |
| **The syringe can be opened quickly whilst protecting any sterility requirements** | (1.8) | (2.0) | (2.0) |
| **The volume numbers and measured graduation lines are clear, visible and easy to read for clinical staff** | (2.0) | (2.0) | (2.0) |
| **There is space to apply a drug label in certain clinical situations without compromising the visibility of graduations - This will only be a criteria for 2ml/5ml/10ml/20ml sizes in luer slip** | (2.0) | (2.0) | (2.0) |
| **The design should enable staff to use the syringe with a one-handed technique** | (2.0) | (2.0) | (2.0) |
| **The syringe should easily draw up and dispense a range of solutions commonly used in clinical practice** | (2.0) | (2.0) | (2.0) |
| **The syringe should accept a range of hypodermic, blunt and filter drawing up needles** | (2.0) | (2.0) | (2.0) |
| **The plunger should not easily be accidentally removed when drawing up a solution** | (2.4) | (2.0) | (1.8) |
| **The handling and use of the syringe should not be affected by wearing of medical gloves** | (2.0) | (2.0) | (2.0) |
| **A range of hypodermic, filter & blunt drawing up needles that are secured to a luer slip syringe can be removed safely using a sharps container needle remover lid.** | (2.0) | (2.0) | (2.0) |

## Supplier Name - BD Plastipak

| Product Code & Description | FWC429<br>Syringe Hypodermic<br>Tuberculin Luer Slip<br>1ml 100 Graduations at<br>0.01ml Increments<br>BD Plastipak<br>303172 | FWC000<br>Syringe hypodermic<br>concentric luer slip<br>2ml<br>BD Plastipak<br>300185 | FWC306<br>Syringe hypodermic<br>concentric luer slip<br>5ml<br>BD Plastipak<br>302187 | FWC128<br>Syringe hypodermic<br>eccentric luer slip<br>10ml<br>BD Plastipak<br>302188 | FWC021<br>Syringe hypodermic<br>eccentric luer slip<br>20ml<br>BD Plastipak<br>300613 | FWC067<br>Syringe hypodermic<br>eccentric luer slip<br>30ml<br>BD Plastipak<br>301231 | FWC035<br>Syringe hypodermic<br>eccentric luer slip<br>50ml<br>BD Plastipak<br>300866 |
|---|---|---|---|---|---|---|---|
| |  |  |  |  |  |  |  |
| **Unit of issue** | Box 120 | Box 100 | Box 100 | Box 100 | Box 120 | Box 60 | Box 60 |
| **Graduation lines measured in** | 0.01ml | 0.1ml | 0.2ml | 0.5ml | 1ml | 1ml | 1ml |

| Score | Meaning |
|---|---|
| 0 | This does not meet the criteria |
| 1 | The partially meets the criteria |
| 2 | This meets the criteria |
| 3 | This exceeds the criteria |

**NHS CET Scoring Matrix**

| CLINICAL CRITERIA - IV Luer Slip 3 Piece Syringes | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating |
|---|---|---|---|---|---|---|---|
| **The product type, size, lot number and expiry date is simple for staff to identify on the external packaging** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **The external packaging is of a robust construction for storage and simple to access for removal of products** | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.2) |
| **The product type, size, lot number and expiry date is simple to identify on the syringe wrapper** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (1.8) | ★★☆ (1.8) | ★★☆ (1.8) | ★★☆ (1.8) | ★★☆ (1.8) |
| **The syringe wrapper should give a clear indication of how to open** | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) |
| **The syringe can be opened quickly whilst protecting any sterility requirements** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **The volume numbers and measured graduation lines are clear, visible and easy to read for clinical staff** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **There is space to apply a drug label in certain clinical situations without compromising the visibility of graduations - This will only be a criteria for 2ml/5ml/10ml/20ml sizes in luer slip** | **Not Applicable** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | **Not Applicable** | **Not Applicable** |
| **The design should enable staff to use the syringe with a one-handed technique** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **The syringe should easily draw up and dispense a range of solutions commonly used in clinical practice** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **The syringe should accept a range of hypodermic, blunt and filter drawing up needles** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **The plunger should not easily be accidentally removed when drawing up a solution** | ★★☆ (1.8) | ★★☆ (2.0) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.0) |
| **The handling and use of the syringe should not be affected by wearing of medical gloves** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **A range of hypodermic, filter & blunt drawing up needles that are secured to a luer slip syringe can be removed safely using a sharps container needle remover lid.** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |

## Supplier Name -Bbraun Omnifix

| Product Code & Description | FWC075<br>Syringe Hypodermic Tuberculin<br>1ml 100 Graduations at 0.01 ml Increments<br>B Braun Omnifix<br>9161406V | FWC403<br>Syringe hypodermic concentric luer slip<br>2ml<br>B Braun Omnifix<br>4616022V | FWC189<br>Syringe hypodermic concentric luer slip<br>2 - 3ml<br>B Braun Omnifix<br>4616025V | FWC283<br>Syringe hypodermic eccentric luer slip<br>5ml<br>B Braun Omnifix<br>4616057V | FWC068<br>Syringe hypodermic eccentric luer slip<br>10ml<br>B Braun Omnifix<br>4616103V | FWC975<br>Syringe hypodermic eccentric luer slip<br>20ml<br>B Braun Omnifix<br>4616200V | FWC230<br>Syringe hypodermic eccentric luer slip<br>30ml<br>B Braun Omnifix<br>4616308F | FWC517<br>Syringe hypodermic eccentric luer slip<br>50/60ml luer slip<br>B Braun Omnifix<br>4616502F |
|---|---|---|---|---|---|---|---|---|
| |  |  |  |  |  |  |  |  |
| **Unit of issue** | Box 100 | Box 100 | Box 100 | Box 100 | Box 100 | Box 100 | Box 100 | Box 100 |
| **Graduation lines measured in** | 0.01ml | 0.1ml | 0.1ml | 0.2ml | 0.5ml | 1ml | 1ml | 1ml |

| Score | Meaning |
|---|---|
| 0 | This does not meet the criteria |
| 1 | The partially meets the criteria |
| 2 | This meets the criteria |
| 3 | This exceeds the criteria |

**NHS CET Scoring Matrix**

| CLINICAL CRITERIA - IV Luer Slip 3 Piece Syringes | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating | CET Evaluation Rating |
|---|---|---|---|---|---|---|---|---|
| **The product type, size, lot number and expiry date is simple for staff to identify on the external packaging** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (1.8) |
| **The external packaging is of a robust construction for storage and simple to access for removal of products** | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (2.0) | ★★☆ (1.8) | ★★☆ (1.8) | ★★☆ (1.8) |
| **The product type, size, lot number and expiry date is simple to identify on the syringe wrapper** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (1.8) | ★★☆ (1.8) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **The syringe wrapper should give a clear indication of how to open** | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) | ★☆☆ (1.2) |
| **The syringe can be opened quickly whilst protecting any sterility requirements** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (1.8) |
| **The volume numbers and measured graduation lines are clear, visible and easy to read for clinical staff** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **There is space to apply a drug label in certain clinical situations without compromising the visibility of graduations - This will only be a criteria for 2ml/5ml/10ml/20ml sizes in luer slip** | **Not applicable** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | **Not applicable** | **Not applicable** |
| **The design should enable staff to use the syringe with a one-handed technique** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (1.8) | ★★☆ (1.8) | ★★☆ (1.8) |
| **The syringe should easily draw up and dispense a range of solutions commonly used in clinical practice** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★½☆ (1.4) | ★½☆ (1.4) | ★★☆ (2.0) |
| **The syringe should accept a range of hypodermic, blunt and filter drawing up needles** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **The plunger should not easily be accidentally removed when drawing up a solution** | ★★☆ (1.8) | ★★☆ (2.0) | ★★☆ (2.2) | ★★☆ (2.2) | ★★☆ (1.8) | ★★☆ (2.2) | ★★☆ (1.8) | ★★☆ (2.0) |
| **The handling and use of the syringe should not be affected by wearing of medical gloves** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |
| **A range of hypodermic, filter & blunt drawing up needles that are secured to a luer slip syringe can be removed safely using a sharps container needle remover lid.** | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) | ★★☆ (2.0) |

## Further considerations and recommendations for the future

The review of hypodermic luer slip syringes has enabled the NHS to develop and test new clinical criteria for the requirements of a product in clinical use.

The developed criteria have demonstrated the importance of packaging both in external boxes and internal wrappers and the need for clinical staff to quickly be able to identify the key attributes of the product.

The indication of how to open syringe wrappers scored lower across the majority of suppliers and this may want to be considered by industry in future packaging design. NHS teams have clearly indicated that future design of syringes should continue to enhance the clarity of graduation markings and measurements.

The evaluation team have found that much of the criteria identified by NHS clinical staff is covered to some degree in the ISO standards associated with the product and it is recommended that we should make these requirements more visible and accessible to NHS staff so that they can understand how quality and safety is built into medical device development and manufacture.

Overall this evaluation has shown the majority of criteria identified met the minimum standards and products could be considered similar in practice; however we would recommend for safety and consistency in practice that the mixing of brands at different sizes should be minimised where possible and standardised across an organisation unless clinical exceptions are required.

Based on the intended use of a luer slip syringe we have not identified these exceptions at a national level. However, there may still need to be a requirement for local NHS organisations to provide any examples of exceptions which can feed into future evaluation/specification development.

## References

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Bouwman Y, Le Brun P. Practical Pharmaceutics: An International Guideline for the Preparation, Care and Use of Medicinal Products. United Kingdom: Springer; 2015.

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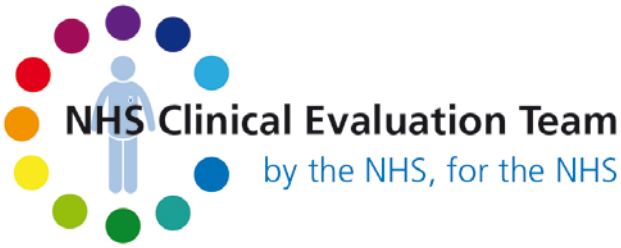


**‘Quality, safety and value are at the heart of our work and it’s important that we use our clinical experience to deliver high standards of care while reducing cost and waste in the NHS.’**

Mandie Sunderland
Chair, Clinical Reference Board
(Governing body of the NHS Clinical Evaluation Team)