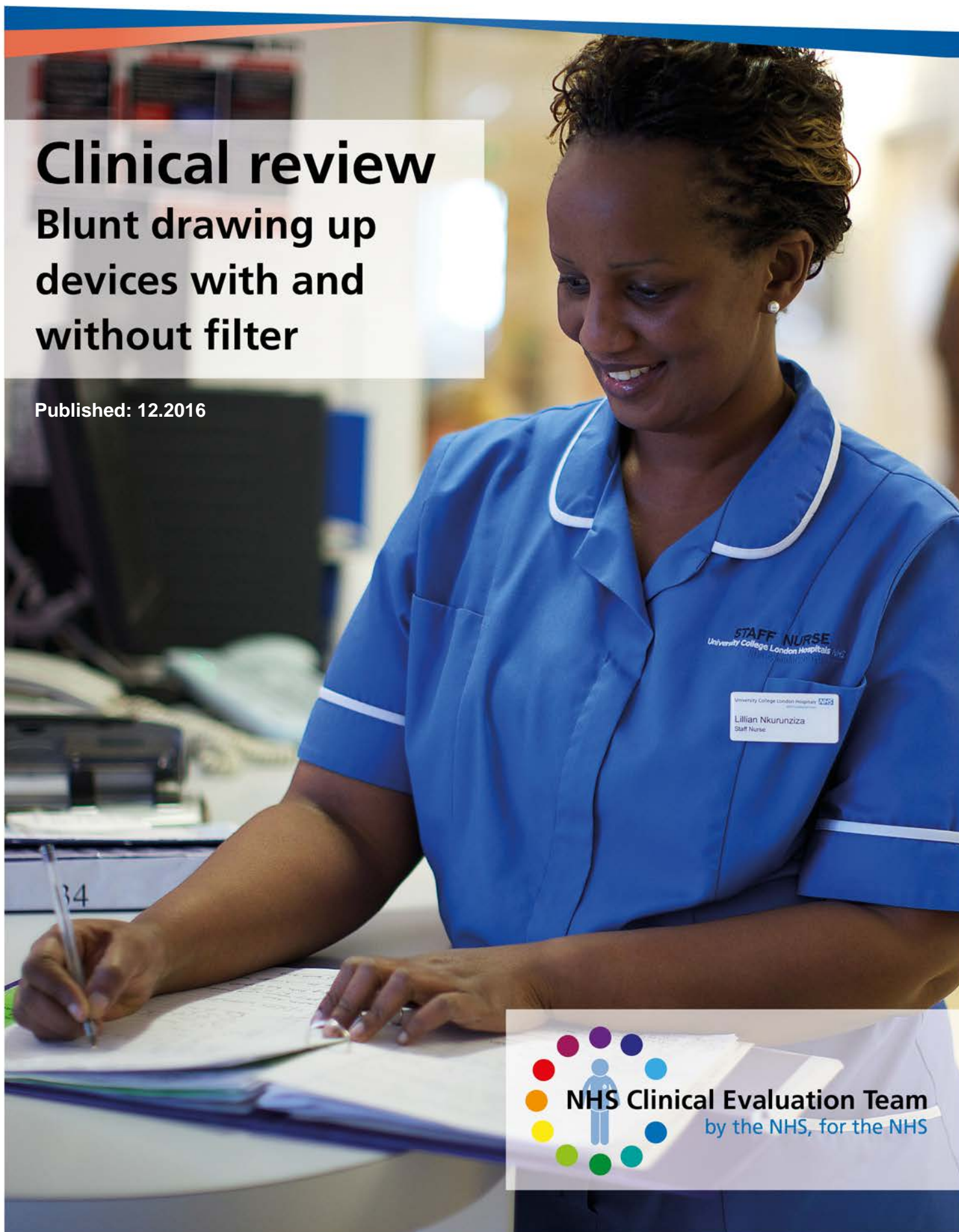


Clinical review

Blunt drawing up devices with and without filter

Published: 12.2016



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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 nurse's 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 the blunt drawing up devices (with or without an in-hub filter) that are available to the NHS from the national procurement provider. Secondly, to provide a clinical statement of desired functions and properties that the NHS requires of blunt drawing up devices for use in future procurement activities.

It is clear from the evidence that blunt drawing-up devices, 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, 251 different Trusts are using 56 million blunt drawing up devices annually with a total spends approaching £7 million. There are 20 different national product codes in the category supplied via 8 different suppliers. This report covers the range of products available as at August 2016.

Intelligence about blunt drawing up devices 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 for blunt drawing up devices from front line NHS clinicians. This information was used to develop clinical criteria for blunt drawing up devices, against which all brands available from the national procurement provider were reviewed.

Findings from these clinical reviews are collated into a product assessment report to allow users to identify products and see how they performed 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

The title for this project has been given some thought; it captures devices referred to by such terms as blunt fill needles, blunt filter needles, blunt needles, blunt plastic cannula, safety filter needles, blunt mixing needles, med prep cannula and needle-free drawing up devices. It was felt that the term blunt drawing up devices (with and without in-hub filters) was a suitable “catch-all” and goes someway to describing the intended use of the devices in the clinical world. In this report the use of the term “blunt drawing up device(s)” is taken to infer with and/or without an in-hub filter unless specific reference is made to one or the other.

It will be apparent to readers that there are also sharp needles and other sharp devices (with and without filters) that can be used for similar purposes to the intended use of the blunt devices reported on herein. Given that specific UK legislation exists to protect healthcare workers from avoidable needlestick injuries this report specifically excludes these sharp analogues as they are deemed out of scope.

Intended clinical use

A blunt drawing up device is intended for use in conjunction with a syringe as a device for the aspiration (drawing up) of drugs or sterile mixing fluid, from a single or multi-dose medicine storage vial or ampoule for further preparation and /or onward injection into a patient’s intravenous system or to be injected via a hypodermic needle directly into a patient via intramuscular or other route of injection. They are single use devices and are provided in sterile (within their final packaging) form for use in the clinical area. They are not for use in direct patient injections.

There are two presentations of blunt drawing up devices. Without a filter they are intended for use with ampoules which are protected for access purposes by a rubber (or similar) bung; with a filter in-hub they are intended for use in drawing up from medicine vials that do not have such a bung e.g. an all glass vial where the glass top is snapped off in order to access the drug contained therein.

It is recognised from literature review and from conversation with clinical colleagues that the blunt drawing up devices under consideration are also used for other purposes within clinical practice (e.g. local anaesthesia; oral/dental cleaning) but these are not the device manufacturers stated intended use and therefore fall outside the scope of this report in terms of the final evaluation against the clinical criteria being developed and subsequent reporting.



Product technical design

Blunt drawing up devices are presented in a range of styles, some made entirely of rigid, moulded plastic but with most being similar in design to hypodermic needles (Luer tapered hub with needle shaft bonded to this). Unlike a hypodermic needle the needle shaft is not cut, bevelled, sharpened and polished. It is generally held that the force required to pierce a surface with a blunt drawing up device is between 9 and 10 times that which would be required by a hypodermic needle; for the sake of interest, this was first developed and assessed for appropriateness using reindeer hide as the test medium. The principle size seen within NHS settings is an 18 gauge device of 40mm needle length however 16, 19 and 20 gauge are also marketed and both shorter and longer lengths exist.

The in-hub filter contained within the body of some blunt drawing up devices is a 5 micron filter as supplier testing demonstrates this to be adequate for removal of the glass particles that they are principally designed to remove from medication as it is prepared for use.

Clinical practice

It is widely expected that changes in clinical practice, principally driven by the legislative paradigm surrounding the reduction of sharps injuries in UK healthcare [*the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013*] and stricter enforcement and inspection regimes which are being experienced by Trusts from the Health and Safety Executive, will see these volumes of blunt drawing up devices increase at the expense of the previously used wider gauge hypodermic needles. Certainly, anecdotal evidence supports this contention as shown by increasing numbers of enquiries about blunt drawing up devices experienced within clinical forum such as the Clinical Procurement Specialists Network.



Clinical impact

The clinical impact of this work will be to allow clinical staff faced with the legislative and compliance pressures described as well as improved understanding of good clinical practice around the effective and safe preparation of medicines for injection to make the necessary choices in the blunt drawing up equipment which they are increasingly required to use. The report should also enable other colleagues to understand this complex landscape in order to best support safe and effective care at the frontline. It is believed that the increased, appropriate use, of blunt drawing up devices will further serve to reduce harms associated with needlestick (sharps) injuries as sharp hypodermics usage is reduced commensurately with the uplift in usage of blunt drawing up devices.

In highlighting the value which filtered blunt drawing up devices can bring, this report will build on patient safety levels as particulate levels within the medicines administered will be significantly reduced by the increased uptake of blunt drawing up devices with in-hub filters. If this does not occur, patients will continue to have avoidable harms caused such as pain, inflammation and phlebitis (infection associated with injection and intravenous access). In severe examples emboli, disabling injury or death can occur.



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 been invited to submit clinically relevant evidence of their own; some have submitted others have not.

International and other standards as they pertain to the devices (e.g. ISO, EN and/or BSI) have been reviewed.

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 blunt drawing up device and how it should best perform in order to satisfy those identified and confirmed clinical requirements.

Literature search

Initially an evidence search was performed across the NICE service (<https://www.evidence.nhs.uk/Search?q=blunt+drawing+up+needles>). This highlighted best practice considerations in the use of blunt aspirating devices being used to draw up drugs (*Anaesthesia* 2008, 63; 1027-36). There were no returns from this search generating statements of clinical requirements in the design and supply of such a product however.

The search terms used (see below) generated many returns however, there was little new information generated. There was support to emphasise that the use of filters in-hub is useful when safely drawing up medication from all-glass ampoules and also some concerns expressed about the incidents of coring through ampoule stoppers where the device is pushed through these to access the medication within. Unfortunately the evidence was contradictory with regard to techniques to prevent incidents of coring.



Search criteria	Databases searched
<ul style="list-style-type: none"> • Blunt drawing up needles • Blunt filter needles • Blunt fill • Blunt filter • Safety needle • Blunt needle • Drawing up needle • Filter needle • Blunt hypodermic • Blunt aspirating needle • Coring (for use in filtering) • Needle(s) (for use in filtering) • Blunt (for use in filtering) 	<ul style="list-style-type: none"> • NICE website Evidence search https://www.evidence.nhs.uk/ • 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)

Figure 1 Literature and other sources searches – Blunt Drawing up devices (with and without filter)

National procurement provider specification

The specification as used by the NHS national procurement provider (NHS Supply Chain, 2016) gives little clarity around the clinical criteria required of a blunt drawing up device. It recognises that the blunt device is inherently a latent safety product and as such will support Trusts in compliance with the *Health and Safety (Sharp Instruments in Healthcare) Regulations 2013* and thus encourages suppliers to offer products that are suitable.

There is no description of what constitutes a suitable blunt drawing up device; indeed, the team found products that are sharp within the blunt category, together with unclear, poor product descriptions and evidence of incorrect sizing and descriptions within the resultant, current catalogue. There is no clear statement of what (if any) international or other standards are applicable for this type of device. All devices offered must demonstrate compliance with Medical device Directive 93/42/EEC; some suppliers certificate as a class 1 device whilst others are certificated as class 2a devices.

National and international safety and quality 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).

The Medicines & Healthcare products Regulatory Agency (MHRA) website (<https://www.gov.uk/drug-device-alerts>) returned no product alerts relating to this product category against the search terms previously described.



Product suppliers and manufacturers

Request for information were sent to all suppliers on the NHS Supply Chain framework. Some suppliers returned data whilst others have yet to do so.

Quality of evidence

In “evidence based practice in nursing & healthcare: a guide to best practice” (B.M. Melnyk & E. Fineout-Overholt; 2005; p10) the evidence hierarchy is demonstrated within the table below.

Hierarchy ranking	Description
Level 1	A systematic review of all relevant randomised controlled trials (RCT) or evidence based clinical practice guidelines based on systematic reviews of RCT evidence
Level 2	Evidence from at least one well designed RCT
Level 3	Evidence from well-designed controlled trials; non-randomised, quasi experimental
Level 4	Well-designed case-control & cohort studies
Level 5	Systematic reviews of descriptive and qualitative studies
Level 6	Evidence from a single, descriptive or qualitative study
Level 7	Evidence from the opinion of authorities and/or reports of expert committees

Figure 2 – Hierarchy ranking

The full review of evidence shows a real scarcity of high quality information. At best, evidence is seated primarily at level 7 with some arguably at level 6.



NHS clinical engagement

In order to develop a shared vision of what a blunt drawing up device 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 focussed 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 used:

- regional and national face-to-face events with NHS clinical colleagues
- focussed visits to NHS clinicians
- website subscription
- attendance at specialist network 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, 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.

NHS clinician colleagues were asked to score the importance of each criteria, with 0 as having no important and 10 as having critical importance.



Blunt drawing up devices (with filter and without filter)	
Criteria / question	
Any specific packaging requirements for this product?	
Any specific issues with how we open and prepare this product for clinical use?	
How important is that you can identify the correct product to use quickly?	
Does colour help with this?	
Have you ever found the fit between device/needle and syringe to be an issue?	
The device must pierce the membrane on a drug ampoule.	
How important is the sharpness of a blunt device for this?	
How important is it to have no coring when drawing up device is used?	
How important is it that you can expel air / fluid easily?	
How important is the effort to draw up when using a blunt drawing up device?	
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?	
What features would it have?	

Figure 3 - Examples of the evidence gathering criteria questions posed for blunt drawing-up devices.

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 to 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 – blunt drawing up devices (with or without in-hub filter)	
Packaging	
It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	
It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	
Opening and preparation for clinical use	
It must be easy to identify an unfiltered from a filtered drawing up device	
The device can easily be prepared for safe clinical use	
The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design.	
Clinical use	
In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	
In clinical use it must be easy and timely to draw up a viscous fluid/diluent	
The device must pierce bung of ampoule with appropriate effort	
Disposal after use	
The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	

Figure 4 – NHS Clinical Criteria Blunt drawing up devices; October 2016



Product evaluation

Evaluation methodologies are defined for each and every clinical criterion. 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:

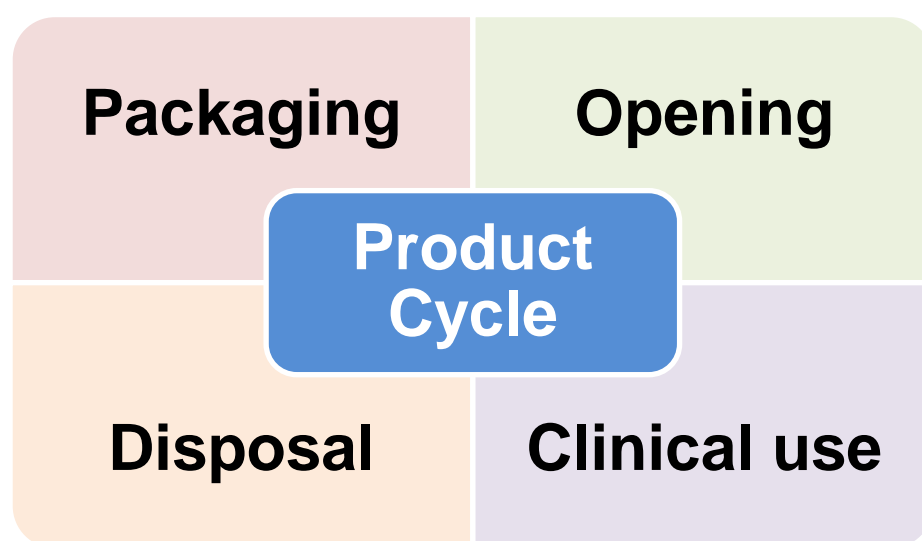


Figure 5 – NHS Clinical Evaluation Team Product Cycle

The evaluation product was ordered and picked from NHS distribution centres so we were reviewing LOT numbers in use across the NHS. Products evaluated will be 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 test” 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 below:

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 6 – NHS CET Scoring Methods

These numerical scores from all evaluators were totalled and a mean value determined. This mean value has then been converted into a star rating against the individual product compliance per each criterion (see reports below).

The mean values convert to a star 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 7 – 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 record comments where they felt necessary to provide rationale for their scoring and answers.

The results obtained have been validated by the NHS Clinical Evaluation Team moderation committee for consistency of scoring and interpretation. These results are presented in the product assessment reports herein.

























































Product assessment results

The below product assessment results summary 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 matrix. 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. They are presented here by supplier. Most suppliers offer both a filtered and not-filtered product but two do not.



There are two sets of information; the first two pages allow the reader to review similar products (i.e. products with a filter and products without a filter) against the clinical criteria. There then follow a series of supplier product pages showing the individual supplier's range and how they performed against the clinical criteria.




BLUNT DRAWING UP DEVICES - WITH FILTER		Supplier	BECTON DICKINSON	VYGON	B BRAUN MEDICAL	MEDICINA	SMITHS MEDICAL	MEDTRONIC (COVIDIEN UK)
		Brand	BD Blunt Filter	SOL-M	Sol-Care	Medicina	Jelco	Monoject
		MPC	305211	110022F	110022F	BN02	BN1815F	8881305109
		NPC	FTR436	FTR1923	FTR1986	FTR1769	FTR1930	FTR1828
NHS CET Product Assessment Cycle	Assessment criteria	Description	18g, 40mm drawing up device With 5µm filter	18g, 40mm drawing up device With 5µm filter	18g, 40mm drawing up device With 5µm filter	18g, 40mm drawing up device With 5µm filter	18g, 40mm drawing up device With 5µm filter	18g, 80mm drawing up device With 5µm filter
		Unit of issue	100	100	100	100	100	100
Packaging	It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	Scores	 (2.2)	 (1.8)	 (2.0)	 (2.0)	 (2.0)	 (1.8)
	It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	Scores	 (2.2)	 (2.0)	 (2.0)	 (2.2)	 (2.0)	 (2.0)
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	Scores	 (3.0)	 (2.6)	 (2.0)	 (2.6)	 (2.6)	 (2.4)
	The device can easily be prepared for safe clinical use	Scores	 (2.0)	 (2.2)	 (2.0)	 (1.8)	 (1.8)	 (2.0)
	The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design.	Scores	 (2.0)	 (2.0)	 (2.8)	 (2.0)	 (2.0)	 (1.8)
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	Scores	 (2.2)	 (2.2)	 (1.8)	 (2.2)	 (2.2)	 (2.2)
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	Scores	 (1.8)	 (1.8)	 (2.0)	 (2.0)	 (2.0)	 (1.0)
	The device must pierce bung of ampoule with appropriate effort	Scores	 (2.2)	 (1.6)	 (2.2)	 (2.2)	 (2.2)	 (1.8)
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	Scores	 (2.0)	 (1.6)	 (1.8)	 (2.0)	 (2.0)	 (2.0)

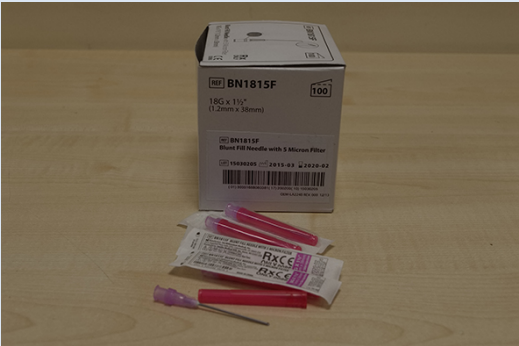

BLUNT DRAWING UP DEVICES - WITHOUT FILTER		Supplier	BECTON DICKINSON	VYGON	B BRAUN MEDICAL	MEDICINA	SMITHS MEDICAL	MEDTRONIC (COVIDIEN)		CODAN	TERUMO
		Brand	BD Blunt Fill	SOL-M	Sterican MIX	Medicina	Jelco	Monoject	Monoject	Codan	Terumo
		MPC	303129	110022	4550400-01	BN01	BN1815	8881540111	8881202355	32-18-BDUN	BN-1838
		NPC	FTR1988	FTR1922	FTR1768	FTR1770	FTR1929	FTR1830	FTR1827	FTR286	FTR285
		Description	18g, 40mm drawing up device Without filter	18g, 40mm drawing up device Without filter	18g, 40mm drawing up device Without filter	18g, 40mm drawing up device Without filter	18g, 40mm drawing up device Without filter	16g, 14mm drawing up device without filter	19g, 40mm drawing up device without filter	18g, 40mm drawing up device Without filter	18g, 40mm drawing up device Without filter
Product Assessment Cycle	Assessment criteria	Unit of issue	100	100	100	100	100	100	100	100	100
Packaging	It is easy to identify necessary detail on shelved/stored item in the clinical setting when in outer carton	Scores	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(1.8)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.00)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>
	It is easy to identify necessary detail on shelved/stored item in the clinical setting when stored separately to the outer carton in the clinical area	Scores	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(1.75)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(1.6)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(1.8)</div>
Opening and preparing for clinical use	It must be easy to identify an unfiltered from filtered drawing up device	Scores	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(3.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.4)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.8)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.4)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.6)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.6)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.25)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>
	The device can easily be prepared for safe clinical use	Scores	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.00)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(1.8)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>
	The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design	Scores	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.00)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	Scores	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.6)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.00)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.4)</div>
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	Scores	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.6)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.50)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>
	The device must pierce bung of ampoule with appropriate effort	Scores	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.2)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(1.8)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.00)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(1.6)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	Scores	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.00)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(1.6)</div>	<div><div></div><div></div><div></div><div></div><div></div></div> <div>(2.0)</div>

BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	BECTON DICKINSON UK LTD	Supplier	BECTON DICKINSON UK LTD
					
NHS CET Product Assessment Cycle	Assessment criteria	Brand	BD Blunt Filter	Brand	BD Blunt Fill
		MPC	305211	MPC	303129
		NPC	FTR436	NPC	FTR1988
		Description	18g, 40mm drawing up device With 5µm filter	Description	18g, 40mm drawing up device Without filter
		Unit of issue	100	Unit of issue	100
		Score		Score	
Packaging	It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	★ ★ ★ (2.2)		★ ★ ★ (2.2)	
	It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	★ ★ ★ (2.2)		★ ★ ★ (2.2)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★ ★ ★ (3.0)		★ ★ ★ (3.0)	
	The device can easily be prepared for safe clinical use	★ ★ ★ (2.0)		★ ★ ★ (2.0)	
	The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design.	★ ★ ★ (2.0)		★ ★ ★ (2.0)	
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	★ ★ ★ (2.2)		★ ★ ★ (2.0)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★ ★ ★ (1.8)		★ ★ ★ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★ ★ ★ (2.2)		★ ★ ★ (2.0)	
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	★ ★ ★ (2.0)		★ ★ ★ (2.0)	


BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	VYGON UK LTD	Supplier	VYGON UK LTD
					
NHS CET Product Assessment Cycle	Assessment criteria	Brand	SOL-M	Brand	SOL-M
		MPC	110022F	MPC	110022
		NPC	FTR1923	NPC	FTR1922
		Description	18g, 40mm drawing up device With 5µm filter	Description	18g, 40mm drawing up device Without filter
		Unit of issue	100	Unit of issue	100
		Score		Score	
Packaging	It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	★★★★ (1.8)		★★★★ (1.8)	
	It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	★★★★ (2.0)		★★★★ (2.0)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★★★★ (2.6)		★★★★ (2.4)	
	The device can easily be prepared for safe clinical use	★★★★ (2.2)		★★★★ (2.2)	
	The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design.	★★★★ (2.0)		★★★★ (2.0)	
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	★★★★ (2.2)		★★★★ (2.0)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★★★★ (1.8)		★★★★ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★★★★ (1.6)		★★★★ (2.0)	
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	★★★★ (1.6)		★★★★ (2.0)	

BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	B BRAUN MEDICAL LTD	Supplier	B BRAUN MEDICAL LTD
					
NHS CET Product Assessment Cycle	Assessment criteria	Brand	Sol-Care	Brand	Sterican MIX
		MPC	110022F	MPC	4550400-01
		NPC	FTR1986	NPC	FTR1768
		Description	18g, 40mm drawing up device With 5µm filter	Description	18g, 40mm drawing up device Without filter
		Unit of issue	100	Unit of issue	100
		Score		Score	
Packaging	It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	★★★☆☆ (2.0)		★★★☆☆ (2.0)	
	It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	★★★☆☆ (2.0)		★★★☆☆ (2.0)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★★★★☆ (2.8)		★★★★☆ (2.8)	
	The device can easily be prepared for safe clinical use	★★★☆☆ (1.8)		★★★☆☆ (2.0)	
	The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design.	★★★☆☆ (2.0)		★★★☆☆ (2.0)	
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	★★★☆☆ (2.2)		★★★☆☆ (2.2)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★★★☆☆ (1.8)		★★★☆☆ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★★★☆☆ (2.0)		★★★☆☆ (2.0)	
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	★★★☆☆ (2.0)		★★★☆☆ (2.0)	

BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	MEDICINA LIMITED	Supplier	MEDICINA LIMITED
					
NHS CET Product Assessment Cycle	Assessment criteria	Brand	Medicina Ltd	Brand	Medicina Ltd
		MPC	BN02	MPC	BN01
		NPC	FTR1769	NPC	FTR1770
		Description	18g, 40mm drawing up device With 5µm filter	Description	18g, 40mm drawing up device Without filter
		Unit of issue	100	Unit of issue	100
		Score		Score	
Packaging	It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	★ ★ ★ (2.0)		★ ★ ★ (2.0)	
	It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	★ ★ ★ (2.2)		★ ★ ★ (2.0)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★ ★ ★ (2.6)		★ ★ ★ (2.4)	
	The device can easily be prepared for safe clinical use	★ ★ ★ (1.8)		★ ★ ★ (2.2)	
	The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design.	★ ★ ★ (2.0)		★ ★ ★ (2.0)	
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	★ ★ ★ (2.2)		★ ★ ★ (2.2)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★ ★ ★ (2.0)		★ ★ ★ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★ ★ ★ (2.2)		★ ★ ★ (2.2)	
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	★ ★ ★ (2.0)		★ ★ ★ (2.0)	

BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	SMITHS MEDICAL INTERNATIONAL LTD	Supplier	SMITHS MEDICAL INTERNATIONAL LTD
					
NHS CET Product Assessment Cycle	Assessment criteria	Brand	Jelco	Brand	Jelco
		MPC	BN1815F	MPC	BN1815
		NPC	FTR1930	NPC	FTR1929
		Description	18g, 40mm drawing up device With 5µm filter	Description	18g, 40mm drawing up device Without filter
		Unit of issue	100	Unit of issue	100
		Score		Score	
Packaging	It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	★★★★ (2.0)		★★★★ (2.0)	
	It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	★★★★ (2.0)		★★★★ (2.0)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★★★★ (2.6)		★★★★ (2.6)	
	The device can easily be prepared for safe clinical use	★★★★ (1.8)		★★★★ (2.0)	
	The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design.	★★★★ (2.0)		★★★★ (2.0)	
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	★★★★ (2.2)		★★★★ (2.2)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★★★★ (2.0)		★★★★ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★★★★ (2.2)		★★★★ (1.8)	
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	★★★★ (2.0)		★★★★ (2.0)	

BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	COVIDIEN UK	Supplier	COVIDIEN UK	Supplier	COVIDIEN UK
							
NHS CET Product Assessment Cycle	Assessment criteria	Brand	Monoject	Brand	Monoject	Brand	Monoject
		MPC	8881305109	MPC	8881540111	MPC	8881202355
		NPC	FTR1828	NPC	FTR1830	NPC	FTR1827
		Description	18g, 80mm drawing up device With 5µm filter	Description	16g, 14mm drawing up device without filter	Description	19g, 40mm drawing up device without filter
		Unit of issue	100	Unit of issue	100	Unit of issue	100
		Score		Score		Score	
Packaging	It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	 (1.8)		 (2.0)		 (2.00)	
	It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	 (2.0)		 (2.0)		 (1.75)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	 (2.4)		 (2.6)		 (2.25)	
	The device can easily be prepared for safe clinical use	 (2.0)		 (2.0)		 (2.00)	
	The safety blunt drawing up or mixing device should safely attach to a range of luer tapered devices (6% taper) of both a lock and no-lock design.	 (1.8)		 (2.0)		 (2.00)	
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	 (2.2)		 (2.6)		 (2.00)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	 (1.0)		 (2.6)		 (2.50)	
	The device must pierce bung of ampoule with appropriate effort	 (1.8)		 (2.0)		 (2.00)	
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	 (2.0)		 (2.0)		 (2.00)	

<p>BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER</p>		Supplier	CODAN LTD
			
NHS CET Product Assessment Cycle	Assessment criteria	Brand	Codan
		MPC	32-18-BDUN
		NPC	FTR286
		Description	18g, 40mm drawing up device Without filter
		Unit of issue	100
		Score	
Packaging	It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	★ ★ ★ (2.0)	
	It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	★ ★ ★ (1.6)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★ ★ ★ (2.0)	
	The device can easily be prepared for safe clinical use	★ ★ ★ (1.8)	
	The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design.	★ ★ ★ (2.0)	
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	★ ★ ★ (2.2)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★ ★ ★ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★ ★ ★ (1.6)	
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	★ ★ ★ (1.6)	

<p>BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER</p>		Supplier	TERUMO UK LTD
			
NHS CET Product Assessment Cycle	Assessment Criteria	Brand	Terumo
		MPC	BN-1838
		NPC	FTR285
		Description	18g, 40mm drawing up device Without filter
		Unit of issue	100
		Score	
Packaging	It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	★ ★ ★ (2.2)	
	It is easy to identify necessary detail on shelved / stored item in the clinical setting when stored separately to the outer carton in the clinical area.	★ ★ ★ (1.8)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★ ★ ★ (2.0)	
	The device can easily be prepared for safe clinical use	★ ★ ★ (2.0)	
	The safety blunt drawing up or mixing device should safely attach to a range of Luer tapered devices (6% taper) of both a lock and no-lock design.	★ ★ ★ (2.0)	
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	★ ★ ★ (2.4)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★ ★ ★ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★ ★ ★ (2.0)	
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy.	★ ★ ★ (2.0)	

Recommendations for the future

During the course of compiling this report and evaluating the products offered to the NHS it has become apparent that several of the suppliers to the NHS are not manufacturers of these products but are distributing for a third party manufacturer.

There is evidence to suggest that several of the suppliers are in fact using the same manufacturer to source product from. The current framework pricing attached to these suppliers shows different pricing; common sense suggests it would be worth amalgamating these suppliers to one intermediary who can offer the best value for aggregated volume.

The second recommendation to come forward is that clarity is required as to the correct classification for products within this category – it makes little sense to have some devices certified as class 1 whilst others are class 2a.

Finally, clinical colleagues highlight three important requirements which would be “Even Better If”:

- a) It must be easy to identify at speed in a clinical setting whether a blunt drawing up device has a filter or does not have a filter when the two products are presented next to each other as happens in some store areas. One suggestion is that the plastic shield/guard is coloured in accordance with the hub colour of the device rather than as found at present.
- b) It would also be helpful if the national contracting authority for the NHS could mandate a standard hub colour for a device with a filter and a different hub colour for devices without a filter. At present there is no consistency with silver, red, green or pink being evident. This increases clinical risk if alternate suppliers are used where a pink hub could, for example, be seen on both types of device.
- c) That a device with an in-hub filter is easy to draw up necessary medication through in a timely manner and without causing undue hand strain in the process. Many practitioners report that they believe this is a major barrier to best practice when drawing up from glass ampoules using a filtered device.



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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)

