NHS Clinical Evaluation Team
by the NHS, for the NHS

Clinical review

Blunt drawing up devices with and without filter

Version 2 May 2018

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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 us at: **clinical.evaluationteam@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.

Version Two – Published May 2018

This version has been updated from the original blunt fill device report published in December 2016 to include results from new suppliers to the UK market

New sections have also been included:

4.2.1 Criteria explanation- inclusion

4.2.2 Criteria explanation- exclusion

These have been added to provide guidance as to the rationale for the inclusion and exclusion of the clinical criteria featured in this blunt fill device report.

1. 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. The original report covers the range of products available as at August 2016, this newer version includes products new to the market as of November 2017.

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

2. Clinical Context

2.1 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.

Sharp Needles and Devices
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.

2.2 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.

2.3 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.

2.4 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.

2.5 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.

3. Pathway Methods for Blunt Drawing Up Devices

3.1 Intelligence Gathering

In preparation of the criteria, account has been taken of academic and related clinical evidence, known guidance and nationally recognised publications as further described in this Section 3.

3.1.1. Literature search

A literature search has been undertaken to establish what current academic knowledge exists on the products for evaluation. It should be noted that the team have not conducted a comprehensive or systematic review of literature. However, the team have interrogated the information to look for common themes which supported the development of the clinical criteria.

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
• 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)	• 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)**

3.1.2. 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.

3.1.3. 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.

3.1.4. Product suppliers and manufacturers

Requests for information were sent to all suppliers listed on the national procurement provider framework. Some suppliers provided some level of information from product brochure through to technical datasheets and compliance with standards. Not all suppliers submitted evidence.

3.1.5. Quality of evidence

Hierarchy of evidence

Levels of evidence sometimes referred to as hierarchy of evidence are assigned to studies based on the methodological quality of their design, validity, and applicability to patient care.

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: Evidence based practice in nursing & healthcare: a guide to best practice" (B.M. Melnyk & E. Fineout-Overholt; 2005; p10)

4. NHS Clinical Engagement

In order to develop a shared vision of what blunt drawing up devices should offer several methods of engagement were used. These engagement events were used to formulate thoughts, ideas and needs from differing clinicians familiar with these products; identifying their own expectation(s) of the product for their given patient group, and intended patient outcome, being used in a variety of differing clinical environments.

Mapping exercises were undertaken to determine personnel that should be involved and/or consulted regarding these products. This stage of the report focused on clinical staff that are:

a) recognised as subject experts, and/or
b) recognised regular users of the devices in their clinical practice

Various methods of engagement were undertaken to ensure these clinical opinions were robust, and validated by peers from around the country, options of engagement included:

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)

4.1 Clinical Conversations

To build a broad caucus of attendees at our events letters were sent inviting Trusts to nominate clinical colleagues to attend a series of regional group events. These were hosted by NHS organisations throughout England to enable the widest possible access for all invited. This ensured to set aside any pre-existing regional variance.

Details of the discussion outcomes were recorded from the open events, then used together with the evidence gathered at the previous project stage to inform a list of clinical criteria against which the product(s) are measured against.

Much of these national clinical conversations featured opinions by generalist health care professionals, and allied health professionals. For the purpose of wound care products, ratification and validation was sought of the proposed criteria by tissue viability specialists. Engagement at regional tissue viability networks took place to obtain this validation. Furthermore these events were used to gain consent from these specialist clinicians to provide valuable feedback on the performance of products being used in their own clinical environment against the proposed criteria.

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.

4.2 Clinical Criteria

The data received from all the NHS clinical conversation events, alongside the data collected from individual experts, was assimilated into a series of clinical criteria.

A clinical criterion is defined for the purposes of this report as a principle or standard by which products may be evaluated. It is a statement which describes the clinician’s requirements for the product.

The proposed criteria were validated by workshop attendees and all other clinical experts engaged in the development process. In addition, other clinical experts who are likely to add further useful insight were also included, leading to the finalised clinical criteria listed below.

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

Clinical criteria are published online at www.nhsbsa.nhs.uk/CET .

4.2.1 Criteria explanation- Inclusion (Blunt Fill Devices)

To enhance the readers understanding of this report, and to provide value to the results, an explanation for the defined clinical criteria is captured.

Packaging Criteria	Explanation
It is easy to identify necessary detail on shelved / stored item in the clinical setting when in outer carton	Some clinical areas retain their blunt fill devices in the original box, therefore identification of product is made looking at the outer packaging
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.	Some clinical areas decant their blunt fill devices from the original box into trays and/or drawers, as such identification of the correct device is through individual product packet

Opening and Preparation Criteria	Explanation
It must be easy to identify an unfiltered from a filtered drawing up device	Filtered devices are used for the prevention(filtration) of glass particles passing into the patient, recognition of the difference between devices is a patient safety concern
The device can easily be prepared for safe clinical use	Effective preparation of device i.e. ease of use and ability to maintain sterility is important for patient and staff safety
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	Blunt fill devices are designed to be universal, thus should fit a range of different luer slip, and luer lock syringes

Clinical Use Criteria	Explanation
In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	The blunt fill device should be simple and easy to use for its primary function of drawing up fluids and solutions in a timely manner
In clinical use it must be easy and timely to draw up a viscous fluid/diluent	The viscosity of fluids and solutions requiring drawing up through blunt fill devices will vary, as such the device needs to be able to perform well above criteria with different fluid viscosities
Conformability The device must pierce bung of ampoule with appropriate effort	Some solutions for “drawing up” will be in ampules with a bung, the blunt fill device needs to effectively pierce the bung allowing access to the solution contained within, without the need for excessive force- and should not leave particles of bung which may enter the solution

Clinical Use Criteria	Explanation
The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per local guidance or policy	Ease of disposal of the blunt fill device enhances patient and nurse experience, and reduces risk of harm

4.2.2 Criteria explanation- Exclusion (Blunt Fill Devices)

To capture true representation of clinical opinion, this report also aims to capture criteria that were raised, but not included as final criteria when the evaluation of these dressings took place.

Proposed Criteria	Explanation for exclusion
Lumen width of blunt fill	Whilst lumen width was considered for evaluation, further clinical conversation highlighted that the lumen diameter was considered in relation to ease of drawing up fluid, an actual number associated with this diameter would potentially give no clear indication of ease. It was therefore agreed that evaluating ease of fluid uptake using a variety of different viscous solutions would prove more valuable to the user.

5. Product Evaluation

Evaluation methodologies are defined for each and every clinical criterion. They reflect a simulated clinical environment; actual clinical environment, or a laboratory test environment.

Wherever possible, 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. Where this has not been possible it was acknowledged as part of the product assessment results matrix.

The tests were formulated to move through the key aspects of product use using the NHS Clinical Evaluation Team product cycle:

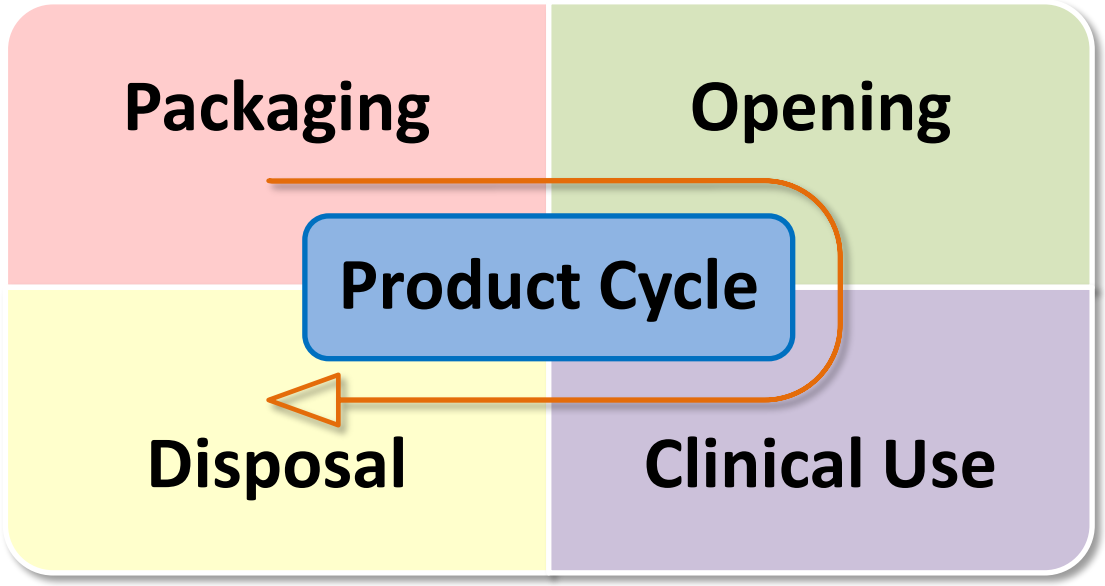

Figure 4 – NHS Clinical Evaluation Team Product Cycle

The evaluation product was ordered and picked from the NHS distribution centres. 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 the products in accordance with the developed criteria. It was not possible to ‘blind’ the evaluations; in the sense that the evaluators were aware of the product brand; however, the product to be evaluated was independently picked in accordance with the product selection criteria in Section 2 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.

As part of the evaluation preparation, each evaluator was given a more detailed and product specific definition for each of the scores

The defined criteria either prompted a 'yes/no' answer, represented with a √/ X, or a score was given between 0 and 2, or 0 and 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 (see matrix below).

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

Point scored	Star value
0 to 0.99	0 Stars
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

The above scoring mechanisms will not be followed where the criterion identified by the CET cannot reasonably exceed expectations. For example, if the clinical criterion was whether the removal of an adhesive dressing was atraumatic and with the individual patient reporting no pain or skin damage, then it cannot reasonably be expected that a product could exceed that criteria. Therefore, in such circumstances, the relevant criteria will be based on the scoring regime of:

a. If the criterion is a Yes/No response, the responses will be converted into aggregate percentages and then star ratings as follows:

Percentages (Yes)	Star value
0% to 24.99%	0 star
25% to 49.99%	1 star
50% to 74.99%	1.5 stars
75% to 100%	2 stars

Figure 7 – Percentage scores to star rating

b. For other subjective criteria, the responses will be converted into mean scores and then star ratings as follows:

Point scored	Star value
0 to 0.49	0 star
0.5 to 0.99	1 star
1 to 1.49	1.5 stars
1.5 to 2	2 stars

Figure 8 – Points scores to star rating

On the basis that clinical evaluators will be providing scores as follows:

- 0 stars – Does not meet the criteria
- 1 star – Partially meets the criteria
- 2 stars – Meets the criteria

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 also encouraged to record comments where they felt it 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.

6. Product Assessment Results

The following product assessment results pages show the tested clinical criteria listed horizontally on the left-hand side of the page with the tested device found vertically across the top of the matrix. The accompanying photographs were taken during evaluation. These photographs are of sample products 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 February 2017.

Results can be seen within the product matrix. Each clinical product has been given a star rating and the evaluator's collated comments are included in the matrix.

The product assessment results have been divided into two sub categories; blunt fill with filter; blunt fill without filter.

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 5 µm 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)	★★½ (2.6)	★★☆ (2.0)	★★½ (2.6)	★★½ (2.6)	★★½ (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)	★½☆ (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 inappropriate sharps container as per local guidance or policy	Scores	★★☆ (2.0)	★½☆ (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	MATZ MEDICAL LTD
		Brand	BD Blunt Fill	SOL-M	Sterican MIX	Medicina	Jelco	Monoject	Monoject	Codan	Terumo	Matz
		MPC	303129	110022	4550400-01	BN01	BN1815	8881540111	8881202355	32-18-BDUN	BN-1838	MML_SY_1
		NPC	FTR1988	FTR1922	FTR1768	FTR1770	FTR1929	FTR1830	FTR1827	FTR286	FTR285	FSW1035
		Description	18g, 40 mm drawing up device Without filter	18g, 40 mm drawing up device Without filter	18g, 40 mm drawing up device Without filter	18g, 40 mm drawing up device Without filter	18g, 40 mm drawing up device Without filter	18g, 40 mm drawing up device Without filter	18g, 40 mm drawing up device Without filter	18g, 40 mm drawing up device Without filter	18g, 40 mm drawing up device Without filter	Safety Needle Blunt fill Drawing Up 18g x 38mm (1.5”)
Product Cycle	Assessment criteria	Unit of issue	100	100	100	100	100	100	100	100	100	100
Packaging	It is easy to identify necessary detailon shelved/stored item in the clinical setting when in outer carton	Scores	★★☆ (2.2)	★★☆ (1.8)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.2)	★★☆ (2.13)
	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)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (1.75)	★½☆ (1.6)	★★☆ (1.8)	★★☆ (1.88)
Opening and preparingfor clinicaluse	It must be easy to identify an unfiltered from filtered drawing up device	Scores	★★★ (3.0)	★★½ (2.4)	★★★ (2.8)	★★½ (2.4)	★★½ (2.6)	★★½ (2.6)	★★½ (2.25)	★★☆ (2.0)	★★☆ (2.0)	★★½ (2.25)
	The device can easily be prepared for safe clinical use	Scores	★★☆ (2.0)	★★☆ (2.2)	★★☆ (2.0)	★★☆ (2.2)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (1.8)	★★☆ (2.0)	★★☆ (2.13)
	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)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.00)
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	Scores	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.2)	★★☆ (2.2)	★★☆ (2.2)	★★½ (2.6)	★★☆ (2.0)	★★☆ (2.2)	★★½ (2.4)	★★☆ (2.13)
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	Scores	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★½ (2.6)	★★½ (2.5)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.00)
	The device must pierce bung of ampoule with appropriate effort	Scores	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.2)	★★☆ (1.8)	★★☆ (2.0)	★★☆ (2.0)	★½☆ (1.6)	★★☆ (2.0)	★★½ (2.63)
Safe Disposal	The safety blunt drawing up and/or mixing device can be safely disposed of in appropriate sharps container as per localguidance or policy	Scores	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★★☆ (2.0)	★½☆ (1.6)	★★☆ (2.0)	★★☆ (2.00)

BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	BECTON DICKINSON UK LTD	Supplier	BECTON DICKINSON UK LTD	Supplier	VYGON UK LTD	Supplier	VYGON UK LTD
									
NHS CET Product Assessment Cycle	Assessment criteria	Brand	BD Blunt Filter	Brand	BD Blunt Fill	Brand	SOL-M	Brand	SOL-M
		MPC	305211	MPC	303129	MPC	110022F	MPC	110022
		NPC	FTR436	NPC	FTR1988	NPC	FTR1923	NPC	FTR1922
		Description	18g, 40mm drawing up device With 5µm filter	Description	18g, 40mm drawing up device Without filter	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	Unit of issue	100	Unit of issue	100
		Score		Score		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)		★★☆ (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	★★☆ (2.2)		★★☆ (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	★★★ (3.0)		★★★ (3.0)		★★½ (2.6)		★★½ (2.4)	
	The device can easily be prepared for safe clinical use	★★☆ (2.0)		★★☆ (2.0)		★★☆ (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)		★★☆ (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)		★★☆ (2.2)		★★☆ (2.0)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★★☆ (1.8)		★★☆ (2.0)		★★☆ (1.8)		★★☆ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★★☆ (2.2)		★★☆ (2.0)		★½☆ (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	★★☆ (2.0)		★★☆ (2.0)		★½☆ (1.6)		★★☆ (2.0)	

BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	B BRAUN MEDICAL LTD	Supplier	B BRAUN MEDICAL LTD	Supplier	MEDICINA LIMITED	Supplier	MEDICINA LIMITED
									
NHS CET Product Assessment Cycle	Assessment criteria	Brand	Sol-Care	Brand	Sterican MIX	Brand	Medicina Ltd	Brand	Medicina Ltd
		MPC	110022F	MPC	4550400-01	MPC	BN02	MPC	BN01
		NPC	FTR1986	NPC	FTR1768	NPC	FTR1769	NPC	FTR1770
		Description	18g, 40mm drawing up device With 5µm filter	Description	18g, 40mm drawing up device Without filter	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	Unit of issue	100	Unit of issue	100
		Score		Score		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)		★★☆ (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)		★★☆ (2.2)		★★☆ (2.0)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★★★ (2.8)		★★★ (2.8)		★★½ (2.6)		★★½ (2.4)	
	The device can easily be prepared for safe clinical use	★★☆ (1.8)		★★☆ (2.0)		★★☆ (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)		★★☆ (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)		★★☆ (2.2)		★★☆ (2.2)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★★☆ (1.8)		★★☆ (2.0)		★★☆ (2.0)		★★☆ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★★☆ (2.0)		★★☆ (2.0)		★★☆ (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)		★★☆ (2.0)		★★☆ (2.0)	

BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	COVIDIEN UK	Supplier	COVIDIEN UK	Supplier	COVIDIEN UK	Supplier	MATZ MEDICAL LTD
									
NHS CET Product Assessment Cycle	Assessment criteria	Brand	Monoject	Brand	Monoject	Brand	Monoject	Brand	Brand Matz
		MPC	8881305109	MPC	8881540111	MPC	8881202355	MPC	MML_SY_1
		NPC	FTR1828	NPC	FTR1830	NPC	FTR1827	NPC	FSW1035
		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	Description	Safety Needle Blunt fill Drawing Up 18g x 38mm (1.5")
		Unit of issue	100	Unit of issue	100	Unit of issue	100	Unit of issue	100
		Score		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)		★★☆ (2.0)		★★☆ (2.13)	
	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)		★★☆ (1.88)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★★½ (2.4)		★★½ (2.6)		★★½ (2.25)		★★½ (2.25)	
	The device can easily be prepared for safe clinical use	★★☆ (2.0)		★★☆ (2.0)		★★☆ (2.0)		★★☆ (2.13)	
	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)		★★☆ (2.0)		★★☆ (2.00)	
Effective clinical use	In clinical use it must be easy and timely to draw up a non-viscous fluid/diluent	★★☆ (2.2)		★★½ (2.6)		★★☆ (2.0)		★★½ (2.13)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★☆☆ (1.0)		★★½ (2.6)		★★½ (2.5)		★★☆ (2.00)	
	The device must pierce bung of ampoule with appropriate effort	★★☆ (1.8)		★★☆ (2.0)		★★☆ (2.0)		★★½ (2.63)	
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)		★★☆ (2.0)		★★☆ (2.00)	

BLUNT DRAWING UP DEVICES - WITH AND WITHOUT FILTER		Supplier	SMITHS MEDICAL INTERNATIONAL LTD	Supplier	SMITHS MEDICAL INTERNATIONAL LTD	Supplier	CODAN LTD	Supplier	TERUMO UK LTD
									
NHS CET Product Assessment Cycle	Assessment criteria	Brand	Jelco	Brand	Jelco	Brand	Codan	Brand	Terumo
		MPC	BN1815F	MPC	BN1815	MPC	32-18-BDUN	MPC	BN-1838
		NPC	FTR1930	NPC	FTR1929	NPC	FTR286	NPC	FTR285
		Description	18g, 40mm drawing up device With 5µm filter	Description	18g, 40mm drawing up device Without filter	Description	18g, 40mm drawing up device Without filter	Description	18g, 40mm drawing up device Without filter
		Unit of issue	100	Unit of issue	100	Unit of issue	100	Unit of issue	100
		Score		Score		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)		★★☆ (2.0)		★★☆ (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	★★☆ (2.0)		★★☆ (2.0)		★★☆ (1.6)		★★☆ (1.8)	
Opening and preparing for clinical use	It must be easy to identify an unfiltered from a filtered drawing up device	★★½ (2.6)		★★½ (2.6)		★★½ (2.0)		★★½ (2.0)	
	The device can easily be prepared for safe clinical use	★★☆ (1.8)		★★☆ (2.0)		★★☆ (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)		★★☆ (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)		★★☆ (2.2)		★★½ (2.4)	
	In clinical use it must be easy and timely to draw up a viscous fluid/diluent	★★☆ (2.0)		★★☆ (2.0)		★★☆ (2.0)		★★☆ (2.0)	
	The device must pierce bung of ampoule with appropriate effort	★★☆ (2.2)		★★☆ (1.8)		★★☆ (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	★★☆ (2.0)		★★☆ (2.0)		★★☆ (1.6)		★★☆ (2.0)	

7. Using the Product Assessment Results Matrix

The clinical criteria displayed are designed to capture key clinical elements that health professionals may wish to consider when reviewing/selecting products for their own clinical practice. The report is intended as a guidance tool to aid product selection and is not intended to be a universal determination of the clinical effectiveness of any particular product. Each clinical practitioner should therefore make their own assessments taking into account all relevant considerations for their particular situation.

Not all clinical criteria cited in the report will be relevant or important in all environments,

i.e. Recognition of product only from individual packaging, where clinical environment does not decant individual products into baskets/trays

Likewise not all clinical criteria will be relevant or important for all patient groups;

i.e. Ability to draw up viscous fluid for patients attending an anti-coagulation clinic

Clinicians may identify the criteria that most represent their clinical environment and patient demographic, and may choose to build their own hierarchy of importance to aid product(s) selection for patient outcome goals using the matrix presented in this report, their own clinical knowledge, as well as any other resources (including publications) to provide informed choice and transparency of their decision for product(s) being used.

8. Further Considerations and Recommendations

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.

9. Barcodes

The CET are aware of the Scan4Safety project and are aligned with the ambitions of the programme, which will deliver significant benefits in terms of patient safety and efficiency, to the NHS. The adoption of standards, driven by Scan4Safety, enables patient, product and location identification and traceability from the supply chain to the patient.

Adoption of these standards has also been shown to improve the quality of care by minimising the risk of human error.

The CET will be considering the inclusion of an evaluation criteria relating to the presence of GS1 compliant barcodes in future reports, as following our clinical conversations we have seen clinical staff asking for it to be included, but further information will be issued by the CET on this to stakeholders in advance.

10. Disclaimer

Reports published by the NHS Clinical Evaluation Team represent general guidance and the team's opinions on products are based on the clinical evaluations undertaken, using the information and clinical criteria generated from extensive stakeholder engagement in line with the team's requirements and evaluation pathway. Reports will be reviewed and updated at the team's discretion as deemed appropriate to reflect any changes.

You should make your own assessment and not take or rely on the opinions expressed by the NHS Clinical Evaluation Team, as contained in the reports, as

recommendations or advice to buy or not buy (as the case may be) particular products.

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Reports are accurate at the time of publication, any recommendations or best practice guidance should be checked for updates.

11. Acknowledgements

On behalf of the Clinical Reference Board and the NHS Clinical Evaluation Team, we would like to acknowledge the support, help and advice given by our colleagues across a range of organisations. We would particularly like to thank the Department of Health and Social Care, NHS Business Services Authority and their Communications team along with publishing partners The APS Group and, most importantly, our NHS colleagues who have supported our work.

The team would also like to acknowledge the inspiration of Mandie Sunderland who saw this opportunity and who, through her personal drive and enthusiasm, has ensured that the clinical voice and the need for quality, safety and value throughout the NHS has been heard.

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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
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(Governing body of the NHS Clinical Evaluation Team)