NHS Clinical Evaluation Team
by the NHS, for the NHS

Clinical Review

Needle-Free Connectors (Needle–free valves and needle-free extension set single lumen)

October 2018

Contents

Guidance for use

This clinical evaluation report is aimed primarily at the NHS and all those working to support patient care.

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

1. Introduction

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

Everyday healthcare consumables are products that are found in the majority of wards, clinics, health centres, treatment rooms and district nurses' bags across the NHS. The purpose of this report is two-fold: firstly, to provide a clinical assessment of the usability and requirements from the NHS for Needle-Free Valves (NFVs) and Needle-Free Extension Sets (Single Lumen), that are available to the NHS from the national procurement provider and secondly, to provide a clinical statement of desired functions and properties that the clinicians in the NHS require of these products for use in future procurement activities.

It is clear from the evidence that NFV's and Needle-Free Extension Sets (Single Lumen) 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 culminating in the production of this report for their approval in October 2018.

Based on 2018 data supplied by NHS Supply Chain, in the NHS, Trusts are annually spending a total of approximately £30 million on products under the Needle-Free Connector umbrella. The market is growing year on year with NHS Supply Chain having 70% of the market share. The annual growth in volume for 2016 was 4.8% and 2017 was 5.71%. There are 311 different product codes in the category of Needle Free Connectors supplied via 15 different suppliers. This report covers the NFV's and Needle-Free Extension Sets (Single Lumen) available as of May 2018.

Intelligence about these two products 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 the products, from frontline NHS clinicians. This information was used to develop clinical criteria for NFV's and Needle-Free Extension Sets (Single Lumen) against which 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.supplychain.nhs.uk/CET

2. Clinical Context

2.1 Clinical Definition and Scope

The title for this project is Needle-Free Connectors (Needle-Free Valves and Needle-Free Extension Sets, Singe Lumen). For this report the title reflects a Needle-Free Valve (NFV) and Needle-Free Connector with one lumen. This is a needle-less system or safety device system which is a substitute for a needle or a sharp access catheter in various designs, that effectively reduces the risk of sharps injury and subsequent blood borne virus exposure to healthcare workers (RCN 2016)

This report does not include Needle-Free bag spikes, stopcocks, arterial connectors or disinfectant caps, double, triple or quadruple lumen devices or any other device under the Needle-Free Connector umbrella.

This report will be evaluating Needle-Free Valves (NFV's) and Needle-Free Extension Sets with a single lumen. A number of double lumen devices were evaluated and the results of the evaluation did not show any differences to the Needle-Free devices between the two product ranges. Therefore due to the limited resources available, it was decided by the NHS Clinical Evaluation Team to continue with their evaluations for single lumen devices only.

2.2 Intended Clinical Use

NFV's and Needle-Free Extension Sets (Single Lumen) are a medical device, accessed via a septum (a flexible partition separating two chambers) that permits devices to connect an intravascular cannula, catheter, syringe or the end of a catheter extension set by means of a luer lock/slip removing the need for needles. This minimises the risk of needle-stick injury, occlusion, microbial and/or water ingress or seepage (Curran 2016). Also in conjunction with the European Directive (Council Directive 2010/32/EU) developed for the purpose of protecting Healthcare workers (RCN 2013) from the potential of infection from blood borne pathogens, such as Hepatitis B and C.

2.3 Clinical Practice

NFV's and Needle-Free Extension Sets (Single Lumen) are used in conjunction with Intravenous therapy (IV) devices such as:

- Central Venous Access Devices (CVAD) including but not limited to Peripherally Inserted Central Catheter (PICC) lines and Skin Tunnelled Catheters
- Some Peripheral Venous Access Devices such as Straight Cannulae and Midline Catheters used for:
- Parenteral Nutrition
- Chemotherapy
- Antibiotic therapy

- Blood Transfusion
- Blood Sampling
- Radiological procedures

All infusion related procedures such as site preparation, insertion of peripheral or central venous access devices and management of infusion related equipment such as administration sets, add on devices and dressings require the use of an aseptic technique and standard precautions (RCN 2016). Correct care and maintenance of NFV's and Needle-Free Extension Sets (Single lumen) can extend the life of the device as well as ensure the safety of the patient and the Healthcare professional (HCP). The NFV and Needle-Free Extension Sets (Single lumen) can harbour bacteria and biofilm. Biofilms are plasma proteins that adhere to the catheter surface. Platelets, neutrophils and free floating bacteria then adhere. As the biofilm matures, bits slough off and if insufficient cleaning occurs these can be injected into the patients system and infection may occur. (Kelly et al 2017).

2.4 Clinical Impact

Catheter Related Blood Stream Infections (CRBSI) are a known associated risk of intravascular devices and there is a plethora of research available linking the variation in quality of disinfection procedures to the risk of infection. Other associated risks include, phlebitis which may be caused by chemicals, infection or mechanical reaction. These complications could arise when a NFV's or Needle-Free Extension Set (Single Lumen) is attached to a peripheral cannula and due to the bulk of the device and the force that is required to depress the membrane of the NFV. This can lead to irritation and mechanical phlebitis (Kelly et al 2017).

2.5 Other Clinical Considerations

NFV's and Needle-Free Extension Set (Single Lumen) vary in life span; this can be between 72 hours or seven days, or limited to the number of activations recommended. Owing to the variations within the devices manufacturer's recommendations should be followed and implemented into clinical polices.

2.6 Product Technical Design

A valve is defined as a mechanical device that controls the flow of fluid within a system. Needle-Free Valves (NFV) may be categorised by the complexity of their internal mechanisms and how they function. For example, split septum. This means the tip of the syringe, separates a split present in the septum as it is inserted into the valve. Fluid in the syringe then passes straight through the tip of the syringe and valve into the patient's bloodstream. Mechanical valves depress and deform the membrane within the valve and allow the fluid to go around the membrane. Valves can be opaque which means, they are shaded or dark and not transparent, impenetrable by visible light or unable to see through. Or they can be clear which means transparent, easily seen.

Another way to describe NFV's and Needle-Free Extension Set (Single Lumen) relates to how they function. This involves the presence of fluid displacement inside the device (Jarvis 2010). This includes:

- Positive Displacement forces a small amount of fluid into the catheter end to prevent occlusion from blood and should be clamped after disconnection.

- Negative Displacement allows a small amount of blood to move back into the catheter and should be clamped before disconnection

- Neutral Displacement indicates no movement back into the catheter after disconnection. No clamping required. However clamping may be required to prevent air embolism.

- Some devices may have metal parts which may cause issues with magnetic resonance imaging (MRI) with the potential to cause image distortion or a 'pull' on the catheter.

3. Pathway Methods

CET follows a standardised approach to evaluations. This can be found in the CET Operating Manual on our website: www.supplychain.nhs.uk/CET.

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 evidence service: https://www.evidence.nhs.uk/ this suggested best practice considerations in the use of Needle-Free connectors, then extended using an Open Athens account, where numerous articles were found, comparing catheter related blood stream infections (CRBSI), disinfection, fluid displacement and technical aspects of the Needle-Free connectors.

The search terms used (see below) generated many returns, however, there was little new information generated.

Search criteria	Databases searched
• **Needle-free** • **Needle-free connectors** • **Needle-free/infection control** • **Needle-free Valves**	• **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 – EMBASE, HMIC, Medline, CINAHL, HEALTH BUSINESS ELITE databases searched) • Further search of specialist resources including Infection Prevention Society (IPS) and NIVAS, the national multi professional society specialising in vascular access and infusion therapies.
Date Range	**Since 2008**
Language	**English**

Figure 1 Literature and other sources searches – **Needle-Free Connectors and Valves**

3.1.2 National procurement provider specification

As the national procurement provider, NHS Supply Chain manages a framework of suppliers who are then listed in the national catalogue. The framework covers a wider selection of products than just NFV's and Needle-Free Extension Set (Single Lumen).

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.

The specification, as used by the NHS national procurement provider (NHS Supply Chain, 2016), provides insufficient detail relating to the clinical criteria relevant for NFV's and Needle-Free Extension Set (Single Lumen). The specification makes reference to a number of standards and legislation, however it is considered in the process for the development of such criteria.

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. from the International Organisation for Standardisation (ISO), European Standards (EN) and/or British Standards Institution (BSI).

Medical Device Directive 93/42/EEC as amended, currently in transition to the new Medical Device Regulation MDR 2017/745

EN ISO 13485:2016 (Quality management systems).

Guidance for Industry and FDA Staff Medical Devices with Sharps Injury Prevention Features. U.S. Department of Health and Human Services Food and Drug Administration Centre for Devices and Radiological Health Document Issued on: August 9, 2005.

- All products classified as a Medical Device must have their CE marking clearly evident on the product and/or packaging and meet the requirements set out within the standard(s) related to labelling.

A review of Medicines & Healthcare products Regulatory Agency (MHRA) alerts has also been performed. The MHRA website (https://www.gov.uk/drug-device-alerts) returned one product alert relating to this product category against the search terms previously described.

- (All manufacturers) some pre-filled glass syringes are incompatible with some needle-free connectors; and when adaptor stays attached after use there is a possible risk of infection and or air embolus to patients. (MDA/2011/068) December 2014.

3.1.4 Product suppliers and manufacturers

All suppliers listed within the national framework were invited to submit relevant evidence, product information and testing data to help support the review.

All suppliers provided some level of information from product brochure through to technical datasheets and compliance with standards.

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.

In relation to NFV's and Needle-Free Extension Set (Single Lumen), no evidence above level 5 (see Figure 2) was found during literature search or suppliers' submissions.

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)

3.2 Best Practice Guidelines

Professional organisations have produced guidance specific to infusion therapy which includes NFV's and Needle-Free Extension Set (Single Lumen):

- Standards for infusion therapy (RCN 2016)
- epic 3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England (IPS 2014)
- Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011 (CDC)
- Policies and Procedures for Infusion Therapy (Infusion Nurses Society 2016).
- Guidelines for the Prevention of Intravascular Catheter Related Infections (CDC 2011)

3.3 Patient Perspectives

Today a huge goal in the clinical setting is to eliminate healthcare associated infections. Catheter related blood stream infections remain a real and significant risk to patients. Antimicrobial resistance and untreatable infections is a realistic possibility. As long as intravenous therapy remains a critical component of healthcare it is vital for patients that healthcare workers have access to equipment which, when used correctly will minimize all possible risks (Curran 2016)

4. NHS Clinical Engagement

In order to develop a shared vision of what is required from NVF's and Needle-Free Extension Set (Single Lumen), several methods of engagement were used. These events were used to formulate thoughts, ideas and needs from different 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 who 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 online from the open events, transcribed and then used together with the evidence gathered at the previous project stage to inform a list of clinical criteria against which the product has been tested. Specialist groups such as The Infection Prevention Society (IPS), IV Special Interest Group (IPS) and NIVA's were contacted and contributed to the information used in the clinical criteria.

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.

4.2.2 Criteria explanation – Inclusion

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

	Clinical Criteria – Needle-Free Extension Set (Single lumen)	Rationale
PACKAGING		
1	All labelling information is present.	To confirm that the information on the packaging meets standards required by the EU directive and EN ISO 13485:2016 MDD93/42EEC or MDR2017/745
2	Does it state clearly that the Needle-Free Extension Set (single Lumen) (NFES) latex free?	General and specialist clinicians have requested this information as patients/staff may have an allergy to latex. This information informs choice.
3	Does it state clearly that the NFES is MRI compatible?	General and specialist clinicians have requested this information as connectors may be removed if compatibility unknown. This may increase the infection risk. The image may be distorted if metal is inside the NFES. This information informs choice.
4	The product category is stated on the packaging	General and specialist clinicians have requested this information to facilitate an appropriate clinical choice
5	Does it state whether the NFES is Positive, negative or neutral displacement.	General and specialist clinicians have requested this information to ensure the correct technique of use is being performed as this could cause occlusion of the device and risks to patients. This informs appropriate clinical choice.
6	The length of the NFES is stated on the inner packaging?	General and specialist clinicians have requested this information to ensure the NFES is the appropriate length for the patient. Ensuring comfort and reducing the risk of inflammation and pain. This informs choice.
7	The maximum number of uses is stated on the inner/individual packaging	General and specialist clinicians have requested this information to reduce risk of infection and inform local policy. This informs appropriate clinical choice
8	The priming volume is stated on the inner/individual packaging	General and specialist clinicians have requested this information to ensure all air is removed from the system and dead space is minimal. To maintain patient safety. This informs choice.
9	The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	General and specialist clinicians have requested this information to reduce risk of infection and inform local policy. This informs appropriate clinical choice
10	Are the instructions for use visible on the inner packaging?	General and specialist clinicians have requested this information to inform practice and knowledge.
11	The NFES is visible through one side of the inner packaging?	Clinicians have said this could potentially reduce waste in terms of minimising the wrong device being opened. 90% of Clinicians consulted stated this was very important
12	Does it state that the NFES is glass syringe compatible?	General and specialist clinicians have requested this information as the NFES may need to be removed in emergency situations due to risk of occlusion of the device. This may increase the risk of infection and may be a safety issue for the patient. This informs choice.

13	Is it stated clearly on the packaging if contraindications of use. (Cannot be used with certain drugs).	General and specialist clinicians have requested this information as some drugs may be detrimental to the NFES. This informs choice
14	Is the flow rate stated on the inner packaging?	General and specialist clinicians have requested this information, to understand the IV fluid delivery rates available to patients. This informs choice.
OPENING		
15	Indication for opening is clear?	To facilitate an efficient and standardised opening and preparation technique to maintain ANTT™
16	The individual packaging is easy to open whilst maintaining product sterility	Clinicians stated that inner packaging needs to be EASY to open to facilitate ANTT™/Sterility. 90% stated of consulted clinicians/users stated this was very important
CLINICAL USE		
17	Does the NFES have flat smooth surfaces, to aid effective cleaning?	General and specialist clinician have requested this information to facilitate good practice, reduce infection and is in line with epic 3 guidelines.
18	Does the device have clear instructions for decontamination?	General and specialist clinician have requested this information to facilitate good practice, reducing the risk of infection and is in line with epic 3 guidelines and Standards for Infusion Therapy by the Royal College of Nursing.
19	Is the device sealed to ensure a closed system?	General and specialist clinicians have requested this information to ensure components of the system are compatible and secured to minimise leaks and breaks and reduce the risk of infection and to facilitate an appropriate clinical choice.
20	Does it state that the NFES can be used in an emergency situation fast flow/power injectable?	General and specialist clinicians have requested this information to prevent occlusion of the device, ensure patient safety, reduce infection and facilitate an appropriate clinical choice
21	Is the NFES compatible with luer slip syringe	General and specialist clinicians have requested this information to ensure components of the system are compatible and secure to minimise leaks and breaks and reduce the risk of infection and to facilitate an appropriate clinical choice.
22	Is the NFES compatible with luer lock syringe	General and specialist clinicians have requested this information to ensure components of the system are compatible and secure to minimise leaks and breaks and reduce the risk of infection and to facilitate an appropriate clinical choice.
23	Is the NFES easy to handle when connecting to the cannula and accessing with a syringe, without breaching ANTT.	General and specialist clinicians have requested this information to ensure components of the system are compatible and secure to minimise leaks and breaks and reduce the risk of infection and to facilitate an appropriate clinical choice. 90% stated in the survey monkey this was very important.
24	Is the tubing damaged when the clamp is released?	General and specialist clinicians have requested this information, to reduce the risk of replacing NFES unnecessarily due to occlusion. This minimises the risk of infection and discomfort to the patient. However it was noted that this did not affect the products

		functionality. 90% of consulted clinicians/users stated this was very important.
DISPOSAL		
25	Does it state clearly that the outer and inner packaging be recycled?	Clinicians indicated that the ability to be able to recycle packaging is an important environmental factor

Figure 3- Defining the clinical criteria for Needle-Free connectors

	Clinical Criteria – Needle free Valves (NFV)	Rationale
PACKAGING		
1	All labelling information is present.	To confirm that the information on the packaging meets standards required by EU directive and ISO. .MDD93/42EEC or MDR2017/745
2	Does it state clearly that the NFV is latex free?	General and specialist clinicians have requested this information as patients/staff may have an allergy to latex. This information informs choice.
3	Does it state clearly that the NFV is MRI compatible?	General and specialist clinicians have requested this information as connectors may be removed if compatibility unknown. This may increase infection risk. The image may be distorted if metal is inside the NFC. This information informs choice.
4	The product category is stated on the packaging, (NFV)	General and specialist clinicians have requested this information to facilitate an appropriate clinical choice
5	Is it clearly stated that the NFV is compatible with chlorhexidine and 70% alcohol swabs.	General and specialist clinician have requested this information to facilitate good practice, reduces the risk of infection and is in line with epic 3 guidelines and Standards for Infusion Therapy by the Royal College of Nursing.
6	The NFV valve is visible through one side of the inner packaging?	Clinicians have said this could potentially reduce waste in terms of minimising the wrong device being opened. 90% of Clinicians consulted stated this was very important
7	Is the flow rate stated on the inner packaging/instruction leaflet	General and specialist clinicians have requested this information, to understand the IV fluid delivery rates available to patients. This informs choice.
8	Does it state that the NFV is glass syringe compatible?	General and specialist clinicians have requested this information as the NFC may need to be removed in emergency situations. Occlusion of device may occur. This may increase the risk of infection and may be a safety issue for the patient. This informs choice.
9	Does it state the maximum number of uses on the packaging?	General and specialist clinicians have requested this information to reduce risk of infection and inform local policy. This informs appropriate clinical choice

10	Does it state the duration of use on the packaging e.g., 72 hours?	General and specialist clinicians have requested this information to reduce risk of infection and inform local policy. This informs appropriate clinical choice
11	Are the instructions for use clear on the outer or inner packaging?	General and specialist clinicians have requested this information to inform practice and knowledge.
12	Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs e.g., emergency/chemotherapy.	General and specialist clinicians have requested this information to ensure patient safety, reduce infection and facilitate an appropriate clinical choice
13	Are contraindications of use, (e.g., cannot be used with certain drugs) stated clearly on the packaging?	General and specialist clinicians have requested this information as some drugs may be detrimental to the NFC. This informs choice
14	Is it stated that the valve can be used with pumps? E.g volumetric.	General and specialist clinicians have requested this information to ensure patient safety, reduce infection and facilitate an appropriate clinical choice
OPENING		
15	There is an indicator illustrating where to open the packet or this is obvious.	To facilitate an efficient and standardised opening and preparation technique to maintain ANTT. Reducing the risk of infection.
16	The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	Clinicians stated that inner packaging needs to be EASY to open to facilitate ANTT/Sterility. 90% consulted stated this was very important.
CLINICAL USE		
17	Does the NFV have a smooth flat surface at the end of the device where drugs are administered to aid decontamination	General and specialist clinician have requested this information to facilitate good practice, reduce infection and is in line with epic 3 guidelines.
19	Does the NFV fit securely to the luer lock and luer slip syringes?	General and specialist clinicians have requested this information to ensure components of the system are compatible and secured to minimise leaks and breaks and reduce the risk of infection and to facilitate an appropriate clinical choice.
20	Does the NFV fit the syringe allowing the user to maintain sterility/ANTT	General and specialist clinicians have requested this information to ensure components of the system are compatible and secured to minimise leaks and breaks and reduce the risk of infection and to facilitate an appropriate clinical choice. 90% of clinicians/users stated this was very important.
21	Can the syringe be removed from the NFV allowing the user to maintain sterility/ANTT	General and specialist clinicians have requested this information to ensure components of the system are compatible and secured to minimise leaks and breaks and reduce the risk of infection and to facilitate an appropriate clinical choice. 90% of clinicians/users consulted this was very important.
DISPOSAL		
22	Does it state clearly that the Inner packaging can be recycled	Clinicians indicated that the ability to be able to recycle packaging is an important environmental factor
23	Does it state clearly that the outer packaging can be recycled	Clinicians indicated that the ability to be able to recycle packaging is an important environmental factor

4.2.3 Criteria explanation- Exclusion

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 NFV and Needle-Free Extension Set (Single Lumen) took place.

Excluded Criteria	Rationale for exclusion
Are the NFV licenced/used in the Paediatric patient group?	Due to lack of product information, this made assessment for paediatric use specifically difficult to quantify. This aspect needs to be assessed separately to ensure that this speciality and all its different needs are catered for. For example, priming volume, dead space, size and length of device.

4.3 Product Evaluation

Evaluation methodologies are defined for each and every clinical criterion. They reflect a simulated clinical 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:

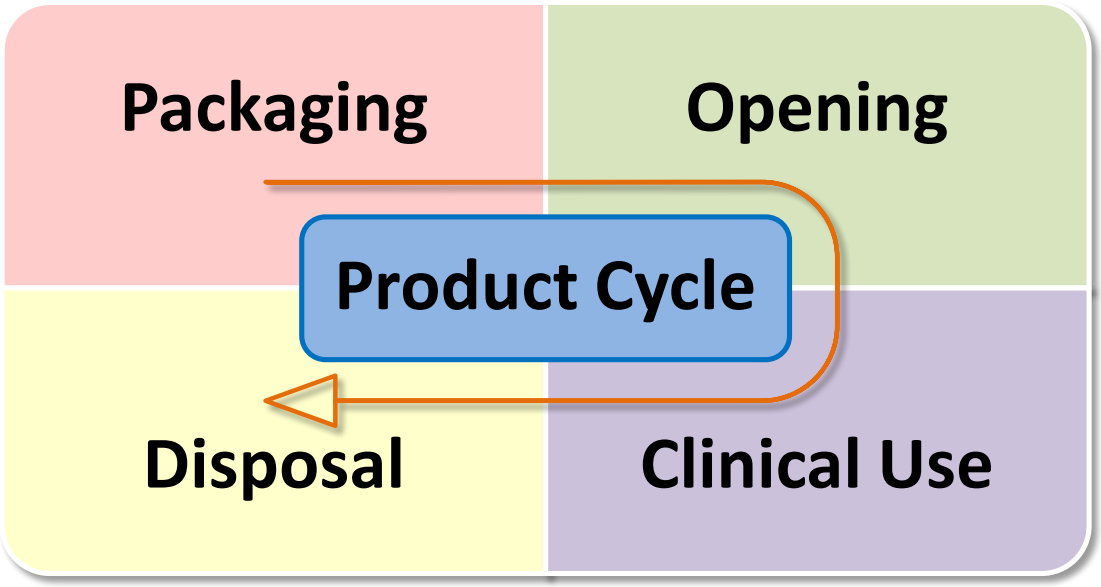


Figure 4 – NHS Clinical Evaluation Team Product Cycle

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 into their own electronic device. 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, which has been represented with a √ / **X,** or a score was given between 0 and 3, or 0 and 2 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**	**3.00**	**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 2.00	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.

5. 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 March 2018 and the products that were available on the evaluation days.

Results can be seen within the product matrix. Each clinical product has been given a star rating.

The product assessment results have been divided into 2 sub-categories as illustrated by the hierarchy below:

- Needle-Free valves
- Needle-Free extension set (Single lumen)

6. Using the Product Assessment Results Matrix

The clinical criteria displayed are designed to reflect 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,

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

i.e. A patient admitted for a short time for rehydration would have a set of different criteria than a patient with a central line undergoing long term chemotherapy.

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.

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
by the NHS, for the NHS

	BAXTER HEALTHCARE LTD
	
BRAND	One Link
MPC	7N8390K
DESCRIPTION	Catheter Extension Set. Bonded Needle-Free IV Connector. With Nuetral fluid displacement. Power injectable
INTENDED USE	Single Use
UNIT OF ISSUE	200
DURATION OF USE	7 days
NUMBER OF ACTIVATIONS	200
CLINICAL CRITERIA	Score
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/EEC). BS EN ISO 15223-1:2016	✓
Is the NFC latex free?	✓
Does it state clearly that the NFC is latex free?	★★ (2.00)*
Is the NFC MRI Compatible?	✓
Does it state clearly the product is MRI compatible?	★★ (0.00)*
What is the maximum pressure (psi)	(325 psi / 2241 kPa)
The product category is stated on the packaging?	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	SS
What is the displacement type?	Neutral
Does it state that the NFC is Positive, negative or neutral displacement	✗
What is the length of the NFC	8.5” (21.6 cm)
The length of the NFC is stated on the individual packaging?	✓
The maximum number of uses is stated on the inner/individual packaging	✗
What is the priming volume?	0.30 ml
The priming volume is stated on the inner/individual packaging	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✗
Are the instructions for use clearly visible on the inner packaging?	★★☆ (2.13)
The NFC is clearly visible through one side of the inner packaging?	★★ (2,00)*
Is the NFC glass syringe compatible?	✓
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.13)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★★ (0.00)*
What is the flow rate?	
Is the flow rate stated on the individual packaging?	✗
There is an indicator illustrating where to open the packet or this is obvious	★★ (2.00)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (2.00)*
Does the device have clear instructions for decontamination?	★★ (0.50)*
Is the device sealed to ensure a closed system?	★★ (2.00)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (2.00)*
Is the NFC compatible with luer slip syringe?	✓
Is the NFC compatible with luer lock slip syringe?	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
by the NHS, for the NHS

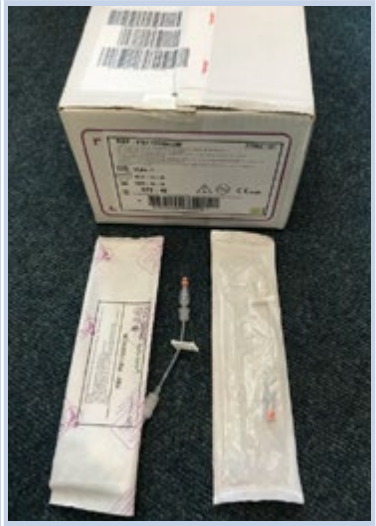
	B BRAUN		
			
BRAND	**Caresite**	**Safeflow**	**Caresite**
MPC	**470108**	**4097154N**	**470100-01**
DESCRIPTION	**Caresite Extension Set**	**Safeflow Extension Set**	**Small Bore Extension Set**
INTENDED USE	**Single Use**	**Single Use**	**Single Use**
UNIT OF ISSUE	**100**	**100 or unit of 1**	**100 or unit of 1**
DURATION OF USE		**7 days**	**7 days**
NUMBER OF ACTIVATIONS		**200**	**216**
CLINICAL CRITERIA	**Score**	**Score**	**ScoreScor**
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/ EEC). BS EN ISO 15223-1:2016	✓	✓	✓
Is the NFC latex free?	✓	✓	✓
Does it state clearly that the NFC is latex free?	★★ (1.75)*	★★ (1.88)*	★★ (1.63)*
Is the NFC MRI Compatible?	✓	✓	✓
Does it state clearly the product is MRI compatible?	★★ (0.38)*	★★ (0.00)*	★★ (0.00)*
What is the maximum pressure (psi)	300 psi (10ml per sec.)		300 psi (10ml per sec.)
The product category is stated on the packaging?	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	SS	SS	SS
What is the displacement type?	0.03mls positive	0.02mls negative	0.03 mls positive
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗
What is the length of the NFC	20cm		20 cm
The length of the NFC is stated on the individual packaging?	✗	✓	✓
The maximum number of uses is stated on the inner/individual packaging	✓	✗	✗
What is the priming volume?	0.5ml	0.20ml	0.5ml
The priming volume is stated on the inner/individual packaging	✓	✗	✓
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✗	✗	✗
Are the instructions for use clearly visible on the inner packaging?	★½☆ (1.25)	★½☆ (1.63)	★☆☆ (1.00)
The NFC is clearly visible through one side of the inner packaging?	★★ (1.50)*	★★ (2.00)*	★★ (1.50)*
Is the NFC glass syringe compatible?	✓	✓	✓
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★★ (0.63)*	★★ (0.00)*	★★ (0.00)*
What is the flow rate?	184.28 mls/min	330ml/min	98.06 ml/min
Is the flow rate stated on the individual packaging?	✗	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★★ (1.88)*	★½ (1.38)*	★★ (1.88)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (1.88)*	★★ (1.86)*	★★ (2.00)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★½ (1.38)*	★½ (1.25)*	★★ (1.50)*
Does the device have clear instructions for decontamination?	★☆ (0.75)*	☆☆ (0.00)*	★½ (1.00)*
Is the device sealed to ensure a closed system?	★★ (1.63)*	★★ (1.88)*	★½ (1.38)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★☆ (0.38)*	☆☆ (0.00)*	★½ (1.00)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★½ (1.00)*	★½ (1.25)*	★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✓	✓	✓

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
by the NHS, for the NHS

	BD/CAREFUSION		
			
BRAND	**BD Q-Syte**	**Neutraclear**	**Neutraclear**
MPC	**385102**	**PB11008NCM**	**PB1201NCM**
DESCRIPTION	**Extension Set**	**Nuetraclear. + clamp Extension Set**	**Nuetraclear+clamp+ mobile ring**
INTENDED USE	**Single Use**	**Single Use**	**Single Use**
UNIT OF ISSUE	**50**	**40**	**40**
DURATION OF USE	**6 days**	**7 days**	**7 days**
NUMBER OF ACTIVATIONS	**100**	**600**	**600**
CLINICAL CRITERIA	**Score**	**Score**	**Score**
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/ EEC). BS EN ISO 15223-1:2016	✓	✓	✓
Is the NFC latex free?	✓	✓	✓
Does it state clearly that the NFC is latex free?	★☆ (0.88)*	★½ (1.38)*	★★ (1.63)*
Is the NFC MRI Compatible?	✓	✓	✓
Does it state clearly the product is MRI compatible?	☆☆ (0.00)*	☆☆ (0.13)*	☆☆ (0.00)*
What is the maximum pressure (psi)	45PSI	325PSI	325PSI
The product category is stated on the packaging?	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	Split Septum	Mechanical valve	Mechanical valve
What is the displacement type?	Negative	Neutral	Neutral
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗
What is the length of the NFC	15cm	14cm	19cm
The length of the NFC is stated on the individual packaging?	✓	✓	✓
The maximum number of uses is stated on the inner/individual packaging	✗	✓	✗
What is the priming volume?	0.34ml	0.29ml	0.41ml
The priming volume is stated on the inner/individual packaging	✗	✗	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✗	✓	✓
Are the instructions for use clearly visible on the inner packaging?	★½☆ (1.63)	★☆☆ (1.13)	☆☆☆ (0.88)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*	★★ (1.88)*	★★ (1.88)*
Is the NFC glass syringe compatible?			
Does it clearly state that the NFC is glass syringe compatible?	☆☆ (0.00)*	☆☆ (0.00)*	☆☆ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	☆☆ (0.38)*	☆☆ (0.38)*	☆☆ (0.38)*
What is the flow rate?	3000ml/hr	3600ml/hr	3600ml/hr
Is the flow rate stated on the individual packaging?	✗	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★½ (1.38)*	★☆ (0.88)*	★☆ (063)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (1.88)*	★★ (1.88)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★½ (1.38)*	★★ (1.88)*	★★ (1.88)*
Does the device have clear instructions for decontamination?	★☆ (0.88)*	★☆ (0.63)*	☆☆ (0.38)*
Is the device sealed to ensure a closed system?	★★ (1.75)*	★★ (2.00)*	★★ (2.00)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	☆☆ (0.00)*	☆☆ (0.38)*	★☆ (050)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (1.88)*	★★ (1.88)*	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★½ (1.00)*	★½ (1.00)*	★½ (1.13)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
by the NHS, for the NHS

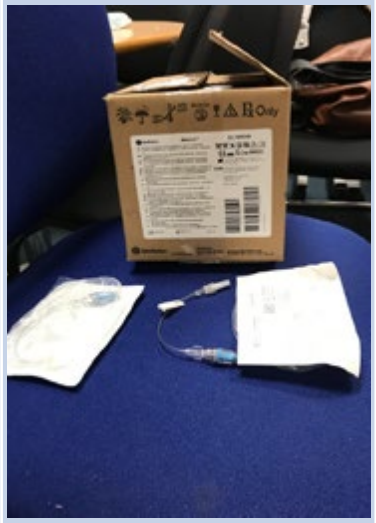
	CAREFUSION			
				
BRAND	SmartSite	SmartSite	SmartSite	Max Plus
MPC	20039E7D	MFX2273E	20021E7D	MP2002C-0006
DESCRIPTION	SmartSite Extension Set with Needle Free Valve	T Extension Set with SmartSite Valve	J-Loop Extention Set. 1 Needle Free Valve	Extension Set with clear Needl Less Connector
INTENDED USE	Single Use	Single Use	Single Use	Single Use
UNIT OF ISSUE	25	50	25	50
DURATION OF USE	7 days	7 days	7 days	
NUMBER OF ACTIVATIONS	200	200	200	
CLINICAL CRITERIA	Score	Score	Score	Score
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/EEC). BS EN ISO 15223-1:2016	✓	✓	✓	✓
Is the NFC latex free?	✓	✓	✓	✓
Does it state clearly that the NFC is latex free?	★★½ (1.00)*	★★½ (1.00)*	★★½ (1.00)*	★★½ (1.63)*
Is the NFC MRI Compatible?	✓	✓	✓	✓
Does it state clearly the product is MRI compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
What is the maximum pressure (psi)				
The product category is stated on the packaging?	✓	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	MV	MV	MV	MV
What is the displacement type?	Negative	Negative	Negative	Positive
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗	✗
What is the length of the NFC	15cm	12cm	15cm	18cm
The length of the NFC is stated on the individual packaging?	✓	✓	✓	✓
The maximum number of uses is stated on the inner/individual packaging	✓	✓	✓	✓
What is the priming volume?	0.16ml	0.33ml	1.2ml	0.51ml
The priming volume is stated on the inner/individual packaging	✗	✗	✗	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✓	✓	✓	✓
Are the instructions for use clearly visible on the inner packaging?	★★★ (1.88)	★★★ (1.75)	★★★ (1.75)	★★★ (1.88)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*
Is the NFC glass syringe compatible?	✓	✓	✓	✓
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs)	★★ (0.00)*	★★ (0.13)*	★★ (0.42)*	★★ (0.25)*
What is the flow rate?				
Is the flow rate stated on the individual packaging?	✓	✓	✓	✗
There is an indicator illustrating where to open the packet or this is obvious	★★ (1.88)*	★★½ (1.00)*	★★ (1.75)*	★★½ (1.63)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*	★★ (2.00)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (2.00)*	★★ (1.75)*	★★ (2.00)*	★★ (2.00)*
Does the device have clear instructions for decontamination?	★★½ (1.00)*	★★ (0.75)*	★★ (0.88)*	★★ (0.50)*
Is the device sealed to ensure a closed system?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (0.75)*	★★ (0.13)*	★★ (0.28)*	★★ (0.00)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*	★★ (1.88)*
Is the tubing undamaged when the clamp is released?	★★½ (1.13)*	★★½ (1.13)*	★★½ (1.00)*	★★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
by the NHS, for the NHS

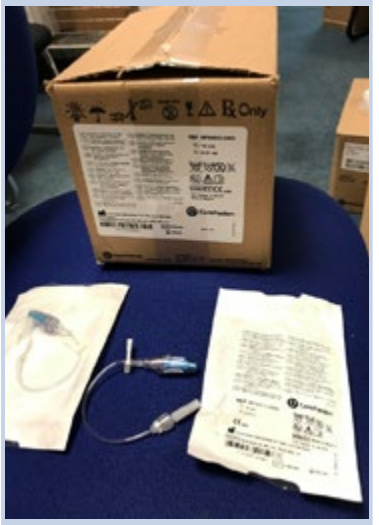
	CAREFUSION			
				
BRAND	CareFusion SmartSite	CareFusion TPS	CareFusion MaxZero	SmartSite
MPC	MFX2203EV	TPS-09-10	MZ5301	20049E7D
DESCRIPTION	SmartSite Needl Free System	Extention Set with Needl Free Valve	Needle Free Extention Set	Smartsite Extention Set. Needle Free Valve
INTENDED USE	Single Use	Single Use	Single Use	Single Use
UNIT OF ISSUE	100	200	50	100
DURATION OF USE	7 days	7 days	7 days	7 days
NUMBER OF ACTIVATIONS	200	200	200	200
CLINICAL CRITERIA	Score	Score	Score	Score
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/ EEC). BS EN ISO 15223-1:2016	✓	✓	✓	✓
Is the NFC latex free?	✓	✓	✓	✓
Does it state clearly that the NFC is latex free?	★½ (1.25)*	★★ (1.88)*	★★ (1.88)*	★½ (1.00)*
Is the NFC MRI Compatible?	✓	✓	✓	
Does it state clearly the product is MRI compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
What is the maximum pressure (psi)			325 PSI	
The product category is stated on the packaging?	✓	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	MV	MV	MV	
What is the displacement type?	Negative	Negative	Positive	Negative
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗	✗
What is the length of the NFC	155cm	10cm	18cm	30.5cm
The length of the NFC is stated on the individual packaging?	✗	✗	✗	✗
The maximum number of uses is stated on the inner/individual packaging	✓	✓	✓	✓
What is the priming volume?	10.5ml	N/A	0.3ml	0.31ml
The priming volume is stated on the inner/individual packaging	✗	✗	✗	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✓	✓	✓	✓
Are the instructions for use clearly visible on the inner packaging?	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (1.75)
The NFC is clearly visible through one side of the inner packaging?	★★ (1.88)*	★★ (1.63)*	★★ (2.00)*	★★ (2.00)*
Is the NFC glass syringe compatible?	✓	✓	✓	
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs)	★★ (0.13)*	★★ (0.13)*	★★ (0.25)*	★★ (0.50)*
What is the flow rate?			3.17L/hr	
Is the flow rate stated on the individual packaging?	✗	✗	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★★ (1.75)*	★★ (1.63)*	★★ (1.75)*	★½ (1.25)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*	★★ (1.63)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (2.00)*	★★ (1.50)*	★★ (2.00)*	★★ (2.00)*
Does the device have clear instructions for decontamination?	★★ (0.88)*	★★ (0.25)*	★★ (0.75)*	★★ (0.88)*
Is the device sealed to ensure a closed system?	★★ (2.00)*	★★ (1.75)*	★★ (2.00)*	★★ (2.00)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (0.25)*	★★ (0.13)*	★★ (0.63)*	★★ (0.00)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*
Is the tubing undamaged when the clamp is released?	★½ (1.38)*	★½ (1.00)*	★½ (1.00)*	★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
by the NHS, for the NHS

	CAREFUSION			
				
BRAND	SmartSite	SmartSite	MaxPlus	Max Plus
MPC	MFX2289E	MFX1608E	MP9081C-0006	MP9001C-0006
DESCRIPTION	Extension Set with Clamp and SmartSite Vallve	Extension Set with SmartSite Valve and Clamp	Maxi Plus Extension Set with clear Needle less Connector	Maxi Plus Extension Set with clear Needle less Connector
INTENDED USE	Single Use	Single Use	Single Use	Single Use
UNIT OF ISSUE	100	100	50	50
DURATION OF USE	7 days	7 days	7 days	
NUMBER OF ACTIVATIONS	200	200	200	
CLINICAL CRITERIA	Score	Score	Score	Score
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/EEC). BS EN ISO 15223-1:2016	✓	✓	✓	✓
Is the NFC latex free?	✓	✓	✓	✓
Does it state clearly that the NFC is latex free?	★½ (1.00)*	★½ (1.00)*	★★ (1.75)*	★★ (1.75)*
Is the NFC MRI Compatible?	✓	✓	✓	
Does it state clearly the product is MRI compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
What is the maximum pressure (psi)				
The product category is stated on the packaging?	✓	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	MV	MV	MV	
What is the displacement type?	Negative	Negative	Positive	Positive
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗	✗
What is the length of the NFC	200cm	19cm	20cm	20cm
The length of the NFC is stated on the individual packaging?	✗	✗	✓	✓
The maximum number of uses is stated on the inner/individual packaging	✓	✓	✓	✓
What is the priming volume?	0.9ml	0.2ml	1.2ml	0.5ml
The priming volume is stated on the inner/individual packaging	✗	✗	✗	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✓	✓	✓	✓
Are the instructions for use clearly visible on the inner packaging?	★½☆ (1.63)	★★☆ (1.75)	★½☆ (1.25)	★½☆ (1.50)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*	★★ (2.00)*	★★ (1.75)*	★★ (2.00)*
Is the NFC glass syringe compatible?				
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs)	★★ (0.38)*	★★ (0.00)*	★★ (0.25)*	★★ (0.25)*
What is the flow rate?				
Is the flow rate stated on the individual packaging?	✗	✗	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★½ (1.38)*	★½ (1.38)*	★½ (1.38)*	★½ (1.38)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (2.00)*	★★ (1.75)*	★★ (2.00)*	★★ (2.00)*
Does the device have clear instructions for decontamination?	★☆ (0.88)*	★☆ (0.75)*	★½ (1.00)*	☆☆ (0.38)*
Is the device sealed to ensure a closed system?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★½ (1.00)*	★½ (1.00)*	★½ (1.13)*	★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
by the NHS, for the NHS

	CAREFUSION		
			
BRAND	Max Plus	SmartSite	CareFusion TPS Brand
MPC	MP2005C-0006	20035E7D	TPS-01-10
DESCRIPTION	Maxi Plus Extension Set with clear Needle less Connector	SmartSite Extension Set. 1 Needle Free Valve	Extension Set Luer Lock Connector
INTENDED USE	Single Use	Single Use	Single Use
UNIT OF ISSUE	50	100	1
DURATION OF USE		7 days	
NUMBER OF ACTIVATIONS		200	
CLINICAL CRITERIA	Score	Score	Score
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/EEC). BS EN ISO 15223-1:2016	✓	✓	✓
Is the NFC latex free?	✓	✓	✓
Does it state clearly that the NFC is latex free?	★★ (1.88)*	★★½ (1.13)*	★★½ (1.13)*
Is the NFC MRI Compatible?			
Does it state clearly the product is MRI compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
What is the maximum pressure (psi)			
The product category is stated on the packaging?	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?			
What is the displacement type?	Positive	Negative	Negative
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗
What is the length of the NFC	18cm	15.2cm	12cm
The length of the NFC is stated on the individual packaging?	✓	✗	✗
The maximum number of uses is stated on the inner/individual packaging	✓	✓	✗
What is the priming volume?	0.9ml	0.36ml	N/A
The priming volume is stated on the inner/individual packaging	✗	✗	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✓	✓	✗
Are the instructions for use clearly visible on the inner packaging?	★★★ (1.75)	★★★ (1.88)	★★★ (0.25)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*	★★ (1.88)*	★★ (2.00)*
Is the NFC glass syringe compatible?			
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs)	★★ (0.25)*	★★ (0.50)*	★★ (0.00)*
What is the flow rate?			
Is the flow rate stated on the individual packaging?	✗	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★★½ (1.38)*	★★½ (1.25)*	★★ (1.88)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (1.75)*	★★ (1.75)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (2.00)*	★★ (1.88)*	★★ (1.63)*
Does the device have clear instructions for decontamination?	★★ (0.50)*	★★ (0.75)*	★★ (0.00)*
Is the device sealed to ensure a closed system?	★★ (2.00)*	★★ (1.88)*	★★ (1.88)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★★½ (1.13)*	★★½ (1.00)*	★★½ (1.13)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
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	CAREFUSION	
		
BRAND	**Alaris**	**Alaris**
MPC	**2.04E-002**	**2.00E-002**
DESCRIPTION	**Extension Set 0.2 Micron. Needle Free Valve Low. Sorbing**	**Extension Set 0.2 Micron. Needle Free Valve**
INTENDED USE	**Single Use**	**Single Use**
UNIT OF ISSUE	**100**	**100**
DURATION OF USE		
NUMBER OF ACTIVATIONS		
CLINICAL CRITERIA	**Score**	**Score**
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/EEC). BS EN ISO 15223-1:2016	✓	✓
Is the NFC latex free?		
Does it state clearly that the NFC is latex free?	★☆ (0.63)*	★☆ (0.50)*
Is the NFC MRI Compatible?		
Does it state clearly the product is MRI compatible?	☆☆ (0.00)*	☆☆ (0.00)*
What is the maximum pressure (psi)		
The product category is stated on the packaging?	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?		
What is the displacement type?		
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗
What is the length of the NFC		
The length of the NFC is stated on the individual packaging?	✓	✓
The maximum number of uses is stated on the inner/individual packaging	✓	✓
What is the priming volume?		
The priming volume is stated on the inner/individual packaging	✗	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✓	✓
Are the instructions for use clearly visible on the inner packaging?	★★☆ (1.88)	★★☆ (1.75)
The NFC is clearly visible through one side of the inner packaging?	★½☆ (1.38)*	★★ (2.00)*
Is the NFC glass syringe compatible?		
Does it clearly state that the NFC is glass syringe compatible?	☆☆ (0.00)*	☆☆ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★☆ (0.63)*	☆☆ (0.25)*
What is the flow rate?		
Is the flow rate stated on the individual packaging?	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★★ (1.63)*	★½ (138)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (1.75)*	★★ (1.75)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (1.63)*	★★ (1.75)*
Does the device have clear instructions for decontamination?	★☆ (0.75)*	★☆ (0.88)*
Is the device sealed to ensure a closed system?	★★ (1.88)*	★★ (1.88)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	☆☆ (0.00)*	☆☆ (0.00)*
Is the NFC compatible with luer slip syringe?	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★½ (1.00)*	★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
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	CODAN
	
BRAND	**Swan-Lock**
MPC	**714518**
DESCRIPTION	**10 CM Swan-Lock. Extension Set**
INTENDED USE	**Single Use**
UNIT OF ISSUE	**100**
DURATION OF USE	**7 days**
NUMBER OF ACTIVATIONS	**200**
CLINICAL CRITERIA	**Score**
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/EEC). BS EN ISO 15223-1:2016	✓
Is the NFC latex free?	✓
Does it state clearly that the NFC is latex free?	★★½ (1.14)*
Is the NFC MRI Compatible?	✓
Does it state clearly the product is MRI compatible?	★★ (0.00)*
What is the maximum pressure (psi)	
The product category is stated on the packaging?	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	SS
What is the displacement type?	Negative, 0.02ml
Does it state that the NFC is Positive, negative or neutral displacement	✗
What is the length of the NFC	
The length of the NFC is stated on the individual packaging?	✓
The maximum number of uses is stated on the inner/individual packaging	✗
What is the priming volume?	0.09ml
The priming volume is stated on the inner/individual packaging	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✗
Are the instructions for use clearly visible on the inner packaging?	★★★ (0.29)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*
Is the NFC glass syringe compatible?	✓
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★★ (0.00)*
What is the flow rate?	150ml/min (1m water column, NACl)
Is the flow rate stated on the individual packaging?	✗
There is an indicator illustrating where to open the packet or this is obvious	★★ (1.57)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (1.71)*
Does the device have clear instructions for decontamination?	★★ (0.00)*
Is the device sealed to ensure a closed system?	★★ (2.00)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (0.00)*
Is the NFC compatible with luer slip syringe?	✓
Is the NFC compatible with luer lock slip syringe?	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
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	FANNIN		
			
BRAND	**Fannin Flowart**	**Flowart**	**Flowart**
MPC	**AU1010**	**AUL1010L 11**	**AU1010L 15**
DESCRIPTION	**Flowart Closed Connector with Extension Line**	**Flowart Needlefree Valve with Extension Line**	**Flowart Needlefree Valve with Extension Line**
INTENDED USE	**Single Use**	**Single Use**	**Single Use**
UNIT OF ISSUE	**100**	**100**	**100**
DURATION OF USE	**Over 7 days**	**Over 7 days**	**Over 7 days**
NUMBER OF ACTIVATIONS	**600**	**600**	**600**
CLINICAL CRITERIA	**Score**	**Score**	**Score**
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/ EEC). BS EN ISO 15223-1:2016	✓	✓	✓
Is the NFC latex free?	✓	✓	✓
Does it state clearly that the NFC is latex free?	★★ (1.75)*	★★ (1.50)*	★★ (1.63)*
Is the NFC MRI Compatible?	✓	✓	✓
Does it state clearly the product is MRI compatible?	★★ (0.38)*	★★ (1.88)*	★★½ (1.25)*
What is the maximum pressure (psi)			
The product category is stated on the packaging?	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	SS	SS	SS
What is the displacement type?			
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗
What is the length of the NFC			
The length of the NFC is stated on the individual packaging?	✗	✗	✗
The maximum number of uses is stated on the inner/individual packaging	✓	✓	✓
What is the priming volume?			
The priming volume is stated on the inner/individual packaging	✓	✓	✓
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✗	✓	✓
Are the instructions for use clearly visible on the inner packaging?	★★★ (1.88)	★ (1.00)	★ (1.00)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the NFC glass syringe compatible?	✓	✓	✓
Does it clearly state that the NFC is glass syringe compatible?	(0.00)*	★★ (1.50)*	★★½ (1.25)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★ (0.63)*	(0.00)*	(0.00)*
What is the flow rate?			
Is the flow rate stated on the individual packaging?	✗	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★★ (1.50)*	★★ (1.63)*	★★½ (1.13)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (2.00)*	★★ (1.75)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (1.88)*	★★½ (1.38)*	★★½ (1.13)*
Does the device have clear instructions for decontamination?	★★ (0.88)*	★★½ (1.00)*	★★½ (1.00)*
Is the device sealed to ensure a closed system?	★★ (2.00)*	★★½ (1.25)*	★★½ (1.38)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	(0.00)*	★★ (1.50)*	★★ (1.75)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (1.63)*	★★ (1.88)*
Is the tubing undamaged when the clamp is released?	★★½ (1.38)*	★★½ (1.00)*	★★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
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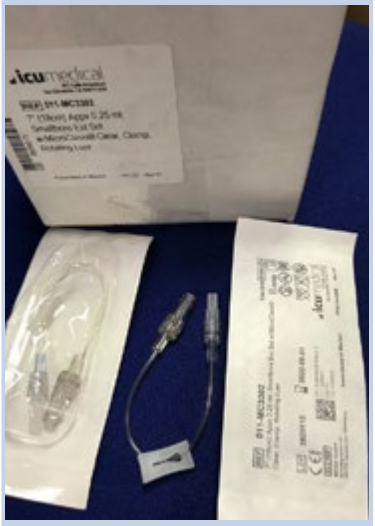
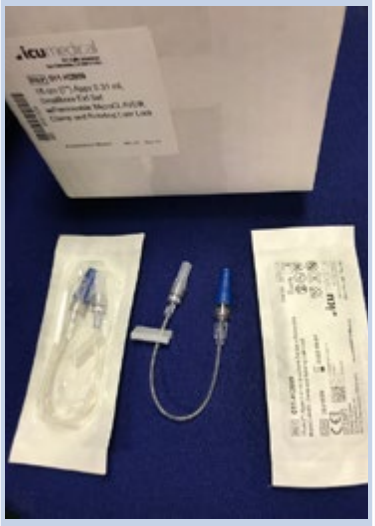
	ICU MEDICAL			
				
BRAND	ICU Medical	ICU Medical	ICU Medical	ICU Medical
MPC	011-C3302	011-H2509	011-H2573	011-A1045
DESCRIPTION	Small Bore Extension Set with Mocroclave Clear and Clamp (18cm). Rotating Luer	Needle Free Extensuion Set . Small bore (18CM). With removeable Micro Clave Clear and Calmp	Small Bore Extension Set with Microvlave and clamp (14cm)*	Small Bore Extension Set with Mocroclave Clear and Clamp (18cm). Luer Lock
INTENDED USE	Single Use	Single Use	Single Use	Single Use
UNIT OF ISSUE	1	1	1	1
DURATION OF USE	7 days	7 days	7 days	7 days
NUMBER OF ACTIVATIONS	700	700	700	700
CLINICAL CRITERIA	Score	Score	Score	Score
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/ EEC). BS EN ISO 15223-1:2016	✓	✓	✓	✓
Is the NFC latex free?	✓	✓	✓	✓
Does it state clearly that the NFC is latex free?	★★½ (1.38)*	★★½ (1.38)*	★★½ (1.38)*	★★ (0.75)*
Is the NFC MRI Compatible?				
Does it state clearly the product is MRI compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
What is the maximum pressure (psi)	300 PSI	300 PSI	300 PSI	300 PSI
The product category is stated on the packaging?	✓	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	Split Septum	Split Septum	Split Septum	Split Septum
What is the displacement type?	Neutral	Neutral	Neutral	Neutral
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗	✗
What is the length of the NFC				
The length of the NFC is stated on the individual packaging?	✓	✓	✓	✓
The maximum number of uses is stated on the inner/individual packaging	✗	✗	✗	✗
What is the priming volume?	0.24 ml	0.31 ml	0.2 ml	0.24 ml
The priming volume is stated on the inner/individual packaging	✗	✗	✗	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✗	✗	✗	✗
Are the instructions for use clearly visible on the inner packaging?	★★½ (1.63)	★★★ (1.75)	★★★ (1.75)	★★★ (1.75)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*	★★ (2,00)*	★★ (2,00)*	★★ (1.88)*
Is the NFC glass syringe compatible?	✗	✗	✗	✗
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★★ (0.38)*	★★ (0.38)*	★★ (0.38)*	★★ (0.63)*
What is the flow rate?	165 ml/min	165 ml/min	165 ml/min	165 ml/min
Is the flow rate stated on the individual packaging?	✗	✗	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★★½ (1.13)*	★★½ (1.13)*	★★½ (1.13)*	★★ (2.00)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (1.88)*	★★ (1.88)*	★★ (1.88)*	★★ (1.88)*
Does the device have clear instructions for decontamination?	★★ (0.25)*	★★ (0.38)*	★★ (0.38)*	★★ (0.38)*
Is the device sealed to ensure a closed system?	★★ (1.75)*	★★ (1.88)*	★★ (1.88)*	★★ (2.00)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (0.00)*	★★ (0.13)*	★★ (0.13)*	★★ (0.13)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★★½ (1.00)*	★★½ (1.00)*	★★½ (1.00)*	★★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
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	INTEGRITY
	
BRAND	**iNTEGRITY**
MPC	**12011000**
DESCRIPTION	**Single Port Needl Free IV access with 10 cm Extension Tube**
INTENDED USE	**Single Use**
UNIT OF ISSUE	**100**
DURATION OF USE	
NUMBER OF ACTIVATIONS	
CLINICAL CRITERIA	**Score**
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/ EEC). BS EN ISO 15223-1:2016	✓
Is the NFC latex free?	✓
Does it state clearly that the NFC is latex free?	★★ (0.00)*
Is the NFC MRI Compatible?	✓
Does it state clearly the product is MRI compatible?	★★ (0.00)*
What is the maximum pressure (psi)	100PSI (Valve only 300PSI)
The product category is stated on the packaging?	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	SS
What is the displacement type?	
Does it state that the NFC is Positive, negative or neutral displacement	✗
What is the length of the NFC	
The length of the NFC is stated on the individual packaging?	✓
The maximum number of uses is stated on the inner/individual packaging	✗
What is the priming volume?	0.22ml
The priming volume is stated on the inner/individual packaging	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✗
Are the instructions for use clearly visible on the inner packaging?	★★★ (0.00)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*
Is the NFC glass syringe compatible?	✓
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★★ (0.00)*
What is the flow rate?	149ml/min
Is the flow rate stated on the individual packaging?	(0.00)*
There is an indicator illustrating where to open the packet or this is obvious	★★ (1.50)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (1.75)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★½ (1.38)*
Does the device have clear instructions for decontamination?	★★ (0.00)*
Is the device sealed to ensure a closed system?	★★½ (1.38)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (0.00)*
Is the NFC compatible with luer slip syringe?	✓
Is the NFC compatible with luer lock slip syringe?	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (1.88)*
Is the tubing undamaged when the clamp is released?	★★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
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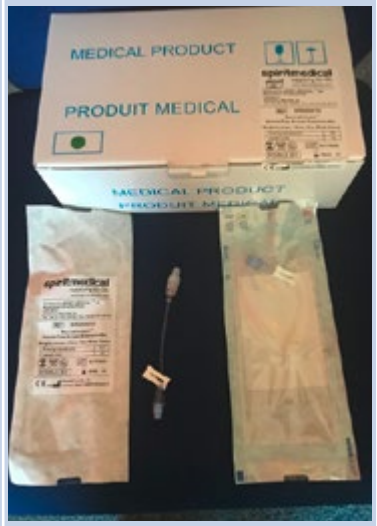
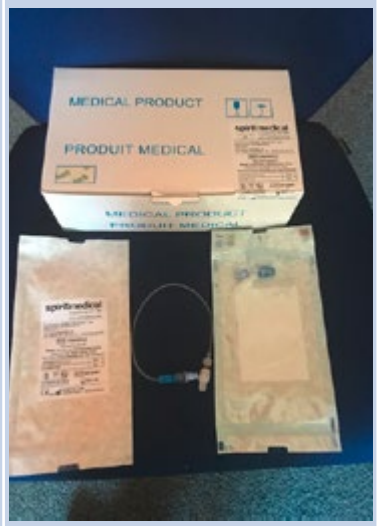
	SPIRIT MEDICAL		
			
BRAND	**Spirit Medical**	**Spirit Medical**	**Spirit Medical**
MPC	**SM000010**	**SM000020**	**SM000021**
DESCRIPTION	**Needle Free Access Administration Assist Extention Set**	**Luer Lock T Connector microbore Extention Set**	**Secure Connect Administration Assist Extention Set**
INTENDED USE	**Single Use**	**Single Use**	**Single Use**
UNIT OF ISSUE	**25 or 200**	**25**	**25**
DURATION OF USE	**7 days**	**7 days**	**7 days**
NUMBER OF ACTIVATIONS	**600**	**600**	**600**
CLINICAL CRITERIA	**Score**	**Score**	**Score**
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/ EEC). BS EN ISO 15223-1:2016	✓	✓	✓
Is the NFC latex free?	✓	✓	✓
Does it state clearly that the NFC is latex free?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the NFC MRI Compatible?	✓	✓	✓
Does it state clearly the product is MRI compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
What is the maximum pressure (psi)	1200 PSI	1200 PSI	1200 PSI
The product category is stated on the packaging?	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	SS	SS	SS
What is the displacement type?	Negative	Negative	Negative
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗
What is the length of the NFC	10 cm	10 cm	10 cm
The length of the NFC is stated on the individual packaging?	✓	✓	✓
The maximum number of uses is stated on the inner/individual packaging			
What is the priming volume?	0.3ml	0.3ml	0.6m
The priming volume is stated on the inner/individual packaging	✓	✗	✓
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✗	✗	✗
Are the instructions for use clearly visible on the inner packaging?	★★★ (0.00)	★★★ (0.00)	★★★ (0.00)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the NFC glass syringe compatible?	✓	✓	✓
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
What is the flow rate?	1300 ml/min	1300 ml/min	1300 ml/min
Is the flow rate stated on the individual packaging?	✗	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★½ (1.33)*	★★ (1.83)*	★★ (1.83)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (1.83)*	★★ (2.00)*	★★ (2.00)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (1.50)*	★★½ (1.33)*	★★ (1.67)*
Does the device have clear instructions for decontamination?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is the device sealed to ensure a closed system?	★★ (1.67)*	★★ (1.50)*	★★ (1.83)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★½ (1.00)*	★★½ (1.17)*	★★ (1.50)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
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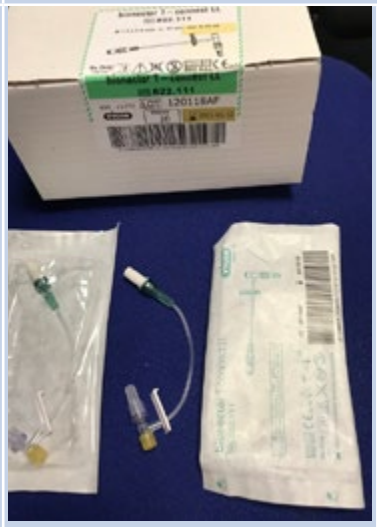
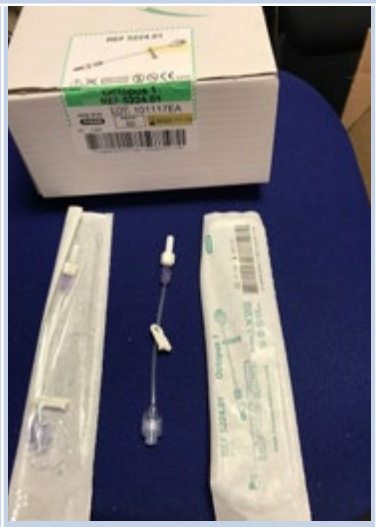
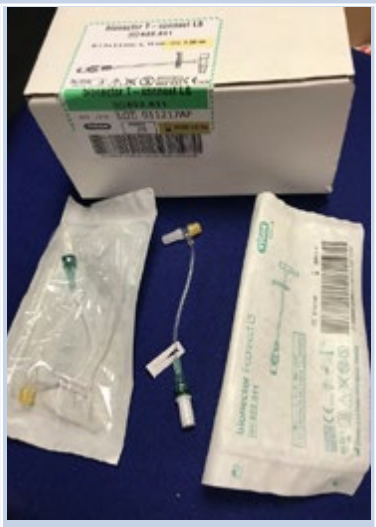
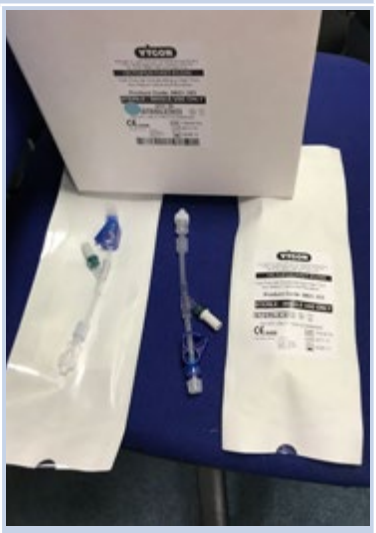
	VYGON			
				
BRAND	**Bionector T LL**	**Octopus 1**	**Bionector T LS**	**Vygon Infu-Safe**
MPC	**822.11**	**5224**	**822.61**	**831103**
DESCRIPTION	**Needle Free Extension Set**	**Needle Free Extension Set**	**Needle Free Extension Set**	**Fast Flow Set Incorporating a High Flow Non Return Valve and Bionector**
INTENDED USE	**Single Use**	**Single Use**	**Single Use**	**Single Use**
UNIT OF ISSUE	**20**	**50**	**20**	**50**
DURATION OF USE	**7 days**	**7 days**	**7 days**	**7 days**
NUMBER OF ACTIVATIONS	**360**	**360**	**360**	**360**
CLINICAL CRITERIA	**Score**	**Score**	**Score**	**Score**
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/ EEC). BS EN ISO 15223-1:2016	✓	✓	✓	✓
Is the NFC latex free?	✓	✓	✓	✓
Does it state clearly that the NFC is latex free?	★★ (0.25)*	★★ (0.88)*	★★ (0.38)*	★★ (0.63)*
Is the NFC MRI Compatible?	✓	✓	✓	✓
Does it state clearly the product is MRI compatible?	★★ (0.75)*	★★ (0.75)*	★★ (0.75)*	★★ (0.88)*
What is the maximum pressure (psi)	350 psi	350 psi	350 psi	350 psi
The product category is stated on the packaging?	✓	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	SS	SS	SS	SS
What is the displacement type?	Neutral	Neutral	Neutral	Neutral
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗	✗
What is the length of the NFC	10cm	10cm	10cm	10cm
The length of the NFC is stated on the individual packaging?	✗	✗	✗	✗
The maximum number of uses is stated on the inner/individual packaging	✓	✓	✓	✓
What is the priming volume?	0.29ml	0.29ml	0.29ml	0.29ml
The priming volume is stated on the inner/individual packaging	✗	✗	✗	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✓	✓	✓	✓
Are the instructions for use clearly visible on the inner packaging?	★★★ (2.13)	★★★ (3.00)	★★★ (2.88)	★★★ (2.88)
The NFC is clearly visible through one side of the inner packaging?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the NFC glass syringe compatible?				
Does it clearly state that the NFC is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★★ (0.38)*	★★ (0.38)*	★★ (0.25)*	★★ (0.25)*
What is the flow rate?	75ml/min under gravity	75ml/min under gravity	75ml/min under gravity	75ml/min under gravity
Is the flow rate stated on the individual packaging?	✗	✗	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★★ (1.72)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (1.50)*	★★ (1.63)*	★★ (1.63)*	★★ (1.50)*
Does the device have clear instructions for decontamination?	★★ (0.63)*	★★ (0.88)*	★★½ (1.00)*	★★½ (1.00)*
Is the device sealed to ensure a closed system?	★★ (1.75)*	★★ (1.88)*	★★ (1.75)*	★★ (2.00)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	★★ (0.25)*	★★ (0.25)*	★★ (0.00)*	★★ (0.13)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★★½ (1.00)*	★★½ (1.14)*	★★½ (1.00)*	★★½ (1.25)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE-FREE CONNECTORS

– Extension Sets (Single lumen)*

NHS Clinical Evaluation Team
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	VYGON		
			
BRAND	**Vadsite LL**	**Octopus 1**	**Octopus 1**
MPC	**822115**	**8522201C**	**5224.014**
DESCRIPTION	**Vadsite T Connect Extension Set**	**Bionector S Needle Free Extension Set**	**Bionector. Needle Free Extension Set**
INTENDED USE	**Single Use**	**Single Use**	**Single Use**
UNIT OF ISSUE	**20**	**50**	**50**
DURATION OF USE	**7 days**	**7 days**	**7 days**
NUMBER OF ACTIVATIONS	**360**	**360**	**360**
CLINICAL CRITERIA	**Score**	**Score**	**Score**
All labelling information is present as stated in MDR 2017/745 (MDD 93/42/ EEC). BS EN ISO 15223-1:2016	✓	✓	✓
Is the NFC latex free?	✓	✓	✓
Does it state clearly that the NFC is latex free?	★☆ (0.63)*	☆☆ (0.00)*	★☆ (0.63)*
Is the NFC MRI Compatible?	✓	✓	✓
Does it state clearly the product is MRI compatible?	☆☆ (0.25)*	☆☆ (0.00)*	★☆ (0.75)*
What is the maximum pressure (psi)	350 psi	350 psi	350 psi
The product category is stated on the packaging?	✓	✓	✓
Is the valve a split septum (SS) or Mechanical Valve (MV)?	SS	SS	SS
What is the displacement type?	Neutral	Neutral	Neutral
Does it state that the NFC is Positive, negative or neutral displacement	✗	✗	✗
What is the length of the NFC	10cm	10cm	10cm
The length of the NFC is stated on the individual packaging?	✗	✓	✓
The maximum number of uses is stated on the inner/individual packaging	✓	✓	✓
What is the priming volume?	0.29ml	0.29ml	0.29ml
The priming volume is stated on the inner/individual packaging	✓	✗	✗
The duration of use is stated on the inner packaging/individual e.g., 72 hours/7days?	✓	✓	✓
Are the instructions for use clearly visible on the inner packaging?	★★☆ (2.13)	★★½ (2.63)	★★★ (2.75)
The NFC is clearly visible through one side of the inner packaging?	★★ (1.88)*	★★ (1.88)*	★★ (1.88)*
Is the NFC glass syringe compatible?	✓		
Does it clearly state that the NFC is glass syringe compatible?	☆☆ (0.00)*	☆☆ (0.00)*	☆☆ (0.00)*
Is it stated clearly on the packaging contraindications of use? (Cannot be used with certain drugs).	★☆ (0.50)*	☆☆ (0.38)*	☆☆ (0.38)*
What is the flow rate?	75ml/min under gravity	75ml/min under gravity	75ml/min under gravity
Is the flow rate stated on the individual packaging?	✓	✗	✗
There is an indicator illustrating where to open the packet or this is obvious	★★ (1.88)*	★★ (1.75)*	★★ (1.75)*
The individual packaging is easy to open and allows the NFC to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (1.88)*	★★ (1.75)*
Does the NFC have flat smooth surfaces, to aid effective cleaning?	★★ (1.63)*	★★ (1.50)*	★★ (1.50)*
Does the device have clear instructions for decontamination?	★☆ (0.50)*	★☆ (0.88)*	★☆ (0.88)*
Is the device sealed to ensure a closed system?	★★ (1.88)*	★★ (1.88)*	★★ (1.88)*
Does it state clearly that the NFC can be used in an emergency situation, fast flow/power injectable?	☆☆ (0.38)*	☆☆ (0.00)*	☆☆ (0.00)*
Is the NFC compatible with luer slip syringe?	✓	✓	✓
Is the NFC compatible with luer lock slip syringe?	✓	✓	✓
Is the NFC easy to handle when connecting to the cannula and accessing with a syringe? Without breaching ANTT?	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Is the tubing undamaged when the clamp is released?	★½ (1.25)*	★½ (1.00)*	★½ (1.00)*
Does it state clearly that the outer and inner packaging can be recycled?	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

NHS Clinical Evaluation Team
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	B BRAUN	
		
BRAND	**Caresite**	**Safeflow**
MPC	**415122-01**	**409100H**
DESCRIPTION	**CARESITE. Luer Access Device**	**Needle Free Injection/ Infusion Valve**
INTENDED USE	**Single Use**	**Single Use**
UNIT OF ISSUE	**100**	**50**
DURATION OF USE	**7 days**	**7 days**
NUMBER OF ACTIVATIONS	**216**	**200**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓	✓
Is the NFV latex free?	✓	✓
Does it state that the NFV is latex free?	✓	✓
Is the NFV MRI compatible?	✓	✓
Does it state clearly the NFV is MRI compatible?	✗	✗
The product category is stated on the outer packaging	✓	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	SS	SS
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✗	✗
The NFV is visible through one side of the packaging	✓	✓
What is the flow rate?	208 ml/min	360ml/min
Is the flow rate stated on the inner packaging	✗	✗
Is the NFV glass syringe compatible?	✓	✓
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✗	✗
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (0.00)*	★★ (0.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★ (1.13)	★ (0.75)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★ (1.13)	★ (0.75)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	(0.38)	(0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★ (1.00)	(0.00)
There is an indicator of where to open the packet or this is obvious	★½ (1.13)*	★½ (1.38)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (1.88)*	★★ (2.00)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (1.50)*	★★ (2.00)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (2.00)*	★★ (2.00)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (1.88)*	★★ (2.00)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (1.75)*	★★ (2.00)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*	★★ (2.00)*
Is it stated clearly that the inner packaging can be recycled	✓	✓
Is it stated clearly that the outer packaging can be recycled	✗	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

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	BAXTER
	
BRAND	ONE-LINK
MPC	Baxter ONE-LINK
DESCRIPTION	Needle Free Connector
INTENDED USE	Single Use
UNIT OF ISSUE	200
DURATION OF USE	7 days
NUMBER OF ACTIVATIONS	200
NHS CET PRODUCT ASSESSMENT CYCLE	Score
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓
Is the NFV latex free?	✓
Does it state that the NFV is latex free?	✓
Is the NFV MRI compatible?	✓
Does it state clearly the NFV is MRI compatible?	✗
The product category is stated on the outer packaging	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✗
The NFV is visible through one side of the packaging	✓
What is the flow rate?	maximum of 10mls
Is the flow rate stated on the inner packaging	✓
Is the NFV glass syringe compatible?	
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✓
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (2.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★★★ (3.00)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★ (1.00)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	(0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★ (1.00)
There is an indicator of where to open the packet or this is obvious	★★ (2.00)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (2.00)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (2.00)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (1.67)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (2.00)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*
Is it stated clearly that the inner packaging can be recycled	✗
Is it stated clearly that the outer packaging can be recycled	✓

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

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	BD/CAREFUSION
	
BRAND	**BD Q-Syte**
MPC	**385100**
DESCRIPTION	**Luer Access Split Septum**
INTENDED USE	**Single Use**
UNIT OF ISSUE	**50**
DURATION OF USE	**6 days**
NUMBER OF ACTIVATIONS	**100**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓
Is the NFV latex free?	✓
Does it state that the NFV is latex free?	✓
Is the NFV MRI compatible?	✓
Does it state clearly the NFV is MRI compatible?	✗
The product category is stated on the outer packaging	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	Split Septum
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✓
The NFV is visible through one side of the packaging	✓
What is the flow rate?	32000 ml/hr
Is the flow rate stated on the inner packaging	✗
Is the NFV glass syringe compatible?	✓
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✓
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (0.25)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★★½ (1.50)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★★★ (0.50)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	★★★ (0.50)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★★★ (0.38)
There is an indicator of where to open the packet or this is obvious	★★½ (1.13)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★½ (1.25)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.88)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (1.88)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (1.75)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*
Is it stated clearly that the inner packaging can be recycled	✗
Is it stated clearly that the outer packaging can be recycled	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

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	CAREFUSION			
				
BRAND	**SmartSite**	**Swabinector**	**Max Plus**	**Max Zero**
MPC	**2000E7D**	**TPS**	**MP10000C-0006**	**M21000**
DESCRIPTION	**Needle Free Valve**	**Needle Free Valve**	**Clear Needle Free Connector**	**Needle Less Connector**
INTENDED USE	**Single Use**	**Single Use**	**Single Use**	**Single Use**
UNIT OF ISSUE		**100**	**100**	**100**
DURATION OF USE	**7 days**	**7 days**	**7 days**	**7 days**
NUMBER OF ACTIVATIONS	**200**	**200**	**200**	**200**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**	**Score**	**Score**	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓	✓	✓	✓
Is the NFV latex free?	✓	✓	✓	✓
Does it state that the NFV is latex free?	✓	✓	✓	✓
Is the NFV MRI compatible?	✓	✓	✓	✓
Does it state clearly the NFV is MRI compatible?	✗	✗	✗	✓
The product category is stated on the outer packaging	✓	✓	✓	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	Mechanical Valve	Mechanical Valve	Mechanical Valve	Mechanical Valve
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓	✓	✓	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✗	✗	✗	✓
The NFV is visible through one side of the packaging	✓	✓	✓	✓
What is the flow rate?	8100ml/hr	21600ml/hr	11000ml/hr	8500ml/hr
Is the flow rate stated on the inner packaging	✗	✗	✗	✓
Is the NFV glass syringe compatible?	✓	✓	✓	✓
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✗	✗	✓	✓
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★★★ (0.00)	★★★ (0.00)	★★★ (1.13)	★★½ (1.25)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★★★ (0.00)	★★★ (0.00)	★★★ (0.00)	★★★ (0.00)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	★★★ (0.00)	★★★ (0.00)	★★★ (0.50)	★★★ (0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★★★ (0.00)	★★★ (0.00)	★★★ (0.38)	★★★ (0.88)
There is an indicator of where to open the packet or this is obvious	★★½ (1.00)*	★★ (0.63)*	★★½ (1.25)*	★★½ (1.38)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (1.88)*	★★ (1.75)*	★★ (1.88)*	★★ (2.00)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (2.00)*	★★ (1.88)*	★★ (1.88)*	★★ (1.88)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*	★★ (1.88)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (1.88)*	★★ (2.00)*	★★½ (1.13)*	★★ (1.88)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (1.88)*	★★ (2.00)*	★★ (1.50)*	★★ (1.75)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*	★★ (2.00)*	★★ (1.67)*	★★ (1.75)*
Is it stated clearly that the inner packaging can be recycled	✗	✗	✗	✗
Is it stated clearly that the outer packaging can be recycled	✗	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

NHS Clinical Evaluation Team
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	CAREFUSION
	
BRAND	**Neutraclear**
MPC	**EL200**
DESCRIPTION	**Transparent and Neutral Bidirectional Valve**
INTENDED USE	**Single Use**
UNIT OF ISSUE	**50**
DURATION OF USE	**7 days**
NUMBER OF ACTIVATIONS	**600**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓
Is the NFV latex free?	✓
Does it state that the NFV is latex free?	✓
Is the NFV MRI compatible?	✓
Does it state clearly the NFV is MRI compatible?	✓
The product category is stated on the outer packaging	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	Mechanical Valve
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✓
The NFV is visible through one side of the packaging	✓
What is the flow rate?	8400ml/hr
Is the flow rate stated on the inner packaging	✓
Is the NFV glass syringe compatible?	✗
Does it state clearly that the NFV is glass syringe compatible?	☆☆ (0.00)*
Does it state the maximum number of activations on the packaging	✗
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	☆☆ (0.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★☆☆ (1.00)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	☆☆☆ (0.00)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	☆☆☆ (0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	☆☆☆ (0.63)
There is an indicator of where to open the packet or this is obvious	★½ (1.00)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (1.88)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (1.50)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.50)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (2.00)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (1.50)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (1.50)*
Is it stated clearly that the inner packaging can be recycled	✗
Is it stated clearly that the outer packaging can be recycled	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

NHS Clinical Evaluation Team
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	CODAN	
		
BRAND	**Swan Lock**	**Swan Lock Red**
MPC	**165267**	**165273**
DESCRIPTION	**Negative Displacement, Needle-Free Adapter**	**Negative Displacement Swabable Needle Free Adapters**
INTENDED USE	**Single Use**	**Single Use**
UNIT OF ISSUE	**100**	**100**
DURATION OF USE	**7 days**	**7 days**
NUMBER OF ACTIVATIONS	**200**	**200**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓	✓
Is the NFV latex free?	✓	✓
Does it state that the NFV is latex free?	✓	✓
Is the NFV MRI compatible?	✓	✓
Does it state clearly the NFV is MRI compatible?	✗	✗
The product category is stated on the outer packaging	✓	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	SS	SS
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✓	✓
The NFV is visible through one side of the packaging	✓	✓
What is the flow rate?	150ml/min (1m water column, NACl)	150ml/min (1m water column, NACl)
Is the flow rate stated on the inner packaging	✗	✗
Is the NFV glass syringe compatible?	✓	✓
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✓	✓
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★½ (1.00)*	★★ (0.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★ (1.00)	★★★ (0.00)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★★★ (0.00)	★★★ (0.00)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	★★★ (0.00)	★★★ (0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★★★ (0.00)	★★★ (0.00)
There is an indicator of where to open the packet or this is obvious	★★½ (1.38)*	★★½ (1.38)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (1.88)*	★★ (1.75)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (1.50)*	★★ (1.75)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.75)*	★★ (1.88)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (2.00)*	★★ (2.00)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (2.00)*	★★ (1.88)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*	★★ (2.00)*
Is it stated clearly that the inner packaging can be recycled	✗	✗
Is it stated clearly that the outer packaging can be recycled	✗	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

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	FANNIN	
		
BRAND	**Flowart**	**Flowart**
MPC	**A1010**	**A1010PH**
DESCRIPTION	**Flowart Closed Connector**	**Flowart Closed Connector**
INTENDED USE	**Single Use**	**Single Use**
UNIT OF ISSUE	**250**	**250**
DURATION OF USE	**Over 7 days**	**Over 7 days**
NUMBER OF ACTIVATIONS	**600**	**600**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓	✓
Is the NFV latex free?	✓	✓
Does it state that the NFV is latex free?	✓	✓
Is the NFV MRI compatible?	✓	✓
Does it state clearly the NFV is MRI compatible?	✓	✓
The product category is stated on the outer packaging	✓	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	SS	SS
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✓	✓
The NFV is visible through one side of the packaging	✓	✓
What is the flow rate?	312 ml/min @ 1m (39 in) water head pressure	312 ml/min @ 1m (39 in) water head pressure
Is the flow rate stated on the inner packaging	✓	✓
Is the NFV glass syringe compatible?	✓	✓
Does it state clearly that the NFV is glass syringe compatible?	★☆ (0.75)*	★½ (1.00)*
Does it state the maximum number of activations on the packaging	✓	✓
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★½ (1.00)*	★½ (1.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	☆☆☆ (0.88)	★☆☆ (1.00)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	☆☆☆ (0.88)	☆☆☆ (0.75)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	☆☆☆ (0.38)	☆☆☆ (0.38)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	☆☆☆ (0.63)	☆☆☆ (0.63)
There is an indicator of where to open the packet or this is obvious	★★ (1.88)*	★★ (1.88)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (1.88)*	★★ (2.00)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (1.88)*	★★ (2.00)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.88)*	★★ (2.00)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (2.00)*	★★ (1.88)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (1.88)*	★★ (1.75)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (1.88)*	★★ (1.75)*
Is it stated clearly that the inner packaging can be recycled	✗	✗
Is it stated clearly that the outer packaging can be recycled	✗	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

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	ICU MEDICAL			
				
BRAND	**Microclave**	**Microclave**	**Tego**	**Clave**
MPC	**011-C3300**	**011-MC100**	**D1000**	**044-C1000**
DESCRIPTION	**Microclave Connector**	**Microclave Clear Connector**	**Tego Connector**	**Clave Connector**
INTENDED USE	**Single Use**	**Single Use**	**Single Use**	**Single Use**
UNIT OF ISSUE	**100**	**100**	**100**	**100**
DURATION OF USE	**7 Days**	**7 Days**	**7 Days**	**7 Days**
NUMBER OF ACTIVATIONS	**700**	**700**	**40**	**700**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**	**Score**	**Score**	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓	✓	✓	✓
Is the NFV latex free?	✓	✓	✓	✓
Does it state that the NFV is latex free?	✓	✓	✓	✓
Is the NFV MRI compatible?	✓	✓	✓	✓
Does it state clearly the NFV is MRI compatible?	✗	✗	✗	✗
The product category is stated on the outer packaging	✓	✓	✓	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	Split Septum	Split Septum	Split Septum	Split Septum
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓	✓	✓	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✗	✗	✗	✓
The NFV is visible through one side of the packaging	✓	✓	✓	✓
What is the flow rate?	165 ml/min	165 ml/min	>60cc/min at 36 inch head height gravity flow	165 ml/min
Is the flow rate stated on the inner packaging	✗	✗	✗	✗
Is the NFV glass syringe compatible?	✗	✗	✓	✗
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✗	✗	✗	✗
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (0.00)*	★★ (0.00)*	★★ (0.75)*	★★ (0.75)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★ (1.00)	★ (1.00)	★ (1.00)	★ (1.00)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	(0.00)	(0.00)	(0.00)	(0.00)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	(0.00)	(0.00)	(0.00)	(0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	(0.00)	(0.00)	(0.00)	(0.38)
There is an indicator of where to open the packet or this is obvious	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (1.88)*	★★ (1.88)*	★★ (1.38)*	★★ (1.13)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (2.00)*	★★ (2.00)*	★★ (1.75)*	★★ (1.38)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (1.88)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (1.63)*	★★ (2.00)*	★★ (1.88)*	★★ (1.88)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*	★★ (1.88)*	★★ (2.00)*	★★ (1.75)*
Is it stated clearly that the inner packaging can be recycled	✗	✗	✗	✗
Is it stated clearly that the outer packaging can be recycled	✗	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

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	ICU MEDICAL	
		
BRAND	**Neutron**	**Nano Clave**
MPC	**011-NC100**	**011-A1000**
DESCRIPTION	**Neutron**	**Nano Clave**
INTENDED USE	**Single Use**	**Single Use**
UNIT OF ISSUE	**100**	**100**
DURATION OF USE		
NUMBER OF ACTIVATIONS		
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓	✓
Is the NFV latex free?	✓	✓
Does it state that the NFV is latex free?	✓	✓
Is the NFV MRI compatible?		
Does it state clearly the NFV is MRI compatible?	✗	✗
The product category is stated on the outer packaging	✓	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	SS	SS
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✓	✗
The NFV is visible through one side of the packaging	✓	✓
What is the flow rate?		
Is the flow rate stated on the inner packaging	✗	✗
Is the NFV glass syringe compatible?		
Does it state clearly that the NFV is glass syringe compatible?	☆☆ (0.00)*	☆☆ (0.00)*
Does it state the maximum number of activations on the packaging	✗	✗
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	☆☆ (0.00)*	☆☆ (0.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★☆☆ (1.00)	★☆☆ (1.00)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	☆☆☆ (0.00)	☆☆☆ (0.00)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	☆☆☆ (0.00)	☆☆☆ (0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	☆☆☆ (0.38)	☆☆☆ (0.00)
There is an indicator of where to open the packet or this is obvious	★★ (2.00)*	★★ (2.00)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*	★★ (1.88)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (1.75)*	★★ (1.50)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.75)*	★★ (1.63)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (1.88)*	★★ (1.63)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (1.88)*	★★ (1.75)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*	★★ (2.00)*
Is it stated clearly that the inner packaging can be recycled	✗	✗
Is it stated clearly that the outer packaging can be recycled	✗	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

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	INTEGRITY
	
BRAND	**IV Access Device**
MPC	**12071000**
DESCRIPTION	**Needle-Free IV Access Device**
INTENDED USE	
UNIT OF ISSUE	**100**
DURATION OF USE	**7 days**
NUMBER OF ACTIVATIONS	**140**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓
Is the NFV latex free?	✓
Does it state that the NFV is latex free?	✗
Is the NFV MRI compatible?	✓
Does it state clearly the NFV is MRI compatible?	✗
The product category is stated on the outer packaging	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	SS
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✗
The NFV is visible through one side of the packaging	✓
What is the flow rate?	630ml/min
Is the flow rate stated on the inner packaging	✗
Is the NFV glass syringe compatible?	✓
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✗
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (0.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★★★ (0.13)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★★★ (0.25)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	★★★ (0.25)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★★★ (0.00)
There is an indicator of where to open the packet or this is obvious	★★ (1.88)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (1.75)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★½ (1.38)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.50)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (2.00)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (2.00)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*
Is it stated clearly that the inner packaging can be recycled	✗
Is it stated clearly that the outer packaging can be recycled	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

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	MATZ
	
BRAND	**MATZ NFV**
MPC	**MML NFV I**
DESCRIPTION	**Needle Free Valve**
INTENDED USE	**Single Use**
UNIT OF ISSUE	**50**
DURATION OF USE	
NUMBER OF ACTIVATIONS	
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓
Is the NFV latex free?	✓
Does it state that the NFV is latex free?	✗
Is the NFV MRI compatible?	✓
Does it state clearly the NFV is MRI compatible?	✗
The product category is stated on the outer packaging	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	
Is the NFV is compatible with chlorhexidine and 70% alcohol?	
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✗
The NFV is visible through one side of the packaging	✓
What is the flow rate?	10mins/1000ml
Is the flow rate stated on the inner packaging	✗
Is the NFV glass syringe compatible?	
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✓
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (0.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★★★ (0.00)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★★★ (0.00)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	★★★ (0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★★★ (0.00)
There is an indicator of where to open the packet or this is obvious	★★½ (1.00)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★½ (1.13)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (1.75)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.88)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (1.50)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (1.63)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (1.50)*
Is it stated clearly that the inner packaging can be recycled	✗
Is it stated clearly that the outer packaging can be recycled	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

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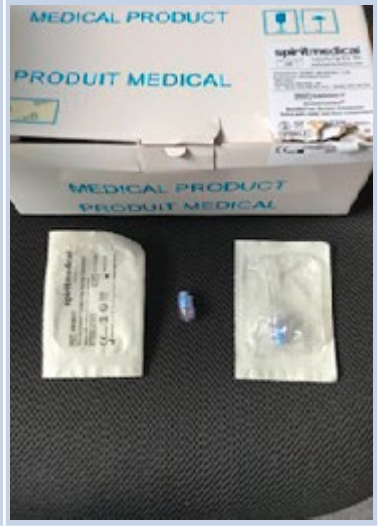
	SPIRIT MEDICAL
	
BRAND	**Spiritmedical**
MPC	**SM000017**
DESCRIPTION	**Needle Free Valve**
INTENDED USE	**Single Use**
UNIT OF ISSUE	**25 or 200**
DURATION OF USE	**7 days**
NUMBER OF ACTIVATIONS	**600**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓
Is the NFV latex free?	✓
Does it state that the NFV is latex free?	✓
Is the NFV MRI compatible?	✓
Does it state clearly the NFV is MRI compatible?	✗
The product category is stated on the outer packaging	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	SS
Is the NFV is compatible with chlorhexidine and 70% alcohol?	
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✗
The NFV is visible through one side of the packaging	✓
What is the flow rate?	1300 ml/min
Is the flow rate stated on the inner packaging	✗
Is the NFV glass syringe compatible?	✓
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✗
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (0.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★★★ (0.00)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★★★ (0.00)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	★★★ (0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★★★ (0.00)
There is an indicator of where to open the packet or this is obvious	★★ (1.00)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (2.00)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (1.67)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.88)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (2.00)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (2.00)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*
Is it stated clearly that the inner packaging can be recycled	✗
Is it stated clearly that the outer packaging can be recycled	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

NHS Clinical Evaluation Team
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	VYGON			
				
BRAND	**Bionector S**	**Bionector TKO**	**Bionector**	**Bionector**
MPC	**89623**	**083801E**	**896.03**	**896.01**
DESCRIPTION	**Needle Free Valve**	**Needle Free Valve**	**Needle Free Valve**	**Needle Less Connector**
INTENDED USE	**Single Use**	**Single Use**	**Single Use**	**Single Use**
UNIT OF ISSUE	**50**	**50**	**50**	**50**
DURATION OF USE	**7 days**	**7 days**	**7 days**	**7 days**
NUMBER OF ACTIVATIONS	**360**	**360**	**360**	**360**
NHS CET PRODUCT ASSESSMENT CYCLE	**Score**	**Score**	**Score**	**Score**
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓	✓	✓	✓
Is the NFV latex free?	✓	✓	✓	✓
Does it state that the NFV is latex free?	✗	✗	✓	✓
Is the NFV MRI compatible?	✓	✓	✓	✓
Does it state clearly the NFV is MRI compatible?	✗	✓	✓	✗
The product category is stated on the outer packaging	✓	✓	✓	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	SS	SS	SS	SS
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓	✓	✓	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✗	✗	✗	✓
The NFV is visible through one side of the packaging	✓	✓	✓	✓
What is the flow rate?	105ml/min	105ml/min	105ml/min	105ml/min
Is the flow rate stated on the inner packaging	✗	✗	✗	✓
Is the NFV glass syringe compatible?				
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✓	✓	✓	✓
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★★½ (2.25)	★★★ (2.13)	★★★ (2.13)	★★★ (2.13)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★★★ (0.88)	★★★ (0.88)	★★★ (0.50)	★★★ (0.25)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	★★★ (0.00)	★★★ (0.00)	★★★ (0.50)	★★★ (0.38)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★★★ (0.38)	★★★ (0.50)	★★★ (0.50)	★★★ (0.50)
There is an indicator of where to open the packet or this is obvious	★★ (1.75)*	★★ (1.88)*	★★ (1.88)*	★★ (1.88)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (1.75)*	★★ (2.00)*	★★ (1.88)*	★★½ (1.13)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★½ (1.38)*	★★½ (1.38)*	★★½ (1.38)*	★★½ (1.38)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.63)*	★★ (1.50)*	★★ (1.50)*	★★ (1.50)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*	★★ (1.88)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★ (2.00)*	★★ (2.00)*	★★ (1.88)*	★★ (1.63)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★ (2.00)*	★★ (2.00)*	★★ (1.75)*	★★½ (1.38)*
Is it stated clearly that the inner packaging can be recycled	✗	✗	✗	✗
Is it stated clearly that the outer packaging can be recycled	✗	✗	✗	✗

*Maximum number of 2 stars attainable

NEEDLE FREE VALVES

NHS Clinical Evaluation Team
by the NHS, for the NHS

	VYGON		
			
BRAND	Vadsite	Vadsite	Bionector S
MPC	898038	898.03	896.21
DESCRIPTION	Needle Free Valve	Needle Free Valve	Needle Free Valve
INTENDED USE	Single Use	Single Use	Single Use
UNIT OF ISSUE	100	100	100
DURATION OF USE	7 days	7 days	7 days
NUMBER OF ACTIVATIONS	360	360	360
NHS CET PRODUCT ASSESSMENT CYCLE	Score	Score	Score
All labelling information is present to meet MDD 93/42/EEC. ISO 15223-1:2016 or MDR 2017/745.	✓	✓	✓
Is the NFV latex free?	✓	✓	✓
Does it state that the NFV is latex free?	✓	✗	✗
Is the NFV MRI compatible?	✓	✓	✓
Does it state clearly the NFV is MRI compatible?	✓	✗	✗
The product category is stated on the outer packaging	✓	✓	✓
Is the NFV a split septum (SS) or Mechanical Valve (MV)?	SS	SS	SS
Is the NFV is compatible with chlorhexidine and 70% alcohol?	✓	✓	✓
Is it stated clearly that the NFV is compatible with chlorhexidine and 70% alcohol swabs. Inner packaging (information Leaflet)	✓	✗	✗
The NFV is visible through one side of the packaging	✓	✓	✓
What is the flow rate?	170ml/min	170ml/min	105ml/min
Is the flow rate stated on the inner packaging	✓	✓	✓
Is the NFV glass syringe compatible?	✓	✓	
Does it state clearly that the NFV is glass syringe compatible?	★★ (0.00)*	★★ (0.00)*	★★ (0.00)*
Does it state the maximum number of activations on the packaging	✓	✓	✓
Does it state clearly the duration of use on the packaging, e.g., 72 hours.	★★ (0.00)*	★★½ (1.13)*	★★ (0.50)*
Are the instructions for use clear on the outer or inner packaging? Instruction leaflet pictorial instructions	★★★ (1.75)	★★★ (1.75)	★★★½ (2.25)
Is it stated clearly on the packaging that the NFV is compatible with a specific group of drugs? e.g, chemotherapy/emergency, information leaflet	★★★ (0.25)	★★★ (0.13)	★★★ (0.75)
Are contraindications of use stated clearly on the packaging e.g., cannot be used with certain drugs	★★★ (0.00)	★★★ (0.25)	★★★ (0.00)
Is it stated clearly the NFV can be used with pumps, e.g., volumetric.	★★★ (0.38)	★★★ (0.50)	★★★ (0.38)
There is an indicator of where to open the packet or this is obvious	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
The individual packaging is easy to open and allows the NFV to come out easily whilst maintaining product sterility/ANTT	★★ (1.88)*	★★ (2.00)*	★★½ (1.13)*
Does the NFV have a smooth flat surface at the end of the device, where drugs are administered. To aid decontamination	★★ (1.63)*	★★ (1.63)*	★★ (1.50)*
Is the NFV sealed to ensure a closed circuit. No gaps where the syringe is disconnected.	★★ (1.75)*	★★ (1.75)*	★★½ (1.38)*
Does the NFV fit securely to the luer lock and luer slip syringes	★★ (2.00)*	★★ (2.00)*	★★ (1.75)*
Does the NFV fit the syringe allowing the user to maintain, ANTT	★★½ (1.38)*	★★½ (1.38)*	★★½ (1.38)*
Can the syringe be disconnected from the NFV, allowing the user to maintain ANTT	★★½ (1.38)*	★★ (1.63)*	★★ (1.63)*
Is it stated clearly that the inner packaging can be recycled	✗	✗	✗
Is it stated clearly that the outer packaging can be recycled	✗	✗	✗

*Maximum number of 2 stars attainable

7. Further Consideration and Recommendations

7.1 Future recommendations

7.1.1 Packaging

The information on the packaging is very important to clinicians. Low scoring of package information may be as a result of the information not being easily found or not found at all.

There were two aspects the clinicians spoke about in great detail, this was with regard to, if the device was MRI and glass syringe compatible. They wanted this to be stated on the packaging.

Clear indication of where to open the packaging to ensure they can maintain an aseptic technique.

Flow rate, fluid displacement, activations and duration of use were also raised as important by the clinicians.

7.1.2 Opening

Clinician's felt that the ability to push the device, particularly the needle-free valves through the packaging, compromised being able to ensure the end that attached to the patient was sterile, potentially increasing the risk of infection. It is recommended that the packaging does not allow the clinician to do this to ensure patient safety and improve Infection Prevention and Control.

7.1.3 Clinical Use

Being able to use glass syringes with NFV's and Needle-Free Extension Set (Single Lumen) was very important to clinicians. Not all products are compatible.

- Devices being MRI compatible was important to clinicians. To ensure the devices would not need to be removed, reducing the risk of infection, occlusion and discomfort for the patient. As previously mentioned metal parts may cause issues with magnetic resonance imaging (MRI) with the potential to cause image distortion or a 'pull' on the catheter.

- Clear/transparent valves to ensure that it is easily seen if there is any substance such as blood left inside the valve.

- Clear decontamination instructions. Is the device compatible with the recommended decontamination solutions?

- Clinicians asked if colour coding for different uses, was being explored, in conjunction with ISO 80369-3:2016 Connectors for enteral applications?

- Some suppliers were informing Clinicians that there products had clear "Backtracking" visibility. Clinicians asked what evidence suppliers had to support this?

7.1.4 Disposal

There are clear instructions/symbols to indicate that any packaging can be recycled.

7.1.5 Further Considerations

During the clinical conversations the clinicians made the following suggestions that they felt would enhance the devices:

- Clamps that cannot be removed.
- Colour coded clamps to match drug colour coding.
- Clamps that are easy to use with one hand.
- Smaller boxes for storage

Some suppliers did suggest that their products may be used in paediatric settings however, further work is recommended to ensure the needs of this particular patient group are catered for.

Potential microbial ingress was raised by one clinician. There have been a number of studies undertaken to assess this. The literature suggests that further studies are recommended.

7.2 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.

8. 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.

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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)