

Clinical Review

Indwelling urethral
urinary catheter

October 2018



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Guidance for use

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

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 is to add independent clinical review to 'everyday healthcare consumables' used by the NHS.

Everyday healthcare consumables are products that are found in the majority of wards, clinics, health centres, treatment rooms and district nurses' bags across the NHS. The purpose of this report is two-fold: firstly, to provide a clinical assessment of the usability and requirements from the NHS for indwelling urethral urinary catheter 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 indwelling urethral urinary catheter for use in future procurement activities.

It is clear from the evidence that indwelling urethral urinary catheter, 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.

Based on 2018 data supplied by NHS Supply Chain, in the NHS, Trusts are using over 2 million indwelling urethral urinary catheters annually with a total spend approaching £5 million. There are 451 different product codes in the category supplied via 8 different suppliers. This report covers a range of the products available as of 2018.

Intelligence about indwelling urethral urinary catheter 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 indwelling urethral urinary catheter from frontline NHS clinicians. This information was used to develop clinical criteria for indwelling urethral urinary catheter, against which all brands available from the national procurement provider were reviewed.

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

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

2. Clinical Context

2.1 Clinical Definition and Scope

The title for this project is indwelling urethral urinary catheter, the title reflects the focus onto only catheters whose purpose is to drain urine from the bladder via the urethral route and are designed to remain in the bladder. This removes supra pubic catheters and/or intermittent urethral catheters from this report. indwelling catheters are held in place with a fluid inflated balloon. The catheters are made of several material types and may also be coated with another material. Catheters can be described in several ways, short term duration and long term duration. Male or female catheters (in reference to their length), the external diameter is measured Charrière (Ch or CH) or sometimes know as French Gauge (F,Fr or FG).

This report will be evaluating size 12ch with a 10ml balloon in all lengths and material types and with only a single drainage lumen.

A laboratory test was also conducted to show the inner diameter of the urine drainage lumen, this report includes size 14ch catheters to allow a comparison between external diameter and inner diameter based on the results and material types. Where possible the 12ch and 14ch have been placed side by side or near its closest match to allow like for like comparison.

2.2 Intended Clinical Use

The intended use of an indwelling urethral urinary catheter is to drain the bladder of urine using a hollow tube inserted into the bladder via the urethra. There are also 3-way catheters with an extra lumen for continual irrigation following certain surgeries etc. to drain blood and other products such as irrigation fluids.

Below are some examples of the reasons for catheter insertion

Neurological

Haematuria

Obstruction or retention

Urology surgery

Damaged skin - open wounds in an incontinent patient which may have a negative impact on wound healing and cause further deterioration of intact skin.

Nursing care end of life or comfort care

Immobility due to physical constraint, for example unstable fracture and unable to use bottles or bedpans

2.3 Clinical Practice

Indwelling urethral urinary catheters must be inserted under sterile conditions to minimise any potential infectious material entering into the urethra or bladder.

Minimal or no contact should be made with any part of the catheter being inserted

into the urethra or bladder. Design of the packaging to enable ease of opening and the sterile inner packaging are paramount in achieving this.

2.4 Clinical Impact

The clinical impact of an indwelling urethral urinary catheter has many associated risks. The most documented risks are bladder or urinary tract infections; these are often known as catheter associated urinary tract infections or CAUTI. Another risk are meatus or urethral erosion, caused by the catheter material eroding the tissue through friction, pressure and time, this will be exacerbated with harder catheter materials.

2.5 Other Clinical Considerations

Consideration should be given to other methods of voiding the bladder of urine, these may be the use of intermittent catheters, suprapubic catheters, no catheters, incontinence pads or if possible retraining of the bladder, or sheath catheters which sit over the penis.

The length of the catheter is an area for concern, with the insertion of a female catheter into a male patient risking major trauma if the balloon was to be inflated whilst still in the urethra, also the use of a male catheter on a female may cause discomfort and create other concerns such as catheters being visible etc. and not serve the best needs of the female. Risk needs to be evaluated at a local level. Female catheters lengths may not be suitable for very obese females due in part to the catheter not clearing the urethra and thighs to minimise any pressure concerns in those areas. When talking to NHS clinicians they were unable to justify why they chose a certain diameter of catheter for patients.

Connection to a catheter bag is governed by the BSI standard EN1616 1997 and is a universal push type fitting.

Studies have demonstrated that a high proportion of patients will develop bacteriuria over a period of around 4 weeks, closed catheter systems where the catheter is sealed to the bag appear to give best outcomes, significantly over the week.

Catheters securing devices will prevent unnecessary trauma or discomfort to the patient and need to be correctly situated.

2.6 Product Technical Design

The design of catheters has changed little over the decades, and although there are a few innovative designs entering the market these have not yet replaced the standard design as the preferred catheter in the majority of NHS hospitals. The standard catheter (The Nelaton) has 2 eyes, eyelets or holes near the tip which are situated above the balloon. The balloon is inflated and deflated to allow insertion and retention of the catheter. Different materials will change the way the balloon will

deflate against the catheter for removal. It is worth noting this may cause discomfort for the patient on removal.

There are also catheters which include an integrated thermometer which will allow core temperature monitoring where required.

BSI standard EN1616 1997 specifies the dimensions and properties of the catheter, such as strength, flow rate, balloon size etc.

Catheter sizes are colour coded to an international standard to allow easy identification, colour code charts can be requested from your catheter supplier.

3. Pathway Methods

The evaluation followed the process given in the CET operating manual and as approved by the overseeing Clinical Reference Board.

3.1 Intelligence Gathering

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

3.1.1. Literature search

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

Initially, an evidence search was performed across the NICE service:

This suggested best practice considerations in the use of indwelling urethral urinary catheter

The search terms used (see below) generated many returns, however, there was little new information generated. Most information centred on infection risks and methods to reduce this, reviewing insertion technique and closed systems.

This report acknowledges a very relevant article in the, European Association of Urology Nurses 2012, "Catheterisation - indwelling catheters in adults - urethral and suprapubic"

Search criteria	Databases searched
<ul style="list-style-type: none"> Urinary catheter Indwelling catheter Bladder catheter 	<ul style="list-style-type: none"> NICE website Evidence search https://www.evidence.nhs.uk/ NICE website journals and databases https://www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases (using Healthcare databases advanced search tool – AMED, EMBASE, HMIC, BNI, Medline, PsycInfo, CINAHL, HEALTH BUSINESS ELITE databases searched)
Date Range	Since 2008
Language	English

Figure 1 Literature and other sources searches – Indwelling urethral urinary catheter

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 indwelling urethral urinary catheter.

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 this indwelling urethral urinary catheter, but are 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). 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 product alerts relating to this product category against the search terms previously described.

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

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

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.

Some suppliers provided a range of information from product brochure through to technical datasheets and evidence of 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.

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

Figure 2 – Hierarchy ranking: Evidence based practice in nursing & healthcare: a guide to best practice” (B.M. Melnyk & E. Fineout-Overholt; 2005; p10)

4. NHS Clinical Engagement

In order to develop a shared vision of what is required from indwelling urethral urinary catheter 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 that are:

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

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

- Regional and national face-to-face events with NHS clinical colleagues
- Focussed visits to NHS clinicians regional and national face-to-face events
- Website subscription
- Attendance at specialist network events
- Attendance at NHS Business Services Authority events
- Web-based surveys and e-engagement tools (e.g. email, WebEx, portal based surveys)

4.1 Clinical Conversations

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

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

4.2 Clinical Criteria

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

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

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

CLINICAL CRITERIA
Packaging
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile, ref number
The final individual packaging has at least one side of the peel pack is transparent allowing the contents to be seen without opening it This includes seeing through the final inner wrap
Product material, including any coatings, is clearly stated on the final individual packaging
Catheter length is clearly stated on final individual packaging
The final individual packaging states in days or weeks the maximum indwelling wear time
There is a clear statement if the catheter is for female urethral use only
Opening
The final individual pack has clear opening instructions
The final individual packaging opens with ease
Ease of maintaining product sterility whilst preparing catheter
Ease of catheter preparation, does the final sterile pouch contain perforations along the top
Clinical Use
The final sterile pouch allows a non-touch technique for insertion of the catheter
The average start of the balloon position from the tip of the catheter in millimetres
The inner channel average diameter
Disposal
The box packaging states if non clinical waste can be recycled
Figure 3- Defining the clinical criteria for Indwelling urethral urinary catheter

4.2.1. 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.

There was a clear concern in being able to perform non-touch technique when introducing a catheter to the patient, this seemed very dependent on the opening and handling of the packaging.

Blocked catheters were discussed and this pointed towards needing an understanding of the inner lumen size.

During conversations with clinicians, they discussed the varying lengths of the tip off each catheter and how this can cause irritation within the bladder wall. During the evaluation it was noted that the balloon often inflated to an irregular shape, this has been captured as an average range.

4.2.2. Criteria explanation- Exclusion

The flexibility of a catheter was mentioned however there are no standardised tests available and this is recommended as a future development.

Material type and resistance to bacteria colonisation would provide a very useful tool, however the scope of this work is beyond this report and timescale.

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:

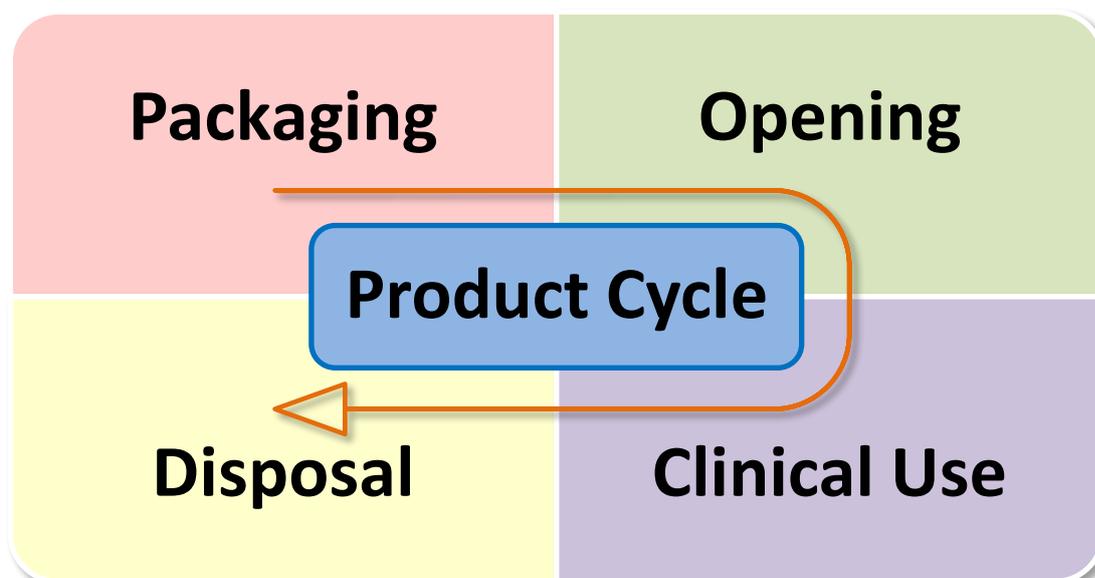


Figure 4 – NHS Clinical Evaluation Team Product Cycle

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 staffs were invited to review the products in accordance with the developed criteria. It was not possible to ‘blind’ the evaluations; in the sense that the evaluators were aware of the product brand; however, the product to be evaluated was independently picked in accordance with the product selection criteria in Section 2 and prepared for evaluation by colleagues who were not otherwise involved in the process.

Each clinical evaluator entered data independently and without inter-rater comparison into their own evaluation results sheet. 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 ✓ / ✗, 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 stars
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 vertically on the left-hand side of the page with the tested device found horizontally across the top of the matrix. The accompanying photographs were taken during evaluation. 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 August 2018

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

INDWELLING URETHRAL Urinary Catheters



BARD



NPC	FSS322	FSS323 / FSS1108	FSS336		FSS183	FSS184
MPC	1245512UK	1245514UK	1269512UK	1269514UK	165812UK	165814UK
BRAND	BARDIA AQUAFIL	BARDIA AQUAFIL	BARDIA AQUAFIL	BARDIA AQUAFIL	BARDIA AQUAFIL	BARDIA AQUAFIL
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	PTFE Coated Latex	PTFE Coated Latex	PTFE	PTFE	Silicone	Silicone
PREFILLED SYRINGE YES/NO	Yes	Yes	Yes	Yes	Yes	Yes
MAXIMUM INDWELL TIME	Up to 28 Days	Up to 28 Days	Up to 28 Days	Up to 28 Days	Up to 90 Days	Up to 90 Days
CATHETER LENGTH	40 cm	40 cm	26 cm	26 cm	40 cm	40 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (1.86)*	★★ (1.86)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (1.71)*	★★ (1.71)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*
Catheter length is clearly stated on final individual packaging	★ (0.43)*	★ (0.43)*	★★ (1.86)*	★★ (1.86)*	★ (0.86)*	★ (0.86)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✓	✓	✓	✓	✓	✓
There is a clear statement if the catheter is for female urethral use only	N/A	N/A	★★★ (2.00)	★★★ (2.00)	N/A	N/A
The final individual pack has clear opening instructions	★★★★ (2.57)	★★★★ (2.57)	★★★★ (2.71)	★★★★ (2.71)	★★★★ (2.57)	★★★★ (2.57)
The final individual packaging opens with ease	★★★ (2.00)	★★★ (2.00)	★★★ (2.14)	★★★ (2.14)	★★★ (2.00)	★★★ (2.00)
Ease of maintaining product sterility whilst preparing catheter	★★ (1.86)*	★★ (1.86)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (1.43)	★★★ (1.43)	★★★ (1.43)	★★★ (1.43)	★★★ (0.86)	★★★ (0.86)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (1.71)*	★★ (1.71)*	★★ (1.86)*	★★ (1.86)*	★★ (1.43)*	★★ (1.43)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (1.43)	★★★ (1.43)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	12.76 mm	Not Tested	11.86 mm	Not Tested	11.57 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.33-1.48	1.66-1.89	1.41-1.49	1.79-1.85	1.28-2.23	1.78-2.76
The box packaging states if non clinical packaging can be recycled	✗	✗	✗	✗	✗	✗

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



BARD



NPC	FSS189	FSS190	FSS311	FSS312	FSS370	FSS372
MPC	166112UK	166114UK	2264S12UK	2264S14UK	236512UKS	236514UKS
BRAND	BARDIA AQUAFIL	BARDIA AQUAFIL	BIO-CATH AQUAFIL	BIO-CATH AQUAFIL	BARDEX IC	BARDEX IC
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	Silicone	Silicone	Hydrogel Coated	Hydrogel Coated	Silver Alloy Coated Hydrogel	Silver Alloy Coated Hydrogel
PREFILLED SYRINGE YES/NO	Yes	Yes	Yes	Yes	Yes	Yes
MAXIMUM INDWELL TIME	Up to 90 Days	Up to 90 Days	21 – 90 Days	21 – 90 Days	Up to 28 Days	Up to 28 Days
CATHETER LENGTH	26 cm	26 cm	40 cm	40 cm	43 cm	43 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.43)*	★★ (1.43)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (1.86)*	★★★ (1.86)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★★ (1.86)*	★★★ (1.86)*	★★★ (1.71)*	★★★ (1.71)*	★★★ (1.86)*	★★★ (1.86)*
Catheter length is clearly stated on final individual packaging	★★★ (1.86)*	★★★ (1.86)*	★★★ (0.57)*	★★★ (0.57)*	★★★ (0.00)*	★★★ (0.00)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✓	✓	✓	✓	✗	✗
There is a clear statement if the catheter is for female urethral use only	★★★ (2.14)	★★★ (2.14)	N/A	N/A	N/A	N/A
The final individual pack has clear opening instructions	★★★ (2.71)	★★★ (2.71)	★★★ (2.57)	★★★ (2.57)	★★★ (2.71)	★★★ (2.71)
The final individual packaging opens with ease	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)
Ease of maintaining product sterility whilst preparing catheter	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (0.86)	★★★ (0.86)	★★★ (1.00)	★★★ (1.00)	★★★ (0.86)	★★★ (0.86)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★★ (1.14)*	★★★ (1.14)*	★★★ (1.29)*	★★★ (1.29)*	★★★ (1.57)*	★★★ (1.57)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)	★★★ (1.86)	★★★ (1.86)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	11.00 mm	Not Tested	13.29 mm	Not Tested	15.36 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	Not Tested	1.50-3.04	1.43-1.49	1.71-1.91	1.43-1.49	1.72-1.85
The box packaging states if non clinical packaging can be recycled	✗	✗	✗	✗	✗	✗

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



BARD



NPC	FSS457	FSS458	FSS925	FSS926	FUR003
MPC	236912UKS	236914UKS	175812EUK	175814EUK	176112EUK
BRAND	BARDEX IC	BARDEX IC	LUBRI-SIL	LUBRI-SIL	LUBRISIL
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch	12ch (pictured above)
MATERIAL TYPE	Silver Alloy Coated Hydrogel	Silver Alloy Coated Hydrogel	Hydrogel Coated Silicone	Hydrogel Coated Silicone	Hydrogel Coated
PREFILLED SYRINGE YES/NO	Yes	Yes	Yes	Yes	Yes
MAXIMUM INDWELL TIME	Up to 28 Days	Up to 28 Days	21 – 90 Days	21 – 90 Days	21 – 90 Days
CATHETER LENGTH	26 cm	26 cm	40 cm	40 cm	26 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.86)*	★★ (1.86)*	★★ (1.57)*	★★ (1.57)*	★★ (1.57)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (1.71)*	★★ (1.71)*	★★ (1.57)*	★★ (1.57)*	★★ (1.57)*
Catheter length is clearly stated on final individual packaging	★ (0.57)*	★ (0.57)*	★ (0.57)*	★ (0.57)*	★★ (1.57)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗	✗	✓	✓	✓
There is a clear statement if the catheter is for female urethral use only	★★★ (1.71)	★★★ (1.71)	N/A	N/A	★★★ (1.86)
The final individual pack has clear opening instructions	★★★★ (2.57)	★★★★ (2.57)	★★★★ (2.57)	★★★★ (2.57)	★★★★ (2.71)
The final individual packaging opens with ease	★★★ (2.00)	★★★ (2.00)	★★★ (1.86)	★★★ (1.86)	★★★ (2.00)
Ease of maintaining product sterility whilst preparing catheter	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (0.86)	★★★ (0.86)	★★★ (0.86)	★★★ (0.86)	★★★ (0.86)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (1.57)*	★★ (1.57)*	★★ (1.71)*	★★ (1.71)*	★★ (1.71)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★★ (2.00)	★★★★ (2.00)	★★★ (1.57)	★★★ (1.57)	★★★ (1.71)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	11.00 mm	Not Tested	11.36 mm	Not Tested	12.29 mm
The inner channel range diameter from narrowest to largest in millimeters	1.44-1.52	1.79-1.88	1.43-2.33	1.78-2.91	1.30-2.25
The box packaging states if non clinical packaging can be recycled	✗	✗	✗	✗	✗

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



BARD



NPC	FSS10121	FSS10122	FSS1023	FSS1024	FSS10085	FSS1027
MPC	226512UK	226514UK	2268512UK	2268514UK	226912UK	226914UK
BRAND	BIOCATH	BIOCATH	BIOCATH AQUAFIL	BIOCATH AQUAFIL	BIOCATH	BIOCATH
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	Hydrogel Coated	Hydrogel Coated	Hydrogel Coated	Hydrogel Coated	Hydrogel Coated	Hydrogel Coated
PREFILLED SYRINGE YES/NO	No	No	Yes	Yes	No	No
MAXIMUM INDWELL TIME	Up to 90 Days	Up to 90 Days	Up to 12 weeks	Up to 12 weeks	Up to 90 Days	Up to 90 Days
CATHETER LENGTH	40 cm	40 cm	26 cm	26 cm	26 cm	26 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.86)*	★★ (1.86)*	★★ (1.71)*	★★ (1.71)*	★★ (1.86)*	★★ (1.86)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Catheter length is clearly stated on final individual packaging	★ (0.43)*	★ (0.43)*	★★ (1.86)*	★★ (1.86)*	★★ (1.71)*	★★ (1.71)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗	✗	✓	✓	✗	✗
There is a clear statement if the catheter is for female urethral use only	N/A	N/A	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)
The final individual pack has clear opening instructions	★★★★ (2.57)	★★★★ (2.57)	★★★★ (2.43)	★★★★ (2.43)	★★★★ (2.43)	★★★★ (2.43)
The final individual packaging opens with ease	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)
Ease of maintaining product sterility whilst preparing catheter	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (1.43)	★★★ (1.43)	★★★ (1.43)	★★★ (1.43)	★★★ (1.29)	★★★ (1.29)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (1.43)*	★★ (1.43)*	★★★ (1.57)*	★★★ (1.57)*	★★★ (1.57)*	★★★ (1.57)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	14.71 mm	Not Tested	12.71 mm	Not Tested	13.29	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.24-1.50	1.50-1.90	1.36-1.47	1.73-1.96	1.40-1.48	1.78-1.92
The box packaging states if non clinical packaging can be recycled	✗	✗	✗	✗	✗	✗

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



BARD



NPC	FSS961	FSS996	FSS977	FSS1001	FSS524	FSS528
MPC	PC17582L12	PC17582L14	PC17585M12	PC17585M14	PC17615M12	PC17615M14
BRAND	PRECONNECT LUBRISIL	PRECONNECT LUBRISIL	PRECONNECT LUBRISIL	PRECONNECT LUBRISIL	BARD PRECONNECT	BARD PRECONNECT
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	Silicone Hydrogel Coated	Silicone Hydrogel Coated	Hydrogel Coated Silicone	Hydrogel Coated Silicone	Hydrogel Coated Silicone	Hydrogel Coated Silicone
PREFILLED SYRINGE YES/NO	No	No	No	No	No	No
MAXIMUM INDWELL TIME	Not stated on final packaging	Up to 90 Days	Up to 90 Days			
CATHETER LENGTH	40 cm	40 cm	40 cm	40 cm	26 cm	26 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (0.00)*	★★ (0.00)*	★★ (0.33)*	★★ (0.33)*	★★ (0.29)*	★★ (0.29)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★★ (1.86)*	★★★ (1.86)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*	★★★ (2.00)*
Catheter length is clearly stated on final individual packaging	N/A	N/A	N/A	N/A	★★ (0.14)*	★★ (0.14)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗	✗	✗	✗	✗	✗
There is a clear statement if the catheter is for female urethral use only	★★★ (0.14)	★★★ (0.14)	★★★★ (0.50)	★★★★ (0.50)	★★★★★ (1.86)	★★★★★ (1.86)
The final individual pack has clear opening instructions	★★★ (1.43)	★★★★ (1.43)	★★★★★ (1.50)	★★★★★ (1.50)	★★★★★ (1.43)	★★★★★ (1.43)
The final individual packaging opens with ease	★★★★ (1.86)	★★★★ (1.86)	★★★★★ (1.83)	★★★★★ (1.83)	★★★★★ (1.86)	★★★★★ (1.86)
Ease of maintaining product sterility whilst preparing catheter	★★★ (2.00)*	★★★ (2.00)*	★★★ (1.83)*	★★★ (1.83)*	★★★ (1.71)*	★★★ (1.71)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★★ (1.00)	★★★★ (1.00)	★★★★ (0.83)	★★★★ (0.83)	★★★★ (0.86)	★★★★ (0.86)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★★ (1.57)*	★★★ (1.57)*	★★★ (1.67)*	★★★ (1.67)*	★★★ (1.71)*	★★★ (1.71)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (1.71)	★★★★ (1.71)	★★★★★ (1.83)	★★★★★ (1.83)	★★★★★ (2.00)	★★★★★ (2.00)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	11.86 mm	Not Tested	12.83 mm	Not Tested	12.14 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.25-2.24	1.77-2.77	1.40-2.26	1.77-2.74	1.15-2.22	1.67-2.85
The box packaging states if non clinical packaging can be recycled	✗	✗	✗	✗	✗	✗

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



CLINISUPPLIES LTD



NPC	FUR001	FUQ092
MPC	PHF12F10	PHF14F10
BRAND	PROSYS	PROSYS
CH SIZE	12ch (pictured above)	14ch
MATERIAL TYPE	Silicone	Silicone
PREFILLED SYRINGE YES/NO	Yes	Yes
MAXIMUM INDWELL TIME	Up to 90 Days	Up to 90 Days
CATHETER LENGTH	23 cm	23 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.14)*	★★ (1.14)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (1.86)*	★★ (1.86)*
Catheter length is clearly stated on final individual packaging	★ (0.29)*	★ (0.29)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗	✗
There is a clear statement if the catheter is for female urethral use only	★★★ (1.43)	★★★ (1.43)
The final individual pack has clear opening instructions	★★★ (0.71)	★★★ (0.71)
The final individual packaging opens with ease	★★★ (1.29)	★★★ (1.29)
Ease of maintaining product sterility whilst preparing catheter	★★ (1.71)*	★★ (1.71)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (2.14)	★★★ (2.14)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (2.00)*	★★ (2.00)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★★ (2.29)	★★★★ (2.29)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	16.86 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.71-2.41	2.02-2.78
The box packaging states if non clinical packaging can be recycled	✓	✓

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



COLOPLAST LTD



NPC	FSS1124	FSU006 / FS1125	FST503	FST424	FSS1059	FSS1060
MPC	AA1412	AA1414	AA6112	AA6114	AA6312	AA6314
BRAND	FOLATEX	FOLATEX	FOLYSIL	FOLYSIL	FOLYSIL	FOLYSIL
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	Latex silicon coating	Latex silicon coating	Silicone	Silicone	Silicone	Silicone
PREFILLED SYRINGE YES/NO	No	No	No	No	No	No
MAXIMUM INDWELL TIME	30 days	30 days	Up to 30 days	Up to 30 days	Up to 30 Days	Up to 30 Days
CATHETER LENGTH	40 cm	40 cm	41 cm	41 cm	40 cm	40 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (1.43)*	★★ (1.43)*	★★ (1.14)*	★★ (1.14)*	★★ (1.14)*	★★ (1.14)*
Catheter length is clearly stated on final individual packaging	★ (0.43)*	★ (0.43)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✓	✓	✗	✗	✗	✗
There is a clear statement if the catheter is for female urethral use only	N/A	N/A	N/A	N/A	N/A	N/A
The final individual pack has clear opening instructions	★★★ (1.00)	★★★ (1.00)	★★★ (1.29)	★★★ (1.29)	★★★ (1.29)	★★★ (1.29)
The final individual packaging opens with ease	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)
Ease of maintaining product sterility whilst preparing catheter	★★ (2.00)*	★★ (2.00)*	★★ (1.71)*	★★ (1.71)*	★★ (1.86)*	★★ (1.86)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (1.86)	★★★ (1.86)	★★★ (0.14)	★★★ (0.14)	★★★ (0.14)	★★★ (0.14)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (1.86)*	★★ (1.86)*	★★ (1.14)*	★★ (1.14)*	★★ (1.14)*	★★ (1.14)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (1.71)	★★★ (1.71)	★★★ (1.00)	★★★ (1.00)	★★★ (1.14)	★★★ (1.14)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	13.86 mm	Not Tested	16.00 mm	Not Tested	22.57 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.54-1.63	2.05-2.24	1.54-1.89	2.01-2.32	1.54-1.92	2.00-2.38
The box packaging states if non clinical packaging can be recycled	✓	✓	✓	✓	✓	✓

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



COLOPLAST LTD



NPC	FSS1044	FSS1045	FSS1054	FSS1055	FSS1050	FSS1051
MPC	AA7112	AA7114	AA7412	AA7414	AA7512	AA7514
BRAND	FOLYSIL	FOLYSIL	FOLYSIL	FOLYSIL	FOLYSIL	FOLYSIL
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone
PREFILLED SYRINGE YES/NO	No	No	No	No	No	No
MAXIMUM INDWELL TIME	Up to 90 Days	Up to 90 Days	Up to 90 days	Up to 90 days	Up to 90 Days	Up to 90 Days
CATHETER LENGTH	41 cm	41 cm	39 cm	39 cm	25 cm	25 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★★ (1.14)*	★★★ (1.14)*	★★★ (1.00)*	★★★ (1.00)*	★★★ (1.14)*	★★★ (1.14)*
Catheter length is clearly stated on final individual packaging	★★★ (1.86)*	★★★ (1.86)*	★★★ (1.71)*	★★★ (1.71)*	★★★ (1.43)*	★★★ (1.43)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗	✗	✗	✗	✗	✗
There is a clear statement if the catheter is for female urethral use only	N/A	N/A	N/A	N/A	★★★ (1.71)	★★★ (1.71)
The final individual pack has clear opening instructions	★★★ (1.43)	★★★ (1.43)	★★★ (1.29)	★★★ (1.29)	★★★ (1.29)	★★★ (1.29)
The final individual packaging opens with ease	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)	★★★ (1.71)	★★★ (1.43)	★★★ (1.43)
Ease of maintaining product sterility whilst preparing catheter	★★★ (1.71)*	★★★ (1.71)*	★★★ (1.71)*	★★★ (1.71)*	★★ (0.86)*	★★ (0.86)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★★ (0.29)	★★★★ (0.29)	★★★★ (0.14)	★★★★ (0.14)	★★★★ (0.43)	★★★★ (0.43)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★★ (1.43)*	★★★ (1.43)*	★★★ (1.29)*	★★★ (1.29)*	★★★ (1.14)*	★★★ (1.14)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (1.00)	★★★ (1.00)	★★★ (1.14)	★★★ (1.14)	★★★ (0.86)	★★★ (0.86)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	16.00 mm	Not Tested	17.14 mm	Not Tested	14.43 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.58-1.96	1.97-2.33	1.53-1.94	2.05-2.77	1.54-1.89	2.04-2.29
The box packaging states if non clinical packaging can be recycled	✓	✓	✓	✓	✓	✓

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



COLOPLAST LTD



NPC	FST033	FST034	FST045	FST046
MPC	AA8112	AA8114	AA8512	AA8514
BRAND	FOLYSIL XTRA	FOLYSIL XTRA	FOLYSIL XTRA	FOLYSIL XTRA
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	Silicone	Silicone	Silicone	Silicone
PREFILLED SYRINGE YES/NO	Yes	Yes	Yes	Yes
MAXIMUM INDWELL TIME	0 – 90 Days	0 – 90 Days	0 – 90 Days	0 – 90 Days
CATHETER LENGTH	41 cm	41 cm	22 cm	22 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (1.14)*	★★ (1.14)*	★★ (1.14)*	★★ (1.14)*
Catheter length is clearly stated on final individual packaging	★★ (1.43)*	★★ (1.43)*	★★★ (1.67)*	★★★ (1.67)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗	✗	✗	✗
There is a clear statement if the catheter is for female urethral use only	N/A	N/A	★★★ (1.43)	★★★ (1.43)
The final individual pack has clear opening instructions	★★★ (1.43)	★★★ (1.43)	★★★ (1.29)	★★★ (1.29)
The final individual packaging opens with ease	★★★ (1.71)	★★★ (1.71)	★★★ (1.57)	★★★ (1.57)
Ease of maintaining product sterility whilst preparing catheter	★★ (1.71)*	★★ (1.71)*	★★ (1.86)*	★★ (1.86)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (0.43)	★★★ (0.43)	★★★ (0.14)	★★★ (0.14)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (1.29)*	★★ (1.29)*	★★ (1.00)*	★★ (1.00)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (1.14)	★★★ (1.14)	★★★ (0.71)	★★★ (0.71)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	14.29 mm	Not Tested	14.86 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.56-1.89	2.09-2.34	1.56-1.90	1.93-2.27
The box packaging states if non clinical packaging can be recycled	✓	✓	✓	✓

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



IMS EURO LTD



NPC	FUS008
MPC	FCS12
BRAND	IMS EURO
CH SIZE	12ch (pictured above)
MATERIAL TYPE	Silicone
PREFILLED SYRINGE YES/NO	No
MAXIMUM INDWELL TIME	7 days
CATHETER LENGTH	40 cm
CLINICAL CRITERIA	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★★ (1.71)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★★ (1.71)*
Catheter length is clearly stated on final individual packaging	★☆☆ (0.00)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗
There is a clear statement if the catheter is for female urethral use only	N/A
The final individual pack has clear opening instructions	★★★☆☆ (1.43)
The final individual packaging opens with ease	★★★☆☆ (1.86)
Ease of maintaining product sterility whilst preparing catheter	★★★ (1.86)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★☆☆ (2.14)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★★ (2.00)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★☆☆ (2.43)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	17.86 mm
The inner channel range diameter from narrowest to largest in millimeters	Not available
The box packaging states if non clinical packaging can be recycled	✗

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



MEDIPLUS LTD



	FUS011	FUS013	FUS014	FUS016
NPC				
MPC	5762	5764	5765	5767
BRAND	MEDPLUS	MEDPLUS	MEDIPLUS	MEDIPLUS
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	Silicone	Silicone	Silicone	Silicone
PREFILLED SYRINGE YES/NO	No	No	No	No
MAXIMUM INDWELL TIME	Not stated on final packaging			
CATHETER LENGTH	40 cm	40 cm	40 cm	40 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.43)*	★★ (1.43)*	★★ (1.43)*	★★ (1.43)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (1.86)*	★★ (1.86)*	★★ (2.00)*	★★ (2.00)*
Catheter length is clearly stated on final individual packaging	★★ (0.29)*	★★ (0.29)*	★★ (0.57)*	★★ (0.57)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗	✗	✗	✗
There is a clear statement if the catheter is for female urethral use only	N/A	N/A	N/A	N/A
The final individual pack has clear opening instructions	★★★ (1.29)	★★★ (1.29)	★★★ (1.14)	★★★ (1.14)
The final individual packaging opens with ease	★★★ (1.43)	★★★ (1.43)	★★★ (1.29)	★★★ (1.29)
Ease of maintaining product sterility whilst preparing catheter	★★ (1.57)*	★★ (1.57)*	★★ (1.86)*	★★ (1.86)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (2.14)	★★★ (2.14)	★★★ (2.00)	★★★ (2.00)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★★ (2.43)	★★★★ (2.43)	★★★★ (2.43)	★★★★ (2.43)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	10.14 mm	Not Tested	3.43 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.22-1.72	1.76-2.28	1.36-1.76	1.70-2.29
The box packaging states if non clinical packaging can be recycled	✗	✗	✗	✗

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



MEDTRONIC MITG



NPC	FSS296	FSS297	FUR005	FSS303
MPC	8887105123	8887105149	8887115122	8887115148
BRAND	ARGYLE	ARGYLE	DOVER	DOVER
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	Silicone	Silicone	Silicone	Silicone
PREFILLED SYRINGE YES/NO	Yes	Yes	Yes	Yes
MAXIMUM INDWELL TIME	Up to 90 Days	Up to 90 Days	Up to 90 Days	Up to 90 Days
CATHETER LENGTH	42 cm	42 cm	25 cm	25 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*
Catheter length is clearly stated on final individual packaging	★ ★ (0.14)*	★ ★ (0.14)*	★★★ (1.43)*	★★★ (1.43)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗	✗	✗	✗
There is a clear statement if the catheter is for female urethral use only	N/A	N/A	★★★ (1.14)	★★★ (1.14)
The final individual pack has clear opening instructions	★★★ (2.14)	★★★ (2.14)	★★★★ (2.29)	★★★★ (2.29)
The final individual packaging opens with ease	★★★ (1.71)	★★★ (1.71)	★★★ (1.86)	★★★ (1.86)
Ease of maintaining product sterility whilst preparing catheter	★★ (1.86)*	★★ (1.86)*	★★★ (1.71)*	★★★ (1.71)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (1.29)	★★★ (1.29)	★★★ (1.00)	★★★ (1.00)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (1.29)*	★★ (1.29)*	★★★ (1.00)*	★★★ (1.00)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (1.14)	★★★ (1.14)	★★★ (0.86)	★★★ (0.86)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	16.43 mm	Not Tested	17.29 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.69-2.42	1.97-2.75	1.83-2.33	1.97-2.77
The box packaging states if non clinical packaging can be recycled	✗	✗	✗	✗

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



TELEFLEX MEDICAL RUSCH



NPC	FUR058	FUR059	FSS857	FSS178	FSS179
MPC	178305-000120	178305-000140	650610-000120	A210112	A210114
BRAND	RUSCH BRILLANT	RUSCH BRILLANT	SIMPLASTIC	RUSCH BRILLANT AQUAFLATE	RUSCH BRILLANT AQUAFLATE
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	12ch (pictured above)	14ch
MATERIAL TYPE	Silicone	Silicone	PVC	Silicone	Silicone
PREFILLED SYRINGE YES/NO	Yes	Yes	No	Yes	Yes
MAXIMUM INDWELL TIME	Up to 12 Weeks	Up to 12 Weeks	0 – 7 Days	Up to 12 weeks	Up to 12 weeks
CATHETER LENGTH	41 cm	41 cm	42 cm	23 cm	23 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.57)*	★★ (1.57)*	★★ (2.00)*	★★ (1.14)*	★★ (1.14)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (2.00)*	★★ (2.00)*	★★ (1.29)*	★★ (2.00)*	★★ (2.00)*
Catheter length is clearly stated on final individual packaging	★★ (1.71)*	★★ (1.71)*	★ (0.29)*	★ (0.14)*	★ (0.14)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✗	✗	✗	✓	✓
There is a clear statement if the catheter is for female urethral use only	N/A	N/A	N/A	★★★ (2.43)	★★★ (2.43)
The final individual pack has clear opening instructions	★★★ (1.00)	★★★ (1.00)	★★★ (1.00)	★★★ (1.29)	★★★ (1.29)
The final individual packaging opens with ease	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)
Ease of maintaining product sterility whilst preparing catheter	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (2.00)	★★★ (2.00)	★★★ (1.86)	★★★ (1.86)	★★★ (1.86)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (1.71)*	★★ (1.71)*	★★ (1.71)*	★★ (1.86)*	★★ (1.86)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★★ (2.29)	★★★★ (2.29)	★★★ (2.00)	★★★★ (2.43)	★★★★ (2.43)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	23.14 mm	Not Tested	13.00 mm	11.71 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.93-2.44	2.30-2.61	Not Tested	1.98-2.48	2.37-2.62
The box packaging states if non clinical packaging can be recycled	✓	✓	✓	✓	✓

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



TELEFLEX MEDICAL RUSCH



NPC	FSS172	FSS173	FSS166	FSS168	FSS150	FSS152
MPC	A310112	A310114	H210112	H210114	H310112	H310114
BRAND	RUSCH BRILLANT AQUAFLATE	RUSCH BRILLANT AQUAFLATE	RUSCH SYMPACATH AQUAFLATE	RUSCH SYMPACATH AQUAFLATE	RUSCH SYMPACATH AQUAFLATE	RUSCH SYMPACATH AQUAFLATE
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	Silicone	Silicone	Hydrogel Coated	Hydrogel Coated	Hydrogel Coated	Hydrogel Coated
PREFILLED SYRINGE YES/NO	Yes	Yes	Yes	Yes	Yes	Yes
MAXIMUM INDWELL TIME	Up to 90 Days	Up to 90 Days	Up to 12 weeks	Up to 12 weeks	Up to 90 Days	Up to 90 Days
CATHETER LENGTH	40 cm	40 cm	23 cm	23 cm	40 cm	40 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (1.57)*	★★ (1.57)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Catheter length is clearly stated on final individual packaging	★ (0.14)*	★ (0.14)*	★ (0.14)*	★ (0.14)*	★ (0.14)*	★ (0.14)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✓	✓	✓	✓	✓	✓
There is a clear statement if the catheter is for female urethral use only	N/A	N/A	★★★ (2.43)	★★★ (2.43)	N/A	N/A
The final individual pack has clear opening instructions	★★★ (1.29)	★★★ (1.29)	★★★ (1.43)	★★★ (1.43)	★★★ (1.29)	★★★ (1.29)
The final individual packaging opens with ease	★★★ (2.00)	★★★ (2.00)	★★★ (1.86)	★★★ (1.86)	★★★ (1.86)	★★★ (1.86)
Ease of maintaining product sterility whilst preparing catheter	★★ (2.00)*	★★ (2.00)*	★★ (1.86)*	★★ (1.86)*	★★ (2.00)*	★★ (2.00)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (1.86)	★★★ (1.86)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (1.86)*	★★ (1.86)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (2.43)	★★★ (2.43)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	10.71 mm	Not Tested	13.00 mm	Not Tested	13.43 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.93-2.45	2.33-2.72	Not Tested	1.92-2.12	1.35-1.48	1.87-1.99
The box packaging states if non clinical packaging can be recycled	✓	✓	✓	✓	✓	✓

*Maximum number of 2 stars attainable

INDWELLING URETHRAL Urinary Catheters



TELEFLEX MEDICAL RUSCH



NPC	FSS141	FSS142	FSS134	FSS136
MPC	P210112	P210114	P310112	P310114
BRAND	RUSCH AQUAFLATE	RUSCH AQUAFLATE	RUSCH AQUAFLATE	RUSCH AQUAFLATE
CH SIZE	12ch (pictured above)	14ch	12ch (pictured above)	14ch
MATERIAL TYPE	PTFE Coated Latex	PTFE Coated Latex	PTFE Coated Latex	PTFE Coated Latex
PREFILLED SYRINGE YES/NO	Yes	Yes	Yes	Yes
MAXIMUM INDWELL TIME	Up to 28 Days	Up to 28 Days	Up to 28 Days	Up to 28 Days
CATHETER LENGTH	23 cm	23 cm	40 cm	40 cm
CLINICAL CRITERIA	Evaluation Scores	Evaluation Scores	Evaluation Scores	Evaluation Scores
Final Individual catheter packaging displays the following information Expiry or manufacture date, sterile and reference number	✓	✓	✓	✓
The final individual packaging has at least one side of the peel pack, which is transparent allowing the contents to be seen without opening it This includes seeing through the final inner sterile pouch	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Product material, including any coatings, is clearly stated on the final individual packaging	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Catheter length is clearly stated on final individual packaging	★★ (0.14)*	★★ (0.14)*	★★ (0.43)*	★★ (0.43)*
The final individual packaging states in days or weeks the maximum indwelling wear time	✓	✓	✓	✓
There is a clear statement if the catheter is for female urethral use only	★★★ (2.43)	★★★★ (2.43)	N/A	N/A
The final individual pack has clear opening instructions	★★★ (1.14)	★★★ (1.14)	★★★ (1.29)	★★★ (1.29)
The final individual packaging opens with ease	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)
Ease of maintaining product sterility whilst preparing catheter	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*	★★ (1.86)*
Ease of catheter preparation, does the final sterile pouch contain perforations along the top	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)
The final sterile pouch allows a non-touch technique for insertion of the catheter	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*	★★ (2.00)*
Ease of removal of sterile packaging to enable inserting the catheter.	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)	★★★ (2.00)
The average start of the balloon position from the tip of the catheter in millimetres (on an inflated balloon)	14.86 mm	Not Tested	12.86 mm	Not Tested
The inner channel range diameter from narrowest to largest in millimeters	1.11-1.46	1.80-2.01	1.28-1.47	1.85-2.06
The box packaging states if non clinical packaging can be recycled	✓	✓	✓	✓

*Maximum number of 2 stars attainable

6. Using the Product Assessment Results Matrix

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

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

i.e. Length of catheter in most instances will not influence a woman's ward to the same level as a male ward in products stocked.

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

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.

7. Further Considerations and Recommendations

Comments made during conversations with clinicians are captured below but not all have been used as evaluation criteria,

- Colour coded catheters linked to their indwelling time.
- Inner diameter measurement being on the packaging.
- Radiopaque line having a clear indication on the packaging
- Use of introducer to enable softer catheters to be easier to insert.

7.1 Future recommendations

7.1.1. Packaging

Several observations have been made towards the packaging.

- Clear packaging to enable the final product to be seen, this also includes correct position of labels as to not cover the clear areas
- Product material and coatings need to be clear on the packaging to enable informed selection.
- The catheter actual length in clear writing
- Clear warnings if female catheter only

7.1.2. Opening

- Opening needs to be simple and consistent each time with clear instructions.
- Perforations need to work every time and the final inner sleeve needs to allow ANTT of the catheter for insertion.

7.1.3. Clinical Use

- The catheter tip beyond the balloon needs to have a consistent length to allow appropriate selection, during evaluation this length varied.
- The inner diameter of the drainage lumen needs to be displayed to allow appropriate selection of the catheter.
- A recommendation for a standardised test of flexibility/ rigidity would also aid selection

7.1.4. Disposal

- Recycling is important and needs to be clearly displayed.

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.

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

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

The NHS Clinical Evaluation Team is not responsible for any errors or omissions, or for the results obtained from the use of the information contained in the reports. The reports are provided 'as is', with no guarantee of completeness, accuracy or timeliness and without representation, warranty, assurance or undertaking of any kind, express or implied, including, but not limited to fitness for a particular purpose.

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

9. Acknowledgements

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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)

