

Issues relating to disposable and reusable vaginal specula.

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Abstract

SMTL carried out a survey of mainly GP practices with regard to their use of disposable and reusable vaginal specula. Disturbing reprocessing practices were revealed in some surgeries, including some practices completely ignoring MDA advice. Most users performing in-house reprocessing were not complying with best practice as recommended by the Department of Health through their various device bulletins and HTM documents.

Many GP practices could reduce the level of risk by investing in better reprocessing systems, contracting out their reprocessing completely, or through the use of disposable specula. Practices may also be able to reduce their costs by using disposable specula or by contracting out their reprocessing.

1 Introduction

SMTL were commissioned by Pelican Healthcare to produce a report on issues relating to disposable and reusable vaginal specula. The report was to cover the following areas:

- A Literature search on the possible cross-infection risks of reusable vaginal specula.
- A risk analyses covering the clinical risk and the actual sterilization procedures that take place in surgeries and hospitals. This would include a survey of a number of GP practices, plus a few hospital departments.
- A cost analyses covering the total life-cycle costs of reusable vaginal specula versus disposable. This would include the cost of reprocessing in surgeries and in hospitals.
- A review of recent Health circulars covering sterilization of medical devices, and the implications for reprocessing.

In addition,

- a user evaluation of the Pelican Pelispec disposable speculum has been performed independently by West Wales General Hospital,
- a laboratory evaluation of the force required to break the Pelispec speculum was performed by SMTL,

and the results included in this report.

2 Literature Review

There is little in the literature relating to the issues surrounding reusable vaginal specula.

McCance *et al*[3] investigated the risk of transmission of human papillomavirus by vaginal specula. They concluded that HPV infected cells can be found on instruments inserted into the vagina of women with HPV infection, and that if these instruments are not cleaned and sterilized properly, they will be a potential source of infection for subsequent patients.

Skegg and Paul[11] noted that practices for cleaning specula vary widely, and that they were aware of clinics reusing plastic vaginal specula after cleaning in tap water and Savlon.

Ayliffe[1] reported that the role of vaginal specula in the transmission of viruses is unknown, but stated that correct pasteurisation (immersion in water at 80°C for 5 minutes) would inactivate papillomaviruses, herpesviruses, and HIV. Whilst non-sporing bacteria would be killed, Hepatitis B may require immersion at 98-100°C for 5 minutes.

He concludes that sterilization is only essential for surgical instruments when spores could cause an infection.

There has also been anecdotal evidence, published on the Internet¹, of HPV transmission in a North London hospital due to non-sterilization of the specula, but it has been impossible to track down any documentation relating to this incident.

¹In the OB-GYN-L forum. <http://forums.obgyn.net/ob-gyn-1/OBGYNL.9612/0763.html>

3 Advice from the Department of Health

3.1 Health Service Circulars

Health service circular 1999/179[9] emphasises the importance of implementing existing guidance on the cleaning and sterilization of medical devices. The circular states that:

- Washer-disinfectors should be validated and managed in accordance with HTM 2030[8], with particular emphasis on ensuring that the cleaning process is effective.
- sterilization equipment should be validated and managed in accordance with HTM 2010[7].

The circular notes that,

Decontamination is the combination of processes, including cleaning, disinfection and/or sterilization, used to render a re-usable medical device safe for further episodes of use.

In order to sterilize medical devices effectively, all organic debris (e.g. blood, tissue and other bodily fluids) have to be removed from the item prior to disinfection and/or sterilization.

Health Technical Memorandums

3.1.1 HTM 2010 - Sterilization

HTM 2010 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of the types of sterilizer commonly found in the NHS.

HTM 2010, part 1, outlines the major responsibilities of management in ensuring that sterilizers are operated safely and effectively, and in compliance with existing and anticipated legislation and standards. These responsibilities include:

- to ensure that sterilization is carried out in compliance with the law and with the policy of the UK health departments;
- to ensure sterilization is carried out in compliance with the law and with the policy of the UK health departments ensure that all personnel connected with sterilization, whether NHS employees or contract personnel, are suitably qualified and trained for their responsibilities;
- to ensure that sterilizers are subject to a documented scheme of periodic tests at yearly, quarterly, weekly and (in some cases) daily intervals;
- to ensure that sterilizers are subject to a documented scheme of preventative maintenance;
- to ensure that procedures for production, quality control and safe working practices are documented and adhered to in the light of statutory requirements and accepted best practice;

Other parts deal with installation, malfunctions etc.

The statutory requirements that impinge on sterilization include the various health and safety regulations, but perhaps more importantly from the point of view of patients, it also includes the Consumer Protection Act (1987). This act implements provisions for paying compensation to persons injured by a defective product, and it is likely that civil action could be taken against an organisation for supplying "sterile" products that were not in fact sterile, and caused an infection in a patient. The act also introduces a "general safety requirement" on the suppliers of "consumer goods" only. It is a criminal offence to supply unsafe consumer goods, whether or not actual harm has been caused. The HTM notes that it is not clear whether products from sterilizers are to be regarded as consumer goods.

Section 5 of Part 1 deals with personnel, and states that:

5.2 It is essential that personnel at all levels have a sound general knowledge of the principles, design and functions of sterilizers. They should be trained on those types and models of sterilizers with which they are concerned. They should have some knowledge of the basic elements of microbiology in order to ensure personal safety, safety of others and general safety. Training given to individuals should be recorded and reviewed regularly.

Later on, in the same section, the document defines key roles in the management of sterilizers, as follows:

Management

5.12 Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the sole operation of its premises.

User

5.13 The user is defined as the person designated by management to be responsible for the sterilizer.

5.14 In a hospital, the user could be a sterile services department manager, laboratory manager or theatre manager; in primary care he or she could be a general practitioner, dentist, or other health professional. Where a sterilizer is used to process medicinal products, the user is normally the production manager in charge of the entire manufacturing process.

5.15 The principal responsibilities of the user are as follows:

- a. to certify that the sterilizer is fit for use;
- b. to hold all documentation relating to the sterilizer, including the names of other key personnel;
- c. to ensure that the sterilizer is subject to periodic testing and maintenance;
- d. to appoint operators where required and ensure that they are adequately trained;
- e. to maintain production records;
- f. to establish procedures for product release (for medical products, in cooperation with the quality controller).

3.1.2 HTM 2030 - Washer-disinfectors.

HTM 2030 gives guidance on the choice, specification, purchase, installation, validation, periodic testing, operation and maintenance of washer-disinfectors (WDs) in use in the National Health Service for processing medical devices, laboratory ware and sanitary products.

The memorandum summarises management responsibilities in a similar manner to 2010, to include compliance with legislation and standards, training of personnel, adherence to a documented system of working (including maintenance, testing, quality control), and adherence to best practice.

Thus it is clear that for a hospital department or a GP surgery carrying out cleaning and sterilization of medical devices, they should have a well documented system in place including trained personnel.

4 Advice from the Medical Devices Agency

4.1 Device Bulletins

The Medical Devices Agency issued MDA DB 9605[4] in 1996, which was aimed at all owners and users of small benchtop steam sterilizers, in particular General Practitioners, community healthcare workers, dental practitioners, podiatrists, and staff in various hospital departments.

The bulletin states that

Wherever possible, all instruments and other equipment should be sterilized in a central sterile services department. When this is not possible or practicable unwrapped instruments and utensils may be sterilized in a small benchtop steam sterilizer.

It therefore seems clear that consideration should be given to using a central sterile services department (CSSD) for reprocessing of equipment before a decision is made to reprocess in-house.

The Bulletin also notes that failure to carry out periodic tests and maintenance tasks could compromise safety and may have legal and insurance implications for the user or owner of the sterilizer. To this end, it recommends a schedule of periodic testing, to include daily, weekly, quarterly and yearly testing, the details of which should be recorded in a log book dedicated to each sterilizer. This log book should also include details of maintenance, faults and modifications for future reference.

Daily and weekly testing should be carried out by the user of the machine, and details are included in the bulletin. Quarterly and annual testing should be conducted by a Test person (sterilizers).

The sterilizers should also be subject to periodic preventative maintenance as per the manufacturers recommendations, and the user should follow the manufacturer's recommendations for the quality of water to be used to charge the reservoir, frequency of changing the water, and routine maintenance of the reservoir.

The bulletin also lists practices which the MDA considers to be detrimental to the safe and effective operation of benchtop steam sterilizers:

- Processing of wrapped instruments and utensils - all forms of wrapping materials, including pouches, are considered by the MDA as being inappropriate for use with benchtop steam sterilization.
- The processing of instruments and utensils with lumens - benchtop steam sterilization should not be used to process equipment with lumens or cavities.
- Benchtop steam sterilizers are not suitable for processing porous loads e.g. swabs, towels, dressings, gowns and drapes.
- Reprocessing medical devices - single use devices must not be re-sterilized.
- The storage of instruments and utensils after sterilization - benchtop steam sterilizers are designed for the processing of equipment for immediate use within a clinical environment.

Recently, DB2000(04)[5] was issued by the MDA. Although the focus is on single-use devices, the bulletin examines the problems associated with reprocessing, including:

- Inadequate cleaning and decontamination,
- Material alteration,
- Mechanical failure,
- Potential for cross infection,
- Reactions to endotoxins,
- Residues from chemical decontamination agents.

4.2 Guidance on Decontamination.

The MDA have published guidance on decontamination[6] in three parts. Part 2 covers the protocols which should be followed for decontamination using cleaning, disinfection and sterilization. It gives guidance on the need for systems of work, and includes detailed protocols for all three aspects for decontamination.

The guidance notes that it is essential to maintain adequate records demonstrating how a particular device was reprocessed, as litigation under the Consumer protection Act (1987) may commence up to ten years after a defective product is supplied.

The documents include guidance in the following areas:

- Cleaning
 - Use of thermal washer-disinfectors
 - Use of chemical washer-disinfectors
 - Use of ultrasonics
 - Manual cleaning
- Disinfection
 - Liquid chemical immersion
- sterilization
 - by steam
 - by hot air
 - by ethylene oxide
 - by low temperature steam and formaldehyde

For each process, it lists the preferred usage, operating procedure, advantages and disadvantages of the process.

5 Survey of users of disposable and reusable specula.

A survey was carried out by SMTL of mainly GP practices, to find out why certain practices preferred reusable specula over disposable and vice versa, and if they used reusable, what systems they had in place for reprocessing.

The list of questions used is in Appendix A.

A total of 14 questionnaires were completed and the following summarises the results.

5.1 Do you use reusable or disposable vaginal specula?

1. 5 practices use reusable only
2. 7 practices use disposable only
3. 2 practices use both

5.2 How many uses do you have per month ?

1. Reusable 50-140
2. Disposable 10-170
3. Both 40-50

5.3 Why do you use these specula ?

1. Disposable Specula
 - (a) 4/7 users of disposable specula stated patient safety as their prime reason.
 - (b) 2/7 users also stated cost and that it was the doctor's decision.
2. Reusable Specula
 - (a) 3/5 users of reusable specula stated their selection was due to custom and practice.
 - (b) 2/5 stated that cost was their prime reason.
3. Users of both disposable and reusable specula stated patient safety as their prime reason for selection.

5.4 How do you clean them ?

1. The Colposcopy clinic was the only user of reusable specula that used a CSSD department for their reprocessing.
2. The remaining practices that internally sterilized their specula use either Hibiscrub, Decon 90, Hospec or Savlon then scrub the device.

5.5 How are they sterilized ? ²

1. 2 users possess Eschmann SES 2000 (one of whom sometimes uses pouches).
2. 2 users possess Eschmann Little Sister autoclaves
3. 2 users could not specify the model.

²Colposcopy clinic uses the CSSD department, therefore the following 10 questions were not applicable.

5.6 Are any records kept ?

1. 2 users stated no
2. 2 users stated unknown
3. 1 stated yes
4. 1 did not know

5.6.1 How frequently is the sterilizer checked ?

1. 1 user stated on a daily basis
2. The remainder were checked during the maintenance visit which was either twice or once a year.

5.7 Do you have 3rd party inspection ?

All stated that this was conducted by the maintenance contractor. The question was meant to check whether a 3rd party such as notified body or an independent organisation carried out an inspection of the facility. None of the departments surveyed (with the exception of the CSSD department) had independent 3rd party inspection.

5.8 Do you have a record to show that the sterilizer reached the correct temperature for the correct time ?

1. 4 users stated "No" due to the automation of the process and the LCD display.
2. 2 specifically said yes but did not give further details

5.9 Do you have written policies and procedures for dealing with vaginal specula ?

1. 4 stated no
2. 1 yes
3. 1 unknown

5.10 Have you ever received training in cleaning and sterilizing reusable devices ?

1. 3 stated no
2. 3 stated yes with 1 of the users specifically stating that training was given to use the sterilizer.

5.11 Are you happy that your current practice addresses the issues of control of infection with reusable devices ?

1. 2 stated no
2. 4 stated yes with 1 of the users stating that they were concerned about residual debris on the specula after sterilization.

5.12 Have you seen or been made aware of health circular HSC 1999/170 ?

1. 3 stated no
2. 1 stated yes
3. 1 did not answer
4. 1 stated that it was possible that the document had been seen.

5.13 Have you seen or been made aware of HTM 2030 (washer disinfectors) ?

1. 3 stated no
2. 1 stated yes
3. 1 did not answer
4. 1 stated that it was possible that the document had been seen.

5.14 Have you seen or been made aware of HTM 2010 (sterilizers) ?

1. 3 stated no
2. 1 stated yes
3. 1 did not answer
4. 1 stated that it was possible that the document had been seen.

5.15 Have you considered using a 3rd party (such as a CSSD department) to carry out your reprocessing ?

1. 4 stated no with 1 of the users stating that they might be interested in pursuing this option
2. 1 user specifically stated that this was the doctors decision
3. 1 user specifically stated that this was not cost effective

5.16 Have you ever tried a single use vaginal speculum?

Of the 5 who only use reusable, all said they had used disposable specula several years ago.

5.17 Do you have any concerns about single use specula ?

1. 1 user stated that the specula she had used previously tended to 'pinch a bit'
2. 1 user stated that patients such as the obese and those women who had many children could not accept them, although they did not state what size was used
3. 2 users specified that they were concerned about the strength

4. 1 user specified that they were concerned about the cost
5. 1 user specified that the reusable were easier to insert and were more manoeuvrable.
6. 1 user stated that the doctors did not like using them, but no reason was given.

5.18 If there was a financial benefit in moving to disposable specula would you do so ?

Of the 5 reusable users:

1. 1 stated yes
2. 1 stated no as the practice nurse who performs cervical smears found them unacceptable
3. 2 stated that it was possible if they were clinically acceptable and if there were cost implications.
4. 1 stated that it would be the decision of the practice doctors.

5.19 How much do you think a disposable speculum costs ?

Of those using reusables only, 4 did not know the cost and 1 user estimated the cost at 90 pence.

6 Problems and risks associated with reusable vaginal specula.

Reusable vaginal specula have to be reprocessed after each use. There are 2 main alternatives available to the users:

1. Contract out the reprocessing to a CSSD department or commercial company.
2. Reprocess in house.

6.1 Contracting out to a CSSD department.

If the reprocessing is contracted out to a local CSSD department, then the costs associated with the purchase and maintenance of an autoclave and washer disinfectant do not have to be borne by the practice or department. In addition, many CSSD departments possess independent 3rd party accreditation of their systems and processes, which means they have a documented quality system, that their equipment is tested regularly, and that they evaluate their procedures regularly (for example, performing endotoxin testing on devices after cleaning to confirm the efficacy of their cleaning procedures).

However, there are a number of problems associated with this option:

- **Availability** - not every practice has a local CSSD department offering this service.
- **Stock** - because of the turnaround times, practices have to keep a larger stock of specula to keep them going while devices are with the CSSD department.
- **Transport costs** - postage or delivery charges may be required to cover transport of the used devices to the CSSD department.
- **Turn-around times** - CSSD departments may take 2-3 days to reprocess a device, and may only collect once or twice a week, so that turnaround times may be between a few days and a week.

However, this appears to work well in at least one hospital in West Wales, which performs this service for local surgeries, eliminating the difficulties associated with in-house processing.

In addition, many CSSDs are inspected by an independent 3rd party, and can apply the CE mark to their reprocessed products.

6.2 In-house reprocessing.

Performing in-house reprocessing is still fairly common, although according to the survey (section 5) many practices are now turning to disposable specula, either solely or in conjunction with reusable specula.

However, it is clear from the survey that many GP practices are not reprocessing in accordance with best practice as defined in HTM2010 *et al.*

The survey highlighted the following problems in some of the practices:

- **Training** - many nurses had no training in reprocessing medical devices and using the sterilizing equipment.
- **Testing** - although most sterilizers were subject to regular maintenance visits, no testing was performed in between these visits.

- **Documentation** - no log books or other form of records were kept by many practices, so it was impossible to show when the sterilizer last had its water changed, or that it reached a particular temperature. Many practices had no documented procedures for operating their sterilizers, relying on verbal training from other nurses in the practices.
- **3rd party inspection** - none of the practices contacted were inspected by an independent 3rd party (such as a notified body) to check their procedures and systems.
- **Not following DoH advice** - at least one practice was packing the specula into pouches before sterilization, even though the MDA have issued a bulletin [4] stating that all forms of wrapping materials, including pouches, are considered by the MDA as inappropriate for use with benchtop steam sterilizers. The nurses in the practice had never been shown any of the MDA bulletins nor the HTM documents.
- **Storage of sterilized items** - because devices sterilized in benchtop sterilizers should not be processed in wrapping or pouches, when they are removed from the sterilizer there is no barrier to maintain their sterility, and many are stored in cupboards or draws. Thus the devices are not sterile when used on a patient (although they have been subjected to a sterilization process).

Because most users had no formal method of keeping records or logs, it is impossible, for example, to know when the water was last changed. Endotoxins are not inactivated by sterilization, and it is probable that the water reservoir in the sterilizers are regularly being topped up with endotoxin from the used instruments.

7 Cost Analyses of reprocessing reusable vaginal specula.

For a practice reprocessing reusable vaginal specula in accordance with advice and guidance from the Department of Health, and in accordance with best practice, the following costs have to be borne:

7.1 Inventory of devices.

A stock of devices has to be purchased initially so that patients do not have to wait for instruments to be sterilized.

7.2 Training

According to the DoH guidelines (see 3.1.1), personnel using sterilizers should have a sound general knowledge of the principles, design and functions of sterilizers, and should be trained on those types and models of sterilizers with which they are concerned. Thus practice nurses responsible for using the sterilizers should have this level of knowledge and training, and after the initial training should keep up to date through regular audit meetings.

7.3 Maintenance & Testing

The autoclave manufacturers now offer a complete maintenance and testing schedule for practices wishing to comply with HTM 2010, including annual maintenance, annual multi-point thermocouple testing plus quarterly thermocouple testing. These records would, under normal circumstances, be monitored and audited by an *Authorised Person*. As there are only around 30 authorised persons in the UK, including GP practices in their workload would probably not be practicable in the short term.

7.4 Record keeping

Records of all above activities should be kept for a number of reasons. Firstly, to comply with the HTM documents, which require production records and schedules of maintenance and testing, but also as part of the practices quality system, so that they could prove, if necessary, that their machines had been maintained/tested, and that training requirements of staff were up to date.

7.5 Cost Analyses

7.5.1 Basic Costs for a GP Surgery

For example, if a GP surgery with 3 nurses and 1 benchtop autoclave were to adhere to the DoH guidelines, the following costs would have to be borne:

Item	Cost	Notes
Purchase of autoclave	£4,000	Conservative estimate
Purchase of washer disinfectator	£4,000	
Training of staff	£270	3 nurses on initial training course plus annual audit meeting. 1 day each (at salary cost of £90/day each and assuming the courses are free.)
Production of documentation	£450	1 nurse 30 hours work.
Annual maintenance contract of autoclave	£300	By manufacturer
Annual testing of autoclave	£184	By manufacturer
Quarterly testing of autoclaves	£420	£105 per quarter - by manufacturer.
Weekly and daily testing of autoclaves	£390	Based on a nurse spending 30 minutes/week, 52 weeks per year. Manufacturers can advise on the tests required.
Record Keeping	£780	1 hour a week for 52 weeks of the year.
Purchase of Inventory	£200	20 specula @ £10 each. Should last for 2 years,

NOTES:

- Nursing time has been costed out at £15/hour.
- Costs for purchase of autoclaves and specula will vary according to manufacturers and deals on offer.

7.5.2 Calculation of annual costs - GP Surgery

- 1 autoclave @ £4000, guaranteed for 5 years: £800/annum
- 1 washer/disinfectator @ £4000, guaranteed for 5 years: £800/annum
- Staff Training time or audit time: £270/annum
- Production of documentation (1st year only): £450
- Annual maintenance, testing and quarterly testing: £904
- Staff time on weekly/daily testing: £390
- Staff time on record keeping: £780
- Inventory of specula apportioned over 2 years: £100
- **Total cost: £4,494 in the first year, £4,044 for subsequent years.**

So for this hypothetical practice, the cost of maintaining a safe sterilization system in compliance with best practice and government guidelines would cost over £4,000 per annum.

The busiest practices in the survey were performing 170 procedures per month. At £1.00 per speculum, this would equate to an annual disposable specula cost of £2,040.

It would therefore appear that it is more cost effective to purchase disposable specula than to reprocess reusable specula, although this assumes that the autoclave is only used for specula and no other reusable instruments.

The cost of purchasing the disposable Pelispec vaginal speculum is usually less than £1.

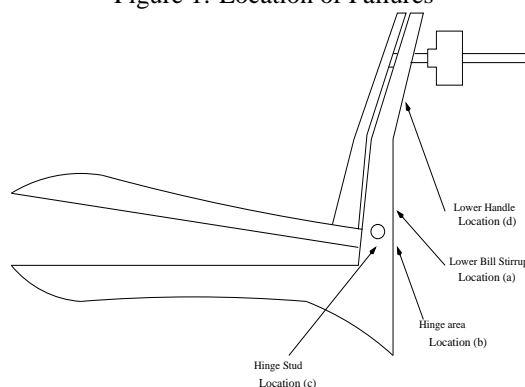
7.5.3 CSSD Department

The CSSD department who reprocess the instruments for CC1 are ISO certified, and can apply the CE mark under the Medical Device Directive.

The accredited system includes regular testing of equipment on a daily, weekly, quarterly and annual basis.

The cost of reprocessing in CSSD1 was 54p per device (excluding transport/postage and packaging). However, these costs will vary between CSSD departments, covering the range of 50 pence to £1.00.

Figure 1: Location of Failures



8 Failure Testing of disposable Vaginal Specula.

The force required to cause failure of a Pelican disposable Pelispec speculum when locked in an open position was determined using the SMTL test method, TM-334 (Speculum Break Testing).³

In this method the speculum is locked in an open position using the integral screw thread and locking nut, and is then placed in a foam retention jig for testing. The jig is then positioned on the lower compression plate of a constant rate of traverse tensiometer and the upper compression plate is moved down onto the upper bill of the speculum. An increasing compressive force is applied to the speculum until the speculum fails. The position of the failure and the force at failure are then recorded.

Speculum size	Force at failure (N)	Location of failures
Small	174.81 (40.46)	7 failed at a+b 1 failed at a 2 failed at b
Medium	57.25 (2.04)	2 failed at b+c 2 failed at a+d 6 failed at b
Large	49.85 (5.09)	9 failed at b 1 failed at a+d

Results represent the mean of 10 determinations

Results in brackets represent standard deviation

The location of the failures are shown in Figure 1. As can be seen from the above data and figure 1, all failures occurred *outside* the vagina, so that if a failure of the product had occurred, no shards of plastic would be left in the vagina itself.

³The full report is SMTL report no 00/1222/1. Note that the test is a test to destruction, and does not imply that the specula would fail in normal use.

9 User Evaluation

Ten users within Carmarthenshire NHS Trust were requested to compare the disposable vaginal speculum with the existing product in use. This evaluation was carried out independently by the CSSD department to determine the possibility of reducing the number of reusable specula in the hospital, as it could be cost effective to move to increased disposable use.

The results of one of the evaluation forms has been omitted from the analyses below, as there was some doubt as to whether the user had understood the questionnaire based on their answers.

Question	Yes	No	Comments
Is the labelling clear, accurate and compliant with existing European standards ?	6	0	3 users did not answer
Is the packaging easily opened ?	8	1	2 users suggested that the handle should be at the opening end of package. 1 user found it difficult to open the packaging of large sized specula
Are the sizes clearly marked on the package ?	8	0	1 user did not answer 1 user suggested that the information should be presented on the front of the package.
Is the range of sizes available adequate ?	4	4	1 user did not answer. 2 users stated that wider and narrower specula were required. 1 user required a child's size.
Are the specula easily accessed ? (i.e., can the item be obtained easily from the packaging, without compromising sterility or the contents.)	5	1	3 users did not answer
Is the speculum comfortable for the patient ?	9	0	
Is there any apparent noise in the operation of the speculum.	0	8	1 user did not answer
Is the speculum strong enough during use ?	5	3	1 user did not answer. 1 user stated that difficulty may be experienced if vaginal walls are prolapsing. 1 user stated that the strength is not always adequate, especially in the obese patient.

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Does the retaining nut operate on the threaded runner easily?	8	1	1 user stated that it seemed to take longer to operate to full than metal cusco.
Is the speculum compatible with any other equipment that may be required to be used ?	4	2	1 user did not answer. 1 user stated that item was not compatible for treatments in Colposcopy. 1 stated 'not applicable'
Has any incident occurred with this product during the evaluation period ?	0	7	2 users did not answer

General comments included at the end of the evaluation were as follows:

- Specula are not suitable for Colposcopy⁴
- Design should be equivalent to virgin-metal cusco⁵
- Shape of specula not as good as metal equivalent
- Broader tip is required
- Specula were not assessed during insertion of IUCD

⁴This comment was from a consultant who noted that a lot of pressure was required to hold the disposable in the vagina, which was unacceptable for extended examinations. The users stated that the devices were acceptable for cervical smears.

⁵We take this to mean that they require a disposable version of the virgin cusco speculum.

10 Conclusions.

In 1992, Alison Fuller published an article on sterilization in GP surgeries[2], in which she described the principles and best practices that surgeries should follow when reprocessing medical devices. These included quarterly servicing and weekly checks (in line with the version of HTM10 which was then available). The results of the survey presented above suggest that best practice for reprocessing is only being followed by a few GP surgeries. Many GP surgeries are not following best practice as recommended by infection control nurses 8 years ago, let alone complying with the current DoH recommendations. It appears, therefore, that little has changed since 1989, when Rogers[10], in a survey of 6 surgeries, showed a lack of understanding of the principles of sterilization and disinfection by GPs and their nurses - where surgeries are reprocessing vaginal specula, very few have the appropriate controls and systems in place.

In contrast, CSSD departments have adopted the best practices recommended by the DoH. In fact, most CSSD departments attempt to comply fully or in part with the various HTMs, and many now have third party inspection from notified bodies, regular testing of their premises, and regular testing of instruments for endotoxin and bioburden levels. Staff are well trained, and courses and conferences are arranged by their professional institute. Many CSSD departments are able to affix the CE mark to products produced by them due to the rigorous nature of the controls and systems they have introduced over recent years.

It is possible that surgeries who do not comply with best practice are putting their patients at risk. The MDA bulletin DB 9605[4] states that failure to follow MDA advice could compromise safety and may have legal and insurance implications for the user or owner of the sterilizer. Many of the GP practices surveyed are ignoring MDA advice regarding the way they manage their reprocessing systems (e.g., no documentation, use of pouches, infrequent testing). The reasons for GP practices accepting these risks appear to be based on inadequate resources (usually financial), inadequate training, and lack of knowledge about the alternatives.

For a GP surgery to bring itself into line with reprocessing best practice would involve an investment in training, maintenance, testing and possibly equipment. The survey responses show that some practices are not willing to consider 3rd party reprocessing by CSSD departments, with one stating that it was not cost effective. It does not seem that some GP practices are willing, at present, to accept the extra costs of reprocessing in line with best practice.

An alternative for many of these practices would be to use disposable specula, as cost was only an issue with one of the practices surveyed. Although the use of disposable specula may incur an extra financial burden at present for some of the practices, it is possible that it may be a cheaper alternative when compared to the cost of fully implementing the DoH guidelines for reprocessing. Half of the practices surveyed are already using disposable specula, with 4 users stating patient safety as their prime reason, and 2 citing cost as a factor in their decision making.

Of the practices unwilling to use disposable specula, some stated that strength was a problem. However, there is no evidence that the specula tested by SMTL are not strong enough. The specula were tested to destruction (i.e., force was applied until the specula failed), and the force required to break them was equivalent to 5 x 1Kg bags of sugar piled on the jaws. The specula tested are designed to break in a 'safe' fashion, so that they break outside the vagina, and this was confirmed by the test results. Presumably strength is not an issue with the 7 practices using disposable specula only⁶, and for unusual patients it would be cost effective to have a small number of reusable specula available which had been reprocessed and packed commercially (perhaps by a CSSD department).

⁶In fact GP practice no 4 stated that disposables were used "for convenience and strength".

Other practices stated that the range of sizes available was not sufficient. This may be due to the fact that some of the nurses interviewed had last used a disposable speculum many years ago, when the range of products was smaller. Although not all disposable manufacturers make a range of sizes, the specula examined by SMTL are available in small, medium and large sizes. Whilst this still means that certain sizes (such as the virgin size referred to by one practice in the survey) are not available as disposables, it may be that these lesser used sizes could be made available through a small stock of reusable specula which are processed by a 3rd party, as above.

Although there is little in the literature regarding cross-infection from inadequately sterilized specula, we live in an increasingly litigious society. One strand in the defence against patient claims of cross infection from poorly decontaminated and sterilized instruments would be complete documentation of the process, including logbooks, written operating procedures, training records, test results and maintenance data. The other possibility is to use pre-sterilized disposable CE marked equipment from a reputable manufacturer. Either would make it more difficult for a patient to mount a successful legal claim.

GP practices should institute a thorough review of the risks and costs inherent in their current reprocessing practice, and compare these with the cost of complying with Department of Health advice, commercial reprocessing, or the use of disposables.

Approved by: _____ **Date:** _____

Pete Phillips, Deputy Director, SMTL.

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A Questionnaire used for User Interviews.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?		
How many uses do you have per month ?		
Why do you use these specula ?		
How do you clean them ?		
How are they sterilized ?		
Are any records kept ?		
How frequently is the sterilizer checked ?		
Do you have 3rd party inspection ?		
Do you have a record to show that the sterilizer reached the correct temperature for the correct time ?		
Do you have written policies and procedures for dealing with vaginal specula ?		
Have you ever received training in cleaning and sterilizing reusable devices ?		
Are you happy that your current practice addresses the issues of control of infection with reusable devices ?		
Have you seen or been made aware of health circular HSC 1999/170 ?		
Have you seen or been made aware of HTM 2030 (washer disinfectors) ?		
Have you seen or been made aware of HTM 2010 (sterilizers) ?		
Have you considered using a 3rd party (such as a CSSD department) to carry out your reprocessing ?		
Have you ever tried a single use vaginal speculum?		
Do you have any concerns about single use specula ?		
If there was a financial benefit in moving to disposable specula would you do so ?		
How much do you think a disposable speculum costs ?		

B Interviews with users of vaginal specula.

B.1 General Practice No 1 (GP1)

GP1 is a busy general practice employing 3 practice nurses.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Reusable.	
How many uses do you have per month ?	140	
Why do you use these specula ?	Cost (the GP's and practice manager say they must use them.	
How do you clean them ?	Scrub with Savlon, sometimes use an ultrasonic bath, depending on how dirty they appear.	
How are they sterilized ?	In an Eschmann SES 2000 sterilizer.	Although the series 2000 were originally designed to accept pouches, the MDA advise against this.
Are any records kept ?	No. (The water is changed every 2 weeks).	
How frequently is the sterilizer checked ?	Annual maintenance (probably with Eschmann).	
Do you have 3rd party inspection ?	Only the maintenance visits.	
Do you have a record to show that the sterilizer reached the correct temperature for the correct time ?	No - it is an automated cycle.	
Do you have written policies and procedures for dealing with vaginal specula ?	No	
Have you ever received training in cleaning and sterilizing reusable devices ?	No	
Are you happy that your current practice addresses the issues of control of infection with reusable devices ?	No	
Have you seen or been made aware of health circular HSC 1999/170 ?	No	
Have you seen or been made aware of HTM 2030 (washer disinfectors) ?	No	

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Have you seen or been made aware of HTM 2010 (sterilizers) ?	No	
Have you considered using a 3rd party (such as a CSSD department) to carry out your reprocessing ?	No, but would be interested if practice manager agreed.	
Have you ever tried a single use vaginal speculum ?	Yes - about 20-25 years ago.	
Do you have any concerns about single use specula ?	Yes - they used to "pinch a bit".	
If there was a financial benefit in moving to disposable specula, would you do so ?	Yes	
How much do you think a disposable speculum costs ?	No idea.	

B.2 General Practice No2 (GP2)

GP2 is a busy general practice employing 3 practice nurses.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Reusable.	
How many uses do you have per month ?	80	
Why do you use these specula ?	Cost and strength (see later).	
How do you clean them ?	Soak in Hibitane, followed by scrubbing with a brush.	
How are they sterilized ?	In an Eschmann Little Sister 3 sterilizer.	
Are any records kept ?	No.	
How frequently is the sterilizer checked ?	6 monthly intervals (probably with Eschmann).	
Do you have 3rd party inspection ?	Only the maintenance visits.	
Do you have a record to show that the sterilizer reached the correct temperature for the correct time ?	No - the LCD display indicates when the temperature is reached, but no record kept.	
Do you have written policies and procedures for dealing with vaginal specula ?	No	
Have you ever received training in cleaning and sterilizing reusable devices ?	No	

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Are you happy that your current practice addresses the issues of control of infection with reusable devices ?	Yes, but have some concerns that they are truly clean due to what appears to be residual organic debris on some specula.	
Have you seen or been made aware of health circular HSC 1999/170 ?	No	
Have you seen or been made aware of HTM 2030 (washer disinfectors) ?	No	
Have you seen or been made aware of HTM 2010 (sterilizers) ?	No	
Have you considered using a 3rd party (such as a CSSD department) to carry out your reprocessing ?	No - it would be up to the GP's	
Have you ever tried a single use vaginal speculum ?	Yes - between 3-5 years ago.	
Do you have any concerns about single use specula ?	Yes - some patients wouldn't accept the plastic ones, and they would not hold the folds in obese patients or patients who had delivered many children. Both nurses noted that they had never had one break.	
If there was a financial benefit in moving to disposable specula, would you do so ?	No - the nurse who took smears said she would not be happy with plastic specula.	
How much do you think a disposable speculum costs ?	90 pence	

B.3 Colposcopy Clinic (CC1)

CC1 is a colposcopy clinic in a busy District general Hospital. employing 2 nurses.

Question	Response	Notes
Do you use reusable or disposable vaginal specula?	Reusable.	
How many uses do you have per month ?	?	
Why do you use these specula ?	Custom and practice.	
How do you clean them ?	CSSD department.	
Have you ever tried a single use vaginal speculum?	Yes - between 3-5 years ago.	
Do you have any concerns about single use specula ?	Yes - whether they would be strong enough.	

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If there was a financial benefit in moving to disposable specula, would you do so ?	Possibly, if they were clinically acceptable. They were keen on the fact that it would make life easier for them, instead of having to deal with collection and dispatch to CSSD. They were also concerned whether a sufficient range of sizes was available (S/M/L widths, and different lengths (virgins, retroverted wombs etc).	
How much do you think a disposable speculum costs ?	No idea.	

The nurses noted that sometimes reusables were required as they could be coated, which was required for some laser treatments.

B.4 CSSD department

The CSSD department who reprocess the instruments for CC1 are ISO certified, and can apply the CE mark under the Medical Device Directive.

Their reprocessing system comprises the following:

- Soaking for at least 1 hour.
- Use of an enzymatic cleanser
- 3/4 hour washing/disinfecting cycle
- 50°C wash with detergent
- decontamination wash at up to 90°C
- rinsing stage with reverse osmosis water
- drying stage
- packed in a monitored clean room
- sterilized in a porous load autoclave

The accredited system includes regular testing of equipment on a daily, weekly, quarterly and annual basis.

The cost of reprocessing in CSSD1 was 54p per device (excluding transport/postage and packaging). However, these costs will vary between CSSD departments, covering the range of 50 pence to £1.00.

B.5 General Practice No 3 (GP3)

GP3 is a small general practice employing 2 practice nurses.

Question	Response	Notes
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Do you use reusable or disposable vaginal specula ?	Disposable. Only use specula without ratchet.	
How many uses do you have per month ?	100	
Why do you use these specula ?	No specific answer Doctors preference	

B.6 General Practice No 4 (GP4)

GP4 is a large general practice employing 10-12 practice nurses.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Disposable	
How many uses do you have per month ?	100	
Why do you use these specula ?	Convenience and strength Doctors preference.	

B.7 General Practice No 5 (GP5)

GP5 is a small general practice employing 2 practice nurses.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Disposable.	
How many uses do you have per month ?	170	
Why do you use these specula ?	Patient safety	

B.8 General Practice No 6 (GP6)

GP6 is a small general practice employing 3 practice nurses.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Disposable	
How many uses do you have per month ?	20-40	
Why do you use these specula ?	Cost and patient safety	

B.9 General Practice No 7 (GP7)

GP7 is a general practice employing 2 practice nurses.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Disposable	
How many uses do you have per month ?	50	
Why do you use these specula ?	Patient safety and design. Family planning clinic found these specula acceptable and therefore surgery purchased these items	

B.10 General Practice No 8 (GP8)

GP8 is a general practice employing 1 practice nurse.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Disposable	
How many uses do you have per month ?	100	
Why do you use these specula ?	Cost, convenience and patient safety Specula were already in use before practice nurse took up post. Response is her own clinical opinion.	

B.11 General Practice No 9 (GP9)

GP9 is a general practice employing 1 practice nurse.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Disposable and reusable	
How many uses do you have per month ?	50	
Why do you use these specula ?	Primarily for patient safety, followed by design, range of sizes, convenience, strength and cost	
How do you clean them ?	Scrub	
How are they sterilized ?	In an Eschmann SES 2000	
Are any records kept ?	No answer given	

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How frequently is the sterilizer checked ?	Annually	
Do you have 3rd party inspection ?	Yes	
Do you have a record to show that the sterilizer reached the correct temperature for the correct time ?	Yes	
Do you have written policies and procedures for dealing with vaginal specula ?	No	
Have you ever received training in cleaning and sterilizing reusable devices ?	Yes	
Are you happy that your current practice addresses the issues of control of infection with reusable devices ?	Yes	
Have you seen or been made aware of health circular HSC 1999/170 ?	No answer given	
Have you seen or been made aware of HTM 2030 (washer disinfectors) ?	No answer given	
Have you seen or been made aware of HTM 2010 (sterilizers) ?	No answer given	
Have you considered using a 3rd party (such as a CSSD department) to carry out your reprocessing ?	No	
Have you ever tried a single use vaginal speculum?	Yes as stated above	
Do you have any concerns about single use specula ?	Cost	
If there was a financial benefit in moving to disposable specula would you do so ?	Possibly	
How much do you think a disposable speculum costs ?	1 pound	

B.12 General Practice No 10 (GP10)

GP10 is a general practice employing 2 practice nurses.

Question	Response	Notes
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Do you use reusable or disposable vaginal specula ?	Reusable	
How many uses do you have per month ?	50	
Why do you use these specula ?	No specific answer given. General practice to use them.	
How do you clean them ?	Soak for 24 hours in Decon 90 and scrubbed	
How are they sterilized ?	Bench top steam sterilizer. Model unknown	
Are any records kept ?	Unknown	
How frequently is the sterilizer checked ?	Annual maintenance contract	
Do you have 3rd party inspection ?	Only the maintenance contractor	
Do you have a record to show that the sterilizer reached the correct temperature for the correct time ?	No, however LCD displays temperature reached	
Do you have written policies and procedures for dealing with vaginal specula ?	No	
Have you ever received training in cleaning and sterilizing reusable devices ?	No	
Are you happy that your current practice addresses the issues of control of infection with reusable devices ?	Yes	
Have you seen or been made aware of health circular HSC 1999/170 ?	Possibly. Cannot recall the document numbers but may have read them when issued.	
Have you seen or been made aware of HTM 2030 (washer disinfectors) ?	Possibly	
Have you seen or been made aware of HTM 2010 (sterilizers) ?	Possibly	
Have you considered using a 3rd party (such as a CSSD department) to carry out your reprocessing ?	No	
Have you ever tried a single use vaginal speculum?	Yes.	

Do you have any concerns about single use specula ?	Yes. The doctors used them a couple of times but general opinion was that the metal specula were easier to insert and to manoeuvre whilst in-situ.	
If there was a financial benefit in moving to disposable specula would you do so ?	Possibly. Cost implications would have to be assessed.	
How much do you think a disposable speculum costs ?	No idea	

B.13 General Practice No 11 (GP11)

GP11 is a busy general practice employing 2 practice nurses.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Reusable	
How many uses do you have per month ?	>100	
Why do you use these specula ?	No specific answer given. General practice to use them.	
How do you clean them ?	Scrub with Hibitane	
How are they sterilized ?	Bench top steam sterilizer. Model unknown.	
Are any records kept ?	Not known	
How frequently is the sterilizer checked ?	Not known	
Do you have 3rd party inspection ?	Yes, annual maintenance contract	
Do you have a record to show that the sterilizer reached the correct temperature for the correct time ?	No, however LCD displays temperature reached	
Do you have written policies and procedures for dealing with vaginal specula ?	Unknown	
Have you ever received training in cleaning and sterilizing reusable devices ?	Yes. Trained to use the sterilizer	
Are you happy that your current practice addresses the issues of control of infection with reusable devices ?	No	

Have you seen or been made aware of health circular HSC 1999/170 ?	No	
Have you seen or been made aware of HTM 2030 (washer disinfectors) ?	No	
Have you seen or been made aware of HTM 2010 (sterilizers) ?	No	
Have you considered using a 3rd party (such as a CSSD department) to carry out your reprocessing ?	No. Practice is satisfied with internally sterilizing the specula	
Have you ever tried a single use vaginal speculum?	Yes. Doctors have used them over 10 years ago, but did not like them	
Do you have any concerns about single use specula ?	As above	
If there was a financial benefit in moving to disposable specula would you do so ?	Doctors would have to make this decision	
How much do you think a disposable speculum costs ?	No idea	

B.14 General Practice No 12 (GP12)

GP12 is a busy general practice employing 3 practice nurses.

Question	Response	Notes
Do you use reusable or disposable vaginal specula ?	Both Disposable is used for routine smear procedures. Nut and thread design have been found to be the most convenient due to range of size. Reusable is used for coil fitting or difficult smear procedures i.e., obese patients where extra strength and range of size is required.	
How many uses do you have per month ?	40	
Why do you use these specula ?	Primarily for patient safety, followed by strength, design, cost, range of sizes and convenience.	
How do you clean them ?	Washed and scrubbed with Hospec	
How are they sterilized ?	Little Sister 3 autoclave	
Are any records kept ?	Yes	

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How frequently is the sterilizer checked ?	Daily	
Do you have 3rd party inspection ?	Yes	
Do you have a record to show that the sterilizer reached the correct temperature for the correct time ?	Yes	
Do you have written policies and procedures for dealing with vaginal specula ?	Yes	
Have you ever received training in cleaning and sterilizing reusable devices ?	Yes	
Are you happy that your current practice addresses the issues of control of infection with reusable devices ?	Yes	
Have you seen or been made aware of health circular HSC 1999/170 ?	Yes	
Have you seen or been made aware of HTM 2030 (washer disinfectors) ?	Yes	
Have you seen or been made aware of HTM 2010 (sterilizers) ?	Yes	
Have you considered using a 3rd party (such as a CSSD department) to carry out your reprocessing ?	Not cost effective	
Have you ever tried a single use vaginal speculum?	Yes	
Do you have any concerns about single use specula ?	Strength	
If there was a financial benefit in moving to disposable specula would you do so ?	Currently using both disposable and reusable specula	
How much do you think a disposable speculum costs ?	Currently purchasing Pelican specula	

B.15 General Practice No 13 (GP13)

GP13 is a small general practice employing 1 practice nurse.

Question	Response	Notes
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Do you use reusable or disposable vaginal specula ?	Disposable	
How many uses do you have per month ?	10-15	
Why do you use these specula?	Cost and convenience	