

# SMTL Report Summary



**Pelican Healthcare Ltd**

[www.pelicanhealthcare.co.uk](http://www.pelicanhealthcare.co.uk)

## The SMTL Report

Pelican Healthcare Ltd commissioned an independent NHS laboratory report, which addresses issues relating to re-usable and disposable speculum. The report identifies the possible cross-infection risks associated with re-usable vaginal specula, an in-depth review of relevant Health Publications and a cost analysis of re-usable vaginal speculums compared with disposable ones. The full content of the SMTL report can be read and assessed at your convenience by visiting [www.pelicanhealthcare.co.uk](http://www.pelicanhealthcare.co.uk) and clicking on the "Downloads & Links" icon. A summary of the report is included below.

## Cross-Infection Risks/ Review of Health Circulars

"Human Papilloma Virus (HPV) infected cells can be found on instruments inserted into the vagina of women with HPV infection and if these instruments are not cleaned and sterilised properly, they will be a potential source of infection for subsequent patients."

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

"It is possible that surgeries who do not comply with best practice are putting their patients at risk. The MDA bulletin DB9605 (2) states that failure to follow MDA advice could compromise safety and may have legal and insurance implications for the user or owner of the steriliser. Many of the G.P. practices surveyed are ignoring MDA advice regarding the way they manage their reprocessing systems, (e.g. no documentation, use of pouches, infrequent testing)."

"The Consumer Protection Act (1987) implements provision 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 MDA guidance on decontamination 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 report goes on to conclude that, "we live in an increasingly litigious society. One strand in the defence against patient claims of cross-infection from poorly decontaminated and sterilised 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-sterilised disposable CE-marked equipment from a reputable manufacturer. Either would make it more difficult for a patient to mount a successful legal claim."

## Cost Analysis

'It therefore appears that it can be more cost effective to purchase disposable specula than to reprocess re-usable specula.' Also, 'the cost of reprocessing, using the CSSD department is, in the vast majority of cases, more expensive than using disposable specula.'

"An alternative for many of these practices would be to use disposable specula."

## User Evaluation

"In virtually all cases, in the independent study of doctor's surgeries, the important issues are not adhered to, either in maintenance or report keeping, putting the surgery staff at risk (both management and the user of any steriliser)".

The independent survey carried out on users of disposable and re-usable specula, in summary shows that the majority of those using disposable specula state patient safety as their prime reason, others state cost effectiveness.

The report concludes by stating that;

"G.P. 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."

## Strength Test

One of the issues around disposable specula in general, is their strength. The Pelispec Disposable Vaginal Speculum was tested to destruction and documented as part of the report. The report states that: -

"There is no evidence that the specula tested by them (namely the Pelispec) are not strong enough. In the test to destruction, the force required to break them was equivalent to at least 5 x 1 Kg bags of sugar piled on the jaws. Also, all the Pelispecs tested to destruction broke in a 'safe' fashion, i.e. outside of the vaginal area, at the handle."

"Presumably strength is not an issue with the practices detailed who were using disposable specula only." (In fact, one practice stated that disposables were used 'for convenience and strength').

## Failure Testing of The Pelispec

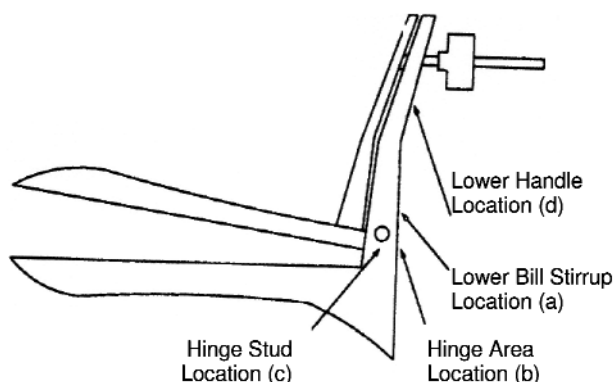
The force required to cause failure of a Pelican disposable Pelispec Speculum when locked in an open position was determined using the SMTL test method, TM-334 (Speculum Break Testing).<sup>3</sup>

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
Medium Long/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.

**Figure 1: Location of Failures**



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.