

ASSESSMENT REPORT
ENDOZIME INSTRUSPONGE
Peskett Solutions Ltd

Hospital Infection Research Laboratory
City Hospital NHS Trust
Dudley Road
Birmingham B18 7QH

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PRODUCT NAME	Endozime Intrusponge
SUPPLIER/MANUFACTURER	Peskett Solutions Ltd. Unit 66 Hammonds Drive Industrial Estate, Eastbourne, East Sussex, BN23 6PW

DESCRIPTION

The Endozime Instrusponge is an enzymatic detergent impregnated sponge designed to clean long narrow lumens of accessible channels of flexible endoscopes. Currently single use brushes are used.

Objective

To compare the efficacy of the Intrusponge and single use brush by assessing the removal of an artificial soil from surrogate devices supplied by Peskett Solutions Ltd.

Test Methods

Soiling

Five ml of artificial soil - Edinburgh soil or respiratory soil (HTM 2030,1997), was passed through the lumens of the surrogate devices using a 20ml syringe. The same syringe was used to pass 2 x 20ml volumes of air through, so forcing excess soil out of the distal end of the device. The devices were allowed to dry for 30 minutes.

The lumens were cleaned following the manufacturers instructions using either the detergent impregnated sponge or a cleaning brush and neutral detergent solution. After cleaning the lumens were visually examined for the presence of soil and washings were tested by the ninhydrin test to detect residual soil.

The test was repeated 10 times with both Edinburgh and respiratory soil, and with both the Endozime Intrusponge and Single use flexible brushes.

Cleaning with Endozime Intrusponge

The appropriate size sponge was selected for the size of device to be cleaned (3mm or 4mm were used).

The foam end was moistened with water to activate the enzymes and this was inserted into the channel and passed along its length.

The sponge tip was examined on exit from the distal end of the device, and the presence of soil recorded.

The sponge tip was rinsed in water using gloved fingers under water (to reduce aerosols).

The Intrusponge was fully retracted from the device and rinsed as described above.

The process of insertion, rinse and retraction was repeated until there was no debris visible on the foam tip.

The number of passes was recorded.

Cleaning with brush and detergent solution

One size single use brush was used for both the 3mm and 4mm size lumen. The brush was moistened in warm water with detergent added and this was inserted into the channel of the device and passed along its length.

The brush tip was examined on exit from the distal end of the device, and the presence of soil recorded.

The brush tip was cleaned (using the supplied brush) under water to reduce aerosols.

The brush was fully retracted and rinsed before re-insertion.

The process of insertion, rinse and retraction was repeated until there was no debris visible on the brush tip.

The number of passes was recorded.

After cleaning, the clear plastic channel of the device was observed to record the presence of any visible soil.

The device was flushed through with 20ml sterile water, and 2 x 20ml volumes of air (in order to mimic what happens in practice).

Ninhydrin Test

After cleaning and flushing, the device was rinsed with 3ml of sterile distilled water and this was tested for residual protein using ninhydrin. Sterile swabs were dipped into the rinse water, 3 drops of ninhydrin solution was applied, the swabs incubated for 1 hour and the results recorded. A positive and negative control was included with all ninhydrin tests.

Additional ninhydrin testing was carried out after soiling, drying and 1, 2, 3 or 4 passes with the Intrusponge or the single use brush.

Results

After cleaning, a standardised water flush through the channel of the surrogate device before testing for residual protein aimed to mimic on-site cleaning procedures. The ninhydrin results for residual protein were negative for both Edinburgh and respiratory soil for both the Intrusponge and the single use brushes. These results can be seen in Table 1 & 2. These results also demonstrate that fewer passes of the Instrusponge are required compared to the brush.

Table 3 shows that only 2 passes of the endozime intrusponge were required to achieve a negative ninhydrin result, whereas 3 passes were required with the single use brush.

Figures 3, 4,& 5 illustrates the physical movement of soil within the surrogate device when using the Intrusponge, the snug fit of the sponge within the lumen causing the soil to be pushed along. However although the single use brush touches the sides of the lumen, the arrangement of the bristles allow soil to remain within the channel even though it has been dislodged. This emphasises the need for flushing after brushing to remove dislodged debris. This can be seen in figures 6, 7 & 8. These benefits however, would not be obvious to an operator in an endoscopy unit where the internal channels cannot be viewed.

Table 1

Edinburgh Soil							
Test No	Device	Intrusponge			Brush		
		No Passes	Visible Soil	Residual Protein	No Passes*	Visible Soil	Residual Protein
1	A 3mm	3	+	Negative	8*	+	Negative
2	B 4mm	2	-	Negative	8*	+	Negative
3	A 3mm	4	+	Negative	8*	+	Negative
4	A 4mm	3	-	Negative	8*	+	Negative
5	A 3mm	4	+	Negative	8*	+	Negative
6	A 4mm	3	-	Negative	8*	+	Negative
7	A 3mm	3	-	Negative	8*	+	Negative
8	A 4mm	4	+	Negative	8*	+	Negative
9	A 3mm	4	-	Negative	8*	+	Negative
10	A 4mm	4	-	Negative	8*	+	Negative

Table 2

Respiratory Soil							
Test No	Device	Intrusponge			Brush		
		No Passes	Visible Soil	Residual Protein	No Passes	Visible Soil	Residual Protein
1	A 3mm	4	-	Negative	8*	+	Negative
2	B 4mm	4	-	Negative	8*	+	Negative
3	A 3mm	4	-	Negative	8*	+	Negative
4	A 4mm	4	-	Negative	8*	+	Negative
5	A 3mm	4	-	Negative	8*	+	Negative
6	A 4mm	4	-	Negative	8*	+	Negative
7	A 3mm	4	-	Negative	8*	+	Negative
8	A 4mm	4	-	Negative	8*	+	Negative
9	A 3mm	4	-	Negative	8*	+	Negative
10	A 4mm	4	-	Negative	8*	+	Negative

NB A Pass = Insertion into, and retraction from the device

At 8 passes with the brush, blood staining was still observed on exit at the distal end of the surrogate devices, and blood stained material was still visible within the lumen.

Table 3

Ninhydrin Results after:	Edinburgh Soil – 30 minutes drying time	
	Intrusponge	Brush
1 Pass	Weak Positive	Positive
2 Pass	Negative	Weak Positive
3 Pass	Negative	Negative
4 Pass	Negative	Negative

Figure 1 Endoscope channel before soiling



Figure 2 Soiled channel before cleaning



Figure 3 Instrusponge passed halfway along channel



Figure 4 One pass of Instrusponge



Figure 5 2 passes of Instrusponge



Figure 6 Cleaning brush passed halfway along channel

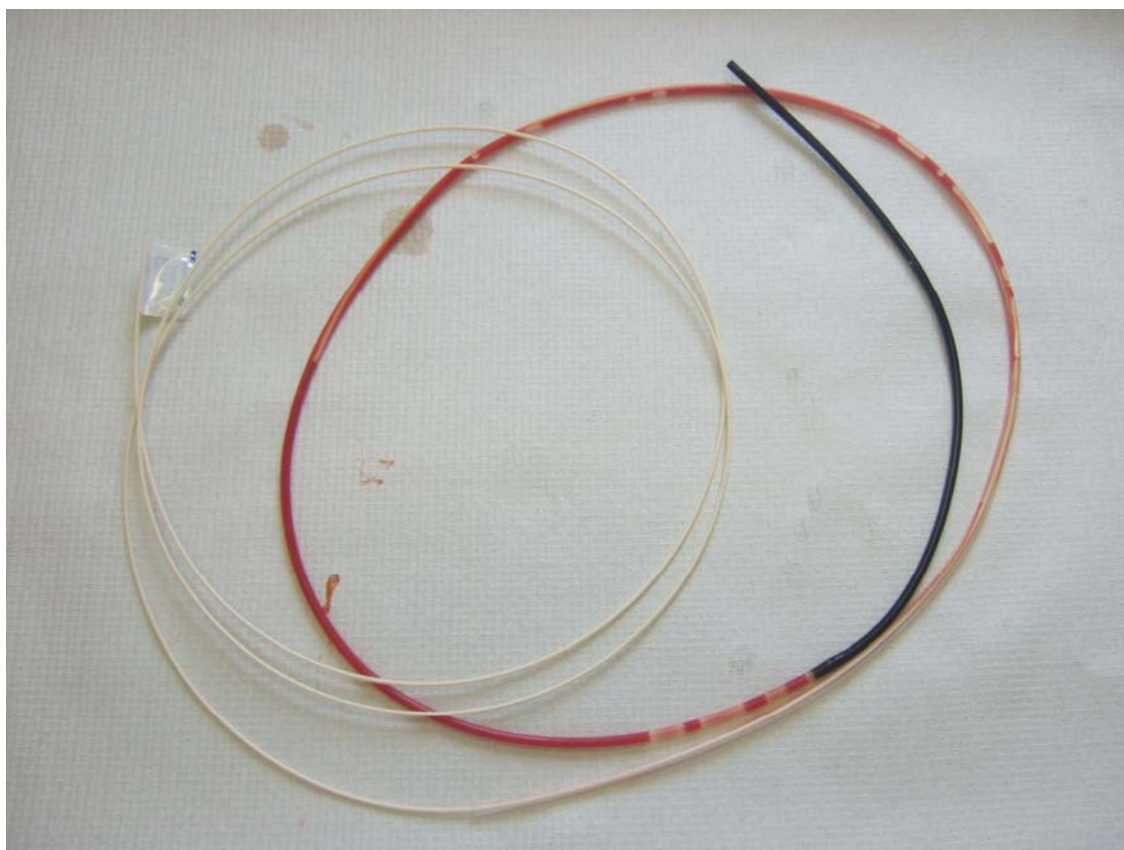


Figure 7 One pass of cleaning brush

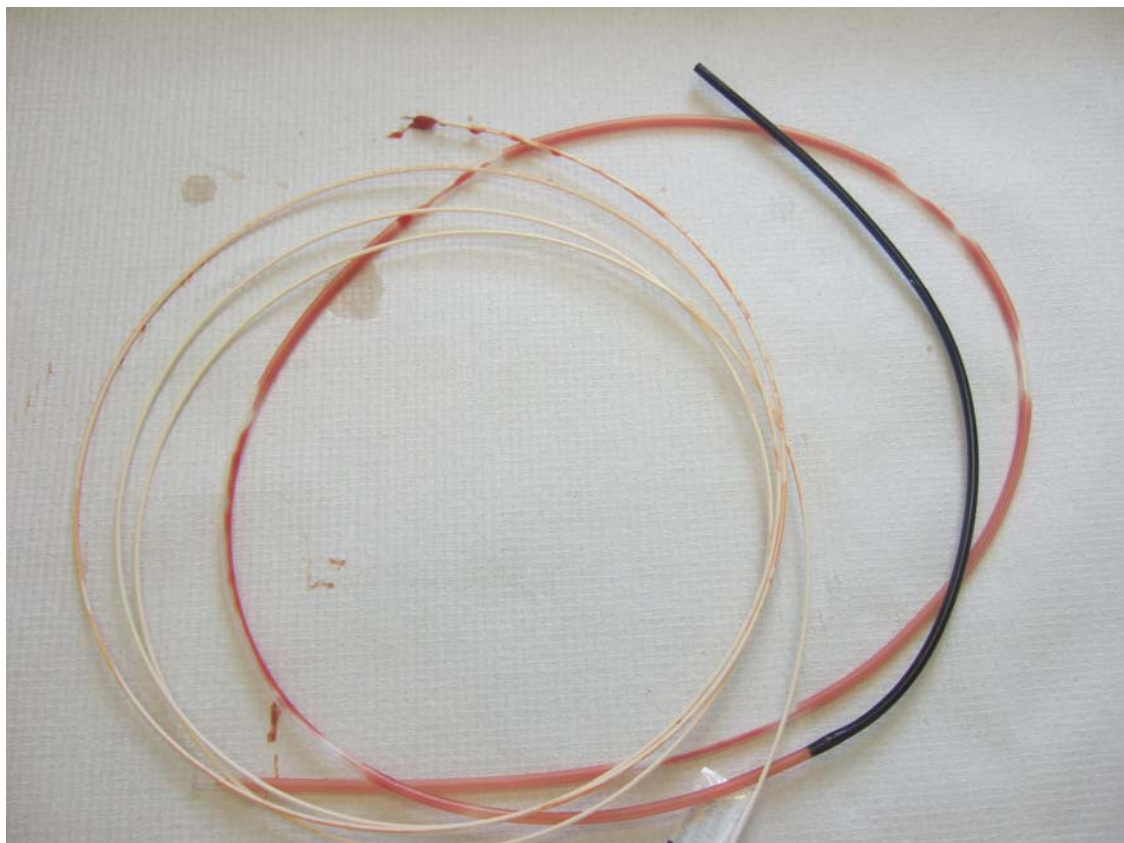


Figure 8 2 passes of cleaning brush



CONCLUSION

Manual cleaning of all endoscope channels is recommended prior to processing in an automated endoscope reprocesor. Single use devices are recommended. The Instrusponge is a detergent impregnated sponge designed to clean accessible channels as an alternative to a brush. This study was designed to compare the efficacy of the Instrusponge compared with a brush.

The method of cleaning using the endozime intrusponge was modified slightly from that described by the manufacturer in that no scrubbing action was used during insertion into the surrogate device. This was in order to reduce any bias caused by more or less energetic action. The same method was employed while using the single use brushes, again to standardise the test.

It was observed that the Endozime Intrusponge required less passes through the surrogate devices to achieve the end point of the test, with both Edinburgh and Respiratory soil, than the single use brush. After cleaning with the endozime intrusponge, visible soil was observed after cleaning in 4 out of 10 tests with Edinburgh soil, but none of the respiratory soil tests. However visible soil was observed after cleaning in all tests with the single use brushes.

These tests were designed to demonstrate the efficacy of cleaning and not an endorsement of compatability of the cleaning devices with the endoscopes.

Testing by the Hospital Infection ResearchLaboratory does not imply approval or endorsement.

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EA Traynor
Biomedical Scientist

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CR Bradley
Laboratory Manager

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Dr AP Fraise
Director