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FOR ENDOSCOPY

THE HISTORY OF THE WATER BOTTLE



1980s

Bottles were filled with tap water. Post list care was a quick rinse and left to dry over taps!



2000s:

The birth of the daily disposable water bottle top which is used directly on sterile water bottles.



2018:

Filter the air going into the bottle to pressurise it. The Pure offers safe water all day!

1990s:

Sterile water used to fill bottles. Reusable bottles had to be reprocessed to manufacturers guidance and sent to sterile service each night.



2017:

BSG recommend that any bottles should be changed after 3 hours to come in line with use of an endoscope.





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REUSABLE WATER BOTTLES

Water bottles have always been used in endoscopy to allow irrigation during procedures. They were used on a daily basis and then sent to be autoclaved at the end of the day.

If you read Olympus recommendations on how to clean they should be fully dismantled into seven separate pieces, washed and fully dried prior to being autoclaved.

Many CSSD department have been reluctant to do so (and even refused to process) as they are so hard to reprocess, as they contain a lumen within a lumen. This is extremely difficult to dry and does not allow the correct temperature to be reached and cannot guarantee that the steam makes contact within the lumens, potentially allowing microorganisms to proliferate into biofilms.

Other issues users faced with the reusable bottles were the expense, becoming brittle after multiple reprocesses, hair line cracks which again made it impossible to guarantee HLD. Slow turnaround times meant more stock and a wait to start the list in the morning.



THE CASE FOR THE DAILY DISPOSABLE

In 2005 a report was published showing that 92% of bottles tested, that despite HLD of various methods, that reusable water bottles were contaminated with a multitude of organisms (See attached). At that point a disposable range of water bottles was launched to remove the difficulty of reprocessing bottles and the risks associated with reusing potentially contaminated bottles. There are several bottles caps now on the market all connecting to a bottle of sterile water and are thrown away at the end of the day/ list.

The real issue though, whether using reusable or disposable bottles, is how did they get contaminated in the first place?



HOW DOES CONTAMINANT ENTER THE BOTTLE?

The water bottle is pressurised by air from the processor to the force water down the endoscope during the procedure. This air is drawn into the processor direct from the room with no method of filtration, so environmental contamination is unavoidable from the very first second air is drawn into sterile water bottle. It can even occur before the first patient procedure just by the initial pre check of the scope.

By the very nature of the procedures being performed close to the processors means the potential of contamination is high. No other system, whether it be a washer disinfector or drying cabinet where 'scopes are cleaned / stored, use unfiltered air for this very reason.

In addition to this, the bottles sit next to the warm processor for the whole list encouraging bacterial growth as the day / list goes on. The water quality throughout the list subsequently deteriorates.



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THE CASE FOR 3-HOUR CHANGING

Recently the BSG advised that water bottles whether reusable or disposable should be changed after 3 hours. (See attached Section 4.3.7) This brings the use of the bottle in line with an endoscope which you are not allowed to be used 3 hours post-disinfection. This is due to the risk of re growth of microorganisms following reprocessing. The scope is normally stored in a covered tray protected from the environment, this is obviously not the case with the bottles.

BSG guideline '4.7.3 Accessories' (2016 revision) -

“Water bottles should be changed after each endoscopy session i.e. 3 hours. They should be detached, emptied and cleaned as per manufacturers’ instructions, and then sent for steam sterilisation (refer to manufacturer’s instructions for use). They should be filled with fresh sterile water immediately prior to use. The sterilisation of the water bottles and the sterile water used should be tracked for purposes of traceability. Single use water bottles and connectors are available but there is no strong evidence to support their use over a reusable system.”

IPS Care setting improvement tool

Question set: Decontamination- accessories

7. – *If disposable water bottles are used, are you changing them at the end of each session?*

With this in mind we decided to test normal disposable bottles after use and found that they too were contaminated. We found fungal and faecal species (see attached report).



THE PURE RANGE

We have now launched our *PURE range* and inserted a filter into the top of all our bottle caps to protect the water from such contamination. We have done this, for all our types of irrigation tubing, whether it be the small water bottles or the large irrigation systems used alongside the endoscope.

We then repeated the testing using our *PURE range* and found that the water quality was maintained throughout the whole of the list. This means every patient gets high quality water and critically, the cap can be used all day, no need to change every 3 hours which means cost savings too.



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REPORT ON CONTAMINATED
WATER BOTTLES
(using disposable caps)

Introduction

Aims

Methodology

Outcome

Results

Conclusion

In association with  medipure™

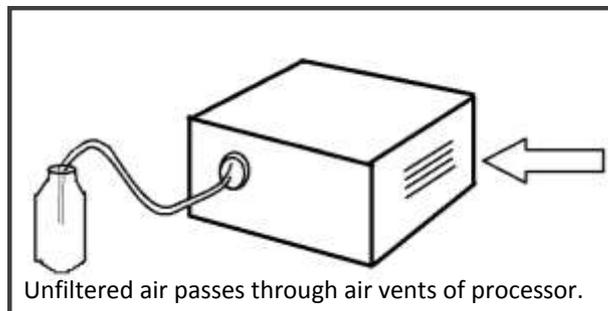


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INTRODUCTION

Sterile water is used in endoscopy procedures to flush seemingly contamination-free water through the endoscope to the patient. However, room air being drawn through the processor in order to pressurise the water bottle allows the water to come into contact with environmental contamination. So, from the very first patient the water quality is compromised. Following research into superior methods of improving water sterility, we developed our product 'The Pure'. This product is designed to filter any potential contamination between procedures through its filter, thus preventing the possibility of infection.



This report was written in response to BSG guideline '4.7.3 Accessories' (2016 revision) -

“Water bottles should be changed after each endoscopy session i.e. 3 hours. They should be detached, emptied and cleaned as per manufacturers’ instructions, and then sent for steam sterilisation (refer to manufacturer’s instructions for use). They should be filled with fresh sterile water immediately prior to use. The sterilisation of the water bottles and the sterile water used should be tracked for purposes of traceability. Single use water bottles and connectors are available but there is no strong evidence to support their use over a reusable system.”

Following the above guidelines and suspected discrepancies of disposable caps, we at Partners for Endoscopy commissioned a series of tests on water bottles using disposable caps. Medipure is an accredited biotechnology company that we selected to conduct the tests, as they provide high quality laboratory testing services to organisations involved in Infection Control & Prevention such as ourselves.

AIMS

The primary aim of this series of tests is to determine the quality of water within a sterile water bottle using a disposable water bottle top versus a filtered top (The Pure) used during an endoscopy list. Should the water quality in the filtered cap be as high as when first used, our aim is to prove that our bottles are a superior alternative, requiring less changing as initially suggested by 2016 BSG guidelines.

The secondary aim is to determine what species, if any, are located in the water bottles. This aim allows us to find detailed information regarding potential contamination of endoscopy patients.



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METHODOLOGY

PFE sales representatives contacted local endoscopy units in the various areas covered, to request permission to take water samples for testing. The team gathered a total of 6 disposable cap water bottles at the end of a patient list and gathered 6 bottles of The Pure used for two patient lists. Samples were secured and sent within 24 hours to Medipure for testing.

Medipure laboratories stored all samples at 30°C, measuring TVC (total viable count) performed on the water in the bottles after 48 hours. Medipure Work instruction 020 was used for this test—gaining UKAS recognition. 100 mls water filtered through a sterile 0.45-micron filter, with said filter placed on a Tryptone soya agar plate. Sample was then incubated for 5 days at 30 C in line with HTM0106.

OUTCOME

Two out of six bottles tested positive for *geotrichum sp.* Results are available to view below. *Geotrichum sp.* is associated with contamination from faeces and sputum, which demonstrates that bottles using disposable caps cannot guarantee sterility following first use. Two breeds of *geotrichum sp.* were present in the water samples: cream circular entire moist colony, and a white filamentous spreading colony.

When testing our Pure bottles, Medipure found no traces of microorganisms which is evidence that our filtered caps offer sterility from the first to the last patient on a list. This highlights that it is not necessary to replace the caps/bottles as often as BSG guidelines suggest, should the most effective filter cap be used.

Our aims were met in this test, and the outcome proved that our product is an effective product, ultimately countering claims made in the BSG report that water bottles require replacement every three hours.

This is indicative that our product is far superior than water bottles with disposable caps.



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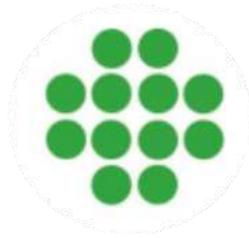
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COMPETITOR CAPS - RESULTS

Sample Number	Sample Name	T.V.S 48 hrs @ 30C (CFU/100ml) Limit <10	T.V.C 5 days @ 30C (CFU/100ml) Limit <10
3914	1	0	0
3915	2	0	0
3916	3	0	0
3917	4	0	0
3918	5	2	2
3919	6	3	3

THE PURE - RESULTS

Sample Number	Sample Name	T.V.S 48 hrs @ 30C (CFU/100ml) Limit <10	T.V.C 5 days @ 30C (CFU/100ml) Limit <10
4757	1	0	0
4848	1	0	0
5429	30/10	0	0
5430	30/10	0	0
5431	31/10/0	0	0
5432	31/10	0	0



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Water tests

HTM 01-06

This report may contain confidential or privileged information.
It should not be disclosed without consultation with Medipure or the main recipient

Report recipient(s): Partners For Endoscopy

Hospital	Bottle Test	Department	
Model	Medivators	Identity	
Time received	11:00	Test Engineer	PFE
Collected	Various	Received	06/08/18
Tested	06/08/18	Reported	13/08/18

In the event of a query please quote **Report number: R0812 Pt2**

Sample Number	Sample Name	T.V.C 48 hrs @ 30°C (CFU/100ml) Limit <10	T.V.C 5 days @ 30°C (CFU/100ml) Limit <10
3914	1 30/07/18	0	0
3915	2 25/07/18	0	0
3916	3 28/07/18	0	0
3917	4 31/07/18	0	0
3918	5 31/07/18	2	2
3919	6 No date	3	3

Comments:-

Culture from 3918 :- Cream Circular entire moist colony Gram -ve Cocci
Culture from 3919 :- White filamentous spreading colony Mould sp

Details	Sign Off	Name	Signature
TVCs	Author	Ian Clyde	<i>I. C</i>
Version 2	Checked	Gordon Karling	<i>G.K</i>



Water tests

HTM 01-06

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Report recipient(s): Partners For Endoscopy

Hospital	Bottle Test	Department	
Model		Identity	
Time received	11:00	Test Engineer	PFE
Collected	21/09/18	Received	22/09/18
Tested	22/09/18	Reported	26/09/18

In the event of a query please quote **Report number: R0996 Pt2**

Sample Number	Sample Name	T.V.C 48 hrs @ 30°C (CFU/100ml) Limit <10	T.V.C 5 days @ 30°C (CFU/100ml) Limit <10
4757	1	0	0

Comments:-

Details	Sign Off	Name	Signature
TVCs	Author	Ian Clyde	<i>I. C</i>
Version 2	Checked	Gordon Karling	<i>G.K</i>

Water tests

HTM 01-06

This report may contain confidential or privileged information.
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Report recipient(s): Partners For Endoscopy

Hospital	Alexandra Redditch	Department	Bottle Test
Model		Identity	
Time received	11:00	Test Engineer	Sohail Shami
Collected	30 + 31/10/18	Received	01/11/18
Tested	01/11/18	Reported	06/11/18

In the event of a query please quote **Report number: R1145 Pt2**

Sample Number	Sample Name	T.V.C 48 hrs @ 30°C (CFU/100ml) Limit <10	T.V.C 5 days @ 30°C (CFU/100ml) Limit <10
5429	30/10	0	0
5430	"	0	0
5431	31/10	0	0
5432	"	0	0

Comments:-

Details	Sign Off	Name	Signature
TVCs	Author	Ian Clyde	<i>I. C</i>
Version 2	Checked	Gordon Karling	<i>G.K</i>