New solutions for Instrument's Sterilization

VES Annual meeting May 2018 Lisbon

Antoine Adam

Endoscopy and laparoscopy for 12 years

Vetmidi : Vetclinics in Switzerland

Swissvetgroup : Vet Group in Switzerland

I do prefer surgery rather than bacteriology

But I had the chance to discover this machine few month ago

I saw immediatly what are the benefits for me everyday

So I'm gonna talk about bacteriology

And at the end of this presentation I'll show quickly few videos because I prefer laparoscopy

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We always wanted solutions like

Re-sterilization of a ligasure ?

Re-sterilization of a surgisleeve ?

Re-sterilization of a stone basket

Sterilization of a flexible scope ?

Increase life time of the scope

Affordable and available for vet clinics

Yes we can !

On March 9, 2018, the FDA issued Warning Letters to all three manufacturers (Fujifilm Medical Systems USA, Inc, Olympus Medical Systems Corporation, Pentax of America), who make duodenoscopes sold in the U.S. for failure to provide sufficient data to address the postmarket surveillance studies requirements under

On February 26, 2018, the FDA, Centers for Disease Control and Prevention (CDC), American Society for Microbiology (ASM) together with other endoscope culturing experts released voluntary standardized protocols for duodenoscope surveillance sampling and culturing.

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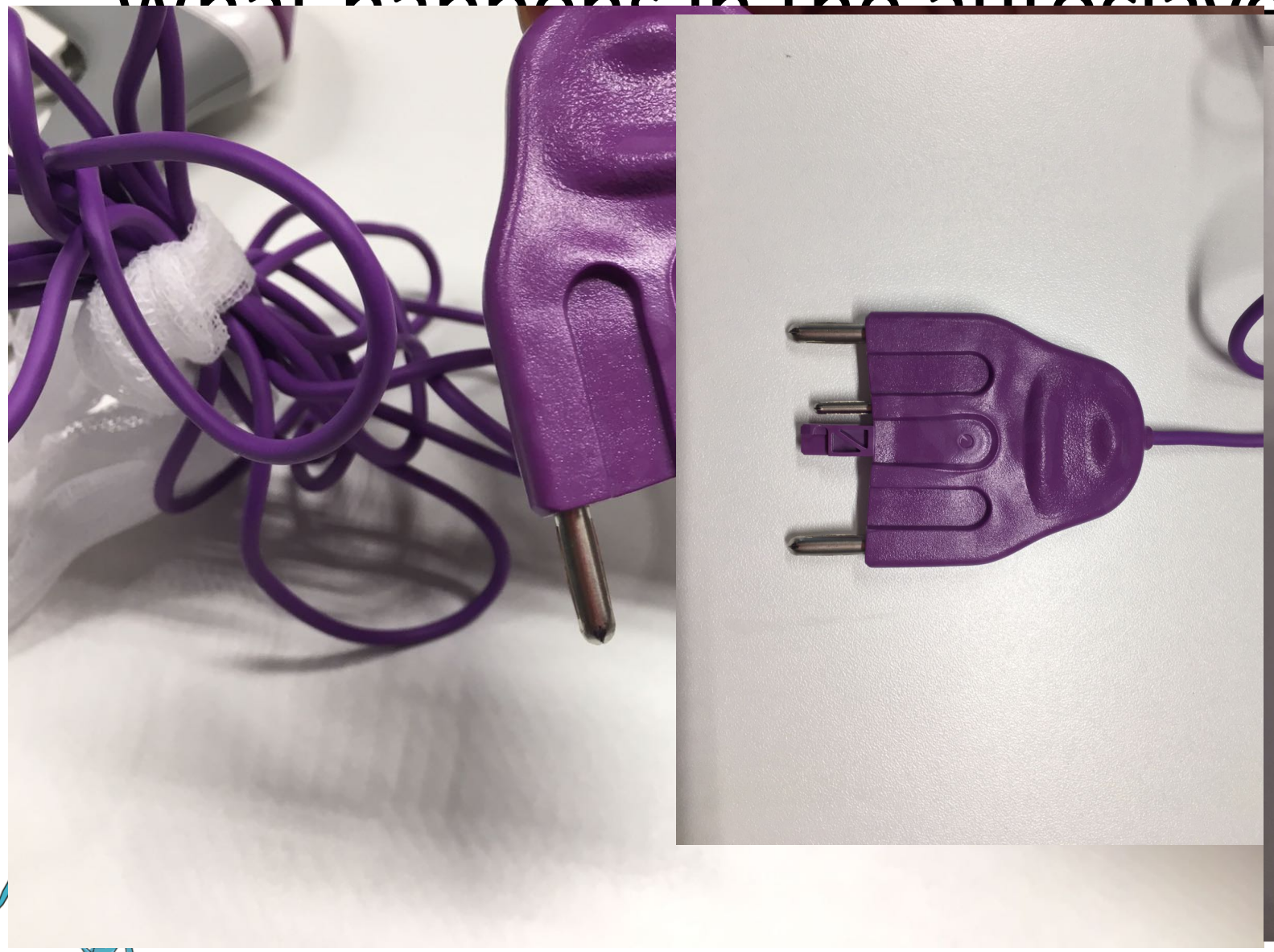
What happens in the autoclave ?



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Ozone

Ozone /ˈoʊzoʊn/, or **trioxygen**, is an inorganic molecule with the chemical formula $\mathbf{O_3}$.

L'**ozone** (de l'allemand *ozon*, dérivé du grec *ozô* « exhaler une odeur » smelling)

Ozone's O_3 structure was determined in 1865.

Ozone is a unique antimicrobial agent. In fact, it is the most aggressive oxidating antimicrobial agent known to man

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Ozone

OZONE LEVELS AND THEIR EFFECT

0.001 ppm

Lowest value detectable by hypersensitive humans. Too low to measure accurately with elaborate electronic equipment.

0.003 ppm

Threshold of odor perception in laboratory environment, 50 per cent confidence level.

0.003 ppm to 0.010 ppm

The threshold of odor perception by the average person in clean air. Readily detectable by most normal persons.

0.020 ppm

Threshold of odor perception in laboratory environment, 90 per cent confidence level.

0.001 to 0.125 ppm

Typical ozone concentrations found in the natural atmosphere. These levels of concentration vary with altitude, atmospheric conditions and locale.

0.100 ppm

The maximum allowable ozone concentration in industrial working areas: permissible human exposure - 8 hours per day, 6 days a week.

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Instrument Sterilization

I have a test machine for 3 months

Not heating at all.

No chemicals product (finish the f….g ETO)

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Instrument Sterilization

Principal of the machine : Ozone creation inside a closed box

High level of Ozone concentration + Humidity

Continuous measurement of the ozone level inside the box

Destruction of the Ozone at the end

Identification of the box, set and user

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Instrument Sterilization

This machine is finishing the process for human sterilization CE approaval

Tested with *Geobacillus stearothermophilus* one of the most heat-resistant spores of aerobic microorganisms

Log reduction 12 !!!

Log 12 means : 99.999999999999 % of destruction of the microorganisme

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Instrument Sterilization

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COVIDIEN

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900-2986


E5E2-098


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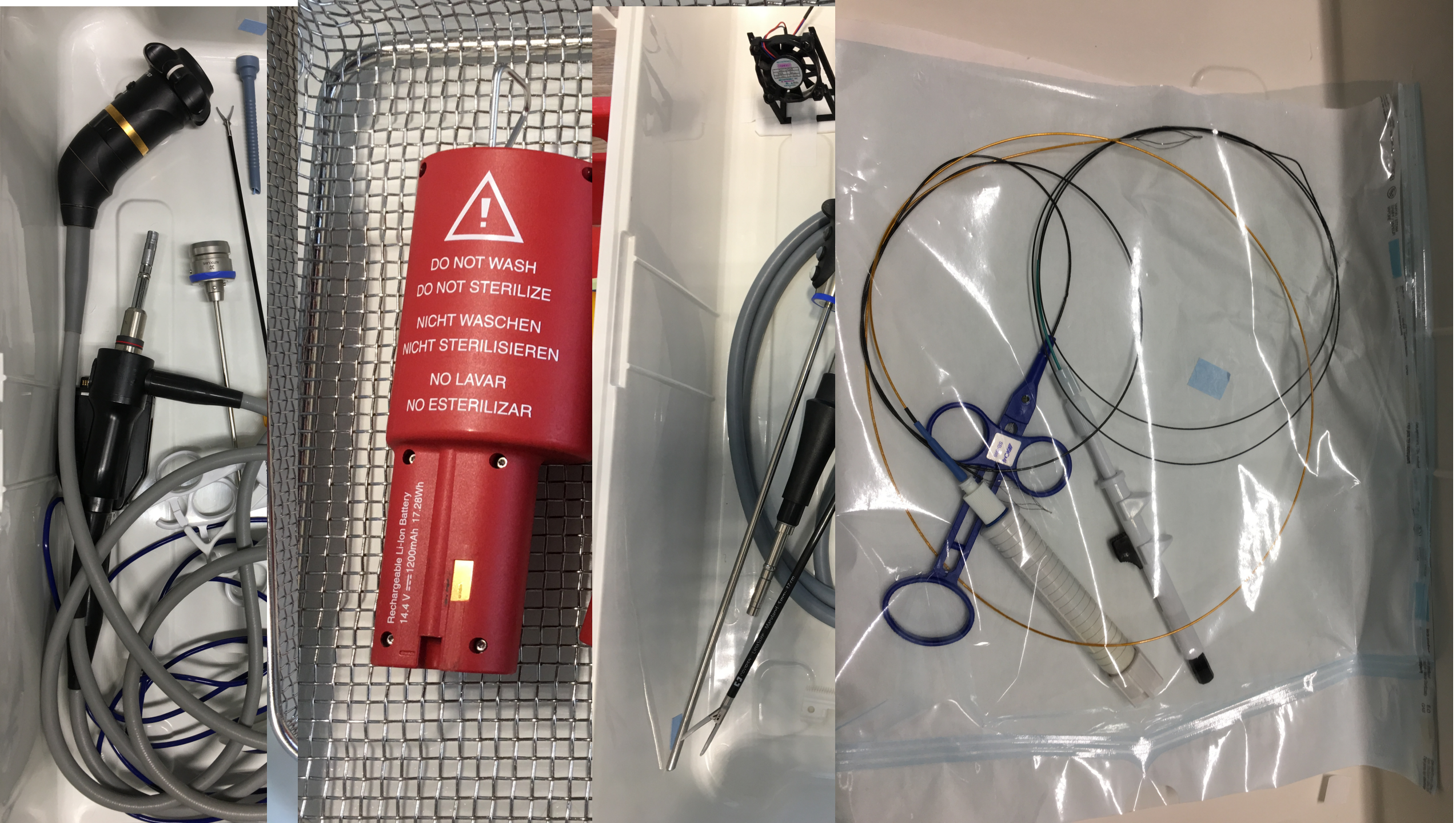
DO NOT WASH
DO NOT STERILIZE
NICHT WASCHEN
NICHT STERILISIEREN
NO LAVAR
NO ESTERILIZAR
Rechargeable Li-Ion Battery
14.4 V ⎓ 1200mAh 17.28Wh

Cycle 3:

For this test, I made 3 lines on a TSA plate with each cotton swab (3A and 3B). Figure 4 shows the results of this plating. Three distinctive lines formed of CFUs obtained from cotton swab 3A can be observed, whereas no CFUs are present on the lines from 3B. This clearly shows that there is a high reduction of bacteria that occurred during the sterilization process. It is not possible to make a quantitative analysis on the exact log reduction, but qualitatively it can be said that the sterilization cycle was effective.

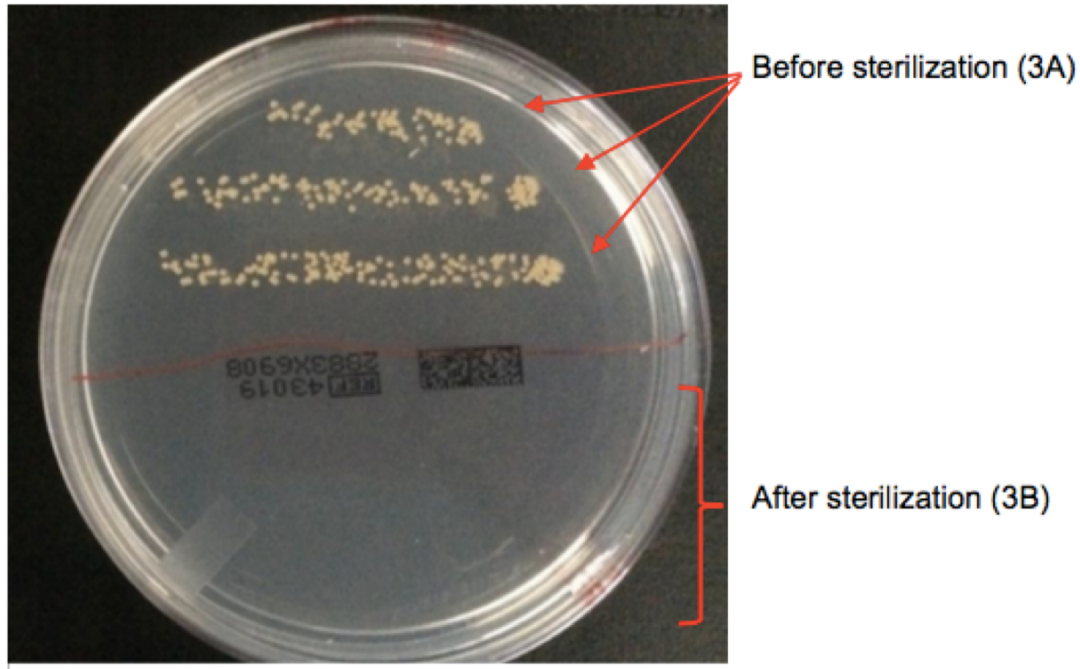

Figure 4 Made three lines with cotton swabs 3A (Top) and 3B (Bottom).

The plating of the solution of 3A can be seen in Figure 5; many CFU are visible showing that after the cleaning step there remained a lot of bacteria on the tool. However, I did not perform a similar plating for the sample after the sterilization process as I wanted to test the bioMérieux tube. It would be interesting if the bacteria could also grow in these tubes as they can show the presence of a single bacteria.

There were no CFU on the first plate (sample taken directly after the cleaning), but there were many CFU on the second plate (in the order of 100). It is possible that several bacteria (not enough to find them on the first plate) survived the cleaning and were able to proliferate during the 12 hours before the sterilization process was started. Moreover, the tool was stored openly (i.e. not inside a closed box) and it could have been contaminated with bacteria during this time. Additionally, it was handled without gloves and this could also have increased the contamination. After the sterilization no bacteria could be found again.

Endoscope flexible - Exterior

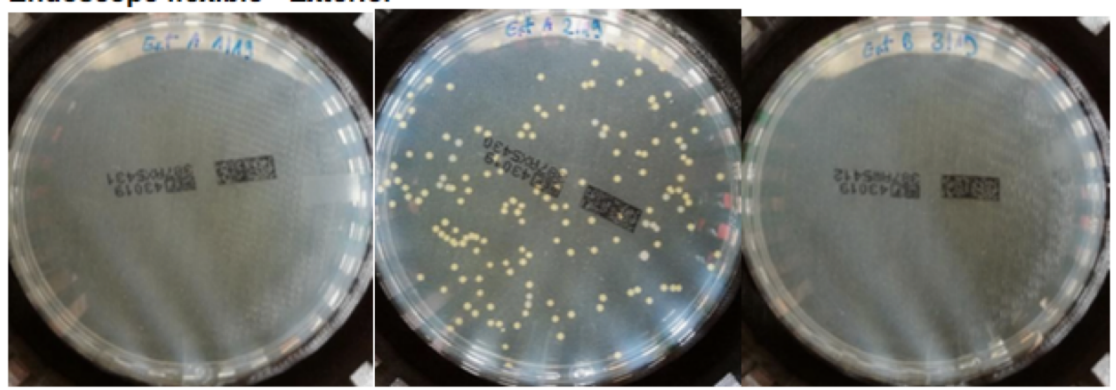

Figure 22 Plated 0.5ml of a 2ml solution in which the cotton swab of the endoscope exterior samples were put. On the left is the first sample that was taken directly after the cleaning. In the middle is the sample that was taken 12 hours after the cleaning and on the right the one after the sterilization.

The same results were observed as for the channel samples.
Note: The plate A 2 | 19 (Figure 22 middle) seems to have two different kinds of CFU. Most colonies are yellowish, but some are more white. This could mean that there were two types of bacteria on the device or that the white colonies are contaminations as there are no such colonies on the middle plate seen in Figure 21. Note: It is more probable to have had contaminations on the exterior than in the interior of the endoscope. Thus there could have been proliferation of bacteria and contaminations.

It is rather weird that there were no or nearly no bacteria on this endoscope and inside the channel. The results of previous endoscopes always showed very high numbers of bacteria. It is possible that the cleaning was this time more effective and that we therefore found no colonies on the first plate (no biofilms present). Another rather improbable possibility would be that the samples were taken in a way that no or nearly no bacteria were recovered.
It could also have been that the bacteria did not survive the time between the sample taking and the plating, but as the samples of cycle 17 showed growth of bacteria and were taken even earlier and plated at the same time, this should not have been a problem.

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Wound protector

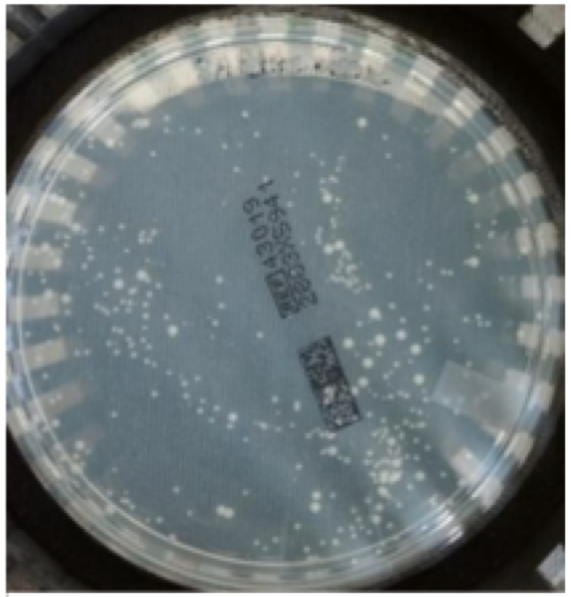

Figure 15 Plated 0.5ml of a 3ml solution in which the cotton swab of 8A from the wound protector was placed (before sterilization).

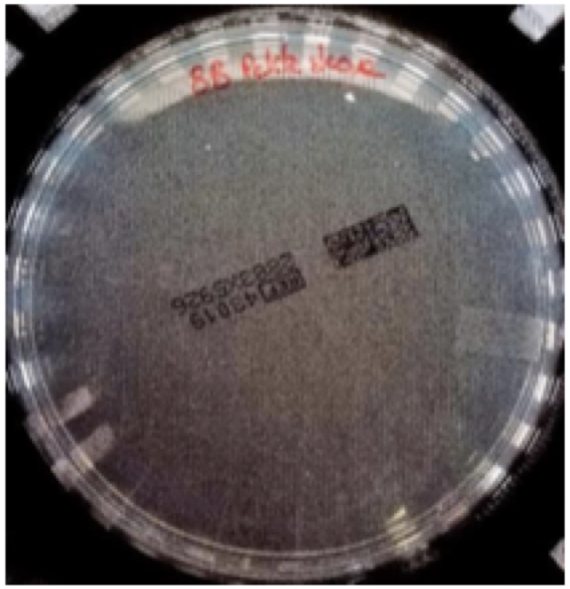

Figure 14 Plated 0.5ml of a 3ml solution in which the cotton swab of 8B from the wound protector was placed (after sterilization).

Contrary to the bistoury, we found many colonies on the sample from the wound protector before the sterilization (see Figure 15). After the sterilization no colonies were detected (see Figure 14).

Cycle 28

Electronic bistouries

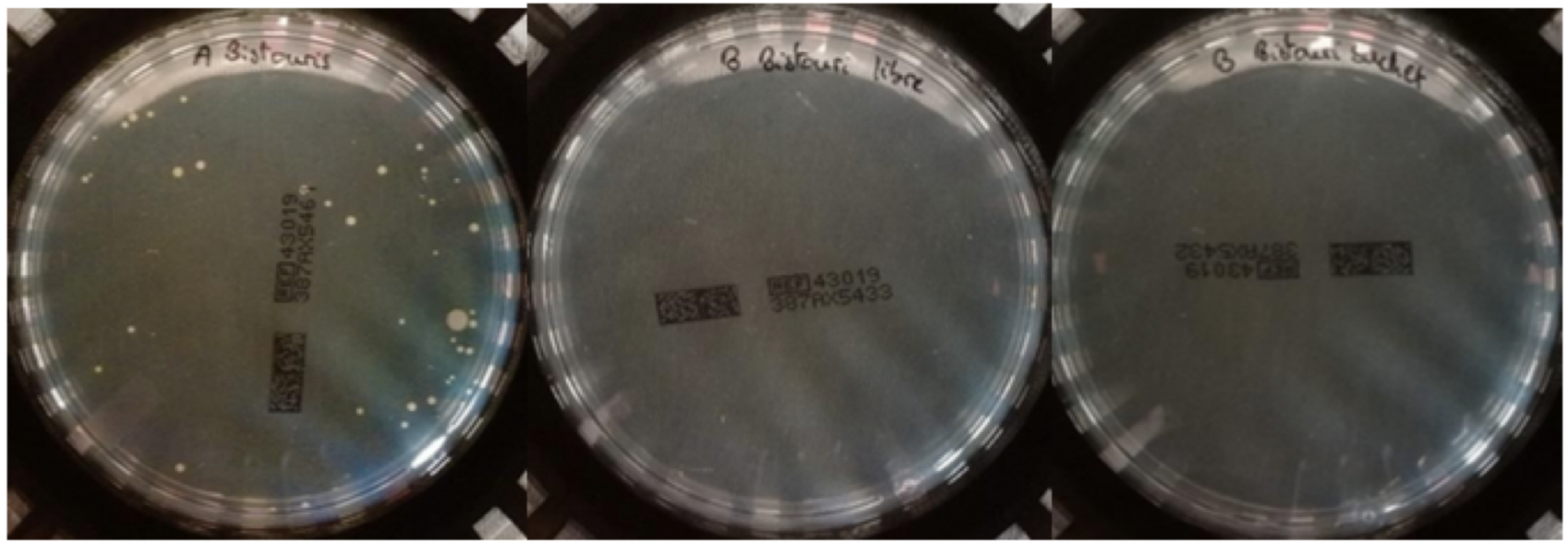

Figure 32 Plated 0.5ml of the 2ml solutions in which the cotton swabs of the Bistouries samples were put. On the left is the sample from both bistouries together before sterilization. In the middle is the Bistoury sample after sterilization of the one that was laid on the bottom of the SteriBox. And on the right we have the B sample of the Bistoury that was put inside a sterilization pouch.

There were 50 CFU on the A plate and it seemed to be at least 3 different kinds of bacteria. No CFU were found on the B plates, not even on the one from inside the sterilization pouch. This indicates that there was at least 1 log reduction of bacteria with this low ozone dose.

It is more than likely that the bacteria such as pseudomonas, E. coli, etc, die much faster than the Geobacillus spores. It is therefore possible to have higher log reductions for much less high ozone doses.

Shaver and Blade

We were given only the A sample of the Shaver. Around 400 CFU were found on this plate. Meaning that there were around 1200 CFU on the cotton swab that we were given.

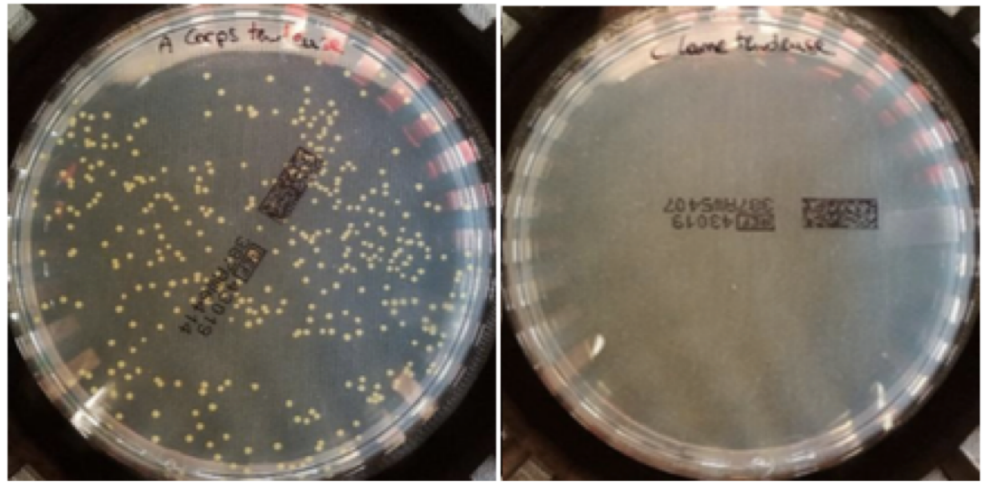

Figure 27 Plated 0.5ml of 2ml solutions in which the cotton swabs of the shaver blade samples were put. On the left is the sample before sterilization, in the middle is the sample after cycle 23 and on the right the one after cycle 24.

On the A plate of the shaver blade were around 40 CFU (10 times less than for the Shaver itself). No colonies were found on the B and C plates, meaning the low dose of the cycle 23 was sufficient to kill all the CFU.

Instrument Sterilization : comments

We had no oxydation or problem with scopes, electronic component, etc …

Side effects of Ozone can be
Coloration of the plastic
Glue effect for some plastic, it is transitory effect

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Endoscope flexible (Broncho) - Channel

Figure 11 Plated 0.6ml solution in which the cc 7A was placed.

Endoscope flexible - Exterior

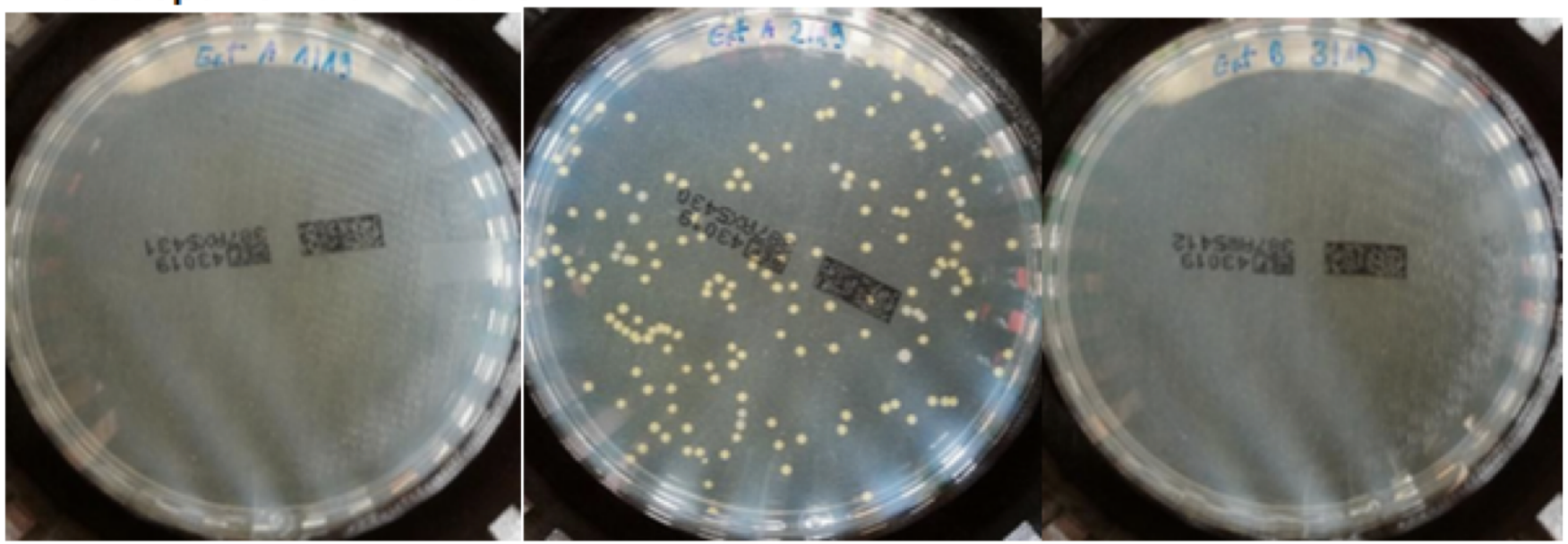

Figure 22 Plated 0.5ml of a 2ml solution in which the cotton swab of the endoscope exterior samples were put. On the left is the first sample that was taken directly after the cleaning. In the middle is the sample that was taken 12 hours after the cleaning and on the right the one after the sterilization.

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Instrument Sterilization : future

This machine will be available soon, maybe next year

The micro-organisme we have in the clinic are much more sensitive than geophilus stearothermophilus
We are still doing tests for vets about Staph, E Coli, Pseudomonas, etc …
Relation between bacterial charge and time for sterilization

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