Good afternoon, and many thanks to all involved in the running of this symposium, for giving me the opportunity to present to you today.

My name is Edward Palmer and I am the international Sales Director for Medisafe UK Ltd. I have worked for Medisafe for over 5 years, and during this time have been fortunate to visit in excess of 40 countries in the world and gain an over view as to how surgical devices are being reprocessed.

Ultrasonic cleaning of today's instruments…and tomorrow's!

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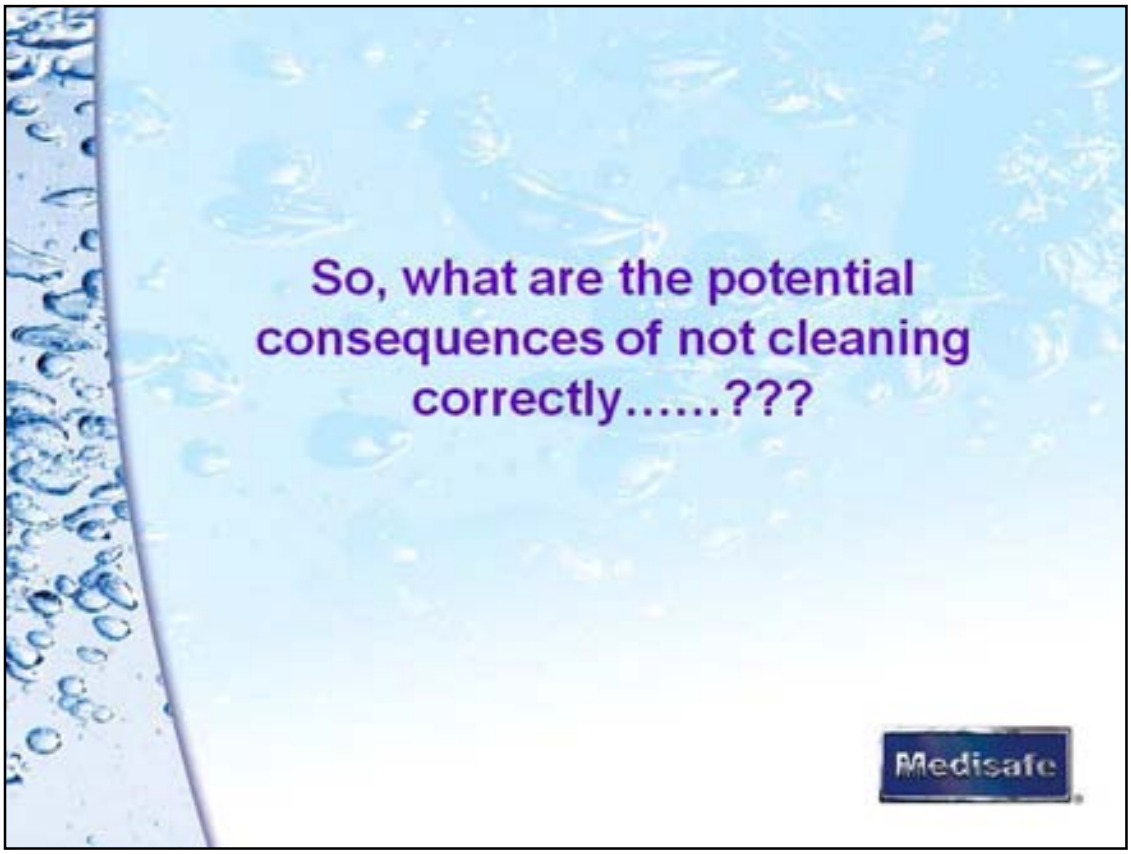
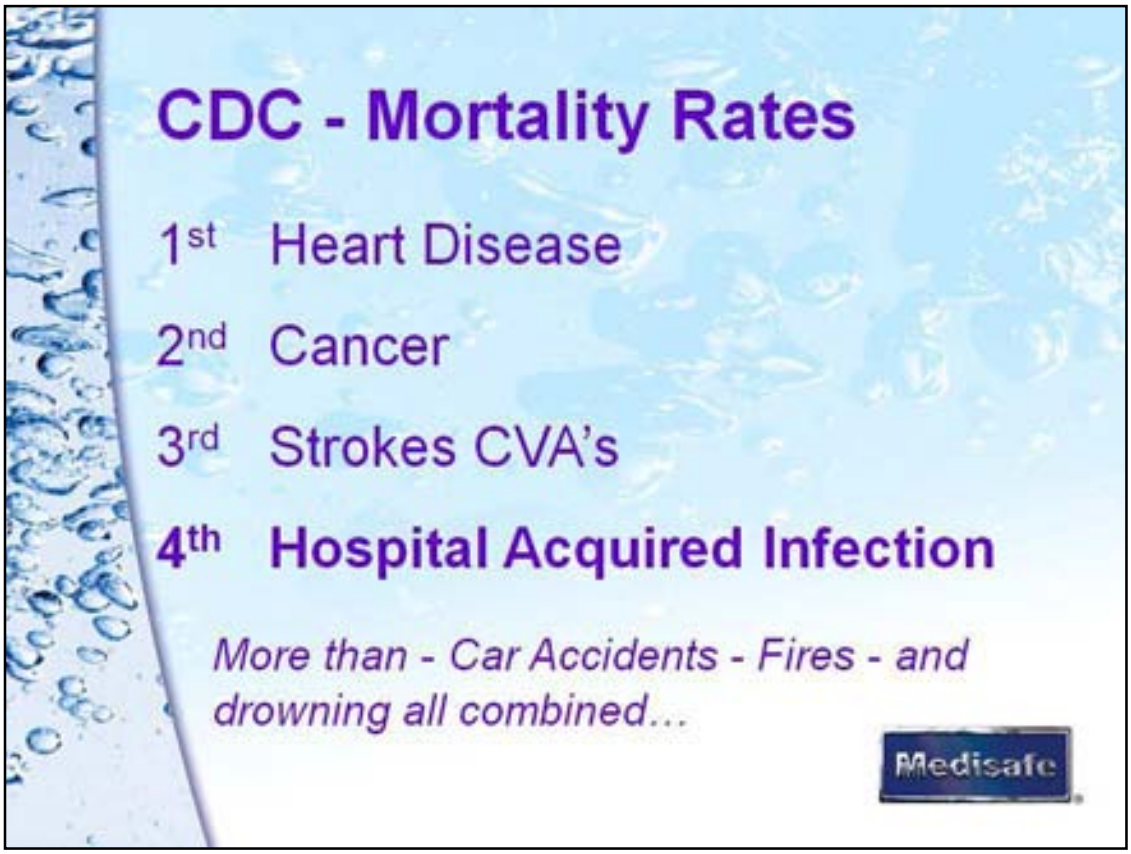
I'd like to highlight to you during this presentation today, an outline of some of the problems faced with the growing complexity, in the design of surgical devices, and how ultrasonics, paired with the correct technology, can provide a solution.

I'd like to give some back ground on the problems faced, the potential consequences and the testing that has been carried out, in order that we may find a solution.



So, what are the consequences of not cleaning correctly ??



The following figures produced by the Centre for disease control (CDC) illustrates the potential threat caused by re-introducing inappropriately reprocessed instruments.

The information, although based on the U.S.A., is transferable in the same way to the rest of the world.

Deaths linked to hospital germs represent the fourth leading cause of mortality, - behind heart disease, - cancer and - strokes,… -

And - according to the CDC, these infections kill more people each year than car accidents, fires and drowning combined.

This information is NOT widely known by “the public”


What are the types of "specialist" applications we are having to deal with?
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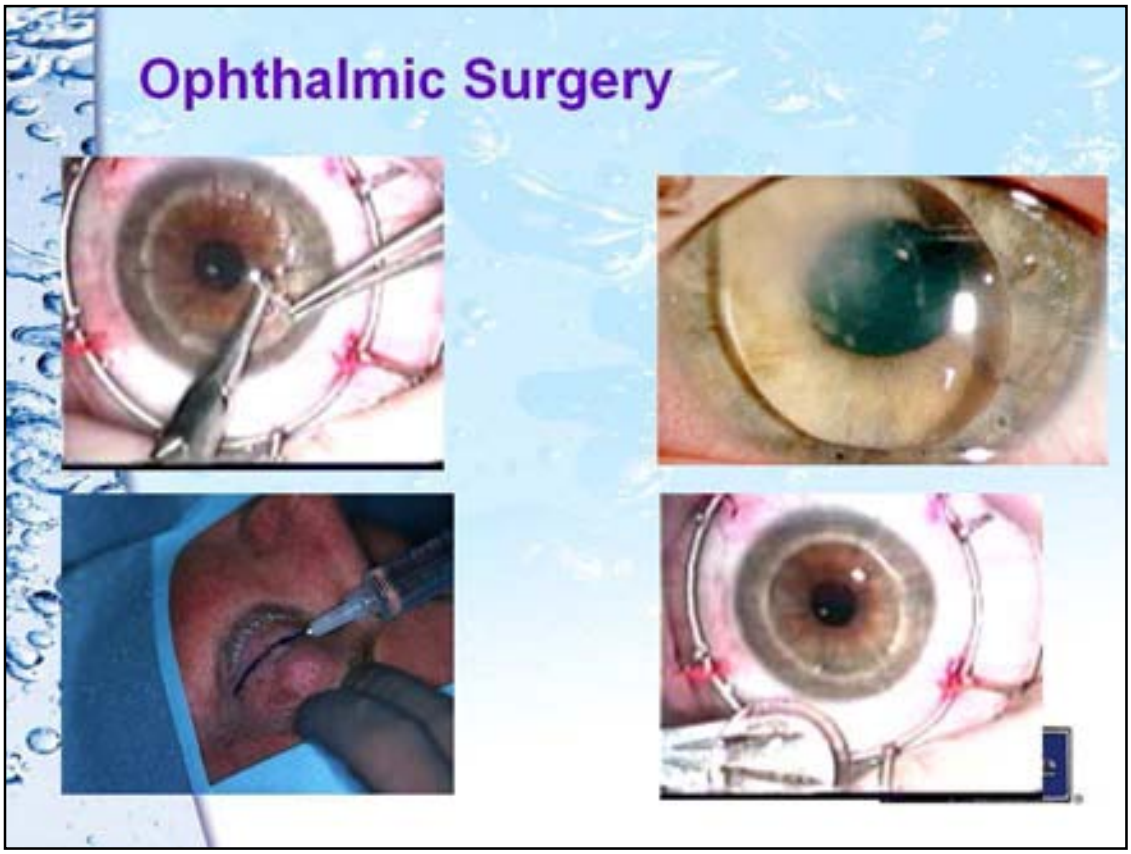
The following slides are to give a reminder to the types of instrumentation we are increasingly being faced with, and gives an outline as to how the complexity of these devices is evolving.

Although primarily the benefit of this type of instrument development has been to help minimise the potential threat of an infection caused by a major cavity exposure, we should consider the impact of delivering the same bacteria via the medium of incorrectly reprocessed instrumentation !!



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Certainly it is clear that the complexity of these types of instrumentation is increasing and the number of procedures is growing in popularity, so it's fair to assume the potential risk for cross contamination, could also be increasing ??

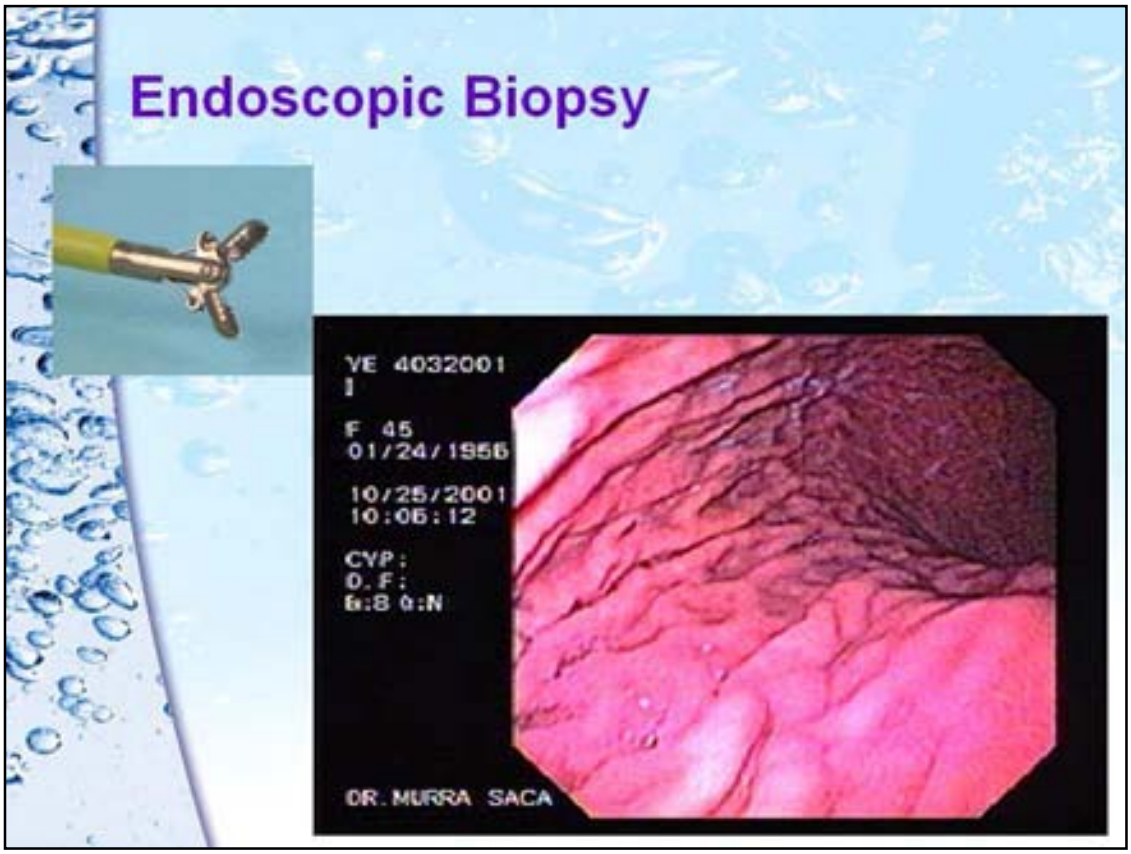
So, how do we address this ??

We have to evolve the cleaning systems also !!

In short, if we have specialist instrumentation for specialist procedures, isn't reasonable to assume, that we require SPECIALIST equipment to reprocess these instruments ??

An example of where existing cleaning technology, can fall short, is illustrated when it comes to reprocessing an item such as a 1.25m long , sphictertones..with 3 lumens and internal diametres as small as 0.3mm.

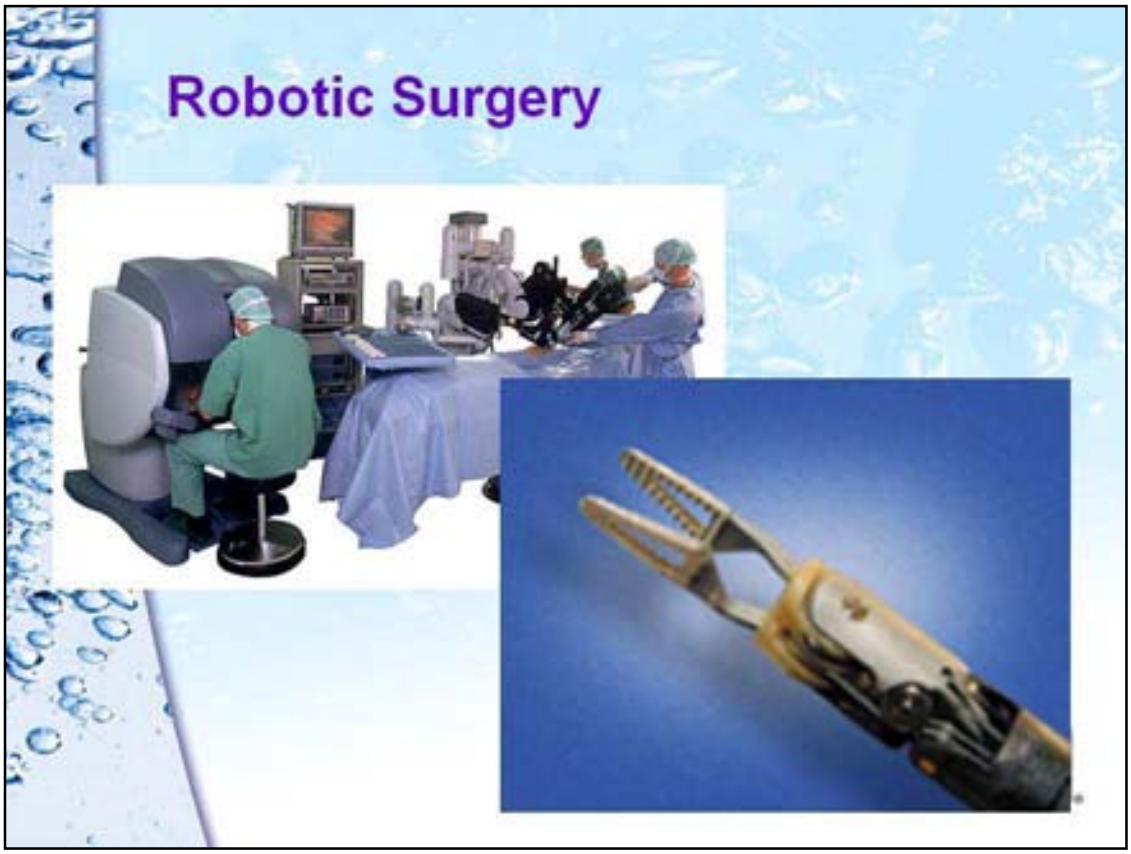
Can we seriously expect the same type of technology that is designed for reprocessing forceps and scalpels to be used for cleaning this type of complex instrumentation ??



In the UK, we have seen further examples of the confusion that can occur when instruments have not been reprocessed successfully and patients have undergone surgical procedures because of a positive tissue result that has occurred…… due to contamination of the instrument from a previous patient !!!

I'm certain that the UK is not unique in this respect, as we are all pretty much using the same equipment…and all have similar difficulties in reprocessing these types of device

There are of course disposable options available, but the cost can be prohibitive. I have also seen circumstances in some countries where these single use items, are being reprocessed. It might surprise you if I told you….I saw this exact same thing in Japan….only a short time ago !!!



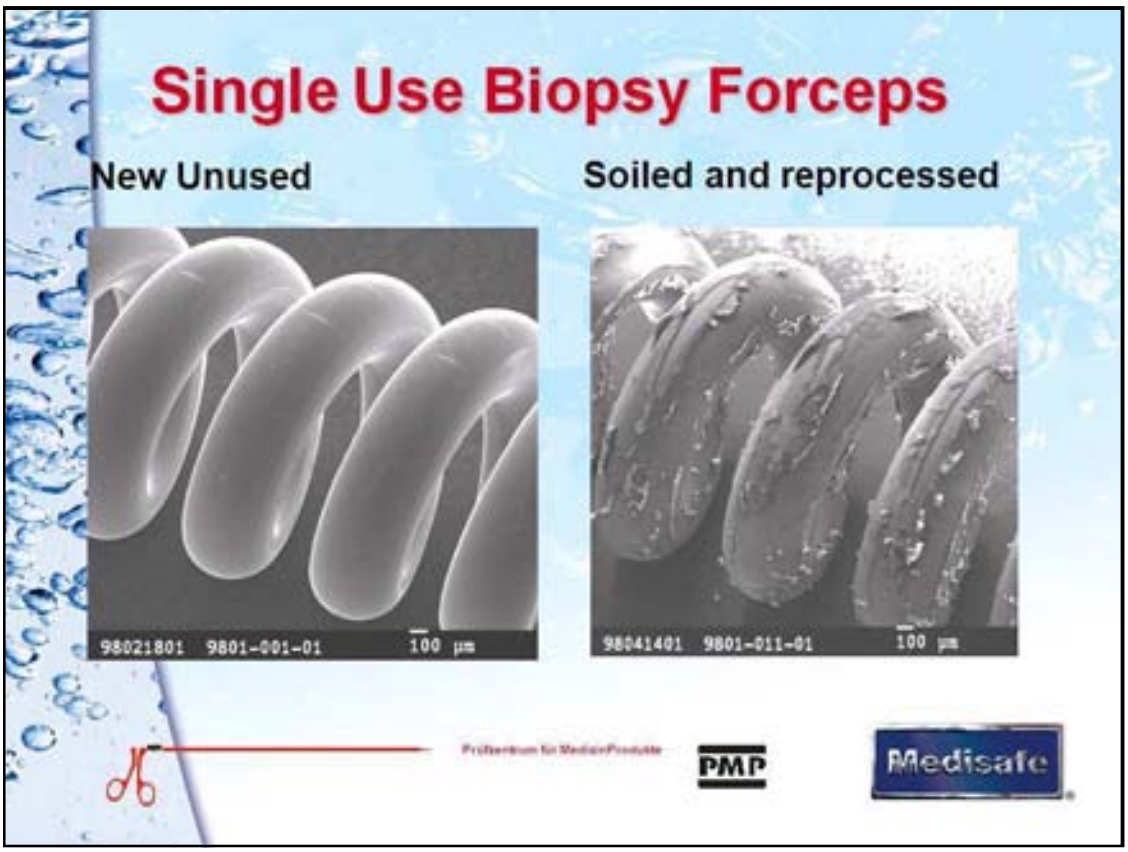
Robotic surgery,..

This is a further example of the difficulty faced in cleaning highly complex instrumentation. This is an Endo wrist from a Da Vinci machine.

The “Endo Wrist” instrument clearly illustrates the difficulties in cleaning complex instruments.. This instrument is a 10 times use instrument ! – so we have to clean it – sterilise it at least 10 times !!!!!

Yet…as I mentioned earlier, with all the advancements in surgical technology and complex instrumentation…you are expected to be able to reprocess these devices with only basic cleaning technology !!!

We need equipment that is fit for purpose…..the right tool for the right job !!!



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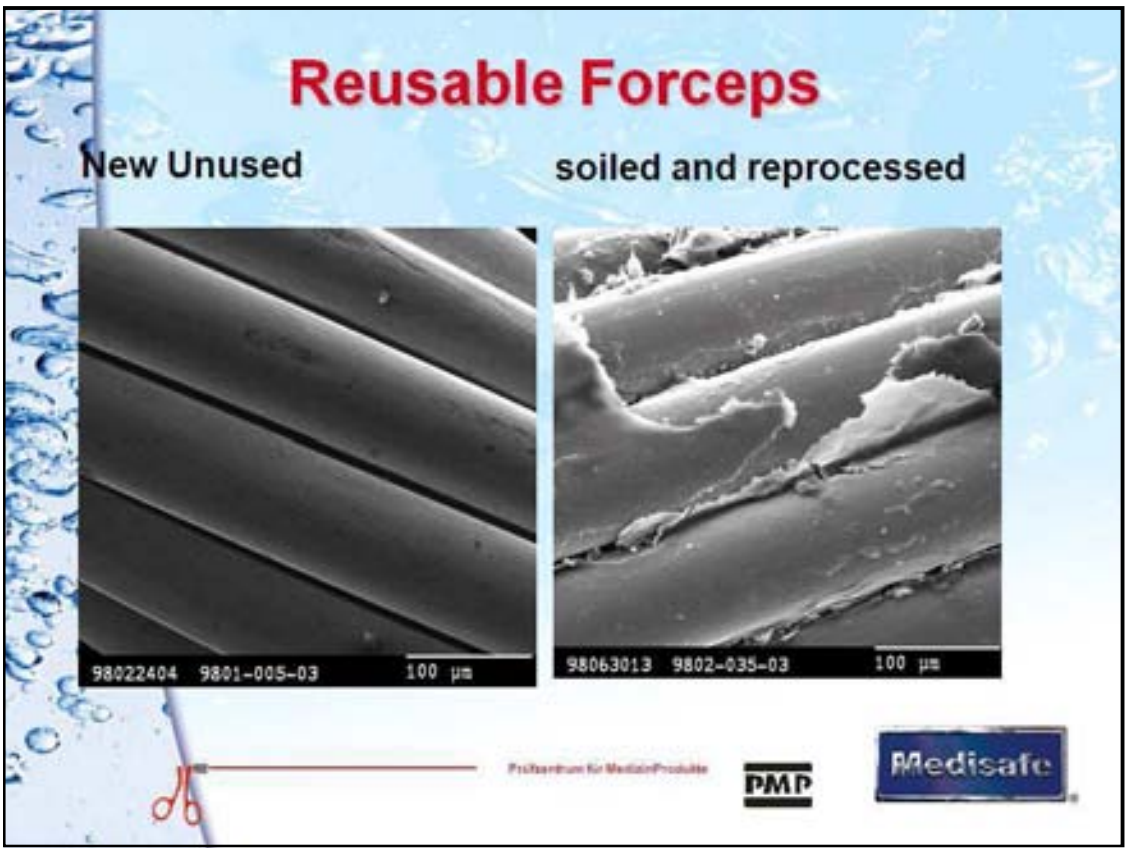
Consequently the development in the design of instrumentation has had to be matched by the methods used to identify the problems.

Here is an example of some work carried out by a reputable laboratory in Germany who we work with.

Here are some examples of the type of instruments we have tested.



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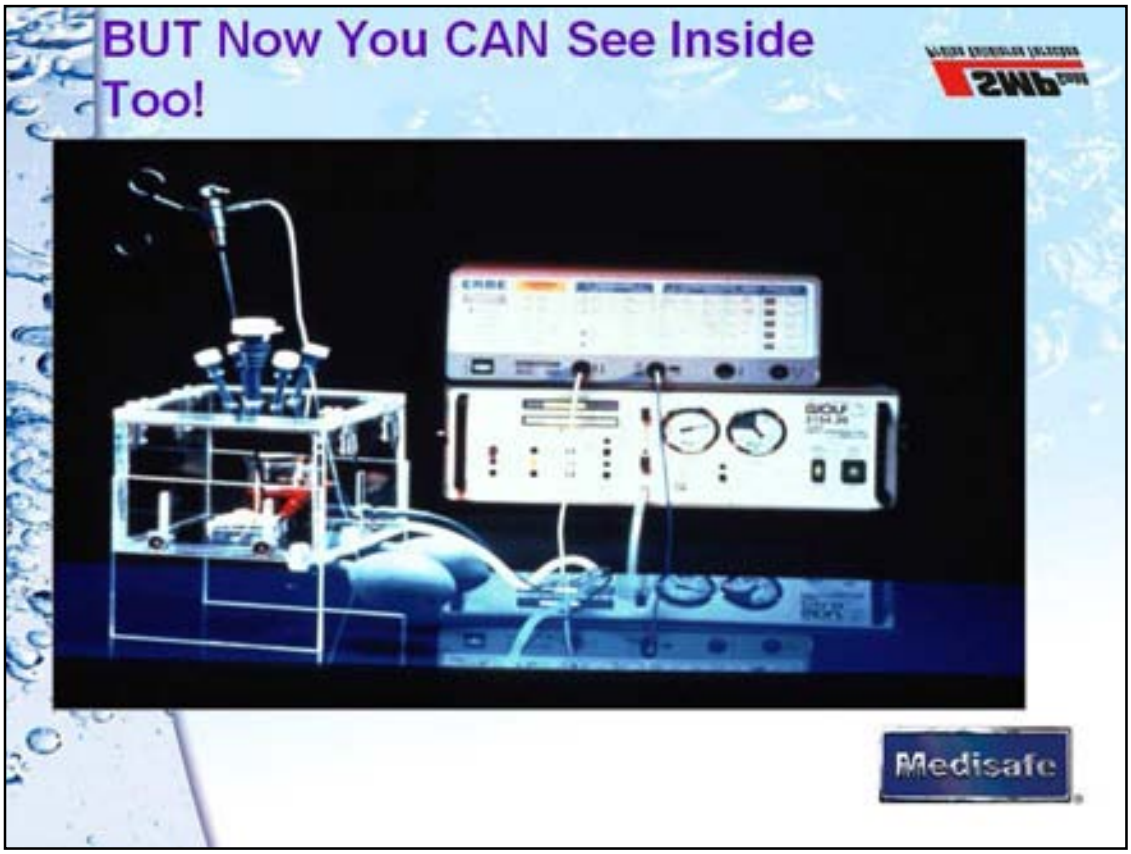
Clearly the equipment available to them, to view this type of debris is expensive and unavailable to most, but now that we are aware of it, I'm sure you will agree that it is important to target it….after all….we can only call something clean, when it is 100% clean ….there is no half clean !!



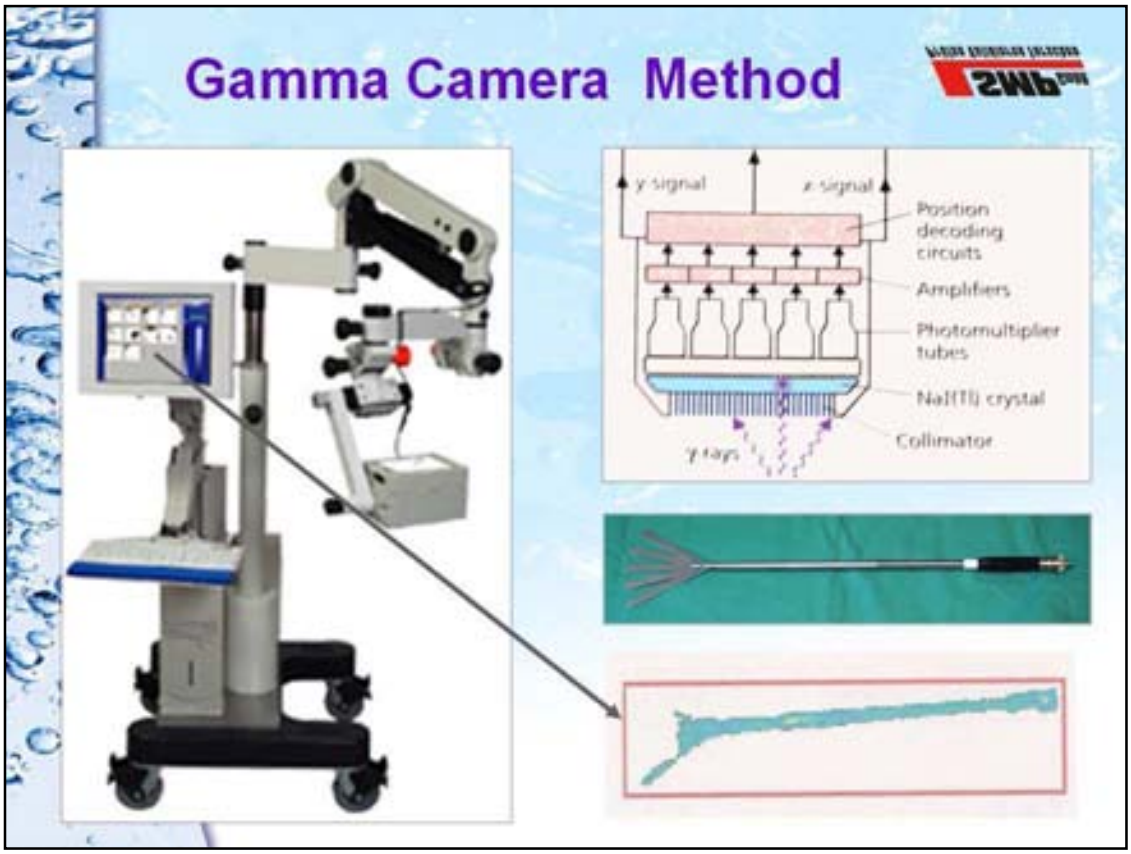
This is another, more advanced test that has been developed by Professor Klaus Roth in Germany,… This system is most accurate and realistic to life..

Klaus takes the **blood from one of his students** and mixes it with an **radioactive tracer** … The mixture is basically identical to REAL blood

The Radioactive blood is then put in the test dummy and instruments inserted in exactly the same way as a Laparoscopic procedure..

The Pressure of the dummy abdomen is then increased until it is similar to that of a normal Laparoscopic procedure

The Radio Active blood - is now under pressure - and escapes up inside the instrument – which means that our instrument is now FULLY contaminated and now **visible using a gamma camera …**



The Gamma Camera can see through stainless steel instruments - Giving an accurate picture of the contamination inside the lumen..

The instrument is placed under a Gamma Camera and scanned into the computer which generates a picture as seen here..

This Laparoscopic Instrument HAS NOT BEEN CLEANED !!!!! …. YET !!! And it is interesting to see how much debris and contamination is left after a wash in a standard washing machine.

The First picture is used as a control and has not been cleaned or reprocessed in anyway !

The Second Picture shows the same FAN retractor after processing for 15 seconds with a water jet gun – and 45 minutes in the washer disinfector with a LAP / MIS RACK..

The Bottom Picture shows the instrument after processing for 10 Minutes in a Medisafe Sonic Irrigator.

This process is excellent for all types of instrument and clearly shows cleaning throughout the lumen..

The blue marks on the right is radio active soil that has been trapped in the handle – and would not normally be contaminated. This was a prototype device provided by Karl Storz for testing, prior to release to the market. Because of the test, they were able to correct the flaw in the instrument design, to ensure it is reprocessable.

The Remaining SOIL residue is shown here in BLUE – is the GAMMA CAMERA'S interpretation of the areas inside the instrument that have not been cleaned..

So we consider this test method superior for two reasons.

•It allows the manufacturer of the Sonic Irrigator or washer disinfector to fine

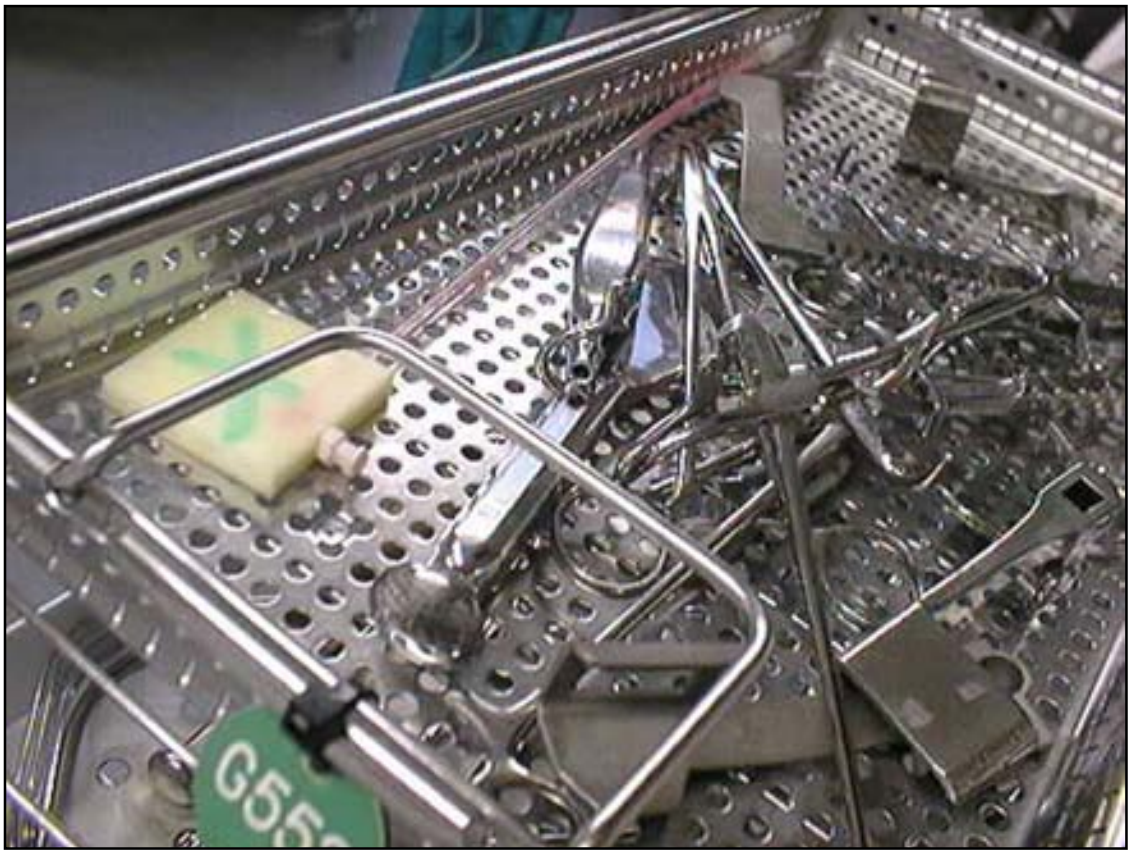
To understand better the problems faced… Medisafe designed a simple method to highlight the problem. We placed a “transparent TEST instrument” with a FLUSH PORT in the shape of a Laparoscopic device,.. In a normal hospital wash load ..

This shows the soil TRAPPED INSIDE the instrument BEFORE the washing process ..

This tray with ALL the other soiled instruments was then processed in the normal way..

After the washing process the soil INSIDE the test device is still VISABLE – indicating that this COMMONLY used process is NOT effective for complex surgical instruments..

You may have similar basic types of testing that you are able to carry out yourselves ??



This second tray - shows more clearly the SOIL Remaining INSIDE the instrument… and again indicating that this process is NOT effective for cleaning hollow or complex instruments.

This inefficiency has been a constant influence on the design of our “hollow instrument cleaning systems” . We have to understand the problem in order to innovate a solution…

I think it is important we focus on ensuring that consideration is given to the ability of a department to reprocess instrumentation being purchased….

A number of departments within the hospital, such as

Purchasing

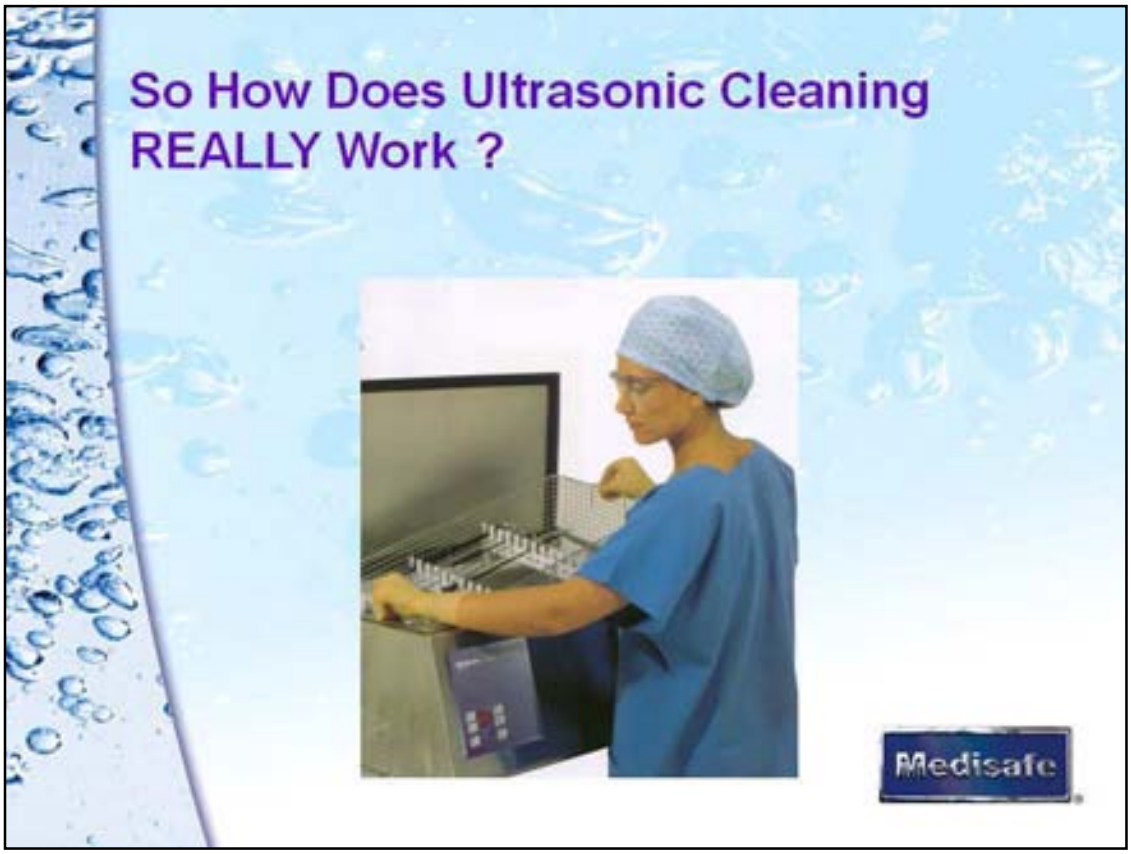
Theatre

CSSD

All have a responsibility to ensure that any instrument which is purchased, can be safely reprocessed.

As an example….I recently visited the European Hospital in Paris, where the manager of the CSSD explained how a surgeon had been responsible for purchasing a Laproscopic instrument that was for a particular obesity case he was performing. The instrument cost approx US $2000 and was returned from the CSSD to the surgeon with a note explaining that it had to be considered as single use, as it could not be reprocessed in the department, as it would not fit in to any of the normal equipment that they would use to reprocess.

As you can imagine, the surgeon was not particularly happy, but the manager of the CSSD was of course correct to do as she did.

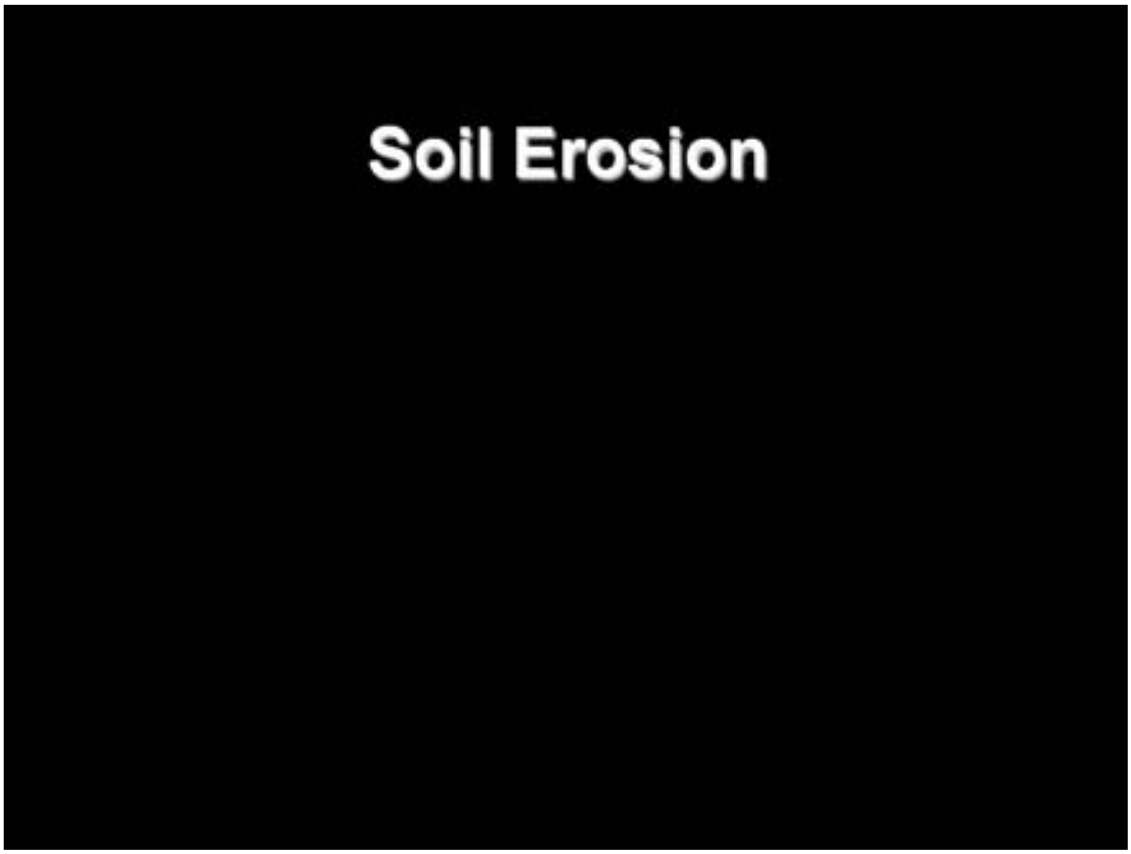


So, to give a brief overview of the options available…… We are trying to help reduce cross infection by offering specialized equipment that reduce the risk of infection from hard to clean instruments…

This is one of our machines….

This is a similar ultrasonic system to the one described in the previous slide, and to illustrate and measure the performance, we have used a piece of foil to demonstrate the cavitation taking place.

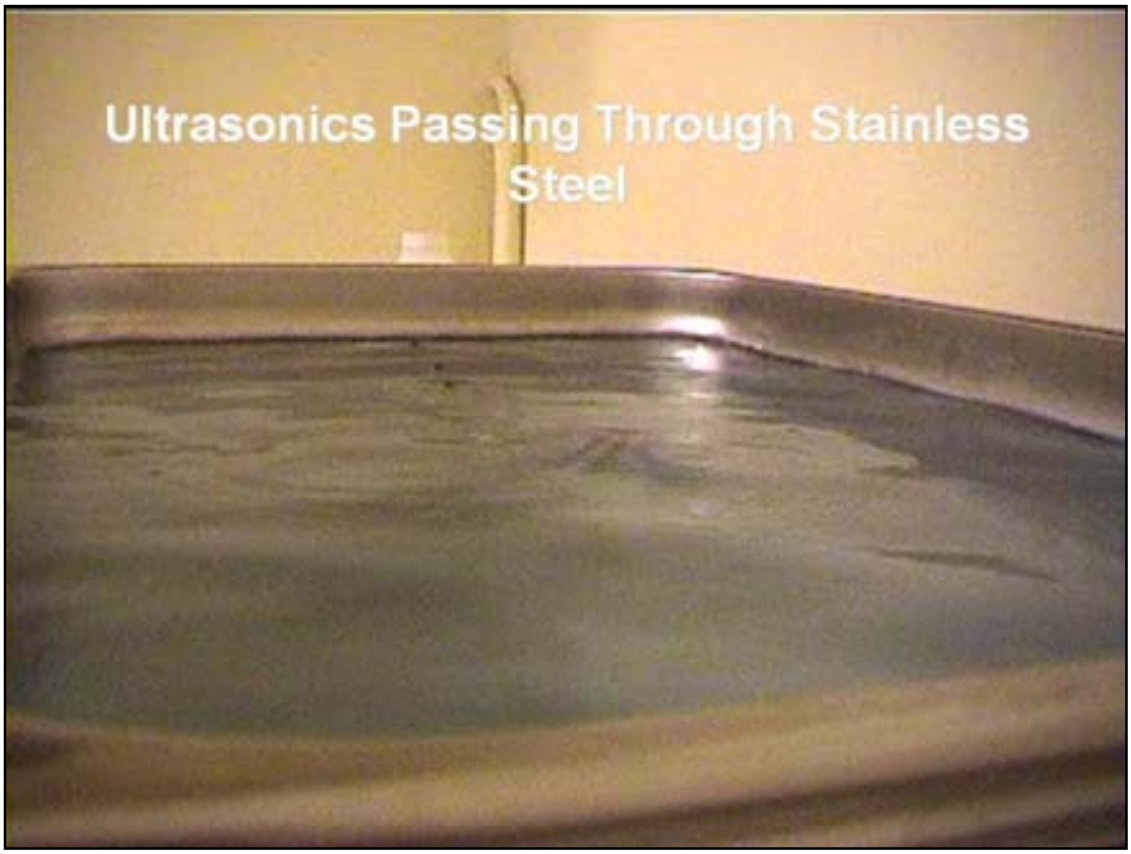
The foil acts as an indicator … … … we can use this indicator to prove our capability of cleaning INSIDE the instrument..



This video shows the effect of ultrasonic cleaning action on a soiled instrument..

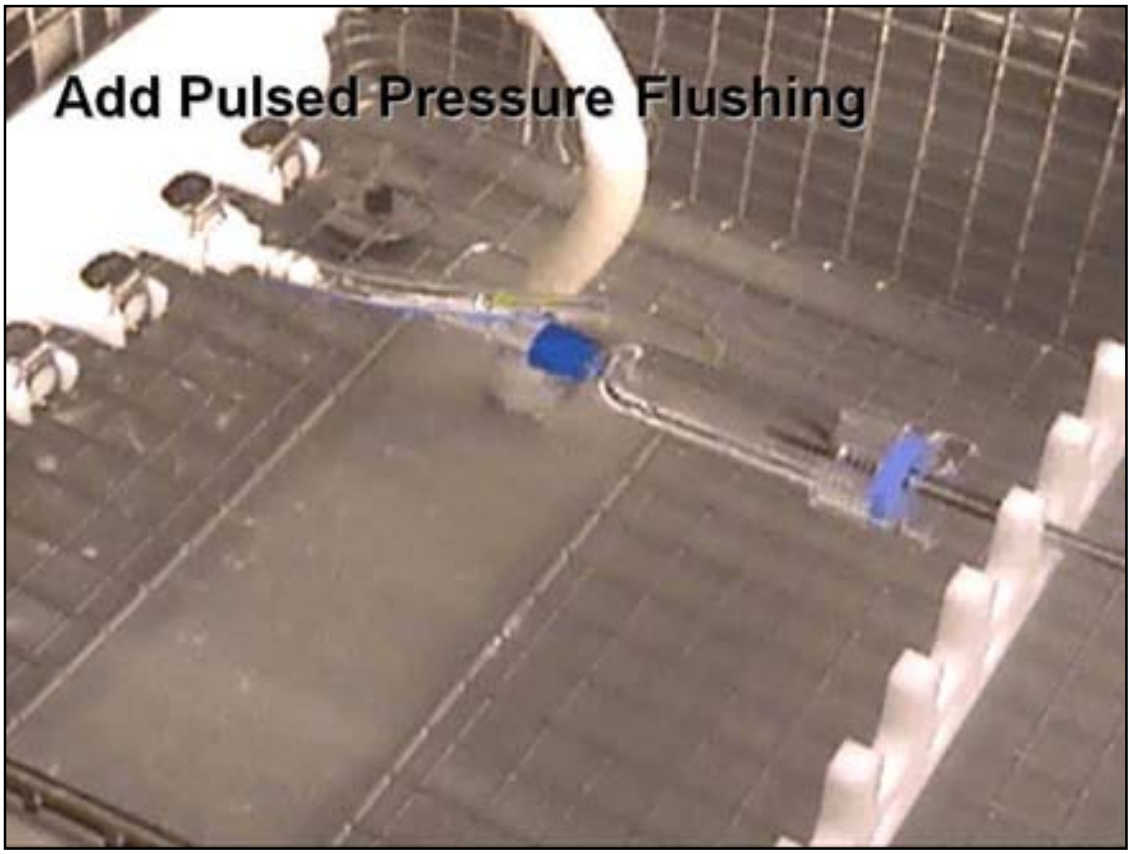
The effects of ultrasonic cleaning are clear, but it is vital to understand, that it is only the presence of water that allows the ultrasonic cavitation to take place. This is of fundamental importance when we consider how we clean on the inside of a complex cannulated device, and how we ensure that water is present in ALL areas where bio-burden may be present.

So, how do we do this ??



This video shows how ultrasonic cleaning action can penetrate through a stainless steel tank..

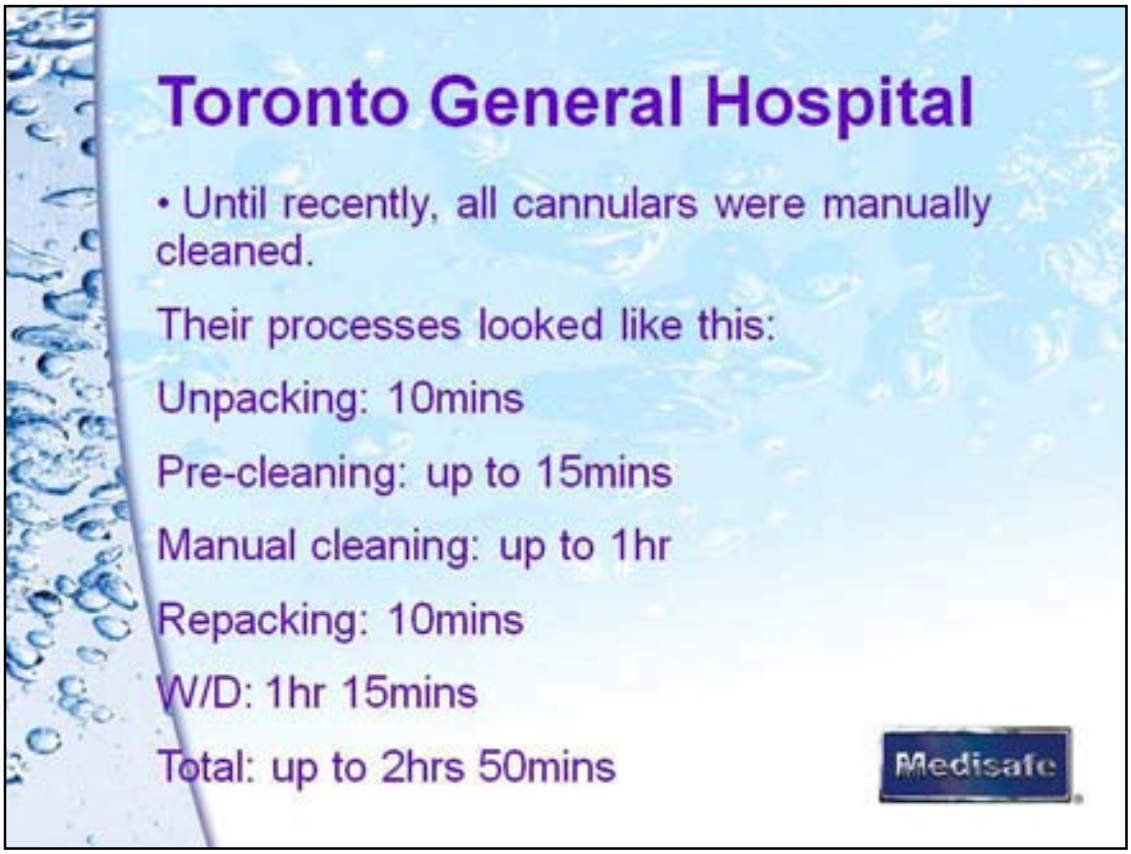
So, just finishing…a couple of videos to illustrate that what might look clean on the outside, doesn't necessarily mean it is clean on the inside !!


Add Pulsed Pressure Flushing

Here a few examples of the types of surgical devices that we are faced with reprocessing.

Please remember….specialist instruments, specialist methods of reprocessing !!

In conclusion, it is also important to remember the other important advantage offered by automated cleaning.


Toronto General Hospital
• Until recently, all cannulars were manually cleaned.
Their processes looked like this:
Unpacking: 10mins
Pre-cleaning: up to 15mins
Manual cleaning: up to 1hr
Repacking: 10mins
W/D: 1hr 15mins
Total: up to 2hrs 50mins
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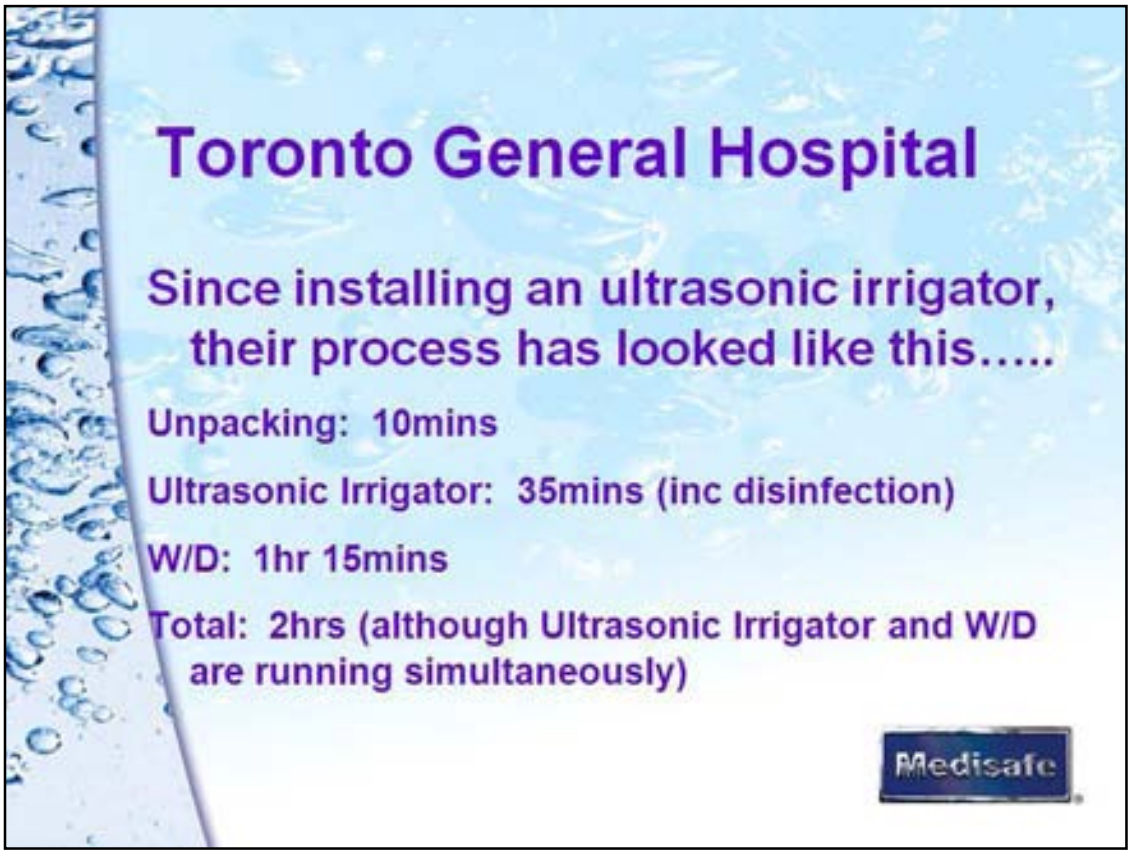
Toronto General Hospital
Since installing an ultrasonic irrigator, their process has looked like this…..
Unpacking: 10mins
Ultrasonic Irrigator: 35mins (inc disinfection)
W/D: 1hr 15mins
Total: 2hrs (although Ultrasonic Irrigator and W/D are running simultaneously)
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The London Clinic, London
10mins sorting cannulated instruments
25mins of washing in Ultrasonic Irrigator
10mins Un-loading and re-loading time
1hr 10mins in Washer/Disinfector
Total: 2hrs 05mins
(Fast Track is 4 hours)
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How Much Time Can We Save?
• The London Clinic has a total process time of 2hrs 5mins, for washing and disinfection ONLY
• This is made up of different phases in their protocol
• By combining these phases, it is possible to reduce the time taken to less than 30mins!
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Thank you - questions are most welcome…