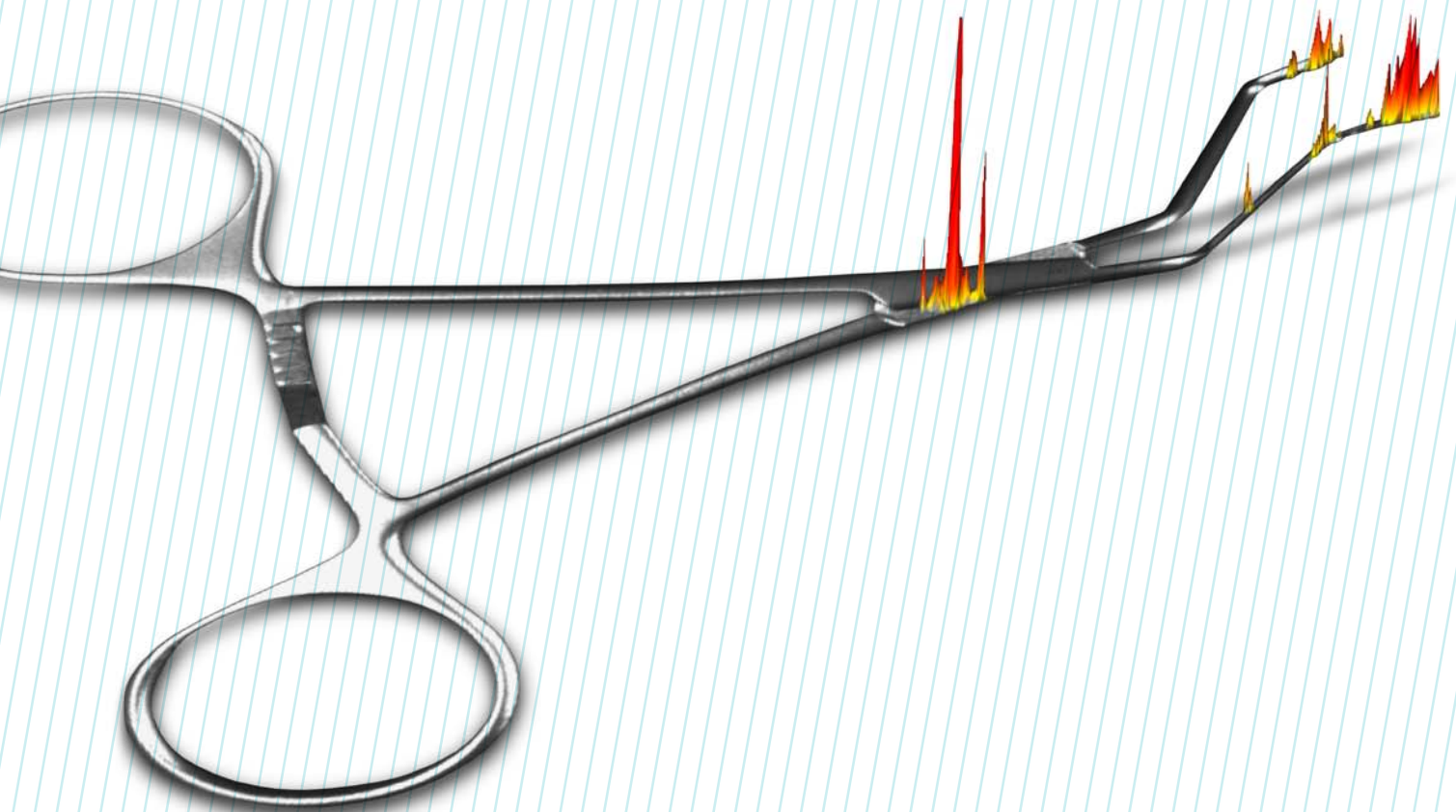

A quick, sensitive, in-situ test
to detect residual proteins
using fluorescence

Making it easy to check the
cleanliness of reprocessed
surgical instruments

ProReveal

Fluorescence Protein Detection Test



The ProReveal Fluorescence Protein Detection Test has been developed in response to the need to find a more sensitive and accurate method of checking for residual proteins that can remain on surgical instruments after the washer disinfection process.

The ideal solution for an SSD

Recent research into possible methods for the checking of surgical instruments has shown that in-situ fluorescent testing methods can produce a very high level of confidence into the effectiveness of the washer disinfectant process. The ProReveal Protein Detection Test is a highly sensitive fluorescence-based patented test for checking the presence of residual protein on surgical instruments after going through any washer disinfectant process.

The test is cost-effective and delivers objective, visual and quantifiable results and removes any doubt as to whether the washing decontamination process has left instruments clean enough to meet residual protein level standards. The frequency of checking instruments is typically determined by either local or national guidelines.

And this is important because

The quality of any washer disinfection process is dependent on a number of variables; type of washing machine, the process, instrument position in the washing tray, water quality, detergent, to name just a few. Hence, an effective check process is required to ensure that surgical instruments have been cleaned to the required standard during the washing process.

Commonly used tests include on-instrument swab tests or visual inspection. It has been found that neither of these can detect the lower levels of protein that can remain on an instrument after washing and which can be a major source of cross infection particularly with prions such as vCJD. The added problem with any swab test is that only part of an instrument can be tested and the results remain very subjective as to whether the operator has performed the test correctly and interpreted the results accurately. Instruments that remain 'dirty' after washing can be a prime source of infection and can result in cancelled operations, closed theatres and of course worse still have a catastrophic effect on patient safety.

The importance of regularly checking the washing process

A common perception is that the sterilisation process makes an instrument safe to re-use. However, this has been shown to not be the case. The main reasons why sterilisation may not be effective are described in more detail, to the right.

Prions

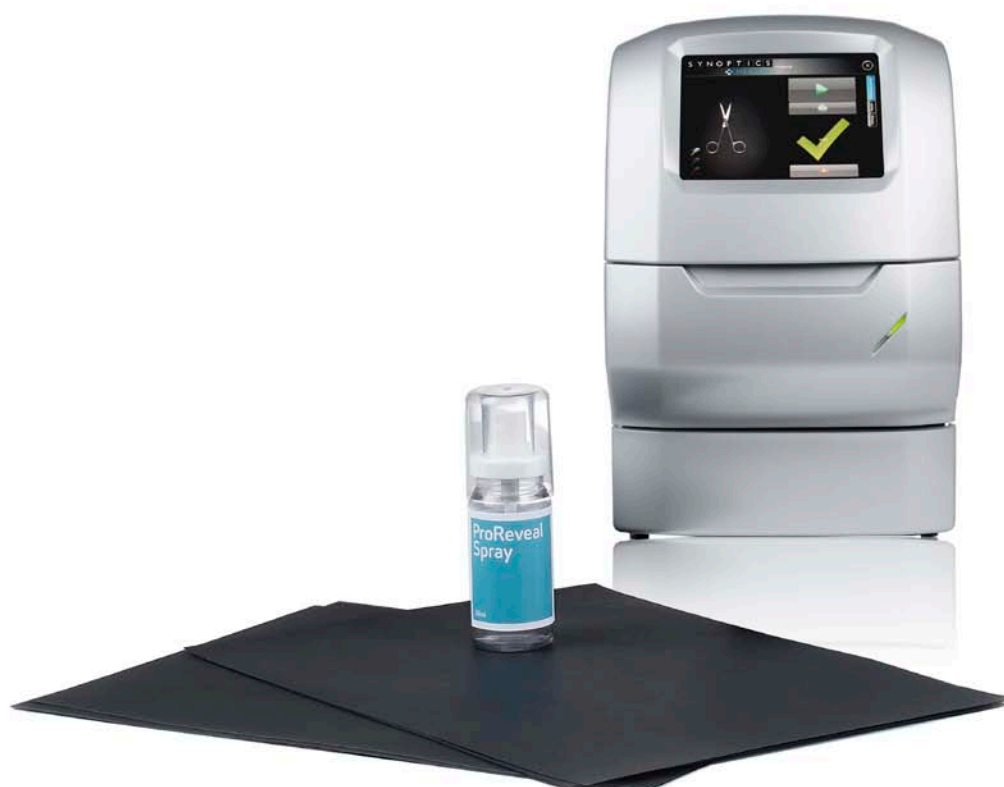
Variant Creutzfeld-Jacob Disease (vCJD) is transmitted by 'prions' (infectious proteins) which are resilient to current instrument washing processes and steam sterilisation and also have a high affinity to steel surfaces making it difficult to remove 'prions' from surgical instruments.

Endotoxins

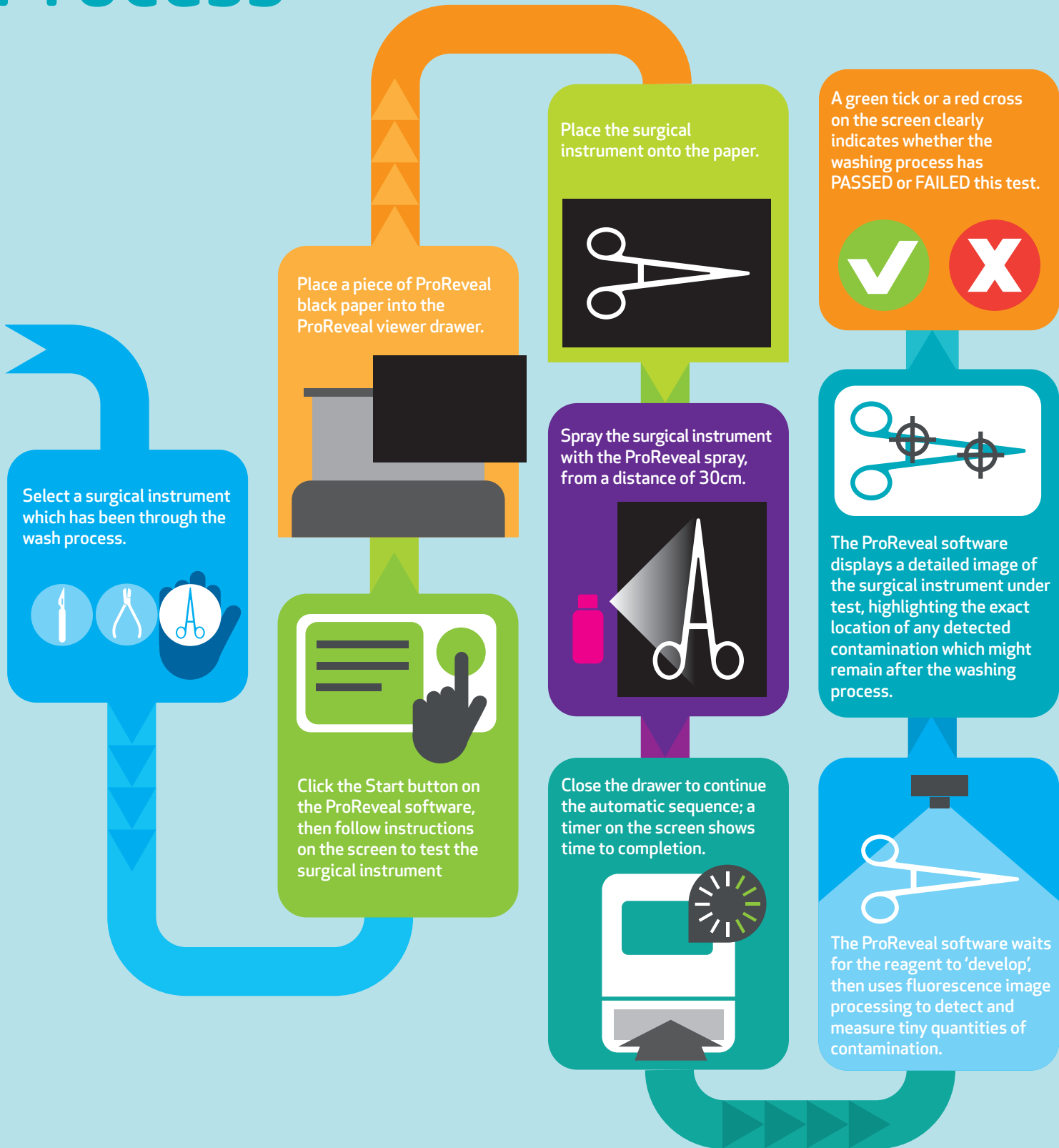
Gram negative bacteria release endotoxins when they denature and can be dangerous due to their association with systemic inflammatory infections such as sepsis. Endotoxins are extremely heat stable and they often stay viable even after conventional autoclaving.

Bioburden

It is recommended that the monitoring of bioburden (the amount of contaminant present on any item) present on a surgical instrument prior to sterilisation is critical in maintaining the effectiveness of the sterilisation process.

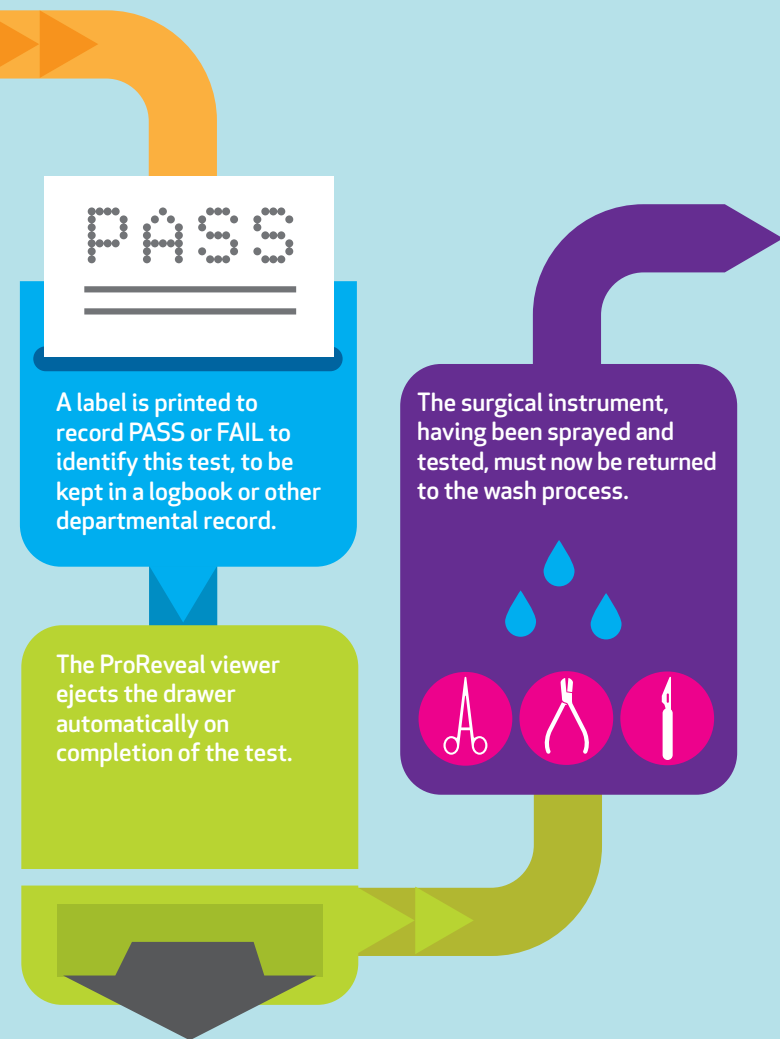


The ProReveal Process



How it works

The ProReveal test is simple to perform, requires little training and can be completed in less than 4 minutes. The flow diagram here shows an overview of this simple process.



The testing process

The test consists of a specially patented reagent based on a fluorescent spray which reacts with any residual proteins remaining on an instrument after the washer disinfectant process. The instrument to be tested is placed in the open drawer of the ProReveal viewer. Users then apply the ProReveal spray as a light mist over the whole instrument. Once the drawer is closed the viewer immediately starts its process. Special lighting within the viewer creates fluorescence where the spray has reacted with the residual protein. An image of the instrument is captured and displayed on the screen of the ProReveal viewer. This image shows any fluorescence on the instrument and hence indicates any remaining proteins.

Digital analytical assessment

Integral software within the ProReveal Viewer quantitatively assesses the level of fluorescence and hence the quantity of any protein remaining on the instrument. The viewer can be set with a detection limit (typically set at 2 micrograms) and will automatically check if residual protein levels are above or below this limit. The viewer displays a pass or fail indication as a green tick or red cross. This shows whether the washing process has met the required standard, eliminating the need for subjective user decisions on how well the decontamination process has worked.

Archiving capability

The viewer stores a copy of each image together with test data of each test for future review if required. It also prints a Pass/Fail report for logging.

Calibration

The ProReveal viewer will require recalibration every 6 months to ensure continued accuracy.

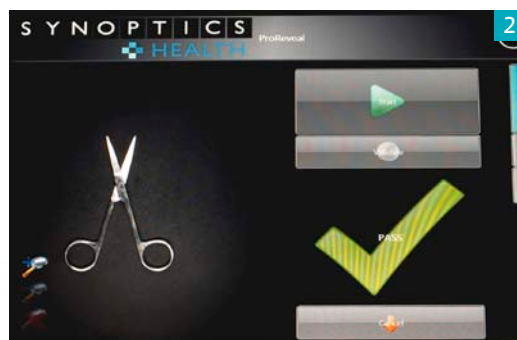
The components and test

Using ProReveal's unique patented technology you will obtain rapid, sensitive protein detection, which will help ensure that your decontamination process really is producing clean surgical instruments.

1 The ProReveal viewer is a simple to use system with a large instrument drawer and a touch screen control system.



2 The ProReveal viewer features simple to use touch screen driven software.



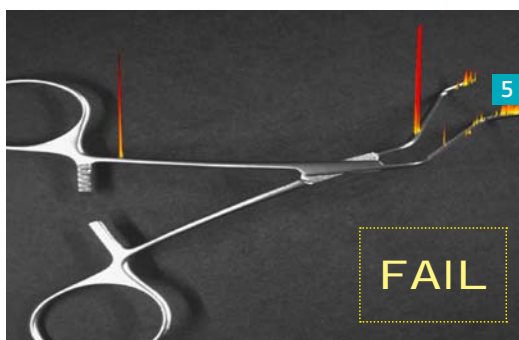
3 Pass or Fail labels are generated after each test.



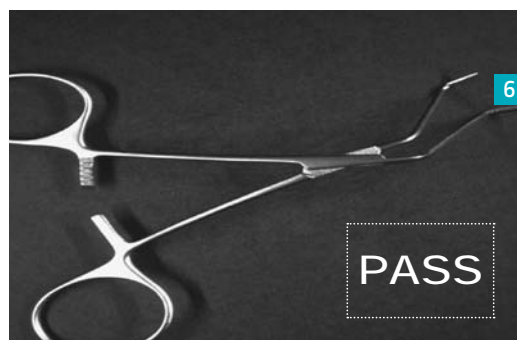
4 The ProReveal Protein Test Kit contains consumables to allow up to 20 instrument tests. It contains a bottle of ProReveal spray and 20 sheets of non-fluorescent black paper.



5 Proteins rapidly show up on the viewer screen allowing the user to detect instruments that will fail this unique test.



6 Using ProReveal's unique patented technology you will obtain rapid, sensitive protein detection, which will help ensure that your decontamination process really is producing clean surgical instruments.



Key Features

Feature	Benefit
Whole instrument can be measured	Assurance that the whole instrument has been tested
Quantitative result	Peace of mind – no need to worry about interpretation of results
Instant result	Test performed in less than 4 minutes with a PASS or FAIL indicator
Easy to use	No additional training required
Report generation	Full traceability for quality control – reports can be generated for all images saved and are downloadable to a USB stick
3D visual display as to the location of the proteins and how much is present	Pin points difficult areas to clean
Highly sensitive test	Detects less than 50ng of residual protein
Programmable	ProReveal can be set for user defined levels to meet any local or national guidelines
Network port	Suitable for connection to internal hospital network facilities

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