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How clean are your single use instruments?

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How clean are your single use instruments?

Harry Gray, owner of Avondale Surgical UK, discusses the single use instrument market and discovers that there's no substitute for quality over quantity.

The main reason for the sudden demand for single use instruments was the reports of a potential risk of spreading creutzfeldt-jakob disease (CJD) from patient to patient through using the same set of surgical instruments that may be carrying residual protein and the virtually impossible to destroy rogue prion. The Government declared that all surgical instruments used on tonsillectomies should be destroyed and replaced with single use disposable sets. It was from this course of action that many other single use procedure packs started to be introduced over the following years.

As a result of this I was approached by one of the instrument manufacturers to work with them promoting single use instruments. Through sheer luck, one of my customers was asked if he knew of anyone that could supply disposable surgical instruments. The company in question had a long history of supplying various medical goods. At the time of our first meeting they had never even sold one pair of scissors. By the time they were up and running we had designed literature and a range of products that lifted them way above what was available in the market. This approach made them one of the leaders in single use supply. Eventually other suppliers raised their standards and things became more competitive, right up to the point of price cutting. Whereas before you could present the products to the buying teams and know that many would tell you that they were a better quality than the ones they bought as reusable, it started to tail off and price became the major purchasing factor over quality.

The main production area for the instrument manufacturers is the town of Sialkot in Pakistan. It is here that extremely high quality instruments are produced and supplied to companies all over the world and marketed under well know brand names. It is also here that single use instruments are produced. Both types of instruments are produced by people that have had their skills handed down between many generations and both types of instruments need many specialised processes to turn a piece of steel in to an instrument. Now that the prices are



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dominating the sales market the high quality reusable instrument manufacturers are able to absorb any decreases in profits and still produce beautiful items which the lower end of the single use markets cannot. The manufacturer I worked with accepted the fact that I would say to potential customers that there is no excuse for poor quality single use and he kept to it.

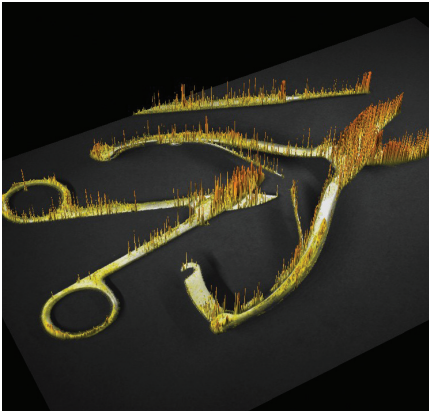
My company deals mainly in the Middle East offering a variety of medical products,

but there is one unique product that we show each year at Arab Health, the ProReveal Residual Protein Detection System. As it needs instruments for the presentation I started to use sealed sterile procedure packs obtained from UK kit packers and was met with alarming results.

Highlighting problems

The most consistent problem highlighted by the ProReveal is unidentified manufacturing debris and protein on ready to use sterile instruments. Just because they look clean does not mean they are. Manufacturing debris can come from various sources starting with the initial cleaning of the instruments after manufacturing due to poor quality cleaning chemicals, not enough time left in the ultrasonic cleaner, ultrasonic cleaner not functioning fully, and too many instruments stacked in the basket to allow the chemical to reach all parts. It can also come from handling washed products without gloves, using non approved oil to make the instrument function smoothly, or trying to wipe the instrument clean with a soiled cloth. If you check the screen of your mobile phone you will see smears that are difficult to remove. These smears are amino acids from your face and the same happens when instruments are handled without gloves, except you cannot see it on the instruments. The same applies to reusable instruments and it is only in the last few years when the ProReveal became available that some central sterile services departments (CSSDs) started to accept this method of checking the quality of their reprocessing on a more regular basis. As a result they have been able to identify what action needs to be taken to eliminate any identified problems.

With so many specialised processes an instrument has to go through before being considered perfect, there are ways of trying to lower production costs by cutting short some of them. Rushed milling and grinding on an instrument will show up on close inspection. I use a small microscope to examine instruments and have found on a number of occasions very poor machining on



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dissecting forceps, which results in strands of cloth being snagged on the inside of the blades, particularly near to the block end where they are welded together. Nail cutters can prove to be very stiff to operate due to joints not being machined correctly. Scissors with the blades crossing over near the tips and given a spot of oil to make sure they cut as this is much quicker than setting them correctly. This can cause the scissors to jump when operated slowly. In some cases the oil (which may or may not be medical grade) can leave stains on the sterile field after the instrument has been sterilised. Quality control on incoming or outgoing products not carried out as it should be due to costs and pressure to complete an order. All these things add up to cost savings, which supposedly give the kit packer an advantage over their competitors, but none whatsoever in terms of a medical advantage to the patient.

Providing quality products

Single use instruments are being sold in good faith but they could be carrying a hidden enemy which is unseen by the human eye. Up until recently there was no reliable method available of checking their cleanliness in terms of manufacturing debris or protein. The new HTM 01-01 recognises the dangers of non-clean reusable instruments and has set an acceptable limit which many hospitals will aim to beat and achieve zero results. For those people that have read this important document it would seem that some of the detection methods used in the past have been shown to be insensitive for absorbing protein from the surface of an instrument. The HTM 01-01 also states that single use instruments should be the same quality as reusable ones and buyers need to focus on quality and not just price.

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If hospitals start checking incoming sterile single use packs for cleanliness and quality and begin rejecting deliveries that fail on either, or both of these checks, it will help them avoid buying in a potential source of hospital acquired infection (HAI).

Single use instruments made correctly can take a lot of the strain off a busy CSSD and give them more time to concentrate on maintaining high levels of reprocessing and a quick turnaround service. Quality single use procedure packs will also help infection control in their task of trying to reduce the chances of cross-infections and HAIs.

There are so many positive gains to be made with single use instruments including stock control, ready to use packs with all the necessary components, accurate costing per procedure, traceability, accountability and prevention of cross-contamination for the patient and also the medical staff. Add to this the various off-site clinics and doctors' surgeries with no reprocessing facilities and you can see why this market is predicted to continue expanding. Now is the time for manufacturers, kit packers, medical staff and purchasing departments to focus on providing quality healthcare via quality single use procedure packs.

The manufacturers in Pakistan take great pride in the finishing quality of their products and want to see an end to the cut-price low

quality single use instruments that have resulted in a price war where nobody really wins, including the end users. All that they ask is a fair price for their products based on quality and they will be able to deliver clean, well made disposable instruments to the kit packers and the patients.

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About the author



Harry Gray has been the owner of Avondale Surgical UK since 2009.

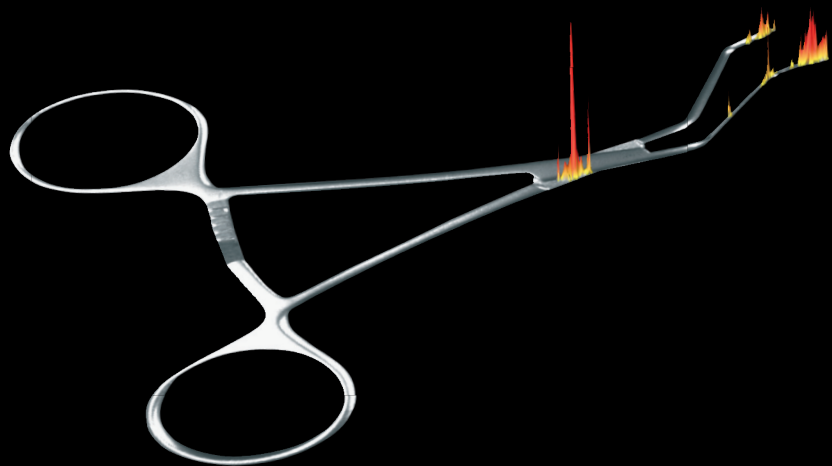
His entry in to the medical field began when he was invited to join a company which sold personal protective equipment (PPE) products over 20 years ago. The company exhibited powder free gloves at the National Association of Theatre Nurses (NATN) event in Harrogate and this is where Gray first met Matthew Peskett, managing director of Peskett Solutions Ltd. A chance miscall a few years later from the NHS gave Gray an entrance to the single use market and resulted in him spending some eight years travelling to and from Pakistan where he worked with one of the leading manufacturers and held meetings with UK kit packers. The time came when he wanted to move on and start his own company, which now focuses on sales to the Middle East. Gray's regular contact with Peskett resulted in Avondale Surgical becoming the Middle East distributor for ProReveal.

ProReveal

Fluorescence Protein Detection Test

A quick, sensitive, in-situ test to detect residual proteins using fluorescence
Making it easy to check the cleanliness of reprocessed surgical instruments

Currently the **only**
Protein Detection
Test that is fully
compliant to the
protein detection
requirements of
the updated
HTM01:01



Key features of the ProReveal Test

- A highly sensitive test able to detect less than 50ng of residual protein
- A user defined level of residual protein can be set to meet the HTM01:01 guidelines
- A rapid test with results in less than 4 minutes with a PASS or FAIL indicator
- Provides a quantitative measurement over the whole of the instrument
- A visual display as to the location of any residual protein
- 3D view of the instrument shows where protein is present and how much
- Report generation, stored data or downloadable to a USB stick or mirror storage to an external drive or network
- Patented viewer and reagent spray
- Touch a spot of contamination on the displayed image to show a localised readout of the protein mass detected for that spot
- The ProReveal generates a list of editable questions before each measurement. Washer disinfectant details etc.
- The stored measurement data can be analysed using the monitor history graph
- PCD's (Process Challenge Devices) under development



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