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**Providing the best Surgical instrument solution for SSD in the current economic climate**

**The aim of this paper is to provide an insight into the approach a modern day manufacturer takes, when trying to offer the NHS the best value for money on instrumentation. There is big investment in public sector organisations such as NHS supply chain, to drive purchasing prices down, but there is a danger that this pricing factor will blur the necessity of keeping instrument standards high. Key variables that will be discussed in relation to the quality and price balance are:**

- **Current Macro Economical Trends**
- **Issues with Imports**
- **The Modern Day Manufacturer**
- **Patterns and Steel Quality**
- **The Importance of Flexibility in Small business and how this can benefit the NHS**
- **Quality steps that can be taken to ensure instruments reprocess smoothly**

Our experiences over the past few years as a specialised surgical instrument manufacturer have seen a trend towards HSDU and theatres choosing the products that are cheaper end of the scale. Coupled with this the introduction of reverse e-auctions and extensive tender exercises, in mid 2006, 121 procurement exercises were in progress, the highest number compared to other UK public sector organisations, (PASA, 2006). The NHS supply chain aims to provide £1 billion of savings to the NHS, so that resources are released for patient care, (NHS Supply Chain, 2008). This raises issues with the products that are currently on the market and if it is really possible to maintain a balance between cost and quality, where the hospital still get the product quality they want, but at a price that's beneficial to all.

What is crucial to Sterile Services is that with more stringent washing processes, steel quality needs to be as high as ever. Macro economical factors are influencing the quality of surgical instruments that are available in hospitals. While hospitals may be demanding European Steel quality, realistically budgets only allow for imported steels in general surgical instruments. A premium is paid to obtain material from European producers, rather than Asian brands, even though these may also meet the minimum specifications, as European producers who establish and maintain a reputation for quality and reliability are rewarded with a higher premium for their product, (LME, 2008); these are the factors that mean prices in Europe are generally higher for steels.

So if NHS budgets are not suited to European steels for general surgical instruments, Asian imported steels are the only economically viable option in some cases, for instance Spencer Wells, Halstead Mosquito forceps, Stitch scissors and Rampley Sponge Holding Forceps. The Far East region has also seen higher price levels and increased volatility in recent years. For example, import prices for steel into East and Southeast Asia averaged $222/tonne between 1994 and 2003, but have averaged $424/tonne since then; this is coupled with a hike on price of Nickel in the London metal exchange, (LME, 2008). So even though Asian steel sources are a cheaper than European, prices have almost doubled in the past 5 years, which can only be passed on to the end user by way of higher price, or unfortunately reduction in instrument quality offered. So the option of imported forgings is also becoming an expensive solution, this is why I feel that we should be looking to get the best for the NHS from the current situation we find ourselves in.

So assuming that the trend of driving down price on instruments will continue and prices rises will increase, UK surgical instrument manufacturer are in a position where they have to re-assess and flex their product range and select their source for forgings, depending on the application of the instrument, through consulting a network of suppliers. In my opinion Specialised instruments i.e. neurological/ENT punches in my opinion should always be manufactured from European Steels, as even though they may be of the same chemical compositions as their foreign counterparts they have higher quality reputation and reliability and this is very important with the hardness of these steels, due to the application of these instruments. However, if the NHS are to get the best value for money it is essential to look at an instrument tray and to save money where possible and I can hopefully illustrate that this doesn't have to mean that quality will suffer. Too many times when recently quoting for hospitals have I seen instrument usage per year of i.e. 600 Halstead Mosquito forcep. They may be cheap (with Asian steel prices rising, they will not be for long), but the quality is clearly lacking, if this is the quantity being purchased. Quality can still be achieved from imported instruments, for a very modest price that will mean longevity of instrument life and will also avoid the poor quality instruments cross contaminating trays when re processing.

With the need to move to imported forgings to save money, where possible, we can now look at the export-oriented surgical instrument cluster in Sialkot, which responsible for a very high percentage of surgical instruments imported into Europe (Nadvi 1999). The stainless steel surgical instruments industry of Sialkot is not only a global player in its niche sector, it is also marked by a thick web of social ties through which most local firms are related, (Nadvi, 1999). Nadvi (1999), illustrates the magnitude of the industry in Sialkot, it is made up of some 300, mainly small and medium sized producers. These are supported by over 1500 specialized subcontractors and a further 1000 odd suppliers and ancillary service units. This cluster of local producers is estimated to account for some 20 per cent of world exports, making it the second largest exporter, after Germany, of stainless steel surgical instruments (Nadvi, 1996).

The quality of surgical instruments manufactured in Sialkot is very questionable. This is twofold for me; are the patterns correct and is the steel up to the standard where it is good enough to be put on a tray? Firstly the patterns; Only the other day when looking at a tray of instruments we had in for reprocessing, was it so alarming how much instrument have deviated from their original patterns, The Gillies dissecting forcep, should be a fine dissecting forcep, however what I saw before me certainly was not fine. These patterns would have originally been established with a curator and surgeon at the hospital, who would then work with the surgical instrument manufacturer to ensure the surgeon receives the pattern they require. We retain original patterns for all our instruments, some 40 years old, to ensure there is no deviation from the original purpose and requirements of the surgeon.

We can now look at how this deviation would occur. Nadvi (1999), underlines Sialkot's prowess in manufacturing exports has a long history. The surgical instrument cluster, for example, has roots that date back over a century. The 1895 District Gazetteer mentions metal forging and manufacture of metal utensils in the region. It particularly notes the skill of Sialkot's ironsmiths in producing high quality ornamental damascening and inlay work, and their ability to repair and manufacture `large quantities of caskets, shields . . . swords, spear-heads, gurka knives, razors, stirrups' to an excellent degree of workmanship. The transition to surgical instrument making came in the 1890s, as a consequence of the demand for repair, and subsequently manufacture, of surgical implements created by the presence of a local Mission hospital. The birth of the sector,

including the `accidental' association between the hospital and local ironsmiths, was thus linked to the presence of specialist knowledge among local artisans of how to forge.

World War Two brought Sialkot into the war effort, becoming an important supplier of surgical instruments (Nadvi 1999). This may be where the first patterns of certain specialist instruments where provided by the UK. The British provided the region with Technology, design blueprints, drawings, know-how and technical experts were brought in from Britain, and a technical support institute was set up in 1941 to assist local industry. This was over 65 years ago, so it's clear how in this time period, patterns have deviated somewhat and why the Gillies Dissecting Forcep certainly did not resemble the established pattern we have on hand. We do not feel it should cost much more to still provide instruments to these original patterns. For the cost factors I have previously highlighted, it is essential to import some Asian forgings, however, these should always be tightly controlled by providing an established pattern for the sub contractor to work from and ensuring this is stuck to.

Manufacture of surgical instruments has changed very little over the past 100 years (illustrations below are taken from an 1890 Arnolds instrument catalogue). A key alteration is of course the forging process, as I previously mentioned. This has been replaced by the purchase of pre manufactured castings and forgings. However, there is still the necessity for essential skills in stages such as Grinding, Filing, Fitting and Turning, which allow for bespoke instrument manufacture. Advances in these processes have seen the introduction of CNC machinery into the manufacturing process, automated inventory systems and computerised instrument marking/laser marking.

As a modern day manufacturer, having the ability to alter an instrument to our customers' specification, generally raises good interest from customers, as the belief that something can be manufactured in the UK, seems to have all but disappeared.

Our past years experience in different hospitals has stressed the need for the ability to provide a variation in patterns depending on the hospital. We adapt our approach incrementally through our experience with our customer and learning from them (Johnson and Scholes 2002). For the NHS to get the most for their money from surgical instruments, working with a small business in partnership affords this, as the direct feedback from sterile Services or Theatres, feeds straight back into the manufacturer and can be immediately reflected in the quality of our instrumentation. Tray lists may look very similar, but quite often, consultants have certain patterns that they prefer and there is the belief that only 'off the shelf' is available. Having a multi skilled workforce in place, gives us flexibility between jobs (Barrett and Rainnie 2002) and the ability to produce instruments exactly as requested. I recognise that the skilled employees in my organisation are the key to a degree of competitive advantage (Bell, Taylor and Thorpe 2001), as there are not many manufacturers in the UK that can alter or manufacture instruments on site. As a manufacturer, we happy to share our knowledge on steels and manufacture process to the benefit of us and our customer and always actively encourage their education in these areas.

Our passion as manufacturer, is to promote the fact that the flexibility still exists in the market to provide an instrument exactly as the hospital require and to a quality which will ensure longevity of life of the instrument, as this doesn't mean that the instruments should be more expensive than their simply imported counterparts. The key is in the quality control of the patterns and to be aware that if you buy an i.e. Gillies Dissecting Forcep from Sialkot, it may not look like it's

original pattern, but retaining our manufacturing arm allows proactively to ensure original patterns are restored and imported forgings are manufactured to the correct patterns.

In relation to the steel quality with rigors of the hard water wash, steel quality and hardness are essential. However, the current market is demanding low prices on instruments such as Spencer Wells, Halstead Mosquito forceps, Stitch scissors and Rampley Sponge Holding Forceps. To avoid corrosion on these instruments, when they are reprocessed, several factors have come into plays which need to be addressed on 'problem areas' in relation to reprocessing these instruments. After all, if imported instruments are to be mixed on trays with European steel instruments, there is an enhanced risk of cross contamination, if the instruments are not quality controlled.

These are the instruments that imported steels may be used on, so I believe that all serrations and box joints should be bright polished, to enhance their washing properties and corrosion resistance. Having the artery forceps 'set' against established patterns, as previously mentioned, prior to despatch to customers is also key, to adding extra value to what would be simply an imported instrument, especially as it is predicted the the price of Asian steel will continue to rise (LME 2008). Finally, passivation is crucial, particularly with laser marking being applied. Working with our local SSD peers, we have found that passivation prior to laser marking is a more effective procedure (although some manufacturers passivate after laser marking). It means that when the instruments are laser marked, the surface of the steel is not disturbed, only the oxide layer which has been formed by the passivation, it also means the marking lasts longer, which is essential when instruments are to be tracked by 2D matrix.

For the steels themselves, the higher carbon content in the steel, the more susceptible to corrosion. Carbon steels can be hardened due to their higher carbon content, these are Martensitic. As you can see from table below, 420S45 has most carbon and will be harder once heat treated and is therefore used for instruments needing these properties. Steels with very low carbon cannot be hardened and are Austenitic. As per BS 5194 Part 1 ISO 7153-1, the steels used for the manufacture of surgical instruments and their applications are as follows (Molybdenum omitted for purposes of this table):

| | **Cr** | | **Ni** | | **Mn** | | **C** | | **Si** | | **P** | **S** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **SPEC** | **min** | **max** | **min** | **max** | **min** | **max** | **min** | **max** | **min** | **max** | **max** | **min** | **max** | **possible uses** |
| Austenitic 303 | 17 | 19 | 8 | 11 | 1 | 2 | | 0.12 | 0.2 | 1 | 0.045 | 0.15 | 0.03 | Machining & turned parts |
| Austenitic 304 | 17.5 | 19 | 9 | 11 | 0.5 | 2 | | 0.06 | 0.2 | 1 | 0.45 | | 0.03 | bending and welding |
| Austenitic 316 | 16.5 | 18.5 | 10 | 13 | 0.5 | 2 | | 0.07 | 0.2 | 1 | 0.045 | | 0.03 | containers, baskets, trays |
| Martensitic 420S29 | 11.5 | 13.5 | | 1 | | 1 | 0.14 | 0.2 | | 0.8 | 0.04 | | 0.03 | artery forceps, needle holders, sponge holders |
| Martensitic 420S37 | 12 | 14 | | 1 | | 1 | 0.2 | 0.28 | | 0.8 | 0.04 | | 0.03 | bone cutters, punch forceps, scissors |
| Martensitic 420S45 | 12 | 14 | | 1 | | 1 | 0.28 | 0.36 | | 0.8 | 0.04 | | 0.03 | knives, gouges, osteotome, super cut scissors |

This of course reduces the risk of corrosion with instruments such as Spencer Wells, as they do have a lower carbon content, but should raise awareness on instruments such as super cut scissors that are manufactured from imported steels, as a lesser quality steel and higher carbon content would definitely increase the chance of failure and corrosion. The key difference with the European steels and imported steels is reliability (LME 2008). Although the imported Asian steel instruments i.e. Metzenbaum Scissors may still fall in the parameters for relevant British standards, it may not be as hard or chemical composition reliable enough as its European counterpart and therefore the longevity of the instruments life may be significantly reduced.

As previously mentioned provided the correct quality controls are in place, using imported steels for certain applications should not raise a reprocessing issue. To re iterate:

- Establishing original patterns
- Ensuring importing forgings have the correct steel composition
- Quality instrument setting
- Bright Polishing on joints and serrations
- Effective Passivation process

These factors may mean a slightly higher price than simply an instrument bought and sold from Sialkot, but it certainly protects the end user in terms of quality and longevity of the instrument life. It is of my view that when repairing instruments and trays of instruments, the same processes should apply, to maintain high standards of quality throughout the instrument trays. This would mean refurbishment of the instruments, rather than just repair.

- Repair
- Re polishing
- Re passivate

The re passivation of the refurbished instruments, is also a very good assessment of the quality of the stainless steels and it allows for weeding out of any instruments which could potentially contaminate a whole tray, in our experience this includes discoveries of instruments made from mild steel, which stresses the importance of this process!

Summary

To summarise, the NHS are looking to save money on their instrument purchases. The concern is that this will affect the quality of instrumentation purchased. This is coupled with a rise in steel prices, not only in Europe but also in Asia, where a vast majority of surgical instruments are exported from. Unfortunately, some of these cost increases have to be passed on, but this leaves the manufacturer in a position, where they have to provide cheaper instruments, but raw material costs are rising. Another conflicting factor to the NHS trying to save money is with more stringent Sterile Services reprocessing controls in place, keeping quality high is key.

The cost factors mean that some instruments that were previously purchased from Europe, may be imported from Asia. I feel this is ok, provided correct quality controls are put in place for correct and established patterns and steel quality monitoring, The instruments should be correctly polished and finished in potential ‘problem areas’ and they should be passivated. But the danger is where manufacturers have to pay more for their steels, these quality factors may be skipped

and this would increase the risk of poor quality instruments, to deviated patterns, causing cross contamination on trays.

I feel it is very important to raise awareness in hospitals that Sterile Services and Theatres do not have to settle for poor deviations on patterns, with Asian imports. The UK still has the manufacturing knowhow and flexibility to work in partnership with the NHS, to ensure that they are getting their instruments exactly as the original patterns, not just ‘off the shelf’, at an economically acceptable price that will mean longevity of instrument life and overall value for money for the hospital.

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