

MOU

# Cautionary Tale: Springs and the Medical Industry

By Mark Hayes



The medical industry may not be the biggest market sector for springs, but it is still significant. IST often asserts that springs are utilized in every manufacturing sector, and the medical industry is good example to consider in detail. Springs are used in drug delivery, including inhalers; in the production process for pills of all types; in the infrastructure of hospitals for beds, doors, counterbalances; in surgeon's tools; in medical devices implanted in the body or used in invasive applications; and in monitoring equipment. In addition, the spring industry often makes small metal components that may not appear to be springs exactly, such as staples, orthodontic devices, and even contraceptive devices.

Among the most frequently used raw materials for nearly all of these products is 302 / 304 stainless steel, and that is the subject for this cautionary tale. When is stainless steel clean enough for a medical application? Do we need to have fully certified clean room facilities to guarantee that our products are surgically clean? These are frequent questions that IST is asked.

The first observation that IST would make is that springs for the medical industry are often made by the medical industry themselves, rather than subcontracted to specialty springmakers. This practice is more prevalent in this sector than any other. There may be sales opportunities here if springmakers can put forth an argument that they could do better

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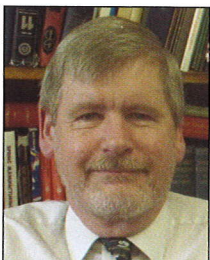
(commercially, logistically, and technically) than any in-house spring manufacturing operation.

The normal process for the manufacture of medical springs is as follows:

- 1) Purchase stainless steel, either dry drawn (soap coated) or wet drawn.
- 2) Coil on automatic coiler.
- 3) Stress relieve heat treat.
- 4) Prestress (often not done).
- 5) Clean, or passivate.

The medical industry particularly dislikes the yellowish color that occurs during heat treatment. Medical springs can be heat treated at a temperature below 350°C (662° F) so the color is too pale to see, or passivated to remove the color. The yellow color is just a trick of the light – it indicates a translucent oxide thick enough to refract the yellow part of the incoming spectrum. It is a corrosion-resistant oxide that will not harm the performance of stainless steel springs.

Notwithstanding, the corrosion resistance of 302/304 stainless steel springs is enhanced by passivation in accordance with ASTM A380. IST utilizes five percent nitric acid, and has shown that a direct result of passivation is an increased number of hours' exposure to salt spray conditions before the onset of red rust. But there's a word of caution – long term storage of these stainless steels in a saline solution could lead to a risk of red rust.



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**with comments about this cautionary tale, and with subjects that they would like to be addressed in future tales. Contact Hayes at (011) 44 114 252 7984, fax (011) 44 114 2527997, or e-mail m.hayes@ist.org.uk.**

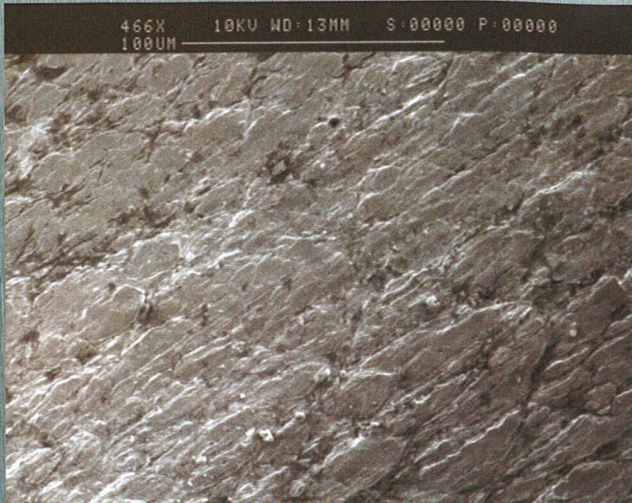


Figure 1: Dry drawn stainless steel x 400

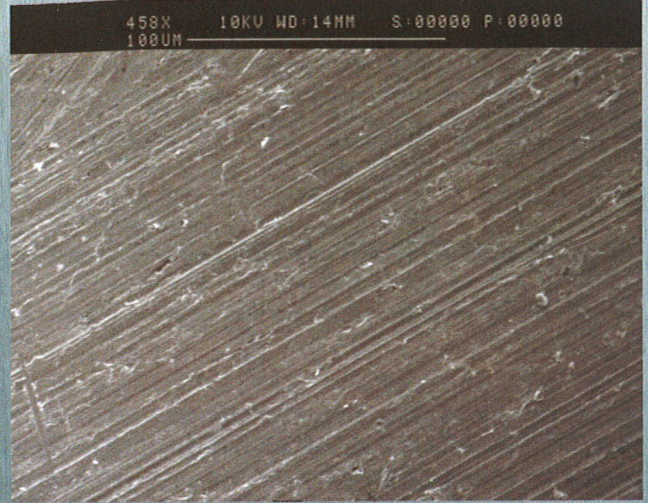
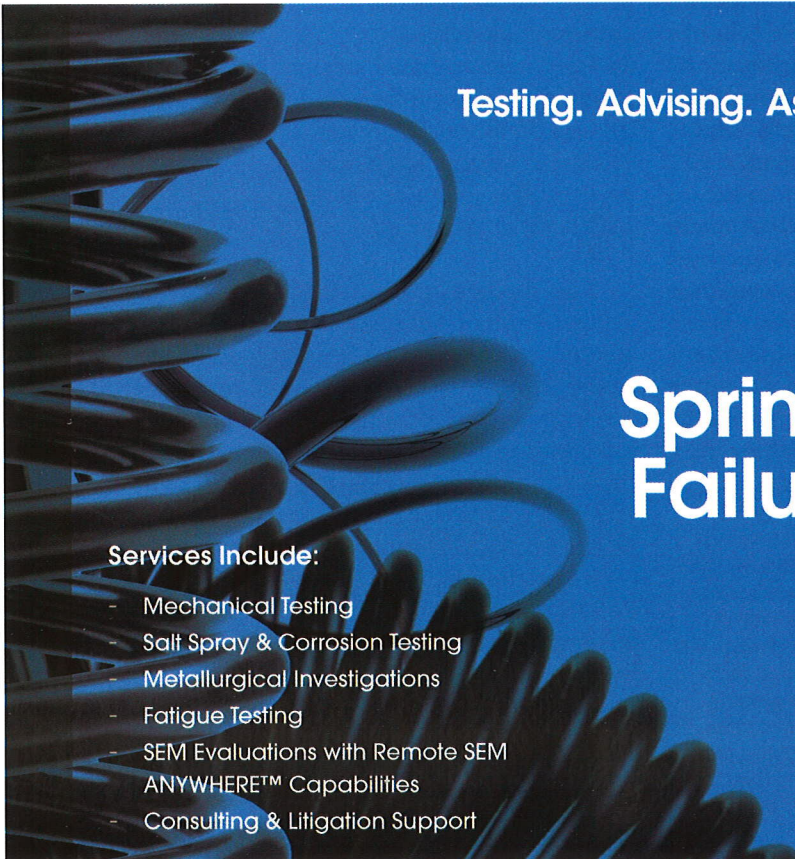


Figure 2: Wet drawn stainless steel x 400


It will still be difficult to say that the stainless steel is surgically clean after acid passivation, because there will be washing and drying to remove the nitric acid. The surface of stainless is always rough, as shown in figures 1 and 2, so it will pick up dust and other dirt very easily unless kept permanently in clean room facilities. It is my experience that cleaning needs to be accomplished as carefully as possible, but there is

not generally a need for springmakers to have a clean room, at least for the medical industry.

The moral of this cautionary tale is that the medical industry is one that offers good commercial potential to spring manufacturers. Medical springs are often assembled, sealed and used only once, and concerns about cleanliness are often unfounded or exaggerated. ♦



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