Medical Device Manufacturing: Designing for X-ray Inspection.

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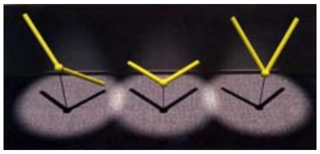
Introduction

When x-ray inspection is used as part of a quality assurance program for any assembled device, steps must be taken early in the design stage to anticipate the use of x-ray inspection later in the development and production processes. This is a lesson that electronic assembly manufacturers learned years ago, and that medical device manufacturers are also discovering.

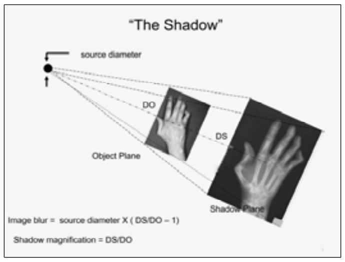
There are several steps involved in learning how to interpret x-ray images, and how to design for x-ray inspection. First, manufacturers need to understand the nature of the x-ray shadow and its modalities; then they need to see how medical device developers and manufacturers are using x-ray inspection; finally, they need to consider taking measures early in the design process to ensure a clear, accurate image when the assembled device undergoes x-ray inspection.

The x-ray shadow

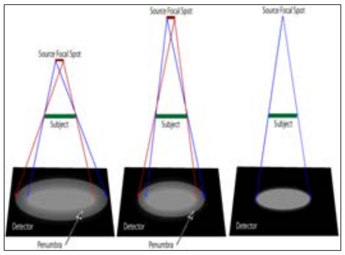
The x-ray image is basically a shadow image of the object, projecting a two-dimensional representation of shape, opacity and thickness. Many different three-dimensional configurations can project similar two-dimensional shadows (Fig. 1). Using the light/shadow analogy, it can be seen that the relative position of components within the object will affect the size and appearance of the x-ray shadow (Fig. 2).



Characteristically, the shadow is distorted by *geometric magnification,* which causes details of the object closer to the x-ray source to be magnified to a greater degree than details further from the source. The magnification of the x-ray image can be calculated as the ratio of the distance from the x-ray source to the shadow plane divided by the distance from the source to the object (Fig 3).



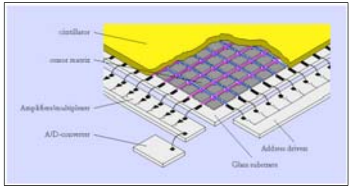
As long as the object has a finite thickness, the x-ray image cannot have true dimensional accuracy. It can also be seen in Fig. 2 that, as the object becomes magnified, it loses edge sharpness. This is the "penumbra effect," which results from the finite size of the x-ray source (Fig. 4).



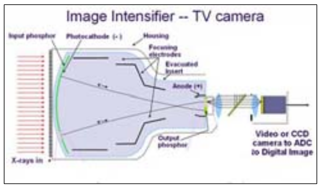
X-ray imaging modalities

For viewing, the x-ray "shadow" can either be exposed to a photographic film or be converted to a video image. Different devices are used to convert the x-ray image to a video or fluoroscopic image. Thomas Edison invented the first fluoroscope in 1896 when he discovered that Calcium Tungstate acted as a *scintillator* and fluoresced when exposed to x-rays. The technology has since progressed somewhat.

Today, the two basic fluoroscopic modalities can be described as static imaging and dynamic imaging. Both depend on a scintillator to convert the x-ray image to a light image. The flat panel imager is basically a scintillator coated onto a CCD array that produces static fluoroscopic images (Fig. 5); that is to say, a series of still x-ray images.

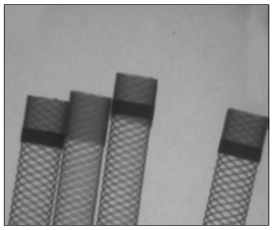


Dynamic, or real-time, fluoroscopy produces x-ray movies. Dynamic imaging fluoroscopes employ a scintillator coupled to an image intensifying device that amplifies the light image and presents it to a video camera for display (Fig. 6). Other imaging modalities include Computerized Radiography, wherein the x-ray image is stored on a "storage phosphor" and read out with a laser; CT or computerized tomography, wherein the image is mathematically reconstructed from many measurements of the transmission value of a pencil beam of x-rays.

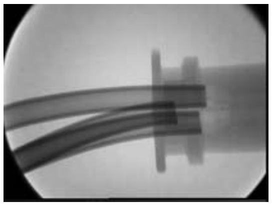


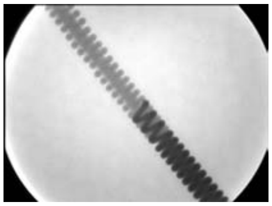
How x-ray inspection is used in medical device manufacturing

In the most obvious of applications, x-ray inspection is used to detect the presence or absence of catheter and stent *radio-markers*, even after packaging (Fig. 7, 8).



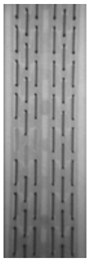
Increasingly, injection molders are using x-ray inspection as a quality assurance instrument in the development and production of molded medical components. For catheter



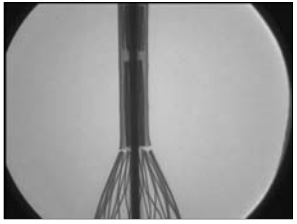


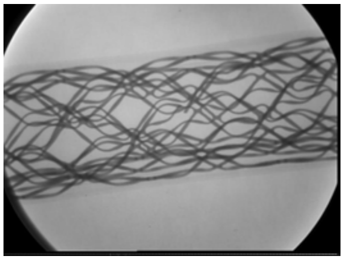
hubs, x-ray inspection is ensuring that lumens are properly seated and that there are no voids (Fig. 9, 10).

Even in the molding of PEEK (polyetheretherketone) implants, which are formulated to exhibit x-ray transparency, sensitive x-ray imaging technology detects voids (Fig. 11). In the manufacture of surgical staples, x-ray inspection is ensuring the presence of all staples after packaging (Fig. 12, 13), and to assure the completeness of surgical trays.

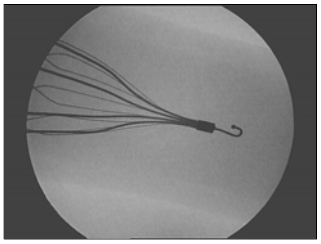


In the development of stents, high-resolution magnification fluoroscopy permits the observation and fluoroscopic video recording of the stent deployment as an “x-ray movie” (Fig. 14). In addition, stent wire breaks following fatigue testing can be detected. For this application, the detection of the break requires observing the stent with dynamic fluoroscopy as it rotates slowly. In this way, the complete wire structure can be observed (Fig. 15).

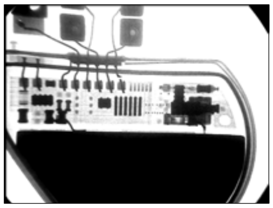




High-resolution magnification fluoroscopy has also contributed to the research and development of vena cava filters. In the laboratory, it has allowed researchers to observe and video record the action of a filter design in snaring simulated blood clots in an excised pig’s vena cava (Fig 16a).



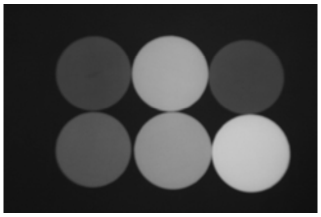
X-ray inspection has contributed even more significantly to the manufacture and quality assurance of implantable devices such as pacemakers, defibrillators and batteries. The newer, high-resolution magnification fluoroscopic technology can detect wire breaks and tenuous electrical attachment (Fig. 16b).



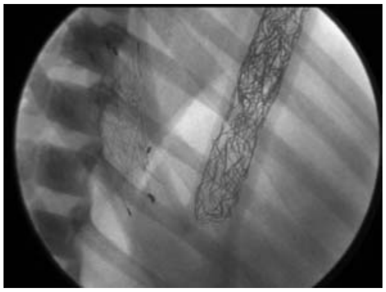
Designing for x-ray fluoroscopic inspection

When anticipating the use of real-time x-ray systems in the development and quality assurance of medical devices, a number of factors need to be considered. Primary among them is x-ray opacity, or radiopacity.

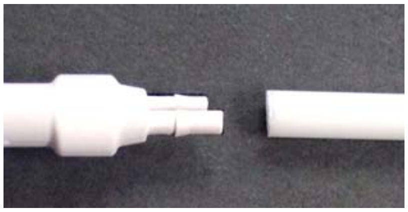
Different materials have different radiopacities. This is illustrated by comparing the radiopacity of various polymeric materials (Fig. 17a, 17b). It is important to note that an object of high

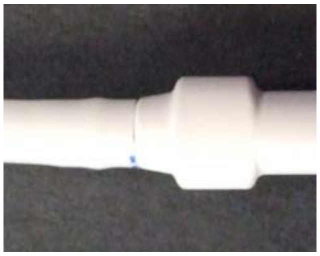


radiopacity can veil the details of an object of low radiopacity, regardless of whether one object is in front of or behind the other.

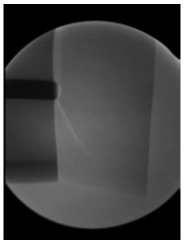


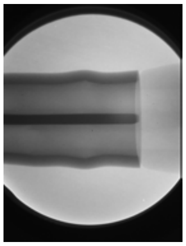
Stent development offers an example of designing for x-ray inspection of devices used in angiographic procedures. In Fig. 18, the difference in radiopacity is seen in the fluoroscopic images of nitinol (nickel-titanium) and stainless steel stents in a preserved rat. The nitinol stent on the left has visibly less radiopacity than the stainless steel stent on the right, requiring the nitinol stent to have platinum markers on the tips for fluoroscopic detection. Because radiopacity is a function of the atomic weight of the device’s constituent elements, the platinum tips, having higher atomic weight, add radiopacity.



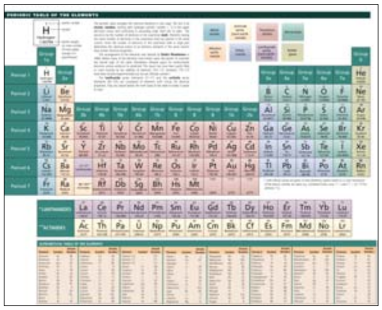


In a case study, the medical device shown in Fig. 19 consisted of a flexible tube on the left and a molded connector on the right. The tube is intended to be assembled to the connector, as shown in Fig 20. On assembly, visual inspection reveals cracks in the connector prongs. Since the tubing has been radiopacified while the connector has not, after assembly, the cracks in the lower opacity connector prongs (Fig 21) are obscured by the higher opacity tube (Fig 22).

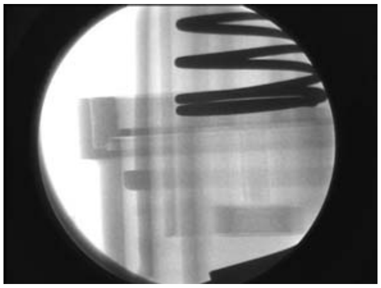


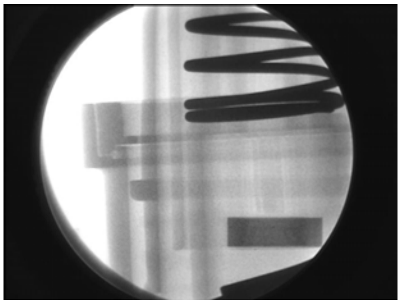


The relative radiopacity of a material can be anticipated by the atomic weight of the constituent elements of that material (Fig. 23). Barium and Bismuth have atomic weights close to lead and tungsten, accounting for their high radiopacity. Therefore, the radiopacity of a polymer can be enhanced through the use of inert additives such as Barium Sulfate or Bismuth Trioxide.



As an example, in the design of a critical drug delivery device, it was found that an internal, moving plastic component needed to be x-ray inspected carefully as part of a quality assurance program. At an early stage of development, opacifying the polymer was considered and implemented successfully. The difference is shown in Figs. 24 and 25.





Conclusion

X-ray inspection is being used increasingly in the development and manufacture of medical devices. However, the factors affecting the x-ray shadow are not always clearly understood by users, which can lead to misinterpretation of the x-ray image. Just as radiologists must know the anatomy thoroughly before they can interpret the radiograph, so must medical device manufacturers understand the nature of their devices' constituent parts and how they will interact with the x-ray inspection process. By learning how to design for, interpret and use x-ray inspection, in addition to other quality assurance instrumentation, medical device manufacturers can demonstrate their commitment to Good Manufacturing Practices.

Gil Zweig is president of Glenbrook Technologies, which provides x-ray inspection systems to the electronics, medical device and small animal research industries.