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Application News

Microfocus X-Ray CT System

Case Study of Observing Syringes with an inspeXio™ SMX™-225 CT FPD HR Plus System

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User Benefits

- Non-destructive and easy inspection of fit between parts in product assemblies and inclusions inside sealing materials.
- Analysis of product wall thickness and visualization with 3D imaging.

■ Introduction

Syringes are medical devices used to inject drugs into the human body. Because such devices are used for the human body, their safety and reliability are crucial. If a gap or irregularity in the product allows foreign material or air bubbles to get into the drug, it could result in a medical accident. Therefore, it is important to thoroughly inspect the fit between parts in the product assembly and the interior of sealing materials. In addition, since medical devices require reliability, It is also important to reduce any variability in product quality.

Because X-ray CT systems can non-destructively visualize the interior of objects in three dimensions , they are ideal for observing the fit between parts in products and analyzing inclusions.

This article describes a case study of analyzing the component parts and assembly status of a syringe with a inspeXio SMX-225CT FPD HR Plus microfocus X-ray CT system (Fig. 1).

Fig. 1 inspeXio SMX-225 CT FPD HR Plus Microfocus X-Ray CT System

■ Fluoroscopic Observation of the Syringe

Figs. 2-A and B show photographs of the syringe and needle unit, whereas C and D are fluoroscopic images. The syringe assembly consists of a needle unit, gasket, barrel, and plunger, and furthermore the needle unit can be classified into needle, seal, and hub. Fig. 2-C is a fluoroscopic image of the syringe assembly, and Fig. 2-D is a fluoroscopic image of the needle tip area indicated with a red box. In fluoroscopic images, the denser or thicker the object, the darker it appears since it is more difficult for X-rays to penetrate. As shown in Figs. 2- C and D, the inspeXio SMX-225CT FPD HR Plus microfocus X-ray CT system allows the magnification to be changed so that the product can be observed via any field of view, from the entire product to a specific micro-area, without disassembling the product.

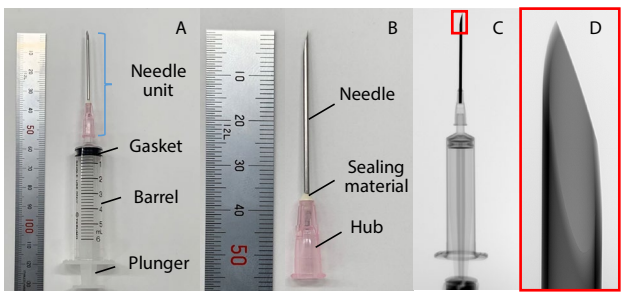

Fig. 2–A: External Image of the Syringe B: External Image of the Needle Unit
C: Fluoroscopic Image of the Syringe
D: Fluoroscopic Image of the Needle Tip

■ Observation of Seal Surfaces between the Barrel and Gasket

A rubber sealing material called a gasket is attached to the tip of the plunger. The gasket observed in this study has a two-stage seal structure with an upper and lower sealing edges that prevent leakage.

Fig. 3 shows unrolled cylindrical cross-section images of a syringe created with the 3D analysis software VG STUDIO MAX. By changing the unrolling position, indicated by the purple lines, cross-section images of ① the gasket, ② the gasket/barrel seal surfaces, and ③ the barrel can be displayed. The cross-section position is indicated by the purple line in corresponding cross-section images with a red border in Fig. 3, where the cross-section radius increases in ascending order of cross-section number ①, ②, and ③.

Yellow arrows indicate an intentional cut in the gasket that was made with scissors. The images show that the cut extends to near the center of the lower gasket seal. In this manner, by using an unwrapped cylindrical section image, it is possible to observe the state of the gasket/barrel seal surfaces.

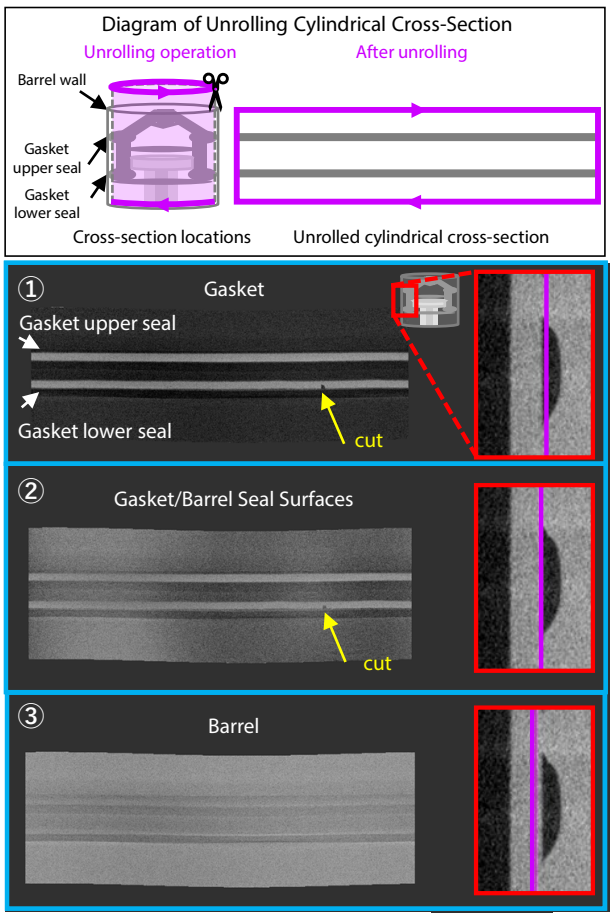

Fig. 3 Unrolled Cylindrical Cross-Section Images of Gasket and Barrel

■ Observation of Needle Sealing Material

To prevent leakage of drug solution and contamination by foreign matter, the gap between the needle and needle hub is sealed with adhesive. If voids are created during sealing, cracks may occur starting from adjacent voids.

Fig. 4-A shows a three-dimensional image created from cross-section images, where voids appear as white dots inside the sealing. Fig 4-B shows the voids color-coded based on void size, where large voids are indicated in red and small voids in blue, which allows checking the location and size of voids. Since voids generally extend in three dimensions, X-ray CT systems are ideal for observing voids.

Fig. 5 shows unrolled cylindrical cross-section images of the sealing material, with the cross-section radius increasing in ascending order of cross-section number ①, ②, and ③. These cross-section images enable the distribution of sealing material to be observed.

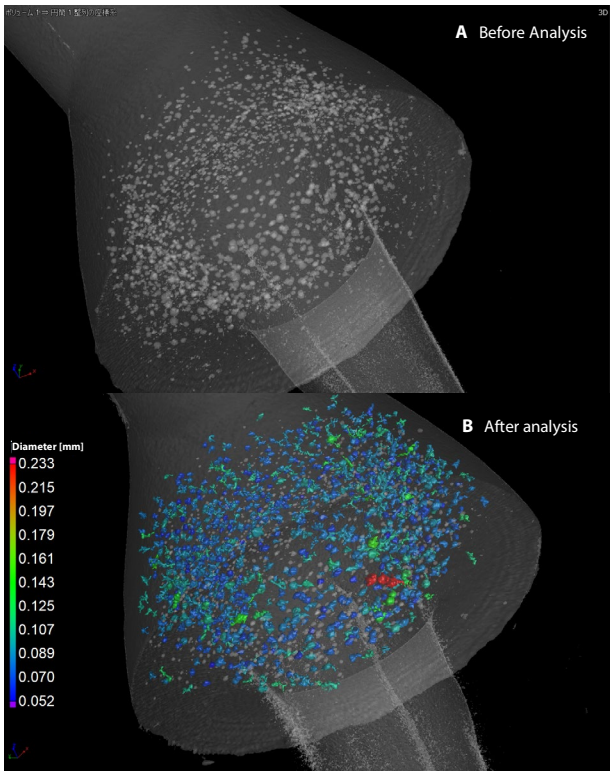

Fig. 4 Sealing Material Void Analysis Images

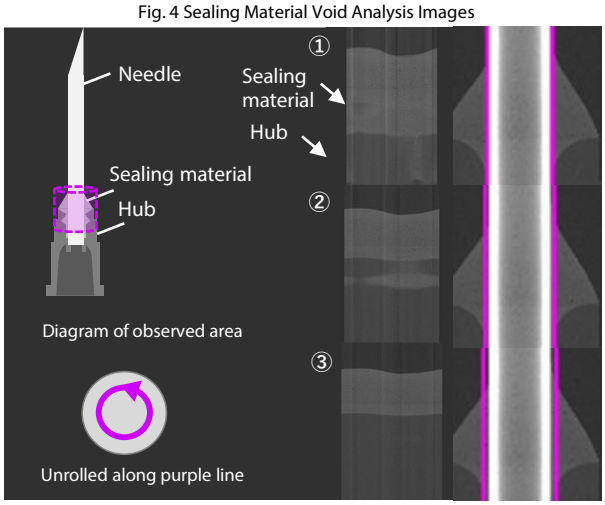

Fig. 5 Diagram of Unrolling Cylindrical Cross-Sections of Sealing Material

■ Observation of Syringe Needle

The needle is formed by stamping out a thin metal sheet with a press machine, and then rounding and stretching the sheet in stages to form a cylindrical shape. Inspection of needles is essential because any burrs or scratches from that process can cause pain and could leave residual metal fragments in the body.

Fig. 6 shows a three-dimensional color-coded image of needle wall thicknesses created from cross-section images. Thick areas are displayed in red and thin areas in blue. Although the needles appear to be uniform, the analysis results show that there are difference of about 10 µm in wall thickness. Also, there are linear scratches in the areas indicated by the white arrows.

As shown by this image, wall thickness analysis with three-dimensional images enables all thickness differences to be observed at the same time, making it easy to locate scratches or other non-uniformities.

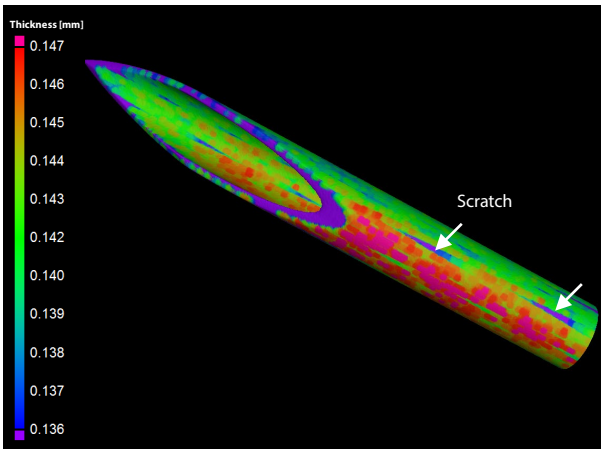

Fig. 6 Thickness Analysis Image of Commercial Syringe Needle

■ Conclusion

As presented in this article, the inspeXio SMX-225CT FPD HR Plus microfocus X-ray CT system can analyze the entire syringe, including checking the fit between parts, identifying voids, and checking the wall thickness of each part by changing the magnification. Although this article described the observation of simulated defects, actual products can be inspected in a similar manner.

Therefore, this system can be used for a variety of applications involving inspection or analysis of medical devices that require high reliability.

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