

FDA clearance for the Planmed XFI® full-body weight-bearing CT scanner

*The United States Food and Drug Administration (FDA) has issued a 510(k) clearance letter for the **Planmed XFI®** full-body CT scanner on September 26, 2025. Planmed XFI is the first cone-beam computed tomography (CBCT) system in the world that can be used to image the entire human body in either an upright or supine position.*

The Finnish medical imaging company Planmed is pleased to introduce and bring **Planmed XFI®**, the world's first full-body weight-bearing CT, to the U.S. market. The Planmed XFI system can image the entire body, both lying down and under natural load. It will bring views previously not seen in diagnostic imaging to the disposal of medical professionals, helping them in their most important task – making an accurate diagnosis.


Planmed XFI is the newest member of the renowned Planmed cone-beam computed tomography (CBCT) family. The scanner has been designed to find subtle fractures and misalignments during the first visit to the clinic. CBCT technology offers insights into conditions that are commonly missed when only using conventional methods, such as 2D radiographs.

Planmed XFI is a unique solution to the challenge of detecting problems that are not apparent when the body is at rest; it provides fast 3D imaging at the point of care. The scanner delivers ultra-high resolution and patient adaptability and can be used for both pre-and postoperative imaging.

“Planmed XFI is the first and only full-body CT system in the world that can image seated, supine, and standing patients. We are excited that this innovative, low dose orthopedic imaging system is now available in the U.S. We are confident that it will be well received,” states **Jan Moed**, Managing Director of Planmed Oy.

Planmed's products are well-known for their exquisite design, user ergonomics, and image quality. The U.S. subsidiary Planmed USA, Inc., located in Charlotte, NC, is responsible for the sales, marketing, and tech support for the Planmed products in North America. “We are very pleased to expand our CT imaging equipment line. Many of our customers have been looking forward to this clearance,” continues Moed.

Planmed XFI will be on display at the RSNA Annual Meeting starting on November 30, 2025, in Chicago, IL.

 Planmed Oy Planmed XFI is FDA 510(k) cleared (K250318), pending CE mark approval

Planmed XFI is not cleared for imaging the head in the US

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Planmed Oy and Planmeca Group

Planmed Oy dedicates its effort to the development and manufacturing of advanced imaging equipment and accessories that provide a unique combination of image quality and ease of use for medical imaging professionals. The company offers products for

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mammography and orthopedic imaging that are known for their outstanding imaging performance, user-friendliness and ergonomics.

Planmed Oy is part of the Finnish Planmeca Group, which consists of several healthcare technology brands, each committed to innovation and design. With 4,400 employees worldwide, Planmeca Group companies achieved a combined turnover of EUR 1.2 billion in 2024.

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