PAXMAN
PIONEERS IN SCALP COOLING

PAXMAN announces the acceptance of the Paxman Limb Cryocompression System (PLCS) into the FDA's Safer Technologies Program (STeP).

Paxman announces today that the U.S. Food and Drug Administration (FDA) has accepted the Paxman Limb Cryocompression System (PLCS) into the FDA's Safer Technologies Program (STeP).

The FDA's Safer Technologies Program (STeP) is a voluntary initiative designed to accelerate the development and clearance of medical devices that have the potential to reduce known risks associated with current treatments for non-life threatening conditions.

Paxman submitted the STeP Designation Request Q240974/S002 in August 2025. Confirmation that the PLCS meets the eligibility factors for STeP is a significant milestone in Paxman's regulatory pathways towards FDA clearance of this new technology.

Chemotherapy-induced peripheral neuropathy (CIPN) is a severe dose-limiting toxicity of paclitaxel and docetaxel, which are both widely used drugs for the treatment of common cancers including breast, ovarian, endometrial, lung, and gastric cancers. CIPN is an unseen, debilitating, and lifelong condition that severely impacts the quality of life of cancer patients.

Acceptance into STeP underscores the innovative potential of the Paxman device to address this important unmet clinical need of reducing the incidence and severity of CIPN in cancer patients receiving systemic neurotoxic chemotherapy or combination therapy.

Richard Paxman, CEO comments, "Inclusion in STeP not only highlights the promise of the new Paxman technology but reflects the FDA's confidence in our commitment to safety, quality, and innovation. We look forward to continued development and regulatory progress as we move toward future submissions, clinical milestones and ultimately commercial availability of the device to help improve the quality of life for cancer patients around the world."

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About Us

The Paxman Scalp Cooling System has been developed by the Paxman family to reduce hair loss in breast cancer patients undergoing chemotherapy. The concept behind the system came when the mother of four, Sue Paxman, experienced first-hand the trauma of chemotherapy-induced hair loss. In 2025, PAXMAN AB acquired Dignitana, merging to form a stronger united company.
Today, PAXMAN's portfolio includes both the Paxman and DigniCap systems with several thousand installations in hospitals, clinics and treatment centres worldwide, reaffirming PAXMAN as the leading global supplier of Scalp Cooling technology.
PAXMAN AB (publ) has its headquarters in Karlshamn (Sweden). Subsidiaries of the PAXMAN Group are Paxman Coolers Limited (Huddersfield UK), Paxman Inc. (Houston, Texas US), Paxman Canada (Toronto, Ontario CA), Dignitana AB (Lund, Sweden), Dignitana Inc. (Dallas, TX US), and Dignitana S.r.l. (Milan, IT).

The PAXMAN share is listed on Nasdaq First North Growth Market.
FNCA Sweden AB is the company's Certified Adviser.

Attachments

PAXMAN announces the acceptance of the Paxman Limb Cryocompression System (PLCS) into the FDA's Safer Technologies Program (STeP).