



Dignitana receives FDA clearance for DigniCap Delta

On June 26th Dignitana announced that the United States Food and Drug Administration cleared DigniCap Delta[®] for use by U.S. health care providers.

The new device is the fourth generation of The DigniCap[®] Scalp Cooling System and is indicated to prevent chemotherapy-induced hair loss in patients with solid tumors. European installations of DigniCap Delta began last month after the device received CE Marking in March 2019.



DigniCap Delta uses solid state cooling for precise temperature control in an advanced and redesigned model of the 2015 FDA cleared DigniCap Scalp Cooling System. The new device delivers significant improvements over other scalp cooling systems on the market:

- **Single patient use** - New cap system gives each patient a flexible Cooling Wrap and an adjustable Thermal Cap designed to optimize scalp cooling outcomes and minimize clinic storage needs.
- **Smaller size** - Streamlined profile is 54 percent smaller than the previous unit.
- **Reduced nursing time** - Intuitive interface and technical advances provide up to an 80 percent reduction in nursing time per patient infusion versus the existing device.

DigniCap Delta is now available to medical centers in the United States and deliveries are being scheduled. The current DigniCap device is already in use in 30 states in the U.S. and in 37 markets globally.

The addition of a disposable cap for single patient use provides a new global revenue stream for the company. Existing revenue comes from leasing fees, treatment fees to patients, service agreements and machine sales outside the United States. [Read full press release here.](#)

Investor Relations Communication

- The monthly In Brief newsletter is typically posted in the first half of the month, however publication date may be dependent on when some content can be released. [Subscribe here](#) to receive the newsletter by email.
- The email address for investor relations is investorrelations@dignitana.com
- Per MAR guidelines, company announcements are posted at www.dignitana.se and distributed to Nasdaq OMX, First North Stockholm, Nordic News Agencies, EU Transparency, and financial websites.

Dignitana signs Atrium Health for DigniCap Delta

Dignitana has signed a contract with Atrium Health in the U.S. to provide DigniCap Delta to Atrium Health's Levine Cancer Institute sites. Installation is expected in September.

Atrium Health is a leading healthcare provider in the U.S. and the first new customer with multiple locations to contract with Dignitana for the DigniCap Delta device. [Read full press release here.](#)

DigniCap in the United States

The DigniCap Scalp Cooling System is now [available](#) at medical centers in 30 states. New locations since the last newsletter include:

- Dignity Health Dominican – Santa Cruz, California
- Inova Schar Cancer Institute Fairfax West Infusion Center – Fairfax, Virginia
- New York Cancer and Blood Specialists Patchogue Medical Oncology – Patchogue, New York
- New York Cancer and Blood Specialists Setauket Medical Oncology – Setauket, New York
- Ochsner High Grove – Baton Rouge, Louisiana
- Cancer Care Associates of York – York, Pennsylvania
- Atrium Health, Levine Cancer Institute Morehead – Charlotte, North Carolina
- Florida Cancer Specialists – Tallahassee, Florida
- Cedars Sinai Towers – Los Angeles, California

Scalp Cooling Promoted at MASCC Conference

Dignitana co-sponsored the Scalp Cooling Symposium at the Multinational Association for Supportive Care in Cancer (MASCC) Annual Meeting, held June 21-23 in San Francisco, California.

The session reviewed recent scalp cooling research and addressed the therapy's impact on quality of life.



22 June 2019 – Panel for the Scalp Cooling Symposium at MASCC: Dr. Mario Lacouture, Memorial Sloan Kettering (USA); Dr. Hope Rugo, University of California San Francisco (USA); Jaime Zapata, patient UCSF (USA); Dr. Fran Boyle, Mater Hospital (Australia); and Dr. Corina van den Hurk, Integraal Kankercentrum Nederland (The Netherlands)