



## Media Guidelines for Promotion of The DigniCap® Scalp Cooling System

We are delighted to be working with you to get the word out in your community about the benefits and availability of The DigniCap Scalp Cooling System. DigniCap is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors. In the pivotal trial 66% of patients kept the majority of their hair and the device received FDA clearance in 2015. DigniCap is a proven way to safely and effectively minimize hair loss from chemotherapy.

This reference sheet provides you with a few branding guidelines and attribution stipulations. Please follow these points and let us know if we can provide you with assistance.

### Important Reminders

#### DigniCap is FDA Cleared not Approved

There is a difference between FDA "clearance" and FDA "approval." For low-risk medical devices like the DigniCap system, the correct terminology is "FDA cleared."

#### DigniCap Trademark

DigniCap is a registered trademark and any reference to The DigniCap® Scalp Cooling System should include the registered trademark symbol (®) in the first instance.

#### Product References

The product should be referred to as "DigniCap" or "The DigniCap Scalp Cooling System" DigniCaps (plural) and Dignicap (no capitalization) are incorrect.

DigniCap Delta® is the latest generation of The DigniCap® Scalp Cooling System. The correct name for this model is "DigniCap Delta" and not simply "Delta" or "the Delta."

#### Scalp cooling vs. cold caps

Since the 1970s patients have used various types of "cold caps" to protect hair follicles. These are sometimes called chemo caps, gel caps or ice caps. These caps are filled with a gel, cooled with dry ice or special freezers, and require that someone change the caps for the patient every 20 minutes. This is a very uncomfortable process for the patient and a lot of work for whoever is changing the caps. More importantly, these older manual gel caps do NOT have FDA clearance. There is no way to regulate the temperature of the caps touching the scalp, so "cold caps" do not meet the safety requirements to receive FDA clearance.

#### Messaging Suggestions

- DigniCap has been used in the U.S. since receiving FDA clearance in 2015 and has been widely used outside the U.S. since 2009.
- DigniCap was the first scalp cooling device to receive FDA clearance. In December 2015, The DigniCap Scalp Cooling System was FDA cleared to treat women with breast cancer undergoing chemotherapy.
- In July 2017, the FDA expanded the clinical indications for DigniCap to include men and women with solid tumor cancers undergoing chemotherapy. DigniCap was the first scalp cooling system to receive this expanded clearance.
- Patients with solid tumors such as those associated with breast, prostate, ovarian, uterine, lung and other tissues can consider scalp cooling during chemotherapy.
- In the U.S. pivotal trial 66.3% of patients with breast cancer kept at least 50% of their hair, compared to a control group where all patients experienced significant hair loss.
- Treatment success is measured by a patient not feeling the need to wear a head covering such as a wig, scarf or hat.
- Hair loss is considered the most troublesome side effect of chemotherapy. It is estimated that 10-15% of patients decline prescribed chemotherapy for fear of losing their hair.
- Scalp cooling is not about vanity. Patients who choose to use scalp cooling typically do so for reasons related to protecting privacy, preserving dignity, supporting self-esteem, and maintaining control over some aspect of their treatment.

# DIGNICAP<sup>®</sup>

*Hair loss is no longer inevitable*

- In the U.S., scalp cooling is not yet universally covered by insurance, but some patients are receiving reimbursement at varying levels. Updates are posted at [www.dignicap.com/insurance](http://www.dignicap.com/insurance).
- Dignitana is a founding partner of HairToStay ([www.HairToStay.org](http://www.HairToStay.org)), a 501(c)3 national non-profit foundation that provides financial assistance for scalp cooling to U.S. patients with demonstrated need.
- DigniCap is manufactured by Dignitana AB. The company is based in Lund, Sweden but operations headquarters are in Dallas, Texas.

## Sample Media Coverage

A comprehensive list of DigniCap media coverage is online [www.dignicap.com/media-coverage](http://www.dignicap.com/media-coverage)

## Clinical Media:

[NIH National Cancer Institute](#)

[Journal of the American Medical Association Feb 2017](#)

## National Coverage:

[New York Times](#)

[CNN](#)

[Forbes](#)

[The Knot](#)

## U.S. Regional Features:

[Kansas City](#)

[Denver](#)

## Images

DigniCap images are available at [www.dignicap.com/product-images](http://www.dignicap.com/product-images) Contact us for other specific image needs, high resolution images, or video b-roll.

## Locations

A list of current locations providing DigniCap can be found at <https://dignicap.com/locations/>

## Social Media Collaboration

Like/share/follow us on [Facebook](#), [Instagram](#), [Twitter](#) and [YouTube](#) (@DigniCap). We will be happy to share your content. If you would like to collaborate on a social media campaign, please let us know.

## Media Relations Support

The Dignitana public relations team is available to help you plan and implement media outreach to publicize the availability of DigniCap at your facility.

## Dignitana Contacts

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