



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, the first name in scalp cooling. This medical device was rigorously tested in multi-center clinical trials and was first cleared by the FDA in 2015. It is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

This reference sheet provides you with a few branding guidelines and attribution stipulations that we are required to maintain by the FDA. Please consider these points and let us know if you have any questions, or 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

Please refer to the product as "DigniCap" or "The DigniCap Scalp Cooling System" DigniCaps (plural) and Dignicap (no capitalization) are incorrect.

Messaging Suggestions

- 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 expanded clearance.
- With expanded clinical indications from the FDA, oncologists treating cancer patients with solid tumors such as those associated with breast, prostate, ovarian, uterine, lung and other tissues can consider scalp cooling treatments for patients receiving chemotherapy infusions.
- In the clinical trial, 66.3% of patients with breast cancer kept at least 50% of their hair.
- In the clinical trial, it was concluded that scalp cooling using DigniCap prevented hair loss in 66.3% of patients with breast cancer receiving adjuvant chemotherapy 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.
- Scalp cooling is not yet universally covered by insurance, but some patients are receiving reimbursements at varying levels. The latest updates are posted at www.dignicap.com/insurance.
- Dignitana is a founding partner of **HairToStay** (www.HairToStay.org), a 501(c)3 national non-profit foundation that subsidizes scalp cooling therapeutics for the prevention of hair loss related to chemotherapy.
- 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 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 is manufactured in Sweden by Dignitana AB. Headquartered in Dallas, Texas, Dignitana, Inc. is the U.S. subsidiary of Dignitana AB.

Sample Media Coverage

A comprehensive list of DigniCap media coverage is online 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](#)

Regional Features:

[Kansas City](#)

[Denver](#)

Images

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

Locations

A list of current location providing DigniCap can be found at www.dignicap.com/locations-list

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.

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