PATIENT INFORMATION

The DigniCap® Scalp Cooling System

FDA cleared for men and women with solid tumor cancers

DIGNICAP®

Hair loss is no longer inevitable

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Scalp Cooling Historical Timeline

- **1970s** – First known use of manual gel caps for scalp cooling
- **1999** – DigniCap invented in Sweden by nurse Yvonne Olofsson
- **2001** – DigniCap available in Europe
- **2009** – Dignitana publicly traded in Sweden
- **2010** – DigniCap registered in Mexico, Russia and South Korea
- **2011** – DigniCap registered in Canada and Colombia

Hair loss is not inevitable.

Hair loss is a common side effect of many chemotherapy drugs. The DigniCap Scalp Cooling System minimizes hair loss from certain chemotherapy treatments for men and women with solid tumor cancers such as those associated with breast, prostate, ovarian, uterine, and other tissues.

DIGNICAP – THE FIRST FDA CLEARED SCALP COOLING SYSTEM

The DigniCap Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced hair loss in cancer patients with solid tumors.

The DigniCap Scalp Cooling System >

2012 DigniCap registered in Australia and Singapore

2013 DigniCap US multi-center clinical trial

2014

2015 DigniCap study presented at ASCO. DigniCap received FDA clearance for women with breast cancer

2016 Quality of Life data from DigniCap study presented at SABCS

2017 DigniCap available in Middle East

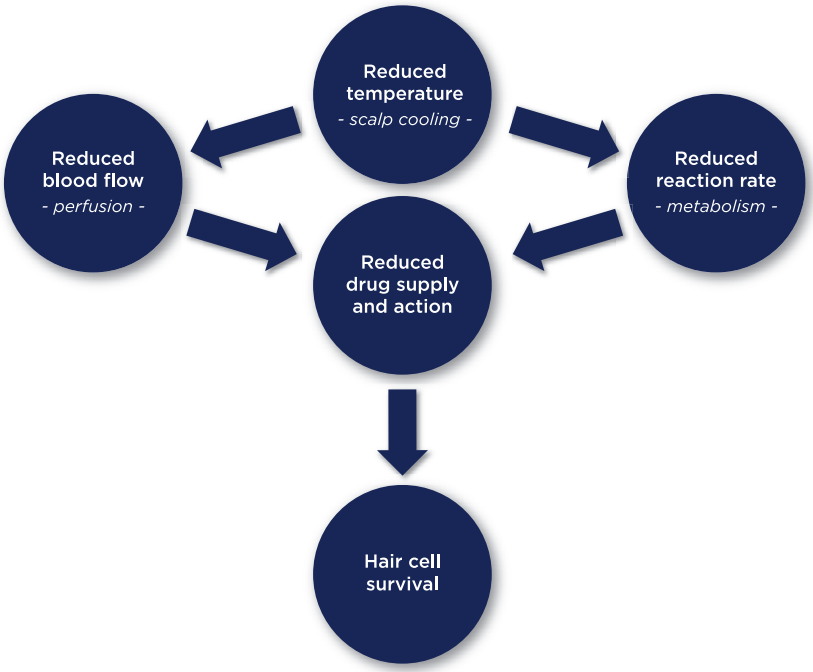
2017 DigniCap study published in JAMA. DigniCap received expanded FDA clearance for men and women with solid tumor cancers

WHAT IS SCALP COOLING?

Some chemotherapy drugs can damage your hair. Cooling of the scalp is a proven approach to reduce chemotherapy-induced hair loss. It has been used successfully by tens of thousands of patients worldwide.

During scalp cooling two things happen to minimize hair loss from chemo:

1. **Reduced blood flow** – vasoconstriction in the localized scalp area limits the amount of chemotherapy agent delivered to the scalp and hair follicles.
2. **Reduced reaction rate** – lower scalp temperature decreases metabolism causing normal cellular activity in the localized scalp area to slow dramatically. Fewer chemotherapy agents are then absorbed by the hair cells and damage is significantly reduced.



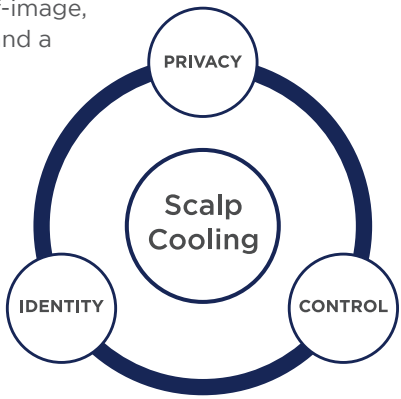
"Not having that reminder every time you look in the mirror that you are sick, and you look normal to your friends and family, made the chemo much more bearable. Instead of illness, I saw myself. Many people had no idea I had cancer."

- Carolyn Dempsey, New York, NY

WHY SCALP COOLING MATTERS

Many cancer patients rate hair loss as one of the most devastating side effects of chemotherapy. It is an unwelcome reminder of disease that can negatively affect self-image, confidence, overall sense of well-being and a patient's attitude toward treatment.

Hair loss is no longer inevitable. The DigniCap Scalp Cooling System helps patients maintain privacy, self-esteem and control during a critical period of treatment.



My DigniCap Story - *by Donna Tookes, Stamford, CT*

My hair has always been my "signature" feature, ever since I turned prematurely silver at age 25, so when I was diagnosed with cancer at age 59, I was devastated. I knew chemotherapy meant my hair would inevitably fall out. I walked out of the room when the doctors told me. I felt dizzy, weak at the knees, because I just envisioned myself very skinny with no hair, going through chemo.

With the use of the cap, I was able to keep my hair and could choose to stay more private about my battle with cancer. I didn't have to walk into the grocery store and have to explain what I was going through to the same people who had complimented me on my beautiful hair for so many years. I still looked like myself. For some women, losing their hair is a badge of courage, but for me it was a very big issue. I'm so grateful to DigniCap.

THE DIGNICAP SCALP COOLING SYSTEM

The DigniCap Scalp Cooling System consists of a computerized cooling unit and an attached cooling cap with patented integrated sensors. Temperature-regulated coolant continuously circulates through specially designed channels in the cooling caps.

The ability to maintain continuous, direct contact between the cooling cap and the scalp for a consistent treatment temperature is a key factor in the effectiveness of DigniCap.

System Features

- System detects temperature deviations and continuously makes adjustments based on cap sensor feedback.
- Touch screen interface simplifies operation and allows settings to be altered for various chemotherapy regimens.
- Independently controlled, continuous cooling systems enable simultaneous treatment of two patients.
- Gradual cool-down from room temperature provides patient comfort.

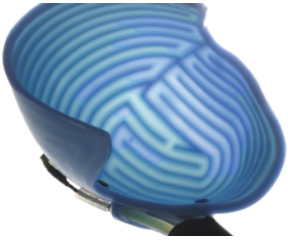
"Cold-cap therapy is empowering. It allows women to maintain their self-esteem and sense of well-being, as well as to protect their privacy. Without these caps, 100% of the women lose their hair by the second treatment."

- Tessa Cigler, MD, MPH
Assistant Professor Clinical Medicine,
Weill Cornell Medical College, Weill Cornell Breast Center
New York-Presbyterian Hospital

THE DIGNICAP SCALP COOLING SYSTEM

Cap Features

- Outer neoprene DigniTherm™ Click Cap provides a customized and secure fit that maintains direct contact and the ideal treatment temperature.
- Four cap sizes for individualized fit.
- Contoured shape leaves patient's ears uncovered for comfort and ease of hearing.
- Cap is put on at room temperature for a comfortable transition.
- Cap can be easily detached from the cooling unit for bathroom breaks.
- Built-in security sensor ensures scalp temperature always remains above 32° F/0° C.

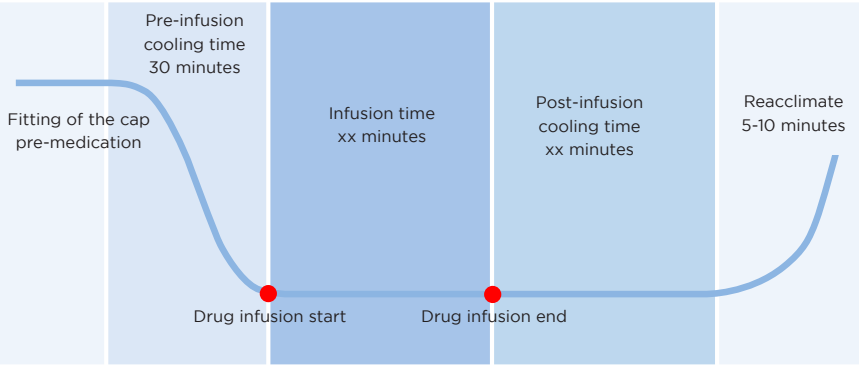


WHAT TO EXPECT DURING TREATMENT WITH DIGNICAP

DigniCap will be used during each cycle on the day of chemotherapy administration.

The cap is connected to the cooling and control unit, so you will need to be connected to the system during treatment. The clinician may disconnect the cap from the system for brief restroom visits. During the break, the cooling cap and the outer neoprene cap remain on your head.

DigniCap Treatment Cycle



The chemotherapy agent is still active in the bloodstream following the infusion. Therefore, the scalp cooling treatment continues for a cycle of post-infusion cooling. Depending on drug and dose, typically this will last from 90-180 minutes.

As shown in the table above, in addition to the actual infusion time, there is a 30 minute pre-infusion cooling period, as well as a 90-180 minute post-infusion time.

Consult the Getting Started Guide in your Custom Fit Kit for detailed information about fitting your cap and what to expect during treatments.

Detailed information also at DigniCap.com/patient.

"I just wanted my friends and family to treat me "normally" while I was going through devastating cancer treatment. When I went out, no one knew what I was going through. This helped me to keep a positive attitude and the strength to continue my treatments. I forged ahead with the rest of my chemo, surgery and radiation with such a positive attitude, which I honestly believe helped me recover much more quickly."

- Susan, New Jersey

MYDIGNICAP PATIENT PORTAL

myDigniCap.com

The Patient Portal is convenient place for you to connect with us directly, receive updates on scalp cooling, review your account, and share your experience. You will also find stories from other men and women that have used The DigniCap Scalp Cooling System.

As soon as you've scheduled your first chemotherapy appointment with your provider, visit myDigniCap.com to create your account. Instructions are in the Getting Started Guide that your doctor will provide.

Depending on the facility, payment will either be made to the facility or online through myDigniCap.com. *You must arrange for payment and give consent prior to each treatment.*

BEFORE YOUR FIRST TREATMENT

It is important for you to watch the training videos located at DigniCap.com/patient.

Watch the video several times until you are familiar with the capping process.

To see some of the recent media coverage of DigniCap visit DigniCap.com/media.

U.S.News & World Report · Chicago Tribune · allure · Popular Mechanics · Good Housekeeping · AARP · CNN · abc · NBC · CBS This Morning · The New York Times · HUFFPOST

HAIR CARE

Practical recommendations to minimize hair loss during chemotherapy in conjunction with scalp cooling:

- Wash your hair at home prior to scalp cooling/chemotherapy treatments as oily hair may affect the thermal contact. Do not use conditioner on the morning of treatment.
- Wash your hair no more than twice per week.
- Comb your hair with a wide tooth comb twice per day. Always comb your hair before washing to prevent tangles and matting.
- Let your hair dry naturally as much as possible. Avoid using heat tools, such as hair-dryers, curling irons, straightening irons, and hot rollers on your hair.
- Avoid harsh chemicals that can lead to dry hair, breakage, progressive hair thinning and hair loss.
- Most patients will experience a heavy shedding phase roughly 14-21 days from the first chemotherapy date.

All patients should review the detailed Hair Care Recommendations which can be found in the brochure in your Custom Fit Kit or online at DigniCap.com/haircare.

"For me, it's a very personal thing and with the DigniCap, I've responded really well so people who see me have no clue that I had cancer. One of the things I've always had going for me was a good head of hair. When cancer patients lose their hair it dramatically affects the way people treat them. All my wife's friends were just saying, 'Allen's never looked better'."

- Allen Wasserman, Weston, CT

SHARE YOUR STORY

Knowing you are not alone in your fight with cancer can be a great source of strength. You may find it liberating to document your journey, and your story may also help inspire others as they face their toughest challenge.

Send your DigniCap story to us at share@DigniCap.com.

My Story - *by Angela Farino, Irvine, CA*

I had injured my chest last fall when I was in a car accident, but the last thing in the world I expected was a cancer diagnosis. The medical staff was examining the area during an ultrasound when they discovered a tiny lump in my breast that turned out to be cancer.

I started a regimen of surgery, radiation and chemo-therapy right away. I wanted to keep my treatment private, but I knew that chemo would cause the telltale sign of hair loss. I heard that DigniCap had been successfully used on cancer patients in Europe for more than ten years and joined UCLA's clinical trial at the Jonsson Comprehensive Cancer Center.

During the process, I tolerated the scalp cooling very well, and my body was kept warm with an electric blanket.

Accepting the fact that I was going to lose my hair was very difficult because I felt as if I would be losing part of my identity. With the DigniCap, it allowed me to have control over something in a process where I really had no control.

AFTER CHEMOTHERAPY

Share your experience with scalp cooling and insurance at scalpcoolingsurvey.org.

FREQUENTLY ASKED QUESTIONS

Why does chemo cause hair loss?

Chemotherapy affects cells that are in the phase of division or growth. All the cells in the body may be affected by chemotherapy, not just the cancer cells. This means that even healthy cells, especially cells with a high growth rate, such as your hair, are likely to be affected by the chemotherapy.

When would I use The DigniCap Scalp Cooling System?

The DigniCap Scalp Cooling System will be used during each cycle of chemotherapy administration. Scalp cooling should begin with the first infusion of any chemotherapy that causes hair loss.

Will scalp cooling work for me?

Almost everyone can expect to experience some degree of hair loss during chemotherapy. Scalp cooling is an effective method for reducing the risk of chemotherapy-induced hair loss in men and women with solid tumor cancers. The outcome is dependent on several factors including the chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism and other medical considerations.

Scalp cooling has been evaluated mainly with regimens including taxanes (such as paclitaxel and docetaxel) and anthracyclines (such as doxorubicin and epirubicin). It's not always possible to know how effective the scalp cooling outcome will be until you try it. The effectiveness of scalp cooling with chemotherapy regimens that include sequential anthracycline and taxane chemotherapy in the same infusion day has not been well studied. Your clinician can tell you if scalp cooling is compatible and likely to be successful with your treatment.

"After 4 rounds of AC and 12 rounds of Paclitaxel in 135 days, I've finished chemo and saved my hair with DigniCap."

- Monika Dockendorf, Washington DC
#canceratthirty

How long does scalp cooling treatment last?

The DigniCap Scalp Cooling System is operated by hospital personnel and will be used during each chemotherapy session. Scalp cooling begins approximately 30 minutes before chemotherapy starts, continues during the infusion and must continue for a set period after the conclusion of treatment depending on the chemotherapy drug and dose, typically 90–180 minutes post infusion. After completion of the post-infusion cooling time, the cooling cap remains on your scalp for another 5-10 minutes while you re-acclimate to room temperature.

How does it feel?

Most patients tolerate scalp cooling with The DigniCap Scalp Cooling System very well. Common side effects include a feeling of coldness, headache, scalp pain and/or light-headedness. Your doctor can provide a pain reliever if you develop a headache. A warm drink and blanket can also help during treatments.

What should I bring with me to the hospital on the day of the scalp cooling treatment?

Your clinician can best tell you what you should bring on the day of the treatment. Suggestions are included on the Patient Instructions page of the Getting Started Guide.

Do I need a wig or head covering?

The use of a wig or head covering is a personal choice and may be desirable for reasons other than hair loss - for example, changes in hair color, hair texture, or hair quality, or for patients experiencing patchy hair loss or thinning.

How should I take care of my hair?

Scalp cooling can minimize hair loss during chemotherapy, but chemotherapy could cause scalp irritation, making the hair dry and brittle and more difficult to manage. For detailed hair care recommendations visit DigniCap.com/haircare.

Who should not use The DigniCap Scalp Cooling System?

Contraindications

Pediatric patients should not use The DigniCap Scalp Cooling System.

Adult patients with the following conditions and cancer types should not use The DigniCap Scalp Cooling System:

- Cold sensitivity
- Cold agglutinin disease
- Cryoglobulinemia
- Cryofibrinogenemia
- Cold urticaria
- CNS malignancies (either primary or metastatic)
- Squamous cell carcinoma of the lung
- Small cell carcinoma of the lung
- Cancers of the head and neck
- Hematological malignancies treated with curative intent by chemotherapy
- Skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma
- Solid tumor malignancies with a high likelihood of metastases in transit
- Patients who are scheduled for bone marrow ablation chemotherapy
- Patients who are scheduled to undergo skull irradiation
- Patients who have previously received skull irradiation

The DigniCap Scalp Cooling System is FDA cleared for men and women with solid tumor cancers.

Warnings

- Scalp and/or cutaneous metastases have been reported in patients with non-small cell lung cancer, colon cancer, renal cell carcinoma, ovarian cancer, and bladder cancer. Patients with advanced forms of these cancers may be more likely to experience scalp metastases with the scalp cooling system.
- Use of Scalp Cooling in the palliative setting in patients with metastatic cancer may also increase the risk for scalp metastases.
- Patients infused with taxanes and anthracyclines in the same infusion day have not been shown to respond to scalp cooling for reducing chemotherapeutic drug-induced alopecia. The DigniCap Scalp Cooling System should not be used in these patients.
- Scalp radiation can cause stenosis of small cutaneous vessels decreasing device effectiveness.
- The effectiveness of this device in patients who have received previous chemotherapy has not been evaluated.
- The risk of scalp-cooling may outweigh the benefits in patients receiving chemotherapeutic agents with low incidence of inducing alopecia.
- Long-term effects of scalp-cooling and risk of scalp metastasis have not been fully studied.
- Clinical studies have demonstrated variable success rates in patient reduction of chemotherapy-induced alopecia with scalp cooling since the outcome is dependent on multiple factors including chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism, and concomitant comorbidities. Data have shown that women who experience hair loss in spite of using scalp cooling might have worse quality of life than women who did not have scalp cooling.

The DigniCap Scalp Cooling System is a proven approach to reduce chemotherapy-induced alopecia, used successfully by thousands of patients worldwide to maintain privacy, self-esteem and control during a critical period of treatment.

CONSIDERATIONS AND WARNINGS

Adverse Events

Most patients tolerate scalp cooling with The DigniCap Scalp Cooling System very well. In the clinical study conducted in the U.S. for FDA clearance, three of 101 patients discontinued scalp cooling because of intolerance to the cooling.

Approximately half of the patients experienced a mild to moderate headache that was triggered or exacerbated by scalp cooling using The DigniCap Scalp Cooling System.

Mild scalp pain was experienced by the majority of the patients, but rarely required pain medications to control the pain. Up to 10% of patients may experience claustrophobia.

Clinical studies have produced variable success rates in patient reduction of chemotherapy induced alopecia with scalp cooling since the outcome is dependent on several factors including chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism, and concomitant comorbidities. Increasing age may decrease the effectiveness of the cooling cap. Data have shown that women who experience hair loss in spite of using scalp cooling might have worse quality of life than women who did not have scalp cooling.

Long Term Adverse Events

When using scalp cooling, less chemotherapy is distributed to the hair cells, and cancer cells could theoretically survive locally within the scalp area. There has been a concern for scalp and skin metastases when scalp cooling patients. Based on medical literature, scalp and skin metastases are rare occurrences regardless of cancer stage (scalp metastases as first sign of recurrence occurs in one out of 4,000 patients, and in one out of 100 patients who already have other sites of metastasis). The observed risk of scalp metastasis does not seem to differ between patients who have and have not used scalp cooling.

There is a theoretical possibility that the scalp may act as a reservoir for cancers which have a high likelihood of metastases traveling in the blood stream. While the patient wears the cooling cap up to 5 hours, cancer cells in your blood stream may be resistant to your immune system during transit through your cooled scalp and less susceptible to chemotherapy. These cells may then metastasize and alter your prognosis.

The long-term effect of scalp cooling has not been fully studied. Scalp cooling system may increase the risk of scalp metastasis, metastasis elsewhere in the body, or impact the natural course of the cancer.

ALTERNATIVE THERAPIES

The DigniCap Scalp Cooling System was the first device to receive clearance from the FDA to reduce the risk of hair loss during chemotherapy in men and women with solid tumor cancers. However, you should discuss with your physician whether any other treatments, or the use of a wig or other head covering, would be more appropriate for you.

PIVOTAL TRIAL – CLINICAL STUDY IN STAGE I AND II BREAST CANCER

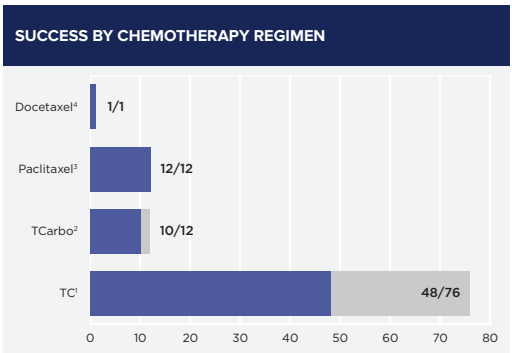
In 2015, after a rigorous review by the FDA, DigniCap was the first scalp cooling system to receive clearance in the United States.

Summary

It was concluded that the DigniCap Scalp Cooling System 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. Scalp cooling treatment was well-tolerated and no scalp metastases have been observed.

As Published

Association Between Use of a Scalp Cooling Device and Alopecia After Chemotherapy for Breast Cancer
Journal of the American Medical Association 2017; 317(6):606-614
Rugo, H; Klein, P; Melin, S; et al.



1. TC: Docetaxel/cyclophosphamide x 4-6
2. TCarbo: Docetaxel/carboplatin + HER2 targeted therapy x 4-6
3. Paclitaxel: Paclitaxel weekly x 12
4. Docetaxel + HER2 targeted therapy x 4-6

Scalp cooling is dependent on several factors including the chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism and concomitant comorbidities.

Conclusions

- The DigniCap System is highly effective in reducing chemotherapy-induced alopecia with clinically meaningful benefit.
- The DigniCap System prevented hair loss in 66.3% of patients with breast cancer receiving neo/adjuvant chemotherapy, compared to control where all patients experienced significant hair loss.
- Treatment was safe and well tolerated.

For more information on clinical studies visit DigniCap.com/research.

"It was a powerful experience to look healthy throughout chemotherapy and be treated as a healthy person by others. I identified as someone who was healing instead of someone who was sick."

- Deborah Cohan, MD, San Francisco, CA

RESEARCH OVERVIEWS

Solid Tumors

The DigniCap Scalp Cooling System has been shown to be safe and effective in reducing chemotherapy-induced alopecia in cancer patients with solid tumors.

As Published

The influence of various parameters on the success of sensor-controlled scalp cooling in preventing chemotherapy-induced alopecia.
Oncology Research and Treatment (Vol. 38. 2015, 489-495)
Schaffrin-Nabe, D, et al.

Scalp Metastases

The incidence of scalp metastases was low regardless of scalp cooling. This analysis suggests that scalp cooling does not increase the incidence of scalp metastases.

As Published

Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systematic review and meta-analysis.
Breast Cancer Research and Treatment, 2017: 163:199–205
Rugo, H, et al.

Multiple articles have also appeared in industry publications including: New England Journal of Medicine, Med Tech Intelligence, medGadget, Medical Plastic, and Oncology Nurse Advisor.

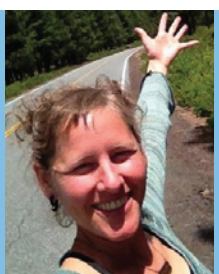
Quality of Life

Minimizing hair loss helps patients to preserve personal identity and self-esteem and appear normal as opposed to sick. Additionally, scalp cooling patients gain a much-needed sense of control in an otherwise overwhelming experience – even eliminating its often long-term negative psychological and social effects.

As Published

Body image in women with breast cancer using a scalp cooling system to reduce chemotherapy induced alopecia.
San Antonio Breast Cancer Symposium Abstract, December 2016
Cigler, T, et al.

For more information on clinical studies visit DigniCap.com/research.



FINANCIAL ASSISTANCE

Insurance

Scalp cooling represents an additional cost that you may not have planned for. Visit DigniCap.com/insurance to find out more about insurance coverage for scalp cooling or see details in the Getting Started Guide.

Patient Assistance Programs

Dignitana was a founding partner of HairToStay, a national non-profit foundation that provides subsidies to scalp cooling patients with demonstrated financial need.

In addition, some patients have received funding from individual medical center foundations, community health funds and other philanthropic entities that work to increase awareness and provide financial assistance to scalp cooling patients in their communities. Listed below are a few of these organizations. Ask your healthcare provider if there are any local or regional organizations in your area such as Cold Capital Fund serving the Washington DC area and Hope for Hair Foundation in North Carolina.

HairToStay
hairtostay.org

Cold Capital Fund
coldcapitalfund.org

Hope for Hair Foundation
hopeforhair.org

"Dignitana's mission remains focused on providing cancer patients with the best possible care and outcomes as they undergo treatment. We have seen firsthand the tremendous impact this new technology can have on patient well-being. Together with our medical center partners we are working to lessen the emotional burden that so many patients around the world have faced until now."

- William Cronin
Chief Executive Officer, Dignitana

ABOUT DIGNITANA

Our mission is to provide cancer patients with dignity and control during a very challenging time. Working directly with both clinicians and patients, we provide an innovative medical device in combination with expertise, education and support throughout the scalp cooling process.

With operations based in Dallas, Texas, Dignitana AB is a publicly-traded medical technology company headquartered in Lund, Sweden. Dignitana produces the patented DigniCap Scalp Cooling System to counteract chemotherapy-related hair loss and contribute to improved patient well-being and quality of life.

The DigniCap Scalp Cooling System has been used around the world since 2001. In 2015, after a multi-center clinical trial, DigniCap became the first scalp cooling system to receive FDA clearance in the United States. It is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

DIGNICAP®

Hair loss is no longer inevitable

Available on the iPhone App Store

ANDROID APP ON Google play

www.DigniCap.com

DigniCap® is a product of Dignitana AB, a public, Swedish medical device company. DigniCap is a patented scalp cooling system that offers men and women with solid tumor cancers the ability to keep their hair during chemotherapy. DigniCap provides continuous cooling with high efficacy, safety and acceptable patient comfort. The company is the first FDA cleared provider of scalp cooling technology. Dignitana, DigniCap, DigniCard, DigniCool, DigniStick, DigniTherm, and DigniLife are trademarks of Dignitana AB (publ). Dignitana, DigniCap and DigniLife are registered trademarks owned by Dignitana AB (publ). The company is certified under ISO 13485 and DigniCap is CE certified as a Class IIa medical device.

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