The DigniCap® Scalp Cooling System
Featuring the DigniTherm™ Click Cap

Minimize the most visible side effect of chemotherapy

FDA cleared for men and women with solid tumor cancers
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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.

Scalp Cooling Historical Timeline

First known use of manual gel caps for scalp cooling
DigniCap invented in Sweden by nurse Yvonne Olofsson
DigniCap available in Europe
Dignitana publicly traded in Sweden
DigniCap registered in Mexico, Russia and South Korea
DigniCap registered in Canada and Colombia
WHAT IS SCALP COOLING?

Scalp cooling is a proven approach to reduce chemotherapy-induced alopecia that has been used successfully by thousands of patients worldwide for several decades. Reduced temperature results in a decreased blood flow to the scalp area so that less chemotherapy reaches the hair cells. Hair cells are therefore not exposed to the full dose of chemotherapy and may be able to survive the chemotherapy treatment. As a result, hair is less likely to fall out.

How Scalp Cooling Works

Two physiologic reactions occur during scalp cooling:

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 – the 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.

Why Scalp Cooling Matters

A patient’s hair can be a major part of their identity, and many patients rate hair loss as one of the most devastating side effects of chemotherapy. Chemotherapy-induced alopecia is an unwelcome reminder of disease, one 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 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.

DIGNICAP – THE FIRST FDA CLEARED SCALP COOLING SYSTEM

The DigniCap Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.
DIGNICAP – THE INTELLIGENT SCALP COOLING SYSTEM

The DigniCap Scalp Cooling System consists of a computerized cooling unit managed through a touch screen display and an attached cooling cap with integrated sensors. Temperature-regulated coolant continuously circulates through specially designed channels in the cooling caps. Unlike other scalp cooling systems, the patented sensors ensure the proper scalp temperature is maintained throughout the treatment.

System Features

- System software detects temperature deviations and continuously makes adjustments based on sensor feedback throughout the cooling cap.
- Intuitive touch screen interface simplifies system operation and allows settings to be easily 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.
- The DigniStick™ flash drive provides easy access for software upgrades and troubleshooting, as well as non-identifiable treatment data and usage reports.

Cap Features

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

- Four cap sizes for individualized fit.
- Contoured shape leaves patient’s ears uncovered for comfort and ease of hearing.
- Smooth inner surface ensures optimal scalp contact.
- Outer neoprene cap creates secure fit and maintains ideal treatment temperature.
- Cap is first placed on the patient’s head at room temperature for a comfortable and controlled cooling transition.
- Caps can be easily detached for bathroom breaks.
- Two patented dual sensor-monitored cooling compartments ensure consistent, uniform cooling for temperature management.
- Built-in security sensor ensures scalp temperature always remains above 32°F/0°C.

DigniCap Treatment Cycle

The chemotherapy agent is still active in the patient’s 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.
## TECHNICAL SPECIFICATIONS

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions</td>
<td>23” wide x 25” deep x 43” tall including wheels</td>
</tr>
<tr>
<td>Weight</td>
<td>Approx. 165 pounds with empty tank</td>
</tr>
<tr>
<td>Mobility</td>
<td>Machine is on wheels and can be easily moved</td>
</tr>
<tr>
<td>Power Supply</td>
<td>115 VAC</td>
</tr>
<tr>
<td>Fuse</td>
<td>16 A</td>
</tr>
<tr>
<td>Alarms</td>
<td>Safety system</td>
</tr>
<tr>
<td></td>
<td>Low coolant level</td>
</tr>
<tr>
<td></td>
<td>Temperature out of range</td>
</tr>
<tr>
<td></td>
<td>DigniCap not connected</td>
</tr>
<tr>
<td></td>
<td>Pause (when pause &gt; 8 min.)</td>
</tr>
<tr>
<td></td>
<td>Desired temperature in tank not reached</td>
</tr>
<tr>
<td></td>
<td>Tank temperature too high</td>
</tr>
<tr>
<td></td>
<td>Tank temperature too low (below -10° C (14° F))</td>
</tr>
<tr>
<td></td>
<td>Malfunctioning sensor</td>
</tr>
<tr>
<td></td>
<td>Malfunctioning sensor cable contact</td>
</tr>
<tr>
<td></td>
<td>Service indicator</td>
</tr>
<tr>
<td></td>
<td>System failure</td>
</tr>
<tr>
<td>Operating Conditions</td>
<td>Temperature: 64 - 86° F</td>
</tr>
<tr>
<td></td>
<td>Humidity range: 30 – 90% RH</td>
</tr>
<tr>
<td></td>
<td>Altitude: ≤ 6561 feet</td>
</tr>
<tr>
<td>Refrigeration Unit</td>
<td>Fully hermetically sealed unit, using CFC-free R404A refrigerant</td>
</tr>
<tr>
<td>DigniCool (Coolant)</td>
<td>Diluted monopropylene glycol</td>
</tr>
<tr>
<td></td>
<td>Low toxicity under normal conditions of handling and use</td>
</tr>
<tr>
<td></td>
<td>Combustible material and a slight eye irritant</td>
</tr>
<tr>
<td></td>
<td>MSDS Available</td>
</tr>
<tr>
<td>Coolant Tank</td>
<td>2.25 Gallons</td>
</tr>
<tr>
<td>Cap Material</td>
<td>Silicone inner cap</td>
</tr>
<tr>
<td></td>
<td>Neoprene outer cap</td>
</tr>
<tr>
<td>Sensors in Cap</td>
<td>2 temperature sensors (front &amp; back)</td>
</tr>
<tr>
<td></td>
<td>1 safety sensor</td>
</tr>
</tbody>
</table>
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.

Study Design

A clinical study comparing hair loss in 117 breast cancer patients who used and did not use The DigniCap Scalp Cooling System was performed. All patients had either Stage I or Stage II breast cancer and underwent at least four cycles of specific chemotherapy regimens. Sixteen of these women did not use the scalp cooling system and 101 patients used scalp cooling.

The average age of the women was 53.0 years (range 28-77); 77.4% were White, 10.4% were Black and 9.4% Asian.

Chemotherapy Regimens in Treatment and Control Groups

<table>
<thead>
<tr>
<th>CHEMOTHERAPY REGIMENS &amp; DOSE</th>
<th>DigniCap N (%)</th>
<th>Controls N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Totals</td>
<td>101</td>
<td>16</td>
</tr>
<tr>
<td>Docetaxel 75 mg/m² &amp; cyclophosphamide 600 mg/m² every 3 weeks or 4-6 cycles</td>
<td>76 (75%)</td>
<td>10 (62.5%)</td>
</tr>
<tr>
<td>Paclitaxel 80 mg/m² weekly for 12 cycles</td>
<td>12 (12%)</td>
<td>2 (12.5%)</td>
</tr>
<tr>
<td>Docetaxel 75 mg/m², carboplatin AUC 6 for 6 cycles every 3 weeks, trastuzumab weekly or every 3 weeks, with or without pertuzumab every 3 weeks</td>
<td>12 (12%)</td>
<td>3 (19%)</td>
</tr>
<tr>
<td>Docetaxel 75 mg/m², trastuzumab &amp; pertuzumab every 3 weeks for 6 cycles</td>
<td>1 (1%)</td>
<td>0</td>
</tr>
<tr>
<td>Doxorubicin 60 mg/m² &amp; cyclophosphamide 600 mg/m² every 3 weeks for 4 cycles</td>
<td>0</td>
<td>1 (6%)</td>
</tr>
</tbody>
</table>

Results when observed a month after the last chemotherapy cycle. In comparison, 100% in the control group that did not use DigniCap lost more than half of their hair.

View the complete description of the clinical trial at dignicap.com/clinicaltrials
Key Findings

Success rate did not differ when analyzed by hair thickness, history of previous chemotherapy, median age, median body mass index, use of prior hormone replacement therapy or menopausal status. No scalp metastases have been observed, which means follow up from last chemotherapy administration of 12.9 months (range 6.7 to 18 months).

At one month after the last chemotherapy treatment, almost half of the women who had used The DigniCap Scalp Cooling System reported that they never used a wig, cap, scarf or other head cover due to hair loss.

Patient Satisfaction

Patients in the study filled out an Alopecia Self-Report questionnaire. Results clearly showed that 101 patients who had an average of 3.6 cycles of chemotherapy and used The DigniCap Scalp Cooling System were satisfied with the decision to use scalp cooling and expressed higher satisfaction with their hair quantity and hair quality as compared to controls.

In contrast, the 16 patients in the control group had an average of 1.5 cycles before discontinuing reporting due to hair loss. Patients reported a satisfaction score (0 to 100) of 25.6 for hair quantity, and a mean score of 37.6 satisfaction with hair quality. Alopecia Self-Report results indicated 0.9 cycles with no significant change in hair texture.

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

Six women reported seven adverse reactions caused by The DigniCap Scalp Cooling System. These were headache (four women), itchiness (one woman), pain of skin (one woman) and head discomfort (one woman). None of these reactions were rated severe and one headache was the only reaction rated moderately severe and the rest were mild.

Three of 106 women discontinued use of scalp cooling because of cold discomfort, while 102 out of 106 women had a feeling of chilliness during the cooling down period. Less than half of the women (43/106) reported that headaches were triggered or exacerbated by scalp cooling. Although headaches occurred, they were not reported at every cycle of scalp cooling.

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. |

Clinical Trial Sites

The DigniCap Scalp Cooling System was studied in women with breast cancer at some of the most prestigious medical centers in the nation, including:

- UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA
- Wake Forest Baptist Medical Center, Winston-Salem, NC
- Weill Cornell Breast Center, New York, NY
- Mount Sinai Chelsea Comprehensive Cancer Center, New York, NY
- UCLA Jonsson Comprehensive Cancer Center, Santa Monica, CA

Since 2001 The DigniCap Scalp Cooling System has been used successfully around the world. It was the first scalp cooling system to receive FDA clearance in the United States.
As published in numerous academic journals, The DigniCap Scalp Cooling System has been shown to be safe and effective in reducing chemotherapy-induced alopecia in cancer patients with solid tumors.

Of 226 patients with various solid tumors and undergoing different chemotherapies 65% showed no visible hair loss.

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.

Summary

- The analysis of scalp cooling data of 226 patients with various solid tumors and undergoing different chemotherapies revealed that 65% showed no visible hair loss (CTC grades 0–1), which means 2/3 of patients needed no head cover.
- These findings directly correspond to the results of Rugo et al. study presented at the ASCO Meeting 2015.
- The type of substance, dose, and combination of the cytostatics used, the patient’s age, menopausal status, and systemic comorbidities with related regular co-medication, as well as hair density significantly influence the success of scalp cooling; a statistical influence was also seen for nicotine abuse.

Results

- 226 patients with various solid tumors were treated with different chemotherapy regimens in the (neo)adjuvant or palliative setting simultaneously to scalp cooling.
- 146 (65%) patients showed a positive effect of scalp cooling with no or only mild alopecia (not visible, chemotherapy-induced alopecia grades 0 and 1) after completing (neo) adjuvant chemotherapy or after a minimum of 3 months of palliative chemotherapy.
- 28% of the studied 226 patients opted for a wig.
- The scalp cooling success rate of the 136 patients with breast cancer receiving different (neo) adjuvant chemotherapies was 65% (88 patients).
- A subgroup of 76 patients treated with epirubicin cyclophosphamide/paclitaxel scalp cooling was successful in 52 (68%) patients.
- A total of 5 patients developed chemotherapy-induced alopecia grade 2 after epirubicin cyclophosphamide treatment, but experienced complete hair regrowth during subsequent paclitaxel treatment and successfully finished scalp cooling after chemotherapy with chemotherapy-induced alopecia grade 1.

Conclusion

Sensor controlled scalp cooling is an effective supportive method to prevent chemotherapy-induced alopecia. It is well tolerated, and in the majority of cases it generates considerable benefit for the patients.

The DigniCap Scalp Cooling System is FDA cleared for men and women with solid tumor cancers.
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 has never looked better’.”

- Allen Wasserman, Weston, CT
RESEARCH OVERVIEW – QUALITY OF LIFE

Minimizing hair loss helps patients to preserve personal identity and self-esteem and appear normal as opposed to sick. Protecting privacy and gaining the ability to choose whether to disclose a cancer diagnosis is significant to many patients. Additionally, scalp cooling patients gain a much-needed sense of control in an otherwise overwhelming experience.

As Published

Body image in women with breast cancer using a scalp cooling system to reduce chemotherapy induced alopecia.
Cigler, T, et al.

A total of 117 patients were enrolled in the pivotal trial. 101 received scalp cooling using DigniCap and 16 were in the control group with no scalp cooling.

Quality of Life BR 23 and BIS Responses at the Last Chemotherapy Cycle

<table>
<thead>
<tr>
<th>QUALITY OF LIFE</th>
<th>DigniCap (N=101)</th>
<th>Control (N=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you lost any hair?</td>
<td>36%</td>
<td>81%</td>
</tr>
<tr>
<td>Have you felt physically less attractive as a result of your disease or treatment?</td>
<td>23%</td>
<td>50%</td>
</tr>
<tr>
<td>Have you been dissatisfied with your appearance when dressed?</td>
<td>15%</td>
<td>38%</td>
</tr>
<tr>
<td>My hair is important to me</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patients responding Quite a Bit/Very much

Summary

Women with breast cancer receiving scalp cooling using DigniCap versus control during chemotherapy:

• Were significantly less likely to lose ≥ 50% of their hair
• Felt significantly more physically attractive
• Were significantly less dissatisfied with their appearance when dressed
• Regarded the importance of hair significantly more

“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
SCALP COOLING BIBLIOGRAPHY

7. Schaffrin-Nabe, D, et al. “Hair-mass-Index (HMI) as indicator for the efficacy of scalp cooling(SC)and the associated quality of life.” Journal of Clinical Oncology. 34. 2016. (suppl; abstr e21692)
CONTRAINDICATIONS AND WARNINGS

Contraindications

The use of DigniCap is contraindicated in pediatric patients.

The use of DigniCap is contraindicated in adult patients with:
- 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
- Skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma
- Hematological malignancies treated with curative intent by chemotherapy
- 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

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 indicated to reduce the likelihood of chemotherapy-induced hair loss in cancer patients with solid tumors.
Step 1: Sizing and Fitting
Providers should schedule a cap fitting session prior to their first treatment to determine which of the four DigniCap sizes will be used. DigniCap is available in four sizes, XS, S, M and L. It is important that the silicone cap is fitted very closely to your scalp. Any air trapped between the scalp and the cap may negatively affect the cooling and results.

Step 2: Wetting the Hair
Before placing the cap, the patient should wet their hair thoroughly. Once wet, hair should be combed flat. (They may wish to come to the appointment with damp hair.)
Step-By-Step (continued)

Step 3: Place the Inner Silicone Cap
Place the silicone cap on the head fully covering the front hairline.

Step 4: Place Knit Cap
Position the knit cap over the silicone cap and pull down tightly. Cross the knit ends under the chin and secure to the velcro to the opposite side.

Step 5: Secure the DigniTherm Click Cap
Place the neoprene cap over the knit cap. Secure the chin strap and twist the Boa dials until the fit is tight.

Boa Dial - How It Works
TURN TO TIGHTEN + QUICK RELEASE
PUSH IN TO ENGAGE
TURN TO TIGHTEN
PULL OUT FOR QUICK RELEASE

The patient’s Custom Fit Kit contains a Getting Started Guide with detailed instructions on fitting and securing DigniCap and the DigniTherm Click Cap.

Step 6: Begin the Scalp Cooling Treatment
Clinical personnel will connect the cooling cap to the system to begin scalp cooling. When the treatment starts, the temperature on the scalp gradually decreases from room temperature to the target temperature of 37-41° F (3-5° C).

Step 7: Completion of Treatment
After completing 90-180 minutes of post-infusion cooling, the cooling cap remains on for another 5-10 minutes to allow the temperature to slowly increase back to room temperature and diminish discomfort.
myDigniCap is a convenient place for patients to manage their scalp cooling treatment. Here they can provide consent and pay for treatments, access scalp cooling information, share their experiences with Dignitana, and receive updates on advancements in scalp cooling.

As soon as patients have scheduled their first chemotherapy appointment with you, they should go online to myDigniCap.com to create an account.

“ 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 all of 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 am so grateful to DigniCap.”

- Donna Tookes, Stamford, CT
THE DIGNITANA ADVANTAGE

Experienced clinical team provides ongoing training and support
Led by a nationally respected oncology nurse, the DigniCap clinical support team is available to patients and clinicians by phone, online, app, and in person.

Superior results in the pivotal trial for FDA clearance
DigniCap achieved 66.3% success with taxanes in the U.S. clinical trial vs the competitor’s success rate of 59% with taxanes and 50.5% overall.

Longer clinical trial treatment evaluation period
More hair loss will occur with a greater number of treatments. For accuracy, success must be measured at end of treatment. In the clinical trial DigniCap was evaluated one month after the end of all the patient’s chemotherapy cycles, whereas the competitor’s trial was evaluated after just four chemotherapy sessions.

Wide range of cap sizes
DigniCap is available in four sizes to fit a wide range of head shapes and sizes.

Extensive experience in the U.S. market
In 2015, DigniCap became the first scalp cooling device to receive FDA clearance.

Expanded clinical indications from the FDA
After an extensive review of worldwide studies, in 2017 the FDA expanded the clinical indication for DigniCap to include men and women with solid tumor cancers.

In-cap sensors for superior temperature control and safety
DigniCap is the only scalp cooling system with patented dual sensors in the cooling compartments for consistent cooling and temperature management, plus a built-in safety sensor to ensure scalp temperature always stays above 32°F / 0°C.

Marketing services with extensive media attention
Proactive promotion of your institution, clinicians, and patient stories to consumer and healthcare media.

DigniCap vs Manual Gel Caps

<table>
<thead>
<tr>
<th>Feature</th>
<th>DigniCap</th>
<th>Manual Gel Caps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proven track record of efficacy</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>FDA clinical trial completed</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>FDA cleared</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Safety &amp; Efficacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous, consistent cooling</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Dual sensor-monitored compartments for cooling efficacy</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Cap sensors for temperature management</td>
<td>YES¹</td>
<td>NO</td>
</tr>
<tr>
<td>Temperature safety sensor</td>
<td>YES¹</td>
<td>NO</td>
</tr>
<tr>
<td>Comfort &amp; Convenience</td>
<td></td>
<td></td>
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<tr>
<td>Single cap fitting per treatment</td>
<td>YES</td>
<td>NO²</td>
</tr>
<tr>
<td>Gradual cool down cycle</td>
<td>YES</td>
<td>NO³</td>
</tr>
<tr>
<td>Trained clinical staff administers treatment</td>
<td>YES</td>
<td>NO⁴</td>
</tr>
</tbody>
</table>

Notes
1. The DigniCap Scalp Cooling System incorporates a number of features and technological advances that combine to improve the patient experience.
2. Manual gel caps must be refitted every 20 minutes throughout treatment. DigniCap is fitted once at the start of treatment and remains on until completion.
3. Since manual gel caps warm up during use, each cap must be at approximately -31°F / -35°C at time of fitting. DigniCap is cooled down gradually from room temperature for patient comfort. The safety sensors in the DigniCap ensure that the scalp cooling temperature never falls below 32°F / 0°C.
4. Manual gel cap patients must typically acquire and return caps from a third-party supplier and have a capping assistant present throughout each treatment.
SCALP COOLING CLINICAL INTEGRATION PROGRAM

The DigniCap Scalp Cooling Clinical Integration Program is a multi-level approach to ensure the success of your scalp cooling program. We review your organizational priorities, workflow, and clinical needs from several levels of stakeholders, then synthesize that information into a customized training plan and deliver that training based on your availability. We remain actively involved, providing resources and insights as you implement and grow your scalp cooling program. This approach ensures that your staff develops an expertise in providing this new treatment and that your greater community is aware scalp cooling is a treatment option available at your facility.

| ASSESS | • Goals  
| • Workflow  
| • Leadership Vision  
| • Clinical Staff Input |
| INFORM | • Physicians  
| • Clinical Staff  
| • Other Personnel |
| INSTALL | • Space Needs  
| • Workflow Considerations |
| TRAINING | • Super Users  
| • Nurses  
| • Medical Assistants  
| • Non-Clinical Staff Awareness |
| IMPLEMENT | • Patient Progress  
| • Reporting Process  
| • Marketing & Media  
| • Community Outreach |
| INTEGRATE | • Ongoing Resources  
| • Physicians & Staff  
| • Community Awareness  
| • Establish Staff Expertise |

Initial training for equipment operation and certification will require approximately 2.5 hours and is scheduled based on your staff schedules and shifts.

Equipment operators are thoroughly trained in unit operation and patient protocols. Following the completion of training and demonstrated proficiency with unit operation, each operator will receive a certificate as a Certified DigniCap Unit Operator.

As Dignitana continues to enhance the equipment, software and operating protocols, we will maintain an ongoing training and education program for all existing and new operators.

“Integrating new technology into any medical facility requires planning, precision and clinical preparation. We have developed this program to provide comprehensive and ongoing training and support to our clinical partners, allowing for easy and efficient integration into their daily routines.”

- Bill Cronin, CEO, Dignitana
“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.”

- Angela Farino, Los Angeles, CA

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

- Monika, Washington DC

#canceratthirty
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).