DIGNITANA

PATIENT CONSENT

I, the undersigned patient, consent to the use of The DigniCap® Scalp Cooling System as part of my chemotherapy treatment.

About Dignitana and The DigniCap Scalp Cooling System

The DigniCap Scalp Cooling System (the "DigniCap System") is a patented scalp cooling system which is marketed in the U.S. by Dignitana, Inc. The DigniCap System is intended to reduce hair loss in individuals undergoing chemotherapy for the treatment of solid tumors. It is believed that the efficacy of scalp cooling is related to two mechanisms. First, cooling the scalp results in the constriction of vessels, limiting the amount of chemotherapy agent delivered to the hair follicles. A lower scalp temperature also decreases the reaction rate causing normal cellular activity in the localized scalp area to slow dramatically.

The DigniCap System consists of an inner cap which is connected to a cooling and control unit. An outer cap insulates and keeps the inner cap in place. The FDA cleared the DigniCap System for use in the U.S. under what is known as a 510(k) clearance. This clearance does not guarantee any results. No person shall have the right to make any representation of end results of use of the DigniCap System other than as set forth in this Patient Consent.

The Scalp Cooling Procedure

Thirty minutes prior to the chemotherapy infusion, the inner cap and outer cap are placed on the patient's head, and the temperature is gradually lowered to the target temperature. Scalp cooling continues during the complete chemotherapy infusion and for an extended period of time following the infusion.

Benefits and Risks

The DigniCap System offers you the ability to reduce the likelihood of chemotherapy-induced hair loss. However, most people will lose some hair. Of the 101 women who participated in the study for FDA clearance who used the DigniCap System, 67 women (66.3%) lost less than half of their hair. In comparison, 16 women (100%) in the control group lost more than half of their hair.

Warnings

- There is a potential for cold injury, even when providing cooling within the prescribed treatment settings. Special care should be taken when applying the cooling inner cap to ensure that there is no direct contact between a patient's exposed skin and the cap's cooling surface. Individuals who experience any unusual swelling, skin discoloration or discomfort should immediately discontinue the use of the DigniCap System and consult their healthcare professional. Particular attention should be paid to the top of the ear, the forehead and back of the neck. Patients may wish to use a headband to prevent direct skin contact with the inner cooling cap.
- The risk of scalp cooling may outweigh the benefits in patients receiving chemotherapeutic agents with a low incidence of causing hair loss.
- Scalp and/or skin 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 with taxanes plus anthracyclines when used in combination on the same day has not been shown to be successful in preventing chemotherapy induced hair loss. The DigniCap System should not be used in these patients.
- Scalp radiation can cause the hardening of small skin vessels decreasing the effectiveness of the DigniCap System.
- The effectiveness of the DigniCap System in patients who received previous chemotherapy has not been evaluated.
- Long-term effects of scalp cooling and risk of scalp metastases have not been fully studied.
- Clinical studies have demonstrated variable success rates in reducing chemotherapy-induced hair loss 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.

Consent, Waiver, Release, and Indemnity

With my signature below, I consent to the use of the DigniCap System. I voluntarily request my physician or health care provider, and such associates, technical assistants and other health care providers as deemed necessary, to use the DigniCap System in connection with my chemotherapy treatment. The benefits, risks, reasonable alternatives, tolerability and side effects have been explained to me and my questions have been answered to my satisfaction.

I AGREE TO WAIVE, RELEASE, DEFEND, INDEMNIFY, and HOLD HARMLESS (collectively referred to as the "Waiver, Release, and Indemnity") Dignitana, the facility where the scalp cooling procedure occurred, the facility's staff, the manufacturer of the DigniCap System, as well as any of their respective affiliates, agents, employees, and representatives (collectively the "Released Parties") from and against any and all claims, causes of action, suits, liabilities, damages, and losses of every kind and nature, including attorneys' fees and legal expenses, (collectively the "Claims"), which are caused by, related to, arising out of, and in way connected with the use of the DigniCap System and the services provided therewith.

THIS WAIVER, RELEASE, AND INDEMNITY EXPRESSLY INCLUDES, BUT IS NOT LIMITED TO, ALL CLAIMS FOR NEGLIGENCE AND GROSS NEGLIGENCE, INCLUDING THE SOLE, JOINT, CONTRIBUTORY, AND/OR CONCURRENT NEGLIGENCE AND GROSS NEGLIGENCE OF THE RELEASED PARTIES.

In addition to negligence and gross negligence, this Waiver, Release, and Indemnity also expressly includes, but is not limited to, Claims for strict products liability or product defect, premises liability or premises defect, as well as breach of contract or breach of warranty. **I UNDERSTAND THAT THE PRODUCTS AND SERVICES PROVIDED ARE FURNISHED WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ALL SUCH WARRANTIES ARE EXPRESSLY DISCLAIMED.**

I HAVE REVIEWED A COPY OF THE PATIENT INFORMATION BOOKLET. I UNDERSTAND THE BENEFITS RISKS AND CONTRAINDICATIONS ASSOCIATED WITH USING THE DIGNICAP SYSTEM, AND I CHOOSE TO USE THE DIGNICAP SYSTEM REGARDLESS OF THE RISKS INVOLVED. _____ (Patient's Initials)

I certify that I have read and understand this consent.

Patient

Print Name: _____

Signature: _____

Date: _____