

Indication for Use

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

Intended Use

A cooling device intended to reduce or prevent the frequency and severity of alopecia during chemotherapy in which alopecia inducing chemotherapy agents are used.

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.
- Use of scalp cooling with taxanes plus anthracyclines when used together or in sequence has not been shown to be successful in preventing 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.

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 stopped scalp cooling because they could not tolerate the temperature of the cooling.

Approximately half of the patients experienced a mild to moderate headache that was triggered or worsened 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, or a fear of confined spaces while wearing the cooling cap.

Clinical studies have produced variable success rates in patient reduction of chemotherapy-induced alopecia, or hair loss, with scalp cooling. This is because 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. In breast cancer patients there has been a concern for scalp and skin metastases with scalp cooling patients. Based on medical literature, scalp and skin metastases are rare occurrences regardless of breast cancer stage (scalp metastases as first sign of recurrence occurs in 1 out of 4,000 patients, and in 1 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 chemotherapy during transit through your cooled scalp and less susceptible to chemotherapy. These cells may then metastasize and alter your prognosis.

Alternative Therapies

The DigniCap Scalp Cooling System was the first device to be granted marketing permission by the FDA to reduce the risk of hair loss during chemotherapy in cancer patients with solid tumors. 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.



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