



Battle Creek



Affix Patient Label

Name _____ Date of Birth _____

This information is given to you so that you can make an informed decision about using the **DigniCap® Scalp Cooling System.**

Reason and Purpose of using the DigniCap® - Scalp Cooling System:

Chemotherapy medications can affect hair follicles in the scalp. This may cause hair loss. The intent of the system is to reduce chemotherapy-induced hair loss. The DigniCap® system may reduce hair loss caused by chemotherapy. The scalp cooling system lowers the scalp temperature. This constricts the blood vessels in the scalp, and reduces delivery of the drug to the scalp.

Benefits of this procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Decreased hair loss in comparison to a non-cooling procedure.
- Successful procedures are defined as maintaining greater than 50% of pre-chemotherapy hair volume.
- In a study of 101 women, 67 women (almost 70%) lost less than half their hair.

Risks of the Procedure:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- It is not possible to know who will benefit from the scalp cooling, and Dignitana and Bronson Healthcare Group cannot guarantee results. You may not get the results you desire.
- Side effects include headache, itching, skin pain, head discomfort and a feeling of coldness. The side effect events were not common, not serious and non-severe in the patients.

Risks Associated with DigniCap Use

If you choose to use the DigniCap® Scalp Cooling System, the time you spend in the infusion treatment area will increase. The time spent using the Scalp Cooling System is not known until your chemotherapy treatment has been decided.

Your treatment will include three stages:

1. During the first stage, the scalp temperature is cooled to about 3 - 5 degrees Celsius (37 - 41 degrees Fahrenheit). This process takes approximately 30 minutes.
2. You will receive chemotherapy. This may be from 1-3 hours.
3. The Post Infusion Recovery Stage. The length of time in this stage depends upon the chemotherapy drug you received. The Cooling Cap use is performed until the strength of the drug has been reduced by your liver. This time period has been studied and can be from 1 to 3 hours.

All of these times are variable, and may depend upon your physical condition. In any event, your time spent in the infusion area will be increased if you choose to use the DigniCap Scalp Cooling System.

Risks specific to you:

Alternative Treatments:

Other choices:

- Do nothing. You can decide not to use the DigniCap® Scalp Cooling System.

If you choose not to have this treatment:

- Chemotherapy will result in a high percentage of your scalp hair being lost.
- Time spent in the chemotherapy infusion room will decrease.

General Information

Students, technical sales people and other staff may be present during the procedure. My doctor or his designee will supervise them.

Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

By signing this form I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. I have had my questions answered.
- I want to have this procedure.
- I understand that my doctor will delegate nurses to perform equipment operation.

Patient signature _____

Relationship: Patient Guardian Durable Power of Attorney for Healthcare Legal Next of Kin _____
(Relationship to patient)

Interpreter's Statement: I have translated this consent form and the doctor's explanation to the patient, guardian, DPOA, or legal next of kin.

Interpreter (if applicable) _____ Date _____ Time _____
(Name or Cyracom ID number)

For Provider use only:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options and possibility of complications and side effects of the intended intervention. I have answered questions and patient has agreed to the procedure.

Provider signature _____ Date _____ Time _____

Teach Back

Patient shows understanding by stating in his or her own words:

- _____ Reason(s) for the treatment/procedure: _____
- _____ Area(s) of the body that will be affected: _____
- _____ Benefit(s) of the procedure: _____
- _____ Risk(s) of the procedure: _____
- _____ Alternative(s) to the procedure: _____

OR

_____ Patient elects not to proceed: _____ (patient signature)

Validated/Witness signature _____ Date _____ Time _____