Clinical Evidence
Sysmex has initiated a clinical trial with breast cancer patients in the biggest German Breast Center in Hamburg and in two breast centers in France. At the time of writing, more than 100 patients have been recruited for this study with good overall success rates. The majority of patients treated felt so comfortable with the outcome that they decided not to wear a wig.

More scientific data on DigniCap™ system are already published (see references). In addition to data from breast cancer patients the first publications on patients with ovarian cancer, endometrial cancer, and one patient with sarcoma are available.

In addition, the extent of hair retention as a result of application of the DigniCap™ system under conventional chemotherapy treatments (based on anthracyclines, taxanes, cyclophosphamide and platinum compounds) has been evaluated in the past 10 years on more than 6,000 patients in various countries in Europe, Asia and South America. The average success rate was 83%. These patients maintained so much hair that they did not require a wig or other head covering.

References:
Hair loss caused by cytostatic drugs administered during chemotherapy, for many cancer patients has a negative influence on quality of life. Alopecia is an additional burden, not only for the patient, but also for their family and friends: Appearance is a continual reminder of the disease and its treatment, often for a significant time after completion of the chemotherapy. The hair loss is not just a cosmetic problem as the potential psychological distress experienced by a patient cannot be underestimated. The positive impact of hair retention is a supportive element through the patients’ therapeutic journey.

Chemotherapy-induced hair loss can be reduced by cooling the scalp during the infusion. The reduced temperature results in a narrowing of the small blood vessels and thus lower levels of cytostatics reach the hair cells. In addition, cellular metabolism within the hair cells is slowed down. Consequently, drug delivery and activity are reduced in the hair roots leading to less damage to, and greater retention of, the hair.

The DigniCap™ system has been developed specifically for this application. Previous treatment results with the DigniCap™ system show that 81% of users were pleased with the degree of hair preservation and the fact that they did not need a wig or other head covering during, or following, the entire period of chemotherapy.

**The DigniCap™ system**

The DigniCap™ system consists of a cooling and control unit, a silicone cap – (‘The DigniCap™’) – and a matching neoprene cap. The latter is used to ensure that the DigniCap™ fits effectively and ensures optimum temperature insulation. From the control unit a coolant is passed through the channels of the DigniCap™, and a continuous circulation is maintained. The DigniCap™ has sensors dedicated to control and regulate the temperature during the whole treatment period.

With one system 2 patients can be treated simultaneously, but independently with cooling of the scalp controlled independently via the computer interface. This cooling takes place during the entire chemotherapy session. Depending on the regime a post-cooling period of between 30 minutes and 2.5 hours is required. For a high quality result the appropriate Cap (available in 4 sizes) should be selected and correctly applied by properly trained staff. Therefore Sysmex offers targeted training on site or at our training center, the Sysmex Academy.

**Routine Clinical Use**

With one DigniCap™ system approximately 40 – 60 patients can be treated in routine per year. The exact number of patients is dependent upon various factors, such as number of treatment days per week or working hours of the institution.

**Our DigniLife includes:**

- concept development
- personnel support in the initial phase
- roadshows
- training of employees
- annual retraining of staff
- marketing support
- information service
- hotline service

**Application of the DigniCap™**

<table>
<thead>
<tr>
<th>pre-cooling</th>
<th>cytostatic treatment</th>
<th>post-cooling</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 – 30 min</td>
<td>x min</td>
<td>30 – 150 min</td>
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**Scalp Cooling**

- preparation/ premedication
- start of cytostatic infusion
- end of cytostatic infusion