Abstract  
**Background:** Analysis of tumor biopsy material represents only assessable tumor and represents the state at the time of diagnosis. This approach neglects tumoral heterogeneity changes occurring during disease progression. However, during systemic therapies tumors undergo molecular changes and usually develop resistance mechanisms. Reevaluation of tumors after therapy, at disease progression and before new treatment initiation would be informative for the selection of appropriate next steps. However, re-biopsies are not often feasible and can cause morbidity. Liquid biopsy, i.e. isolating and analyzing circulating tumor cells (CTCs), can be an additional source of diagnosis, prognosis, evaluation of treatment efficacy, and molecular tumor evolution and metastatic sites. The GILUPI CellCollector®, an intravascularly in-dwelling device, screens blood for CTCs directly in the vein of the cancer patient. The device has specific monoclonal antibodies attached to pull down epithelial derived CTCs. Here, we conducted a study using this effective device, to monitor CTC counts before as well as on different time points after surgery in non-small cell lung cancer (NSCLC) patients. 

**Methods:** In total, 18 lung cancer patients (with different stages) were screened for CTCs at different time points: preoperative, 30 minutes after resection, 1 week postoperative as well as in 3-monthly intervals up to 2 years. In addition, 1 patient with a benign lung disease were included in this study. 

**Results:** Applying the GILUPI CellCollector®, CTCs were isolated independent from the tumor stages and tumor size. Moreover a difference between CTC occurrence before and after surgery was seen and we were able to detect a correlation between CTC enumeration and clinical lack of recurrence. 

**Conclusions:** The GILUPI CellCollector® overcomes blood volume limitations of other diagnostic approaches and thereby increases the diagnostic sensitivity of CTC analysis. It allows enumeration and molecular characterization of CTCs which might help to monitor therapy efficacy and improve treatment strategies.

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**Enumeration of circulating tumor cells in lung cancer patients using the GILUPI CellCollector®**

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**Study design and CTC enumeration**

**Study Design**

- **Visit 1:** preoperative
- **Visit 2:** immediately after surgery
- **Visit 3:** 6-8 days postoperative
- **Visit 4:** all three months (up to 2 years)

**CTC enumeration**

Schematic representation of the study design.

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**Summary**

- **CTC can be captured in vivo** with the GILUPI CellCollector®
- **Detection of CTCs in early tumor stages** could be shown
- **Increased CTC numbers** 30 min after resection
- **Absence of CTCs after 3 month correlates with clinical lack of recurrence (verified till patient 7 - visit 4)**
- The implementation of the GILUPI CellCollector® into clinical practice can **improve early detection, prognosis and therapy monitoring of lung cancer patients.**

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**GILUPI CellCollector® - an in vivo CTC isolation technology**

Figure 1: The device, The functionalized surface of the stainless steel wire consists of a gold layer and a hydrosol which bears covalently bound antibody against epithelial cell surface marker EpCAM.

Figure 2: The device application, Insertion of the GILUPI CellCollector® through an indwelling cannula into a peripheral arm vein for 30 min. During the application the 40 mm long functionalized tip comes into direct contact with the blood circulation and captures CTCs via EpCAM binding.

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**Results**

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**Figure 3:** Schematic representation of the study design.

**Figure 4:** Representative images of CTCs and CTC clusters isolated with the GILUPI CellCollector®. Representative images of CTCs and CTC clusters isolated with the GILUPI CellCollector®. Note: Green - CTC (verified till patient 7 - visit 4).

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**Figure 5:** Clinical correlation.

(a) CTC enumeration and clinical data of 7 NSCLC patients up to visit 7 (Visit 1 = before surgery; Visit 2 = 30 min after surgery; Visit 3 - 1 week postoperative; Visit 4 - 3 month postoperative; Visit 5 - 6 month postoperative; Visit 6 - 9 month postoperative; Visit 7 - 12 month postoperative).

(b) CTC enumeration of all 18 patients (c) 4 CTC enumeration of 3 different patients.