

## Study Summary

### Improved Adenoma Detection with the ENDOCUFF VISION™ Device: The Adenoma Randomized Controlled Trial

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#### Conclusion

The ENDOCUFF VISION™ device enhances the adenoma detection rate in patients in the UK bowel cancer screening program in comparison to standard colonoscopy.

#### Objective

To evaluate the impact of the ENDOCUFF VISION™ device on the adenoma detection characteristics in a colorectal cancer screening population.

#### Design

Multicenter randomized controlled trial comparing the ENDOCUFF VISION™ device -assisted colonoscopy to standard colonoscopy; enrollment of patients from seven hospitals and 48 colonoscopists in the UK.

#### Indication

Patients referred to colonoscopy as part of the postpolypectomy surveillance program or patients part of the Bowel Cancer Screening Program with a positive fecal occult blood test (FOBT).

#### Participants

Within the study, 884 patients were enrolled into the standard colonoscopy (SC) arm and 888 in the ENDOCUFF VISION™ arm. Of all patients, 797 were part of the UK Bowel Cancer Screening Program (BCSP) with a positive FOBT (SC n= 403; ENDOCUFF VISION™ device n= 394). All other patients were non-BCSP patients and therefore not tested with a FOBT.

#### Results

- The ENDOCUFF VISION™ device improved the ADR in the total population by 4.7 percentage points (SC 36.2% vs. ENDOCUFF VISION™ 40.9%;  $p < 0.001$ ).
- In the FOBT-positive subgroup, the ENDOCUFF VISION™ device substantially improved ADR by 10.8 percentage points (SC 50.9% vs. 61.7% ENDOCUFF VISION™;  $p < 0.001$ ).
- Additionally, patients screened with the ENDOCUFF VISION™ device had higher mean adenomas per procedure and a larger number of left-sided, diminutive and small adenomas.
- No difference in adverse events was detected between the two groups.

#### Key Findings

The ENDOCUFF VISION™ device increases the adenoma detection rate in a screening population, most clearly in a FOBT + population.

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