

# CASE REPORT FORM (CRF)

## CAD-EYE VS. White Light: A Multi-Centric Study ELIGIBILITY FORM

<b>Patient number:</b>	<input type="text"/> <input type="text"/> <input type="text"/>	<b>Date:</b>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
<b>Date of birth:</b>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	<b>Gender:</b>	<input type="checkbox"/> Female <input type="checkbox"/> Male
<b>Length (cm)</b>	<input type="text"/>	<b>Weight (kg)</b>	<input type="text"/>

<b>INCLUSION CRITERIA</b>	<b>Yes</b>	<b>No</b>
1. Subject is 40-80 years old	<input type="checkbox"/>	<input type="checkbox"/>
2. Subject is undergoing colonoscopy for the following <ul style="list-style-type: none"> <li>a. Primary CRC screening</li> <li>b. Post-polypectomy surveillance</li> <li>c. Work up following FIT positivity</li> <li>d. Symptoms/signs suspicions of CRC</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
3. Subjects must be willing to give written informed consent for the trial	<input type="checkbox"/>	<input type="checkbox"/>

<b>EXCLUSION CRITERIA</b>	<b>YES</b>	<b>No</b>
1. Patient is: <40 years old	<input type="checkbox"/>	<input type="checkbox"/>
2. Unable to consent	<input type="checkbox"/>	<input type="checkbox"/>
3. Contraindicated to undergo endoscopy,	<input type="checkbox"/>	<input type="checkbox"/>

4. Already hospitalized for another illness		
5. Pregnant or lactating		
6. Patients with the following conditions: <ul style="list-style-type: none"> <li>○ History of colon resection</li> <li>○ History of CRC</li> <li>○ Antithrombotic therapy precluding colon resection</li> <li>○ Inflammatory Bowel Disease (IBD)</li> <li>○ Familial Adenomatous Polyposis (FAP)</li> </ul>		
7. Poor bowel preparation: BBPS 0 or 1 in a segment		

**RANDOMIZATION**

White-light

CAD-EYE

**INFORMED CONSENT SIGNED:**

YES

NO

Date consented:

## PATIENT INFO

**Date & time of admission:**

**Indication for colonoscopy:**

- Surveillance
- GI Symptoms, please specify:
  - Per-rectal bleeding
  - Abdominal pain
  - Weight loss
- Primary CRC Screening
- Family history of CRC
- FIT positive
- Other:

**Drug History:**

- Anti-thrombotics. If yes, dose:
- Others:
  - 1.
  - 2.
  - 3.
  - 4.
  - 5.

**Endoscopic History:**

No previous history

Previous endoscopy (please list summary of report)

1.

Date:

2.

Date:

3.

Date:

4.

Date:

## PROCEDURAL INFO

### Endoscopy:

Date of procedure:

Endoscope system used:

Intubation:  Yes  No

Propofol:  Yes, mention dosage                      mg  
 No

Midazolam:  Yes, mention dosage                      mg  
 No

Blood pressure:                      (mmHg)

O2 saturation:                      %

Pulse:                      (b/m)

### BBPS Score (0-9)

- Right colon:
- Transverse colon:
- Left colon:

### Intraprocedural information:

Insertion time (min):

Withdrawal time (min):

Ileocecal valve intubation: yes/ no

- If yes, please provide time:                      Min

if no, please specify distance from anal verge reached:                      cm

**Post procedural Information:**

Patient Excluded from study (post procedure): Yes No

If yes, please provide reason:

**Adverse Events**

- None
- GI Symptoms
- Perforation
- Hemorrhage
- Infection
- Others:

# WHITE LIGHT FORM

Polyps (Number )

- Lesion
- Container
- Site location
  - Segment:
    - Rectum
    - Sigmoid
    - Left colon
    - Transverse colon
    - Right colon
    - Cecum
  - Distance from anal verge  (cm)
- Paris type (check appendix):
  - 0-1p
  - 0-1ps
  - 0-1s
  - 0-IIa
  - 0-IIb
  - 0-IIc
  - 0-III
- Polypectomy:
  - YES:
  - NO:

- Biopsy for histopathology:
    - YES:
    - NO:
  - Histopathology result:
    - Hyperplastic
    - Adenoma with no dysplasia
    - Adenoma with low grade dysplasia
    - Adenoma with high grade dysplasia
    - Adenocarcinoma in situ
    - Adenocarcinoma
    - Others:
  - Characterization (white light Endoscopic assessment of lesion):
    - Hyperplastic
    - Adenoma
  - Characterization (BLI Endoscopic assessment of lesion):
    - Hyperplastic
    - Adenoma
  - Images for each polyp:
    - Yes
    - No
  - Remarks:
-



## CAD-EYE FORM

**POLYP** (Number )

- Lesion
- Container
- Site location
  - Segment
    - Rectum
    - Sigmoid
    - Left colon
    - Transverse colon
    - Right colon
    - Cecum
  - Distance from anal verge (cm)
- Paris type (check appendix):
  - 0-1p
  - 0-1ps
  - 0-1s
  - 0-IIa
  - 0-IIb
  - 0-IIc
  - 0-III
- Polypectomy
  - YES

- NO
- Biopsy for histopathology
  - YES
  - NO
- Histopathology result:
  - Hyperplastic
  - Hyperplastic
  - Adenoma with no dysplasia
  - Adenoma with low grade dysplasia
  - Adenoma with high grade dysplasia
  - Adenocarcinoma in situ
  - Adenocarcinoma
  - Others:
- Characterization (white light Endoscopic assessment of lesion):
  - Hyperplastic
  - Adenoma
- Characterization (BLI Endoscopic assessment of lesion):
  - Hyperplastic
  - Adenoma
- CAD EYE Detection of lesion
  - Yes:
  - No:
- Characterization (by CAD-EYE):
  - Hyperplastic

- Adenoma
  - CAD EYE Accuracy of lesion
    - FN
    - TP-C
    - TP-E
    - FP
  - IN CASE of resection:
    - CAD Characterization of resection plane
      - CAD eye detected residual lesions at resection edges
        - Yes
        - No
          - If yes what was your next step:
          - Took another biopsy from edges
          - More resection of the residual lesions
          - No further action
  - Images for each polyp
    - Yes
    - No
  - Remarks:
-

## Appendix

### Paris classification:

- 1) Polypoid:
  - 0-1p: pedunculated
  - 0-1ps: Subpendunculated
  - 0-1s: Sessile polyps
- 2) Non-polypoid lesions:
  - 0-IIa: superficial slightly elevated
  - 0-IIb: flat
  - 0-IIc: superficial depressed
  - 0-III: excavated

### CAD EYE Accuracy of Lesion

	<b>Endoscopist</b>	<b>CAD EYE</b>
<b>False Negative (FN)</b>	Detected And Confirmed as Polyp	Not Detected
<b>False Positive (FP)</b>	Not Detected And Confirmed as Not Polyp	Detected
<b>True Positive CADEYE (TP-C)</b>	Not Detected Before CAD Eye alarm	Detected And Confirmed as Polyp
<b>True Positive Endoscopist (TP-E)</b>	Detected And Confirmed as Polyp	Detected And Confirmed as Polyp