



# RANDOMISATION FORM

Go to [rectalcancersurgery.eu](http://rectalcancersurgery.eu) to register patient, or send this form by email to [trialbureau@iknl.nl](mailto:trialbureau@iknl.nl)

Hospital:.....

Name responsible physician: .....

E-mail:.....

Telephone or pager: .....

**PATIENT KEY** ..... | | | | | | | | - | | | | | |

### STRATIFICATION

1) T stage (1=T1-3a, 2 =T3b+), assessed by central review ..... | |

2) Downstaged with chemoradiotherapy (0=No, 1=yes, 2=NA) ..... | |

3) Preoperatieve radiotherapy (0=No, 1=Yes) ..... | |

4) Height of the tumour (1=0-2.0cm, 2=2.1-5.0cm, 3=5.1-10.0cm), assessed by central review ..... | |

5) Sex (1=Male, 2=Female)..... | |

6) BMI (1= ≤30.0, 2= >30.0) ..... | |

### Inclusion criteria 0=No, 1=Yes

1) Solitary adenocarcinoma of the rectum within 10 cm from anal verge defined by MRI ..... | |

2) Stage 1-3 according to the AJCC classification including downstaged tumours based on adequate imaging of the thorax and abdomen..... | |

3) Intention for Low Anterior Resection (LAR) with total mesorectal excision(TME) with an anastomosis either colorectal or coloanal ..... | |

4) Suitable for elective laparoscopic surgical resection ..... | |

5) Informed consent according to local requirements ..... | |

### Exclusion criteria 0=No, 1=Yes

1) T3 tumour with margins less than 1 mm to the mesorectal fascia or T4 tumour, determined by MRI-scan (staged after (chemo)radiotherapy if applicable)..... | |

2) Intention to perform no anastomosis (APR) ..... | |

3) Malignancy other than adenocarcinoma at histological examination..... | |

4) Patients under 18 years of age ..... | |

5) Pregnancy ..... | |

6) Previous radical prostatectomy or rectal surgery (excluding TURP or local excision)..... | |

7) Signs of acute intestinal obstruction..... | |

8) Multiple colorectal tumours..... | |

9) Familial Adenomatosis Polyposis Coli (FAP), Hereditary Non-Polyposis Colorectal Cancer (HNPCC), active Crohn's disease or active ulcerative colitis ..... | |

10) Planned synchronous abdominal organ resections ..... | |

11) Other malignancies in medical history, except adequately treated basocellular carcinoma of the skin or in situ carcinoma of the cervix uteri, in the last 5 years..... | |

12) Absolute contraindication to general anaesthesia ..... | |

**Is this patient eligible for randomisation? (0=no, 1=yes)**..... | |

**Date:**..... **Investigator's signature:**.....