FOLLOW-UP FORM - 6 months (6-12-18-24-36-48-60)

INSTRUCTIONS: Please complete this form send it within 3 months after surgery to IKNL clinical research department trialbureau@iknl.nl

Patient seqnr. |__|__|__|__| **Site nr:** |__|__|__|__|__| **Hospital:** …… **Physician:**……

DATE OF VISIT

Exact date of visit ..... |__|__||__|__||__|__|__|__|

Number of months after Surgery ..... |__|

COMPLICATIONS

LATE COMPLICATIONS (0=No, 1=Yes) ..... |__|

Anastomotic leak/ (pre)sacral abscess(0=No, 1=Yes) ..... |__|

Date of anastomotic leak ..... |__|__||__|__||__|__|__|__|

Grade of leakage ..... |__|

1= Requiring no active therapeutic intervention
2= Requiring active therapeutic intervention but manageable without relaparotomy
3= Requiring re-laparotomy

Diagnosis by (1= CT scan, 2= Endoscopy, 3=MRI..... |__|

Treated by (0=None, 1= Percutaneous drainage, 2=Trans anastomotic drainage, 3=Endovac, 4=

Colostomy (Takedown of anastomosis) ..... |__|

Clavien Dindo (1-2-3a-3b-4a-4b-5)..... |__|

Chronic presacral sinus ..... …… |__|

Diagnosis by (1= CT scan, 2= Endoscopy, 3=MRI, 4=Other ..... |__|

If other, specify .....

Treated by .....

ClavienDindo (1-2-3a-3b-4a-4b-5)..... |__|

Complication	**0=No, 1=Yes**	**Clavien-Dindo** (1-2-3a-3b-4a-4b-5)	**Date complication**
Chronic presacral abscess	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Pain	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Urinary incontinence	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Sexual dysfunction	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Faecal incontinence	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Fascial dehiscence	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Fistula	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Small bowel obstruction	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Parastomal hernia	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Stenosis anastomosis	|__|	|__|__|	|__|__|__|__|__|__|__|__|
Incisional hernia	|__|	|__|__|	|__|__|__|__|__|__|__|__|

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

FOLLOW-UP FORM - 6 months (6-12-18-24-36-48-60)

INSTRUCTIONS: Please complete this form send it within 3 months after surgery to IKNL clinical research department trialbureau@iknl.nl

Patient seqnr. |__|__|__|__| **Site nr:** |__|__|__|__|__| **Hospital:** …… **Physician:**……

Other |__| |__|__| |__|__||__|__||__|__|__|__|

specify .....

RE-ADMISSIONS

Re-admissions (0=No, 1=Yes) .....|__|

If yes, duration in days. …… .....|_|

If yes, reason.. .....|_|

Please complete serious adverse event form if this is possibly related to study treatment

RE-INTERVENTIONS(incl ileostomy reversal)

Re-interventions(0=No, 1=Yes) .....|__|

If yes please complete event form

Has ileostomy been reversed(0=No, 1=Yes, 2= NA) .....|__|

If yes, date ..... |__|__||__|__||__|__|__|__|

Complications after ileostomy reversal (0=No, 1=yes).....|__|

Ileus (0=No, 1=Yes).....|__|

Diagnosis by (1= CT scan, 2= Ultrasound, 3=MRI, 4=Clinical, 5=Other .....|__|

If other, specify .....

Treated by .....

Clavien Dindo (1-2-3a-3b-4a-4b-5).....|__|

Anastomotic leak (0=No, 1=Yes).....|__|

Grade of leakage .....|__|

1= Requiring no active therapeutic intervention
2= Requiring active therapeutic intervention but manageable without relaparotomy
3= Requiring re-laparotomy

Diagnosis by (1= CT scan, 2= Endoscopy, 3=MRI.....|__|

Treated by (0=None, 1= Percutaneous drainage, 2=Trans anastomotic drainage, 3=Endovac, 4= Colostomy).....|__|

Clavien Dindo (1-2-3a-3b-4a-4b-5).....|__|

Abdominal abscess (0=No, 1=Yes) .....|__|

If other, specify .....

Treated by .....

Clavien Dindo (1-2-3a-3b-4a-4b-5).....

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

FOLLOW-UP FORM - 6 months (6-12-18-24-36-48-60)

INSTRUCTIONS: Please complete this form send it within 3 months after surgery to IKNL clinical research department trialbureau@iknl.nl

Patient seqnr. |__|__|__|__| **Site nr:** |__|__|__|__|__| **Hospital:** …… **Physician:**……

Wound infection (0=No, 1=Yes) ..... |__|

Treated by .....

Clavien Dindo (1-2-3a-3b-4a-4b-5).....

Other, specify.....

Diagnosis by (1= CT scan, 2= Endoscopy, 3=MRI, 4=Other ..... |__|

If other, specify .....

Treated by .....

Clavien Dindo (1-2-3a-3b-4a-4b-5).....

ADJUVANT TREATMENT

Adjuvant therapy (0=None, 1= Chemotherapy, 2= Radiotherapy, 3= Chemo + RT) ..... |__|

Specify.....

EXAMINATIONS

CEA level..... |__|.|__|

ABDOMINAL EXAMINATIONS

Colonoscopy(0=Not done, 1= Yes) ..... |__|

CT-colonography(0=Not done, 1= Yes) ..... |__|

CT-abdomen(0=Not done, 1= Yes)..... |__|

Liver ultrasound(0=Not done, 1= Yes) ..... |__|

Liver MRI (0=Not done, 1= Yes)..... |__|

Pelvic MRI (0=Not done, 1= Yes)..... |__|

Pelvic CT (0=Not done, 1= Yes)..... |__|

Other, if yes specify..... |__|

THORACIC EXAMINATION

X-ray (0=Not done, 1= Yes)..... |__|

CT-scan (0=Not done, 1= Yes) ..... |__|

Other, if yes specify..... |__|

PET(0=Not done, 1= Yes) ..... |__|

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

FOLLOW-UP FORM - 6 months (6-12-18-24-36-48-60)

INSTRUCTIONS: Please complete this form send it within 3 months after surgery to IKNL clinical research department trialbureau@iknl.nl

Patient seqnr. |__|__|__|__| **Site nr:** |__|__|__|__|__| **Hospital:** …… **Physician:**……

Results (0=Normal, 1= recurrence, 2= Stenosis, 3= 2nd tumour, 4=other) .....|__|

RECURRENCE

Recurrence (0=No, 1=Yes).....|__|

If yes complete recurrence form

DEATH

Death (0=No, 1=Yes).....|__|

Date of death ..... |__|__||__|__||__|__|__|__|

Cause of death (1= Not cancer related, 2=Rectal cancer related, 3= Other cancer).....|__|

Specify cause of death ……

COMMENTS

.....

.....

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