CONFIDENTIAL

# The **PROBESE** Randomized

### **Controlled Trial**

### **Case Report Form**

version 1.2.1

Protective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in Obese Patients

| center | patient |
|--------|---------|

Local investigator 1 (intraoperative)

Local investigator 2 (postoperative)

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| Case ID |                |
|---------|----------------|
|         | center patient |

#### 1. Inclusion Criteria

|  | yes | no |
|--|-----|----|
| Patient scheduled for surgery under general anesthesia                               |     |    |
| Intermediate-to-high risk for PPCs following surgery, <b>ARISCAT risk score ≥ 26</b> |     |    |
| BMI $\geq$ 35 kg/m <sup>2</sup>  |     |    |
| Expected duration of surgery $\geq$ 2 h  |     |    |

#### 2. Exclusion Criteria

| Previous lung surgery (any)  | yes | no<br>□ |
|--|-----|---------|
| Persistent hemodynamic instability, intractable shock (considered hemodynamically unsuitable for the study by the patient's managing physician)  |     |         |
| History of previous severe chronic obstructive pulmonary disease (COPD) (non-invasive ventilation and/or oxygen therapy at home, repeated systemic corticosteroid therapy for acute exacerbations of COPD) |     |         |
| Recent immunosuppressive medication (patients receiving chemotherapy or radiation therapy up to two months prior to surgery)   |     |         |
| Severe cardiac disease (New York Heart Association class III or IV, acute coronary syndrome or persistent ventricular tachyarrhythmia)   |     |         |
| Invasive mechanical ventilation longer than 30 minutes (e.g., general anesthesia for surgery) within last 30 days  |     |         |
| Pregnancy (excluded by anamneses and/or laboratory analysis)   |     |         |
| Prevalent acute respiratory distress syndrome expected to require prolonged postoperative mechanical ventilation   |     |         |
| Severe pulmonary arterial hypertension, defined as systolic pulmonary artery pressure > 40 mmHg  |     |         |
| Intracranial injury or tumor   |     |         |
| Neuromuscular disease (any)  |     |         |
| Need for intraoperative prone or lateral decubitus position  |     |         |
| Need for one-lung ventilation  |     |         |
| Cardiac surgery or neurosurgery  |     |         |
| Planned reintubation following surgery   |     |         |
| Enrolled in other interventional study or refusal of informed consent  |     |         |
| Patient excluded from the study?   |     |         |

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| Case ID |                |  |
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|         | center patient |  |

**1** Preoperative Visit

#### 3. ARISCAT Score (modified according to study design)

|   |            | Poi | nts             | Ро             | ints | Points          |
|---|------------|-----|-----------------|----------------|------|-----------------|
| Age   | ≤ 50       | 0   | 51-80           | □ <sup>3</sup> | > 80 |                 |
| Preoperative SpO <sub>2</sub> [%]<br>10 min in room air, beach chair position | ≥ 96       | 0   | 91-95           | 8              | ≤ 90 | 24              |
| Respiratory Infection (last month)  | No         | 0   | Yes             |                |      |                 |
| Preoperative Anemia<br>(Hb ≤ 6,2 mmol/l or ≤10 g/dl)                          | No         | 0   | Yes             | 11             |      |                 |
| Emergency procedure   | No         | 0   | Yes             | 8              |      |                 |
| Surgical Incision   | peripheral | 0   | upper abdominal |                |      |                 |
| Planned duration of surgery [hr]  |            |     | > 2-3           |                | > 3  | □ <sup>23</sup> |
| Total Risk Score  |            |     | +               |                | +    |                 |

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| Case ID |                |  |
|---------|----------------|--|
|         | center patient |  |

| 1 | Preoperative | Visit |
|---|--------------|-------|
|---|--------------|-------|

#### **4** Patient details

| Written informed consent yes no                       | Date informed consent signed / / 20 |
|---|-------------------------------------|
| Age [yrs]   | Gender male female                  |
| Height [cm]   | Weight [kg]                         |
| Waist/Hip Ratio according to WHO (definition page 34) |                                     |

#### 5 History of previous disease

| ASA Score [1-5]                           |                |                 |              |   |
|---|----------------|-----------------|--------------|---|
| Cumulated Ambulation Score                | e (page 34) [0 | )-6]:           |              |   |
| Heart failure                             | yes            | no 🗌            | if yes       | NYHA Score [1-4]:                               |
| Coronary heart disease                    | yes            | no 🗌            | if yes       | CCS Score [0-4]:                                |
| Atrial flutter / fibrillation             | yes            | no 🗌            | if yes       | acute paroxysmal chronic                        |
| Obstructive sleep apnea                   | yes            | no 🗌            | if yes       | Apnea/Hypopnea Index [events/hr]:               |
|   |                |                 | if no        | STOP-Bang Score (page 34) [0-8]:                |
| COPD                                      | yes            | no 🗌            | if yes       | steroids use yes no                             |
|   |                |                 |              | inhalation therapy yes no                       |
| Respiratory infection within last month   | yes            | no 🗌            | if yes       | upper lower respiratory infection               |
| Smoking status                            | never          | former (ces     | ssation >3m  | nonths) current                                 |
| Use of noninvasive<br>ventilatory support | yes            | no 🗌            | if yes       |   |
|   |                |                 |              | duration [hrs/day]: intensity [pressure level]: |
| Active cancer                             | yes            | no 🗌            | if yes       | cancer type:                                    |
|   |                |                 |              | actual cancer classification: TMN               |
| Diabetes mellitus                         | yes            | no 🗌            | if yes       | dietary oral medication insulin                 |
|   | if oral medic  | cation, specify | /            | type: dose [mg/day]:                            |
| Arterial hypertension                     | yes            | no 🗌            |              |   |
| Gastroesophageal reflux                   | yes            | no 🗌            | if yes       | events ≥1/day ≥1/week ≥1/month                  |
| Alcohol status (past 2 weeks)             | 0-2 drinks/d   | lay 📄 >2        | 2 drinks/day |   |
| Use of antibiotics<br>(last 3 months)     | yes            | no 🗌            | if yes       | indication:                                     |
| Use of statins                            | yes            | no 🗌            | if yes       | type: dose [mg/day]:                            |
| Use of aspirin                            | yes            | no 🗌            | if yes       | dose [mg/day]:                                  |

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| Case ID |                |
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**1** Preoperative Visit

| 6.1 A | ctual organ | function - | mandatorv | measurements |
|-------|-------------|------------|-----------|--------------|
|-------|-------------|------------|-----------|--------------|

| SpO <sub>2</sub> beach chair position + 10 min in room air possible? | yes   | no 🔲 | if yes | SpO <sub>2</sub> [%]:                                     |
|--|-------|------|--------|---|
|  |       |      | if no  | SpO <sub>2</sub> [%]: and FiO <sub>2</sub> [%] (page 35): |
| RR [/min]  |       |      |        |   |
| HR [/min]  |       |      |        | ABP mean [mmHg]   |
| Temperature [°C]   |       |      |        | tympanic axillar inguinal oral rectal                     |
|  |       |      |        | other if other Specify:                                   |
| Airway secretion   | yes   | no 🗌 | if yes | purulent not purulent                                     |
| VAS dyspnea [1-10cm]   |       |      |        | VAS thoracic pain [1-10cm]                                |
| VAS abdominal rest pain [1-7   | 10cm] |      |        | VAS abdominal incident pain [1-10cm]                      |

#### 6.2 Non-mandatory measurements

| Spirometry                |                                | Laboratory tests |          |       |
|---------------------------|--------------------------------|------------------|----------|-------|
| FVC [L]                   | FVC[% predicted]               | Hb               | mmol/I   | g/dl  |
| FEV <sub>1</sub> [L/1sec] | FEV <sub>1</sub> [% predicted] | WBC              | GPt/L    |       |
|                           |                                | Platelets        | GPt/L    |       |
| Chest X-ray obtained      | yes no                         | PT               | INR      |       |
| if yes                    |                                | PTT              | sec      |       |
| infiltrates               | yes no                         | Creatinine       | µmol/l   | mg/dl |
| pleural effusion          | yes no                         | BUN              | mmol/I   | mg/dl |
| atelectasis               | yes no                         | ALT              | µmol/s*l | U/L   |
| pneumothorax              | yes no                         | AST              | µmol/s*l | U/L   |
| cardiopulmonary edema     | yes no                         | Bilirubin        | µmol/l   | mg/dl |

| Investigator |  |
|--------------|--|
|              |  |

\_\_\_\_\_ Signature \_\_\_\_\_

| Case ID                     | center p                                       |                         |                | т                          | ne PROBESE Rando            | omized Controlled Trial |
|-----------------------------|--|-------------------------|----------------|----------------------------|-----------------------------|-------------------------|
|                             |  |                         | ]              |                            |                             | 2 Intraoperative Visit  |
| Randomiza                   | tion   | Low PEEP \              | without RI     | N                          | High PEEP with              | RM                      |
| 1 Anestheti<br>1.1 Inductio | c Overview<br>on                               |                         |                |                            |                             |                         |
|                             | anesthesia [min]<br>extubation (or exit from 0 | OR if on mechanical ven | itilation)     |                            |                             |                         |
| Antibiotic pr               | ophylaxis                                      | yes 🔲 no                |                | Central veno               | us line y                   | res no                  |
| Arterial line               |  | yes 📄 no                |                | Cardiac outp<br>measuremer |                             | res no                  |
| Regional an                 | esthesia                                       | yes 📃 no                | D if y         | yes epidura                |                             | mbar                    |
|                             |  |                         |                | plexus                     | cervical 🔲 br               | achial 🔲 lumbar 🗌       |
| other:                      |  |                         |                | periphe<br>nerve           | ral <sub>upper</sub> 🔲 lowe | er extremity            |
| Use of NIV of               | during induction                               | yes 🔲 no                | p 🔲 if :       | yes CPAP                   |                             |                         |
| Patient's pos               | sition during induc                            | tion angle of           | head elevation | on_0-15° 1                 | 5-30° 🔄 30-45° 🗌            | >45°                    |
|                             | Thuida Transford                               |                         |                |                            |                             |                         |
| 1.2 Drugs, I                | Fluids, Transfusi                              |                         | tive dose      |                            |                             | cumulative dose         |
| Analgetics                  | Alfentanyl                                     | yes                     |                | Anesthetics                | Dexmedetomidine             | yes                     |
| [mg]                        | Fentanyl                                       | yes                     |                | [mg]                       | Etomidate                   | yes 🔲                   |
|                             | Lidocaine                                      | yes                     |                |                            | Ketamine                    | yes                     |
|                             | Morphine                                       | yes                     |                |                            | Midazolam                   | yes                     |
|                             | NSAIDs   | yes 🔲                   |                |                            | Propofol                    | yes 🔲                   |
|                             | Piritramide                                    | yes 🔲                   |                |                            | Thiopental                  | yes 🔲                   |
|                             | Procaine                                       | yes 🔲                   |                |                            | other                       | yes 🔲                   |
|                             | Remifentanil                                   | yes 🔲                   |                | if other                   | type:                       |                         |
|                             | Sufentanil                                     | yes 🔲                   |                |                            | type:                       |                         |
|                             | other  | yes 🔲                   |                | Muscle                     | Atracurium                  | yes                     |
| if other                    | type:  |                         |                | Relaxants                  | Cis-Atracurium              | yes 🔲                   |
|                             | type   |                         |                | [mg]                       | Mivacurium                  | yes 🔲                   |
| Vapors                      | Desflurane                                     | yes                     |                |                            | Pancuronium                 | yes 🔲                   |
| [vol%*min]                  | Enflurane                                      | yes 🔲                   |                |                            | Rocuronium                  | yes 🔲                   |
| _                           | Halothane                                      | yes 🔲                   |                |                            | Succinylcholine             | yes 🔲                   |
|                             | Isoflurane                                     | yes 🔲                   |                |                            | Vecuronium                  | yes 🔲                   |
|                             | Sevoflurane                                    | yes 🔲                   |                |                            | other                       | yes 🔲                   |
|                             | other  | yes 🔲                   |                | if other                   | type:                       |                         |
| if other                    | type:  |                         |                |                            | type:                       |                         |

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|         | center patient |  |

#### **2** Intraoperative Visit

|                            |                     | cumulative dose |              |  | С     | umulative dose |
|----------------------------|---------------------|-----------------|--------------|--|-------|----------------|
| Artificial                 | HES                 | yes             | Crystalloids | [ml]                                   | yes   |                |
| Colloids                   | Gelatine            | yes             | Albumin [ml] |  | yes   |                |
| [ml]                       | Dextran             | yes             |              |  |       |                |
| Transfusion                | PRBC                | yes             | Vaso-        | Dobutamine                             | yes   |                |
| [ml]                       | FFP                 | yes             | active       | Dopamine                               | yes 🗖 |                |
|                            | FP24                | yes             | Drugs        | Epinephrine                            | yes 🗖 |                |
|                            | Fibrinogen [g]      | yes             | [mg]         | Norepinephrine                         | yes 🔲 |                |
|                            | Cryoprecipitate     | yes             | -            | Phenylephrine                          | yes 🗖 |                |
|                            | PPSB [IU]           | yes             | -            | other                                  | yes 🗖 |                |
|                            | Platelets           | yes             | if other     | type:                                  |       |                |
|                            | other               | yes             | -            | type:                                  |       |                |
| if other                   | type:               |                 | -            |  |       |                |
| 1.3 End of an              | esthesia            |                 |              |  |       |                |
| ∑ Blood loss [r            | ml]                 |                 | ∑ Urine out  | put [ml]                               |       |                |
| Temperature [              | °C] at end of surge | ery             | tympanic     | axillar inguinal                       | oral  | rectal         |
|                            |                     |                 | other        | if other specify:                      |       |                |
| Neuromuscula<br>monitored? | ar function         | yes no          | if yes C     | esidual<br>urarization at<br>xtubation | yes   | no 🗌           |

if yes

| 117 | 631 | ua | шл |
|-----|-----|----|----|
|     | est |    |    |

Curarization antagonized?

Signature \_\_\_\_\_

no

yes

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cholinesterase inhibitor

sugammadex

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|---------|--------|---------|
|         | center | patient |

#### 2 Intraoperative Visit

#### 2 Surgical overview

| from incision to clo                                 |                 |              |                   |                  |                   |             |                 |
|--|-----------------|--------------|-------------------|------------------|-------------------|-------------|-----------------|
|  |                 |              | cumulative do     | ose              |                   |             | cumulative dose |
| Transfusion  | PRBC            | yes          |                   |                  | FFP               | yes         |                 |
| before   | FP24            | yes          |                   |                  | Fibrinogen [g]    | yes         |                 |
| surgery  | Cryoprecipitate | yes          |                   |                  | PPSB [IU]         | yes         |                 |
| (last 6hrs)  | Platelets       | yes          |                   |                  | other             | yes         |                 |
| [ml]   |                 |              |                   | if other         | type:             |             |                 |
| Priority of sur see below)                           | gery(definition | elective     | urgent            | emergency        |                   |             |                 |
| Surgical wou<br>classification<br>(definition see be |                 | clean        | clean-contamin    | ated Contan      | ninated dirty     |             |                 |
| Surgical proc  | edure           | visceral     | thoracic          | vascular 🔲 ortho | pedic 🔲 gynecolog | jic 🔲 urolo | ogic other      |
|  |                 | specify pr   | ocedure:          |                  |                   |             |                 |
| Patient's posi<br>surgery                            | ition during    | supine       | trendelenburg     | reverse tre      | ndelenburg 🔲 lith | notomy      | seated          |
| Surgical appr  | oach            | laparoscopi  |                   | if abdominal     | intraabdominal p  | oressure [n | nmHg]           |
|  |                 | assisted lap | aroscopic         | if abdominal     | intraabdominal p  | oressure [n | nmHg]           |
|  |                 | open         |                   |                  |                   |             |                 |
|  |                 | conversion   | from laparoscopic | c to open        |                   |             |                 |

#### **3 Definitions**

#### Surgical wound classification

| Clean              | Elective, not emergency, non-traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered. |
|--------------------|--|
|                    |  |
|                    | Urgent or emergency case that is otherwise clean; elective opening of respiratory,   |
| Clean-contaminated | gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g. appendectomy) not   |
|                    | encountering infected urine or bile; minor technique break.  |
|                    |  |
|                    | Non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or   |
| Contaminated       | genitourinary tract in the presence of infected bile or urine; major break in technique;   |
|                    | penetrating trauma <4 hours old; chronic open wounds to be grafted or covered.   |
| Distri             | Purulent inflammation (e.g. abscess); preoperative perforation of respiratory,   |
| Dirty              | gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old.   |
|                    | gastiontestinal, billary of genitournaly tract, penetrating tradina >4 hours ou.   |

#### Priority of surgery

| Elective  | Surgery that is scheduled in advance because it does not involve a medical<br>emergency    |
|-----------|--|
| Urgent    | Surgery required within < 48 hrs   |
| Emergency | Non-elective surgery performed when the patient's life or well-being is in direct jeopardy |

| Investigator | Signature |
|--------------|-----------|
| <b>o</b>     | 5         |

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| Case ID center patient   | The PROBESE Randomized Controlled Trial                      |
|--|--|
| 4 Protocol adherence   | <b>2</b> Intraoperative Visit                                |
| Any deviation from the yes no  | if yes   |
| •  | sponsive to fluids and/or vasoactive drugs                   |
| 2) New arrhythmias unresponsive to inter-  | vention (according to ACLS-Guidelines) yes                   |
| 3) Need for a dosage of vasoactive drugs   | at the tolerance limit yes                                   |
|  | tent of >50% of blood volume in 4 hours to maintain $y_{es}$ |
| <ul> <li>Hct ≥ 21% (Hb &gt; 4,2 mmol/l or 7 g/dl)</li> <li>5) Life-threatening surgical complication (<br/>brain, including major bleeding, tension</li> </ul> | injury to the hemodynamic and respiratory system and yes     |
| 6) Other reason, specify:  | yes  |
| Specify protocol deviation:  |  |
| Could the protocol be yes no no  |  |
| 5 Adverse events (AE) / severe adverse eve   | ents (SAE)   |
| Any adverse events yes no  | if yes specify according to table:                           |
| Event (details, including treatment) Serie   | ,  |
|  | unrelated mild   |
| yes  | possible moderate  |
| no   | probable severe death  |
|  | unassessable unassessable unknown                            |
|  | resolved - no sequelae mild mild                             |
|  | unrelated mild resolved - sequelae                           |
| yes  |  |
| no   | unassessable unassessable                                    |
|  |  |
|  | resolved - no sequelae mild mild                             |
| yes  | resolved - sequelae  |
| yes  | probable severe  |
|  | unassessable unassessable                                    |
|  |  |
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| Investigator Signature _   | Version 1.2.1, Aug. 2014, Thomas Bluth                       |

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|         | center patient |  |

#### **2** Intraoperative Visit

#### 6 Mechanical ventilation protocol

| Patient's height [cm] | IBW [kg]<br>M: 50+0.91*(height-152.4), F: 45.5+0.91*(height-152.4)  |  |  |  |  |  |
|-----------------------|---|--|--|--|--|--|
| Modus                 | Volume controlled ventilation   |  |  |  |  |  |
| FiO <sub>2</sub>      | ≥40%, adjust to maintain SpO₂ ≥93%  |  |  |  |  |  |
| I:E ratio             | :2  |  |  |  |  |  |
| RR                    | adjust to normocapnia (ETCO <sub>2</sub> 35-45mmHg or 4,6-6kPa)   |  |  |  |  |  |
| PEEP                  | according to randomization: 4 vs. 12 cmH <sub>2</sub> O   |  |  |  |  |  |
| Inspiratory $V_{T}$   | 7 ml/kg IBW =ml   |  |  |  |  |  |
| Recruitment           | 1. Peak inspiratory pressure limit = $55 \text{ cmH}_2\text{O}$   |  |  |  |  |  |
| maneuver              | 2. $V_T = 7 \text{ ml/kg IBW}$ and RR $\ge 6/\text{min}$ , while PEEP = 12 cmH <sub>2</sub> O (or higher during rescue)   |  |  |  |  |  |
| (perform directly     | 3. I:E = 1:1  |  |  |  |  |  |
| after induction or    | 4. Increase V <sub>T</sub> in steps of 4 ml/kg IBW until Pplat reaches 40 – 50 cmH <sub>2</sub> O   |  |  |  |  |  |
| hourly recording      | 5. If Pplat <40 cmH <sub>2</sub> O with highest possible $V_T$ , increase PEEP to maximum 20 cmH <sub>2</sub> O   |  |  |  |  |  |
| or disconnection)     | <ol> <li>Allow three breaths while maintaining Pplat = 40 – 50 cmH<sub>2</sub>O</li> <li>Set RR, I:E, inspiratory pause and V<sub>T</sub> back to pre-recruitment values, while maintaining PEEP at 12 cmH<sub>2</sub>O (or higher if during rescue)</li> </ol> |  |  |  |  |  |

#### 7 Rescue strategy (if $SpO_2 \leq 92\%$ )

First exclude airway problems, auto-PEEP, hemodynamic impairment and ventilator malfunction!

| Conventional group |                              |                            |  |  |  |  |  |  |  |
|--------------------|------------------------------|----------------------------|--|--|--|--|--|--|--|
| Step               | Step   FiO <sub>2</sub> PEEP |                            |  |  |  |  |  |  |  |
| 1                  | 0.5                          | 4 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 2                  | 0.6                          | 4 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 3                  | 0.7                          | 4 cmH₂O                    |  |  |  |  |  |  |  |
| 4                  | 0.8                          | 4 cmH₂O                    |  |  |  |  |  |  |  |
| 5                  | 0.9                          | 4 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 6                  | 1.0                          | 4 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 7                  | 1.0                          | 5 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 8                  | 1.0                          | 6 cmH₂O                    |  |  |  |  |  |  |  |
| 9                  | 1.0                          | 7 cmH <sub>2</sub> O (+RM) |  |  |  |  |  |  |  |
| (+RM),             | recruitme                    | ent maneuver optional      |  |  |  |  |  |  |  |

#### **Protective Group**

| Step*    | FiO <sub>2</sub>                     | PEEP                        |  |  |  |  |  |  |  |
|----------|--------------------------------------|-----------------------------|--|--|--|--|--|--|--|
| 1 Excluc | 1 Exclude any hemodynamic impairment |                             |  |  |  |  |  |  |  |
| 2        | 0.4                                  | 14 cmH <sub>2</sub> O (+RM) |  |  |  |  |  |  |  |
| 3        | 0.4                                  | 16 cmH <sub>2</sub> O (+RM) |  |  |  |  |  |  |  |
| 4        | 0.4                                  | 18 cmH <sub>2</sub> O (+RM) |  |  |  |  |  |  |  |
| 5        | 0.5                                  | 18 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 6        | 0.6                                  | 18 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 7        | 0.7                                  | 18 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 8        | 0.8                                  | 18 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 9        | 0.9                                  | 18 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 10       | 1.0                                  | 18 cmH <sub>2</sub> O       |  |  |  |  |  |  |  |
| 11       | 1.0                                  | 20 cmH <sub>2</sub> O (+RM) |  |  |  |  |  |  |  |

(+RM), recruitment maneuver optional

\*At any step: If SpO<sub>2</sub> deteriorates further in an otherwise hemodynamic stable patient, consider reducing the PEEP to 10 and then 8 cmH<sub>2</sub>O

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|         | center patient |  |

#### **2** Intraoperative Visit

#### 8 Intraoperative variables

#### - Record variables within 5 min after anesthesia induction and hourly thereafter (Induction, Hr 1, Hr 2...)

- Record recruitment variables *during* peak phase of recruitment maneuver (RM 1, RM 2...)

| -                              | Induc-<br>tion | RM 1 | Hr1 | RM 2 | Hr 2 | RM 3 | Hr 3 | RM 4 | Hr 4 | RM 5 | Hr 5 |
|--------------------------------|----------------|------|-----|------|------|------|------|------|------|------|------|
| Time [hh:mm]                   |                |      |     |      |      |      |      |      |      |      |      |
| Ppeak [cmH <sub>2</sub> O]     |                |      |     |      |      |      |      |      |      |      |      |
| Pplat [cmH <sub>2</sub> O]     |                |      |     |      |      |      |      |      |      |      |      |
| PEEP [cmH <sub>2</sub> O]      |                |      |     |      |      |      |      |      |      |      |      |
| V <sub>T</sub> insp [ml]       |                |      |     |      |      |      |      |      |      |      |      |
| RR [/min]                      |                |      |     |      |      |      |      |      |      |      |      |
| I:E [x:x]                      |                |      |     |      |      |      |      |      |      |      |      |
| FiO <sub>2</sub> [%]           |                |      |     |      |      |      |      |      |      |      |      |
| SpO <sub>2</sub> [%]           |                |      |     |      |      |      |      |      |      |      |      |
| ETCO <sub>2</sub> [mmHg / kPa] |                |      |     |      |      |      |      |      |      |      |      |
| MAP [mmHg]                     |                |      |     |      |      |      |      |      |      |      |      |
| HR [bpm]                       |                |      |     |      |      |      |      |      |      |      |      |

#### AE/SAE

| New hypotensio    | n (BPsys «  | < 90mmHg (             | or BPsys dr | op > 10mm               | Hg, if BPsy | s < 90 befo | re)      |          |          |          |          |
|-------------------|-------------|------------------------|-------------|-------------------------|-------------|-------------|----------|----------|----------|----------|----------|
|                   | yes / no    | yes / no               | yes / no    | yes / no                | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |
| New bradycardi    | a (HR <50   | opm or HR o            | drop > 20%  | , if HR < 50            | before)     | 1           |          |          | 1        | 1        |          |
|                   | yes / no    | yes / no               | yes / no    | yes / no                | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |
| New hypoxemia     | (SpO₂ ≤ 92  | 2% or SpO <sub>2</sub> | drop > 5%,  | if SpO <sub>2</sub> < 9 | 2% before)  |             | 1        | 1        | 1        | 1        |          |
|                   | yes / no    | yes / no               | yes / no    | yes / no                | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |
| Other event (plea | ase specify | on page 10             | )           | L                       |             |             | •        | •        |          |          |          |
|                   | yes / no    | yes / no               | yes / no    | yes / no                | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |
| Disconnection fi  | rom the v   | entilator              | L           | L                       |             |             | •        | •        |          |          | •        |
|                   |             |                        | yes / no    |                         | yes / no    |             | yes / no |          | yes / no |          | yes / no |
| Rescue according  | to page 11  | (if SpO₂ ≤             | 92%)        |                         |             |             |          |          |          |          |          |
|                   | yes / no    | yes / no               | yes / no    | yes / no                | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |

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| Case ID |                |  |
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|         | center patient |  |

#### **2** Intraoperative Visit

#### 9 Intraoperative variables continuation

|                            | RM 6 | Hr 6 | RM 7 | Hr 7 | RM 8 | Hr 8 | RM 9 | Hr 9 | RM<br>10 | Hr 10 | RM<br>11 |
|----------------------------|------|------|------|------|------|------|------|------|----------|-------|----------|
| Time [hh:mm]               |      |      |      |      |      |      |      |      |          |       |          |
| Ppeak [cmH <sub>2</sub> O] |      |      |      |      |      |      |      |      |          |       |          |
| Pplat [cmH <sub>2</sub> O] |      |      |      |      |      |      |      |      |          |       |          |
| PEEP [cmH <sub>2</sub> O]  |      |      |      |      |      |      |      |      |          |       |          |
| V <sub>T</sub> insp [ml]   |      |      |      |      |      |      |      |      |          |       |          |
| RR [/min]                  |      |      |      |      |      |      |      |      |          |       |          |
| I:E [x:x]                  |      |      |      |      |      |      |      |      |          |       |          |
| FiO <sub>2</sub> [%]       |      |      |      |      |      |      |      |      |          |       |          |
| SpO <sub>2</sub> [%]       |      |      |      |      |      |      |      |      |          |       |          |
| ETCO <sub>2</sub> [mmHg /  |      |      |      |      |      |      |      |      |          |       |          |
| kPa]                       |      |      |      |      |      |      |      |      |          |       |          |
| MAP [mmHg]                 |      |      |      |      |      |      |      |      |          |       |          |
| HR [bpm]                   |      |      |      |      |      |      |      |      |          |       |          |

#### AE/SAE

| New hypotension (BPsys < 90mmHg or BPsys drop > 10mmHg, if BPsys < 90 before) |                  |                        |            |                         |            |          |          |          |          |          |          |
|---|------------------|------------------------|------------|-------------------------|------------|----------|----------|----------|----------|----------|----------|
|   | yes / no         | yes / no               | yes / no   | yes / no                | yes / no   | yes / no | yes / no | yes / no | yes / no | yes / no | yes / no |
| New bradycardia   | a (HR <50b       | opm or HR o            | drop > 20% | , if HR < 50            | before)    |          |          |          |          |          |          |
|   | yes / no         | yes / no               | yes / no   | yes / no                | yes / no   | yes / no | yes / no | yes / no | yes / no | yes / no | yes / no |
| New hypoxemia   | $(SpO_2 \le 92)$ | 2% or SpO <sub>2</sub> | drop > 5%, | if SpO <sub>2</sub> < 9 | 2% before) |          |          |          |          |          |          |
|   | yes / no         | yes / no               | yes / no   | yes / no                | yes / no   | yes / no | yes / no | yes / no | yes / no | yes / no | yes / no |
| Other event (plea   | ase specify      | on page 10             | )          |                         |            |          |          |          |          |          |          |
|   | yes / no         | yes / no               | yes / no   | yes / no                | yes / no   | yes / no | yes / no | yes / no | yes / no | yes / no | yes / no |
| Disconnection fr  | om the v         | entilator              |            |                         |            |          |          |          |          |          |          |
|   |                  | yes / no               |            | yes / no                |            | yes / no |          | yes / no |          | yes / no |          |
| Rescue according  | to page 11       | (if $SpO_2 \leq 1$     | 92%)       |                         |            |          |          |          |          |          |          |
|   | yes / no         | yes / no               | yes / no   | yes / no                | yes / no   | yes / no | yes / no | yes / no | yes / no | yes / no | yes / no |

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

| Case ID |                |  |
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|         | center patient |  |

#### **2** Intraoperative Visit

#### 10 Intraoperative variables continuation

|                                | Hr 11 | RM<br>12 | Hr 12 | RM<br>13 | Hr 13 | RM<br>14 | Hr 14 | RM<br>15 | Hr 15 | RM<br>16 | Hr 16 |
|--------------------------------|-------|----------|-------|----------|-------|----------|-------|----------|-------|----------|-------|
| Time [hh:mm]                   |       |          |       |          |       |          |       |          |       |          |       |
| Ppeak [cmH <sub>2</sub> O]     |       |          |       |          |       |          |       |          |       |          |       |
| Pplat [cmH <sub>2</sub> O]     |       |          |       |          |       |          |       |          |       |          |       |
| PEEP [cmH <sub>2</sub> O]      |       |          |       |          |       |          |       |          |       |          |       |
| V <sub>T</sub> insp [ml]       |       |          |       |          |       |          |       |          |       |          |       |
| RR [/min]                      |       |          |       |          |       |          |       |          |       |          |       |
| I:E [x:x]                      |       |          |       |          |       |          |       |          |       |          |       |
| FiO <sub>2</sub> [%]           |       |          |       |          |       |          |       |          |       |          |       |
| SpO <sub>2</sub> [%]           |       |          |       |          |       |          |       |          |       |          |       |
| ETCO <sub>2</sub> [mmHg / kPa] |       |          |       |          |       |          |       |          |       |          |       |
| MAP [mmHg]                     |       |          |       |          |       |          |       |          |       |          |       |
| HR [bpm]                       |       |          |       |          |       |          |       |          |       |          |       |

#### AE/SAE

| New hypotensic   | on (BPsys < | < 90mmHg (             | or BPsys dr | op > 10mm                 | Hg, if BPsy | s < 90 befo | re)      |          |          |          |          |
|------------------|-------------|------------------------|-------------|---------------------------|-------------|-------------|----------|----------|----------|----------|----------|
|                  | yes / no    | yes / no               | yes / no    | yes / no                  | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |
| New bradycardi   | a (HR <50t  | opm or HR              | drop > 20%  | , if HR < 50              | before)     |             |          |          |          |          |          |
|                  | yes / no    | yes / no               | yes / no    | yes / no                  | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |
| New hypoxemia    | (SpO₂ ≤ 92  | 2% or SpO <sub>2</sub> | drop > 5%,  | , if SpO <sub>2</sub> < 9 | 92% before) |             |          |          |          |          |          |
|                  | yes / no    | yes / no               | yes / no    | yes / no                  | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |
| Other event (ple | ase specify | on page 10             | )           |                           |             |             |          |          |          |          |          |
|                  | yes / no    | yes / no               | yes / no    | yes / no                  | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |
| Disconnection f  | rom the v   | entilator              |             |                           |             |             |          |          |          |          |          |
|                  | yes / no    |                        | yes / no    |                           | yes / no    |             | yes / no |          | yes / no |          | yes / no |
| Rescue according | to page 11  | (if SpO₂ ≤             | 92%)        |                           |             |             |          |          |          |          |          |
|                  | yes / no    | yes / no               | yes / no    | yes / no                  | yes / no    | yes / no    | yes / no | yes / no | yes / no | yes / no | yes / no |

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

| Case ID |                |
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|         | center patient |

**3** Postoperative Visit Day 1

## **POSTOPERATIVE DAY 1 (first 24hrs period)** report events within this period if not stated otherwise

| 1 Recovery                 |                 |             |           |            |                                      |
|----------------------------|-----------------|-------------|-----------|------------|--------------------------------------|
| Lost to follow             | up              | yes         | no 🗌      | if yes     | reason                               |
| Continuation after surgery | of MV directly  | yes         | no 🗌      | if yes     | duration [hrs] indication:           |
| New requirer               | nent of NIV     | yes         | no 🗌      | if yes     | CPAP NPPV duration [hrs]             |
|                            |                 |             |           |            | maximum intensity [pressure level]:  |
|                            |                 |             |           | indication | n standard of care resp. failure     |
| New requiren               | nent of         | yes         | no 🗌      | if yes     | duration [hrs]                       |
|                            |                 |             |           | indication | n resurgery resp. failure other      |
| ICU stay                   |                 | yes         | no 🗌      | if yes     | preop scheduled unscheduled          |
| PONV                       |                 | yes         | no 🗌      |            |                                      |
| Physiotherap               | у               | yes         | no 🗌      |            |                                      |
| Breathing exc              | ercises         | yes         | no 🗌      | if yes     | incentive spirometry yes no          |
| Cumulated A                | mbulation Score | e (page 34) | [0-6]:    |            |                                      |
| Impairment o<br>healing    | f wound         | yes         | no 🗌      | if yes     | superficial deep                     |
| Surgical wou               | nd infection    | yes         | no 🗌      | if yes     | superficial deep                     |
|                            |                 |             |           | if yes     | abscess empyema phlegmon             |
| Return of boy              | wel function    | yes         | no 🗌      |            |                                      |
| 2 Fluids/ Dru              | ıgs             |             |           |            |                                      |
|                            |                 |             | cumulativ | e dose     | cumulative dose                      |
| Artificial                 | HES             | yes         |           |            | Crystalloids [ml] yes                |
| Colloids                   | Gelatine        | yes         |           |            | Albumin [ml] yes                     |
| [ml]                       | Dextran         | yes         |           |            |                                      |
| Transfusion                | PRBC            | yes         |           |            | FFP yes                              |
| [ml]                       | FP24            | yes         |           |            | Fibrinogen [g] yes                   |
|                            | Cryoprecipitat  | e yes       |           |            | PPSB [IU] yes                        |
|                            | Platelets       | yes         |           |            | other yes                            |
|                            |                 |             |           |            | if other type:                       |
| Antibiotics                |                 | yes         | no 🗌      | if yes     | prophylaxis therapy                  |
| Vasoactive d               | rugs            | yes         | no        | if yes     | Dobutamine Dopamine Epinephrine      |
|                            |                 |             |           |            | Norepinephrine Phenylephrine other   |
|                            |                 |             |           | if other   | type                                 |
|                            |                 |             |           |            | Case Report Form PROBESE stud        |
| Investigato                | or              | Sigr        | nature    |            | Version 1.2.1, Aug. 2014, Thomas Blu |
| ·                          |                 |             |           |            |                                      |

| Case ID |                |
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|         | center patient |

**3** Postoperative Visit Day 1

| 3.1 Actual organ function -  | - mandatory measure            | ements | (status at visit,     | , 12-24hrs after end of surg        | ery)   |
|--|--------------------------------|--------|-----------------------|-------------------------------------|--------|
| SpO <sub>2</sub> beach chair position + 10 min in room air possible? | yes no                         | if yes | SpO <sub>2</sub> [%]: |                                     |        |
|  |                                | if no  | SpO <sub>2</sub> [%]: | and FiO <sub>2</sub> [%] (page 35): |        |
| RR [/min]  |                                |        |                       |                                     |        |
| HR [/min]  |                                |        | ABP mean [mm          | Hg]                                 |        |
| Temperature [°C]   |                                |        | tympanic axil         | lar 🔄 inguinal 🔄 oral 🔄 i           | rectal |
|  |                                |        | other if              | other Specify:                      |        |
| Airway secretion   | yes no                         | if yes | purulent n            | ot purulent                         |        |
| VAS dyspnea [1-10cm]   |                                |        | VAS thoracic pa       | ain [1-10cm]                        |        |
| VAS abdominal rest pain [1-1   | 0cm]                           |        | VAS abdomina          | l incident pain [1-10cm]            |        |
| 3.2 Non-mandatory measu  | rements                        |        |                       |                                     |        |
| Spirometry   |                                |        | Laboratory tes        | sts                                 |        |
| FVC [L]  | FVC[% predicted]               |        | Hb                    | mmol/I                              | g/dl   |
| FEV <sub>1</sub> [L/1sec]  | FEV <sub>1</sub> [% predicted] |        | WBC                   | GPt/L                               |        |
|  |                                |        | Platelets             | GPt/L                               |        |
| Chest X-ray obtained   | yes no                         |        | PT                    | INR                                 |        |
| if yes   |                                |        | PTT                   | sec                                 |        |
| infiltrates  | yes no                         |        | Creatinine            | µmol/l                              | mg/dl  |
| pleural effusion   | yes no                         |        | BUN                   | mmol/I                              | mg/dl  |
| atelectasis  | yes no                         |        | ALT                   | µmol/s*l                            | U/L    |
| pneumothorax   | yes no                         |        | AST                   | µmol/s*l                            | U/L    |
| cardiopulmonary edema  | yes no                         |        | Bilirubin             | µmol/l                              | mg/dl  |

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|      | estigator |  |

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|         | center patient |

**3** Postoperative Visit Day 1

#### 4 Pulmonary complications (see also detailed definitions, page 36)

| Aspiration pneumonitis       yes       no         resp. failure alter inhalation of gastric contents       yes       no         Bronchospasm       yes       no         Mid respiratory failure       yes       no         Sp0-store       Yes       no         Severe respiratory failure       yes       no       if yes         reed for noh-massive of invasive mechanical ventilation       mild       moderate       severe         Pulmonary infection       mol       no       no CXR         Pulmonary infection       now/ progressive infiltrates + 2: antibiotics, fever, lexkocytosiz/ isucopenia and/or purulent secretions       yes       no       no CXR         Petural effusion       mol       no CXR       petulentate       yes       no       no CXR         Preumothorax       and o congestor - interstitui infiltrates/increased vascular markings on chest X-ray       yes       no       no CXR         Preumothorax       mol costsphereic angle (standingh hazy opaciy in one hemithorax (supine) on chest X-ray  |   |   |                  |                        |                   |             |
|--|---|---|------------------|------------------------|-------------------|-------------|
| newly explicatory whearing treated with transchollators       /************************************  | 1 |   |                  |                        | yes no            |             |
| Mid respiratory failure       yes       no         Sp0-set%s rep2-se0mmHg for 10min in room air, responding to oxygen > 2//min       yes       no         Sp0-set%s rep2-se0mmHg for 10min in room air, responding to oxygen > 2//min       yes       no         Sp0-set%s rep3-se0mmHg for 10min in room air, responding to oxygen > 2//min       yes       no         ARDS       sccording to Berlin definition       yes       no         ARDS according to Berlin definition       mild       moderate       severer         Pulmonary infection       yes       no       no       no C XR         Arblectasis       high opacification with shift of surrounding tissue/ organ towards the affected area       yes       no       no C XR         Pleural effusion       yes       no       no C XR       pes       no       no C XR         Preumothorax       free arin the pleural space on chest X-ray       yes       no       no C XR       pes         New pullmonary infiltrates       wes       no       no C XR       pes       no       no C XR         Result uision       yes       no       no C XR       pes       no       no C XR         Butting of costophrenic angle (standingly hazy opacity in one hemithorax (supine) on chest X-ray       yes       no       no C XR <t< td=""><td>I</td><td></td><td></td><td></td><td>yes no</td><td></td></t<>   | I |   |                  |                        | yes no            |             |
| Sp0:2-80% or Pa0_settion fail for 10min in oom air, responding to oxygen > 2/min       ymin       ymin         Severer respiratory failure<br>need for non-invasive or invasive mechanical ventilation       yes       no         ARDS<br>sccording to Berlin definition       yes       no       if yes         Pulmonary infection<br>new progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions       yes       no       no CXR         Atelectasis<br>Lung opacification with shift of surrounding tissue/ organ towards the affected area       yes       no       no CXR         Pleural effusion<br>burning of exospherine langle (standingly hazy opacity in one hemithorax (supine) on chest X-ray       yes       no       no CXR         Preumothorax<br>tree air in the pleural space on chest X-ray / utrasonic imaging       yes       no       no CXR         New pulmonary infiltrates<br>monolateral/ bilateral infitrates without other dinical signs       yes       no       no CXR         Stratapulmonary complications (see also detailed definitions, page 37)       SIRS       yes       no       severe sepsis         Severe Sepsis       yes       no       o       severe sepsis       no       severe sepsis         Sepsis with organ dysfunction , hypoperfusion or hypotension       yes       no       sepsis with relation hary other (extrapulmonary infection       yes       no       sepsis with rela | I |   | to oxygen ≤ 2l/  | 'min                   | yes no            |             |
| Severe respiratory failure       yes       no         need for non-invasive or invasive mechanical ventilation       yes       no         ARDS       secording to Berlin definition       mild       moderate       severe         Pulmonary infection       mol       no       no       CRCR         Arelectasis       yes       no       no       CRCR         Ling opacification with shift of surrounding itssue/ organ towards the affected area       yes       no       no       CRCR         Cardiopulmonary edema       dirical signs of congestion + interstitial infitrates/ increased vascular markings on chest X-ray       yes       no       no       CRCR         Pleural effusion       yes       no       no CXR       yes       no       no CXR         Pneumothorax       ges       no       no CXR       yes       no       no CXR         SIRS       yes       no       no CXR       yes       no       no CXR         SIRS       yes       no       no CXR       yes       no       no CXR         SiRS       yes       no       sepsis       no       sepsis       no       sepsis         SiRS       yes       no       sepsis       no       sepsis       no <td>I</td> <td>Moderate respiratory failure<br/>SpO<sub>2</sub>&lt;90% or PaO<sub>2</sub>&lt;60mmHg for 10min in room air, responding t</td> <td>to oxygen &gt; 2l/</td> <td>/min</td> <td>yes no</td> <td></td>  | I | Moderate respiratory failure<br>SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding t | to oxygen > 2l/  | /min                   | yes no            |             |
| ARDS       according to Berlin definition       mild   |   | Severe respiratory failure  |                  |                        | yes no            |             |
| according to Berlin definition       mild moderate severe         Pulmonary infection<br>new progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions       yes       no       no CXR         Atelectasis<br>Lung opacification with shift of surrounding tissue/ organ towards the affected area       yes       no       no CXR         Cardiopulmonary edema<br>dirical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray       yes       no       no CXR         Pleural effusion<br>burnting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray       yes       no       no CXR         Pneumothorax<br>tree air in the pleural space on chest X-ray/ ultrasonic imaging       yes       no       no CXR         Sets       Mew pulmonary infiltrates       yes       no       no CXR         SiRS       25 Extrapulmonary complications (see also detailed definitions, page 37)       SiRS         SiRS       28 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl       yes       no         Servere Sepsis       yes       no       sesses with organ dysfunction, hypoperfusion or hypotension       yes       no         Servere Sepsis       yes       no       gesis with refractory hypoperfusion or hypotension       yes       no       gesis with refractory hypoperfusion or hypotension                |   | ARDS  |                  |                        | yes no            | if yes      |
| new progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions       ///       ///       ///       ///       ///         | _ | according to Berlin definition  |                  |                        | mild moderate     | severe      |
| Lung opacification with shift of surrounding tissue/ organ towards the affected area       yes       Inclined surrounding tissue/ organ towards the affected area         Cardiopulmonary edema       yes       Inclined surrounding tissue/ organ towards the affected area       yes       Inclined surrounding tissue/ organ towards the affected area         Pieural effusion       bunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray       yes       Inclined X-ray         Pneumothorax       refere air in the pleural space on chest X-ray/ ultrasonic imaging       yes       Inclined X-ray         New pulmonary infiltrates       yes       Inclined X-ray       yes       Inclined X-ray         SExtrapulmonary complications (see also detailed definitions, page 37)       SIRS       Inclined X-ray       yes       Inclined X-ray         Sepsis       SiRS       yes       Inclined X-ray       yes       Inclined X-ray       inclined X-ray         Severe Sepsis       SiRS       yes       Inclined X-ray       yes       Inclined X-ray       Inclined X-ray         Severe Sepsis       SiRS       yes       Inclined X-ray       yes       Inclined X-ray       Inclined X-ray         Severe Sepsis       SiRs       inclined X-ray       yes       Inclined X-ray       Inclined X-ray       Inclined X-ray       Inclined X-ray   |   |   | ucopenia and/    | or purulent secretions | yes no            | no CXR      |
| clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray       yes       no       no CXR         Pleural effusion       yes       no       no CXR       no CXR         Pneumothorax       yes       no       no CXR       no CXR         Interior doctsophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray       yes       no       no CXR         New pulmonary infiltrates       yes       no       no CXR       no CXR         Starpulmonary complications (see also detailed definitions, page 37)       SIRS       s2 findings: Temp <36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl       yes       no       .         Sepsis       Sirs in response to a confirmed infective process       yes       no       .       .         Septic shock       yes       no       .       .       .       .         Septic shock       yes       no       .       .       .       .       .         Septic shock       yes       no       .  | 1 |   | the affected ar  | ea                     | yes no            | no CXR      |
| bunning of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray       yes       ins       ins<  | ( |   | ular markings    | on chest X-ray         | yes no            | no CXR      |
| free air in the pleural space on chest X-ray/ ultrasonic imaging       yet       int       int<  |   |   | mithorax (supir  | ne) on chest X-ray     | yes no            | no CXR      |
| monolateral/ bilateral infiltrates without other clinical signs       yet       yet       yet         SIRS       22 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl       yets       no         Sepsis       SiRS in response to a confirmed infective process       yets       no   |   |   |                  |                        | yes no            | no CXR      |
| SIRS       22 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl       yes       no         Sepsis       yes       no   | I | New pulmonary infiltrates<br>monolateral/ bilateral infiltrates without other clinical signs                          |                  |                        | yes no            | no CXR      |
| ≥2 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl       yes       no         Sepsis       yes       no          Severe Sepsis       yes       no          Sepsis with organ dysfunction, hypoperfusion or hypotension       yes       no          Sepsis with organ dysfunction, hypoperfusion or hypotension despite adequate fluid resuscitation       yes       no          Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation       yes       no          Extrapulmonary infection       yes       no           wound infection + any other (extrapulmonary) infection       yes       no           Coma       yes       no             Acute myocardial infarction       yes       no <td>ļ</td> <td>5 Extrapulmonary complications (see also detailed</td> <td>d definitior</td> <td>ns, page 37)</td> <td></td> <td></td>  | ļ | 5 Extrapulmonary complications (see also detailed   | d definitior     | ns, page 37)           |                   |             |
| SiRS in response to a confirmed infective process       yes       no         Severe Sepsis       yes       no         Septic shock       yes       no         Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation       yes       no         Extrapulmonary infection       yes       no          wound infection + any other (extrapulmonary) infection       yes       no          Coma       yes       no           Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives       yes       no          Acute myocardial infarction       yes       no           rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death       yes       no          Acute renal failure       renations       yes       no       if yes         Risk: increased Crea x1.5/ GFR decrease > 25% or UO < 0.5 ml/kg/h x 12 hr   | ; |   | n; WBC < 4.00    | )0 or > 12.000/µl      | yes no            |             |
| Severe Sepsis       yes       no         Sepsis with organ dysfunction, hypoperfusion or hypotension       yes       no         Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation       yes       no         Extrapulmonary infection       yes       no  | ; |   |                  |                        | yes no            |             |
| Septic shock       yes       no         Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation       yes       no         Extrapulmonary infection       yes       no          Coma       yes       no          Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives       yes       no          Acute myocardial infarction       yes       no          rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death       yes       no          Acute renal failure       yes       no       if yes        no       if yes         Inisk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr  | ; | Severe Sepsis   |                  |                        | yes no            |             |
| Extrapulmonary infection       yes       no         wound infection + any other (extrapulmonary) infection       yes       no         Coma       glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives       yes       no         Acute myocardial infarction       yes       no       yes       no         rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death       yes       no       if yes         Acute renal failure       Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr  |   | Septic shock  | quate fluid resu | uscitation             | yes no            |             |
| Coma       yes       no         Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives       yes       no         Acute myocardial infarction       rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death       yes       no         Acute renal failure       Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr  |   |   | -                |                        | yes no            |             |
| rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death <ul> <li>Acute renal failure</li> <li>Risk: increased Crea x1.5/ GFR decrease &gt; 25% or urine output (UO) &lt; 0.5 ml/kg/h x 6 hr</li> <li>Injury: increased Crea x2 or GFR decrease &gt; 50% or UO &lt; 0.5 ml/kg/h x 12 hr</li> <li>Failure: increase Crea x3 or GFR decrease &gt; 75% or UO &lt; 0.3 ml/kg/h x 24 hr or anuria x 12 hrs</li> <li>Loss: complete loss of kidney function &gt; 4 weeks</li> </ul> R         I         F         L         I           Disseminated intravascular coagulation according to DIC score > 5         yes         no         if yes           Hepatic failure         1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery         yes         no         if yes           2 = food intolerance (FI) or intra-abdominal hypertension (IAH)         3 = FI and IAH         1         2         3         4           4 = abdominal compartment syndrome (ACS)         Signature         Case Report Form PROBESE stu   | ( | Coma  |                  |                        | yes no            |             |
| Acute renal failure       yes       no       if yes         Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr  | 1 |   | of cardiac isc   | hemia/sudden death     | yes no            |             |
| Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs   |   |   | (UO) < 0.5 ml/   | kg/h x 6 hr            | yes no            | if yes      |
| Disseminated intravascular coagulation according to DIC score > 5       yes       no         Hepatic failure bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0       yes       no         Gastrointestinal failure 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery 2 = food intolerance (FI) or intra-abdominal hypertension (IAH) 3 = FI and IAH 4 = abdominal compartment syndrome (ACS)       yes       no       if yes         Investigator       Signature       Case Report Form PROBESE stu   |   | Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 m   |                  | or anuria x 12 hrs     | R I I F           |             |
| Hepatic failure       yes       no         bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0       ges       no         Gastrointestinal failure       1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery       ges       no       if yes         2 = food intolerance (FI) or intra-abdominal hypertension (IAH)       3 = FI and IAH       1       2       3       4       1         4 = abdominal compartment syndrome (ACS)       Case Report Form PROBESE stu       Case Report Form PROBESE stu   | l | Disseminated intravascular coagulation  |                  |                        | yes no            |             |
| Gastrointestinal failure       1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery       yes       no       if yes         2 = food intolerance (FI) or intra-abdominal hypertension (IAH)       3 = FI and IAH       1       2       3       4       1         4 = abdominal compartment syndrome (ACS)       Case Report Form PROBESE stu  |   | Hepatic failure   | • 1.0            |                        | yes no            |             |
| 2 = food intolerance (FI) <i>or</i> intra–abdominal hypertension (IAH)<br>3 = FI and IAH<br>4 = abdominal compartment syndrome (ACS)<br>Investigator Signature   | ( | Gastrointestinal failure  |                  | ter surgery            | yes no            | if yes      |
| Investigator Signature Case Report Form PROBESE stu  |   | 2 = food intolerance (FI) <i>or</i> intra–abdominal hypertension (IAH)<br>3 = FI and IAH                              |                  |                        |                   | 4           |
| Investigator Signature   |   | 4 = abdominal compartment syndrome (ACS)  |                  | Cas                    | se Report Form PR | OBESE study |
|  |   | Investigator Signature  |                  |                        |                   | •           |

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|         | center patient |

**4** Postoperative Visit Day 2

#### report events within this period of not stated otherwise 1 Recovery yes no Lost to follow up if yes reason CPAP NPPV no yes New requirement of NIV if yes duration [hrs] intensity [pressure level]: standard of care treatment of resp. failure New requirement of yes 🗌 no if yes duration [hrs] invasive MV resp. failure other resurgery indication yes no 🔽 preop scheduled unscheduled ICU stay if yes indication: no Physiotherapy yes yes yes no no **Breathing exercises** incentive spirometry if yes Cumulated Ambulation Score (page 34) [0-6]: Impairment of wound deep superficial yes no 🗌 if yes healing Surgical wound infection yes no 🛛 superficial deep if yes abscess empyema phlegmon if yes yes no Return of bowel function 2 Fluids/ Drugs cumulative dose cumulative dose FFP Transfusion PRBC yes yes FP24 [ml] Fibrinogen [g] yes yes PPSB [IU] Cryoprecipitate yes yes Platelets other yes yes type: if other therapy yes no prophylaxis Antibiotics if yes yes no Dobutamine Dopamine Epinephrine Vasoactive drugs if yes Norepinephrine Phenylephrine other if yes type

**POSTOPERATIVE DAY 2 (last 24hrs period)** 

| Investigator Signature |  |
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4 Postoperative Visit Day 2

| 3.1 Actual organ function – mandatory measurements (status at visit)                                      |   |        |  |   |  |
|---|---|--------|--|---|--|
| SpO <sub>2</sub> beach chair position + 10 min in room air possible?                                      | yes no  | if yes | SpO <sub>2</sub> [%]:  |   |  |
|   |   | if no  | SpO <sub>2</sub> [%]: and FiO <sub>2</sub> [%] (page 35):  |   |  |
| RR [/min]   |   |        |  |   |  |
| HR [/min]   |   |        | ABP mean [mmHg]  |   |  |
| Temperature [°C]  |   |        | tympanic axillar inguinal oral rectal  |   |  |
|   |   |        | other if other specify:  |   |  |
| Airway secretion  | yes no  | if yes | purulent not purulent  |   |  |
| VAS dyspnea [1-10cm]  |   |        | VAS thoracic pain [1-10cm]   |   |  |
| VAS abdominal rest pain [1-   | 10cm]   |        | VAS abdominal incident pain [1-10cm]   |   |  |
| 3.2 Not mandatory measu   | rements   |        |  |   |  |
| Spirometry  |   |        | Laboratory tests   |   |  |
| -p.: •  |   |        |  |   |  |
| FVC [L]   | FVC[% predicted]  |        | Hb mmol/l g/dl   | ] |  |
|   | FVC[% predicted] FEV <sub>1</sub> [% predicted]                                   |        |  | ] |  |
| FVC [L]   |   |        | Hb mmol/I g/dl   | ] |  |
| FVC [L]   |   |        | Hb mmol/I g/dl WBC GPt/L   | ] |  |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]  | FEV <sub>1</sub> [% predicted]  |        | Hb mmol/I g/dl WBC GPt/L Platelets GPt/L   | ] |  |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained  | FEV <sub>1</sub> [% predicted]  |        | Hb mmol/l g/dl g/dl WBC GPt/L Platelets GPt/L INR  |   |  |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained<br>if yes                                    | FEV <sub>1</sub> [% predicted]  |        | Hb mmol/l g/dl g/dl WBC GPt/L<br>Platelets GPt/L<br>PT INR<br>PTT Sec  |   |  |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained<br>if yes<br>infiltrates                     | FEV <sub>1</sub> [% predicted]  |        | Hb     mmol/l     g/dl       WBC     GPt/L       Platelets     GPt/L       PT     INR       PTT     sec       Creatinine     μmol/l     mg/dl  |   |  |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained<br>if yes<br>infiltrates<br>pleural effusion | FEV1 [% predicted]         yes       no         yes       no         yes       no |        | Hb         mmol/l         g/dl           WBC         GPt/L           Platelets         GPt/L           PT         INR           PTT         sec           Creatinine         μmol/l         mg/dl           BUN         mmol/l         mg/dl |   |  |

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|         | center patient |

#### 4 Postoperative Visit Day 2

#### 4 Pulmonary complications (see also detailed definitions, page 36)

| Aspira<br>resp.  | tion pneumonitis<br>ailure after inhalation of gastric contents   | yes no                           |
|------------------|---|----------------------------------|
|                  | nospasm<br>expiratory wheezing treated with bronchodilators   | yes no                           |
|                  | spiratory failure<br>90% or PaO₂<60mmHg for 10min in room air, responding to oxygen ≤ 2l/min  | yes no                           |
| Moder<br>SpO2-   | ate respiratory failure<br>90% or PaO₂<60mmHg for 10min in room air, responding to oxygen > 2l/min  | yes no                           |
| Sever<br>need    | e respiratory failure<br>or non-invasive or invasive mechanical ventilation   | yes no                           |
| ARDS             |   | yes no if yes                    |
|                  | ling to Berlin definition   | mild moderate severe             |
|                  | nary infection<br>rogressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions   | yes no no CXR                    |
| Atelec           | asis<br>pacification with shift of surrounding tissue/ organ towards the affected area  | yes no no CXR                    |
|                  | pulmonary edema<br>I signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray   | yes no no CXR                    |
|                  | l effusion<br>g of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray  | yes no no CXR                    |
|                  | nothorax<br>r in the pleural space on chest X-ray/ ultrasonic imaging   | yes no no CXR                    |
| New p            | ulmonary infiltrates<br>ateral/ bilateral infiltrates without other clinical signs  | yes no no CXR                    |
| 5 Extr           | apulmonary complications (see also detailed definitions, page 37)   |                                  |
| SIRS<br>≥2 fin   | lings: Temp < 36 $^{\circ}$ C or > 38 $^{\circ}$ C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl  | yes no                           |
| Sepsis           | n response to a confirmed infective process   | yes no                           |
|                  | e Sepsis<br>with organ dysfunction, hypoperfusion or hypotension  | yes no                           |
|                  | shock<br>with refractory hypoperfusion or hypotension despite adequate fluid resuscitation  | yes no                           |
|                  | ulmonary infection<br>I infection + any other (extrapulmonary) infection  | yes no                           |
| Coma<br>Glaso    | ow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives   | yes no                           |
| Acute            | myocardial infarction<br>Il of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death   | yes no                           |
| Acute            | renal failure<br>ncreased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr   | yes no if yes                    |
| Injury<br>Failur | increased Crea x2 or GFR decrease > 50% <i>or</i> UO < 0.5 ml/kg/h x 12 hr<br>e: increase Crea x3 or GFR decrease > 75% <i>or</i> UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs |                                  |
| Disser           | complete loss of kidney function > 4 weeks<br>ninated intravascular coagulation<br>ling to DIC score > 5  | yes no                           |
| Hepat            | c failure<br>n on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0  | yes no                           |
| Gastro           | intestinal failure<br>teral feeding with under 50% of calculated needs or no feeding 3 days after surgery   | yes 🔲 no 🗍 if yes                |
| 2 = fo<br>3 = Fl | od intolerance (FI) <i>or</i> intra–abdominal hypertension (IAH)<br>and IAH   |                                  |
|                  | dominal compartment syndrome (ACS) Ca   | se Report Form PROBESE study     |
| Inve             | stigator Signature  | n 1.2.1, Aug. 2014, Thomas Bluth |

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|         | center patient |

5 Postoperative Visit Day 3

| <b>POSTOPERATIVE DAY 3 (last 24hrs period)</b><br>report events within this period of not stated otherwise |                 |               |               |             |   |
|--|-----------------|---------------|---------------|-------------|---|
| 1 Recovery   |                 | report e      | events within | n this peri | od of not stated otherwise                    |
| Lost to follow   | up              | yes           | no 🗌          | if yes      | reason  |
| New requirem   | nent of NIV     | yes           | no 🗌          | if yes      | CPAP NPPV duration [hrs]                      |
|  |                 |               |               |             | intensity [pressure level]:                   |
|  |                 |               |               |             | standard of care intreatment of resp. failure |
| New requirem invasive MV   | nent of         | yes           | no 🗌          | if yes      | duration [hrs]                                |
|  |                 |               |               | indication  | resurgery resp. failure other                 |
| ICU stay   |                 | yes           | no 🗌          | if yes      | preop scheduled unscheduled                   |
|  |                 |               |               |             | indication:                                   |
| Physiotherap   | у               | yes           | no 🗌          |             |   |
| Breathing exe  | ercises         | yes           | no 🗌          | if yes      | incentive spirometry yes no                   |
| Cumulated Ar   | mbulation Score | e (page 34) [ | [0-6]:        |             |   |
| Impairment of<br>healing   | fwound          | yes           | no 🗌          | if yes      | superficial deep                              |
| Surgical wour  | nd infection    | yes           | no 🗌          | if yes      | superficial deep                              |
|  |                 |               |               | if yes      | abscess empyema phlegmon                      |
| Return of bow  | vel function    | yes           | no 🗌          |             |   |
| 2 Fluids/ Dru  | gs              |               |               |             |   |
|  |                 |               | cumulative    | e dose      | cumulative dose                               |
| Transfusion  | PRBC            | yes           | ]             |             | FFP yes                                       |
| [ml]   | FP24            | yes           | ]             |             | Fibrinogen [g] yes                            |
|  | Cryoprecipitate | e yes         | ]             |             |   |
|  | Platelets       | yes           | ]             |             | other yes                                     |
|  |                 |               |               | if          | other type:                                   |
| Antibiotics  |                 | yes           | no 🗌          | if yes      | prophylaxis therapy                           |
| Vasoactive dr  | ugs             | yes           | no 🗌          | if yes      | Dobutamine Dopamine Epinephrine               |
|  |                 |               |               |             | Norepinephrine Phenylephrine other            |
|  |                 |               |               | if yes      | type  |

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**5** Postoperative Visit Day 3

| 3.1 Actual organ function – mandatory measurements (status at visit)                                      |   |        |  |  |             |
|---|---|--------|--|--|-------------|
| SpO <sub>2</sub> beach chair position + 10 min in room air possible?                                      | yes no  | if yes | SpO <sub>2</sub> [%]:                                    |  |             |
|   |   | if no  | SpO <sub>2</sub> [%]:                                    | and $FiO_2$ [%] (page 35):                                 |             |
| RR [/min]   |   |        |  |  |             |
| HR [/min]   |   |        | ABP mean [mmH  | g]   |             |
| Temperature [°C]  |   |        | tympanic 🔲 axillar                                       | r 📄 inguinal 📄 oral 📄                                      | rectal      |
|   |   |        | other if ot  | her Specify:   |             |
| Airway secretion  | yes no  | if yes | purulent not   | purulent   |             |
| VAS dyspnea [1-10cm]  |   |        | VAS thoracic pai   | N [1-10cm]   |             |
| VAS abdominal rest pain [1-1  | I0cm]   |        | VAS abdominal i  | ncident pain [1-10cm]                                      |             |
| 3.2 Non-mandatory measu   | rements   |        |  |  |             |
|   |   |        |  |  |             |
| Spirometry  |   |        | Laboratory test  | S  |             |
| <b>Spirometry</b><br>FVC [L]  | FVC[% predicted]                                |        | Laboratory test  | s mmol/I   | g/dl        |
|   | FVC[% predicted] FEV <sub>1</sub> [% predicted] |        | -  |  | g/dl        |
| FVC [L]   |   |        | Hb   | mmol/l   | g/dl        |
| FVC [L]   |   |        | Hb<br>WBC  | mmol/I<br>GPt/L  | g/dl        |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]  | FEV <sub>1</sub> [% predicted]                  |        | Hb<br>WBC<br>Platelets                                   | mmol/l<br>GPt/L<br>GPt/L                                   | g/dl        |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained  | FEV <sub>1</sub> [% predicted]                  |        | Hb<br>WBC<br>Platelets<br>PT                             | mmol/I<br>GPt/L<br>GPt/L<br>INR                            | g/dl  mg/dl |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained<br>if yes                                    | FEV <sub>1</sub> [% predicted]                  |        | Hb<br>WBC<br>Platelets<br>PT<br>PTT                      | mmol/I<br>GPt/L<br>GPt/L<br>INR<br>sec                     |             |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained<br>if yes<br>infiltrates                     | FEV <sub>1</sub> [% predicted]                  |        | Hb<br>WBC<br>Platelets<br>PT<br>PTT<br>Creatinine        | mmol/I<br>GPt/L<br>GPt/L<br>INR<br>sec<br>μmol/I           | mg/dl       |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained<br>if yes<br>infiltrates<br>pleural effusion | FEV <sub>1</sub> [% predicted]                  |        | Hb<br>WBC<br>Platelets<br>PT<br>PTT<br>Creatinine<br>BUN | mmol/l<br>GPt/L<br>GPt/L<br>INR<br>sec<br>μmol/l<br>mmol/l | mg/dl       |

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#### 4 Pulmonary complications (see also detailed definitions, page 36)

| Aspiration pneumonitis<br>resp. failure after inhalation of gastric contents  | yes no                           |
|---|----------------------------------|
| Bronchospasm<br>newly expiratory wheezing treated with bronchodilators  | yes no                           |
| Mild respiratory failure<br>SpO₂<90% or PaO₂<60mmHg for 10min in room air, responding to oxygen ≤ 2l/min  | yes no                           |
| Moderate respiratory failure<br>SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min  | yes no                           |
| Severe respiratory failure<br>need for non-invasive or invasive mechanical ventilation  | yes no                           |
| ARDS  | yes 🔄 no 🔄 if yes                |
| according to Berlin definition  | mild moderate severe             |
| Pulmonary infection<br>new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions  | yes no no CXR                    |
| Atelectasis<br>lung opacification with shift of surrounding tissue/ organ towards the affected area   | yes no no CXR                    |
| Cardiopulmonary edema<br>clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray  | yes no no CXR                    |
| Pleural effusion<br>blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray   | yes no no CXR                    |
| Pneumothorax<br>free air in the pleural space on chest X-ray/ ultrasonic imaging  | yes no no CXR                    |
| New pulmonary infiltrates<br>monolateral/ bilateral infiltrates without other clinical signs  | yes no no CXR                    |
| 5 Extrapulmonary complications (see also detailed definitions, page 37)   |                                  |
| SIRS<br>≥2 findings: Temp < 36 °C or > 38 °C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl  | yes no                           |
| Sepsis<br>SIRS in response to a confirmed infective process   | yes no                           |
| Severe Sepsis<br>Sepsis with organ dysfunction, hypoperfusion or hypotension  | yes no                           |
| Septic shock<br>Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation  | yes no                           |
| Extrapulmonary infection<br>wound infection + any other (extrapulmonary) infection  | yes no                           |
| Coma<br>Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives  | yes no                           |
| Acute myocardial infarction<br>rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death   | yes no                           |
| Acute renal failure<br>Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr  | yes no if yes                    |
| Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr<br>Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs<br>Loss: complete loss of kidney function > 4 weeks |                                  |
| Disseminated intravascular coagulation<br>according to DIC score > 5  | yes no                           |
| Hepatic failure<br>bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0  | yes no                           |
| Gastrointestinal failure<br>1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery   | yes no if yes                    |
| 2 = food intolerance (FI) <i>or</i> intra–abdominal hypertension (IAH)<br>3 = FI and IAH  |                                  |
| 4 = abdominal compartment syndrome (ACS)  | se Report Form PROBESE study     |
| Investigator Signature  | n 1.2.1, Aug. 2014, Thomas Bluth |
|   |                                  |

| Case ID |                |  |
|---------|----------------|--|
|         | center patient |  |

6 Postoperative Visit Day 4

report events within this period of not stated otherwise

| 1 Recovery                       | •                    |           | •          |   |
|----------------------------------|----------------------|-----------|------------|---|
| Lost to follow up                | yes                  | no 🗌      | if yes     | reason  |
| New requirement o                | NIV yes              | no 🗌      | if yes     | CPAP NPPV duration [hrs]                      |
|                                  |                      |           |            | intensity [pressure level]:                   |
|                                  |                      |           |            | standard of care interatment of resp. failure |
| New requirement o<br>invasive MV | yes                  | no 🗌      | if yes     | duration [hrs]                                |
|                                  |                      |           | indication | resurgery resp. failure resp. failure         |
| ICU stay                         | yes                  | no 🗌      | if yes     | preop scheduled unscheduled                   |
|                                  |                      |           |            | indication:                                   |
| Physiotherapy                    | yes                  | no 🗌      |            |   |
| Breathing exercises              | yes                  | no        | if yes     | incentive spirometry yes no                   |
| Cumulated Ambula                 | tion Score (page 34) | [0-6]:    |            |   |
| Impairment of wour healing       | id yes               | no 🗌      | if yes     | superficial deep                              |
| Surgical wound infe              | ection yes           | no 🗌      | if yes     | superficial deep                              |
|                                  |                      |           | if yes     | abscess empyema phlegmon                      |
| Return of bowel fur              | ction yes            | no 🗌      |            |   |
| 2 Fluids/ Drugs                  |                      |           |            |   |
| U                                |                      | cumulativ | re dose    | cumulative dose                               |
| Transfusion PRB                  | C yes                | 7         |            | FFP yes                                       |
| [ml] FP24                        | yes                  | 1         |            | Fibrinogen [g] yes                            |
| Cryo                             | orecipitate yes      | <br>-     |            | PPSB [IU] yes                                 |
| Plate                            | lets yes             | ī         |            | other yes                                     |
|                                  |                      |           | if         | other type:                                   |
| Antibiotics                      | yes                  | no 🗌      | if yes     | prophylaxis therapy                           |
| Vasoactive drugs                 | yes                  | no 🗌      | if yes     | Dobutamine Dopamine Epinephrine               |
|                                  |                      |           |            | Norepinephrine Phenylephrine other            |
|                                  |                      |           | if yes     | type  |

| Investigator | Signature |
|--------------|-----------|
|              |           |

| Case ID |                |
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|         | center patient |

6 Postoperative Visit Day 4

| 3.1 Actual organ function – mandatory measurements (status at visit)               |   |   |        |  |  |  |
|--|---|---|--------|--|--|--|
| SpO <sub>2</sub> beach chair position + 10 min in room air possible?               | yes no  | yes SpO <sub>2</sub> [%]:   |        |  |  |  |
|  |   | no $SpO_2[\%]$ : and $FiO_2[\%]$ (page 35):   |        |  |  |  |
| RR [/min]  |   |   |        |  |  |  |
| HR [/min]  |   | ABP mean [mmHg]   |        |  |  |  |
| Temperature [°C]   |   | tympanic axillar inguinal oral  | rectal |  |  |  |
|  |   | other if other specify:   |        |  |  |  |
| Airway secretion   | yes no  | yes purulent not purulent   |        |  |  |  |
| VAS dyspnea [1-10cm]   |   | VAS thoracic pain [1-10cm]  |        |  |  |  |
| VAS abdominal rest pain [1-1   | 10cm]   | VAS abdominal incident pain [1-10cm]  |        |  |  |  |
| 3.2 Non-mandatory measu  | rements   |   |        |  |  |  |
| Spirometry   |   | Laboratory tests  |        |  |  |  |
|  |   |   |        |  |  |  |
| FVC [L]  | FVC[% predicted]  | Hb mmol/I   | g/dl   |  |  |  |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]   | FVC[% predicted]<br>FEV <sub>1</sub> [% predicted]                                | Hb mmol/l<br>WBC GPt/L  | g/dl   |  |  |  |
|  |   |   | g/dl   |  |  |  |
|  |   | WBC GPt/L   | g/dl   |  |  |  |
| FEV <sub>1</sub> [L/1sec]  | FEV <sub>1</sub> [% predicted]  | WBC     GPt/L       Platelets     GPt/L   | g/dl   |  |  |  |
| FEV <sub>1</sub> [L/1sec] Chest X-ray obtained                                     | FEV <sub>1</sub> [% predicted]  | WBC     GPt/L       Platelets     GPt/L       PT     INR  | g/dl   |  |  |  |
| FEV <sub>1</sub> [L/1sec] Chest X-ray obtained if yes                              | FEV <sub>1</sub> [% predicted]  | WBC     GPt/L       Platelets     GPt/L       PT     INR       PTT     sec  |        |  |  |  |
| FEV <sub>1</sub> [L/1sec] Chest X-ray obtained if yes infiltrates                  | FEV <sub>1</sub> [% predicted]  | WBC GPt/L Platelets GPt/L PT INR PTT sec Creatinine   | mg/dl  |  |  |  |
| FEV <sub>1</sub> [L/1sec] Chest X-ray obtained if yes infiltrates pleural effusion | FEV1 [% predicted]         yes       no         yes       no         yes       no | WBC     GPt/L       Platelets     GPt/L       PT     INR       PTT     sec       Creatinine     µmol/l       BUN     mmol/l | mg/dl  |  |  |  |

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| Case ID |                |
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|         | center patient |

| 6 | Posto | perative | Visit | Day | 4 |
|---|-------|----------|-------|-----|---|
|---|-------|----------|-------|-----|---|

#### 4 Pulmonary complications (see also detailed definitions, page 36)

| Aspiration pneumonitis<br>resp. failure after inhalation of gastric contents  | yes no  |
|---|---|
| Bronchospasm<br>newly expiratory wheezing treated with bronchodilators  | yes no  |
| Mild respiratory failure<br>SpO₂<90% or PaO₂<60mmHg for 10min in room air, responding to oxygen ≤ 2l/min  | yes no  |
| Moderate respiratory failure<br>SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min  | yes no  |
| Severe respiratory failure<br>need for non-invasive or invasive mechanical ventilation  | yes no  |
| ARDS  | yes no if yes   |
| according to Berlin definition  | mild moderate severe  |
| Pulmonary infection<br>new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretion   | yes no no CXR no  |
| Atelectasis<br>lung opacification with shift of surrounding tissue/ organ towards the affected area   | yes no no CXR   |
| Cardiopulmonary edema<br>clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray  | yes no no CXR   |
| Pleural effusion<br>blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray   | yes no no CXR   |
| Pneumothorax<br>free air in the pleural space on chest X-ray/ ultrasonic imaging  | yes no no CXR   |
| New pulmonary infiltrates<br>monolateral/ bilateral infiltrates without other clinical signs  | yes no no CXR   |
| 5 Extrapulmonary complications (see also detailed definitions, page 37)   |   |
| SIRS<br>≥2 findings: Temp < 36 <sup>0</sup> C or > 38 <sup>0</sup> C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl  | yes no  |
| Sepsis<br>SIRS in response to a confirmed infective process   | yes no  |
| Severe Sepsis<br>Sepsis with organ dysfunction, hypoperfusion or hypotension  | yes no  |
| Septic shock<br>Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation  | yes no  |
| Extrapulmonary infection<br>wound infection + any other (extrapulmonary) infection  | yes no  |
| Coma<br>Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives  | yes no  |
| Acute myocardial infarction<br>rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death   | yes no  |
| Acute renal failure<br>Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr  | yes no if yes   |
| Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr<br>Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs<br>Loss: complete loss of kidney function > 4 weeks |   |
| Disseminated intravascular coagulation<br>according to DIC score > 5  | yes no  |
| Hepatic failure<br>bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0  | yes no  |
| Gastrointestinal failure<br>1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery   | yes no if yes   |
| 2 = food intolerance (FI) <i>or</i> intra–abdominal hypertension (IAH)<br>3 = FI and IAH  |   |
| 4 = abdominal compartment syndrome (ACS)  | Doog Doport Form DDODESE atude                                    |
| Investigator Signature  | Case Report Form PROBESE study ion 1.2.1, Aug. 2014, Thomas Bluth |
|   | -   |

| Case ID |                |
|---------|----------------|
|         | center patient |

7 Postoperative Visit Day 5

| 1 Recovery               |                 | report e      | vents within | n this perio | od of not stated otherwise                    |
|--------------------------|-----------------|---------------|--------------|--------------|---|
| Lost to follow           | up              | yes           | no 🗌         | if yes       | reason  |
| New requirem             | nent of NIV     | yes           | no 🗌         | if yes       | CPAP NPPV duration [hrs]                      |
|                          |                 |               |              |              | intensity [pressure level]:                   |
|                          |                 |               |              |              | standard of care intreatment of resp. failure |
| New requirem             | nent of         | yes           | no 🗌         | if yes       | duration [hrs]                                |
|                          |                 |               |              | indication   | resurgery resp. failure other                 |
| ICU stay                 |                 | yes           | no 🗌         | if yes       | preop scheduled unscheduled                   |
|                          |                 |               |              |              | indication:                                   |
| Physiotherap             | у               | yes           | no 🗌         |              |   |
| Breathing exe            | ercises         | yes           | no 🗌         | if yes       | incentive spirometry yes no                   |
| Cumulated Ar             | mbulation Score | e (page 34) [ | 0-6]:        |              |   |
| Impairment of<br>healing | fwound          | yes           | no 🗌         | if yes       | superficial deep                              |
| Surgical wour            | nd infection    | yes           | no 🗌         | if yes       | superficial deep                              |
|                          |                 |               |              | if yes       | abscess empyema phlegmon                      |
| Return of bov            | vel function    | yes           | no 🗌         |              |   |
| 2 Fluids/ Dru            | igs             |               |              |              |   |
|                          | •               |               | cumulative   | e dose       | cumulative dose                               |
| Transfusion              | PRBC            | yes           |              |              | FFP yes                                       |
| [ml]                     | FP24            | yes           |              |              | Fibrinogen [g] yes                            |
|                          | Cryoprecipitate | e yes         |              |              | PPSB [IU] yes                                 |
|                          | Platelets       | yes           |              |              | other yes                                     |
|                          |                 |               |              | if           | other type:                                   |
| Antibiotics              |                 | yes           | no           | if yes       | prophylaxis therapy                           |
| Vasoactive dr            | rugs            | yes           | no 🗌         | if yes       | Dobutamine Dopamine Epinephrine               |
|                          |                 |               |              |              | Norepinephrine Phenylephrine other            |
|                          |                 |               |              | if yes       | type  |

**POSTOPERATIVE DAY 5 (last 24hrs period)** 

| Investigator Signature |  |
|------------------------|--|
|------------------------|--|

| Case ID |                |
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|         | center patient |

7 Postoperative Visit Day 5

| 3.1 Actual organ function  | <ul> <li>mandatory measurem</li> </ul> | ents (status at visit)  |
|--|--|---|
| SpO <sub>2</sub> beach chair position + 10 min in room air possible? | yes no if                              | yes SpO <sub>2</sub> [%]:   |
|  | if                                     | no $SpO_2[\%]$ : and $FiO_2[\%]$ (page 35):                                 |
| RR [/min]  |  |   |
| HR [/min]  |  | ABP mean [mmHg]   |
| Temperature [°C]   |  | tympanic axillar inguinal oral rectal                                       |
|  |  | other if other Specify:   |
| Airway secretion   | yes no if                              | ves purulent not purulent   |
| VAS dyspnea [1-10cm]   |  | VAS thoracic pain [1-10cm]  |
| VAS abdominal rest pain [1-  | 10cm]                                  | VAS abdominal incident pain [1-10cm]  |
| 3.2 Non-mandatory measu  | irements                               |   |
| Spirometry   |  | Laboratory tests  |
| FVC [L]  | FVC[% predicted]                       | Hb mmol/l g/dl  |
| FEV <sub>1</sub> [L/1sec]  | FEV <sub>1</sub> [% predicted]         | WBC GPt/L   |
|  |  | Platelets GPt/L   |
| Chest X-ray obtained   | yes no                                 | PT INR  |
| if yes   |  | PTT sec   |
| infiltrates  | yes no                                 | Creatinine µmol/l mg/dl   |
|  |  |   |
| pleural effusion   | yes no                                 | BUN mmol/l mg/dl  |
| pleural effusion<br>atelectasis                                      | yes no                                 | BUN         mmol/l         mg/dl           ALT         μmol/s*l         U/L |
|  |  |   |

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| Case ID |                |
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|         | center patient |

| 7 | Posto  | perative | Visit | Dav | 5 |
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#### 4 Pulmonary complications (see also detailed definitions, page 36)

| Aspiration pneumonitis<br>resp. failure after inhalation of gastric contents  | yes no  |
|---|---|
| Bronchospasm<br>newly expiratory wheezing treated with bronchodilators  | yes no  |
| Mild respiratory failure<br>SpO₂<90% or PaO₂<60mmHg for 10min in room air, responding to oxygen ≤ 2l/min  | yes no  |
| Moderate respiratory failure<br>SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min  | yes no  |
| Severe respiratory failure<br>need for non-invasive or invasive mechanical ventilation  | yes no  |
| ARDS  | yes no if yes   |
| according to Berlin definition  | mild moderate severe  |
| Pulmonary infection<br>new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretion   | yes no no CXR no  |
| Atelectasis<br>lung opacification with shift of surrounding tissue/ organ towards the affected area   | yes no no CXR   |
| Cardiopulmonary edema<br>clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray  | yes no no CXR   |
| Pleural effusion<br>blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray   | yes no no CXR   |
| Pneumothorax<br>free air in the pleural space on chest X-ray/ ultrasonic imaging  | yes no no CXR   |
| New pulmonary infiltrates<br>monolateral/ bilateral infiltrates without other clinical signs  | yes no no CXR   |
| 5 Extrapulmonary complications (see also detailed definitions, page 37)   |   |
| SIRS<br>≥2 findings: Temp < 36 <sup>0</sup> C or > 38 <sup>0</sup> C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µl  | yes no  |
| Sepsis<br>SIRS in response to a confirmed infective process   | yes no  |
| Severe Sepsis<br>Sepsis with organ dysfunction, hypoperfusion or hypotension  | yes no  |
| Septic shock<br>Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation  | yes no  |
| Extrapulmonary infection<br>wound infection + any other (extrapulmonary) infection  | yes no  |
| Coma<br>Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives  | yes no  |
| Acute myocardial infarction<br>rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death   | yes no  |
| Acute renal failure<br>Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr  | yes no if yes   |
| Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr<br>Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs<br>Loss: complete loss of kidney function > 4 weeks |   |
| Disseminated intravascular coagulation<br>according to DIC score > 5  | yes no  |
| Hepatic failure<br>bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0  | yes no  |
| Gastrointestinal failure<br>1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery   | yes no if yes   |
| 2 = food intolerance (FI) <i>or</i> intra–abdominal hypertension (IAH)<br>3 = FI and IAH  |   |
| 4 = abdominal compartment syndrome (ACS)  | Doog Doport Form DDODESE atude                                    |
| Investigator Signature  | Case Report Form PROBESE study ion 1.2.1, Aug. 2014, Thomas Bluth |
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| Case ID |                |
|---------|----------------|
|         | center patient |

8 Discharge/Day90

## DISCHARGE (period from last visit to discharge) + POSTOPERATIVE DAY 90 report events within this period of not stated otherwise

| 1 Recovery                        |                |                |            |  |
|-----------------------------------|----------------|----------------|------------|--|
| Lost to follow up                 | yes            | no 🗌           | if yes     | reason                                       |
| Date of discharge                 | /              | / 20           |            | Postop day of discharge [1-90]               |
| Hospital free days on day 90      |                |                |            |  |
| New requirement of NIV            | yes            | no 🗌           | if yes     | CPAP NPPV duration [hrs]                     |
|                                   |                |                |            | intensity [pressure level]:                  |
|                                   |                |                |            | standard of care itreatment of resp. failure |
| New requirement of<br>invasive MV | yes            | no 🗌           | if yes     | duration [hrs]                               |
|                                   |                |                | indication | resurgery resp. failure other                |
| ICU stay                          | yes            | no 🗌           | if yes     | preop scheduled unscheduled                  |
|                                   |                |                |            | indication:                                  |
| Cumulated Ambulation Score        | e (actual stat | e, page 34) [( | 0-6]:      |  |
| Impairment of wound<br>healing    | yes            | no 🗌           | if yes     | superficial deep                             |
| Surgical wound infection          | yes            | no 🗌           | if yes     | superficial deep                             |
|                                   |                |                | if yes     | abscess empyema phlegmon                     |
| Antibiotics                       | yes            | no 🗌           | if yes     | prophylaxis therapy                          |
|                                   |                |                |            |  |

Investigator \_\_\_\_\_ Signature \_\_\_\_\_

| Case ID |                |
|---------|----------------|
|         | center patient |

8 Discharge/Day90

| 2.1 Actual organ function -   | <ul> <li>mandatory measure</li> </ul>           | ements | s (status at visit)  |   |
|---|---|--------|--|---|
| SpO <sub>2</sub> beach chair position + 10 min in room air possible?                                      | yes no  | if yes | SpO <sub>2</sub> [%]:  |   |
|   |   | if no  | SpO <sub>2</sub> [%]: and FiO <sub>2</sub> [%] (page 35):  |   |
| RR [/min]   |   |        |  |   |
| HR [/min]   |   |        | ABP mean [mmHg]  |   |
| Temperature [°C]  |   |        | tympanic axillar inguinal oral rectal  |   |
|   |   |        | other if other specify:  |   |
| Airway secretion  | yes no  | if yes | purulent not purulent  |   |
| VAS dyspnea [1-10cm]  |   |        | VAS thoracic pain [1-10cm]   |   |
| VAS abdominal rest pain [1-1  | 10cm]   |        | VAS abdominal incident pain [1-10cm]   |   |
| 2.2 Non-mandatory measu   | rements   |        |  |   |
|   |   |        |  |   |
| Spirometry  |   |        | Laboratory tests   |   |
| Spirometry<br>FVC [L]   | FVC[% predicted]                                |        | Laboratory tests       Hb     mmol/l g/dl  | ] |
|   | FVC[% predicted] FEV <sub>1</sub> [% predicted] |        |  | ] |
| FVC [L]   |   |        | Hb mmol/l g/dl   | ] |
| FVC [L]   |   |        | Hb mmol/l g/dl g/dl WBC GPt/L  | ] |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]  | FEV <sub>1</sub> [% predicted]                  |        | Hb mmol/l g/dl<br>WBC GPt/L<br>Platelets GPt/L   | ] |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained  | FEV <sub>1</sub> [% predicted]                  |        | Hb mmol/l g/dl WBC GPt/L Platelets GPt/L PT INR  | ] |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained<br>if yes                                    | FEV <sub>1</sub> [% predicted]                  |        | Hb mmol/l g/dl<br>WBC GPt/L<br>Platelets GPt/L<br>PT INR<br>PTT sec  | ] |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained<br>if yes<br>infiltrates                     | FEV <sub>1</sub> [% predicted]                  |        | Hb     mmol/l     g/dl       WBC     GPt/L       Platelets     GPt/L       PT     INR       PTT     sec       Creatinine     μmol/l     mg/dl                                | ] |
| FVC [L]<br>FEV <sub>1</sub> [L/1sec]<br>Chest X-ray obtained<br>if yes<br>infiltrates<br>pleural effusion | FEV <sub>1</sub> [% predicted]                  |        | Hb     mmol/l     g/dl       WBC     GPt/L       Platelets     GPt/L       PT     INR       PTT     sec       Creatinine     μmol/l     mg/dl       BUN     mmol/l     mg/dl | ] |

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| Case ID |                |  |
|---------|----------------|--|
|         | center patient |  |

#### 8 Discharge/Day90

#### 3 Pulmonary complications (see also detailed definitions, page 36)

| o rumonary complications (see also detailed definitions, page co)   |                             |
|---|-----------------------------|
| Aspiration pneumonitis<br>resp. failure after inhalation of gastric contents  | yes no                      |
| Bronchospasm<br>newly expiratory wheezing treated with bronchodilators  | yes no                      |
| Mild respiratory failure<br>SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen $\leq 21/min$                                       | yes no                      |
| Moderate respiratory failure<br>SpO <sub>2</sub> <90% or PaO <sub>2</sub> <60mmHg for 10min in room air, responding to oxygen > 2l/min  | yes no                      |
| Severe respiratory failure<br>need for non-invasive or invasive mechanical ventilation  | yes no                      |
| ARDS  | yes no if yes               |
| according to Berlin definition  | mild moderate severe        |
| Pulmonary infection<br>new/ progressive infiltrates + 2: antibiotics, fever, leukocytosis/ leucopenia and/or purulent secretions  | yes no no CXR               |
| Atelectasis<br>lung opacification with shift of surrounding tissue/ organ towards the affected area   | yes no no CXR               |
| Cardiopulmonary edema<br>clinical signs of congestion + interstitial infiltrates/ increased vascular markings on chest X-ray  | yes no no CXR               |
| Pleural effusion<br>blunting of costophrenic angle (standing)/ hazy opacity in one hemithorax (supine) on chest X-ray   | yes no no CXR               |
| Pneumothorax<br>free air in the pleural space on chest X-ray/ ultrasonic imaging  | yes no no CXR               |
| New pulmonary infiltrates<br>monolateral/ bilateral infiltrates without other clinical signs  | yes no no CXR               |
| 4 Extrapulmonary complications (see also detailed definitions, page 37)   |                             |
| SIRS<br>≥2 findings: Temp < 36 <sup>0</sup> C or > 38 <sup>0</sup> C; HR > 90 bpm, RR > 20 bpm; WBC < 4.000 or > 12.000/µI  | yes no                      |
| Sepsis<br>SIRS in response to a confirmed infective process   | yes no                      |
| Severe Sepsis<br>Sepsis with organ dysfunction, hypoperfusion or hypotension  | yes no                      |
| Septic shock<br>Sepsis with refractory hypoperfusion or hypotension despite adequate fluid resuscitation  | yes no                      |
| Extrapulmonary infection<br>wound infection + any other (extrapulmonary) infection  | yes no                      |
| Coma<br>Glasgow-Coma-Scale ≤ 8 without therapeutic coma/ sedatives  | yes no                      |
| Acute myocardial infarction<br>rise/ fall of cardiac markers + symptoms/ ECG changes/ /imaging of cardiac ischemia/sudden death   | yes no                      |
| Acute renal failure<br>Risk: increased Crea x1.5/ GFR decrease > 25% or urine output (UO) < 0.5 ml/kg/h x 6 hr  | yes no if yes               |
| Injury: increased Crea x2 or GFR decrease > 50% or UO < 0.5 ml/kg/h x 12 hr<br>Failure: increase Crea x3 or GFR decrease > 75% or UO < 0.3 ml/kg/h x 24 hr or anuria x 12 hrs |                             |
| Loss: complete loss of kidney function > 4 weeks Disseminated intravascular coagulation   | yes no                      |
| according to DIC score > 5<br>Hepatic failure   | yes no                      |
| bilirubin on postop day5/day1 > 1,7 + INR on postop day5/day1 > 1,0<br>Gastrointestinal failure   |                             |
| 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after surgery<br>2 = food intolerance (FI) <i>or</i> intra–abdominal hypertension (IAH)           | yes no if yes               |
| 3 = FI and IAH<br>4 = abdominal compartment syndrome (ACS)  |                             |
|   |                             |
| Investigator Signature  | e Report Form PROBESE study |

| Case ID |              |     |
|---------|--------------|-----|
|         | center patie | n t |

#### **DEFINITIONS and SCORES**

#### 1 Waist-Hip-Ratio measurement according to WHO protocol

Waist circumference should be measured at the midpoint between the lower margin of the least palpable rib and the top of the iliac crest, using a stretch - resistant tape that provides a constant 100 g tension. Hip circumference should be measured around the widest portion of the buttocks, with the tape parallel to the floor.

For both measurements, the subject should stand with feet close together, arms at the side and body weight evenly distributed, and should wear little clothing. The subject should be relaxed, and the measurements should be taken at the end of a normal expiration. Each measurement should be repeated twice; if the measurements are within 1 cm of one another, the average should be calculated. If the difference between the two measurements exceeds 1 cm, the two measurements should be repeated

(WHO. Waist Circumference and Waist–Hip Ratio: Report of a WHO Expert Consultation. Geneva, World Health Organization (WHO), 2008)

#### 2 STOP-BANG Score

| 1. Snoring            | Do you snore loudly (loud enough to be heard through closed doors)? | yes   | no 🗌 |
|-----------------------|---|-------|------|
| 2. Tired              | Do you often feel tired, fatigued, or sleepy during daytime?        | yes   | no 🗌 |
| 3. Observed           | Has anyone observed you stop breathing during your sleep?           | yes   | no 🗌 |
| 4. Blood pressure     | Do you have or are you being treated for high blood pressure?       | yes   | no 🗌 |
| 5. BMI                | BMI more than 35 kg m <sup>-2</sup> ?                               | yes 🗌 | no 🗌 |
| 6. Age:               | Age over 50 years old?  | yes   | no 🗌 |
| 7. Neck circumference | Neck circumference >40 cm?  | yes 🗌 | no 🗌 |
| 8. Gender             | Male?   | yes   | no 🗌 |
| Total score           | Yes to questions  |       |      |

#### **3 Cumulated Ambulation Score (CAS)**

The patient is assessed on the following functions:

|  | Able to perform function independently | Only able to perform<br>function with<br>assistance from one or<br>two people | Unable to perform<br>function despite<br>assistance from two<br>people |
|--|--|---|--|
| Transfer from supine-to-sitting-to-<br>supine                    | 2                                      | 1   | 0  |
| Transfer from sitting-to-standing-to-<br>sitting (from armchair) | 2                                      | 1   | 0  |
| Walking (with appropriate walking aid)                           | 2                                      | 1   | 0  |

Total Score [Sum of all values on a given day]: \_\_\_\_\_

| Method                   | O <sub>2</sub> flow (I/min) | Estimated FiO <sub>2</sub> (%) |
|--------------------------|-----------------------------|--------------------------------|
| Nasal cannula            | 1                           | 24                             |
|                          | 2                           | 28                             |
|                          | 3                           | 32                             |
|                          | 4                           | 35                             |
|                          | 5                           | 40                             |
|                          | 6                           | 44                             |
| Nasopharyngeal catheter  | 4                           | 40                             |
|                          | 5                           | 50                             |
|                          | 6                           | 60                             |
| Face mask                | 5                           | 40                             |
|                          | 6-7                         | 50                             |
|                          | 7-8                         | 60                             |
| Face mask with reservoir | 6                           | 60                             |
|                          | 7                           | 70                             |
|                          | 8                           | 80                             |
|                          | 9                           | 90                             |
|                          | 10                          | 95                             |

#### 4 Converting oxygen therapy from $\rm O_2$ to $\rm FiO_2$

#### 6 DEFINITIONS of pulmonary post-operative complications

• Aspiration pneumonitis:

Defined as respiratory failure after the inhalation of regurgitated gastric contents

• Bronchospasm:

Defined as newly detected expiratory wheezing treated with bronchodilators

• Mild respiratory failure:

 $PaO_2 < 60 \text{ mmHg or } SpO_2 < 90\%$  in room air during at least 10 min air *but responding* to supplemental oxygen (excluding hypoventilation)

• Moderate respiratory failure:

PaO<sub>2</sub> < 60 mmHg or SpO<sub>2</sub> < 90% despite supplemental oxygen (excluding hypoventilation)

• Severe respiratory failure:

Need for non-invasive or invasive mechanical ventilation (excluding hypoventilation)

ARDS:

Mild, moderate or severe according to the Berlin definition:

| Time            | Within one week of a known clinical insult, or new/worsening respiratory symptoms   |  |                                 |  |  |
|-----------------|---|--|---------------------------------|--|--|
| Chest imaging*  | Bilateral opacities not fully explained by effusions, lobar/lung collapse or nodules  |  |                                 |  |  |
| Origin of edema | Respiratory failure not fully explained by cardiac failure or fluid overload; need objective assessment to exclude hydrostatic edema if no risk factor present (e.g., echocardiography) |  |                                 |  |  |
|                 | Mild Moderate Severe  |  |                                 |  |  |
|                 | Mild  | Moderate   | Severe                          |  |  |
| Oxygenation**   | <b>Mild</b><br>200 < PaO <sub>2</sub> / FiO <sub>2</sub> < 300  | <b>Moderate</b><br>100 < PaO <sub>2</sub> / FiO <sub>2</sub> < 200 | Severe<br>$PaO_2/FiO_2 \le 100$ |  |  |

ARDS: acute respiratory distress syndrome; PaO<sub>2</sub>: partial pressure of arterial oxygen; FiO<sub>2</sub>: inspired fraction of oxygen; PEEP: positive end-expiratory pressure; CPAP: continuous positive airway pressure

\*: chest X-ray or CT scan

\*\*: if altitude higher than 1,000 meters, correction factor should be made as follows: PaO<sub>2</sub> / FiO<sub>2</sub>9 (barometric pressure/760)

\*\*\*: this may be delivered non-invasively in the mild ARDS group

#### • Pulmonary infection:

Defined as new or progressive radiographic infiltrate plus at least two of the following: antibiotic treatment, tympanic temperature > 38<sup>a</sup>C, leukocytosis or leucopenia (WBC count < 4,000cells/mm3 or > 12,000cells/mm3) and/or purulent secretions

#### • Atelectasis:

Suggested by lung opacification with shift of the mediastinum, hilum, or hemidiaphragm towards the affected area, and compensatory overinflation in the adjacent nonatelectatic lung

• Cardiopulmonary edema:

Defined as clinical signs of congestion, including dyspnea, edema, rales and jugular venous distention, with the chest X–ray demonstrating increase in vascular markings and diffuse alveolar interstitial infiltrates

• Pleural effusion:

Chest X-ray demonstrating blunting of the costophrenic angle, loss of the sharp silhouette of the ipsilateral hemidiaphragm in upright position, evidence of displacement of adjacent anatomical structures, or (in supine position) a hazy opacity in one hemithorax with preserved vascular shadows

Pneumothorax:

Defined as air in the pleural space with no vascular bed surrounding the visceral pleura

• New pulmonary infiltrates:

Chest X-ray demonstrating new monolateral or bilateral infiltrate without other clinical signs

#### 7 DEFINITIONS of extra-pulmonary post-operative complications

• Systemic inflammatory response syndrome (SIRS):

Presence of two or more of the following findings: Body temperature  $< 36^{\circ}$ C or  $> 38^{\circ}$ C – Heart rate > 90 beats per minute – Respiratory rate > 20 breaths per minute or, on blood gas, a P<sub>a</sub>CO<sub>2</sub> < 32 mmHg (4.3 kPa) – WBC count < 4,000 cells/mm3 or > 12,000 cells/mm3 or > 10% band forms

Sepsis:

SIRS in response to a confirmed infectious process; infection can be suspected or proven (by culture, stain, or polymerase chain reaction (PCR)), or a clinical syndrome pathognomonic for infection. Specific evidence for infection includes WBCs in normally sterile fluid (such as urine or cerebrospinal fluid (CSF), evidence of a perforated viscera (free air on abdominal x–ray or CT scan, signs of acute peritonitis), abnormal chest x–ray (CXR) consistent with pneumonia (with focal opacification), or petechiae, purpura, or purpura fulminans

• Severe sepsis:

Sepsis with organ dysfunction, hypoperfusion, or hypotension

• Septic shock:

Sepsis with refractory arterial hypotension or hypoperfusion abnormalities in spite of adequate fluid resuscitation; signs of systemic hypoperfusion may be either end-organ dysfunction or serum lactate greater than 4 mmol/dL. Other signs include oliguria and altered mental status. Patients are defined as having septic shock if they have sepsis plus hypotension after aggressive fluid resuscitation, typically upwards of 6 liters or 40 ml/kg of crystalloid

- Extra-pulmonary infection:
  - Wound infection + any other infection

#### Coma:

Glasgow Coma Score  $\leq 8$  in the absence of the rapeutic coma or sedation

• Acute myocardial infarction:

Detection of rise and/or fall of cardiac markers (preferably troponin) with at least one value above the 99<sup>th</sup> percentile of the upper reference limit, together with: symptoms of ischemia, ECG changes indicative of new ischemia, development of pathological Q-waves, or imaging evidence of new loss of viable myocardium or new regional wall motion abnormality *Or:* sudden unexpected cardiac death, involving cardiac arrest with symptoms suggestive of cardiac ischemia (but death occurring before the appearance of cardiac markers in blood)

• Acute renal failure:

Renal failure documented as follows: Risk: increased creatinine x1.5 or GFR decrease > 25% or urine output (UO) <  $0.5 \text{ ml/kg/h} \times 6 \text{ hr}$  – Injury: increased creatinine x2 or GFR decrease > 50% or UO <  $0.5 \text{ ml/kg/h} \times 12 \text{ hr}$  – Failure: increase creatinine x3 or GFR decrease > 75% or UO <  $0.3 \text{ ml/kg/h} \times 24 \text{ hr}$  or anuria x 12 hrs – Loss: persistent ARF = complete loss of kidney function > 4 weeks

• Disseminated intravascular coagulation:

DIC score documented as follows: Platelet count < 50 (2 points), < 100 (1 point), or  $\ge$  100 (0 points) – D– dimer > 4 µg/ml (2 points), > 0.39 µg/ml (1 point) or  $\le$  0.39 µg/ml (0 points) – prothrombin time > 20.5 seconds (2 points), > 17.5 seconds (1 point) or  $\le$  17.5 seconds (0 points); if  $\ge$  5 points: overt DIC

• Hepatic failure:

Hepatic failure during short term follow up (5 postoperative days) is considered as follows: Ratio of total bilirubin on postoperative day 5 to postoperative day 1 > 1,7 and ratio of international normalized ratio (INR) on postoperative day 5 to postoperative day 1 >1,0; during long term follow up (until postoperative day 90) at new presence of hepatic encephalopathy and coagulopathy (INR > 1,5) within 8 weeks after initial signs of liver injury (e.g. jaundice) without evidence for chronic liver disease

- Gastro-intestinal failure:
  - Gastro-intestinal bleeding

Gastro--intestinal failure (GIF) score documented as follows: 0 = normal gastrointestinal function; 1 = enteral feeding with under 50% of calculated needs or no feeding 3 days after abdominal surgery; 2 = food intolerance (FI) *or* intra--abdominal hypertension (IAH); 3 = FI and IAH; and 4 = abdominal compartment syndrome (ACS)

#### A Postoperative adverse events

| Adverse events (AE) / severe adverse events (SAE) |               |   |  |                        |  |  |
|---|---------------|---|--|------------------------|--|--|
| Any adverse events yes                            | no 🔲          | if yes specify a                                  | ccording to table:                         |                        |  |  |
| Event (details, including treatment)              | Serious       | Intervention                                      | Recovery                                   | Outcome                |  |  |
|   | yes 🔄<br>no 🛄 | unrelated<br>possible<br>probable<br>unassessable | mild moderate severe unassessable          | resolved - no sequelae |  |  |
|   | yes 🔄<br>no 🗌 | unrelated<br>possible<br>probable<br>unassessable | mild moderate severe unassessable          | resolved - no sequelae |  |  |
|   | yes<br>no     | unrelated<br>possible<br>probable<br>unassessable | mild<br>moderate<br>severe<br>unassessable | resolved - no sequelae |  |  |
|   | yes<br>no     | unrelated<br>possible<br>probable<br>unassessable | mild moderate severe unassessable          | resolved - no sequelae |  |  |
|   | yes<br>no     | unrelated possible probable unassessable          | mild moderate severe unassessable          | resolved - no sequelae |  |  |