**CRF 1 (NEO) – Study entry**

Signed written informed consent:  □ yes, date: ____________________
Sex: □ female □ male  Age at time of first surgery: _____ years
Height: ___ cm  Weight: ___ kg
Pregnancy at time of surgery:  □ yes  □ no
Pacemaker / implanted defibrillator:  □ yes  □ no
If yes, side: □ left □ right  Type (if known): __________________
Inclusion and exclusion criteria checked and fulfilled:  □ yes  □ no

**Race / ethnic group [optional; multiple selection possible]:**

*U.K. categories:*
□ Asian or Asian British  □ Black, Black British, Caribbean, or African
□ Mixed or multiple  □ White  □ Arab

*U.S. categories:*
□ White: Not Arab  □ White: Arab  □ Asian
□ Black / African American  □ Amer. Indian / Alaska Native  □ Hispanic / Latino
□ Native Hawaiian / Pacific Islander  □ other: ____________________________

Systemic therapy (> 6 weeks duration) before surgery:  □ yes  □ no
If yes → continue filling out this CRF form
If no → use CRF PRIMARY SURGERY!

**Stage at time of diagnosis**

**Left breast**
□ invasive BC  □ DCIS  □ none
If invasive BC or DCIS:
Total number of lesions to be removed: ___
Number of separate specimens to be removed: ___
If invasive BC:
Tumor stage: □ cT1 □ cT2 □ cT3 □ cT4
Nodal status: □ cN0 □ cN+
If cN+, number of suspicious lymph nodes:
□ 1 □ 2 □ 3 □ ≥ 4 □ unknown

**Right breast**
□ invasive BC  □ DCIS  □ none
If invasive BC or DCIS:
Total number of lesions to be removed: ___
Number of separate specimens to be removed: ___
If invasive BC:
Tumor stage: □ cT1 □ cT2 □ cT3 □ cT4
Nodal status: □ cN0 □ cN+
If cN+, number of suspicious lymph nodes:
□ 1 □ 2 □ 3 □ ≥ 4 □ unknown
History of ipsilateral BC:
- □ invasive
- □ in situ
- □ no
History of ipsilateral breast irradiation:
- □ yes
- □ no
Additional lesions (e.g., benign) to be removed:
- □ yes, details: _________________
- □ no

History of ipsilateral BC:
- □ invasive
- □ in situ
- □ no
History of ipsilateral breast irradiation:
- □ yes
- □ no
Additional lesions (e.g., benign) to be removed:
- □ yes, details: _________________
- □ no

Please enter the patient into the **Subject Identification Log** and fill in the **eCRF online** so that the study patient can be registered.

*This printed form is for internal documentation only. Its use is thus optional.*
Important: Lesions that are going to be removed in one specimen are documented as one lesion. Multiple lesions or lesion groups to be removed in separate specimens (e.g., in case of multicentric or bilateral cancer) are documented as separate lesions (one per specimen).

Lesion (group) 1 = CRF 2a, 3a, 4a, 5a, 7a, 8a
Lesion (group) 2 = CRF 2b, 3b, 4b, 5b, 7b, 8b

You will find additional CRF pages at the end of this file.

### Breast lesion (group) 1 – CRF 2a (NEO)

These questions refer to information available at time of diagnosis (imaging and minimally invasive biopsy) and marker/clip placement before or during neoadjuvant therapy.

<table>
<thead>
<tr>
<th>Side: □ left □ right</th>
<th>Location: _____ o’clock</th>
</tr>
</thead>
<tbody>
<tr>
<td>or quadrant: □ upper outer □ upper inner □ lower outer □ lower inner □ central</td>
<td></td>
</tr>
<tr>
<td>Closest tumor-to-nipple distance: _____ cm</td>
<td></td>
</tr>
<tr>
<td>Number of lesions: □ 1 □ 2 □ 3 □ ≥ 4</td>
<td></td>
</tr>
</tbody>
</table>

### Minimally invasive biopsy:

- □ core needle biopsy
- □ vacuum-assisted biopsy
- □ fine-needle aspiration
- Date: __________
- □ invasive cancer with or without DCIS
- □ DCIS
- □ other: __________________

### Histology of minimally invasive biopsy:

(in case some items are unknown, leave questions unanswered)

- □ NST/ductal □ lobular □ mixed ductal-lobular □ other: __________
- Grading: □ G1 □ G2 □ G3
- In situ component: □ yes □ no
- Ki67: ___ % □ unknown
- HER2: □ positive □ negative
- ER: ___ % or ___ IRS or Allred: ___
- PgR: ___ % or ___ IRS or Allred: ___
- Lymphovascular invasion: □ yes □ no □ not reported

### Imaging performed at diagnosis:

- □ Mammography □ Ultrasound □ MRI □ PET-CT □ Breast-CT

Size of the largest target lesion: ____ x ____ x ____ mm

If the lesion group consists of > 1 lesion:

Size of the lesion group: ____ x ____ x ____ mm □ not reported / not applicable
Marker placement into the lesion (group) before or during neoadjuvant therapy:
- ☐ yes, number of markers: _____ Date (if known): ____________ ☐ no

Type of marker: *(multiple selection possible)*
- ☐ Clip/Coil (Manufacturer / brand: ____________________________)
- ☐ Magseed ☐ Sirius Pintuion ☐ Savi Scout
- ☐ LOCalizer ☐ Radioactive seed
- ☐ Carbon suspension (Type: ____________)
- ☐ Other: ___________________________________________________

Marker located in the lesion: ☐ yes ☐ no, closest marker-to-lesion distance: _____ mm
If no: another marker placement performed? ☐ yes ☐ no
If yes, details: ___________________________________________________

Have any complications related to marker placement occurred?
- ☐ yes, specify: _________________________________ ☐ no ☐ unknown
If yes: was any of the following necessary? *(multiple selection possible)*:
- ☐ Antibiotics
- ☐ Surgical intervention under local/regional anesthesia
- ☐ Surgical intervention under general anesthesia
- ☐ Blood transfusion
- ☐ Other: _________________________________
# Breast lesion (group) 1 – CRF 3a (NEO)

## Response to neoadjuvant therapy

<table>
<thead>
<tr>
<th>Type of neoadjuvant therapy: (multiple selection possible)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Chemotherapy</td>
</tr>
<tr>
<td>□ Anti-HER2 therapy</td>
</tr>
<tr>
<td>□ Immune checkpoint inhibitor</td>
</tr>
<tr>
<td>□ Endocrine therapy</td>
</tr>
<tr>
<td>□ Other: _________________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Palpability after neoadjuvant therapy:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Clearly palpable</td>
</tr>
<tr>
<td>□ Faintly palpable</td>
</tr>
<tr>
<td>□ Non-palpable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Residual lesion visible:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ yes</td>
</tr>
<tr>
<td>□ no</td>
</tr>
</tbody>
</table>

Size of the largest target lesion: ___ x ___ x ___ mm

If the lesion group consists of > 1 lesion:

Size of the lesion group: ___ x ___ x ___ mm □ not reported / not applicable
Breast lesion (group) 1 – CRF 4a (NEO)

Preoperative marker placement for localization

Marker placement into the lesion (group) before surgery:

- Yes, number of markers: _____ Date: _______________  No  if no → go to CRF 5

In case of > 1 marker placed: closest distance between markers: _____ mm  Unknown

DIAGNOSTICIAN SATISFACTION QUESTIONNAIRE

Important: The Questionnaire should be completed directly after the procedure.

The Questionnaire is also available as a separate file.

How easy was the marking procedure, on a scale from 0 to 10?

0 = unable to mark  10 = very easy

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

How satisfied are you with the marking method used in this patient, on a scale from 0 to 10?

0 = very dissatisfied  10 = very satisfied

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

Are there any improvements you would like to see in this localization device/method?

______________________________________________________________________________

______________________________________________________________________________

Marker placed by:

- Radiologist
- Surgeon (Breast or General)
- Gynecologist
- Radiographer
- Other: __________________________

Type of marker:

- Clip/Coil (Manufacturer / brand: __________________________)
- Magsed
- Sirius Pintuition
- Savi Scout
- LOCalizer
- Radioactive seed
- Technetium
- Carbon suspension (Type: ________________)
- Other: ________________________________
Under what guidance was the marker inserted? ☐ Ultrasound ☐ Mammography ☐ MRI ☐ PET-CT ☐ other: ________________________________

Control mammogram after marker placement performed: ☐ yes ☐ no

Control MRI after marker placement performed: ☐ yes ☐ no

Marker located in the lesion: ☐ yes ☐ no, closest marker-to-lesion distance: _____ mm

If no: another marker placement performed? ☐ yes ☐ no

If yes, details: ________________________________

Have any complications related to marker placement occurred? ☐ yes, specify: ________________________________ ☐ no

If yes: was any of the following necessary? *(multiple selection possible)*:

☐ Antibiotics
☐ Surgical intervention under local/regional anesthesia
☐ Surgical intervention under general anesthesia
☐ Blood transfusion
☐ Other: ________________________________

☐ None of the above

If a patient received a marker/clip before or during neoadjuvant therapy:

Closest distance between the marker used for preoperative localization and the one placed before: _____ mm ☐ unknown ☐ no marker/clip placed before or during therapy
Breast lesion (group) 1 – CRF 5a (NEO)
Preoperative wire placement

Preoperative wire-localization performed:

**Important:** This section refers to wire placement before surgery. If a wire was placed in the surgical room using intraoperative ultrasound, answer this question with a “no”.

- yes, number of wires: ________
- no  **if no → go to CRF 6**

In case of > 1 wire: closest distance between wire ends: _____mm   □ unknown

### DIAGNOSTICIAN SATISFACTION QUESTIONNAIRE

**Important:** The Questionnaire should be completed directly after the procedure.

The Questionnaire is also available as a separate file.

How easy was the localization procedure, on a scale from 0 to 10?

0 = unable to mark 10 = very easy

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

How satisfied are you with the localization method used in this patient, on a scale from 0 to 10?

0 = very dissatisfied 10 = very satisfied

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

Are there any improvements you would like to see in this localization device/method?

_______________________________________________________________________
_______________________________________________________________________

Wire placed by:  □ Radiologist  □ Surgeon (Breast or General)

□ Gynecologist  □ Radiographer  □ Other: _____________________________

Type of wire / manufacturer: ___________________________________________
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under what guidance was the wire inserted?</td>
<td>Ultrasound, Mammography, MRI, PET-CT, Other: ___________________</td>
</tr>
<tr>
<td>Timepoint of wire placement:</td>
<td>day of surgery, day before surgery, other: _______</td>
</tr>
<tr>
<td>Control mammogram after wire placement performed:</td>
<td>yes, no</td>
</tr>
<tr>
<td>Control MRI after wire placement performed:</td>
<td>yes, no</td>
</tr>
<tr>
<td>Wire located in the lesion:</td>
<td>yes, no, closest wire-to-lesion distance: _____ mm</td>
</tr>
<tr>
<td>If no: another wire/marker placement performed?</td>
<td>yes, no</td>
</tr>
<tr>
<td>If yes, details:</td>
<td>___________________________________________________</td>
</tr>
<tr>
<td>If a patient received a marker/clip before or during neoadjuvant therapy:</td>
<td>Closest distance between the wire end and the marker/clip: _____ mm</td>
</tr>
<tr>
<td>Control mammogram after placement performed:</td>
<td>yes, no</td>
</tr>
<tr>
<td>Control MRI after wire placement performed:</td>
<td>yes, no</td>
</tr>
<tr>
<td>Have any complications related to wire placement occurred?</td>
<td>yes, specify: _____________________________, no</td>
</tr>
<tr>
<td>If yes: was any of the following necessary? (multiple selection possible):</td>
<td>Antibiotics, Surgical intervention under local/regional anesthesia, Surgical intervention under general anesthesia, Blood transfusion, Other: _____________________________</td>
</tr>
<tr>
<td>None of the above</td>
<td></td>
</tr>
</tbody>
</table>
**CRF 6 (NEO) = Surgery =**

<table>
<thead>
<tr>
<th>Date of surgery: ________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total time from incision to skin closure: __________ min.</td>
</tr>
<tr>
<td>Surgical procedures other than breast and axillary surgery performed at the same time (e.g., insertion of a port, laparoscopy etc.)?</td>
</tr>
</tbody>
</table>

**Surgery of the left breast:**
- ☐ performed
- ☐ not performed
  - If performed:
    - ☐ Breast-conserving surgery
    - ☐ Mastectomy
  - Oncoplastic breast surgery (e.g., reduction mammoplasty, [perforator] flaps, or other, excluding simple approximation of tissue): ☐ yes ☐ no

Did an oncoplastic procedure impact the resection volume? ☐ yes ☐ no ☐ unknown

**Axillary surgery:**
- ☐ performed
- ☐ not performed
  - If yes: ☐ Sentinel lymph node biopsy (SLNB) ☐ Axillary lymph node dissection
    - ☐ Axillary sampling
    - ☐ Target lymph node biopsy (TLNB)
    - ☐ Targeted axillary dissection (TAD = TLNB + SLNB)
    - ☐ Other: ________________________________
  - Has a marker been placed into one or more lymph nodes at any time point prior to surgery? ☐ yes, number of marked nodes: ________ ☐ no

**Type of axillary marker (multiple selection possible):**
- ☐ Clip/Coil (Manufacturer / brand: ____________________________)
- ☐ Magseed
- ☐ Sirius Pintuition
- ☐ Savi Scout
- ☐ LOCAlizer
- ☐ Radioactive seed
- ☐ Carbon suspension (Type: ________________)
- ☐ Other: ________________________________

If SLNB (multiple selection possible): ☐ Dye
- ☐ Technetium
- ☐ SPIO (e.g., MagTrace)
- ☐ Indocyanine green
- ☐ Other: __________________________

In case of more than one marker placed into breast or axilla: was it possible to distinguish markers from each other? ☐ yes ☐ no, specify: __________________________

**Surgery of the right breast:**
- ☐ performed
- ☐ not performed
  - If performed:
    - ☐ Breast-conserving surgery
    - ☐ Mastectomy
  - Oncoplastic breast surgery (e.g., reduction mammoplasty, [perforator] flaps, or other, excluding simple approximation of tissue): ☐ yes ☐ no

Did an oncoplastic procedure impact the resection volume? ☐ yes ☐ no ☐ unknown

**Axillary surgery:**
- ☐ performed
- ☐ not performed
If yes: □ Sentinel lymph node biopsy (SLNB) □ Axillary lymph node dissection
  □ Axillary sampling □ Target lymph node biopsy (TLNB)
  □ Targeted axillary dissection (TAD = TLNB + SLNB)
  □ Other: ____________________________________________________________
Has a marker been placed into one or more lymph nodes at any time point prior to surgery? □ yes, number of marked nodes: ______ □ no
Type of axillary marker (*multiple selection possible)*:
  □ Clip/Coil (Manufacturer / brand: ________________________________)
  □ Magseed □ Sirius Pintuition □ Savi Scout
  □ LOCalizer □ Radioactive seed
  □ Carbon suspension (Type: ______________)
  □ Other: __________________________________________________________
If SLNB (*multiple selection possible*): □ Dye □ Technetium
  □ SPIO (e.g., MagTrace) □ Indocyanine green □ Other: ______________
In case of more than one marker placed into breast or axilla: was it possible to distinguish markers from each other? □ yes □ no, specify: ____________________________
In case a patient has a pacemaker / implanted defibrillator and a magnetic, radar or radiofrequency marker was used:
Have any marker- or probe-related problems occurred during or after surgery? □ yes, specify: ____________________________________________________________ □ no
Were any precautions taken before surgery because of the localization technique? □ yes, specify: ____________________________________________________________ □ no
**In case a marker (other than a clip/coil) was used at any timepoint:**
MRI performed between marker placement and surgery? □ yes, date: _______ □ no
  If yes, marker-associated artifacts? □ yes, size: _____ mm □ no
  If yes, assessment of MRI limited due to artifacts? □ yes □ no
**Date of discharge from the hospital / clinic:**
  □ same day as surgery □ another date: ___________

**Do not forget:**
Patient-reported outcomes questionnaire should be completed between surgery and postoperative visit.
# Breast lesion (group) 1 – CRF 7a (NEO)
= Intraoperative localization =

Which techniques were used? *(multiple selection possible; CAVE: this question refers to the breast and not the axilla!)*:
- Wire guidance
- Intraoperative ultrasound
- SaviScout probe
- SentiMag probe
- Sirius Pintuition probe
- LOCalizer probe
- Gamma probe (ROLL)
- Gamma probe (Radioactive seed)
- Carbon visualization
- Other: _____________________________

In case of intraoperative ultrasound: wire placement under anesthesia:
- yes
- no

Ultrasound machine and probe used: ____________________________________________

How many procedures using this localization technique have already been performed by the surgeon?
- < 10
- 11-29
- ≥ 30

**Specimen radiography** performed:
- yes
- no

If yes, lesion successfully removed:
- yes
- no
- no residual lesion

If yes, marker successfully removed:
- yes
- no
- not applicable

Clear margins (= lesion not touching the edges of the specimen):
- yes
- no

Minimal margin: ____ mm, in which direction (e.g., lateral): __________  
- not reported

**Specimen ultrasound** performed:
- yes
- no

If yes, lesion successfully removed:
- yes
- no
- no residual lesion

If yes, marker successfully removed:
- yes
- no
- not applicable

Clear margins (= lesion not touching the edges of the specimen):
- yes
- no

Minimal margin: ____ mm, in which direction (e.g., lateral): __________  
- not reported

Have other techniques been used for margin evaluation?
- yes, which: _____________________________  
- no

If yes, result: close/positive margins:
- yes, direction: __________  
- no

**Intraoperative re-excision / shaving** performed:
- yes, direction: __________  
- no

Intraoperative wire dislocation:
- yes
- no
- not applicable

Intraoperative marker dislocation:
- yes
- no
- not applicable

Have any other problems related to localization technique or marker occurred before, during or after surgery?
- yes, specify: _____________________________  
- no
SURGEON SATISFACTION QUESTIONNAIRE

Important: The Questionnaire should be completed directly after the procedure.

The Questionnaire is also available as a separate file.

How easy was the intraoperative detection procedure, on a scale from 0 to 10?

0 = unable to localize
10 = very easy
0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

How satisfied are you with the localization method used in this patient, on a scale from 0 to 10?

0 = very dissatisfied
10 = very satisfied
0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

Are there any improvements you would like to see in this localization device/method?
_______________________________________________________________________
_______________________________________________________________________
Breast lesion (group) 1 – CRF 8a (NEO)  
= Postoperative histopathology after first surgery =

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the lesion (group) been removed at first surgery?</td>
<td>☐ yes ☐ no</td>
</tr>
<tr>
<td>If yes, histology:</td>
<td>☐ residual invasive cancer ☐ residual DCIS ☐ no residual cancer</td>
</tr>
<tr>
<td></td>
<td>☐ Other: ________________</td>
</tr>
<tr>
<td>If no, describe the problems:</td>
<td>____________________________________________________________________</td>
</tr>
<tr>
<td>Have all markers inserted into the lesion (group) been removed at first surgery?</td>
<td>☐ yes ☐ no ☐ not applicable (no markers used)</td>
</tr>
<tr>
<td>If no, describe the problems:</td>
<td>____________________________________________________________________</td>
</tr>
<tr>
<td>If no: is one or more markers still in the patient?</td>
<td>☐ yes ☐ no ☐ unclear</td>
</tr>
<tr>
<td>Additional imaging to identify lost marker(s) performed:</td>
<td>☐ yes, specify: __________</td>
</tr>
<tr>
<td>Was an additional procedure necessary to remove lost marker(s) or is it planned?</td>
<td>☐ yes, specify: ____________________________________________________________________</td>
</tr>
<tr>
<td>Specimen weight:</td>
<td>☐ not reported</td>
</tr>
<tr>
<td>If reported:</td>
<td>☐ weight in the operating room ☐ weight reported in the pathological report</td>
</tr>
<tr>
<td>Specimen size:</td>
<td>_____ mm x _____ mm x _____ mm ☐ not reported</td>
</tr>
</tbody>
</table>

In case of residual invasive breast cancer (including microinvasive BC):

Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is not necessary to measure additional dimensions outside of clinical routine.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invasive tumor size:</td>
<td>__ x __ x __ mm</td>
</tr>
<tr>
<td>Margin status – invasive cancer:</td>
<td>Clear margins (&quot;no tumor on ink&quot;): ☐ yes ☐ no</td>
</tr>
<tr>
<td></td>
<td>Min. margin: _______ mm, direction (e.g., lateral): ________________</td>
</tr>
<tr>
<td>In situ component:</td>
<td>☐ yes, max. size: _____ mm ☐ no</td>
</tr>
<tr>
<td></td>
<td>____________________________________________________________________</td>
</tr>
<tr>
<td>If yes:</td>
<td>____________________________________________________________________</td>
</tr>
<tr>
<td>Margin status – in situ component:</td>
<td>Clear margins (&quot;no tumor on ink&quot;): ☐ yes ☐ no</td>
</tr>
<tr>
<td></td>
<td>Min. margin: _______ mm, direction (e.g., lateral): ________________</td>
</tr>
<tr>
<td>Tumor in intraoperative re-excision specimen(s):</td>
<td>☐ yes, invasive ☐ yes, in situ ☐ no</td>
</tr>
<tr>
<td></td>
<td>☐ not applicable (no intraoperative re-excision performed)</td>
</tr>
<tr>
<td>Clear margins achieved in the main specimen:</td>
<td>☐ yes ☐ no</td>
</tr>
</tbody>
</table>

In case of residual DCIS without invasion:

Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is not necessary to measure additional dimensions outside of clinical routine.
| Size: ___ x ___ x ___ mm |
| Clear margins (“no tumor on ink”): ☐ yes ☐ no |
| Min. margin: _______ mm, direction (e.g., lateral): ________________ |
| Tumor in intraoperative re-excision specimen: ☐ yes, in situ ☐ no |
| ☐ not applicable (no intraoperative re-excision performed) |
| Clear margins achieved in the main specimen: ☐ yes ☐ no |
CRF 9 (NEO)
= Postoperative histopathology of all lesions after first surgery =

**Left breast** (if applicable):

<table>
<thead>
<tr>
<th>Tumor stage:</th>
<th>ypT0</th>
<th>ypTis</th>
<th>ypT1</th>
<th>ypT2</th>
<th>ypT3</th>
<th>ypT4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymph node status:</td>
<td>ypN0</td>
<td>ypN0 (i+)</td>
<td>ypN1mi</td>
<td>ypN1</td>
<td>ypN2</td>
<td>ypN3</td>
</tr>
<tr>
<td>Number of removed lymph nodes:</td>
<td>_____</td>
<td>Number of metastatic lymph nodes:</td>
<td>_____</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Postoperative complications in the breast** *(multiple selection possible):*

- None
- Hematoma
- Infection
- Seroma
- Other: _______________________________________________________

If yes: was any of the following necessary? *(multiple selection possible):*

- Antibiotics
- Surgical intervention under local/regional anesthesia
- Surgical intervention under general anesthesia
- Blood transfusion
- Other: _______________________________________________________
- None of the above

Additional diagnostics recommended: □ yes, specify: ___________________ □ no

Further breast surgery recommended: □ yes, mastectomy □ yes, re-excision □ no

Further breast surgeries performed: □ yes, number: _____ □ no

Negative margins (“no tumor on ink”) reached after last surgery: □ yes □ no

**Final result:** □ Breast conservation □ Mastectomy

**Right breast** (if applicable):

<table>
<thead>
<tr>
<th>Tumor stage:</th>
<th>ypT0</th>
<th>ypTis</th>
<th>ypT1</th>
<th>ypT2</th>
<th>ypT3</th>
<th>ypT4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymph node status:</td>
<td>ypN0</td>
<td>ypN0 (i+)</td>
<td>ypN1mi</td>
<td>ypN1</td>
<td>ypN2</td>
<td>ypN3</td>
</tr>
<tr>
<td>Number of removed lymph nodes:</td>
<td>_____</td>
<td>Number of metastatic lymph nodes:</td>
<td>_____</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Postoperative complications in the breast** *(multiple selection possible):*

- None
- Hematoma
- Infection
- Seroma
- Other: _______________________________________________________
If yes: was any of the following necessary? *(multiple selection possible):*

- [ ] Antibiotics
- [ ] Surgical intervention under local/regional anesthesia
- [ ] Surgical intervention under general anesthesia
- [ ] Blood transfusion
- [ ] Other: ____________________________________________
- [ ] None of the above

Additional diagnostics recommended:  

- [ ] yes, specify: ____________________________  
- [ ] no

Further breast surgery recommended:  

- [ ] yes, mastectomy  
- [ ] yes, re-excision  
- [ ] no

Further breast surgeries performed:  

- [ ] yes, number: ______  
- [ ] no

Negative margins ("no tumor on ink") reached after last surgery:  

- [ ] yes  
- [ ] no

**Final result:**  

- [ ] Breast conservation  
- [ ] Mastectomy
Additional CRF pages.

Use only for patients with more than one lesion (group):

**Breast lesion (group) 1 – CRF 2b (NEO)**

These questions refer to information available at time of diagnosis (imaging and minimally invasive biopsy) and marker/clip placement before or during neoadjuvant therapy.

<table>
<thead>
<tr>
<th>Side: □ left □ right</th>
<th>Location: ___ o’clock</th>
</tr>
</thead>
<tbody>
<tr>
<td>or quadrant: □ upper outer □ upper inner □ lower outer □ lower inner □ central</td>
<td></td>
</tr>
<tr>
<td>Closest tumor-to-nipple distance: _____ cm</td>
<td></td>
</tr>
<tr>
<td>Number of lesions: □ 1 □ 2 □ 3 □ ≥ 4</td>
<td></td>
</tr>
<tr>
<td><strong>Minimally invasive biopsy:</strong> □ core needle biopsy □ vacuum-assisted biopsy □ fine-needle aspiration □ invasive cancer with or without DCIS □ DCIS □ other: ____________________</td>
<td></td>
</tr>
<tr>
<td>Date: ____________</td>
<td></td>
</tr>
</tbody>
</table>

**Histology of minimally invasive biopsy:**

*(in case some items are unknown, leave questions unanswered)*

| Subtype: □ NST/ductal □ lobular □ mixed ductal-lobular □ other: ____________ |
| Grading: □ G1 □ G2 □ G3 |
| In situ component: □ yes □ no |
| Ki67: ___ % □ unknown |
| HER2: □ positive □ negative |
| ER: ___ % or ___ IRS or Allred: ____ |
| PgR: ___ % or ___ IRS or Allred: ____ |
| Lymphovascular invasion: □ yes □ no □ not reported |

**Imaging performed at diagnosis:**

□ Mammography □ Ultrasound □ MRI □ PET-CT □ Breast-CT

Size of the largest target lesion: ___ x ___ x ___ mm

If the lesion group consists of > 1 lesion:

Size of the lesion group: ___ x ___ x ___ mm □ not reported / not applicable

**Marker placement into the lesion (group) before or during neoadjuvant therapy:**

□ yes, number of markers: _____ Date (if known): ____________ □ no

**Type of marker:** *(multiple selection possible)*

□ Clip/Coil (Manufacturer / brand: ____________________________) □ Magseed □ Savi Scout □ LOCalizer □ Radioactive seed
| □ Carbon suspension (Type: ______________) |
| □ Other: ......................................................... |

Marker located in the lesion: □ yes  □ no, closest marker-to-lesion distance: _____ mm
If no: another marker placement performed? □ yes  □ no
   If yes, details: ________________________________________________________

Have any complications related to marker placement occurred?
□ yes, specify: _________________________________  □ no  □ unknown
If yes: was any of the following necessary? (*multiple selection possible*):
   □ Antibiotics
   □ Surgical intervention under local/regional anesthesia
   □ Surgical intervention under general anesthesia
   □ Blood transfusion
   □ Other: _________________________________
Breast lesion (group) 1 – CRF 3b (NEO)
Response to neoadjuvant therapy

<table>
<thead>
<tr>
<th>Type of neoadjuvant therapy: (multiple selection possible)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Chemotherapy</td>
</tr>
<tr>
<td>□ Anti-HER2 therapy</td>
</tr>
<tr>
<td>□ Immune checkpoint inhibitor</td>
</tr>
<tr>
<td>□ Endocrine therapy</td>
</tr>
<tr>
<td>□ Other: ______________________________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Residual lesion visible:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ yes</td>
</tr>
<tr>
<td>□ no</td>
</tr>
</tbody>
</table>

Size of the largest target lesion:   ___ x ___ x ___ mm

If the lesion group consists of > 1 lesion:

Size of the lesion group: ___ x ___ x ___ mm   □ not reported / not applicable
Breast lesion (group) 1 – CRF 4b (NEO)
Preoperative marker placement for localization

Marker placement into the lesion (group) before surgery:

- [ ] yes, number of markers: _____  Date: ________________  [ ] no  [ ] if no → go to CRF 5

In case of > 1 marker placed: closest distance between markers: _____ mm  [ ] unknown

DIAGNOSTICIAN SATISFACTION QUESTIONNAIRE

**Important:** The Questionnaire should be completed directly after the procedure.

The Questionnaire is also available as a separate file.

How easy was the marking procedure, on a scale from 0 to 10?

- 0 = unable to mark  
- 10 = very easy

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

How satisfied are you with the marking method used in this patient, on a scale from 0 to 10?

- 0 = very dissatisfied  
- 10 = very satisfied

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

Are there any improvements you would like to see in this localization device/method?

_______________________________________________________________________  
_______________________________________________________________________

Marker placed by:  
- [ ] Radiologist  
- [ ] Surgeon (Breast or General)
- [ ] Gynecologist  
- [ ] Radiographer  
- [ ] Other: __________________

**Type of marker:**
- [ ] Clip/Coil (Manufacturer / brand: _____________________________)
- [ ] Magseed  
- [ ] Sirius Pintuition  
- [ ] Savi Scout
- [ ] LOCalizer  
- [ ] Radioactive seed  
- [ ] Technetium
- [ ] Carbon suspension (Type: _____________)
- [ ] Other: ___________________________________________
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under what guidance was the marker inserted?</td>
<td>☐ Ultrasound ☐ Mammography ☐ MRI ☐ PET-CT ☐ other: ____________________________________</td>
</tr>
<tr>
<td>Control mammogram after marker placement performed:</td>
<td>☐ yes ☐ no</td>
</tr>
<tr>
<td>Control MRI after marker placement performed:</td>
<td>☐ yes ☐ no</td>
</tr>
<tr>
<td>Marker located in the lesion:</td>
<td>☐ yes ☐ no, closest marker-to-lesion distance: _____ mm</td>
</tr>
<tr>
<td>If no: another marker placement performed?</td>
<td>☐ yes ☐ no</td>
</tr>
<tr>
<td>If yes, details:</td>
<td>______________________________________________</td>
</tr>
<tr>
<td>If a patient received a marker/clip before or during neoadjuvant therapy:</td>
<td></td>
</tr>
<tr>
<td>Closest distance between the marker used for preoperative localization and the one placed before: _____ mm ☐ unknown ☐ no marker/clip placed before or during therapy</td>
<td></td>
</tr>
<tr>
<td>Have any complications related to marker placement occurred?</td>
<td>☐ yes, specify: ____________________________________ ☐ no</td>
</tr>
<tr>
<td>If yes: was any of the following necessary? (multiple selection possible):</td>
<td></td>
</tr>
<tr>
<td>☐ Antibiotics</td>
<td></td>
</tr>
<tr>
<td>☐ Surgical intervention under local/regional anesthesia</td>
<td></td>
</tr>
<tr>
<td>☐ Surgical intervention under general anesthesia</td>
<td></td>
</tr>
<tr>
<td>☐ Blood transfusion</td>
<td></td>
</tr>
<tr>
<td>☐ Other: ____________________________________</td>
<td></td>
</tr>
<tr>
<td>☐ None of the above</td>
<td></td>
</tr>
</tbody>
</table>
Breast lesion (group) 1 – CRF 5b (NEO)
Preoperative wire placement

Preoperative wire-localization performed:

**Important:** This section refers to wire placement before surgery. If a wire was placed in the surgical room using intraoperative ultrasound, answer this question with a “no”.

- ☐ yes, number of wires: ______
- ☐ no  **if no → go to CRF 6**

In case of > 1 wire: closest distance between wire ends: _____ mm  ☐ unknown

### DIAGNOSTICIAN SATISFACTION QUESTIONNAIRE

**Important:** The Questionnaire should be completed directly after the procedure.

The Questionnaire is also available as a separate file.

How easy was the localization procedure, on a scale from 0 to 10?

0 = unable to mark  10 = very easy

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

How satisfied are you with the localization method used in this patient, on a scale from 0 to 10?

0 = very dissatisfied  10 = very satisfied

0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

Are there any improvements you would like to see in this localization device/method?

________________________________________________________________________________

Wire placed by:

- ☐ Radiologist
- ☐ Surgeon (Breast or General)
- ☐ Gynecologist
- ☐ Radiographer
- ☐ Other: ____________________________

Type of wire / manufacturer: ______________________________________________________
Under what guidance was the wire inserted?  □ Ultrasound  □ Mammography
□ MRI    □ PET-CT   □ Other: _____________________________
Timepoint of wire placement: □ day of surgery  □ day before surgery  □ other: ______
Control mammogram after wire placement performed: □ yes  □ no
Control MRI after wire placement performed: □ yes  □ no
Wire located in the lesion: □ yes  □ no, closest wire-to-lesion distance: _____ mm
If no: another wire/marker placement performed? □ yes □ no
If yes, details: _________________________________________________

If a patient received a marker/clip before or during neoadjuvant therapy:
Closest distance between the wire end and the marker/clip: _____ mm
□ unknown  □ no marker/clip placed before or during therapy

Have any complications related to wire placement occurred?
□ yes, specify: ___________________________________________________ □ no
If yes: was any of the following necessary? (multiple selection possible):
□ Antibiotics
□ Surgical intervention under local/regional anesthesia
□ Surgical intervention under general anesthesia
□ Blood transfusion
□ Other: ______________________________________________________
□ None of the above
**Breast lesion (group) 1 – CRF 7b (NEO) = Intraoperative localization =**

Which techniques were used? *(multiple selection possible; CAVE: this question refers to the breast and not the axilla!)*:

- [ ] Wire guidance
- [ ] Intraoperative ultrasound
- [ ] SaviScout probe
- [ ] SentiMag probe
- [ ] Sirius Pintuition probe
- [ ] LOCalizer probe
- [ ] Gamma probe (ROLL)
- [ ] Gamma probe (Radioactive seed)
- [ ] Other: _______________________________________________________

In case of intraoperative ultrasound: wire placement under anesthesia: [ ] yes [ ] no

Ultrasound machine and probe used: __________________________________________

How many procedures using this localization technique have already been performed by the surgeon?  
[ ] < 10  [ ] 11-29  [ ] ≥ 30

**Specimen radiography** performed:  
[ ] yes  [ ] no

If yes, lesion successfully removed:  
[ ] yes  [ ] no  [ ] no residual lesion

If yes, marker successfully removed:  
[ ] yes  [ ] no  [ ] not applicable

Clear margins (= lesion not touching the edges of the specimen):  
[ ] yes  [ ] no

Minimal margin: ____ mm, in which direction (e.g., lateral): __________  [ ] not reported

**Specimen ultrasound** performed:  
[ ] yes  [ ] no

If yes, lesion successfully removed:  
[ ] yes  [ ] no  [ ] no residual lesion

If yes, marker successfully removed:  
[ ] yes  [ ] no  [ ] not applicable

Clear margins (= lesion not touching the edges of the specimen):  
[ ] yes  [ ] no

Minimal margin: ____ mm, in which direction (e.g., lateral): __________  [ ] not reported

Have other techniques been used for margin evaluation?  
[ ] yes, which: ______________________________________________________  [ ] no

If yes, result: close/positive margins:  
[ ] yes, direction: ________________  [ ] no

**Intraoperative re-excision / shaving performed**  
[ ] yes, direction: __________  [ ] no

Intraoperative wire dislocation:  
[ ] yes  [ ] no  [ ] not applicable

Intraoperative marker dislocation:  
[ ] yes  [ ] no  [ ] not applicable

Have any other problems related to localization technique or marker occurred before, during or after surgery?  
[ ] yes, specify: _________________________________  [ ] no
SURGEON SATISFACTION QUESTIONNAIRE

Important: The Questionnaire should be completed directly after the procedure.

The Questionnaire is also available as a separate file.

How easy was the intraoperative detection procedure, on a scale from 0 to 10?
0 = unable to localize
10 = very easy
0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

How satisfied are you with the localization method used in this patient, on a scale from 0 to 10?
0 = very dissatisfied
10 = very satisfied
0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

Are there any improvements you would like to see in this localization device/method?
_______________________________________________________________________
_______________________________________________________________________
## Breast lesion (group) 1 – CRF 8b (NEO)

= Postoperative histopathology after first surgery =

### Has the lesion (group) been removed at first surgery?

- □ yes
- □ no

If yes, histology:
- □ residual invasive cancer
- □ residual DCIS
- □ no residual cancer
- □ Other: __________________________

If no, describe the problems:

### Have all markers inserted into the lesion (group) been removed at first surgery?

- □ yes
- □ no
- □ not applicable (no markers used)

If no, describe the problems:

If no: is one or more markers still in the patient?

- □ yes
- □ no
- □ unclear

Additional imaging to identify lost marker(s) performed:

- □ yes, specify: ____________
- □ no

Was an additional procedure necessary to remove lost marker(s) or is it planned?

- □ yes, specify: _____________________________
- □ no

### Specimen weight:

- □ ______ g
- □ not reported

If reported:

- □ weight in the operating room
- □ weight reported in the pathological report

### Specimen size:

- □ _____ mm x _____ mm x _____ mm
- □ not reported

### In case of residual invasive breast cancer (including microinvasive BC):

*Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is not necessary to measure additional dimensions outside of clinical routine.*

#### Invasive tumor size:

- □ ___ x ___ x ___ mm

#### Margin status – invasive cancer:

Clear margins ("no tumor on ink"):

- □ yes
- □ no

Min. margin: _______ mm, direction (e.g., lateral): ____________

In situ component:

- □ yes, max. size: ____ mm
- □ no

If yes:

#### Margin status – in situ component:

Clear margins ("no tumor on ink"):

- □ yes
- □ no

Min. margin: _______ mm, direction (e.g., lateral): ____________

Tumor in intraoperative re-excision specimen(s):

- □ yes, invasive
- □ yes, in situ
- □ no

not applicable (no intraoperative re-excision performed)

Clear margins achieved in the main specimen:

- □ yes
- □ no

### In case of residual DCIS without invasion:

*Some questions below refer to the lesion size. If only one or two dimensions are available, fill in only those. It is not necessary to measure additional dimensions outside of clinical routine.*
<table>
<thead>
<tr>
<th>Clear margins (&quot;no tumor on ink&quot;):</th>
<th>☐ yes</th>
<th>☐ no</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. margin:</td>
<td>_______ mm, direction (e.g., lateral):</td>
<td>_______________</td>
</tr>
<tr>
<td>Tumor in intraoperative re-excision specimen:</td>
<td>☐ yes, in situ</td>
<td>☐ no</td>
</tr>
<tr>
<td>☐ not applicable (no intraoperative re-excision performed)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clear margins achieved in the main specimen:</td>
<td>☐ yes</td>
<td>☐ no</td>
</tr>
</tbody>
</table>