## CRF 1 (PS) – Study entry

| **Signed written informed consent:** | □ yes, date: ____________________ |
| **Sex:** | □ female □ male |
| **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
- □ other: __________________

**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 no → continue filling out this CRF form
If yes → use CRF NEOADJUVANT!

### Preoperative short-term (≤ 6 weeks) endocrine therapy administered:
- □ yes, ____ days □ no
  - If yes: □ Aromatase inhibitor □ Tamoxifen □ GnRH agonist

### Stage at time of diagnosis

<table>
<thead>
<tr>
<th><strong>Left breast</strong></th>
<th><strong>Right breast</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>□ invasive BC □ DCIS □ none</td>
<td>□ invasive BC □ DCIS □ none</td>
</tr>
<tr>
<td>If invasive BC or DCIS:</td>
<td>If invasive BC or DCIS:</td>
</tr>
<tr>
<td>Total number of lesions to be removed: ____</td>
<td>Total number of lesions to be removed: ____</td>
</tr>
<tr>
<td>Number of separate specimens to be removed: ____</td>
<td>Number of separate specimens to be removed: ____</td>
</tr>
<tr>
<td>If invasive BC:</td>
<td>If invasive BC:</td>
</tr>
<tr>
<td>Tumor stage: □ cT1 □ cT2 □ cT3 □ cT4</td>
<td>Tumor stage: □ cT1 □ cT2 □ cT3 □ cT4</td>
</tr>
<tr>
<td>Nodal status: □ cN0 □ cN+</td>
<td>Nodal status: □ cN0 □ cN+</td>
</tr>
<tr>
<td>If cN+, number of suspicious lymph nodes:</td>
<td>If cN+, number of suspicious lymph nodes:</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>-----------------------------------------</td>
</tr>
<tr>
<td>□ 1 □ 2 □ 3 □ ≥ 4 □ unknown</td>
<td>□ 1 □ 2 □ 3 □ ≥ 4 □ unknown</td>
</tr>
<tr>
<td>History of ipsilateral BC:</td>
<td>History of ipsilateral BC:</td>
</tr>
<tr>
<td>□ invasive □ in situ □ no</td>
<td>□ invasive □ in situ □ no</td>
</tr>
<tr>
<td>History of ipsilateral breast irradiation:</td>
<td>History of ipsilateral breast irradiation:</td>
</tr>
<tr>
<td>□ yes □ no</td>
<td>□ yes □ no</td>
</tr>
<tr>
<td>Additional lesions (e.g., benign) to be removed:</td>
<td>Additional lesions (e.g., benign) to be removed:</td>
</tr>
<tr>
<td>□ yes, details: _______________________ □ no</td>
<td>□ yes, details: _______________________ □ no</td>
</tr>
</tbody>
</table>

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 (PS)**
These questions refer to information available before surgery (imaging and minimally invasive biopsy).

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

**In case of invasive cancer:**
*(in case some items are unknown, leave questions unanswered)*

<table>
<thead>
<tr>
<th>Subtype:</th>
<th>□ NST/ductal □ lobular □ mixed ductal-lobular □ other: __________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grading:</td>
<td>□ G1 □ G2 □ G3</td>
</tr>
<tr>
<td>In situ component:</td>
<td>□ yes □ no</td>
</tr>
<tr>
<td>Ki67: ___ % □ unknown</td>
<td></td>
</tr>
<tr>
<td>HER2: □ positive □ negative</td>
<td></td>
</tr>
<tr>
<td>ER: ___ % or ___ IRS or Allred: ____</td>
<td></td>
</tr>
<tr>
<td>PgR: ___ % or ___ IRS or Allred: ____</td>
<td></td>
</tr>
<tr>
<td>Lymphovascular invasion: □ yes □ no □ not reported</td>
<td></td>
</tr>
</tbody>
</table>

**In case of DCIS:**
*(in case some items are unknown, leave questions unanswered)*

<table>
<thead>
<tr>
<th>□ high grade □ intermediate grade □ low grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comedo necrosis: □ yes □ no</td>
</tr>
</tbody>
</table>
**Imaging**

*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>Modality</th>
<th>Performed</th>
<th>Not performed</th>
<th>Target lesion visible</th>
<th>Size of the largest target lesion: ___ x ___ x ___ mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammography</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>□ yes</td>
<td>□ no</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>□ yes, clearly visible</td>
<td>□ yes, but not clearly</td>
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<td></td>
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<td></td>
<td></td>
<td>□ no</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ not reported / not applicable</td>
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</tr>
<tr>
<td>Tomosynthesis</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Target lesion visible</td>
<td></td>
<td></td>
<td></td>
<td>□ not reported / not applicable</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Microcalcifications</td>
<td></td>
<td></td>
<td></td>
<td>□ yes, size: ___ x ___ x ___ mm</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ no</td>
</tr>
<tr>
<td>Initial BIRADS (if known):</td>
<td>□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Ultrasound</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>□ yes, clearly visible</td>
<td>□ yes, but not clearly</td>
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<td></td>
<td></td>
<td></td>
<td>□ no</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>□ not reported / not applicable</td>
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<tr>
<td>MRI</td>
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<td></td>
<td></td>
<td></td>
<td>□ yes, clearly visible</td>
<td>□ yes, but not clearly</td>
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<td>□ no</td>
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<td></td>
<td>□ not reported / not applicable</td>
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<tr>
<td>Initial BIRADS (if known):</td>
<td>□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6</td>
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<tr>
<td>PET-CT</td>
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<td></td>
<td></td>
<td></td>
<td>□ yes, clearly visible</td>
<td>□ yes, but not clearly</td>
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<td></td>
<td></td>
<td></td>
<td>□ no</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>□ not reported / not applicable</td>
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<td></td>
</tr>
<tr>
<td>Initial BIRADS (if known):</td>
<td>□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Breast-CT</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>□ yes, clearly visible</td>
<td>□ yes, but not clearly</td>
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<td>□ no</td>
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<td></td>
<td>□ not reported / not applicable</td>
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<td></td>
</tr>
<tr>
<td>Initial BIRADS (if known):</td>
<td>□ 0 □ 1 □ 2 □ 3 □ 4 □ 5 □ 6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Breast lesion (group) 1 – CRF 3a (PS)**  
**Marker placement at time of minimally invasive biopsy**

**Marker placement into the lesion (group) at time of minimally invasive biopsy:**
- □ yes, number of markers: _____  □ no  ***if no → go to CRF 4***

In case of > 1 marker: closest distance between markers: _____ mm  □ unknown

**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  
- □ 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
Breast lesion (group) 1 – CRF 4a (PS)  
Marker placement between minimally invasive biopsy and surgery

Marker placement into the lesion (group) between minimally invasive biopsy and surgery:

- yes, number of markers: _____  Date: ________________  no  if no → go to CRF 5
In case of > 1 marker: 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?

<table>
<thead>
<tr>
<th>0 = unable to mark</th>
<th>10 = very easy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>0 = very dissatisfied</th>
<th>10 = very satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10</td>
<td></td>
</tr>
</tbody>
</table>

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>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under what guidance was the marker inserted?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Ultrasound</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- Mammography</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- MRI</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- PET-CT</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- Other: __________________________________________________________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control mammogram after marker placement performed:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- No</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Control MRI after marker placement performed:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- No</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Marker located in the lesion:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- No, closest marker-to-lesion distance: _____ mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If no: another marker placement performed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Yes</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- No</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Have any complications related to marker placement occurred?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Yes, specify: __________________________________________________________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>If yes: was any of the following necessary? (multiple selection possible):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Antibiotics</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- Surgical intervention under local/regional anesthesia</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- Surgical intervention under general anesthesia</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- Blood transfusion</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>- Other: __________________________________________________________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- None of the above</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
Breast lesion (group) 1 – CRF 5a (PS)
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: _______________________________________________

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
**Date of surgery:** __________

**Total time from incision to skin closure:** ________ min.  
☐ unknown

Surgical procedures other than breast and axillary surgery performed at the same time  
(e.g., insertion of a port, laparoscopy etc.)?  ☐ yes  ☐ no

**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  ☐ 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  ☐ 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 (PS)  
= 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)
- LOCalizer probe
- 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

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

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 (PS)
= Postoperative histopathology after first surgery =

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Has the lesion (group) been removed at first surgery?                    | yes/no                          | lesion already removed at minimally invasive biopsy/no
If yes, histology: Invasive cancer/DCIS/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/no, specify: __________ |
Was an additional procedure necessary to remove lost marker(s) or is it planned? yes/no |
Specimen weight: ______ g/no reported |
If reported: weight in the operating room/weight reported in the pathological report |
Specimen size: _____ mm x _____ mm x _____ mm/no reported |

In case of 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

To complete only if assessed in the surgical specimen and different from the minimally invasive biopsy:
Subtype: NST/ductal/lobular/mixed ductal-lobular/other: __________
Grading: G1/G2/G3
Ki67: ___ %/unknown
HER2: positive/negative
MELODY-CRF PRIMARY SURGERY

<table>
<thead>
<tr>
<th>ER: ___ % or ___ IRS or Allred: ___</th>
<th>PgR: ___ % or ___ IRS or Allred: ___</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphovascular invasion:</td>
<td>□ yes      □ no      □ not reported</td>
</tr>
</tbody>
</table>

**In case of 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>Size: ___ x ___ x ___ mm</th>
<th>□ high grade □ intermediate grade □ low grade</th>
<th>Comedo necrosis: □ yes □ no</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear margins (“no tumor on ink”): □ yes □ no</td>
<td>Min. margin: __________ mm, direction (e.g., lateral): ________________</td>
<td></td>
</tr>
<tr>
<td>Tumor in intraoperative re-excision specimen: □ yes, in situ □ no</td>
<td>□ not applicable (no intraoperative re-excision performed)</td>
<td></td>
</tr>
<tr>
<td>Clear margins achieved in the main specimen: □ yes □ no</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### CRF 9 (PS)

= Postoperative histopathology of all lesions after first surgery =

**Left breast (if applicable):**

- **Tumor stage:**
  - □ pTx
  - □ pTis
  - □ pT1
  - □ pT2
  - □ pT3
  - □ pT4

- **Lymph node status:**
  - □ pNx
  - □ pN0
  - □ pN0 (i+)
  - □ pN1mi
  - □ pN1
  - □ pN2
  - □ pN3

- **Number of removed lymph nodes:** _____  
  **Number of metastatic lymph nodes:** _____

**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):**

- **Tumor stage:**
  - □ pTx
  - □ pTis
  - □ pT1
  - □ pT2
  - □ pT3
  - □ pT4

- **Lymph node status:**
  - □ pNx
  - □ pN0
  - □ pN0 (i+)
  - □ pN1mi
  - □ pN1
  - □ pN2
  - □ pN3

- **Number of removed lymph nodes:** _____  
  **Number of metastatic lymph nodes:** _____

**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) 2 – CRF 2b (PS)**
These questions refer to information available before surgery (imaging and minimally invasive biopsy).

<table>
<thead>
<tr>
<th>Side:</th>
<th>□ left</th>
<th>□ right</th>
<th>Location: ___ o’clock</th>
</tr>
</thead>
<tbody>
<tr>
<td>or quadrant:</td>
<td>□ upper outer</td>
<td>□ upper inner</td>
<td>□ lower outer</td>
</tr>
<tr>
<td>Closest tumor-to-nipple distance: ______ cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Closest tumor-to-skin distance: ______ mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of lesions: □ 1 □ 2 □ 3 □ ≥ 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palpability:</td>
<td>□ Clearly palpable</td>
<td>□ Faintly palpable</td>
<td>□ Non-palpable</td>
</tr>
<tr>
<td>Minimally invasive biopsy:</td>
<td>□ core needle biopsy</td>
<td>□ vacuum-assisted biopsy</td>
<td></td>
</tr>
<tr>
<td>□ fine-needle aspiration</td>
<td>Date: __________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ invasive cancer with or without DCIS</td>
<td>□ DCIS</td>
<td>□ other: __________________</td>
<td></td>
</tr>
</tbody>
</table>

**In case of invasive cancer:**
*(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 |

**In case of DCIS:**
*(in case some items are unknown, leave questions unanswered)*

| □ high grade | □ intermediate grade | □ low grade |
| Comedo necrosis: | □ yes | □ no |

**Imaging**

*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.*

<p>| Mammography | □ performed | □ not performed |
| Contrast-enhanced: | □ yes | □ no | Tomosynthesis: | □ yes | □ no |</p>
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Performed</th>
<th>Not Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasound</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MRI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PET-CT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast-CT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Target lesion visible:**
- ☐ yes, clearly visible
- ☐ yes, but not clearly
- ☐ no

**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

**Microcalcifications:**
- ☐ yes, size: ___ x ___ x ___ mm
- ☐ no

**Initial BIRADS (if known):**
- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6

**Ultrasound:**
- ☐ performed
- ☐ not performed

**Target lesion visible:**
- ☐ yes, clearly visible
- ☐ yes, but not clearly
- ☐ no

**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

**Initial BIRADS (if known):**
- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6

**MRI:**
- ☐ performed
- ☐ not performed

**Target lesion visible:**
- ☐ yes, clearly visible
- ☐ yes, but not clearly
- ☐ no

**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

**Initial BIRADS (if known):**
- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6

**PET-CT:**
- ☐ performed
- ☐ not performed

**Target lesion visible:**
- ☐ yes, clearly visible
- ☐ yes, but not clearly
- ☐ no

**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

**Initial BIRADS (if known):**
- ☐ 0
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6

**Breast-CT:**
- ☐ performed
- ☐ not performed

**Target lesion visible:**
- ☐ yes, clearly visible
- ☐ yes, but not clearly
- ☐ no

**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) 2 – CRF 3b (PS)
Marker placement at time of minimally invasive biopsy

Marker placement into the lesion (group) at time of minimally invasive biopsy:
- ☐ yes, number of markers: _____ ☐ no if no → go to CRF 4
In case of > 1 marker: closest distance between markers: _____ mm ☐ unknown

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
- ☐ 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
Breast lesion (group) 2 – CRF 4b (PS)
Marker placement between minimally invasive biopsy and surgery

Marker placement into the lesion (group) between minimally invasive biopsy and surgery:

- yes, number of markers: ____ Date: ________________
- no  \[\text{if no } \rightarrow \text{go to CRF 5}\]
In case of > 1 marker: closest distance between markers: ____ mm  \[\text{if unknown}\]

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  \[\text{10 = very easy}\]
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  \[\text{10 = very satisfied}\]
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:  
- \[\text{Radiologist}\]
- \[\text{Surgeon (Breast or General)}\]
- \[\text{Gynecologist}\]
- \[\text{Radiographer}\]
- \[\text{Other: __________________}\]

Type of marker:  
- \[\text{Clip/Coil (Manufacturer / brand: _____________________________)}\]
- \[\text{Magseed}\]
- \[\text{Sirius Pintuition}\]
- \[\text{Savi Scout}\]
- \[\text{LOCalizer}\]
- \[\text{Radioactive seed}\]
- \[\text{Technetium}\]
- \[\text{Carbon suspension (Type: _______________)}\]
- \[\text{Other: _____________________________}\]
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
Breast lesion (group) 2 – CRF 5b (PS)
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>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: _____________________________ □ None of the above</td>
</tr>
</tbody>
</table>
Breast lesion (group) 2 – CRF 7b (PS)
= Intraoperative localization =

<table>
<thead>
<tr>
<th>Which techniques were used? (multiple selection possible; CAVE: this question refers to the breast and not the axilla!):</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Wire guidance</td>
</tr>
<tr>
<td>☐ Intraoperative ultrasound</td>
</tr>
<tr>
<td>☐ Sirius Pintuition probe</td>
</tr>
<tr>
<td>☐ Gamma probe (Radioactive seed)</td>
</tr>
<tr>
<td>☐ Other: __________________________________________________</td>
</tr>
</tbody>
</table>

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
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
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) 2 – CRF 8b (PS)
= Postoperative histopathology after first surgery =

<table>
<thead>
<tr>
<th>Has the lesion (group) been removed at first surgery?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ yes □ lesion already removed at minimally invasive biopsy □ no</td>
</tr>
<tr>
<td>If yes, histology: □ Invasive cancer □ DCIS □ Other: __________________________</td>
</tr>
<tr>
<td>If no, describe the problems: __________________________________________________________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have all markers inserted into the lesion (group) been removed at first surgery?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ yes □ no □ not applicable (no markers used)</td>
</tr>
<tr>
<td>If no, describe the problems: __________________________________________________________________________</td>
</tr>
<tr>
<td>If no: is one or more markers still in the patient? □ yes □ no □ unclear</td>
</tr>
<tr>
<td>Additional imaging to identify lost marker(s) performed: □ yes, specify: __________ □ no</td>
</tr>
<tr>
<td>Was an additional procedure necessary to remove lost marker(s) or is it planned?</td>
</tr>
<tr>
<td>□ yes, specify: ________________________________________________________________________________________ □ no</td>
</tr>
</tbody>
</table>

| Specimen weight: ______ g □ not reported |
| Specimen size: _____ mm x _____ mm x _____ mm □ not reported |

**In case of 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 |

To complete only if assessed in the surgical specimen and different from the minimally invasive biopsy:

| Subtype: □ NST/ductal □ lobular □ mixed ductal-lobular □ other: ___________ |
| Grading: □ G1 □ G2 □ G3 |
| Ki67: ____ % □ unknown HER2: □ positive □ negative |
### ER: ___ % or ___ IRS or Allred: ___  
PgR: ___ % or ___ IRS or Allred: ___

**Lymphovascular invasion:**  
- [ ] yes  
- [ ] no  
- [ ] not reported

**In case of 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>Size: ___ x ___ x ___ mm</th>
</tr>
</thead>
</table>
| [ ] high grade  
| [ ] intermediate grade  
| [ ] low grade  
| Comedo necrosis:  
| [ ] yes  
| [ ] no  
| 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