MELODY-CRF PRIMARY SURGERY **Patient-ID: _ _ - _ _ _ - _ _ _**

CRF 1 (PS) – 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 ☐ 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

Left breast	**Right breast**
☐ invasive BC ☐ DCIS ☐ none	☐ invasive BC ☐ DCIS ☐ none
If invasive BC or DCIS:	If invasive BC or DCIS:
Total number of lesions to be removed: ___	Total number of lesions to be removed: ___
Number of separate specimens to be removed: ____	Number of separate specimens to be removed: ____
If invasive BC:	If invasive BC:
Tumor stage: ☐ cT1 ☐ cT2 ☐ cT3 ☐ cT4	Tumor stage: ☐ cT1 ☐ cT2 ☐ cT3 ☐ cT4
Nodal status: ☐ cN0 ☐ cN+	Nodal status: ☐ cN0 ☐ cN+

MELODY-CRF <u>PRIMARY SURGERY</u> **Patient-ID: _ _ - _ _ _ - _ _ _**

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	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

Please enter the patient into the <u>Subject Identification Log</u> and fill in the <u>eCRF</u> online so that the study patient can be registered.
This printed form is for internal documentation only. Its use is thus optional.

MELODY-CRF <u>PRIMARY SURGERY</u> **Patient-ID: _ _ - _ _ _ - _ _ _**

<u>Important</u>: 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 <u>before</u> surgery (imaging and minimally invasive biopsy).

Side: ☐ left ☐ right Location: ___ o'clock

<u>or</u> quadrant: ☐ upper outer ☐ upper inner ☐ lower outer ☐ lower inner ☐ central

Closest tumor-to-nipple distance: _____ cm

Closest tumor-to-skin distance: _____ mm Number of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

Palpability: ☐ Clearly palpable ☐ Faintly palpable ☐ Non-palpable

Minimally invasive biopsy: ☐ core needle biopsy ☐ vacuum-assisted biopsy

☐ fine-needle aspiration Date: _____

☐ invasive cancer with or without DCIS ☐ DCIS ☐ other: _____

<u>In case of invasive cancer:</u>

(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

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

☐ high grade ☐ intermediate grade ☐ low grade

Comedo necrosis: ☐ yes ☐ no

MELODY-CRF PRIMARY SURGERY **Patient-ID: _ _ - _ _ _ - _ _ _**

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.

Mammography ☐ performed ☐ not performed

Contrast-enhanced: ☐ yes ☐ no Tomosynthesis: ☐ yes ☐ no

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

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) 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?

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: _____

MELODY-CRF PRIMARY SURGERY **Patient-ID: _ _ - _ _ _ - _ _ _**

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 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

CRF 6 (PS)
= Surgery =

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: _____

MELODY-CRF PRIMARY SURGERY **Patient-ID: _ _ - _ _ _ - _ _ _**

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) ☐ 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 =

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

☐ yes ☐ 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, 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 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 <u>not</u> 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

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

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.*
Size: ___ x ___ x ___ mm ☐ 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

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).

Side: ☐ left ☐ right Location: ___ o'clock

or quadrant: ☐ upper outer ☐ upper inner ☐ lower outer ☐ lower inner ☐ central

Closest tumor-to-nipple distance: _____ cm

Closest tumor-to-skin distance: _____ mm Number of lesions: ☐ 1 ☐ 2 ☐ 3 ☐ ≥ 4

Palpability: ☐ Clearly palpable ☐ Faintly palpable ☐ Non-palpable

Minimally invasive biopsy: ☐ core needle biopsy ☐ vacuum-assisted biopsy

☐ fine-needle aspiration Date: _____

☐ invasive cancer with or without DCIS ☐ DCIS ☐ other: _____

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.

Mammography ☐ performed ☐ not performed

Contrast-enhanced: ☐ yes ☐ no Tomosynthesis: ☐ yes ☐ no

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

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 **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?

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: _____

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: _____

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

Breast lesion (group) 2 – CRF 7b (PS)
= Intraoperative localization =

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

☐ Intraoperative ultrasound ☐ SaviScout probe ☐ Wire guidance
☐ Sirius Pintuition probe ☐ LOCalizer probe ☐ SentiMag probe
☐ Gamma probe (Radioactive seed) ☐ Gamma probe (ROLL)
☐ Other: _____ ☐ Carbon visualization

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 =

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

☐ yes ☐ 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, 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 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 <u>not</u> 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

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

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.*
Size: ___ x ___ x ___ mm ☐ 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