

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

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

invasive BC DCIS none

If invasive BC or DCIS:

Total number of lesions to be removed: _____

Number of separate specimens to be removed: _____

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: _____

Tumor stage: cT1 cT2 cT3 cT4

Nodal status: cN0 cN+

If cN+, number of suspicious lymph nodes:

1 2 3 ≥ 4 unknown

MELODY-CRF PRIMARY SURGERY

Patient-ID: ___ - ___ - ___

History of ipsilateral BC: <input type="checkbox"/> invasive <input type="checkbox"/> in situ <input type="checkbox"/> no History of ipsilateral breast irradiation: <input type="checkbox"/> yes <input type="checkbox"/> no Additional lesions (e.g., benign) to be removed: <input type="checkbox"/> yes, details: _____ <input type="checkbox"/> no	History of ipsilateral BC: <input type="checkbox"/> invasive <input type="checkbox"/> in situ <input type="checkbox"/> no History of ipsilateral breast irradiation: <input type="checkbox"/> yes <input type="checkbox"/> no Additional lesions (e.g., benign) to be removed: <input type="checkbox"/> yes, details: _____ <input type="checkbox"/> no
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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).

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 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 unknownMarker 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 noControl MRI after marker placement performed: yes noMarker located in the lesion: yes no, closest marker-to-lesion distance: ____ mmIf no: another marker placement performed? yes no

If yes, details: _____

Have any complications related to marker placement occurred?

 yes, specify: _____ noIf 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

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: _____

MELODY-CRF PRIMARY SURGERY

Patient-ID: _ _ - _ _ - _ _

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. unknownSurgical 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 performedIf performed: Breast-conserving surgery MastectomyOncoplastic breast surgery (e.g., reduction mammoplasty, [perforator] flaps, or other, excluding simple approximation of tissue): yes noDid an oncoplastic procedure impact the resection volume? yes no unknown**Axillary surgery:** performed not performedIf 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: _____ noType 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 performedIf performed: Breast-conserving surgery MastectomyOncoplastic breast surgery (e.g., reduction mammoplasty, [perforator] flaps, or other, excluding simple approximation of tissue): yes noDid an oncoplastic procedure impact the resection volume? yes no unknown**Axillary surgery:** performed not performedIf 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*):

Intraoperative ultrasound SaviScout probe Wire guidance
 Sirius Pintuition probe LOCalizer probe SentiMag probe
 Carbon visualization Other: _____
 Gamma probe

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 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

Patient-ID: ___ - ___ - ___

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 noClear 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 pT1 pT2 pT3 pT4Lymph 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 aboveAdditional diagnostics recommended: yes, specify: _____ noFurther breast surgery recommended: yes, mastectomy yes, re-excision noFurther breast surgeries performed: yes, number: _____ noNegative margins ("no tumor on ink") reached after last surgery: yes no**Final result:** Breast conservation Mastectomy**Right breast (if applicable):**Tumor stage: pTx pT1 pT2 pT3 pT4Lymph node status: 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: _____

MELODY-CRF PRIMARY SURGERY

Patient-ID: _ _ - _ _ - _ _

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

MELODY-CRF PRIMARY SURGERY

Patient-ID: ___ - ___ - ___

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 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 unknownMarker 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 noControl MRI after marker placement performed: yes noMarker located in the lesion: yes no, closest marker-to-lesion distance: ____ mmIf no: another marker placement performed? yes no

If yes, details: _____

Have any complications related to marker placement occurred?

 yes, specify: _____ noIf 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

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) 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: _____

MELODY-CRF PRIMARY SURGERY

Patient-ID: _ _ - _ _ - _ _

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*):

Intraoperative ultrasound SaviScout probe Wire guidance
 Sirius Pintuition probe LOCalizer probe SentiMag probe
 Carbon visualization Other: _____
 Gamma probe

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 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

Patient-ID: ___ - ___ - ___

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 noClear 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