Belgian Cancer Registry

Barrett Esophagus - RadioFrequency Ablation (BE-RFA) - Primary registration form

All variables are 'necessary' variables and are obliged to fill in unless stated otherwise (denoted by 'if applicable' or 'if possible').

The variables with a ❍ are single select variables; only one answer can be selected.
The variables with a ❑ are multi-select variables; more than one answer can be selected.

The primary registration form needs to be filled out for every RFA treatment from which one or more sessions were performed after April 1st, 2016 (or the later date of inclusion in the list of recognized medical centers) and can include up to 8 RFA treatment sessions.

The primary registration consists of 2 parts that each need to be completed and sent separately and at a different timepoint.

Part I

- Contains information regarding the patients' medical history (pre-treatment) and the first RFA session (RFA1)
- Needs to be filled out as soon as possible after the first RFA treatment session (preferably within 3 months after performing RFA1)

Part II

- Contains information regarding subsequent RFA treatment sessions (RFA 2 - 8)
- Should only be completed if more than 1 RFA session is performed in a patients' treatment
- Needs to be completed one year after performing the last RFA treatment session (i.e. the patient should be 1 year RFA-free)

Administrative patient data

Hospital: .....
Health insurance institution: .....
National number for social security (INSZ/NISS): .....
Last name: .....
First name: .....
Postal code: .....
City: .....
Country: .....
Health insurance number: .....
Date of birth: ……/……/…… (dd/mm/yyyy)
Date of death: ……/……/…… (dd/mm/yyyy) (if applicable)
Sex: O Male
O Female

1. General

Which RFA treatment session(s) will be registered?

O First RFA session (RFA 1, start of a new treatment)

Please fill out sections 2-6.

O Subsequent RFA session(s) (RFA 2-8)

Please fill out section 7 for all subsequent RFA sessions in the current treatment.

***PART I** (To complete after first RFA treatment session)*

2. Patient history (prior to the start of this registration)

Date of the initial diagnosis of Barrett esophagus, if possible: ……/……/…… (dd/mm/yyyy)

Did the patient already receive a RFA treatment after which complete remission was determined?

O No

O Yes

- Date of last RFA session of previous RFA treatment,
  if possible: ……/……/…… (dd/mm/yyyy)

3. Endoscopic and histological diagnosis of the current dysplasia/neoplasia

Date of diagnosis of the current dysplasia/neoplasia: ……/……/…… (dd/mm/yyyy)

Prague classification at this endoscopy, if possible: C: …… (cm) M: …… (cm)

Was the first RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?

O No

- Was a biopsy performed prior to RFA?
  - O No
  - O Yes
    - Please specify the worst histology on biopsy:
      - O Barrett esophagus with intestinal metaplasia
      - O Barrett esophagus with low grade dysplasia (LGIN)
      - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
      - O Invasive adenocarcinoma

O Yes

- Date of the latest pre-RFA treatment: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Type of pre-RFA treatment(s) performed:
    - ❑ Endoscopic (sub)mucosal resection (EMR/ESD)°
        - ❑ EMR, please specify if possible:
            - ❑ En bloc EMR by means of cap EMR
            - ❑ En bloc EMR by means of band EMR
            - ❑ Piecemeal EMR by means of cap EMR
            - ❑ Piecemeal EMR by means of multiband EMR
            - ❑ Unknown
        - ❑ ESD
        - ❑ Other, specify: ……..
    - ❑ Ablation techniques (other than RFA)
        - ❑ Argon plasma coagulation (APC)
        - ❑ Cryoablation
        - ❑ Other, specify: ……

° If option 'Endoscopic (sub)mucosal resection (EMR/ESD)' is selected, please fill out the following variables:

- Please specify the worst histology on EMR/ESD:
    - O Barrett esophagus with intestinal metaplasia
    - O Barrett esophagus with low grade dysplasia (LGIN)
    - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
    - O Invasive adenocarcinoma*

** If option 'Invasive adenocarcinoma' is selected, please fill out the following variables:*

- Depth of tumor invasion:
    - O T1a
    - O T1a m1 (into the lamina propria)
    - O T1a m2 (into the superficial muscularis mucosae)
    - O T1a m3 (in between the muscularis mucosae layers)
    - O T1a m4 (into the deep muscularis mucosae)
    - O T1b
    - O T1b sm1
    - O T1b sm2
    - O T1b sm3
    - O Not applicable
    - O Unknown

- Differentiation grade (if possible):
  - O 1 = Well differentiated
  - O 2 = Moderately differentiated
  - O 3 = Poorly differentiated
  - O 4 = Undifferentiated (anaplastic)
  - O 9 = Unknown

- Lymphovascular invasion (if possible):
  - O No
  - O Yes
  - O Cannot be determined
  - O Not reported

- Deep margin of the resected specimen (if possible):
  - O Negative for carcinoma (margin < 1 mm)
  - O Negative for carcinoma (margin ≥ 1 mm)
  - O Negative for carcinoma (margin not reported)
  - O Positive for carcinoma
  - O Cannot be determined
  - O Unknown

- Lateral margin of the resected specimen (if possible):

  (only the most advanced histology)
  - O Negative for metaplasia / dysplasia / carcinoma
  - O Positive for intestinal metaplasia
  - O Positive for LGIN
  - O Positive for HGIN or carcinoma
  - O Cannot be determined (i.e. piecemeal resection)
  - O Unknown

- Early complications during or shortly after pre-RFA treatment(s):
  - O No
  - O Yes
    - ❑ Bleeding
    - ❑ Perforation
    - ❑ Other, specify: ……..

- Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA), if possible:
  - O No
  - O Yes
    - Date: ……/……/…… (dd/mm/yyyy)

- Was a biopsy performed prior to RFA for which a more advanced histology was found compared to the worst histology on EMR/ESD?
    - O No
    - O Yes
        - Please specify the worst histology on biopsy:
            - O Barrett esophagus with intestinal metaplasia
            - O Barrett esophagus with low grade dysplasia (LGIN)
            - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
            - O Invasive adenocarcinoma

4. Second opinion of histological diagnosis

Worst histology prior to first RFA session:

- O Barrett esophagus with intestinal metaplasia
- O Barrett esophagus with low grade dysplasia (LGIN)
- O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
- O Invasive adenocarcinoma

Was the worst histology confirmed by a separate, second opinion?

- O No
- O Yes (i.e. the second opinion was performed by another doctor-specialist that belongs to another hospital or partnership)
- O The second opinion was performed by a doctor-specialist that belongs to the same hospital or partnership

5. MOC/COM discussion

Has a MOC/COM discussion been done before starting the RFA treatment for the new lesion?

- O No
- O Yes, by the center that performed the RFA
- O Yes, by the center that referred the patient to a RFA center
- O Unclear whether a MOC/COM discussion was done in the referring center

6. First RFA treatment session (RFA 1)

Please fill out the following variables concerning the first RFA treatment session that was performed:

Date of first RFA: ……/……/…… (dd/mm/yyyy)

Prague classification: C: …… (cm) M: …… (cm)

Endoscopic (macroscopic) diagnosis at first RFA:

- ❑ Islands of intestinal metaplasia
  - Number of islands, if possible: ……
  - Smallest diameter of islands, if possible: …… (mm)
  - Largest diameter of islands, if possible: …… (mm)
- ❑ Barrett esophagus without visible focal lesion (flat Barrett)
- ❑ Barrett esophagus with visible focal, suspicious lesion
- ❑ Other, specify: ……

Was a biopsy performed on the day of the first RFA?

- O No
- O Yes
  - Please specify the worst histology on biopsy:
    - O Barrett esophagus with intestinal metaplasia
    - O Barrett esophagus with low grade dysplasia (LGIN)
    - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
    - O Invasive adenocarcinoma

Number of RFA catheters used during the first RFA treatment session:

- O 1 catheter*
- O 2 catheters*, **

** Please fill out the following variables concerning the first RFA catheter that was used:*

- Type of first RFA catheter used:
  - O Circumferential device: HALO/BARRX 360 Express RFA catheter
  - O Focal device: HALO/BARRX 90 catheter
  - O Focal device: HALO/BARRX 60 catheter
  - O Focal device: HALO/BARRX Ultra long catheter
  - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
  - O Other

- Was the first RFA catheter attested to the authorities for compensation?
  - O No
  - O Yes

O 172616-172620
O 172631-172642
O 172653-172664

- Associated protocol used:
  - O 2 x 10 J
  - O 2 x 12 J
  - O 3 x 12 J
  - O 3 x 15 J
  - O 10 J - clean - 10 J
  - O 12 J - clean - 12 J
  - O 2 x 12 J - clean - 2 x 12 J
  - O 2 x 15 J - clean - 2 x 15 J
  - O Other, specify: ……

*** Please fill out the following variables concerning the second RFA catheter that was used:*

- Type of second RFA catheter used:
  - O Circumferential device: HALO/BARRX 360 Express RFA catheter
  - O Focal device: HALO/BARRX 90 catheter
  - O Focal device: HALO/BARRX 60 catheter
  - O Focal device: HALO/BARRX Ultra long catheter
  - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
  - O Other

- Was the second RFA catheter attested to the authorities for compensation?
  - O No
  - O Yes
    - O 172616-172620
    - O 172631-172642
    - O 172653-172664

- Associated protocol used:
  - O 2 x 10 J
  - O 2 x 12 J
  - O 3 x 12 J
  - O 3 x 15 J
  - O 10 J - clean - 10 J
  - O 12 J - clean - 12 J
  - O 2 x 12 J - clean - 2 x 12 J
  - O 2 x 15 J - clean - 2 x 15 J
  - O Other, specify: ……

Was the z-line treated?

O No

O Yes

Acute complications (during RFA and/or within 24 hours):

O No

O Unknown

O Yes

- ❑ Bleeding
- ❑ Fever
- ❑ Perforation

❑ Other, specify: ……..

If for the first question the option "First RFA session (RFA 1, start of a new treatment)" was chosen, the registration can be terminated here.

PART II (To complete one year after last RFA treatment session)

7. Subsequent RFA treatment session(s) (RFA 2-8)

If for the first question the option "Subsequent RFA session(s) (RFA 2-8)" was chosen, please fill out the following variables in general and for each of the subsequent RFA treatment sessions!

How many RFA treatment sessions were performed in total (including RFA 1, which has been registered previously)?

O 2 O 6
O 3 O 7
O 4 O 8
O 5

Note: In case some of the RFA sessions have been performed at another center, only indicate the total number of RFA sessions performed at your center unless you are able to complete all information regarding the RFA sessions performed at the other center

Only fill out if RFA sessions within the current RFA treatment were performed in another center:

- If certain RFA session(s) was/were performed in another center, please specify which RFA session(s):

❑ RFA 1 ❑ RFA 5
❑ RFA 2 ❑ RFA 6
❑ RFA 3 ❑ RFA 7
❑ RFA 4 ❑ RFA 8

- In which other center were these RFA sessions performed? .....

If the RFA treatment was prematurely discontinued, please specify the reason:

❑ Patient's request
❑ Comorbidities
❑ Patient died due to complications of the RFA treatment
❑ Patient died due to other reasons
❑ Other, specify: .....

Late complications (more than 24h after first RFA session and before a subsequent EMR/ESD and/or RFA session):

O No
O Unknown
O Yes

❑ Severe bleeding
❑ Symptomatic stenosis/strictures with need for dilatation

- Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible: ……
- Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration?
  - O No
  - O Unknown
  - O Yes

❑ Poor healing (significant inflammation still present ≥ 3 months post-RFA)

❑ Severe esophageal pain

❑ Other, specify: ……..

If option '2'-'8' is selected, please fill out the variables concerning the second RFA treatment session:

Was the (second) RFA preceded by a separate endoscopy (without pre-RFA treatment)?

O No

O Yes

- Date of the latest endoscopy: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Was a biopsy performed during this/these endoscop(y)(ies)?
  - O No
  - O Yes
    - Please specify the worst histology on biopsy:
      - O Barrett esophagus with intestinal metaplasia
      - O Barrett esophagus with low grade dysplasia (LGIN)
      - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
      - O Invasive adenocarcinoma

Was the (second) RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?

O No

O Yes

- Date of the latest pre-RFA treatment: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Type of pre-RFA treatment(s) performed:
  - ❑ Endoscopic (sub)mucosal resection (EMR/ESD)°
    - ❑ EMR, please specify if possible:
      - ❑ En bloc EMR by means of cap EMR
      - ❑ En bloc EMR by means of band EMR
      - ❑ Piecemeal EMR by means of cap EMR
      - ❑ Piecemeal EMR by means of multiband EMR
      - ❑ Unknown
    - ❑ ESD
    - ❑ Other, specify: ……..
  - ❑ Ablation techniques (other than RFA)
    - ❑ Argon plasma coagulation (APC)
    - ❑ Cryoablation
    - ❑ Other, specify: ……

° If option 'Endoscopic (sub)mucosal resection (EMR/ESD)' is selected, please fill out the following variables:

- Please specify the worst histology on EMR/ESD:
  - O Barrett esophagus with intestinal metaplasia
  - O Barrett esophagus with low grade dysplasia (LGIN)
  - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
  - O Invasive adenocarcinoma*

** If option 'Invasive adenocarcinoma' is selected, please fill out the following variables:*

- Depth of tumor invasion:
  - O T1a
  - O T1a m1 (into the lamina propria)
  - O T1a m2 (into the superficial muscularis mucosae)
  - O T1a m3 (in between the muscularis mucosae layers)
  - O T1a m4 (into the deep muscularis mucosae)
  - O T1b
  - O T1b sm1
  - O T1b sm2
  - O T1b sm3
  - O Not applicable
  - O Unknown

- Differentiation grade (if possible):
  - O 1 = Well differentiated
  - O 2 = Moderately differentiated
  - O 3 = Poorly differentiated
  - O 4 = Undifferentiated (anaplastic)
  - O 9 = Unknown

- Lymphovascular invasion (if possible):
  - O No
  - O Yes
  - O Cannot be determined
  - O Not reported

- Deep margin of the resected specimen (if possible):
  - O Negative for carcinoma (margin < 1 mm)
  - O Negative for carcinoma (margin ≥ 1 mm)
  - O Negative for carcinoma (margin not reported)
  - O Positive for carcinoma
  - O Cannot be determined
  - O Unknown

- Lateral margin of the resected specimen (if possible):

  (only the most advanced histology)
  - O Negative for metaplasia / dysplasia / carcinoma
  - O Positive for intestinal metaplasia
  - O Positive for LGIN
  - O Positive for HGIN or carcinoma
  - O Cannot be determined (i.e. piecemeal resection)
  - O Unknown

- Early complications during or shortly after pre-RFA treatment(s):
  - O No
  - O Yes
    - ❑ Bleeding
    - ❑ Perforation
    - ❑ Other, specify: ……..

- Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA), if possible:
  - O No
  - O Yes
    - Date: ……/……/…… (dd/mm/yyyy)

Date of second RFA: ……/……/…… (dd/mm/yyyy)

Prague classification: C: …… (cm) M: …… (cm)

Endoscopic (macroscopic) diagnosis at second RFA:

- ❑ Remaining islands of intestinal metaplasia
  - Number of islands, if possible: ……
  - Smallest diameter of islands, if possible: …… (mm)
  - Largest diameter of islands, if possible: …… (mm)
- ❑ Barrett esophagus without visible focal lesion (flat Barrett)
- ❑ Barrett esophagus with visible focal, suspicious lesion
- ❑ Other, specify: ……

Was a biopsy performed on the day of the second RFA?

- O No
- O Yes
  - Please specify the worst histology on biopsy:
    - O Barrett esophagus with intestinal metaplasia
    - O Barrett esophagus with low grade dysplasia (LGIN)
    - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
    - O Invasive adenocarcinoma

Number of RFA catheters used during the second RFA treatment session:

- O 1 catheter*
- O 2 catheters*, **

** Please fill out the following variables concerning the first RFA catheter that was used:*

- Type of first RFA catheter used:
  - O Circumferential device: HALO/BARRX 360 Express RFA catheter
  - O Focal device: HALO/BARRX 90 catheter
  - O Focal device: HALO/BARRX 60 catheter
  - O Focal device: HALO/BARRX Ultra long catheter
  - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
  - O Other

- Was the first RFA catheter attested to the authorities for compensation?
  - O No
  - O Yes
    - O 172616-172620
    - O 172631-172642
    - O 172653-172664

- Associated protocol used:
    - O 2 x 10 J
    - O 2 x 12 J
    - O 3 x 12 J
    - O 3 x 15 J
    - O 10 J - clean - 10 J
    - O 12 J - clean - 12 J
    - O 2 x 12 J - clean - 2 x 12 J
    - O 2 x 15 J - clean - 2 x 15 J
    - O Other, specify: ……

*** Please fill out the following variables concerning the second RFA catheter that was used:*

- Type of second RFA catheter used:
    - O Circumferential device: HALO/BARRX 360 Express RFA catheter
    - O Focal device: HALO/BARRX 90 catheter
    - O Focal device: HALO/BARRX 60 catheter
    - O Focal device: HALO/BARRX Ultra long catheter
    - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
    - O Other

- Was the second RFA catheter attested to the authorities for compensation?
    - O No
    - O Yes
        - O 172616-172620
        - O 172631-172642
        - O 172653-172664

- Associated protocol used:
    - O 2 x 10 J
    - O 2 x 12 J
    - O 3 x 12 J
    - O 3 x 15 J
    - O 10 J - clean - 10 J
    - O 12 J - clean - 12 J
    - O 2 x 12 J - clean - 2 x 12 J
    - O 2 x 15 J - clean - 2 x 15 J
    - O Other, specify: ……

Was the z-line treated?
- O No
- O Yes

Acute complications (during RFA and/or within 24 hours):

O No
O Unknown
O Yes
- ❑ Bleeding
- ❑ Fever
- ❑ Perforation
- ❑ Other, specify: ……..

Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):

O No
O Unknown
O Yes
- ❑ Severe bleeding
- ❑ Symptomatic stenosis/strictures with need for dilatation
  - Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible: ……
  - Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration? (if possible)
    - O No
    - O Unknown
    - O Yes
- ❑ Poor healing (significant inflammation still present ≥ 3 months post-RFA)
- ❑ Severe esophageal pain
- ❑ Other, specify: ……..

If option '3'-'8' is selected, please fill out the variables concerning the third RFA treatment session:

Was the (third) RFA preceded by a separate endoscopy (without pre-RFA treatment)?

O No

O Yes

- Date of the latest endoscopy: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Was a biopsy performed during this/these endoscop(y)(ies)?

  O No

  O Yes

  - Please specify the worst histology on biopsy:

    O Barrett esophagus with intestinal metaplasia

    O Barrett esophagus with low grade dysplasia (LGIN)

    O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

    O Invasive adenocarcinoma

Was the (third) RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?

O No

O Yes

- Date of the latest pre-RFA treatment: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Type of pre-RFA treatment(s) performed:

  ❑ Endoscopic (sub)mucosal resection (EMR/ESD)°

  ❑ EMR, please specify if possible:

  ❑ En bloc EMR by means of cap EMR

  ❑ En bloc EMR by means of band EMR

  ❑ Piecemeal EMR by means of cap EMR

  ❑ Piecemeal EMR by means of multiband EMR

  ❑ Unknown

  ❑ ESD

  ❑ Other, specify: ……..

  ❑ Ablation techniques (other than RFA)

  ❑ Argon plasma coagulation (APC)

  ❑ Cryoablation

  ❑ Other, specify: ……

  ° If option 'Endoscopic (sub)mucosal resection (EMR/ESD)' is selected, please fill out the following variables:

- Please specify the worst histology on EMR/ESD:
  - O Barrett esophagus with intestinal metaplasia
  - O Barrett esophagus with low grade dysplasia (LGIN)
  - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
  - O Invasive adenocarcinoma*

  ** If option 'Invasive adenocarcinoma' is selected, please fill out the following variables:*

  - Depth of tumor invasion:
    - O T1a
    - O T1a m1 (into the lamina propria)
    - O T1a m2 (into the superficial muscularis mucosae)
    - O T1a m3 (in between the muscularis mucosae layers)
    - O T1a m4 (into the deep muscularis mucosae)
    - O T1b
    - O T1b sm1
    - O T1b sm2
    - O T1b sm3
    - O Not applicable
    - O Unknown

  - Differentiation grade (if possible):
    - O 1 = Well differentiated
    - O 2 = Moderately differentiated
    - O 3 = Poorly differentiated
    - O 4 = Undifferentiated (anaplastic)
    - O 9 = Unknown

  - Lymphovascular invasion (if possible):
    - O No
    - O Yes
    - O Cannot be determined
    - O Not reported

- Deep margin of the resected specimen (if possible):
  - O Negative for carcinoma (margin < 1 mm)
  - O Negative for carcinoma (margin ≥ 1 mm)
  - O Negative for carcinoma (margin not reported)
  - O Positive for carcinoma

O Cannot be determined
O Unknown

- Lateral margin of the resected specimen (if possible):

(only the most advanced histology)

O Negative for metaplasia / dysplasia / carcinoma
O Positive for intestinal metaplasia
O Positive for LGIN
O Positive for HGIN or carcinoma
O Cannot be determined (i.e. piecemeal resection)
O Unknown

- Early complications during or shortly after pre-RFA treatment(s):

O No
O Yes

❑ Bleeding
❑ Perforation
❑ Other, specify: ……..

- Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA), if possible:

O No
O Yes

- Date: ……/……/…… (dd/mm/yyyy)

Date of third RFA: ……/……/…… (dd/mm/yyyy)

Prague classification: C: …… (cm) M: …… (cm)

Endoscopic (macroscopic) diagnosis at third RFA:

❑ Remaining islands of intestinal metaplasia
- Number of islands, if possible: ……
- Smallest diameter of islands, if possible: …… (mm)
- Largest diameter of islands, if possible: …… (mm)

❑ Barrett esophagus without visible focal lesion (flat Barrett)
❑ Barrett esophagus with visible focal, suspicious lesion
❑ Other, specify: ……

Was a biopsy performed on the day of the third RFA?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Number of RFA catheters used during the third RFA treatment session:

O 1 catheter*

O 2 catheters*, **

** Please fill out the following variables concerning the first RFA catheter that was used:*

- Type of first RFA catheter used:

O Circumferential device: HALO/BARRX 360 Express RFA catheter

O Focal device: HALO/BARRX 90 catheter

O Focal device: HALO/BARRX 60 catheter

O Focal device: HALO/BARRX Ultra long catheter

O Focal device: HALO/BARRX Channel TTS (RFA catheter)

O Other

- Was the first RFA catheter attested to the authorities for compensation?

O No

O Yes

O 172616-172620

O 172631-172642

O 172653-172664

- Associated protocol used:

O 2 x 10 J

O 2 x 12 J

O 3 x 12 J

O 3 x 15 J

O 10 J - clean - 10 J

O 12 J - clean - 12 J

O 2 x 12 J - clean - 2 x 12 J

O 2 x 15 J - clean - 2 x 15 J

O Other, specify: ……

*** Please fill out the following variables concerning the second RFA catheter that was used:*

- Type of second RFA catheter used:
  - O Circumferential device: HALO/BARRX 360 Express RFA catheter
  - O Focal device: HALO/BARRX 90 catheter
  - O Focal device: HALO/BARRX 60 catheter
  - O Focal device: HALO/BARRX Ultra long catheter
  - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
  - O Other

- Was the second RFA catheter attested to the authorities for compensation?
  - O No
  - O Yes
    - O 172616-172620
    - O 172631-172642
    - O 172653-172664

- Associated protocol used:
  - O 2 x 10 J
  - O 2 x 12 J
  - O 3 x 12 J
  - O 3 x 15 J
  - O 10 J - clean - 10 J
  - O 12 J - clean - 12 J
  - O 2 x 12 J - clean - 2 x 12 J
  - O 2 x 15 J - clean - 2 x 15 J
  - O Other, specify: ……

Was the z-line treated?
- O No
- O Yes

Acute complications (during RFA and/or within 24 hours):
- O No
- O Unknown
- O Yes
  - ❑ Bleeding
  - ❑ Fever
  - ❑ Perforation
  - ❑ Other, specify: ……

Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):

O No
O Unknown
O Yes

- ❑ Severe bleeding
- ❑ Symptomatic stenosis/strictures with need for dilatation
  - Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible: ……
  - Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration? (if possible)

    O No
    O Unknown
    O Yes
- ❑ Poor healing (significant inflammation still present ≥ 3 months post-RFA)
- ❑ Severe esophageal pain
- ❑ Other, specify: ……..

If option '4'-'8' is selected, please fill out the variables concerning the fourth RFA treatment session:

Was the (fourth) RFA preceded by a separate endoscopy (without pre-RFA treatment)?

O No

O Yes

- Date of the latest endoscopy: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Was a biopsy performed during this/these endoscop(y)(ies)?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Was the (fourth) RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?

O No

O Yes

- Date of the latest pre-RFA treatment: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Type of pre-RFA treatment(s) performed:

❑ Endoscopic (sub)mucosal resection (EMR/ESD)°

❑ EMR, please specify if possible:

❑ En bloc EMR by means of cap EMR

❑ En bloc EMR by means of band EMR

❑ Piecemeal EMR by means of cap EMR

❑ Piecemeal EMR by means of multiband EMR

❑ Unknown

❑ ESD

❑ Other, specify: ……..

❑ Ablation techniques (other than RFA)

❑ Argon plasma coagulation (APC)

❑ Cryoablation

❑ Other, specify: ……

° If option 'Endoscopic (sub)mucosal resection (EMR/ESD)' is selected, please fill out the following variables:

- Please specify the worst histology on EMR/ESD:
  - O Barrett esophagus with intestinal metaplasia
  - O Barrett esophagus with low grade dysplasia (LGIN)
  - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
  - O Invasive adenocarcinoma*

  ** If option 'Invasive adenocarcinoma' is selected, please fill out the following variables:*

  - Depth of tumor invasion:
    - O T1a
    - O T1a m1 (into the lamina propria)
    - O T1a m2 (into the superficial muscularis mucosae)
    - O T1a m3 (in between the muscularis mucosae layers)
    - O T1a m4 (into the deep muscularis mucosae)
    - O T1b
    - O T1b sm1
    - O T1b sm2
    - O T1b sm3
    - O Not applicable
    - O Unknown

  - Differentiation grade (if possible):
    - O 1 = Well differentiated
    - O 2 = Moderately differentiated
    - O 3 = Poorly differentiated
    - O 4 = Undifferentiated (anaplastic)
    - O 9 = Unknown

  - Lymphovascular invasion (if possible):
    - O No
    - O Yes
    - O Cannot be determined
    - O Not reported

- Deep margin of the resected specimen (if possible):
  - O Negative for carcinoma (margin < 1 mm)
  - O Negative for carcinoma (margin ≥ 1 mm)
  - O Negative for carcinoma (margin not reported)
  - O Positive for carcinoma
  - O Cannot be determined
  - O Unknown

- Lateral margin of the resected specimen (if possible):

  (only the most advanced histology)
  - O Negative for metaplasia / dysplasia / carcinoma
  - O Positive for intestinal metaplasia
  - O Positive for LGIN
  - O Positive for HGIN or carcinoma
  - O Cannot be determined (i.e. piecemeal resection)
  - O Unknown

- Early complications during or shortly after pre-RFA treatment(s):
  - O No
  - O Yes
    - ❑ Bleeding
    - ❑ Perforation
    - ❑ Other, specify: ……..

- Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA), if possible:
  - O No
  - O Yes
    - Date: ……/……/…… (dd/mm/yyyy)

Date of fourth RFA: ……/……/…… (dd/mm/yyyy)

Prague classification: C: …… (cm) M: …… (cm)

Endoscopic (macroscopic) diagnosis at fourth RFA:
- ❑ Remaining islands of intestinal metaplasia
  - Number of islands, if possible: ……
  - Smallest diameter of islands, if possible: …… (mm)
  - Largest diameter of islands, if possible: …… (mm)
- ❑ Barrett esophagus without visible focal lesion (flat Barrett)
- ❑ Barrett esophagus with visible focal, suspicious lesion
- ❑ Other, specify: ……

Was a biopsy performed on the day of the fourth RFA?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Number of RFA catheters used during the fourth RFA treatment session:

O 1 catheter*

O 2 catheters*, **

** Please fill out the following variables concerning the first RFA catheter that was used:*

- Type of first RFA catheter used:

O Circumferential device: HALO/BARRX 360 Express RFA catheter

O Focal device: HALO/BARRX 90 catheter

O Focal device: HALO/BARRX 60 catheter

O Focal device: HALO/BARRX Ultra long catheter

O Focal device: HALO/BARRX Channel TTS (RFA catheter)

O Other

- Was the first RFA catheter attested to the authorities for compensation?

O No

O Yes

O 172616-172620

O 172631-172642

O 172653-172664

- Associated protocol used:

O 2 x 10 J

O 2 x 12 J

O 3 x 12 J

O 3 x 15 J

O 10 J - clean - 10 J

O 12 J - clean - 12 J

O 2 x 12 J - clean - 2 x 12 J

O 2 x 15 J - clean - 2 x 15 J

O Other, specify: ……

*** Please fill out the following variables concerning the second RFA catheter that was used:*

- Type of second RFA catheter used:
  - O Circumferential device: HALO/BARRX 360 Express RFA catheter
  - O Focal device: HALO/BARRX 90 catheter
  - O Focal device: HALO/BARRX 60 catheter
  - O Focal device: HALO/BARRX Ultra long catheter
  - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
  - O Other

- Was the second RFA catheter attested to the authorities for compensation?
  - O No
  - O Yes
    - O 172616-172620
    - O 172631-172642
    - O 172653-172664

- Associated protocol used:
  - O 2 x 10 J
  - O 2 x 12 J
  - O 3 x 12 J
  - O 3 x 15 J
  - O 10 J - clean - 10 J
  - O 12 J - clean - 12 J
  - O 2 x 12 J - clean - 2 x 12 J
  - O 2 x 15 J - clean - 2 x 15 J
  - O Other, specify: ……

Was the z-line treated?
- O No
- O Yes

Acute complications (during RFA and/or within 24 hours):
- O No
- O Unknown
- O Yes
  - ❑ Bleeding
  - ❑ Fever
  - ❑ Perforation
  - ❑ Other, specify: ……

Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):

O No
O Unknown
O Yes

❑ Severe bleeding
❑ Symptomatic stenosis/strictures with need for dilatation
- Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible: ……
- Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration? (If possible)

O No
O Unknown
O Yes

❑ Poor healing (significant inflammation still present ≥ 3 months post-RFA)
❑ Severe esophageal pain
❑ Other, specify: ……..

If option '5'-'8' is selected, please fill out the variables concerning the fifth RFA treatment session:

Was the (fifth) RFA preceded by a separate endoscopy (without pre-RFA treatment)?

O No

O Yes

- Date of the latest endoscopy: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Was a biopsy performed during this/these endoscop(y)(ies)?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Was the (fifth) RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?

O No

O Yes

- Date of the latest pre-RFA treatment: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Type of pre-RFA treatment(s) performed:

❑ Endoscopic (sub)mucosal resection (EMR/ESD)°

❑ EMR, please specify if possible:

❑ En bloc EMR by means of cap EMR

❑ En bloc EMR by means of band EMR

❑ Piecemeal EMR by means of cap EMR

❑ Piecemeal EMR by means of multiband EMR

❑ Unknown

❑ ESD

❑ Other, specify: ……..

❑ Ablation techniques (other than RFA)

❑ Argon plasma coagulation (APC)

❑ Cryoablation

❑ Other, specify: ……

° If option 'Endoscopic (sub)mucosal resection (EMR/ESD)' is selected, please fill out the following variables:

- Please specify the worst histology on EMR/ESD:
  - O Barrett esophagus with intestinal metaplasia
  - O Barrett esophagus with low grade dysplasia (LGIN)
  - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
  - O Invasive adenocarcinoma*

  ** If option 'Invasive adenocarcinoma' is selected, please fill out the following variables:*

  - Depth of tumor invasion:
    - O T1a
    - O T1a m1 (into the lamina propria)
    - O T1a m2 (into the superficial muscularis mucosae)
    - O T1a m3 (in between the muscularis mucosae layers)
    - O T1a m4 (into the deep muscularis mucosae)
    - O T1b
    - O T1b sm1
    - O T1b sm2
    - O T1b sm3
    - O Not applicable
    - O Unknown

  - Differentiation grade (if possible):
    - O 1 = Well differentiated
    - O 2 = Moderately differentiated
    - O 3 = Poorly differentiated
    - O 4 = Undifferentiated (anaplastic)
    - O 9 = Unknown

  - Lymphovascular invasion (if possible):
    - O No
    - O Yes
    - O Cannot be determined
    - O Not reported

- Deep margin of the resected specimen (if possible):
  - O Negative for carcinoma (margin < 1 mm)
  - O Negative for carcinoma (margin ≥ 1 mm)
  - O Negative for carcinoma (margin not reported)
  - O Positive for carcinoma
  - O Cannot be determined
  - O Unknown

- Lateral margin of the resected specimen (if possible):

  (only the most advanced histology)
  - O Negative for metaplasia / dysplasia / carcinoma
  - O Positive for intestinal metaplasia
  - O Positive for LGIN
  - O Positive for HGIN or carcinoma
  - O Cannot be determined (i.e. piecemeal resection)
  - O Unknown

- Early complications during or shortly after pre-RFA treatment(s):
  - O No
  - O Yes
    - ❑ Bleeding
    - ❑ Perforation
    - ❑ Other, specify: ……..

- Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA), if possible:
  - O No
  - O Yes
    - Date: ……/……/…… (dd/mm/yyyy)

Date of fifth RFA: ……/……/…… (dd/mm/yyyy)

Prague classification: C: …… (cm) M: …… (cm)

Endoscopic (macroscopic) diagnosis at fifth RFA:
- ❑ Remaining islands of intestinal metaplasia
  - Number of islands, if possible: ……
  - Smallest diameter of islands, if possible: …… (mm)
  - Largest diameter of islands, if possible: …… (mm)
- ❑ Barrett esophagus without visible focal lesion (flat Barrett)
- ❑ Barrett esophagus with visible focal, suspicious lesion
- ❑ Other, specify: ……

Was a biopsy performed on the day of the fifth RFA?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Number of RFA catheters used during the fifth RFA treatment session:

O 1 catheter*

O 2 catheters*, **

** Please fill out the following variables concerning the first RFA catheter that was used:*

- Type of first RFA catheter used:

O Circumferential device: HALO/BARRX 360 Express RFA catheter

O Focal device: HALO/BARRX 90 catheter

O Focal device: HALO/BARRX 60 catheter

O Focal device: HALO/BARRX Ultra long catheter

O Focal device: HALO/BARRX Channel TTS (RFA catheter)

O Other

- Was the first RFA catheter attested to the authorities for compensation?

O No

O Yes

O 172616-172620

O 172631-172642

O 172653-172664

- Associated protocol used:

O 2 x 10 J

O 2 x 12 J

O 3 x 12 J

O 3 x 15 J

O 10 J - clean - 10 J

O 12 J - clean - 12 J

O 2 x 12 J - clean - 2 x 12 J

O 2 x 15 J - clean - 2 x 15 J

O Other, specify: ……

*** Please fill out the following variables concerning the second RFA catheter that was used:*

- Type of second RFA catheter used:
  - O Circumferential device: HALO/BARRX 360 Express RFA catheter
  - O Focal device: HALO/BARRX 90 catheter
  - O Focal device: HALO/BARRX 60 catheter
  - O Focal device: HALO/BARRX Ultra long catheter
  - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
  - O Other

- Was the second RFA catheter attested to the authorities for compensation?
  - O No
  - O Yes
    - O 172616-172620
    - O 172631-172642
    - O 172653-172664

- Associated protocol used:
  - O 2 x 10 J
  - O 2 x 12 J
  - O 3 x 12 J
  - O 3 x 15 J
  - O 10 J - clean - 10 J
  - O 12 J - clean - 12 J
  - O 2 x 12 J - clean - 2 x 12 J
  - O 2 x 15 J - clean - 2 x 15 J
  - O Other, specify: ……

Was the z-line treated?
- O No
- O Yes

Acute complications (during RFA and/or within 24 hours):
- O No
- O Unknown
- O Yes
  - ❑ Bleeding
  - ❑ Fever
  - ❑ Perforation
  - ❑ Other, specify: ……

Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):

O No
O Unknown
O Yes

❑ Severe bleeding
❑ Symptomatic stenosis/strictures with need for dilatation
- Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible: ……
- Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration? (If possible)

O No
O Unknown
O Yes

❑ Poor healing (significant inflammation still present ≥ 3 months post-RFA)
❑ Severe esophageal pain
❑ Other, specify: ……..

If option '6'-'8' is selected, please fill out the variables concerning the sixth RFA treatment session:

Was the (sixth) RFA preceded by a separate endoscopy (without pre-RFA treatment)?

O No

O Yes

- Date of the latest endoscopy: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Was a biopsy performed during this/these endoscop(y)(ies)?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Was the (sixth) RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?

O No

O Yes

- Date of the latest pre-RFA treatment: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Type of pre-RFA treatment(s) performed:

❑ Endoscopic (sub)mucosal resection (EMR/ESD)°

❑ EMR, please specify if possible:

❑ En bloc EMR by means of cap EMR

❑ En bloc EMR by means of band EMR

❑ Piecemeal EMR by means of cap EMR

❑ Piecemeal EMR by means of multiband EMR

❑ Unknown

❑ ESD

❑ Other, specify: ……..

❑ Ablation techniques (other than RFA)

❑ Argon plasma coagulation (APC)

❑ Cryoablation

❑ Other, specify: ……

° If option 'Endoscopic (sub)mucosal resection (EMR/ESD)' is selected, please fill out the following variables:

- Please specify the worst histology on EMR/ESD:
  - O Barrett esophagus with intestinal metaplasia
  - O Barrett esophagus with low grade dysplasia (LGIN)
  - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
  - O Invasive adenocarcinoma*

  ** If option 'Invasive adenocarcinoma' is selected, please fill out the following variables:*

  - Depth of tumor invasion:
    - O T1a
    - O T1a m1 (into the lamina propria)
    - O T1a m2 (into the superficial muscularis mucosae)
    - O T1a m3 (in between the muscularis mucosae layers)
    - O T1a m4 (into the deep muscularis mucosae)
    - O T1b
    - O T1b sm1
    - O T1b sm2
    - O T1b sm3
    - O Not applicable
    - O Unknown

  - Differentiation grade (if possible):
    - O 1 = Well differentiated
    - O 2 = Moderately differentiated
    - O 3 = Poorly differentiated
    - O 4 = Undifferentiated (anaplastic)
    - O 9 = Unknown

  - Lymphovascular invasion (if possible):
    - O No
    - O Yes
    - O Cannot be determined
    - O Not reported

- Deep margin of the resected specimen (if possible):
  - O Negative for carcinoma (margin < 1 mm)
  - O Negative for carcinoma (margin ≥ 1 mm)
  - O Negative for carcinoma (margin not reported)
  - O Positive for carcinoma
  - O Cannot be determined
  - O Unknown

- Lateral margin of the resected specimen (if possible):

  (only the most advanced histology)
  - O Negative for metaplasia / dysplasia / carcinoma
  - O Positive for intestinal metaplasia
  - O Positive for LGIN
  - O Positive for HGIN or carcinoma
  - O Cannot be determined (i.e. piecemeal resection)
  - O Unknown

- Early complications during or shortly after pre-RFA treatment(s):
  - O No
  - O Yes
    - ❑ Bleeding
    - ❑ Perforation
    - ❑ Other, specify: ……..

- Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA), if possible:
  - O No
  - O Yes
    - Date: ……/……/…… (dd/mm/yyyy)

Date of sixth RFA: ……/……/…… (dd/mm/yyyy)

Prague classification: C: …… (cm) M: …… (cm)

Endoscopic (macroscopic) diagnosis at sixth RFA:

- ❑ Remaining islands of intestinal metaplasia
  - Number of islands, if possible: ……
  - Smallest diameter of islands, if possible: …… (mm)
  - Largest diameter of islands, if possible: …… (mm)
- ❑ Barrett esophagus without visible focal lesion (flat Barrett)
- ❑ Barrett esophagus with visible focal, suspicious lesion
- ❑ Other, specify: ……

Was a biopsy performed on the day of the sixth RFA?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Number of RFA catheters used during the sixth RFA treatment session:

O 1 catheter*

O 2 catheters*, **

** Please fill out the following variables concerning the first RFA catheter that was used:*

- Type of first RFA catheter used:

O Circumferential device: HALO/BARRX 360 Express RFA catheter

O Focal device: HALO/BARRX 90 catheter

O Focal device: HALO/BARRX 60 catheter

O Focal device: HALO/BARRX Ultra long catheter

O Focal device: HALO/BARRX Channel TTS (RFA catheter)

O Other

- Was the first RFA catheter attested to the authorities for compensation?

O No

O Yes

O 172616-172620

O 172631-172642

O 172653-172664

- Associated protocol used:

O 2 x 10 J

O 2 x 12 J

O 3 x 12 J

O 3 x 15 J

O 10 J - clean - 10 J

O 12 J - clean - 12 J

O 2 x 12 J - clean - 2 x 12 J

O 2 x 15 J - clean - 2 x 15 J

O Other, specify: ……

*** Please fill out the following variables concerning the second RFA catheter that was used:*

- Type of second RFA catheter used:
  - O Circumferential device: HALO/BARRX 360 Express RFA catheter
  - O Focal device: HALO/BARRX 90 catheter
  - O Focal device: HALO/BARRX 60 catheter
  - O Focal device: HALO/BARRX Ultra long catheter
  - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
  - O Other

- Was the second RFA catheter attested to the authorities for compensation?
  - O No
  - O Yes
    - O 172616-172620
    - O 172631-172642
    - O 172653-172664

- Associated protocol used:
  - O 2 x 10 J
  - O 2 x 12 J
  - O 3 x 12 J
  - O 3 x 15 J
  - O 10 J - clean - 10 J
  - O 12 J - clean - 12 J
  - O 2 x 12 J - clean - 2 x 12 J
  - O 2 x 15 J - clean - 2 x 15 J
  - O Other, specify: ……

Was the z-line treated?
- O No
- O Yes

Acute complications (during RFA and/or within 24 hours):
- O No
- O Unknown
- O Yes
  - ❑ Bleeding
  - ❑ Fever
  - ❑ Perforation
  - ❑ Other, specify: ……

Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):

O No
O Unknown
O Yes

❑ Severe bleeding
❑ Symptomatic stenosis/strictures with need for dilatation
- Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible: ……
- Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration?
O No
O Unknown
O Yes

❑ Poor healing (significant inflammation still present ≥ 3 months post-RFA)
❑ Severe esophageal pain
❑ Other, specify: …….

If option '7'-'8' is selected, please fill out the variables concerning the seventh RFA treatment session:

Was the (seventh) RFA preceded by a separate endoscopy (without pre-RFA treatment)?

O No

O Yes

- Date of the latest endoscopy: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Was a biopsy performed during this/these endoscop(y)(ies)?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Was the (seventh) RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?

O No

O Yes

- Date of the latest pre-RFA treatment: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Type of pre-RFA treatment(s) performed:

❑ Endoscopic (sub)mucosal resection (EMR/ESD)°

❑ EMR, please specify if possible:

❑ En bloc EMR by means of cap EMR

❑ En bloc EMR by means of band EMR

❑ Piecemeal EMR by means of cap EMR

❑ Piecemeal EMR by means of multiband EMR

❑ Unknown

❑ ESD

❑ Other, specify: ……..

❑ Ablation techniques (other than RFA)

❑ Argon plasma coagulation (APC)

❑ Cryoablation

❑ Other, specify: ……

° If option 'Endoscopic (sub)mucosal resection (EMR/ESD)' is selected, please fill out the following variables:

- Please specify the worst histology on EMR/ESD:
  - O Barrett esophagus with intestinal metaplasia
  - O Barrett esophagus with low grade dysplasia (LGIN)
  - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
  - O Invasive adenocarcinoma*

  ** If option 'Invasive adenocarcinoma' is selected, please fill out the following variables:*

  - Depth of tumor invasion:
    - O T1a
    - O T1a m1 (into the lamina propria)
    - O T1a m2 (into the superficial muscularis mucosae)
    - O T1a m3 (in between the muscularis mucosae layers)
    - O T1a m4 (into the deep muscularis mucosae)
    - O T1b
    - O T1b sm1
    - O T1b sm2
    - O T1b sm3
    - O Not applicable
    - O Unknown

  - Differentiation grade (if possible):
    - O 1 = Well differentiated
    - O 2 = Moderately differentiated
    - O 3 = Poorly differentiated
    - O 4 = Undifferentiated (anaplastic)
    - O 9 = Unknown

  - Lymphovascular invasion (if possible):
    - O No
    - O Yes
    - O Cannot be determined
    - O Not reported

- Deep margin of the resected specimen (if possible):
  - O Negative for carcinoma (margin < 1 mm)
  - O Negative for carcinoma (margin ≥ 1 mm)
  - O Negative for carcinoma (margin not reported)
  - O Positive for carcinoma
  - O Cannot be determined
  - O Unknown

- Lateral margin of the resected specimen (if possible):

  (only the most advanced histology)
  - O Negative for metaplasia / dysplasia / carcinoma
  - O Positive for intestinal metaplasia
  - O Positive for LGIN
  - O Positive for HGIN or carcinoma
  - O Cannot be determined (i.e. piecemeal resection)
  - O Unknown

- Early complications during or shortly after pre-RFA treatment(s):
  - O No
  - O Yes
    - ❑ Bleeding
    - ❑ Perforation
    - ❑ Other, specify: ……..

- Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA), if possible:
  - O No
  - O Yes
    - Date: ……/……/…… (dd/mm/yyyy)

Date of seventh RFA: ……/……/…… (dd/mm/yyyy)

Prague classification: C: …… (cm) M: …… (cm)

Endoscopic (macroscopic) diagnosis at seventh RFA:
- ❑ Remaining islands of intestinal metaplasia
  - Number of islands, if possible: ……
  - Smallest diameter of islands, if possible: …… (mm)
  - Largest diameter of islands, if possible: …… (mm)
- ❑ Barrett esophagus without visible focal lesion (flat Barrett)
- ❑ Barrett esophagus with visible focal, suspicious lesion
- ❑ Other, specify: ……..

Was a biopsy performed on the day of the seventh RFA?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Number of RFA catheters used during the seventh RFA treatment session:

O 1 catheter*

O 2 catheters*, **

** Please fill out the following variables concerning the first RFA catheter that was used:*

- Type of first RFA catheter used:

O Circumferential device: HALO/BARRX 360 Express RFA catheter

O Focal device: HALO/BARRX 90 catheter

O Focal device: HALO/BARRX 60 catheter

O Focal device: HALO/BARRX Ultra long catheter

O Focal device: HALO/BARRX Channel TTS (RFA catheter)

O Other

- Was the first RFA catheter attested to the authorities for compensation?

O No

O Yes

O 172616-172620

O 172631-172642

O 172653-172664

- Associated protocol used:

O 2 x 10 J

O 2 x 12 J

O 3 x 12 J

O 3 x 15 J

O 10 J - clean - 10 J

O 12 J - clean - 12 J

O 2 x 12 J - clean - 2 x 12 J

O 2 x 15 J - clean - 2 x 15 J

O Other, specify: ……

*** Please fill out the following variables concerning the second RFA catheter that was used:*

- Type of second RFA catheter used:
  - O Circumferential device: HALO/BARRX 360 Express RFA catheter
  - O Focal device: HALO/BARRX 90 catheter
  - O Focal device: HALO/BARRX 60 catheter
  - O Focal device: HALO/BARRX Ultra long catheter
  - O Focal device: HALO/BARRX Channel (RFA catheter)
  - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
  - O Other

- Was the second RFA catheter attested to the authorities for compensation?
  - O No
  - O Yes
    - O 172616-172620
    - O 172631-172642
    - O 172653-172664

- Associated protocol used:
  - O 2 x 10 J
  - O 2 x 12 J
  - O 3 x 12 J
  - O 3 x 15 J
  - O 10 J - clean - 10 J
  - O 12 J - clean - 12 J
  - O 2 x 12 J - clean - 2 x 12 J
  - O 2 x 15 J - clean - 2 x 15 J
  - O Other, specify: ……

Was the z-line treated?
- O No
- O Yes

Acute complications (during RFA and/or within 24 hours):
- O No
- O Unknown
- O Yes
  - ❑ Bleeding
  - ❑ Fever
  - ❑ Perforation
  - ❑ Other, specify: ……..

Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):

O No
O Unknown
O Yes

❑ Severe bleeding
❑ Symptomatic stenosis/strictures with need for dilatation

- Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible: ……

- Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration? If possible

O No
O Unknown
O Yes

❑ Poor healing (significant inflammation still present ≥ 3 months post-RFA)
❑ Severe esophageal pain
❑ Other, specify: ……..

If option '8' is selected, please fill out the variables concerning the eighth RFA treatment:

Was the (eighth) RFA preceded by a separate endoscopy (without pre-RFA treatment)?

O No

O Yes

- Date of the latest endoscopy: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Was a biopsy performed during this/these endoscop(y)(ies)?

  O No

  O Yes

  - Please specify the worst histology on biopsy:

    O Barrett esophagus with intestinal metaplasia

    O Barrett esophagus with low grade dysplasia (LGIN)

    O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

    O Invasive adenocarcinoma

Was the (eighth) RFA preceded by a pre-RFA treatment (e.g. EMR/ESD, non-RFA ablation)?

O No

O Yes

- Date of the latest pre-RFA treatment: ……/……/…… (dd/mm/yyyy)

- Prague classification, if possible: C: …… (cm) M: …… (cm)

- Type of pre-RFA treatment(s) performed:

  ❑ Endoscopic (sub)mucosal resection (EMR/ESD)°

  ❑ EMR, please specify if possible:

  ❑ En bloc EMR by means of cap EMR

  ❑ En bloc EMR by means of band EMR

  ❑ Piecemeal EMR by means of cap EMR

  ❑ Piecemeal EMR by means of multiband EMR

  ❑ Unknown

  ❑ ESD

  ❑ Other, specify: ……..

  ❑ Ablation techniques (other than RFA)

  ❑ Argon plasma coagulation (APC)

  ❑ Cryoablation

  ❑ Other, specify: ……

° If option 'Endoscopic (sub)mucosal resection (EMR/ESD)' is selected, please fill out the following variables:

- Please specify the worst histology on EMR/ESD:
  - O Barrett esophagus with intestinal metaplasia
  - O Barrett esophagus with low grade dysplasia (LGIN)
  - O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*
  - O Invasive adenocarcinoma*

  ** If option 'Invasive adenocarcinoma' is selected, please fill out the following variables:*

  - Depth of tumor invasion:
    - O T1a
    - O T1a m1 (into the lamina propria)
    - O T1a m2 (into the superficial muscularis mucosae)
    - O T1a m3 (in between the muscularis mucosae layers)
    - O T1a m4 (into the deep muscularis mucosae)
    - O T1b
    - O T1b sm1
    - O T1b sm2
    - O T1b sm3
    - O Not applicable
    - O Unknown

  - Differentiation grade (if possible):
    - O 1 = Well differentiated
    - O 2 = Moderately differentiated
    - O 3 = Poorly differentiated
    - O 4 = Undifferentiated (anaplastic)
    - O 9 = Unknown

  - Lymphovascular invasion (if possible):
    - O No
    - O Yes
    - O Cannot be determined
    - O Not reported

- Deep margin of the resected specimen (if possible):
  - O Negative for carcinoma (margin < 1 mm)
  - O Negative for carcinoma (margin ≥ 1 mm)
  - O Negative for carcinoma (margin not reported)
  - O Positive for carcinoma
  - O Cannot be determined
  - O Unknown

- Lateral margin of the resected specimen (if possible):

  (only the most advanced histology)
  - O Negative for metaplasia / dysplasia / carcinoma
  - O Positive for intestinal metaplasia
  - O Positive for LGIN
  - O Positive for HGIN or carcinoma
  - O Cannot be determined (i.e. piecemeal resection)
  - O Unknown

- Early complications during or shortly after pre-RFA treatment(s):
  - O No
  - O Yes
    - ❑ Bleeding
    - ❑ Perforation
    - ❑ Other, specify: ……..

- Endoscopic evaluation of the latest pre-RFA treatment (prior to date of RFA), if possible:
  - O No
  - O Yes
    - Date: ……/……/…… (dd/mm/yyyy)

Date of eighth RFA: ……/……/…… (dd/mm/yyyy)

Prague classification: C: …… (cm) M: …… (cm)

Endoscopic (macroscopic) diagnosis at eighth RFA:
- ❑ Remaining islands of intestinal metaplasia
  - Number of islands, if possible: ……
  - Smallest diameter of islands, if possible: …… (mm)
  - Largest diameter of islands, if possible: …… (mm)
- ❑ Barrett esophagus without visible focal lesion (flat Barrett)
- ❑ Barrett esophagus with visible focal, suspicious lesion
- ❑ Other, specify: ……

Was a biopsy performed on the day of the eighth RFA?

O No

O Yes

- Please specify the worst histology on biopsy:

O Barrett esophagus with intestinal metaplasia

O Barrett esophagus with low grade dysplasia (LGIN)

O Barrett esophagus with high grade dysplasia (HGIN) / Carcinoma *in situ*

O Invasive adenocarcinoma

Number of RFA catheters used during the eighth RFA treatment session:

O 1 catheter*

O 2 catheters*, **

** Please fill out the following variables concerning the first RFA catheter that was used:*

- Type of first RFA catheter used:

O Circumferential device: HALO/BARRX 360 Express RFA catheter

O Focal device: HALO/BARRX 90 catheter

O Focal device: HALO/BARRX 60 catheter

O Focal device: HALO/BARRX Ultra long catheter

O Focal device: HALO/BARRX Channel TTS (RFA catheter)

O Other

- Was the first RFA catheter attested to the authorities for compensation?

O No

O Yes

O 172616-172620

O 172631-172642

O 172653-172664

- Associated protocol used:

O 2 x 10 J

O 2 x 12 J

O 3 x 12 J

O 3 x 15 J

O 10 J - clean - 10 J

O 12 J - clean - 12 J

O 2 x 12 J - clean - 2 x 12 J

O 2 x 15 J - clean - 2 x 15 J

O Other, specify: ……

*** Please fill out the following variables concerning the second RFA catheter that was used:*

- Type of second RFA catheter used:
  - O Circumferential device: HALO/BARRX 360 Express RFA catheter
  - O Focal device: HALO/BARRX 90 catheter
  - O Focal device: HALO/BARRX 60 catheter
  - O Focal device: HALO/BARRX Ultra long catheter
  - O Focal device: HALO/BARRX Channel TTS (RFA catheter)
  - O Other

- Was the second RFA catheter attested to the authorities for compensation?
  - O No
  - O Yes
    - O 172616-172620
    - O 172631-172642
    - O 172653-172664

- Associated protocol used:
  - O 2 x 10 J
  - O 2 x 12 J
  - O 3 x 12 J
  - O 3 x 15 J
  - O 10 J - clean - 10 J
  - O 12 J - clean - 12 J
  - O 2 x 12 J - clean - 2 x 12 J
  - O 2 x 15 J - clean - 2 x 15 J
  - O Other, specify: ……

Was the z-line treated?
- O No
- O Yes

Acute complications (during RFA and/or within 24 hours):
- O No
- O Unknown
- O Yes
  - ❑ Bleeding
  - ❑ Fever
  - ❑ Perforation
  - ❑ Other, specify: ……

Late complications (more than 24 hours after RFA and before a subsequent EMR/ESD and/or RFA session):

O No
O Unknown
O Yes

- ❑ Severe bleeding
- ❑ Symptomatic stenosis/strictures with need for dilatation
  - Number of dilatations needed before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration, if possible: ……
  - Was this complication resolved before the start of a subsequent RFA session or, if this was the final RFA session, at the end of this registration? If possible

    O No
    O Unknown
    O Yes
- ❑ Poor healing (significant inflammation still present ≥ 3 months post-RFA)
- ❑ Severe esophageal pain
- ❑ Other, specify: ……..