# ELECTRa Registry CRF
# European Lead Extraction ConTRolled Registry

*** mandatory fields**

# *Site Number __

# *1. Patient Characteristics*

# *Patient Number __ __ - __ __

## 1.1 Demographics and Enrolment Data

**Inclusion criteria:**
All consecutive patients scheduled for a Lead Extraction Procedure in the participating centres during the enrolment period

*Date of birth (DD/MM/YYYY) *Gender: Male Female

Height (cm ) Weight (Kg) BMI (calculate variable)

Ethnicity: a.Caucasian b. Hispanic c. Afro-Caribbean

***Date of Enrollment (DD/MM/YYYY) (before procedure)**

***Date of Planned Extraction Procedure (DD/MM/YYYY)**

*1)Emergent Procedure: Yes/No

*Reasons for emergent intervention (specify):…….
……...

*Extraction procedure 1) Done 2) Not Done

*If not done reason - Withdrawn consent

- Complications not related to procedure
Please specify ……..

- Complications related to procedure
Please specify……

- Other …….

# *2. Patient History*

## 2.1 Clinical History

*Coronary Artery Disease Δ No Δ Yes Δ Unknown

*Valvular Heart Disease Δ No Δ Yes Δ Unknown

*Dilated Cardiomyopathy Δ No Δ Yes Δ Unknown

*Hypertrophic Cardiomyopathy Δ No Δ Yes Δ Unknown

*Congenital Heart Disease Δ No Δ Yes
If Yes Previous Repair Δ No Δ Yes
If Yes describe……..
……..

*Previous Sternotomy Δ No Δ Yes Δ Unknown

*Chronic Heart Failure: Δ No ΔYes ΔUnknown
If Yes, NYHA class Δ I Δ II Δ III Δ IV

*LV Ejection Fraction __ __ % Δ Unknown

*Primary Electrical Disease Δ No Δ Yes Δ Unknown

*Other Heart Diseases Δ No Δ Yes Δ Unknown
If Yes specify……

## 2.2 Risk Factors

*Hypertension Δ No Δ Yes Δ Unknown

*Diabetes Mellitus Δ No Δ Yes Δ Unknown
If Yes Δ type 1 Δ type 2

## 2.3 Concomitant Diseases

*Chronic Kidney disease Δ No Δ Yes Δ Unknown
If Yes Pre-op Serum Creatinine ……. (mg/dl)

*COPD (chr obstr pulm dis) Δ No Δ Yes Δ Unknown

# *3. Device (CIED) History*

*Implanted Device (multiple choice)

Δ Pacemaker Δ Defibrillator Δ CRT-Pacemaker

Δ CRT-Defibrillator Δ No generator

If PM - Indication for CIED implantation (multiple choice)

Δ Sinus Node Disease Δ A-V block ΔCarotid Sinus Syndrome
ΔHearth Failure ΔOthers…….

If Defibrillator -Prevention of SD Δ Primary Δ Secondary

*Previous complications to CIED system? Δ No Δ Yes

If yes **:** Δ Infection Δ Malfunction Δ Chronic pain

Δ Venous Thrombosis Δ Others…….

*Number of previous system revisions _____

Number of generator replacements _____

CIED upgrades Δ No Δ Yes

*Was the patient considered for open chest extraction (=discussed with surgeons)?

Δ No Δ Yes

*Previous extraction attempt? Δ No Δ Yes Δ Unknown

If yes: Δ Manual traction ineffective Δ extraction with tools ineffective

Wich tools ……

Δ Lead damaged

# *4. Investigations*

## 4.1 Investigations

**ECG** Δ Spontaneous rhythm Δ Paced Rhythm ΔRA ΔRV ΔLV ΔBIV Δ____

*PM dependency (dependency=pat assumed not to manage without pacing for > 24h)

Δ No Δ Yes

**Blood Pressure ___/___mmHg**

***Chest-X-Ray**

*Number of leads in RA___RV___CS or Branches___ LA___LV endo _____

*Number of leads from Right side____Left side ___ femoral___ epicardial____

***TTE Assessment pre-extraction performed** Δ No Δ Yes

If yes: Tricuspid valve regurgitation? Δ No Δ Yes Δ Not measured

If yes *Grade* I II III IV

Pericardial fluid? Δ No Δ Yes Δ Not measured

If yes (….mm)

Vegetations? Δ No Δ Yes

If yes (____ x _____mm) Location Δ lead Δvalve

***TEE Assessment pre-extraction performed** Δ No Δ Yes

If yes: Vegetations? Δ No Δ Yes

If yes (____ x _____mm) Location Δ lead Δvalve

***Laboratory test pre-extraction performed** Δ No Δ Yes

If yes ESR _____
WBC count _____
C-reactive protein

# *5. Treatments*

*Anticoagulation preoperatively Δ No Δ Yes
If Yes Δ warfarin Δ low molecular hep Δ hep
Δ other specify:
Interrupted Δ No Δ Yes
If Yes interruption time (days before procedure)_____
Bridged Δ No Δ Yes
If Yes Δ low molecular hep Δ hep Δ other specify:

*Antiplatelet preoperatively Δ No Δ Yes
If Yes Δ aspirine Δ clopidogrel Δ both Δ other
Interrupted Δ No Δ Yes
If Yes interruption time (days before procedure)_____

*Antibiotic treatment before extraction?
Δ No Δ Yes
if yes, time since start of appropriate treatment (in days)_____
Δ Empirical Δ Culture-guided

Other Therapies Δ None Δ Digoxin Δ Diuretics Δ Ace/ATII-inhibitors
Δ b-blockers Δ Ca-antag Δ Antiarrhythmics

# *6. Indication for Lead Extraction*

(multiple choice)

*Infection Δ No Δ Yes

If yes, Δ Local (eg. pocket abscess, device erosion, skin adherence, or chronic draining sinus without clinically evident involvement of the transvenous portion of the lead system)

Δ Systemic (eg. as evidenced by valvular endocarditis, lead endocarditis, sepsis or bacteremia)

Positive culture? Δ No Δ Yes

If yes, microorganism identified: Δ CoNS Ms-SA Δ Mr-SA Δ Gram- Δ Other Gram+ Δ Fungal Δ Polymicrobial

Has the patient responded to treatment at time of extraction? (disappearance of signs of infection) Δ No Δ Yes

Date of first symptom of infection: (DD/MM/YYYY)

*Chronic Pain Δ No Δ Yes

*Thrombosis or Venous Stenosis Δ No Δ Yes

Signs and symptoms of venous occlusion. Δ No Δ Yes

If yes: Was a preoperative venogram performed? Δ No Δ Yes

If yes: Was an occlusion noted? Δ No Δ Yes

If yes:location: Δ SVC Δ Innominate Δ Subclavian Δ Other Δ right Δ left (multiple choice)

*Functional Leads Δ No Δ Yes

*Non functional Leads Δ No Δ Yes

*Recalled Lead Δ No Δ Yes

*Upgrading indication Δ No Δ Yes

*MRI indication Δ No Δ Yes

*Malignancy treatment Δ No Δ Yes

*Other……

# *7. Lead Extraction procedure*

*Date _____ dd/mm/yyyy

## 7.1 Lead Extraction Preparation

*Procedural Room: Δ OR Δ Cath-Lab ΔHybrid

*Anesthesia used at start of operation Δ Local Δ Sedation Δ General

*Was an arterial line placed pre-op for BP monitoring? Δ No Δ Yes

*Was antibiotic prophylaxis given for the extraction procedure? Δ No Δ Yes

*Primary extractor: Δ Cardiologist Δ Cardiothoracic Surgeon Δ Other: specify:

*Assistant: Δ Cardiologist ΔCardiothoracic Surgeon Δ Scrub nurse/technician
Other: specify:

## 7.2 Pre-Procedure Lead Information

*N. of leads targeted for removal from RA___RV___
CS or Branches___ Other _____

*N. of leads targeted for removal from Right side ____ Left side _____
femoral_____ epicardial_____

Retained lead impedance, sensing, threshold, pre-procedure
(measured with analyzer and not with implanted device).

a. Retained Lead 1 Manufacturer……Model…….....
ohms: threshold: V sensing: mV

b. Retained Lead 2 Manufacturer……Model……....
ohms: threshold: V sensing: mV

c. Retained Lead 3 Manufacturer……Model……....
ohms: threshold: V sensing: mV

# 7.3 Target Lead Characteristics (a-b-c-d-e-f)

| | Lead a | Lead b | Lead c | Lead d | Lead e | Lead f |
|---|---|---|---|---|---|---|

*Manufacturer Δ Unknown

*Model Code Δ Unknown

*Lead Type
PM U=unipolar B=bipolar
ICD S=single, D=dual coil Sub=Subcutaneous
LV U=unipolar B=bipolar Q=quadripolar

*Vein of insertion: a) Cephalic b) Subclavian c) Internal Jugular d) External Jugular e) Femoral f)Not appl
1=left 2= right Δ Unknown

*Lead Tip Location
RA=Atrium, RV=RVentricle, CS branches=Sinus, LA=Left Atrium, LV=Left Ventricle
PE= Suspected Penetration or perforation of myocardial wall FF=free floating
OTHER=……..explain

*Fixation
A=Active P=Passive

Date of Lead Implant (MM/*YYYY)

# 7.4 Lead Extraction Approaches and Tools (a-b-c-d-e-f)

*Approach for Lead Extraction *Choose all that apply*
SR=Superior R, SL=Superior L, F=Femoral

*Stylet Used *Choose all that apply*
List of Models: Standard,, locking LLD Spectranetics, locking Vascomed, l

locking Cook

*Locking Stylet Engagement to tip Δ Yes Δ No Δ Not Appl

*Sheath used Δ Yes Δ No ΔNot Appl
If yes: Sheath Type: ΔMechanical, ΔEvolution, ΔLaser, ΔEDS
Maximum Sheath Size used (external diameter)
Total number of sheaths used _____

Sheath Time (from starting to use sheath to lead extracted or procedure abandoned in minutes) _____

*Was An Alternate Approach Required ? Δ Yes Δ No
If Yes: 1= femoral 2= jugular 3= other,

*Other Tools used: Δ Yes Δ No
If Yes: lasso, snare, pigtail, EP catheter, Deflectable wires, Basket, Catchers, Other , specify)

*Technical issues during extraction: Δ Yes Δ No
If yes **:** 1) Insulation breaking 2) Conductor breaking 3) Lead to lead adherence 4) Fragment migration 5) Other …….(specify)
Using wich tool? …….(specify)

# 7.5 Lead extraction results (a-b-c-d-e-f)

*Lead Removed with Traction Alone ? Δ Yes Δ No

*Individual Lead Removal Radiological Success
1=Complete, 2=Partial, 3=Failure (more than 4 cm)

*Assumed Clinical Success Δ Yes Δ No

*Reason Clinical Success was not achieved (If applicable):_____

# 7.6 Post-Procedure Information

Retained lead impedance, sensing, threshold, pre-procedure

(measured with analyzer and not with implanted device).

a. Retained Lead 1 Manufacturer……Model……....

ohms: threshold: V sensing: mV

b. Retained Lead 2 Manufacturer……Model……....

ohms: threshold: V sensing: mV

c. Retained Lead 3 Manufacturer……Model……....

ohms: threshold: V sensing: mV

*Total Leads Removed Right Side___ Left Side___Femoral__ Total _____

*Anestesia at the end of the procedure

Δ Local Δ Sedation Δ General

*In case of failure: Δ lead abandonment . Δ surgical extraction

*In case of partial extraction: Δ lead abandonment Δ surgical extraction

*PM dependent: Δ No Δ Yes

If yes: per-op method of stimulation:

Δ temporary femoral pacing Δ other temporary pacing
Δ isoprenaline iv. Δ epicardial permanent Δ transvenous permanent

*TTE Assessment post-extraction performed Δ No Δ Yes

If yes: Tricuspid valve regurgitation? Δ No Δ Yes Δ Not measured

If yes *Grade* I II III IV

Pericardial fluid? Δ No Δ Yes Δ Not measured

If yes (….mm)

Vegetations? Δ No Δ Yes

If yes (____ x _____mm) Location Δ lead Δvalve

*TEE Assessment post-extraction performed Δ No Δ Yes

If yes: Vegetations? Δ No Δ Yes

If yes (____ x _____mm) Location Δ lead Δvalve

Total Procedure time? (skin to skin) minutes

*Total Extraction time? (sheath + other tools, all leads) minutes

Total Fluoroscopic time? Minutes

Duration of hospital stay related to extraction: days

# 7.7 Acute and Post-procedural Complications (Prior to Discharge)

Definition
**1)** Intra-procedural : any event related to the performance of a procedure that occurs or becomes evident from the time the patient enters the operating room until the time the patient leaves the operating room. This includes complications related to the preparation of the patient, the delivery of anesthesia, and opening and closing the incision.
**2)** Post-procedural**:** Any event related to the procedure that occurs or becomes evident prior to discharge

*Were there any MAJOR Intraprocedural or Post-procedural Complications (prior to discharge)?

Δ No Δ Yes

If yes: I = Intraprocedural
P= Postprocedural

MAJOR choose all that apply:

1. Death
   Cause of Death: ΔCardiac, ΔVascular, ΔNon cardiovascular, ΔUnknown.
   If Cardiac: Tamponade, Arrhythmia, Heart Failure, AMI, Acute, massive valvular rigurgitation
   If Vascular: Systemic Hemorrhage, Hemothorax, Pulmonary embolism, Periferal embolism, Ischemic stroke, Hemorragic stroke
   If non Cardiovascular: Sepsis, Acute Multiorgan Failure Syndrome, DIC, Other, specify
   In case of death specify date _____DD/MM/YYYY
   and how many days after the procedure:
   Δsame day, Δday after, Δ≥ 2 days

2. Cardiac avulsion or tear requiring sternotomy, thoracotomy, pericardiocentesis, chest tube, or surgical repair
3. Vascular avulsion or tear requiring sternotomy, thoracotomy, pericardiocentesis, chest tube, or surgical repair
4. Pulmonary embolism requiring surgical intervention
5. Respiratory arrest or anesthesia related complication leading to prolongation of hospitalization

6. Pacing system related infection of a previously non-infected site
7. Stroke

*Were there any MINOR Intraprocedural or Post-procedural Complications (prior to discharge)?

Δ No Δ Yes

If yes: I = Intraprocedural
P= Postprocedural

MINOR choose all that apply:

1. Pericardial effusion not requiring pericardiocentesis or surgical intervention
2. Hemothorax not requiring a chest tube
3. Hematoma at the surgical site requiring reoperation for drainage
4. Arm swelling or thrombosis of implant veins resulting in medical intervention
5. Vascular repair near the implant site or venous entry site
6. Hemodynamically significant air embolism
7. Migrated lead fragment without sequelae
8. Blood transfusion related to blood loss during surgery
9. Pneumothorax requiring a chest tube
10. Pulmonary embolism not requiring surgical intervention

**Complication Management**

*Was transfer to OR required for patient rescue? Δ No Δ Yes

*Time from complications to intervention _____ min

Please provide details around nature of the complication and timeline

_____

# *8. Reimplantation*

*Was a new CIED system implanted during hospital stay? Δ No Δ Yes

*If no why? Δ absence of indication

Δ delayed Δ < 1 month Δ >1 < 3 month Δ > 3 months

Δ patient refusal

Δ other……

*If yes: Δ PM Δ ICD; Δ same type Δ upgrade downgrade

*time from extraction to reimplantation: Δ same intervention

__days Δ before extraction

Δ after extraction

Pace dependency Δ Yes Δ No

* Type of reimplantation:

1. Transvenous contralateral
2. Transvenous ipsilateral
3. Epicardial
4. Subcutaneous
5. Other……

*Complication during reimplantation Δ No Δ Yes

If yes:Δ Pneumothorax or emothorax requiring chest tube
Δ Cardiac tamponade requiring pericardiocentisis
Δ Bleeding requiring blood transfusion
Δ Lead dislogement requiring reintervention
Δ Any complication requiring intervention (specify)

# *9. Investigations and Treatment at discharge*

**ECG** Δ Spontaneous rhythm Δ Paced Rhythm ΔRA ΔRV ΔLV ΔBIV Δ____

***Chest-X-Ray**

Number of leads in RA___RV___CS or Branches___ LA___LV endo _____

Number of leads from Right side____Left side ___ femoral___ epicardial____

***Laboratory test post-extraction performed** Δ No Δ Yes

If yes ESR _____
WBC count _____
C-reactive protein

*Antibiotic treatment after discharge?

Δ No Δ Yes

If yes: Antibiotics for Δ0 Δ1 Δ2 Δ4 Δ6 Δ8 weeks

Other Therapies Δ None Δ Digoxin Δ Diuretics Δ Ace/ATII-inhibitors
Δ b-blockers Δ Ca-antag Δ Antiarrhythmics
Δ Anticoagulants Δ Antiplatetelet

***Wearable Cardioverter Defibrillator (WCD) at discharge** Δ No Δ Yes

*If no why?

Δ ICD reimplantation

Δ ICD no longer indicated/ no VT/VF risk

Δ Did not offer WCD

Δ Did offer WCD, patient refused

# *10. Follow-up*

*Date of follow-up _____ (10-14 months)

*Alive Δ Yes Δ No

*If no a) Date of death _____ DD/MM/YYYY

1. Non-cardiovascular death, including unknown
   a. non-sudden
   b. sudden (trauma, homicide)
2. Cardiovascular death
   - a. cardiac
     - i. sudden (including arrhythmic, myocardial infarction)
     - ii. non-sudden
   - b. vascular (e.g. embolic, SAB, stroke, other)
     - i. sudden
     - ii. non-sudden
3. Unknown

If Cardiac: Tamponade, Arrhythmia, Heart Failure, AMI, Other……..

If Vascular: Systemic Hemorrhage, Hemothorax, Pulmonary embolism, Periferal embolism, Ischemic stroke, Hemorragic stroke, Other……

If non Cardiovascular: Sepsis, Acute Multiorgan Failure Syndrome, DIC, Other…..,

Was death related to indication for extraction, Δ Yes Δ No
If yes: explain……..

Was death related to extraction procedure, Δ Yes Δ No
If yes: explain……..

*If yes NYHA class ΔI ΔII ΔIII ΔIV

*Infective complications Δ Yes Δ No
If yes: Δ local Δ systemic

*Non infective complications Δ Yes Δ No

If yes: Δ Lead Dislogement Δ Lead Failure
Δ Pocket Ematoma Δ Other……
Δ Heart Failure pacing related Δ Other……

*Surgical Reintervention to treat CIED complications Δ Yes Δ No

*New extraction procedure? Δ Yes Δ No

if Yes Δ Transvenous Δ Surgical

*In case of no reimplantation was a late reimplantation performed?

Δ Yes Δ No

If yes : Δ PM Δ ICD; Δ same type Δ upgrade downgrade

* Type of reimplantation:

1. Transvenous contralateral
2. Transvenous ipsilateral
3. Epicardial
4. Subcutaneous
5. Other……

*Complication during reimplantation Δ No Δ Yes

If yes:Δ Pneumothorax or emothorax requiring chest tube
Δ Cardiac tamponade requiring pericardiocentisis
Δ Bleeding requiring blood transfusion
Δ Lead dislogement requiring reintervention
Δ Any complication requiring intervention (specify)

*In case of no reimplantation before discharge was a wearable cardioverter defibrillator used? Δ No Δ Yes

If yes, duration of WCD use: _____ Weeks

If yes, did the WCD deliver treatment? Δ No Δ Yes

If yes: Δ appropriate

Δ inappropriate