



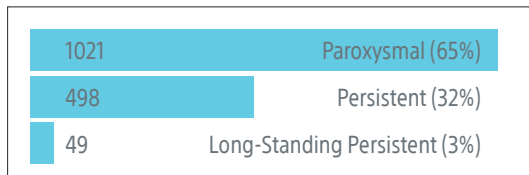
# 1-yr outcomes from *MANIFEST-PF* registry<sup>1</sup>

## OBJECTIVE

Retrospective analysis of safety, procedural endpoints, and long-term outcomes they included all consecutive (de novo ablation) cases, inclusive of learning curve, from March 1, 2021 - May 30, 2022.

## EU-PORIA REGISTRY DESIGN

- 24 European centers with 77 operators
- 1568 all-comer AF ablation patients (de novo ablation)

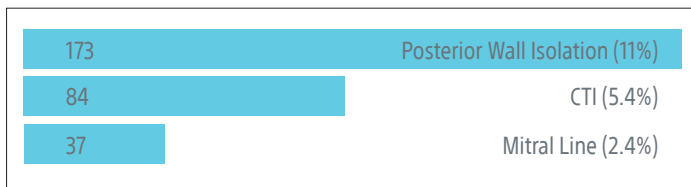
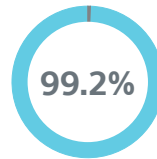


## ENDPOINTS

- **Safety:** Acute and chronic major and minor adverse events.
- **Primary effectiveness outcome:** Freedom from atrial arrhythmia (AF/AFL/AT) recurrence  $\geq$  30 sec post 3-month blanking.
- **Secondary effectiveness outcome:** Freedom from atrial arrhythmia (AF/AFL/AT) post 3-month blanking **AND** freedom from Class I/III AAD **AND** freedom from redo ablation.

## ACUTE RESULTS

- Total procedure time: 61 [40-90\*] min
- Fluoroscopy time: 12 [7-19] min
- PVI was performed in 100% of cases with a 99.2% acute success rate (per patient rate)
- Non-PV ablation was performed in 359 (22.8%) cases, the most common additional lesions were:

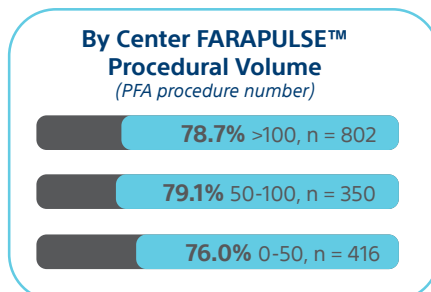
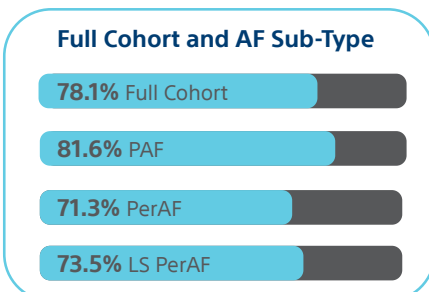


\*Data presented as median (IQR)

## LONG-TERM OUTCOMES

(Median Follow-Up = 367 [289-421])

- ~1 year freedom from AF/AFL/AT



## LONG-TERM OUTCOMES (Cont.)

- In the patients that came back for a redo ablation (9.3%, 147/1568), 72.6% of PVs were durably isolated (45.5% of patients had all PVs durably isolated)

## ADVERSE EVENTS

- There was a 1.9% rate of acute major adverse events, with no reported esophageal damage or PV stenosis
- There was a 4.0% rate of reported acute minor adverse events

## CONCLUSIONS

In an all-comer AF patient population of the first patients undergoing ablation with FARAPULSE.

- The acute PV isolation rate was 99.2% with ~1 hour procedure times
- The 1-year freedom from AF/AFL/AT was:
  - 78.1% full patient cohort
  - 81.6% paroxysmal AF
  - 71.3% persistent AF
  - Similar by center FARAPULSE procedural volume
- The adverse event rates were low with no reported esophageal damage or PV stenosis