

# RETROSPECTIVE MONOCENTRIC STUDY EVALUATING THE PROPER USE AND EFFECTIVENESS OF TYRX® ABSORBABLE ANTIBACTERIAL ENVELOPE IN A RHYTHMOLOGY DEPARTMENT

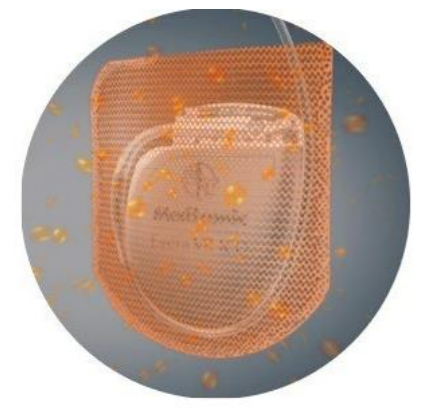
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## CONTEXT



- Active Implantable Medical Device (Class III).
- Absorbable knitted filament mesh (fully absorbed in 9 weeks).
- Elutes Rifampicin and Minocycline into the generator pocket for 7 days.

**Objective :** To assess adherence to national HAS guidelines and clinical efficacy in a real-world setting.

**French Health Authority (HAS) Guidelines<sup>1</sup>:** Reimbursed since 2021 for:

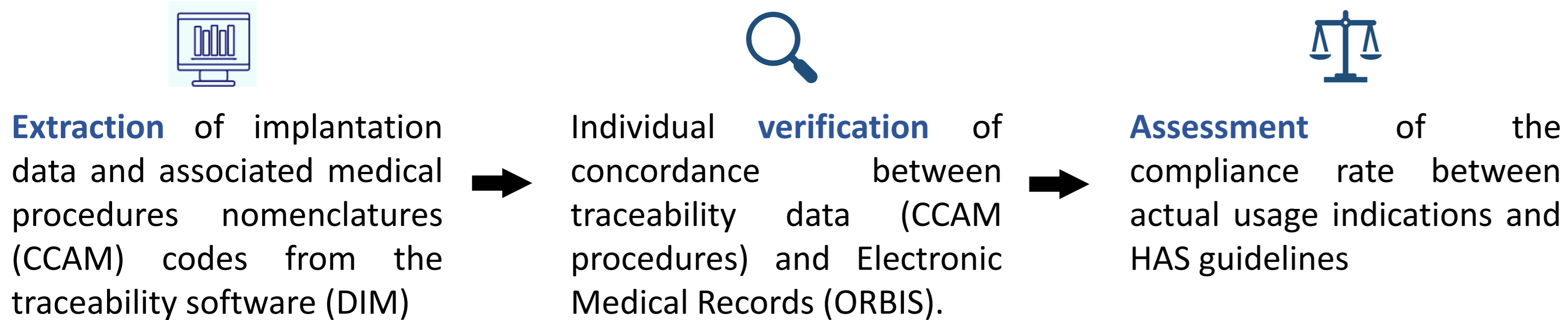
*Infection prevention during cardiac implantable electronic device (CIED) procedures:*

- Replacement, revision, or upgrade of Pacemakers (PM) or Implantable Cardioverter-Defibrillator (ICD) single/dual/triple chamber.
- De novo implantation of CRT-D (Triple chamber ICD)

## MATERIALS AND METHODS

### Assessing the proper use

### Efficacy assessment



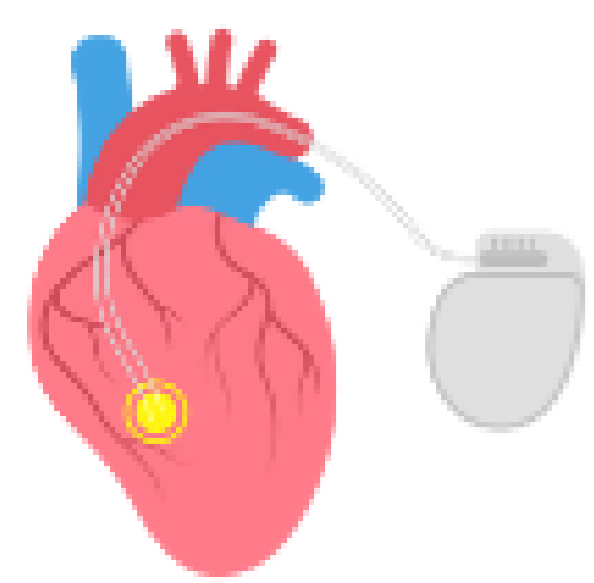
- Extraction of rehospitalization data (ORBIS)
  - Assessment of the one-year post-implantation infection rate
  - Compared with infection rates reported in the WRAP-IT<sup>2</sup> trial

**Cohort A = 2021 cohort**  
Patients eligible for TYRX®  
Non-implanted ❌

**Cohort B = 2022 +2023 cohort**  
Patients eligible for TYRX®  
Implanted ✅

## RESULTS

### Indications for the implantation of TYRX® antibacterial envelopes

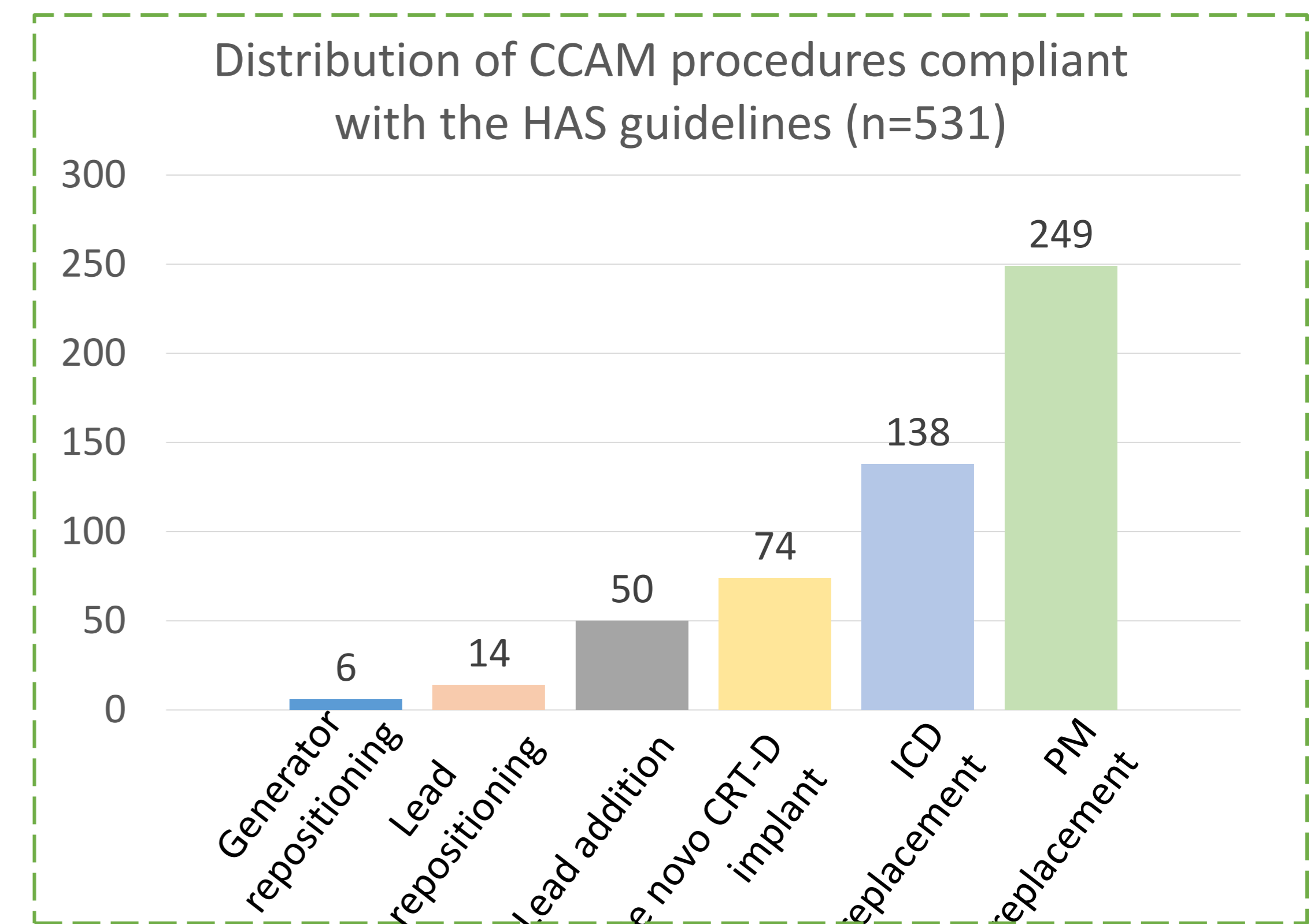


Baseline characteristics	Values
Age (y), mean ± SD	69 ± 16,5
Sex: Male, % (n/N)	64 (377/578)

620 TYRX® tracked  
June 2021 and April 2024

2 failed implantations  
13 TYRX® reported twice

N = 606 TYRX®  
Successfully implanted  
587 patients  
(19 received 2 TYRX®)

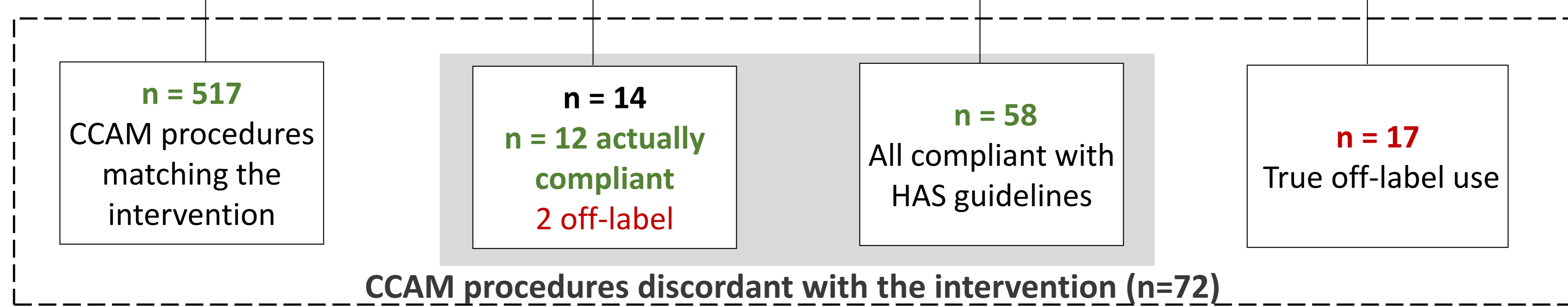


CCAM procedures coded by medical staff



Estimated extra-cost  
82 224 € (incl. tax)

Verified CCAM procedures



96.8 % compliance  
with HAS guidelines  
( n = 587)

### Main off-label uses of TYRX® (n=17)

- Primary triple chamber pacemaker (PM) implantation (n=11)
- Primary dual chamber pacemaker implantation (n=6)

### Rehospitalization data

Baseline characteristics	Group 1 (N <sub>1</sub> = 273)	Group 2 (N <sub>2</sub> =295)
Age (y), mean ± SD	72,7± 15,9	69,4 ±16,2
Sex: Male, % (n/N)	63,7 (174/273)	62,3 (184/295)
Infection requiring rehospitalization, % (n/N)	0,37 (1/273)	0,34 (1/295)
Type of infection	<i>Candida albicans</i>	<i>Exophiala dermatitidis</i>

## DISCUSSION AND CONCLUSION

- TYRX® antibacterial-eluting envelopes are increasingly used in our hospital, mostly in compliance with the HAS guidelines (96.8 %).
- The rhythmology department's traceability rate remains high. However, we estimate a 11.8% rate of discrepancies with coded medical procedures (non-reimbursed interventions) and inaccuracies (missing tracking or double entries) → Targeted training for medical staff is necessary.
- Observed infection rates are lower than those reported in the WRAP-IT study: 0.37% and 0.34% versus 1.2% (Antibiotics alone) and 0.7% (TYRX® + Antibiotics), respectively.
- Effectiveness data are exploratory and require prospective evaluation in a study with a higher level of evidence.



<sup>1</sup>TYRX – CNEDiMTS assessment September 1, 2020

<sup>2</sup>Tarakji KG, Mittal S, Kennegren C, Corey R, Poole JE et al. Antibacterial envelope to prevent cardiac implantable device infection. N Engl J Med. 2019 May 16;380(20):1895-1905