EUROPEAN COMMISSION

Expert decision and opinion in the context of the Clinical Evaluation Consultation Procedure (CECP)

Expert panels on medical devices and in vitro diagnostic devices (Expamed)

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Scope of this expert opinion

This scientific opinion reflects the views of independent experts (MDR Article 106) on the clinical evaluation assessment report (CEAR) of the notified body. The advice is provided in the context of the clinical evaluation consultation procedure (CECP), which is an additional element of conformity assessment by notified bodies for specific high-risk devices (MDR Article 54 and Annex IX, Section 5.1).

The notified body is obliged to give due consideration to views expressed in the scientific opinion of the expert panel and in particular in case experts find the level of clinical evidence not sufficient or have serious concerns about the benefit-risk determination, the consistency of the clinical evidence with the intended purpose including the medical indication(s) or with the post-market clinical follow-up (PMCF) plan.

Having considered the expert views, the notified body must, if necessary, advise the manufacturer on possible actions, such as specific restrictions of the intended purpose, limitations on the duration of the certificate validity, specific post-market follow-up (PMCF) studies, adaption of instructions for use or the summary of safety and clinical performance (SSCP) or may impose other restrictions in its conformity assessment report.

In accordance with MDR Annex IX, 5.1.g., the notify body shall provide a full justification where it has not followed the advice of the expert panel in its conformity assessment report.

1 ADMINISTRATIVE INFORMATION

Date of reception of the dossier	02/09/2022
Notified Body number	0123
Internal CECP dossier #	2022-000235
Medical device type	Single chamber, extravascular implantable cardioverter defibrillator (ICD)
Intended purpose	The system is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients who are indicated for an ICD and who do not have symptomatic bradycardia.
Risk class / type	☒ class III implantable ☐ class IIb active device intended to administer or remove medicinal products(s)
Screening step: medical field / competence area	Circulatory system/ Active implantable cardiac devices and electrophysiological devices

1 DECISION AND OPINION

PART 1 – DECISION OF SCREENING EXPERTS: NOTIFICATION OF NB AND COMMISSION REGARDING THE INTENTION TO PROVIDE AN OPINION

1.1 Decision of the screening experts

Table covers all three criteria, intended to support their consistent and conscientious application

Date of decision	05/10/2022
Screening panel decision	
Is there intention to provide a scientific opinion?	☒ **Yes** ☐ **No** ☐ **Insufficient information to reach a conclusion**
In case the information was found insufficient to reach a conclusion: summary of reasons (see MDR Annex IX Section 5.1 point c)	
Not applicable	
Summary as to why there is intention to provide an opinion	
Criterion 1 is fulfilled. Extravascular ICD is a novel approach to prevention of sudden cardiac death. At the time of providing this decision, there are no other devices on the market, known to the co-rapporteurs, that could be compared in full extension to the device in question. In addition, recently published clinical data[1] indicate a 7.3% rate of major complications 6 months after implantation indicating a potentially significant health impact.	
Summary as to why there is *no* intention to provide an opinion	
Not applicable	
Any other comments	
No additional comments	

1.2 Assessment of the three screening criteria

Criterion 1: Novelty of device under assessment and possible clinical / health impact
1.1 Novelty of device and/or of related clinical procedure
☐ No novelty: Neither device nor clinical procedure is novel ☒ Novelty: **Device** is novel ☒ Novelty: **Procedure** is novel

[1] Friedman P, Murgatroyd F, Boersma LVA, *et al*. Extravascular ICD Pivotal Study Investigators. Efficacy and Safety of an Extravascular Implantable Cardioverter-Defibrillator. N Engl J Med. 2022 Oct 6;387(14):1292-1302. doi: 10.1056/NEJMoa2206485. Epub 2022 Aug 28. PMID: 36036522.

Short description of the novelty, including main dimension(s) of novelty
Currently employed strategy for prevention of sudden cardiac death include implantation of implantable cardioverter-defibrillator with either intravascularly placed leads or a subcutaneous system with defibrillation electrode located under the skin without entering the thoracal cavity. Intravascular system allows full functionality in terms of delivering both defibrillation therapy, antitachycardia pacing and bradycardia pacing, however lead placement inside the circulatory system is associated with the risk of lead malfunction and device- and lead-related infections. Placed extrathoracically, subcutaneous ICD system eliminates the risk of complications related to the presence of the foreign body (leads) in the blood vessels. However, cardiac pacing for prevention of pauses in cardiac cycles and antitachycardia therapy are not available. Extravascular ICD employs defibrillation lead that is placed inside thorax but outside the heart thus avoiding intravascular placement and minimize the risk of related complications. At the same time, this approach should allow pacing (both antitachycardia pacing and, in a limited extent, pacing for prevention of pauses). This is novel.
Overall degree of novelty
☐ Low level *or* ☐ Medium level *or* ☒ High level ☐ Not Applicable (neither the device nor the procedure is novel)
Uncertainties related to novelty
None
1.2 Possible negative clinical / health impact resulting from novelty
Early clinical experience from a published study[1] indicates a 7.3% rate of major complications during 6 months of device use. Assuming that the device is intended for a long-term use of a few years, this may indicate a potential problem, which needs attention and follow-up.
Estimated* severity of clinical and/or health impact * This can entail uncertainty. Not only *known* clinical / health impacts but also *possible* ones (conceivable uncertainties, hazards, risks) should be taken into account but need to be supported by a scientific, clinical or technical reasoning. Uncertainties need to be described.
☐ No clinical or health impact ☐ Minor clinical or health impact ☒ Moderate clinical or health impact ☐ Major clinical or health impact
Uncertainties related to clinical/health impact
Clinical experience with this novel device is still limited.

Criterion 2: Scientifically valid health concerns leading to significantly adverse changes in the benefit-risk profile of a specific group / category of devices and relating to **a) Component(s)**

b) Source material(s) c) Impact on health in case of failure of the device	
2.1 Information received from Secretariat:	☐ Yes ☒ No
2.2 Other information available to experts:	☐ Yes ☒ No

Criterion 3: Significant increase of serious incidents of a specific group / category of devices relevant for the device under assessment *(if information is available, it will always be provided by the expert panel secretariat)*	
3.1 Information received from secretariat?	☐ Yes ☒ No

1.3 Indication of appropriate thematic panel in case opinion is required

Indication of appropriate thematic panel and competence area		
	Expert panels	Medical and scientific/technical competence areas (these may correspond to sub-groups)
☐	**Orthopaedics, traumatology, rehabilitation, rheumatology**	☐ 1. Joint replacements (hip, knee, shoulder) ☐ 2. Spinal devices ☐ 3. Non-articulating devices, rehabilitation
☒	**Circulatory system**	☐ 1. Prosthetic heart valves and devices for heart valve repair ☐ 2. Cardiovascular stents (metallic and bio-resorbable) and vascular prostheses ☒ 3. Active implantable cardiac devices and electrophysiological devices ☐ 4. Structural interventions and new devices (e.g. LAA/PFO occluders, heart failure devices) ☐ 5. Cardiac surgery including extracorporeal membrane oxygenation, cardiopulmonary bypass devices, artificial hearts and left ventricular assist devices
☐	**Neurology**	☐ 1. Central and peripheral nervous system devices ☐ 2. Implants for hearing and vision (sensory recovery) ☐ 3. Neurosurgical devices
☐	**Respiratory, anaesthesiology, intensive care**	☐ Respiratory and anaesthetic devices
☐	**Endocrinology and diabetes**	☐ Endocrinology and diabetes devices
☐	**General and plastic surgery Dentistry**	☐ 1. Surgical implants and general surgery ☐ 2. Plastic surgery and wound care ☐ 3. Maxillofacial surgery & Devices for dentistry e.g. oral surgery, implantology, dental materials etc.
☐	**Obstetrics and gynaecology including reproductive medicine**	☐ Devices for obstetrics and gynaecology
☐	**Gastroenterology and hepatology**	☐ Devices for gastroenterology and hepatology
☐	**Nephrology and urology**	☐ Devices for nephrology and urology
☐	**Ophthalmology**	☐ Devices for ophthalmology

PART 2 – SCIENTIFIC OPINION OF THE THEMATIC EXPERT PANEL/SUB-GROUP

2.1 Information on panel and sub-group

Date of opinion	11/11/2022
Expert panel name	Circulatory system
Sub-group of expert panel (where relevant)	Active implantable cardiac devices and electrophysiological devices

2.2 Summary of expert panel opinion

This is an implantable cardiac defibrillator (ICD), which is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients who are indicated for an ICD and who do not have symptomatic bradycardia. The device is positioned in a lateral thoracic position in the middle axillary line with an entirely extravascular lead positioned via sub-xiphoidal approach, between the sternum and the pericardium. Implantation procedure can be performed by the electrophysiologist, but because of the invasive access, general anaesthesia was recommended and used in almost all the implantations (98.7%)[2].

- **Novelty**

Although this is considered a novel device, some of its features are not novel, as there is already a CE marked subcutaneous ICD (S-ICD) which doesn´t affect the vascular system either. The extravascular ICD (EV-ICD) differs from the S-ICD in three main aspects:

1) The lead is close enough to the heart muscle to provide ventricular stimulation both for significant bradyarrhythmia (pauses > 5 sec) and sustained VT (sVT) that can benefit from anti-tachycardia pacing (ATP).
2) There is a significant lower defibrillation threshold, allowing the use of smaller devices (not larger than a conventional intravascular devices).
3) A longer duration of the battery is assumed (although not proven in the clinical context).

In the Notified Body (NB)'s conclusion (p63 of the CEAR), it is mentioned that the design of the ICD generator does not contain any degree of novelty. This is true if compared with a transvenous ICD (TV-ICD), but not with a S-ICD, which is the most similar device. However, the lead connector has a new design, and the software for ECG signal detection had to be adopted for this non-transvenous ICD system.

[2] Supplement to: Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and safety of an extravascular implantable cardioverter–defibrillator. N Engl J Med. DOI: 10.1056/NEJMoa2206485

On the same page (p63 of the CEAR), it is also mentioned that the implantation technique and the technical specifications of the lead are not considered novel. This cannot be agreed, as this procedure requires a completely new approach for the electrophysiologist and the lead is entirely novel.

The potential negative issues that might arise from the use of this novel technology are:

1) Implantation of the lead in an infra-sternal position what is a new access for electrophysiologists, with possible complications due to the advancement of the introducer into the mediastinal space.
2) Risk of dislocation and repositioning of the lead.
3) Need of general anaesthesia for the implantation procedure[2].
4) ATP efficacy of 50,8% for termination of sVT[2] is lower than expected, if compared to the use of transvenous ICD (TV-ICD) that is about 78%-94%[3].
5) Pacing tolerability: ATP and bradycardia pacing has been reported as being disagreeable or even not acceptable. The rate of ATP switching off was 25%, in many cases due to intolerability, as at least 15% of the patients could not accept the pacing threshold testing[2].
6) High rate of potentially harmful inappropriate shocks (IAS)[1]: almost 10% in 11 months, with 80% of inappropriate shocks caused by device-technical issues like oversensing of P-/T- waves or noise artifacts.
   (Compared to recent trials like the PRAETORIAN[4] or the UNTOUCHED[5], both showing a rate of IAS around 2% (PRAETORIAN) at 6 months, 5% (PRAETORIAN) and 3% (UNTOUCHED) at 1 year and 4% at 18-months (UNTOUCHED) according to the Kaplan-Meier estimations presented in those studies).
7) High rate of overall "major complications" (7.3% in 6 months)[1].
8) High cardiac device related-infection rate (4%)[1], with no information yet regarding potential device-related mediastinitis.
9) Battery longevity is assumed, but not proven yet in real life. This is relevant because a failure in the estimates would negatively impact the expected health outcomes.

- **Adequacy of clinical evidence assessment by notified body**

The clinical data provided by the manufacturer was adequately assessed by the NB, confirming that the device could be considered an alternative for patients with indication for ICD therapy, in particular for the use of the S-ICD.

The manufacturer presented for the assessment data acquired from a pilot study and a (at the time ongoing) pivotal study. The latter was recently published[2], highlighting issues that need to be reassessed by the NB.

- **Sufficiency of clinical evidence**

[3] De Maria E, Giacopelli D, Borghi A *et al.* Antitachycardia pacing programming in implantable cardioverter defibrillator: A systematic review. World J Cardiol. 2017 May 26;9(5):429-436. doi: 10.4330/wjc.v9.i5.429. PMID: 28603590; PMCID: PMC5442411.

[4] Knops RE, Olde Nordkamp LRA, Delnoy PHM *et al*.; PRAETORIAN Investigators. Subcutaneous or transvenous defibrillator therapy. N Engl J Med. 2020; 383:526–536. doi: 10.1056/NEJMoa1915932

[5] Gold MR, Lambiase PD, El-Chami MF, *et al*. Primary results from the Understanding Outcomes with the S-ICD in Primary Prevention Patients with Low Ejection Fraction (UNTOUCHED) trial. Circulation. 2021;143:7–17. doi: 10.1161/CIRCULATIONAHA.120.048728.

According to the data presented by the manufacturer and assessed by the notified body, there is sufficient clinical evidence on:

- Low risk of acute complications during implantation procedure.
- Efficacy in detecting and treating ventricular fibrillation (VF), even in the medium term (months).
- Stability of pacing and defibrillation threshold.
- Low risk of lead extraction at leads in the short term (within some months after implantation).

Data to allow for definite conclusions is still missing regarding the following issues:

- Lead stability.
- ATP efficacy especially during follow-up.
- Pacing tolerability.
- Risk of infections.
- Rate and causes of inappropriate shocks.
- Absolute rate of complications at 6 months (7.3%) is high. Long-term risks are unknown.

- **Adequacy of benefit-risk determination**

The novelty and associated risks are appropriately reflected in the benefit-risk determination as known at the time of the submission of the application. However, and because most the risks can only be correctly analysed in the mid and long-term after the implantation of the device, the conclusion of the pivotal study[1] has brought more data that requires a detailed analysis. Additionally, more follow-up data are also needed, in particular regarding lead stability, ATP efficacy and pacing tolerability, and risk of infection.

- **Consistency of clinical evidence with purpose / medical indication(s)**

The clinical evidence is consistent with the intended purpose and medical indications of the device. However, the data acquired from the final pivotal study[1], and not available at the time of the NB's assessment, shows that the initial conclusions might have been partially favorable regarding some critical issues, like the complication rates (e.g., overall "major complications", inappropriate shocks, infections, lead dislodgment and pacing switched off due to painful pacing).

- **Consistency of clinical evidence with PMCF plan**

The clinical evidence presented is consistent with the PMCF plan. The additional activities planned, i.e., the use of the Post Surveillance Registry (PSR) platform to follow proactively all the patients with the device implanted as well as the annual literature reviews seem adequate to acquire the missing mid and long-term data regarding the use of the device. The follow-up periods proposed for the planned activities are adequate to capture the clinical events of higher interest.

- **Overall conclusions and recommendations on clinical evaluation**

Data provided by the manufacturer for the initial submission was adequately assessed by the NB and confirmed that the device can be considered as an option for patients with indication for ICD therapy, in particular S-ICD, who could also benefit from ATP.

It is recommended that manufacturers and NBs update their clinical reports with the latest relevant clinical information as it becomes available, in particular the incidence of major complications related to the device. In this case, the lack of up-to-date clinical data might have led to partial conclusions and possibly to an underestimation of the true clinical risks (e.g., rates of inappropriate shocks, infections, lead dislodgment).

In addition, the rate of 25% for ATP switching off, in many cases due to intolerability (at least 15% of the patients did not accept the pacing threshold testing), the limited efficacy of "contactless" ATP and the potential contraindications to future epicardial access for VT ablation need to be considered for the clinical indications. Possible limitations in patients with known and frequent sVT also needs to be considered.

The acquisition of more long-term safety data is highly recommended.

2.3 Detailed aspects of the opinion as required by MDR Annex IX Section 5.1

Opinion of the expert panel on the specific aspects of the clinical evaluation assessment report of the notified body (CEAR)[6]
1. Overall opinion on the NB's assessment of the adequacy of the manufacturer's clinical evaluation report
The clinical data provided by the manufacturer was adequately assessed by the NB, confirming that the device could be considered as an alternative for patients with indication for ICD therapy, in particular for the use of the S-ICD. The manufacturer presented for the assessment three early human feasibility studies: • The ASD study[7] to demonstrate that substernal defibrillation is feasible with energy available in current TV-ICDs. • The SPACE study[8] to demonstrate that ventricular pacing is possible from the substernal location. • The ASD2 study[9] to demonstrate that pacing, sensing, and defibrillation is feasible with a lead designed specifically for the substernal space. Additionally, the manufacturer presented for the assessment data acquired from a pilot study and a (at the time ongoing) pivotal study. The latter was recently published[1], highlighting issues that need to be reassessed by the NB (more details given ahead).
2. Opinion on the NB's assessment of the sufficiency of the clinical evidence provided by the manufacturer
From the data presented by the manufacturer and assessed by the notified body, and from the data acquired from the pivotal study[1], there is sufficient clinical evidence regarding:

[6] According to Annex IX Section 5.1 of Regulation (EU) 2017/745 - Assessment procedure for certain class III and class IIb devices.

[7] Chan JYS, Lelakowski J, Murgatroyd FD, *et al*. Novel Extravascular Defibrillation Configuration With a Coil in the Substernal Space: The ASD Clinical Study. JACC Clin Electrophysiol. 2017;3(8):905-910.

[8] Sholevar DP, Tung S, Kuriachan V, *et al*. Feasibility of extravascular pacing with a novel substernal electrode configuration: The Substernal Pacing Acute Clinical Evaluation study. Heart Rhythm 2018; 15(4): 536-542.

[9] Boersma LVA, Merkely B, Neuzil P, *et al*. Therapy From a Novel Substernal Lead: The ASD2 Study. JACC Clin. Electrophysiol. 2019; 5(2): 186-196.

- Low risk of acute complications during the implantation procedure and until 3 months after the implantation attempt ("incidence of major EV-ICD System/procedure-related complications estimated by the Kaplan-Meier method was 0.9% at the day of implant attempt and 3.7% at 10 days post implant attempt and remained 3.7% through 90 days post implant attempt" – p 194 of the CER).
- Efficacy in detecting and treating ventricular fibrillation (VF), even in the medium term (months).
- Stability of pacing and the defibrillation threshold.
- Low risk of lead extraction, at least in the short term (within months after implantation).
- The possibility to use a smaller device than the S-ICD.

However, some questions remain open, pending on the acquisition of more data, namely:

- Rate of overall "major complications".
- Lead stability and dedicated location.
- Poor efficacy of the outstanding feature of "contactless ATP".
- Pacing tolerability.
- Rate of inappropriate shocks.
- Causes of inappropriate shocks (almost 10% at 11 months, 80% non-arrhythmic).
- Infection rate (currently 4%) and severity.

A comparison to the available non-transvenous system of the subcutaneous ICD is presented briefly (p22 of the CEAR), but some of the claims made are not proven or proved incorrect by more recent studies[1] like the one regarding a potential superiority regarding "longer battery longevity" (due to reduced defibrillation energy) or the one regarding "potentially fewer inappropriate shocks" (due to better signals).

3. Opinion on the NB's assessment of the adequacy of the manufacturer's benefit-risk determination

This expert panel can agree with the assessment and conclusions of the NB about the benefit-risk determination of this device on the following points:

- *"The potential benefits of the EV-ICD System are consistent with the lifesaving ICD therapy provided by currently approved single chamber ICDs".*
- *"EV-ICD System may provide access to ICD therapy for patients who are unable to receive a transvenous system".*
- *"In addition to the standard benefits of ICD therapy, there may be additional benefits specific to the EV-ICD system, as systemic infection, embolism, vascular/superior vena cava tears, and lead extraction injuries are expected to be reduced".*
- *"A smaller device increases patient comfort and acceptance".*
- *"The design for MRI Conditional labelling provides the benefit of allowing patient access to MRI imaging".*

However, this expert panel does not completely agree with the NB's conclusions on the following:

- *"As compared to a transvenous system, the EV ICD system is expected to have a lower risk of procedural complications"*. According to the PRAETORIAN trial[4], the 6-months complication rate is similar to that of TV-ICD (about 6%).
- *"Additional potential benefits as compared to the subcutaneous ICD systems currently on the market, as better signal-to-noise ratio from the substernal space as compared to a subcutaneous,*

configuration, resulting in better detection/discrimination algorithms for sensing arrhythmias (and potentially fewer inappropriate shocks)". Considering the higher rate of P wave oversensing, this is not proven, and the rate of inappropriate shocks is not reduced in comparison with S-ICD[1,4].

- Improved battery longevity is assumed considering the reduced defibrillation energy required to defibrillate as compared to a subcutaneous configuration, but this not proven in particular considering the high pacing thresholds.
- Post-shock pacing is also available in the S-ICD.
- Pause-prevention pacing and anti-tachycardia pacing are available in the EV-ICD, but long-term efficacy and tolerability show critical limitations[1].
- *"Furthermore, the safety and performance outcomes of the EV-ICD system is comparable to transvenous ICD systems (…) all residual risks are minimized to an acceptable threshold, therefore, the benefit-risk ratio is considered acceptable (…). All known risks that could have a significant impact on the benefit-risk analysis are evaluated in the clinical evaluation".* After the publication of the pivotal study results[1], this conclusion cannot be fully agreed.

Because the device claims a similar intended purpose to the other ICDs currently on the market, including the benefits of the TV-ICD and of the S-ICD together, the benefits and risks need to be fully assessed in perspective with the other types of ICDs, in particular with the S-ICD in terms of duration, efficacy of VT/VF treatment and procedure complications and with the TV-ICDs in terms of ATP and pacing thresholds.

In terms of functionality, this device is similar to a transvenous single chamber ICD system without all its pacing capabilities. However, in comparison with a conventional TV-ICD, the benefits of avoiding a venous and intracardiac position should be more stressed, as should the risk of unknown long-term effects of mediastinal position. In comparison with the S-ICD, it is possible to provide ATP and ventricular pacing in case of pauses.

The most recent data from the pivotal study[1] was not included in the assessment, leading to incomplete conclusions regarding some critical issues, as major complications, inappropriate shocks, infections, lead dislodgment rate and the need of pacing switched off due to pain. The different reasons for inappropriate shocks (compared with both TV-ICD and S-ICD) should be highlighted. This new data also shows that the new design is associated with the risk of oversensing due to P-wave oversensing and lead movement. These risks were not considered in the benefit-risk determination.

Differently from the S-ICD (that provides shock therapy only), the EV-ICD can terminate sVT with ATP in at least 50% of patients and treat significant ventricular pauses, even if not shock-related. However, the reasons for the inefficiency of the device´s unique feature of "contactless" ATP in half of the cases was not discussed. Finally, the 25 % rate of ATP switching off, in many cases due to intolerability, as at least 15% of the patients did not accept the pacing threshold testing, needs further investigation.

4. Opinion on the NB's assessment of the consistency of the manufacturer's clinical evidence with the intended purpose, including medical indication(s)

The conclusions of the NB on the manufacturer's clinical evidence consistency with the intended purpose and medical indications can be followed. However, because of the limited effect of ATP pacing and the mediastinal position, the use of the device in patients with known history of sVT can be questionable and the advantages over the available S-ICD system need to be verified. Patients with

previous cardiac surgery were excluded from the studies and are unlikely to be candidates for this device, thus limiting even further the use of the device in clinical practice.

5. Opinion on the NB's assessment of the consistency of the manufacturer's clinical evidence with the PMCF plan

The clinical evidence presented is consistent with the PMCF plan. The additional activities planned, i.e., the use of the Post Surveillance Registry (PSR) platform to follow proactively all the patients with the device implanted as well as the annual literature reviews seem adequate to acquire the missing mid and long-term data regarding the use of the device. The follow-up periods proposed for the planned activities are adequate to capture the clinical events of higher interest.

2.4 Overall conclusions and recommendations

Overall conclusions:

According to data presented, there is sufficient clinical evidence regarding:

- Low risk of acute complications during implantation procedure.
- The efficacy in detecting and treating VF, even in the medium term (months).
- The stability of pacing and defibrillation threshold.
- Low risk of lead extraction at least within some months after implantation.
- Smaller device than S-ICD.
- Longer lifespan of the generator (compared to S-ICD).

From the currently available data, including the results of the pivotal study[2], doubts remain regarding:

- Lead stability.
- ATP efficacy, especially during follow-up.
- Pacing tolerability.
- Rate and causes of inappropriate shocks (almost 10% at 11 months, 80% non-arrhythmic).

The use in patients with known sustained VT should be considered carefully (if even considered), taking into account the low (50%) efficacy or tolerability of ATP.

Recommendations:

It is the recommendation of this expert panel that a more comprehensive analysis of the benefits and the risks on the use of this device should be undertaken by the NB, also considering what is known from the pivotal study conclusions[1]. Due to the currently limited available information, it is strongly recommended to acquire more data on the safety and performance of this device.

This expert panel also recommends that manufacturers and NBs update their clinical reports with the latest relevant clinical information as it becomes available, in particular the incidence of major complications related to the device. In this case, the lack of up-to-date clinical data may have led to partial conclusions and possibly to an underestimation of the true clinical risks (e.g., rates of inappropriate shocks, infections, lead dislodgment).

2.5 Stakeholder information, where available

Relevant information provided by stakeholders, if applicable[10]
Has the Secretariat provided information from stakeholders?
☐ Yes ☒ No
Summary of the information that was taken into account and how it was taken into account.
Not applicable.

2.6 Divergent positions in case no consensus was reached

Summary of divergent positions
Not applicable.

Please indicate how many of the experts of the panel or sub-group had divergent views
No divergent views.

[10] According to Article 106.4 of Regulation (EU) 2017/745, expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals when preparing their scientific opinions.