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Discussions with cardiologists and the scientific literature indicate that a failure rate of 0.5% per year (meaning that 0.5% of the implanted leads fail each year) is considered standard and acceptable during the first ten years following implantation. According to a large-scale meta-analysis from 2015, the Durata (St. Jude Medical), Endotak Reliance (Boston Scientific), and Sprint Quattro (Medtronic) coils, for example, have an annual failure rate between 0.29% and 0.45%. We reviewed the medical scientific literature and found 14 studies that calculate the failure rate of the Linox. In 12 of these, the Linox performs (significantly) worse than 0.5% per year, and worse than lead types from other brands (Durata, Endotak Reliance, and Sprint Quattro). Six of these studies show problems primarily occurring five years or more after implantation.

We would like to draw particular attention to the two largest studies on Linox: the Biotronik-sponsored study by Good et al. (2016) and the independent study by Oosterwerff et al. (2024). Although Linox performs worse in both studies than the failure rates mentioned above (0.29%–0.45% per year), we observe significant differences in the outcomes of the two studies. In Oosterwerff et al., Linox performs even worse than in Good et al.: After 6.3 years, the absolute lead failure rate for both types of leads (Linox and Linox Smart) is 10.6 percent. After ten years, the authors report a failure rate of 14.1 percent for Linox and 18.3 percent for Linox Smart.

Here, we note that the Biotronik-sponsored study by Good et al. only looks up to five years post-implantation (Oosterwerff up to ten years post-implantation), does not use data from home monitoring (Oosterwerff does), and uses different criteria (so-called ISO criteria) to define lead failure.

1. What is your opinion of the failure rates reported in the Oosterwerff study? What failure rate do you currently use for Linox leads, based on what data, and why do you choose to use that specific failure rate?
2. A number of more recent studies (published between 2017 and 2024) show that the failure rate increases starting five years after implantation; why has Biotronik never initiated a new study (with a longer follow-up period, e.g., 10 years) for Linox leads?

Reported failure rates for ICD leads vary widely across studies because they differ in followup duration, data sources, and definitions of lead failure. For example, the Oosterwerff study applies different criteria to define lead failure than ISO-based studies. As a result, its reported rates are not directly comparable to those from other publications.
BIOTRONIK therefore does not rely on a single study or one published failure rate but evaluates Linox lead performance using multiple data sources and consistent definitions across large patient populations. Our Product Performance Report provides an aggregated overview of overall device performance, offering further transparency and context alongside insights from large realworlddata initiatives such as EP PASSION.
EP PASSION is a multistakeholder collaboration involving the US Food and Drug Administration (FDA), cardiac implantable device manufacturers, the US Heart Rhythm Society,

and academic researchers, designed to enable longterm assessment of lead safety and performance in routine clinical practice. This longterm performance is already being continuously assessed through the EP PASSION project (Dhruva et al., 2023). EP PASSION reflects a broader shift toward realworld evidence in postmarket surveillance.
This realworlddata initiative combines U.S. device tracking data with Medicare insurance claims, allowing inclusion of far more patients and substantially longer followup than contemporary clinical studies. For Linox leads, this dataset extends out to approximately 16 years postimplantation. This means data assessment is well beyond ten years.
Analyses of EP PASSION data do not show the same performance decay beginning at five years that has been reported in some smaller or methodologically different studies. It shows a freedomfromcomplications rate of 94.4% for Linox S after 13 years and 94.0% for Linox Smart S after 12 years. Validation of this realworlddata approach demonstrated a 99.7 percent overall agreement in identifying lead complications when compared with traditional postapproval studies (Mullane et al., 2024).

3. Why did Good et al. choose to follow patients for only up to five years?

Good et al. did not conduct original clinical trials themselves. Their publication analyzed and reported the clinical outcomes of two studies that had already been completed by Biotronik: the GALAXY Trial (NCT00836589) and the CELESTIAL Trial (NCT00810264). These studies served as postapproval studies (PAS) for the Linox and Corox lead families but also contained many Linox Smart ICD leads.
The followup of these trials is five years. This was defined by regulatory requirements set by the U.S. Food and Drug Administration (FDA). Under FDA regulations (21 CFR 814.82(a)(2) and 21 CFR 814.82(a)(9)) and as specified in the premarket approval (PMA) for the Linox and Linox Smart ICD leads, BIOTRONIK was required to conduct postapproval studies with a mandated fiveyear followup period. Good et al.'s analysis therefore reflects the data that the original studies were designed to collect.
Please note that this fiveyear PAS follow-up period applies to all manufacturers of cardiovascular implantable electronic devices (CIEDs) and leads. In general, medical devices are subject to stringent regulatory processes established by international standards organizations and governmental health authorities, which define both the scope and duration of required postmarket clinical followup.

4. Why did Good et al. choose to define lead failure according to ISO standards, while all other (independent) researchers use a definition they consider more clinically relevant?

BIOTRONIK uses the ISO standard "Cardiac Pacemakers–Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads" (ISO 5841-2:2000), which was developed by the AdvaMed association in collaboration with the FDA and US Heart-Rhythm-Society (HRS).
This standard is used by all manufacturers of cardiovascular implantable electronic devices (CIEDs) in their Product Performance Reports (PPRs) to provide a standardized approach to assess, for example, whether an incident qualifies as a lead failure.

BIOTRONIK's postapproval studies (PAS) were performed using a multicenter, prospective design and included leadfailure definitions in accordance with the ISO standard. In contrast, most published studies reporting on the performance of Linox (Smart) ICD leads were retrospective, which means that already available clinical records or databases were analyzed after events have occurred. These retrospective studies often apply different leadfailure definitions, making comparison of failure rates difficult.

5. Why did Good et al. choose not to use home monitoring to identify lead failure?

Good et al. did not make an active decision to exclude Home Monitoring, but their publication combined and analyzed existing data from the GALAXY and CELESTIAL studies.
With both studies, BIOTRONIK strongly recommended the use of Home Monitoring in line with professional guidance. But its actual use was left to the discretion of healthcare providers, depending on their routine clinical practice. Adoption varies across sites depending on local systems, resources, and organizational factors.
In the GALAXY and CELESTIAL studies, patients were seen very frequently, with regular inperson clinic visits and device checks defined by the study protocols. Because of this close followup, any leadrelated problems were reliably identified during these scheduled visits, even without Home Monitoring.

Therefore, while Home Monitoring is highly valuable in realworld care, its use in these studies would not have changed the number of adverse events detected. In this clinical study setting, the added value of Home Monitoring lies in earlier detection, but it does not lead to the detection of more events.
We have spoken with several patients who received inappropriate shocks due to Linox failure. Several of these patients received dozens of shocks in succession. They say they are severely traumatized by these unnecessary shocks, and in some cases, their trust in their ICD has been seriously damaged, even after the Linox leads were removed.

6. Would you like to respond to this?

We understand that inappropriate shocks can be extremely distressing for patients. We take these reports very seriously, and we recognize the lasting emotional and physical impact such events can have, even after a lead has been replaced.

ICD systems, including ICD leads such as Linox, are indicated for patients at risk of sudden cardiac death caused by ventricular tachyarrhythmias, such as ventricular tachycardia (VT) or ventricular fibrillation (VF). These devices are lifesaving technologies, and their ability to terminate malignant arrhythmias using antitachycardia pacing or shock therapy is well established and supported by prospective, randomized clinical trials. For many patients, ICD therapy is the most effective—and often the only—means of preventing sudden cardiac death.

At the same time, ICD therapy does not come without risks. Inappropriate shocks are a known and documented adverse effect that can significantly impact quality of life. As described by Daubert et al. (2008), up to 11.5 percent of patients may experience one or more inappropriate shocks. In that analysis, the most common triggers were atrial fibrillation (44 percent) and

supraventricular tachycardia (36 percent), while inappropriate sensing, such as that related to lead issues, accounted for approximately 20 percent. Even when comparatively less frequent, inappropriate shocks related to sensing issues can be particularly distressing for patients.

Because these complications can be so burdensome, manufacturers and clinicians work continuously to reduce their occurrence. Patient safety is the central priority. This is why BIOTRONIK strongly recommends the use of Home Monitoring, which enables earlier identification of abnormal device signals or arrhythmia patterns and allows physicians to intervene sooner.

ICD systems are regularly updated to reduce the risk of unnecessary shocks by improving rhythm detection and discrimination, including more accurate differentiation between malignant ventricular and benign supraventricular rhythms, as well as enhanced sensing performance. These developments reflect the continuous evolution of complex implantable CIED technologies across the industry, helping to make therapy safer while preserving its lifesaving role. BIOTRONIK likewise continues to invest in such advancements.

All medical devices, including ICDs and leads, are subject to stringent regulatory oversight established by international standards organizations and governmental health authorities. BIOTRONIK complies fully with these requirements and operates a robust postmarket surveillance and complainthandling system. This system ensures that reports of device performance issues are systematically collected, investigated, and evaluated, so that lessons learned can be incorporated into clinical guidance, product improvements, and future technologies.

We are committed to continuing our efforts as industry with clinicians and regulators to reduce these events and to support patients who rely on these devices for their lives.

7. Biotronik has not issued a recall or safety warning. Some of the people we spoke with, including former employees, argue that Biotronik should demonstrate responsibility in other ways, such as through psychological aftercare for patients who have received (dozens of) inappropriate shocks. What is Biotronik doing in this regard for those patients who have received inappropriate shocks?

We fully understand how distressing inappropriate shocks can be, particularly when patients experience multiple shocks in a short period of time.
As a medical device manufacturer, BIOTRONIK does not have a direct relationship with patients. We do not have access to identifiable patient data and are not able to contact patients directly. Clinical care, including followup, counseling, and psychological aftercare, is coordinated by the treating physicians and healthcare providers, who are best placed to assess and address the individual medical and emotional needs of their patients.
BIOTRONIK takes its responsibility for patient safety and focuses its efforts where it can have the greatest and most appropriate impact: reducing risks, preventing complications, and supporting clinicians with tools and information to improve patient outcomes. This includes continuous investment in product quality, postmarket surveillance, and ongoing improvement of sensing and detection algorithms aimed at reducing inappropriate therapies.
We spoke to, among others, a patient who received dozens of unnecessary shocks after several scientific studies had already pointed out problems with the lead. He did not have home monitoring at the time of the shocks (2020). He concludes that his unnecessary shocks

could have been prevented if Biotronik had acted more proactively and, for example, issued a safety warning.

8. What is your response to this?

We do not comment on individual patient cases or on hypothetical conclusions drawn from them. Patient safety remains BIOTRONIK's highest priority. All reports concerning device performance, including instances of inappropriate therapy, are carefully and thoroughly evaluated through our robust postmarket surveillance system and individually reported to the local national health authority as well as the U.S. FDA.
Medical devices are subject to stringent regulatory oversight worldwide. Any decisions regarding safety communications or corrective actions are based on comprehensive data review and analysis in close cooperation with the relevant regulatory authorities.
Cardiologists worldwide told us that the leads did not work properly, broke down quickly, and consequently delivered false shocks more often than other leads. They say that whenever they shared incidents involving faulty leads or research data with Biotronik, they were routinely turned down. Biotronik told them that their research data was incorrect, that they had implanted the leads poorly themselves, or that Biotronik had no knowledge of failing leads in other hospitals. Some doctors found this response disappointing and hoped for more transparency and reflection. Given the failure rate of the Linox leads, the doctors also wonder why Biotronik has never issued a market warning or recall.

9. Is it true that Biotronik systematically denies to cardiologists that there are problems with Linox leads?
10. What is your response to this?

BIOTRONIK fosters a transparent and scientific approach when discussing lead performance with concerned clinicians. When cardiologists report incidents or raise questions, the company engages in direct dialogue and evaluates the information provided, acknowledging individual center experiences while also discussing known influencing factors.

These discussions can include clinical circumstances. Where analysis of returned products indicates patterns consistent with lead-handling or implantationrelated issues, such as an accumulation of subclavian crush cases, implantation technique may also be addressed. This is a standard part of medical device performance evaluation and is intended to achieve a complete and balanced understanding of individual cases rather than dismiss reported concerns.

In response to the broader question, BIOTRONIK encourages its customers to report incidents both to BIOTRONIK and to their respective national competent authorities, ensuring transparency and regulatory oversight. The company's assessment of lead performance is based on robust and comprehensive clinical evidence, including large, independent studies with proactive followups conducted under the guidance of the U.S. Food and Drug Administration (FDA).

The FDAreviewed GALAXY and CELESTIAL studies demonstrated that Linox ICD leads are safe and reliable. Across these two trials, 3,933 ICD leads from the Linox family were

implanted in 3,840 patients at 146 U.S. study centers, with lead performance and safety evaluated for up to five years postimplantation. All relevant clinical and systemrelated adverse events were recorded at each followup and confirmed by a clinical events committee of independent electrophysiologists.

When interpreted in a broader context, Linox lead performance should be assessed against large, contemporary comparative datasets. This broader view is supported by analyses of the U.S. ICD Registry, including the propensitymatched survival analysis by Resnic et al. (2020), which evaluated 374,132 patients receiving an ICD system for the first time, including patients implanted with Linox leads. In this large realworld cohort, no safety alerts were triggered for the primary safety endpoint of lead failure for any of the highenergy ICD leads studied. Importantly, the analysis did not identify statistically significant differences in freedomfromcomplications rates between leads from various manufacturers. The estimated freedom from lead failure at five years is ranging from 97.7% to 98.9% across the four highenergy leads evaluated.

11. Why has Biotronik never issued a safety warning or recall for Linox and/or LinoxSmart?

BIOTRONIK evaluates the performance of its products through its entire lifecycle, this includes evaluation of Post-Approval-Studies and Real-World-Data sources like EP-PASSION, monitoring of complaint data including analysis of returned products as well as trend analysis and risk assessment. For both the Linox and Linox Smart the risk-benefit profile remains unchanged, and there is no indication for issuing a Field Safety Notice.

A doctor told us that he had been invited to Berlin to discuss the Linox leads. There, Biotronik admitted that they weren't working properly and that the design had therefore been modified.

12. Is it true that it has been acknowledged internally that the Linox isn't working properly and that the design has therefore been modified?

Like all responsible medical device manufacturers, we continuously evaluate product performance throughout the entire product lifecycle. The phase-out of older device families is common practice in the innovative medical device industry. In the case of Linox, first launched to the market in 2006, its update with Linox Smart and later with Protego was in response to the need for a lubricous coating to further improve implantability as well as a DF4 connector design. Please find additional information on our product improvement and innovation strategy in answer to question 19.

We also invest in ongoing research and development. Design refinements are a normal and essential part of medical innovation. All changes are implemented in accordance with global and local regulatory requirements. Patient safety remains our top priority and guiding principle for all product and therapy decisions.

A study on Linox leads was conducted at Isala Hospital in Zwolle, resulting in the 2015 abstract titled "Characteristics and failure rate of the Biotronik Linox implantable cardioverter defibrillator lead." The study was never published in a scientific journal. The researchers were scheduled to present their findings at a cardiology conference in Milan in june 2015 but withdrew at the last minute. Sources tell us this is because researchers were pressured within the hospital by Biotronik not to publish.

13. Is it true that you visited this hospital to discuss the study with the researchers?
14. Is it true that Biotronik pressured the researchers? Why did you do this?

As a company, we do not comment on allegations that are not supported by verifiable facts.
BIOTRONIK engages regularly in scientific exchange with clinicians and research institutions worldwide. These interactions are conducted as part of standard, transparent collaborations aimed at understanding clinical experience and advancing patient care.
We support independent research and open scientific dialogue, while fully respecting the autonomy of clinicians and institutions. We will not speculate on incomplete or unverified information and remain focused on evidence-based evaluation and patient safety.
We are available to provide general information about our processes and standards where appropriate.

A doctor told us that Biotronik threatened to cut off funding for his educational program if he published his data on failing Linox leads. The doctor ultimately published the data anyway, and the threat was not carried out, he claims.

15. Would you like to comment on this?

We do not comment on unsubstantiated claims attributed to undisclosed sources. All interactions with healthcare professionals are governed and in accordance with strict compliance, ethical, and transparency standards.
As the allegations referenced are presented in general terms without specific sourcing and verifiable details, we are not in a position to provide further comment.

In the Maude database, we found 934 reports of inappropriate shocks caused by malfunctioning Linox leads over the past ten years. Each report includes Biotronik's response to the incident. We see that in no case does Biotronik acknowledge that the Linox lead failed. Even in 264 reports where doctors sent the leads to Biotronik for investigation, the company attributes the cause of failure to factors outside its control. We see the same explanation recurring. It is not the design or the material of the lead itself, but "severe mechanical stress on the lead," for example due to "movement of the lead" and "interaction with atypical tissues," that is said to explain the damage to the lead. In almost all cases, Biotronik concludes with the statement "there are no indications of a material defect or a manufacturing error."

16. Why does Biotronik consistently respond with a standard response to reports filed with the FDA?
17. Why does Biotronik state in every case that the cause of the problem lay outside of Biotronik itself? How can Biotronik be certain that it is not due to the design of the lead itself?

BIOTRONIK's regulatory responses to reports filed with authorities such as the FDA follow defined, standardized formats because regulatory reporting requires clear, objective, and consistent language. This ensures compliance with applicable reporting standards. While the wording may appear repetitive, each report is based on a casespecific investigation that includes review of the clinical information provided, analysis of returned devices where available, and evaluation under established quality and vigilance procedures.
When BIOTRONIK concludes that there are no indications of a material defect or manufacturing error, this statement is based on the results of a formal technical investigation.

In cases where leads are returned, they are examined using standardized analytical methods to assess mechanical integrity, material properties, and manufacturing conformity. If these analyses do not reveal evidence of a manufacturing or material defect, and if observed damage patterns are consistent with known external influences, such as mechanical stress or anatomical interaction, these factors are documented accordingly.
According to literature (Swerdlow et al, 2020) “ICD lead failure is often considered in the context of design or construction defects, but is more appropriately considered in the context of the finite service life of a mechanical component placed in chemically stressful environment and subjected to continuous mechanical stresses.”
We hear from former Biotronik employees that there is a culture within the company in which critical questions and research data regarding Biotronik products are ignored. For example, employees were given “talking points” to refute critical studies on Linox, such as the Canadian study by Padfield (2014). Biotronik is also said to have never provided training on how to handle reports of defective products.

18. Does Biotronik recognize this? If not, what is incorrect about it?

This description does not reflect BIOTRONIK’s experience or understanding of the related matter. Patient safety, quality, and compliance are core elements of our quality system, which is subject to regular audits by international regulatory bodies and governmental health authorities.
BIOTRONIK sales representatives receive structured training on product use, regulatory requirements, and appropriate handling of complaint reports to support professional collaboration with healthcare providers in line with industry standards.
Scientific questions and device performance data are continuously reviewed through our postmarket surveillance and complaint handling processes.
Three years after the introduction of the Linox in 2006, Biotronik released an upgrade in 2009. The “Linox Smart” received a new, smooth silicone coating intended to make the lead more resistant to friction (which turned out not to work). Four years later, Biotronik reinforced the connector that attaches the lead to the heart chamber. In 2017, the company launched a new and stronger model (Plexa). Cardiologists we spoke with suspect that Biotronik made these changes to the Linox leads because the company was indeed aware of the problems with the lead but did not want to issue a recall or market warning.

19. Is this correct? If not, why did Biotronik introduce new versions so quickly in succession? If so, why was there no recall?

The successive introductions of Linox Smart, Protego, and later Plexa are consistent with BIOTRONIK’s longstanding strategy of incremental product innovation, which is standard practice in the cardiac rhythm management industry and is aimed at continuously improving patient safety, usability, and alignment with stateoftheart technology.
With the launch of Linox Smart in 2009, BIOTRONIK introduced the SilGlide™ coating to improve handling and implantability by reducing surface friction of the silicone lead body. This change was driven by clinical feedback and evolving expectations regarding ease of implantation, rather than by a confirmed safety defect in the original Linox lead. Importantly, SilGlide™ is not a proprietary or experimental BIOTRONIK development. It is a wellestablished

silicone coating produced by Applied Membrane Technology that had already been used for years and continues to be used by Guidant/Boston Scientific, before its adoption by BIOTRONIK. The coating is considered effective, and BIOTRONIK has not received complaints indicating safety or performance concerns related specifically to SilGlide™, which remains in use on current ICD lead platforms.
The later reinforcement of the connector and adoption of the DF4 standard with the Protego platform reflected broader industrywide technological evolution rather than corrective action for a known defect. The transition to DF4 connectors was driven by the desire to simplify systems, reduce connector bulk, and improve reliability, while enhanced strainrelief designs further aligned the leads with contemporary engineering standards and regulatory expectations.
The introduction of the Plexa lead family in 2017, featuring a new helical conductor design and increased mechanical robustness, similarly represents ongoing innovation. The pace of these product generations illustrates the frequency of device advancement in the implantable medical device field, where manufacturers routinely introduce new platforms as materials science and design methodologies progress.
In medical device regulation, recalls are based on confirmed safety risks and the presence of a systematic root cause associated with high failure rate, not on the introduction of newer or enhanced product generations. As such, the phased replacement of Linox with Linox Smart, Protego, Plexa and eventually Pamira reflects the normal lifecycle of medical device platforms at BIOTRONIK, driven by continuous improvement and innovation rather than undisclosed safety concerns.
Because Biotronik no longer sells the old Linox leads and the certificate has expired, its Notified Body, 'Tüv Süd,' no longer bears responsibility for monitoring the Linox and LinoxSmart. TÜV Süd states that it has not monitored the safety of these devices since 2015 (Linox) and 2019 (LinoxSmart), as it has not been responsible for certification since then.

20. Is this correct?
21. How does Biotronik ensure that it continues to exercise responsibility over the entire life cycle of the products, including those whose certification has already expired? And would you like to comment on this?

It is correct that once a product is no longer marketed and its CE certificate has expired, the specific product certificate itself is no longer actively maintained. However, this does not mean that BIOTRONIK or its Notified Body, TÜV Süd, cease all oversight with respect to those products. In addition to issuing CE certificates for individual products such as Linox and Linox Smart, TÜV Süd certified BIOTRONIK's Quality Management System in accordance with EN ISO 13485:2016.
This certification covers the full set of lifecyclerelevant processes, including complaint handling, vigilance, postmarket surveillance, clinical evaluation, risk management, and corrective and preventive actions. TÜV Süd continues to perform regular announced and unannounced audits of BIOTRONIK's quality management system on an annual basis, thereby exercising ongoing oversight of these processes irrespective of whether specific product certificates remain active.
BIOTRONIK ensures responsibility over the entire product life cycle, including for products whose CE certificates have expired. This includes postmarket surveillance and vigilance

obligations under European regulatory law. In accordance with Article 10(12) of the EU Medical Device Regulation (MDR), BIOTRONIK reports serious incidents to both the competent authorities and TÜV Süd not only for products with an active CE certificate issued by TÜV, but also for products with expired or returned certificates where TÜV Süd was involved in the original technical evaluation.
This obligation expressly includes serious adverse events related to the Linox and Linox Smart ICD lead families occurring within CE markets. These reports continue to be submitted to and assessed by TÜV Süd, ensuring regulatory continuity and oversight even after the end of active certification.
In addition, all Linoxrelated adverse events that are reported to BIOTRONIK as the manufacturer are also submitted to the U.S. FDA.
In 2014 and 2022, settlements were reached between Biotronik and U.S. authorities regarding allegations of bribery of physicians. According to the Dutch newspaper NRC, the Dutch investigative authority FIOD has been investigating since 2020 possible bribery by Biotronik of cardiologists at the Isala Hospital in Zwolle. Two Biotronik employees are also reportedly under suspicion.

22. Is it true that the Dutch criminal investigation concerns Biotronik's conduct?
23. Is it true that two Biotronik employees are suspected by the FIOD of bribery in that case?

As a company, we cooperate with competent authorities as required and comply with all applicable local and international laws and regulations. We do not comment on broad, vaguely described allegations that do not allow for proper verification and meaningful review.

24. Can you comment on the settlements in the U.S.?

The settlements reached in the United States are a matter of public record and relevant company statements have been publicly disclosed. BIOTRONIK refers to those public disclosures as the appropriate source of information.

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Thank you for this extensive response. As our research progresses, we'd like to share something else with you.

We obtained the following document: "Field Information (December 5, 2014): Communication Aid Regarding Article in JCE Journal Reporting Increased Failure Rates of Linox ICD Leads". The document, written by Biotronik, was distributed to Biotronik employees. It contains 10 "key arguments" on how to address customer questions and concerns following the Padfield study, which found a high failure rate for Linox leads. Among other things, we read the following sentence: "Do not proactively engage in a debate about the long-term performance of our Linox ICD leads in the context of this article." It says: For questions regarding this matter, feel free to contact the marketing department in Berlin, headed by Thomas Herrmann.

- Why did Biotronik distribute this document to employees after the Padfield study was published?

- Why does Biotronik tell employees, "Do not proactively engage in a debate about the long-term performance of our Linox ICD leads in the context of this article."

Antwoord door Biotronik 12-05-2026

Thank you for your questions and patience. First of all, it is important to clarify one aspect: the Padfield et al. publication is not a clinical study and should not be confused with it. It is a retrospective analysis of existing clinical data from four hospitals introducing their own definition of "real" lead failure.

This means that it does not fulfill the same quality criteria as clinical studies (GALAXY and CELESTIAL are examples of large clinical studies) and is particularly susceptible to publication-bias.

With reference to your questions and the document you referenced: The document was shared to support colleagues in the field by informing them about the publication and providing contextual, scientifically grounded information about the publication and its findings. It forms part of a regular corporate service aimed at ensuring that employees who are not scientifically trained are made aware of current developments and have access to relevant background, methodological context, and limitations of clinical publications. This is to ensure that they are informed and can support balanced, fact-based discussions with healthcare professionals when questions arise.

In the case of the Padfield analysis, the publication might have raised questions or concerns among health care professionals because it reported higher "true lead failure" rates for Linox ICD leads compared to a comparator. At the same time, the analysis had important limitations

in its retrospective design and applied methods, including differences in the patient cohorts, an uneven distribution of implants across centers, and an unconventionally defined failure endpoint. These are aspects that can significantly influence how results should be interpreted, but may not be obvious to colleagues without a scientific background.

The field information document therefore summarized key data from the publication, highlighted the limitations, and pointed to additional sources of performance data, such as broader surveillance and registry information.

With regard to the instruction, “Do not proactively engage in a debate about the long-term performance of our Linox ICD leads in the context of this article,” this guidance should be understood as encouraging reactive, not promotional communication. The intent was to avoid initiating discussions or debates about a single publication with questionable methodology in isolation, and instead to respond appropriately and proportionately when healthcare professionals themselves raised questions.