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Two Regimes, One Body: How Design Decisions Set the Boundary of Legitimate Implantation

Jiaxing Du

1259456511@qq.com

Suzhou Vocational Institute of Industrial Technology

Research Article

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Abstract

Implanted devices can create dependencies that outlast the clinical encounter, research trial, purchase, or employment relationship through which they are acquired. Clinical ethics has developed accounts of consent, maintenance, device abandonment, and explantation, whereas scholarship on non-clinical implantation has often addressed acceptance and bodily integrity. These literatures do not establish that non-clinical recipients lack legal protection, but they leave unresolved which continuing responsibilities should accompany implantation across settings. This article develops a conceptual and normative comparison across consent, maintenance, legibility, exit, and redress. It argues that three properties shaped by design and supply decisions matter across the clinical boundary: whether recipients can understand device behaviour, whether continued function depends on one supplier, and what recipients must bear to stop using a device. Control over foreseeable and avoidable bodily dependence grounds prima facie responsibilities to provide usable information, plan continuity of support, and preserve clinically appropriate exit options. These responsibilities are shared according to actors' control and capacity, constrained by safety and feasibility, and cannot be discharged by initial consent alone. The argument does not establish the prevalence of governance failures or equate passive identification chips with active neural implants. Its strongest prospective application concerns complex implanted consumer neurotechnology. Implantation is ethically defensible only if the continuing relationship it creates is considered alongside the decision to implant.

1 Introduction

A person may consent to an implanted device while having little control over the conditions under which it will continue to work. Its operation may depend on proprietary software, specialist programming, replacement components, or a manufacturer that remains willing and able to provide support. The difficulty becomes acute when support ends or the person wishes to stop using the device. For an object inside a body, ending a commercial or clinical relationship need not end the dependence that relationship created.

Clinical scholarship has made these continuing burdens visible. Work on deep brain stimulation describes maintenance as a source of demands and harms in its own right (Pateraki and Gilbert 2026). Research on implanted neural devices addresses abandonment, post-trial responsibility, and explantation (Okun et al. 2024; Vooijs et al. 2025; Higgins et al. 2026). These contributions challenge the view that successful implantation and valid initial consent exhaust the relevant responsibilities. They also invite a question beyond the clinic: which responsibilities should accompany similar forms of bodily dependence when a device is acquired through purchase or employment?

Non-clinical implantation is documented in studies of workplace acceptance, hobbyist use, and the Swedish microchipping context (Gauttier 2019; Heffernan et al. 2016; Petersén 2019). Its legal and ethical implications have also been examined, including bodily integrity and liability (Roosendaal 2012a, 2012b). This literature should not be treated as an empty field. Nor does its different emphasis establish

an absence of protection in practice. Consumer law, employment arrangements, and contracts may provide relevant remedies even where no dedicated bioethical framework is described. The unresolved issue is whether these arrangements secure the continuing information, care, and exit opportunities that carrying an implant can require.

Implant ethics already encompasses therapeutic and non-therapeutic uses, including questions about turning devices off (Hansson 2005). Legal scholarship has also examined the difficulty of separating integrated persons from integrated goods (Quigley and Ayihongbe 2018). The contribution proposed here is narrower than establishing a new ethical domain. It connects continuing responsibilities across acquisition settings to three properties that actors can partly shape before recipients become dependent. The question is what those choices require of their makers, rather than whether non-medical implantation has previously received ethical attention.

The comparison needs an important qualification at the outset. Many documented non-clinical implants are passive identification transponders. They are not technically equivalent to deep brain stimulators, cochlear implants, or other complex clinical devices. This article therefore makes no controlled comparison of the same hardware under different institutions. Existing practices establish a non-clinical setting for implantation; clinical experience identifies dependencies that become especially consequential as implanted consumer neurotechnology is contemplated. The latter application is prospective, consistent with emerging ethical and regulatory debate (Bublitz and Ligthart 2024; Bublitz et al. 2025).

The central argument concerns responsibility rather than the relative performance of two regimes. Legibility, service dependence, and exit cost are partly shaped by design and supply choices. When actors control foreseeable dependencies that recipients cannot readily reverse, those actors have prima facie duties to justify avoidable restrictions and provide proportionate safeguards. The argument connects clinical concerns about consent and continuing care with engineering decisions that make those concerns easier or harder to address. It does not show that design outweighs institutions as a cause of harm, or that every technically possible form of openness is ethically desirable.

2 Approach and scope

2.1 A purposive conceptual comparison

This is a conceptual and normative analysis using published scholarship selected for its relevance to five dimensions of implantation: consent, maintenance, legibility, exit, and redress. It is not a systematic review, an inventory of national laws, or an empirical comparison of recipients' outcomes. The dimensions organise questions about who can act, who is responsible, and what remains available when an implantation relationship changes. They do not measure how frequently either setting fails.

Faulkner and Kent (2001) compared the histories of breast implants and artificial hips to examine how institutional context shapes regulation. Their approach motivates attention here to the relationships

surrounding devices rather than treating technology as self-explanatory. The present comparison extends that question across clinical and non-clinical settings, without importing the causal conclusions that a matched historical or empirical study might support. Clinical implantation itself includes different arrangements for routine treatment and research. Non-clinical implantation includes purchases, workplace schemes, and self-directed practices that may also differ substantially.

The analysis distinguishes three kinds of statement. Published studies establish that particular experiences, practices, or debates have been reported. Comparisons identify responsibilities that are explicit in parts of the clinical literature but less clearly specified in the non-clinical sources considered here. Normative argument then asks which responsibilities should follow from controllable dependence, whether or not existing institutions already recognise them. Limited coverage of an arrangement in scholarship is not evidence that the arrangement does not exist. No priority claim about the first comparison of these settings is required for the argument.

2.2 Devices and relationships

An implanted device is placed wholly or partly inside the body and intended to remain there. Non-clinical implantation refers here to acquisition or use outside a therapeutic or clinical-research relationship. It does not identify a single legal category, and the absence of a therapeutic indication does not by itself determine regulatory status. Whether an implantation is ethically acceptable likewise cannot be settled by calling it treatment or enhancement.

Two applications must remain distinct. For passive transponders already used in non-clinical settings, questions about consent, bodily integrity, compatibility, and removal can matter even when firmware updates and ongoing servicing do not. For active or software-dependent consumer implants, the potential importance of continuing support, programming access, and manufacturer withdrawal is greater. The present analysis concerns this second class most strongly. It proposes questions for prospective governance rather than reporting that such devices are already widespread or that their recipients have experienced the same failures as clinical populations.

A recipient may also occupy more than one relationship. An employer may arrange implantation, a clinician may perform the procedure, and a separate firm may supply the device. The comparison therefore concerns sources and allocations of responsibility, not two sealed systems. A clinical procedure does not automatically settle an employer's duties, and a consumer purchase does not remove the professional responsibilities of a clinician who later treats the recipient.

2.3 Terms and ethical focus

Legibility is the extent to which recipients can obtain and understand information about what their own device is doing and why. It includes access to relevant information and an intelligible account of it. It does not require complete understanding of every technical process. Service dependence is reliance on a single supplier for continued function, updates, programming, or repair. Exit cost is the surgical,

informational, financial, and support burden of stopping use, deactivating a device, or having it removed. These are different actions with different consequences.

The distinction between physically carrying an implant and experiencing it as part of oneself is also important. Philosophical accounts disagree about incorporation and the relation between bodies and technologies (De Preester and Tsakiris 2009; Verbeek 2008; van Daal et al. 2024). Qualitative research on deep brain stimulation reports varied experiences of authenticity, including becoming more oneself (Kraemer 2013; de Haan et al. 2017). No claim that implantation necessarily produces estrangement is needed here. The ethical issue is whether a person can sustain or reconsider the relationship with a device, including when incorporation succeeds and support becomes especially important.

3 Comparing continuing responsibilities

The clinical literature makes several responsibilities identifiable without showing that they are consistently fulfilled. The non-clinical sources establish practices and ethical concerns without supplying a comprehensive account of continuing arrangements. Table 1 records this difference in the available accounts. Its third column identifies matters to investigate, rather than reporting the universal absence of protection.

Table 1
Responsibilities described in clinical scholarship and questions for non-clinical implantation

Dimension	Responsibilities described in clinical scholarship	Questions for non-clinical implantation
Consent	Professional assessment and consent; research ethics review where applicable.	Who explains dependence and support limits? Can a purchaser or employee refuse without undue disadvantage?
Maintenance	Continuing care and post-trial responsibility are objects of explicit ethical analysis.	Which actor supplies support, for how long, and with what transition if the product line or firm closes?
Legibility	Clinical interpretation, monitoring, and debates about recipient access to device information.	Can recipients obtain a usable account of device behaviour, directly or through a competent intermediary?
Exit	Deactivation and explantation have clinical processes and a developed ethical literature.	Which options are clinically appropriate, who assesses them, and who bears the costs? Separate passive from active devices.
Redress	Professional, institutional, research, and legal routes may apply; effective access varies.	What do applicable law, contracts, and employment arrangements actually secure? Assess coverage and accessibility.

The table compares themes in the sources considered, not measured outcomes or the coverage of all legal systems. Clinical responsibilities are not universal guarantees. The non-clinical column identifies questions for investigation and does not establish absence of protection.

3.1 Consent and gatekeeping

Clinical consent takes place within professional and institutional relationships that can provide independent assessment, explanations, and routes for reconsideration. These arrangements are neither uniform nor immune to conflicts of interest. Their ethical significance is that responsibility for deciding whether to proceed need not rest with the supplier alone. Debates about parental refusal of cochlear implantation, for example, ask how clinical benefit, parental discretion, and Deaf identity constrain justified intervention (Bradfield 2022).

Studies of workplace insideables examine acceptance and ethical acceptability, including differences across national settings (Gauttier 2019; Gauttier et al. 2024). They show why purchase or expressed willingness cannot be the only ethical questions. Where an employer proposes an implant, refusing it may have practical consequences even when participation is formally voluntary. Whether particular schemes provide meaningful alternatives requires examination of their terms and implementation. The argument here is conditional: consent is ethically weakened if refusing implantation or later withdrawing entails avoidable employment disadvantages that the employer controls.

Consent must also address what follows implantation. A person cannot authorise a relationship adequately if its dependence on servicing, support duration, and exit arrangements is obscured. Even clear initial disclosure does not resolve every later question. Preferences may change as a device becomes incorporated into daily life, a problem considered in recent work on embodied brain-computer interfaces (Zhao and Lin 2026). Continuing information and an opportunity to reconsider therefore matter alongside the initial decision.

3.2 Maintenance and continuity

Maintenance is part of living with a complex implant rather than a peripheral service added after treatment. Pateraki and Gilbert (2026) examine burdens associated with sustaining deep brain stimulation. Higgins et al. (2026) develop consensus recommendations on post-trial responsibility in implanted neural-device research. These sources identify care, technical expertise, infrastructure, and funding as matters requiring allocation. They do not establish an enforceable guarantee for every clinical recipient.

For non-clinical implantation, an adequate assessment would examine what the supplier, installer, employer, insurer, or another institution actually undertakes. Some devices need little active maintenance; others could become unusable without continuing support. The absence of a published framework does not prove the absence of a warranty or servicing agreement. Equally, an ordinary warranty should not be presumed adequate without considering the support horizon, what occurs if the firm fails, and whether another party can take over.

Service dependence links these institutional arrangements to architecture. Proprietary programming tools or undocumented interfaces can make transfer of support more difficult, while documentation and

arrangements for qualified third parties may preserve options. These are design questions with safety and commercial constraints. Their ethical significance is that the cost of withdrawal can be foreseeable before any particular malfunction occurs.

3.3 Legibility and control

Information can reach a clinical recipient through a professional who interprets device behaviour. This is a useful form of mediation, but it can leave recipients dependent on explanations they cannot independently assess. Work on remote monitoring examines the distribution of information and the ethical implications of manufacturer access (Cohen et al. 2020). Research on artificial-intelligence-driven closed-loop neurotechnology asks what explanations clinicians need (Schopp et al. 2025). Neither an available data stream nor an expert intermediary alone guarantees that recipients can answer questions relevant to their own lives.

The United States copyright exemption for accessing data generated by a patient's own medical device provides a concrete example of legal and technical interaction. The provision permits specified circumvention by or on behalf of a patient; a separate exemption addresses diagnosis, maintenance, and repair (U.S. Copyright Office 2024, § 201.40(b)(7), (17)). These exceptions do not themselves provide tools, clinical interpretation, or a general licence to alter operation. Nor does their wording establish equivalent protection for every non-medical implant. The example shows that practical access can depend on licensing and legal permissions as well as interfaces.

The relevant design question is which information a recipient can obtain safely and usefully, directly or through a trusted intermediary. Intellectual-property control over integrated devices and restrictions on repair have been analysed as consequential for bodily interests (McMahon and Kolawole 2025; Lindgren et al. 2022). This does not imply that all data or source code should be publicly accessible. Legibility can sometimes be improved through limited records, documented states, or independent professional access without unrestricted reprogramming.

3.4 Exit and continued use

Exit is not a single event. A person may stop using external components, deactivate stimulation, leave an inert implant in place, or undergo explantation. Each possibility depends on the device and the clinical circumstances. Literature on neural-device explantation addresses medical complications, benefit, identity, finance, autonomy, and post-trial conditions (Vooijs et al. 2025). Formal work on abandonment also helps distinguish recipients choosing not to use a device from institutions or manufacturers ceasing to support it (Okun et al. 2024).

Exit can protect autonomy, but removal can also threaten it. Non-voluntary explantation has been examined in relation to mental integrity and psychological continuity (Cassinadri and Ienca 2026). The suitability of advance agreements binding recipients to later removal is contested (Hurst and Bobier 2025). It would therefore be mistaken to infer that easier removal is always the preferred outcome. What

matters is preserving a clinically appropriate process in which continued use and possible exit can both be considered, rather than letting a support failure settle the matter by default.

Non-clinical recipients may obtain removal through ordinary medical care or private arrangements. The literature considered here does not establish how accessible those routes are, who pays, or how often recipients cannot use them. These are empirical questions. For passive identification chips, the relevant burden may be modest compared with complex neural hardware. For future active implants, design and support decisions may substantially affect the available choices. Neither scenario licenses a common estimate of exit cost.

3.5 Redress and legal protection

Clinical relationships offer identifiable addressees for some complaints and requests, including professionals, care institutions, and research sponsors. Consensus guidance on withdrawal of cardiovascular implantable electronic-device therapy illustrates a developed professional response (Lampert et al. 2010). These responsibilities coexist with legal remedies and may themselves be contested or inadequately funded. Their presence should not be confused with effective access for every recipient.

Non-clinical recipients may have rights under sales, product-liability, data-protection, and employment law. Existing analysis of European neurotechnology regulation cautions against treating the non-medical category as simply unregulated (Bublitz and Ligthart 2024). It is also too strong to claim that consumer remedies inherently stop at removal costs. Article 14(3) of Directive (EU) 2019/771 expressly addresses removal and installation costs when qualifying installed goods require repair or replacement (European Parliament and Council 2019). Whether a particular implant, transaction, or claim falls within that provision requires legal analysis; its applicability cannot be inferred from the present comparison.

The defensible question is narrower than whether protection exists. Do the applicable arrangements provide an accessible route to information, continuing support, and clinically appropriate exit, including when support ends without an immediately apparent malfunction? Answering it requires attention to device classification, jurisdiction, national implementation, contractual terms, and the defendant's ability to perform. The present argument does not resolve those matters. It identifies the functions that a satisfactory arrangement should perform, whether supplied through clinical duties, consumer protection, contract, or another mechanism.

4 From design choices to moral obligations

4.1 Why controllable dependence creates responsibilities

The fact that a property can be designed differently does not alone establish an obligation to change it. A normative premise is needed. The premise proposed here is that actors who foreseeably create or control another person's difficult-to-reverse bodily dependence owe that person proportionate measures

against avoidable impairment of agency and bodily interests. This is a prima facie responsibility: it requires justification and action where reasonable, while allowing countervailing safety, feasibility, and resource considerations. It does not assign responsibility for every adverse outcome merely because an actor contributed to a device.

The argument has three steps. First, control of information, continued function, or exit can affect a recipient's ability to decide what happens to their body over time. Second, where another actor can foresee and materially shape that dependence, some of its burdens are within that actor's practical authority. Third, accepting the benefits of supplying or deploying the device while leaving all avoidable burdens with the recipient requires justification, particularly when the recipient cannot escape those burdens through an ordinary change of provider. Together, these premises support duties to disclose relevant dependence, reduce it where proportionate, and arrange responsibility for what remains.

The argument is compatible with differences in the value of implantation. A device that restores important capabilities may justify risks that an optional convenience device does not. Yet the absence of therapeutic purpose does not remove the recipient's interests in bodily integrity and continuing agency. Conversely, a therapeutic benefit does not automatically justify every restriction on access or servicing. The clinical label matters to the benefit-risk assessment and institutional allocation, but it cannot settle the permissibility of each design restriction by itself.

Initial consent authorises exposure to specified burdens; it does not make every later exercise of another party's control ethically acceptable. A person may accept surgical risk and a disclosed period of support without thereby authorising misleading information, an undisclosed technical lock, or arbitrary denial of an agreed service. Some future uncertainty is unavoidable, so valid consent cannot require perfect foresight. It does require an intelligible account of known dependence and the arrangements for foreseeable changes. These duties express the recipient's continuing status as a person whose interests matter after the transaction or procedure has ended.

4.2 Duties concerning information and support

Legibility supports a qualified duty to provide information that recipients can use in decisions about their device. Relevant information may include operational status, dependence on external services, support limits, and who can assist when a problem arises. The appropriate form depends on complexity and risk. A recipient may reasonably rely on a clinician or independent technical intermediary; requiring them to become an engineer would reproduce the burden the duty is intended to reduce. The duty concerns effective access to an account, not the mere availability of uninterpretable records.

Service dependence supports a duty to plan for foreseeable disruption. A supplier that knows continued use requires its proprietary tools should address what happens if it discontinues the product. Proportionate measures could include a stated support horizon, secure transfer to a qualified provider, preserved documentation, or arrangements to fund clinically appropriate management when support ends. These are proposed implications of the argument, not established requirements applying to every

device. Their adequacy depends on the role the device plays in the recipient's life and the realistic alternatives available.

The duty is not an unlimited promise that one firm must operate indefinitely. No design can guarantee a manufacturer's survival, and maintaining a dangerous or obsolete system may be inappropriate. The requirement is to take foreseeable dependence seriously before recipients become committed to it. A finite support period can be ethically defensible if its implications are clear and a credible transition is arranged. It is harder to justify a model that benefits from exclusive control while treating the consequences of losing that control as exclusively the recipient's problem.

Design ethics already provides resources for this allocation. Value sensitive design treats values as part of technological specification, and capability-oriented approaches connect design to practical opportunities for wellbeing (Friedman and Hendry 2019; Cenci and Cawthorne 2020). Responsible innovation adds anticipation, inclusion, and responsiveness (Stilgoe et al. 2013). The contribution here is to specify why continuing bodily dependence gives these commitments a particular object: the recipient's ability to understand, sustain, and reconsider life with an implant.

4.3 Duties concerning exit and safety

Exit cost supports a duty to preserve reasonable options and explain the constraints on them. It does not support an unconditional right to immediate explantation, safe removal in every case, or unilateral reprogramming. The options may include supervised deactivation, continued support, symptom management, leaving a device in place, or removal. What can be offered depends on the device, clinical judgement, and the recipient's preferences. The ethical requirement is that these options receive deliberate consideration and a responsible addressee.

Some exit costs are physical. Tissue integration and surgical location can make removal hazardous even with good design. This is the surgical floor. It is not wholly fixed across designs, because materials, placement, and integration can themselves influence removal, but no plausible argument requires all surgical risk to be eliminable. The duty concerns proportionate reduction of avoidable burdens and honest explanation of unavoidable ones. Documentation, transfer of records, and arrangements for later clinical assessment can matter even when a device cannot safely be removed.

Safety also limits legibility and servicing. Attacks on cardiac devices and neural-device security concerns show why programming access cannot be treated as an ordinary consumer convenience (Halperin et al. 2008; Denning et al. 2009; Pycroft et al. 2016). Reading and writing are different functions, but read access can itself expose sensitive data or create attack routes. A defensible design must assess these risks rather than assume that readable logs are harmless. Authenticated access, limited disclosure, and qualified intermediaries are possibilities to evaluate, not solutions proven sufficient here.

Restrictions are therefore sometimes justified. The relevant demand is that a restriction be connected to a credible safety need and considered alongside less burdensome feasible arrangements. A security rationale for limiting reprogramming does not by itself explain why service documentation should

disappear when a product line closes. Equally, a demand for independent servicing does not justify bypassing competence requirements. The obligation is to reconcile continuing agency with safety through specific reasons, rather than treating either openness or closure as inherently decisive.

4.4 Who bears the responsibilities

Responsibilities should track control, knowledge, and capacity to act. Engineers may identify dependencies, document alternatives, and raise foreseeable risks within their roles. Firms typically control support commitments, licensing, access to tools, and resources for transition. Employers control the conditions under which an offered implant can be refused and what happens when employment ends. Clinicians assess procedures and continuing care within their competence. Research sponsors and institutions have additional responsibilities arising from trial participation (Higgins et al. 2026). These roles can overlap, but they are not interchangeable.

This allocation avoids placing the whole burden on an individual designer. Architectures emerge from teams, supply chains, budgets, standards, and regulation. The problem of many hands makes responsibility difficult to assign, as does the separation of ownership from accountability in computerised systems (van de Poel et al. 2012; Nissenbaum 1996). A particular engineer may lack authority to authorise third-party servicing or fund future care. The appropriate duty may then be to identify, explain, and escalate the issue, while the organisation that controls the decision remains responsible for its disposition.

Shared responsibility also requires coordination. A recipient should not have to infer which of several parties will answer after a support failure. Agreements can designate a point of contact and allocate technical, financial, and clinical tasks in advance. This proposal does not establish that any one contractual arrangement will be enforceable or sufficient. It explains why responsibility cannot be adequately discharged by each actor pointing to the existence of another actor somewhere in the chain.

5 Objections and limits

5.1 Technical differences and prospective comparison

The strongest objection concerns the mismatch between passive non-clinical chips and active clinical implants. The mismatch limits the descriptive comparison. A passive identification device may not require software updates, specialist programming, or a manufacturer that remains in business. It therefore cannot establish the service dependence anticipated for an active neural implant. Nor can the costs of removing one class be transferred to another. The present argument would overreach if it used passive-chip practices to claim that complex non-clinical implants already exhibit equivalent failures.

The normative argument survives in a more limited form. Responsibilities increase with the dependence that a particular device creates and the control that other actors exercise over it. Where that dependence is minimal, the obligations concerning continuity may also be modest. Where an implanted consumer

system is designed around continuing proprietary support, the corresponding questions become more demanding. The comparison supplies a prospective reason to address these matters before deployment. It does not predict a failure rate or demonstrate that clinical and non-clinical recipients will fare differently once technical factors are held constant.

5.2 Institutions and the limits of design

An institutional explanation is a credible rival to a design-centred account of governance differences. Clinical arrangements can include professional duties, healthcare funding, ethics review, liability, and reporting mechanisms. These features help explain why maintenance and exit have identifiable addressees. Faulkner and Kent (2001) likewise emphasise institutions in their comparison within medicine. The current analysis cannot establish the independent causal contribution of design or show that it explains more than these institutional arrangements.

Design and institutions instead constrain one another. A well-documented interface is of little practical value if no competent service is affordable. A funded duty to maintain a device may be difficult to fulfil if access to essential tools is restricted. Regulation can also require design changes, so design is not always temporally prior to governance. The narrower point is that responsibilities for continuing care have technical preconditions, while technical possibilities need institutional support. Engineering responsibility supplements rather than displaces collective arrangements for care and accountability.

5.3 Voluntary risk and the possibility of refusal

A recipient might knowingly prefer a low-cost implant with limited support over a more expensive device with extensive safeguards. Respect for autonomy gives that preference weight. The argument does not require every device to provide the maximum possible service or prohibit adults from accepting significant risks. It requires that the choices be represented honestly and that actors justify the avoidable dependencies they control. Whether a proposed safeguard is proportionate depends on its costs, the expected burden, and available alternatives. If the foreseeable burdens are severe and no proportionate arrangement can address them, responsible practice may require deferring implantation rather than relying on disclosure alone.

There are also limits to what an agreement can settle. An employer's description of participation as voluntary does not establish that refusal is practically costless. A consent form stating that support may end does not establish that no reasonable transition could have been arranged. A blanket waiver may leave burdens with a recipient who had little bargaining power, although its legal validity is a separate matter. These concerns require contextual assessment; they do not show that every employment scheme is coercive or every limited-support contract is unacceptable.

5.4 Incorporation and contested exit

A successful implant may become deeply involved in a recipient's sense of self. Van Daal et al. (2024) use entanglement to examine the relationship between regenerative implants and embodied experience. Although their devices differ from programmable neural systems, their analysis cautions against treating

the implant as an ordinary detachable possession. Gipe's (2021) account of biofixtures and debates about cardiac-device deactivation similarly question the moral significance of becoming part of a functioning body (Huddle 2019; Hester and Swota 2019).

These debates constrain any general prescription to switch off or remove. They also strengthen the case for continuing responsibility: the more a device matters to agency or bodily life, the less satisfactory an unplanned loss of support becomes. Duties to preserve options include protecting a recipient from involuntary discontinuation as well as providing a route to consider exit. The argument does not decide every contested request. It seeks conditions under which the request can be heard and assessed without a commercial default determining the result.

6 Implications for care and governance

The comparison suggests a common set of questions that can be asked in clinical review, product development, and workplace arrangements. Before implantation, who will explain what the device does and what its continued function depends on? During use, who will respond when support changes? If the relationship ends, who can assess deactivation, continued use, or removal, and how will necessary costs be allocated? These questions express the functions at stake without presupposing that all settings require identical institutions.

For clinical ethics, the implication is that meaningful consent and continuing care depend partly on procurement and design. A clinician's explanation cannot compensate for a support commitment that has never been made. Institutions purchasing or authorising implants can ask suppliers to specify support horizons, access conditions, and transition arrangements before recipients depend on them. The ethical justification for doing so concerns care over time, rather than technical openness as an end in itself. Guidance on recalled implanted devices offers one related account of responsibilities when a device relationship changes (Manahan 2021).

For non-clinical implantation, equivalent functions might be provided through ordinary law and existing services rather than a dedicated implant regime. If so, that would weaken a claim of descriptive governance disparity while satisfying part of the normative concern. Where the functions are not secured, adding a warning at purchase may be insufficient. It may be necessary to allocate duties among supplier, employer, installer, and healthcare provider, with safeguards proportionate to the actual device. Whether this calls for new regulation depends on what existing arrangements can deliver.

Two kinds of empirical work would discriminate between these possibilities. First, studies of actual contracts, warranties, workplace policies, and recipient experiences could establish who provides support and exit in particular jurisdictions. Device classes should be separated, and account should be taken of implantation route, support requirements, and removal complexity. A finding of accessible and effective arrangements outside the clinic would revise the descriptive contrast. Evidence that recipients repeatedly encounter unallocated responsibilities would give it firmer support.

Second, studies of design and procurement could examine when dependence is recognised, which alternatives are considered, and who has authority to choose among them. Research on how neurotechnology start-ups understand ethical futures offers a relevant precedent (Knopf et al. 2023). Such work could test whether restrictions are driven primarily by safety, cost, organisational convention, or commercial strategy, and whether proposed alternatives would preserve function safely. It would turn the present account of controllable choices into a more precise account of which changes are feasible and who can implement them.

The present evidence cannot determine how often such decisions cause harm, rank clinical and non-clinical settings as wholes, or establish which legal remedy will succeed. Its contribution is a normative test: continuing responsibilities should be proportionate to foreseeable bodily dependence and allocated to actors able to address it. The test applies even where implantation benefits recipients and incorporation succeeds. It concerns the conditions of sustaining that benefit, not an assumption that life with an implant is necessarily alienating.

7 Conclusion

The ethical assessment of implantation should extend beyond the initial decision to place a device in a body. Design, licensing, and support arrangements help determine whether recipients can understand its behaviour, sustain its function, and reconsider its place in their lives. Where actors foreseeably control difficult-to-reverse dependence, they owe proportionate safeguards and reasons for avoidable restrictions. Initial consent does not discharge all of these continuing responsibilities.

Clinical ethics provides developed accounts of several relevant duties, while non-clinical practices raise questions about how equivalent functions are secured. The available comparison does not demonstrate a universal absence of protection outside medicine, and its strongest application to complex consumer neurotechnology is prospective. The conclusion is correspondingly bounded: consideration of continuing information, support, and clinically appropriate options is a necessary part of ethically defensible implantation, alongside benefit, risk, consent, and context. Responsibility for those conditions belongs to the institutions that arrange implantation and to the actors whose decisions shape what recipients can subsequently do.

Declarations

Author Contribution

J.D is the sole author of this manuscript and was responsible for all aspects of the work, including study conception and design, literature review and analysis, development of the conceptual framework and normative arguments, and manuscript drafting and revision. The author reviewed and approved the final version and assumes full responsibility for the accuracy and integrity of the work.

References

1. Bradfield, Owen M. 2022. Hearing Parents' Voices: Parental Refusal of Cochlear Implants and the Zone of Parental Discretion. *Journal of Bioethical Inquiry* 19(1):143–150. https://doi.org/10.1007/s11673-021-10154-8
2. Bublitz, and Christoph and Sjors Ligthart. 2024. The new regulation of non-medical neurotechnologies in the European Union: overview and reflection. *Journal of Law and the Biosciences* 11(2):lsae021. https://doi.org/10.1093/jlb/lsae021
3. Bublitz, Christoph, Jennifer A. Chandler, Fruzsina Molnár-Gábor, Marta Sosa Navarro, Philipp Kellmeyer, and Surjo R. Soekadar. 2025. A Moratorium on Implantable Non-Medical Neurotech Until Effects on the Mind are Properly Understood. Neuroethics 18(3): 46. https://doi.org/10.1007/s12152-025-09612-6
4. Cassinadri, Guido Marcello Ienca. 2026. Non-voluntary BCI explantation: assessing possible neurorights violations in light of contrasting mental ontologies. *Journal of Medical Ethics* 52(6):415–422. https://doi.org/10.1136/jme-2023-109830
5. Cenci, Alessandra Dylan Cawthorne. 2020. Refining Value Sensitive Design: A (Capability-Based) Procedural Ethics Approach to Technological Design for Well-Being. *Science and Engineering Ethics* 26(5):2629–2662. https://doi.org/10.1007/s11948-020-00223-3
6. Cohen, I., Sara Glenn, Gerke, and Daniel B. Kramer. 2020. Ethical and Legal Implications of Remote Monitoring of Medical Devices. *The Milbank Quarterly* 98(4):1257–1289. https://doi.org/10.1111/1468-0009.12481
7. de Haan, Sanneke, Erik Rietveld, Martin Stokhof, and Damiaan Denys. 2017. Becoming more oneself? Changes in personality following DBS treatment for psychiatric disorders: Experiences of OCD patients and general considerations. *PLOS ONE* 12(4):e0175748. https://doi.org/10.1371/journal.pone.0175748
8. De Preester, Helena Manos Tsakiris. 2009. Body-extension versus body-incorporation: Is there a need for a body-model? *Phenomenology and the Cognitive Sciences* 8(3):307–319. https://doi.org/10.1007/s11097-009-9121-y
9. Denning, Tamara, and Yoky Matsuoka, Tadayoshi Kohno. 2009. Neurosecurity: security and privacy for neural devices. *Neurosurgical Focus* 27(1):E7. https://doi.org/10.3171/2009.4.focus0985
10. European Parliament and Council. 2019. Directive (EU) 2019/771 of 20 May 2019 on certain aspects concerning contracts for the sale of goods. Official Journal of the European Union L 136: 28–50. Article 14(3). https://eur-lex.europa.eu/eli/dir/2019/771/oj. Accessed 19 October 2026.
11. Faulkner, Alex Julie Kent. 2001. Innovation and regulation in human implant technologies: developing comparative approaches. *Social Science & Medicine* 53(7):895–913. https://doi.org/10.1016/s0277-9536(00)00389-0
12. Friedman, Batya, and David G. Hendry. 2019. *Value Sensitive Design: Shaping Technology with Moral Imagination*. Cambridge, MA: MIT Press. https://doi.org/10.7551/mitpress/7585.001.0001

13. Gauttier, Stéphanie. 2019. I've got you under my skin' - The role of ethical consideration in the (non-) acceptance of insideables in the workplace. *Technology in Society* 56:93–108. https://doi.org/10.1016/j.techsoc.2018.09.008
14. Gauttier, Stéphanie, Mario Arias-Oliva, Kiyoshi Murata, and Jorge Pelegrín-Borondo. 2024. The ethical acceptability of human enhancement technologies: A cross-country Q-study of the perception of insideables. *Computers in Human Behavior: Artificial Humans* 2(2):100092. https://doi.org/10.1016/j.chbah.2024.100092
15. Gipe, Kelsey. 2021. Heartbeats, Burdens, and Biofixtures. *Cambridge Quarterly of Healthcare Ethics* 30(2):285–296. https://doi.org/10.1017/s0963180120000845
16. Halperin, Daniel, Thomas S. Heydt-Benjamin, Benjamin Ransford, Shane S. Clark, Benessa Defend, Will Morgan, Kevin Fu, Tadayoshi Kohno, and William H. Maisel. 2008. Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses. In 2008 IEEE Symposium on Security and Privacy, 129–142. IEEE. https://doi.org/10.1109/sp.2008.31
17. Hansson, S. O. 2005. Implant ethics. *Journal of Medical Ethics* 31(9):519–525. https://doi.org/10.1136/jme.2004.009803
18. Heffernan, Kayla J., Frank Vetere, Shanton, and Chang. 2016. You Put What, Where? Hobbyist Use of Insertable Devices. In Proceedings of the 2016 CHI Conference on Human Factors in Computing Systems, 1798–1809. New York: Association for Computing Machinery. https://doi.org/10.1145/2858036.2858392
19. Hester, D., Micah, and Alissa Swota. 2019. Choosing to Stop a Heart: The Ethical Status of Deactivating an Implantable Cardiac Device. *Cambridge Quarterly of Healthcare Ethics* 28(2):327–328. https://doi.org/10.1017/s0963180119000136
20. Higgins, Nathan, Brette Blakely, Roland Everingham, Frederic Gilbert, Sarah Griffin, Alexander R. Harris, Sally Herring, Calvin Wai Loon Ho, Kate Hoy, Scott Kiel-Chisholm, Julian Koplin, Sharon Lawn, Allan McCay, Nitya Phillipson, Bernadette Richards, and Jeffrey V. Rosenfeld. Ehsan Shamsi Gooshki, John Noel Viana, John Gardner, and Adrian Carter. 2026. Recommendations on post-trial responsibility in implantable neural device research: a multidisciplinary consensus study. BMC Medical Ethics 27(1): 153. https://doi.org/10.1186/s12910-026-01475-7
21. Huddle, Thomas S. 2019. A Moral Argument against Turning Off an Implantable Cardiac Device: Why Deactivation Is a Form of Killing, Not Simply Allowing a Patient to Die. *Cambridge Quarterly of Healthcare Ethics* 28(2):329–337. https://doi.org/10.1017/s0963180119000148
22. Hurst, Daniel J., A. Christopher, and Bobier. 2025. Neuro-Nonsense: Why Ulysses Contracts don't Compute in Brain-Computer Interface Research. *Neuroethics* 18(2):39. https://doi.org/10.1007/s12152-025-09611-7
23. Knopf, Sophia, Nina Frahm, and Sebastian M. Pfotenhauer. 2023. How Neurotech Start-Ups Envision Ethical Futures: Demarcation, Deferral, Delegation. *Science and Engineering Ethics* 29(1):4. https://doi.org/10.1007/s11948-022-00421-1

24. Kraemer, Felicitas. 2013. Me, Myself and My Brain Implant: Deep Brain Stimulation Raises Questions of Personal Authenticity and Alienation. *Neuroethics* 6(3):483–497. https://doi.org/10.1007/s12152-011-9115-7
25. Lampert, Rachel, David L. Hayes, George J. Annas, Margaret A. Farley, Nathan E. Goldstein, Robert M. Hamilton, G. Neal Kay, Daniel B. Kramer, Paul S. Mueller, Luigi Padeletti, Leo Pozuelo, Mark H. Schoenfeld, Panos E. Vardas, and Debra L. Wiegand, Richard Zellner. 2010. HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. *Heart Rhythm : The Official Journal Of The Heart Rhythm Society* 7(7):1008–1026. https://doi.org/10.1016/j.hrthm.2010.04.033
26. Lindgren, Lars, Aaron S. Kesselheim, and Daniel B. Kramer. 2022. The Right to Repair Software-Dependent Medical Devices. *Journal of Law Medicine & Ethics* 50(4):857–859. https://doi.org/10.1017/jme.2023.28
27. Manahan, M. A. 2021. What Do Clinicians and Organizations Owe Patients With Recalled Implanted Devices or Materials? *AMA Journal of Ethics* 23(9):E679–684. https://doi.org/10.1001/amajethics.2021.679
28. McMahon, Aisling M, I. Opeyemi, and Kolawole. 2025. Intellectual property rights over 'integrated' medical devices: the potential health impacts and bioethical implications of rightsholders' control. *Medical Law Review* 33(1):fwaf001. https://doi.org/10.1093/medlaw/fwaf001
29. Nissenbaum, Helen. 1996. Accountability in a computerized society. *Science and Engineering Ethics* 2(1):25–42. https://doi.org/10.1007/bf02639315
30. Okun, Michael S., Timothy Marjenin, Jinendra Ekanayake, Frederic Gilbert, and Sean P. Doherty. Jack Pilkington, Jennifer French, Cynthia Kubu, Gabriel Lázaro-Muñoz, Timothy Denison, and James Giordano. 2024. Definition of Implanted Neurological Device Abandonment: A Systematic Review and Consensus Statement. *JAMA Network Open* 7(4): e248654. https://doi.org/10.1001/jamanetworkopen.2024.8654
31. Pateraki, Marilena Frederic Gilbert. 2026. Beyond Innovation: The Burdens and Harms of Maintenance in Deep Brain Stimulation. *Science and Engineering Ethics* 32(5):42. https://doi.org/10.1007/s11948-026-00628-6
32. Petersén, Moa. 2019. *The Swedish Microchipping Phenomenon*. Bingley: Emerald Publishing. https://doi.org/10.1108/9781789733556
33. Quigley, Muireann Semande Ayihongbe. 2018. Everyday Cyborgs: On Integrated Persons and Integrated Goods. *Medical Law Review* 26(2):276–308. https://doi.org/10.1093/medlaw/fwy003
34. Roosendaal, Arnold. 2012a. Carrying Implants and Carrying Risks; Human ICT Implants and Liability. In Human ICT Implants: Technical, Legal and Ethical Considerations, ed. Mark N. Gasson, Eleni Kosta, and Diana M. Bowman, 69–79. The Hague: T. M. C. Asser Press. https://doi.org/10.1007/978-90-6704-870-5_7
35. Roosendaal, Arnold. 2012b. Implants and Human Rights, in Particular Bodily Integrity. In Human ICT Implants: Technical, Legal and Ethical Considerations, ed. Mark N. Gasson, Eleni Kosta, and Diana

M. Bowman, 81–96. The Hague: T. M. C. Asser Press. https://doi.org/10.1007/978-90-6704-870-5_8

36. Schopp, Laura, Georg Starke, Marcello Ienca. 2025. Clinician perspectives on explainability in AI-driven closed-loop neurotechnology. *Scientific Reports* 15(1):34638. https://doi.org/10.1038/s41598-025-19510-9
37. Stilgoe, Jack, Richard Owen, and Phil Macnaghten. 2013. Developing a framework for responsible innovation. *Research Policy* 42(9):1568–1580. https://doi.org/10.1016/j.respol.2013.05.008
38. Copyright Office, U. S. 2024. Exemptions to prohibition against circumvention. Code of Federal Regulations, title 37, section 201.40(b)(7), (17). Current text reproduced by the Legal Information Institute. https://www.law.cornell.edu/cfr/text/37/201.40. Accessed 19 October 2026.
39. van Daal, Manon, Anne-Floor, J., Karin R. de Kanter, Annelien L. Jongsma, Bredenoord, and Graeff Nienke de. 2024. Embodiment and regenerative implants: a proposal for entanglement. *Medicine Health Care and Philosophy* 27(2):241–252. https://doi.org/10.1007/s11019-024-10199-7
40. van de Poel,. Ibo, Jessica Nihlén Fahlquist, Neelke Doorn, Sjoerd Zwart, and Lambèr Royakkers. 2012. The Problem of Many Hands: Climate Change as an Example. *Science and Engineering Ethics* 18(1): 49–67. https://doi.org/10.1007/s11948-011-9276-0
41. Verbeek, Peter-Paul. 2008. Cyborg intentionality: Rethinking the phenomenology of human-technology relations. *Phenomenology and the Cognitive Sciences* 7(3):387–395. https://doi.org/10.1007/s11097-008-9099-x
42. Vooijs, Manuela, Katherine Bassil, Anne van den Brink, Odile C. van Stuijvenberg, Nick F. Ramsey, and Karin R. Jongsma. 2025. Ethical, legal, and sociocultural considerations in neural device explantation: a systematic review. *Frontiers in Neuroscience* 19:1568800. https://doi.org/10.3389/fnins.2025.1568800
43. Zhao, Yue, and Yuan Lin. 2026. Consent in flux: when brain-computer interface embodiment undermines informed consent. *BMC Medical Ethics* 27(1):188. https://doi.org/10.1186/s12910-026-01540-1