# Insurance for Early-Stage Medical Device Companies

### Q: Who should buy liability insurance, and when?

Any company should acquire liability insurance as soon as a liability exposure exists — which can be earlier than most founders expect. Even a pre-operational company can face claims for defamation or personal injury under a General Liability policy's personal injury provisions.

Common triggers for obtaining coverage include:

- Forming a legal entity
- Entering into any contract that requires insurance
- Raising capital
- Occupying office or laboratory space
- Initiating clinical trials

The key types of liability insurance for medical device companies are:

- • General Liability — covers premises-related incidents and personal/advertising injury (e.g., defamation).
- • Products Liability — covers bodily injury or property damage caused by a product you test, manufacture, or distribute.
- • Clinical Trial Liability — covers injuries to study participants and related claims.
- • Errors & Omissions (E&O) — covers financial loss from improper training or inaccurate guidance (especially relevant for SaMD and AI/ML devices).
- • Directors & Officers (D&O) — covers claims arising from alleged mismanagement by company leadership.

The appropriate insurance program evolves as the company's activities and exposures evolve.

### Q: How much does liability insurance cost?

Premiums vary significantly based on device class, development stage, clinical activity, and revenue. Broad ranges for early-stage companies include:

- General Liability: ~$500–$5,000/year
- Products Liability: ~$5,000–$20,000/year (pre-commercial); rises substantially once commercialized
- Clinical Trial Liability: ~$10,000–$150,000+/year (driven by patient count, trial phase, invasiveness, and duration)
- E&O / Professional Liability: ~$5,000–$75,000+/year
- D&O: ~$5,000–$25,000/year (seed/pre-Series A); $20,000–$80,000+ after Series A

These are estimates only. Actual premiums depend on device class (I vs. II vs. III), implantable vs. non-implantable, revenue, markets, governance, and overall risk profile.

# Vertical Risk Management

Insurance for Medical Device Companies

FAQ's

## Q: How long should liability insurance be maintained?

For claims-made policies — which include most Clinical Trial Liability, E&O, D&O, and Products Liability programs — coverage must remain in force for as long as a claim could arise. Unlike occurrence-based policies (which respond based on when an incident happened), claims-made policies require an active policy at the time the claim is filed.

General guidance by coverage type:

- Clinical Trial Liability: Maintain through the trial and typically 3–7 years post-last patient follow-up; purchase a tail if the policy is discontinued.
- E&O / Professional Liability: Maintain while providing services or software; purchase a tail (typically 3–6 years) upon wind-down or policy cancellation.
- D&O: A 6-year run-off (tail) policy is standard practice upon acquisition, merger, or wind-down — directors and officers can face claims for decisions made years earlier.
- Products Liability: Maintain as long as the product is in use; for implantables, this can represent a very long horizon.

Rule of thumb: For any claims-made policy, keep coverage in force as long as you could realistically face a claim — and purchase a tail if you ever discontinue the policy.

## Q: Does insurance cover all company devices, or is a separate policy needed for each?

In most cases, a single insurance program covers all of a company's products. However, the insurer prices the policy based on the specific products disclosed at binding. If a company later develops a meaningfully different or higher-risk product — for example, shifting from a Class I wearable diagnostic to an implantable therapeutic device — that new product is not automatically covered.

Failure to disclose a new, higher-risk product can result in a coverage denial for any related claims. Companies should notify their broker whenever there is a material change in the product portfolio.

## Q: How should an early-stage company select an insurance broker?

The large global brokers — Marsh, Aon, Gallagher — have deep life sciences capabilities, but their business models are built for scale. Senior resources are typically reserved for accounts generating meaningful commission revenue; as a rule of thumb, that threshold is around $100,000 in annual premium. Most early-stage medical device companies are well below that level.

For a founder at the early stage, the right question is not 'find a life sciences broker' — it is find the right life sciences broker for your stage. That broker should:

- Understand the lifecycle and business model of an early-stage company (pre-revenue, capital raises, CRO agreements, FDA milestones)
- Know which coverages are actually appropriate at each stage — not just what is available
- Have genuine marketplace access for smaller premium accounts, including carrier relationships that produce competitive pricing
- Act as a strategic advisor — reviewing contracts and agreements to ensure the company is in compliance with its insurance obligations

A common and costly mistake: companies that are out of compliance with the insurance requirements in their license agreements, clinical trial agreements, or investor documents — simply because no one reviewed those documents. Contract review is one of the most important services a broker should provide at this stage.

### Q: How can an early-stage broker afford to service small accounts?

It requires an intentional business model. At Valiant Risk Management, our three senior partners have already had long careers at major national and global brokerage firms. We are not building books from scratch or meeting production milestones — we built the firm around a different question: Can we create a platform that is both commercially successful and aligned with a mission we actually care about?

Our mission is straightforward: we are proud and grateful for the opportunity to help the people who are trying to help others.

Practically, our senior expertise allows us to serve larger, more complex clients — including public companies and organizations up to roughly $2 billion in market cap — and that revenue base supports our early-stage life sciences practice. Early-stage companies are not expected to carry the economic weight of the platform on day one.

The result is that startups receive senior-level expertise and a genuine strategic partner at the most critical phase of their development — and we build long-term relationships with companies that grow with us.

### Q: Can a well-designed insurance program help a company raise capital?

Yes — directly and practically. Investors conducting diligence are not evaluating insurance for its own sake; they are evaluating risk management and governance. A properly structured insurance program:

- Enables independent board members to join (D&O coverage is often a prerequisite)
- Allows clinical trials to launch and key agreements to be executed
- Demonstrates contract compliance, removing friction from the diligence process
- Signals institutional-grade management to investors

Companies that cannot answer basic insurance questions at a funding close face delays, escrow holdbacks, repricing, or loss of key board members. Insurance at this stage is not a cost — it is a capital-enabling tool.

### Q: What if I want to conduct clinical trials outside the U.S.?

This is a common source of confusion. A U.S. policy may state 'worldwide' territory — but that does not mean it satisfies the requirements of foreign institutions or regulators. When conducting a clinical trial outside the United States, the hospital, research institution, or regulatory authority will almost always require locally admitted insurance: a policy issued by an insurer licensed in that country, governed by local law, and able to respond to claims in that jurisdiction.

A U.S. surplus lines policy — even with worldwide language — will generally not be accepted. The requirements vary by country and may include specific minimum limits, policy wording, and patient compensation schemes.

Founders should ensure their broker has a global network capable of arranging locally admitted placements in each country where the trial will be conducted. 'Worldwide territory' is not the same as international compliance.

### Q: What are the five biggest mistakes early-stage companies make with insurance?

- Waiting until the last minute. Engage your broker before contracts are finalized and clinical trial sites are selected. Late engagement locks you into requirements that may be difficult or expensive to satisfy — and limits the time available to properly market the risk.
- Overly optimistic exposure estimates. Insurers price premiums on projected activity during the policy period. For clinical trial liability, for example, use realistic near-term enrollment numbers — not total study projections. Optimism costs money, and the insurer will not return premium if actual activity comes in lower.
- Selecting a broker who does not act as a strategic advisor. Your broker should review your contracts and agreements, design coverage appropriate to your stage, and translate complex insurance terms into plain language for non-insurance professionals.
- Selecting a broker without demonstrated life sciences expertise. Your broker should cover all relevant segments, access a broad carrier marketplace, and have capabilities such as arranging locally admitted foreign coverage when needed.
- Treating insurance as a one-time transaction. As an early-stage company, your insurance program must evolve with you — from pre-revenue through commercialization and, ultimately, to a liquidity event. Select a broker who can grow with the company through every phase.

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