



Medical devices

Product brochure
Canada

Overview

The manufacture and sale of medical devices is a huge responsibility with companies facing a variety of complex risks. These include injury to a user due to defective design or mislabelling of the product, bodily injury or financial loss arising from negligent advice, instruction in the sale of the product, and a loss of income as a result of an interruption to business caused by a malicious cyber attack to list a few. Our medical device package policy provides a comprehensive solution, providing clear coverage for a wide range of medical device complexities companies may face such as development faults and injury to a user.



About CFC

CFC is a specialist insurance provider, pioneer in emerging risk and market leader in cyber. Our global insurance platform uses cutting-edge technology and data science to deliver smarter, faster underwriting and protect customers from today's most critical business risks.

Headquartered in London with offices in New York, Austin, Brussels and Brisbane, CFC has over 700 staff and is trusted by more than 100,000 businesses in 90 countries. Learn more at [cfc.com](https://www.cfc.com) and [LinkedIn](https://www.linkedin.com/company/cfc).

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Coverage highlights

Products liability

Our policy provides cover for accidental bodily injury and property damage arising out of the sale of tangible implantable and non-implantable medical devices and associated software. It also provides peace of mind in the event a defective, mislabelled or contaminated product is released to market.

Technology errors & omissions

The supply, development, installation and maintenance of technology has become a pivotal component in the transformation of medical diagnostics/therapeutics and the development of new devices. We cover software as a medical device and software in a medical device.

Cyber

Our cyber and privacy clause has been tailored to address the specific cyber exposures. This includes cover for damages following an unintentional breach of confidential information, exposures faced by traditional medical device manufacturers, distributors and software creators. Not only do we include a separate section for extortion to address the growing threat of ransomware, but we also cover fines and penalties.

General liability

Our cover protects you against legal expenses and compensation claims following non product or service related bodily injury or property damage claims made against by external individuals.

Property damage

We offer property damage on all all risks basis covering your premises, fixtures and fittings, contents & stock.

Business interruption

We offer 'flexible first loss' cover, which means our policy responds to the first insurable interruption up to the full limit, so you only have to purchase one limit.

Clinical trials

The clinical trial phase is considered the most important part of the research and development process and the success of this is paramount to a sponsor company. Our policy provides protection with ancillary costs and expenses in the event of injury to a research subject from the pilot studies through to post marketing.

Appetite

What we consider

Companies importing, manufacturing, distributing or leasing the following:

- Laboratory equipment manufacturers
- Software as a medical device
- Tangible products
- Tangible, invasive and non-invasive implantable and non-implantable devices

What we ordinarily decline

- Breast implants
- Contraceptive devices
- Devices containing DEHP or lead
- Fall detection pendants and necklaces
- Hip and knee joint replacement kits and components
- Implantable silicone
- Inferior vena cava filters
- Infusion devices (except on an excess basis)
- Mesh (other than used in dental surgery)
- Narcotic or alcohol detection kits
- Nebulisers and pressure regulators for medical gas

Limits, deductibles and premiums	\$CAD
Maximum errors & omissions limit	\$15m
Maximum products liability limit	\$15m
Maximum general liability limit	\$15m
Maximum clinical trials limit	\$15m
Maximum property damage/BI (per event)	\$4m
Maximum revenue	\$2.5bn
Minimum deductible	\$1k
Minimum premium	\$500 for \$1m E&O/Products

Coverage is subject to underwriting and the terms, conditions, and limits of the issued policy.