



Insurance for Medical Device Companies

Nationwide Recall of Medical Device Linked to Infections
Orthopaedic Device Firm Fails to Meet Quality Systems Standards
FDA Issues New Warnings to Medical Device Trial Operators

The future seems unlimited for the medical device industry with its rapid technological advances, global marketplace and increasing demand. New forms of imaging, minimally invasive surgical procedures, non-invasive diagnostic techniques, biodegradable implant materials, medical lasers and device miniaturisation offer vast profit potential. But breakthroughs are counter-balanced by concerns over increased government oversight, emergence of micro-organisms resistant to conventional sterilisation methods, pressures of a merger-dominated business climate and an increasing trend in class action litigation.

That's why Chubb has developed the next generation of insurance protection —*for Life Sciences*. This portfolio offers a myriad of innovative insurance products tailored specifically for medical device companies, including dual-trigger general liability, products and human clinical trials liability, and first-party protection for radioactive contamination. With a unit dedicated to the life sciences industry, Chubb has unique expertise in helping companies manage risks with enterprise-wide insurance products supported by outstanding claim and loss control services.

Property

Broad “all-risk” perils cover is available to respond to the needs of medical device companies.

Research & development property is defined as processes or cultures, prototypes, written or inscribed documents, plans, records or formulas produced and directly associated with research and development operations.

Broad “all-risk” property perils such as water damage, inundation, abrupt and accidental mechanical breakdown and surface water are included.

Contamination from a wide variety of causes including bacteria, mildew, microorganisms, mold, viruses, pathogens, airborne microbes – and even overexposure to radiation – can be included. Protection is afforded at scheduled, unnamed and newly acquired locations.

Contaminant cleanup and removal responds to costs incurred to clean up or remove contaminants, including radioactive contaminants, from land, water or air, either inside or outside of a building.



Business Income

Chubb's Life Sciences sets the standard in business income protection. Regardless of the extent of your operations, your company needs this insurance. The following forms of Business Income protection are available:-

Operational restoration extends business income protection beyond physical restoration of property. A loss will be paid until operations are restored to the level that existed prior to the covered property loss. This continued protection is essential for facilities that must be validated by government authorities, such as the FDA, before manufacturing can resume. These procedures can take months, and in some cases go on for more than a year after physical restoration is completed.

Dependent business premises protection is available on a scheduled basis. Reliance on others, such as component suppliers and outsourced contract research, manufacturing and packaging organisations, creates susceptibility to business interruption from a loss at any of these firms.

Extra expense insurance can be included as part of the business income form to pay expenses over and above the usual expenses a company would have incurred to continue operations had it not sustained a covered loss.

General Liability

General liability has tailored definitions of your product and of the products/completed operations hazard. Further, lessors of leased equipment and volunteers are automatically included as insureds.

A **hybrid general liability** contract offers a dual trigger — an occurrence trigger for Premises/Operations and a claims-made trigger for Products/Completed Operations. This single form offers convenience and reduces potential for conflicts in the claims process.

An **extended occurrence period** of one year fills a potential gap for delayed occurrences from products that may still be in the hands of consumers after a recall or ban.

Product withdrawal & crisis management expense protection up to \$25,000 for Class 1 recall is offered to companies with a formal product recall program.

Insured status is granted for typical contractor relationships based on activities performed, as contractually required.

Customised **human clinical trial reporting conditions** offer greater efficiency by recognising the various roles and responsibilities associated with these activities.

Blanket protection applies to human clinical trials initiated after the policy inception within the same drug or medical device family. Certain exceptions may require advanced underwriting approval.

Emergency medical expenses are covered for bodily injury in connection with human clinical trials, including trial-related athletic activities.

Employees who voluntarily participate in a human clinical trial are not excluded, as their participation is not deemed to be within the scope of their employment.

LOSS SCENARIO #1

A manufacturer of dental equipment sterilises its products via exposure to radiation. Overirradiation during a sterilisation procedure resulted in physical damage to the equipment. Chubb's *Life Sciences Contamination* section responded to cover the cost to replace the damaged equipment.



LOSS SCENARIO #2

A manufacturer of a home-use blood pressure monitor withdrew its product in accordance with its product recall program. Not all consumers were aware of the recall. Six months later, a woman suffered an injury from using the monitor for the first time and filed a claim against the manufacturer. With Chubb's *Life Sciences' optional Extended Occurrence Period*, this company had the needed protection.

LOSS SCENARIO #3

A manufacturer of MRI equipment issued a notice concerning the failure of one model. A hospital owned two of the failed models and endured the lengthy repairs. While unable to use the MRI machines, the hospital had to decrease its patient load and refer patients to other hospitals. The hospital claimed reduced revenue for the patients turned away. Chubb's *Life Sciences' Errors & Omission* policy responded to the financial injury claim made against the MRI manufacturer.

Errors & Omissions

Errors & Omissions insurance helps protect your company from lawsuits claiming a financial loss resulting from a failure of your product or service to perform to specifications. It is affordable protection against a significant threat to your company's financial well-being. General liability insurance does not protect you from these emerging vulnerabilities.

Errors & Omissions protection can provide financial injury compensation to a third party resulting from the need to stop using your product due to the risk of future **bodily injury or property damage**.

Oral & written contractual liability insurance is provided for insured contracts and includes the obligation to defend an indemnitee where provided by such contract.

Notice of circumstances provision provides the opportunity to preserve insurance for known circumstances that may result in a claim.

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More Options

Round out your insurance program with additional products:

Umbrella & Excess — can be structured to include products liability on a follow-form basis

Environmental – protects against liability for first-party remediation costs as well as third-party bodily injury, property damage and remediation costs resulting from new or existing pollution incidents

Commercial Automobiles – includes nonowned and hired cars

Workers Compensation – includes protection for employees while travelling overseas

Executive Protection Liability — includes Crime and Employment Practices

Political Risk and Trade Credit — help protect your overseas investments

Global

You can easily expand your domestic property and liability insurance worldwide with a global extension. Differences in conditions or limits that may exist between the domestic program and the local (admitted) insurance contracts are insured subject to the terms and conditions of the policy. Where admitted insurance is required, Chubb can write primary policies through its network of wholly owned offices or affiliates, including the compulsory coverages for human clinical trials in many countries.

Chubb's dedication to the life sciences industry is evidenced by its product innovation, quality of services, precision underwriting and depth of expertise.

FIND OUT MORE

If you would like more information about Chubb's Life Science insurance, please contact your nearest Chubb office.

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Chubb refers to the insurers of Chubb Group of Insurance Companies: Federal Insurance Company, Vigilant Insurance Company, Great Northern Insurance Company, Pacific Indemnity Company, Northwestern Pacific Indemnity Company, Texas Pacific Indemnity Company, Executive Risk Indemnity Inc., Executive Risk Specialty Insurance Company, Quadrant Indemnity Company, Chubb Custom Insurance Company, Chubb Indemnity Insurance Company, Chubb Insurance Company of New Jersey, Chubb National Insurance Company, Chubb Lloyds Insurance Company of Texas. Not all insurers do business in all jurisdictions.

This literature is descriptive only. Actual coverage is subject to the language of the policies as issued.

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