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LS Prime® Feature: Recall Exception for Implants

Did you know?

Manufacturers of implantable medical devices (or their components) understand the importance of producing quality devices. The consequences of a suspected faulty or failed product can require costly product recalls.

Product liability policies—even those crafted specifically for life sciences companies—exclude claims for product recalls. This means that the costs associated with repairing, replacing or removing faulty or potentially faulty product is not covered, as no bodily injury has occurred. The uncovered costs of the recall, while a significant business expense, are usually not catastrophic when the recalled products are simply pulled off a warehouse shelf and returned to the manufacturer.

But what if the defective product is already implanted in the human body? Most Life Science liability policies would also exclude the cost of surgically removing an implanted device, since the device has not yet caused bodily injury. This is also the case for transplanted tissues, organs or biological materials which have been implanted but have not yet caused injury.

How is LS Prime® different?

While the cost of recalling a product is generally excluded[1], LS Prime® differentiates itself by making a critical exception to this exclusion: if bodily injury is caused by the removal of a marketed product that is subject to a **Class I Product Recall**, or a medical device used in a clinical trial from a **clinical trial participant** this exclusion does not apply. The exception to the exclusion applies to implanted medical devices, or even transplanted tissues, organs, or biological materials.

It is important to note that bodily injury does not have to be caused by the defective product to be excepted from the exclusion. The exception applies to the removal of the product.

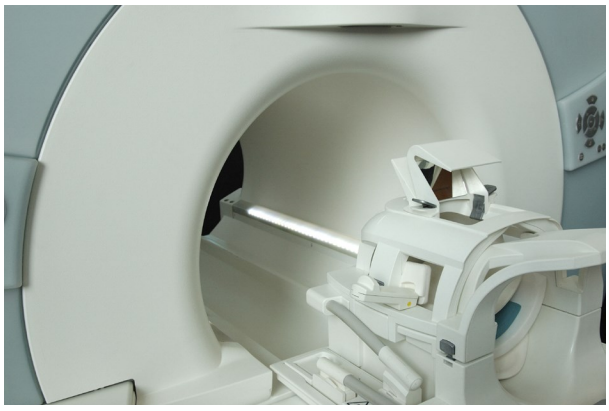
Who needs this coverage?

- Medical Device Manufacturers
- Medical Device Component Manufacturers

See reverse side for Claims Examples

How does this coverage work?

LS Prime's® Recall of Products, Work or Impaired Property exclusion contains exception language which states that the exclusion does not apply to the removal of implanted medical devices, transplanted tissues, organs or biological materials where such removal is as a result of a **Class I Product Recall** or at the request of a **clinical trial participant**.



[1]A sublimit for Product Withdrawal Expense may be offered at your underwriter's discretion to cover costs such as consultants, attorneys, public relations firms, transportation and storage as the result of a Class I Recall

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Recall Exception for Implants Claims Examples

Pacemaker: A patient is implanted with a pacemaker. It is later discovered that the pacemaker has a defect which could cause a higher than expected failure rate. The device manufacturer issues a **Class I Product Recall**. Though the patient hasn't experienced any difficulty with his implant, he decides to have the pacemaker surgically removed and replaced with a different model. The recall exclusion in most Liability policies would likely preclude coverage for the cost of this surgery since bodily injury as a result of the defect has not occurred, but LS Prime® would cover such an event.

Hip Implant Clinical Trial: A clinical trial participant has been implanted with an artificial hip. The participant is in a great deal of pain after the hip is implanted. It is determined that a lubricant, used during the manufacturing process, was still present when the hip was implanted. This lubricant prevents the replacement hip from bonding properly to the bone. The participant then chooses to have the implant removed and replaced. The bodily injury caused by this removal may be excluded in most Liability policies. This is not the case with LS Prime®.

Cranial Implant: Cranial Implants are recalled because of improper sterilization that could lead to infection, intracranial abscess, sepsis, or long-term neurological deterioration. A patient who has a cranial implant learns of the **Class I Product Recall** and decides to have the implant removed even though the patient has not experienced any problems associated with the implant. Bodily injury caused by the removal of the product (not the defect) triggers coverage under LS Prime®.

Discs: A Class I Product Recall is issued for lumbar discs because of the potential for transference of metal particles from the disc packaging to the disc itself. Implantation of such defective discs can result in a higher rate of infection and pain. A patient with this implant wishes to have it removed and replaced before it causes him harm. Bodily injury caused by the removal of the product (not the defect) triggers coverage under LS Prime®.