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# The defect in a medical device manufactured in series presumes the existence of such defect in all the units from the same series

*Judgement of the European Court of Justice (ECJ), of 5 March 2015, Case C-503/13 (Boston Scientific), regarding liability for defective medical devices*

## Background

A manufacturer of pacemakers and automatic implantable cardioverter defibrillators realized that a component for the hermetic seal used in the pacemakers could undergo a progressive degradation that might lead to an early battery rundown, resulting in loss of telemetry and/or in loss of output without warning.

He also verified that the proper working of the automatic implantable cardioverter defibrillators could be affected by a defect in one of its components, which could limit its efficacy.

The company communicated both incidences to the physicians who had implanted the products and recommended to replace the pacemakers and deactivate the magnetic switch of the defibrillators. Following these recommendations, the pacemakers or defibrillators that some of the patients had were replaced by others, and the products removed were destroyed without examining their functioning.

The insurance companies claimed from the manufacturer the costs of the implantation of the first pacemakers that were replaced and the reimbursement of the cost of replacing the defibrillator, arguing that the insurance companies were only liable for the costs of replacement of those specific units that were defective. The judgments of the first instance ruled in favour and sentenced the manufacturer to pay such costs.

## Proof of the defect and batch unit

When the case reached Bundesgerichtshof, the German Court considered that in order to resolve the litigation an interpretation of the EU product liability Directive was necessary, and thus, it decided to refer to the ECJ for a preliminary ruling two important questions.

The Court of the European Union concludes that in the case of medical devices such as pacemakers and cardioverter defibrillators, considering their purpose and the vulnerability of patients that use them, the security requirements that the patients can expect from such products are particularly high. Under these conditions, as they are products of the same model and production series, after a defect has been detected in a unit, the other units of the same model or batch can be classified as defective without being necessary to prove the existence of the defect in each of the units.

On the other hand, the costs of the surgical operation necessary for the removal of the defective product and its replacement with a new one are damages for which the manufacturer is responsible when surgery is required in order to remove this defective product. According to the Court, the compensation for the damage must include the costs of replacing the defective product because this is the only way to restore the safety level that any person is legally entitled to.