

Latex, Polyvinyl Chloride and Implantable Device Systems

SUMMARY

Some patients may have health-related concerns regarding materials that may be used in Boston Scientific CRM products. This article provides information on what products may or may not use latex and/or polyvinyl chloride (PVC).

Latex is a rubber material used in thousands of consumer and healthcare products due to its excellent tactile characteristics, tear resistance and elasticity.

PVC is one of the most commonly used plastics in the world. PVC is either flexible or inflexible (rigid), and is used to make items ranging from building materials to medical supplies.

ICD: Implantable Cardioverter Defibrillator

CRT-D: Cardiac Resynchronization Therapy Defibrillator

CRT-P: Cardiac Resynchronization Therapy Pacemaker

CRM PRODUCTS REFERENCED*

See text

*Products referenced herein may not be approved in all geographies.

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The following information may be useful for patients and their physicians who may have health-related concerns associated with the use of **latex** or **PVC** materials in Boston Scientific products.

Boston Scientific CRM products that contain Latex and/or PVC:

- A latex balloon is used in the ARROW balloon catheter (Models 6714, 6746, 6747). These disposable, non-implantable catheters are commonly used to facilitate implantation of EASYTRAK[®] coronary venous pacing leads.
- Rigid PVC is used in the packaging trays of some pacing leads. However, this PVC material is not chemically active and therefore will not migrate into the implantable leads that are stored in the packaging. Note that the rigid PVC material used in Boston Scientific packaging does not include any plasticizers (including the di-2-ethylhexyl phthalate plasticizer known as DEHP).

Boston Scientific CRM products that do not contain Latex and/or PVC:

- Implantable leads
- Implantable ICDs, CRT-Ds, CRT-Ps and pacemakers
- Implantable lead accessories, including lead caps and suture sleeves
- Non-implantable lead accessories, including introducers, stylets, vein picks and catheters (except where previously noted)
- Packaging for ICDs, CRT-Ds, CRT-Ps and pacemakers
- Packaging for implantable leads (except where previously noted)

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