

# **Boston Scientific Corporation Product Replacement Policy for Implanted Devices Global Countries (Excluding European Region)**

## **Products Covered:**

**AMS 700™ Inflatable Penile Prosthesis**

**AMS Ambicor™ Inflatable Penile Prosthesis**

**Spectra™ Concealable Penile Prosthesis**

To the extent any country-specific deviations to this policy are required, they shall be provided in a separate document reflecting the affected country and the specific change(s) to this policy, which shall become effective only upon written approval of the General Manager of BSC Men's Health.

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This is a revision to the Product Replacement Policy for BSC Penile Prostheses that was last revised in 2010. This current Boston Scientific Corporation ("BSC") policy is effective January 1, 2018.

- A. This policy applies only to a hospital or physician's office (hereafter referred to as "Institution") which purchases a BSC Penile Prosthesis to treat a previously implanted patient under warranty in accordance with this policy.

BSC will, consistent with these policy terms and conditions, either, i) replace, or ii) issue the Institution a credit invoice for any applicable warranty credit for a BSC Penile Prosthesis, or components thereof (hereafter referred to as "Device") explanted within the first year because of mechanical, surgical, or medical problems. If BSC issues a credit under this warranty, the credit value shall be either i) the price of the original Device, or ii) current market value of the replacement Device, whichever is lower. No credit will be issued or recompense offered for any medical expenses beyond the price of the original Device or the current market value of the replacement Device.

The one year period of credit eligibility begins upon the implant date of the Device.

- B. BSC, at its sole discretion, will either i) replace, or ii) issue a credit invoice to the Institution replacing the explanted BSC Device(s) after verifying that all of the following conditions have been satisfied:
1. The BSC Patient Information Form from the original (first) Penile Prosthesis implantation surgery must be on file at BSC.
  2. In cases where the patient is re-implanted with a new Device, a credit will be provided only when the original Device is a BSC Penile Prosthesis and the replacement Device is also a BSC Penile Prosthesis.
  3. A BSC Product Return Form must be completed by the Institution and returned to BSC along with all explanted Device components that shall then become the property of BSC.
  4. A BSC Patient information Form must be completed by the Institution for the revision (replacement) implant and returned to BSC.

NOTE: Replacement of the prosthesis or component of the prosthesis will be limited to the same product category as the original Device implanted in the patient and credit, if issued, will be at the original purchase price. Product categories are defined as follows:

Category I: Spectra™ Concealable Penile Prosthesis

Category II: AMS Ambicor™ Inflatable Penile Prosthesis

Category III: AMS 700™ Inflatable Penile Prosthesis,

Category IV: AMS 700™ Inflatable Penile Prosthesis with Inhibizone™ Antibiotic Surface Treatment

If BSC no longer manufactures the same or similar model penile prosthesis within a product category of the prosthesis to be replaced, at its sole option and upon request, BSC may issue an appropriate credit to the Institution.

- C. BSC, at its sole discretion, may elect to have a third party perform an independent audit of an Institution's claims for warranty. BSC reserves the right to modify an Institution's warranty terms or eligibility if BSC deems the results from an independent audit are found to be incomplete, inaccurate, and/or unsatisfactory.
- D. BSC, at its sole discretion, will either i) replace, or ii) issue a credit invoice to the Institution for Open but Unused Devices (outer packaging opened/non-sterile), if the Device is found to be unusable due to a *bona fide* issue with its material or workmanship as verified by BSC upon receipt of such Device.
- E. Devices implanted or purchased prior to the effective date of this Product Replacement Policy (January 1, 2018) will be covered by the Product Replacement Policy in effect on the original implant or purchase date.
- F. This Product Replacement Policy is not a guarantee. The only warranty being given to customer is that which is provided in the approved labeling of the purchased Device. The credit set forth in this Product Replacement Policy shall be the exclusive remedy available to any person.

**TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THIS PRODUCT REPLACEMENT POLICY IS EXPRESSLY IN LIEU OF ANY AND ALL OTHER REPRESENTATIONS, CONDITIONS AND WARRANTIES, EXPRESS OR IMPLIED, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BOSTON SCIENTIFIC EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

Handling and storage of the Device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond our control may directly affect the Device and results obtained from it. Boston Scientific shall not be liable for medical expenses or any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of the Device or this Product Replacement Policy. Boston Scientific neither assumes, nor authorizes any other person to assume for Boston Scientific, any other or additional liability or responsibility in connection with the Device or this Product Replacement Policy.

- G. Requests for product replacement and questions regarding this policy should be directed to BSC Customer Service at:

United States: 1 800 328 3881

International: +31 20 593 8800

BSC periodically updates product literature. If you have questions regarding the currency of this information, please contact BSC.



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