



EFFECTIVE FOR PRODUCTS IMPLANTED APRIL 1, 2022, OR LATER

Global Men's Health Products Listed Below: Ten-Year Replacement Policy

Subject to the exceptions described in this paragraph, Coloplast will replace or provide a credit for a Titan[®] IPP, Genesis[®] malleable implant, or Torosa[®] prostheses, or any component thereof that has been returned to Coloplast as described below (collectively, the "Returned Device"), with the same model of Coloplast prosthesis or component, or, at Coloplast's sole option, a newer model of such Returned Device, during the first ten (10) years from implant date. Any such replacement or credit is subject to the terms and conditions in this document. This policy does not cover Returned Devices when standard documentation, available to Coloplast as of the time of the request for replacement, describes a Returned Device that was explanted due to

- (a) any adverse bodily reaction to any Returned Device including, but not limited to infections, erosions, etc.,
- (b) alterations to, mishandling or misuse of the Returned Device prior to or after implant, or
- (c) any use not described in the "instructions for use" for the Returned Device (i.e., off-label use).

Coloplast's responsibility under the terms of this policy is limited to a credit only for the eligible replacement, or replacement, of the recipient's malfunctioning Coloplast Returned Device. In no event shall Coloplast be responsible for any medical, hospital, or surgical costs, including costs related to implantation procedures, replacement procedures, follow up care, reimbursement for the cost of Returned Devices or any components thereof, not manufactured by Coloplast, or incidental or consequential costs of any kind, including patient injury. This policy replaces and rescinds any prior replacement policy for Returned Devices implanted on March 31, 2022, or earlier.

Replacement credit requests in the U.S. shall be made by the recipient's surgeon to Coloplast at the toll-free number or email address listed below. Replacement requests outside the U.S. shall be made by the hospital or by the distributor to Coloplast by addressing a complaint at fr_complaints@coloplast.com or by contacting a local representative. Coverage under this policy will require documentation regarding appropriate storage, handling, and implantation of the Returned Device. This information might include information about the surgical technique used to implant the Returned Device to demonstrate conformance with Coloplast's product information.

Upon receipt of all the information necessary for Coloplast to evaluate and process a replacement request, Coloplast will provide return instructions. To be considered for a replacement Returned Device or credit, the explanted Coloplast Returned Device must be received by Coloplast, whether at a location in the United States, Denmark or France as soon as possible, but in any case, within 31 calendar days from the explant date. The explanted Returned Device shall become the property of Coloplast. If eligible under this policy, the resulting replacement or credit will be issued to the surgeon or other health care provider, hospital, or distributor, as applicable, after receipt and inspection of the Coloplast Returned Device. Coloplast reserves the right to charge for replacement products if the Returned Device does not meet the terms of this policy.

TO THE EXTENT PERMITTED BY LAW, THE REPLACEMENT REMEDY SET FORTH ABOVE IS EXCLUSIVE OF ALL WARRANTIES, REMEDIES AND CONDITIONS, WHETHER ORAL OR WRITTEN, STATUTORY, EXPRESS, OR IMPLIED. AS PERMITTED BY APPLICABLE LAW, COLOPLAST SPECIFICALLY DISCLAIMS ANY AND ALL STATUTORY OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. COLOPLAST SHALL HAVE NO RESPONSIBILITY FOR ANY STATEMENTS OR REPRESENTATIONS, WHETHER ORAL OR WRITTEN, MADE BY ANY OTHER PERSON OR ENTITY.

Coloplast makes no representation as to the functional life of any Returned Device; to the contrary, Coloplast notes that there are a variety of conditions which may cause these devices to malfunction or wear out and require replacement.

In any instance in which Coloplast provides a Returned Device replacement or credit under this policy, Coloplast will indicate on the invoice or other record sent to the requesting surgeon or other health care provider, hospital, or distributor, as applicable, that the Returned Device has been provided at no cost pursuant to this replacement policy and will state the credit amount issued. It shall be the responsibility of the surgeon or other health care provider receiving the replacement Returned Device to comply with all applicable reimbursement protocols or requirements consistent with this notice including, but not limited to, fully and accurately reporting the replacement device as having been provided free of charge in any claim or report filed with any government payer if the recipient patient is a federal health care program beneficiary.

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