

Teva Women's Health, Inc.
ParaGard® T 380A
(Intrauterine Copper Contraceptive)
ParaGard® Replacement Policy

Teva Women's Health, Inc. will, in its sole discretion and judgment, consider all justifiable requests for replacement of a ParaGard® T 380A Intrauterine Copper Contraceptive. Teva Women's Health will replace merchandise providing the conditions stated below are met. Such requests are subject to Teva Women's Health's approval. Other than for shipping or ordering errors (see Section 4), Teva Women's Health does not offer credit or refunds for returned product; all sales are final.

Replacement Conditions

Teva Women's Health requires an authorization number for each ParaGard® T 380A being replaced. To qualify for a replacement, contact ParaGard customer service at 1-877-ParaGard following the occurrence. Replacement requests will be processed within 4-6 weeks upon receipt of the pertinent documents.

Replacement Process

1. **Medical** - A ParaGard T 380A Intrauterine Copper Contraceptive may be considered for replacement if it has been expelled or removed for medical reasons within 90 days of insertion. To request a medical replacement:

- a. Within 30 days of removal, contact Teva Women's Health's Medical/Safety department at 1-877-ParaGard. Please have the patient's medical record available. Also, we will request the lot number of the ParaGard T 380A.
- b. Provide information in accordance with regulations pertaining to an Adverse Drug Event (ADE) as required by the Food and Drug Administration (FDA).
- c. ParaGard Customer Service will provide a replacement authorization number and will fax or mail the ParaGard Replacement Product Request form to you.
- d. Complete, sign, and return the ParaGard Replacement Product Request form to ParaGard Customer Service via fax (1-800-299-8332) or mail within 30 days of receipt.
- e. ParaGard Customer Service will process the replacement within 4-6 weeks upon receipt of all pertinent information.

2. **Product Complaint** - Return of a ParaGard T 380A will be requested if a physical or mechanical defect in the product, its packaging or labeling is suspected. To request a product complaint replacement:

- a. Contact Teva Women's Health's Medical/Safety department at 1-877-ParaGard. We will request the lot number of the ParaGard® T 380A being returned.

b. Provide descriptive information pertaining to the defect.

A post-paid mailer will be provided for return of the product. If appropriate, a ParaGard T 380A replacement will be issued.

3. **Dropped or Contaminated** - A ParaGard T 380A IUC may be considered for replacement if the device (unwrapped) has been dropped or otherwise inadvertently contaminated. To request a replacement:

- a. Within 1 week following the drop or contamination, contact ParaGard Customer Service at 1-877-ParaGard to request a replacement authorization number. We will require the lot number of the ParaGard T 380A being replaced.
- b. ParaGard Customer Service will provide a replacement authorization number and will fax or mail the ParaGard Replacement Product Request form to you.
- c. Within 30 days of receipt, complete, sign, and return the Replacement Product Request Form, along with the dropped or contaminated unit and its package, to the following:
Teva Women's Health, Inc.
Attention: Replacement Department
825 Wurlitzer Drive
N. Tonawanda, New York 14120
- c. ParaGard Customer Service will process the replacement within 4-6 weeks upon receipt of returned unit and all pertinent documents.

4. **Shipping or Ordering Errors** - Contact ParaGard Customer Service at 1-877-ParaGard within 48 hours of receipt of product.

Non-returnable Product

Teva Women's Health reserves the right to exchange or destroy any returned merchandise, which, in its judgment, is not returnable for replacement or credit.

Merchandise is considered to be non-returnable for replacement or credit if:

- a. the return of merchandise is unauthorized
- b. the merchandise was subjected to improper storage conditions or intended to reduce inventory.
- c. the merchandise was damaged by fire, smoke, heat, or water resulting from a casualty occurrence or insurable hazard.
- d. any other reason which Teva Women's Health determines, in its sole discretion.