# **Paragard® IUS Replacement Policy**



CooperSurgical, Inc. will, in its sole discretion and judgment, consider all justifiable requests for replacement of a Paragard<sup>\*</sup> T380A (intrauterine copper contraceptive). CooperSurgical will replace merchandise providing the conditions stated below are met. Other than for shipping or ordering errors, CooperSurgical does not offer credit or refunds for returned product. All sales are final.

#### **Non-returnable Product**

CooperSurgical 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 for reasons including, but not limited to: the return of merchandise is unauthorized; the merchandise was subjected to improper storage conditions or intended to reduce inventory; the merchandise was damaged by fire, smoke, heat, or water resulting from a casualty occurrence or insurable hazard, or any other reason that CooperSurgical determines, in its sole discretion.

### I. Replacement Associated with Adverse Event

A Paragard unit may be considered for replacement when associated with an adverse event within 90 days of placement. To request a replacement associated with an adverse event:

- 1. Immediately following event, contact CooperSurgical by calling 1-877-PARAGARD. Please have the patient's medical record and the lot number of the unit readily available.
- 2. Provide information required by the U.S. Food and Drug Administration (FDA) pertaining to an Adverse Drug Event (ADE).
- 3. Upon receipt of all required information, you will be provided with a Product Replacement Form inclusive of a unique case number.
- 4. The request will be processed and the replacement Paragard unit will be shipped within 1 business day.

### **II.** Replacement Associated with Product Quality Issue

A Paragard unit may be considered for replacement if there is a suspected product quality issue, which includes a physical or mechanical defect in the product, its packaging, or labeling. To request a replacement associated with a product quality issue:

- 1. Immediately following event, contact CooperSurgical by calling 1-877-PARAGARD. Please have the patient's medical record and the lot number of the unit readily available.
- 2. Provide the lot number of the unit, and descriptive information pertaining to the event. You will be provided with a pre-paid mailer to return the original Paragard unit to the following address:
  - CooperSurgical, Inc. 825 Wurlitzer Drive North Tonawanda, NY 14120
- 3. Upon receipt of all required information, you will be provided with a Product Replacement Form inclusive of a unique case number.
- 4. The request will be processed and the replacement Paragard unit will be shipped within 1 business day.

#### III. Replacement for Dropped / Contaminated Unit

A Paragard unit may be considered for replacement if the unwrapped unit has been dropped or otherwise inadvertently contaminated. To request a replacement for a dropped or contaminated unit:

- 1. Within 1 week of the event, contact CooperSurgical by calling 1-877-PARAGARD.
- 2. Provide the lot number of the unit, and descriptive information pertaining to the event.
- 3. Upon receipt of all required information, you will be provided with a Product Replacement Form inclusive of a unique case number and return shipping instructions.
- 4. The request will be processed and the replacement Paragard unit will be shipped within 1 business day.
- 5. Within 30 days of receipt of the Product Replacement Form, please return the dropped or contaminated unit in the original Tyvek pouch and package to the following address:

CooperSurgical, Inc. Attention: Replacement Department 825 Wurlitzer Drive North Tonawanda, NY 14120

## **IV. Shipping or Ordering Errors**

A Paragard unit is not eligible for return or refund unless a shipping or ordering error has occurred. All sales are final. To rectify a shipping or ordering error:

- 1. Report the issue within 48 hours of receipt of the product by calling 1-877-PARAGARD.
- 2. If CooperSurgical determines that a shipping or ordering error occurred at the fault of Paragard Direct<sup>5M</sup>, a refund, replacement, or credit to your account will be issued.

If you obtained a Paragard unit through one of our specialty pharmacies, please contact them directly for assistance obtaining a replacement unit in accordance with the policy outlined above.

For Paragard full Prescribing Information, visit Paragard.com or call 1-877-PARAGARD.

