LILETTA® (levonorgestrel-releasing intrauterine system) 52 mg
REPLACEMENT POLICY

This LILETTA® Replacement Policy applies to LILETTA product sold in the U.S. by AbbVie. AbbVie will, in its sole discretion and judgment, consider all justifiable requests for replacement of a LILETTA system on a unit-by-unit basis, provided that AbbVie determines that the conditions stated below are met.

To report an adverse event only, please call 1-800-678-1605 and select the option to report a side effect or adverse event.

REPLACEMENT CONDITIONS

Product may qualify for replacement if:

1) Unit has been removed from sterile packaging and contaminated preinsertion without coming into contact with a patient, and the replacement request is submitted within thirty (30) days of drop or contamination

2) Unit has come into contact with a patient, and insertion was unsuccessful, and the replacement request is submitted within thirty (30) days of attempted insertion

3) Customer desires to return unit due to product quality complaint, and the replacement request is submitted within thirty (30) days of identifying the defect

4) Unit was inserted successfully into a patient and was expelled or removed for medical reasons, and the replacement request is submitted within thirty (30) days of the expulsion or removal

In order for the replacement to be processed, all required information must be provided by the HCP office. Any delays in providing information could result in a delay of obtaining the replacement.

To qualify for a replacement, a LILETTA Product Replacement Request Form ("RRF") must be submitted to AbbVie regardless of the reason for the request. Follow the instructions below. Note that AbbVie requires that the lot number and expiration date of the LILETTA unit sought to be replaced be provided on the RRF. AbbVie further requires that units sought to be replaced be returned in accordance with the instructions below before a replacement unit is issued. Replacement requests will be processed within ten (10) business days upon receipt of the pertinent documents/units.

REPLACEMENT REQUEST PROCESS

1) Accidentally Dropped or Contaminated Preinsertion – A unit may be considered for replacement if it has been accidentally dropped or otherwise inadvertently contaminated prior to insertion into a patient. To request replacement of a unit because it has been dropped or contaminated preinsertion, **within thirty (30) days:**

a) Download an RRF at https://www.lilettahcp.com/resources#downloadable-resources.

b) Complete, scan, and **email the RRF to LILETTASupport@abbvie.com**. A return authorization number ("RA#"), prepaid shipping label, and **instructions on how to return the product** will be provided within three (3) to five (5) business days.

c) Please return the product as instructed using the shipping label provided within thirty (30) days of receipt of return authorization. Any unit returned after thirty (30) days from receipt of the RA# and shipping instructions may, at AbbVie's sole discretion, no longer be eligible for replacement.

d) Your replacement request will be evaluated by AbbVie, and if AbbVie determines in its sole discretion that a replacement is appropriate, a replacement unit will be issued.

Any units returned for replacement without the RA# will not be processed for replacement. AbbVie reserves the right to return or destroy units that are sent without prior return authorization.

REPLACEMENT REQUEST PROCESS (CONTINUED)

2) Incomplete Insertion – A unit may be considered for replacement if it is contaminated due to an incomplete insertion procedure. **LILETTA® does not need to be returned in instances of incomplete insertion. Within thirty (30) days:**

a) Download an RRF at https://www.lilettahcp.com/resources#downloadable-resources.

b) Complete, scan, and **email the RRF to Liletta_Intake@abbvie.com**. If you wish to speak to a representative about the incomplete insertion, please contact AbbVie at 1-800-678-1605 and select the option to report a product quality complaint.

c) Your replacement request will be evaluated upon receipt of a signed, complete RRF. If, after internal processing, AbbVie determines in its sole discretion that a replacement is appropriate, a replacement unit will be issued within approximately ten (10) business days.

3) Product Quality Complaint – A unit may be considered for replacement if a physical or mechanical defect in the product, its packaging, or labeling is suspected. To report a suspected quality defect, within thirty (30) days of identifying the defect:

a) Download an RRF at https://www.lilettahcp.com/resources#downloadable-resources.

b) Complete, scan, and **email the RRF to Liletta_Intake@abbvie.com**. If you wish to speak to a representative about the product quality, please contact AbbVie Product Quality Complaints at 1-800-678-1605.

c) Your replacement request will be evaluated upon receipt of a signed, complete RRF. If, after internal processing, AbbVie determines in its sole discretion that a replacement is appropriate, a replacement unit will be issued within approximately ten (10) business days. **In some circumstances, the unit may be requested for return.**

4) Expulsion or Removal – A unit may be considered for replacement following expulsion or removal for medical reasons if the replacement request is made within thirty (30) days of the expulsion or removal and the RRF contains the patient's initials, where indicated.

a) Download an RRF at https://www.lilettahcp.com/resources#downloadable-resources.

b) Complete, scan, and **email the RRF to USAEAGN@abbvie.com**. If you wish to speak to a representative about the expulsion or removal, please contact the AbbVie Safety Department at 1-800-678-1605 and choose the option to report a side effect or adverse event.

c) Your replacement request will be evaluated upon receipt of a signed, complete RRF. If, after internal processing, AbbVie determines in its sole discretion that a replacement is appropriate, a replacement unit will be provided to the requesting healthcare practitioner for the unit that was expelled/removed from the patient listed on the RRF form, within approximately ten (10) business days.

In the event that the patient does not present to receive the replacement LILETTA unit, please call 1-855-LILETTA, for information on how to return the unused unit.

DESTRUCTION OF RETURNED PRODUCT

AbbVie reserves the right to destroy any product returned under this LILETTA Replacement Policy, even if AbbVie determines that no replacement can be issued for such product.

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