LILETTA® (levonorgestrel-releasing intrauterine system) 52 mg
PRODUCT REPLACEMENT REQUEST FORM

REPLACEMENT CONDITIONS

This form is to be used for requests to:

(1) replace a product that is accidentally dropped or contaminated pre-insertion*
(2) replace a product that has come into contact with a patient but was not inserted successfully*
(3) request a new unit for a patient following expulsion or removal for medical reasons†
(4) replace a unit due to a product quality complaint

Please provide the following information for ALL requests:
NOTE: Failure to complete this form in full may result in a delay in processing or a denial of the product replacement request.

Indicate Inserter Type: □ Single-Handed □ Two-Handed

Date of Request: ___________________________

Contact Name: ___________________________ Contact Title: ___________________________

Contact Email Address: ___________________________

Phone Number: ___________________________ Fax Number: ___________________________

Healthcare Facility Name: ___________________________

Healthcare Facility Street Address: ___________________________

Healthcare Facility City, State, ZIP: ___________________________

Healthcare Facility LILETTA AccessConnect℠ Customer Account Number: ___________________________

Healthcare Practitioner Name: ___________________________

Healthcare Practitioner NPI #: ___________________________ DEA #: ___________________________

Return Unit Information: LILETTA Lot #: □ □ □ □ □ □ – □ □ Expiration Date: ___________________________

Patient Initials: ___________________________ Patient DOB: ___________________________

* Product Placement Request Form must be submitted within one (1) week of drop/contamination or incomplete insertion.
† Product Placement Request Form must be submitted within thirty (30) days of expulsion/removal (which must occur within ninety (90) days of insertion).
Please certify your request by checking ONE box corresponding to the reason for the replacement request:

1. **Accidentally Dropped or Contaminated Pre-insertion:**
   - □ Request to replace product that was accidentally dropped or contaminated pre-insertion **within one (1) week of drop or contamination**:
     - I certify that the unit I am seeking to replace has been accidentally dropped or inadvertently contaminated pre-insertion.
     - I certify that the LILETTA unit being returned has not been contaminated with any human bodily fluids or tissue and in no way represents a biohazard.
   
   Return Authorization # ____________________________
   (For dropped or contaminated product pre-insertion cases, RA# to be provided by Allergan upon receipt of replacement request and required in advance of return.)

   For accidentally dropped or contaminated pre-insertion cases, completed form must be emailed to Allergan Customer Relations at CustomerRelations@Allergan.com within one (1) week after the drop or contamination. Upon acceptance of a completed form, a Return Authorization number (“RA”), pre-paid shipping label, and return instructions will be provided within two business days. 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 Allergan’s sole discretion, no longer be eligible for replacement. Any units returned for replacement without the RA# will not be processed for replacement. Allergan reserves the right to return or destroy units that are sent without prior authorization. For questions, you may call 855-LILETTA (855-545-3882), option 7.

   **GO TO PAGE 4 TO COMPLETE THIS REQUEST**

2. **Incomplete Insertion:**
   - □ Request to replace product that is contaminated due to an incomplete insertion procedure **within one (1) week of incomplete insertion**:

   Return Authorization # ____________________________
   (For incomplete insertion cases, RA# to be provided by Allergan upon receipt of replacement request and required in advance of return.)

   For incomplete insertion cases, completed form must be received by Allergan Quality Complaints via email at AUS-PSReporting@allergan.com or via fax at 800-972-2368 within one (1) week after the incomplete insertion. Upon acceptance of a completed form, a replacement LILETTA® unit will be provided to the requesting Healthcare Practitioner whose associated Healthcare Facility and LILETTA AccessConnect℠ Customer Account Number appear above within approximately ten (10) business days. In the event that the patient does not present to receive the replacement LILETTA® unit or for additional questions, please call 1-855-LILETTA (545-3882) for information on how to return the unused unit to Allergan.

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3. Expelled or Removed Units:

☐ Request to replace product that is accidentally expelled or removed pre-insertion within ninety (90) days of insertion. This form must be submitted within thirty (30) days after expulsion or removal:
  ➢ I certify that the LILETTA product reported on this form, for which the patient is requesting replacement, was expelled or removed for medical reasons by a trained medical professional from the patient whose initials and date of birth appear above.
  ➢ I certify that I have reported the expulsion or removal for medical reasons to Allergan Quality Complaints at 1-855-LILETTA (545-3882).
  ➢ I certify that LILETTA is a medically-appropriate product for the patient notwithstanding the expulsion or removal for medical reasons.
  ➢ I authorize the new unit to be shipped to my office, and I certify that such new unit will be reserved for the exclusive use of the patient whose initials and date of birth appear above. If the patient does not present I will return the unit to Allergan, per the instructions provided below.

For expelled or removed units, completed form must be received by Allergan Quality Complaints via email at AUS-PSReporting@allergan.com or via fax at 800-972-2368 within thirty (30) days after expulsion or removal for medical reasons by a trained medical professional. Upon acceptance of a completed form, a replacement LILETTA® unit will be provided to the requesting Healthcare Practitioner whose associated Healthcare Facility and LILETTA AccessConnect™ Customer Account Number appears above within approximately ten (10) business days. The unit will be provided for exclusive use of the patient whose Expelled/Removed Unit Information, Patient Initials, and Date of Birth appear above within approximately ten (10) business days. In the event the patient does not present to receive the replacement LILETTA® unit or for additional questions, please call 1-855-LILETTA (545-3882) for information on how to return the unused unit to Allergan.

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4. Product Quality Complaint:

☐ Request to replace product due to suspected physical or mechanical defect in the product, its packaging, or labeling.

For product quality complaints, send completed form to Allergan Quality Complaints via email at AUS-PSReporting@allergan.com or via fax at 800-972-2368 to request a replacement. You will be contacted to provide information about the complaint. Your replacement request will be evaluated upon receipt by Allergan, and if Allergan determines, in its sole discretion, that a replacement is appropriate, a replacement unit will be issued.

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Please provide a detailed description of and reason for the event leading to this request:

______________________________________________________________________________________________________

______________________________________________________________________________________________________

______________________________________________________

Date of Insertion: _________ Date of Event: _____________ Was patient contact made with the unit? ☐ YES ☐ NO

Was the unit placed? ☐ YES ☐ NO  Were the threads cut? ☐ YES ☐ NO  If yes to both, would you describe the event as: ☐ partial expulsion or ☐ complete expulsion or ☐ medical event requiring removal

Is the unit available for return? ☐ YES ☐ NO  (Note: Unit must be available for return to receive replacement.)

Please complete your product replacement request by certifying the following:

➢ I certify that the LILETTA product reported on this form, for which I am requesting replacement, was purchased by the Healthcare Practitioner Office/Customer Account identified herein.
➢ I certify that I am authorized to act for the Healthcare Practitioner Office/Customer Account for which I am signing.
➢ I certify that I will not bill the patient or the patient’s insurer for the courtesy product replacement unit requested herein.
➢ I certify that no replacement will be requested for product that has not met the conditions set forth in the LILETTA Replacement Policy.
➢ I authorize the replacement unit to be shipped to my office for in-facility use.
➢ I certify that I have received the patient’s written consent/authorization to release and disclose patient identifiable information contained in this form to Allergan, its subsidiaries, affiliates, and agents for the purposes set forth herein.

I further certify that the information provided in this form is complete and accurate to the best of my knowledge and I agree to notify Allergan of any changes I become aware of which could affect the evaluation or consideration of this replacement request.

Signatures (Required):

Healthcare Practitioner Signature (Required): ____________________________________________________________

Print Healthcare Practitioner Name (Required): __________________________________________________________

For Expelled or Removed Units ONLY, patient acknowledgment of this replacement request is required:

Patient Acknowledgment – Initials Only (Required): ________________________________________________________

ALL INFORMATION ON THIS FORM IS REQUIRED UNLESS OTHERWISE STATED, INCLUDING THE HEALTHCARE PRACTITIONER SIGNATURE. FAILURE TO COMPLETE THE FORM IN FULL MAY RESULT IN A DELAY IN PROCESSING OR A DENIAL OF THE PRODUCT REPLACEMENT REQUEST.

As instructed above, for units that have been dropped or contaminated pre-insertion, please send completed form to Allergan Customer Relations via email at CustomerRelations@Allergan.com. For all other units, please send completed form to Allergan Quality via email at AUS-PSReporting@Allergan.com or via fax at 800-972-2368. If you have questions or require additional information, please contact Allergan Customer Relations at 855-LILETTA (855-545-3882).

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