

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL12-08*

May 16, 2012

- Item:** Certain lots of Ethicon HARMONIC® HPBLUE and HP054 hand pieces are not compatible with the Ethicon HARMONIC® Generator Model 300 (GEN04)
- Specific Incident:** Ethicon Endo-Surgery states that the operation of their Model 300 HARMONIC® Generator (GEN04) will be interrupted after a cumulative activation time of 60 seconds (typically 10 activations) while using certain lot numbers of HPBLUE and HP054 hand pieces. The GEN04 goes into stand-by mode and will not operate unless the system is reset. The interruption does not occur during activation of the hand piece, while transecting or coagulating tissue. It can only occur after releasing the activation button. There have been no adverse events reported related to this issue; however, the unexpected switch to stand-by mode will interrupt the procedure, which could lead to hemorrhage and patient harm.
- General Information:** Ethicon has supplied a list of the affected lot numbers and detailed instructions in Attachment 1 and has a website (www.ees.com/handpiece) where updates will be posted.
- Some facilities may have both the older GEN04 generator and the newer GEN11 generator. While affected hand pieces are not compatible with the GEN04, they are compatible (i.e., will work as intended) with GEN11 generators.
- Depending on a facility's mix of GEN04 and GEN11 generators and their inventory of hand pieces, staff will need to make different decisions as summarized in the VHA Action Decision Chart provided in Attachment 2. For example, if the facility has affected hand pieces and only the GEN04 generators, staff need to remove and replace either the affected hand pieces or the GEN04 generators.
- Actions:**
1. By Close of Business (COB) May 21, 2012, **the Medical Center Director (or designee)** shall ensure that all physicians and dentists using this device and support staff involved with these procedures shall be made aware of this Patient Safety Alert.
 2. By COB May 28, 2012, **the Chief Biomedical Engineer (or designee)** shall call Ethicon at 1-800-873-3636, option 6 to request a package

including a printed copy of Attachment 1 and a sufficient number of Hand Piece Compatibility Labels for the GEN04 generators in their inventory.

3. By COB June 25, 2012, **the Chief Biomedical Engineer (or designee)** shall

- a) identify the location of the GEN04 and GEN11 generators in the facility, and
- b) assist the department managers in carrying out the actions in the Ethicon Urgent Product Correction Notification (see Attachment 1) and in Attachment 2.

4. By COB July 2, 2012, the **Patient Safety Manager** must document on the VHA Hazard Alerts and Recalls website that medical center leadership has reviewed and implemented these actions or that individual actions are not applicable to your facility.

Additional Information:

This issue is due to a supplier component change in the hand pieces that communicate with the generators. The interruption will continue to occur when using the GEN04 generator every time the system is reset - if one minute of cumulative activation time is reached.

Per Ethicon:

The following HARMONIC[®] Hand Piece (HP054) and HARMONIC[®] Blue Hand Piece (HPBLUE) lots are not compatible with the HARMONIC[®] Generator 300 (GEN04):

HARMONIC[®] HP054 Hand Pieces

All lots beginning with J9, including future lots you may receive, as well as the following lot: H92Y3M.

HARMONIC[®] Blue Hand Pieces (HPBLUE)

All lots beginning with J9, including future lots you may receive.

NOTE: Monitor the Ethicon website (see the link in General Information) for updates, and consider replacing your GEN04 generators with GEN11 generators.

If a user finds that an incompatible hand piece is inadvertently used with the GEN04 and the interruption occurs during a procedure, the user can reset the generator to resume its operation. To reset the generator, press the stand-by key on the front panel to take it out of stand-by. This typically takes 10 to 15 seconds. All user settings are retained therefore no control adjustments should need to be made. After the procedure is completed, the facility Patient Safety Manager should be notified that an incompatible

AL12-08*

hand piece was used so actions may be taken to prevent use of incompatible hand pieces in future procedures.

While Ethicon will supply Hand Piece Compatibility Labels for the GEN04 generators, the actions within this Patient Safety Alert remove the identified non-compatible hand pieces from use and return them for credit or assure that they are only used with the GEN11 generator. Labels are regarded as a weak mitigation strategy, but should be applied as directed to help staff continue to identify non-compatible hand pieces in the procedure rooms.

Source: Ethicon Endo-Surgery

Attachments:

1. Ethicon Endo-Surgery Urgent Product Correction Notification
2. AL12-08 Action Decision Chart

Contact: Alerts and Advisory Team at the National Center for Safety (734) 930-5890

ATTACHMENT 1: Ethicon Endo-Surgery Urgent Product Correction Notification



URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC® Hand Pieces (H P054) and HARMONIC® Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC® Generator 300 (GEN04)

April 2, 2012

Operating Room Directors and Materials Managers:

Ethicon Endo-Surgery (EES) has confirmed a compatibility issue that occurs between certain lot numbers of HARMONIC® Hand Pieces (HARMONIC® Hand Pieces - HP054 and HARMONIC® Blue Hand Pieces - HPBLUE) and the HARMONIC® Generator 300 (GEN04).

<p>Issue Detail</p>	<p>The issue is the result of a supplier component change to a chip in the HARMONIC® Hand Pieces (HP054 and HPBLUE) that communicates with the Generator 300 (GEN04). The issue occurs after successful set up and initial use of affected lots of HARMONIC® Hand Pieces (HP054 and HPBLUE) with the Generator 300 (GEN04). The procedure is interrupted when the Generator 300 (GEN04) goes into stand-by mode after one minute of cumulative activation time (approximately 10 activations). Once the Generator 300 (GEN04) goes into stand-by mode, the device cannot be activated to complete the procedure without fully re-setting the system. The issue will continue to occur each time the system is re-set and one minute of cumulative activation time is reached. Note: The Generator 300 (GEN04) only goes into stand-by mode <u>after</u> release of the activation button. The generator <u>will not</u> go into stand-by mode while the activation button is depressed (e.g.it does not stand-by during transection/coagulation). There have been no patient adverse events reported related to this issue.</p> <p>EES is working on a solution to resolve this issue. Our goal is to begin producing new compatible hand pieces in the July time frame, but it will take several months until we have the ability to fully meet global demand.</p>
<p>Note to GEN11 users</p>	<p>If your facility exclusively uses the EES Generator (GEN11), you <u>are not</u> impacted by this issue because all HARMONIC® Hand Pieces are compatible with the EES Generator (GEN11). However, we ask that you review the entire communication and complete the attached Business Reply Form (BRF) to confirm that you are aware of this issue.</p>
<p>Action Required 5-Steps</p>	<p>Please complete the following (5) Five Action Steps.</p> <ol style="list-style-type: none"> 1. Do not use the affected HARMONIC® Hand Pieces (HP054 and HPBLUE) with the Generator 300 (GEN04). However, you may still use these Hand Pieces and all disposable HARMONIC® devices with the EES Generator (GEN11). 2. Affix the enclosed Hand Piece compatibility labels to all Generator 300 (GEN04) generators in your facility. This label is intended to help your teams continue to identify non-compatible Hand Pieces while in the OR. See Appendix B for a guide on where to affix the Hand Piece compatibility labels on the generator. If you need additional labels, call 1-800-USE-ENDO, option 6.

ATTACHMENT 1 (continued)



URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC[®] Hand Pieces (H P054) and HARMONIC[®] Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC[®] Generator 300 (GEN04)

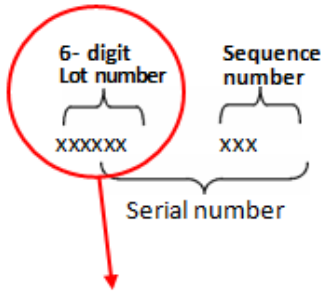
<p>Action Required <i>continued</i></p>	<ol style="list-style-type: none"> 3. You may return affected HARMONIC[®] Hand Pieces (HP054 and HPBLUE). If you choose this option, EES will issue your facility a credit based upon the invoice price of the returned product. Product return instructions are provided on the Business Reply Form (BRF). Note: EES is working with the hand piece component supplier on a solution to resolve the compatibility issue. See <i>Issue Detail</i> above. 4. Fill out the attached Business Reply Form (BRF) and fax it to Stericycle at 1- 888- 912-7091 within 3 business days of receipt of this letter, verifying receipt of this notification and any action steps you are taking to keep or return affected product. 5. Share this letter with all appropriate staff at your facility and post <i>Appendix A</i> in your inventory stocking area to help identify compatibility of your Hand Piece inventory. Note: Even if you do not currently have affected lots, please post <i>Attachment A</i> to help identify compatibility of future shipments.
<p>Questions, Comments, Complaints</p>	<ul style="list-style-type: none"> • See <i>Appendix C</i> for a list of Frequently Asked Questions (FAQs) • Questions about <i>this action</i>: call Stericycle at 877-542-5927 and reference Event 2634. • General Questions: call 1-800-USE-ENDO, option 6 • Complaints: call 1-800-USE-ENDO, option 5 • Email option: eestechsupport@its.jnj.com • A searchable listing of all affected lot numbers can be found at http://www.ees.com/handpiece. EES will continue to update this site as necessary. • As always, you may contact your local sales representative for support. • As with any medical device, adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program online, by regular mail or by fax. <ul style="list-style-type: none"> • Online: http://www.fda.gov/medwatch/report.htm • Regular Mail: Use postage-paid FDA form 3500 available at: http://www.fda.gov/MedWatch/getforms.htm and mail to: Med Watch 5600 Fishers Lane, Rockville, MD 20852-9787 • Fax: 1-800-FDA-0178



URGENT: PRODUCT CORRECTION NOTIFICATION
 Certain lots of HARMONIC® Hand Pieces (HP054) and HARMONIC® Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC® Generator 300 (GEN04)

Impacted Lots

Below is a reference table to help your teams identify **current** and **future** HARMONIC® Hand Pieces (HP054 and HPBLUE) that are not compatible with the HARMONIC® Generator 300 (GEN04). **Note:** Each hand piece has a unique nine character alpha numeric serial number, where:



Affected HARMONIC® HP054 Hand Pieces Lot Numbers produced to-date			
H92Y3M	J9039C	J90817	J90E7C
J9000C	J90432	J9084W	J90E7Z
J90029	J90470	J9088L	J90F3G
J9006C	J9054E	J9093L	J90F7Z
J9011D	J9056K	J9095C	J90G32
J90151	J9057V	J90974	J90G9Y
J9018H	J9058L	J90A45	J90H37
J9020F	J90624	J90A72	J90H4U
J9023D	J90681	J90C7X	J90H7D
J9027C	J9069F	J90C84	J90H9Y
J90314	J90726	J90D4N	J90J2N
J9034N	J90762	J90E0R	J90J8E
J9038W	J9076A	J90E29	

Affected HARMONIC® HPBLUE Hand Pieces Lot Numbers produced to-date			
J9001P	J9053N	J9091G	J90D84
J9005J	J9057E	J90A2C	J90E55
J9010E	J9065U	J90A64	J90F76
J9042G	J90696	J90C36	J90G4C
J9050E	J9086W	J90C7U	J90H46

Note: Until further notice, all future shipments of 6-digit lot numbers beginning with **J9xxxx** are also not compatible with the GEN04. For an updated list, or to search for a lot number, visit

ATTACHMENT 1 (continued)



URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC® Hand Pieces (H P054) and HARMONIC® Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC® Generator 300 (GEN04)

Locating lot numbers	<p>Each hand piece has a unique nine character alpha numeric code, where:</p> <div data-bbox="386 562 600 777"><p>6-digit lot number Sequence number</p><p>XXXXXXXX XXX</p><p>Serial Number</p></div> <p>The lot number is located on the cable at the base of the Hand Piece and on the side label of the single unit box.</p> <p>For your convenience, we've provided several options to help you identify affected Hand Piece lot numbers:</p> <ul style="list-style-type: none">• Table of affected lots numbers on the previous page• Product Identification Tool in <i>Appendix A</i>• A searchable listing of all affected lot numbers can be found at http://www.ees.com/handpiece. EES will continue to update this site as necessary.• Enclosed Hand Piece compatibility labels that should be placed on all Generator 300 (GEN04) in your facility. See <i>Appendix B</i> for a guide on where to affix the Hand Piece compatibility labels on the generator.
-----------------------------	--

We apologize for any inconvenience this issue may cause you and your staff. If you have additional questions, **please call 1-800-USE-ENDO, option 6, or contact your local sales representative.**

Regards,

Rick Sedlatschek

VP, Quality and Regulatory
Compliance Ethicon Endo-Surgery

ATTACHMENT 1 (continued)



URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC® Hand Pieces (HP054) and HARMONIC® Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC® Generator 300 (GEN04) Business Reply Form (BRF)

So that we can complete our records, please fill-out this Business Reply Form (BRF) and fax it to Stericycle at 1- 888-912-7091 within (3) three business days of receipt of this letter. Please reference Event 2634. Please make a copy of this form to include with your product return shipment.

Please check (v) all that apply:

- I acknowledge receipt of this letter.
- I confirm that my facility has Generator 300 (GEN04) generators and we have affixed the Hand Piece compatibility labels to all of our GEN04 generators. (Insert number of GEN04 generators below).
- My facility has the EES Generator (GENII) and we will continue to use our inventory of HARMONIC® Hand Pieces (HP054 and HPBLUE).
- My facility is returning HARMONIC® HP054 and/or HPBLUE Hand Pieces that are not compatible. Please follow instructions below for returning affected product for account credit.

Returning Affected Product

1. Ensure any used Hand Piece is cleaned according to the instructions within the IFU.
2. Below, provide the 9-digit serial number for each affected hand piece you are returning. This will support our effort to credit your account appropriately. See **Appendix A** for location of serial number (noted as Lot number on box).
3. Make a photocopy of your completed Business Reply Form(BRF), place it in the box with your cleaned or unused product, and affix the pre-printed UPS shipping label to return to Stericycle at :

Stericycle
 2670 Executive Drive, Suite A
 Indianapolis, IN 46241

HCS Account #:	
Your Name:	Facility Name:
Signed*:	Date:
Fax Number:	Telephone Number:
9-digit serial numbers if returning affected product for credit (see above):	Confirm number of GEN04 generators with stickers applied (if applicable):
Number of Hand Pieces returned:	
<i>*Your signature provides confirmation that you have received and understood this notification.</i>	



URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC[®] Hand Pieces (H P054) and HARMONIC[®] Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC[®] Generator 300 (GEN04)

Appendix A

Product Identification Tool

HARMONIC[®] Hand Pieces and HARMONIC[®] Blue Hand Pieces

This tool will help you identify the lot numbers on the Hand Piece devices and on the packaging. This document applies to the Hand Piece device and the single unit label (found on the single unit carton) for the following product codes:

- **HPBLUE**
- **HP054**

HARMONIC[®] Generators

This tool will help you identify whether you have a Generator 300 (GEN04) or an EES Generator G11 (GEN11).

Please note: There are no compatibility issues with the use of HARMONIC[®] Hand Pieces and EES Generator (GEN11).

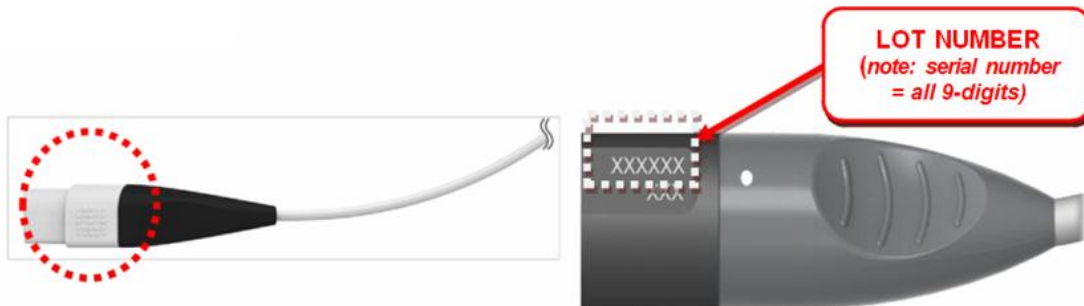


URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC® Hand Pieces (H P054) and HARMONIC® Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC® Generator 300 (GEN04)

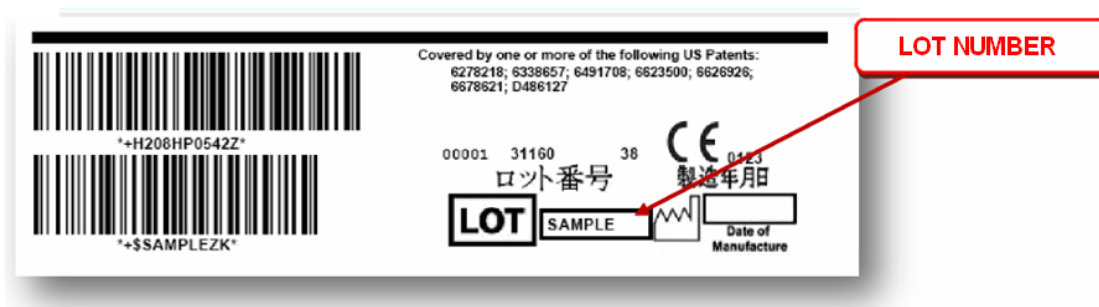
Lot Number Location
on HARMONIC® Hand Piece (HP054) and
HARMONIC® Blue Hand Piece (HPBLUE) Devices



The HARMONIC® Hand Piece devices have a lot number laser etched **on the power cord (plug end) of the device**. The diagram below indicates where to locate the number.



The lot number can also be found on the single unit barcode label of the HARMONIC® Hand Pieces carton as noted in the diagram below. The single unit label is found on the back panel of single unit carton.





URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC® Hand Pieces (H P054) and HARMONIC® Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC® Generator 300 (GEN04)
HARMONIC® Generators

This tool will help you identify whether you have a Generator 300 (GEN04) or an EES Generator (GEN11).

Please note: There are no compatibility issues with the use of HARMONIC® Hand Pieces and EES Generator (GEN11).

HARMONIC® Generator 300 (GEN04) - IMPACTED
Front Panel



HARMONIC® Generator G11 (GEN11) - NOT IMPACTED
Front Panel





URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC® Hand Pieces (H P054) and HARMONIC® Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC® Generator 300 (GEN04)

Appendix B

Hand Piece Compatibility Labels Placement Instructions



This tool provides placement instructions for the HARMONIC® Generator 300 (GEN04) Hand Piece Compatibility Labels. This label is intended to help your teams continue to identify non-compatible Hand Pieces while in the OR.

Enclosed are two labels that EES requests that you affix to the HARMONIC® Generator 300 (GEN04) units in your facility.

Label 1

Please affix to the front panel of the generator as shown.

Label 2

Please affix to right side panel as shown.



Please note: There are no compatibility issues related to the use of HARMONIC® Hand Pieces with the EES Generator (GEN11).



URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC[®] Hand Pieces (H P054) and HARMONIC[®] Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC[®] Generator 300 (GEN04)

Appendix C

<p>Frequently Asked Questions</p>	<p>Q. What are my options if I only have Generator 300 (GEN04) generators?</p> <p>A. Option 1: You may return any affected HARMONIC[®] Hand Pieces (HP054 and HPBLUE) that are not compatible with the GEN04 generator. If you choose this option, EES will issue your facility a credit based upon the invoice price of the returned product. Product return instructions are provided on the Business Reply Form (BRF).</p> <p>Note: EES is working with the hand piece component supplier on a solution to resolve the compatibility issue. Our goal is to begin producing new universally compatible hand pieces (compatible with both GEN04 and GEN11) in the July time frame, but it will take several months until we have the ability to fully meet global demand.</p> <p>Option 2: If you have Hand Pieces that are not identified as affected lots, you can still use these with your Generator 300 (GEN04).</p> <p>Option 3: Work with your EES Sales Representative to replace your Generator 300 (GEN04) generators with an EES Generator (GEN11) so that you can use all HARMONIC[®] Hand Pieces.</p> <p>Q. I do not have affected product. Why did I receive this notification?</p> <p>A. We are notifying all potential customers that order HARMONIC[®] Devices or HARMONIC[®] Hand Pieces, as future Hand Piece shipments may also be impacted (see lot identification on page 3).</p> <p>Q. Can I still use affected lots of HARMONIC[®] Hand Pieces (HP054 and HPBLUE) on the EES Generator (GEN11)?</p> <p>A. Yes. The compatibility issue only occurs between affected lots of the HARMONIC[®] Hand Pieces (HP054 and HPBLUE) and the Generator 300(GEN04).</p> <p>Q. What are my options if I have both the Generator 300 (GEN04) and EES Generator (GEN11):</p> <p>A. Option 1: You can continue to use all Hand Pieces with your EES Generator (GEN11).</p> <p>Option 2: If you have Hand Pieces <i>not</i> included in affected lots, you can still use them with your Generator 300 (GEN04). You may wish to separate your Hand Pieces that are only compatible with the EES Generator (GEN11) from those that are compatible with both generators. By using Hand Pieces compatible with <i>both</i> generators only with your Generator 300 (GEN04), you can optimize your inventory.</p>
--	---



URGENT: PRODUCT CORRECTION NOTIFICATION
Certain lots of HARMONIC® Hand Pieces (H P054) and HARMONIC® Blue Hand Pieces (HPBLUE) are not compatible with the HARMONIC® Generator 300 (GEN04)

Q. What is causing the issue?

A. The issue is the result of a supplier component change to a chip in the of HARMONIC® Hand Pieces (HP054 and HPBLUE) that communicates with the generator. EES is working with the supplier on a solution to resolve this issue. The issue only occurs with the Generator 300 (GEN04).

Q. When will this issue be resolved? When will I have Hand Pieces (HP054 and HPBLUE) that are compatible with the HARMONIC® Generator 300 (GEN04).

A. EES is working with the hand piece component supplier on a solution to resolve the compatibility issue. Our goal is to begin producing new universally compatible hand pieces (compatible with both GEN04 and GEN11) in the July time frame, but it will take several months until we have the ability to fully meet global demand.

Until we are able to resolve this compatibility issue, all orders for new Hand Pieces will be filled with Hand Pieces that are compatible only with the EES Generator (GEN11). You will be notified by us directly, as well as by your EES Sales Representative, when new Generator 300 (GEN04) compatible Hand Pieces are available.

ATTACHMENT 2: AL12-08 Action Decision Chart

AL12-08 Action Decision Chart			
	Only affected hand pieces in use at facility	Some affected hand pieces in use at facility	No affected hand pieces in use at facility
Only GEN04 Generators in use at facility	Remove and replace affected hand pieces <u>OR</u> Remove and replace GEN04 Generators	Remove and replace affected hand pieces <u>OR</u> Remove and replace GEN04 Generators	No Action needed
Both GEN04 & GEN11 Generators in use at facility	Remove and replace affected hand pieces OR Remove and replace GEN04 Generators	Remove and replace affected hand pieces OR Remove and replace GEN04 Generators	No Action needed
Only GEN11 Generators in use at facility	No Action needed	No Action needed	No Action needed

NOTE: For facilities with GEN04 Generators, affix the Hand Piece Compatibility Labels.