

Bard Parker Conventional Stainless Steel Surgical Blade #12B Alert (10/16)

Reason/Information:

Hill-Rom Issued a Voluntary Market Alert Notice on the following materiel. **Reason:** Hill-Rom has become aware that the Conventional Stainless Steel Surgical Blade catalog number 371712 lot 0095559 in a single unit package was incorrectly identified as 12 instead of 12B.

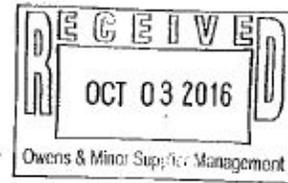
Disposition/Instructions:

Actions to be taken:

--Hill-Rom recommends contacting them if customers would like to return the blades for replacement.

If customers have questions regarding this notification, the POC may be reached by email at Pedro.Garcia@WelchAllyn.Com

Additional information may be found below.



Urgent: Medical Device Correction
2nd Notification

Subject: Bard Parker Conventional Blade Catalog 371712 Lot# 0095559

FSCA-identifier: 2016-021 / MODALP1248

Type of action: Corrective Action Notification

Date: September 30, 2016

To:

Chief Executive
Facility Risk Manager
Facility Administrator
Facility Engineer
Vigilance Manager
Biomedical
Engineering
Medical Device Liaison Officer

Affected device:

Conventional Stainless Steel Surgical Blade #12B Catalog 371712 Lot# 0095559

Background:

Hill-Rom has become aware that the Conventional Stainless Steel Surgical Blade catalog number 371712 lot 0095559 in a single unit package was incorrectly identified as 12 instead of 12B. One complaint has been received for this issue and has not resulted in any hazard or harm. Hill-Rom would like to remind customers that they have received the correct blades, all case units of packaging including the unit of sale package is properly identified. The incorrect identification is on the single unit level foil package as shown below:



Action to be taken by the user:

This notification is being sent out for customers to determine if you would like to keep the product as is or if you would prefer to return the blades for replacement. You will find enclosed the response form which must be returned to via mail, email or fax, who will process the responses. Please fill in the form clearly and legibly and check the proposed options. This will allow our local coordinator to manage the necessary elements and to follow up in a timely manner if necessary. In the meantime, please ensure that for the specific blades from this lot you may have in inventory, you maintain awareness of the incorrect identification prior to use.

Transmission of this Field Safety Notice:

Please communicate this Customer Medical Device Notification to all those who need to be aware within your organization and/or to any organization where the affected devices have been transferred

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action (if appropriate).

Contact reference person:

If you have any questions concerning this correction, please contact me at Pedro.Garcia@WelchAllyn.Com

Consumer Adverse Event Reporting:

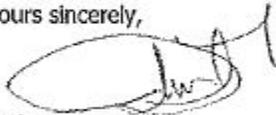
Adverse reactions or quality problems associated with this product may be reported to the FDA's MedWatch Adverse Event Reporting program, either online, by FAX, or by regular mail:

- Online: www.fda.gov/medwatch/report.htm
- FAX: 800-FDA-0178
- Regular mail: use the postage-paid FDA form 3500, available at www.fda.gov/medwatch/getforms.htm, and mail to:

MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

Your help and support in this matter is much appreciated. Please accept our sincere apologies for the inconvenience this situation may have caused.

Yours sincerely,



Pedro Garcia
QA/RA Manager
Management Representative



Aspen Surgical Company

CUSTOMER RESPONSE FORM/RECEIPT

Bard Parker Stainless Steel Surgical Blade – 128 Catalog 371712, lot # 0095559

Please complete and return this Response Form within 15 days. See instructions at bottom of page.

Customer Information

Facility Name: _____

Address: _____

City: _____ State: _____ *Zip: _____

Authorized Customer Contact:

Name: _____ Title: _____

Email: _____ Phone #: _____ Fax #: _____

We, the undersigned, acknowledge receipt of this letter:

Signature: _____ Date: _____

Check Action

Keep product and make an annotation of awareness prior to use.

Return product and request:

REPLACEMENT PRODUCT

or

CREDIT – Requested Refund Amount \$ _____

RMA # _____ Eaches Quantity to Return _____

Destroy product (I certify product was properly destroyed) and request:

REPLACEMENT PRODUCT – Requested replacement Quantity (Eaches) _____

or

CREDIT – Requested Refund Amount \$ _____

We want to be contacted by Hill-Rom for further information. (A Hill Rom representative will contact you as quickly as possible once receiving the response form)

Instructions:

- Please complete and return Response Form within 15 days
- If a RMA is needed for a product return, please call 616-698-7100 to receive return instructions.
- Return form via Mail, Fax, or Email:

Mail to: Elizabeth Lebron, Compliance Administrator
PO Box 2007
Las Piedras, PR 00771

Fax to: 787-912-2412 . Attention: Elizabeth Lebron

Email to: lebrone@aspensurgical.com