



Genesee

BIOMEDICAL, INC.

Design beyond standard

URGENT FIELD SAFETY NOTICE

Genesee BioMedical Sternal Retractor Blade(s)

FSCA Date: 12/28/15

Action: Advice for Inspection of Device

02/10/16

Attention: Elke Kerwick, MHRA

Details on affected Device(s):

Sternal Retractor Blade(s): Model numbers SR-SBL, SR-DBL, CSR-CB, CSR-SB, PSR-SB, PSR-NB & NSR-CR

Description of Problem:

Corrosion was found to have caused blade failure in a retractor that was more than 10 years old. In the area of the blade where the bearing/button meets the blade body, corrosion had formed, weakening the welded joint, causing the bearing/button to break.

Action to be taken by User:

Blades should be inspected regularly for corrosion or damage. Any blades that show signs of corrosion or noticeable wear should not be used.

The following information has been added to the Instructions for Use for these retractors. Please transfer this information to those departments responsible for cleaning, inspection and/or sterilization of surgical instruments.

“Inspect all parts after each and every use for any corrosion or suspected damage. If corrosion or damage is identified, do not use the corroded part. Contact Genesee BioMedical, Inc. for repair or replacement. Do not use parts from any other manufacturer. Use of parts from any other manufacturer may cause damage to the retractor. The use of parts from other manufacturers will void the warranty.”

Contact Information:

Jon Potter, QA Manager
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Denver, CO 80223-4509
Tel: (303) 777-3000 x110
Fax: (303) 777-8866
Email: jpotter@geneseebiomedical.com

EU Contact Information:

Greg Thomas
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Acknowledgement receipt

Please fax to the following number: 001 303 777 8866
Or email to: Shanna Flint at sflint@geneseebiomedical.com

Reference: FSCA-15- 03

<u>Product Code</u>	<u>Description</u>
SR-SBL	Adult Standard Blade
SR-DBL	Adult Deep Blade
CSR-CB	Child Blade
CSR-SB	Child Small Blade
PSR-SB	Pediatric Small Blade
PSR-NB	Pediatric Newborn Blade
NSR-CR	Neonate Curved Rack with Attached Neonate Blade

I have read and understood this Field Safety Notice and have distributed the current Instructions for Use (IFU) to all possibly impacted departments within my organization.

Hospital	
Department	
Address	
Postcode	City
Contact Name	
Job title	
Contact Telephone Number	
Contact E-mail Address	
Signature	Date :

This form must be returned to Genesee BioMedical before this action can be considered closed for your account.

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