

Patient Safety Alert

Veterans Health Administration Warning System
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- Item: Minor Surgery/Exam lights: CoolSpot™ and Outpatient® Fleximount™ Single Ceiling and Track Mount with Single Trolley manufactured by Burton Medical before August 2000. Specific model numbers are 0100540, 0100740, 0100580, 0102180 and 0102540.
- Specific Incident: Due to an inherent weakness in the original composition of the pivot support casting, the pivot joint can fail and the light may fall onto a patient. These lights are typically found in areas where minor surgeries, exams and/or procedures are performed.
- Action: If you have not already done so:
1. Review Burton Medical's notice (attached and available on-line at <http://www.burtonmedical.com/safetyNote.htm>).
 2. Identify and inspect all units affected by this alert for cracked pivot supports, and complete Burton Medical's form to obtain new pivot supports and arms.
 3. For identified lamps with cracked pivot supports - If possible, remove them from service. Otherwise:
 - a. Users: Inspect each light daily before use for normal movement and stability. If the light appears loose or unstable, contact Engineering to have it checked.
 - b. Engineering: Inspect identified lights every two weeks until new components are installed.
- Addl Information: Please contact CEOSH if you are affected and did not receive Burton Medical's original letter.
- Source: CEOSH, FDA and Manufacturer
- Contact: Sharon Anderson, Customer Service, Burton Medical at (800) 444-9909 X164.
- Paul Sherman, VA Center for Engineering & Occupational Safety and Health (CEOSH) at (314) 543-6712

March 2004

URGENT NOTICE:

MEDICAL DEVICE SAFETY CORRECTION PROGRAM

To: Users of Burton Medical Products CoolSpot™ and Outpatient® Fleximount™ ***Single Ceiling and Track Mount with Single Trolley*** (Model #'s 0100540, 0100740, 0100580, 0100780, 0102180 and 0102540) ***manufactured prior to August 2000.***

From: Wayne Okazaki
Quality Assurance Manager
Burton Medical Products

Re: Safety Replacement Program

Records supplied by our distributors indicate that you purchased one or more of the pre-2000 models listed above that are covered by Burton's SAFETY REPLACEMENT Program.

Due to an inherent weakness in the original composition of the pivot support casting, the switch assembly and extension arm for your Outpatient®/CoolSpot™ Fleximounts listed above should be replaced to prevent any risk of the light falling or separating from the ceiling mount. ***In keeping with a high quality standard, Burton Medical products will replace all pivot support and extension arms for single ceiling mount manufactured prior to August 2000.***

Please complete Attachment A and return to Burton Medical Products by APRIL 30, 2004. If you need assistance, please contact Sharon Anderson in Customer Service at (800) 444-9909 Ext. 164, fax to (800) 765-1770 or email sharona@burtonmedical.com.

Notes:

1. Units manufactured after July 2000 are not subject to this safety replacement. Pivot support-switch assemblies manufactured after July 2000 incorporate a single machined pivot that inherently limits the risk of the lightheads separating from the ceiling mounts.
2. Double Outpatient®/CoolSpot™ mounts are not subject to this safety replacement due to their pivot assembly design that inherently limits the rotation of the lightheads and prevents separation from the ceiling mount

APRIL 2004

Log No. _____

ATTACHMENT A

URGENT MEDICAL DEVICE SAFETY CORRECTION
COOLSPOT™ AND OUTPATIENT® FLEXIMOUNT™ SINGLE CEILING AND FASTRAC
MOUNT WITH SINGLE TROLLEY (MODEL #'S 0100540, 0100740, 0100580, 0100780,
0102180 AND 0102540) MANUFACTURED PRIOR TO AUGUST 2000.

Name of
Facility: _____

Contact
Person: _____

Address: _____

Telephone: _____ Email: _____

In order to determine if your unit(s) are affected by this Medical Device Safety Correction, please inspect the Burton lights at your facility and complete the following information (Quantity for both categories is required in order to prevent processing delays):

Units with model #'s covered by Safety Correction that:

A. Look like the attached drawing and NEED REPLACEMENT:
Serial Nos. _____ Qty. _____

B. Do not look like attached drawing and DO NOT APPEAR TO BE AFFECTED:
Serial Nos. _____ Qty. _____

After completing the above steps and information, please return to Burton Medical Products via fax at (800) 765-1770. Please contact Sharon Anderson, sharona@burtonmedical.com, at Burton within 30 days of the date of this letter.

