Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: October 30, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Quest Medical, Inc. – RECALL [Drug]

AFFECTED PRODUCT: Myocardial Protection System (MPS) Delivery Sets

SUMMARY: Unclassified Recall; The recall has been initiated because the product(s) have been found to intermittently exhibit a seal failure during use, which potentially could result in patient blood loss.

Recalled Product(s) were manufactured from May 2015 to September 2015 and distributed from June 2015 to September 2015.

The following models/UDI/ID numbers are subject to the recall:

MPS® Delivery Sets – Recall

Device Name	MPS Delivery Set w/arrest agent and additive cassettes, heat exchanger & 10 ft. delivery tubing	MPS Delivery Set with 6 ft. delivery tubing	MPS Low Volume Delivery Set
Device Model	01102	5001102-AS	7001102
UDI	00634624501126	00634624521124	00634624701120
Affected Lots	0491795E04, 0492175E04, 0492185E06, 0492195E06, 0492615E06, 0492625E08 0492635E08, 0489905Y04, 0490245Y06, 0493075U02, 0493085U02, 0493435U04 0493675U04, 0493685U07, 0494465U07, 0494475U09, 0494855G01, 0495215U11 0495225U11, 0495505G02, 0495515G02, 0496535G08, 0496875G08, 0496885G08 0497245S02	0492205E03 0493695U04 0494485U07 0495525G02 0497265S02	0492765E07

The recalled products were distributed nationwide.

SUGGESTED ACTION: For consumer inquiry only. Consumers with questions may contact the company via telephone at 1-800-627-0226 Monday through Friday between the hours of 9am and 5pm (CT). Consumer may also contact the company via e-mail at custserv@questmedical.com.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Recall: Firm Press Release
Quest Medical, Inc. Issues Recall of MPS® Delivery Set
FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

For Immediate Release

October 28, 2015

Contact

Consumers

custserv@questmedical.com
1-800-627-0226

Firm Press Release

One Allentown Parkway Allen, TX 75002 USA
800-627-0226/www.questmedical.com

On October 28, 2015, Quest Medical, Inc. initiated a nationwide recall of Myocardial Protection System (MPS) Delivery Sets, Models 5001102, 5001102-AS, and 7001102 of specified lots. The product(s) have been found to intermittently exhibit a seal failure during use, which potentially could result in patient blood loss.

There are no other recalls related to this product.

Consumers who have the applicable lots of the MPS Delivery Set(s) should cease use of the affected lots and contact Quest Medical, Inc. to return the product and request replacement. Additionally, consignees are being notified via written correspondence.

Recalled Product(s) were manufactured from May 2015 to September 2015 and distributed from June 2015 to September 2015.

The following models/UDI/ID numbers are subject to the recall:

MPS® Delivery Sets – Recall

Device Name	MPS Delivery Set w/arrest agent and additive cassettes, heat exchanger & 10 ft. delivery tubing	MPS Delivery Set with 6 ft. delivery tubing	MPS Low Volume Delivery Set
Device Model	5001102	5001102-AS	7001102
UDI	00634624501126	00634624521124	00634624701120
Affected Lots	0491795E04, 0492175E04, 0492185E06, 0492195E06, 0492615E06, 0492625E08 0492635E08, 0489905Y04, 0490245Y06, 0493075U02, 0493085U02, 0493435U04 0493675U04, 0493685U07, 0494465U07, 0494475U09, 0494855G01, 0495215U11 0495225U11, 0495505G02, 0495515G02, 0496535G08, 0496875G08, 0496885G08 0497245S02	0492205E03 0493695U04 0494485U07 0495525G02 0497265S02	0492765E07

The affected product lot information can be identified by product labeling on shipper and individual sterile trays.

Quest Medical, Inc. voluntarily recalled the applicable lots of MPS Delivery Sets after becoming aware of complaints alleging patient blood loss from the device during use. Quest Medical, Inc. has notified the FDA of this action.

The identified lots of MPS Delivery sets have shown a possible seal failure along the blood source channel of main pump cassette, resulting in blood loss from the bypass circuit and interruption of cardioplegia solution delivery. The firm has received twenty (20) complaints alleging this seal failure which have resulted in 16 instances of patient blood loss during surgery. There have been no reports of patient injuries as a result of the alleged issue to date. The firm has reported these events via the FDA MEDWATCH program.

Quest Medical, Inc. is notifying its distributors and customers by certified letter/return receipt and is arranging for return and replacement of all recalled product(s).

Consumers with questions may contact the company via telephone at 1-800-627-0226 Monday through Friday between the hours of 9am and 5pm (CT). Consumer may also contact the company via e-mail at custserv@questmedical.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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