THE METRIX COMPANY

FOR IMMEDIATE RELEASE

AUGUST 28, 2019

The Metrix Company
4400 Chavenelle Road
Dubuque Iowa, 52002
Contact: Michael Regan
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The Metrix Company of Dubuque, Iowa is recalling specific lots of the empty IV flexible containers (bag) marketed under the Metrix Secure EVA Dual Chamber and Baxter ExactaMix names, due to the potential for leaking of the IV bag at the chamber divider rod, which could result in a serious infection to the patient.

These bags are used for use in an intravenous admixture program, to store and deliver intravenous parenteral admixtures to patients. The empty bag is filled with parental admixtures by a healthcare provider (e.g. licensed pharmacist) under normal pharmacy conditions, e.g. laminar flow hood.

Product Name	**Product Code**	**Lot Number(s)**
1500 ml EVA Dual Chamber Bag – ExactaMix	H938901	63615- A1768, A1770, A1772, A2648, A2650, A2652, A2653, A2654, A2656, A2658, A2660, A2662, A3951, A3953, A3955, A3958, A3960, A3962, A3964, A3966, A3967, A5337, A5339, A5341, A5343, A5345, A5347, A5349
3000 ml EVA Dual Chamber Bag – ExactaMix	H938905	63630- A1769, A1771, A1773, A2647, A2649, A2651, A2655, A2657, A2659, A2661, A3950, A3952, A3954, A3956, A3957, A3959, A3961, A3963, A3965, A3968, A5338, A5340, A5342, A5344, A5346, A5348, A5350
1500 ml EVA Dual Chamber Bag - with Manifold	66616	A2442, A2524, A2725, A2906, A2974, A3033, A3309, A3310, A3318, A3520, A3554, A3559, A3737, A3773, A3794, A3977, A4081, A4147, A4443, A4516, A5064, A5281, A5410, A5550, A5669
3000 ml EVA Dual Chamber Bag - with Manifold	66631	A2443, A2564, A2629, A2772, A2975, A3004, A3311, A3456, A3483, A3553, A3558, A3738, A3774, A3795, A3978, A4082, A4148, A4444, A4517, A5065, A5282, A5411, A5555, A5670

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4000 ml EVA Dual Chamber Bag - with Manifold	66641	A2630, A2683, A3005, A3560, A3796, A3979, A4220, A4473, A4543, A5066, A5283, A5412, A5556, A5671
1500 ml EVA Dual Chamber Bag – Legless	66615	A3539, A5098
3000 ml EVA Dual Chamber Bag – Legless	66630	A2771, A4282
4000 ml EVA Dual Chamber Bag – Legless	66640	A2404, A4324

These products were supplied to distributors throughout the United States and Canada from 11/01/2016 thorough 07/29/2019.

The product code and lot number can be identified on the outer box label on the cardboard carton and on the outer bag label. The complete product identifier consists of a 5-digit product code with a unique 5-digit lot number after the hyphen.

The recall was initiated after receipt of eight complaints of leaking bags, in which the leak occurred near the divider rod and channel, when the rod was being removed. Use of the defective product, with a breach of the sterile barrier could result in serious infection to the patient. Subsequent investigation indicates the problem was caused by the assembly machine malfunction, creating additional stress on the rod, channel and bag film resulting in a potential to cause a material anomaly that is concealed until the rod is removed at the point of use.

No reports of death, illnesses or injuries have been reported to date from the use of this product.

Metrix is working with distributors and consumers to facilitate prompt return and replacement of the product affected by this recall, to minimize impact on patient therapy. Pharmacies who have purchased EVA Dual Chamber containers (bags), are urged to contact their distributor for further instructions on the return, see table for a complete list of product codes and lot numbers affected. Therefore:

1) Patients are urged to immediately inform their Healthcare Provider, if they observe a leaking bag. If a patient observes a leak, **DO NOT INFUSE THE BAG**
2) Healthcare Providers should consult with the patient and determine the benefit / risk of continuing the use of a recalled product versus awaiting replacement product. Healthcare Providers should inform the Pharmacist who dispensed the product of the leaking bag.

If the recalled product **is** intended for immediate use, and there is no alternative, your Healthcare Provider will make a determination on the risk/benefit associated with you using the potentially non-sterile product.

If product **is not** for immediate use, immediately discontinue use of the product and contact the place of purchase or pharmacy for further instructions for returning and replacing the affected product.

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Consumers with questions about this recall, including facilitating replacement product, may contact The Metrix Company at 1-800-752-3148, Monday through Friday, 8:00 AM to 5:00 PM Central time or email; recallcoordinator@metrixco.com. The Metrix Company regrets any inconvenience this may cause and is committed to patient safety and customer satisfaction.

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
- Regular Mail or Fax: Download form 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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