IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA
MINNEAPOLIS DIVISION

DEBRA CAMPBELL,	§	
	§	
PLAINTIFF,	§	CIVIL ACTION NO. _____
	§	
VS.	§	
	§	**JURY DEMANDED**
TORAX MEDICAL, INC., AND	§	
ETHICON, INC.	§	
	§	
DEFENDANTS.	§	

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff Debra Campbell files this, her Original Complaint, against Defendants Torax Medical, Inc. and Ethicon Inc., and respectfully states follows:

I.
Preliminary Statement

Defendant's Torax Medical, Inc. and Ethicon, Inc. manufactured a defective medical device such that Plaintiff suffered significant injury. Here, a defectively manufactured LINX was surgically implanted in Plaintiff to control her gastroesophageal reflux disease (GERD). After the LINX was implanted in Plaintiff, Defendants became aware of the manufacturing defect in Plaintiff's LINX. Defendants recalled Plaintiff's LINX as well as numerous other LINX devices in the United States and European Union. Moreover, Defendants admit that Plaintiff's LINX was defectively manufactured.

Here, Plaintiff seeks to vindicate her rights at law for having to experience a severe recurrence of her GERD symptoms and undergo another invasive surgery to remove the defective

LINX. Plaintiff also faces another invasive surgery to fix what she thought had been corrected by the LINX. This, as a result of the Defendants' defective manufacture of the LINX..

II.

Parties

1. Plaintiff Debra Campbell is a resident of the State of Texas.

2. Defendant Torax Medical, Inc. (Torax) is a Delaware corporation with its headquarters and principal place of business in Shoreview, Minnesota. Torax may be served with process through its registered agent, The Corporation Trust Company at 1209 Orange St., Wilmington, Delaware 19801, or wherever it may be found. While headquartered in Minnesota, Torax's medical devices, including the LINX, are distributed, marketed, sold, and used on medical patients in all fifty United States, including Minnesota, and the European Union. Therefore, Torax is subject to personal jurisdiction in the State of Minnesota.

3. Ethicon, Inc. (Ethicon) is a New Jersey corporation with its headquarters and principal place of business in the State of New Jersey. Ethicon may be served with process through its registered agent Johnson & Johnson, at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-0000, or its president Nefertiti Green, at Johnson & Johnson, Rt. 22 West, Somerville, New Jersey 08876, or wherever he may be found. While headquartered in New Jersey, Ethicon's medical devices, including the LINX, are distributed, marketed, sold, and used on medical patients in all fifty United States, including Minnesota, and the European Union. Therefore, Ethicon is subject to personal jurisdiction in the State of Minnesota.

III.

Jurisdiction & Venue

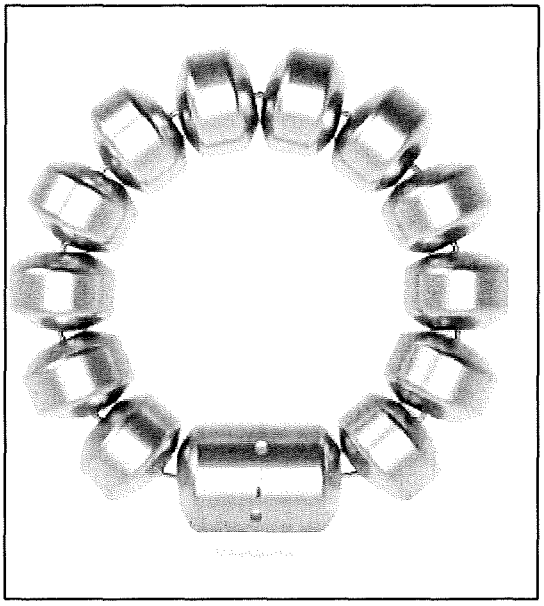
4. This Court has jurisdiction over this proceeding pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds $75,000.00.

5. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b)(1) and (2).

IV.

Facts Applicable to All Counts

6. This case arises from the defective manufacturing by Defendants Torax and Ethicon of a medical device known as the "LINX Reflux Management System" ("LINX"). LINX is a titanium bead-and-wire ring surgically implanted around a patient's lower esophageal sphincter (LES) to augment the LES and prevent acid reflux. These devices can only be implanted surgically, and they are used to treat gastroesophageal reflux disease (GERD) which is a disease predominately suffered by the elderly.

 [1]

[1] https://www.jnj.com/innovation/johnson-johnson-medical-innovations-reshaping-future-surgery

7. The LINX required pre-market approval by the Food & Drug Administration prior to it being placed in the stream of commerce and used on patients in the United States and the European Union. Specifically, in December 2010, Defendant Torax applied for this pre-market approval, including its manufacturing process, and this approval was granted on March 22, 2012. The LINX is considered a "restricted" device, meaning it is subject to numerous FDA regulations regarding the manufacture, distribution, and marketing of the device.

8. Defendant Ethicon, Inc. (Ethicon) is the parent-corporation for Defendant Torax and participated in the manufacture, distribution, and post-market surveillance of the LINX.

9. On May 31, 2018, Defendant Torax initiated a recall of numerous LINX due to "an out of specification condition" which would allow "a bead component to separate from an adjacent wire link."[2] This means that the LINX device, normally a continuous loop, would become discontinuous and open due a defect resulting from improper manufacture.

T O R A X

URGENT: FIELD SAFETY NOTICE (REMOVAL)
LINX® Reflux Management System

Torax has become aware of an out of specification condition which may affect a small number of devices and allow a bead component to separate from an adjacent wire link. This condition may result in a discontinuous or open LINX device.

This recall, classified as a Class 2 recall, is considered by the FDA as "a method of removing...products that are in violation of laws" administered by the FDA. FDA records show that there were 9,131 LINX devices in the stream of commerce as of May 2018.

[2] *See* Exhibit "A" – Notice of Recall

10. A 15-bead LINX was surgically implanted in Plaintiff on September 28, 2016. This LINX was subject to the recall described in ¶ 6.

11. Plaintiff had her defective LINX removed on September 25, 2019.

12. Plaintiff alleges that Defendants Torax and Ethicon manufactured the LINX which was implanted in Plaintiff and subsequently failed due to a manufacturing defect. Plaintiff alleges that Defendants Torax and Ethicon placed Plaintiff's LINX device into the stream of commerce. Plaintiff alleges that Defendants Torax and Ethicon are corporations who regularly design, test, assembly, manufacture, sell, and distribute medical devices intended for human use.

V.
Causes of Action

A. Manufacturing Defect As to Defendant Torax – Strict Liability

13. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from, in strict liability for product defect, from Defendant Torax for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

14. Specifically, the LINX implanted in Plaintiff was manufactured in violation of the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and federal regulations promulgated under these laws and administered by the FDA. The device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications approved by the FDA and provided by Defendant Torax for its pre-market approval. Plaintiff's LINX was also manufactured in deviation of Current Good Manufacturing Practice requirements. The LINX was also defectively manufactured in violation of Minnesota law that parallels federal requirements.

15. Specifically, Defendant Torax was required to manufacture the defective LINX device according to Federal Regulations, including but not limited to the following, and failed to do so in:

- 21 CFR 820.5 – failure to establish and adhere to a quality system to prevent the manufacture of defective LINX;
- 21 CFR 820.20 – failure to adhere to approved quality system procedures;
- 21 CFR 820.70(a),(g), (h), (i) – failure to control production processes to ensure device conformance with specifications;
- 21 CFR 820.72 – failure to inspect, measure, and test manufacturing equipment and materials such that the LINX was defectively manufactured;
- 21 CFR 820.75 – failure to adhere to process validation and implement process validation such that the LINX was placed in the stream of commerce in a defective condition;
- 21 CFR 820.90 – failure to prevent non-conforming product, e.g. Plaintiff's LINX, from entering the stream of commerce in a defective condition;
- 21 CFR 820.100 – failure to implement corrective processes and preventative actions due to nonconformities.

16. As a result of Defendant Torax's violations of federal regulation, approved-manufacturing process, and manufacturing standard of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Torax, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

17. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

B. Manufacturing Defect As to Defendant Torax – Negligence

18. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from Defendant Torax for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

19. Specifically, Defendant Torax owed Plaintiff a duty of ordinary care as would a reasonable and prudent manufacturer of medical devices to manufacture the LINX such that it would be safe for its intended use. Plaintiff alleges that Defendant Torax failed to use ordinary care by various acts and omissions, which constitute negligence, in at least the following ways:

- Failure to manufacture the LINX consistent with approved manufacturing standards such that it was defective and unreasonably dangerous for its intended use;
- Failure to manufacture the LINX consistent with approved design such that it was defective and unreasonably dangerous for its intended use;
- Failure to test and inspect the device prior to placing it in the stream of commerce in a defective and unreasonably dangerous condition; and
- Failure to prevent the defectively manufactured device from entering the stream of commerce in a defective and unreasonably dangerous condition.

20. As a result of Defendant Torax's breach of its duty of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Torax, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

21. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

C. Manufacturing Defect As to Defendant Torax – Negligence Per Se

22. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from, in negligence per se, from Defendant Torax for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

23. Specifically, the LINX implanted in Plaintiff was manufactured in violation of the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and federal regulations promulgated under these laws and administered by the FDA. The device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications approved by the FDA and provided by Defendant Torax for its pre-market approval. Plaintiff's LINX was also manufactured in deviation of Current Good Manufacturing Practice requirements. The LINX was also defectively manufactured in violation of Minnesota law that parallels federal requirements.

24. Specifically, Defendant Torax was required to manufacture the defective LINX device according to Federal Regulations, including but not limited to the following, and failed to do so in:

- 21 CFR 820.5 – failure to establish and adhere to a quality system to prevent the manufacture of defective LINX;
- 21 CFR 820.20 – failure to adhere to approved quality system procedures;
- 21 CFR 820.70(a),(g), (h), (i) – failure to control production processes to ensure device conformance with specifications;

- 21 CFR 820.72 – failure to inspect, measure, and test manufacturing equipment and materials such that the LINX was defectively manufactured;
- 21 CFR 820.75 – failure to adhere to process validation and implement process validation such that the LINX was placed in the stream of commerce in a defective condition;
- 21 CFR 820.90 – failure to prevent non-conforming product, e.g. Plaintiff's LINX, from entering the stream of commerce in a defective condition;
- 21 CFR 820.100 – failure to implement corrective processes and preventative actions due to nonconformities.

25. These violations constitute negligence per se.

26. As a result of Defendant Torax's violations of federal regulation, approved-manufacturing process, and manufacturing standard of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Torax, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

27. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

D. Manufacturing Defect As to Defendant Ethicon – Strict Liability

28. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from, in strict liability for product defect, from Defendant Ethicon for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

29. Specifically, the LINX implanted in Plaintiff was manufactured in violation of the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and federal regulations promulgated under these laws and administered by the FDA. The device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications approved by the FDA. Plaintiff's LINX was also manufactured in deviation of Current Good Manufacturing Practice requirements. The LINX was also defectively manufactured in violation of Minnesota law that parallels federal requirements.

30. Specifically, Defendant Ethicon was required to manufacture the defective LINX device according to Federal Regulations, including but not limited to the following, and failed to do so in:

- 21 CFR 820.5 – failure to establish and adhere to a quality system to prevent the manufacture of defective LINX;
- 21 CFR 820.20 – failure to adhere to approved quality system procedures;
- 21 CFR 820.70(a),(g), (h), (i) – failure to control production processes to ensure device conformance with specifications;
- 21 CFR 820.72 – failure to inspect, measure, and test manufacturing equipment and materials such that the LINX was defectively manufactured;
- 21 CFR 820.75 – failure to adhere to process validation and implement process validation such that the LINX was placed in the stream of commerce in a defective condition;
- 21 CFR 820.90 – failure to prevent non-conforming product, e.g. Plaintiff's LINX, from entering the stream of commerce in a defective condition;

- 21 CFR 820.100 – failure to implement corrective processes and preventative actions due to nonconformities.

31. As a result of Defendant Ethicon's violations of federal regulation, approved-manufacturing process, and manufacturing standard of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Ethicon, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

32. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

E. Manufacturing Defect As to Defendant Ethicon – Negligence

33. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from Defendant Ethicon for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

34. Specifically, Defendant Ethicon owed Plaintiff a duty of ordinary care as would a reasonable and prudent manufacturer of medical devices to manufacture the LINX such that it would be safe for its intended use. Plaintiff alleges that Defendant Ethicon failed to use ordinary care by various acts and omissions, which constitute negligence, in at least the following ways:

- Failure to manufacture the LINX consistent with approved manufacturing standards such that it was defective and unreasonably dangerous for its intended use;
- Failure to manufacture the LINX consistent with approved design such that it was defective and unreasonably dangerous for its intended use;

- Failure to test and inspect the device prior to placing it in the stream of commerce in a defective and unreasonably dangerous condition; and
- Failure to prevent the defectively manufactured device from entering the stream of commerce in a defective and unreasonably dangerous condition.

35. As a result of Defendant Ethicon's breach of its duty of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Ethicon, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

36. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

F. Manufacturing Defect As to Defendant Ethicon – Negligence Per Se

37. Plaintiff incorporates the above paragraphs and would show the Court that she is entitled to recover from, in negligence per se, from Defendant Ethicon for the defective manufacture of the LINX device surgically-implanted in Plaintiff.

38. Specifically, the LINX implanted in Plaintiff was manufactured in violation of the Federal Food, Drug, and Cosmetic Act, the Medical Device Amendments, and federal regulations promulgated under these laws and administered by the FDA. The device implanted in Plaintiff was manufactured in deviation from the manufacturing specifications approved by the FDA. Plaintiff's LINX was also manufactured in deviation of Current Good Manufacturing Practice requirements. The LINX was also defectively manufactured in violation of Minnesota law that parallels federal requirements.

39. Specifically, Defendant Ethicon was required to manufacture the defective LINX device according to Federal Regulations, including but not limited to the following, and failed to do so in:

- 21 CFR 820.5 – failure to establish and adhere to a quality system to prevent the manufacture of defective LINX;
- 21 CFR 820.20 – failure to adhere to approved quality system procedures;
- 21 CFR 820.70(a),(g), (h), (i) – failure to control production processes to ensure device conformance with specifications;
- 21 CFR 820.72 – failure to inspect, measure, and test manufacturing equipment and materials such that the LINX was defectively manufactured;
- 21 CFR 820.75 – failure to adhere to process validation and implement process validation such that the LINX was placed in the stream of commerce in a defective condition;
- 21 CFR 820.90 – failure to prevent non-conforming product, e.g. Plaintiff's LINX, from entering the stream of commerce in a defective condition;
- 21 CFR 820.100 – failure to implement corrective processes and preventative actions due to nonconformities.

40. These violations constitute negligence per se.

41. As a result of Defendant Ethicon's violations of federal regulation, approved-manufacturing process, and manufacturing standard of care, Plaintiff's LINX was defectively manufactured and failed as a result of that defect. At the time the LINX device left the control of Defendant Ethicon, it was outside of manufacturing specification and was unreasonably dangerous due to its defective manufacture.

42. Each of the foregoing violations, whether taken singularly or in any combination, were a proximate cause of Plaintiff's injuries and damages which are described in more detail above and below. Plaintiff seeks compensatory damages, jointly and severally.

VI.

Damages

43. Plaintiff suffered, as a proximate and direct result of the wrongful actions and/or omissions of the Defendants in this matter, each of the following damages:

A. Reasonable medical care and expenses in the past. These expenses were incurred by the Plaintiff for the necessary care and treatment of the injuries resulting from the manufacturing defect alleged and such charges are reasonable and were usual and customary charges for such services;

B. Reasonable and necessary medical care and expenses which will in all reasonable probability be incurred in the future;

C. Physical pain and suffering in the past;

D. Physical pain and suffering which will in all reasonable probability be suffered in the future;

E. Mental anguish sustained in the past;

F. Mental anguish that, in reasonable probability, Plaintiff will sustain in the future;

G. Physical impairment in the past;

H. Physical impairment which, in all reasonable probability, will be suffered in the future;

I. Disfigurement; and

J. Costs of Court.

VI.

Request for Jury Trial

Pursuant to Federal Rule of Civil Procedure 38, Plaintiff makes her demand for trial by jury on all issues so triable.

VII.

Prayer

Plaintiff request that the Court award her the following relief against the Defendants above as may be appropriate:

(1) A Judgment awarding actual, compensatory, damages in the amount of not less $1,000,000.00;

(2) Costs of court;

(3) Pre- and post-judgment interest at the highest legal rate allowed by law from the earliest time allowed by law; and

(4) All other relief to which Plaintiff is justly entitled.

Respectfully submitted,

/s/ Ashleigh Raso

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Pro hac vice motions pending

EXHIBIT "A"

T O R A X MEDICAL INC

URGENT: FIELD SAFETY NOTICE (REMOVAL)

LINX® Reflux Management System

(Product Codes LX-xx and LXM-xx)

[Date]

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

Torax Medical, Inc ("Torax") is issuing a Field Safety Notice (removal) of certain lots of the LINX® Reflux Management System, identified below. Competent Authorities are aware of this action.

Our records indicate that you have ordered the **LINX Reflux Management System** and may have received the product lots subject to this recall. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL PERSONNEL RESPONSIBLE FOR or WHO MAY USE the LINX Reflux Management System in your facility.**

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING
LINX Reflux Management System Lot Numbers.

PRODUCT NAME	PRODUCT CODE	LOT NUMBERS (Between)	DESCRIPTION / SIZE
LINX Reflux Management System	LX-xx	6100 through 14055, 14122, 14423, 15288, 15316	Implant, Clasp, 12-16 Bead, 0.7T
LINX Reflux Management System	LXM-xx		Implant, Clasp, 13-16 Bead, 1.5T

Torax has become aware of an out of specification condition which may affect a small number of devices and allow a bead component to separate from an adjacent wire link. This condition may result in a discontinuous or open LINX device.

If a device separation occurs following implantation, risk to patients may include the following:

1) Recurrence of Gastroesophageal reflux disease (GERD) symptoms
2) Need for surgical intervention to remove and/or replace the LINX Reflux Management System

The issue may not be readily detectable during the procedure by the implanting physician but may be detected by the physician or patient postoperatively. If a patient has a recurrence of GERD symptoms, physicians should consider the use of x-ray imaging to aid in determining if a device separation has occurred. **Torax does not recommend explantation of the device unless a separation has been confirmed through the use of x-ray imaging and the treating physician determines explantation to be an appropriate option for the patient.**

Even if your facility no longer has affected lots in stock, you may have patients who may warrant further diagnostic assessment (i.e. x-rays) because they previously received impacted product and now exhibit a recurrence of their GERD symptoms.

URGENT: FIELD SAFETY NOTICE (REMOVAL)
LINX® Reflux Management System
(Product Codes LX-xx and LXM-xx)

ACTION REQUIRED: NEXT STEPS and IDENTIFICATION OF THE PRODUCT LOTS SUBJECT TO THIS RECALL:

1. Refer to Attachment 1 for assistance in identifying the product lots subject to this recall. Examine your inventory immediately to determine if you have any products subject to this recall on hand and quarantine such product(s).

2. Remove the products subject to this recall from your inventory and communicate the issue to all relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. If any of the devices subject to this recall have been forwarded to another facility, please contact that facility to arrange return.

3. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and return it to Torax Medical, Inc. within **three (3)** business days via email at brf@toraxmedical.com. **Please return the BRF even if you do not have the product lot subject to this recall.** Please feel free to contact your Torax Sales Representative if you need assistance completing the BRF.

4. Customers are required to return all unused LINX Reflux Management System subject to this recall that are in their inventory immediately. Only unused LINX Reflux Management System subject to this recall will be eligible for replacement.

5. To return unused LINX Reflux Management System subject to this recall, photocopy the completed BRF, place it in the box with the subject product(s), and do one of the following: 1) Affix the pre-paid authorized shipping label and invoice included with this notification letter and ship the devices directly to Torax Medical or 2) Contact your Distributor and coordinate shipment of affected devices to them. To help facilitate shipment of the device(s), please contact your Torax Sales Representative or contact the Quality First International at the telephone number below.

If you have additional questions regarding this Field Safety Notice, please contact Authorized Representative, Quality First International (QFI) at +44 (0) 208 221 2361.

At Torax Medical, Inc., our first priority is to support the needs of our customers and their patients, and that includes promoting the safe and effective use of our products. We recognize that this recall is disruptive to your facility and we apologize for any inconvenience it may cause.

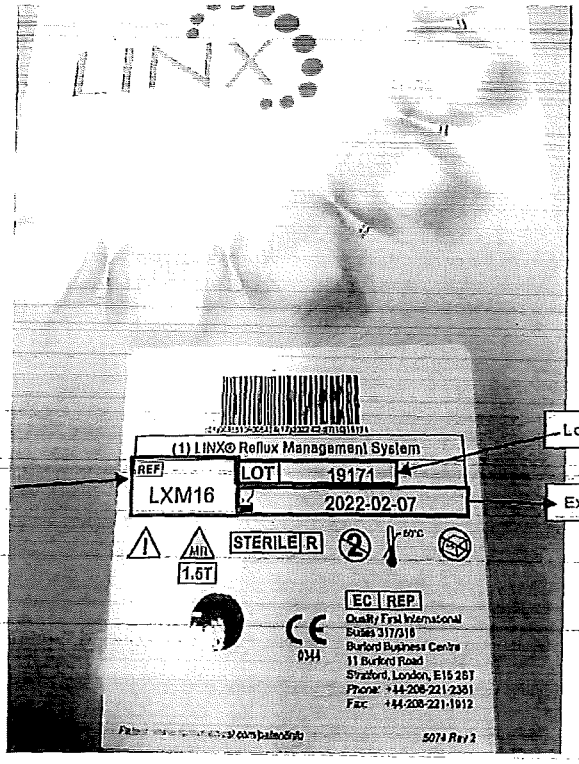
Attachments:
Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form

URGENT: FIELD SAFETY NOTICE (REMOVAL)
LINX® Reflux Management System
(Product Codes LX-xx and LXM-xx)

ATTACHMENT 1: Product Identification Tool for LINX Reflux Management System (See Table 1 for affected product codes and lots.)

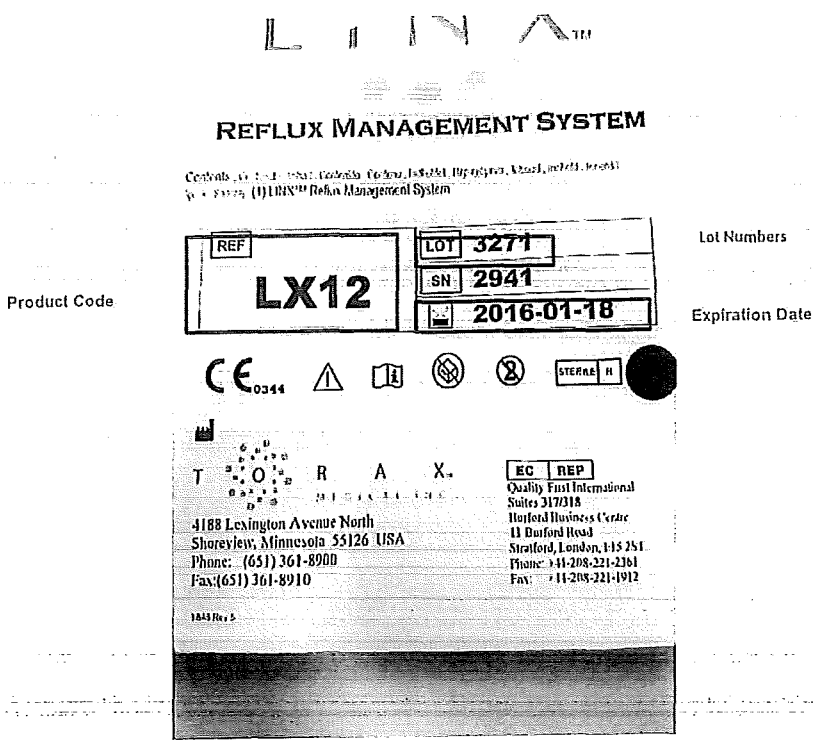
This tool will help customers identify the product lot of LINX Reflux Management System subject to this recall. Please refer to the table above for the product expiration dates subject to this recall.

1.5T LINX® CARTON (Model Number LXM-xx)



URGENT: FIELD SAFETY NOTICE (REMOVAL)
LINX® Reflux Management System
(Product Codes LX-xx and LXM-xx)

0.7T LINX® CARTON (Model Number LX-xx)



Product Code

Lot Numbers

Expiration Date

URGENT: FIELD SAFETY NOTICE (REMOVAL)
LINX® Reflux Management System
(Product Codes LX-xx and LXM-xx)

[Account Name]
[Account Address]
[Customer Number]

ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and return this form to brf@toraxmedical.com **within 3 business days, even if you do not have the product subject to this recall to return.**

If you have product subject to this recall to return, please make a photocopy of your completed BRF and enclose with your return and ship the product and copy of the form to Torax Medical using the pre-paid FedEx shipping label provided. Thank you for your cooperation.

Product Inventory – Please check one:

☐ **We have NO remaining LINX Reflux Management System subject to this recall.**

☐ **We have LINX Reflux Management System subject to this recall and are returning the product listed below and requesting replacement product.**

PRODUCT NAME	PRODUCT CODE	LOT #	Quantity Returning (Eaches)
~~Print Name of Person Completing Form:~~		~~Telephone Number:~~	
Signed*: **Your signature provides confirmation that you have received and understood this notification*		~~Date:~~	
LINX Reflux Management System			