April XX 15, 2017

MEDICAL DEVICE LABELING CORRECTION/RECALL

LIPIFLOW® SYSTEM ACTIVATOR (DISPOSABLE)

cc Chairman Medical Board and relevant Head of Departments

Customer Name
Address
Address
Address

Dear TearScience Partner:

The purpose of this letter is to advise you that TearScience is correcting the labeled storage temperature conditions for Activator Model LFD-1000, used as part of the LipiFlow® Thermal Pulsation System. The LipiFlow® System is intended for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye.

Reason for Labeling Correction:

The Activator Package Label, Box Label, Package Insert and the LipiFlow® System Instructions for Use distributed between January 1, 2014 and February 3, 2017 specify 10°C to 40°C for the Activator storage temperature. TearScience intended that the Activator would be stored in a temperature-controlled room environment (with heat and air conditioning) with allowance for occasional temperature fluctuations between 10°C and 40°C, as supported by product testing.

Upon review of the Activator labeling, the U.S. Food and Drug Administration (FDA) brought to our attention that the labeled storage temperature should be consistent with the temperature conditions tested for the entire duration of the shelf-life. Therefore, the storage temperature on the Activator Package and Box Labels has been revised to specify, "**Store at controlled room temperature**." The revised Activator Package Insert and LipiFlow® System Instructions for Use specify the following conditions as supported by testing: "**Store the Activator at controlled room temperature (20°C to 25°C) with short-term (< 72 hours) excursions permitted between 5°C and 38°C.**"

There have been no reports of any problems with the Activator package or the device related to the storage temperature conditions. In addition, there have been no adverse events associated with the labeled Activator storage temperature conditions.

Risk to Health:

Product testing demonstrates there is no risk to patient health if the Activator is stored in a controlled room temperature environment (with heat and air conditioning), such as a physician's office or clinic. Testing also demonstrates that the Activator package and device can withstand temporary temperature fluctuations to the extremes of the 10°C and 40°C range. Furthermore, there are no data indicating that the Activator package or the device would be adversely affected if exposed to the extremes of the labeled range for an extended period.

Storage in an environment that is not temperature-controlled (without heat and air conditioning) is not expected because this environment would likely result in temperatures outside of the labeled limits of 10°C and 40°C based on diurnal and seasonal variation. However, testing has not been conducted to evaluate Activator storage at the extreme temperatures over the entire four-year shelf life. Therefore, if the packaged device is stored in uncontrolled temperature environment (without heat and air conditioning) for an extended time, possible risk of compromise to the Activator package or device cannot be ruled out. A comprehensive risk assessment determined that if the Activator package integrity or device were compromised, there is a potential for minor or temporary injury to the patient.

How to Recognize if the Activator Package or Device is Compromised:

As stated in the existing Activator Package Insert and LipiFlow® System *Instructions for Use*, inspect the package for damage prior to use to ensure the package is intact. **Do not use Activator (Disposable) if the package is open or damaged.** Inspect the Activator lid warmer, eye cup and handle prior to use to ensure that there are no rough or sharp edges. **Do not use Activator (Disposable) if it appears broken or has rough surfaces upon inspection**.

Actions to be Taken by Customer:

Within 10 business days of receipt of this letter, please take the following actions:

1) Complete the enclosed Acknowledgement and Receipt form and return the form by email or mail.

2) If you have stored Activators in an environment that is not temperature-controlled (without heat and air conditioning), discontinue use of these Activators and contact TearScience at customerservice@tearscience.com or contact your TearScience sales representative.

Product and Distribution Information Table				
Product Name	**Model Number**	**Lot Numbers**	**Distribution Dates**	**Expiration Date (MM/YYYY)**
LipiFlow System	LFD-1000	Lots between	January 1, 2014 to	07/2017 to

Activator (Disposable)		distribution dates	February 3, 2017	02/2021

Type of Action by the Company:

A list of Frequently Asked Questions, the revised LipiFlow® Activator Package Insert and the revised LipiFlow® System Instructions for Use are enclosed. These documents specify the corrected Activator storage temperature.

NOTE:

- The LipiFlow® System Help File is a prior version of the LipiFlow® System Instructions for Use. Please disregard the Help File and refer to the enclosed, revised LipiFlow® System Instructions for Use. The Help File will be addressed soon.

For any questions regarding this letter, please contact TearScience at customerservice@tearscience.com or contact your TearScience sales representative. We want to thank you for being a valuable TearScience partner, and as always would like to thank you for your business, your trust, and your commitment to treating MGD.

Sincerely,

Stephen Beversluis
Vice President, Quality

Attachments:

- Acknowledgement and Receipt Form
- Frequently Asked Questions
- Revised LipiFlow® Activator Package Insert
- Revised LipiFlow® System Instructions for Use

MEDICAL DEVICE LABELING CORRECTION/RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

cc Chairman Medical Board and relevant Head of Departments

Customer Name
Address
Address
Address

LIPIFLOW® SYSTEM ACTIVATOR (DISPOSABLE)

Model LFD-1000 distributed between Jan. 1, 2014 and Feb. 3, 2017

1. I have read and understand the labeling correction and recall instructions provided in the April XX, 2017 letter.

Yes ☐ No ☐

2. Have you stored your Activators in a controlled room temperature environment (with heat and air conditioning)?

Yes ☐ No ☐

If **No**, please explain:

_____

_____

_____

If you have stored Activators in an environment that is not temperature-controlled (without heat and air conditioning), discontinue use of these Activators and contact TearScience at customerservice@tearscience.com or contact your TearScience sales representative.

3. Any adverse events associated with a compromise to the Activator package or device that may be related to storage temperature?

Yes ☐ No ☐

If **Yes**, please explain:

_____

_____

_____

4. Return Response Box:

Please provide any additional information, if applicable.

5. Questions:

☐ Please have TearScience or my sales representative contact me.

6. Signature of Receipt: _____

Name/Title	
Telephone	
Email address	

Please scan and email this completed form to: customerservice@tearscience.com

OR mail this completed form to:

TearScience
ATTN: Activator Labeling Change
5151 McCrimmon Parkway, Suite 250
Morrisville, NC 27560 USA