

2020年11月30日

お客様各位

コーニングインターナショナル株式会社
ライフサイエンス事業部**Transwell® 製品 1製品 製品名およびラベル・製品規格書・
品質保証書一部表記変更のご案内**

拝啓 時下ますますご清栄のこととお喜び申し上げます。日頃より当社製品をご愛用いただき誠にありがとうございます。

さて、このたびトランズウェル トランズウェルクリアー 24ウェル 8.0 μm 細胞培養表面処理済み（カタログ番号：3464）の製品名が下記の通り変更となります。これに伴い、ラベル、製品規格書、品質保証書の表記も一部変更となります。

本変更は、定義を明確にし、実際の製造や試験内容と一致させることを目的としたものです。製品の製造工程や製品そのものに変更はございません。

敬具

記

対象製品

カタログ番号	製品名
3464	トランズウェルクリアー 24 ウェル 8.0 μm 細胞培養表面処理済み

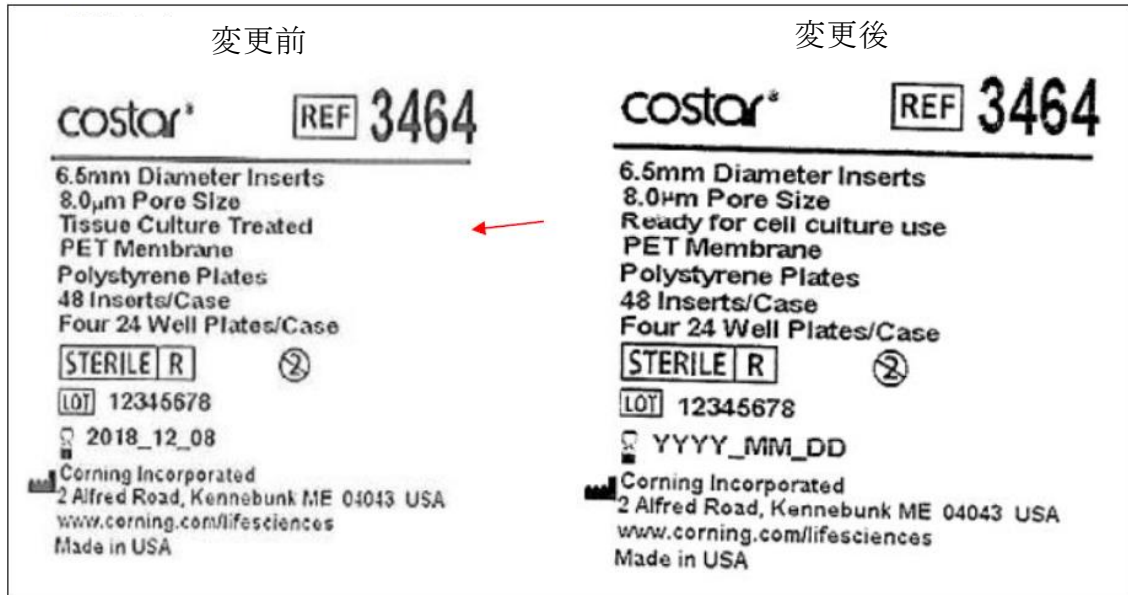
変更点

変更前のラベルには“TCT（細胞培養表面処理）”と記載されていますが、本製品は元来親水性で細胞接着に適しており、TCTは必要ありません。TCTあるいはTC表記をそれぞれ次のように変更いたします。

製品名（和名）：“細胞培養表面処理済み”を削除
ラベル、製品規格書、品質保証書：“Ready for cell culture use”に変更
ウェブページ：“Membrane surface suitable for cell culture”に変更

変更点の詳細は次ページ以降をご確認ください。

ラベル見本



外箱ならびにバーコードラベルも同様の変更がなされます


製品規格書

変更前

<p>Corning Incorporated Life Sciences</p> <p>Registered ISO 9001:2008</p>	<h2>Product Description</h2>
<p>Catalog Number: 3464</p> <p>Product Description: Costar® Transwell®, 6.5mm, TC treated, 8.0 µm pore size, in a 24-well cluster plate with lid</p> <p>Component Materials: Plate/Lid - Virgin Polystyrene, meets USP, Class VI requirements for plastic containers and closures.</p>	

<p>Cell Attachment and Growth Characteristics: The product has been tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line in a serum supplemented media.</p> <p>Performance Testing: Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.</p> <p>Cell Culture Treatment: Wettability test using water to insure the presence of a hydrophilic surface.</p> <p>Visual Attributes: Visual and microscopic examination of the product.</p> <p>Packaging: Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.</p>

変更後


 Registered ISO 9001	Product Description
Catalog Number:	3464
Product Description:	Costar® Transwell®, 6.5mm, 8.0 µm pore size, in a 24-well cluster plate with lid
Component Materials:	
Plate/Lid	- Virgin Polypropylene, meets USP Class VI requirements for plastic containers and

Tissue Culture: Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. A minimum of 95% confluency is required for acceptance.

Quality Control Testing: Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:
 Visual Inspection-Pass
 Packaging Inspection-Pass

品質保証書

変更前

 Corning Incorporated - Life Sciences 2 Alfred Road Kennebunk ME 04043 USA www.corning.com/lifesciences Refer to website for regional contact information.	Certificate of Compliance										
	Page: 1 / 1										
<table border="1" style="width: 100%;"> <tr> <td>Product Name</td> <td>: TW, 6.5MM, 8.0UM, TCT, PET, S, 12/PL, 48/CS</td> </tr> <tr> <td>Catalog Number</td> <td>: 3464</td> </tr> <tr> <td>Lot ID</td> <td>: 27220018</td> </tr> <tr> <td>Expiration Date</td> <td>: 2023-09-28</td> </tr> <tr> <td>Manufacture Date</td> <td>: 2020-09-28</td> </tr> </table>		Product Name	: TW, 6.5MM, 8.0UM, TCT, PET, S, 12/PL, 48/CS	Catalog Number	: 3464	Lot ID	: 27220018	Expiration Date	: 2023-09-28	Manufacture Date	: 2020-09-28
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Quality Management System - Complies with the current version of the ISO 9001 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

BSE/TSE - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

Sterility - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products- Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10⁻³.

Tissue Culture - Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. A minimum of 95% confluency is required for acceptance.

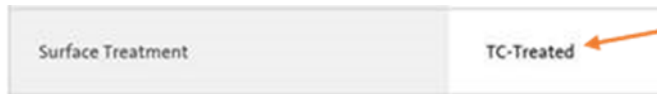
Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

- Visual Inspection - Pass
- Packaging Inspection - Pass
- Cell Attachment & Growth Treatment Verification - Pass

変更後は、“TCT”表記と“Cell Attachment & Growth Treatment Verification – Pass”表記が削除されます。

ウェブページ

変更前



変更後



変更時期

即時

なお、本製品に関するお問合せは、弊社代理店営業ご担当者様または弊社営業担当までお願い申し上げます。

以上