TRINSEO™

CALIBRE™ MEGARAD™ 2081

聚碳酸酯树脂 Polycarbonate Resins

ISO 13485:2016*

伽玛消毒应用首选医疗级材料
Medical Polycarbonate Resins Ideal for Gamma Sterilization Applications

CALIBRE™ MEGARAD™ 2081 聚碳酸酯 (PC) 系列，是伽玛、电子束消毒应用的首选材料。测试证明此树脂在消毒的过程中及消毒程序完成后，其性能表现均能保持优越，并具备行业所需的颜色回复技术。

此外，我们还提供不同熔融率的选择，并提供一个高抗环境应力开裂的牌号。技术资讯详见下表：

CALIBRE™ MEGARAD™ 2081 Polycarbonate (PC) Resins are the preferred material for medical applications involving gamma and electron-beam sterilization. They have been tested to be able to retain excellent property performance under and after the sterilization process, as well as the required color recovery technology.

We also offer several melt flow rate options, as well as an alternative with enhanced ESCR resistance.

等级 Grade	性能 Features	含脱模剂 Mold Release Agent	熔融率 MFR (g/10mins, ASTM D1238)	生物相容性 Biocompatibility
CALIBRE™ MEGARAD™ 2081-6LR	• 抗脂性 Lipid resistant	是 Yes	6 (300°C/1.2kg)	ISO 10993
CALIBRE™ MEGARAD™ 2081-15	• 平衡性能 Good balance of properties		15 (300°C/1.2kg)	
CALIBRE™ MEGARAD™ 2081-22	• 高流动 High flow		22 (300°C/1.2kg)	

CALIBRE™ MEGARAD™ 2081 PC 系列在不同消毒方法下的表现：
Performance of CALIBRE™ MEGARAD™ 2081 PC Resins under various sterilization methods:

蒸汽高压消毒 (循环) Steam Autoclave (Cycles)	伽玛辐射 Gamma Radiation	电子束 Electron Beam	环氧乙烷 (EtO, 循环) Ethylene Oxide (EtO, Cycles)
1-5	up to 7.5 Mrad	up to 7.5 Mrad	1-5

*盛禧奥的医疗制造设施及全球其他相关部门，均通过 ISO 13485 最新的 2016 版本认证，具更严谨的风险管理和工艺验证。Trinseo's medical manufacturing facilities and related global functions are ISO 13485 certified with the latest 2016 version that places a greater emphasis on risk management and process validation.

伽玛射线消毒要求
Gamma Sterilization **Requirements**

伽玛辐射是以钴 60 源照射，是被广泛应用于医疗设备消毒的方法。伽玛射线能穿透大部份的包装材料，医疗设备可在已包装的情况下进行消毒。其消毒要求包括：

- 普遍消毒使用的伽玛剂量为 2.5 Mrad (25 kGy)，在特定应用情况下，较高的剂量如 5.0 及 7.5 Mrad (50 及 75 kGy) 也会使用
- 消毒循环时间取决于所需的伽玛辐射水平

Gamma radiation, which involves exposure to photons from a cobalt-60 source, is widely used for sterilizing medical devices. Gamma rays can easily penetrate most packaging materials, enabling sterilization of devices that are already assembled and packaged. The sterilization requirements are as follows:

- Common gamma dosage for sterilization is 2.5 Mrad (25 kGy); higher doses of 5.0 and 7.5 Mrad (50 and 75 kGy) are also used depending on application needs.
- Sterilization cycle time is dependent on the level of gamma radiation required.

标准及订制颜色
Standard & Custom **Colors**

盛禧奥的 CALIBRE™ MEGARAD™ 2081 PC 树脂提供 3 个标准颜色，客户可按其应用及消毒水平作选择。

我们的 CALIBRE™ MEGARAD™ 2081 PC 树脂亦提供订制颜色，如红及蓝。而所有订制颜色均符合 ISO 10993 标准。

Trinseo's CALIBRE™ MEGARAD™ 2081 PC Resins offer three standard tints as a starting point, enabling customers to select the color compensation package best suited to their applications and radiation levels.

Custom colors are also available, such as red and blue, and are compliant with ISO 10993.

色号：Color codes:

030006　030116　030105　红 Red　蓝 Blue

色号 Color Code	建议伽玛辐射水平 Recommended Gamma Radiation Level
030006	2.5 Mrad (25kGy)
030116	5.0 Mrad (50kGy)
030105	7.5 Mrad (70kGy)

独特优势
Distinctive Advantages

盛禧奥深明医疗制造商的材料需求，我们的 CALIBRE™ MEGARAD™ 2081 系列是专门为伽玛及电子束消毒方法而设的材料，尤其是伽玛消毒。以下是 CALIBRE™ MEGARAD™ 2081 系列的独特优势：

Trinseo understands the requirements of the medical industry and the material needs of medical device manufacturers. Our CALIBRE™ MEGARAD™ 2081 specially designed for gamma and eBeam sterilization methods,particularly gamma sterilization. The distinctive advantages of CALIBRE™ MEGARAD™ 2081 PC Resins are as follows:

物理性能保持出色
Excellent Physical Performance Retention

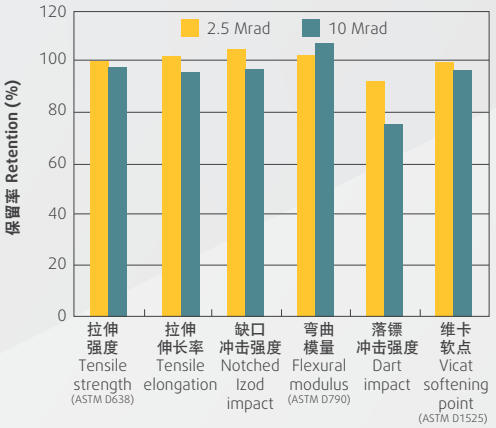
CALIBRE™ MEGARAD™ 2081-15 PC 树脂样本以 10 Mrad 伽玛消毒，10 Mrad 是模拟“最坏情况的消毒”情况。其物理性能表现总结在右图，显示出在辐射剂量高达 10 Mrad (100 kGy) 时，其物理性能仍然保持出色。

虽然在落镖冲击性能方面有轻微下降，但其它所有物理性能几乎与消毒前相同。

Samples of CALIBRE™ MEGARAD™ 2081-15 PC Resins were exposed to gamma sterilization at 10 Mrad, in order to simulate a 'worst-case' type of exposure. Physical property data is summarized in the figure on the right, which shows excellent retention of physical properties, even at radiation doses of up to 10 Mrad (100 kGy).

While there is a small reduction in the dart impact performance, all other physical properties are nearly identical to its pre-sterilization state.

伽玛消毒对 CALIBRE™ MEGARAD™ 2081-15 030105 PC 树脂在物理性能方面的影响
Effects of gamma sterilization on property retention of CALIBRE™ MEGARAD™ 2081-15 030105 PC Resins



关键性能保持稳定
Excellent Long-Term Key Properties Retention

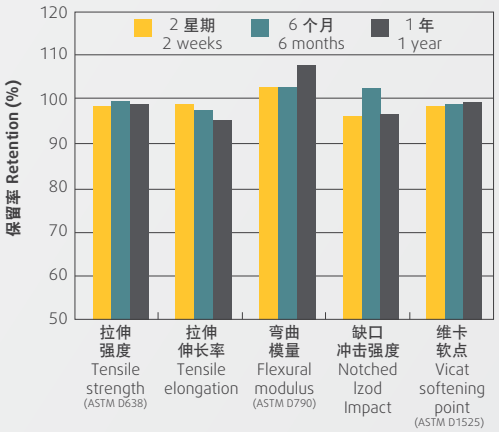
材料的物理完整性能长时间保持不变是重要的，因产品不一定在制造/消毒后立刻被使用。

我们内部对 CALIBRE™ MEGARAD™ 2081-15 PC 树脂进行了物理性能研究，评估其物理性能在消毒并储存一年后的改变。在右图可见，其关键性能在消毒后，并没有随时间发生显着变化。事实上，95%以上的性能都能在消毒后保留。

The physical integrity of the material over time is important, because of the delay between the time of manufacture/sterilization and the time the device is actually used.

An internal study was conducted to evaluate the physical properties of CALIBRE™ MEGARAD™ 2081-15 PC Resins after sterilization and storage of up to one year. The retention of key properties is shown in the figure on the right, which indicates that time after sterilization does not significantly affect the material's performance. In fact, all properties were retained at more than 95% of their pre-sterilization values.

伽玛消毒 (2.5 Mrad) 对 CALIBRE™ MEGARAD™ 2081-15 030006 PC 树脂的长期影响
Long-term effects of gamma sterilization (2.5 Mrad) on CALIBRE™ MEGARAD™ 2081-15 030006 PC Resins



极佳的颜色回复性能
Excellent Color Recovery

众所周知，伽玛辐射会令 PC 树脂变色。CALIBRE™ MEGARAD™ 2081-15 PC 树脂正正是针对此问题而设，此树脂可有效减低透明产品消毒后的色变。我们为此树脂提供 3 种标准颜色，有助于不同辐射量消毒后的颜色回复。下图显示了 CALIBRE™ MEGARAD™ 2081-15 PC 树脂在接受2.5 Mrad (25 kGy) 伽玛辐射后的颜色回复情况。

Gamma radiation is known to cause discoloration of PC resins. CALIBRE™ MEGARAD™ 2081-15 PC Resins are designed to reduce post-sterilization color shift for transparent products. Three standard tints have been developed to help compensate for color changes after sterilization at various radiation doses. The graph below clearly indicates the color recovery of CALIBRE™ MEGARAD™ 2081-15 PC Resins after 2.5 Mrad (25 kGy) of gamma radiation.

CALIBRE™ MEGARAD™ 2081-15 030006 PC 树脂在伽玛辐射后的颜色回复表现
Color recovery after gamma radiation of **CALIBRE™ MEGARAD™ 2081-15 030006 PC Resins**

原本样本
Original sample

伽玛幅射后
After gamma radiation
(2.5 Mrad/25 kGy)

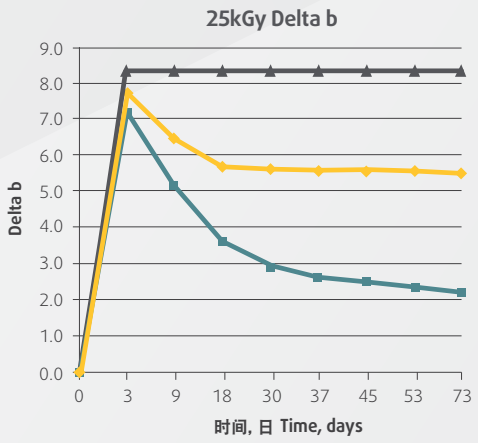
7 日
7 days

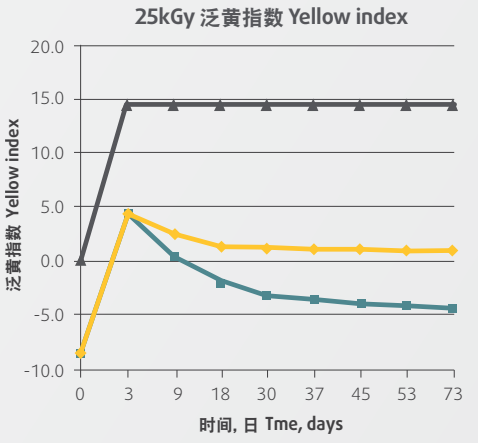
14 日
14 days

储存环境亦是色变的重要因素。为了评估储存的照明条件带来的影响，我们把已幅射的 CALIBRE™ MEGARAD™ 2081 PC 树脂样品储存在灯光及黑暗环境下，并测量其颜色变化（见右图）。0 时间表示消毒前的情况，最初三个样本的泛黄指数都在上升，但 CALIBRE™ MEGARAD™ 2081 PC 树脂的指数则随时间慢慢下降。相比普通透明 PC，CALIBRE™ MEGARAD™ 2081 PC 树脂在颜色回复性能方面，显示出其优胜之处。

Storage conditions can also play a role in color shift. To determine the effect of storage lighting conditions, samples of irradiated CALIBRE™ MEGARAD™ 2081 PC Resins and regular transparent PC samples were stored in fluorescent light and dark conditions with any color shift measured (please refer to the figures on the right). The yellowness prior to sterilization is shown as time zero. Initially, an increase in yellowness was observed for all three samples, while CALIBRE™ MEGARAD™ 2081-15 PC Resins' yellowness diminished with time. Compared with regular transparent (no color) PC, CALIBRE™ MEGARAD™ 2081-15 PC Resins demonstrate excellent performance in color recovery.

伽玛消毒 (@2.5Mrad) 后在光源及黑暗环境下的颜色回复表现
Color recovery performance after gamma sterilization (@2.5Mrad) under light and in dark conditions.





普通透明 Regular transparent PC 25 kGy
CALIBRE™ MEGARAD™ 2081-15 PC 树脂, 光源下储存
CALIBRE™ MEGARAD™ 2081-15 PC Resins, stored under light
CALIBRE™ MEGARAD™ 2081-15 PC 树脂, 黑暗环境下储存
CALIBRE™ MEGARAD™ 2081-15 PC Resins, stored in the dark

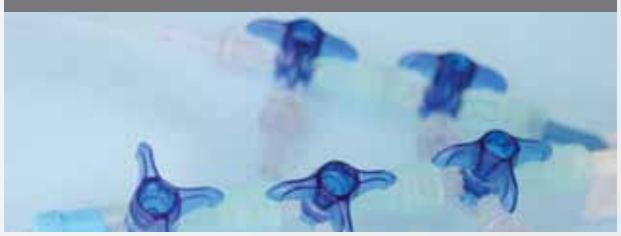
应用推介
Recommended Applications

CALIBRE™ MEGARAD™ 2081 PC 系列是伽玛消毒应用的理想材料，典型的应用包括：

CALIBRE™ MEGARAD™ 2081 PC Resins are ideal for medical applications requiring gamma sterilization. Typical applications include:

血液透析管及端盖
Hemodialyzer Tube and End Caps

三通阀
Triple Valves



法规支援及品控程序
Regulatory Support and **Quality Processes**

我们理解医疗合规的重要性，盛禧奥已设立了完善的内部流程，确保行业严格的法规得以遵守。我们的法规专家服务全球；我们非常重视合规性，并努力保持领先地位。

盛禧奥以严格的质控指引、监控条件、及经过验证的各种流程来生产医疗等级树脂，并关注供应的稳定性。我们致力为客户提供一致、可信赖和可持续的产品。为了满足正规要求和文件需要，我们改善了管理流程，包括：

- 锁定配方
- 变更通知 (NOC)
- 批次追溯性
- 长期记录和样品保存期

我们的目标是给客户提供一站式的服务和支援。

We understand that medical regulatory compliance is critical for all manufacturers. Trinseo has developed internal processes to ensure the industry's stringent guidelines are met. As such, our regulatory expertise is recognized and appreciated globally, and we place a strong emphasis on maintaining this leadership position.

Trinseo produces its medical grade resins under stringent quality guidelines, controlled conditions and validated processes. Our multiple resin sources provide an assurance of supply. We are committed to providing product consistently, predictably and sustainably. To accommodate formal requirements and the need for documentation, we offer a Management of Change process that includes:

- Formulation Lock
- Notification of Change (NOC)
- Lot Traceability
- Extended Record and Sample Retention

Our goal is to provide end-to-end support to our customers.

TRINSEO™

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产品监管 PRODUCT STEWARDSHIP

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Trinseo and its affiliated companies have a fundamental concern for all who make, distribute, and use their products and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health, and environmental information on our products so that appropriate steps may be taken to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Trinseo products – from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

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医疗应用注意事项
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