



# 医疗器械灭菌： 环氧乙烷替代方法的业界需求

## Medical device sterilization:

### The need for industrial alternatives to Ethylene Oxide

**Byron Lambert**

**Miguel Ávila**



**Abbott**

[Byron.Lambert@Abbott.com](mailto:Byron.Lambert@Abbott.com)



[Miguel.Avila@Cordis.com](mailto:Miguel.Avila@Cordis.com)



## 议程 Agenda

- 市场历史、行业压力与业界代表性现状  
Market history, industry pressures & Industry's situation
- 美国食品药品监督管理局（FDA）回复  
FDA's response
- Abbott战略  
Abbott Strategy
- Cordis战略  
Cordis Strategy

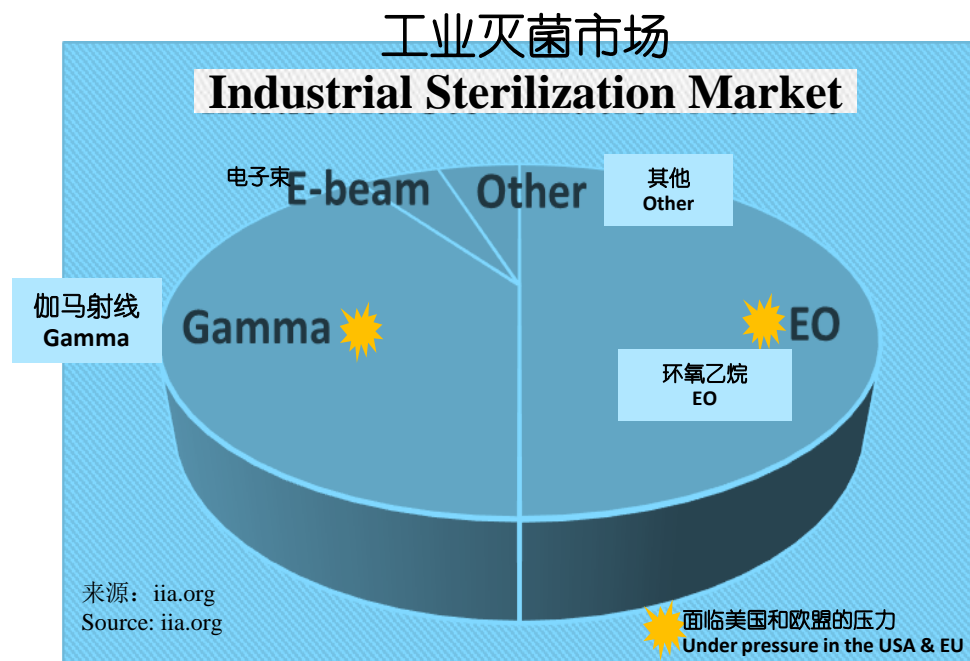


## 建议概要 Executive Summary

- 医疗器械企业、我们所服务的社区和全球监管机构均希望能够妥善管理并守护环境  
Medical device companies, the communities we serve, and global regulatory bodies want to be good stewards of the environment
- 许多相关的灭菌变革即将发生——其中涉及到全新变革；应当首先明确期望结果  
Many related sterilization changes are forthcoming – some of them are novel; clarity on expectations is necessary
- 行业需要全球统一的监管审批流程  
Industry needs a global harmonized regulatory approval process
  - ✓ 确保向全球患者供应产品，并  
to ensure the supply of products to patients around the globe *and*
  - ✓ 提供切实可行和可预测的监管途径，减少各地区实现新型和环保变革的障碍  
to provide practical & predictable regulatory pathways to reduce barriers toward novel and environmentally favorable changes in all geographies

# 市场历史 ~ 一次性使用器械

# MARKET HISTORY ~ Single Use Devices



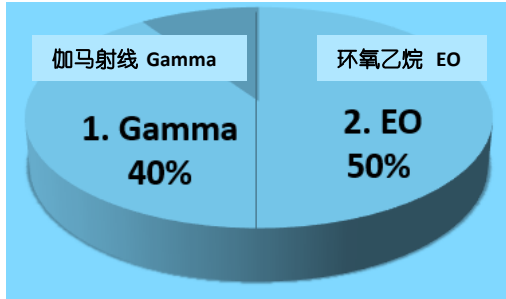
来源: iia.org- “伽马射线、电子束、X射线和环氧乙烷技术用于医疗器械和医疗保健产品的工业灭菌的比较”

Source: iia.org – “A comparison of Gamma, E-beam, X-ray, and Ethylene Oxide Technologies for the Industrial Sterilization of Medical Devices and Healthcare Products”

Abbott内部采用的模式 *Modalities used within Abbott*

1. 环氧乙烷 (EO)
2. 辐射 *Radiation*
  - 电子束 *E-beam*
  - 伽马射线 *Gamma*
3. 蒸汽 *Steam*
4. 液体化学品/无菌加工  
*Liquid Chemical / Aseptic Processing*

# FDA回复 FDA Response



FDA正在采取措施, 缓解EO领域日益增长的压力  
FDA initiatives underway to mitigate growing industry pressures on EO

## FDA创新挑战1: FDA INNOVATION CHALLENGE 1:

确定新的灭菌方法和技术 *Identify new sterilization methods and technologies*

### FDA主文件试点计划 FDA Master File Pilot Programs:

- 2019年 (变更EO周期)、2021年 (EO → 新模式\*) 和2023年 (伽马射线或EO → 电子束或X射线)
- 2019 (change EO cycles), 2021 (EO → **new modality\***) & 2023 (Gamma or EO → E-beam or x-ray)

\*FDA已建立的B类和新型模式 \* FDA Established Category B and Novel modalities

## FDA创新挑战2: FDA INNOVATION CHALLENGE 2:

减少环氧乙烷排放 *Reduce ethylene oxide emissions*

FDA ‘协作社区’ ——与基尔默社区的讨论, 2023年

(<https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together>)

FDA ‘Collaborative Community’ – in discussion with the Kilmer Community, 2023  
(<https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together>)



通过以下方式实现可持续灭菌

**Sustainable sterilization will be achieved through**

- (1) 转换环氧乙烷 (EO) 灭菌方式, 及  
switching sterilization from Ethylene Oxide (EO) sterilization and
- (2) 降低必须进行EO灭菌的产品的EO浓度  
reducing EO concentration for products that must be EO sterilized

<b>变更模式*</b> <b>Change Modalities *</b>	<b>减少EO用量</b> <b>EO Reduction</b>
<p>产品转换减少供应链产能限制 Product conversion reduces supply chain capacity constraints</p>	<p>优化EO周期, 包括降低每个周期的EO浓度 EO cycle optimization including reduced concentration of EO per cycle</p>

\* 变更为电子束辐射或替代气体灭菌, 例如: 蒸汽过氧化氢灭菌、二氧化氮灭菌

\* *Change to E-beam radiation or to alternative gas sterilization, for example: vaporized hydrogen peroxide sterilization nitrogen dioxide sterilization*



## 医疗器械

### MEDICAL DEVICES

利用侵入性更小、更准确的技术引领互联医疗

Leading in connected care with less-invasive, more-accurate technologies

#### 糖尿病护理

#### DIABETES CARE

#### 心血管

#### CARDIOVASCULAR

- 血管护理  
Vascular care
- 结构性心脏病  
Structural heart
- 心衰  
Heart failure
- 心脏电生理  
Electrophysiology
- 心脏节律管理  
Cardiac rhythm management

#### 神经调控

#### NEUROMODULATION

- Abbott是全球领先的.....  
拥有应用先进医疗保健技术的  
广泛产品组合  
Abbott is a world leader ...  
broad portfolio of advanced  
healthcare technologies
- 更快速、更有效、侵入性更小的  
技术  
Technologies that are faster,  
more effective, and less  
invasive



- 电子束辐射  
E-beam Radiation
- 替代气体灭菌  
Alternative gas sterilization
- 较温和的EO  
Soft EO



美国佛罗里达州迈阿密湖  
Miami Lakes, Florida, USA



墨西哥华雷斯城  
Ciudad Juárez, Mexico



美国加利福尼亚州圣克拉拉  
Santa Clara, California, USA



爱尔兰卡舍尔  
Cashel, Ireland



美国加利福尼亚州尔湾  
Irvine, California, USA



瑞士尼翁  
Nyon, Switzerland

# Cordis®

全球领先的介入血管技术开发和制造商，60多年来始终致力于开创性、突破性的心血管技术，为数百万患者提供治疗。

A worldwide leader in the development and manufacturing of interventional vascular technology with a more than 60-year history of pioneering breakthrough cardiovascular technologies to treat millions of patients.





# Cordis®

愿景：

**VISION:**

通过开创性、突破性的心血管技术，挽救亿万患者的生命。  
Saving billions of lives by pioneering breakthrough cardiovascular technologies.

使命：

**MISSION:**

通过快速开发差异化解决方案，提高患者生活质量，降低护理成本，从而满足客户需求。Cordis倡导多元化、赋权文化，助力团队成员实现职业抱负。

We delight our customers by developing differentiated solutions at pace that improve patient vitality and lower the cost of care. We embrace a diverse, empowered culture where teammates can fulfill their career aspirations.

我们对所供应医疗产品的安全和疗效充满信心。

**We provide medical products that we would be proud to have used on our loved ones.**



# 血管疾病的诊断和治疗

## Diagnosis and Treatment of Vascular Disease



导引鞘  
Introducer  
Sheaths



Dx/导丝  
Dx / GuideWires



Dx导管  
Dx Catheters



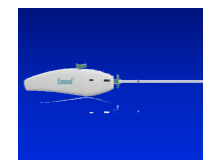
导引导管  
Guiding Catheters



支架/输送系统  
Stents / Delivery  
Systems



PTA/PTCA球囊  
PTA/ PTCA  
Balloons

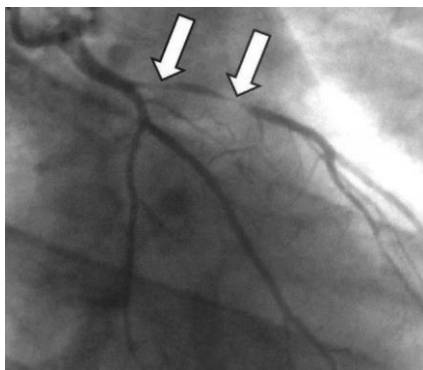


血管封堵系统  
Vascular Closure

### 心脏

#### Cardiac (Heart)

- 缺血性心脏病  
Ischemic heart disease
  - 心肌梗死  
Myocardial infarction
  - 心绞痛  
Angina
  - 心衰  
Heart failure



### 外周血管

#### Peripheral

- 器官和肢体缺血  
Organ and Limb Ischemia

### 静脉

#### Veins

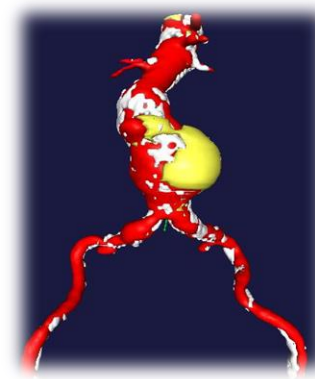
- 血栓栓塞  
Thromboembolism
- 阻塞  
Obstruction



### 外周血管

#### Peripheral

- 颈动脉疾病  
Carotid disease
- 腹主动脉瘤  
Abdominal Aorta Aneurysm





# Cordis灭菌战略 - 五年计划 (2023 – 2027)

## Cordis Sterilization Strategy Five-Year Plan (2023 – 2027)

通过以下方式实现环氧乙烷灭菌替代方法

Alternatives to ethylene oxide sterilization will be achieved through

- 研究其他灭菌技术  
Investigating other sterilization technologies
- 减少EO用量（改进EO周期设计和过程）  
EO usage reduction (Enhanced EtO Cycle design and Processes)

替代技术 Alternative Technologies
<p>研究替代灭菌技术，二氧化氯气体、超临界CO<sub>2</sub>、伽马射线、电子束、X射线、过氧化氢气体</p> <p>Investigating alternative sterilization technologies, Chlorine Dioxide gas, Supercritical CO<sub>2</sub>, Gamma, E-beam, X-Ray, Hydrogen Peroxide Gas</p>

减少EO用量 EO Usage Reduction
<p>与合同灭菌商合作，实施可持续的环氧乙烷SEO周期，显著减少EO排放</p> <p>Partnered with our contract sterilizers to implement sustainable ethylene oxide <b>SEO</b> Cycle to significantly reduce EO emissions</p>



# 替代灭菌模式面临的挑战

## Alternative Sterilization Modality Challenges

- 了解替代模式相关材料的影响  
Understanding the impact of materials from alternate modalities
- 行业和监管机构采纳批准新模式的周期较长  
Slow adoption of new modalities by industry and regulators
- 合同灭菌商的产能有限，大规模生产受限  
Limited capacity at contract sterilizers & availability for large scale volumes
- 进一步了解监管审批所需的数据  
Better understanding of required data for regulatory approval

随着医疗器械行业的不断创新和对新灭菌模式的探索，需要制定替代模式的国际行业标准，以提供指导并协助监管部门审批。

As the medical device industry continues to innovate and investigate new sterilization modalities there is a need for international industry standards for alternative modalities to help provide guidance and assist with regulatory approval.

FDA和全球监管机构在确保制造商的灭菌方法得到适当确认方面发挥重要作用。

FDA and global regulators play an important role in ensuring that manufacturers sterilization methods are properly validated.

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## Medical device sterilization: The need for industrial alternatives to Ethylene Oxide

**Byron Lambert**



**Abbott**

**Miguel Ávila**



感谢您的观看

**Thank you**