



Investor Presentation

投资者报告

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NYSE: MLSS

# Safe Harbor Statement 安全港声明

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*This presentation contains forward-looking statements regarding the timing and financial impact of Milestone's ability to implement its business plan, expected revenues, timing of regulatory approvals and future success. These statements involve a number of risks and uncertainties and are based on assumptions involving judgments with respect to future economic, competitive and market conditions, future business decisions and regulatory developments, all of which are difficult or impossible to predict accurately and many of which are beyond Milestone's control. Some of the important factors that could cause actual results to differ materially from those indicated by the forward-looking statements are general economic conditions, failure to achieve expected revenue growth, changes in our operating expenses, adverse patent rulings, FDA or legal developments, competitive pressures, changes in customer and market requirements and standards, and the risk factors detailed from time to time in Milestone's periodic filings with the Securities and Exchange Commission, including without limitation, Milestone's Annual Report for the year ended December 31, 2019. The forward-looking statements in this presentation are based upon management's reasonable belief as of the date hereof. Milestone undertakes no obligation to revise or update publicly any forward-looking statements for any reason.*

# Executive Summary 概要

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- Milestone Scientific Inc. (MLSS) is a leading developer of computerized drug delivery instruments that provides virtually painless and precise injections. / Milestone Scientific Inc. (MLSS)是计算机控制的药物递送仪器的领先开发商，开发的仪器提供几乎无痛和精准的注射。
- MLSS has now entered into a significant expansion in the world-wide dental market. 现在，MLSS已在全球的牙科市场进入了一个重要的扩张阶段。
- Based on MLSS fundamental technology of pressure force feedback with the additional patented technology of pulse wave which given MLSS an additional 20 years of patent protection, MLSS will be pursuing a number of different areas in the medical sector, which will comport with MLSS razor/razor blade business model. 基于MLSS的压力反馈的基本技术和额外的脉冲波专利技术，使MLSS获得了额外的20年的专利保护，MLSS将在医疗行业探索多个不同的领域，这将与MLSS的剃刀/刀片商业模式相一致。
- This presentation addresses the medical and dental business and how MLSS believe it can improve healthcare outcome at lower costs. 这个报告介绍医疗和牙科业务，以及MLSS相信它能以较低的成本提升医疗保健结果。

# Company History 公司历史

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Milestone Scientific Inc. (MLSS) is a leading medical research and development company that designs and patents innovative injection technology. Milestone's computer-controlled systems make injections precise, efficient, and virtually painless. / Milestone Scientific Inc. (MLSS)是一家领先的医学研究和开发公司，设计创新的注射技术并申请专利。Milestone的计算机控制系统使注射变得精确、高效，而且几乎没有痛苦。

**With 133 foreign patents and 19 US patents issued Milestone Scientific is the leader in modern injection technology / Milestone Scientific 拥有133项国外专利和19项美国专利，是现代注射技术的领导者。**

# Why Enter the Epidural Market? 为什么要进入硬膜外市场?

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## Market Size 市场规模

Epidural procedures are one of the fastest growing procedures in the US and worldwide. It is estimated that over 11 million epidural procedures are performed each year in the US and over 30 million worldwide. 硬膜外麻醉手术是美国和全世界增长最快的手术之一。据估计，美国每年进行的硬膜外麻醉手术超过1100万例，全球超过3000万例。

Over \$5 billion is spent annually on epidural injections in the US alone. The approximate break down of epidural procedures in the US is 仅在美国，每年用于硬膜外注射的费用就超过\$50亿。在美国，硬膜外手术的大致细分情况是：

- 2.4 million labor procedures out of almost 4 million births 在近400万次分娩中，有240万次分娩手术
- 9 million pain intervention steroid injections / 900万次疼痛干预类固醇注射
- ~900,000 total and growing Neuroaxial Regional Blocks for hip and knee surgeries 用于髋关节和膝关节手术的神经轴区阻断器总数约为900,000个，并在不断增加。



# Current Technology Being Used Today!

## 当前正在使用的技术!



The technique of "single-shot" lumbar epidural anesthesia was first developed in 1921 by Spanish military surgeon Fidel Pagés, and hasn't changed significantly since. 腰部硬膜外麻醉的“单发”技术是由西班牙军事外科医生Fidel Pagés在1921年首次开发的，此后一直没有明显变化。



Glass Loss of Resistance  
玻璃阻力损失 (LOR) 1946



"Modern" LOR Syringes 现  
代的“LOR”注射器

# Listening to Providers, Addressing Unmet Needs


## 倾听医护人员的意见，解决未满足的需求

- Placement of an epidural needle is difficult; Requiring 60-90 placements before reaching an adequate skill level 放置硬膜外针很困难；需要60-90次的放置才能达到足够的技能水平。
- 17% of failure rates are due to false loss of resistance (False Loss of resistance is when the needle enters soft tissue or fatty tissue and the provider believes it is in the epidural space when it is not) resulting in a failure to provide pain relief. This requires another attempt while the patient remains in labor and pain. / 17%的失败率是由于假性失抗（假性失抗是指针头进入软组织或脂肪组织，而提供者认为它是在硬膜外空间，其实不是），导致无法缓解疼痛。这就需要再次尝试，而患者仍然处于分娩和疼痛中。
- Epidural Dural punctures are as high as 5+%. An Epidural puncture is when the Dura is breached and the needle enters into the spinal canal, causing cerebral spinal fluid to leak resulting in headaches, pain, infection, and other morbidities costing insurance companies and hospitals additional time and money. 硬膜外硬膜穿刺的比例高达5%以上。硬膜外穿刺是指硬膜被突破，针头进入椎管，导致脑脊液渗出，造成头痛、疼痛、感染和其他病症，使保险公司和医院付出额外的时间和金钱。
- 20% of epidural blood patches also fail and require additional care (A blood patch is a procedure to try and repair the Dural punctures) / 20%的硬膜外血贴也会失败，需要额外的护理（血贴是一种尝试修复硬膜穿刺的程序）。



**COMPUFLO™**  
EPIDURAL INSTRUMENT

# Cost Savings of More Than \$500 Per Hospital Stay on Average 平均每次住院可节省\$500以上的费用



## Cost Effectiveness Analysis of Two Labor Epidural Analgesia Techniques; Real-Time Pressure Sensing Technology and Traditional Technique

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**Introduction**

Accidental dural puncture (ADP) is a complication of epidural anesthesia with reported rates of 0.5-4% (1). Following ADP, the incidence of post-dural puncture headache (PDPH) has been reported to be more than 75%. It is a significant cause of increased cost, prolonged hospitalization and need for further treatment and interventions such as epidural blood patch (2). The use of continuous real-time pressure sensing technology (CompuFlo) has been recently validated as a tool to identify the epidural space and is gaining popularity as an alternative to traditional loss of resistance (LOR) technique (3).

The aim of this study was to conduct a cost-effectiveness analysis of real-time pressure sensing technology and traditional LOR technique in parturients requesting labor epidural analgesia.

**Methods**

With approval of the Institutional Review Board, we collected data from electronic health records at UTMB to identify parturients aged between 18 and 50 who had epidural anesthesia for planned vaginal delivery between 2015 and 2019.

For the cost-effectiveness analysis, we estimated the total cost for the hospital stay for delivery and readmission for epidural blood patch (EBP) if any. We first categorized patients into two groups by the presence of epidural replacement. Within each group, we further categorized the patients into three groups: 1) no headache or EBP; 2) with headache but no EBP; 3) with EBP. Patients who had multiple orders for epidural anesthesia during the hospitalization were considered to have epidural replacement. Headache after epidural anesthesia was identified using international classification of diseases codes. All costs were adjusted to the same time period, using the consumer price index for medical care.

**Results**

We included 4483 deliveries from 4353 parturients in this study. We examined the parturient characteristics at the inpatient visit for delivery are presented in Table 1. The cost-effectiveness was performed using TreeAge. The model is presented in Figure 1. Incremental cost of both techniques are presented in Table 3.

**Table 1. Patient characteristics at the inpatient visit for delivery**

Patient characteristic	Mean ± SD	Median
Age (years)	27.4 ± 5.7	26.7
BMI (kg/m <sup>2</sup> )	32.3 ± 6.5	31.3
Gravidity	2.7 ± 1.7	2.0
Parity	1.7 ± 1.3	1.0

Race/Ethnicity	N	%
Asian	168	3.75
African American	358	11.29
Caucasian/White	1197	26.70
Hispanic or Latino	2501	57.80
Other	21	0.47

\*SD: standard deviation. BMI: body mass index


**Table 2. Incremental cost of traditional method compared to real-time pressure sensing technology method**

Method	Cost	Incremental Cost	Effect (pain score)	Dominance
Study device	16303.02	0.00	2.00	
Traditional	16866.96	\$504	2.00	Dominated

Study device: (continuous real-time pressure sensing technology)

**Conclusion**

To our knowledge, this is the first study in the literature, we report cost of the real-time pressure sensing technique and the traditional LOR technique in parturients requesting labor epidural analgesia. Compared to the traditional LOR technique, real-time pressure sensing technology costs about \$504 less per hospital stay on average.



- Department of Anesthesiology, University of Texas Medical Branch at Galveston 德克萨斯大学加尔维斯顿分校医学部麻醉学系
- Objective:** Cost effectiveness analysis of CompuFlo with real-time pressure sensing technology and traditional LOR technique in parturients requesting labor epidural analgesia  
目的：采用实时压力感应技术的CompuFlo和传统的LOR技术对要求进行分娩硬膜外麻醉的产妇进行成本效益分析
- 4483 deliveries from 4353 parturients were included in the study / 4353名产妇的4483次分娩被纳入研究。
- Conclusion:** CompuFlo costs about \$504 less per hospital stay on average  
结论：采用CompuFlo每次住院的费用平均少了约\$504。
- For a hospital with 6000 epidural procedures per year, potential cost savings could be 3 million dollars 对于一家每年有6000例硬膜外手术的医院，潜在的成本节约可能是\$300万。



# Innovating a New Standard of Care in Anesthesia 创新麻醉护理的新标准

- Now with our patented CompuWave™ and CathCheck™ features, anesthesiologists should be able to save significant time and institutions should save significant costs 现在，利用我们获得专利的CompuWave™和CathCheck™功能，麻醉师应能节省大量时间，机构应能节省大量成本。
- Correlates subjective feel with objective visual and audible verification of pressure changes 将主观感觉与压力变化的客观视觉和听觉验证联系起来
- Offers real-time needle location with consistent distinction of true loss of resistance 提供实时的针头定位，对真正的阻力损失进行一致的区分
- Builds physician confidence resulting in fewer attempts; less Dural punctures reducing complications and costs 建立医生的信心，减少尝试次数；减少硬脑膜穿刺，减少并发症和费用。
- Accelerates procedure learning curve for residents and trainees 加快住院医师和受训者的学习曲线



Welcome to the 21<sup>st</sup> Century  
欢迎来到21世纪

# Two New Features added to the CompuFlo Epidural Instrument / CompuFlo Epidural仪器增加了两个新功能

With the addition of the patented CompuWave™ technology we can now not only verify epidural placement but also confirm catheter placement in real time with the patients' pulse 随着专利CompuWave™技术的加入，我们现在不仅可以验证硬膜外的位置，还可以通过患者的脉搏实时确认导管的位置。



# What Do These New Features Mean?

## 这些新功能意味着什么？

When performing an epidural the CompuFlo™ instrument objectively identifies the False Loss of Resistance and True Loss of Resistance. 在进行硬膜外手术时，CompuFlo™仪器能客观地识别假性失抗和真性失抗。

CompuWave™ allows the practitioner to also verify that the needle is in the epidural space when the pulsatile waveform is displayed 当显示脉动波形时，CompuWave™还能让医生验证针头是否在硬膜外腔中。



False Loss of Resistance  
假性失抗

True Loss of Resistance  
真性失抗

# What Do These New Features Mean?

## 这些新功能意味着什么？

Until now clinicians check catheters by administering a bolus of anesthetic to a patient and are then required to wait 20-40 minutes to see if patient's pain has subsided, if it doesn't the catheter has to be removed and another epidural must be performed. 到目前为止，临床医生通过给患者注射麻醉剂来检查导管，然后需要等待20-40分钟，看患者的疼痛是否已经缓解，如果没有缓解，就必须拔掉导管，并再次进行硬膜外麻醉。

With **CathCheck™** they can, in 1-2 minutes identify if the catheter is in place or has become dislodged from the epidural space. 有了**CathCheck™**，他们可以在1-2分钟内确定导管是否在适当位置或已从硬膜外空间移位。

This saves considerable time and money and provides better patient care. 这可以节省大量时间和金钱，并提供更好的患者护理。



If the Catheter is in the epidural space the waveform indicates it. If it's not that will be indicated as well. 如果导管在硬膜外空间，波形会显示出来。如果它不在，也会被显示出来。



# Milestone Scientific- Market Re-Cap 市场概述

## Epidural is one of the fastest growing segments in Medicine 硬膜外是医学界增长最快的领域之一

- 11 million performed in the US and 30 million worldwide 在美国进行了1100万次，在全球进行了3000万次
- 2.4 million Labor and Delivery-US / 240万例分娩手术 – 美国
- 9 million nerve blocks for pain intervention-US / 900万例神经阻断用于疼痛干预 – 美国
- 900,000+ for pain blocks in Hips and Knees- US / 90多万例用于髋和膝盖阻断疼痛
- Over a \$5+ Billion Dollar Market in the US and growing 在美国有超过\$50亿的市场，而且还在不断增长。

## Peripheral Nerve Blocks 外周神经阻断(PNB)

- Globally there are 41 million Peripheral Nerve blocks performed, US market is expected to reach \$430 Million by 2027. 全球有4100万例外周神经阻断手术，美国市场预计到2027年将达到\$4.3亿。
- Study performed by Dr. Oliver Choquet at the Lapeyronie University Hospital-Montpellier concludes that high injection pressure during PNB procedures should be avoided and pressure monitoring should be sensitive and easy to use to improve the safety of PNB. 蒙彼利埃Lapeyronie大学医院的Oliver Choquet博士进行的研究得出结论：PNB手术中应避免高注射压力，压力监测应敏感且易于使用，以提高PNB的安全性。
- With the passing of the Substance Abuse Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) act, physicians are using more pain blocks to reduce the opioid use post surgery. 随着促进患者和社区的阿片类药物恢复和治疗的物质滥用障碍预防法案（SUPPORT）的通过，医生们正在使用更多的止痛块来减少手术后的阿片类药物使用。

Insurance companies now require at least 3 pain injections for prognostic and diagnostic workup prior to approving surgery in orthopedics and spine. 保险公司现在要求在批准骨科和脊柱的手术前，至少要进行3次疼痛注射，以进行预后和诊断工作。

# Beyond Epidural: The Medical Opportunity

## 硬膜外以外：医学机会



### Catheter Check 导管检查

- ✓ Now with our patented CompuWave™ technology the CompuFlo Epidural Instrument can now check catheters in 1-2 minutes not 20-40 minutes. 现在，采用我们的专利 CompuWave™技术，CompuFlo Epidural仪器现在可以在1-2分钟内检查导管，而不是20-40分钟。



### Thoracic 胸腔

- ✓ High-risk nature of procedure; 3 – 5 % of all epidurals, Study currently underway. 手术的高风险性； 占有硬膜外手术的3-5%，目前正在进行研究。



### Peripheral Nerve Block 外周神经阻断

- ✓ Received peripheral nerve block patent 获得了周围神经阻断专利



### Intra-articular 关节内

- ✓ Large worldwide market for injections into the joints 关节注射的全球大市场



### Botox 肉毒素

- ✓ Received US Patent in April 2020 于2020年4月获得美国专利



[milestonescientific.com](http://milestonescientific.com)

Thank You! 谢谢!

NYSE: MLSS