COMPUFLO®

EPIDURAL INSTRUMENT

NOW WITH

CATHCHECK™

A modern approach to not only epidural space identification and confirmation, but checking and confirming catheter placement in real time.

MILESTONE SCIENTIFIC®

Objectively identify the epidural space with a **99% success rate** on the first attempt.

A new, modern technique for objective identification and confirmation of the epidural space in real time for all your patients.

Since 1921

THE CONVENTIONAL APPROACH

Until recently, the identification of the epidural space has been based on the subjective perception of a "loss of resistance (LOR)", when inserting an epidural needle to identify the epidural space.

- Subjective tactile feel only - Requires subjective loss of resistance to air or saline
- Sensitive but not specific - Detects pressure differences by loss of resistance, but is unable to differentiate between intermuscular planes, cysts, ligaments and the epidural space
- Studies show it takes up to 90 epidural procedures to reach basic clinical competency

The New Standard

COMPUFLO® USES DPS DYNAMIC PRESSURE SENSING TECHNOLOGY® [2-4, 8]

- Subjective tactile feel + objective DPS® - differentiates between true loss and false loss of resistance
- 25% reduction in procedure time for labor and delivery epidurals
- Clinicians can successfully perform epidural procedures with fewer attempts
- Detects subtle pressure changes 4 times a second, making it extremely responsive to minor pressure changes
- Precisely controls the flow rate of fluid with real-time feedback, based on exit pressure at the needle tip
- Compared to the traditional LOR technique, real-time pressure sensing technology costs about $504 dollars less per hospital stay on average
- The CompuWave™ graph displays the pulsatile waveform found in the epidural space, again confirming needle and catheter placement

Introducing CompuFlo's® newest feature...CathCheck™!

COMPUFLO®
EPIDURAL INSTRUMENT

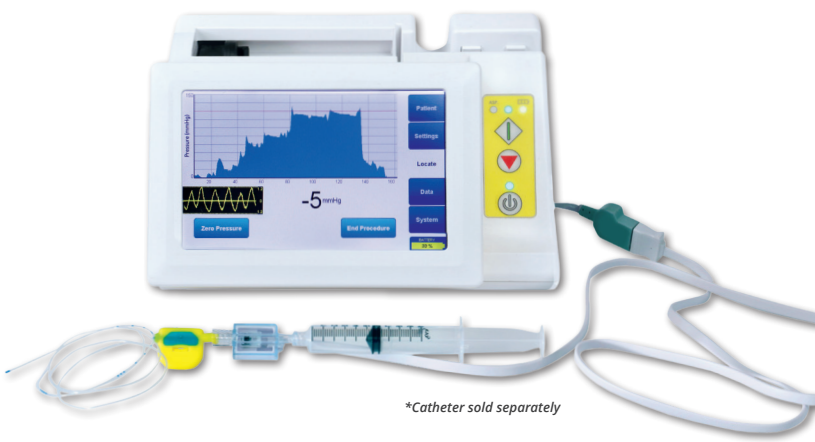
NOW WITH
CATHCHECK™

A new, modern technique for checking your catheter placement in real time.

Benefits

EPIDURAL CATHETER VERIFICATION SYSTEM

- Instant epidural catheter verification with CompuWave™ displaying the pulsatile wave form
- Saves the anesthesia provider time, enabling them to make clinical decisions faster regarding ineffective epidural catheters and the next course of treatment
- The anesthesia provider may flush with sterile anesthetic or sterile saline
- Increases the anesthesia provider's daily effectiveness
- Provides confirmation to the anesthesia provider post-catheter placement
- Reduces the amount of time the patient is in pain, due to an ineffective catheter



*Catheter sold separately

	Catheter Dosing	CompuFlo® CompuWave™
Connects directly to the patient's catheter	X	X
Flush with anesthetic	X	X
Flush with sterile saline		X
Time required for patient response	15-30 minutes	10 seconds
Instantly and objectively displays the epidural pulsatile waveform found in the epidural space		X

The Modern Epidural Solution

Instrument Features

DPS DYNAMIC PRESSURE SENSING TECHNOLOGY®

- High-quality 17.5 cm (7 in) touchscreen
- Lightweight - allowing the instrument to be moved from room to room
- Contains 2 power sources: a standard AC plug, as well as a built-in lithium-ion battery
- Optional hands-free control with a foot pedal
- Internal memory stores patient files and are accessible through a USB 2.0 port

Benefits

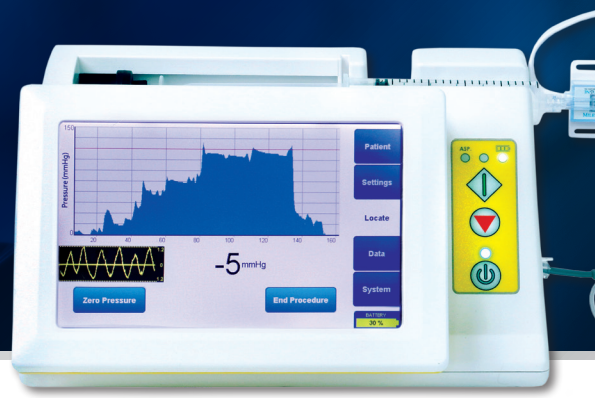
COMPUFLO® + CATHCHECK™

- Connects to any traditional loss-of-resistance syringe, maintaining the standard tactile feel technique
- CompuFlo® can be used with the needle of your choice
- Objectively discriminates between a true loss-of-resistance and a false loss-of-resistance
- Constantly and in real-time measures tissue pressure
- 97% accuracy in labor/delivery, and 96% accuracy in patients with BMI >31[1]
- Check catheter placement in seconds, not minutes

	Loss-of-Resistance Syringe	CompuFlo®
Uses tactile feel[5]	X	X
Objectively measures tissue pressure constantly and in real-time, numerically and graphically[5]		X
Objectively measures tissue pressure constantly and in real-time, via audible tone		X
Recognizes the presence of pulsatile waveform when the epidural space is accessed with CompuWave™		X
Reduced procedure time in a randomized clinical trial (COMPASS)		X
Reduced needle passes to the epidural space in a randomized clinical trial (COMPASS)		X
Reduced accidental dural punctures in a randomized clinical trial (COMPASS)		X
Compared to the traditional LOR technique, real-time pressure sensing technology costs about $504 dollars less per hospital stay on average[8]		X

Published Studies & Papers

9 peer reviewed published studies showing the safety and efficacy of the CompuFlo® Epidural System.



New Clinical Trial Finds CompuFlo® Instrument a Safe Alternative to Current Standards of Care

ANESTHESIA & ANALGESIA - NOVEMBER 2019

- 160 labor and delivery (L&D) patients - 400 total
- 99% effective in identifying the epidural space on the first attempt
- 14% more successful in patients with a high BMI
- L&D epidurals using CompuFlo® resulted in 0 dural punctures, compared to 4 dural punctures with the current LOR technique
- Procedure time reduced by 1 minute with CompuFlo®

Objective Epidural Space Identification Using Continuous Real-Time Pressure Sensing Technology: A Randomized Controlled Comparison With Fluoroscopy and Traditional Loss of Resistance

Ralf E. Gebhard, MD,* Tobias Moeller-Bertram, MD,† Douglas Dobecki, MD,‡ Feyce Peralta, MD,§ Evan G. Pivalizza, MBChB, FFASA,‖ Madhumani Rupasinghe, MBBS, FRCA,‖ Sanja Ilic, MD,¶ and Mark Hochman, DDS#

BACKGROUND: Performance of epidural anesthesia and analgesia depends on successful identification of the epidural space (ES). While multiple investigations have described objective and alternative methodologies to identify the ES, traditional loss of resistance (LOR) and fluoroscopy (FC) are currently standard of care in labor and delivery (L&D) and chronic pain (CP) management, respectively. While FC is associated with high success, it exposes patients to radiation and requires appropriate radiological equipment. LOR is simple but subjective and consequently associated with higher failure rates. The purpose of this investigation was to compare continuous, quantitative, real-time, needle-tip pressure sensing using a novel computer-controlled ES identification technology to FC and LOR for lumbar ES identification.

METHODS: A total of 400 patients were enrolled in this prospective randomized controlled noninferiority trial. In the CP management arm, 240 patients scheduled to receive a lumbar epidural steroid injection had their ES identified either with FC or with needle-tip pressure measurement. In the L&D arm, 160 female patients undergoing lumbar epidural catheter placements were randomized to either LOR or needle-tip pressure measurement. Blinded observers determined successful ES identification in both arms. A modified intention-to-treat protocol was implemented, with patients not having the procedure for reasons preceding the intervention excluded. Noninferiority of needle-tip pressure measurement regarding the incidence of successful ES identification was established if the lower limit of the 95% confidence interval (CI) for the odds ratio (OR) was above 0.50. OR% less likely to identify the ES) and *P* value for noninferiority <.025.

RESULTS: Demographics were similar between procedure groups, with a mild imbalance in relation to gender when evaluated through a standardized difference. Noninferiority of needle-tip pressure measurement was demonstrated in relation to FC where pain management patients presented a 100% success rate of ES identification with both methodologies (OR, 1; 1-, 97.27%; CI, 0.52–8.74; *P* = .021 for noninferiority), and L&D patients experienced a noninferior success rate with the novel technology (97.13% vs 91%; OR, 3; 1-, 97.27% CI, 0.62–21.54; *P* = .018) using a prior noninferiority delta of 0.50.

CONCLUSIONS: Objective lumbar ES identification using continuous, quantitative, real-time, needle-tip pressure measurement with the CompuFlo Epidural Computer Controlled Anesthesia System resulted in noninferior success rates when compared to FC and LOR for CP management and L&D, respectively. Benefits of this novel technology may include nonexposure of patients to radiation and contrast medium and consequently reduced health care costs. (Anesth Analg 2019;129:1319–27)

KEY POINTS

- **Question:** Is continuous quantitative real-time needle-tip pressure measurement noninferior to current standards of care (fluoroscopy and loss of resistance) for epidural space identification?
- **Findings:** Needle-tip pressure measurement using a novel computer-controlled pressure sensing technology was found to be noninferior to fluoroscopy and loss of resistance regarding success rates, procedural times, and complications.
- **Meaning:** Needle-tip pressure sensing is a potential alternative to current standards of care and may avoid exposure to radiation when compared to fluoroscopy and offer greater accuracy when compared to loss of resistance.

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Funding: This clinical trial was funded by Milestone Scientific, Livingston, NJ.

Conflicts of Interest: See Disclosures at the end of the article.

Clinical trial number: NCT02139727. ClinicalTrials.gov.

Reprints will not be available from the authors.

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Anesthesiology Research and Practice

JANUARY 2019

- 120 patient clinical study
- CompuFlo® blocks performed successfully with no complications
- Consistent differentiation of true loss-of-resistance

Anesthesiology Research and Practice
Volume 2019, Article ID 5157901, 4 pages
https://doi.org/10.1155/2019/5157901

Research Article

Differentiating False Loss of Resistance from True Loss of Resistance While Performing the Epidural Block with the CompuFlo® Epidural Instrument

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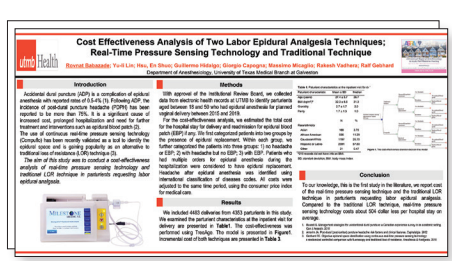
Cost Effectiveness Analysis of Two Labor Epidural Analgesia Techniques; Real-Time Pressure Sensing Technology and Traditional Technique

APRIL 2020

- Compared to the traditional LOR technique, real-time pressure sensing technology costs about $504 dollars less per hospital stay on average



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

Rovnat Babazade; Yu-li Lin; Hau, En Shun; Guillermo Hidalgo; Giorgio Capogna; Massimo Micaglio; Rakesh Vadhera; Ralf Gebhard

Department of Anesthesiology, University of Texas Medical Branch at Galveston

Introduction

Methods

Results

Conclusion

Specifications & Order Information

CompuFlo® Epidural Instrument Specifications	
Voltages	100-264 V, 50/60 Hz
Internal Battery	Up to 2 hrs of use
Weight	2.3 kg (5.0 lbs)
Dimensions	24.38 x 17.15 x 14 cm (9.6 x 6.75 x 5.5 in)
Operational Temperature	10-35 °C (50-95 °F)
Operational Humidity	30-70% RH
Storage Temperature	-20-45 °C (-4-113 °F)
Storage Humidity	15-90% RH
Compliance	IEC 60601-1 3.1 (2012) Edition "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance" "Medical Electrical Equipment: Part 1-2 General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility Requirements and Test"

CompuFlo® Epidural Instrument	
CompuFlo® Epidural Instrument 110	EPI-6000-110
CompuFlo® Epidural Instrument 220	EPI-6000-220

CathCheck™ Equipment	
CathCheck™ ID Adaptor & Kit	EPI-6010-03

CompuFlo® Epidural Disposables	
CompuFlo® Epidural ID Adaptor & Kit	EPI-6010

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CompuFlo® Epidural Computer Controlled Anesthesia System is marketed as the CompuFlo® Epidural Instrument.

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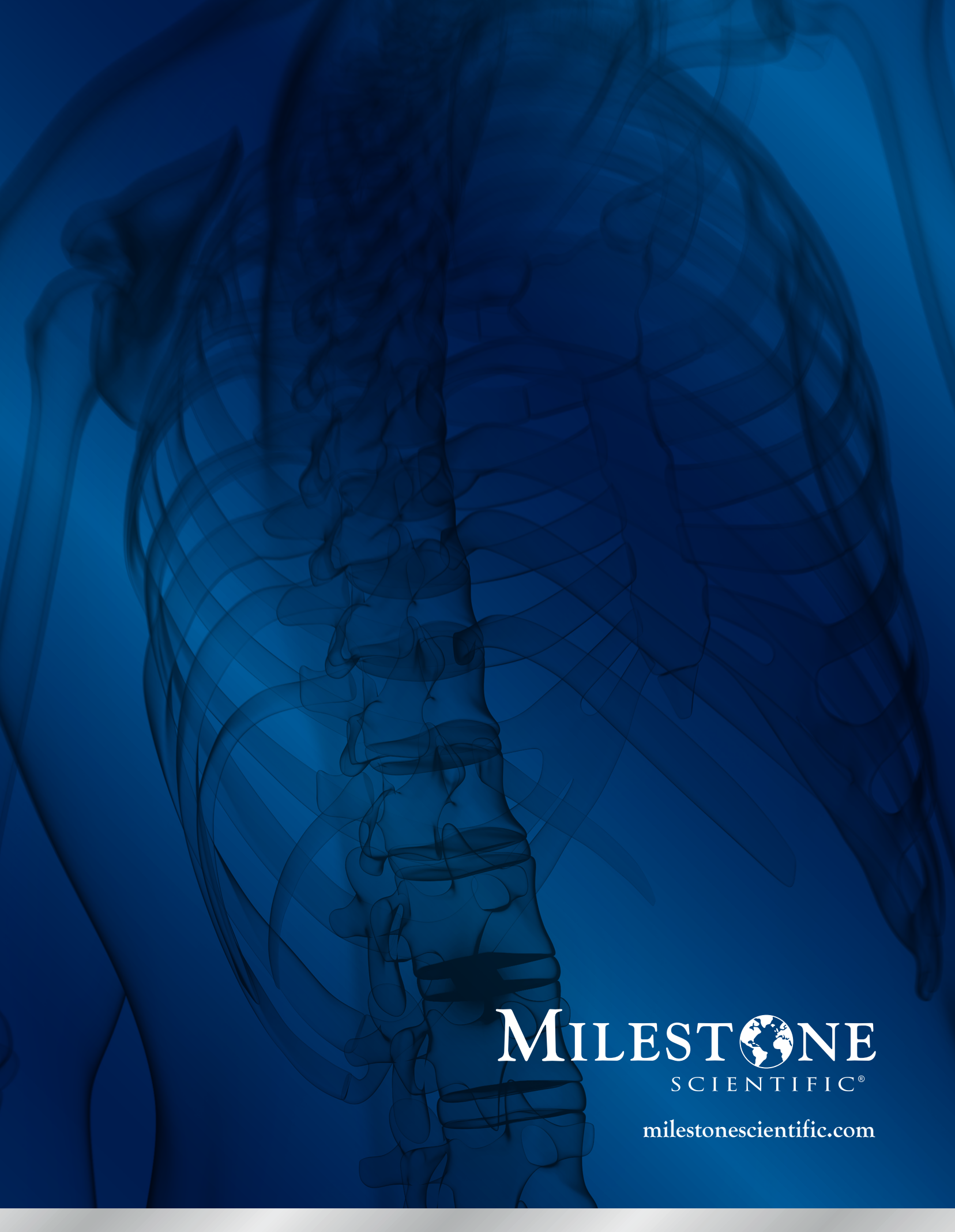
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