

SAFIRA[®]

Giving Anesthesiologists Control

Revolutionary Technology
for Regional Anesthesia

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MEDOVATE
Developing Innovation

A groundbreaking new technology for regional anesthesia

SAFIRA® - SAFer Injection for Regional Anesthesia

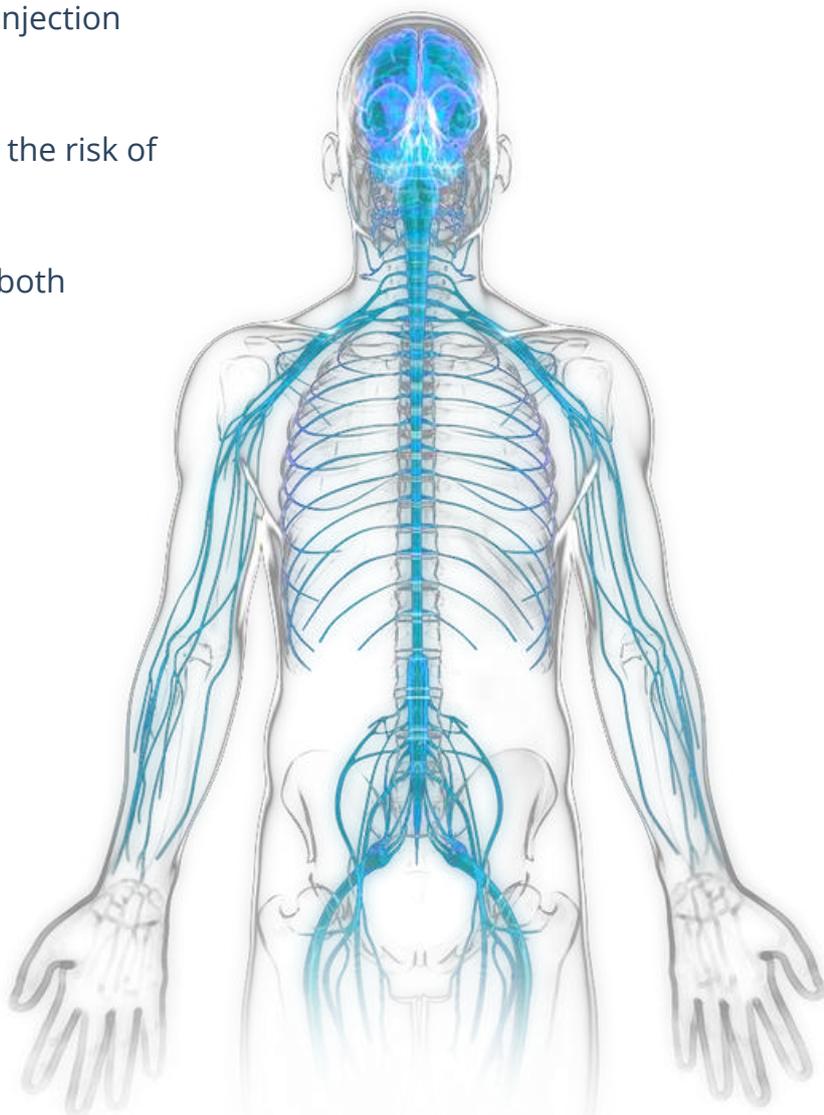
Revolutionary new technology

SAFIRA® makes regional anesthesia a one person procedure, putting control in the hands of the anesthesiologist.

A unique engineered in safety solution limits injection pressure to 20-psi.

This helps improve patient safety by reducing the risk of potential nerve damage.

SAFIRA® helps promote better outcomes for both patients and professionals.



SAFIRA® helps reduce the risk of nerve damage and improves patient outcomes^[1]

Current procedure

Regional anesthesia is currently a two-person procedure

The anesthesiologist holds the ultrasound scanner to guide the needle tip placement, while a second operator injects the anesthetic at the required pressure.

Anesthetic solutions are often injected at high pressure

This can cause nerve damage, serious nerve damage occurs in up to 1% of procedures and transient nerve damage in up to 8% of cases.

Procedure with SAFIRA®

SAFIRA® transforms regional anesthesia into a one-person procedure

It allows a single operator, an anesthesiologist, to conduct the whole regional block at safer pressures.

SAFIRA® helps to prevent injection at unsafe pressures

A built in system helps to prevent injection at pressures above 20psi, which reduces the risk of incidences of transient or serious nerve damage occurring as a result of the regional anesthesia procedure.



How to use SAFIRA®

SAFIRA® is intended for use by trained clinicians to administer local anesthetic below a specified pressure threshold to a target nerve bundle for regional anesthesia.

SAFIRA® consists of :

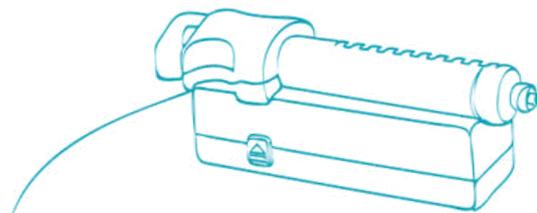
- 1 SAFIRA® Driver**
(Product reference: 900029)
- 2 Single use sterile Luer syringe**
(Product reference: 900016)

Choice of operator:

- 3 Foot pedal operator**
(Product reference: 900044)
- 4 Palm operator**
(Product reference: 900059)

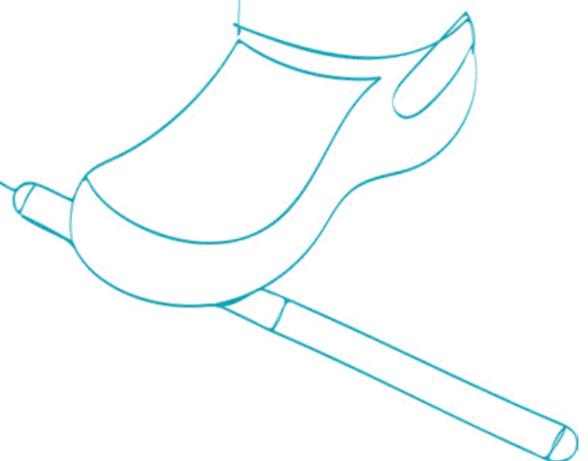


The proprietary single use syringe securely connects to the SAFIRA® driver



The driver is engineered to help limit injection pressure to 20psi by automatically stopping

The driver and both options of operator are designed to perform 200 standard blocks before replacement is required



Operator options for SAFIRA®

SAFIRA® is available with a choice of a foot pedal or palm operator.

Both operators are controlled by pressing green to infuse and yellow to aspirate.

Foot pedal



Palm operator



The palm operator is designed to be used under a gloved hand.

Quality standards and approvals

- SAFIRA® is manufactured in compliance with the highest FDA and international industry standards
- SAFIRA® has FDA Clearance and European CE Mark Certification
- Medovate is ISO 13485 certified

What do leading anesthesiologists say?

According to 30 world leading regional anesthesiologists (EU & US): ^[4]

1/30

confident in their assistance applying the correct pressure ^[4]

2/30

confident they themselves could apply the the correct pressure ^[4]

23/30

believed SAFIRA® would be able to help them save 5 (or more) minutes per procedure ^[5]



5 Reasons to make the switch to SAFIRA®

SAFIRA® gives anesthesiologists the tools to take control

1. SAFIRA®: SAFer Injection for Regional Anesthesia

SAFIRA® is a safer injection system for regional anesthesia, allowing a single anesthesiologist to conduct a whole regional block at safer pressures.

2. It makes Regional Anesthesia a one person procedure

SAFIRA® is a safer injection system for regional anesthesia, allowing a single anesthesiologist to conduct a whole regional block at safer pressures.

The anesthesiologist controls all aspects of the injection themselves.

4. SAFIRA® promotes better outcomes for patients

SAFIRA® incorporates a safety feature to help prevent injection at pressures above 20psi. This reduces the risk of nerve damage in patients, promoting improved safety for regional anesthesia.

3. It helps improve patient safety by controlling the injection pressure threshold

With its integrated safety solution to help limit the injection pressure threshold, SAFIRA® can help reduce the risk of accidental nerve damage, potentially omitting follow up procedures or litigation cases.^[1]

5. SAFIRA® has the potential to save time and money

SAFIRA® has the potential to save up to 5 minutes per procedure and an estimated \$58.00 in costs associated with extra operators.^{[5][6]}

When time is money, SAFIRA® could save you both.

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Appointed distributor for SAFIRA® in the US:

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LinkedIn: @MedicalMercury

References:

1. Heij R, Eldin E, Young P, Carter J, Gibson J, Ali A, et al. Regional Anesthesiology Injection Pressures comparing Skilled Assistants With SAFIRA in a Simulated Ultrasound Guided Technique. In: The Anesthesiology annual meeting [Internet]. 2013 [cited 2020 Mar 31]. Available from: <http://www.asaabstracts.com/strands/asaabstracts/abstract.htm?year=2013&index=17&absnum=3085>
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3. Jeng CL, Torrillo TM, Rosenblatt MA. Complications of peripheral nerve blocks. Br J Anaesth [Internet]. 2010 [cited 2020 Mar 31];105(S1):97–107. Available from: https://academic.oup.com/bja/article-abstract/105/suppl_1/i97/235950
4. Health Enterprise East (HEE). Research results using a cohort of volunteer anaesthetists.
5. Fong-Soe-Khioe R. Health Economic report Medovate commissioned written by a health economist from the University of East Anglia (UEA).
6. MP-007-6018-v1.0 SAFIRA Budget Analysis Report_June2020_US - figure of \$58.00 generated using SAFIRA® cost model and budget analysis report commissioned by Medovate from Health Enterprise East (HEE).