SAFIRA®
FREQUENTLY ASKED QUESTIONS

BACKGROUND

1. Who are Medovate?

Medovate are a dynamic medical device company dedicated to the development and commercialisation of innovative medical technologies created within the UK National Health Service (NHS) and beyond.

We accelerate innovative medical technologies to market for the benefit of patient care and healthcare delivery. Our core business is focused on medical technologies in anaesthesia, airway management, critical care and surgery.

2. Why was SAFIRA® (SAFer Injection for Regional Anaesthesia) developed?

Current regional anaesthesia procedures require two operators: an anaesthetist who holds an ultrasound scanner and uses this to guide the needle tip placement, and a second operator to inject the anaesthetic solution.

Anaesthetic can be injected at high pressures, potentially leading to nerve injury, with serious nerve damage occurring in up to 1% of procedures [1] and transient nerve damage in up to 8% of cases [2].

SAFIRA® gives control and confidence to anaesthetists by allowing them to conduct the entire procedure themselves at safer pressures. Using the SAFIRA® system, clinicians are able to control infusion and aspiration without the need for an assistant. Additionally, the built-in safety feature automatically limits injection pressure to a specified threshold by stopping injection, helping to reduce the risk of nerve injury.

3. What is SAFIRA® indicated for?

The SAFIRA® system is intended for use by trained clinicians in a hospital or surgical environment to administer peripheral nerve blocks to a target nerve bundle below a specified pressure threshold. Appropriate procedures include upper and lower limb peripheral nerve blocks, such as brachial plexus and interscalene blocks.

The device is not intended for paediatrics or for epidural or spinal anaesthesia procedures of any kind.

4. How does SAFIRA® benefit anaesthetists?

The SAFIRA® system gives anaesthetists full control of the injection process during regional anaesthesia and provides additional confidence with a built-in safety system that helps reduce the risk of nerve damage.

Making regional anaesthesia a single operator procedure means that assistant staff are no longer required to control the injection of anaesthetic, freeing them up to focus on other vital tasks. This promotes the effective use of resources, contributing to a time and cost-effective solution.

5. How does SAFIRA® benefit the patient?

The SAFIRA® system helps to reduce the risk of nerve damage, promoting patient safety and improved outcomes.

SAFIRA® was awarded 'Patient Safety Innovation of the Year' at the 2021 HSJ Patient Safety Awards.

USING THE SAFIRA® SYSTEM

6. How do you use SAFIRA®?

The SAFIRA® system was developed with clinicians for clinicians. As a result, the device fits into existing practice and is intuitive to use, without requiring extensive training.

During a regional anaesthesia procedure, the SAFIRA® system enables clinicians to independently control all aspects of injection. Using either a foot pedal or palm operator clinicians control infusion and aspiration themselves. The SAFIRA® driver is designed to deliver local anaesthetic at a controlled rate of 0.5ml/second. A built-in safety system automatically limits injection pressure to a specified threshold by automatically stopping injection.

For full instructions on how to use SAFIRA®, please refer to the 'Instructions for Use', available via the Medovate website.

7. What volumes of anaesthetic can be injected using SAFIRA®?

The system holds a volume of 20ml and is suitable for both single and multi-shot nerve blocks. A second syringe can be used for additional volume if required.

9. How do you continue injection once it has been automatically stopped?

SAFIRA® helps to reduce the risk of nerve injury through automatically limiting injection pressure to a specified threshold by stopping injection. A red flashing light on the SAFIRA® driver will indicate that infusion has been automatically stopped, prompting the clinician to make necessary checks and reposition the needle if required.

To reset the red flashing light indicating 'infusion stopped' on the SAFIRA driver, either aspirate until the light goes out or release the SAFIRA® syringe and re-click into place.

For further information please refer to the 'Instructions for Use', available via the Medovate website

10. What type of needles/extension tubing are compatible with SAFIRA®?

The SAFIRA® system is able to be attached to standard sterile needles and extension tubing. The minimum size needle gauge approved for use is 22G. The maximum length of needle approved for use with this system is 120mm.

Further details of approved needle types can be found in the 'Instructions for Use', available via the Medovate website.

11. Is SAFIRA® available with NRFit™ connectors?

To support the changing needs of clinicians and promote improved patient safety, the SAFIRA® system is now available with both Luer and NRFit™ connector options.

12. Is SAFIRA® single-use or re-usable?

The SAFIRA® driver, foot pedal and palm operator are all re-usable and designed to perform 200 standard blocks before replacement is required. All re-usable components should be cleaned before and after use in accordance with local infection prevention guidelines.

Both the Luer and NRFit™ SAFIRA® sterile syringes are single patient use and must be discarded in the same manner as standard sterile syringes using biohazard disposal procedures.

REGULATORY

13. Where has SAFIRA® received regulatory approval?

The SAFIRA® system has been granted CE Certification in Europe, FDA clearance in the US, TGA approval in Australia, and inclusion on the WAND database in New Zealand.

Medovate is actively working to secure further regulatory approvals to increase the availability of SAFIRA® across the world.

Further details of regulatory approvals are available via the Medovate website.

CLINICAL FEEDBACK

14. What do clinicians think of the SAFIRA® system?

Clinician testimonials are available in both video and written form and can be accessed via the Medovate website and Medovate YouTube channel.

APPOINTED DISTRIBUTORS

15. How do I get a SAFIRA® system?

Please contact the appointed SAFIRA® distributor in your region and they will be able to help you.

Find your local distributor by visiting the Medovate website.

FURTHER DETAILS

For further information on SAFIRA® please visit the SAFIRA® product page on the Medovate website or contact sales@medovate.co.uk

Email: sales@medovate.co.uk
Twitter: @Medovate
LinkedIn: Medovate Limited

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References

1. Borgeat A, Blumenthal S. Nerve injury and regional anaesthesia [Internet]. Vol. 17, Current Opinion in Anaesthesiology. 2004 [cited 2020 Mar 31]. p. 417–21. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17023899

2. 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

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