
SAFIRA™ FREQUENTLY ASKED QUESTIONS

BACKGROUND

1. About Medovate

Medovate is a dynamic medical device company dedicated to the development and commercialization 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 anesthesia, airway management, critical care and surgery.

2. What is the need for SAFIRA™ (SAFer Injection for Regional Anesthesia)?

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

Anesthetic solutions are often injected at high pressure, this can cause damage to nerve fascicles, with serious nerve damage occurring in up to 1% of procedures¹ and transient nerve damage in up to 8% of cases.²

SAFIRA™ has a built in system to help prevent injection at pressures above 20psi. This helps to reduce the chances of incidences of transient or serious nerve damage occurring as a result of the regional anesthesia procedure.

3. How does SAFIRA™ benefit anesthesiologists?

SAFIRA™ makes regional anesthesia a one operator procedure.

Giving clinicians control of the whole procedure, they can manage all aspects of the procedure including injection of the anesthetic.

This improves safety and frees up resource

as a second supporting operator is no longer required, contributing to a more time and cost-effective solution.³

4. How does SAFIRA™ benefit the patient?

With its integrated safety solution to help limit the injection pressure threshold, SAFIRA™ can help reduce the chance of accidental nerve damage, reducing the need for follow up procedures.⁴

REGULATORY AND LEGAL

5. Where is SAFIRA™ approved for use?

SAFIRA™ has been granted Food and Drug Administration (FDA) clearance and is set to be launched in the United States in April 2020, it will then launch across the European Union pending Medical Device Directive (MDD) approval later on in the year.

INDICATIONS

6. What is SAFIRA™ indicated for?

The SAFIRA™ device is intended for use by trained clinicians to administer regional anesthesia below a specified pressure threshold to a target nerve bundle.

ADMINISTRATION

7. How do you use SAFIRA™?

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

8. What are the different components of the SAFIRA™ device?

SAFIRA™ consists of three separate components: a Sterile Syringe, the Driver, and the Foot Pedal.

The Sterile Syringe is connected to the SAFIRA™ driver unit. The battery-operated Driver is activated by means of a cable connected Foot Pedal. SAFIRA™ is engineered to prevent injection above 20psi.

Approved needle types and extension tubing can be attached to the SAFIRA™ syringe. Details of approved needle types can be found in the 'Instructions for Use', which is available via the Medovate website.

9. Is SAFIRA™ a re-useable device?

The SAFIRA™ Sterile Syringe is single patient use and must be discarded using standard biohazard disposal procedures.

The SAFIRA™ Driver has internal batteries which are adequate for approx. 200 procedures. The Driver should be cleaned before and after use in accordance with local infection prevention guidelines.

The SAFIRA™ Foot Pedal component is reusable (limited to 200 procedures) and should be

cleaned before and after use in accordance with local infection prevention guidelines.

10. Where can the SAFIRA™ system be used?

SAFIRA™ is designed for use by appropriately trained and qualified clinicians, in either a hospital or surgical environment.

11. What type of device is SAFIRA™?

SAFIRA™ is a Type BF device.

The SAFIRA™ components are not conductive and can be immediately released from the patient. The needle and tubing (not supplied by Medovate) attached to the device is the part in physical contact with the patient and can also be immediately released from the patient.

CONTRAINDICATIONS

12. In which patients is SAFIRA™ contraindicated?

SAFIRA™ is not intended for the following uses: intravascular delivery, delivery of blood, blood products, lipids, fat emulsions or Total Parenteral Nutrition (TPN); infusion of fluids that will enter or contact circulatory blood or cerebrospinal fluid; delivery of life supporting medications where under- or over delivery may cause serious injury or death and use with neonates (up to 28 days).

Contact us to find out more:

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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 3. Fong-Soe-Khioe R. Health Economic report Medovate commissioned written by a health economist from the University of East Anglia (UEA). 4. 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>