SAFIRA®
FREQUENTLY ASKED QUESTIONS

BACKGROUND

1. About Medovate

Medovate is 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. What is the need for SAFIRA® (SAFer Injection for Regional Anaesthesia)?

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 solutions are often injected at high pressure, this can cause damage to nerve fascicles, with serious nerve damage occurring in up to 1% of procedures[1] 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 anaesthesia procedure.

3. How does SAFIRA® benefit anaesthetists?

SAFIRA® makes regional anaesthesia a one operator procedure.

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

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 CE Certification and has been granted Food and Drug Administration (FDA) clearance in the US.

INDICATIONS

6. What is SAFIRA® indicated for?

The SAFIRA® device is intended for use by trained clinicians to administer regional anaesthesia 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 shoud 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

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