

SO WHAT SHOULD I SAY ABOUT THE ICG... HANDOUT

Medtronic

...when I want to talk about the VS3-IR for tissue perfusion and blood flow fluorescence imaging for open or MIS?

- “Use the VS3-IR ICG kit that is co-packaged with the system.”

...if a surgeon asks me if he/she can use the ICG from the pharmacy?

- “Using the ICG from the pharmacy is Off-Label, because the VS3-IR is cleared for use by FDA as a combination product and is only cleared for use with the VS3-IR ICG kit that is co-packaged for perfusion imaging.”
- A surgeon is authorized to use another ICG based on his/her medical judgment as part of the HCP's practice of medicine. We cannot solicit/encourage/promote such use, and any further questions from the surgeon on this matter shall be handled by the Office of Medical Affairs (OMA).
- For demo units, strictly adhere to the recent communication on supply for free of the co-packaged VS3-IR ICG kit.

...if the hospital pushes back and argues that we are wrong by stating that ICG is approved for our indication with the VS3-IR system?

- “The VS3-IR is cleared for use by FDA as a combination product with the VS3-IR ICG kit being co-packaged for tissue perfusion imaging through the 510(k) pathway. Our 510(k) clearance covers our system when co-packaged with the VS3-IR ICG kit for tissue perfusion imaging by open and MIS.”

...if I discover *afterwards* that the surgeon is not using the right ICG?

- HCP are allowed to apply their best medical judgment to choose suitable clinical options. You should however remind the surgeon that the VS3-IR is cleared for use by FDA with the VS3-IR ICG kit that is co-packaged with the device.

...if a surgeon asks for information about its contraindications?

- Strictly refer to the user manual:
 - ICG contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides.
 - The VS3-IR should not be used during surgical procedures with patients who are known to be sensitive to iodides or iodinated contrast agents.

SO WHAT SHOULD I SAY ABOUT THE ICG...

...if a surgeon asks for information about the suitable ICG dosage for a particular clinical case?

- Strictly refer to the user manual:
 - Prescribed dosages are at the medical discretion of the prescribing physician.
 - When imaging through the skin, a dose of 10 mg of ICG is recommended for plastic and reconstructive surgery use. This corresponds to 4 ml of ICG/Water mixture.
 - When not imaging through skin, a dose of 5mg of ICG is recommended. This corresponds to 2ml of ICG/Water mixture.
 - The total dose of dye injected should be kept below 2 mg/kg.

...if a surgeon asks for information about how to inject the ICG?

- Strictly refer to the user manual.

...if I am aware of an adverse reaction that may potentially be related to the ICG?

- Report it per the usual complaints and reporting process.