

Verdyne™ (Indocyanine Green)

# Use of ICG in Reconstructive Surgery



## Diagnostic Green is the leading provider of trusted high quality fluorescence products for physicians worldwide.

Reconstructive surgery is performed to treat structures of the body affected aesthetically or functionally by congenital defects, trauma, infection, developmental abnormalities, tumours or disease. In the US alone, over 1 million reconstructive procedures are performed annually with 0.5 million plastic/reconstructive procedures following tumour removal and breast reconstruction.<sup>1</sup> The global breast reconstruction surgery market is on track to nearly double over the next decade – from USD 4.9 billion in 2025 to USD 10.1 billion by 2035, growing at a steady 7.5% Compound Annual Growth Rate (CAGR). Surgical reconstruction will continue to lead the way, representing over three-quarters (77.2%) of all procedures in 2025, driven by the rising number of post-mastectomy reconstructions.<sup>2</sup>

### PERFUSION ASSESSMENT IS KEY

Plastic surgeons face daily challenges and risks when harvesting skin, pedicled or free flaps. They are motivated more than any other surgeon to use rapid, reliable, safe and easy to use approaches to assess tissue viability and perfusion before, during and after surgical procedures.

### ICG USE IN TISSUE PERFUSION ASSESSMENT IN PLASTIC MICRO-RECONSTRUCTIVE SURGERY

| Breast Reconstruction (Flaps) | Head & Neck Reconstruction | Trauma & Burns |
|-------------------------------|----------------------------|----------------|
|-------------------------------|----------------------------|----------------|

### BREAST RECONSTRUCTION (FLAPS)

Breast reconstruction has greatly changed in the last decade as skin-sparing and nipple sparing mastectomies, post tumour removal, have been shown to be oncologically safe allowing better aesthetic and functional results.<sup>3</sup> Skin perfusion in skin sparing mastectomies and the areolar-papillary complex (APC) perfusion as undertaken in nipple sparing mastectomies, are fundamental to the success of a patient's breast reconstruction procedure. Failure to detect perfusion problems that could compromise tissue vascularisation may result in postoperative complications including necrosis, infection, implant loss and reoperation.<sup>4</sup>

Across 18 studies involving over 3,200 patients, intraoperative ICG fluorescence angiography (ICGFA) consistently reduced key complications in breast reconstruction. Use of ICGFA halved the incidence of fat necrosis in autologous reconstruction from 21.9% to 10.4% and reduced mastectomy skin flap necrosis from 16.7% to 11.1%. In implant-based reconstruction, necrosis rates fell from 17.2% to 11.9%. ICGFA also lowered reoperation rates by up to 60% and significantly reduced infection risk, helping to preserve flap viability, optimise aesthetic outcomes, and improve overall surgical success.<sup>5</sup>



*Fig 1: Breast Flap reconstruction - greyscale image of DIEP Flap using Verdyne, checking vascular perfusion of the perforator blood vessel feeding the tissue flap.*

Source: Prof. Juame Masia, Hospital de la Santa Creu i Sant Pau.

## *Pooled outcomes from meta-analysis of ICG use in breast reconstruction<sup>5</sup>*

### Use of ICGA compared to clinical assessment alone resulted in:

- 50% reduction in fat necrosis rates in autologous breast reconstruction ( $p < 0.001$ )
- Lower mastectomy skin flap necrosis rates (11.1% vs 16.7%;  $p < 0.0001$ )
- Reduced necrosis in implant-based reconstruction (11.9% vs 17.2%;  $p = 0.02$ )
- Up to 60% fewer reoperations across reconstruction types ( $p < 0.0001$ )
- Significant reduction in postoperative infection risk ( $p = 0.02$ )
- Improved flap viability and overall reconstruction success rates (No statistically significant difference in flap viability outcomes (total flap loss  $p = 0.57$ ; partial flap loss  $p = 0.55$ ), although a numerical trend favoured ICG angiography)

## HEAD & NECK RECONSTRUCTION

A meta-analysis of four studies involving 701 patients found that intraoperative ICG fluorescence angiography significantly reduced total flap loss rates in reconstructive surgery (3.56% vs 7.18%;  $p = 0.04$ ). Partial flap loss was also lower (4.49% vs 13.04%), although this did not reach statistical significance ( $p = 0.13$ ). These findings highlight ICGFA's value in enhancing flap survival, supporting better surgical outcomes, and helping surgeons make confident, data-driven intraoperative decisions, where early detection of vascular compromise and prompt correction are critical to procedural success.<sup>5,11</sup>

## TRAUMA SURGERY

In trauma surgery, where rapid and accurate assessment of tissue viability is critical, ICG fluorescence angiography has emerged as a valuable intraoperative tool. Published evidence demonstrates that ICG enables real-time visualisation of tissue perfusion, supporting the detection of avital tissue and more precise determination of resection or debridement margins. Its use has been shown to support surgical decision-making across a range of complex trauma scenarios, including extremity injuries, extremity pedicle flaps, extremity free flaps and craniofacial free flaps. Overall, ICG has been reported to influence intraoperative decision-making in approximately 28.5% to 78.9% of cases across published studies and is associated with reductions in postoperative complications and fewer required debridement procedures, with no reported ICG-related adverse events. These findings highlight the potential of ICGFA to enhance surgical precision and improve outcomes in complex trauma settings.<sup>6</sup>

## BURNS

ICG angiography has been reported to be highly efficacious in assessing burn depth (with an accuracy of almost 100%) and predicting long-term wound outcomes. In studies it has been considered superior to Laser Doppler Imaging for evaluating burn wounds.<sup>7</sup> In the 30 burn sites that were assessed, in one study, the accuracy of ICG angiography was 100%, compared with 50% for clinical assessment ( $p < 0.001$ ). Clinical assessment yielded a sensitivity of 33.3% and specificity of 66.7%, while ICG angiography yielded both a sensitivity and specificity of 100%.<sup>7</sup>

## Why use ICG in plastic and reconstructive surgeries?

While many surgeons still assess flap perfusion and viability based solely on clinical experience, there is an increasing wealth of evidence now available to recommend using ICG for dynamic perfusion imaging during flap reconstruction, be that breast reconstruction, head & neck reconstruction surgery or burn and trauma reconstructive procedures. Studies have shown that employing ICG as a method to evaluate perfusion reduces complication rates, lowers morbidity, shortens hospital stays and produces for the patient a better overall result.<sup>5,8,9,10,11,12</sup>

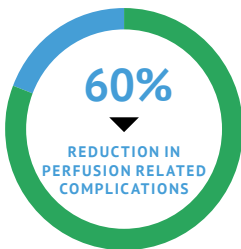
### THE ADVANTAGE OF TISSUE PERFUSION ASSESSMENT USING ICG

- ⊙ Easy to implement<sup>9</sup>
- ⊙ Improved perforator selection<sup>12</sup>
- ⊙ Provides real time perfusion assessment (flap & skin at attachment site)<sup>12</sup>
- ⊙ Optimises flap design<sup>13</sup>
- ⊙ Supports intraoperative flap monitoring<sup>13</sup>
- ⊙ Gives surgeon a tool to facilitate flap planning, dissection and insertion<sup>8</sup>

### COST BENEFITS ON USE OF ICG DURING RECONSTRUCTIVE SURGERY

A retrospective review of prospectively gathered data from patients who underwent breast reconstruction revealed that laser-assisted ICG angiography used to assess perfusion improved clinical outcomes and reduced costs.<sup>5,14</sup>

#### Overall Reoperation Rate<sup>5</sup>



#### Mastectomy Skin Flap Necrosis<sup>5</sup>



#### Increased costs associated with surgical complications

Complete flap failure - increased by \$11k inpatient costs per patient<sup>14</sup>

#### Potential savings with the use of ICG in free flap surgery

Up to \$972 per patient due to avoidance of costly, complication related reoperations<sup>14</sup>

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## VERDYE ABBREVIATED PRESCRIBING INFORMATION

### Verdye

5 mg/ml powder for solution for injection

### Composition:

Active substance: Indocyanine green (ICG); vials containing 25 mg and 50 mg (to be reconstituted with 5 ml respectively 10 ml water for injections).

### Indications:

Cardiac, circulatory and micro-circulatory diagnostic agent for measurement of cardiac output and stroke volume, circulating blood volumes and cerebral perfusion; liver function diagnostic agent for measurement of liver blood flow and excretory function of the liver; ophthalmic angiography diagnostic agent for measurement of perfusion of the choroid. Intraoperative identification of sentinel lymph nodes and visualization of lymphatic pathways in breast cancer (registered only in some European countries).

### Posology:

Cardiac, circulatory, micro-circulatory and tissue perfusion diagnostics as well as cerebral blood flow (adults and children): 0.1-0.3 mg/kg body weight (BW) as single i.v. bolus per measurement; liver function diagnostics (adults and children): 0.25-0.5 mg/kg BW as single i.v. bolus per measurement; ophthalmic angiography (adults and children): 0.1-0.3 mg/kg BW as single i.v. bolus per measurement. Total daily dose:  $\geq 12$  yrs:  $< 5$  mg/kg BW, 2-11 yrs:  $< 2.5$  mg/kg BW,  $< 2$  yrs:  $< 1.25$  mg/kg BW. Identification of sentinel lymph nodes and visualization of lymphatic pathways regardless of BW (adults): 5-10 mg per single injection (intradermal, subcutaneous or peritumoral). Total daily dose:  $\leq 10$  mg.

### Contraindications:

Hypersensitivity to ICG, sodium iodide or iodine, hyperthyroidism, autonomic thyroid adenomas, hyperbilirubinemia requiring exchange transfusion in premature infants or neonates, history of poor tolerance to Verdye.

### Interactions:

Anticonvulsants, bisulphite compounds, haloperidol, heroin, pethidine, metamazole, methadone, morphine, nitrofurantoin, opium alkaloids, phenobarbital, phenylbutazone, cyclopropane, probenecid, rifamycin.

### Undesirable effects:

*Very rare (<1 in 10.000):* nausea, urticaria, anaphylactic/anaphylactoid reaction, coronary arteriospasm.  
*Frequency not known:* injection site discoloration.

Prescription only.

This product information may differ in some countries. For detailed information see prescribing information by territory visit {website}.

Diagnostic Green Ltd.

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