Comprehensive References for Intraoperative Perfusion and Vessel Blood Flow Assessment

Compiled for Investors and Acquirers (as of January 2026)
This broad reference supports diverse due diligence: clinical evidence, economic impact, market context, regulatory compliance, and historical foundations.

Quick Navigation for Non-Academics

Focus on these high-impact items first: - Graft flow issues in CABG (≈1 in 5 grafts <50% target flow): #31 (Nakajima et al., 2014) – full open access. - TTFM adoption and plan changes (25% surgical revisions): #28 (Taggart et al., 2020 REQUEST study). - Economic burden of complications (e.g., $100K+ per necrosis case in breast recon): #18 (Newman et al., 2012 poster) and #24 (Sood & Glat, 2013). - Necrosis reduction in breast reconstruction (23.4% to 13% with ICG; reops 14.1% to 5.9%): #7 (Duggal et al., 2014). - Market growth: Blood flow devices ≈$544M (2024) to $875M+ by 2032 (CAGR ~6-8.5%); Near-IR imaging ≈$1.25B (2025) to $2.07B by 2030 (CAGR 10.6%). - Global volumes: ≈313M major procedures/year (2012 estimate; likely higher now, ~350-500M+).

Peer-Reviewed Publications (1–40)

[Perfusion] 1. Agzarian J et al. The cost burden of clinically significant esophageal anastomotic leaks—a steep price to pay. J Thorac Cardiovasc Surg. 2019;157(5):2086-2092. doi:10.1016/j.jtcvs.2018.10.137. https://doi.org/10.1016/j.jtcvs.2018.10.137 (publisher); PubMed: https://pubmed.ncbi.nlm.nih.gov/30558876/.

2. Arezzo A et al. Intraoperative use of fluorescence with indocyanine green reduces anastomotic leak rates in rectal cancer surgery: an individual participant data analysis. Surg Endosc. 2020;34(10):4281-4290. doi:10.1007/s00464-020-07735-w. https://doi.org/10.1007/s00464-020-07735-w; PubMed: https://pubmed.ncbi.nlm.nih.gov/32556696/.

3. Blanco-Colino R, Espin-Basany E. Intraoperative use of ICG fluorescence imaging to reduce the risk of anastomotic leakage in colorectal surgery: a systematic review and meta-analysis. Tech Coloproctol. 2018;22(1):15-23. doi:10.1007/s10151-017-1731-8. https://doi.org/10.1007/s10151-017-1731-8; PubMed: https://pubmed.ncbi.nlm.nih.gov/29230591/.

4. Bliss LA et al. Readmission after resections of the colon and rectum: predictors of a costly and common outcome. Dis Colon Rectum. 2015;58(12):1164–1173.

doi:10.1097/DCR.0000000000000433. PubMed: https://pubmed.ncbi.nlm.nih.gov/26544814/.

5. Brennan TA et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. N Engl J Med. 1991;324:370-376. doi:10.1056/NEJM199102073240604. https://doi.org/10.1056/NEJM199102073240604; PubMed: https://pubmed.ncbi.nlm.nih.gov/1988735/.

6. Dip F et al. Does near-infrared fluorescent cholangiography with indocyanine green reduce bile duct injuries during cholecystectomy? – A meta-analysis. Surgery. 2021;169(5):1150-1157. doi:10.1016/j.surg.2020.12.008. PubMed: https://pubmed.ncbi.nlm.nih.gov/33478756/.

7. Duggal CS et al. An Outcome Analysis of Intraoperative Angiography for Postmastectomy Breast Reconstruction. Aesthetic Surgery Journal. 2014;34(1):61-65. doi:10.1177/1090820X13514995. PubMed: https://pubmed.ncbi.nlm.nih.gov/24396073/. (Key: reduced necrosis 23.4% → 13%, reops 14.1% → 5.9%).

8. Gawande AA et al. The incidence and nature of surgical adverse events in Colorado and Utah in 1992. Surgery. 1999;126(1):66-75. doi:10.1067/msy.1999.98664. PubMed: https://pubmed.ncbi.nlm.nih.gov/10418594/.

9. Hoek VT et al. Arterial calcification is a risk factor for anastomotic leakage after esophagectomy: A systematic review and meta-analysis. Eur J Surg Oncol. 2020;46(11):1975-1988. doi:10.1016/j.ejso.2020.06.019. PubMed: https://pubmed.ncbi.nlm.nih.gov/32883552/.

10. James JT. A new, evidence-based estimate of patient harms associated with hospital care. J Patient Saf. 2013;9:122-128. doi:10.1097/PTS.0b013e3182948a69. PubMed: https://pubmed.ncbi.nlm.nih.gov/23860193/.

(Continuing similarly for brevity—full list as in previous cleaned version, up to #40 Secemsky et al.)

[Vessel Flow]
26–33: As previously consolidated (Thuijs, Gaudino, Taggart [#28 REQUEST], Niclauss, Amin, Nakajima [#31 key flow stats], Kieser x2).

[General/Global]
34–40: Weiser, Haynes, Satomura (1962 flowmeter), Leevy (1962 ICG), Feng (CABG readmissions), Montrief, Secemsky.

Market and Industry Reports (41–44)

41. Inkwood Research. Global Blood Flow Measurement Devices Market... (updated forecasts). https://inkwoodresearch.com/reports/blood-flow-measurement-device-market/.

42. MarketsandMarkets. Near Infrared Imaging Market... https://www.marketsandmarkets.com/Market-Reports/near-infrared-imaging-market-174869738.html.

43. Life Science Intelligence. Procedure Volumes Database. 2020.

44. Medistim ASA. Annual Report 2021. https://medistim.com/wp-content/uploads/2022/03/annual-report-2021-esef-compliant.pdf. (700K CABG; probes in 42%).

Regulatory and Government Documents (45–48)

45. U.S. FDA. Class I Device Listing: Surgical Camera and Accessories (KQM). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=608479&lpcd=KQM.

46. U.S. FDA. Medical Devices; Exemptions From Premarket Notification... Federal Register 2017. https://www.govinfo.gov/content/pkg/FR-2017-04-13/pdf/2017-07468.pdf.

47. World Health Organization. New Checklist to Help Make Surgery Safer. 2008. https://www.who.int/news/item/24-06-2008-new-checklist-to-help-make-surgery-safer.

48. Eurofins MET Laboratories (MET Mark Certification Listing). Certification ID: E212655. (IEC-related product safety certification; MET Mark is OSHA NRTL-recognized for US/Canada electrical/electronic safety compliance, often IEC 60601 series for medical devices like imaging/surgical systems. Public database: https://corp.metlabs.com/metsafety/. Status: Noted as expired/renewal pending in legacy docs, potentially via contract mfg. Contact Eurofins MET for current verification.)

Company Materials and Press Releases (49–51)

49. Stryker Corporation. SPY Elite Fluorescence Imaging System. https://www.stryker.com/us/en/endoscopy/products/spy-elite.html.

50. Biospace. Novadaq Corp Announces Transfer of SPY Elite Business... 2014. https://www.biospace.com/article/releases/novadaq-corp-announces-transfer-of-spy-and-174-elite-business-from-lifecell-corporation-/.

51. Beth Israel Deaconess Medical Center. Study Finds More Than 1 in 6 Patients... 2017. https://www.bidmc.org/about-bidmc/news/1-in-6-patients-with-pad-who-undergo-revascularization-readmitted-within-30-days.

Additional Notes & Excerpts (Raw / Unmerged Fragments)

- 23.4% necrosis in breast reconstruction (pre-ICG/SPY); reduced with assessment. https://pubmed.ncbi.nlm.nih.gov/24396073/; https://www.stryker.com/us/en/endoscopy/products/spy-elite.html.
- Published literature... excess cost $99,908 per flap necrosis case ($63,079 hospital + $36,829 professional fees). Tied to Newman poster (#18) and Sood (#24).
- Medistim REQUEST study (25% changed surgical plan). https://pubmed.ncbi.nlm.nih.gov/31685277/.
- 1 in 5 bypass grafts had less than ½ of target flow. https://cardiothoracicsurgery.biomedcentral.com/articles/10.1186/s13019-014-0188-3.
- Normal flow reference. https://pubmed.ncbi.nlm.nih.gov/8076048/.
- 30-day CABG readmission rates 9.2% to 18.9% in 14 studies (intraop risks not significant). https://academic.oup.com/eurjcn/article/20/7/717/6231582.
- Median time to readmit 11 days, LOS 6 days, cost $13,499 ± $201 (CABG readmissions). https://pubmed.ncbi.nlm.nih.gov/30553740/.
- CABG readmissions: 16.1% overall; highest Medicare/Medicaid. https://pubmed.ncbi.nlm.nih.gov/29678620/.
- Up to 14% post-CABG patients to ED within 30 days. https://pubmed.ncbi.nlm.nih.gov/30217621/.
- 58% averted emergencies: 14% reduced to 5.9% necrotic emergency procedures in breast recon via perfusion assessment. https://pubmed.ncbi.nlm.nih.gov/24396073/; Stryker SPY page.

Historical/Legacy Methods

- 1962 Pulsed Ultrasonic Transit Time Flowmeter. https://ieeexplore.ieee.org/document/4322948.
- 1962 ICG for hepatic blood flow. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC291025/.
- 1963 Retinal venous blood oxygen saturation photographic study. https://www.semanticscholar.org/paper/A-Study-of-Retinal-Venous-Blood-Oxygen-Saturation-Hickam-Frayser/04c3130ca5ac4ff6bc8a0c42ea6d2b8cfb56cb70.

Miscellaneous Market/Quote Snippets

- Global vascular graft market: $4.99B (2020) to $8.14B by 2030 (CAGR 4.98%); 197.2M with IHD in 2019. https://www.dicardiology.com/article/vascular-graft-market-size-expected-reach-813-billion-2030.

- “Quality control in coronary artery bypass surgery is probably one of the most important predictors of outcomes, and this (TTFM) is perhaps the easiest way to do it,” Husam Balkhy, M.D. https://www.dicardiology.com/content/british-national-health-service-endorses-ultrasound-bypass-graft-flow-evaluation-system.

Device-Specific Regulatory Notes

- FDA Class I exempt (surgical camera/accessories, KQM, 878.4160) unless provides interpretation/clinical implication. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=5995.
- Original listing expired/renewed; planned under MPE/EIT/contract mfg.
- World Health Org: 313M/year major procedures (2012); ~450M in 2021 est. https://pubmed.ncbi.nlm.nih.gov/26313057/.
- Partnering: LifeCell/Novadaq Alliance 2010–2014. https://www.biospace.com/article/releases/novadaq-corp-announces-transfer-of-spy-and-174-elite-business-from-lifecell-corporation-/.