stryker

SPY-PHI

Extending boundaries of the surgeon's eye

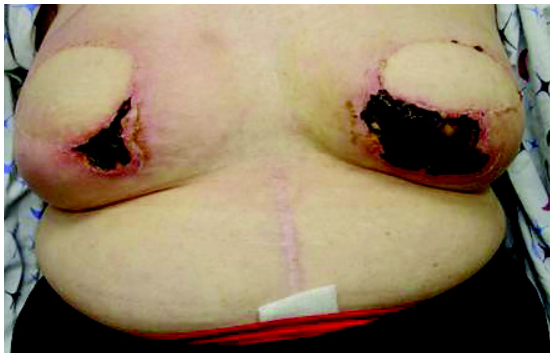
Adequate tissue perfusion

is vital to the success of surgery

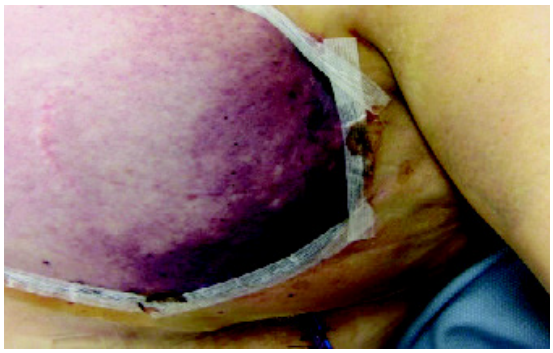
Perfusion is a critical indicator of tissue health.[1] It is crucial to surgical success and the body's ability to heal. Even a few hours of impaired perfusion can cause irreversible damage and costly complications.[2]

At present in the OR, clinical judgment is the most common method used for perfusion assessment. Despite excellent surgical techniques, perfusion-related complications still occur.

Skin necrosis following facial reconstruction



Wide necrosis on mastectomy breast flaps



Tissue exhibiting venous congestion

Assess perfusion
with more confidence

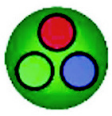
The SPY Portable Handheld Imaging (PHI) System is designed to provide surgeons with real-time visualization of tissue perfusion and lymphatic vessels and nodes during a variety of surgical procedures.

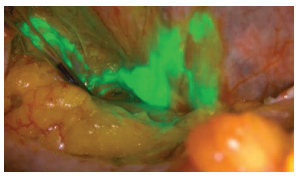
The SPY-PHI System

- Is an active device used to visualize circulation, including lymphatics and blood vessels, as well as related tissue perfusion with near infrared fluorescence imaging during a variety of surgical procedures.
- Is designed to enhance the surgeons ability to assess perfusion, which may improve patient outcomes.[3]
- Features SPY-QP, the latest fluorescence assessment software that allows for further analysis of tissue perfusion through relative values (%) and color maps.
- Contains four fluorescence imaging modalities, shown below. [4]

Multiple visualization modes

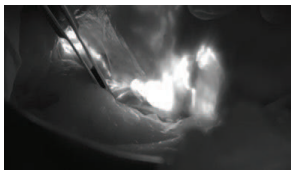
Combines enhanced fluorescence signal information with vivid 1080p white light images in real-time:





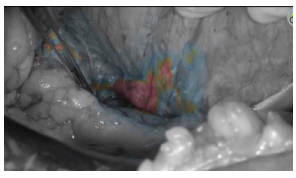
SPY Overlay mode:

In SPY overlay mode the fluorescence image (green) is displayed over a 1080p white light image. Surgeons can operate in fluorescence overlay or switch between fluorescence imaging and white light by the touch of a button.



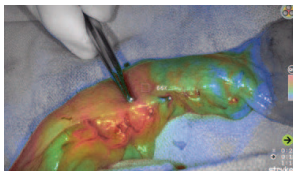
SPY Contrast mode:

SPY mode is a fluorescence image displayed in grayscale, providing the highest level of contrast between fluoresced and non-fluoresced tissue.



SPY CSF mode:

In SPY CSF mode, a white light image is displayed in grayscale with fluorescence overlaid in a color scale. Increasing intensities of fluorescence transition from blue to yellow to red.



SPY Color Maps mode:

In color maps mode, a white light image is displayed in grayscale with fluorescence overlaid in a color scale. This mode replaces CSF mode when SPY-QP is active, and can provide a more detailed color map to evaluate a wider range of fluorescence intensities to better define areas of differing perfusion (available when VPI is upgraded with SPY-QP).

Clinically proven

SPY Technology

SPY Fluorescence imaging technology was first introduced to the market in 2005.[5] Since that time, due to the clinical and economic benefits associated with the assessment of blood flow and tissue perfusion as well as lymphatics, it's use has expanded into multiple surgical specialties. To date, there have been 300+ published clinical studies demonstrating the use of SPY fluorescence imaging.[6]

Clinical data

Breast reconstruction

Harless et al, Mayo Clinic, Rochester, Minnesota (2016)[7]
In a retrospective comparative analysis of 269 consecutive patients (467 breast reconstructions) undergoing implant-based breast reconstruction Authors found a 52% reduction (13.8% versus 6.6%, p=0.01) in all complications with an 86% reduction (6.7% versus 0.9%, p=0.02) in mastectomy skin flap necrosis alone in patients who were assessed by LA-ICGA. The implementation of LA-ICGA allows surgeons to objectively assess mastectomy flap perfusion and intraoperatively modify their breast reconstruction in real time which may aid in significantly reducing overall complications.

Harless et al, Mayo Clinic, Rochester, Minnesota (2015)[8]
Authors performed a retrospective comparative analysis of 942 breast reconstructions that occurred between 2010-2013, 590 without LA-ICGA and 352 with LA-ICGA. Authors calculated the use of LAICGA could potentially avoid 59 episodes of skin necrosis over a 5-year period for a cost-savings of $852,019.

Momeni et al, Stanford University Medical Center, Palo Alto, California (2020)[9]
A retrospective study of two cohorts was performed evaluating patients before and after implementation of protocolized indocyanine green–guided flap excision. Comparing by cohort, the standard debridement group showed 18 of 79 flaps with fat necrosis (22.8 percent), whereas the indocyanine green–informed debridement group showed only two of 58 flaps with fat necrosis (3.4 percent). Intraoperative use of indocyanine green angiography was associated with significantly lower odds of fat necrosis. This technology may reduce additional revision operations and improve patient satisfaction.

Colorectal surgery

Starker et al, Overlook Medical Center, New York, New York (2017)[10]
The PINPOINT group (n=238) had two (0.84%) anastomotic failures, while the non-PINPOINT group (n=109) had six (5.5%) anastomotic failures. Lower direct costs associated with complications justified the initial expense of the PINPOINT imaging system after just 143 cases.

Jafari et al, Stanford University Medical Center, Palo Alto, California (2015)[1]
This study prospectively evaluated 139 patients undergoing colectomy and left anterior resection at multiple institutions. The anastomotic leak rate was 1.4%(n=2), and SPY changed surgical plans in 11 (8%) patients. There were no anastomotic leaks in the 11 patients who had a change in surgical plan based on perfusion assessment.

Clinically proven

SPY Technology

Lymphatic mapping in cervical and uterine cancer

Frumovitz et al, University of Texas MD Anderson Cancer Center, Houston Texas (2018)[11]

Authors sought to compare the performance of ICG fluorescence with isosulfan blue dye visualized with white light for sentinel lymph node biopsies in patients with stage I endometrial or cervical cancer. ICG outperformed isosulfan blue in terms of successful bilateral mapping (78% vs. 31%), identifying at least one SLN (96% vs. 74%), and identifying metastatic diseased nodes (100% vs. 62%).

Amputations

De Silva et al, Washington University School of Medicine, St Louis, Missouri (2018)[12]

Over an 8-month period the authors reviewed all patients who underwent lower extremity amputation and LAFA (laser assisted fluorescence angiography) with SPY Technology. The study concludes that LAFA is a useful adjunct for intra-operative stump perfusion assessment and can predict areas of poor stump healing and eschar formation.

Esophageal surgery

Zehetner et al, Keck School of Medicine, Los Angeles, California (2014)[13]

Intraoperative LAA was used to assess graft perfusion in 150 consecutive patients undergoing esophagectomy with planned GPU reconstruction. An esophagogastric anastomosis was performed in 144 patients, and a leak was found in 24 patients (16.7%). Leaks were significantly less likely when the anastomosis was placed in an area of good perfusion compared with when the anastomosis was placed in an area of less robust perfusion by LAA (2%vs 45%,$P<0.0001$). Intraoperative real-time assessment of perfusion with LAA correlated with the likelihood of an anastomotic leak and confirmed the critical relationship between good perfusion and anastomotic healing.

Endocrine surgery

Fortuny et al, University Hospitals of Geneva, Geneva Switzerland (2018)[14]

A total of 196 patients underwent ICG angiography during thyroid surgery, of whom 146 had at least one well perfused parathyroid gland on ICG angiography and were randomized. None of these patients presented with hypoparathyroidism, including those who did not receive calcium supplementation. ICG angiography reliably predicts the vascularization of the parathyroid glands and obviatesthe need for postoperative measurement of calcium and PTH, and supplementation with calcium inpatients with at least one well perfused parathyroid gland.

Coronary Artery Bypass Surgery

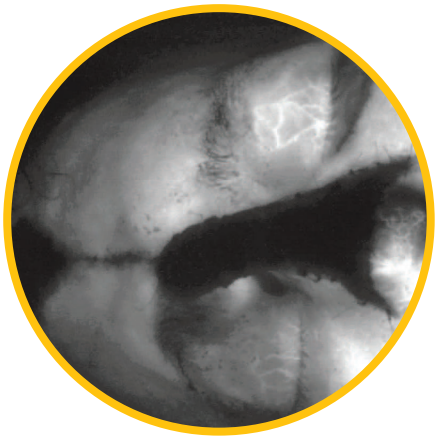
Desai et al, University of Toronto, Toronto Canada (2005)[15]

A total of 348 coronary bypass grafts were studied. Each ICG angiogram took 2.2 ± 1.1 min to perform. Information from ICG angiograms led to graft revisions for technical problems in 4.2% of patients that required major revisions and would have otherwise gone unrecognized. Intraoperative angiography is an emerging tool for improving the quality of coronary bypass surgery.

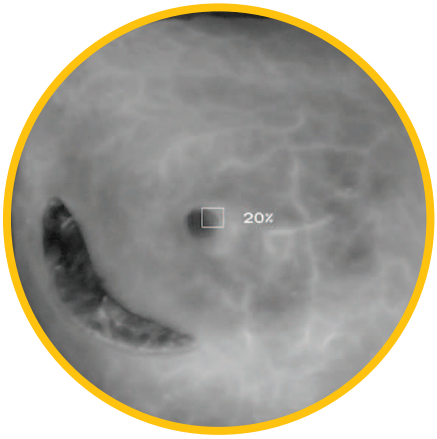
Changing the way you see your patients

The SPY-PHI Fluorescence Imaging System enables real-time visualization of tissue perfusion throughout the body, and visualization of lymphatics

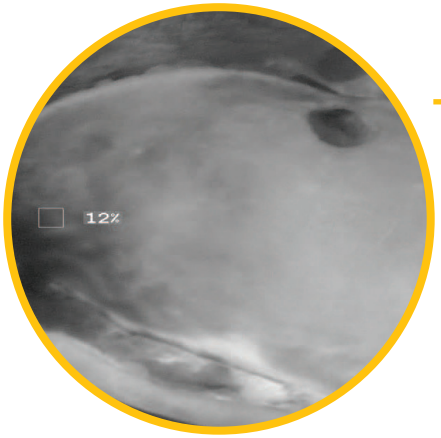
Assessing forehead flap perfusion post inset



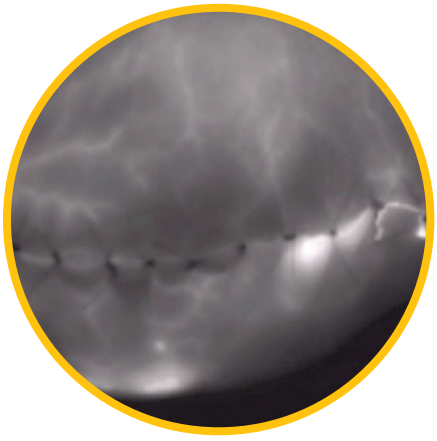
Assessing perfusion post nipple-sparing reconstruction

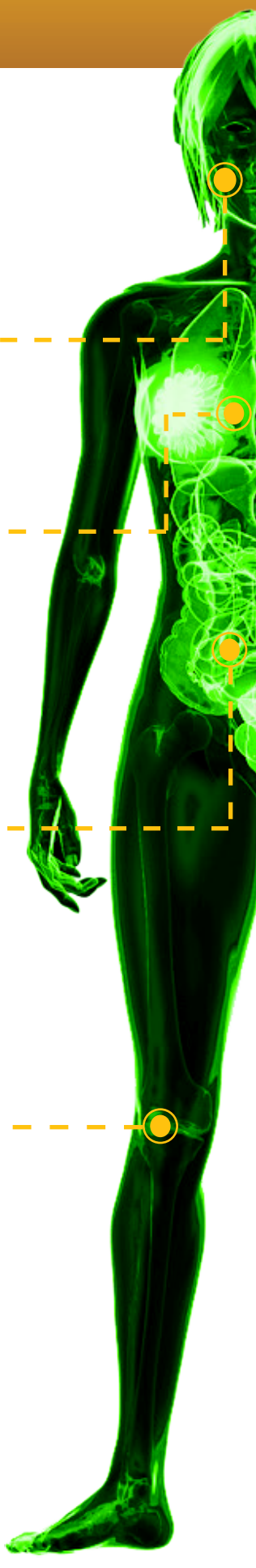


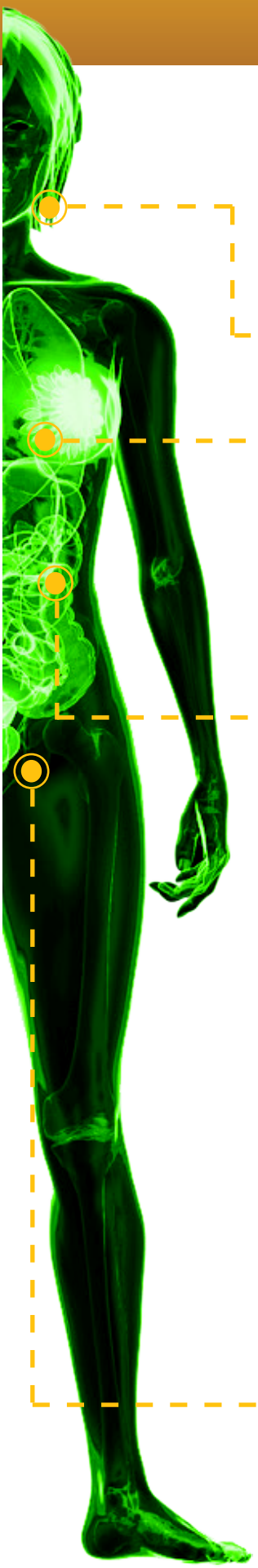
Visualizing ideal zones of perfusion after the DIEP flap was raised



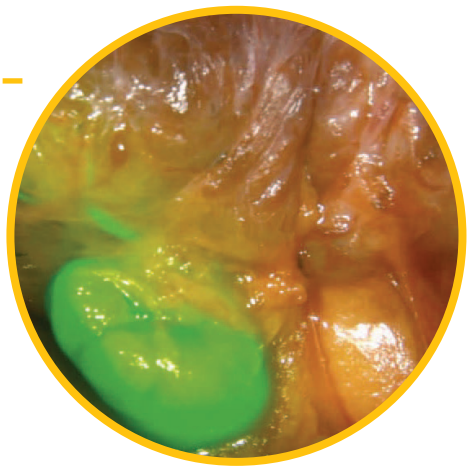
Visualizing suture line perfusion during an above the knee amputation



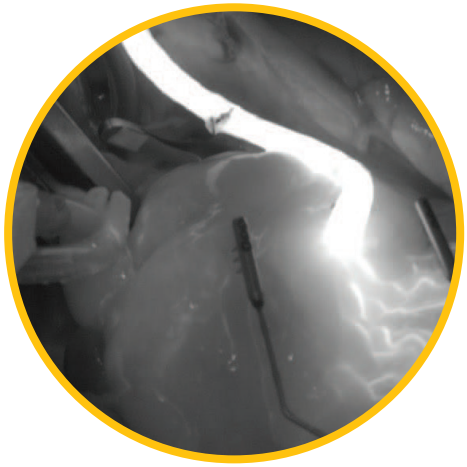




Assessment of perfusion to the Parathyroid Gland

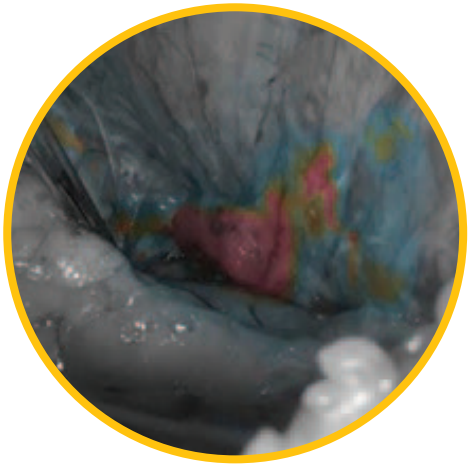


Visualizing graft patency in a Coronary Artery Bypass Graft (CABG) procedure



Assessment of the Colon prior to the Proximal Transection

Visualization of lymphatic vessels and nodes in cervical and uterine cancer



The SPY-PHI Fluorescence Imaging System

4K display monitor

- 32″ monitor is engineered to provide consistently bright, crystal-clear images in 4K or 1080p resolution

Maneuverable imaging head

- Ergonomic handheld imaging system with a flexible working distance is designed to allow for more versatility in the operating room
- Button mapping allows for complete control from the sterile field

Connected OR Hub

- Engineered for capturing still images and videos that can be played back in the operating room or sent directly to your PACS system with DICOM integration

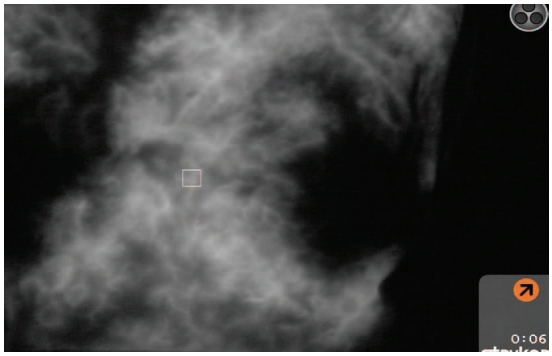
SPY-QP Fluorescence assessment software

- Real time, surgeon controlled fluorescence assessment software
- Allows the surgeon to further evaluate the intensity of the fluorescence signal through Relative Values (%) and a Color Maps mode
- Features a timer that is automatically activated when fluorescence is detected, and icons indicating ingress and the fluorescence assessment window

Analyze perfusion
intraoperatively

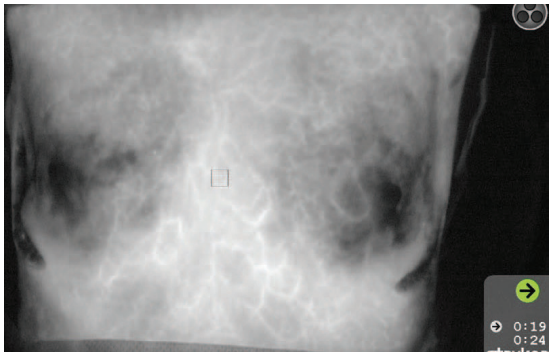
The SPY-PHI Fluorescence Imaging System now features SPY-QP. This intraoperative and surgeon controlled fluorescence assessment software was designed to allow surgeons to objectively assess the intensity of the fluorescence signal through Relative Values (%) or a Color Maps mode, which can supplement clinical judgment and may allow for increased confidence in surgical perfusion assesment.

Onset fluorescence detection



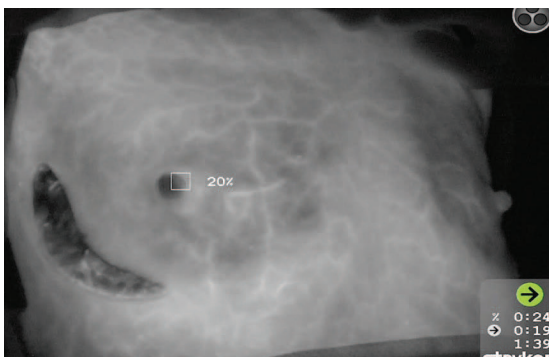
When SPY-QP is activated and the imaging agent is injected, a timer will automatically start and an **Orange Icon** will appear in the bottom right corner of the screen, thus signaling the onset of fluorescence.

Assessment window



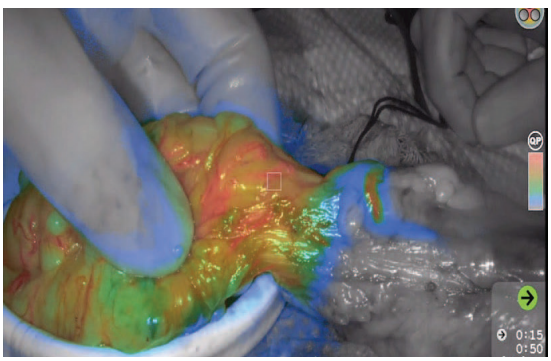
When the intensity of the fluorescence signal has stabilized, a green arrow will automatically appear, meaning the Fluorescence Assessment Window has been reached. This means that you have entered into the recommended time to assess fluorescence, and you may choose to assess further with Relative Values (%) or the Color Map mode.

Relative Percentage Values



The surgeon can aim the quantification box at a region of interest (ex. healthy tissue), set the reference (hold B button on camera head), and evaluate perfusion with relative percentage values.

Color maps



Color Maps mode shows increasing intensities of the fluorescence signal through a Color Map, with colors increasing from blue (less perfused) to green, to yellow, and to red (most perfused). A color legend is provided on the right side of the screen.

SPY-PHI System Benefits

Intraoperative Perfusion Assessment

Is designed to allow surgeons to visualize perfusion intraoperatively and in real-time.

Repeatable Technique

Involves no ionizing radiation and utilizes a non-nephrotoxic fluorescence imaging agent with a very short half-life thus allowing surgeons to repeat intraoperative perfusion assessment numerous times throughout the procedure.[5,6]

Improved Outcomes

Enhances the surgeon's ability to assess perfusion, which may improve patient outcomes.[3]

Indications for Use

The SPY Portable Handheld Imaging System is an active device used to visualize circulation, including lymphatics and blood vessels, as well as related tissue perfusion with near infrared fluorescence imaging during a variety of surgical procedures.

The SPY-QP Fluorescence Assessment Software is an upgrade to the SPY-PHI System that enables relative quantification of near-infrared (NIR) fluorescence. The software detects the onset and stability of the fluorescence signal within the field of view and displays fluorescence signal intensity as a color map and percentage value relative to a reference set by the user.

Information obtained through the use of SPY-QP should be used in combination with other clinically relevant information when planning or providing interventions.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate images. SPY-QP is a complement to the Fluorescence Imaging Device procedures.

1. Jafari et al, Stanford University Medical Center, Palo Alto, California. "Perfusion Assessment in Laparoscopic Left-Sided/Anterior Resection (PILLAR II)" (2015)
2. Yan C, Fischer JP, Wes AM, et al. The cost of major complications associated with immediate two-stage expander/implant-based breast reconstruction. J Plast Surg HandSurg. 2015;49(3):166-171. doi:10.3109/2000656X.2014.970639
3. Sood M, Glat P. Potential of the SPY intraoperative perfusion assessment system to reduce ischemic complications in immediate postmastectomy breast reconstruction. Annals of Surgical Innovation and Research 7.1 (2013): 9.
4. Data on File 4-0003045
5. SPY 200 510K: K042961
6. Data on File 1000903302
7. Harless CA. Tailoring through Technology: A Retrospective Reviewof a Single Surgeon's Experience with Implant -Based Breast Reconstruction before and after Implementation of Laser Assisted Indocyanine Green Angiography. The Breast Journal. 2016; 22(3):274-81.
8. Harless CA. Currentstrategieswith2-staged prosthetic breast reconstruction. Gland Surgery. 2015; 4(3):204-11.
9. Data on File 1000903462
10. Data on File 1000902996
11. Frumovitz et al, University of Texas MD Anderson Cancer Center, Houston, Texas. "Near-infrared fluorescence for detection of sentinel lymph nodes in women with cervical and uterine cancers (FILM)" (2018)
12. De Silva et al, Washington University School of Medicine, St Louis, Missouri. "Amputation stump per Amputation stump perfusion is pr fusion is predictive of postoperite of post-operative necrotic eschar formation" (2018)
13. Zehetner et al, Keck School of Medicine, Los Angeles, California. "Intraoperative Assessment of Perfusion of the Gastric Graft and Correlation With Anastomotic Leaks After Esophagectomy" (2014)
14. Data on File 1000903604
15. Desai; Improving the Quality of Bypass Surgery with Intraoperative Angiography. Journal of the American College of Cardiology. Vol. 46. No. 8. 20057.
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17. Data on File 1000903604
18. Data on File 4-0003045
19. Data on File 1000903302

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Stryker Endoscopy
Herikerbergweg 145,
1101 CN Amsterdam
t: 020 808 2300
www.stryker.com