

## Osprey Medical increases addressable market with new DyeTect™ Automated Contrast Monitoring System

### Highlights

- **DyeTect increases the value of Osprey's addressable market by 40% to US\$1.8 billion**
- **FDA cleared and CE Mark secured with full commercial release expected in CY 4Q 2017 at an expected selling price of US\$149 per procedure**
- First clinical use of new DyeTect™ Automated Contrast Monitoring System at University of Michigan Health System and University Health System in Texas
- DyeTect enables real-time dye threshold monitoring and accurate accounting of total dye dose to the patient for all dye based heart procedures

**July 3, 2017 – Melbourne, Australia and Minnesota, United States** – Osprey Medical (ASX:OSP) today announced the first clinical use of the DyeTect Automated Contrast Monitoring System at University of Michigan Health System and University Health System in Texas. This new product leverages technologies from the DyeVert Plus system and more than doubles the number of patients who can benefit from Osprey's portfolio of kidney protection devices.

### **DyeTect increases Osprey's addressable market by 40% to US\$1.8 billion**

Osprey will position the new DyeTect System for non-CKD heart patients and it will continue to sell the DyeVert Plus for patients with poor kidney function where dye minimization is recommended. The Company estimates the addressable market for DyeTect is 3.5M procedures per year in the US and Western EU.

The list price for the consumable components of the DyeTect System is expected to be US\$149 per procedure making the addressable market for DyeTect worth approximately US\$526 million per year. When added to the DyeVert Plus, the total addressable market for Osprey's product portfolio is expected to be 6.7M procedures per year, which equates to a US\$1.8 billion market opportunity.

Full US commercial release of DyeTect is expected in CY 4Q 2017 following the completion of injection moulded manufacturing of components. A limited release is currently underway with key opinion leading physicians throughout the United States.

Osprey's President and CEO, Mike McCormick, said:

*"The development of our new product, DyeTect, is a direct response to customer requests for the benefits of DyeVert Plus contrast monitoring for non-chronic kidney disease patients. This exciting new product increases our addressable market and further supports our long-term company vision: to lower kidney damage in all heart imaging procedures."*

**Approved by key regulators in US and Europe and supported by clinical experts**

DyeTect™ has received European CE Mark and US FDA 510k clearance enabling a commercial launch in both markets.

The company validated its dye threshold monitoring and accurate accounting of dye dose through initial market testing with Dr. Hitinder Gurm at University of Michigan Health System and Dr. Anand Prasad at University Health System in Texas. The product received strong positive feedback on the utility of real-time contrast monitoring, dose accounting, and ease-of-use.



Professor Hitinder Gurm of the University of Michigan Health System said:

*“The monitoring of contrast dose is a valuable feature, you know exactly where you are at each point during an intervention. Incorporating this into our routine workflow will help raise awareness of total dye administered, which in turn will modify our practice and eventually result in better patient outcomes.”*

Dr. Anand Prasad at University Health System commented:

*“The easy to use Bluetooth-enabled smart syringe and display offer real-time accounting of the contrast delivered to the patient which is a valuable tool for interventional cardiologists. Real-time monitoring could help reduce the amount of dye administered in the majority of patients.”*

### **DyeTect™ was developed in direct response to customer requests**

The concept for DyeTect originated from customers who had used Osprey Medical’s DyeVert Plus and wanted the benefits of real-time dye threshold monitoring and accurate accounting of total dye dose for all dye-based procedures.

The new system leverages the DyeVert Plus wireless “smart syringe” and reusable LCD monitor to actively manage dye administration during heart procedures. Cardiology performance measures address the need for dye management and accurate dye dose reporting for all heart procedures. DyeTect allows for real-time dye monitoring and keeps physicians informed when limits (based on kidney function) are reached and it accurately reports the total dye dose to the patient.

The product is targeted for patients *without* chronic kidney disease, as DyeTect does not minimize the amount of dye used. For patients with chronic kidney disease the DyeVert Plus is needed because it reduces the amount of dye which is indicated for patients with compromised kidneys. DyeVert Plus and DyeTect target different patient groups with the strong differentiation of dye minimization that is needed for chronic kidney disease patients.

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### **About Osprey**

Osprey Medical’s vision is to make heart imaging procedures safer for patients with poor kidney function. The amount of dye (contrast) used during angiographic imaging procedures increases the patient's risk for dye-related

kidney damage known as Contrast Induced Acute Kidney Injury (AKI). The Company's core technologies originated from research conducted by Dr David Kaye at Melbourne's Baker Institute. Its proprietary dye reduction and monitoring technologies are designed to help physicians minimize dye usage and monitor the dose of dye real time throughout the procedure. The Company's DyeVert™ Plus System reduces contrast while maintaining image quality in a self-adjusting easy-to-use design that monitors dye usage. Osprey Medical's Board and Management are comprised of experienced and successful personnel with established track records covering medical device development, regulatory approvals, sales and marketing, and mergers-acquisitions. Osprey Medical's advisory board comprises world-recognised experts in heart and kidney diseases.

### **Forward-Looking Statements**

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position. Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Osprey does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Osprey may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

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Osprey's CHES Depository Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of Osprey's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.