

Table 4: Cardiac Surgery Regulatory Landscape

COUNTRY	APPROVAL DATE	INDICATION
Argentina	April 2012	to selectively decrease pulmonary arterial pressure in patients with perioperative pulmonary hypertension in conjunction with heart surgery
Australia	April 2019	to selectively decrease pulmonary arterial pressure in patients with perioperative pulmonary hypertension in conjunction with heart surgery
Chile	June 2012	to selectively decrease pulmonary arterial pressure in patients with perioperative pulmonary hypertension in conjunction with heart surgery
Columbia	October 2013	to selectively decrease pulmonary arterial pressure in patients with perioperative pulmonary hypertension in conjunction with heart surgery
EU	March 2011	as part of the treatment of peri- and post-operative pulmonary hypertension in adults and newborn infants, infants and toddlers, children and adolescents, ages 0-17 years in conjunction to heart surgery, in order to selectively decrease pulmonary arterial pressure and improve right ventricular function and oxygenation.
Japan	2015	is indicated for the improvement of peri-operative pulmonary hypertension associated with heart surgery. INOflo ¹ selectively decreases pulmonary arterial pressure and improves right ventricular function and oxygenation.
Mexico	March 2012	to selectively decrease pulmonary arterial pressure in patients with perioperative pulmonary hypertension in conjunction with heart surgery
Uruguay	July 2013	to selectively decrease pulmonary arterial pressure in patients with perioperative pulmonary hypertension in conjunction with heart surgery

¹ nitric oxide is branded as INOflo in Japan.