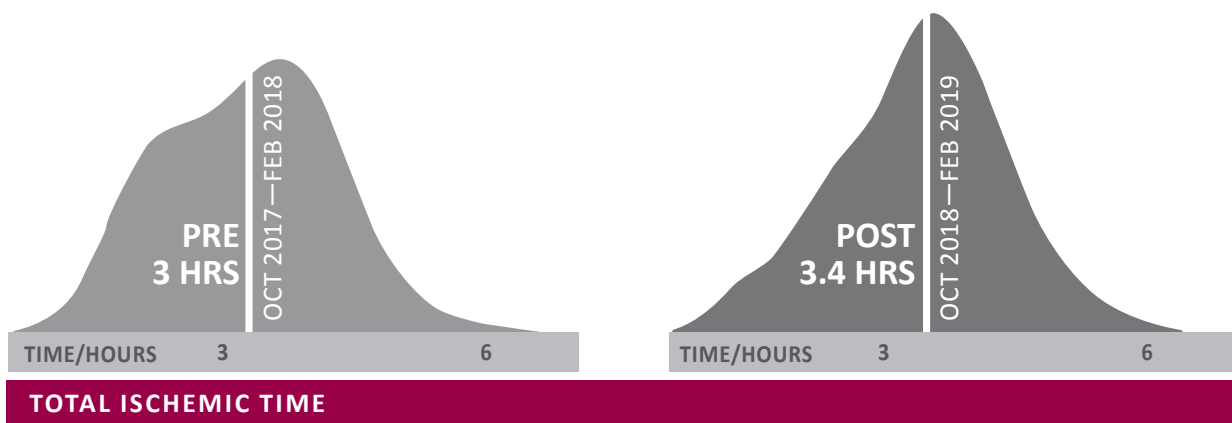


# Increase in Ischemic Times

## UNOS Analysis: 2018 Heart Allocation Policy

### Allocation policy increased ischemic time/travel distance

- According to a recent UNOS report, the mean total ischemic time increased 13% from the pre vs. post implementation of the 2018 Heart Allocation Policy (3 hours vs. 3.4 hours;  $p < 0.001$ ).<sup>1</sup>
- Increased ischemic time equals higher odds of primary graft dysfunction (PGD): “Each additional hour of ischemic time [is] associated with a 1.8 greater odds of primary PGD ( $p < 0.001$ ).”<sup>2</sup>
- Donor hearts, when transported on ice, risk cold injury at  $< 2^{\circ}\text{C}$  in less than 30 minutes due to uncontrolled temperature range.<sup>3-7</sup>



### Paragonix SherpaPak™ offers every possible advantage

- The only FDA cleared and CE marked transport device for heart transplantation.
- Provides a controlled temperature range outside the range of ice injury.
- Includes real-time temperature monitoring for temperature verification and reporting via Bluetooth® to mobile devices for data analysis.
- Six-sigma quality to ensure every heart experiences a consistent process.
- Reimbursable preservation cost via Medicare cost report and private payors.

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1. Linblad and Lehman. Four-Month Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System Report. OPTN Thoracic Committee, April 2019. 2. Nicoara et al. Am J Transplant. 2018;18:1461–1470. 3. Kobashigawa et al. J Heart Lung Transplant 2014;33:327–340. 4. Michel et al., Heart, Lung, and Vessels 2015; 7(3):246-255. 5. Ingemansson et al., Ann Thorac Surg. 1996; 61; 1413-7. 6. Rubinsky. Heart Failure Reviews 2003;8:277-284. 7. Keon et al. Ann Thorac Surg 1988; 46:337-341.

Indications for Use: The Paragonix SherpaPak™ Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the heart. The intended organ storage time for the Paragonix SherpaPak™ Cardiac Transport System is up to 4 hours. Donor hearts exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.

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