Clinical Process Instruction Manual

PRC Coordination of the OCS Heart Equipment Process Instruction

Policy:

Ontario Health – Trillium Gift of Life Network (TGLN) and the University Health Network (UHN) have developed a protocol to use the TransMedics Organ Care System (OCS™ HEART) machine for heart recovery from controlled Donation after Death by Circulatory Determination (DCD) donors, and out-of-province (OOP) neurological determination of death (NDD) donors where extended Cold Ischemic Time (CIT) would have otherwise prevented organ acceptance of hearts, as outlined below.

For donor cases where the University Health Network (UHN) Heart Transplant program identifies they would like to include the TransMedics Organ Care System (OCS™ HEART) machine in the recovery process, the Trillium Gift of Life Network (TGLN) will assist in incorporating it's use into the organ recovery planning process. See Exhibit 1.

Hearts from controlled DCD donors at hospitals within 2.5 hours driving distance of UHN's Toronto General Hospital (TGH) will be considered for DCD heart donation using the OCS™ HEART machine See Appendix 1. In the event resources are not available at the hospital for the purposes of testing (e.g. angiogram) and organ recovery, or a hospital is outside of the 2.5 hour catchment area, the option to transfer a potential donor to another hospital for the purposes of DCD heart recovery will be explored.

For DCD donors, the total amount of time that the UHN Heart Transplant program will wait is 3 hours after withdrawal of life sustaining measures (WLSM). They will be using functional warm ischemic time (fWIT) as the measurement to determine if the heart will be recovered for transplant. fWIT is the period of time between the last systolic blood pressure reaching 50mmHg to flush in the donor OR (i.e., [start of perfusion Date-Time] – [Date-Time of the closest record prior to the perfusion Date-Time where systolic blood pressure was less than 50 mmHg]). This time must be 30 minutes or less in order for the heart to be considered for transplant.

UHN will be responsible for the storage facility/room, supplies exclusively used for the OCS™ HEART machine, maintenance records, and cleaning processes.

This Process instruction details the Provincial Resource Centre's (PRC) coordination of activities to use the OCS™ HEART machine for heart recovery.

Process:

DCD Heart Donation using OCS™ HEART machine

1. Upon acceptance of a heart for transplant by the UHN Heart Transplant program, where the OCS™ HEART machine will be used, the CSC will confirm with the on-site Organ and Tissue Donation

Coordinator (OTDC) that the donor OR can accommodate the use of the OCS™ HEART machine during the donor recovery.

2. The OTDC will confirm if the hospital has pre-approved WLSM in or near the Operating Room (OR) for DCD heart donation. If the hospital does not have a policy to WLSM in the OR, the OTDC will advise the MOC.

3. The OTDC will communicate the need for the following requirements with the donor OR:

    3.1.1. Largest available OR/OR closest to location of WLSM
    3.1.2. Back table set up
    3.1.3. OR to be available for 6 hours

4. If the hospital is unable to accommodate WLSM in or near the OR, the MOC and DSP will be consulted to determine if further escalation in the hospital is warranted. The CSC will communicate to the MOTC if the donor hospital is, or is not able to accommodate incorporating the use of the OCS™ HEART machine in the donor recovery process.

5. If it is a multi-organ donor, the CSC will make arrangements for two Surgical Recovery Coordinators (SRC) to attend the recovery and will inform the SRC's of the plan to use the OCS™ HEART machine on the recovery, as per *CPI-9-406, Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction*.

6. The SRC(s) and recovery team(s) will be dispatched to arrive at the donor OR 1 - 2 hours before the planned WLSM. The SRC(s) should allow for an additional 30 minutes to load the OCS™ HEART machine for transport at the time of pick up.

7. The UHN DCD Heart Recovery Team will consist of two perfusionists and two recovery surgeons who are trained in DCD heart recoveries. The UHN DCD Heart Recovery Team will be responsible for bringing the OCS™ HEART machine, perfusion sets and all additional supplies that will be necessary for its use in the donor OR to the designated meeting spot.

8. An SRC will assist the UHN DCD Heart Recovery Team with loading the machine into the van for transport.

9. The SRC will be responsible for driving the van containing the OCS™ HEART machine to the donor site.

10. If it is a multi-organ donor, the other SRC will be responsible for the transport of recovery surgeons and all other organ recovery supplies to the donor OR site. In the event that 2 SRCs are required and a 2nd SRC is not available for the recovery, alternate arrangements for the transport of recovery surgeons and all other organ recovery supplies to the donor site may be made by the CS

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Upon Arrival at Recovery Hospital

11. The SRC assists the UHN DCD Heart Recovery Team with the unloading of the OCS™ HEART machine.

12. The UHN DCD Heart Recovery Team ensures the OCS™ HEART machine is plugged in during the organ donor recovery in the OR.

13. The UHN DCD Heart Recovery Team is responsible for ensuring that all additional supplies for the use of the OCS™ HEART machine in the donor OR are set up accordingly.

Post Recovery

14. The SRC notifies the CSC of cross clamp time and estimated time of departure – factoring in the additional time requirements as necessary.

15. The SRC assists the UHN DCD Heart Recovery Team with the re-loading of the OCS™ HEART machine into the van for transport – ensuring the device is not tilted at any time.

16. The SRC assists the UHN DCD Heart Recovery Team with the unloading of the OCS™ HEART machine on arrival to the transplant centre.

NDD Heart Donation Using OCS™ HEART Machine

17. Upon acceptance of a heart for transplant from Out-Of-Province (OOP) by the UHN Heart Transplant program, where the OCS™ HEART machine will be used, the CSC will confirm with the OOP coordinator that the donor OR can accommodate the use of the OCS™ HEART machine during the donor recovery.

    17.1. The CSC will communicate the need for the following requirements in the donor OR:
    - Largest available OR
    - Back table set up
    - OR to be available for 6 hours

    17.2. The CSC will send the *Expanding Cold Ischemic Time Boundaries in NDD Heart Recovery* document to the OOP coordinator, and ask to review 2.2 Operating Planning/Booking. The CSC will request that the OOP coordinator advise if any required supplies are not available. The CSC will notify the transplant program of any issues, as required.

18. The CSC will communicate to the MOTC if the donor hospital is, or is not able to accommodate incorporating the use of the OCS™ HEART machine in the donor recovery process.

19. Upon acceptance of the NDD heart using the OCS™ HEART machine and confirmation of donor OR planned start time, the CSC will arrange transportation. When making transportation arrangements, the CSC will plan for the team to arrive at the donor hospital 1-2 hours before the planned OR start time.

    19.1. All air transportation is booked through the ORNGE Communication Center.

    19.2. When a flight request is made, the CSC will provide the required information, as outlined in *CPI-9-404 Transportation Coordination of Teams, Bloods and* Organs.

    19.3. In addition to the required information for a standard flight request, the CSC will also advise that the OCS™ HEART machine is being used and requires air transportation, as well as ground transportation after landing at the OOP donor airport.

    19.4. For each air transport request by TGLN involving the OCS™ HEART machine, ORNGE shall select and arrange for an aircraft from a predetermined list of suitable aircrafts and carriers See Exhibit 2.

        19.4.1. For each air transport request, ORNGE will arrange ground transportation from the OOP donor airport to the OOP donor hospital using a predetermined list of car service vendors that have suitable vehicles for transportation of the OCS™ HEART machine from the airport to the donor hospital.

20. If the flight request cannot be facilitated, the CSC will initiate the ORNGE Escalation Process, as outlined in *CPI-9-404 Transportation Coordination of Teams, Bloods and* Organs.

21. Once flight details have been confirmed, the CSC and SRC will determine a suitable pick up time, keeping in mind that the team is required to arrive at the donor hospital 1-2 hours prior to the planned OR time. The SRC(s) should allow for an additional 30 minutes to load the OCS™ HEART machine for transport at the time of pick up, and an additional 30 minutes to load the OCS™ HEART machine into the aircraft.

22. The UHN Heart Recovery Team will consist of two perfusionists and two recovery surgeons heart recoveries using the OCS™ HEART machine. The UHN Heart Recovery Team will be responsible for bringing the OCS™ HEART machine, perfusion sets and all additional supplies that will be necessary for its use in the donor OR to the designated meeting spot.

23. An SRC will assist the UHN Heart Recovery Team with loading the machine into the van for transport.

24. The SRC will be responsible for driving the van containing the OCS™ HEART machine to the airport.

Upon Arrival at the Airport – Outward flight

25. The SRC assists the UHN Heart Recovery Team with the unloading of the OCS™ HEART machine from the vehicle and loading the machine into the aircraft.

26. The SRC will ensure to bring the straps used to secure the OCS™ Heart machine during each leg of transportation.

27. The SRC assists the UHN Heart Recovery Team with securing the OCS™ HEART machine in the aircraft. See Exhibit 2 for guidance on how to properly secure the OCS™ HEART machine.

Upon Arrival at the Donor Airport

28. The SRC assists the UHN Heart Recovery Team with the unloading of the OCS™ HEART machine from the aircraft and loading and securing the machine into the vehicle.

Upon Arrival at the Donor Hospital

29. The SRC assists the UHN Heart Recovery Team with the unloading of the OCS™ HEART machine from the vehicle, and transportation of the machine to the donor OR.

30. The UHN Heart Recovery Team ensures the OCS™ HEART machine is plugged in during the organ donor recovery in the OR.

31. The UHN Heart Recovery Team is responsible for ensuring that all additional supplies for the use of the OCS™ HEART machine in the donor OR are set up accordingly.

Recovery

32. The SRC notifies the CSC of cross clamp time and estimated time of departure – factoring in the additional time requirements as necessary.

33. The SRC assists the UHN Heart Recovery Team with the loading of the OCS™ HEART machine into the vehicle for transport – ensuring the device is not tilted at any time.

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Upon Arrival at the Donor Airport – Return Flight

34. The SRC assists the UHN Heart Recovery Team with the unloading of the OCS™ HEART machine from the vehicle and loading of the machine into the aircraft - ensuring the device is not tilted at any time.

35. The SRC assists the UHN Heart Recovery Team with securing the OCS™ HEART machine in the aircraft.

Upon Arrival at the Transplant Airport – Return Flight

36. The SRC assists the UHN Heart Recovery Team with the unloading of the OCS™ HEART machine from the aircraft and loading of the machine into the vehicle – ensuring the device is not tilted at any time.

37. The SRC will be responsible for driving the van containing the OCS™ HEART machine from the airport to the transplant hospital.

38. The SRC assists the UHN DCD Heart Recovery Team with the unloading of the OCS™ HEART machine on arrival to the transplant centre.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)

- No records

References:

- *Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction, CPI-9-406*
- *Expanding Cold Ischemic Time Boundaries in NDD Heart Recovery*

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Appendix 1: Heart Donation Following Death by Circulatory Determination (DCD) Participating Hospitals

Hearts from controlled DCD donors **within 2.5 hour driving distance (at night)** of Toronto General Hospital will be considered for DCD heart recovery on site.

In the event resources are not available at the hospital for the purposes of testing (e.g. angiogram) and organ recovery, or a hospital is outside the 2.5-hour catchment area, next of kin of potential donors will be approached for consent to transfer their loved one to another hospital for the purposes of DCD heart recovery.

The following list outlines, by hospital, where the DCD heart donation will be offered and where transfer to another facility may be required.

Hospital Corporation	Hospital Site	Transfer Required (due to testing resources; location)
Alexandra Hospital Ingersoll		Yes
Alexandra Marine & General Hospital		Yes
Bluewater Health	Sarnia	Yes
	Petrolia	Yes
Brant Community Health Care System	Brantford General Hospital	Yes
Brockville General Hospital		Yes
Cambridge Memorial Hospital		Yes
Chatham-Kent Health Alliance		Yes
Children's Hospital of Eastern Ontario		Yes
Collingwood General and Marine		Yes
Cornwall Community Hospital		Yes
Erie Shores Healthcare	Leamington and District Memorial Hospital	Yes
Georgian Bay General Hospital		Yes
Grand River Hospital		Yes
Grey Bruce Health Services	Owen Sound Hospital	Yes
	Lion's Head Hospital	Yes
	Meaford Hospital	Yes
	Southhampton Hospital	Yes
	Wiarton Hospital	Yes
	Markdale Hospital	Yes
Guelph General Hospital		Yes

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Hospital Corporation	Hospital Site	Transfer Required (due to testing resources; location)
Halton Healthcare	Georgetown Hospital	Yes
	Milton District Hospital	
	Oakville-Trafalgar Memorial Hospital	
Hamilton Health Sciences Centre	Hamilton General Hospital	
	Juravinski Hospital	
	McMaster Children's Hospital	
Hanover & District Hospital		Yes
Hawkesbury General Hospital		Yes
Headwaters Health Care Centre		Yes
Health Sciences North		Yes
Hôpital Montfort		Yes
Humber River Hospital		Yes
Huron Perth Healthcare Alliance	Stratford General Hospital	Yes
Joseph Brant Memorial Hospital		Yes
Kingston Health Sciences Centre		
Kirkland and District Hospital		Yes
Lake of the Woods District Hospital		Yes
Lakeridge Health	Ajax Pickering Hospital	
	Bowmanville Hospital	
	Oshawa Hospital	
	Port Perry Hospital	
	Whitby Hospital	
Lennox and Addington County General Hospital		Yes
London Health Sciences Centre	Children's Hospital of Western Ontario	
	University Hospital	
	Victoria Hospital	
Mackenzie Health		
Markham Stouffville Hospital	Markham	
	Uxbridge	Yes
Middlesex Health Alliance	Four Counties Health Services	Yes
	Strathroy Middlesex General Hospital	Yes

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Hospital Corporation	Hospital Site	Transfer Required (due to testing resources; location)
Muskoka Algonquin Healthcare	Huntsville District Memorial Hospital	Yes
	South Muskoka Memorial Hospital	Yes
Niagara Health System	Douglas Memorial site	
	Greater Niagara General site	
	Port Colborne site	
	St. Catharine's site	
	Welland site	
Norfolk General Hospital		
North Bay Regional Health Centre		Yes
North York General Hospital		
Northumberland Hills Hospital		Yes
Orillia Soldier's Memorial Hospital		Yes
Pembroke Regional Hospital		Yes
Peterborough Regional Health Centre		
Queensway Carleton Hospital		Yes
Quinte Health Care Corporation	Belleville General Hospital	Yes
	North Hastings Hospital	Yes
	Prince Edward County Memorial Hospital	
	Trenton Memorial Hospital	
Ross Memorial Hospital		Yes
Royal Victoria Regional Health Centre		
Sault Area Hospital		Yes
Scarborough Health Network	Birchmount Hospital	
	Centenary Hospital	
	General Hospital	
Sinai Health System	Bridgepoint Active Healthcare	Yes
	Mount Sinai Hospital	Yes
Southlake Regional Health Centre		
St. Joseph's General Hospital Elliot Lake		Yes
St. Joseph's Healthcare Hamilton		
St. Mary's General Hospital		
St. Thomas - Elgin General Hospital		

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Hospital Corporation	Hospital Site	Transfer Required (due to testing resources; location)
Sunnybrook Health Sciences Centre		
Temiskaming Hospital		Yes
The Hospital for Sick Children		
The Ottawa Hospital	Civic Campus	Yes
	General Campus	Yes
Thunder Bay Regional Health Sciences Centre		Yes
Tillsonburg District Memorial Hospital		Yes
Timmins and District Hospital		Yes
Toronto East Health Network	Michael Garron Hospital	
Trillium Health Partners	Credit Valley Hospital	
	Mississauga Hospital	
Unity Health Toronto	St. Joseph's Health Centre - Toronto	Yes
	St. Michael's Hospital	
University Health Network	Toronto General Hospital	
	Toronto Western Hospital	
University of Ottawa Heart Institute		Yes
West Nippising General Hospital		Yes
West Parry Sound Health Centre		Yes
William Osler Health System	Brampton Civic Hospital	
	Etobicoke General Hospital	
Windsor Regional Hospital	Metropolitan Campus	Yes
	Ouellette Campus	Yes
Woodstock General Hospital		Yes

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Exhibit 1: OCS™ HEART Machine

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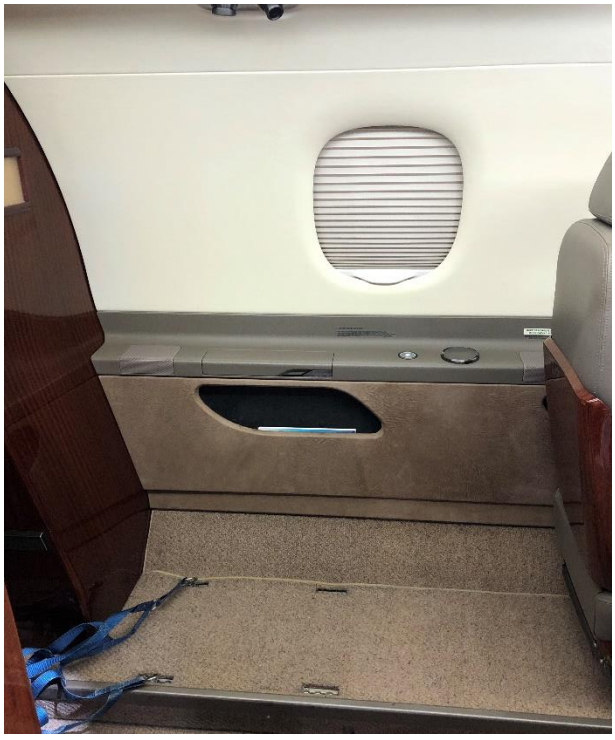
Exhibit 2: Suitable Aircrafts and Guidance on Securing the OCS™ HEART Machine

1) Phenom 300 from FlyGTA



*Please note that the OCS™ HEART Machine may be secured on the extra seating (see left above) or to the floor (see right) if the seat is removed and should be secured to the grips on the aircraft floor.

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2) Gulfstream Astra SPX (G100 YLD, G100 RJZ, G100 BSW) from Latitude Air.

- Configuration A (with stretcher)

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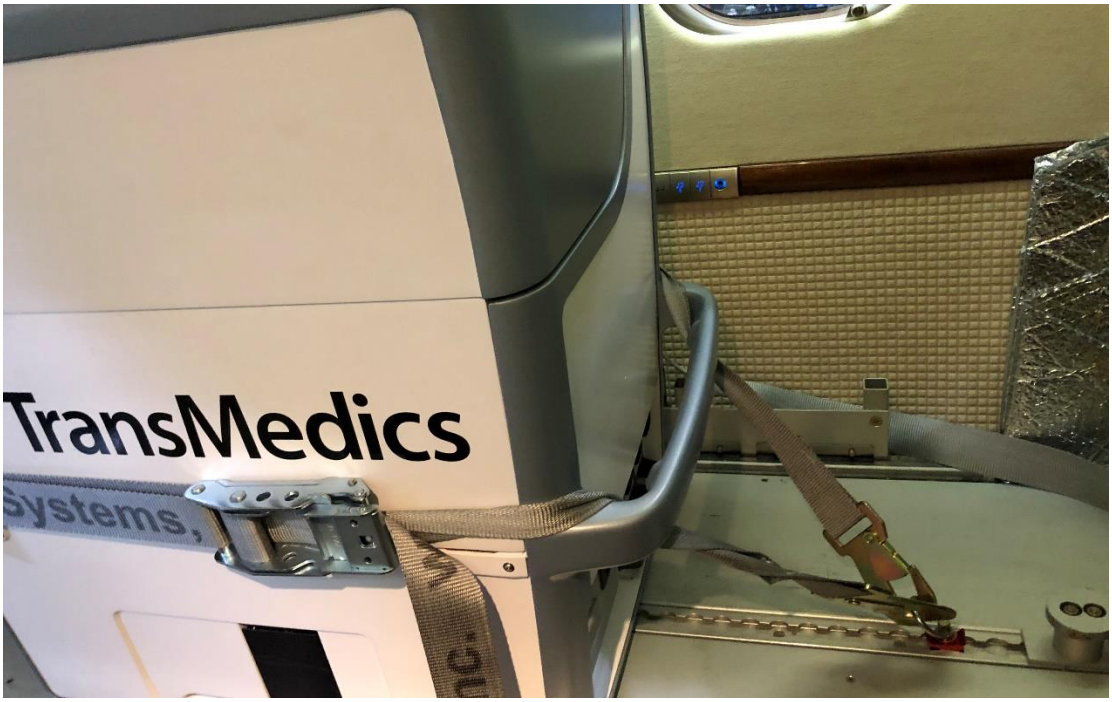

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***Note: Fasteners (pictured above) are provided by aircraft to secure OCS™ HEART Machine**

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- Configuration B (on floor)

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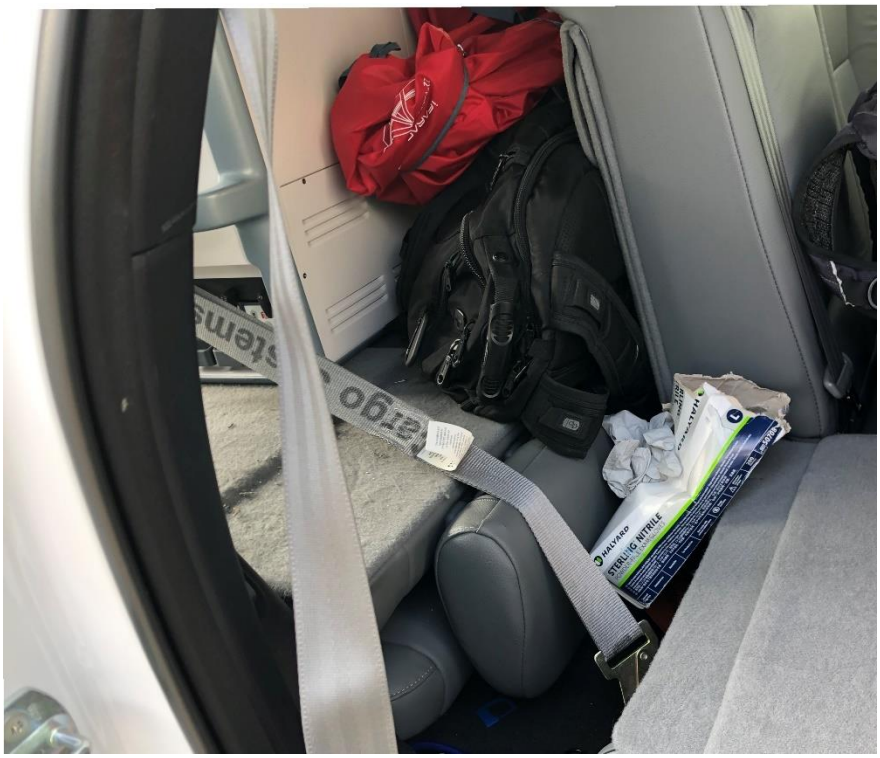

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1) WW24Jet from Skycare

- Configuration A

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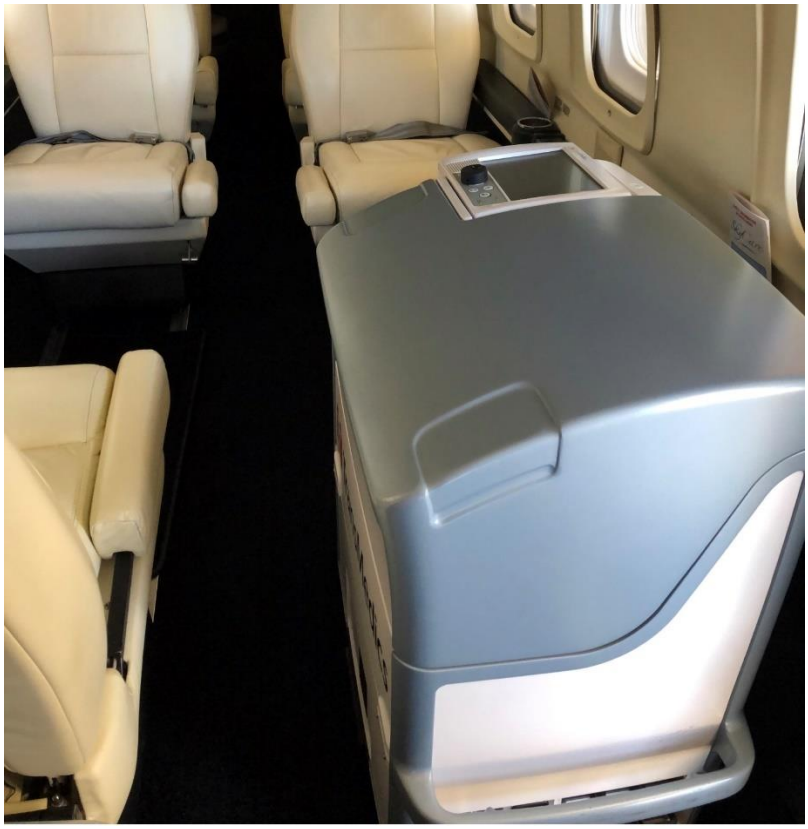
- Configuration B



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***Note: Fasteners (pictured above) are provided by aircraft to secure OCS™ HEART Machine and should be set up in a similar fashion as seen in Gulfstream Astra SPX (Configuration A pg. 15-17).**