Special ELSO Communication: Update on US Availability of Extracorporeal Circuit Supplies

Revised and updated 3/26/2016 (This replaces previous updates)

ELSO Centers have reported difficulties with obtaining a variety of disposables from Maquet in recent weeks and have queried ELSO leadership. We have been able to obtain the following unofficial information as follows:

1. Concerns were raised regarding endotoxin testing procedures at the German manufacturer of Maquet disposables, including Quadrox oxygenators and CARDIOHELP disposables, leading to a product hold by Maquet.

2. The following Maquet products have resumed shipping:
   a. Quadrox PMP oxygenators (Adult and Pediatric) resumed 2/4/16 (Bioline are in higher demand, and are manufactured in greater supplies; Softline production has been accordingly decreased and supplies may be slower to be received)
   b. Rotaflow pumps resumed 2/5/16
   c. Single Use Quadrox & Rotaflow may experience some allocation issues as customers are using in lieu of their tubing packs while they are being rebuilt
   d. HLS resumed 2/8/16
      1. 5.0 available without backorder
      2. 7.0: Over 220+ shipped the first week in March. Most CARDIOHELP customers are now off backorder. Maquet must continue to allocate based on emergency needs until full resupplied
      3. Custom ECLS tubing pack shipments have restarted. New packs with proper endotoxin testing have begun to ship. This will still take significant time to resume routine shipment. See below for explanation.
   e. Full production has resumed and full inventory should be available by 3/29/16
   b. Maquet is hopeful that supplies can catch up. However, due to production backlog and custom tubing ETO sterilization time requirements, as well as high demand given the international influenza outbreak, catch up may be delayed. Absent FDA classification as “medically necessary”, Maquet has suggested that centers construct their own tubing sets in the interim.
   c. A voluntary recall of all Maquet cardiopulmonary products produced prior to January 1, 2016 was issued by Maquet on 2/23/2016. The use of these products would need to be assessed for risk/benefit by centers.
   d. ELSO does understand the medical necessity, efficiency and overall safety of having pre-built packs and is advocating for this option.
   e. CARDIOHELP: Disposables as above have been in relatively temporary low supply, but are now released:
      i. HLS 5.0 sets are available without backorder per our understanding
ii. HLS 7.0 sets are in backorder but partial ordering is in effect

iii. World Health Organization requirements for pandemic flu are higher than expected both globally and in the USA. Production requirements with delays for improvements to LAL testing will likely continue allocation plans globally until the end of March.

iv. By 3/15/16, full inventory should be on board- Flu season dependent

f. CARDIOHELP hardware sales have been suspended for now to assist in lessening the issue of currently available disposables

3. Hospitals with inventory levels less than a 2 day supply should contact their Maquet Clinical Perfusionist Manager or Sales Associate as they will expedite allocation for your hospital.

Sorin is reporting availability of its new PMP oxygenators and tubing, and could also serve as an alternative supplier for centers.

Xenios reports that they are able now to supply all three sizes of their Medos oxygenators with plasma tight PMP membrane that are now cleared for sale in the US market. Despite unforeseen increases in demand they expect to be able to cover the expected demand.

ELSO is committed to advocacy, education and clinical support at all times. We will provide further information as we become aware of issues or resolution. Please consult the ELSO website (elso.org) for ongoing information, and please feel free to contact us via the site for further questions and concerns. Thank you for your patience as we all work to seek available to provide lifesaving extracorporeal care for our children and adults.

Sincerely,

The Extracorporeal Life Support Organization