

EXPANDED ACCESS PROGRAM EDS PROCEDURE CHECKLIST

One checklist for each EryDex System Process
Original copy remains at site in operator/patient's file
DOC-ID 954_DOC_EDS REV 00

Patient ID	
Treatment number	
Treatment date (DD/MMM/YYYY)	
Department	

EryDex Process start time* (24 hrs clock)	
EryDex Process stop time (24 hrs clock)	
Confirm if a TEST PROCESS (50 mL sterile saline instead of blood) or not?	<input type="checkbox"/> YES (FILL IN ONLY APPLICABLE PARTS); <input type="checkbox"/> NO

* Start of preparatory activities

Procedure phase	Comments
1. AVAILABILITY OF THE REQUIRED ITEMS <ul style="list-style-type: none"> <input type="checkbox"/> Red Cell Loader (RCL): S/N _____ <input type="checkbox"/> EryKit_01: Lot _____ <input type="checkbox"/> Syringe kit: Lot _____ <input type="checkbox"/> 2 mL Heparin 5000 units/mL: Lot _____; Manufacturer _____; Expiry date (DD/MMM/YYYY) _____ <input type="checkbox"/> Hypotonic solution 1 (400 mL): Lot _____ <input type="checkbox"/> Hypotonic solution 2 (200 mL): Lot _____ <input type="checkbox"/> Hypertonic solution (PIGPA; 3 mL): Lot _____ <input type="checkbox"/> Water for injection: Lot _____; Manufacturer _____; Expiry date (DD/MMM/YYYY) _____ <input type="checkbox"/> Dexamethasone Sodium Phosphate 25 mg 10 mL: Lot _____ ADDITIONAL MATERIAL <ul style="list-style-type: none"> <input type="checkbox"/> 4x sterile gloves <input type="checkbox"/> 8x Disinfecting wipes or disinfectant <input type="checkbox"/> 5x Needles <input type="checkbox"/> 2x 1L Saline Solution <input type="checkbox"/> 2x Millex syringe filters 0.22 µm <input type="checkbox"/> 20 mL syringe <input type="checkbox"/> 5 mL syringe <input type="checkbox"/> Blood infusion set <input type="checkbox"/> Tube Stripper <input type="checkbox"/> Sterile Tube Welder <input type="checkbox"/> Tube Sealer 	
2. ERYKIT_01 INSTALLATION. TURN ON THE RCL AND FOLLOW THE INSTRUCTIONS ON THE SCREEN TO ENSURE ADHERENCE AS BELOW: <ul style="list-style-type: none"> <input type="checkbox"/> Hang the Reservoir on hook 2 	

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<ul style="list-style-type: none"> <input type="checkbox"/> Hang the Hemofilter on hook 4 <input type="checkbox"/> Position the Transfer bag on the agitator plate and secure it <input type="checkbox"/> Firmly insert the Cassette on the top of the Red Cell Loader and ensure the line is fitted into the air sensor <input type="checkbox"/> Position the Bowl into its plate and duly connect the Bowl fixing arm <input type="checkbox"/> Hang the final collection bag on hook 1 <input type="checkbox"/> Hang the Waste bag on hook 2 <input type="checkbox"/> Connect the tube with the black Pump" label to the vacuum pump (metal connector) <input type="checkbox"/> The self-diagnostic phase is passed <input type="checkbox"/> The pump-tubing segments are correctly aligned under the three pumps after the self-diagnostic test 	
<p>3. ERYKIT_01 SOLUTIONS AND BLOOD SET-UP. FOLLOW THE ON-SCREEN PROMPTS TO ENSURE:</p> <ul style="list-style-type: none"> <input type="checkbox"/> The 2 L Saline solutions are firmly connected to the proper lines (yellow label) and hanged on hook nr 3 <input type="checkbox"/> The hypotonic solution 1 is firmly connected to the proper line (blue label) and hanged on hook nr 1 <input type="checkbox"/> The hypotonic solution 2 is connected to the proper line (red label) and hanged on hook number 1 <input type="checkbox"/> 50mL of the donor blood is connected using the sterile tube welder to the proper line (green label) and inserted in the syringe holder <input type="checkbox"/> report exact volume in Syringe Kit: _____ mL <input checked="" type="checkbox"/> Confirm that between blood collection and start of EryDex process, no more than 2 hours has passed. Insert time _____ hours:minutes 	
<p>4. ERYDEX SYSTEM PROCESS</p> <ul style="list-style-type: none"> <input type="checkbox"/> Prepare 11 ml of WFI in a 20 ml syringe <input type="checkbox"/> Add the 5 ml of Dexamethasone Sodium Phosphate solution, in the same syringe with the 11 mL WFI and mix <input type="checkbox"/> Check that the volume of the mixed syringe is exactly 16 mL and confirm _____ mL <input type="checkbox"/> Injection of the Drug + WFI (phase 11) <input type="checkbox"/> Injection of 3 ml of hypertonic solution (PIGPA) (phase 13) <input type="checkbox"/> The Encapsulation procedure is successfully completed 	
<p>5. FINAL OPERATIONS</p> <ul style="list-style-type: none"> <input type="checkbox"/> Report Total Volume of the Final collection bag, as reported on the display (phase 18): _____ mL <input type="checkbox"/> Remove the final collection bag <input type="checkbox"/> Gently mix final collection bag and fill the satellite sample bag with approximately 1 mL of EDS-EP by gravity. 	

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<ul style="list-style-type: none"> <input type="checkbox"/> Detach the satellite sample bag, transfer the content in a cryovial as an "encapsulated DSP sample", label with patient's ID and date and IMMEDIATELY store under refrigeration (-20° C) <input type="checkbox"/> IMMEDIATELY infuse encapsulated red cells in final bag using a suitable infusion set with inline microaggregate filter. Infusion duration of approximately 40 minutes, at a rate of 6-8 drops/10 seconds. <input type="checkbox"/> Confirm: the time from the start of the infusion through to the end of the EryDex process is no more than 30 minutes. Insert time _____ min <input type="checkbox"/> Remove the EryKit and all the bags from the Red Cell Loader (RCL) and dispose as hazardous waste 	
<p>6. ERYDEX SYSTEM PROCESS COMPLIANCE</p> <p><input type="checkbox"/> Was EryDex System process performed and completed? <input type="checkbox"/> YES; <input type="checkbox"/> NO, reason: _____</p> <p>NOTE: the EryDex System process should be started again with freshly drawn blood as soon as medically feasible based on the status of the patient and clinical judgement of the Treating Physician. If it is not possible to start the EDS process again during the same visit, it should be rescheduled as soon as feasible. No infusion should be performed less than 14 days after the prior infusion.</p> <p><input type="checkbox"/> If EryDex System process was not performed and complete, rescheduling date (DD/MMM/YYYY): _____</p> <p><input type="checkbox"/> In case the EryDex System process needs to be rescheduled, please fill in a new EDS procedure checklist and add the new information in EDC/eCRF</p>	
<p>7. ERYDEX SYSTEM END PRODUCT INFUSION</p> <p>NOTE: the EryDex System end product infusion must be started within 30 minutes from completion of the EryDex System process</p> <p><input type="checkbox"/> Actual infusion start time (24 hrs clock): _____</p> <p><input type="checkbox"/> Actual infusion stop time (24 hrs clock): _____</p> <p><input type="checkbox"/> Was the infusion of EryDex system end product completed successfully: <input type="checkbox"/> YES; <input type="checkbox"/> NO, please confirm reason i.e. (difficult blood collection/technical difficulty: interfering adverse event: schedule conflict: other, please specify): _____</p> <p>_____</p> <p>NOTE: please complete the Medical Device Report Log and send it to technicalservice@erydel.com in case infusion not possible</p>	

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Operator's name	
Operator's signature	
Date (DD/MMM/YYYY)	

Person responsible for EryDex System End-Product infusion The person responsible witnesses that exactly 5 mL DSP and exactly 11 mL WFI has been mixed together and injected when prompted by machine	
Signature	
Date (DD/MMM/YYYY)	