Procedures for Intravenous Infusion
(Lyophilized)
Gammagard SD 10% Solution
Reconstitution directions for a
10% product using one 5 gram vial

1) Clean area that will be used for mixing and preparing for the treatment with alcohol. Put clean towel on clean surface. Reconstitute immediately before use.

2) Set up mixing supplies on table.
   a) IVIG Gammagard S/D vial
   b) Sterile Water 100ml vial (provided separately)
   c) 18 gauge needle
   d) 60 ml syringe
   e) 3 Alcohol swabs

   DISCARD THE VIAL OF STERILE WATER AND TRANSFER DEVICE THAT IS SUPPLIED IN THE GAMMAGARD S/D BOX!

3) Wash hands for at least 30 seconds with antibacterial soap. NOTE: anytime you touch a surface outside the clean area you will need to wash your hands.

4) If product refrigerated warm the diluent (Sterile Water for Injection) to room temperature.

5) Remove caps from Gammagard S/D (concentrated product) and diluent (Sterile Water) vials to expose the central portion of the rubber stoppers.

6) Swab top of each vial with an alcohol swab in one swipe away from you.

7) Remove the 18 gauge needle from the overwrap. Remove the 60ml syringe from the overwrap. Attach the needle to the 60mL syringe.

8) Place the diluent (Sterile Water) (100 ml) on a flat surface. Pull back on the syringe plunger to the 50m mark (air is now in the syringe). Remove cap from the 18 gauge needle. Insert the needle on the syringe into the rubber stopper of the Sterile Water vial at a 45 degree angle.

9) Invert the Sterile Water vial and the syringe/needle unit then push up on the plunger to push some air into the vial. The Sterile Water will flow into the syringe. Continue to push air into the vial to allow the water to flow into the syringe until 50ml Sterile Water is withdrawn. There will be 50mL remaining in the Sterile Water vial. Discard water vial.
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10) To add the Sterile Water in the syringe to the Gammagard S/D vial take the 50mL syringe with Sterile Water and insert the needle into the central portion of the rubber stopper at a 45 degree angle.

11) There is a vacuum in the Gammagard S/D 5 gram vial so the Sterile Water will transfer quickly from the syringe into the vial. Once all the water is transferred remove the syringe/needle from the Gammagard S/D vial. Discard the empty syringe/needle into the Sharps container.

12) Thoroughly wet the dried material by tilting or gently rotate the bottle.

13) DO NOT SHAKE TO AVOID FOAMING. Product may take up to 20-40 minutes to go into solution. Rotate the vial gently in a circular motion.

14) Let the Gammagard vial sit until solution is clear. The product should look like it is equally distributed.
Procedures for Intravenous Infusion
(Lyophilized)
Gammagard S/D 10% Solution
Reconstitution directions for a
10% product using one 10 gram vial

1) Clean area that will be used for mixing and preparing for the treatment. Reconstitute immediately before use.

2) Set up mixing supplies on table.
   a) Gammagard S/D vial and
   b) Sterile Water vial (100mL-provided separately)
   c) Transfer device (Comes with product in box)
   d) 3 Alcohol swabs

   DISCARD THE VIAL OF STERILE WATER THAT IS SUPPLIED IN THE GAMMAGARD S/D BOX!

3) Wash hands for at least 30 seconds with antibacterial soap. NOTE: anytime you touch a surface outside the clean area you will need to wash your hands.

4) Remove caps from Gammagard S/D (concentrated product) and diluent (Sterile Water) vials to expose the central portion of the rubber stoppers.

5) Swab top of each vial with an alcohol swab in one swipe away from you.

6) Remove the transfer device that is in the box of Gammagard product.

7) Remove the protective covering from one end of the transfer device. Hold the Sterile Water vial and insert the spike in the center of the vial stopper. Remove the other protective cover from the transfer device

8) Hold concentrated product bottle firmly and at an angle of approximately 45 degrees, invert the Sterile Water vial with the transfer device in it, at an angle of 45 degrees and insert the spike directly in the middle of the concentrate bottle rubber stopper.

9) *Insert the vial rapidly into the 10 gram Gammagard S/D vial in order to avoid loss of the vacuum and of the Sterile Water.

10) The Sterile Water will flow into the powder concentrate quickly. When the Sterile Water transfers completely, remove the empty Sterile Water vial and transfer spike.

11) Thoroughly wet the dried material by tilting or gently rotating the bottle.
Procedures for Intravenous Infusion
(Lyophilized)
Gammagard S/D 10% Solution

12) Swab the rubber stopper with alcohol prep pad with one swipe away from you.

13) DO NOT SHAKE TO AVOID FOAMING. Product may take up to 20-40 minutes to go into solution. Rotate the vial gently in a circular motion.

14) Let the Gammagard S/D vial sit until solution is clear. The product should look like it is equally distributed.