Instructions for use
RISPERDAL® CONSTA® requires close attention to these step-by-step Instructions for Use to help ensure successful administration.

**SINGLE-USE DEVICE**
Do not reuse. Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

**Important Information**

**Dose pack contents**

**Use components provided**
The components in this dose pack are specifically designed for use with RISPERDAL® CONSTA®. RISPERDAL® CONSTA® must be reconstituted only in the diluent supplied in the dose pack.

**Do not substitute ANY components of the dose pack.**

**Do not store suspension after reconstitution**
Administer dose as soon as possible after reconstitution to avoid settling.

**Proper dosing**
The entire contents of the vial must be administered to ensure intended dose of RISPERDAL® CONSTA® is delivered.
Step 1  Assemble components

Take out dose pack

- **Wait 30 minutes**
  Remove dose pack from the refrigerator and allow to sit at room temperature for at least 30 minutes before reconstituting.
  **Do not** warm any other way.

Connect vial adapter to vial

- **Remove cap from vial**
  Flip off colored cap from vial.
  Wipe top of the grey stopper with an alcohol swab. Allow to air dry.
  **Do not** remove grey rubber stopper.

- **Prepare vial adapter**
  Hold sterile blister as shown. Peel back and remove paper backing.
  **Do not** remove vial adapter from blister.
  **Do not** touch spike tip at any time. This will result in contamination.

- **Connect vial adapter to vial**
  Place vial on a hard surface and hold by the base. Center vial adapter over the grey rubber stopper. Push vial adapter straight down onto vial top until it snaps securely into place.
  **Do not** place vial adapter on at an angle or diluent may leak upon transfer to the vial.
Step 1  Assemble components (continued)

Connect prefilled syringe to vial adapter

Remove sterile blister

**Incorrect**

Remove vial adaptor from sterile blister only when you are ready to remove the white cap from the prefilled syringe.

Keep vial vertical to prevent leakage. Hold base of vial and pull up on the sterile blister to remove.

**Do not** shake.

**Do not** touch exposed luer opening on vial adapter. This will result in contamination.

Use proper grip

Hold by white collar at the tip of the syringe.

**Do not** hold syringe by the glass barrel during assembly.

Remove cap

Holding the white collar, snap off the white cap.

**Do not** twist or cut off the white cap.

**Do not** touch syringe tip. This will result in contamination.

Connect syringe to vial adapter

Hold vial adapter by skirt to keep stationary.

**Hold syringe by white collar** then insert tip into the luer opening of the vial adapter.

**Do not** hold the glass syringe barrel. This may cause the white collar to loosen or detach.

Attach the syringe to the vial adapter with a firm **clockwise twisting motion** until it feels snug.

**Do not** over-tighten. Over-tightening may cause the syringe tip to break.

When the cap is removed, the syringe will look like this.

The broken-off cap can be discarded.
Step 2  Reconstitute microspheres

Inject diluent
Inject entire amount of diluent from syringe into the vial.

Vial contents will now be under pressure. Keep holding the plunger rod down with thumb.

Inject entire amount of diluent from syringe into the vial.

Suspend microspheres in diluent
Continuing to hold down the plunger rod, shake vigorously for at least 10 seconds, as shown.

Check the suspension. When properly mixed, the suspension appears uniform, thick and milky in color. Microspheres will be visible in the liquid.

Immediately proceed to the next step so suspension does not settle.

Transfer suspension to syringe
Invert vial completely. Slowly pull plunger rod down to withdraw entire contents from the vial into the syringe.

Remove vial adapter
Hold white collar on the syringe and unscrew from vial adapter.

Tear section of the vial label at the perforation. Apply detached label to the syringe for identification purposes.

Discard both vial and vial adapter appropriately.

Step 3  Attach needle

Select appropriate needle
Choose needle based on injection location (gluteal or deltoid).

Attach needle
Peel blister pouch open part way and use to grasp the base of the needle, as shown.

Holding the white collar on the syringe, attach syringe to needle luer connection with a firm clockwise twisting motion until snug.

Do not touch needle luer opening. This will result in contamination.

Resuspend microspheres
Fully remove the blister pouch.

Just before injection, shake syringe vigorously again, as some settling will have occurred.
Inject dose

**Step 4**

**Remove transparent needle protector**
Move the needle safety device back towards the syringe, as shown. Then hold white collar on syringe and carefully pull the transparent needle protector straight off.

**Do not** twist transparent needle protector, as the luer connection may loosen.

**Remove air bubbles**
Hold needle upright and tap gently to make any air bubbles rise to the top. Slowly and carefully press plunger rod upward to remove air.

**Inject**
Immediately inject entire contents of syringe intramuscularly (IM) into the gluteal or deltoid muscle of the patient.

Gluteal injection should be made into the upper-outer quadrant of the gluteal area.

**Do not administer intravenously.**

**Step 4** (continued)

**Secure needle in safety device**
Using **one hand**, place needle safety device at a 45-degree angle on a hard, flat surface. Press down with a firm, quick motion until needle is fully engaged in safety device.

**Avoid needle stick injury:**

**Do not** use two hands.

**Do not** intentionally disengage or mishandle the needle safety device.

**Do not** attempt to straighten the needle or engage the safety device if the needle is bent or damaged.

**Properly dispose of needles**
Check to confirm needle safety device is fully engaged. Discard in an approved sharps container.

Also discard the unused needle provided in the dose pack.

**IMPORTANT RESOURCES**
For additional information, visit risperdalconsta.com or call Janssen Pharmaceuticals, Inc. at 1-800-526-7736, 9am-8pm (ET), Monday through Friday, and 9am-5pm (ET), Saturday and Sunday.