CHAPTER 1: INTRODUCTION		
1	Title: **ZYPREXA RELPREVV Reconstitution and Administration Training Video** **CHAPTER ONE: INTRODUCTION**	
2	Text on-screen: **ZYPREXA RELPREVV (olanzapine) For Extended Release Injectable Suspension is an antipsychotic agent indicated for treatment of schizophrenia in adults.**	
3	Text on-Screen: **All healthcare professionals who administer this product must view this video before giving an injection of ZYPREXA RELPREVV.** **For important safety Information, including boxed warnings, see the end of this program and the full prescribing information provided.**	**Narrator:** All healthcare professionals who administer this product must view this video before giving an injection of ZYPREXA RELPREVV
4	Fade up to video of nurse (talent) talking to camera. Text on-Screen: **Vial strengths** **210 mg, 300 mg, and 405 mg** **Dosing schedules** **Every 2 weeks: 150-mg, 210-mg, or 300-mg doses** **Every 4 weeks: 300-mg or 405-mg doses**	**Narrator:** ZYPREXA RELPREVV is a long acting injectable formulation of olanzapine. It is indicated for treatment of schizophrenia in adults. The efficacy of ZYPREXA RELPREVV is consistent with the established efficacy of orally administered Zyprexa for treatment of schizophrenia in adults. ZYPREXA RELPREVV is available in 210-, 300-, and 405-milligram vials. It may be administered every 2 weeks in 150-mg, 210-mg, or 300-mg doses, or every 4 weeks in 300-mg or 405-mg doses.
5	Text on-Screen: • **Description of Post-Injection Delirium/ Sedation Syndrome** • **Demonstration of ZYPREXA RELPREVV product reconstitution** • **Demonstration of**	**Narrator:** The purpose of this video is to teach you how to properly reconstitute and administer ZYPREXA RELPREVV. First we will begin by explaining the Post-Injection Delirium/Sedation Syndrome events that occurred with ZYPREXA RELPREVV in pre-marketing clinical trials. Then, we will demonstrate step-by-step instructions on how to properly reconstitute the product. Once it has been

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<table>
<tr><td></td><td>injection technique
• Real-time demonstration of reconstitution and administration process</td><td>reconstituted, we will show you the proper administration techniques and demonstrate the entire reconstitution and administration process in real time.

Please watch the end of this video and see accompanying full prescribing information for important safety information including boxed warnings.</td></tr>
<tr><td colspan="3">CHAPTER 2: POST-INJECTION DELIRIUM/SEDATION SYNDROME</td></tr>
<tr><td>6</td><td>Text on screen: CHAPTER TWO: POST-INJECTION DELIRIUM/ SEDATION SYNDROME

Events occurred: in<0.1% of injections
in approximately 2% of patients
Symptoms:
Sedation: ranging from mild in severity up to coma
Delirium: confusion, disorientation, agitation, anxiety and other cognitive impairment.
Other Symptoms: extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension, possible convulsion.

PDSS
<table><tr><th>Time of Onset of Symptoms</th><th>Patients</th></tr><tr><td><60 minutes</td><td>~80%</td></tr><tr><td>1 to 3 hours</td><td>~ 14%</td></tr><tr><td>>3 hours</td><td>~ 6%</td></tr></table>
Observe patients for 3 hours for symptoms of PDSS
If parenteral benzodiazepines are required for patient management during a PDSS event, careful evaluation of clinical status for excessive</td><td>Narrator: During pre-marketing clinical studies, events that presented with signs and symptoms consistent with olanzapine overdose were reported in some patients following an injection of ZYPREXA RELPREVV. These events occurred in <0.1% of injections and in approximately 2% of patients who received injections for up to 46 months.

Most of these patients developed symptoms of sedation, ranging from mild in severity up to coma, and/or delirium, including confusion, disorientation, agitation, anxiety and other cognitive impairment. Other symptoms noted include extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension or possible convulsion.

In pre-marketing clinical trials, the potential for onset of a PDSS event was greatest within the first hour. The majority of cases have occurred within the first 3 hours after injection; however the event has occurred after 3 hours. Patients should be advised of this potential risk and the need to be observed for 3 hours in a healthcare facility each time ZYPREXA RELPREVV is administered.

Patients experiencing post-injection delirium/sedation syndrome should be managed as clinically appropriate. Patients may be treated symptomatically.

If a Post-injection Delirium/Sedation Syndrome event is suspected, close medical supervision and monitoring should be conducted in a facility capable of resuscitation.</td></tr>
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	sedation and cardiorespiratory depression is recommended. **Notify hospital or ER personnel of:** **"…a probable olanzapine overdose following administration of Olanzapine For Extended Release Injectable Suspension."** **IMPORTANT: Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection**.	If parenteral benzodiazepines are required for patient management during a PDSS event, careful evaluation of clinical status for excessive sedation and cardiorespiratory depression is recommended. If the patient is sent to a hospital or ER for further observation or management, notify the hospital or ER personnel that the patient is experiencing "a probable olanzapine overdose following administration of Olanzapine For Extended Release Injectable Suspension." An important reminder: before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.
7	Text on-Screen: **After each injection:** • **Patients should be observed for at least 3 hours by appropriately qualified personnel in a healthcare facility with ready access to emergency response services** • **The patient should be located where he or she can be seen and/or heard at all times**	**Narrator:** After each ZYPREXA RELPREVV injection: • Patients should be observed for at least 3 hours by appropriately qualified personnel in a healthcare facility with ready access to emergency response services • The patient should be located where he or she can be seen and/or heard at all times
8	Text on-Screen: **Before patient leaves the healthcare facility:** • **Confirm that the patient is alert, oriented, and without signs or symptoms of a post-injection delirium/sedation syndrome event**	**Narrator:** Before the patient leaves the healthcare facility: • Confirm that the patient is alert, oriented, and without signs or symptoms of a post-injection syndrome event • Advise patients and their caregivers to be vigilant for symptoms of a post-injection syndrome event for the remainder of the day and be able to obtain assistance if needed • All patients should be accompanied to their next

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	• **Advise patients and their caregivers to be vigilant for symptoms of a post -injection delirium/sedation syndrome event for the remainder of the day and be able to obtain assistance if needed** • **All patients should be accompanied to their next destination upon leaving the facility**	destination upon leaving the facility
9	Text on-Screen: **After patient leaves the healthcare facility:** • **Patients should not drive or operate heavy machinery for remainder of day**	**Narrator:** After leaving the healthcare facility: ➢ Patients should not drive or operate heavy machinery for the remainder of day In addition, patient ID cards and wristbands are available for distribution to patients who receive ZYPREXA RELPREVV. The patient ID cards can be used to record the date and time of injection, concomitant medications, and emergency contact information. The wristbands can be used to note the date of the injection and an emergency contact number. Please contact your Lilly sales representative to receive a supply of patient ID cards and wristbands to use in your treatment facility.
10	Text on-Screen: **Increased contact with blood can occur:** ➢ **Partial injection into vasculature** ➢ **Significant vessel injury during IM injection (nick or puncture)** ➢ **Substantial bleeding at injection site**	**Narrator:** ZYPREXA RELPREVV is much more soluble in blood than in muscle. Increased contact with a substantial volume of blood could occur in several ways, such as ➢ Partial injection into vasculature ➢ Vessel injury associated with the intramuscular injection (a nick or puncture of the blood vessel) ➢ And substantial bleeding at injection site

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	Text on-screen: **Deep intramuscular gluteal injection:** • **Intended for deep muscular gluteal injection only** ○ **Not for intravenous, subcutaneous, or deltoid injection** • **Aspirate syringe prior to injection to ensure no blood is visible** • **If blood is visible, discard the syringe and use a new product kit**	Therefore, ZYPREXA RELPREVV is intended for deep intramuscular gluteal injection only. It is important to aspirate the syringe prior to injection to ensure no blood is visible. Administrators must not proceed with the injection if blood is visible. If blood is visible, discard the syringe and use a new product kit.
	Text on-screen: • **Post-Injection Delirium/Sedation Syndrome can occur at any injection**	Post-injection Delirium/Sedation Syndrome can occur at any injection, so safety precautions should be observed every time the product is administered.
CHAPTER 3: PREPARE MATERIALS		
11	Text on-screen: **CHAPTER THREE:** **STEP 1- Prepare Materials** Pair of hands placing gloves and alcohol wipes on counter. Arrange materials on counter. Close-up of contents of kit. Put gloves on hands.	**Narrator:** Let's begin by preparing for the ZYPREXA RELPREVV injection. First, you will need to gather and prepare your materials. Obtain 1 pair of gloves, several alcohol wipes, and the prescribed dose of ZYPREXA RELPREVV. The medication comes packaged in a convenience kit that includes the following items: A vial of ZYPREXA RELPREVV powder; a 3ml vial of diluent, one Needle-Pro® 3ml syringe with attached 19 gauge, 1.5 inch safety needle, 2 additional 19-gauge, 1.5 inch safety needles, a Reconstitution and Administration leaflet, and a patient Medication Guide. Open the kit, remove all items, and arrange them conveniently to prepare for reconstitution. You will need to wear gloves when reconstituting

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		ZYPREXA RELPREVV, as the medication can be irritating to the skin. If the medication contacts skin, flush it with water.
CHAPTER 4: DETERMINE RECONSTITUTION VOLUME		
12	Text on-screen: **CHAPTER FOUR: STEP 2: DETERMINE RECONSTITUTION VOLUME** Close-up of table… Text on-screen: **There will be excess diluent remaining in the vial.**	**Narrator:** Next you will need to determine the reconstitution volume. Please refer to the table in the full-color reconstitution and administration instructions for the proper volumes of diluent to add for each vial strength. For example, if you are preparing a 210mg dose, you will need to add 1.3ml of diluent to the 210mg powder vial. It is important to note that no matter what dose you are preparing, there will be excess diluent remaining in the vial. This extra diluent will not be needed.
CHAPTER 5: RECONSTITUTE		
13	Text on-screen: **CHAPTER FIVE: RECONSTITUTE** Tap the vial. Withdraw 1.3ml of diluent. Inject diluent into vial. While needle is still in vial, pull back on the plunger. Hold vial upright when removing needle Engage safety syringe. Tap vial on hard surface. Text on screen: **Tap firmly and repeatedly**	**Narrator:** Now you are ready to reconstitute ZYPREXA RELPREVV. The process of reconstitution and administration should take around 5 minutes to complete. First, loosen the powder by lightly tapping the vial a few times. The powder should be free flowing. This step helps to ensure the powder suspends easily and thoroughly after the diluent is added. Withdraw the proper amount of diluent into the syringe. In this case, the vial strength is 210mg, so we will withdraw 1.3ml of solution. Inject the diluent into the powder vial. Before you withdraw the needle, pull back on the plunger to withdraw some air. This will help equalize pressure in the vial. Hold the vial upright when removing the needle to prevent any loss of medication. Next, engage the safety needle and push the air out of the syringe. The suspension must be mixed correctly to ensure proper dosing. Tap the vial firmly and repeatedly on a hard, cushioned surface until there is no powder

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		visible. Avoid shaking the vial before tapping, as this can make it more difficult to suspend.
	Close-up of vial, looking for clumps. Tap vial again, if clumps are seen.	Check for clumps by inspecting the sides and bottom of the vial. Unsuspended powder appears as light yellow, dry clumps clinging to the vial. If clumps are visible, tap the vial again to break the clumps free.
	Shake vial vigorously. Close-up of suspension.	Shake the vial vigorously until the suspension appears smooth and consistent in color and texture.
	Foam in vial. Set vial on hard surface for foam to dissipate.	Sometimes foam will form from shaking the vial. The foam will dissipate if you let the vial stand briefly. You should avoid drawing foam up into the syringe, as the excess air bubbles are hard to remove and may affect the accuracy of the dose.
	Text on-screen: **Product is stable in the vial for 24 hours after reconstitution.**	Once reconstituted, the suspension is stable in the vial for up to 24 hours and does not require refrigeration. However, if the suspension is not used immediately, it should be shaken to resuspend before being drawn into the syringe for administration. Once drawn up into the syringe, this medication should be injected immediately.
CHAPTER 6: INJECT ZYPREXA RELPREVV		
14	Text on-Screen: **CHAPTER SIX: INJECT ZYPREXA RELPREVV**	**Narrator:** Attach a new safety needle to the syringe.
	Close-up of table in instructions.	For all doses, the concentration of olanzapine in the suspension is 150 mg per 1 ml. When preparing to draw up the prescribed dose, refer to the table in the instructions for the correct injection volume.
	1.4ml withdrawn from vial.	For a prescribed dose of 210mg, you will withdraw 1.4ml from the reconstituted vial. To prevent the product from leaking from the stopper, do not add air to the vial. Slowly withdraw the desired amount into the syringe. By doing this slowly, you will avoid excess air bubbles being drawn into the syringe.
	Text on-screen: **There will be excess medication remaining in the vial.**	There will be excess medication remaining in the vial. To ensure the full dose is given, tap the syringe with your fingers to remove all excess air bubbles.
	Tap the syringe.	Once the desired dose is withdrawn, remove the needle from the vial, and engage the needle safety

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	Engage needle safety device. Safety needle attached to syringe.	device. Attach a new safety needle to the syringe.
15	Text on-screen: Important: **Prior to administration, you must make sure that the patient receiving ZYPREXA RELPREVV will be accompanied to his or her destination following the 3-hour observation period. If this cannot be confirmed, do not give the injection.** Text on-screen: **Important: The patient may not drive to his or her destination for the rest of the day.** Text On-Screen: **Do not inject the medication intravenously or subcutaneously.** Graphic/Model showing ventrogluteal and dorsogluteal muscles.	**Narrator:** Prior to administration, you must make sure that the patient receiving ZYPREXA RELPREVV will be accompanied to his or her destination following the 3-hour observation period. If this cannot be confirmed, do not give the injection. Even if accompanied, the patient may not drive to his or her destination or for the rest of the day of injection. Now you are ready to give the injection of ZYPREXA RELPREVV. Once the medication is drawn into the syringe, it should be injected immediately. First, select and prepare a site for injection. This injection can be given in the ventrogluteal or the dorsogluteal muscle. These two areas have large muscle density and are clinically appropriate sites for deep gluteal injections. For these demonstrations, we are using an anatomical model. The model is not designed to receive product, so we will be using an empty syringe to show the injection should be administered.
CHAPTER 7: VENTROGLUTEAL INJECTION		
16	Text on-screen: **CHAPTER SEVEN: VENTROGLUTEAL INJECTION** Insert needle into correct location on model. Pull back on plunger. Withdraw needle from model, engage safety device.	**Narrator:** To give a ventrogluteal injection, place the heel of your hand on the greater trochanter, or hip bone at the top of the thigh. Your wrist will be in line with the person's thigh. Point your thumb at the groin and fingers towards the person's head. Form a "V" by opening a space between your pointer finger and the other three fingers. The place to give the injection is in the middle of the V-shaped triangle.

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	Dispose of vials, syringe safely.	Insert the needle into the muscle, then aspirate slowly for several seconds by pulling back on the plunger of the syringe. If any blood is drawn into the syringe, discard the syringe and the dose, and begin with a new kit. In this case, no blood is seen, so we will inject the medication with steady pressure. After withdrawing the needle carefully from the muscle, engage the needle safety device. Do not massage the injection site. Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.
CHAPTER 8: DORSOGLUTEAL INJECTION		
17	Text on-screen: **CHAPTER EIGHT: DORSOGLUTEAL INJECTION** Insert needle into correct location on model. Pull back on plunger. Withdraw needle from model, engage safety device. Text On-Screen: **Do not massage the area after the injection.** Dispose of vials, syringe safely. Text On-Screen: **Note: The vial is for single use only.**	**Narrator**: To administer a dorsogluteal injection, first locate the upper quadrant of the buttocks by drawing an imaginary line across and down, dividing the buttocks into 4 quadrants. Insert the needle into the gluteal muscle, then aspirate slowly for several seconds by pulling back on the plunger of the syringe. If any blood is drawn into the syringe, discard the syringe and the dose, and begin with a new kit. In this case, no blood is seen, so we will inject the medication with a steady pressure. After withdrawing the needle carefully from the gluteal muscle, engage the needle safety device. Do not massage the injection site. Finally, after the injection, make sure to dispose of the vials, needles, and syringe appropriately.
CHAPTER 9: RECAP		
18	Text on Screen: **CHAPTER NINE: RECAP** • **Prepare Materials** • **Determine Reconstitution Volume**	**Narrator:** To summarize, the process of reconstituting and administering ZYPREXA RELPREVV can be broken down into four easy steps, One: Prepare Materials. Two: Determine Reconstitution Volume. Three: Reconstitute; and four, Inject.

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	• **Reconstitute** • **Inject**	
19	Go through process of reconstitution in real-time. Provide Stop Watch to be shown on-screen.	**Narrator:** Watch as we demonstrate the entire process in real time. Remember, for these demonstrations, we are using an anatomical model. The model is not designed to receive product, so we will be using an empty syringe to show how the injection should be administered.
20	Text on Screen: **1-800-LillyRx (1-800-545-5979)** **www.ZyprexaRelprevv.com**	**Narrator:** If you have any questions about reconstituting and administering ZYPREXA RELPREVV please contact the number on-screen or visit the following website.
CHAPTER 10: IMPORTANT SAFETY INFORMATION (scrolled no voice-over)		
21	Text on-screen: **Current ISI will scroll at the end of the video**	

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Instructions to Reconstitute and Administer ZYPREXA RELPREVV

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ZYPREXA® Relprevv™
(olanzapine) For Extended Release Injectable Suspension

! FOR DEEP INTRAMUSCULAR GLUTEAL INJECTION ONLY.
NOT TO BE INJECTED INTRAVENOUSLY OR SUBCUTANEOUSLY.

For Important Safety Information, including boxed warnings, see the full Prescribing Information provided.

STEP 1 PREPARING MATERIALS

Figure 1: *Contents of convenience kit.*

Convenience kit includes:
(See Figure 1 on left)

- Vial of ZYPREXA RELPREVV powder
- 3-mL vial of diluent
- One 3-mL syringe with pre-attached 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro® needle with needle protection device
- Two 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needles with needle protection device.
  - For obese patients, a 2-inch (50 mm), 19-gauge or larger needle (not included in convenience kit) may be used for administration.

! *ZYPREXA RELPREVV must be suspended using only the diluent supplied in the convenience kit.*

It is recommended that gloves are used when reconstituting, as ZYPREXA RELPREVV may be irritating to the skin. Flush with water if contact is made with skin.

STEP 2 DETERMINING RECONSTITUTION VOLUME

Dose	Vial Strength	Diluent to Add
150 mg	210 mg	1.3 mL
210 mg	210 mg	1.3 mL
300 mg	300 mg	1.8 mL
405 mg	405 mg	2.3 mL

Refer to the table at left to determine the amount of diluent to be added to powder for reconstitution of each vial strength.

! *It is important to note that there is more diluent in the vial than is needed to reconstitute.*

STEP 3 RECONSTITUTING ZYPREXA RELPREVV

Figure 2: *Tap firmly to mix.*

Figure 3: *Check for unsuspended powder and repeat tapping if needed.*

Figure 4: *Vigorously shake vial.*

3.1 Loosen the powder by lightly tapping the vial.

3.2 Open the prepackaged Hypodermic Needle-Pro syringe and needle with needle protection device.

3.3 Withdraw the pre-determined diluent volume (Step 2) into the syringe.

3.4 Inject the diluent into the powder vial.

3.5 Withdraw air to equalize the pressure in the vial by pulling back slightly on the plunger in the syringe.

3.6 Remove the needle from the vial, holding the vial upright to prevent any loss of material.

3.7 Engage the needle safety device (refer to complete Hypodermic Needle-Pro instruction for use).

3.8 Pad a hard surface to cushion impact *(see Figure 2)*. Tap the vial firmly and repeatedly on the surface until no powder is visible.

3.9 Visually check the vial for clumps. Unsuspended powder appears as yellow, dry clumps clinging to the vial. Additional tapping may be required if large clumps remain *(see Figure 3)*.

3.10 Shake the vial vigorously until the suspension appears smooth and is consistent in color and texture. The suspended product will be yellow and opaque *(see Figure 4)*.

If foam forms, let the vial stand to allow foam to dissipate.

If the product is not used right away, it should be shaken vigorously to re-suspend. Reconstituted ZYPREXA RELPREVV remains stable for up to 24 hours in the vial.

STEP 4 INJECTING ZYPREXA RELPREVV

Dose	Final Volume to Inject
150 mg	1 mL
210 mg	1.4 mL
300 mg	2 mL
405 mg	2.7 mL

Refer to the table above to determine the final volume to inject. **Suspension concentration is 150 mg/mL ZYPREXA RELPREVV.**

! *IMPORTANT*

Before administering the injection, confirm there will be someone to accompany the patient after the 3-hour observation period. If this cannot be confirmed, do not give the injection.

4.1 Attach a new safety needle to the syringe.

4.2 Slowly withdraw the desired amount into the syringe.

! *SOME EXCESS PRODUCT WILL REMAIN IN THE VIAL.*

4.3 Engage the needle safety device and remove needle from syringe.

4.4 For administration, select the 19-gauge, 1.5-inch (38 mm) Hypodermic Needle-Pro needle with needle protection device. For obese patients, a 2-inch (50 mm), 19-gauge or larger needle (not included in convenience kit) may be used. **To help prevent clogging, a 19-gauge or larger needle must be used.**

4.5 Attach the new safety needle to the syringe prior to injection. Once the suspension has been removed from the vial, it should be injected immediately.

! **FOR DEEP, INTRAMUSCULAR GLUTEAL INJECTION ONLY.**
DO NOT INJECT INTRAVENOUSLY OR SUBCUTANEOUSLY.

4.6 Select and prepare a site for injection in the **gluteal** area.

4.7 After insertion of the needle into the muscle, ! *aspirate for several seconds to ensure that no blood appears.* If any blood is drawn into the syringe, discard the syringe and the dose and begin with a new convenience kit. The injection should be performed with steady, continuous pressure.

! *DO NOT MASSAGE THE INJECTION SITE.*

4.8 Engage the needle safety device.

4.9 Dispose of the vials, needles, and syringe appropriately after injection. The vial is for single-use only.

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Zyprexa® Relprevv™
(olanzapine) For Extended Release Injectable Suspension

LA568 REV.001

JELCO® HYPODERMIC NEEDLE-PRO® NEEDLE with NEEDLE PROTECTION DEVICE

1. DESCRIPTION:

The Jelco Hypodermic Needle-Pro device is a sterile, single-use device. It includes a needle and needle safety sheath. The Needle-Pro device can be used with a Luer slip or Luer lock syringe.

2. INDICATIONS FOR USE:

This device is intended for injection or aspiration of fluids. The needle protection device covers the needle after use to help prevent needle sticks.

3. CONTRAINDICATIONS:

None known.

4. WARNINGS:

4.1 A needle stick with a contaminated needle may cause infectious diseases.

4.2 Intentional disengagement of the Needle-Pro device may result in a needle stick with a contaminated needle.

4.3 Bent or damaged needles can result in breakage or damage to the tissue or accidental needle puncture. If the needle is bent or damaged, no attempt should be made to straighten the needle or engage the Needle-Pro device. The Needle-Pro device may not properly contain a bent needle and/or the needle could puncture the needle protection device, which may result in a needle stick with a contaminated needle.

4.4 Mishandling of the needle protection device may cause needles, especially short or small gauge needles, to bend whereby they protrude from the needle protection sheath, which may result in a contaminated needle-stick.

4.5 Do not use with Paraldehyde.

5. CAUTION:

5.1 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.

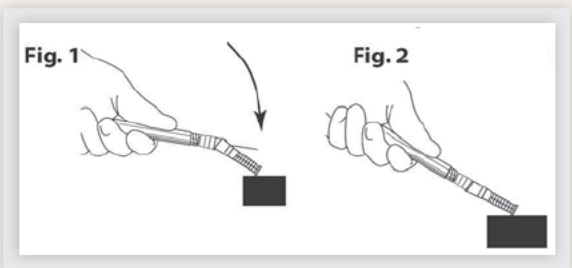
5.2 Follow standard infection control procedures as specified by the Centers for Disease Control and Prevention (USA) or local equivalent.

6. INSTRUCTIONS FOR USE:

6.1 Peel blister pouch and remove device.

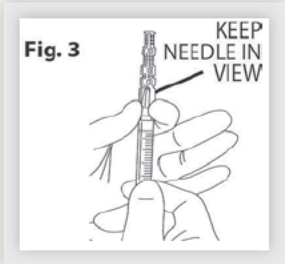
6.2 Attach a syringe (if not already attached) to the Luer connection of the Needle-Pro device with an easy twisting motion. Seat the needle firmly on the Needle-Pro device with a push and a clockwise twist, then pull the needle cap straight away from the needle.

6.3 After procedure is completed, press the needle into the sheath using a one-handed technique. Perform a one-handed technique by gently pressing the sheath against a flat surface. As The Sheath Is Pressed (Fig. 1), The Needle Is Firmly Engaged Into The Sheath (Fig. 2).



6.4 Visually confirm that the needle is fully engaged into the needle protection sheath.

6.5 Only remove the Needle-Pro device with engaged needle from the syringe when required by a specific medical procedure. Remove by grasping the Luer hub of the needle protection device with thumb and forefinger, keeping the free fingers clear of the end of the device containing the needle point (Fig. 3).



6.6 After use, place sharps in a suitable sharps container. Dispose of contaminated product in a safe manner according to Centers for Disease Control and Prevention, USA and Federal/State/Local regulations (EPA, OSHA) and health care facility guidelines or local equivalent.

NOTE: Additional dead space added by Needle-Pro device averages 0.036mL.

! **Caution** • Do Not Reuse • Not made with natural rubber latex • Do not use if package is damaged • Sterilized using ethylene oxide • Non-pyrogenic fluid path • **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician • Catalogue Number • Batch Code • Date of Manufacture • Use by • Quantity

The Smiths Medical and Jelco design marks; Needle-Pro; and the color orange applied to the needle protection device are trademarks of Smiths Medical. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark Office and certain other countries.

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www.smiths-medical.com

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