

Document Detail

Type: 0060-GR DT
Document No.: 0060-GR870132[8]
Title: DFU - Jenker Needle Recapper
Comment
Status: CURRENT
Effective Date: 12-Jul-2019

Approvals

<u>Role</u>	<u>Sign-off By</u>	<u>Sign-off Date</u>	
DPD Document Control	Lucy Brenneman	02-Jul-2019 1:07 pm	GMT
0060-Preventive UDI Approver	Priyanka Kute	02-Jul-2019 3:01 pm	GMT
DPD Marketing Management	Angela Donohue	03-Jul-2019 6:19 pm	GMT
DPD Research and Development	Tom Simonton	02-Jul-2019 5:19 pm	GMT
DPD Operations-Manufacturing	Dorin Ghergulescu	03-Jul-2019 5:27 pm	GMT
DPD Clinical	Michele Lash	08-Jul-2019 1:32 pm	GMT
DPD Pharmaceutical Management	Joe Santos	02-Jul-2019 3:18 pm	GMT
DPD Quality Assurance/Regulatory Management	Heather Shellenberger	09-Jul-2019 5:50 pm	GMT
DPD ERP Coordinator	Pauline Templin	09-Jul-2019 6:40 pm	GMT
0060-Preventive UDI Approver	Jean Gardner	11-Jul-2019 2:23 pm	GMT
DPD Document Control	Lucy Brenneman	12-Jul-2019 1:05 pm	GMT

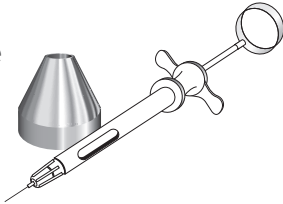
JENKER™

Needle Recapper

Directions For Use

Caution:

For Professional Use Only.

**Indications For Use:**

The Jenker Needle Recapper is a receptacle for holding the needle cap for one-handed recapping after injection. Use of the Jenker Needle Recapper can prevent accidental needle stick injuries and eliminate a source of cross contamination of infectious diseases.

Precautions:

Recapping step must be carried out one-handed to prevent the possibility of needle sticks.

Step-By-Step Instructions:

1. Remove needle cap and place into the Jenker Needle Recapper.
2. For recapping - Place Jenker Needle Recapper on a stable, solid surface. With the needle cap resting in the Jenker receptacle (from step 1), use one hand to guide the syringe with the uncapped needle down into the cap.

DO NOT HOLD THE JENKER DEVICE.

3. If re-injection is required, repeat steps 1 and 2.
4. Dispose of needle in compliance with State and Federal law.

**Cleaning Instructions:**

- Carefully remove the recapped needle and dispose in compliance with State and Federal Law.
- Prepare an instrument cleaning solution per the manufacturer's recommendation.
- Immerse the Jenker Needle Recapper in an ultrasonic cleaner containing the prepared solution for the contact time specified by the solution manufacturer.
- Operate the ultrasonic cleaner in accordance with the manufacturer's instructions.
- Rinse the Jenker Needle Recapper under running tap water for a minimum of 30 seconds and allow to dry completely.
- Visually inspect the Jenker Needle Recapper for visible soil and repeat the cleaning procedure if necessary.
- Dry with a clean cloth or allow the Jenker Needle Recapper to air dry.

Sterilization Instructions:

The Jenker Needle Recapper can be sterilized utilizing the following procedure:

- Place the Jenker Needle Recapper in a steam sterilization pouch. Place the bagged Jenker Needle Recapper into the steam sterilizer per manufacturer's instructions.
- Gravity Steam Sterilization: Cycle at 132°C - 135°C (270°F - 275°F) for 10 - 15 minutes
- Pre-vacuum Steam Sterilization: Cycle at 132°C - 135°C (270°F - 275°F) for 3 - 4 minutes
- To dry, use the drying cycle of the sterilizer. Set cycle for 20 - 30 minutes.
- To maintain sterility, instruments should remain bagged until ready for use and stored in a dry, clean location.