

Non-Sterile Sales Syringe Adapter

Instructions for Use

Important

- This product is intended to be used by an individual with appropriate training and experience.
- Do not attempt to use the Sales Syringe Adapter before completely reading and understanding the information contained in this Instructions for Use

Device Description

The Sales Syringe Adapter is an attachment for a BD Luer-Lok 1 ml/cc syringe with a stock keeping unit, SKU, 309628. The purpose of the Sales Syringe Adapter is to aid user's one-handed dexterity in any applicable setting by enhancing user's grip, control, and comfort in operating a syringe in a non-surgical procedure.

The device consists of "depressor" and "grip" units that can be positioned based on user's preferred hand positioning. The two units may be used alone or together based on the user's preference.



Figure 1: Syringe adapter with the "depressor" to the left and "grip" to the right

Contents of Packaging

- Depressor
- Grip
- Instructions for Use

How Supplied

Devices are bulk packaged, clean, and non-sterile.

Storage

Devices should be stored at room temperature to avoid morphing of product: 22° C to 26° C (72° F to 78° F).

Device storage temperature must not exceed 70° C (158° F).

Indications for Use

The Sales Syringe Adapter is indicated for individuals who require increased ease of use or increased control when operating a standard BD Luer-Lok 1ml/ 1 cc syringe in any non- surgical applicable setting.

Contraindications

- Do not use SSA for surgical procedures.

Warnings

- This device is for use on a BD Luer-Lok 1 ml/cc of SKU 309628 syringe only.
- Single use only.
- This device is not intended to be used in sterile procedures. If the device is used in a sterile setting, it may lead to surgical site infection.

Precautions

- Not designed to displace the full length of the syringe.
- If there are any variations between these Instructions for Use and your facility's policies, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with the device.
- Prior to use, inspect devices to ensure proper function and condition. If cracked, do not use, as sharp edges can harm the user or patient.
 - ⊖ Refer to Figure 2 to view proper physical conditions of the device.
- Do not use the Syringe Adapter if it does not satisfactorily perform its intended function of aiding to enhance control while dispersing a fluid.
- Do not use if primary packaging is open or damaged.
- Avoid bending and twisting the device, as it may damage the device.

Adverse Events

Observed Adverse Events

Zero adverse events have been observed using the SSA.

Adverse Event Reporting

For any adverse event involving the Sales Syringe Adapter contact Iowa MADE customer services. To reach Iowa MADE customer services, call (319) 384-3425 or email iowa-made@uiowa.edu.

Directions for Use

Assembly Instructions

Reference diagram for assembly:

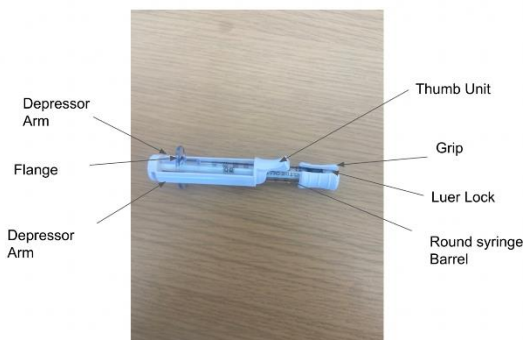


Figure 2: Reference picture for assembly directions.

Assembly Directions

1. Ensure that the device arrives packaged properly and the device components are intact and properly functional. Refer to Figure 2 to understand the component names of the syringe and Sales Syringe Adapter.

2. Orient the round syringe barrel such that the flange fits in the space between the two arms of the “depressor”.

3. The round housing of the “depressor” is designed such that the round syringe plunger will snap into the “depressor”. Orient the barrel of the syringe parallel to the “depressor” arms. The barrel should be sitting on the two arms of the “depressor” with flange in between the depressor’s arms. The barrel is now ready to be snapped in between the “depressor” arms.

4. Before snapping the barrel in, orient the barrel up or down the flange depending on personal preference for grip. This will largely depend on the user’s hand size and preferences. Keep in mind that the “grip” portion of the syringe adapter will snap onto the barrel below the “depressor” arms.

5. When orientation is per preference, snap the syringe barrel into the “depressor”. This can be done by holding the “depressor” and syringe plunger together between the thumb and index finger of one hand, and simultaneously pinching the “depressor” onto the syringe barrel by placing the thumb of the other hand on the “Thumb” surface of the depressor. Pinch together until an audible click is heard. An audible click indicates the “depressor” is now seated on the syringe.

6. The use of the “grip” portion of the syringe adapter is optional to use, per user’s preference, and can increase ergonomic ease when using the syringe. If the “grip” is

used, it is to be attached before the attachment of the syringe needle.

7. Unlike the “depressor”, the “grip” slides onto the syringe from the bottom, not clicked into place. To place the “grip” below the depressor, use one hand to grip the syringe by the barrel. (Not the “depressor”). With the other hand, slide the “grip” over the Luer Lock and seat it on the syringe barrel with a twisting motion until it is secure. The “grip” is now seated on the syringe.

Hand Positions for Use

There are 3 hand positions that can be used with the Sales Syringe Adapter.

Pencil Grip, Hand position 1:

1. The syringe adapter is assembled with or without the “grip”.
2. The syringe is held like a pencil. The thumb is placed on the “Thumb” surface (as shown in Figure 3 below). The index and middle fingers squeeze either the syringe barrel or the “grip” depending on whether the grip was used.
3. For a visual of this grip, refer to Figure 3 below.

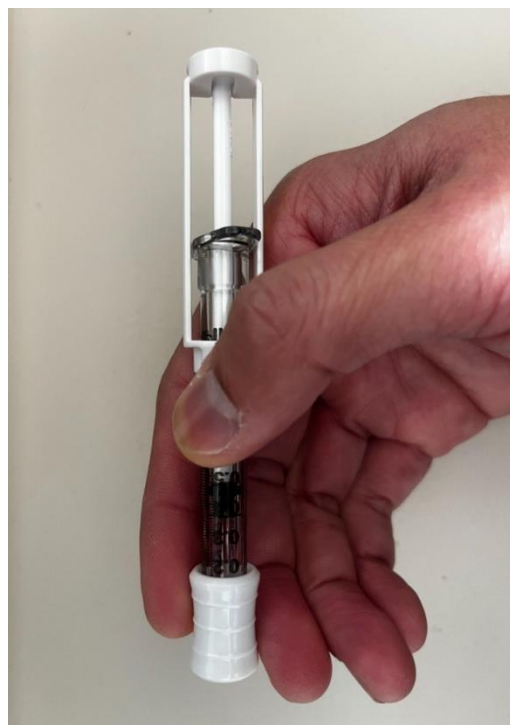


Figure 3: Visual of Pencil Grip, Hand Position

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Pencil Grip, Hand position 2:

1. Assemble the syringe adapter with or without the “grip”.
2. The syringe barrel or “grip” is pinched between the middle finger, ring finger, and thumb. The index finger is placed on the “Thumb” surface.
3. For a visual of this grip, refer to Figure 4 below.



Figure 4: Visual of Pencil Grip, Hand Position 2

TV Remote Grip, Hand Position 3:

1. The syringe adapter is assembled with or without the “grip”.
2. The syringe is held like a TV remote. Orient the bottom of the barrel to rest on the fingertip of the little finger, and the “grip”/bottom of barrel to rest on the fingertip of the index finger. The syringe is then cradled across the middle phalanx of the middle and ring fingers.
3. The thumb is placed on the “Thumb” surface of the depressor.
4. For a visual of this grip, refer to Figure 5 below.



Figure 5: Visual of TV Remote Grip, Hand Position 3

Instrument Cleaning and Sterilization

Sales Syringe Adapter is disposable and not intended for repeat use between different cases. To clean for use during the same case, rinse in a saline solution.



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