

September 28, 2021

Cone Health  
Attn. Wendy Turner  
Clinical Laboratory Director

Email: Wendy.Turner@conehealth.com

**Subject: Safety Subculture Unit (Product Code A100720) Product Change Notification**


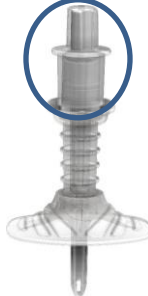


Dear Wendy Turner,

This letter is to inform you of a change to the Safety Subculture Unit (SCU), Product Code A100720.

The change to the SCU includes introduction of a new Vent Cap, the current Vent Cap is being discontinued. The change to the new Vent Cap is a slightly different profile and includes a polyester filter to absorb culture discharge. All other product design elements and components remain unchanged. The SCU product code will remain the same (A100720).

SCU with the new Vent Cap has been validated in accordance with ITL's Quality Management System. Cone Health will begin receiving SCU with the new Vent Cap starting January 2022. Lead lot will be communicated in advance.

A100720 with current Vent Cap and A100720 with new Vent Cap

	A100720 (with current Vent Cap)	A100720 (with new Vent Cap)
SCU Image	 <p>Height: 54 ± 1mm</p>	 <p>Height: 61.2 ± 1mm</p>
Vent Cap	 <p>Polyethylene preassembled with filter</p>	 <p>Polyethylene preassembled with filter</p>

Note that there are no changes to product functionality or procedure for use.

Samples of SCU with the new Vent Cap are available upon request.

The SCU Instructions for Use (IFU) have been updated with an image of the new Vent Cap. In addition, the SCU IFU update ensures compliance with the *In Vitro* Diagnostic Medical Device Regulation (EU) 2017/746 effective May 2022.

Specific updates to the IFU include:

- Removed references to “white filter cap”
- Replaced the word “luer” with “port”
- Added “Notification for EU customers”
- Included email address, “[sales@itlbiomedical.com](mailto:sales@itlbiomedical.com)” under manufacturer as per Notification Statement.
- Updated IFU document # to include “Rev #” & “date of revision”.
- Included following statements under “Warnings and Precautions”:
  - Do not place culture bottles with SCU inserted in the bottle in an incubator.
  - Do not leave SCU in the culture bottle after use.
  - Do not reuse SCU

A copy of the updated IFU is attached for reference.

Please contact me at [vipin.kunjachan@itlbiomedical.com](mailto:vipin.kunjachan@itlbiomedical.com) / (703) 435-6700 if you have any questions about this notice or need additional information. ITL is committed to providing its customers with the highest quality products and customer service.

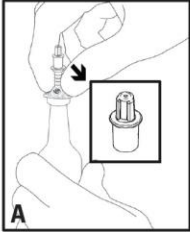
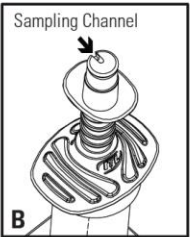
Best regards,



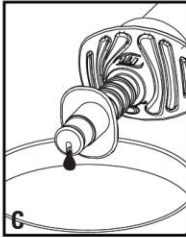
Vipin Kunjachan  
Product Commercialization Manager

# Safety SubCulture Unit

## INSTRUCTIONS FOR USE

- Gently agitate culture bottle to mix contents.
- Disinfect culture bottle as per your facility procedure.
- Open package by peeling apart at the peel tab end.
- Remove device from package by holding the ribbed column being careful not to touch the tip. 
- Hold bottle in place with one hand and with the other hand position tip of the device in the center of the disinfected septum and press down firmly on the flange to pierce culture bottle septum (A).   
**Note:** The SCU will not sit flush with the septum.
- Remove vent cap by holding the SCU in place at the flange with one hand, with the other hand grasp the vent cap and pull up and off. Place vent cap to the side for later retrieval.
- Proceed with obtaining culture sample either by **direct drop** or **syringe draw** method.

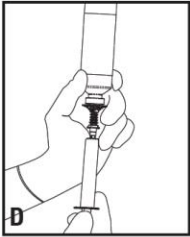
## DIRECT DROP METHOD

- Orient device sampling channel (B) to be close to slide, plate or tube. 
- Tilt culture bottle downward and dispense required number of sample drops for each slide, media plate, or other required test (C).
- Upright the culture bottle. Replace vent cap on the SCU.
- Carefully remove device by holding culture bottle with one hand and with the other hand hold ribbed column and apply a slight twist and pull motion to avoid potential spatter while removing from the culture bottle.
- Dispose according to your facility procedure.

INDICATIONS FOR USE: Safety SubCulture Unit (SCU) is designed to safely transfer positive samples from the culture bottle for further testing. SCU can be used in one of two ways: **direct drop method** or **syringe draw method**. Neither method requires a needle which reduces the risk of potential needle stick injury. There are no known contraindications for the SCU, though care should be taken per the warnings and precautions included in this IFU.

**⚠ WARNINGS AND PRECAUTIONS:** Inserting the SCU into the culture bottle vents the bottle. Caution should be taken because positive culture bottles may contain gas producing organisms and have internal pressure. Wear proper personal protective equipment and vent culture bottles under a safety hood or as your facility procedure requires. Do not place culture bottles with SCU inserted in the bottle in an incubator. Do not leave SCU in the culture bottle after use. Do not reuse SCU.

## SYRINGE DRAW METHOD

- Aseptically remove sampling channel insert (B) by placing fingertips under flat surface of insert, pull out of device and discard. 
- Insert male end of syringe into female port of device.
- Invert culture bottle and syringe and draw required sample into syringe (D).
- Upright culture bottle and pull back slightly on syringe plunger to clear any culture media remaining in the column.
- Remove syringe from device.
- Replace vent cap on the SCU.
- Dispense sample from syringe.
- Carefully remove device by holding culture bottle with one hand and with the other hand hold ribbed column and apply a slight twist and pull motion to avoid potential spatter while removing from the culture bottle.
- Dispose according to your facility procedure.

**⚠ IMPORTANT: DO NOT RE-USE SCU FOR DIRECT DROP AFTER SYRINGE DRAW**

**NOTIFICATION for EU Customers:** Any serious incident that has occurred in relation to the device must be reported to the manufacturer (details below) and the competent authority of the EU Member State where the Customer's facility is established.