

ONSET® MIXING PEN

DEVICE DESCRIPTION:

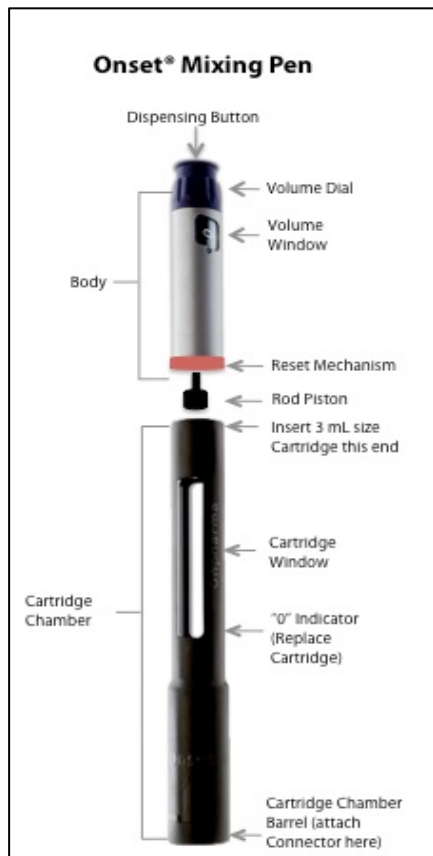
The Mixing Pen is used to dispense a solution from a standard 3 mL size cartridge into a second fluid container, allowing the two solutions to be mixed (the 3 mL size cartridge and second fluid container are not provided). The Mixing Pen is comprised of two parts: 1) the Body, which contains the dispensing components, and 2) the Cartridge Chamber, which houses the 3 mL size cartridge. Additionally, the Barrel end of the Cartridge Chamber is designed to accommodate a connector (for example the Onset Cartridge Connector, provided separately) facilitating the connection of a second fluid container to the Mixing Pen. The Mixing Pen can dispense a precise amount of fluid from the first fluid container to the second fluid container, which, for example, could be a 1.8 mL cartridge. The Mixing Pen is provided non-sterile.

INTENDED USE AND INDICATION FOR USE:

The Mixing Pen is a high precision compounding and dispensing device for mixing two solutions together.

CONTRAINDICATIONS:

The Mixing Pen is not indicated for direct administration of solutions to any patient or user.



DIRECTIONS FOR USE:

The Mixing Pen is designed for use with a connector to allow transfer from a 3 mL size cartridge that has been loaded into the Mixing Pen into a second fluid container that has been temporarily attached to the connector for the purpose of mixing the fluid from the first fluid container into the second fluid container. Assemble the device according to the steps described below, using aseptic technique and a sterile connector, as

appropriate, to ensure sterile fluid transfer when mixing two sterile solutions:

1. Unscrew the Body of the Mixing Pen from the Cartridge Chamber by turning counterclockwise to separate from the Mixing Pen's Body.
2. Check to make sure the Mixing Pen's Piston Rod is fully retracted into the red Reset Mechanism. If the Piston Rod is not fully retracted, hold the Reset Mechanism with your thumb and forefinger while turning the Mixing Pen Body counterclockwise until the Piston Rod stops.
3. Insert a 3 mL sized cartridge septum-end-first into the Cartridge Chamber.
4. Reconnect the Cartridge Chamber to the Mixing Pen Body by screwing back together.
5. Prime the Mixing Pen by dialing the Volume Dial to 20, and push the Dispensing Button until the Piston Rod makes contact with the rubber plunger on the 3mL size cartridge.
6. Dial the Mixing Pen back to "0" before attaching a Connector.
7. Attach a connector (for example an Onset Cartridge Connector) to the Barrel of the Cartridge Chamber to create fluid path from the first fluid container to a second fluid container that can be attached to the connector (e.g. a 1.8 mL cartridge).
8. Attach the second fluid container to the Connector. Then grasp the connector with your thumb and forefinger and turn clockwise one-quarter turn, then push in.
9. Turn the Volume Dial on the Mixing Pen to the desired volume of solution to be dispensed from the first fluid container. Dialing the Mixing Pen to the number "10", for instance, will dispense one tenth of one milliliter (0.10 mL) from the first fluid container to the second fluid container attached to the connector. Likewise, dialing the pen to "18" will dispense 0.18 mL, dialing the Pen to "20" will dispense 0.2 mL, and so on.
10. Push the Dispensing Button on the Mixing Pen to transfer fluid from the first fluid container into the second fluid container (e.g. a 1.8 mL sized cartridge).

WARNINGS, PRECAUTIONS AND ADVERSE EVENTS:

Use only as directed. No known adverse events are associated with the Mixing Pen.

STORAGE AND HANDLING:

Do not autoclave. Clean using standard practice with a disinfectant wipe. Do not spray or immerse the device as this may cause damage.

Symbol			
Definition	Caution, consult accompanying documents	Do not use if package is damaged	Consult instructions for use

CUSTOMER CARE AND QUESTIONS:

Call 1-877-336-6738 for more information, questions or support regarding the Onset Mixing Pen or the referenced Onset Cartridge Connector.

Federal law (U.S.A.) restricts this device to sale by or on the order of a medical practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

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