

Instructions for Use (IFU)

Tissue Grinder System – Closed, Sterile, Disposable

1. Device Description

The Tissue Grinder System is a closed, single-use device designed for the safe and efficient homogenization of tissue samples.



Components:

- Internally Ribbed Collection Tube – for sample preparation
- Pestle with either vitrified or plastic tip and cap – for manual grinding
- Screw Cap – for secure transfer or storage

All components are gamma-sterilized, preassembled, and packaged in a Tyvek® easy-open peel pouch. The device is refrigerator-compatible.

2. Intended Use

For laboratory use only. The Tissue Grinder System is intended for the manual homogenization of biological tissue samples under sterile conditions. Not for use in diagnostic procedures on humans unless validated for such use by the end user

3. Sterility & Packaging

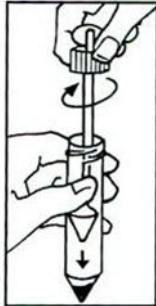
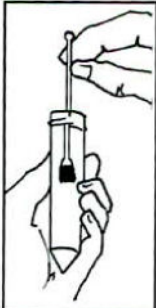
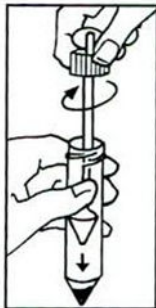
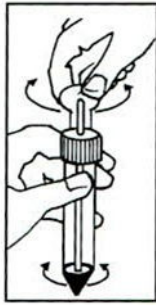
- Sterile unless package is opened, damaged, or past the expiration date
- Individually wrapped in Tyvek® pouch
- Single-use only - do not reuse
- Autoclavable post-use for disposal purposes

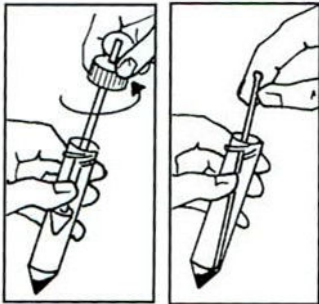
4. Warnings & Precautions

- Wear appropriate PPE (gloves, lab coat, eye protection) during use
- Ensure the cap is fully tightened before processing to prevent fluid escape
- Do not overfill the tube with tissue or fluid; overfilling may cause leakage
- Dispose of all components in accordance with applicable biohazard waste regulations

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5. Directions for Use

1. Prepare Sample – With PPE on, remove the pestle handle and place onto a sterile field or sterile package to maintain aseptic conditions.	
2. Prepare Sample – Place tissue/sample in the collection tube. Add fluid if required, leaving sufficient space for pestle movement.	
3. Assemble – Hold the tube upright. Insert the pestle into the tube and screw on the pestle cap tightly.	
4. Grind – Rotate the pestle handle with gentle downward pressure to homogenize the tissue. The pestle will rise and lower naturally during grinding.	

5. Retrieve Sample – Unscrew cap and remove the pestle cap and pestle handle. Collect the processed sample.	
6. Store or Transfer – Secure the screw cap on the collection tube. Store sample per internal protocols.	
7. Dispose – Autoclave used components prior to disposal per local biohazard handling protocols.	

6. Storage Conditions

- Store device in a cool, dry place
- Avoid exposure to direct sunlight or extreme temperatures

7. Product Identification

- Manufactured in USA
- Tyvek® is a registered trademark of DuPont