

Product Name: CoreDish®

Catalogue No.: M971 series

This document replaces any previous version

1. Product Description:

- **Biopsy Container:** Non-sterile multiple biopsy containers
 - M971-D5B-2 5 compartment Breast Biopsy
 - M971-D8P 8 compartment Prostate Biopsy
 - M971-D8UGI 8 compartment Upper GI track Biopsy
 - M971-D12LGI 12 compartment Lower GI track Biopsy
 - M971-D12P 12 compartment Prostate
 - M971-D5 5 compartment General purpose
 - M971-D58 8 compartment General purpose
 - M971-D12 12 compartment General purpose

2. Packaging:

- **Case:** 10 units per case (packaged individually)

3. Product Specifications:

- **Material:**
 - CoreDish®: Polystyrene
 - O-ring Seal: Silicone
- Patient identification label on each unit
- Temperature range -80°C to +80°C
- Not autoclavable

4. Standards and Conformity:

- **ISO 2859-1:** Sampling and inspection procedures
- **FDA:** Resin conforms to FDA 21 CFR 177.1640
- **CONEG:** Plastics and colorants are in conformity with CONEG standards for heavy metals
- **REACH (SVHC):** Plastic is in conformity to REACH standards
- **LATEX:** Material is Latex Free

5. Quality Assurance:

- Clear, no presence of contamination in plastic
- Visual attributes
- Dimension measurements

6. Traceability:

- **Lot No. Composition:** 8 or 9 digits

- **The lot number can be found in one or all of these locations:**
 1. On exterior case label
 2. On label inserted inside the master case
 3. On the inner bag

7. Storage Conditions:

- Store at room temperature in normal warehouse conditions
- Avoid temperature variations and humidity
- Protect from any possible contamination
- Protect from any damage to the packaging

8. Recommended Use:

- Verify proper cap closure when using biohazard material and / or chemical reagents
- Follow chemical resistance chart recommendations
- For use in automated equipment, follow the equipment manufacturer's instructions

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