

Product Name: INO-LOOP™

Catalogue No.: L200-3A

This document replaces any previous version

1. Product Description:

- **Inoculating Needle:** White, Disposable, sterile needle spreader

2. Packaging:

- **Case:** 100 bags of 10 units / 1 000 units per case
(Packaged sterile in safe, tamperproof, zip-lock resealable bags)

3. Product Specifications:

- **Material:**
 - Loop: High Impact Polystyrene
 - Loop Color: White
- **Length:** 227 mm
- **Gamma radiation sterilized** at a SAL of 10^{-3} ; specified dose between 6.5 kGy and 13.5 kGy
- **Temperature range:** -80°C to +80°C
- **Non autoclavable**

4. Standards and Conformity:

- **ISO 2859-1:** Sampling and inspection procedures
- **FDA:** Resin conforms to FDA 21 CFR 177.1640
- **RoHS:** Plastics and colorants are in conformity with RoHS standards for heavy metals

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 which could compromise the product sterility

8. Recommended Use:

- Smooth and flexible to facilitate uniform streaking without damaging the gel surface.

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