



Biosigma s.r.l.

a Dominique Dutscher Company

Via Valletta, 6 | 30010 Cantarana di Cona (VE), Italy | Tel. ++39 0426 302224 (r.a.) |
Fax ++39 0426 302228 | SMS ++39 348 4077376 |
E-mail info@biosigmaeu.com | <http://www.biosigma.com> |

M521D

Last Updating
07th June 2013

TECHNICAL DATA SHEET

INOCULATION LOOPS



Disposable loops, sterile, in polypropylene. One side is provided of loop head and the other side of inoculating needle. The easy peel-pack open pouch enables fast and easy access to the product especially when wearing gloves. Peel-pack shows lot no and sterility expiry date.

Peel-pack can be of 5, 10, 20 units or individually wrapped.



IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE ONLY

- Use only for laboratory analysis
- Keep out of flame or heat sources which might damage the product
- Do not use after expiry date
- Sterile product: sterility is guarantee only if the box is undamaged
- Do not vary the intended purpose of the product
- Keep out of reach of children
- Store in dry place and far from the direct light
- Disposal: use appropriate personal protective equipment and act according to applicable regulations.

REF	ANSE	CONF.	Q.TA'/CONF.
390527	INOCULATION LOOPS 10 µl in PP STERILE - in Peel Pack 20 pcs.	10.000 pcs.	5 bags of 2.000 pcs.
390528	INOCULATION LOOPS 10 µl in PP STERILE - in Peel Pack 10 pcs.	12.000 pcs.	6 bags of 2.000 pcs.
390530	INOCULATION LOOPS 10 µl in PP STERILE - in Peel Pack 5 pcs.	4.000 pcs.	8 bags of 500 pcs.
390529	INOCULATION LOOPS 10 µl in PP STERILE- individually wrapped	2.100 pcs.	6 bags of 350 pcs.
390531	INOCULATION LOOPS 1 µl in PP STERILE - in Peel Pack of 20 pcs.	10.000 pcs.	5 bags of 2.000 pcs.
390532	INOCULATION LOOPS 1 µl in PP STERILE - in Peel Pack da 10 pcs.	12.000 pcs.	6 bags of 2.000 pcs.
390534	INOCULATION LOOPS 1 µl in PP STERILE- in Peel Pack da 5 pcs.	4.000 pcs.	8 bags of 500 pcs.
390533	INOCULATION LOOPS 1 µl in PP STERILE - individually wrapped	2.100 pcs.	6 bags of 350 pcs.

MANUFACTURER DEFINITION

BIOSIGMA s.r.l.

Via Valletta, 6 - 30010 - Cantarana di Cona (VE) - ITALY

Tel. +39.0426.302224 - Fax +39.0426.302228

E-mail: info@biosigma.com - <http://www.biosigma.com>

INTENDED USE

A hand-held device designed to deliver very small (e.g., 1 or 10 microliters) samples for bacterial inoculation and other related laboratory procedures. It typically consists of a slender handle and an attached wire loop which is used to gather and hold specimen material, e.g., bacterial growth colonies, for the purposes of inoculating culture medium, e.g., agar or broth. This is a single-use device.

FOR IN VITRO USE ONLY



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The use and the manipulation of the devices **are reserved to the medical and technical staff** with the necessary professional qualification.

CLASSIFICATION

In order to the Directive 98/79/CE concerning medical-diagnostic in vitro devices receipt in Italy with D.L. n. 332 G.U.R.I. n. 269 dated 17th November 2000, Biosigma s.r.l., defines all the components of the above-state family as medical-diagnostic in vitro devices and classifies it as "Other medical-diagnostic in vitro devices", in order to make conformable the attachment III of the directive.

DIMENSIONS:

Inoculation loops, polypropylene, disposable, sterile by ethylene oxide, various packaging.

Loop 10 µl

Overall length: 19.5 cm

Color: light blue

Material: Polypropylene

Sterilization: ETO



Loop 1 µl

Overall length: 19.5 cm

Color: white

Material: Polypropylene

Sterilization: ETO



MATERIALS

The materials utilized for the production of the in vitro labware devices are selected on the base of the properties indicated for the individual destination use.

The devices INOCULATION LOOPS are product in Polypropylene (PP).

The **polypropylene** is light, resistant to autoclaving and sterilization. It has excellent characteristics of chemical resistance (to ambient temperature it does not come melted from some dissolvent).

The Declaration of Conformity in accordance to the **Directive 98/79/CE** is available, on request, to the Quality Department Biosigma S.r.l.

Interpretation of the symbols on the package

	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices		Symbol for "Keep dry"
	Symbol for "Do not reuse"		Symbol for "batch code"
	Symbol for "Consult Instructions for Use"		Symbol for "Use by"
	Symbol for "temperature limitation"		Symbol for "Manufacturer"
	Symbol for "In Vitro Diagnostic Medical Device"		Symbol for "Fragile, handle with care"
	Symbol for "Method of sterilization using irradiation"		Symbol for "Method of sterilization using ethylene oxide"
	Symbol for "Do not use if package damaged"		Symbol for "Keep away from heat"