

## **TECHNICAL DATA SHEET**

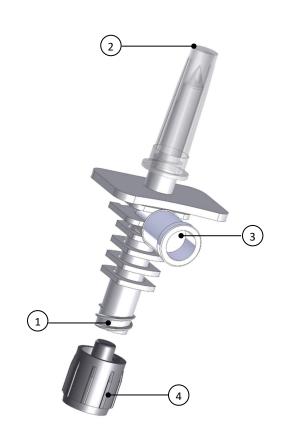
Spike-CRN® Spike-CRN® MEDICAL TECHNOLOGY

**TDS CNSSPKEN** 

Date: 10.09.2024

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### **DEVICE PARTS**



### **INTENDED PURPOSE**

Microperforator for aspiration of drugs to be used with crn®CRONO® *Reservoir* syringes.

#### **CLASSIFICATION**

Class Is medical device, according to Rule 2 of Annex IX of 93/42/EEC European directive and subsequent changes introduced by the 2007/47/EC European directive.

#### **MANUFACTURER**

#### MULTIMEDICAL s.r.l.

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CE MARKING	<b>(</b> € <sub>0123</sub>
ITALIAN REPERTORY NUMBER OF MEDICAL DEVICES (RDM)	1364422
ITALIAN CLASSIFICATION OF DEVICE (CND)	A0704
CANÈ REF	SPIKE/04
MANUFACTURER REF	091548/1

PART No.	DESCRIPTION	MATERIAL
1	Microperforator with female Luer Lock connector (ISO 80369-7)	ABS
2	Tip cover	LDPE
3	l Air tilter	PP 3 μm hydrophobic membrane
4	Male Luer-Lock cap (ISO 80369-7)	ABS

## **DEVICE SPECIFICATION**

Sterile, single-use, non-pyrogenic, non-resterilizable product. Device free of latex and phthalate components (DEHP).



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Spike-CRN® CANE

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PACKAGING	GTIN	PCS	FEATURES	MATERIAL
Primary	08050046231373	1	Blister 12x5 cm	Medical degree Paper PP/PE Plastic film
Secondary	18050046231370	60*	Bag	PE
Tertiary	28050046231377	300	Box 39x29x20 cm	Corrugated cardboard

<sup>\*</sup> each bag of 60 pieces contains an instruction sheet for use.

ENVIRONMENTAL CONDITIONS FOR STORAGE AND TRANSPORT	EXPIRY DATE
Store the product away from direct exposure to sunlight, in dry and clean environments and away from extreme temperatures and excessive humidity.	4 years and 11 months from the date of manufacture.



# WARNINGS

Disposable consumables must be disposed of in accordance with the regulations governing the disposal of medical waste.