

Description:	Skin staple remover
Final dimensions:	12.5 cm
Composition:	High performance polymer.
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	Grey
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Sterility Assur. Level_ SAL	≤10 ⁻⁶

STERILE EO






isento
Latex
free

isento
PVC
free



Nr and Revision Date:	29 -- 2022/10/11
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC
Applicable norms:	EN_ISO_13485.2016 ; EN_ISO_13485.2016_AC18 ; EN 556-1.2001_AC.2006 ; EN_ISO_134852016_A11 ; EN_ISO_11737-2.2009 ; EN_ISO_11737_2_2020 ; EN_ISO_14971.2012 ; EN_ISO_14971_2019 ; EN_ISO_14971_2019_A11 ; EN_ISO10993-1.09_AC.10 ; EN_ISO_10993-1-2020 ; EN_ISO_10993-18.2009 ; EN_ISO_10993-18_2020 ; ASTM_F1980_16 ; ISO_14698_1_2003 ; ISO_14644-1.2015 ; ASTM D4169 ; ISO_14644-5_2004 ; ISTA Standard 2A ; ASTM D4332_01 ; ICH Q1A (2003) ; ASTM D7386-16 ; EN_ISO_15223-1.2016 ; ISO_2759.2014 ; EN_1041.2008_A1.2013 ; ISO_3037_2013 ; EN_ISO_15223-1.2021 ; EN_ISO_11135.2014 ; EN_ISO_11135.14_A1.2019-Not applicable ; EN_ISO 20417_2021 ; EN_ISO10993-7_08 ; EN_ISO_11607_1_2020 ; EN_ISO_11607-2.2020 ; CEN_ISO_TS_16775_2021 ;
GMDN:	47192 - Surgical staple remover, single-use

PACKING		With Instructions for use			
Level	Units	Type	Dimension	Stamp	Labels
	1	1 Rigid peel-open pack	97x195mm		
	2	28 Carton box	200x105x212mm		labeled
	3	112 Carton box	416x223x223mm		labeled

Basic UDI	56056221158002LE
	EAN 1th level/nivel:05605622248110
	EAN 2th level/nivel:05605622448114
	EAN Carton Box/Caixa:05605622048116

Important Notes:	Instructions for use are supplied with the device in order for it to be used correctly and as intended, as the skin staple remover should be placed according with the instructions for use, in order to avoid the risk of pain or skin damage.-
Important Notes:	The device is intended to be used on a single patient during one single procedure to prevent risks from contamination, including possible infections, and/or functional damage.

Storage instructions	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefore, normal conditions of medical devices storage shall apply.
Waste instructions	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended use	For removal of surgical skin staples.- <i>Any modification of the product as presented or any use out of its intended use are not of the manufacturer responsibility.</i>



Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	1885
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ISSUED BY: Quality Management Department, 2022/11/24

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