

**Description:** Curette

<b>Composition:</b>	High performance polymer.
<b>Latex:</b>	Free
<b>PVC:</b>	Free
<b>Re use:</b>	No
<b>CMR:</b>	Free
<b>Endocrine Disruptors:</b>	Free
<b>Colour:</b>	Grey
<b>Sterilization method:</b>	Ethylene Oxide
<b>Shelf life:</b>	60 months
<b>CFU/g</b>	N.A.
<b>Sterility Assur. Level_SAL</b>	≤10 <sup>-6</sup>
<b>Length</b>	139,5 mm

STERILE EO






isento  
Latex  
free

isento  
PVC  
free



<b>Nr and Revision Date:</b>	35 -- 2021/12/06
<b>CE Class:</b>	Ila
<b>CE mark:</b>	CE1639
<b>Compliance with:</b>	MDD 93/42/EEC amended by 2007/47/EC
<b>Applicable norms:</b>	EN_ISO10993-1.09_AC.10 ; EN_ISO_10993-18.2009 ; EN_ISO_10993-18_2020 ; EN_ISO_10993-1-2020 ; ISTA Standard 2A ; ICH Q1A (2003) ; ASTM D4332_01 ; ASTM D4169 ; EN_ISO_15223-1.2021 ; EN_ISO 20417_2021 ; EN_ISO_14971_2019 ; ISO_3037_2013 ; EN_ISO_11607_1_2020 ; EN_ISO_11607-2.2020 ; CEN_ISO_TS_16775_2021 ; EN_ISO_11135.2014_A1.2019-Not applicable ; EN_ISO_14971_2019_A11 ; EN_ISO_134852016_A11 ; ISO_2759.2014 ; EN_ISO_13485.2016 ; EN_ISO_13485.2016_AC18 ; EN_556-1.2001_AC.2006 ; ISO_11135.2014 ; ISO_TS_16775.2014 ; ASTM_F1980_16 ; ISO_14644-1.2015 ; ISO_14644-5_2004 ; ISO_14698_1_2003 ; EN_ISO_14971.2012 ; EN_ISO_15223-1.2016 ; EN_1041.2008_A1.2013 ;
<b>GMDN:</b>	62558 - General-purpose curette

Level	Type	Dimension	Stamp	Labels
 1	1 Rigid peel-open pack	53x173mm		
 2	30 Folding box	176x056x212mm		labeled
 3	120 Carton box	245x188x223mm		labeled

<b>Basic UDI</b>	56056221202002HS
	EAN 1th level/nivel:05605622241265
	EAN 2th level/nivel:05605622441269
	EAN Carton Box/Caixa:05605622041261

**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 scraping, debriding and/or cleaning skin and soft tissues and wounds.-  
*Any modification of the product as presented or any use out of its intended use are not of the manufacturer responsibility.*

<b>Environment - Packaging waste</b>	Weight (gr) of packing material used in 100 pcs	981
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; EN\_ISO\_11607-2.2020 ; CEN\_ISO\_TS\_16775\_2021 ; EN\_ISO\_11135.2014\_A1.2019-Not applicable  
; EN\_ISO\_14971\_2019\_A11 ; EN\_ISO\_134852016\_A11 ; ISO\_2759.2014 ; EN\_ISO\_13485.2016 ; EN\_ISO\_13485.2016\_AC18 ; EN 556-  
1.2001\_AC.2006 ; ISO\_11135.2014 ; ISO\_TS\_16775.2014 ; ASTM\_F1980\_16 ; ISO\_14644-1.2015 ; ISO\_14644-5\_2004 ; ISO\_14698\_1\_2003 ;  
EN\_ISO\_14971.2012 ; EN\_ISO\_15223-1.2016 ; EN\_1041.2008\_A1.2013 ;

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