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PRODUCT_DATA SHEET
MINIMALLY-INVASIVE DEVICE FOR REMOVAL OF CORTICAL BONE IN SURGICAL APPLICATIONS

MICROSS - MICROSS Curve

Code	4049, 5540	5489, 5542
Device name	Micross	Micross Curve
Type of supply	Sterile	
Manufacturer (in accordance to the law 93/42/CE)	META TECHNOLOGIES S.R.L. Via E. Villa n°7 42124 Reggio Emilia (Italy)	

Device Classification (According to annex IX medical device directive 93/42/CEE)

Invasive	**Class**	**Sterile**	**Sterilisation Method**	**Single use**
YES	IIa	YES	EtO	YES

BASIC UDI-DI	805658523MICROSSWF
EMDN	Q010599 DENTAL INSTRUMENTS, SINGLE USE-OTHER
RDM - Italian Repertory of Medical Devices	(Ref.4049) 2286970 (Ref.5540) 2682045 (Ref.5489) 2286984 (Ref.5542) 2682061
General Features	MICROSS and MICROSS Curve are a completely integrated system for the removal and collection of autologous bone in surgical applications. It is typically used in dentistry in order to obtain bone regeneration where this process is lacking due to natural or traumatic causes. The removal of superficial bone cortex is performed by using a particular scraping blade, which generates thin bone scales or chips that are directly collected by the tool. The high technology used by the blade allows the surgeon to perform the cut with optimal precision and under control with only a slight pressure. Bone scales are collected through a slot located at the base of the blade, which channels them behind the blade itself in a special temporary storage compartment, with a capacity of about 0.25 cc, protected by the external steel cannula. During the collection phase, the bone scales, that are intertwined with each other, are mixed with the blood to form a high bone density concentration, which is ideal as a filler in regeneration techniques. The device is closed by a lock ring. By unhooking this lock ring, the external cannula can be slid back to discover the previously removed bone, collected around the blade-holder mini cannula. In this way, the bone is made immediately available to be deposited in the surgical reception site rapidly and safely, eliminating the need for any further manipulation. The reduced size of the blade and grip handle allow the surgeon to access narrow areas, that would be otherwise difficult to reach with conventional products. These features also allow the tool to be introduced through small tunnels opened by the surgeon, so that it won't be necessary to open large portions of tissues coating the bone.

System Quality Standards	EN ISO 13485
Main applicable Product Standards	UNI EN ISO 7153-1 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-7

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	EN ISO 10993-9 EN ISO 10993-10 EN ISO 11607-1

Production (EN ISO 14644-1 - EN ISO 14644-2)	Clean room (ISO 7)

Quality Control	**Type**	**Standard**
	Acceptance checks	UNI 2859-1- Internal Procedures
	In-process checks	UNI 2859-1- Internal Procedures
	In-process checks	UNI 2859-1- Internal Procedures
	Sterile finished product checks	Internal Procedures European - PH

Sterilization	Ethylene oxide sterilisation (EtO) is performed by a qualified outsourced workshop. The sterilization process has suitably been validated in accordance with the UNI EN 556 and UNI EN ISO 11135-1 standards in force. META guarantees product sterility for 3 years, provided that the product is stored in suitable conditions and that its packaging is undamaged when opened for use.

Composition and materials	**Pcs**	**Description**	**Materials (MICROSS)**	**Materials (MICROSS Curve)**
	1	Co-moulded cannula body	AISI-ASTM stainless steel + MABS Green	AISI-ASTM stainless steel + MABS Green
	1	Lock ring	PP blu	PP blu
	1	Central body	//	POM
	1	Handle body	MABS + Green	//
	1	Blade-holder cannula	AISI-ASTM stainless steel	//
	1	Blade	AISI-ASTM stainless steel	AISI-ASTM stainless steel

Packaging	Packaging has been appropriately validated in accordance with UNI EN ISO 11607-1 harmonised standard.	
Type	**Size**	**Materials**
Single-packaged blister with one piece.	**Size:** external volume about 50 x 205 x 20 mm	White medical grid paper. PET + PE non-toxic paired thermoformed transparent film. Printing: non-toxic black ink for heat transfer printer.
Single / one piece per box	**Size:** box External colume: about 210 x 53 x 17 mm	Silk-screen printed cardboard box containing 1 blister and 1 instruction sheet
Shipment box : 110 pieces	**Size:** Cardboard box external size: 39 x 29 x 25 cm	Light brown Meta cardboard box containing 110 pieces.

Storage Conditions	The device does not need to be stored at temperature and humidity conditions different from the normal ones. The device must not be exposed to critical environmental conditions (direct sunlight, rain…)

Conditions for disposal	After use, dispose in special sanitary waste containers as prescribed

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	by the laws in force

Manipulation and Warnings	Before use, make sure that packaging is undamaged. The device is a single-use device. Nobody is allowed to sterilize or re-use a single-use device. The device must be use exclusively by specifically trained medical staff. The operator must always wear sterile gloves during device manipulation and take care not to cut the gloves with the sharp blade point. The Surgeon should first establish whether the patient is eligible for bone graft. The Surgeon should also adopt all the necessary precautions to prevent the risk of infections or complications associated to bone graft procedures. The device has no particular contraindications, provided that it is used according to these instructions. For the production of these devices no latex or natural rubber were used; the device is latex free and natural rubber free. PHATALES: DEHP, DOP, DINP, DIDP, DBP, DNBP, BBP, DNOP are not intentionally used in the manufacturing process(es) of the device. Meta declines all liability for damages resulting from improper use of this product.

Labelling	The information shown on package labels are those required by the Medical Device Directive 93/42/EEC. The symbols used and the package contents are compliant with UNI CEI EN ISO 15223-1

Information container in the labelling				
Type of information	**Symbol**	**Blister**	**Single box**	**Shipment box**
TRADE NAME		**X**	**X**	**X**
PRODUCT DESCRIPTION		**X**	**X**	
NUMBER OF PIECES	QTY		**X**	**X**
CE MARK AND NUMBER OF NOTIFIED BODY	CE 0123	**X**	**X**	**X**
CATALOGUE NUMBER	REF	**X**	**X**	**X**
DATE OF MANUFACTURE		**X**		
USE BY DATE		**X**	**X**	**X**
BATCH **CODE**	LOT	**X**	**X**	**X**
STERILIZED USING ETHYLENE OXIDE	STERILE EO	**X**	**X**	
SINGLE STERILE BARRIER SYSTEM		**X**		

Information container in the labelling				
Type of information	**Symbol**	**Blister**	**Single box**	**Shipment box**
SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING OUTSIDE			**X**	

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DO NOT RESTERILIZE	**X**	**X**	
DO NOT REUSE	**X**	**X**	
DO NOT USE IF PACKAGE IS DAMAGED	**X**	**X**	
CONSULT INSTRUCTIONS FOR USE	**X**	**X**	
CAUTION	**X**	**X**	
KEEP DRY	**X**	**X**	**X**
KEEP AWAY FROM SUNLIGHT	**X**	**X**	**X**
MANUFACTURER DATA	**X**	**X**	**X**
MEDICAL DEVICE, THE ITEM IS A MEDICAL DEVICE	**X**	**X**	**X**
UNIQUE DEVICE IDENTIFIER		**X**	

Rev.	Date	Amendments	Issued by: QC	Approved by: QA
10	24/09/2024	Updated reference codes with the co-branded ones, symbols and applicable standards	N. Osanna	A.Bastoni
09	22/06/2023	Updating labelling information	N. Osanna	F. Grassi
08	31/08/2022	Updated RDM	N. Osanna	F. Grassi
07	16/03/2022	Updating of manufacturer's name and symbol table	N. Osanna	F. Grassi
06	21/05/2021	Updated with Micross Curve	N. Osanna	R. Chendi (RQA)
05	14/09/2015	Update for inserting new logo and adaptation in labelling.	Nicoletta Osanna	Arianna Bastoni (RQA)
04	17/03/2014	Varied Materiali Lock ring	N. Osanna	A. Bastoni (RQA)
03	12/09/2013	Updated normative references	Nicoletta Osanna	A. Bastoni (RQA)
02	2011-19-5	Cap.4, Cap.5. Cap.7, Cap.11, Cap.13.	Nicoletta Osanna	Corrado S. Parmigiani (RQA)
01	2008-06-23	Cap.5, Cap.6. Cap.7, Cap.11, Cap.12.	Sandra Nasi	
00	Jan. 13th, 2004	Document issue	Cavani Fabio	Cavani Fabio (UT)

The information contained in this Product Technical Data Sheet is considered representative of Meta's knowledge at the date of issue and concerns only the specific product; it cannot be considered valid if the product is used for purposes and in ways other than those specified in the technical documentation.