META

PRODUCT DATA SHEET **SMARTACT *evo*** Membrane Tacks positioner				
Code	5450-120, 5450-150, 5450-200			
Color	//			
Type of supply	NON 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**
NO	IIa	NO	N.A	No
CND classification	Q010399			
RDM - Italian Repertory of Medical Devices	**2287371** (5450-120) **/ 2287432** (5450-150) **/2287435** (5450-200)			
General Features	SMARTACT *evo* is a pneumatic system enabling positioning of tacks to secure and stabilise a membrane as part of bone regeneration in oral surgery. It can be used to stabilise both resorbable and non-resorbable membranes. The SMARTACT *evo* system includes a pneumatic pedal to apply a force (adjustable depending on the type of use and linked to the type of bone) to insert the tacks instantly thus firmly securing the membrane to the bone. The extremely compact handpiece is designed with a tapered shape and curved tip so that even the most inaccessible areas of the mouth can be reached easily.			

System Quality Standards	EN ISO 13485

Production (UNI EN ISO 14644-1)	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	N.A. SMARTACT *evo* is supplied non-sterile. The device must be washed with appropriate germicidal detergents immediately after the surgical procedure, and some components (Ref. 5055-5440-5086-5456-5412) must be steam sterilized (always using validated sterilization cycles) before each use.

Composition	**Pcs**	**Code**	**Description**
SMARTACT evo *is manufactured using corrosion-proof materials free of toxic substances.*	1	5450	Central Handpiece Body
	1	5412	Upper Ring Nut
	1	5055	Curved Body
	1	5440	Inertial System
	1	5086	Head Ring Nut
	1	5460	Pedal
	1	5456	Inertial System Locking Wrench
	1	5470 5474 5475	Cable 1,2 m Cable 1,5 m Cable 2,0 m

Packaging		
Type	**Size**	**Materials**
Packaged with one piece.	**Size:** external volume about 32 x 28 x h5,5 cm	Printed cardboard box containing n°1 device and n° 1 instructions for use.

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 by the laws in force
Manipulation And Warnings	SMARTACT *evo* is supplied non-sterile. The device must be washed and some components must be steam sterilized before each use. The SMARTACT *evo* device must be used exclusively by skilled medical staff. The SMARTACT evo device must only be used with SMARTACT Pin evo tacks. The surgeon must assess the suitability of patients for bone regeneration and the appropriate surgical procedure. Never use SMARTACT evo without being sure that all its components have been assembled correctly (see instructions for use). Do not use the product if the package is damaged. Always wear sterile gloves when handling the SMARTACT *evo* device and strictly follow appropriate procedures in order to guarantee sterility. Discard after use in special medical waste containers in compliance with the regulations in force. Meta does not shoulder any responsibility for improper use of the product. For the production of this device (handpiece and cable for connection) is not used the latex or natural rubber; therefore, the handpiece and cable for connection are free of latex and natural rubber.

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 contained in the labelling		
Type of information	**Symbol**	**Blister**
TRADE NAME		**X**
PRODUCT DESCRIPTION		**X**
NUMBER OF PIECES		**X**
CE 0123 MARKING	CE 0123	**X**
CATALOGUE NUMBER	REF	**X**
DATE OF MANUFACTURE		**X**
BATCH NUMBER	LOT	**X**
ATTENTION: SEE INSTRUCTIONS FOR USE		**X**
NON STERILE		**X**
INSTRUCTIONS FOR USE		**X**
KEEP DRY		**X**
KEEP AWAY FROM SUNLIGHT		**X**
MANUFACTURER'S NAME/ADDRESS		**X**
MEDICAL DEVICE	MD	**X**

Rev.	Date	Amendments	Issued by: QC	Approved by: QA
02	31/08/2022	Updated RDM	N. Osanna	F. Grassi
01	16/03/2022	Updating of manufacturer's name and symbol table	N. Osanna	F. Grassi
00	09/03/21	Document issued	Nicoletta Osanna	Rita Chendi (RQA)

The information contained in this Product Data Sheet is believed to be representative of the knowledge gained from Meta at the date of the issue and concern only the specific product, cannot be considered valid if the product is used for purposes and in ways other than those specified in the technical documentation.