META

PRODUCT DATA SHEET

METAPIN

Membrane Tacks

METAPIN 5mm

Membrane Tacks for Soft Bone

Code	4720 / 5030
Color	//
Type of supply	Sterile
Manufacturer (in accordance to the law 93/42/CE)	C.G.M. S.p.A. DIVISIONE MEDICALE META 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	IIb	YES	EtO	YES

CND classification	P09120299
RDM - Italian Repertory of Medical Devices	**1560313** (Metapin) **/ 1560314** (Metapin 5mm)
General Features	The Metapin is a tack titanium fasteners membranes for bone regeneration in oral surgery. In the treatment of bone atrophy of the oral cavity the techniques of bone reconstruction involving the incision of the gingival tissues, the exposure of the bone defect, the insertion of bone substitute and its covering with the protective membrane. Such a membrane may be stabilized with the aid of nails. To complete a regenerative procedure of success is absolutely imperative to give stability to the membrane covering the bone graft, with the use of fastening systems such as Metapin . Our titanium bone tack, combined with the application system Metapin Holder, ensures the best performance in membrane stabilization procedures. The materials and the exclusive design allow: – Great positioning in any kind of a ridge – High resistance to bending and deformation – Precise and stable connection with the handpiece Metapin Holder.

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System Quality Standards	EN ISO 13485:2012	
Applicable Product Standards	ISO 5832-3	
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	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**
	1	Container	PP + GF Grey + PC white
	3	Tack	TITANIUM TI 6AL 4V- Eli GRADE 5

Packaging	Packaging has been appropriately validated in accordance with UNI EN ISO 11607-1 harmonised standard.	
Type	**Size**	**Materials**
Single-packaged blister with three pieces.	**Size:** external volume about 150x100 mm	White medical grid paper. PET + PE non-toxic paired thermoformed transparent film. Printing: non-toxic ink for printer clichè.
Single / one piece per box	**Size:** box External volume: about 160x 107 x 19 mm	Silk-screen printed cardboard box containing 1 blister and 1 instruction sheet

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

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Manipulation and Warnings	• Before use, check that the package is intact. • Do not use the product if the package is damaged. • The Metapin device must be used exclusively by skilled medical staff. • Always wear sterile gloves when handling the Metapin device end strictly follow the procedures in order to guarantee sterility. • The device is a single-use device and absolutely must not be resterilized. • Warning: if it is reused on another patient, there is a risk of cross-contamination and loss of the performance and functional characteristics of the device. • Discard after use in special medical waste containers in compliance with regulations in force. • Meta cannot be held responsible for improper use of the product. For the production of these devices no latex or natural rubber were used; the device is **latex free** and natural rubber free. The device is also **Phthalates Free**.

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

Type of information	Symbol	Blister	Single box
TRADE NAME		X	X
PRODUCT DESCRIPTION		X	X
NUMBER OF PIECES			X
CE 0123 MARKING	CE 0123	X	X
CATALOGUE NUMBER	REF	X	X
EXPIRY DATE		X	X
BATCH NUMBER	LOT	X	X
STERILISATION METHOD	STERILE EO	X	X
"SINGLE USE" WORNING		X	X
DO NOT USE IF PACKAGE IS DAMAGED		X	
ATTENTION: SEE INSTRUCTIONS FOR USE		X	X
INSTRUCTIONS FOR USE		X	X
KEEP DRY		X	X
KEEP AWAY FROM SUNLIGHT		X	X
MANUFACTURER'S NAME/ADDRESS		X	X

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00	25/052018	Document issued	Nicoletta Osanna	Arianna Bastoni
Rev.	Date	Amendments	Issued by: CQ	Approved by: 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, can not be considered valid if the product is used for purposes and in ways other than those specified in the technical documentation.