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INSTRUCTIONS FOR USE

MAGNACAP SYSTEM

PRODUCT DESCRIPTION:

The Technovent Magnacap System is a magnetic attachment system for implant retained craniofacial prostheses.

INTENDED USE:

The Magnacap System is intended for use in conjunction with an implant system as part of a retention system for securing craniofacial prostheses in the auricular, nasal and orbital areas where anatomical structures have been lost due to trauma (including burns), tumour surgery or congenital malformations.

INTENDED USERS:

The Magnacap System is intended for professional use only by surgeons and maxillofacial prosthetists who have experience and training in the use of implant systems. Proper procedures and techniques are the responsibility of the medical professional. They must evaluate the appropriateness of the procedure based on personal training and experience as applied to the patient at hand.

INTENDED PATIENT GROUP:

The Magnacap System intended to be used on patients who have received craniofacial implants to facilitate prosthetic rehabilitation for congenital malformation, tumour surgery or trauma of the craniofacial region.

INDICATIONS OF USE:

The Magnacap System is useable in most situations – see Intended Use (above) for conditions indicating the use of the device.

CONTRAINDICATIONS/LIMITATIONS OF USE:

Not for use on children or pregnant/nursing women or if the patient is undergoing, or will undergo, radio therapy necessitating the removal of the Magnacaps.

PRODUCT RANGE:

Product Code	Description	Product Code	Description
AMC1-S	Mini Magnacap Astra Uni Abutment S-Range	LAA1	Mini Lab Analogue Abutment
AMC2-S	Maxi Magnacap Astra Uni Abutment S-Range	LAA2	Maxi Lab Analogue Abutment
B-LAC1	Mini Magnacap - Lab Analogue - Vistafix Gen 2	LR1	Mini Locator Ring
B-LAC2	Maxi Magnacap - Lab Analogue - Vistafix Gen 2	LR2	Maxi Locator Ring
B-LAC2-OR	Lab Analogue Auricular Cap - Vistafix Gen 2	LR2LL	Maxi Long Lip Locator Ring
B-MC1-S	Mini Magnacap (Branemark) S-Range Vistafix Gen 2	MM0-S	Mini Micro Magnet S-Range
B-MC2-OR-S	Auricular Maxi Magnacap for Vistafix 2 S-Range	M0-S	Micro Magnet (PS) S-Range
B-MC2-S	Maxi Magnacap (Branemark) S-Range	M1-S	Mini Magnet (PS) S-Range
AH-MC1-S	Mini Magnacap AHEAD S-Range	M2-S	Midi Magnet (PS) S-Range
AH-MC2-S	Maxi Magnacap AHEAD S-Range	M3-S	Maxi Magnet Protected (PS) S-Range
AH-MC2-OR-S	Auricular Magnacap AHEAD S-Range	ML0-S	Micro Lip Magnet S-Range
B-MUMC1-S	Mini Multiunit Magnacap S-Range	ML1-S	Mini Lip Magnet S-Range
B-MUMC2-S	Maxi Multiunit Magnacap S-Range	ML2-S	Midi Lip Magnet S-Range
CF1	Mini Hand Capfit Tool	ML3-S	Maxi Lip Magnet S-Range

Product Code	Description	Product Code	Description
CF2	Maxi Hand Capfit Tool	MLL3-S	Maxi Long Lip Magnet S-Range
CF3	Mini Latch Capfit Tool	ML3-SR-S	Maxi Lip Silicone Retentive Magnet S-Range
CF4	Maxi Latch Capfit Tool	MLL3-SR-S	Maxi Long Lip Silicone Retentive Magnet S-Range
EV-AMC2-S	Maxi Magnacap Astra-EV S-Range	MLL2-OR-S	Auricular Midi Magnet S-Range
IK1-S	Mini Insert Keeper S Range	MLL3-OR-S	Maxi O-Ring Magnet S-Range
IK2-S	Maxi Insert Keeper S Range	AMC1	Mini Magnacap Astra Uni Abutment
IT-MC2-S	Maxi Magnacap Southern Implants IT S-Range	AMC2	Mini Magnacap Astra Uni Abutment
IT-MC2	Maxi Magnacap Southern Implants IT	B-MC2	Maxi Magnacap (Branemark) For Vistafix 2
MPMA	Multipurpose Lab Analogue	IK1	Mini Insert Keeper
MPMS	Multipurpose Magnet	IK2	Maxi Insert Keeper
MPMS-NL	Multipurpose magnet (Non Lip)	MM0	Mini Micro Magnet (PS)
MT1	Mini Transfer Magnet	M0	Micro Magnet (PS)
MT2	Maxi Transfer Magnet	ML0	Micro Lip Magnet
O/RB	O rings for MLL3 Red pack size 10	M1	Mini Magnet (PS)
O1B	O rings Black pack size 10	ML1	Mini Lip Magnet
AUR-01	O Rings for Auricular Magnet	M2	Midi Magnet (PS)
P-MC1-S	Mini Magnacap for Medicon Basic Post S-Range	ML2	Midi Lip Magnet
P-MC2-S	Maxi Magnacap for Medicon Basic Post S-Range	M3	Maxi Magnet (PS)
S-MC2-S	Maxi Magnacap Straumann S-Range	ML3	Maxi Lip Magnet
ST0	Seating Tool	ML3-SR	Maxi Lip Silicone Retentive Magnet
VF-LAC1	Mini Lab Analogue Cap - Vistafix Gen 3	MLL3	Maxi Long Lip Magnet
VF-LAC2	Maxi Lab Analogue Cap - Vistafix Gen 3	MLL3-OR	Maxi O-Ring Magnet
VF-LAC2-OR	Lab Analogue Auricular Cap - Vistafix Gen 3	MLL3-SR	Maxi Long Lip Silicone Retentive Magnet
VF-MC1-S	Mini Magnacap for Vistafix 3 S-Range	S-MC2	Maxi Magnacap Straumann
VF-MC2-OR-S	Auricular Maxi Magnacap for Vistafix 3 S-Range	VF-MC2	Maxi Magnacap for Vistafix 3
VF-MC2-S	Maxi Magnacap for Vistafix 3 S-Range	P-MC1	Mini Magnacap for Medicon Basic Post
JB-AFK-1	Mini Impression Magnet	P-MC2	Maxi Magnacap for Medicon Basic Post
JB-AFK-2	Maxi Impression Magnet	*PL-MC2-1.6	Maxi Magnacap for Medicon Plate 1.6mm
JB-AFK2-OR	Auricular Impression Magnet		

DEVICE COMPATIBILITY:

Components of the Magnacap System are available in a range of fitting variants for use with different third-party implant abutment systems. It is the responsibility of the clinician/technician to ensure that the components are compatible with the implant abutments and that the correct fitting tool is used (see below). It is recommended that the Magnacaps are tightened to a torque of 10 Ncm in order to avoid excessive rotational forces being applied to the implant or implant abutment. They are available in two diameter sizes - Mini and Maxi - for each implant system.

Magnacap	Hand Tool	Handpiece Tool
Mini Magnacap	Mini Hand Capfit Tool, CF1	Mini Latch Capfit Tool, CF3
Maxi magnacap/Auricular magnacap	Maxi Hand Capfit Tool, CF2	Maxi Latch Capfit Tool, CF4

When paired with the corresponding Prosthesis Magnet, they provide the following retentive forces (in N):

	Prosthesis Magnet					
	Mini Micro	Micro	Mini	Midi	Maxi	Paired
Mini Magnacap	3.8	4.2	6.5	-	-	MPMS/MPMS NL
Maxi Magnacap	-	-	-	10.5	11.5	6.5

APPLICATION INSTRUCTIONS:

For full details refer to Technovent User Guides at www.Technovent.com

Magnacaps and Keepers fitted to Implant Abutments

Place the magnacap/keeper into a matching size Hand/Latch Capfit Tool so that the tool markers coincide with the flats on the keeper. Screw the magnacap into the implant abutment, in a clockwise direction until flush and firmly seated using 10 Ncm tightening torque. Do not cement the keeper.

*The maxi magnacap for Medicon Plate (PL-MC2-1.6) is ONLY to be used on spanned plates away from the fixation site with no contact with skin or mucosa. For other sites use mini or maxi magnacap for Medicon Basic Post (P-MC1/P-MC2) in conjunction with Medicon Basic Post abutment.

STORAGE:

The components of the Magnacap System are supplied non-sterile and individually packaged for single patient use. It is recommended that they be stored and transported in their original packaging, at ambient temperature (between 15 and 30 degrees Celsius) and out of direct sunlight. Do not use if the packaging is open or has been damaged and do not use after the labelled expiry date. (See below for a list of the applicable harmonized symbols as used on the product labelling which indicate these statements)

PRECAUTIONS / RESIDUAL RISKS / SIDE EFFECTS:

- For single patient use only - reuse of the device may result in a risk of cross-contamination.
- Ensure care is taken to use the correct product variant suitable for the implant system to be connected to. The item code and name clearly indicate which implant system that variant is to be used with. Incorrect pairing may result in damage to the item or the implant and/or implant abutment.
- Ensure care is taken when introducing the Magnacap into the implant abutment that the threads engage cleanly and correctly - do not cross-thread the component - force should not be needed to screw the component down onto the implant. If force is required, it is an indication that the threads are crossed. Damage may be caused to the implant abutment and the Magnacap if the threads are crossed.
- Do not apply more than the recommended torque to the Magnacap (10Ncm) as this may result in excessive rotational force/torque being applied to the implant abutment which could lead to implant failure.
- When an MRI scan is being performed, it is recommended that the prosthesis with magnetic components and the Magnacap be removed by the maxillofacial technician prior to the MRI scan in order to avoid artifacts in the image. The Magnacap can be refitted to the same patient after MRI. A label is provided for the clinician to retain with the patient records to indicate the use of Magnacaps and to indicate the requirement to remove prior to MRI scanning.
- Only use pH neutral soaps/cleansers to clean prosthesis/skin - avoid using aggressive chloride-based and antibacterial cleaning solutions which may cause tarnish or pitting corrosion.
- These products contain stainless steel which has a Nickel content of less than 3%. Though the company has not received any adverse reports of contact sensitivity, it is advised that there may be a minimal chance of reaction in those patients who are highly contact-sensitive to Nickel.
- There is a residual risk of soft tissue irritation with the use of all osseointegrated implant retained prostheses. This should be monitored for and patients advised by their clinician as to appropriate hygiene and maintenance practices.

DISPOSAL:

Disposal of the device should follow local regulations and environmental requirements taking different contamination levels into account.

HARMONISED SYMBOLS:



Consult Instructions for Use



Lot Number



Manufacturer



Product Code/Ref



Manufacturing Date



Do Not Store in Direct Sunlight



Expiry Date



Do Not Use if Packaging is Open/Damaged



Single Use Only



Single Patient Only



Store Between 15-30 Degrees Celsius

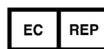


MR Unsafe

Magnetic Resonance Imaging – Unsafe



Medical Device



Authorised Representative
in the European Community