MAGEC® SPINAL BRACING AND DISTRACTION SYSTEM: ROD TEMPLATE INSTRUCTIONS FOR USE

Product Description:

The NuVasive Specialized Orthopedics **MAGEC Spinal Bracing and Distraction System: Rod Template** is an optional, sterile, single-use spinal rod template that may be used during intraoperative planning of a surgical procedure where a spinal rod will be implanted to brace the spine, of a pediatric patient, during growth.

Intended Use:

The MAGEC Rod Template is intended to be used intraoperatively to identify the proper length and morphology of an implant prior to implanting a MAGEC system rod. The MAGEC Spinal Bracing and Distraction System implantable rods come in various sizes and configurations. The template serves as an optional guide, aiding surgeons in the decision making process of implant selection and during surgical planning.

Warnings:

- The MAGEC Rod Templates are supplied sterile and are for single-use only. The template has not been tested to be cleaned or sterilized for multiple uses. If the template is used more than once, the device may not be sterile and could cause a serious infection. Do not resterilize the device.
- Do not use the rod template if the sterile pouch has been damaged or is open.

Table 1: Model Numbers and Description

	Model Number	Description
Sterile, Single-Use Rod Templates	MR2-4070T	4.0 mm MAGEC Rod Template with 70 mm Actuator
	MR2-4090T	4.0 mm MAGEC Rod Template with 90 mm Actuator

Template Procedure:

For optimum results careful pre-operative diagnosis and planning, meticulous intraoperative planning and extended postoperative care by experienced spinal surgeons are essential. Prior to use, the surgeon should be specifically trained in the use of the NuVasive Specialized Orthopedics MAGEC® Spinal Bracing and Distraction System, to ultimately facilitate correct selection and placement of final implanted rods.

General Procedure for MAGEC Rod Template for use with MAGEC Spinal Bracing and Distraction System Implants:

1. Determine desired anchor sites and determine desired foundation constructs for proximal and distal fixation. It is recommended that proximal foundation utilize multiple screws or hooks. For example: claw construct, bilateral construct with cross connector.
2. Make two short incisions, one at the level of each foundation site. If two short incisions are not possible a single long incision may be used. Incisions are preferably made on either side of the expected location of the MAGEC implanted rod.
3. Expose spine at each anchor site.
4. Create foundation to spine at each anchor site.
5. Choose MAGEC rod template with actuator length similar to that of desired MAGEC implant.
6. The MAGEC rod template may be bent, contoured and cut in the gold regions to simulate the regions on the MAGEC implanted rods that can be similarly bent, contoured and cut.
7. The MAGEC rod template may be tunneled subcutaneously between each anchor site.
8. Use the MAGEC rod template to determine the proper MAGEC implant size and configuration best suitable to the patient.
9. Refer to the Instructions for Use for the **MAGEC Spinal Bracing and Distraction System** for complete implantation procedures and instructions for the implantable spinal rod.

MAGEC ROD TEMPLATES

MS2-4090T

MS2-4070T

Symbols Definition:

Symbol	Definition
	Unsafe in Magnetic Resonance Imaging (MRI) Environments
	The MAGEC Rod Template is for Single-Use Only, Do not re-use
	Do not use if package is damaged or sterile barrier is broken
	Do not attempt to re-sterilize the MAGEC Rod Template
	Non-Sterile
 **Rx Only/**	Federal (US) law restricts the sale of this device for use by or on the order of a physician.
	Manufactured By
	Manufactured Date
	Model Number
	Lot Number
 www.globusmedical.com/eifu/	Refer to Instructions For Use www.globusmedical.com/eifu/
	Expiration Date
	Sterilized using irradiation
	Authorized European Representative
	This product has met European Union health, safety, and environmental requirements, which ensure consumer and workplace

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This product, and the use thereof, may be covered by one or more of the following U.S. and/or international patents: US 7,981,025, US 8,057,472, US 8,197,490, US 8,343,192, US 8,382,756, US 8,419,734, US 8,449,543, US 8,734,488, US 8,808,163, CN 101917918, EP 2,114,258. Other US and international patents pending. This product is licensed to the customer for single use only. Any resterilization or subsequent re-use is an unlicensed use and therefore constitutes patent infringement.

℞ Prescription only