Patient Information Leaflet

MRI Safety Information

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Fastlok™

Product(s)	Description
102-1380	6 mm x 23 mm **Fastlok™**
102-1381	8 mm x 23 mm **Fastlok™**

MRI Safety Information



The **Fastlok™ (Buckle and Staple)** is MR Conditional. A patient with Fastlok™ (Buckle and Staple) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

MR Conditional

Parameter	*Condition*
Nominal Values of Static Magnetic Field (T)	1.5-T or 3.0-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000 gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

Infinity-Lock™ Button System

Product(s)	Description
102-1089	**Infinity-Lock™** Button System

MRI Safety Information



The **Infinity-Lock™ Button System** is MR Conditional. A patient with the Infinity-Lock™ Button System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

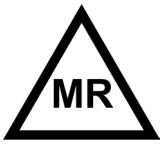
MR Conditional

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MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

Sekure-Lock™

Product(s)	Description
102-1377	**Sekure-Lock™**

MRI Safety Information



The **Sekure-Lock™** is MR Conditional. A patient with the Sekure-Lock™ may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

MR Conditional

Parameter	***Condition***
Nominal Values of Static Magnetic Field (T)	1.5-T or 3.0-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000 gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

Sekure-Loop™

Product(s)	Description
102-4010	**Sekure-Loop™** 10 mm
102-4015	**Sekure-Loop™** 15 mm
102-4020	**Sekure-Loop™** 20 mm
102-4025	**Sekure-Loop™** 25 mm
102-4030	**Sekure-Loop™** 30 mm
102-4035	**Sekure-Loop™** 35 mm
102-4040	**Sekure-Loop™** 40 mm
102-4045	**Sekure-Loop™** 45 mm
102-4050	**Sekure-Loop™** 50 mm
102-4055	**Sekure-Loop™** 55 mm
102-4060	**Sekure-Loop™** 60 mm

MRI Safety Information



The **Sekure-Loop™** is MR Conditional. A patient with the Sekure-Loop™ may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

MR Conditional

Parameter	***Condition***
Nominal Values of Static Magnetic Field (T)	1.5-T or 3.0-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000 gauss/cm)
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MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

Poly-Tape™

Product(s)	Description
102-1005	**Poly-Tape™** 5 mm x 500 mm
102-1086	**Poly-Tape™** 5 mm x 800 mm
102-1087	**Poly-Tape™** 7 mm x 800 mm
102-1080	**Poly-Tape™** 10 mm x 800 mm
102-1081	**Poly-Tape™** 15 mm x 800 mm
102-1082	**Poly-Tape™** 20 mm x 800 mm
102-1083	**Poly-Tape™** 30 mm x 800 mm
MWEB5040	**FORCEWEB™** 5 mm x 500 mm

Infinity-Lock™ Tape

Product(s)	Description
102-1100	**Infinity-Lock™** 3
102-1101	**Infinity-Lock™** 5
102-1102	**Infinity-Lock™** 7

FORCECORD™ Implant

Product(s)	Description
MWEB5580	**FORCECORD™ Implant**

Pitch-Patch™

Product(s)	Description
102-1090	**Pitch-Patch™** Tissue reinforcement 30 mm x 20 mm
102-1091	**Pitch-Patch™** Tissue reinforcement 35 mm x 25 mm

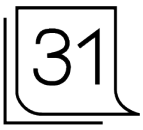
MRI Safety Information

MR

The **Poly-Tape™**, **FORCEWEB™, Infinity-Lock™** Tape, **FORCECORD™ Implant** and **Pitch-Patch™** are MR safe (i.e. items that pose no known hazards) in all MR environments.

Please note, If a MR safe device is supplied or used with a MR conditional device, the MR status of the MR conditional device is to be followed to safely scan the patient.

Symbols Glossary

Symbol	Title	Explanatory Text	Standard / Regulation	Reference Number
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1: Medical devices - symbols to be used with information to be supplied by the manufacturer. Part 1: General Requirements	5.1.1
	Use-by date	Indicates the date after which the medical device is not to be used		5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified		5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified		5.1.6
	Patient identification	Indicates the identification data of the patient		5.7.3
	Patient information website	Indicates a website where a patient can obtain additional information on the medical product		5.7.4
	Health care center or doctor	Indicates the address of the health care center or doctor where medical information about the patient may be found		5.7.5
	Date	Indicates the date that information was entered or a medical procedure took place		5.7.6
	Medical device	Indicates the item is a medical device		5.7.7
	Unique device identifier	Indicates a carrier that contains unique device identifier information		5.7.10

	MR Safe	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic	ASTM 2503: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Table 2
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields		Table 2

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