Instructions for use of EMERYGLIDE™ MR Guidewire

English

INSTRUCTIONS FOR USE

Carefully read the following warnings, precautions and directions prior to use. Failure to do so may result in improper use of this device which could cause the following complications:

- Shearing of the MR Guidewire
- Release of fragments of the MR Guidewire
- Vessel trauma

DESCRIPTION

The EMERYGLIDE™ MR Guidewire is a sterile, disposable MR Guidewire for the introduction and/or placement of diagnostic or interventional devices. The EMERYGLIDE™ MR Guidewire is constructed from a high strength core composite of glass fibers and polymers, protected by a high-strength aramid fiber mantle and covered with a PTFE extrusion. The distal tip of the EMERYGLIDE™ MR Guidewire is marked with discrete ring markers for MRI and X-Ray visibility and comes in different configurations such as straight and angled. MR Guidewires are supplied sterile and non-pyrogenic. The EMERYGLIDE™ MR Guidewire's diameter is 0.035" (0.89 mm).

INDICATIONS FOR USE

The EMERYGLIDE™ MR Guidewire is intended to direct a catheter to the desired anatomical location in the vasculatory system during diagnostic or interventional procedures.

CONTRAINDICATIONS

The EMERYGLIDE™ MR Guidewire is not intended for coronary or cerebral vasculature.

COMPLICATIONS

Complications that may be related to the use of EMERYGLIDE™ MR Guidewire can include but may not be limited to the following:

Thrombus	Emboli
Arterial or venous wall damage	Plaque dislodgement
Hematoma at the puncture site	Infection
Perforation	Vessel spasm
Hemorrhage	Vascular thrombosis
Allergic reaction	Arrhythmia's

Carefully read the list of complications in the instruction for use accompanying the other interventional devices to be used with EMERYGLIDE™ MR Guidewire.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated the EMERYGLIDE™ MR Guidewire is MR Conditional.
A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3.0 T
- Maximum spatial field gradient of 3600 Gauss/cm (36.0 T/m) for 1.5 T systems
- Maximum spatial field gradient of 1800 Gauss/cm (18.0 T/m) for 3.0 T systems
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Operating Mode at 1.5 T)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Operating Mode at 3.0 T)

Under the scan conditions defined above, EMERYGLIDE™ MR Guidewire is expected to produce a maximum temperature rise of less than 0.6 °C after 15 minutes continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from the EMERYGLIDE™ MR Guidewire when imaged with a gradient echo pulse sequence and a 3 T MRI system.

MRI CONSPICUITY

The tip section of EMERYGLIDE™ MR Guidewire is equipped with passive MRI markers.

- Straight tip 4 cm: markers are located at 0, 2, 4 cm from the distal end.
- Angled tip 4 cm: markers are located at 0, 2, 4 cm from the distal end.

The MRI markers are visualized by the routine gradient or spin echo MRI sequences and will appear on the screen as black voids as is shown below as representative picture.

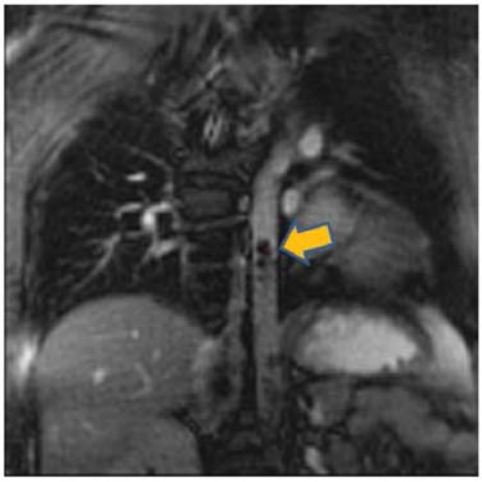

Figure 1. EMERYGLIDE™ MR Guidewire in descending aorta to illustrate the conspicuity and position of the markers. MRI image taken with 1.5 Tesla Avanto (Siemens) using gradient echo real-time scanning (CINE).

WARNINGS

The EMERYGLIDE™ MR Guidewire is a Prescription Use device (Part 21 CFR 801 Subpart D). The device is not for Over-The-Counter Use (Part 21 CFR 801 Subpart C).

- Failure to abide the following warnings might result in damage to the blood vessel and the heart, shearing of the EMERYGLIDE™ MR Guidewire and release of plastic fragments from the EMERYGLIDE™ MR Guidewire. Such pieces or fragments from the wire may have to be removed from the vessel. If not used correctly MR Guidewires can lead to vessel l and heart wall perforation. The damages caused by the perforation may always serious and might lead to death of the patient. According to published literature vessel and heart wall perforation often occurs due to kinking of the wire. During the use of the EMERYGLIDE™ MR Guidewire, cautious handling during insertion is mandatory, in order to avoid a kinking of the wire. An insertion guide has to be used.
- Further literature sources refer to risks occurring due to over insertion of the EMERYGLIDE™ MR Guidewire, which also can lead to serious damage likewise traumatization and/or perforation of the treated vessel.
- Do not attempt to use the EMERYGLIDE™ MR Guidewire if it has been bent, kinked, damaged or cut! Use of a damaged MR Guidewire may result in damage to the vessel or release of wire fragments into the vessel.
- Do not manipulate or withdraw the EMERYGLIDE™ MR Guidewire through a metal entry or needle or a metal dilator! Manipulation and/or withdrawal through a metal entry needle or a metal dilator may result in destruction and/or separation of the PTFE extrusion, requiring retrieval. A plastic entry needle is recommended when using this wire for initial placement. In case a MR Safe (plastic) or MR Conditional needle is not available, access should be obtained outside of the MR environment. We recommend individual inquiry from the manufacturer of such needles to confirm if they are safe for MRI usage.
- Do not use the EMERYGLIDE™ MR Guidewire with devices which contain metal parts such as atherectomy catheters, laser catheters, or metal introduction devices as they may cause the EMERYGLIDE™ MR Guidewire outer extrusion to shear and thus damage the wire!
- **Do not use in combination with a metal torque device** Use of a metal torque device may result in damage of EMERYGLIDE™ MR Guidewire.
- **Do not reshape or cut the EMERYGLIDE™ MR Guidewire by any means**. Attempting to reshape the wire may cause damage, resulting in release of wire fragments into the vessel!
- **Do not push the MR Guidewire by the soft tip back into the dispenser!** This may cause kinking of the tip.
- Do not push a tightened up torque device or Y-connector over the wire as it may result in damage to the wire!

- When exchanging or withdrawing a catheter over the EMERYGLIDE™ MR Guidewire, secure and maintain the MR Guidewire in place under MRI to avoid unexpected MR Guidewire advancement; otherwise damage to the vessel wall by the wire's tip may occur.
- Certain cases of entrapped or breakdown MR Guidewires are reported as well as a possible technique to retrieve the entrapped or broken parts. The user should have knowledge in such techniques (*e.g.* usage of a snare device) in order to prevent serious consequences related to such events. A retrieval procedure can only be initiated outside the MR environment once the patient is transferred to the angiographic suite and after the wire has been removed from the patient's vessel.
- Manipulate the EMERYGLIDE™ MR Guidewire slowly and carefully in the vessel while confirming the behavior and location of the wire's tip under MRI/X-ray. Improper manipulations of the EMERYGLIDE™ MR Guidewire without the appropriate imaging technique confirmation my result in vessel perforation.
- **Do not use EMERYGLIDE™ MR Guidewire in MR-Fields greater than 3.0 Tesla!**
- **Do not apply repetitive bending force to one specific point of the device as this may cause damage to the EMERYGLIDE™ MR Guidewire!**
- If any resistance is felt or if the tip's behavior and/or location seems improper, stop manipulating the EMERYGLIDE™ MR Guidewire and/or the catheter, and determine the cause by the appropriate imaging technique. Continuing to manipulate or rotate the EMERYGLIDE™ MR Guidewire or failure to exercise proper caution may result in bending, kinking, and separation of the MR Guidewire's tip, damage to the catheter, or damage to the vessel.
- **Beware of an initial low torqueability!**
- Consider the use of systemic heparinization to prevent or reduce the possibility of thrombus formation on the surface of the EMERYGLIDE™ MR Guidewire.
- Loss of MR Guidewire due to extreme insertion. Never insert the entire wire through *e.g*. an introducer needle into patient's body. Keep always enough length outside in order to manipulate and steer the wire in a safe manner.
- The EMERYGLIDE™ MR Guidewire may be used with non-braided catheters as well as devices that have no metal or conductive parts in it. However, the risk of use of these catheters is solely the responsibility of the user. We recommend individual inquiry from the manufacturer of such catheters to confirm if they are safe for MRI usage (MR Conditional or MR Safe).
- **EMERYGLIDE™ MR Guidewire is intended for patients with a body weight of ≥40kg and/or with secondary devices of ≥5F.**

PRECAUTIONS

- The combination ability between the EMERYGLIDE™ MR Guidewire and interventional medical device or drug must be verified before the use.
- The EMERYGLIDE™ MR Guidewire should be used by a physician, who is well trained in manipulation and observations of MR Guidewires under proper imaging technique.
- The EMERYGLIDE™ MR Guidewire is provided sterile in an unopened and undamaged package unit. Do not use the product if the package unit or the EMERYGLIDE™ MR Guidewire is broken or soiled. The EMERYGLIDE™ MR Guidewire should be used immediately after opening the package and be disposed of safely and properly after use, following local regulations for medical waste management.
- When using a drug or a device concurrently with the EMERYGLIDE™ MR Guidewire, the operator should have full understanding of the properties/characteristics of the drug or device, so as to avoid damage to the EMERYGLIDE™ MR Guidewire. For example when using the EMERYGLIDE™ MR Guidewire, with a device that emits energy (laser, pressure, ultrasound, *etc.*) confirm, that the EMERYGLIDE™ MR Guidewire is retracted into a position where it not will be impacted by the energy.
- The surface of the EMERYGLIDE™ MR Guidewire has improved gliding properties if wetted. Prior to taking the EMERYGLIDE™ MR Guidewire out of the dispenser, fill the dispenser with heparinized physiological saline solution.
- Due to the possible damaging of the PTFE outer extrusion and/or shearing of the EMERYGLIDE™ MR Guidewire, the withdrawing of the MR Guidewire back through a metal needle must be avoided. The insertion needle should be replaced as soon as possible after the insertion of the EMERYGLIDE™ MR Guidewire into the vessel by a catheter, introducer sheath or vessel dilator.
- When reinserting the EMERYGLIDE™ MR Guidewire back into the dispenser take care not to damage the wire's PTFE outer extrusion with the edge of the dispenser.
- Due to the low friction of the EMERYGLIDE™ MR Guidewire's PTFE outer extrusion, the operator may encounter some difficulties in handling the wire. A torque device, sold separately, is recommended for easier handling/manipulation of the wire.
- Due to variations of certain catheters tip inner diameters, abrasion of the PTFE outer extrusion may occur during manipulation. If any resistance is felt during the introduction of the catheter over the MR Guidewire, it is advisable to stop using such catheters.
- Do not manipulate the EMERYGLIDE™ MR Guidewire through a tightened up rotating hemostasis valve, as this may result in damage to the wire!
- After removal from the patient's vessel, and prior to reinserting it into the same patient during the same catheterization, the EMERYGLIDE™ MR Guidewire should be rinsed in a bowl full of heparinized physiological saline solution. Any blood residues still adhering to

the wire can be removed by wiping once with a gauze moistened with heparinized physiological saline solution. Use of alcohol, antiseptic solvents must be avoided, because they may adversely affect the surface of the EMERYGLIDE™ MR Guidewire.

- The entire operation should be carried out aseptically.
- The EMERYGLIDE™ MR Guidewire has been sterilized by ethylene oxide gas. For single use only. Do not reuse! Do not resterilize! Do not reprocess! Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
- Avoid exposure to water, direct sunlight, extreme temperatures and high humidity during storage. Store under controlled room temperature.
- Please treat this product and its application with reasonable care since interventional diagnostics under MRI is fairly new due to missing instruments in the past. Help us to improve product and process thus informing us in case of any unforeseen or unusual events while using the EMERYGLIDE™ MR Guidewire.

DIRECTIONS FOR USE

1. Remove the EMERYGLIDE™ MR Guidewire and the dispenser together from the package.
2. Fill the dispenser with heparinized physiological saline solution through the hub of the dispenser using a syringe.
3. Remove the EMERYGLIDE™ MR Guidewire from the dispenser and inspect the EMERYGLIDE™ MR Guidewire prior to use, to verify that it is lubricated. If the EMERYGLIDE™ MR Guidewire cannot easily be removed from the dispenser, inject more heparinized physiological saline solution into the dispenser and try again.
4. Prior to use, prime the catheter with heparinized physiological saline solution to ensure smooth movement of the EMERYGLIDE™ MR Guidewire within it.
5. The EMERYGLIDE™ MR Guidewire may slide entirely into the catheter because of its low friction.
6. Keep at least 5 cm of the wire extended out of the hub of the catheter during introduction.

ANNOTATIONS

Symbols used on the labeling of these devices have the following meaning

Symbol	Denotation
	Consult Instructions For Use
	EMERYGLIDE™ MR Guidewire diameter
	Total length
	EMERYGLIDE™ MR Guidewire straight
	EMERYGLIDE™ MR Guidewire angled
	Catalogue number
	Do not use with a metal entry needle
	Manufacturer
	Date of manufacture
	Use by date[1]
	Batch code
	Sterilized using ethylene oxide
	Keep dry
	Keep away from sunlight
	Do not use if package is damaged
	Do not re-use
	Do not resterilize
	Caution
	Non-pyrogenic
	Latex free
	Diethylhexylphthalate (DEHP) free
Rx only	Caution: Federal law restricts this device to sale by or on the order of a (licensed) health practitioner.
	MR conditional 1.5 T or 3.0 T

[1] The symbol is accompanied by a date to indicate that the device may not be used after the end of the year, month or day shown

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