



CLEARPOINT®
NEURO

SF M6 BOLT DRIVER
INSTRUCTIONS FOR USE

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I. Intended Use

The T-handle and Driver are used to insert a surgical bolt into bone in an MR environment up to 3T field strength, or in a general surgical procedure room.

Warning: This device is intended for single use only. Contents of unopened, undamaged package are sterile. Do not re-sterilize.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

II. Device Description

Package Contents:

NGS-BD-M6: SF M6 Bolt Driver
1 M6 Bolt Driver

Associated Devices:

NGS-HX-M6: MR Hex Key
1 Hex Key

III. General Warnings and Precautions

The device is intended for single–use-only and is provided sterile. Do not re-sterilize.

General Precautions

- Handle all components using standard hospital sterile practices.

1.5T & 3T Environment Compatibility:

The SF M6 Bolt Driver is MRI Safe. It contains no metallic components. It is made entirely out of plastic.

The MR Hex Key is made completely of Titanium. It is MR Conditional in a static magnetic field of 1.5 Tesla or 3.0 Tesla, and a spatial gradient field, Bz, of 389 Gauss/cm.

IV. Use Instructions

A. Preparation

The SF M6 Bolt Driver is packaged with a double sterile barrier; a sealed Tyvek/mylar pouch is placed inside a larger sealed mylar/Tyvek pouch. The shelf box contains one (1) double pouched Handle and Driver.

Warning: Do not use the SF M6 Bolt Driver if the packaging is damaged.

Use aseptic transfer if the Bolt Driver is intended to be used in the sterile field.

B. Using the SF M6 Bolt Driver

1. The SF M6 Bolt Driver comes in two parts: the Handle and the Driver.

2. Insert the Oval shaped end of the Driver into the mating slot on the Handle in the axial configuration as shown in **Figure 1**.

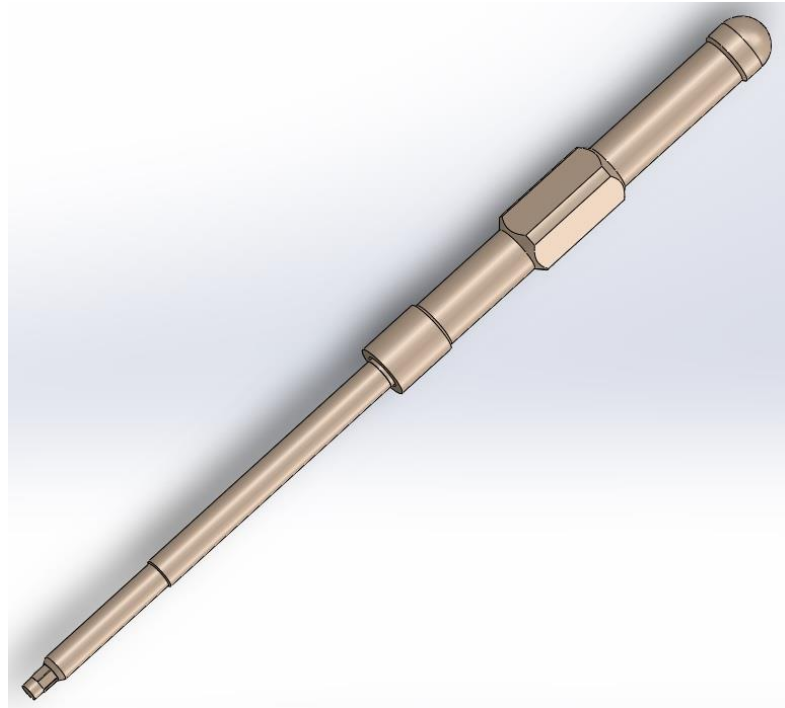


Figure 1 - M6 Driver in the Axial Configuration

3. Attach the desired surgical bolt to the Hex end of the Driver as shown in **Figure 2**.

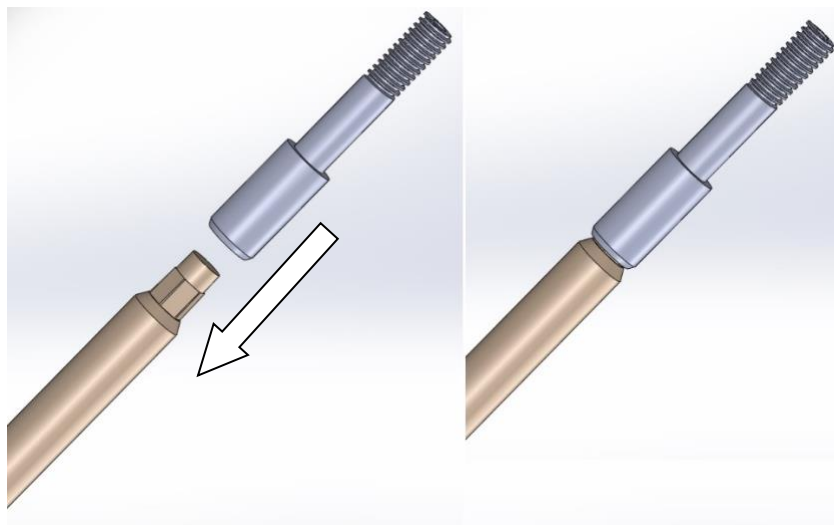


Figure 2 - Bolt attached to the Driver's hex end

4. The Driver will retain a bolt with 5-mm hex width without support. However, prior to placing the Bolt, perform a check to make sure the Bolt is retained by holding the Driver and Bolt over a sterile surface that can catch the Bolt and maintain the Bolt's sterility if it falls.

5. Place the Bolt into the desired hole and turn the Driver to begin securing the Bolt.
Note: Follow the Bolt manufacturer’s recommendation for the hole size. Make sure the Bolt is being inserted into a properly sized hole.
Note: Follow the Bolt manufacturer’s recommendations for securing the Bolt.
6. If securing the Bolt requires more torque than can be achieved in the Axial configuration, then remove the Handle from the Driver by gently pulling on it.
7. Orient the Handle in an orthogonal direction to the Driver, and insert the Driver’s Oval feature into the mating slot in the Handle. The T-handle configuration is shown in Figure 3.

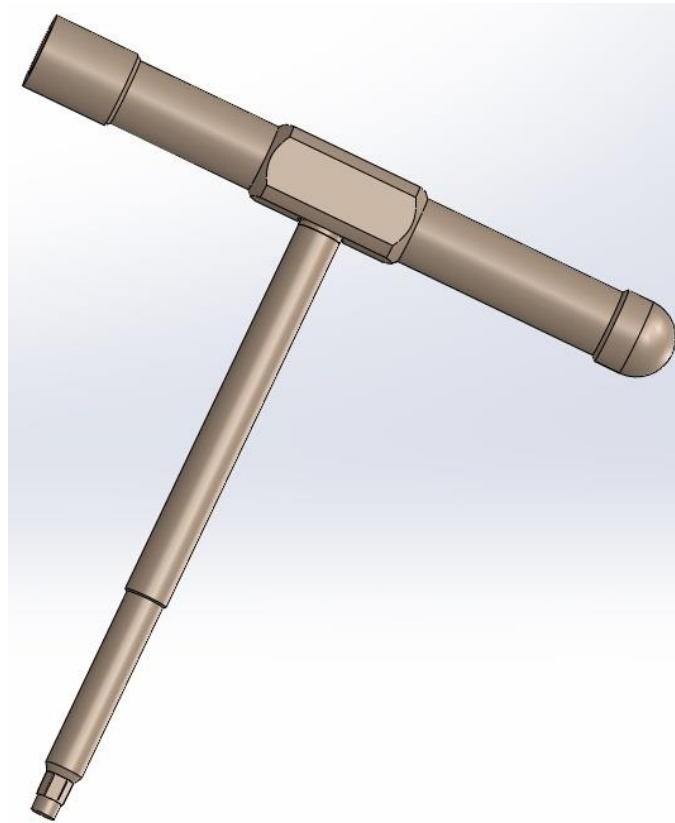


Figure 3 - Handle and Driver in the “T” configuration

8. Continue securing the Bolt per the Bolt manufacturer’s recommendations.
9. When the Bolt is secure, remove the Handle from the Driver by gently pulling on it.
10. Remove the Driver from the Bolt by gently pulling on it.
11. If the Driver is difficult to disengage from the Bolt, reattach the Handle to the Driver and gently wiggle the Driver while rotating it counter-clockwise a very small amount. Pull on the Driver to disengage it from the Bolt.
12. To remove the Bolt, place the Driver hex end into the Bolt until it is fully seated.
13. Attach the Handle to the Driver in the T-configuration.
14. Turn the Handle counter-clockwise until the Bolt is fully removed.

15. If the Bolt cannot be removed with the Driver, then use the MR Hex Key (NGS-HX-M6) to remove the Bolt as shown in Figure 4.

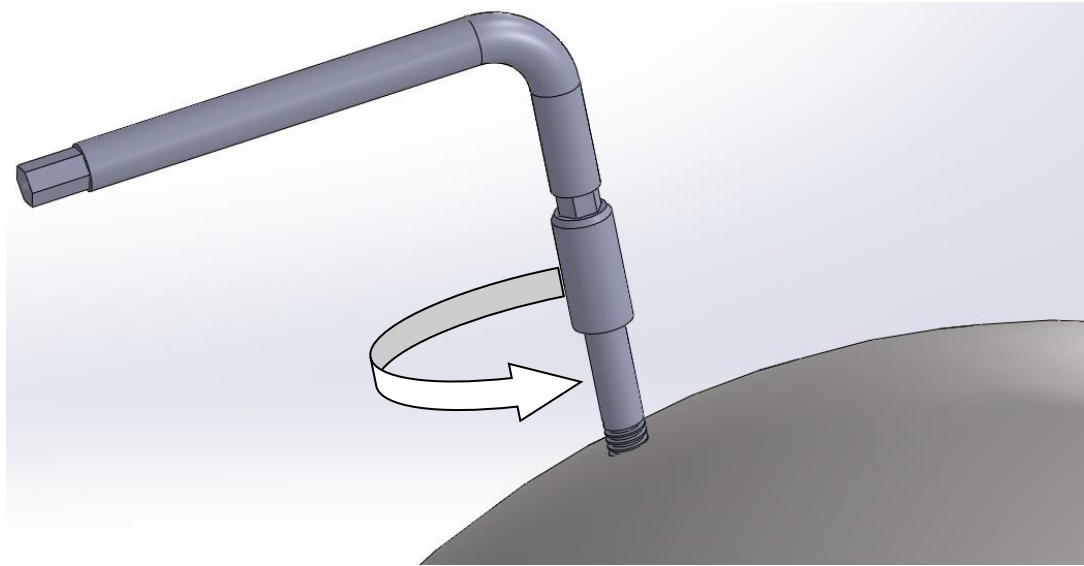


Figure 4 - Using the Hex Key to remove a Bolt

C. Storage and Technical Specifications













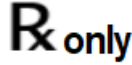


Storage

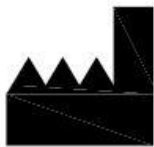
- Store in a cool dry place

Technical Specifications

	Driver Outer Diameter (in/mm)	Hex Width (in/mm)	Mass (g)	Maximum Securing Torque (in-lbf / N-m)
Handle and Driver	.36 / 9.0	.20 / 5.2	40	25 / 2.8

	Outer Diameter (in/mm)	Hex Width (in/mm)	Mass (g)	Maximum Securing Torque (in-lbf / N-m)
MR II Hex Key	.26 / 9.0	.20 / 5.2	14	70 / 8.0

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Consult instructions for use		MR Conditional
	Sterilized using ethylene oxide		MR Safe
	Catalogue number		Keep away from sunlight
	Batch code		Keep Dry
	Use by date		Manufacturer
	Double sterile barrier system		Date of manufacture
	Prescription device		Single use
	Do not use if the product sterilization barrier or its packaging is compromised		



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