

Powered Screw Insertion Guide Cordless Driver 3



Powered Screw Insertion Guide - Cordless Driver 3

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Introduction

In 2011, Stryker Spine received 510(k) clearance for the insertion of Xia®, MANTIS®, and Radius® pedicle screws using the Stryker Spine Power Adaptor, Hudson Modified Trinkle Reamer, and RemB Universal Driver.

Today, Stryker Spine is proud to announce that this powered screw insertion technique has now been cleared for the Stryker Instruments Cordless Driver 3.

Providing a comprehensive and easy to use platform of spinal implants and instrumentation has long been a tradition at Stryker Spine, and the Cordless Driver 3 builds on this.

Occupational ergonomics are a concern for any spine surgeon. The easy to use Stryker system for power screw insertion was designed with the goal of reducing the repetitive stress and fatigue surgeons encounter when inserting screws manually.

Leveraging Stryker Spine's comprehensive range of implants and the advanced instrumentation available through Stryker Instruments, this collaboration marks a step forward for powered instrumentation in spine surgery.

Pairing the Stryker Spine Power Adaptor with the Stryker Instruments Cordless Driver 3 makes this technique possible.



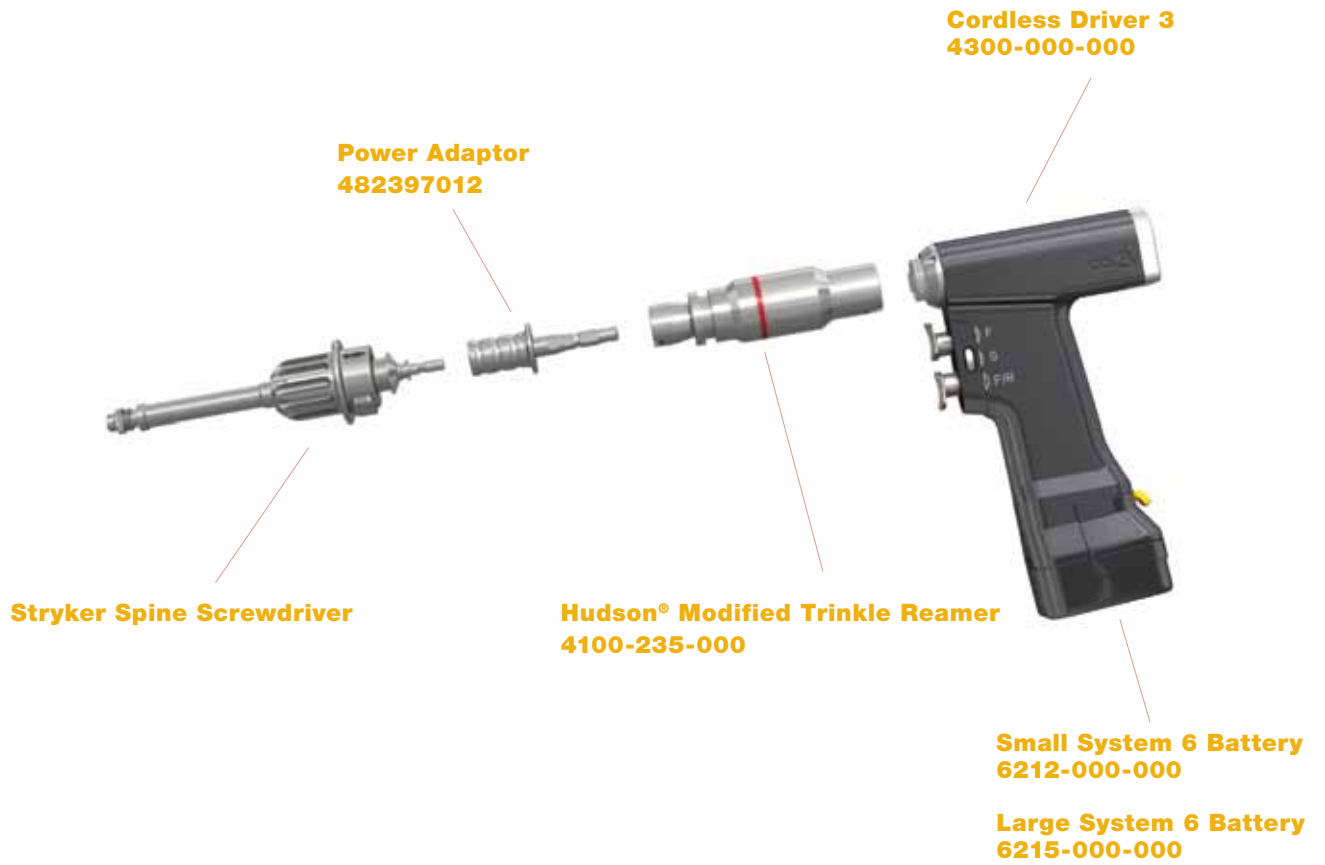
The Power Adaptor provides a connection between dedicated Stryker Spine pedicle screw system screwdrivers* and the Stryker Instruments Cordless Driver 3. The Power Adaptor provides two mechanical interfaces:

- (1) the Stryker Spine screwdrivers interface with the Power Adaptor Quick Connect Coupling and
- (2) the Stryker Instruments Cordless Driver 3 interfaces with the Power Adaptor shaft.

*The Power Adaptor is only to be used with the following Stryker Spine pedicle screw system screwdrivers: Xia® Spinal Systems (Xia® Stainless Steel, Xia® II, Xia® Anterior, Xia® Precision), Xia® 3 Spinal System, Xia® 4.5 Spinal System, Radius® Spinal System, MANTIS® Spinal System and Stryker Instruments Cordless Driver 3 or Stryker Instruments RemB Universal Driver.

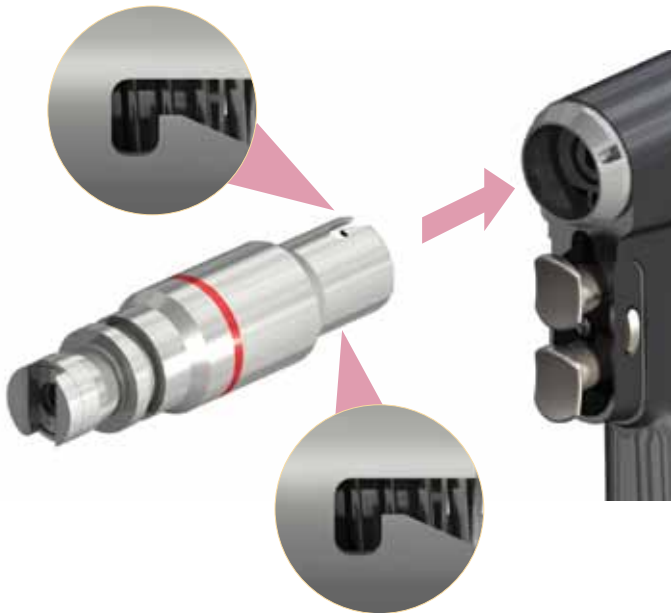
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Assembly of Screwdriver, Power Adaptor, and Cordless Driver 3



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STEP 1: Assemble the Cordless Driver 3 and the Hudson Modified Trinkle Reamer. Vertically align the two J-slots on the Hudson Modified Trinkle Reamer with the Cordless Driver 3 connector. Insert the Hudson Modified Trinkle Reamer until it snaps into place. Gently tug the attachment to verify it is secure.



WARNING: DO NOT attempt to insert or remove the Hudson Modified Trinkle Reamer while the handpiece is operating.

STEP 2: Assemble the Power Adapter to the Hudson Modified Trinkle Reamer. Pull back the coupling interface on the Hudson Modified Trinkle Reamer and introduce the Power Adaptor shaft.



STEP 3: Assemble the appropriate Spinal System Screwdriver according to the corresponding surgical technique.



STEP 4: Assemble the Screw to the Screwdriver according to the corresponding surgical technique.

STEP 5: Pull back the coupling interface on the Power Adaptor and introduce the Screwdriver. This completes the assembly of the Screwdriver to the Power Adaptor, Hudson Modified Trinkle Reamer, and Cordless Driver 3.



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Screw Insertion

With the pedicle pathway prepared¹, and the proper screw diameters and lengths determined, the screws can be inserted into the appropriate pedicles utilizing the Cordless Driver 3^{2,3}.

Once the screw is placed, disengage the screwdriver from the screw according to the corresponding surgical technique⁴.

CAUTION:

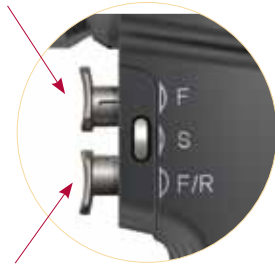
Care must be taken at the beginning of screw insertion to ensure proper screw trajectory. Surgeons must also take the necessary precautions to prevent overdriving of pedicle screws.

Before use, it is recommended that surgeons familiarize themselves with the Cordless Driver 3 and its triggers to ensure they are familiar with how to control the speed at which the screwdriver turns and drives the screw.

NOTE:

1. As outlined in the appropriate Stryker Spine Surgical Techniques, only manual tapping should be performed. Tapping under power has not been assessed for safety and accuracy.
2. Only the Xia® Spinal Systems (Xia® Stainless Steel, Xia® II, Xia® Anterior, Xia® Precision), Xia® 3 Spinal System, Xia® 4.5 Spinal System, Radius® Spinal System and the MANTIS® Spinal System are approved for powered pedicle screw insertion with the Cordless Driver 3.
3. Refer to the appropriate Stryker Spine Surgical Technique for Pedicle Pathway Preparation, Screw Insertion, Rod Contouring and Linkage, Final Tightening, and Cross Connector Placement.
4. If removal of Stryker screws is necessary, manual removal of implants should be performed.

R - Reverse



F - Forward

Function Switch

Symbol Definitions

	Forward - Fully depress the F/R/Safe control to lock the reverse trigger. The forward trigger is functional.
	Safety - Center the F/R/Safe control to lock both triggers.
	Forward/Reverse - Fully extend the F/R/Safe control to unlock both triggers. Both triggers are functional.
	Reverse - Press trigger to operate in the counterclockwise direction.
	Oscillate - Press both triggers to operate the handpiece in the oscillate mode.
	Forward - Press trigger to operate in the clockwise direction.

Disassembly

To Disassemble the Screwdriver/Power Adapter/Hudson Modified Trinkle Reamer/Cordless Driver 3 Assembly, reverse the steps listed above.



WARNING:

Before operating the handpiece, gently tug the Hudson Modified Trinkle Reamer to verify the attachment is secure.

ALWAYS set the function switch to the SAFETY position while the handpiece is idle, when passing the handpiece to another person, or before inserting or removing the Hudson Modified Trinkle Reamer. See next page.

NOTE:

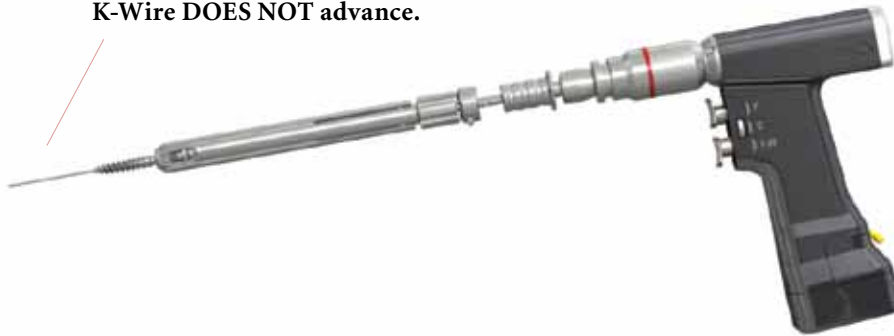
Refer to the Stryker Instruments Cordless Driver 3 IFU for additional information regarding Contraindications, User/Patient Safety, Accessory Information, Features, Symbol Definitions, Instructions, Troubleshooting Guide, and Specifications.

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Percutaneous Powered Pedicle Screw Insertion

When using powered screw insertion with MIS techniques, make sure to monitor the position of the K-Wire to ensure it DOES NOT advance.

K-Wire
Monitor position to ensure
K-Wire DOES NOT advance.



CAUTION: Care must be taken when using MIS techniques to ensure that K-Wires do not advance. Place the Screw/Screwdriver/Power Adapter/Hudson Modified Trinkle Reamer/Cordless Driver 3 over the K-Wire. Use imaging and monitoring, as preferred, for added information during screw insertion.

Battery Charging System

Battery Charger

- Quickly charges Cordless Driver 3 System 6 and non-sterile batteries.
- Modular design allows for 4 different batteries to charge simultaneously.
- Interactive screen allows user to assess the condition of the battery and read battery usage.
- Battery charging station diagnosis battery levels and usage.
- Conditioning cycle for discharging non-sterile batteries.



System 6 Battery Charger
6110-120-000

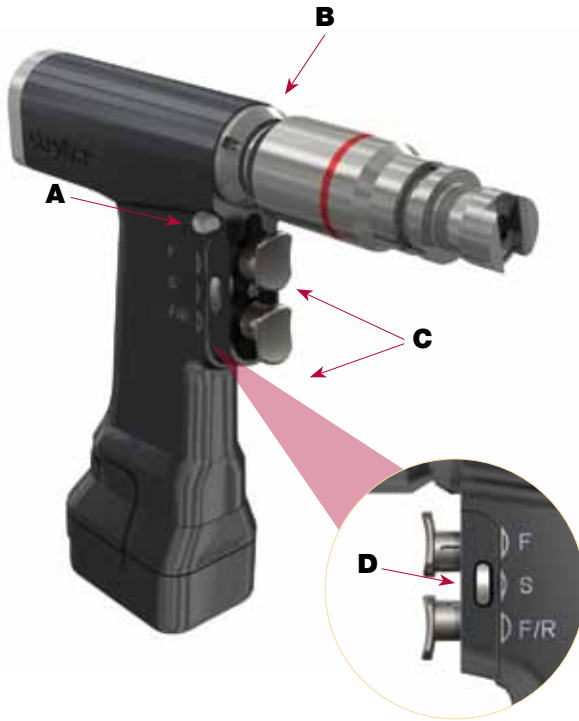


Small System 6 Battery
6212-000-000

Large System 6 Battery
6215-000-000

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Cordless Driver 3 Information



A	Release Button
B	Attachment Connector
C	Triggers
D	Function Switch

Symbol Definitions







	Forward - Fully depress the F/R/Safe control to lock the reverse trigger. The forward trigger is functional.
	Safety - Center the F/R/Safe control to lock both triggers.
	Forward/Reverse - Fully extend the F/R/Safe control to unlock both triggers. Both triggers are functional.
R	Reverse - Press trigger to operate in the counterclockwise direction.
	Oscillate - Press both triggers to operate the handpiece in the oscillate mode.
F	Forward - Press trigger to operate in the clockwise direction.

Specifications

Weight:	20 oz
Drill RPM:	1,500
Drill Torque:	27 in / lbs
Cannulated:	4.0 mm
Reamer RPM:	517 rpm
Reamer Torque:	72 in / lbs
Power (Large Battery):	166 Watts (30%)
Power (Small Battery):	92 Watts (25%)

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Instruments

	Reference #	Description	Stryker Division
	482397012	Power Adaptor	Spine
	4100-235-000	Hudson® Modified Trinkle Reamer	Instruments
	4300-000-000	Cordless Driver 3	Instruments
	6212-000-000	Small System 6 Battery	Instruments
	6215-000-000	Large Small System 6 Battery	Instruments
	6110-120-000	System 6 Battery Charger	Instruments
		Xia®, Radius®, or MANTIS® Screwdrivers*	Spine

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Intended Use/Indications for Use

To facilitate the placement of pedicle screws using the power technique, the use of the Stryker Spine Power Adaptor is intended for exclusive use with the Stryker Instruments Hudson Modified Trinkle Adaptor and the Cordless Driver 3 or RemB Universal Driver. When the adaptors are attached, the Cordless Driver 3 and RemB Universal Driver provide power to rotate screwdrivers for insertion of pedicle screws.

Pedicle screws from select Stryker Spine implant systems may be implanted in the skeletally mature non-cervical spine using powered instrumentation. The systems include the family of Xia® Spinal Systems (Xia® Stainless Steel, Xia® II, Xia® Anterior, and Xia® Precision), Xia® 3 Spinal System, Xia® 4.5 Spinal System, Radius® Spinal System and MANTIS® Spinal Systems.

The Xia® Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Xia® 4.5, Xia® 3, and Radius® Spinal Systems are intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the Xia® 3 Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Mantis® Spinal System and MANTIS® Redux Spinal System are intended for percutaneous, posterior, non-cervical pedicle and non-pedicle fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e.,

fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Potential Adverse Effects

Incorrect maintenance, cleaning or handling may render the instruments unsuitable for their intended use, cause corrosion, dismantling, distortion and/or breakage or cause injury to the patient or operating staff.

Below is a list, albeit not exhaustive, of potential complications:

- Neurological lesion, paralysis, pain, lesion of the soft tissues, the visceral organs or the joints, in the event of incorrect use or breakage of the instruments.
- Infection, if the instruments are not properly cleaned and sterilized.
- Dural leaks, compression of vessels, damage to nerves or nearby organs as a result of slippage or poor positioning of a faulty instrument.
- Damage caused by the involuntary releasing of the springs of certain instruments.
- Damage caused by the instruments used to bend or cut in-situ due to excessive forces occurring when they are used.
- Cutting the gloves or the skin of surgical staff.
- Tissue lesions on the patient or surgical staff and/or an increase in operating time as a result of having to disassemble the instruments during surgery.
- Crack, fracture or involuntary perforation of the bone.

As a result of the mechanical features required, most of the instruments are made of non implantable materials. In the event an instrument breaks, no fragment must remain in the patient as this could cause post-operative complications such as allergies, infections, or complications of a biological nature associated with the release of metal components, possibly requiring further intervention.

Packaging

- STRYKER Spine instruments may be supplied either sterile or non-sterile in instrument containers or individual packaging. Instruments sold sterile are always presented in individual packaging and will be clearly labelled as sterile on the package label. The sterilization method applied is indicated on the product label. The sterile instrument packaging must be intact at the time of receipt and the integrity of the packaging shall be checked prior to use.
- The containers and the packaging of the instruments must be intact when received. The packaging materials must be removed prior to sterilization.

Examination Prior to Use

For instruments designed for re-use:

- The life of the instrument depends on the number of times they are used as well as the precautions taken in handling, cleaning and storage. Great care must be taken of the instruments to ensure that they remain in good working order.
- Instruments should be examined for wear or damage by doctors and staff in operating centers prior to surgery.
- The examination shall include a visual and functional inspection of the working surfaces, articulation points, and springs. It should also include verifying all welded connections, that all components are present, and the cleanliness of the orifices and cavities, as well as the absence of any cracks, distortion, impact, corrosion or other change. For instruments with articulations, lubrication may be necessary. Using a silicone lubricating cream is recommended.
- Special attention should be paid to the clamping keys, especially to the hexagonalshank bits. The latter must not be blunt as this could compromise the clamping of the fittings and lead to a risk of detaching. Similarly instruments designed to cut bone such as reamers, rakers etc, must be rigorously inspected for sharpness.
- Special attention should be paid to the screwdrivers. It is crucial that they are used for the purpose they were designed for, as specifically indicated in the Surgical Technique of each product line.
- Certain surgical intervention requires the use of instruments which include a measuring function. These are to be inspected for wear and the clear visibility of any surface markings.
- STRYKER Spine and its representatives are available to help carry out proper instrument inspections.
- STRYKER Spine shall not be responsible in the event of the use of instruments that are damaged, incomplete, show signs of excessive wear and tear, or that have been repaired or sharpened outside the control of STRYKER Spine. Any faulty instruments must be replaced prior to any intervention.

Recommendations For Using Powered Instrumentation in the Placement of Pedicle Screws

Pedicle screws from select STRYKER Spine implant systems may be implanted in the skeletally mature non-cervical spine using powered instrumentation. These systems include the family of Xia Spinal Systems (Xia Stainless Steel, Xia II, Xia Anterior, Xia Precision), Xia 3 Spinal System, Xia 4.5 Spinal System, Radius Spinal System and the Mantis Spinal Systems.

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To facilitate the placement of pedicle screws (in the power application), the use of the STRYKER Spine Power Adaptor instrument (REF 482397012) is required and must be used exclusively with the STRYKER Instruments Hudson Modified Trinkle Adaptor (PN4100-235-000). The adaptors provide the interface for the power driver. The STRYKER Instruments Cordless Driver 3 (PN 4300-000-000) or STRYKER Instruments RemB Universal Driver (PN 6400-099-000) must be used when driving pedicles screws under power.

Should surgeons prefer to drive screws manually, hand held manual (non-powered) instruments may be used.

For powered insertion of pedicle screws, all instruments must be used in the manner described in the STRYKER Spine Powered Technique Guide. Prior to using the power pedicle screw insertion technique, the surgeon shall have given careful consideration to all aspects of the surgical intervention as well as the limits of the instrumentation. Recommendations for use are provided below and are intended to supplement those provided in the technique guide.

- To prepare the hole for screw insertion, only manual tapping is recommended. Tapping with power has not been assessed for safety and accuracy;
- Before use, it is recommended that surgeons familiarize themselves with the Cordless Driver 3 and its triggers to ensure they are familiar with how to control the speed at which the screwdriver turns and the screw drives.
- Caution must be taken at the beginning of screw insertion to ensure proper screw trajectory. Surgeons must also take the necessary precautions to prevent overdriving of pedicle screws; and
- Caution must be taken when using MIS techniques to ensure that K-wires do not advance.
- The STRYKER Spine Power Adaptor instrument (REF 482397012) has been tested for a three-year simulated lifecycle.

However, the user must examine the device prior to each use as stated above (Examination Prior to Use).

PRE-OPERATIVE PRECAUTIONS

Anyone using STRYKER Spine products can obtain a Surgical Technique by requesting one from a distributor or from STRYKER Spine directly. Those using brochures published more than two years before the surgical intervention are advised to request an updated version.

STRYKER Spine devices may only be used by doctors who are fully familiar with the surgical technique required. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by STRYKER Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable STRYKER Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels. Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

Any electrosurgical devices have the potential for providing an ignition source. Do not use in the presence of flammable substances.

CAUTION

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

Extracting a device

- To obtain the best possible results, the same instruments used to implant a device or instruments specifically designed for extraction must be used.
- To limit the stresses on the implants and the instruments, it is advisable to remove the bone and/or tissue from the area around the implant before performing extraction maneuvers.

Storage

The instruments are packaged in individual packages or in containers. After they are used they must be stored in a clean, dry and temperate place

Removal of Implants

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions.
- Pain or abnormal sensations due to the presence of the implants.
- Infection or inflammatory reactions.
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.
- Failure or mobilization of the implant.

Standard ancillaries provided by Stryker Spine can be used to remove the implants.

Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

Reconstructive

Hips
Knees
Trauma & Extremities
Joint Preservation
Orthobiologics

Medical & Surgical

Power Tools & Surgical Accessories
Image Guided Navigation
Endoscopy & Arthroscopy
Integrated Communications
Beds, Stretchers & EMS
Sustainability Solutions

Neurotechnology & Spine

Craniomaxillofacial
Interventional Spine
Neurosurgical, Spine & ENT
Neurovascular
Spinal Implants

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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