EXPEDIUM® Spine System
VIPER® System

CAUTION: USA law restricts this device to sale by or on the order of physician.

IMPORTANT NOTE TO OPERATING SURGEON

EXPEDIUM® and VIPER® spinal implants like any other temporary internal fixation devices, have a finite useful life. The patient’s activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.

The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

DESCRIPTION

DePuy Spine implants are NOT compatible with implants from other manufacturers unless otherwise specified.

Implants from each of the DePuy Spine systems are NOT interchangeable with implants from other DePuy Spine systems unless otherwise specified.

Implants designed to interface with a specific rod diameter are NOT compatible with other rod diameters unless otherwise specified. Implants designed to interface with a specific rod diameter are compatible with rods from other systems having the same diameter and same material per the table below.

Dual diameter rod components can have a combination of rod diameters corresponding to the existing straight rod diameters from each of the Spine Systems listed in the table below. These dual diameter rods can be used to connect rod constructs formed from the Original System to rod constructs from the Secondary System per the table below.

<table>
<thead>
<tr>
<th>ORIGINAL SYSTEM</th>
<th>SECONDARY SYSTEM(S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXPEDIUM/ VIPER</td>
<td>Connects To</td>
</tr>
<tr>
<td>EXPEDIUM Titanium</td>
<td>Connects To</td>
</tr>
<tr>
<td>EXPEDIUM 5.5 Titanium</td>
<td>Connects To</td>
</tr>
<tr>
<td>Connects To EXPEDIUM/ VIPER, ISOLA/TIMX, MONARCH, MOSS MIAMI</td>
<td></td>
</tr>
<tr>
<td>Connects To MOUNTAINEER</td>
<td></td>
</tr>
<tr>
<td>Connects To Synthes SYNAPSE</td>
<td></td>
</tr>
</tbody>
</table>

Dual diameter rods used to connect EXPEDIUM to the Synthes SYNAPSE System are limited to the 3.5 mm / 5.5 mm and 4.0 mm / 5.5 mm titanium tapered rods from the SYNAPSE System.

Implants made of different materials are NOT compatible unless otherwise specified. The table below specifies implant material compatibility.

<table>
<thead>
<tr>
<th>MATERIAL</th>
<th>COMPATIBLE WITH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless Steel alloys</td>
<td>Stainless Steel alloys, Titanium alloys, Commercially Pure Titanium</td>
</tr>
<tr>
<td>Titanium alloys</td>
<td>Titanium alloys, Commercially Pure Titanium, Cobalt-Chromium-Molybdenum, Cobalt-Nickel-Chromium-Molybdenum, Stainless Steel Alloys</td>
</tr>
<tr>
<td>Cobalt-Chromium-Molybdenum</td>
<td>Titanium alloys, Commercially Pure Titanium, Cobalt-Nickel-Chromium-Molybdenum</td>
</tr>
<tr>
<td>Cobalt-Nickel-Chromium-Molybdenum</td>
<td>Titanium alloys, Commercially Pure Titanium, Cobalt-Chromium-Molybdenum</td>
</tr>
<tr>
<td>Commercially Pure Titanium</td>
<td>Titanium alloys, Commercially Pure Titanium, Stainless Steel Alloys</td>
</tr>
</tbody>
</table>

A subset of EXPEDIUM and VIPER components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging from 4.5 to 6.35), hooks, screws, bolts, and connecting components. Similarly to the EXPEDIUM and VIPER implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

A subset of EXPEDIUM 4.5 and 5.5 components may be used along with the EXPEDIUM Extended Tandem Connectors (referred to as the EXPEDIUM Growing Spine System or...
a growing rod system) for a non-fusion growth enabling construct in pediatric cases that can be surgically lengthened on a periodic basis as the patient grows.

DePuy Spine prepares Surgical Technique Manuals showing the use of the implants and instruments for each Spine System. Contact your DePuy Spine sales representative to obtain copies of these Surgical Technique Manuals.

**EXPEDIATE Spine System**

The EXPEDIATE Spine System consists of longitudinal rods, monoaxial screws, polyaxial screws, uni-planar screws, reduction screws, cable/wire screws, bolts, slotted connectors, wires, hooks, reduction hooks, transverse connectors, SFX Cross Connector System, dual rod connectors, sacral extenders, lateral connectors, and washers.

The EXPEDIATE Spine System is compatible with other systems through the use of single or dual rod connectors, lateral connectors, sacral extenders and dual diameter rods as follows:

- ISOLA Spine System rods
- VIPER System rods
- MONARCH Spine System rods
- MOSS MIAMI Spine System rods
- TIMX Low Back System rods
- Synthes SYNAPSE System rods

The cable/wire screw is intended to be used with stainless steel ISOLA Beaded Sublaminar Wire, manufactured by DePuy Spine, Inc., or with the stainless steel Single Cable with Crimp and Bar and the Single ISOLA Cable with Eyelet Leader components of the Songer Spinal Cable System, manufactured by Pioneer Surgical Technologies and distributed by DePuy Spine, Inc.

The EXPEDIATE Spine System components are available in commercially pure titanium or titanium alloy conforming to ASTM F-67, ASTM F-136 or ASTM F-1472 specifications, stainless steel conforming to ASTM F-138, ASTM F-1314, or F-2229 specifications, cobalt-nickel-chromium-molybdenum alloy wire conforming to ASTM F-562 specifications, as well as longitudinal rods in cobalt-chromium-molybdenum alloy conforming to ASTM F-1537.

Cobalt-chromium-molybdenum alloy rods and cobalt-nickel-chromium-molybdenum alloy wires are intended for use with titanium components only.

Ring nut and set screw assemblies are only intended for use with polyaxial, uni-planar, and monoaxial single innie (SI) pedicle screws and pedicle hooks within the EXPEDIATE 4.5 mm and 5.5 mm stainless steel and titanium Systems.

The extension tabs on the reduction screw and hook components are intended to be removed intraoperatively.

The EXPEDIATE Growing Spine Extended Tandem Connectors are designed to interconnect with 4.5mm-5.5mm dual diameter rods, with the connector accepting the 5.5mm rod portion. The EXPEDIATE Extended Tandem Connectors are manufactured from ASTM F-1472 titanium alloy and ASTM F-138 stainless steel. These connectors are designed in various lengths, 40, 60 and 80mm, and have two window configurations, top view and offset. The EXPEDIATE Extended Tandem Connectors are designed to interact with constructs consisting of rods ranging in diameter from 4.5 to 5.5mm, hooks, screws, offset connectors, and cross connectors.

**VIPER System**

The VIPER System consists of cannulated polyaxial screws, monoaxial screws, uni-planar screws, reduction screws, and rods used in a percutaneous approach. Also, note that the VIPER® 2 System and VIPER PRIME™ are both part of the VIPER System. For simplicity in these instructions for use, just the encompassing VIPER name is used.

The VIPER System is compatible with other systems as follows:

- EXPEDIATE SFX Cross Connector System
- EXPEDIATE Spine System dual rod and lateral connectors, and sacral extenders
- Constructs incorporating inter-system single or dual diameter rods as defined above

The VIPER System components are available in titanium alloy conforming to ASTM F-136 specifications, stainless steel conforming to ASTM F-138 or ASTM F-1314 specifications, as well as longitudinal rods in cobalt-chromium-molybdenum alloy conforming to ASTM F-1537.

Cobalt-chromium-molybdenum alloy rods are intended for use with titanium components only.

Pedicle screw use for Adolescent Idiopathic Scoliosis population is limited to screw sizes of no greater than 7 mm in diameter and 60 mm in length.

**INDICATIONS**

**EXPEDIATE and VIPER Spine Systems**

The EXPEDIATE and VIPER Spine Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIATE and VIPER Spine Systems are intended for noncervical pedicle fixation and nonpedicle fixation 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, pseudarthrosis; and failed previous fusion in skeletally mature patients.
When used in a posterior percutaneous approach with MIS instrumentation, the VIPER System is intended for noncervical pedicle fixation and nonpedicle fixation 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, pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EXPEDIUM and VIPER Spine System metallic implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The EXPEDIUM and VIPER Spine Systems are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

**EXPEDIUM Growing Spine System**

The EXPEDIUM Growing Spine System is indicated for patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The EXPEDIUM Growing Spine System may be used with any cleared traditional 4.5 and 5.5 EXPEDIUM Spine Systems. The EXPEDIUM Growing Spine System is not intended to be used with 4.0mm diameter screws.

**CONTRAINDICATIONS**

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.

Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.

Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system.

Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

**Contraindications for the EXPEDIUM Growing Spine System**

Any case where the implant components selected for use would be too large or too small to achieve a successful result.

Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.

Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.

**USAGE**

**WARNING:** The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

CoCr tapered rods are not intended to connect the EXPEDIUM Spine System to the Synthes SYNAPSE System.

**PRECAUTION:** The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

Refer to the individual system surgical technique manuals for additional important information.

DePuy Spine Spinal System components should not be used with components from other manufacturers unless otherwise specified.

During the surgical procedure, the rods may be cut to size and shaped to provide correction and maintain proper anatomic lordotic and kyphotic alignment.
When using anterior thoracic/lumbar screw fixation systems, staples, staple washers and washers are available to optimize proper staple/screw/rod alignment and stability.

Screw diameters of 11 mm and 12 mm are indicated for use only in the sacrum or ilium. Pre-operative use of CT imaging to determine the appropriate screw diameter, length, insertion trajectory, and clearance is strongly recommended when large diameter screws are indicated.

After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient’s general medical condition and the potential risk to the patient of a second surgical procedure.

These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology, for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion, the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.

POSTOPERATIVE MOBILIZATION

Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended.

Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

MAGNETIC RESONANCE (MR) COMPATIBILITY

The EXPEDITUM and VIPER Spine Systems have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment. The safety of the EXPEDITUM and VIPER Spine Systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as stainless steel and Cobalt-Chromium-Molybdenum or Cobalt-Nickel-Chromium-Molybdenum, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

A. The patient’s weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

B. The patient’s occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
C. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

D. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

E. Foreign body sensitivity. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

F. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

G. Pediatric use, including the EXPEDiUM Growing Spine System. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients not skeletally mature that undergo spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the “crankshaft phenomenon”) due to continued differential growth of the anterior spine. Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk of device-related injury because of their smaller stature.

Growing rod systems / constructs should only be used by surgeons who are experienced with pediatric posterior spine surgery procedures and have undergone hands-on training in both device implantation and adjustment. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with growing rod systems / constructs should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurologic complications.

Growing rod systems / constructs typically require repeated planned-lengthening procedures until a determination is made that the patient is ready for a final fusion procedure. Growing rod patients are more susceptible to post-operative infections and wound-healing issues, as well as the potential for implant breakage requiring unplanned surgical procedures. The physician should discuss these and all other potential complications with the patient and the patient’s guardian.

While the final decision on implant removal is up to the surgeon and the patient, in most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the complications listed under point 3 CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING may occur.

PRECAUTIONS

1. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

3. CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) potential unknown or unexpected long term effects such as carcinogenesis.

The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

4. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient’s ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware
of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

5. CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANT. Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants.

6. The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

POSSIBLE ADVERSE EFFECTS

1. Bending or fracture of implant.
2. Loosening of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Infection, early or late.
5. Nonunion, delayed union.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
11. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
12. Death.
13. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
14. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
15. Damage to lymphatic vessels and/or lymphatic fluid exudation.
16. Spinal cord impingement or damage.
17. Fracture of bony structures.
18. Degenerative changes or instability in segments adjacent to fused vertebral levels.

Additional Possible Adverse Effects Specific to Pediatric Patients

1. Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions and/or distorted anatomy).
2. Pedicle screw malpositioning, with or without neurological or vascular injury.
3. Proximal or distal junctional kyphosis.
4. Pancreatitis.
5. Unintended fusion in growing rod patients.
6. Increased risk of post-operative infection and wound-healing issues in growing rod patients.
7. Increased risk of implant breakage in growing rod patients.
8. Implant prominence (symptomatic or asymptomatic).
9. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.
10. Post-operative change in spinal curvature, loss of correction, height or reduction.
11. Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).

CLEANING AND STERILIZATION

Implants and instruments of the EXPED iUM and V I P E R Spine Systems may be provided either sterile or non-sterile and this will be clearly identified on the product labels.

Sterile Devices

For the devices (implants and instruments) supplied sterile, the contents are sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised.
Remove devices from packaging, using aseptic technique, only after the correct size has been determined.

PRECAUTION: Do not use devices if the condition of the package and/or labeling indicates a chance that the devices may not be sterile.

Devices supplied sterilized from the manufacturer must not be resterilized.

INSTRUCTIONS FOR PROCESSING MEDICAL DEVICES

Non-sterile Implants, and Reusable Instruments, Instrument Trays and Cases

Introduction

DePuy Synthes non-sterile implants and reusable instruments are critical medical devices. These devices must be cleaned, inspected and sterilized prior to surgical use. These instructions are provided to assist health care personnel in the development of effective procedures for the processing of non-sterile implants and reprocessing of reusable devices. It is the responsibility of the facility to ensure that processing is performed using the equipment, materials and competent personnel at a designated processing area.

These instructions are provided for heat-resistant, critical medical devices, unless otherwise noted on specific product inserts. Product specific inserts are given priority over these instructions. This can include heat-sensitive devices and certain power (air- or electric-driven) tool designs that are provided with specific cleaning and sterilization instructions. Consult the product specific instructions for processing in these cases.

DePuy Synthes Instruments do not have an indefinite functional life. All reusable instruments are subjected to repeated stresses related to surgical use, routine cleaning, and sterilization processes. Instruments should be carefully inspected before each use to ensure that they are functional. Scratches, dents or other damage can result in instrument breakage or tissue injury.

DePuy Synthes provides sterile and non-sterile implants. Sterile, single use implants must not be reprocessed or reused. Non-sterile implants must be sterilized prior to use in accordance with these processing instructions. They may be subjected to reprocessing in accordance with these processing instructions, but must be discarded following direct patient contact or use.

Manufacturer Contact

For local contact information, visit www.depuysynthes.com or contact your local sales representative.

Symbols

Warnings and Cautions

These instructions are provided for the processing of heat-resistant, immersible, critical medical devices, unless otherwise noted on specific product inserts. Product specific inserts are given priority over these instructions. This can include heat-sensitive devices and certain power (air- or electric-driven) tool designs that are provided with specific cleaning and sterilization instructions. Consult the product specific instructions for processing in these cases.

The instructions provided are given as guidance for medical device processing and have been validated by the manufacturer. It is the responsibility of the healthcare facility to ensure that processing is performed using the required equipment, materials and personnel at a defined processing area. This will include the handling of devices during transportation, processing and storage prior to surgical use.

Those using these instructions should be qualified personnel with documented training and competency in accordance with local procedures, guidelines, and standards.

Surgically used instruments can be considered biohazard and facilities should ensure that transport and handling procedures comply with local regulations and guidelines.

Sterile, single use implants must not be reprocessed or reused. Sterile implants are labelled as single use and have not been validated for reprocessing.

Non-sterile implants must be processed prior to use in accordance with these processing instructions. They may be subjected to reprocessing in accordance with these processing instructions, but they must be discarded following direct patient contact or use.

Reusable, non-sterile surgical instruments are required to be cleaned, inspected and sterilized prior to surgical use.

Care should be taken in the handling and cleaning of sharp devices.

All devices must be thoroughly cleaned and inspected prior to sterilization. Long, narrow lumens, blind holes, moving and intricate parts require particular attention during cleaning and inspection. During cleaning, only use detergents that are labelled for use on medical devices and in accordance with the manufacturer’s instructions. Cleaning agents with a used dilution pH of within 7 – 9 are recommended. Highly alkaline conditions (pH>10) can damage components / devices, such as aluminium materials. Do not use saline, environmental disinfection (including chlorine solutions) or surgical antiseptics (such as iodine- or chlorhexidine-containing products). Do not use a cleaning aid that can damage the surface of instruments such as steel wool, abrasive cleaners or wire brushes.
Instruments should be carefully inspected before each use to ensure that they are functional. Scratches, dents or other damage can result in instrument breakage or tissue injury.

Instruments must be cleaned separately from instrument trays and cases. Instrument trays and cases are designed as an organizational tool in preparation for sterilization, storage and surgical use. Non-sterile implant sets may be processed in their trays provided.

Automated equipment, including washer-disinfectors and steam sterilizers must be installed, maintained and operated in accordance with manufacturer’s instructions.

Do not exceed 140°C (284°F) during reprocessing steps.

For patients with, or suspected with, Creutzfeldt-Jakob disease (CJD), variant CJD or other transmissible spongiform encephalopathy (TSE) and related infections, it is recommended to treat the patient using single-use instruments. Safely dispose of all devices used in accordance with local procedures and guidelines.

**Limitations on Processing**

Repeated processing cycles in compliance with these instructions for use have minimal effects on device life and function. Instruments do not have an indefinite functional life. End of life of devices is determined by wear and damage due to surgical use and handling. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used.

Non-sterile implants must be discarded following patient use. Any implant with evidence of damage, such as due to handling or processing must be discarded.

**Step 1: Point of Use Care**

Ensure that no instruments or parts are left in the surgical site prior to closure as patient injury may result.

All single use devices and materials should be removed and discarded in compliance to local policies.

The drying of gross soil (blood, tissue and/or debris) on devices following surgical use should be avoided. It is preferred that gross soil is removed from devices following use and in preparation for transportation to a processing area. Gross soil can be removed using sponges, cloths, or soft brushes. Water and/or cleaning detergents (labelled for use on medical devices) may be used.

Do not use saline, environmental disinfection (including chlorine solutions) or surgical antiseptics (such as iodine- or chlorhexidine-containing products. Flush all lumened devices with water (or detergent solution) to prevent the drying of soil and/or debris to the inside.

If gross-soil cannot be removed at the point of use, the devices should be transported to prevent drying (e.g., covered with a towel dampened with purified water) and cleaned as soon as possible at a designated processing area.

Surgical cement should be removed from devices during surgical use and prior to setting. When cement hardens it will typically require physical methods to remove. Chemical solvents should not be used. Hardened cement may be removed with an approved stylus or removing tool, but these may damage devices.

**Step 2: Containment and Transportation**

Surgically used devices may be considered bio-hazardous and should be safely transported to a designated processing area in accordance with local policies.

**Step 3: Cleaning**

**Preparation before Cleaning**

It is recommended that devices should be reprocessed as soon as is reasonably practical following surgical use.

Instruments must be cleaned separately from instrument trays and cases.

Non-sterile implants may be cleaned and disinfected in the provided implant trays.

Care should be taken in the handling and cleaning of sharp devices. These are recommended to be cleaned separately to reduce risks of injury.

Multi-part or complex instruments may require disassembly for cleaning. Refer to any technique guides or other supplemental information for specific device disassembly and/or reassembly instructions.

Any devices with moving parts (e.g. ratchets, box locks, hinges or actuated parts) need to be actuated during manual cleaning to ensure access of the cleaning process.

All devices with lumens need to be manually flushed to remove debris and brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brush size should be approximately the same diameter of the lumen to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the lumen. Refer to any technique guides or other supplemental information for specific device lumen diameters.

After brushing, rinse with water by flushing and blow clean compressed air through all lumens.

**NOTE:** Two cleaning methods are provided, a Manual and an Automated Method, and at least one shall be performed.

**Cleaning: Manual**

1. Prepare a neutral or mild alkaline cleaning solution (pH 7 to 9) in accordance to the detergent manufacturer’s instructions. The temperature of the solution should be ≤40°C (104°F) for manual cleaning.
NOTE: The cleaning solution may contain enzymes. Aluminum-safe alkaline cleaners can be used, but can vary in material compatibility overtime based on their formulation. Material compatibility should be confirmed with the detergent manufacturer.

2. Immerse devices and parts in the detergent solution, and soak for a minimum of 5 minutes.

3. While immersed, use a soft non-metallic bristle brush (plastic bristles, like nylon) or sponge to thoroughly clean all traces of blood and debris from all device surfaces for a minimum of one minute.

4. Ensure all lumens are thoroughly brushed. Push the brush through the entire length of the lumen using a twisting motion to remove debris from both ends for a minimum of one minute.

5. During cleaning, actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Ensure all lumens are flushed for a minimum of one minute.

6. Load the device components in the washer-disinfector in accordance with manufacturer’s instructions, ensuring that the devices and lumens can drain freely.

7. Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 and-2, or to an equivalent standard. Automated washing can be included as part of a validated washing, disinfection, and/or drying cycle in accordance to manufacturer’s instructions. An example of a validated cycle used for cleaning validation included:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Recirculation Time (minutes)</th>
<th>Water Temp</th>
<th>Detergent/ Water Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash</td>
<td>2</td>
<td>Cold Tap Water</td>
<td>N/A</td>
</tr>
<tr>
<td>Enzyme wash</td>
<td>1</td>
<td>&lt; 40°C (104°F)</td>
<td>Neutral, Enzymatic Cleaner</td>
</tr>
<tr>
<td>Wash</td>
<td>5</td>
<td>66°C (151°F)</td>
<td>Neutral pH Detergent</td>
</tr>
<tr>
<td>Rinse</td>
<td>2</td>
<td>&gt; 40°C (104°F)</td>
<td>Tap water</td>
</tr>
<tr>
<td>Rinse</td>
<td>0.25</td>
<td>Ambient</td>
<td>Critical water (RO, deionized or distilled water)</td>
</tr>
</tbody>
</table>

8. Rinse all devices by immersion in ambient, < 40°C (104°F), tap water for a minimum of one minute and until evidence of debris, soil, and cleaning solution are visually removed. Use a large syringe (e.g., 50ml or greater) filled to capacity with tap water to thoroughly flush lumens and channels. Actuate joints, handles and other moveable device features to rinse thoroughly.

9. Remove the devices and repeat the rinsing using in ambient, < 40°C (104°F) critical water (high purity water generated by processes such as RO, deionization or distillation) for at least 15 seconds.

10. Remove and dry device using a clean, soft, lint-free cloth or clean compressed air. Ensure that all lumens and articulated areas are dried using compressed air.

Cleaning: Automated

1. Prepare a neutral or mild alkaline cleaning solution (pH 7 to 9) in accordance to the detergent manufacturer’s instructions. The temperature of the solution should be ≤40°C (104°F) for manual cleaning.

NOTE: The cleaning solution may contain enzymes. Aluminum-safe alkaline cleaners can be used, but can vary in material compatibility overtime based on their formulation. Material compatibility should be confirmed with the detergent manufacturer.

2. Immerse devices and parts in the detergent solution, and soak for a minimum of 5 minutes.

3. While immersed, use a soft non-metallic bristle brush (plastic bristles, like nylon) or sponge to thoroughly scrub all traces of blood and debris from all device surfaces for at least one minute.

4. Ensure all lumens are thoroughly brushed. Push the brush through the entire length of the lumen using a twisting motion to remove debris from both ends for at least one minute.

5. During cleaning, actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable. Ensure all lumens are flushed for at least one minute.

6. Load the device components in the washer-disinfector in accordance with manufacturer’s instructions, ensuring that the devices and lumens can drain freely.

7. Automated washing shall be conducted in a validated washer-disinfector in compliance to ISO 15883-1 and-2, or to an equivalent standard. Automated washing can be included as part of a validated washing, disinfection, and/or drying cycle in accordance to manufacturer’s instructions. An example of a validated cycle used for cleaning validation included:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Recirculation Time (minutes)</th>
<th>Water Temp</th>
<th>Detergent/ Water Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash</td>
<td>2</td>
<td>Cold Tap Water</td>
<td>N/A</td>
</tr>
<tr>
<td>Enzyme wash</td>
<td>1</td>
<td>&lt; 40°C (104°F)</td>
<td>Neutral, Enzymatic Cleaner</td>
</tr>
<tr>
<td>Wash</td>
<td>5</td>
<td>66°C (151°F)</td>
<td>Neutral pH Detergent</td>
</tr>
<tr>
<td>Rinse</td>
<td>2</td>
<td>&gt; 40°C (104°F)</td>
<td>Tap water</td>
</tr>
<tr>
<td>Rinse</td>
<td>0.25</td>
<td>Ambient</td>
<td>Critical water (RO, deionized or distilled water)</td>
</tr>
</tbody>
</table>

Step 4: Thermal Disinfection

Thermal disinfection is recommended to render devices safe for handling prior to steam sterilization. Thermal disinfection should be conducted in a washer-disinfector compliant to ISO 15883-1 and-2, or to an equivalent standard. Thermal disinfection in the washer-disinfector shall be validated to provide an A0 of at least 600 (e.g., 90°C (194°F) for 1 min).
Higher levels of A0 can be achieved by increasing the exposure time and temperature (e.g., A0 of 3000 at >90°C (194°F) for 5 min, in accordance with local requirements). Load the device components in the washer-disinfector in accordance with manufacturer’s instructions, ensuring that the devices and lumens can drain freely. Lumened devices should be placed in a vertical position. If this is not possible due to space limitations within the washer-disinfector, use an irrigating rack /load carrier with connections designed to ensure an adequate flow of process fluids to the lumen or cannulation of the device if provided.

The following automated cycles are examples of validated cycles:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Recirculation Time (minutes)</th>
<th>Water Temp</th>
<th>Water Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermal Disinfection</td>
<td>1</td>
<td>&gt; 90°C (194°F)</td>
<td>Critical water (RO, deionized or distilled water)</td>
</tr>
<tr>
<td>Thermal Disinfection</td>
<td>5</td>
<td>&gt; 90°C (194°F)</td>
<td>Critical water (RO, deionized or distilled water)</td>
</tr>
</tbody>
</table>

**Step 5: Drying**

It is recommended that drying is conducted in a washer-disinfector compliant to ISO 15883-1 and-2, or to an equivalent standard. Drying efficiency in washer-disinfectors can range considerably based on the automated system design and load configuration.

The following automated cycle is an example of a validated cycle:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Recirculation Time (minutes)</th>
<th>Air Temp</th>
<th>Air Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry</td>
<td>7</td>
<td>115°C (239°F)</td>
<td>Medical grade</td>
</tr>
</tbody>
</table>

Following automated drying, inspect the device for residual moisture. Any residual moisture identified should be dried manually (as described below).

**For manual drying:**
- Ensure each device is dried and inspected thoroughly.
- For external surfaces, use a clean, soft, lint-free cloth to avoid damage to the surface.
- Open and close any applicable devices during drying. Pay special attention to any device threads, ratchets and hinges or areas where fluid can accumulate. Clean, compressed air (e.g., medical grade) may be used to facilitate surface drying.
- Dry all lumen/cannulated parts using clean compressed air (e.g., medical grade).

**Step 6: Maintenance and Inspection**

Instruments should be visually inspected under ambient lighting, to verify that the devices do not have visible soil, damage or moisture.

**Inspect devices for:**
- Lack of moisture. If moisture is detected, manually drying should be performed.
- Cleanliness. If any residual soil is discovered during inspection, repeat the cleaning steps on those devices until all visible soil is removed from the device.
- Damage, including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear
- Proper function, including but not limited to, sharpness of cutting tools, bending of flexible devices, movement of hinges/joints/box locks and moveable features such as handles, ratcheting and couplings and missing or removed part numbers

Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should be discarded.

Disassembled devices should be reassembled prior to sterilization when specified.

Lubricate any moving parts with a water-soluble surgical instrument lubricant. The lubricant should be approved for use on medical devices and provided with data to ensure biocompatibility and compatibility with steam sterilization.

**Step 7: Packaging**

Place cleaned, dry devices into the specified locations within the cases provided, if applicable.

Only legally marketed, and locally approved sterilization barriers (e.g. wraps, pouches or containers) should be used for packaging terminally sterilized devices, in compliance to the manufacturer’s instructions.

**Step 8: Sterilization**

Steam (moist heat) sterilization shall be performed in a locally approved, pre-vacuum (forced air removal) cycle. The steam sterilizer should be validated to the requirements of any local standards and guidance such as EN 285 or AAMI/ANSI ST8. The steam sterilizer should be installed and maintained in compliance to manufacturer’s instructions and local requirements. Ensure that the steam sterilizer cycle is chosen that is designed to remove air from porous or lumened device loads in accordance to manufacturer’s instructions and does not exceed the criteria for sterilizer load.
The following steam sterilization cycles are examples of validated cycles:

<table>
<thead>
<tr>
<th>Conditioning Phase</th>
<th>Minimum Sterilization Exposure Time (minutes)</th>
<th>Minimum Sterilization Exposure Temperature</th>
<th>Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>4</td>
<td>132°C (270°F)</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Pre-vacuum</td>
<td>3</td>
<td>134°C (274°F)</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

Extended steam exposure cycle can be used to meet local requirements such as 134°C (274°F) for 18 minutes.

The efficiency of steam sterilizer drying can range considerably depending on the sterilizer design, loading, packaging and steam supply during the sterilization process. The user should employ verifiable methods (e.g., visual inspections) to confirm adequate drying. Extended drying within the sterilizer or in an external drying cabinet in accordance with manufacturer’s instructions may be necessary. Do not exceed 140°C (284°F) during drying.

Immediate-Use steam sterilization is only intended for individual instruments and should only be performed when approved by local policies. DePuy Synthes does not support immediate-use steam sterilization of instrument sets, cases or implants using this method.

The following steam sterilization cycle is an example of a validated cycle for individual instruments:

- Unwrapped instrument
- A minimum 3 (three) pulse pre-vacuum cycle
- 132°C (270°F) for 4 minutes

**Step 9: Storage**

Sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.

Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

**Additional Information**

Cleaning agent information: Examples of detergents that have been used during cleaning validations include Prolystica™ 2X Concentrate Enzymatic Cleaner, Prolystica™ 2X Neutral Detergent, Enzol™, Endozime™, Neodisher Medizym™, Terg-A-Zyme™, and NpH-Klenz™.

The chemical quality of the water used during reprocessing can impact device safety. Facilities should use the recommended water quality requirements for device reprocessing in accordance with local guidance (such as AAMI TIR 34, Water for the reprocessing of medical devices) and these instructions for use.

These instructions for use have been validated in accordance with ISO 17664. It remains the responsibility of the facility to ensure that the processing is performed using equipment, materials and personnel at a designated area, and achieves the desired requirements. This includes validation and routine monitoring of the process. Likewise, any deviation by the processor from these recommendations should be evaluated for effectiveness and any potential adverse consequences.

All personnel using these instructions should be qualified with documented expertise, competency and training. Users should be trained on healthcare facility policies and procedures along with current applicable guidelines and standards.

**LIMITED WARRANTY AND DISCLAIMER**

PRODUCTS FROM DEPUY SYNTHES PRODUCTS, INC. ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT DEPUY SYNTHES SPINE FOR CURRENT INFORMATION AT +1-800-365-6633 OR AT +1-508-880-8100.
SYMBOL TRANSLATION

<table>
<thead>
<tr>
<th>LOT</th>
<th>LOT NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>REF CATALOG NUMBER</td>
</tr>
<tr>
<td>QTY</td>
<td>QUANTITY</td>
</tr>
<tr>
<td>SZ</td>
<td>SIZE</td>
</tr>
<tr>
<td>MADE IN</td>
<td>MADE IN</td>
</tr>
<tr>
<td>NTI</td>
<td>NEURAL TISSUE INSTRUMENT</td>
</tr>
<tr>
<td>IOM</td>
<td>NEUROMONITORING INSTRUMENTS</td>
</tr>
</tbody>
</table>

Federal (USA) law restricts this device to sale by or on the order of a physician.

- **STEROLE** A: Sterile medical device processed using aseptic technique
- **STERILE R**: STERILIZATION BY IRRADIATION
- **STERILE EO**: STERILIZATION BY ETHYLENE OXIDE
- **STERILE**: STERILE
- **LATEX FREE**: LATEX FREE
- **NON STERILE**: NONSTERILE
- **MSR**: MEASURING DEVICE
- **KEEP AWAY FROM SUNLIGHT**: KEEP AWAY FROM SUNLIGHT
- **DO NOT USE IF PACKAGE IS DAMAGED**: DO NOT USE IF PACKAGE IS DAMAGED
- **PACKAGE CONTAINS FLAMMABLE LIQUID**: PACKAGE CONTAINS FLAMMABLE LIQUID
- **ATTENTION, SEE INSTRUCTIONS FOR USE**: ATTENTION, SEE INSTRUCTIONS FOR USE
- **STORAGE AT ROOM TEMPERATURE**: STORAGE AT ROOM TEMPERATURE
- **DO NOT RESTERILIZE**: DO NOT RESTERILIZE

MATERIALS

- **Ti/CoCrMo**: Titanium/Cobalt Chromium Molybdenum
- **SS**: Stainless Steel
- **CoNiCrMo**: Cobalt Nickel Chromium Molybdenum
- **T**: Titanium and its alloys