Instructions for Use
VECTRA and VECTRA-T

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

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Printed on: Mai 18, 2021

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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SE_528366 AE 03/2021

Instructions for Use

VECTRA and VECTRA-T
The VECTRA and VECTRA-T systems are anterior cervical plating systems. The VECTRA and VECTRA-T systems consist of plates with fixed-angle and variable-angle screws.
The plates are available in various configurations and lengths. Screws are offered in different lengths and diameters.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials
Titanium Alloy: TAN (Titanium-6% Aluminium-7% Niobium) according to ISO 5832-11
Titanium: TiCP (Commercially pure Titanium) according to ISO 5832-2
Elgiloy® (40% Cobalt-20% Chromium-16% Iron-15% Nickel-7% Molybdenum) according to ASTM F 1058
Elgiloy® is a registered trademark of Elgiloy Specialty Metals.

Intended Use
The VECTRA and VECTRA-T systems are intended for anterior plate fixation of the cervical spine (C2–C7) as an adjunct to fusion in skeletally mature patients.

Indications
Degenerative spine disease and instabilities

Contraindications
Severe osteoporosis

Patient Target Group
The VECTRA and VECTRA-T systems are intended for use in skeletally mature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Expected Clinical Benefits
When the VECTRA and VECTRA-T systems are used as intended and according to the instructions for use and labeling, these devices provide anterior supplemental stabilization of the motion segment(s) after intervertebral disc removal or corpectomy as an adjunct to fusion, which is expected to improve neck and/or arm pain and/or neurologic disfunction caused by indicated conditions of the spine.

A summary of safety and clinical performance can be found at the following link (upon activation): https://ec.europa.eu/tools/eudamed

Performance Characteristics of the Device
The VECTRA and VECTRA-T systems are anterior cervical plate systems, designed to provide mechanical stability as an adjunct to fusion.

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis, embolism, infection, excessive bleeding, neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, heterotopic ossification, functional impairment of the musculoskeletal system, paralysis (temporary or permanent), complex regional pain syndrome (CRPS), allergy/hypersensitivity reactions, symptoms associated with implant or hardware prominence, esophageal injury, dysphagia, malunion, non-union, ongoing pain; damage to vital organs, adjacent bones, discs (e.g. adjacent level degeneration), or soft tissue; dural tear or spinal fluid leak; spinal cord compression and/or contusion, implant loosening or breakage, device or graft material displacement, vertebral angulation.

Sterile Device

Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.


Do not use when packaging is damaged.

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

Single Use Device


Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, re-use or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions
- It is strongly advised that the VECTRA and VECTRA-T are implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.
- Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.

VECTRA

Surgical approach and plate size selection
Using the standard surgical approach, expose the vertebral bodies to be fused. Select appropriate plate size. Plate may be brought in position with the drill guide.
- It must be considered that the intervertebral discs in the neck region are slightly inclined from anterocaudal to posterocranial. Screws should remain in the vertebral body and not penetrate the intervertebral discs. Make sure there will be enough space between the intact adjacent intervertebral discs and the screws.
- Only bend the plate at the bending notches or else the holes may distort.
- Repeated bending may weaken the plate.
- Do not bend the plate at the holes.

Secure plate with temporary fixation pins
- Intraoperative imaging should be used for a lateral view of the position of the fixation pins to indicate the potential positions of the screws.

Screw insertion
- Intraoperative imaging should be used to verify awl position.
- Intraoperative imaging should be used to check the drilling operation.
- For long spans or suboptimal bone quality, the surgeon is urged to consider the nature of such cases. The treatment may require the use of screws longer than 16 mm, and/or posterior fixation for these kinds of inherently unstable cases.

– It must be considered that the intervertebral discs in the neck region are slightly inclined from anterocaudal to posterocranial. Screws should remain in the vertebral body and not penetrate the intervertebral discs. Make sure there will be enough space between the intact adjacent intervertebral discs and the screws.
– The 4.5 mm screw may be used as an emergency screw where the 4.0 mm screw has stripped the bone and a larger screw thread is required.
– Intraoperative imaging should be used to verify screw position.

VECTRA-T

Implant selection and preparation
Using the standard surgical approach, expose the vertebral bodies to be fused. Select a plate with appropriate hole spacing. Plate may be brought in position with the drill guide.
– It must be considered that the intervertebral discs in the neck region are slightly inclined from anterocaudal to posterocranial. Screws should remain in the vertebral body and not penetrate the intervertebral discs. Make sure there will be enough space between the intact adjacent intervertebral discs and the screws.
– Repeated bending may weaken the plate.
– Do not bend the plate at the holes or carriages.
– Bending the shortest 1- and 2-level plates (450.551, 450.552, 450.561, 450.562 and 450.563) may impede the translational mechanism and is not recommended. These plates are made with additional lordosis.

Secure plate with fixation pins
- Intraoperative imaging should be used for a lateral view of the position of the fixation pins to indicate the potential positions of the screws.

Screw insertion
– Intraoperative imaging should be used to verify awl position.
– Intraoperative imaging should be used to check the drilling operation.
– For long spans or suboptimal bone quality, the surgeon is urged to consider the nature of such cases. The treatment may require the use of screws longer than 16 mm, and/or posterior fixation for these kinds of inherently unstable cases.
– Only the variable angle screws from the system may be placed in the elongated holes of 3- and 4-level plates. The screw head geometry of fixed angle screws may impede translation.
– Any screws from the system may be placed in the round screw holes.
– It must be considered that the intervertebral discs in the neck region are slightly inclined from anterocaudal to posterocranial. Screws should remain in the vertebral body and not penetrate the intervertebral discs. Make sure there will be enough space between the intact adjacent intervertebral discs and the screws.
– The 4.5 mm screw may be used as an emergency screw where the 4.0 mm screw has stripped the bone and a larger screw thread is required.
– Intraoperative imaging should be used to verify screw position.
– The total amount of translation can be customized by removing carriage spacers and moving the carriages within the allowable range before screw placement.
– The carriage on the cranial end (for 3- and 4-level plates only) can translate 3 mm while all other carriages can translate 2 mm.
– Intermediate elongated holes allow screws to translate up to 2 mm.

Implant Removal (VECTRA and VECTRA-T)
Remove screw using screwdriver for extraction
– Do not rotate the sleeve after it has contacted the surface of the plate. While holding the sleeve, turn the handle counterclockwise to extract the screw.
– A screw can be inserted and removed two times. If a screw is removed a third time, the plate needs to be replaced.
– If the inner shaft knob is not fully tightened to the handle, breakage of the driver may occur and could potentially harm the patient.
– The extraction screwdriver should only be used for screw removal; use of the extraction screwdriver for screw insertion may lead to driver and/or implant breakage.

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices
The VECTRA and VECTRA-T plates and screws are applied using the associated VECTRA Instrumentation. The following screw options are available for use with the plates.
– Cervical spine screw (∅ 4.0/4.5 mm) with self-tapping and self-drilling options
– Cervical spine cortex screw (∅ 4.0/4.5 mm)

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance Environment
MR Conditional:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the VECTRA and VECTRA-T systems are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the VECTRA and VECTRA-T implants will produce a temperature rise not greater than 5.5 °C at a maximum whole body averaged specific absorption rate (SAR) of 2 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the VECTRA and VECTRA-T devices.

Treatment before Device is Used
Non-Sterile Device:
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged.

Implant Removal
If a VECTRA and VECTRA-T implant must be removed, the following technique is recommended.

Clean screw head
– If access to the screw head is blocked by tissue, use the Cleaning Instrument for Screw Head to clean out material.
– Insert the instrument into the screw head and twist the handle back and forth until material is removed.

Remove screw
– For screw removal, the Screwdriver for Extraction must be used.
– Insert the driver shaft into the screw head recess.
– Tighten the knob on the handle to thread the threaded tip of the inner shaft into the mating thread of the screw.
– Advance the sleeve downward to contact the upper surface of the plate by turning the sleeve clockwise.

Remove plate
– After all the screws have been removed, the plate can then be removed.

Please note that precautions/warnings related to implant removal are listed in section "Warnings and Precautions".

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

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