Instructions for Use
Orthodontic Bone Anchor

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

DePuy Synthes
CMF
COMPANIES OF Johnson&Johnson

CE
0123

 EUCMF06002 SE_530423 AC 10/2014

Instructions for Use

Orthodontic Bone Anchor
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques Orthodontic Bone Anchor (036.000.935) carefully before use. Ensure that you are familiar with the appropriate surgical technique.
The systems offer bone screws, plates and their instruments.
All implants are offered either sterile or unsterile and individually packed (plates) or in packs of one or four (screws).
All instruments are offered unsterile. In addition the drill bits are offered also sterile.

All articles are packed with an appropriate package material: clear envelope for unsterile articles, clear envelop with plastic tubes for screwdriver blades and carton with window plus double sterile barriers: double clear blisters (sterile screws and sterile drill bits) or double clear envelopes (sterile plates)

Material(s)

Material(s):	Standard(s):
Plate Material: TiCP	
Standard:	
ISO 5832-2:1999	
ASTM F 67:2006	
Screw Material:	
TAN	
Standard	
ISO 5832-11:1994	
ASTM F1295:2005	
Instrument Materials:	
Stainless Steel:	
Standard	
DIN EN 10088-1&3:2005	
Aluminum:	
Standard	
ASTM B209M:2010	
ASTM B221M:2013	
DIN EN 573-3:2007	
DIN 17611:2000	
PTFE:	
FDA-Compliant	

Intended use
The Orthodontic Bone Anchor (OBA) System is intended to be implanted intraorally and used as an anchor for orthodontic procedures. The OBA system includes screw anchors, plate anchors, instruments, and a module case for storage and sterilization.

Indications
The Orthodontic Bone Anchor (OBA) System is indicated for intrusion and extrusion of teeth, distal and mesial movement of teeth, treatment of anterior cross bite and open bite, space closure, 3-D control of teeth.
Contraindications
The Orthodontic Bone Anchor (OBA) System is contraindicated:
- When cortical bone is less than 5 mm thick, or when there is insufficient quantity or quality of bone
- In deciduous or mixed dentition
- When active or latent infection is present
- In patients with an abnormal habit of mastication, as this may affect the retention and stability of the device after implantation
- Patients with mental or neurosurgical conditions who are unwilling or incapable of following post-operative care instructions.

Side effects
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, nerve and/or tooth root damage or injury of other critical structures including blood vessels, excessive bleeding, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, pain, discomfort or abnormal sensation due to the presence of the device, allergy or hypersensitivity reactions, side effects associated with hardware prominence, loosening, bending, or breakage of the device, mal-union, non-union or delayed union which may lead to breakage of the implant, reoperation.
- Tooth root damage due to screw misplacement
- Anchorage losses
- Undesired tooth movement (tipping, rotation and extrusion)
- Inhibition or restriction of maxillary growth
- Patient ingests or chocks on screw/plate fragment due to excessive loading from orthodontic loads or excessive tooth brushing
- Orthodontic Bone Anchor Plate breaks postoperatively prior to achieving optimum aesthetic positioning
- Orthodontic Bone Anchor screw breaks due to excessive loading

Sterile device

STERILE R Sterilized using irradiation

Store implants 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.
Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or 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, reuse 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.

Precautions
Confirm that plate positioning allows for adequate clearance of nerves, tooth buds and/or tooth roots and any other critical structures.
Use the appropriate amount of screws to achieve a stable fixation.
Irrigate thoroughly to prevent overheating of the drill bit and bone.
Excessive and repetitive bending of the implant increases the risk of implant breakage. Avoid excessive bending and reverse bending of the anchor plate.
Care should be taken to remove any sharp edges after cutting the plate to avoid soft tissue irritation or injury.
Drilling speed should never exceed 1800 rpm. Higher speeds can result in thermal necrosis of the bone and increased hole diameter, and may lead to unstable fixation.
Always irrigate during drilling.
Always drill a pilot hole for the 10 mm self tapping anchor screw.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
Drill bit(s) is (are) combined with power tools.

Magnetic Resonance environment
CAUTION:
Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
- Heating or migration of the device
- Artifacts on MR images

Treatment before device is used
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".

Special operating instructions
Choose the implantation site according to the treatment objective and the quality and quantity of bone.
Confirm that the implantation site allows adequate clearance from the tooth roots and nerves.
Choose the anchor screw with the appropriate thread length: 6 mm and 8 mm self-drilling or 10 mm self-tapping.

If desired, make a small incision at the implantation site and dissect through the soft tissue to the bone.
Using the screwdriver shaft, cruciform 1.55, with holding sleeve and the screwdriver handle with hexagonal coupling, load the anchor screw of the desired length and implant it until the distal lip of the anchor screw head sits on top of the soft tissue.
If a pilot hole is desired, use the appropriate 1.1 mm drill bit with stop and a surgical power drill. Irrigate thoroughly to prevent overheating of the drill bit and bone.
Before implanting a 10 mm self-tapping anchor screw, drill a pilot hole using the 1.25 mm MatrixMIDFACE drill bit with 10 mm stop and a surgical power drill. Irrigate thoroughly to prevent overheating of the drill bit and bone.
Using the screwdriver shaft, cruciform 1.55, with holding sleeve, short and the screwdriver handle with hexagonal coupling implant the 10 mm anchor screw until the distal lip of the anchor screw head sits on top of the soft tissue.
Select the appropriate anchor plate between the mesh design, bracket design or domed design with either 4 or 5 holes.
Consider in advance the reshaping and/or trimming of the plate that may be required to conform to the patient's bony anatomy.
Make an appropriately sized incision where the anchor plate neck will protrude through the soft tissue, orienting the incision perpendicular to the long axis of the anchor plate neck, and dissect through the soft tissue to the bone. Make a subperiosteal pocket large enough to allow insertion of the anchor plate and implantation of the screws for plate fixation.
The anchor plate may need to be reshaped and/or trimmed to conform to the patient's bony anatomy. If so, use the bending pliers 3D, left, for Plates 1.0 to 2.0, with contour bending function and/or combined pliers for plates 1.0 to 2.0, for cutting and bending. The anchor plate has a T-configuration, but it may be trimmed to an L- or I-configuration, if it isrequired.
If desired, use the bending pliers 3D, left, for plates 1.0 to 2.0, with contour-bending function to reshape the anchor plate neck where it will protrude through the soft tissue.
Avoid excessive bending and reverse bending of the anchor plate.
Care should be taken to remove any sharp edges after cutting the plate to avoid soft tissue irritation or injury.
Choose the screws for plate fixation of the appropriate length(s). Make certain that they will avoid the tooth roots and nerves.
While holding the anchor plate in the desired location in the subperiosteal pocket, use the screwdriver shaft MatrixMIDFACE, self-holding, with hexagonal coupling and the screwdriver handle with hexagonal coupling to insert the first screw.
Repeat this process for the remaining screws. It is recommended to use at least three screws to secure the anchor plate.
If pilot holes are desired, make one for each screw using the appropriate 1.1 mm drill bit with stop and a surgical power drill.
Irrigate thoroughly to prevent overheating of the drill bit and bone.
If the screw for plate fixation becomes loose in the bone, remove the screw and replace it with the appropriatelength of MatrixMIDFACE emergency screw ø 1.8 mm, self-tapping.
Irrigate the subperiosteal pocket until it is free of debris, and surgically close the incision. Confirm that the stability of the anchor plate is satisfactory.
The anchor plate neck is malleable and can be adjusted if necessary.
Apply orthodontic devices directly to abutment on plate as desired.
Mount a standard orthodontic bracket to the mesh anchor plate using a standard adhesive approved for this intended use and indication.
Apply the standard adhesive directly to the top surface at the end of the mesh anchor plate and spread it evenly over the surface. Add adequate adhesive to the mesh pad of the orthodontic bracket and firmly press the bracket onto the surface of the anchor plate, adjusting the orientation of the bracket as needed. Excess adhesive may be wiped away from the sides and bottom of the mesh anchor plate. Follow the instructions for use of the manufacturer of the adhesive.

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from http://www.synthes.com/reprocessing

CE
0123

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
www.synthes.com