Instructions for Use
Subcondylar Ramus Fixation Set

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Instructions for Use

Subcondylar Ramus Fixation Set
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques 036.000.564 carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Instrument(s):	Material(s):	Standard(s):
Screws, Sleeve, Hook, Retractor, Elevator, Forceps, Handle, Screw Driver Shaft, Drill Bit, Wrench	Stainless steel	ISO 7153-1
Optical retractor handle	Aluminum alloy	DIN EN 573
Plate holder	PPSU	ISO 16061
–	PA 6.6	ISO 7153-1
Manipulator Handle	ULTEM	according supplier specifications

Intended use
The Subcondylar Ramus Fixation set includes specialized instrumentation to support the endoscopic treatment of trauma and orthognathic surgery involving the subcondylar / ramus region of the mandible.
The Subcondylar Ramus Fixation set is intended for endoscopic intraoral and submandibular approaches to subcondylar fractures only.

Indications
Subcondylar Fracture Management
– Endoscopic or open treatment of a noncomminuted subcondylar fracture of the mandible with plate and screw fixation in which a minimum of two screws can be placed through a plate into the proximal fracture fragment.
– Reduction of dislocated fracture fragment.

Orthognathic Surgery
– Endoscopic or open orthognathic procedures involving the ramus and condylar region of the mandible such as:
  – vertical ramus osteotomy with rigid fixation
  – condylectomy
  – condylotomy

General Adverse Events
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, neurological impairments, etc.), thrombosis, embolism, infection 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 hyperreactions, 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.

Device Specific Adverse Events
Device specific adverse events include but are not limited to:
Screw Loosening/pull out, Plate breakage, Explantation, Pain, Seroma, Hematoma, Infection.

Warnings
These devices can break during use (when subjected to excessive forces or outside the recommended surgical technique). While the surgeon must make the final decision on removal of the broken part based on associated risk in doing so, we recommend that whenever possible and practical for the individual patient, the broken part should be removed.

Medical devices containing stainless steel may elicit an allergic reaction in patients with hypersensitivity to nickel.

Precautions
Sufficient periosteum must be elevated from the posterior border of the ramus to allow placement of the optical retractor.

The patient should not be paralyzed during insertion of the trocar so stimulation to the facial nerve can be identified and the trocar redirected if necessary. Initial spreading dissection with a clamp prior to trocar insertion is helpful.

This device should be used only in healthy bone, in an area with adequate bone stock to prevent splitting the bony margins.

If the screwdriver handle is not replaced, loss of reduction and bending of the Manipulation Screw ∅ 1.9 mm may occur.

The Manipulation Screw ∅ 1.9 mm [386.902] is single use only and should be discarded after use.

It is important that the incision be at the mandible angle, to allow an endoscope to fit in the wound parallel to the anterior/posterior borders of the vertical ramus.

Address other fractures, if present, prior to subcondylar fracture fixation.

Sufficient periosteum must be elevated from the sigmoid notch to allow placement of the optical retractor.

To prevent damage to the endoscope, the appropriate sheath must be used.

Notes
Fit a suction tube onto the back end of the Freer Suction Elevator and activate suction by placing a finger over the port.

Low-profile, right-angled drills can be used in this application.

Use the Retractor, curved, double-ended [U44-48220] and Retractor, straight, double-ended [398.415] or the Freer Suction Elevator [386.906] to maximize visualization and access. Fit a suction tube onto the back end of the Freer Suction Elevator and activate suction by placing a finger over the port.

The optical retractor assembly consists of two parts, the Handle for Optical Retractor [386.915] which accepts a lighted endoscope with sheath (2.7 mm – 4.0 mm), and the Insert for Optical Retractor, available in two widths, 12 mm [386.917] and 17 mm [386.918]. The 12 mm blade is typically used for the submandibular approach, requiring a smaller extraoral incision. The 17 mm blade is typically used for the intraoral approach.

Distraction can also be achieved by passing wire through a predrilled hole at the angle, twisting the free ends, and pulling inferiorly. This reduces the number of instruments through the incision.

Combination of medical devices
Drill bit is (are) combined with power tools.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to: http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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