
Instructions for Use Subcondylar Ramus Fixation Set

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

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.

Material(s)

Material(s):	Standard(s):
Stainless steel	ISO 7153-1
Aluminum alloy	DIN EN 573
PPSU	ISO 16061
PA 6.6	ISO 7153-1

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 sub- mandibular 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

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.

Precautions

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

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

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 Threaded Fragment Manipulator may occur.

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

The Threaded Fragment Manipulator 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.

Use the Double-Ended Elevators, curved [U44-482-20] and straight [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 Optical Retractor Handle [386.915] which accepts a lighted endoscope with sheath (2.7 mm – 4.0 mm), and a Retractor Blade, 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.

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

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

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 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>

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