O.S.2°-C & O.S.2°-V

Compression Staple – PEEK
Static Staple - Stainless steel
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O.S.2°-C

Compression staple – PEEK
The O.S.2® staples are indicated for fixation of arthrodesis, osteotomies and fractures in hand or foot surgery. The size of the staple selected should be appropriate for the specific indication.

The O.S.2® staples are available for the NeoSys® single use instrumentation.

O.S.2®-C - Compression staple

- The O.S.2® compression staple is the first osteosynthesis staple manufactured in PEEK-OPTIMA®. This material is recognised for its mechanical properties and radio-transparent qualities in numerous orthopaedic applications.

- The range of compression staples is available with a centre distance of 11mm, 13mm and 15mm with a constant legs length of 15/17 mm.

- The O.S.2®-C staple enables a constant and reproducible compression. The radio-transparent qualities of PEEK-OPTIMA® enable ease of control of bone synthesis.

- The OS2-C compression staple is delivered sterile, ready to use pre-assembled on its inserter.

*Peek-Optima® is a registered trademark of INVIBIO®
RADIO-TRANSPARENT

- PEEK-OPTIMA® is radio transparent. This enables a good level of control of bone consolidation.

COMPRESSION

- The legs of the compression staple converge at 20°. Compression is linked to the mechanical properties of the material. Storage and use of the staple do not require temperature management.

DESIGN

- The legs of the compression staple are a constant length of 15/17mm. It is possible to adapt and shorten the legs by 2mm increments corresponding to each teeth height. Their leg length difference eases insertion.

PRIMARY STABILITY

- The design of the teeth of the compression staple ensure primary stability as soon as they are inserted.
PACKAGING

- The OS2-C staple is delivered sterile on its inserter 1 together with 2 2.5mm diameter drilling wires (lg 70 and 100mm) 2. The staple 3 pre-positioned on the inserter 4, is ready to be loaded.

LOADING OF THE STAPLE

- The staple loading 1 allows the legs to be positioned parallel to each other and thus to permit impaction. Loading the staple also releases the drilling wires for pre-drilling.

IMPLANTING

- Once the staple loaded on its inserter, it is yet ready to be implanted.
- It will be released thanks to the push-button 1.
INSTRUMENTATION

The O.S.2® compression staple range is available with NeoSys® single use instrumentation or with re-usable instrumentation.

- DRILL GUIDE ①
  The drill guide is included with the NEOSYS® instruments and fits the universal Handle. Drilling wires are supplied with each implant.

- DEPTH GAUGE ②
  Allows measuring of leg length.

- INserter ③
  The inserter is adapted to each staple width. It permits positioning and implanting of the staple with one hand only.

- IMPACTOR ④
  The implant holder, once repositioned on the inserter can be used as an impactor.
**INDICATIONS**

- The O.S.2® staples are indicated for fixation of arthrodeses, osteotomies and fractures in hand or foot surgery.
- The Staple size will be chosen according to its specific indication.

**CONTRAINDICATIONS**

- The implant should not be implanted in patients who currently have or have had:
  - acute or chronic local inflammations, whether local or systemic
  - active infections
  - allergy or intolerance to foreign materials, whether suspected or known.
  - vascularisation disorders; a pathological condition of the soft tissues to be sutured to the bone, liable to undermine the rigidity of the fixation by the structure
  - bone deviation, severe osteoporosis, loss of bone mass
  - bone pathologies such as acute cystic developments or acute osteopenia that risk preventing proper drilling of a clean hole or compromising the rigidity of the fixation of the implant
  - the use of steroid derivatives, chemotherapy, ... etc.
OS2®-C Staple Surgical Technique

In2Bones® as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.
The OS2®-C staple is delivered sterile pre-assembled on its inserter with 2 drilling-wire of 2.5mm diam. (70 and 100mm). The staple is protected inside the inserter.

**Set-up**
- Arm the inserter-staple by bringing the 2 pieces together.
- Thus the staple is set under compression and its legs are parallel (0°), the 2 drilling-wires are freed from the inserter and should be kept aside.

- Remove the Staple Holder-protector: the staple can now be implanted.

DO NOT DISCARD THE HOLDER – PROTECTOR at this stage as it is used as impactor at the last stage of the procedure.
2 - BONE PREPARING

- Assemble the drill-guide on the Inserter (opposite to the staple) or on the Neosys® Handle should you be using the Neosys® single use instruments set.

- Place the guide on the bone bridging the osteotomy and select Staple size. The Osteotomy should at equal distance from the 2 drilling shafts.

- Use the 2,5mmDiam lg 70mm drilling-wire to drill the first leg of the staple.

- Leave the drilling-wire on site and drill the second hole using the 2,5mm diam. Lg 100mm drilling-wire.

- Should a 15mm interaxis staple be used, the 2 distal holes of the guide must be used.
3 - STAPLE IMPLANTING

- Implanting
  - Guide the staple in the prepared holes. The leg length offset facilitates implantation ①.
  - The 2 legs being inserted use the Inserter push-button to release the implant ②.
  - The Staple protector can then be re-assembled on the inserter and used as an impactor to finalize staple insertion ③.

- Once released from the inserter the staple resumes to its original form; converging legs will provide desired compression ④.
The O.S.2® staples are indicated for fixation of arthrodesis, osteotomies and fractures in hand or foot surgery. The size of the staple selected should be appropriate for the specific indication.

The O.S.2® staples are available for the NeoSys® single use instrumentation.

**O.S.2®-V - Static staple**

- The O.S.2® -V staple is delivered sterile pre-loaded on its inserter.
- It is available in 8 or 10 mm interaxis with 2 available angles: 26° or 90°.
- Once implanted the staple is freed from its inserter with a slight flexion to release the locking mechanism.
- The inserter can be used either as stand-alone instrument or assembled on the Neosys® Universal handle to increase the lever-arm at release.
INSTRUMENTATION

- The O.S.2®-V staples are available together with the Neosys® single use instruments set or with a conventional metallic instruments set.

- DRILL GUIDE ①
  The O.S.2®-V drill guide is included in the instruments set and connects to the universal Neosys® handle.

- INserter ②
  Adapted for each implant it allows the implantation and release of the staple by a single hand.

- IMPACTOR
  Once the inserter has been detached from the staple, it can be closed and used as an impactor.
INDICATIONS

- The O.S.2® staples are indicated for fixation of arthrodeses, osteotomies and fractures in hand or foot surgery.
- The Staple size will be chosen according to its specific indication.

CONTRAINDICATIONS

- The implant should not be implanted in patients who currently have or have had:
  - acute or chronic local inflammations, whether local or systemic
  - active infections
  - allergy or intolerance to foreign materials, whether suspected or known.
  - vascularisation disorders; a pathological condition of the soft tissues to be sutured to the bone, liable to undermine the rigidity of the fixation by the structure
  - bone deviation, severe osteoporosis, loss of bone mass
  - bone pathologies such as acute cystic developments or acute osteopenia that risk preventing proper drilling of a clean hole or compromising the rigidity of the fixation of the implant
  - the use of steroid derivatives, chemotherapy, ... etc.
In2Bones® as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.
1 - BONE PREPARING

- Introduce the inserter on the NeoSys® handle. ①.

- Position the guide against the bone to select the appropriate implant size (width) and drill the leg holes using the 1,0mm k-Wires supplied with the Neosys® set (1,0mm Diam. Lg 70mm) ②.

- Either hold the guide firmly and drill the second hole or leave the k-wire in situ and use a second k-wire (1,0mm diam. Lg 100mm) to drill the second hole ③ at the desired width: 8 ④ or 10mm ⑤.
2 - STAPLE INSERTION

- The staple is delivered sterile pre-loaded on its inserter.

- Either use the staple as delivered or fit the inserter on the NeoSys® handle to increase the lever arm releasing effect ①.

- Inserting the staple
  - Position the staple legs tips in the prepared holes ②
  - Firmly engage the staple and once fully inserted release the implant by a flexion on the inserter ③ so that the locking hook unlocks ④. The implant is thus released from the inserter.

- Impact the implant if needed. The inserter, closed, can be used to impact the implant or a small graft impactor can be used as well. ⑤
## IMPLANTS

- **O.S.2®-C**
  - T30 SP110 ···· O.S.2®-C Compression Staple ···· Interaxis 11mm ···· Lg 15/17mm
  - T30 SP130 ···· O.S.2®-C Compression Staple ···· Interaxis 13mm ···· Lg 15/17mm
  - T30 SP150 ···· O.S.2®-C Compression Staple ···· Interaxis 15mm ···· Lg 11/13mm

- **O.S.2®-V**
  - T10 SS260 ···· O.S.2®-V Static Staple - kit - Diam 1mm ···· Interaxis 10 mm ··· 26°
  - T10 SS268 ···· O.S.2®-V Static Staple - kit - Diam 1mm ···· Interaxis 8 mm ··· 26°
  - T10 SS900 ···· O.S.2®-V Static Staple - kit - Diam 1mm ···· Interaxis 10 mm ··· 90°
  - T10 SS908 ···· O.S.2®-V Static Staple - kit - Diam 1mm ···· Interaxis 8 mm ··· 90°

## INSTRUMENTS

- **Single use instrumentation**
  - G02 10001 ···· NEOSYS® KIT - OSTEOSYNTHESIS SINGLE USE INSTRUMENTS

- **Re-usable instrumentation**
  - G01 00881 ···· UNIVERSAL HANDLE
  - T02 00061 ···· COMPRESSION STAPLE DRILL-GUIDE
  - T01 00031 ···· STATIC STAPLE DRILL-GUIDE
  - G01 00891 ···· MEASURER
  - G01 00901 ···· DEPTH GAUGE
  - G01 10011 ···· NEOSYS® CONTAINER
  - G01 10021 ···· NEOSYS® CONTAINER LID
RECOMMENDATION
- It is recommended to carefully read the instructions for use available in the package insert.

DEVICES
- Implants:
  - STAPLE: CE Class IIb - CE0499
- Instruments:
  - Single use instruments: CE Class IIa - CE0499

REIMBURSEMENT
- Reimbursement may vary from countries to countries. Check with local authorities.

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DOCUMENT
- Reference: ST-OS2-En-012014
- Revision date: 01/2014
- Version 01

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.
Always refer to the appropriate instructions for use for complete clinical instructions.
Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
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