

OS2[®]-V

VARISATION STAPLE



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Indications

The OS2®-V Varisation staples are indicated for Akin type osteotomies.

Contra-Indications

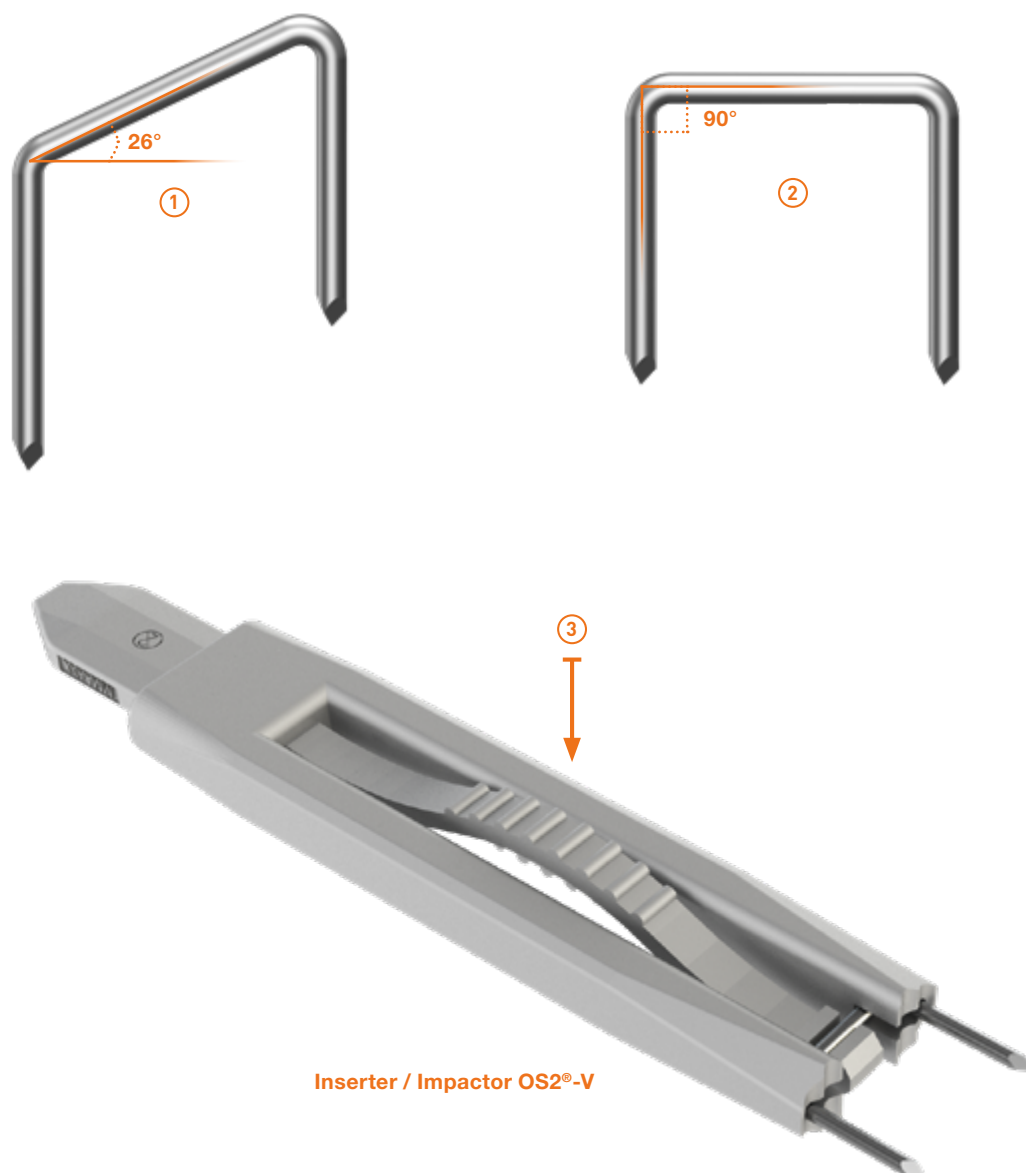
The implant should not be used in a patient who has currently, or who has history of:

- acute or chronic systemic inflammations,
- active infections,
- sensitivity/allergies to the implant material (316L).

OS2®-V

PRODUCT DESCRIPTION

- The OS2®-V variation staple is indicated for Akin type osteotomies.
- It is delivered sterile pre-loaded on its inserter, and the drill guide is packaged with the implant
- It is available in 8 or 10 mm interaxis with 2 available angles: 26°^① or 90°^②.
- Once implanted the staple is freed from its inserter by pushing the button to release the locking mechanism. ^③
- The inserter can be used either as stand-alone instrument or assembled on the Neosys® Universal handle to increase the lever-arm at release.



Single use instruments

DRILL GUIDE

the OS2V drill guide is available with the implant and can be connected to the universal Neosys handle. Please refer to the Neosys brochure for further information.

INSERTER

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.

A Neosys single use instrument set can be used as a complementary of the OS2V instruments in case :

- if the surgeon wants to use the universal Neosys handle,
- if the surgeon wants to use K-wires (Diam. 1.0mm, Lg 70mm or Lg 100mm,
- if the surgeon wants to do an additional surgical procedure.

Please refer to the Neosys brochure.



OS2®-V

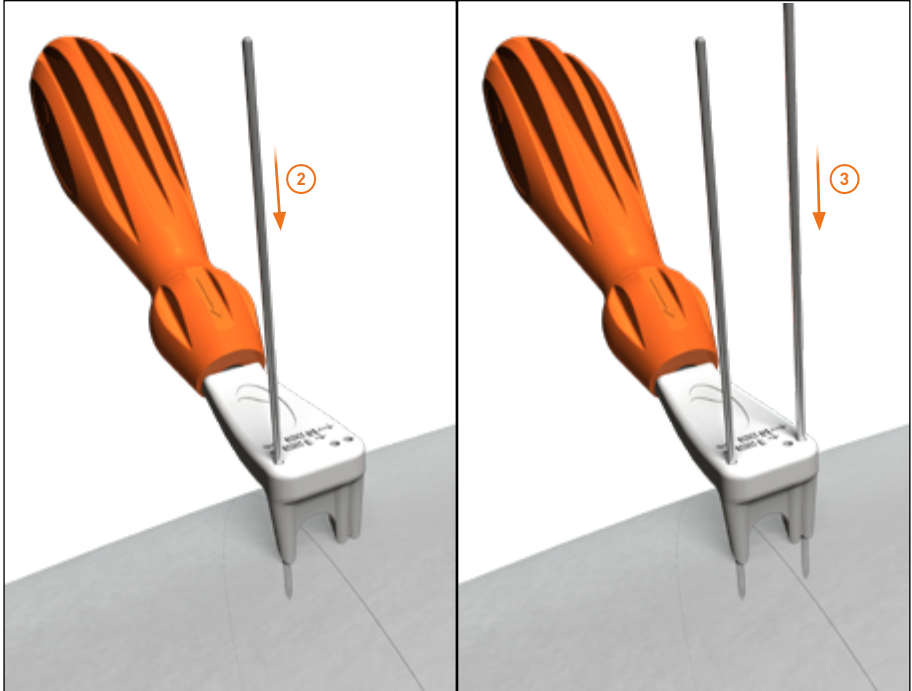
SURGICAL TECHNIQUE

In2Bones® as the manufacturer of this device, does not practice medicine. The surgeon who performs any implants procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient. This surgical technique manual is furnished for information purposes, as an aid to use properly the device and its dedicated instruments.

1 - Bone preparation



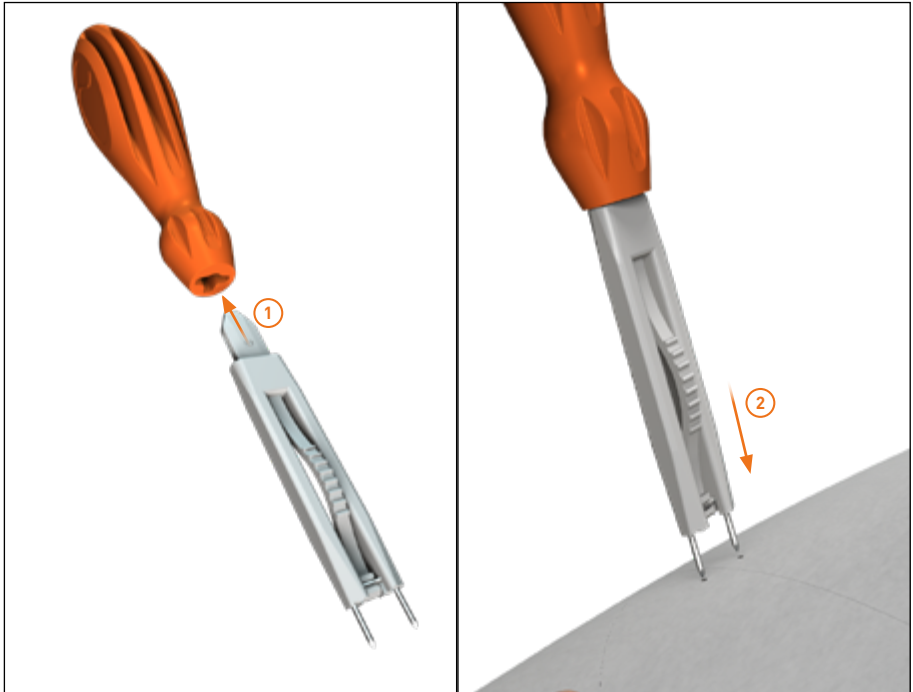
Introduce the drill guide on the NeoSys® handle ①.



Position the guide against the bone to select the appropriate implant size (width) and drill the leg holes **A** using the 1,0mm k-Wires supplied with the Neosys® set (Diam. 1.0mm, 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 (Diam. 1.0mm, Lg 100mm) to drill the second hole ③ at the desired width : 8mm **B** or 10m **C**.

2 - Staple Insertion

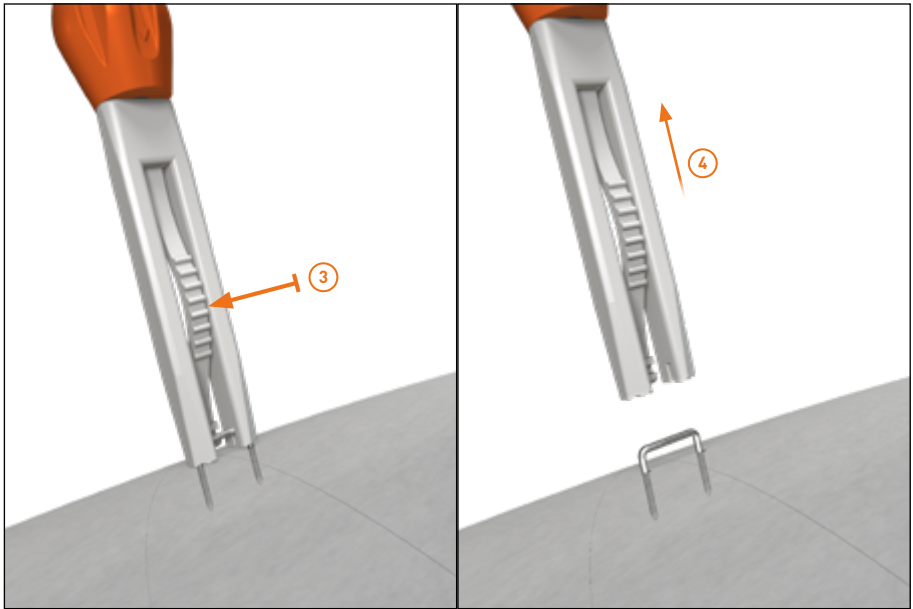


The staple is delivered sterile and pre-loaded on its inserter.

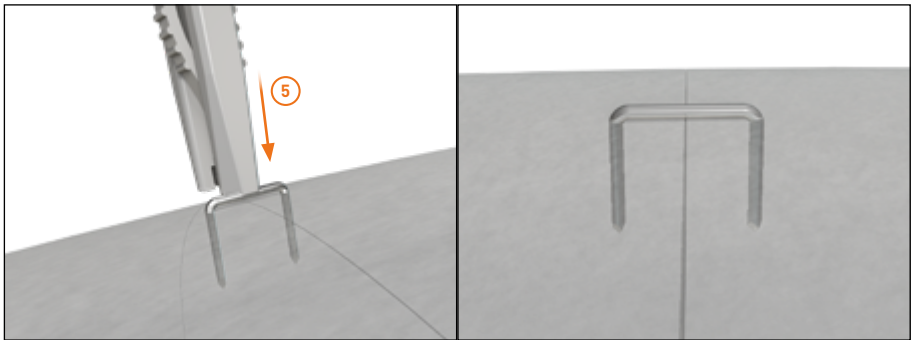
Either use the staple as delivered or fit the inserter on the NeoSys® handle to increase the lever arm releasing effect. ①

Inserting the staple:

- Position the staple legs tips in the prepared holes ②



- Firmly engage the staple and once fully inserted release the implant from the holder. ③ ④



- Impact the implant if needed. The inserter, can be used to impact the implant ⑤ or a small graft impactor can be used instead.

IMPLANTS

OS2[®]-V - Varisation Staple Kit



Designation	Interaxis	Angle	Ref
OS2 [®] -V - Diam. 1 mm	10 mm	26°	T10 SS260
OS2 [®] -V - Diam. 1 mm	08 mm	26°	T10 SS268

Designation	Interaxis	Angle	Ref
OS2 [®] -V - Diam. 1 mm	10 mm	90°	T10 SS900
OS2 [®] -V - Diam. 1 mm	08 mm	90°	T10 SS908

INSTRUMENTS

All the instruments necessary to implant an OS2-V staple are available together in the implant packaging.

The additional use of a Neosys single use set depends on the surgeon's technique.

Please refer to the Neosys brochure for further information.

RECOMMENDATION

It is recommended to carefully read the instructions for use available in the package insert.

DEVICES

CE Classification (Directive MDD 93/42/EC)

- Implants : Class CE IIb - CE2797
- Single use instruments: Class CE IIa - CE2797

REIMBURSEMENT

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

MANUFACTURER

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DOCUMENT

Reference : ST-DIG-OS2V-EN-092020

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.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

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