INSTRUCTIONS FOR USE
VARISATION STAPLE

Product Description

Varisation Staples are implantable devices, class IIb, specifically designed for use in forefoot surgery. They are made from Inox 316L in compliance with ISO 58312-1 standards. The staples are sterilized using gamma irradiation within a dose range of 25 to 42 kGy. They are intended for single-use only and are supplied sterile, packaged in double-blister packaging for optimal safety and sterility. Varisation Staples should only be used with the appropriate Ortho Cape instrumentation.

Varisation Staples are designed for ease of use and enhanced surgical performance. They are available in a range of lengths to meet different surgical needs.

	Varisation Staple 90°	**Varisation Staple 26°**
Dimensions	center distance 8mm or 10mm	center distance 8mm or 10mm
Reference	14.55.02 / 14.55.04	14.55.01 / 14.55.03

Intended purpose

Varisation Staples are used for osteosynthesis and realignment of small osseus fragments, and phalangeal shortening osteotomy, Akin osteotomy procedures.

Medical condition to be treated

Osteotomies, replantations and fusions of small bones.

Intended User/ Intended patient population

Varisation Staples is intended for use exclusively by orthopedic surgeons.

Ortho Cape, as the manufacturer of the Varisation Staples, strongly recommends that users review all relevant documentation before the first use. This includes instructions for use and surgical technique guides. Users must be familiar with the latest medical practices and fully understand the functionality of both the instruments and implants. The surgeon bears responsibility for selecting appropriate patients based on the system's specific indications and contraindications, along with patient-related factors such as activity level, occupation, mental health, age, and bone quality.

There is no specific patient population in terms of sex. The target population for the devices are teens and adults with fractures needing of osteotomies, replantations and fusions of small bones.

Contraindications

- Patients with a known allergy or hypersensitivity to one of the material components; **Not for use with nickel-allergic patients**
- Any active infection, either systemic or localized at the implantation site, is a contraindication due to the risk of infection spreading or preventing proper healing;
- Poor bone quality: conditions such as osteoporosis, osteopenia, or other bone diseases that lead to weak or insufficient bone density make the use of implants unsuitable because they cannot anchor properly in compromised bone structures;
- Mental or neurological conditions: Patients who are unable or unwilling to follow postoperative care instructions - due to factors such as mental illness, substance abuse, or cognitive impairments - are at a higher risk of implant failure.

Note: Contraindications can be either relative or absolute. Users of this device must carefully assess the potential benefits versus the possible risks, taking into account the patient's overall clinical evaluation along with the specific contraindications listed above. Each case should be thoroughly evaluated to ensure the safety and effectiveness of the device for each patient.

Possible Adverse Effects

Adverse reactions are a possibility with any surgical procedure. Below are potential adverse effects specific to orthopedic devices, though this list is not exhaustive and does not account for all possible complications associated with surgery.

- Implant loosening due to inadequate fixation;
- Metal hypersensitivity or allergic reactions to the implant material;
- Bone complications: necrosis, osteoporosis, poor revascularization, bone resorption, or insufficient bone formation, which can lead to early implant failure or breakage;
- Soft tissue irritation or nerve damage resulting from surgical trauma;
- Infections: superficial or deep, occurring either early or late post-surgery;
- Fibrotic tissue reactions around the surgical area;
- Difficulty in implant removal, especially due to improper explantation or bony ingrowth.

Note: The adverse effects listed here are not exclusive to staples and may occur with any orthopaedic implant. If any complications arise in connection with the implants or surgical instruments, please notify Ortho Cape's Quality Department immediately at qualite@ortho-cape.com or respective national competent authority of the state in which the user and/or patient is established.

Warnings and Precautions

- Post-operative care:
  - The device is not designed to withstand an immediate load after surgery and does not allow for immediate resumption of the patient's activities. If necessary, immobilise during osteosynthesis.
  - Premature loading or excessive muscular activity must be avoided by patient to prevent complications.
- Proper handling of the implant is crucial. Avoid bending or altering the device. Implants should not be modified or adjusted in any way;
- The surgeon must select the appropriate size and dimensions of the implant to match the patient's physiological needs and the specific requirements of the osteosynthesis procedure being performed.
- The device should NOT be implanted in contact with other metallic materials of different chemical compositions, as this can lead to an electrochemical reaction, potentially causing galvanic corrosion. Such corrosion can compromise the integrity of the implant and may increase the risk of failure or adverse tissue reactions.
- Patients should be instructed to report any unusual changes around the surgical site (e.g., signs of infection) to their physician immediately.
- The varisation staple has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artefact in the MR environment. The safety of varisation staple in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- Patients must inform healthcare providers that they have a metal implant prior to undergoing MRI or CT scans. The professional conducting the examination will assess the safety of the implant, potential risks to the patient, and any risks of imaging artifacts or loss of information.
- Upon opening the peelable blister, ensure the preservation of the adhesive tracking labels (one for reordering, four for the patient's file).
- Failure to follow indications and contraindications can lead to potential adverse effects, including infection, subclinical neurological sequelae, arterial perforation, tendon issues, metal hypersensitivity, loosening, bending, or fracture of the device and/or bone. Do not use in patients with a known allergy to the implant material.
- The surgeon must carefully control of the speed and force of insertion of screw during surgical procedure. It is the responsibility of the surgeon to ensure safe use.
- The implant is intended for single use and must not be reused under any circumstances.
- Never use products that have been damaged by transport, improper handling in the hospital, or in any other way.
- Removal of Varisation Staples may be warranted if deemed medically necessary in order to avoid possible adverse effects.
- Explanted device(s) should be placed in medical waste disposal containers and disposed of according to the facility procedures and required compliance regulations.
- If an implant fails prematurely, and a link to its geometry, surface quality, or mechanical stability is suspected, please return the device to Ortho Cape in a properly cleaned, disinfected, and sterilized condition for further analysis.
- The manufacturer is not responsible for complications resulting from incorrect diagnosis, improper implant selection, or the use of incompatible implants or instrumentation.

Surgical Technique

The use of these implants requires specific ancillary equipment provided by ORTHO CAPE

- Make one distal hole in the distal fragment, directed forward and outward
- Insert the staple with the straight staple driver(90°) or the oblique staple driver (26°)
- Finish with the impactor (90° or 26°)

Storage

Implants should be stored in their original, undamaged packaging in a clean, dry environment at room temperature. The products must not be stored for extended periods at temperatures below 10°C or above 33°C to avoid compromising their integrity or sterility. Additionally, they should be kept away from direct sunlight, excessive heat, and moisture.

Symbol	Description	Symbol	Description	Symbol	Description
	Consult instructions for use	2803	Notified Body number		Temperature limitation
	Device reference		Unique Device Identifier		Do not reuse
	Lot number		Keep away from rain		Double sterile barrier system
	Medical device		Do not resterilize		Use by date
	CE marking		Don’t use if package is damaged		Manufacturing date
	Manufacturer symbol		Sterilized using irradiation		Attention, see instruction for use

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