

ENGLISH

CLOUZ OneKnot

POLYESTER**DEVICE DESCRIPTION**

CLOUZ OneKnot is a suture with a pre-tied knot for surgical closure and fixation. The CLOUZ OneKnot device provides a single pre-tied sliding and locking knot that enables easy and fast tissue approximation and fixation with a surgical knot.

CLOUZ OneKnot Polyester consists of a polyester suture armed with a surgical needle and a pre-tied, open knot. The suture is a non-absorbable, green braided polyester suture with a silicone coating, medical silicone elastomer MED2174.

CLOUZ OneKnot Polyester is available sterile in various product lengths and USP sizes 0 through 5-0. It is single armed and offered with a variety of needle sizes (see TECHNICAL INFORMATION).

Refer to the use directions and illustrations below for use of device.

INTENDED PURPOSE

CLOUZ OneKnot Polyester is intended for use in general soft tissue approximation and/or ligation, excluding any use in cardiovascular, ophthalmic and neurological procedures. CLOUZ OneKnot delivers a single knot and is intended for single use only.

INDICATIONS

CLOUZ OneKnot Polyester has been developed for fast and efficient placement and closure of surgical knots anywhere the use of non-absorbable sutures is appropriate. The non-absorbable suture may be removed upon healing or left in place indefinitely.

PERFORMANCE

The polyester suture elicits a minimal initial inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue. The polyester herein is not absorbed, nor degraded or weakened by tissue enzymes. The polyester fiber suture material is pharmacologically inactive. Because of its relative inertness and lack of adherence to tissue, the polyester thread may be removed easily and painlessly, and is hence effective as a pull-out suture.

CONTRAINDICATIONS

Use in patients with known sensitivities or allergies to polyester and/or silicone.

WARNINGS/ PRECAUTIONS

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures prior to employing CLOUZ OneKnot. Misuse of this suture, like any other suture, can result in severe injury or death to the patient. When handling the suture, care should be taken to avoid any damage of the material from handling of surgical instruments, such as forceps or needle holders.

Care should be taken when handling surgical needles. Grasp the needle at approximately $\frac{3}{4}$ distance away from the pointed end in order to avoid bending or breakage of the needle. Users should exercise caution to prevent needle-stick injury. Used needles should be discarded in sharps containers. Do not resterilise or reuse the device.

MRI SAFE

Polyester suture in the body poses no known hazards resulting from exposure to any MR environment.

POTENTIAL ADVERSE EVENTS

Adverse reactions associated with the use of this device include minimal initial inflammatory tissue reaction and transient local irritation at the wound site. Any adverse reaction related to the use of this device must be reported to the legal manufacturer, Clouz GmbH, and to the national competent authorities.

STERILITY

CLOUZ OneKnot is sterilised by Ethylene Oxide (EtO). Do not reuse or resterilise. Attempts to reuse or resterilise the device may result in patient harm, device malfunction, or inadequate sterilisation. Do not use if packaging is damaged or has been unintentionally opened before use.

STORAGE

Store CLOUZ OneKnot in a dry place outside of direct sunlight and other heat sources. Do not use after the expiry date.

DISPOSAL

Please dispose of this product or waste material with particular care due to the potential risk of contamination and/or injury. Used needles should be discarded in sharps containers. Improper handling of waste may have negative effects on the environment and on human health. Observe the specific national regulations.

WARRANTY AND LIMITATION

Clouz GmbH warrants that each component of this product has been manufactured, packaged and tested with all reasonable care and will be free from defects in workmanship and material. Clouz will not be liable for any incidental, special or consequential loss, damage or expense, direct or indirect, from the use of its product. Clouz's sole obligation shall be to replace at its option, any device that we deem was defective at time of shipment if notice thereof is received within six (6) months. User assumes all liability, whether arising on warranty, contract, and negligence or otherwise for damages resulting from the handling, possession, use or misuse of the product. Because Clouz has no control over the operation, inspection, maintenance or use of its products after distribution and has no control over the selection of patients, THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER. The remedies set forth in the Warranty and Limitation shall be the exclusive remedy available to any person.

TECHNICAL INFORMATION

Suture length (cm)	65, 90, 120
Suture USP	0, 2-0, 3-0, 4-0, 5-0
Needle type	1/2 Circle, 3/8 Circle, 5/8 Circle
Needle length (mm)	17, 19, 22, 24, 26, 31, 36, 40
Device Weight (gram)	20
Device Size (mm)	40 x 80 x 2.5

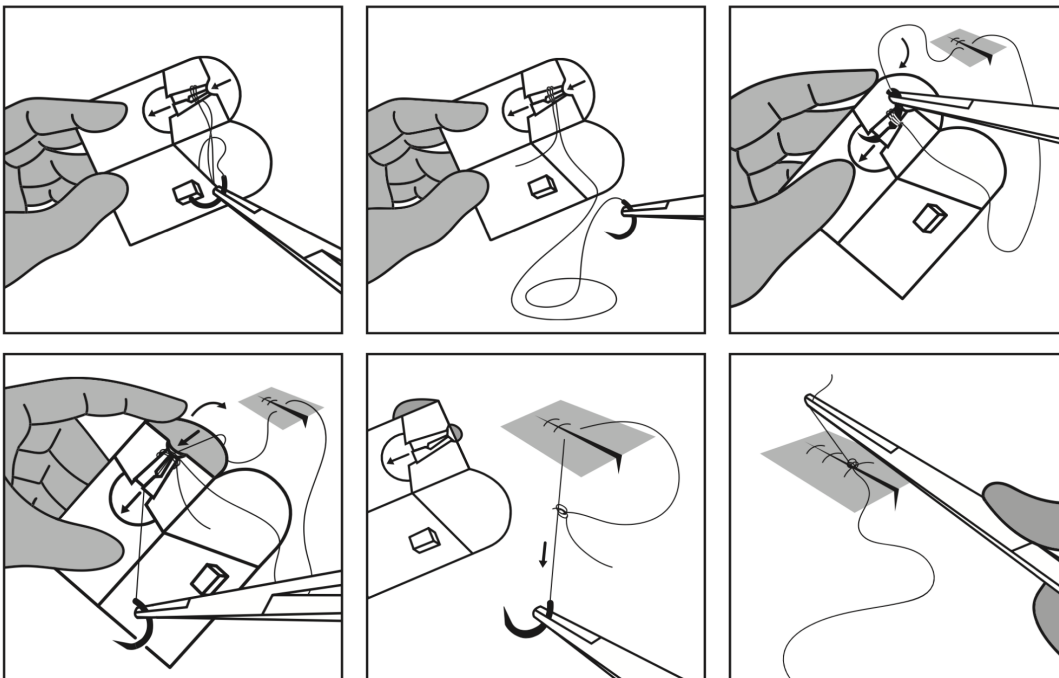
MANUFACTURER INFORMATION

Clouz GmbH
Schinkestr. 9
12047 Berlin
Germany

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DIRECTIONS FOR USE

1. Grasp the needle with an appropriate instrument and pull the suture from the suture pouch.
2. Stitch as required per surgical procedure.
3. To activate knot, pass the needle through the knot holder in direction indicated by arrows.
4. Push down the tip of the paper device and pull suture through the knot loops.
5. Hold the longer thread taut, let go of short end and let the knot slide down to the tissue. Alternatively, hold the longer thread taut and push the knot to the tissue, as appropriate per procedure.
6. To lock the knot, release tension on the long end of thread and pull lightly on the short end.
7. Cut any remaining thread ends and discard the needle.



REGULATORY INFORMATION

Summary of Safety and Clinical Performance is available on www.clouz.one.

Basic UDI-DI: 426074624clz1kUB

EUDAMED DE-MF-000007330: <https://ec.europa.eu/tools/eudamed/#/screen/search-ef/ff8889ef-dea4-4c97-bb29-7fd2a7ae6170>















DECLARATION OF CONFORMITY





Clouz hereby declares that CLOUZ OneKnot is in compliance with the Medical Device Regulation (MDR) and with applicable standards and regulations thereof.

A full text of the EU declaration of conformity may be requested via email to: info@clouz.one.

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SYMBOLS USED IN IFU AND LABELLING OF PRODUCT

	Conformity with European regulatory standards
	Product code
	Batch code
	Sterilization method using ethylene oxide
	Do not reuse
	Caution: read instructions for use
	Manufacturer
	Date of Manufacturing
	Use by Date
	Unique Device Identification
	Do not use if package is damaged.
	Do not reuse
	Caution: read instructions for use
	Medical Device
	MRI safe
	Temperature limit recommendations
	Keep away from moisture
	Keep away from direct sunlight
	Not for General Waste

	Needle shape
1/2c 3/8c 5/8c	Needle curvature
	Needle point type: Reverse Cutting
	Needle point type: Taper Cut
	Needle point type: Taper Point