TAYLOR STITCHER

& STN SUPERELASTIC TRANSOSSEOUS NEEDLE

# DATA SHEET



A product by NCS Lab Srl.

DATA SHEET

# TAYLOR STITCHER

## 1. INDICATIONS

Taylor Stitcher is a surgical instrument to create transosseous curved tunnels for the treatment of lesions to the shoulder rotator cuff. It is suitable both for arthroscopic and mini-open surgical technique.

## 2. DESCRIPTION AND FEATURES

The surgical instrument Taylor Stitcher is composed as shown in Figure 1.

The disposable Superelastic Transosseous Needle STN assembled on the surgical instrument Taylor Stitcher allows the realization of one or more transosseous tunnels, having in common a lateral entry hole and one or more medial exit holes.

The use of the targeting system assembled on Taylor Stitcher, allows to locate the medial exit of the transosseous tunnel.

## 3. ACCESSORIES AND TOOLS

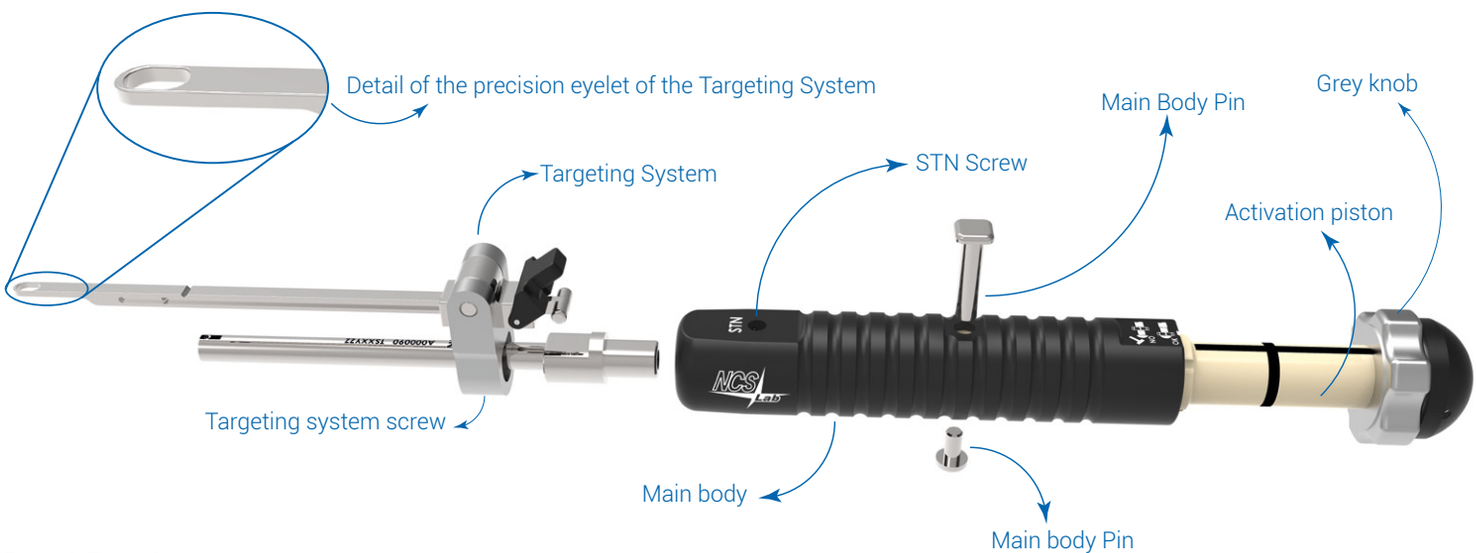


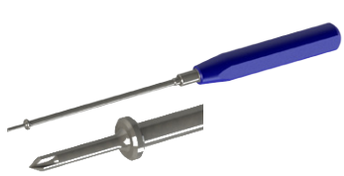

Figure 1: Taylor Stitcher and its parts.

Taylor Stitcher is supplied with four additional tools: a spanner, a screwdriver, a punch and a hammer.

The spanner helps with the assembling and substitution of the disposable STN needle, the screwdriver allows both the operations of substitution of STN single use needle as well as the assembling and disassembling of the cannula of the instrument for the cleaning operations. The punch allows the making of a pre-hole in the humerus cortex, and finally, the hammer is given to facilitate the creation of the transosseus tunnel.

SPANNER

SCREWDRIVER



PUNCH

HAMMER

## 4. PRODUCT CODES

| CODE | CND | RDM | DESCRIPTION | QUANTITY | PACKAGE |
|---|---|---|---|---|---|
| P005_AS034_01 | K0399 | 900854 | Main body TS | 1 | Non sterile |
| P005_AS034_03 | K0399 | 900974 | Punch TS | 1 | Non sterile |
| P005_AS034_04 | K0399 | 901014 | Screwdriver TS | 1 | Non sterile |
| P005_AS034_05 | K0399 | 901074 | Targeting System TS | 1 | Non sterile |
| P005_AS034_06 | K0399 | 901114 | Grey knob TS | 1 | Non sterile |
| P005_AS034_08 | K0399 | 901174 | Screws TS | 1 | Non sterile |
| P005_AS034_09 | K0399 | 901214 | Sterilization case TS | 1 | Non sterile |
| P005_AS034_12 | K0399 | 1205097 | Hammer TS | 1 | Non sterile |
| P005_AS034_16 | K0399 | 1287224 | Spanner 7 mm TS | 1 | Non sterile |
| P005_AS034_17 | K0399 | 1287255 | Cannula TS | 1 | Non sterile |

| MANUFACTURER | STERILIZATION | EXP. |
|---|---|---|
| NCS Lab Srl. | - | - |

## 5. MATERIALS

Taylor Stitcher instrument is made of: Al 6082, PEEK, PTFE, AISI 304, AISI 316, AISI 630, NiTi.

The disposal of the device must be done in accordance with current regulations.

## 6. CLASS OF RISK: Class I

## 7. STORAGE AND TRANSPORTATION

The instrumentation must be stored after its sterilization in a dry and clean place, moreover it should be protected from direct sunlight, insects and extreme conditions of temperature and humidity. For transportation, all instruments must be packed in a suitable, non-sterile packaging. Prior to use, the instruments must be cleaned, disinfected and sterilized.

DATA SHEET

# STN (SUPERELASTIC TRANSOSSEOUS NEEDLE)

## 1. INDICATIONS

Superelastic Transosseous Needle (STN) is a medical device single-use dedicated only to be used with the surgical instrument Taylor Stitcher.

The use of this equipment is focused on the creation of transosseous tunnels for the treatment of the rotator cuff injuries. Its use can be done both with arthroscopic and open surgical technique.

## 2. DESCRIPTION AND FEATURES

Superelastic Transosseous Needle (STN) assembled on the instrument Taylor Stitcher allows to make one or more transosseous tunnels having in common a lateral entry hole, and one or more medial exit holes.

STN needle (Figure 1), thanks to the material it is made of, it is able to recover its original shape and make transosseous pre-shaped tunnels.

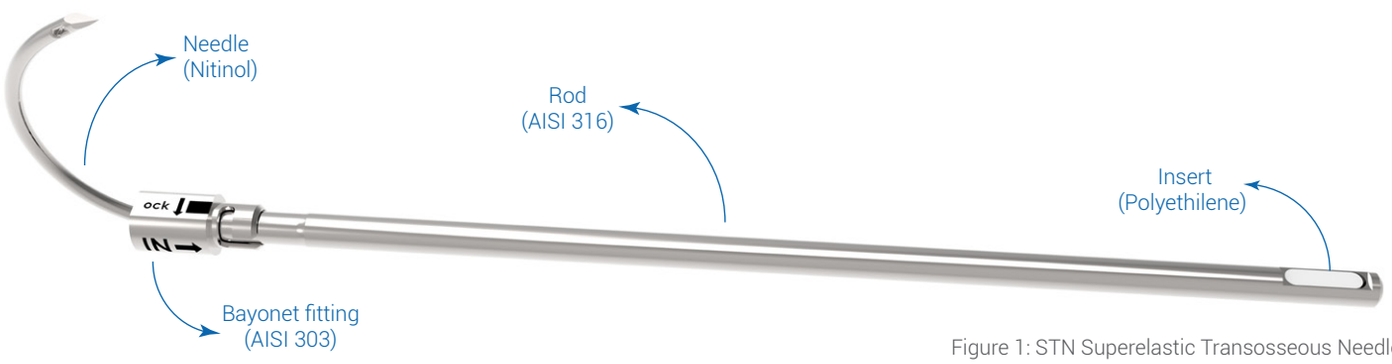



Figure 1: STN Superelastic Transosseous Needle

## 3. PRODUCT CODES

| CODE | CND | RDM | DESCRIPTION | QUANTITY | PACKAGE |
|---|---|---|---|---|---|
| P005_AS034_11 | K0399 | 1205153 | **Superelastic Transosseous Needle (STN)** | 3 pieces | Sterile |

| MANUFACTURER | NOTIFIED BODY | STERILIZATION | SHELF LIFE |
|---|---|---|---|
| NCS Lab Srl. | KIWA-CERMET | Gamma Rays | 5 years sealed |

## 4. KIT CODES

| CODE | RDM | KIT DESCRIPTION | QUANTITY | PACKAGE |
|---|---|---|---|---|
| P005_AS034_20 | 114290 | **KIT STN Transosseous**<br>1 x STN Transosseous Needle<br>3 x Sutures HS Fiber USP 2 (5metric)* | 1 piece | Sterile |
| P005_AS034_21 | 118489 | **KIT Transosseous Tool**<br>3 x Sutures HS Fiber USP 2 (5metric)* | 1 piece | Sterile |
| P005_AS034_22 | 119792 | **STN Transosseous Tape KIT**<br>1 x STN Transosseous Needle<br>1 x Suture HS Fiber Suture Tape* | 1 piece | Sterile |
| P005_AS034_23 | 119793 | **STN Transosseous Tape Plus KIT**<br>1 x STN Transosseous Needle<br>2 x Sutures HS Fiber Suture Tape* | 1 piece | Sterile |

| ASSEMBLER | NOTIFIED BODY | SHELF LIFE |
|---|---|---|
| NCS Lab Srl. | STN Transosseous Needle: KIWA-CERMET<br>Sutures HS Fiber USP 2 (5metric)* and Sutures HS Fiber Suture Tape*: : LNE/G-MED | 5 years sealed |

* See product's data sheet for technical informations.

## 5. MATERIALS

STN is made of NiTi alloy and stainless steel.

The disposal of the device must be done in accordance with current regulations.

## 6. CLASS OF RISK:

- STN NEEDLE: Class IIA
- SUTURES HS FIBER USP 2 (5METRIC): Class III
- SUTURES HS FIBER SUTURE TAPE: Class III

## 7. CE MARKS:

- STN NEEDLE: MED 29111 (Notified body n° 0476)
- SUTURES HS FIBER USP 2 (5METRIC): n° 24789 and n° 24790 (Notified body n° 0459)
- SUTURES HS FIBER SUTURE TAPE: n° 24789 and n° 24790 (Notified body n° 0459)

## 8. CONTRAINDICATIONS

The use of the device STN is contraindicated in the following cases:

- Patients with known allergies or sensitivity to materials of the device STN and of the Taylor Stitcher instrument;
- Patients with active systemic infections or latent diseases that may then be exposed to a greater risk of infection related to the use of the device;
- Patients who don't have fully developed bone;
- Patients with severe osteopenic disease;
- Patients in mental or neurological conditions that do not allow adequate post-operative phase.

## 9. STORAGE AND DISPOSAL

STN (Superelastic Transosseous Needle) should be protected from direct sunlight, insects and extreme conditions of temperature and humidity. Use products in the order they are received (according to the principle first-in, first-out), taking note of any expiration date on the label.

The entire pack including all its components must be disposed of in according to normal hospital procedures in disposable container for dangerous infective sanitary waste intended for the incinerator DPR 254/03 as amended.

DATA SHEET

# TAYLOR STITCHER & STN SYSTEM

## 1. WARNINGS AND PRECAUTIONS

### • GENERAL

- Read carefully the instructions for use. The non compliance with instructions, warnings and precautions can cause serious surgical consequences or injuries to the patient.
- The instrument Taylor Stitcher and all its accessories, are supplied non-sterile, they must be cleaned and sterilized by steam when opening the packaging and prior to their surgical use.
- Do not alter in any way the dedicated instrument Taylor Stitcher. Such manipulations or its improper use, may cause product failure or compromise its performance.
- In the event of total or partial damage to Taylor Stitcher contact your local distributor.
- Taylor Stitcher can be used only in the operating room by competent medical personnel with a medicine degree and qualified to operate strictly on the interested area (shoulder).
- STN needle for Taylor Stitcher instrument is supplied disposable and sterile, do not sterilize or re-use this component.
- The NiTi alloy used to manufacture the STN include elements that can produce allergic hypersensitivity to the immune system.
- The Taylor Stitcher instrumentation is intended to be used on patients of any age, sex and weight, provided that their physiological musculoskeletal processes of growth are complete.

### • IMPLANT PROCEDURE

- Before use, read carefully the surgical technique of Taylor Stitcher recommended by the manufacturer available at:
  - Tel: +39 059 669813
  - E-mail: biomed@ncs-lab.com
  - Web: www.ncs-lab.com
- NCS Lab Srl recommends adequate pre-operative training with qualified personnel before the first use of the Taylor Stitcher.

## 2. PRE-OPERATIVE CHECKS

### TAYLOR STITCHER

Taylor Stitcher is a reusable instrument supplied non sterile.

Before its use, the user must visually inspect the integrity of the instrumentation in its entirety.

| CHECKS |
|---|
| Verify the fluent scrolling of the Taylor Stitcher metal ring. |
| Verify the correct position (central) of the STN needle within the precision eyelet of the targeting system. |
| Before the STN needle activation (needle coming out) and before hitting the handle with the dedicated hammer, verify the position of the metal ring which should be in the final part of the activation piston. |
| In case the activation piston moving back is difficult, verify the complete closure if the STN screw and then proceed with the piston complete moving back. |

WARNING! In the event Taylor Stitcher's integrity is visually compromised, or one or more non-compliances with the above checklist outcome do not use the Taylor Stitcher instrumentation. On the contrary, NCS Lab disclaims any responsibility.

### STN

STN is a medical device supplied sterile and disposable.

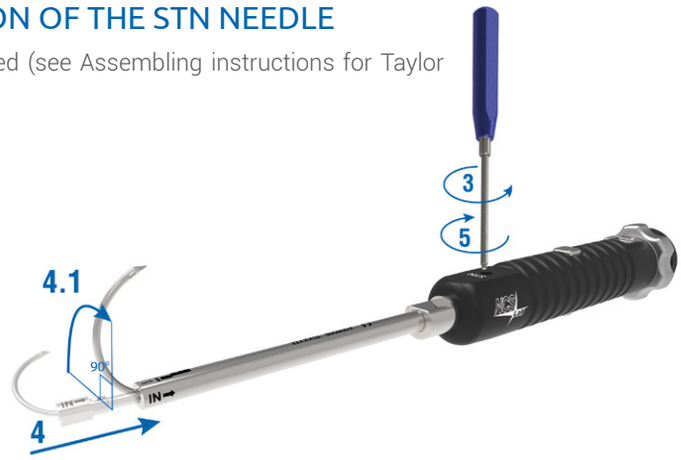
Before use, the user must in any case visually check the integrity of the device in all its parts, and the packaging status. STN needle has a guaranteed shelf life of 5 years.

| CHECKS |
|---|
| Verify the integrity of the packaging. |
| Verify the expiration date. |
| Visually check the integrity of the device in all its parts. |

WARNING! Do not use in case the product is exhausted, or in the case the checks described above have had unfavorable results. On the contrary, NCS Lab disclaims any responsibility.

## 3. OPERATING INSTRUCTIONS FOR THE SUBSTITUTION OF THE STN NEEDLE

1. Assemble the cannula and the main body of Taylor Stitcher, if needed (see Assembling instructions for Taylor Stitcher).
2. Open a new STN needle, after perfoming the required pre-operative checks.
3. Unscrew the "STN" screw on the main body of Taylor Stitcher.
4. Insert the STN needle in the cannula and rotate it 90° clockwise, then match the "IN" mark on the STN with the laser mark on the cannula and turn it counter-clowise until the "lock" position (4.1). Help yourself with the spanner included, if needed.
5. Lock completely the "STN" screw on the main body of Taylor Stitcher.




## 6. OPERATING INSTRUCTIONS FOR THE REALIZATION OF TRANSOSSEOUS TUNNELS

1. Move back axially the piston or rotate anticlockwise the metal ring till its mechanical stop. Verify the correct position of the STN needle tip at the cannula extremity.
2. Move back the metal ring till its mechanical stop before the needle activation (coming out)
3. Insert a PDS shuttle wire size 1 for about 10 cm into the eyelet on the tip of the STN.
4. Heavily decorticate the footprint area of the humerus.
5. Insert the targeting system in the proximal lateral portal created and put it in contact (tangent) with the great tuberosity in correspondence with the desired anchoring area (where is located the desired coming out of the transosseous tunnel)
6. Insert the Lateral cannula in the distal portal shifted of 10-15 mm compared to the previous one
7. Keeping pressed the Taylor Stitcher to the humeral lateral cortex, hit the piston extremity (with the dedicated hammer provided in the instrument kit) to create the transosseous tunnel and to allow the STN needle to come out.
8. Retract the STN in order to relax the PDS shuttle wire to facilitate its recovery through the use of a clamp.
9. Pull out the PDS shuttle wire from the eyelet on the tip of the STN, retract the STN needle rotating the metal ring counterclockwise up to allow its removal

## 5. RE-PROCESSING OF RE-STERILISABLE INSTRUMENTS ACCORDING TO EN ISO 17664-2004 CLEANING AND STERILIZATION

The instrumentation Taylor Stitcher is supplied non-sterile (except the STN needle), it must be cleaned and sterilized in its entirety as soon as possible before and after use. Thoroughly clean long and narrow cannulations and blind holes.

It is recommend the use of detergents with a neutral pH.

Follow the manufacturer's instructions of the enzimatic detergent for dilution, concentration, temperature, exposure time and water quality.

Do not use abrasive cleaning devices.

Whenever possible, use a washer / disinfection system (based on ISO 15883) for implants, instruments and trays. Do not overload the washing baskets for ultrasonic cleaning and washing/disinfection system.

The user is responsible for sterilization of the instruments.

Please ensure that only trained personal performs cleaning, disinfection and sterilization and that the previous mentioned reprocessing steps have been validated.

Inappropriate handling and maintenance as well as alienated application can lead to premature wastage of the instruments.

Anodized coating is damaged by detergents with free halogen ions or sodium hydroxide.

Detergents and disinfectants with fluoride, chloride, bromide, iodide or hydroxyl ions MUST NOT be used.

| PREPARING FOR CLEANING | |
|---|---|
| | Disassemble the Taylor Stitcher by removing the targeting system, the cannula and dispose the STN Needle (follow hospital disposal waste procedures).<br>Disassemble also the instrument main body (see the Assembly Manual for instructions).<br>Remove any residue with a cloth or disposable paper. |

| DECONTAMINATION / CLEANING /DISINFECTION | |
|---|---|
| **OPTION 1:**<br>**ULTRASONIC BATH** | Always wear protective equipment.<br>Immerse all the elements in lukewarm sterile distilled water for 5 minutes at least.<br>Put the Taylor Stitcher and all the instruments in the ultrasonic bath in sterile distilled water, in the manner recommended by the manufacturer of the tank. The wash cycle should be kept as long as necessary but generally lasts from 5 to 7 minutes.<br>Perform a new Ultrasonic wash for 15 minutes at 50 kHz using a phenol disinfectant solution prepared following the instructions provided in disinfectant manufacturers' data sheet;<br>Rinse components in sterile distilled water for at least one minute;<br>After degassing the ultrasonic bath, wash for 30 minutes at 40 kHz using a cleaner based on a pluri-enzymatic system prepared following the instructions provided in detergent manufacturers' data sheet;<br>Rinse components in sterile distilled water for at least one minute; Hand clean to dislodge and remove all visible dirt, carefully using a cloth for external parts, a soft non-shedding brush of appropriate diameter for the internal and a jet washer for more inaccessible area;<br>Perform a new Ultrasonic wash for 15 minutes at 50 kHz using a solution of a disinfectant based on a quaternary ammonium salt, prepared following the instructions provided in disinfectant manufacturers' data sheet;<br>Flush in sterile distilled water for 2 minutes at 15°C.<br><br>All instruments must be totally submerged in the washing solution. Do not mix instruments of different metals (stainless steel, chrome-plated tools, copper, etc..) in the same cleaning cycle. Change the cleaning solution frequently at least at the intervals recommended by the manufacturer of the ultrasonic tank used.<br><br>During rinsing make sure that all parts showing gaps are rinsed carefully like the external surfaces. |
| **OPTION 2:**<br>**MANUAL CYCLE** | Most instrument manufacturers indicate the ultrasonic cleaning as the best and most effective way to clean surgical instruments, particularly those with hinges, locks and other moving parts.<br><br>• If ultrasonic cleaning is not possible we recommend using the following method:<br>• Always wear protective equipment.<br>• Immerse all the elements in lukewarm sterile distilled water for 5 minutes at least.<br>• Fill the receptacle with sufficient solution of a phenolic based disinfectant (prepared in accordance with the indication supplied by the manufacturer) to ensure complete immersion of the items.<br>• Carefully immerse all components in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reached all surfaces, including those of cannulated devices.<br>• Leave the items for 1 hour in the disinfectant solution (or following the instructions provided in detergent manufacturers' data sheet)<br>• **Rinse carefully** all components under sterile distilled water for at least two minutes, moving them slowly to allow the water to reach all its surfaces. The operation must be repeated one more time, checking visually the absence of residuals also of detergent.<br>• Put the components in a receptacle and immerse them with a solution of a cleaner based on a plurienzymatic system prepared following the instructions provided in disinfectant manufacturers' data sheet;<br>• Brush with soft nylon (or plastic) brush all the elements until no residuals are visible; do not use steel wool or metal brushes and pay particular attention at the connection site with the cannula and the inner part of the cannula;<br>• Brush delicate instruments carefully and, if possible rinse, clean and sterilize these instruments separately;<br>• Thoroughly clean long and narrow cannulations and blind holes; |

| | |
|---|---|
| | • Be sure that the entire surface of the instruments is perfectly clean;<br>• After brushing, immerge the instruments for 10 minutes (or following the instructions provided in detergent manufacturers' data sheet)<br>• After brushing, rinse all surfaces and lumens of the instruments under sterile distilled water, at least 2 minutes; during rinsing make sure that all parts showing gaps are rinsed carefully like the external surfaces. The operation must be repeated one more time, checking visually the absence of residuals also of detergent.<br>• Put the components in a receptacle and immerse them with a disinfectant solution based on quaternary ammonium salt prepared following the instructions provided in disinfectant manufacturers' data sheet;<br>• Let the instruments immersed for 30 minutes (or following the instructions provided in detergent manufacturers' data sheet)<br>• Rinse carefully all components under sterile distilled water for at least two minutes, moving them slowly to allow the water to reach all its surfaces. The operation must be repeated one more time, checking visually the absence of residuals also of disinfectant. |
| **DRYING** | |
| | Immediately after the end of the cleaning operations, the components must be completely dried.<br>• Dry with a sterile, soft, absorbent, non- fuzzy cloth.<br>• If an automatic system is used, the temperature should not exceed 100°C. |
| **STERILIZATION** | |
| | Instruments may be loaded into a general-purpose sterilization tray. Cutting edges should be protected and the recommended content or maximum weight not exceeded as indicated by manufacturer of sterilization tray.<br>Sterilize by steam autoclaving, utilizing a fractioned pre-vacuum cycle according to the table below. Trays must be wrapped using sterilization wraps made of nonwoven blend of cellulose and polyester. |

| STEAM STERLIZER TYPE | PRE-VACUUM |
|---|---|
| Preconditioning pulses | 4 pulses |
| Exposure Temperature | 132 °C |
| Minimum Holding time | 4 minutes |
| Drying Time | 30 minutes |

| | |
|---|---|
| | At the end of the autoclaving cycle - before the drying cycle – slightly open the door, then proceed with the drying cycle according to the instructions provided by the manufacturer.<br>If the autoclave door is opened fully before the drying cycle, there would be an abrupt decrease in air temperature inside the autoclave, which would cause condensation on the instruments with the consequent formation of gray spots.<br>In any case use a type of cycle suggested by the official pharmacopoeia. |
| **INSPECTION AND FUNCTION TESTING** | |
| | The instruments should always be checked for proper functioning and cleanliness.<br>Damaged instruments should be rejected and dirty instruments should undergo a further reprocessing cycle. |
| **ADDITIONAL INFORMATION** | |
| | Always use appropriate methods for cleaning/sterilization to maintain the instruments in the best possible condition.<br>Please note that: sterilization does not replace cleaning!<br>It is always very important to verify the proper functioning of equipment for sterilization. Any failure would potentially not achieve sterilization and result in risk of pathogen transmission. Secondly, exposing tools to excessively high temperatures during sterilization, will cause the nature of the steel to be affected and thus loss of its mechanical properties. |

## 6. MEANING OF THE SYMBOLS USED IN THE IDENTIFICATION LABELS

| | | | | |
|---|---|---|---|---|
|  |  |  |  |  |
| NON REUSABLE | USE BY | BATCH CODE | MANUFACTURER | SERIAL NUMBER |
|  |  |  |  |  |
| manufacturing date | READ THE INSTRUCTIONS FOR USE | CE MARK | Attention, see instructions for use / documentation attached. | NON-RE-STERILIZABLE |
|  | Rx Only |  |  |  |
| NON STERILE | PRESCRIPTION DEVICE | DO NOT USE IF PACKAGE IS DAMAGED | GAMMA RAYS STERILIZATION | ETHYLENE OXIDE STERILIZATION |

## 7. DISCLAIMER

"The instructions provided above have been validated by NCS Lab Srl as being a true description of the preparation of a device for first clinical use or for re-use of multiple use devices. It remains the responsibility of the reprocessor to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. The cleaning, disinfection and sterilization processes should be adequately recorded. Likewise, any deviation by the reprocessor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences and should also be appropriately recorded".

Note: ANY DEVICE WHICH IS LABELLED "SINGLE USE ONLY" MUST NEVER BE REUSED. NCS Lab Srl IS ONLY RESPONSIBLE FOR SAFETY AND EFFECTIVENESS FOR THE FIRST PATIENT USE OF SINGLE USE DEVICES.
The institution or practitioner bears full responsibility for any subsequent use of these devices.

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

## 8. MANUFACTURER

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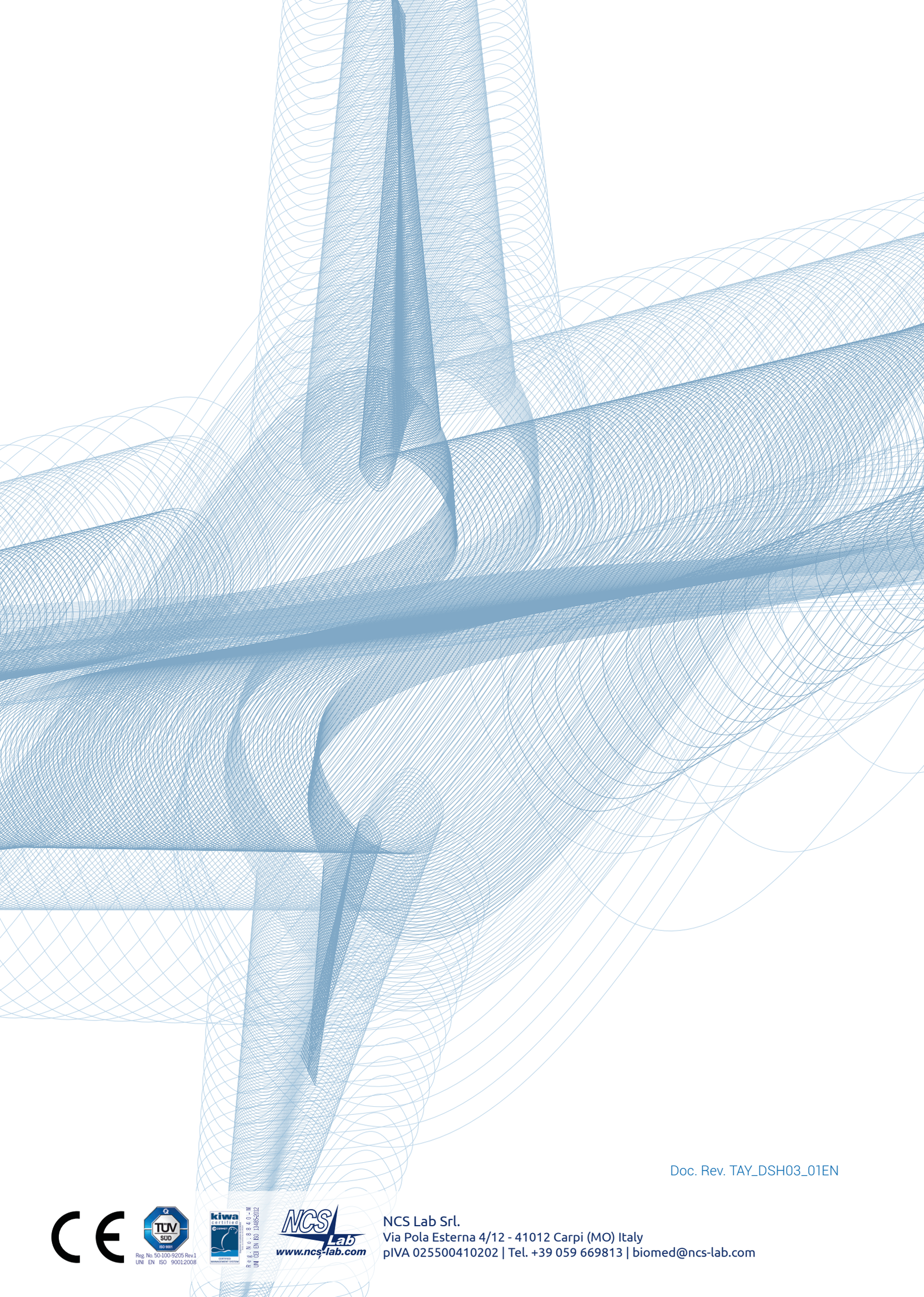
E-mail: biomed@ncs-lab.com
Web: www.ncs-lab.com

## 9. DEALER



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