# NE'X Glue® Surgical Adhesive

## Instructions for use

**Ref. no.: 0206-NX2, 0206-NX5, 0206-NX10, 0206-NX4SM, 0206-NX3WM12, 0206-NX3WM16**

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| GRENA<br>**Grena Biomed Limited,**<br>Chelsea House, Chelsea Street, Nottingham, NG7 7HP, United Kingdom | **Contact information:**<br>Phone/Fax: + 44 115 9704 800 | EC REP<br>**MDML INTL LTD**.<br>10 McCurtain Hill Clonakilty, Co. Cork, P85 K230, Republic of Ireland | CE 1434 | **ENG**<br>IFU-NX-ENG_06 |

**Caution:**

This instruction cannot be used as a manual for surgical techniques used during the work with Surgical Adhesive. To learn adequate knowledge about surgical technique it is necessary to contact our company or authorized distributor and to acquaint with appropriate technical instructions, professional medical literature and graduate proper training under supervision of experienced surgeon. Before use we recommend reading precisely all information included in this manual. Not being obedient to this information may lead to serious surgical consequences such as patient injury, contamination, infection, cross-infection, inappropriate sealing / bonding / reinforcing strength or death.

**Indications:**

NE'X Glue® Surgical Adhesive is indicated to bond, seal and/or reinforce soft tissue. Can be applied as an adjunct to staples, sutures, electrocautery or patches as well as alone for sealing or reinforcing parenchymal organs when other standard methods are impractical or ineffective. Another application is surgical mesh fixation in hernia surgery. Soft tissues where NE'X Glue® is effective are vascular, cardiac, pulmonary, dural, esophageal, gastric, intestinal, colorectal, pancreatic, splenic, biliary, hepatic and genitourinary. NE'X Glue® can be applied prophylactically or after a leak is detected. NE'X Glue® Syringe Applicator Tips and Spreaders are intended to thoroughly mix the NE'X Glue® Surgical Adhesive components and to apply adhesive to the tissue.

Patient target group – adult and young patients, males and females.

Intended users: product is intended to be used exclusively by qualified medical staff.

**Contraindications:**

DO NOT use in cerebrovascular procedures.
DO NOT use on exposed nerves or in a closed locations that are in immediate proximity to nerve structures.
DO NOT use on eyes.
DO NOT use intra-luminally.
DO NOT use intra-vasculary or in contact with circulating blood.
DO NOT use in case of known sensitivity to materials of bovine origin.
DO NOT use as a substitute for sutures or staples in tissue approximations.
DO NOT use on infected or contaminated areas.

**Side effects:**

Possible side effects may include, but are not limited to: failure of glue to adhere to tissue, inflammatory response, immune response, allergic reaction, application to tissue not targeted for the procedure, tissue necrosis, vessel obstruction, bronchus obstruction, luminal obstruction, tissue mineralization, thrombosis and thromboembolism, pulmonary emboli, injury to vessels or tissue, transmission of infectious agents of animal origin.

**Description of the device:**

NE'X Glue® Surgical Adhesive is two component product composed of bovine serum albumin and glutaraldehyde. Each component is closed in separate chamber of the syringe and they are mixed in the applicator tip during application to the tissue. Polymerization starts immediately after application and final strength is reached after 2 minutes. Delivery system consists of prefilled syringe, plunger and applicator tips. Applicator tips are delivered in sets together with Surgical Adhesive (Ref 0206-NX2, 0206-NX5, 0206-NX10) and are also available separately. Product is sterile and non-pyrogenic. It is intended for single-patient use only.

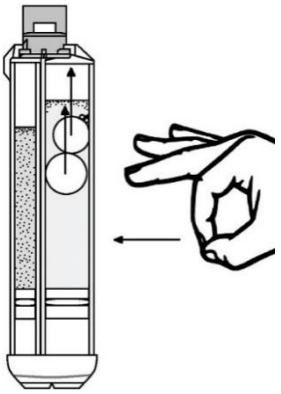
**Single package content:**

| Surgical Adhesive | | Applicator Tips | | | Remarks |
|---|---|---|---|---|---|
| **REF** | **Volume** | **Type** | **REF** | **pcs** | |
| 0206-NX2 | 2 ml | Pinpoint | 0206-NX4SM | 4 | Applicator Tips **also** available **separately** in sets of 4 pcs |
| 0206-NX5 | 5 ml | | | | |
| 0206-NX10 | 10 ml | Spreader 12 mm | 0206-NX3WM12 | 3 | Applicator Tips **also** available **separately** in sets of 3 pcs |
| ---------- | ---------- | Spreader 16 mm | 0206-NX3WM16 | | Applicator Tips available **separately only** in sets of 3 pcs |

**Instructions for use:**

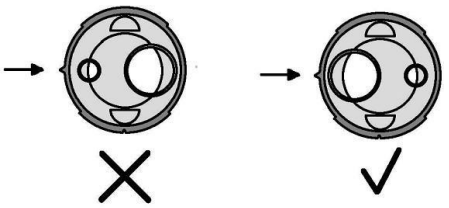
DEVICE PREPARATION:

1. Remove syringe with a glue, plunger and applicator tips from the packaging. Hold the syringe tip upright and tap the syringe chambers few times to let air bubbles in the solutions to rise upto the top of the syringe (pic.1).
   NOTE: It is important to move all the air bubbles to the top of the syringe to remove air prior to priming of the applicator tip. Omitting this step may result in the components not being mixed in the right proportions, which may weaken the effect of the adhesive or cause an irritating effect. Take care to keep holding of the syringe upright during entire assembly procedure.



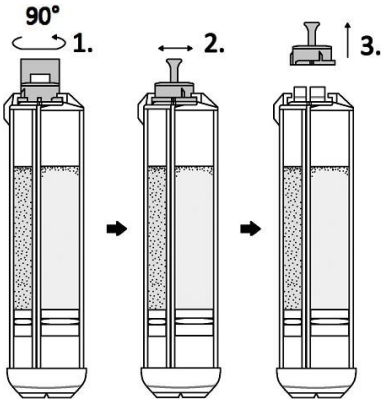
Pic. 1

2. Check if triangle projection of the nut of the applicator tip is located directly over the larger port (pic. 2). If not, hold the shaft of the applicator tip and rotate the nut to locate triangle projection over the larger port. Improper position of the projection relative to the large port will prevent the applicator tip from connecting to the syringe.

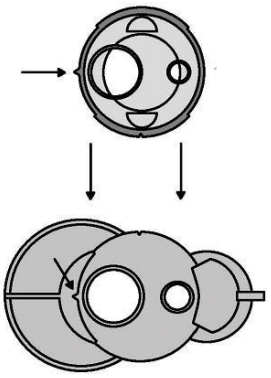


Pic. 2

3. Grasp syringe firmly nose upwards, turn the cap 90° counterclockwise and remove the cap by rocking it side-to side (pic. 3).
4. Align position of the applicator tip with the syringe looking at the triangle projection on the applicator tip and corresponding notch on the syringe and place the applicator tip on the syringe (pic. 4).
   CAUTION: Take care not to spill solutions from the syringe during assembly.

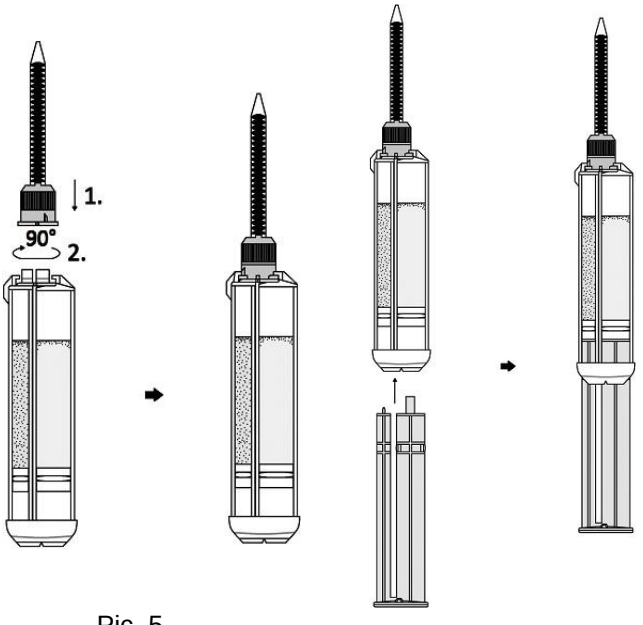



Pic. 3



Pic. 4

5. Push the applicator tip firmly towards the syringe and rotate the applicator tip nut 90° clockwise to lock the tip on the syringe (pic. 5). If the cap is not rotated, the application tip will not be locked and may fall off the syringe before/during application, and leaking glutardehyde unreacted with albumin may lead to tissue damage.
6. Keep the syringe upright and insert double plunger into the back of corresponding syringe chambers until resistance from the silicone plungers is felt (pic. 6).
   CAUTION: DO NOT lay the assembled device on its side.
   CAUTION: DO NOT remove air from above solutions in the syringe and DO NOT prime applicator tip at this stage. Air removal and priming should be done after application site is prepared for immediate NE'X Glue® use. Early air removal and applicator tip priming would block applicator tip.




Pic. 5

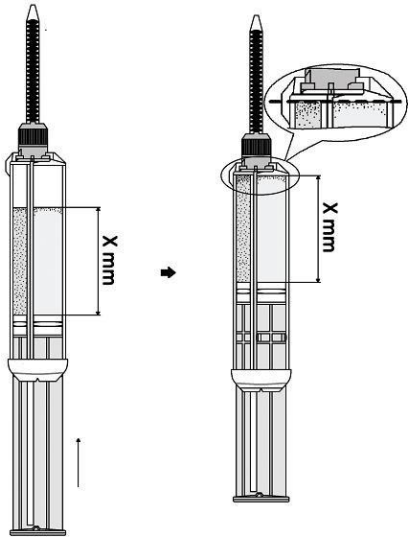
Pic. 6

SITE PREPARATION:

7. Prepare patient according to standard hospital procedures and secure unrestricted and convenient access to the application site.
8. Protect the tissue surrounding the surgical site from the undesired application of NE'X Glue® by placing moist sterile gauze pads in these areas. These pads should be removed immediately after application, while adhesive is still soft. Otherwise, the gauze pads will stick to the tissue. Any excess of adhesive residues should be wiped away from around the site.
9. Take care that application site is dry what can be described as a field that does not restain with blood within 4-5 seconds after wiping dry with a surgical sponge.
   CAUTION: Application of NE'X Glue® on a wet field may result in a failure to adhere.

AIR REMOVAL:

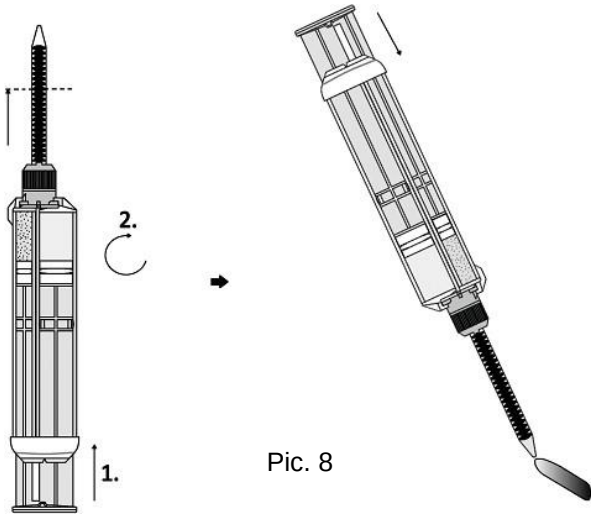
10. Continue to keep syringe upright and make sure that the air bubbles in the solutions are located at the top of the syringe.
11. Compress the plunger until the solutions are even with the top of the syringe body (pic. 7). Once the residual air space has been removed delivery device is ready for applicator tip priming.
    CAUTION: If at this stage solutions enter base of the applicator tip, tip will be occluded with polymerized NE'X Glue® and replacement with a new one before priming will be necessary. To remove occluded applicator tip, grasp the applicator tip nut, rotate the tip nut counterclockwise, and lift the tip off the syringe by rocking it side to side.
    NOTE: Air removal is necessary prior to initial use only.



Pic. 7

APPLICATOR TIP PRIMING:

12. Prime applicator tip by compressing the plunger until Applicator tip will be filled with solutions and approximately 3 cm long ribbon of NE'X Glue® will be expelled onto a sterile disposable surface (e.g. gauze pad). It is recommended to start priming with syringe in the upright position until half of applicator tip is filled with solutions. When solutions fills about half of applicator tip continue compressing the plunger and aim the tip down at an angle to a sterile surface to expel ribbon of NE'X Glue® (pic. 8).
13. Examine the material expelled during priming and ensure that its colour is uniform light yellow to amber and free of air bubbles. If expelled material is colourless or contains bubbles expel longer ribbon of NE'X Glue or repeat priming procedurę until the device delivers a uniform light yellow to amber liquid with no bubbles.
    CAUTION: Avoid direct contact of any tissue with material expelled during priming as it may have an irritating effect.
14. After the applicator tip has been properly primed proceed immediately to application.
    CAUTION: NE'X Glue polymerizes rapidly. Pausing between priming and application can lead to polymerization of NE'X Glue® inside the applicator tip. Should this occur, replace the blocked tip and repeat priming procedure. Do not apply pressure to the plunger once the tip has occluded.
    CAUTION: If surgeon needs to stop application, applicator tip will be occluded with polymerized NE'X Glue®.
    To use remaining solutions after application was paused, applicator tip must be replaced with a new one and priming procedure must be performed again.



Pic. 8

**General techniques for the use of NE'X Glue®:**

1. As proper and smooth device preparation, air removal and priming is critical for good results, it is highly recommended to practice all the steps with the product prior to initial use in the surgical site.
2. Clamp and depressurise vessels prior to applying NE'X Glue® to targeted anastomoses. This will reduce bleeding, which would weaken the effect of the adhesive.
3. For vessel repair apply an even adhesive coating 1,2 – 3,0 mm thick for anastomosis of vessels/grafts greater than 2,5 cm in diameter; apply an even adhesive coating 0,5 – 1,0 mm for vessels/grafts less than 2,5 cm in diameter.
4. For parenchymal repair apply an even adhesive coating 1,5 – 3,0 mm thick.
5. Do not apply thicker layers of adhesive than required, as it does not increase its effectiveness and only limits the elasticity of the layer.
6. The area of adhesive application should **NOT** be compressed or subjected to an extra pressure, which would stiffen the anastomosis in a non-anatomical shape and disturb function of the anastomosed structures.
7. After adhesive polymerizes, trim away excess or irregular adhesive edges with scissors and pickups.

**Specific Techniques for the use of NE'X Glue® in aortic dissection repair:**

1. The dissected layers of the aorta should be initially cleared of blood and thrombus material and should be dried with surgical sponges to the extent possible.
2. For the distal end of the dissection repair, insert a balloon catheter into the true lumen to define the distal terminus for the application of NE'X Glue®. In addition, the dissected layers of the aorta should be closely approximated by inserting a dilator, sponge, or catheter into the true lumen to preserve the natural architecture of the vessel. NE'X Glue® should then be dispensed into the false lumen as far distally as the distal balloon catheter will allow. Filling the false lumen should proceed from distal to proximal with a spiralling out motion for smooth application. Completely fill the false lumen with NE'X Glue®; avoid overfilling the false lumen and spilling NE'X Glue® into the true lumen or surrounding tissue.
3. For the proximal end of the dissection repair, the dissected layers of the aorta should also be closely approximated by using a dilator, sponge, or catheter. If necessary, moist gauze pads should be placed over the aortic valve leaflets to protect them from inadvertent application of NE'X Glue®. NE'X Glue® should then be dispensed to fill the false lumen. Graft material may be sutured directly onto the tissues adhered and reinforced with NE'X Glue® at both the proximal and distal aspects of the dissection repair. Allow NE'X Glue® to completely polymerize without any manipulations for a full two minutes prior to suturing through the adhered tissue layers.

**NE'X Glue® in lung surgery:**
NE'X Glue® can be applied to a deflated or inflated lung.

**Warnings and precautions measures:**

1. Any surgical and minimally invasive procedures should be performed only by persons having adequate training and familiarity with those techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any surgical procedure.
2. It is recommended that surgical gloves, sterile gauze pads/towels, and surgical instruments be maintained moist to minimize the potential for NE'X Glue® inadvertently adhering to these surfaces.
3. Use only the applicator tips indicated in this manual. The use of similar-looking tips from other manufacturers may result in glue leaks, reduced adhesion and necrotic changes.
4. Take care not to spill contents of the syringe because glutardehyde present in the smaller chamber of the syringe, if unreacted with albumine, has an irritating effect on tissues.
5. Do not press plunger while attaching it to the syringe as this will compress the air above the level of the fluids in the syringe, which can lead to leakage from the syringe when the cap is removed.
6. Apply NE'X Glue® onto dry surface as too wet field may result in poor adherence.
7. Do not use blood saving devices when suctioning excess of NE'X Glue® from the surgical field.
8. Avoid any negative pressure during application and polymerization of NE'X Glue® to prevent the entrance of NE'X Glue® into the cardiovascular system. For example, left ventricular vents should be turned off prior to the application of NE'X Glue® as it could be suctioned into the aorta and impeding heart valve function when used in conjunction with an active left ventricular vent.
9. Circumferential application of adhesive may restrict dilatation on growing tissue what suggests caution with the circumferential use of NE'X Glue® in children.
10. Ineffective sealing may be observed when NE'X Glue® is used in the translabyrinthine approach for acoustic neuroma repairs; its use with this surgical approach is not recommended. Recommended for acoustic neuroma repair is the middle fossa or retrosigmoid approach.
11. Excessive application of NE'X Glue® in lung surgery can increase residual air space and cause atelectasis.
12. Do not allow NE'X Glue® to contact or obstruct circulating blood flow during or after application as it could result in local or embolic vascular obstruction.
13. Do not allow NE'X Glue® to obstruct air pathways or any other luminal fluid flow during or after application.
14. Protect tissue not intended for application from contact with NE'X Glue®. If NE'X Glue® adheres to undesired area, allow adhesive to polymerize and then gently dissect the adhesive away from the unintended area with forceps and scissors. Never attempt to peel away adhesive as this could lead to tissue damage. Leaving NE'X Glue in undesired places may lead to serious consequences depending on the location and amount of adhesive left. The consequences may include, but are not limited to: perforation, necrotic changes, ischemia, hemorrhage, myocardial infarction, nerve conduction disorders, tissue mineralization, and adhesions.
15. Direct application of NE'X Glue® to the exposed phrenic nerve can cause acute nerve injury. Direct application of NE'X Glue® to the surface of the sinoatrial node (SAN) of the heart can cause coagulation necrosis that extends into the myocardium, which could reach underlying conduction tissue and may cause acute, focal SAN degeneration. Chlorhexidine gluconate gel (e.g., Surgilube®) can protect the phrenic nerve, the myocardium, and the underlying SAN from potential injury from NE'X Glue® use.
16. Do not use NE'X Glue® if staff is not adequately protected (e.g., wearing gloves, mask, protective clothing, and safety glasses). Unreacted glutaraldehyde may cause irritation to eye, nose, throat, or skin; induce respiratory distress; and cause local tissue necrosis. Prolonged exposure to unreacted glutaraldehyde may cause central nervous system or cardiac pathology. If contact occurs, flush affected areas immediately with water and seek medical attention.
17. Exercise caution with repeated exposure of the patient to NE'X Glue® as hypersensitivity reactions are possible.
18. NE'X Glue® contains material of animal origin, which potentially may be capable of transmitting infectious agents, but strictly controlled manufacturing proces minimized such possibility.
19. Always inspect the site for hemostasis before procedure is finished. Bleeding can be controlled by electrocautery, surgical sutures or additional NE'X Glue® application.
20. No available literature data indicate the need to quantitatively restrict the use of NE'X Glue during the procedure, however, the recommendations of this manual should be strictly followed in relation to the thickness of the applied layers and applications in unintended areas.
21. Dispose of all opened syringes with NE'X Glue® or applicator tips no matter if they were used or not to prevent accidental use of a contaminated device.
22. Store below 25°C, but do not freeze.
23. Use immediately after opening. Storage of the device after package opening leads to its contamination and creates a risk of an infection to the patient.
24. The product requires appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and the environment.
25. This product is intended for single patient and procedure use. Resterilization, reuse, reprocessing, modification may lead to serious consequences with death of patient included.
26. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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| | Do not re-use | | Keep dry | eIFU indicator www.grena.co.uk/IFU | Consult electronic instructions for use | | Manufacturer |
| STERILE EO 1 | Sterilized using ethylene oxide | STERILE R 2 | Sterilized using irradiation | | Do not resterilize | | Do not use if package is damaged and consult instructions for use |
| MD | Medical device | REF | Catalogue number | LOT | Batch code | | Use-by date |
| | Double sterile barrier system | | Caution, consult accompanying documents | BIO | Contains biological material of animal origin | | Quantity in package |
| | Date of manufacture | 25°C 0°C | Temperature limit | EC REP | Authorized representative in the European Community | | |

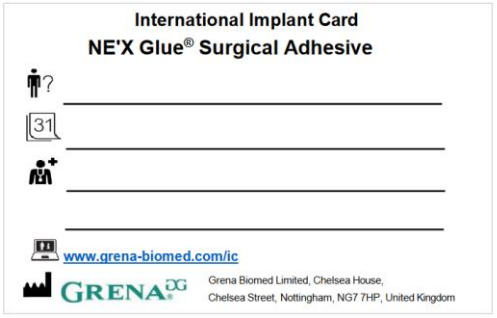
1– refers to applicator tips
2– refers to syringes with solutions

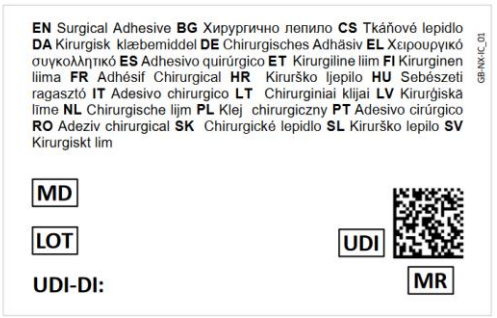
*The hard copies of instructions for use delivered with Grena products are always in English language.*
*If you require a hard copy of IFU in other language, you can contact Grena Ltd.*
*at **ifu@grena.co.uk** or **+ 44 115 9704 800.***

*Please scan the below QR code with the appropriate application.*
*It will connect you with Grena Ltd. website where you can choose eIFU in your preferable language.*

*You can enter the website directly by typing in www.grena.co.uk/IFU in your browser.*
*Make sure that paper version of IFU in your possession is in the latest revision prior to use of the device.*
*Always use the IFU in the latest revision.*

## *IMPLANT CARD INFORMATION*




*Implant card (IC) is delivered with the product, one IC for each device.*
*Implant card is supposed to be completed by a implanting healthcare institution or healthcare provider and should be handed over to the patient who has been implanted.*
*The instructions on how to complete the implant card (IC) in your preferable language you can find on our website* ***www.grena-biomed.com/ic***