DUPLOTIP Applicator

SNAP LOCK ATTACHMENT QUICK REFERENCE GUIDE

TISSEEL [Fibrin Sealant]

Instructions for **SCRUB NURSE**

ASSEMBLE APPLICATOR

1

Prepare TISSEEL [Fibrin Sealant] according to instructions in the package insert.

2

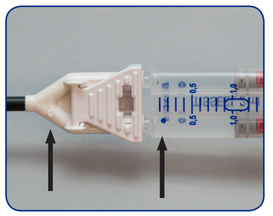
Transfer the applicator to the sterile field using sterile technique.

3

Remove and discard the protective tube.

4

Push the male syringe set luers all the way into the female luer cones on the applicator.



Match the blue dot on the syringe's calibrated side with raised dot on applicator.

5

Push the snap lock all the way down to securely fasten the applicator to the syringe luers.

If multiple syringes are required in a procedure, inconsistent orientation of syringes may cause the dual-chamber applicator to clog.

6

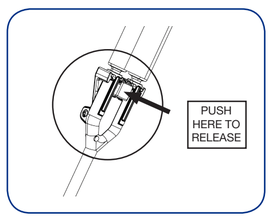
Applicator is ready to use.

NOTE: DUPLOTIP applicators may be angled to improve access or visibility of surgical site.

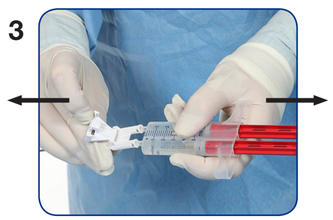
RELEASE APPLICATOR

1

Press the release button on the back of the snap lock.



3



Detach applicator from syringe. Dispose as biohazard waste.

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TISSEEL [Fibrin Sealant]

SNAP ON and USE!

DUPLOTIP Applicator Product Codes

with NEW SNAP LOCK ATTACHMENT

EXISTING CODES	DESCRIPTION	EA PER PACK	NEW CODES
SA374003000000	**DUPLOTIP** WITH SNAP LOCK 20G x 10cm	3/PK	SA374003004444
SA375003000000	**DUPLOTIP** WITH SNAP LOCK 20G x 26cm	3/PK	SA375003005555
SA376003000000	**DUPLOTIP** WITH SNAP LOCK 5mm x 32cm	3/PK	SA376003006666

TISSEEL [Fibrin Sealant]

This abbreviated summary of product characteristics (SPC) is intended for international use. Please note that it may differ from the licensed SPC in the country where you are practicing. Therefore, please always consult your country-specific SPC or package leaflet.

TISSEEL [Fibrin Sealant] Indications

Supportive treatment where standard surgical techniques appear insufficient

- For improvement of hemostasis
- As a tissue glue to improve wound healing or to support sutures
- For tissue sealing, to improve adhesion of the separated tissue
- The efficacy in fully heparinized patients has been proven

The use of TISSEEL is restricted to experienced surgeons who have been trained in the use of TISSEEL.

For epilesional use.

Contraindications:

- TISSEEL alone is not indicated for the treatment of massive and brisk arterial or venous bleeding.
- TISSEEL is not indicated to replace skin sutures intended to close surgical wound.
- TISSEEL must never be applied intravascularly, intravascular application may result in life-threatening thromboembolic events.
- TISSEEL must not be applied in case of hypersensitivity to the active substances or to any of the excipients.

Special warnings and precautions for use.

- Do not apply intravascularly.
- Life-threatening thromboembolic complications may occur if the preparation is unintentionally applied intravascularly.
- Caution must be used when applying fibrin sealant using pressurized gas.
- Any application of pressurized gas is associated with a potential risk of air or gas embolism, tissue rupture, or gas entrapment with compression, which may be life-threatening.
- Apply TISSEEL as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process.
- Life-threatening/fatal air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer fibrin sealants. This event appears to be related to the use of the spray device at higher than recommended pressures and/or in close proximity to the tissue surface. The risk appears to be higher when fibrin sealants are sprayed with air, as compared to CO_2 and therefore cannot be excluded with TISSEEL when sprayed in open wound surgery.
- When applying TISSEEL using a spray device, be sure to use a pressure within the pressure range recommended by the spray device manufacturer.
- TISSEEL spray application should only be used if it is possible to accurately judge the spray distance as recommended by the manufacturer. Do not spray closer than the recommended distances.
- When spraying TISSEEL, changes in blood pressure, pulse, oxygen saturation and end tidal CO_2 should be monitored because of the possibility of occurrence of air or gas embolism.

Reporting of suspected adverse reactions.

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via your national reporting system.

For Posology, method of administration, incompatibilities, interactions and undesirable effects, please refer to the full SPC.

Medicinal products are subject to medical subscription.

In some countries TISSEEL [Fibrin Sealant] is licensed under the trademark TISSUCOL [Fibrin Sealant].

Rx Only: For safe and proper use of the DUPLOTIP device, please refer to full device instructions for use.

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GLBL/MG24/0317/0007

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