

Annex 2: Updated “Instructions for Use”

INSTRUCTIONS FOR USE

Read this before you open the package:

TachoSil comes in sterile packages and therefore it is important:

- *only* to use undamaged packages which have not been opened (post-sterilisation is not possible).
- to have a *non-sterile person* open the outer aluminium cover
- to have a *sterile person* open the inner sterile package
- to use TachoSil *soon after* opening the outer aluminium cover.
- to use TachoSil *immediately* after opening the inner sterile package.

Instructions

Use TachoSil under sterile conditions only.

Find out which size of TachoSil is needed. The size of the sealant matrix depends on the size of the wound. But please note that the matrix should cover 1-2 cm beyond the margins of the wound. If more than one matrix is needed, they should overlap. For smaller wounds, e.g. in minimally invasive surgery, the smaller sizes (4.8 x 4.8 cm or 3.0 x 2.5 cm) or the pre-rolled TachoSil (4.8 cm x 4.8 cm) is recommended. TachoSil can be cut to the appropriate size and shaped to fit the wound.

1. Wipe the wound surface gently before placing TachoSil on the wound. Strong (pulsating) bleeding should be stopped surgically.
2. Open the inner sterile package and remove the matrix. Pre-moisten the flat TachoSil matrix in saline solution and place it on the wound immediately (if the wound is completely wetted by blood and other fluids, there is no need to moisten the matrix before application). The pre-rolled TachoSil should **not** be pre-moistened before passing through the trocar or port.
3. Cleanse surgical instruments, gloves and adjacent tissues, if necessary. TachoSil may stick to surgical instruments, or gloves or adjacent tissues covered with blood. **It is important to note that failure to adequately clean adjacent tissues may cause adhesions.**
4. If a trocar is used for getting access to the wound, the inside of the trocar should be dry. It is recommended to remove the top part of the trocar prior to passing the pre-rolled TachoSil through the trocar.
5. Place the **yellow, active side** of TachoSil against the wound.. Hold down TachoSil with a gentle pressure for 3-5 minutes. Use a moistened glove or a moist pad to keep TachoSil in place. For minimally invasive surgery, the pre-rolled matrix can be un-rolled with instruments at the site of application. The un-rolled TachoSil should then be moistened at the site of application with a moist pad and held in place under gentle pressure for 3-5 minutes.
6. Remove the light pressure carefully after 3-5 minutes. To make sure that TachoSil does not cling to the moistened glove or swab, and loosens itself from the wound, TachoSil can be held down at one end e.g. by using a pair of forceps. There is no residual product which needs to be removed; the entire matrix is dissolved (resorbed).

It is strongly recommended that every time TachoSil is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.