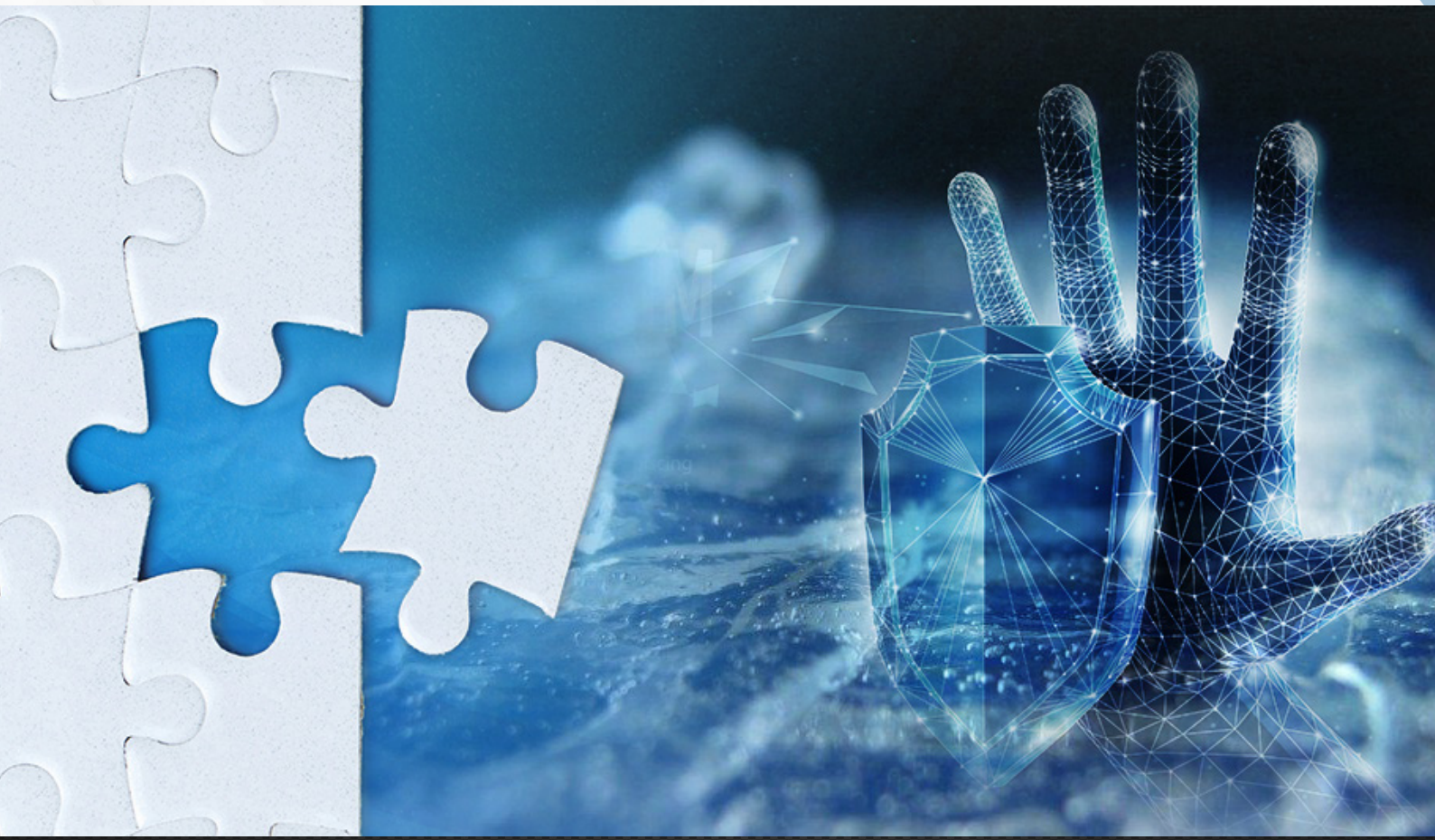
NOVAGENIT®

NOVABarrier

BIO-ABSORBABLE barrier for the prevention
of fibro-adhesions in orthopaedics

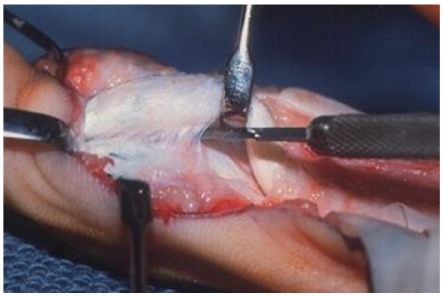


SURGICAL TECHNIQUE

NOVABarrier In Hand Surgery

THE PROBLEM OF POST-SURGICAL ADHESIONS

A common complication of surgical procedures involving tendons and nerves of the hand is the formation of fibro-adhesion which, hindering the normal sliding of tendons and nerves, can lead to complications such as stiffness and sensory problems with a consequent functional deficit of the limb.



NOVABARRIER® - DESCRIPTION, PREPARATION AND APPLICATION

NovaBarrier® at the time of use is in the form of a high viscosity bioabsorbable hydrogel. It is a derivative of hyaluronic acid. The device acts as a temporary barrier protecting and separating the tendon structures and nerves from the surrounding tissues, therefore avoiding the establishment of post-surgical adhesions. This protective action does not interfere with the tissues healing processes.

NovaBarrier® is prepared in the operating room by rehydrating the product in powder portioned into a sterile syringe using sterile water for injection.

The resulting gel is immediately ready for use.

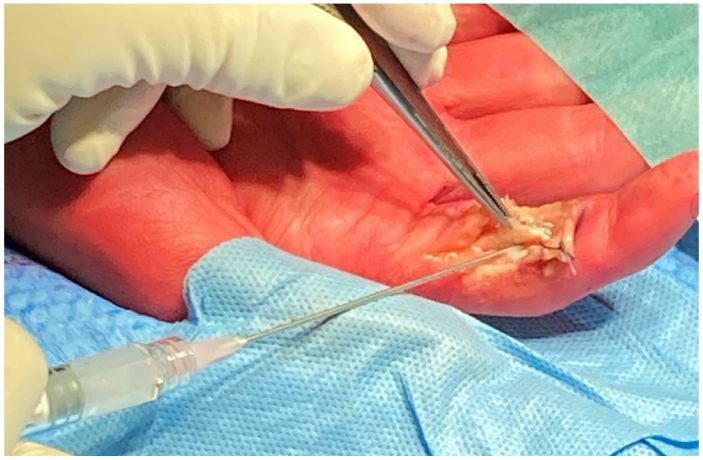
NovaBarrier® is applied after tissue reconstruction along the suture line (tenorraphy or neurorrhaphy) or, in case of tenolysis or neurolysis, on the surface where the adhesions have been removed.

The dispensing of the gel is usually carried out by means of a 7 cm long 18G cannula.

NOVABarrier Application Examples

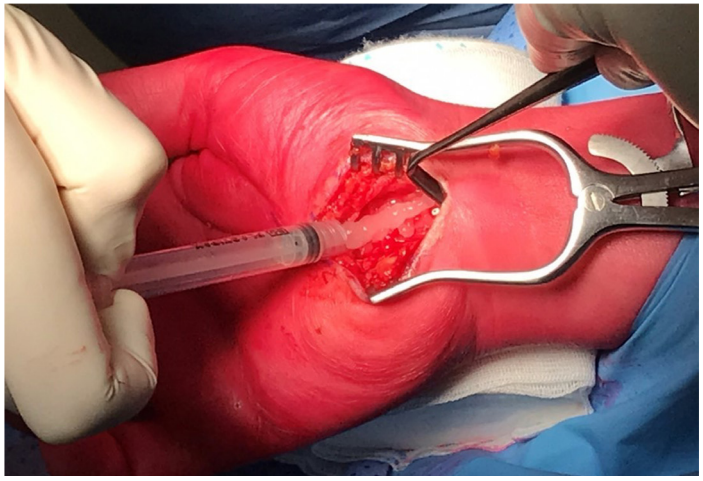
AFTER TENOLYSIS OF THE FLEXOR TENDONS IN ZONE II OF THE HAND

Apply **NovaBarrier®** by using the cannula needle. Distribute the gel evenly on the surface affected from tenolysis ensuring its separation from the surrounding connective tissues. Do not irrigate the operative area after the gel application in order to avoid loss of consistency. Proceed to closure of the skin flaps avoiding dispersion of gel on the incision line.



CARPAL TUNNEL DECOMPRESSION

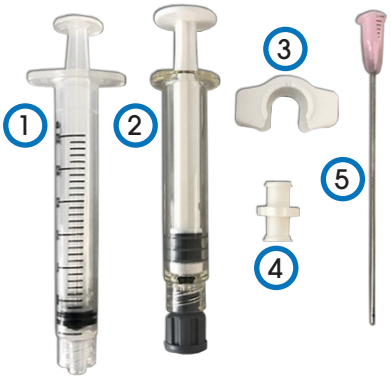
After careful hemostasis, evenly apply **NovaBarrier®** gel on the entire surface of the freed median nerve. Do not irrigate the operative area after applying the gel in order to avoid loss of consistency. Avoid dispersion of the gel near the skin incision before closing the flaps.



NOVABarrier

NovaBarrier® is available in three different formats:

- Ref. NBS021220 kit allowing the preparation of 2ml of Gel
- Ref. NBS020620 kit allowing the preparation of 1ml of Gel
- Ref. NBS020320 kit allowing the preparation of 0.5ml of Gel



The kit **NovaBarrier® S** for the preparation of 2ml hydrogel is constituted by(brackets indicate red and blue respectively the quantities relating to the 1ml and 0.5ml presentations):

1. 5ml (3ml; 1ml) empty graduated syringe.
2. 5ml syringe (2.25ml; 2.25ml) containing 120mg (60mg; 30mg) of dry powder.
3. Backstop.
4. Luer Lock connector.
5. Cannula 18G L70mm.

All the devices contained inside the kit are sterile.

NOVABARRIER® - Gel Preparation

NovaBarrier® gel is obtained by hydrating the powder available in sterile packaging, with water for injections.

NOTE: Water for injections is not included in the NovaBarrier® sterile kits.
DO NOT USE physiological solution or other buffered saline solutions

Fig.1

Open the blister containing the empty graduated syringe and with the aid of a needle (not included in the kit), take a suitable volume of sterile water (Fig.1).
The amount of water to be withdrawn will vary depending on the amount of gel to prepare:

- To prepare 2ml of gel, take 2ml of water.
- To prepare 1ml of gel, take 1ml of water.
- To prepare 0.5ml of gel, take 0.5ml of water.


Fig.2

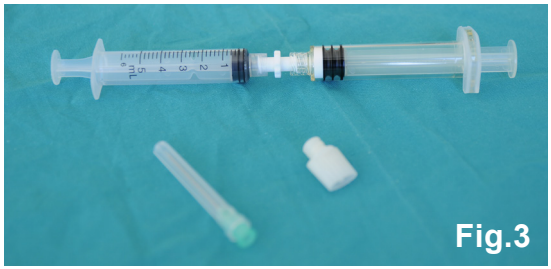


Fig.3

Open the envelope that contains the syringe containing the powder **NovaBarrier®**.
It is recommended to retract slightly the piston and tap on the syringe in order to de-compact the powder to make its hydration easier.
To improve the handling of the syringe it is suggested the application of the flange extender (backstop) (Fig. 2).
Remove the needle from the graduated syringe previously filled in with water and screw the supplied connector.

Remove the cap of the syringe containing the powder and connect it to the syringe containing the water for hydration using the appropriate Luer lock connector (Fig. 3).

Place the two syringes upright with the **NovaBarrier®** powder syringe below the water containing syringe (Fig. 4). Gradually transfer the entire volume of water from the liquid syringe to the syringe containing the **NovaBarrier®** powder by retracting the piston of the powder syringe and lightly pressing on the liquid syringe. Avoid completely closing the powder syringe until all the powder has been released. Then repeatedly transfer the suspension between the syringes until a homogeneous hydrogel is obtained. Once the gel has formed, leave the hydrogel to rest in the syringe for at least 5-10 minutes before use.


Fig.4

Finally, remove the empty syringe together with the connector. Connect the sterile cannula needle contained in the kit to the syringe and apply the gel (Fig.5).

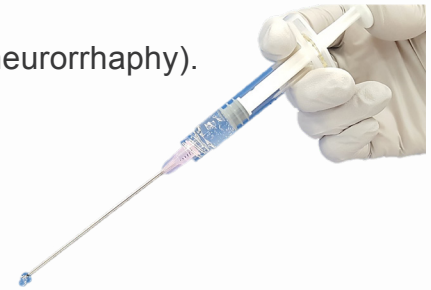

Fig.5

NOVABarrier

A bio-absorbable temporary barrier against adhesions, based on hyaluronic acid.

NovaBarrier® - Indicated in hand surgery for:

- Surgical reconstruction of the tendon and nerve (tenorrhaphy and neurorrhaphy).
- Tenolysis and neurolysis.
- Snap finger and De Quervain syndrome.
- Dupuytren's syndrome.
- Carpal tunnel syndrome.



Available "kit NovaBarrier® S"

Ref.	Description	Vol.
NBS021220	Kit composed of a 5 ml sterile syringe containing 120 mg of dry product, a sterile syringe component set (connector, backstop), an empty sterile 5 ml graduated syringe, a sterile cannula needle.	Hydrate with 2 ml of pure sterile water. 2 ml of final product.
NBS020620	Kit composed of a 2.25 ml sterile syringe containing 60 mg of dry product, a sterile syringe component set (connector, backstop), an empty sterile 3 ml graduated syringe, a sterile cannula needle.	Hydrate with 1 ml of pure sterile water. 1 ml of final product.
NBS020320	Kit composed of a 2.25 ml sterile syringe containing 30 mg of dry product, a sterile syringe component set (connector, backstop), an empty sterile 1 ml graduated syringe, a sterile cannula needle.	Hydrate with 0.5 ml of pure sterile water. 0.5 ml of final product.

OP-NG022_Kit NovaBarrier S_Extremity_EN. rev00

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