FB Medical

CE 2803

MR

INSTRUCTION FOR USE

POWER INJECTION ONCO-GRIP ® AND ONCO-GRIP® 2

CE marking: 2016
Products references: GNXXXXCT– GN2XXXXCT

INDICATIONS

The power injection Onco-Grip® are intended for use in the administration or withdrawal of fluids from implanted ports. They could also be used for blood sampling and parenteral nutrition.
They are also indicated for power injection of contrast media into the central venous system only with an implanted port that is also indicated for power injection.
The cannula shape allows port access limiting to the maximal septum damages and the patient's pain.
The integration of an extension cable with Luer Lock hub to the device bring advantages face to face a simple Huber needle:
- easy use (the hub is much more accessible)
- minimize the infection risk eliminating a connection.
The power injection ONCO-GRIP® has movable grip allowing a good handing of the needle and thus precision during insertion. Its weak thickness and "blunt tray" allow a simple adhesive dressing use for a better comfort of the patient. The risks of needle tear out are much reduced.

CONTRAINDICATIONS:

On the skin against the septum:
• erythema, exanthema,
• unusual pain,
• weeping, discharge of fluid, fistula, abscess, any sign or suspected local infection,
• any sign or suspected turning around of the reservoir,
• difficulty or inability to locate the septum of the port.

During use:
- do not perform a power injection through not power injection adapted devices,
- do not use of small-volume syringes (less than 10mL),
- do not exceed the recommended maximum pressure,
- ensure the patient does not have allergy to iodinated contrast medium
Do not use, in the presence of infection, bacteremia or septicemia known or supposed and related to the implantable access port.
Do not use, if local tissue factors block a stabilization of a suitable access with the needle.
Avoid direct contact between the device and alcohol-based solutions.

WARNINGS:

• Sterile product as long as the packaging hasn't been opened damaged or brake. Single use product. Product sterilized by ethylene oxide. Don't resterilize
• Store in a cool and dry place with ambient temperature. Avoid extreme temperatures and humidity. Avoid rapid and repeated changes of temperature during storage. Conserve in the original packaging.
• Check the integrity of the sterility protector primary packaging. Never use a device which primary packaging is damaged
• Shelf life – Use before expiration date indicated on the package.
• THIS IS NOT a safety medical device
• Only use with devices with continuous flow or under direct control of the operator (syringe…).
• Carefully tighten all connections before and after use. Failure to attach caps can result in an embolism or bleeding.
• Huber needles should only be used by trained personnel.
• Re-use of the device could result in inaccurate flow rate, increased risk of infection or other improper functioning of the device.
• Check with concerned laboratory the compatibility of injected solutions and needle materials.
• This product is a sharp device according to 2010/32/UE directive which may be contaminated after use. Handle and remove it with other sharp / cutting devices according to established medical protocols and other applicable regulations.
• Regularly check for leakage on the infusion line and connections.
• Do not pull too strongly on the tubing before, during or after use. Too much pull strength applied may induce leakage.
• Check that the length of the needle is correct with respect to the depth of the port body. Too long needle can damage the access port; a needle too short may not fully go through the septum and lead to fluid injection from the port and / or blocking of the needle.
• If you feel a resistance at the injection, don't force: this could be the sign of a port catheter thrombosis. Check firstly that the clamp is open and if the line is not bent. Inform the responsible doctor.
• Stop the injection immediately if local pain, swelling, or signs of extravasation are noted

When use for power injection, following warnings apply:

•The power injection Onco-Grip® needles must be used in conjunction with an implanted power-injection port.
• Verify patient has an implanted power injection port. Verify identification methods per port manufacturer's instructions.
• Do not power inject through the needle unless blood return is confirmed.
• Contrast media should be warmed to body temperature before power injecting. Failure to do so may result in device failure.
• Do not exceed the maximum pressure of 325 psi and maximum flow rate as this may result in device failure. Refer to individual product labeling for maximum pressure of the power injector.
• Do not use needles or other sharps with the luer activated needleless injection site. Use only with administration sets or syringes which have luer connectors. Always use aseptic technique when connecting sets/syringes to the Y-site. Make sure the luer connector is securely attached.
• Flush the device using a 10 mL or larger syringe and sterile normal saline prior and immediately following the completion of power injection studies.
• A suitable trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

CAUTIONS:

• Carefully read all instructions prior use, follow all instructions during use.
• This device is not made to be used more than 3 to 4 days.
It is advised to change it daily or more often. In case of replacement by an identical device, the total period of use should not exceed 29 days
• Check that the needle is correctly placed in the port prior to injection. If there is a doubt about the placement of the needle, make an X-ray test to confirm that the positioning is consistent with the approved protocol.
• Any port used for power injection needs to be indicated for power injection. High pressure or use with power injectors in a non-power port may cause leakage or damage.
• Follow all instructions, contraindications, warnings, cautions and precautions for all infusates, ports, IV pumps, IV sets and needleless systems as specified by its manufacturer.
• Implantable port puncture: slightly move up from the last puncture area in order to avoid sluice or fistula between the septum and the patient skin.
• Do not remove and reinsert the needle into the port.
• Avoid excessive manipulation once the needle is in the port.
• Possible complications: occlusion of the system (because of the high density of some contrast), infection, extravasation of contrast media into the soft tissues with swelling or localized erythema or skin ulceration and necrosis, subintimal venous or myocardial injection, breakage of the extension of the non-coring needle or its detachment from the needle, sudden expulsion of the non-coring needle from the silicone septum and thus from the port chamber, detachment of the catheter from the port or breakage of the catheter, embolization of catheter fragments in the central venous or pulmonary arterial circulation.

INSTRUCTIONS FOR USE:

Use aseptic technique. Wear mask and sterile gloves.
Practice a local disinfection of the implantation area **(with cleansing swabs containing 70% Isopropyl Alcohol. Dry)**
Always inspect for integrity of patients skin over the port septum prior to access site. Verify the patient has a power injection port.
1 Needle priming: with a Luer Lock syringe filled of the solution to inject (or sterile physiological serum), make a complete rinsing of the extension line in order to expel the air.
2 Holding the needle from the sides, or the grip, remove the needle cap.
3 Localize the port by palpation and maintain firmly the port between 2 fingers.
4 Prick between the fingers on centre of the septum from perpendicular to the skin
5 Cross slowly the skin, then the septum. **Avoid the contact between the Huber needlepoint and the port bottom (risk of septum damage during the removal).** Remove the ONCO-GRIP® grip.
6 Aspirate for adequate blood return and flush the system with sterile normal saline. **Difficulty in withdrawing blood or injecting the saline may indicate catheter blockage or improper needle position.**
7 Fix the needle on the skin with a hypoallergenic dressing (preferably washable and transparent).
8 Attach the power injection device to the power injection Onco-Grip® and the extension set per the manufacturer's recommendations.
9 Prepare contrast media according to manufacturer's instructions.
10 Instruct the patient to notify the clinician immediately if there is any pain or abnormal sensation during the power injection.
11 Complete the power injection study taking care to not exceed the maximum pressure of 325 psi. See the chart below for specific flow rates with the power injection Onco-Grip®. needle.

Power injection Onco-Grip® Safe size	19G	20G	22G
Maximum Flow Rate with contrast media at 11,8 cPs	3,5 mL/sec	2,8 mL/sec	2 mL/sec
Maximum Pressure	325 psi / 22 Bar		

12 End of the procedure, rinse and lock the port according to the instructions of the manufacturer of the implantable port. (see § RINSING)
Take off frankly the needle pushing the syringe piston.

INJECTION OF SEVERAL DIFFERENT SOLUTIONS:

WARNING: Never inject one after the other 2 products, which could precipitate or interact, without an intermediate rinsing with sterile physiological serum (thrombosis risk). In the event of doubt, make a rinsing.
1. Close the clamp,
2. Take off the first syringe,
3. Adapt the second syringe,
WARNING: Take cares of not introduce air or infections during the change.
4. Open the clamp.

BLOOD SAMPLES:

1. Take 5 ml of blood and throw this sampling (because the blood is mixed to the heparined bolt)
2. Make the blood sampling.
3. Rinse immediately with 10 ml of physiological serum.
4. Heparinise

RINSING:

Injection of 10 ml of sterile normal saline.
Δ Directing the Huber point needle opening in the diametrically opposite direction of the implantable port exit channel increases the flushing efficiency.

HEPARINISATION:

Injection of 3 to 5 ml of a solution containing heparin (100 U/ml).
Routine heparinisation (follow the doctor's opinion)
- arterial catheter: every 7-15 days
- venous catheter: every 15-30 days

The materials of the needles are: needle = stainless steel, grip = POM, tube = PUR, clamp = POM or PP with ABS ID ring, hub = PC, cap = PP, PS , Y = PC, blister = PVC + PGL

MRI Safety Information

MR Conditional

MR

Non-clinical testing demonstrated that the ISO Med Onco-Grip® is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:
• Static magnetic field of 1.5-Tesla and 3-Tesla, only
• Maximum spatial gradient magnetic field of 1500 Gauss/cm or less
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system
• Under the scan conditions defined, the ISO Med Onco-Grip® is expected to produce a maximum temperature rise of 2.7 ˚C after 15-minutes of continuous scanning.

Artifact Information
In non-clinical testing, the image artifact caused by the ISO Med Onco-Grip® extends approximately 100 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

EN: Do not use if the packaging is damaged
FR: Ne pas utiliser si l'emballage est endommagé
DE: Nicht verwenden, wenn die Verpackung beschädigt ist
ES: No utilizar si el embalaje está deteriorado

EN: See instruction for use
FR: Lire la notice
DE: Anleitung lesen
ES: Consulte las intrucciones de uso

EN: Manufactured by
FR: Fabriqué par
DE: Hergestellt von
ES: Fabricado por

EN: Single use
FR: Usage unique
DE: Zum einmaligen Gebrauch
ES: De un solo uso

EN: Sterilized by Ethylene Oxide
FR: Stérilisé à l'oxyde d'éthylène
DE: Mit Ethylenoxid sterilisiert
ES: Esterilizado con óxido de etileno

EN: Reference number
FR: Numéro de référence
DE: Bestellnummer
ES: Número de referencia

EN : Manufacturing date
FR : Date de fabrication
DE :Herstellungsdatum
ES : Fecha de fabricación

EN: Use by
FR: À utiliser avant la date
DE: Verfallsdatum
ES: Utilizar antes de

EN: Batch code
FR: Numéro de lot
DE: Chargennummer
ES: Número de lote

EN: MR conditional see MRI information
FR : utilisation conditionnelle en IRM. Voir information IRM
DE : Bedingt MR sicher. Siehe MRT Informationen.
ES : Condicional según RM, Véase el apartado Información de IRM

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