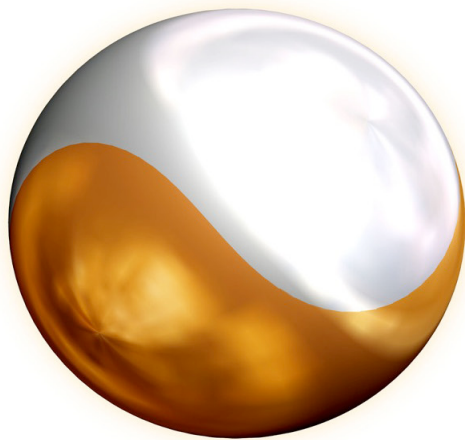

APPLICATION FOR SPINE



GOLDIC®

ORTHOPEDICS
CERVICAL SPINE





GOLDIC[®] SERUM

CERVICAL EPIDURAL INJECTIONS

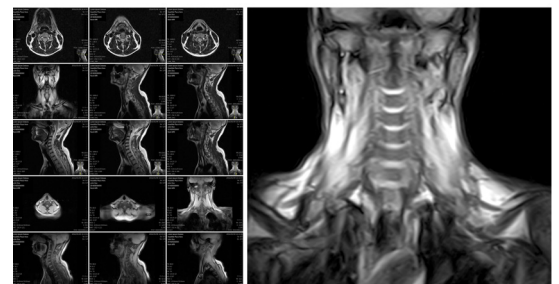
GOLDIC[®] cervical epidural injection procedure is administered to relieve pain in the neck, shoulders and arms caused by a pinched nerve or inflamed nerve(s) in the cervical spine.

GOLDIC[®] is delivered to the epidural space, which is a fat-filled area between the bone and the protective sac of the spinal nerves

All of the procedure is routinely performed on an outpatient basis. Regularly, sedation is not used.

Conditions such as herniated discs, spinal stenosis or arthritis can compress and pinch nerves, causing inflammation and pain. The cervical epidural **GOLDIC[®]** injection procedure involves injections into the surrounding area that help with pinched nerve pain management and decrease the swelling of the inflamed or pinched nerve(s), in addition to reducing inflammation.

Thorough understanding of basic injection principles, knowledge of the underlying anatomy, and consideration of the advantages and disadvantages of the imaging approaches should facilitate selection of the most appropriate technique for any clinical scenario.



PRECAUTIONS

Pre-Injection Precautions

- Appropriate patient education and discussion has occurred with an informed consent signed prior to the initiation of the procedure.*
- Avoid corticosteroid medications for 2 to 3 weeks prior to the procedure.*
- Patients are advised to drink plenty of fluids the day before the procedure.*
- Some patients may require anti-anxiety medication immediately before the procedure.*

**According to the “American Academy of Orthopedic Surgeons” recommendations.*

Injection Precautions

- All necessary materials for the injection (**GOLDIC**® set, needles, etc.) should have been planned and placed on a sterile table adjacent and easily accessible to the physician.
- A doctor or technician prepares the **GOLDIC**® for injection and the affected area is cleansed with disinfectant. The patient's skin is cleansed appropriately and towels or drapes may be used to create an aseptic field.
- Sterile technique is used, including mask, sterile gloves and sterile preparation.
- In light of safety and efficacy differences between guided and blind injections, we adhere to guided injections as the general standard with **GOLDIC**® injections.
- Epidural injection has been used for spinal pain management for many years, but many of these procedures have historically been performed without imaging guidance. Recently, imaging-guided techniques with fluoroscopy or computed tomography increase the precision of these procedures and help confirm needle placement.
- Sterile single use needles should be used with appropriate handling and disposal.
- The patient is placed in an appropriate and comfortable position that allows for sterility and access to the site of injection. The patient is placed in prone position and a spinal cord needle is advanced adjacent to the vertebral bow of the affected level. The needle should have bony contact first. By inclination of the cervical spine the

space between the two vertebral bows will be opened and the needle can be advanced over the upper part of the bow. The ligament should be penetrated by injection of the serum in a parallel way.

- Once the needle is in the proper position, the **GOLDIC**® serum solution is then injected epidural. Although the serum is injected slowly, most patients sense some pressure due to the amount of the serum used (which is app. 3 ml). The pressure of the injection is not generally painful.
- A typical treatment consists of four (4) 3 ml **GOLDIC**® serum injections every 2-3 days.
- Apply a dressing or appropriate bandage to protect the needle entry site.

Post-Injection

- Monitor for post-procedure complications. Important safety considerations include attention to the possibility of bruising and / or soreness at the injection site.
- Following the injection, the patient usually remains for 30 minutes to ensure that there are no immediate complications or adverse reactions, such as allergic reaction or leg weakness / numbness. The doctor or other team member will determine when it is safe for the patient to go home.
- Tenderness at the needle insertion site can occur for a few hours after the procedure and can be treated by applying an ice pack for 10 to 15 minutes once or twice an hour.
- Patients should be given post-procedure instructions, precautions, and emergency contact information.
- Although rare, risks of the cervical epidural injection procedure may include infection, spinal headache and nerve damage.
- In addition, patients are usually asked to rest for the remainder of the day on which they have the intra-articular **GOLDIC**® serum injection.
- The procedure should be recorded in detail with a procedure note including: date, pre/post-procedure diagnosis, procedure title, performing physician w/wo assistants, anesthesia, brief indication of procedure, description of procedure including guidance and instruments.

GOLDIC® PREPARATION GUIDE

www.goldic.co.za



GOLDIC® is a platform technology using specially designed gold particles to produce an autologous conditioned serum. The **GOLDIC®** technology leads to an accumulation of endogenous regenerative cytokines and various factors under the intended use of the medical device.

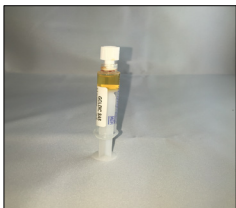
The **GOLDIC® Set** serves as a medical device to optimize the body's own serum. This serum is injected as part of a subsequent medical treatment as an autologous drug without additives.



To get a **good mixture between the gold particles and patient's blood** shake the BTS-tubes by gentle wrist movements.



The important cytokines with growth factors and the **serum enriched with key protein Gelsolin** is then **prepared for the injection** of the patient.



Disconnect the GOLDIC® SAS-tube and seal it with a sterile cap or a sterile injection cannula.

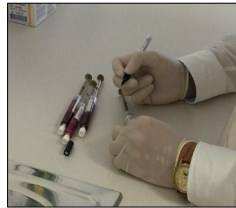
Label each GOLDIC® SAS-tube with patient details.



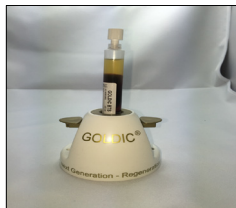
The **GOLDIC® Set** (Gold Induced Cytokine Set) is designed to specifically process autologous blood. It allows the rapid and efficient accumulation of serum with cytokines and growth factors.

GOLDIC® Set includes the following parts:

- 4 x **Blood-Taking-System** (BTS)
- 4 x **Serum-Applications-System** (SAS)
- 1 x Butterfly needle
- 1 x Three-way tap to connect the BTS-tube
- Additional labels



Mark each BTS-tube with the patient's details (name, date of birth, date and time of blood taking).



Afterwards place each BTS-tube in the **"Serum-Transfer-Device" (STD)**.

Rotate the tube 45° to the right direction to fix it.

OPTIONAL !



The **therapy with GOLDIC®** consists usually of **4 injections** of the processed serum for complete treatment.

It is now **injected into the affected joint, tendon or tissue.**

In case of sensitive areas, administering local anesthesia first is recommended.



Use **standard aseptic technique**, prepare the arm vein of the patient for blood removal (tourniquet, alcoholic disinfectant, sterile gloves).

Slowly and carefully (to avoid hemolysis) draw **10 ml** of patient's own blood into each **Blood-Taking-System (BTS-tube)**.

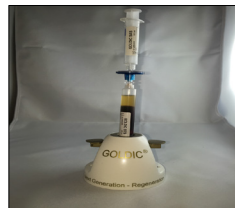
For blood collection, we recommend using the butterfly needle.



Store the BTS-tubes in the **incubator at 37°C (99°F) for 24 hours.**

Please note: Do not store the BTS-tubes directly on the floor of the incubator, but on a grid approximately in the middle.

The prescribed **incubation period should not be exceeded** and monitored by medical personnel.



Unscrew the cap; disinfect the top of the BTS-tube with alcoholic disinfection spray.

Connect the Serum-Application-System (SAS-tube) to the Blood-Taking-System (BTS-tube).



Inject the serum immediately, or store all prepared SAS-tubes together in a storage box / bag at -18°C (-0.4°F) in a freezer until next treatment.

Please **check the integrity and labeling** of the SAS-tubes prior next usage.

Record the process in a lab diary (patient details, date, number of SAS-tubes, noticeable problems).



Using the three-way tap you can **connect up to 2 BTS-tubes** at the same time. Slowly draw 10 ml of patient's own blood into each BTS-tube.

Do NOT use any anticoagulants.

Make sure the lid is properly closed. Screw cap onto port of the BTS-tube and make sure that it is locked tight.



Once this has been done the BTS-tubes will be **centrifuged for app. 10 minutes with 4,000 RPM** to separate the serum from gold particles and blood cells.

Before the start of the centrifugation process it should be checked again whether the cap closes firmly. The BTS-tubes must be placed so that the cap is pointing upwards.



Press down the lateral finger buttons of the Serum-Transfer-Device (STD) to transfer the serum through the filter into the SAS-tube.

OPTIONAL !

Alternatively, the transfer of the serum can be achieved by **manually moving up the syringe plunger** within the BTS-tubes.



This form of treatment involves a special type of **personalized medicine.**

The **GOLDIC®** set is intended for the physician to prepare for **an individual treatment of inflammatory and degenerative diseases.** Here one uses the positive effect of the gold while avoiding any side effects.

The **GOLDIC®** set can be used in professional health care facilities, such as doctors' offices, hospitals, clinics and other medical facilities.

This description of technique including post-injection protocol is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of Goldic®. As part of this professional usage, the medical professional must use their professional judgment in making any determination in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of medical literature and the product's Instructions For Use.