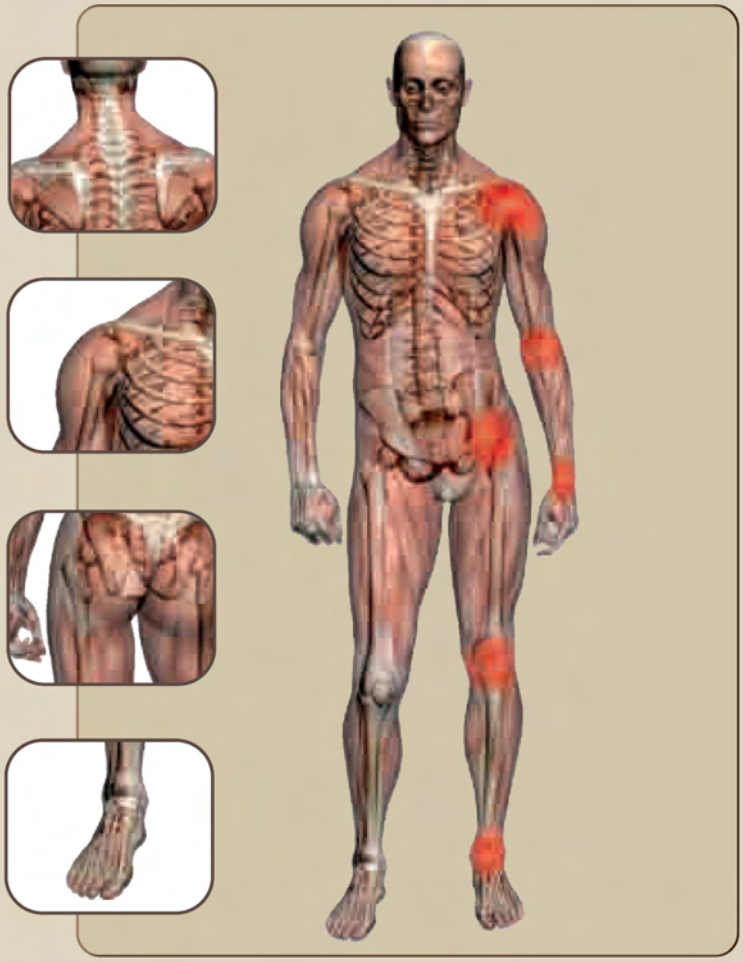
CE 0373

COLLAGEN MEDICAL DEVICES

An effective and innovative approach to the injective treatment of ostheo-arthro-myo-fascial pathologies.



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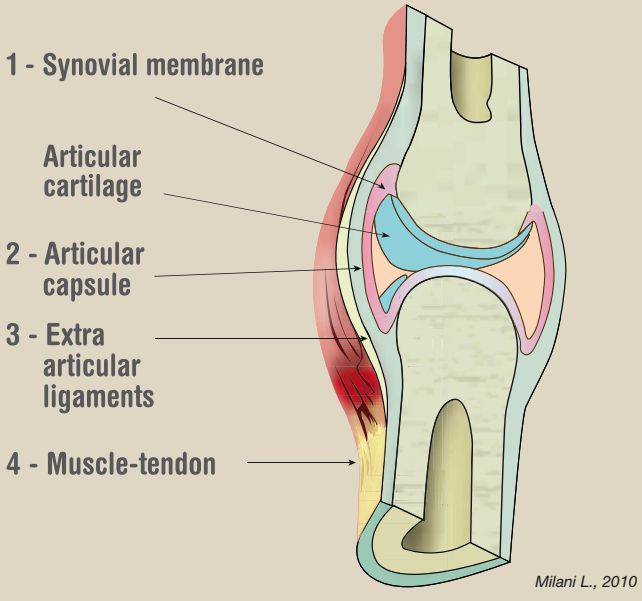
COLLAGEN MEDICAL DEVICES

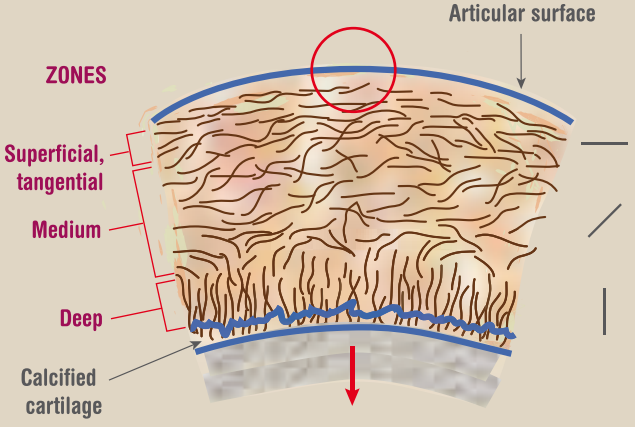
COLLAGEN IS THE MOST ABUNDANT PROTEIN IN THE HUMAN BODY*

1/4 of the total protein mass in the mammals consist of collagen: bone and tendons, joint capsules and muscles, ligaments and fascia, teeth and serous membranes, skin and extracellular matrix*

(Lynsenmeyer, 1991)



Milani L., 2010



Milani L., 2010

THE MECHANICAL SUPPORT PROVIDED BY THE COLLAGEN IS AN EFFECTIVE, NATURAL SCAFFOLDING (BIO-SCAFFOLDING)*

The collagen fibers of the joint cartilage are arranged in vertical fascicles in the major substance of the deep layers, while in the surface layer they are arranged tangentially. The fibrous arches form a structure similar to the Roman Arch*.

* Milani L., A New Refined Injectable Treatment for Musculosceletal Disorders - Bioscaffold Properties of Collagen and Its Clinical Use, Physiological Regulating Medicine, 1/2010

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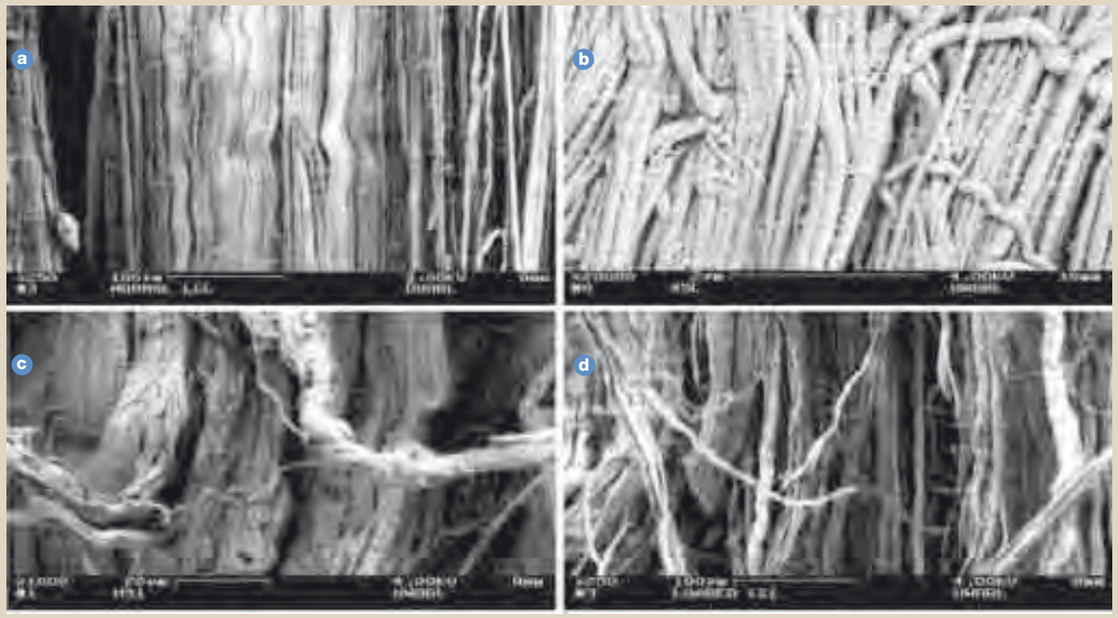
COLLAGEN **M**EDICAL **D**EVICES

THE INTEGRITY OF THE COLLAGEN FIBERS CAN BE DAMAGED BY:

MECHANICAL CHANGES;
INCORRECT POSTURE;
COLLEGANOPATHIES RELATED TO AGING;
CHRONIC INFLAMMATORY CONDITIONS*



Medial collateral ligament:
- **a normal;**
- **b fork-fusion of collagen fibrils;**
- **c wound healing process;**
- **d microstructural damage due to overload** (not breakage)

– Photomicrographs *in* P. Provenzano, Hurschler C., R. Vanderby Jr. - Connective Tissue Research, 42, 123-133, 2001.

COLLAGEN APPLICATION EFFECTS*

Restoration of joint cartilage
Stone et Al., 1997;
Cook et Al., 2006.

Restoration of tendons
Chenet et Al., 2007;
Karaoglu et Al., 2007;
Perry et Al., 2009.

COLLAGEN THERAPY

Ligaments restoration
Nijbizi et Al., 2000;
Musahl et Al., 2006;
Woo et Al., 2006;
Liang et Al., 2006;
Liang et Al., 2008.

Wounds treatment
Lansman et Al., 2009

* Milani L., A New Refined Injectable Treatment for Musculosceletal Disorders - Bioscaffold Properties of Collagen and Its Clinical Use, Physiological Regulating Medicine, 1/2010

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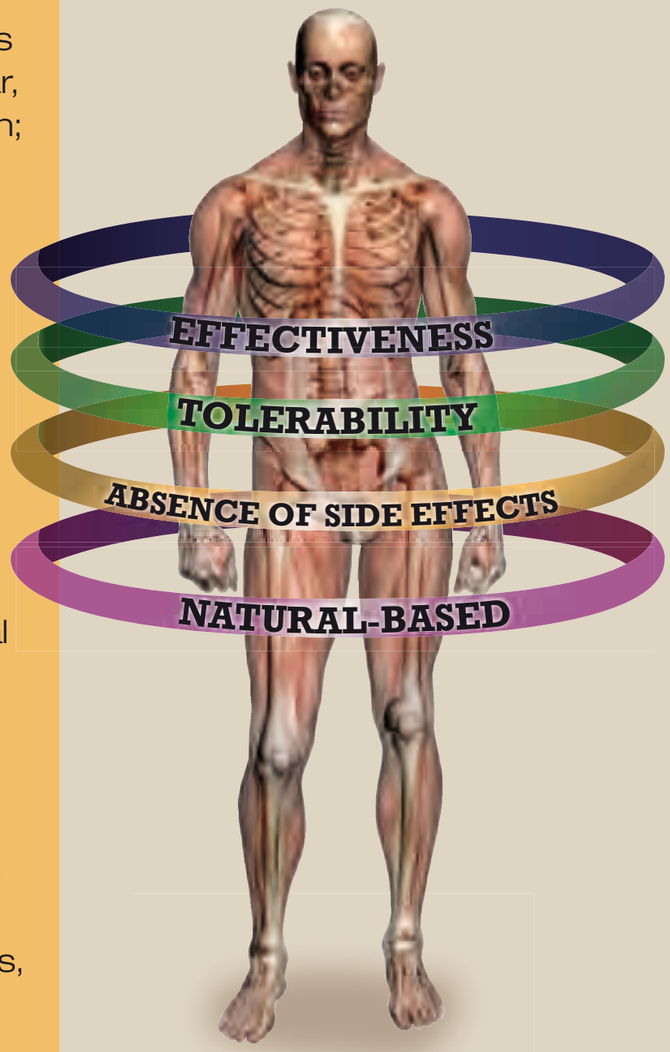
COLLAGEN MEDICAL DEVICES

Collagen Medical Devices:

- are available in 2 ml ampoules via peri-articular, intra-articular, and intra-dermal administration;
- contain collagen, isotonic water and ancillary components. Those last components are natural and allow a better and more focused positioning of the collagen in situ.

With the aim of:

- improving the histological constitution of the anatomical structure in which the Collagen Medical Device is injected;
- offering mechanical support with a clear positive effect on the stabilization of joint hyper-mobility, on movements, pain and quality of life.



Medical Devices are Collagen-based.
3 different manufacturing processes are performed:

→ **Cross-flow filtration**

→ **Sterilization**

→ **Molecular Weight Control**

These processes aim at obtaining a pure product with standardized molecular weight and physical-chemical characteristics.
The high quality of these products makes Collagen Medical Devices the ideal means for collagen supplementation where it is most needed.

↓

They guarantee

CLINICAL SAFETY AND REPRODUCIBILITY OF RESULTS

INDUSTRIAL PROCESS DEVELOPED BY GUNA!

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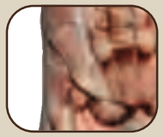
COLLAGEN MEDICAL DEVICES

Effective MDs
as they contain highly purified collagen and natural ancillary components

Innovative MDs
as they are Medical Devices active also on the external joint capsule



MD-HIP (hip)

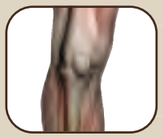
Collagen calcium phosphate

Improve mobility of the hip joint, help muscle stretching on the lumbo-sacral area, help to support peri-articular muscle tissue, soothe local pain and pain due to joint movement or bad posture

MD-ISCHIAL (sciatic nerve)

Collagen rhododendron

Improve leg mobility, leg muscle stretching, help to support leg muscle tissue, soothe leg pain while starting to move legs again after a long inactivity period



MD-KNEE (knee)

Collagen arnica

Improve knee mobility, help muscle stretching, soothe knee pain while moving legs and knee

MD-LUMBAR (lumbar)

Collagen hamamelis

Help lumbar region mobility, help muscle stretching of the lumbo-sacral area, help to support the lumbar muscle tissue, soothe local pain, pain at rest or caused by movement and bad posture

MD-NECK (neck)

Collagen silica

Improve mobility of the cervical region of the spine, promote cervical muscle stretching, help to support cervical muscle tissue, help to support cervical muscle tissue in bad posture disorders, soothe cervical column pain due to movements

MD-SHOULDER (shoulder)

Collagen iris

Improve shoulder- and arm-joint mobility, help muscle stretching, help to support the muscle tissue, soothe local pain and pain due to movement

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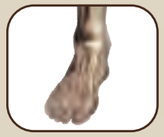
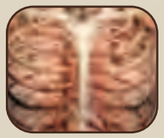
COLLAGEN MEDICAL DEVICES



MD-SMALL JOINTS
(small joints)

Collagen
viola

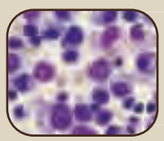
Improve mobility of the small joints of hand, foot and ankle, help muscle stretching, help to support muscle tissue, soothe local pain and pain due to movement



MD-THORACIC
(thorax)

Collagen
cimicifuga

Improve mobility of the thoracic tract of the spine, help muscle stretching, help to support muscle tissue in bad posture disorders, soothe leg pain, pain due to movement and bad posture



MD-MATRIX
(extracellular matrix)

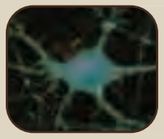
Collagen
citric acid
nicotinamide

Strengthen matrix tissues where the collagen barrier is located, act as a defensive barrier against free radicals

MD-MUSCLE
(muscles)

Collagen
hypericum

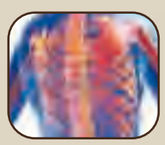
Enhance muscle relaxation and functioning, help to support the muscle tissue in bad posture disorders, improve joint mobility, soothe local pain, pain at rest or caused by movement and bad posture



MD-NEURAL
(nerves)

Collagen
colocynthis

Strengthen perineurium collagen structure, soothe neural local pain



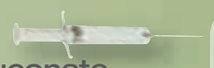
MD-POLY
(joints)

Collagen
drosera

Improve joint mobility, help muscle stretching, help to support the muscle tissue in bad posture disorders, soothe local pain and pain due to joint movement or bad posture

MD-TISSUE
(soft tissues)

Collagen
ascorbic acid
magnesium gluconate
pyridoxine hydrochloride
riboflavin
thiamine hydrocloride



Act as a defensive barrier against free radicals, counterbalance the physiological aging of the connective tissue

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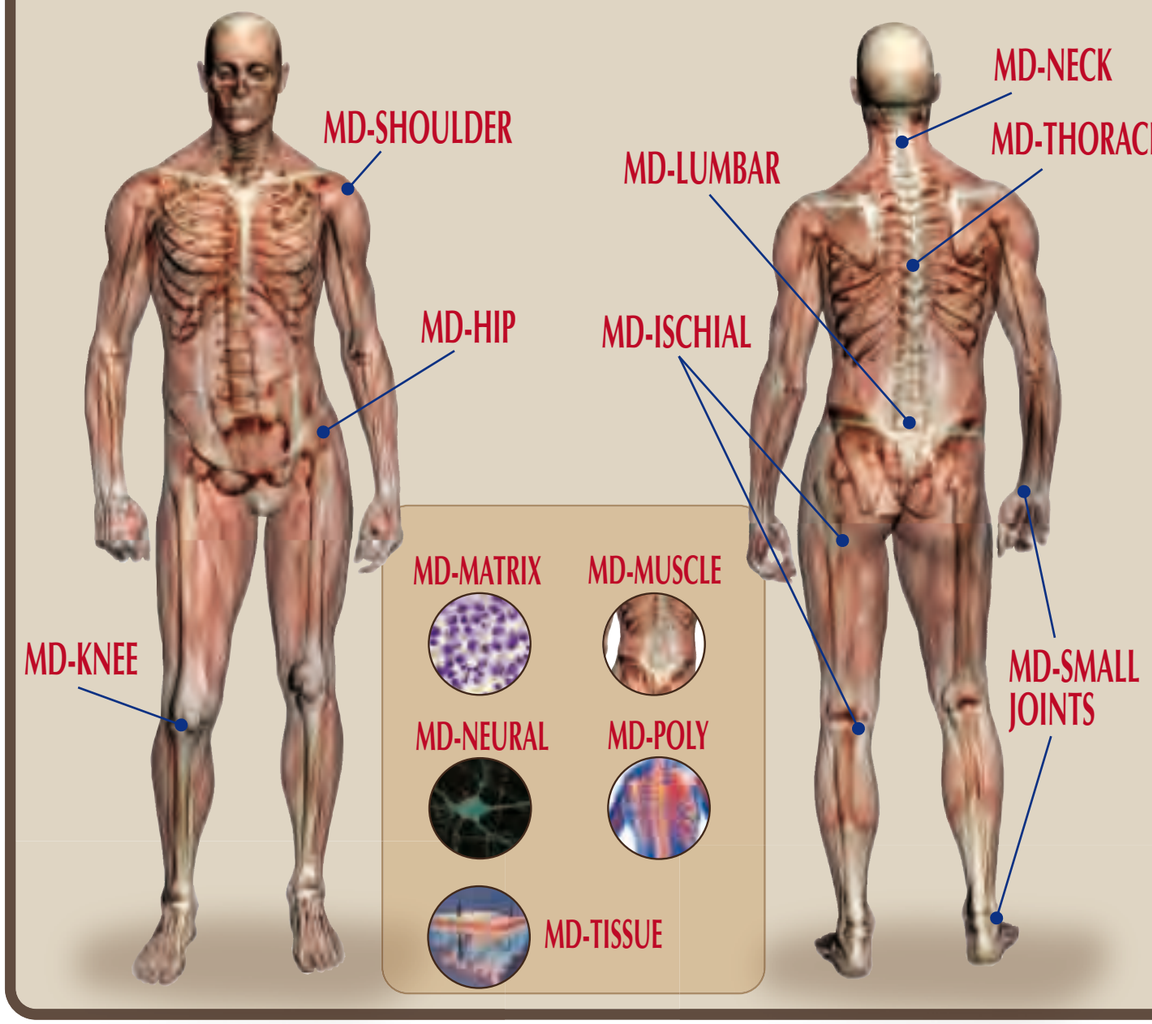
COLLAGEN MEDICAL DEVICES

A complete line for the treatment of all painful forms affecting the musculoskeletal system



Clinical Evidence

Abstracts from a selection of clinical studies performed with Collagen Medical Devices*:

1. **Pain Treatment in chronic cervical myofascial syndrome, local therapy with Collagen Medical Devices vs conventional treatment. Results of a controlled clinical trial;**
2. **Use of Collagen Medical Device MD-Shoulder vs ultrasound therapy in the subacromial impingement treatment;**
3. **Therapy with MD-Hip + MD-Muscle vs electrostimulation of trigger points in the pain management of the hip joint functional deficit;**
4. **Treatment with injectable Collagen Medical Devices in low back pain and sciatica pain in a group of athletes;**
5. **Treatment of chronic neck pain with MD-Neck + MD-Muscle;**
6. **Treatment of shoulder periarthritis with Collagen Medical Devices;**
7. **Therapy of mild and moderate gonarthrosis with MD-Knee + MD-Poly.**

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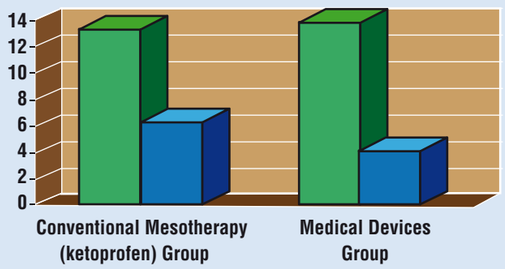
COLLAGEN MEDICAL DEVICES

Clinical Evidence

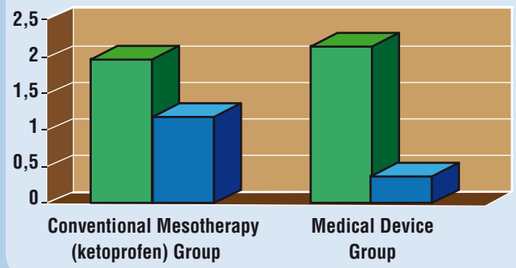
1 Pain Treatment in chronic cervical myofascial syndrome, local therapy with Collagen Medical Devices vs conventional treatment - Results of a controlled clinical trial

This controlled clinical trial enlisted 196 patients affected by chronic neck strain. One group (109 patients) was treated with a combined therapy with MD-Neck 1 ampoule + MD-Muscle 1 ampoule + MD-Neural 1 ampoule (cocktail 6 ml). The other group was treated with a pharmacological therapy (Ketoprofen, 2 ampoules x 2 ml).
Number of applications: one for each patient of both group once weekly for 10 consecutive weeks.
Graphs show a better clinical result in the MDs group vs the ketoprofen group.

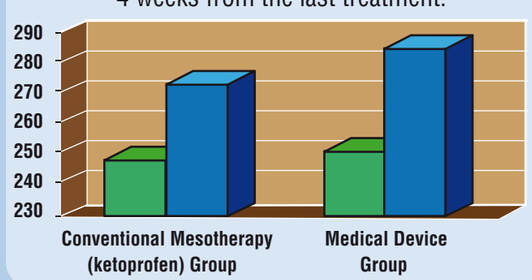
Pain (VAS scale)
Comparison between the 2 groups before and after 4 weeks from the last treatment.



Dizziness (scale 0-4)
Comparison between the 2 groups before and after 4 weeks from the last treatment.

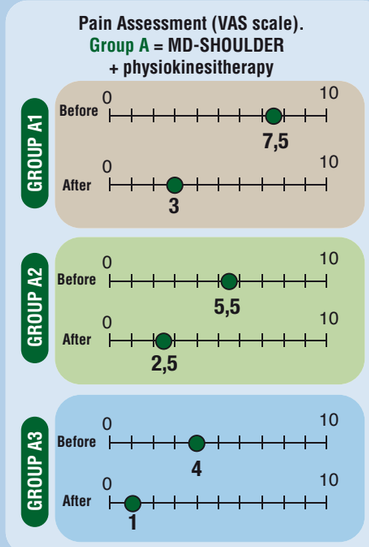


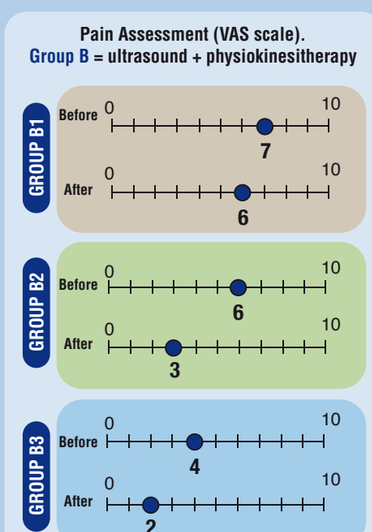
Neck Mobility (degrees)
Comparison between the 2 groups before and after 4 weeks from the last treatment.



Clinical Evidence

2 Use of Collagen Medical Device MD-Shoulder vs ultrasound therapy in the subacromial impingement treatment



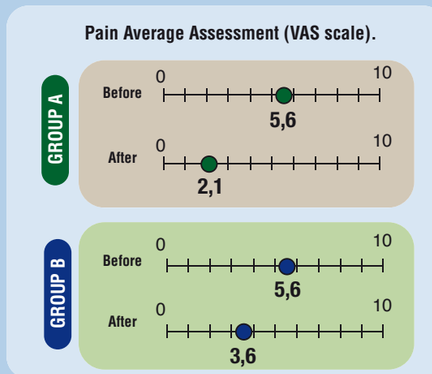


This clinical trial included 50 patients who suffer from shoulder pain due to subacromial impingement. Patients were divided into 2 homogeneous groups:

Group A: MD-Shoulder via periarticular infiltration, 1 ampoule twice weekly for 4 consecutive weeks,

Group B: ultrasound therapy (1 MHz, 2 Watt/cm^2 for 10 minutes) on the aching area.

Both groups were divided into 3 subgroups: A1 and B1 with acute pain, A2 and B2 with sub-acute pain, A3 and B3 with chronic pain. All patients underwent a concomitant physiokinesitherapy. The VAS scale before and after treatment shows a better effectiveness of MD-Shoulder vs ultrasound therapy in all subgroups. As the bottom-left graphs show, acute pain treatment with ultrasound therapy was scarcely effective, unlike that with MD-Shoulder. In fact, 32% of group B patients recurred to FANS treatment to soothe pain. The joint mobility improvement was bigger in group A.



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COLLAGEN MEDICAL DEVICES

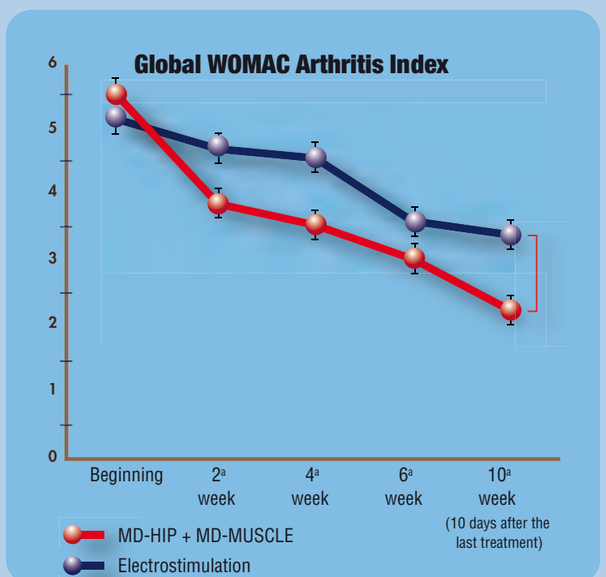
Clinical Evidence

3 Therapy with MD-Hip + MD-Muscle vs electrostimulation of trigger points in the pain management of the hip joint functional deficit

111 patients affected by coxarthrosis were divided into 2 homogeneous groups:
Group A: 57 patients treated with MD-Hip 2 ampoules + MD-Muscle 2 ampoules (cocktail 8 ml) once weekly for 10 consecutive weeks;
Group B: 54 patients who underwent electrostimulation once weekly for 10 consecutive weeks.

Treatment effectiveness was assessed according to the WOMAC scale. Results for both groups are reported below.

Both treatments were proven to be effective in reducing chronic pain due to primary coxarthrosis, even though MD-Hip + MD-Muscle group results were better and more rapid compared to the electrostimulation group.
The improvement was progressive from the first to the 10th week.

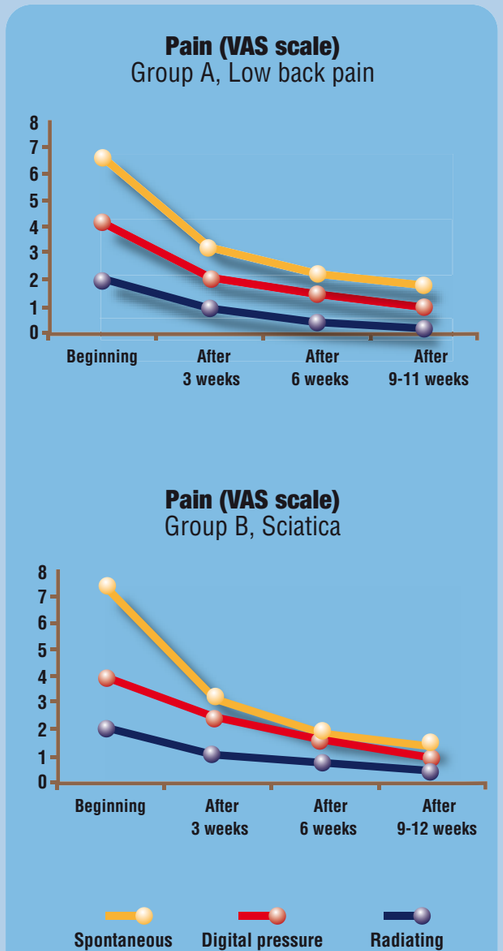


Clinical Evidence

4 Treatment with injectable Collagen Medical Devices in low back pain and sciatica in a group of athletes

92 athletes, aged between 18 and 32, affected by low back pain and sciatica with different severity degrees, took part to this trial. Athletes were divided into two groups:
Group A: 82 athletes affected by low back pain were treated with MD-Lumbar (2 ampoules) + MD-Muscle (1 ampoule) + MD-Neural (1 ampoule). The cocktail was mixed into one syringe for a total volume of 8 ml.
Group B: 10 athletes affected by sciatica were treated with MD-Lumbar (1 ampoule) + MD-Muscle (1 ampoule) + MD-Ischial (2 ampoules). The cocktail was mixed into one syringe for a total volume of 8 ml.

Both groups were treated once weekly for 8/10 weeks; the application area was alongside the lumbar vertebrae (L2 to L5) and, in group B, along the sciatic nerve (MD-Ischial). Results were very satisfying in both groups. Already after 3 treatment weeks, a clear and progressive pain reduction was observed at rest, while moving and at digital pressure. Radiating pain was reduced too.
Tolerability was generally good.



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COLLAGEN MEDICAL DEVICES

Clinical Evidence

5 Treatment of chronic neck pain with MD-Neck + MD-Muscle

This clinical trial assessed the effectiveness of a treatment with MD-Neck 2 ampoules + MD-Muscle 2 ampoules (cocktail 8 ml) on **10 patients** affected by chronic neck pain. Number of applications: 7-11 mesotherapy sessions once weekly.
Results showed a very good therapeutic response on pain reduction, on joint mobility and muscle contraction improvement. In all patients, tolerability was excellent.

Patients	Pain (VAS scale)/		Joint Mobility (degrees)/		Improvement of muscle contraction (0-4 scale)
	Before	After	Before	After	
Patient 1	7	3	40°	70°	3
Patient 2	7	3	45°	75°	3
Patient 3	8	4	35°	60°	2
Patient 4	8	3	50°	70°	3
Patient 5	6	4	35°	65°	3
Patient 6	5	1	45°	80°	3
Patient 7	9	4	30°	60°	3
Patient 8	6	4	40°	75°	3
Patient 9	7	2	40°	70°	3
Patient 10	6	1	50°	75°	3

Clinical Evidence

6 Treatment of shoulder periarthritis with Collagen Medical Devices

The aim of the present study was to assess the effectiveness of two Medical Devices: MD-Shoulder 1 ampoule and MD-Poly 1 ampoule (cocktail 4 ml) in the treatment of shoulder periarthritis.
Periarthritis is a chronic disorder that is very common among adults. The main symptoms are pain and reduced joint mobility. Standard therapy with FANS and cortisone is very effective, although it brings about important side effects. It is then useful to choose alternative therapies for those patients who cannot tolerate the pharmacological treatment. **10 patients**, aged between 50 and 60, were treated with a cocktail containing MD-Shoulder and MD-Poly.
The injection was performed once weekly for 8 weeks.
The treatment was proven to be effective with very good responses on the reduction of pain and muscle contraction and increase of joint mobility.
Tolerability was excellent and there were no side effects.

7 Therapy of mild and moderate gonarthrosis with Collagen Medical Devices MD-Knee + MD-Poly

10 patients were included in this trial: 4 patients with mild symptoms (Group 1) and 6 with moderate symptoms (Group 2). Clinical symptomatology was assessed according to 3 parameters: 1-pain at rest, 2-pain while moving the knee, 3-flection and extension functional deficit. MD-Knee 1 ampoule + MD-Poly 1 ampoule (cocktail 4 ml) treatment was performed once weekly for 10 weeks. Both groups underwent the same therapy protocol.
Results Group 1: good results on pain reduction and joint mobility. The average difference on the VAS scale was 3.75 while the average difference flection-extension was 35° (+78% if compared to the initial value).
Results Group 2: also in this group, good results were observed. The average difference on the VAS scale was 2 while the average difference flection-extension was 20° (+40.8% if compared to the initial value).
To conclude, all patients benefitted from MD-Knee + MD-Poly periarticular injections.
The treatment was very well tolerated and no relevant side effects appeared.

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COLLAGEN **M**EDICAL **D**EVICES

Collagen Medical Devices Handbook

Instruction for use

Scientific documentation for the exclusive use of qualified staff

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COLLAGEN **M**EDICAL **D**EVICES

As a supportive treatment of the following pathologies:

- **A**cts as a defensive barrier against free radicals: **MD-TISSUE**
- **A**rthrosis pain due to hammer toe: **MD-SMALL JOINTS**
- **A**typical facial neuritis: **MD-NEURAL** (in association with **MD-NECK**)

- **B**rachial nerve pain due to cervical entrapment: **MD-NEURAL** (in association with **MD-NECK**)
- **B**rachial pain: **MD-NEURAL** (in association with **MD-NECK**)
- **B**reakbone fever:
  when nerve pain is dominant: **MD-POLY** (in association with **MD-NEURAL**)
  when muscle pain is dominant: **MD-POLY** (in association with **MD-MUSCLE**)

- **C**arpal-tunnel syndrome: **MD-SMALL JOINTS** (in association with **MD-NEURAL**)
- **C**ervical spinal ligament syndrome: **MD-NECK** (in association with **MD-NEURAL**)
- **C**ervical spinal nerve root pain: **MD-NECK** (in association with **MD-NEURAL**)
- **C**ervical, thoracic, lumbar and sacrolumbar nerve root pain: **MD-NEURAL** (respectively in association with **MD-NECK, MD-THORACIC, MD-LUMBAR** and **MD-ISCHIAL**)
- **C**hronic polyarthritis due to auto-immune diseases (e.g. Lupus erithematosus sistemicus):
  when nerve pain is dominant: **MD-POLY** (in association with **MD-NEURAL**),
  when muscle pain is dominant: **MD-POLY** (in association with **MD-MUSCLE**)
- **C**osto-sternal syndrome: **MD-POLY** (in association with **MD-NEURAL**)
- **C**ounterbalance the physiological aging of the connective tissue: **MD-TISSUE**

- **D**e Quervain disease: **MD-SMALL JOINTS** (in association with **MD-NEURAL**)
- **D**ermatomyositis: **MD-MUSCLE**

- **E**picondylitis: **MD-SHOULDER** (in association with **MD-NEURAL** and **MD-POLY**)

- **F**ibromyalgia syndrome: **MD-MUSCLE** (in association with **MD-NEURAL**)
- **F**rozen shoulder: **MD-SHOULDER** (in association with **MD-MUSCLE**)

- **H**and/Foot tendon pain due to prolonged immobilization: **MD-SMALL JOINTS**
- **H**ip joint capsule inflammation: **MD-HIP**
- **H**ip joint osteoarthritis: **MD-HIP**
- **H**ip joint osteoarthritis with rheumatoid arthritis: **MD-HIP** (in association with **MD-POLY**)
- **H**ip joint pain due to prolonged bed rest: **MD-HIP**
- **H**ip joint pain of muscle origin: **MD-HIP** (in association with **MD-MUSCLE**)
- **H**ip joint pain of nerve origin: **MD-HIP** (burning hip, in association with **MD-NEURAL**)

- **J**oint pain due to cancer (chronic leukaemia, multiple myeloma): **MD-POLY** (in association with another Collagen Medical Device containing the same type of collagen contained in the joint to be treated)
- **J**oint pain due to viral or protozoic disease: **MD-POLY** (in association with another Collagen Medical Device containing the same type of collagen contained in the joint to be treated)

- **K**nee acute and chronic arthrosynovitis secondary to arthrosis or to rheumatoid arthritis: **MD-KNEE** (in association with **MD-POLY**)
- **K**nee arthrosis: **MD-KNEE** (in association with **MD-POLY**)
- **K**nee joint preparation to meniscectomy: **MD-KNEE** (in association with **MD-MUSCLE**)
- **K**nee localization of rheumatoid arthritis or of other autoimmune diseases: **MD-KNEE** (in association with **MD-POLY**)

- **L**eg nerve pain due to post-surgery treatment of disc herniation L4-L5, L5-S1: **MD-ISCHIAL**
- **L**ow back pain secondary to musculo-tendinous trigger points: **MD-LUMBAR** (in association with **MD-MUSCLE**)
- **L**umbar and lumbar-sacral mechanical imbalance: **MD-LUMBAR**
- **L**umbar and lumbar-sacral spinal ligament syndrome: **MD-LUMBAR**
- **L**umbar pain secondary to cartilage degenerative lumbar spine disorders (lumbar and lumbar-sacral arthrosis): **MD-LUMBAR**
- **L**umbar-sciatic pain: **MD-ISCHIAL** (in association with **MD-LUMBAR** and **MD-NEURAL**)
- **L**umbar vertebral osteophytosis: **MD-LUMBAR**

- **M**aintenance therapy after knee surgery: **MD-KNEE** (in association with **MD-MUSCLE** and **MD-NEURAL**)
- **M**echanical imbalance (facet joint syndrome): **MD-NECK** (in association with **MD-NEURAL**)
- **M**echanical imbalance (costo-vertebral facet joint syndrome): **MD-THORACIC** (in association with **MD-NEURAL**)
- **M**eniscal lesions: **MD-KNEE** (in association with **MD-MUSCLE**)
- **M**etatarsal pain: **MD-SMALL JOINTS**

Scientific documentation for the exclusive use of qualified staff

In compliance with Eur. Dir. 2007/47/EC

CE 0373

COLLAGEN **M**EDICAL **D**EVICES

As a supportive treatment of the following pathologies:

- **M**etatarsal pain accompanied by Morton's neuroma: **MD-SMALL JOINTS** (in association with **MD-NEURAL**)
- **M**orton neuroma: **MD-ISCHIAL** (in association with **MD-NEURAL**)

- **N**eck pain due to cartilage degenerative cervical spine disorders: **MD-NECK** (cervical osteoarthritis, in association with **MD-POLY**)
- **N**eck pain due to cervical muscular trigger points: **MD-NECK** (in association with **MD-MUSCLE**)
- **N**erve pain in the lower lumbar spine: **MD-ISCHIAL** (in association with **MD-MUSCLE**)
- **N**on-specific diffuse pain: **MD-POLY** (in association with **MD-NECK** and **MD-NEURAL**)

- **O**steoarthritis of fingers pain: **MD-SMALL JOINTS**

- **P**ain due to thoracic spine osteophytosis: **MD-THORACIC** (in association with **MD-NEURAL**)
- **P**ain from spinal osteoporosis: **MD-THORACIC** (in association with **MD-NEURAL** and **MD-MUSCLE**)
- **P**ain management; acute, subacute, chronic: **MD-MUSCLE**
- **P**atello-femoral arthrosis: **MD-KNEE**
- **P**ersistent intercostal neuralgia: **MD-NEURAL** (in association with **MD-THORACIC**)
- **P**ostherpetic neuralgia: **MD-NEURAL** (in association with **MD-THORACIC** or **MD-LUMBAR**)
- **P**ostural low back ache: **MD-LUMBAR** (in association with **MD-NEURAL** and **MD-MUSCLE**)
- **P**ostural neck ache: **MD-NECK** (in association with **MD-NEURAL** and **MD-MUSCLE**)
- **P**ost-traumatic or post-surgery acute and chronic arthrosynovitis: **MD-KNEE**

- **R**eferred somatic pain area management: **MD-MUSCLE** (in association with **MD-NEURAL**)
- **R**heumatoid arthritis of hand/foot: **MD-SMALL JOINTS** (in association with **MD-POLY**)
- **R**hizoarthrosis of the thumb (Forestier disease): **MD-SMALL JOINTS**
- **R**otator cuff syndrome: **MD-SHOULDER** (in association with **MD-MUSCLE**)

- **S**acro-iliac syndrome: **MD-LUMBAR**
- **S**ciatica pain: **MD- ISCHIAL**
- **S**houlder-arm polyarthritis: **MD-SHOULDER** (in association with **MD-POLY**)
- **S**houlder-arm syndrome: **MD-SHOULDER** (in association with **MD-NEURAL** and **MD-MUSCLE**)
- **S**houlder pain due to dislocation: **MD-SHOULDER** (therapeutic rest, in association with **MD-NEURAL**)
- **S**imple neck pain: **MD-NECK** (in association with **MD-NEURAL** and **MD-MUSCLE**)
- **S**mall joints rheumatoid arthritis of hand and foot: **MD-POLY** (in association with **MD-SMALL JOINTS**)
- **S**pinal lumbar and lumbar-sacral nerve root pain: **MD-LUMBAR** (in association with **MD-NEURAL** and **MD-ISCHIAL**)
- **S**tiff neck syndrome: **MD-NECK** (in association with **MD-NEURAL**)
- **S**trenghten matrix tissues where the collagen barrier is located, act as a defensive barrier against free radicals: **MD-MATRIX**

- **T**emporomandibular joint pain: **MD-NEURAL** (in association with **MD-NECK**)
- **T**horacic pain due to cartilage degenerative thoracic spine disorders: **MD-THORACIC** (thoracic osteoarthrosis: in association with **MD-POLY**)
- **T**horacic pain due to scoliosis: **MD-THORACIC** (in association with **MD-MUSCLE** and **MD-NEURAL**)
- **T**horacic pain due to thoracic long muscle trigger points: **MD-THORACIC** (in association with **MD-MUSCLE**)
- **T**horacic spinal ligament syndrome: **MD-THORACIC** (in association with **MD-NEURAL**)
- **T**horacic spinal nerve root pain: **MD-THORACIC** (in association with **MD-NEURAL**)
- **T**raumatic lesions of cruciate or collateral ligaments of the knee: **MD-KNEE**
- **T**rigeminal neuralgia: **MD-NEURAL** (in association with **MD-NECK**)
- **T**rigger points management: **MD MUSCLE** (in association with **MD-NEURAL**)

- **W**hiplash: **MD-NECK** (in association with **MD-NEURAL** and **MD-MUSCLE**)

Scientific documentation for the exclusive use of qualified staff

CE 0373

COLLAGEN MEDICAL DEVICES

Instructions for use*

MD-HIP

Brand Name: MD-HIP
CE 0373
Manufacturer: GUNA S.p.a , Via Palmanova 71, 20132 Milano, Italia
Composition: Collagen
Excipients: Calcium phosphate, NaCl, Water for injection.
For this medical device the following ***packages*** are available:

- Box: 10 ampoules
  (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules
  (single ampoule 2 ml – extraction volume)

Intended use
MD-HIP is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:

- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants.

MD-HIP is a medical device that helps hip movement. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-HIP is a medical device intended to be used by a qualified staff in private or public health facilities.

Directions for use
Treatment protocol:
1 treatment a week for 10 weeks.

Periarticular injection technique: (the site of application must be sterile; insert the needle at 6-8 mm depth).
For this purpose the use of the following materials and accessories is recommended:

- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Intraarticular injection technique:
For this purpose the use of the following materials and accessories is recommended:

- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for skin.
- The application of a topical anaesthetic on the skin area to be treated is recommended.
- Needles: Sterile 27 G.
- Syringes: 2 cc size, according to the volume of the solution to inject.

The trochanteric bursa is located over the lateral prominence of the greater trochanter of the femur. There can be an anterior or a lateral approach to the hip. The patient is lying supine. The anatomic landmark is located 2 cm below the superior border of the greater trochanter in between its anterior and posterior borders. The skin overlying this location is marked and prepared in a sterile way. A 22 gauge needle is injected parallel to the floor and perpendicular to the femoral shaft.

Contraindications / Side effects
Patients treated with anticoagulants or with recognized vessel fragility should be carefully monitored during the therapy.
There is no history of hypersensitivity to MD-HIP. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions
Hip pain requires differential diagnosis for primary or metastatic cancer pain, referred nerve pain from lumbar origin, inguinal hernia.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-HIP may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for acute pain, MD-HIP can be associated with MD-NEURAL, MD-POLY and MD-MUSCLE (together with one or more than one of these).
Moreover, when a supportive treatment is needed for the connective tissue matrix or when the physiological aging process is needed to be slowed down, MD-HIP can be associated with MD-MATRIX and MD-TISSUE.
It may also be used as a mechanical support while treating the following diseases:

- Hip joint osteoarthritis
- Hip joint capsule inflammation
- Hip joint osteoarthritis with rheumatoid arthritis (in association with MD-POLY)
- Hip joint pain of muscle origin (in association with MD-MUSCLE)
- Hip joint pain of nerve origin (burning hip, in association with MD-NEURAL)
- Hip joint pain due to prolonged bed rest.

Administration may vary according to individual needs.

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected. Do not use if the package is damaged.

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COLLAGEN **M**EDICAL **D**EVICES

Instructions for use*

MD-ISCHIAL

Brand Name: MD-ISCHIAL
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Rhododendron, NaCl, Water for injection.
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-ISCHIAL is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:

- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-ISCHIAL is a medical device finalized to help movement, specifically the low back area of the vertebral spine. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-ISCHIAL is a medical device intended to be used by a qualified staff in private or public health facilities.

Direction for use
Treatment protocol:
1 treatment a week for 10 weeks.

Periarticular injection technique: (the site of application must be sterile; insert the needle near the sacroiliac joint at 2-4 mm depth).
For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-ISCHIAL. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions
Sciatic pain requires differential diagnosis for secondary muscle pain, full-blown disc herniation, vertebral canal stenosis, Cauda equine syndrome.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-ISCHIAL may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for acute pain, MD-ISCHIAL can be associated with MD-NEURAL, MD-POLY and MD-MUSCLE (together with one or more than one of these).
Moreover, when a supportive treatment is needed for the connective tissue matrix or when the physiological aging process should be slowed down, MD-ISCHIAL can be associated with MD-MATRIX and MD-TISSUE.

It may also be used as a mechanical support while treating the following diseases:

- Sciatica pain
- Lumbar-sciatic pain (in association with MD-LUMBAR and MD-NEURAL)
- Nerve pain in the lower lumbar spine (in association with MD-MUSCLE)
- Leg nerve pain due to post-surgery treatment of disc herniation L4-L5, L5-S1
- Morton neuroma (in association with MD-NEURAL).

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

MD-LUMBAR

Brand Name: MD-LUMBAR
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Hamamelis, NaCl, Water for injection.
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-LUMBAR is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:

- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-LUMBAR is a medical device finalized to help movement, specifically the lumbosacral area of the vertebral spine. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-LUMBAR is a medical device intended to be used by a qualified staff in private or public health facilities.

Direction for use
Periarticular treatment protocol:
2 treatments for the first 2 weeks. 1 treatment until improvement of symptoms (average 8-10 sessions).

Chronic pathologies: go on with 1 treatment weekly for one month until improvement of symptoms, and then with 1 treatment monthly or – according to individual needs – every 45-50 days.
The site of application must be sterile; insert the needle near the lumbar and lumbosacral joints at 3-4 mm depth.

For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-LUMBAR. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions
Spinal pain requires differential diagnosis for herniated disk, primary or secondary cancer pain; reflex or referred pain from internal organs.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-LUMBAR may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for acute pain, MD-LUMBAR can be associated with MD-NEURAL, MD-POLY and MD-MUSCLE (together with one or more than one of these).
Moreover, when a supportive treatment is needed for the connective tissue matrix or when the physiological aging process should be slowed down, MD-LUMBAR can be associated with MD-MATRIX and MD-TISSUE.

It may also be used as a mechanical support while treating the following diseases:

- Lumbar pain secondary to cartilage degenerative lumbar spine disorders (lumbar and lumbar-sacral arthrosis)
- Lumbar vertebral osteophytosis
- Low back pain secondary to musculo-tendinous trigger points (in association with MD-MUSCLE)
- Postural low back ache (in association with MD-NEURAL and MD-MUSCLE)
- Lumbar and lumbar-sacral mechanical imbalance
- Lumbar and lumbar-sacral spinal ligament syndrome
- Sacro-iliac syndrome
- Spinal lumbar and lumbar-sacral nerve root pain (in association with MD-NEURAL and MD-ISCHIAL).

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

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COLLAGEN MEDICAL DEVICES

Instructions for use*

MD-KNEE

Brand Name: MD-KNEE
CE 0373
Manufacturer: GUNA S.p.a , Via Palmanova 71, 20132 Milano, Italia
Composition: Collagen
Excipients: Arnica, NaCl, Water for injection.
For this medical device the following ***packages*** are available:

- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-KNEE is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:

- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants.

MD-KNEE is a medical device finalized to help knee movement. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-HIP is a medical device intended to be used by a qualified staff in private or public health facilities.

Directions for use
Treatment protocol:
1 treatment a week for 10 weeks.

Periarticular injection technique: (the site of application must be sterile; insert the needle at 2-4 mm depth).
For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Intraarticular injection technique:
For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for skin.
- The application of a topical anaesthetic on the skin area to be treated is recommended.
- Needles: Sterile 22 G.
- Syringes: 2 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-KNEE. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions
Knee pain requires differential diagnosis for collateral or cruciate ligament injuries, prepatellar bursitis, hip joint pathologies, osteochondritis dissecans, inflammatory arthopathy, gout, pseudogout, septic arthiritis.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.

Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-KNEE may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for acute pain, MD-KNEE can be associated with MD-NEURAL, MD-POLY and MD-MUSCLE (together with one or more than one of these).
Moreover, when a supportive treatment is needed for the connective tissue matrix or when the physiological aging process should be slowed down, MD-KNEE can be associated with MD-MATRIX and MD-TISSUE.

It may also be used as a mechanical support while treating the following diseases:

- Knee arthrosis (in association with MD-POLY)
- Patello-femoral arthrosis
- Knee localization of rheumatoid arthritis or of other autoimmune diseases (in association with MD-POLY)
- Knee acute and chronic arthrosynovitis secondary to arthrosis or to rheumatoid arthritis (in association with MD-POLY)
- Post-traumatic or post-surgery acute and chronic arthrosynovitis
- Traumatic lesions of cruciate or collateral ligaments of the knee
- Meniscal lesions (in association with MD-MUSCLE)
- Knee joint preparation to meniscectomy (in association with MD-MUSCLE)
- Maintenance therapy after knee surgery (in association with MD-MUSCLE and MD-NEURAL).

Administration may vary according to individual needs.

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected. Do not use if the package is damaged

CE 0373

COLLAGEN MEDICAL DEVICES

Instructions for use*

MD-MATRIX

Brand Name: MD-MATRIX
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Citric Acid, Nicotinamid, NaCl, Water for injection.
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-MATRIX is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:

- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-MATRIX is a medical device finalized to help movement, specifically the low back area of the vertebral spine. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-MATRIX is a medical device intended to be used by a qualified staff in private or public health facilities.

Direction for use
Treatment protocol:
2 treatments for the first 2 weeks, 1 treatment weekly until improvement of symptoms (average 8-10 sessions).
It is possible to go on with one treatment every other week for 10 weeks at most. For chronic pathologies: go on with 1 treatment weekly for 1 month until improvement of symptoms, then 1 treatment monthly.

- ***Intradermal injection technique:***
the site of application must be sterile; insert the needle at 1-3 mm depth.
- ***Periarticular injection technique:***
the site of application must be sterile; insert the needle near the joint at different depths.

Preparation for Injection:
For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-MATRIX. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour

Warnings and precautions
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-MATRIX may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
It may also be used in patients who need a collagen supplementation or a topical antiaging treatment.

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

MD-MUSCLE

Brand Name: MD-MATRIX
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Hypericum, NaCl, Water for injection.
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-MUSCLE is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:

- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-MUSCLE is a medical device finalized to help joint movement. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-MATRIX is a medical device intended to be used by a qualified staff in private or public health facilities.

Direction for use
Treatment protocol:
1-2 treatments weekly for 10 weeks.
Intramuscular injection technique (the site of application must be sterile; insert the needle into the muscle to be treated at 2-4 mm depth).

For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- The application of a topical anaesthetic to the skin is recommended.
- Needles: sterile 22 G.
- Syringes: 2 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-MUSCLE. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be carefully monitored for 1 hour.

Warnings and precautions
Muscle pain requires differential diagnosis for metameric nerve pain, tendonitis, deep blood accumulation.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-MUSCLE may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for the connective tissue matrix or when an antiaging action is necessary, MD-MUSCLE can be used together with MD-MATRIX and MD-TISSUE.
It may also be used as a mechanical support while treating the following diseases:
- Pain management: acute, subacute, chronic.
- Referred somatic pain area management (in association with MD-NEURAL)
- Trigger points management (in association with MD-NEURAL)
- Fibromyalgia syndrome (in association with MD-NEURAL)
- Dermatomyositis.

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

Scientific documentation for the exclusive use of qualified staff

* Authorized by notified body "Istituto Superiore di Sanità" (www.iss.it) Date of last review: 15.03.2011

CE 0373

COLLAGEN MEDICAL DEVICES

Instructions for use*

MD-NECK

Brand Name: MD-NECK
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Silica, NaCl, Water for injection.
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-NECK is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:

- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-NECK is a medical device finalized to help neck movement, specifically the cervical area of the vertebral spine. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-NECK is a medical device intended to be used by a qualified staff in private or public health facilities.

Direction for use
Treatment protocol:
1-2 treatments weekly for 10 weeks.
• Periarticular injection technique:
the site of application must be sterile; insert the needle at 2-4 mm depth.

Preparation for Injection:
For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
Patients treated with anticoagulants or with recognized vessel fragility or affected by coagulation diseases should be carefully monitored during the therapy.
There is no history of hypersensitivity to MD-NECK. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions
Cervical spine pain requires differential diagnosis for cervical discopathies, primary or secondary cancer pain, spondylolisthesis.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-NECK may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for acute pain, MD-NECK can be associated with MD-NEURAL, MD-POLY and MD-MUSCLE (together with one or more than one of these).
Moreover, when a supportive treatment is needed for the connective tissue matrix or when the physiological aging process should be slowed down, MD-NECK can be associated with MD-MATRIX and MD-TISSUE.
It may also be used as a mechanical support while treating the following diseases:
- Neck pain due to cartilage degenerative cervical spine disorders (cervical osteoarthritis, in association with MD-POLY)
- Neck pain due to cervical muscular trigger points (in association with MD-MUSCLE)
- Stiff neck syndrome (in association with MD-NEURAL)
- Simple neck pain (in association with MD-NEURAL and MD-MUSCLE)
- Whiplash (in association with MD-NEURAL and MD-MUSCLE)
- Postural neck ache (in association with MD-NEURAL and MD-MUSCLE)
- Mechanical imbalance (facet joint syndrome) (in association with MD-NEURAL)
- Cervical spinal ligament syndrome (in association with MD-NEURAL)
- Cervical spinal nerve root pain (in association with MD-NEURAL).

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

MD-NEURAL

Brand Name: MD-NEURAL
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Colocynthis, NaCl, Water for injection.
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-NEURAL is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:

- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-NEURAL is a medical device finalized to help joint movement, specifically in bad posture disorders. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-NEURAL is a medical device intended to be used by a qualified staff in private or public health facilities.

Direction for use
Treatment protocol:
1-2 treatments weekly for 10 weeks.
• Periarticular injection technique:
the site of application must be sterile; insert the needle at 2-4 mm depth.

For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-NEURAL. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions
Nerve pain requires differential diagnosis for visceral pain, primary or metastatic cancer pain. A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-NEURAL may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for the connective tissue matrix or when an antiaging action is necessary, MD-NEURAL can be associated with MD-MATRIX and MD-TISSUE.
It may also be used as a mechanical support while treating the following diseases:
- Brachial pain (in association with MD-NECK)
- Brachial nerve pain due to cervical entrapment (in association with MD-NECK)
- Persistent intercostal neuralgia (in association with MD-THORACIC)
- Postherpetic neuralgia (in association with MD-THORACIC or MD-LUMBAR)
- Atypical facial neuritis (in association with MD-NECK)
- Trigeminal neuralgia (in association with MD-NECK)
- Temporomandibular joint pain (in association with MD-NECK)
- Cervical, thoracic, lumbar and sacrolumbar nerve root pain (respectively in association with MD-NECK, MD-THORACIC, MD-LUMBAR and MD-ISCHIAL).

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

Scientific documentation for the exclusive use of qualified staff

* Authorized by notified body "Istituto Superiore di Sanità" (www.iss.it) Date of last review: 15.03.2011

CE 0373

COLLAGEN MEDICAL DEVICES

Instructions for use*

MD-POLY

Brand Name: MD-POLY
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Drosera, NaCl, Water for injection.
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-POLY is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:
- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-POLY is a medical device finalized to help movement, specifically the vertebral spine. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-POLY is a medical device intended to be used by a qualified staff in private or public health facilities.

Direction for use
Treatment protocol:
1-2 treatments weekly for 10 weeks.
• Periarticular injection technique:
the site of application must be sterile; insert the needle at a 3-6 mm depth.

For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

• Intraarticular injection technique
For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for skin.
- The application of a topical anaesthetic on the skin area to be treated is recommended.
- Needles: sterile 22 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-POLY. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions
Joint pain requires differential diagnosis for acute or subacute joint viral diseases, pain due to overweight (leg joints), hyperuricemia, gout.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-POLY may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for the connective tissue matrix or when an antiaging action is necessary, MD-POLY can be used together with MD-MATRIX and MD-TISSUE.
It may also be used as a mechanical support while treating the following diseases:
- Small joints rheumatoid arthritis of hand and foot (in association with MD-SMALL JOINTS)
- Non-specific diffuse pain (in association with MD-NECK and MD-NEURAL)
- Costo-sternal syndrome (in association with MD-NEURAL)
- Chronic polyarthritis due to auto-immune diseases (e.g. Lupus erithematosus sistemicus) (in association with MD-NEURAL when nerve pain is dominant; in association with MD-MUSCLE when muscle pain is dominant)
- Breakbone fever (when nerve pain is dominant in association with MD-NEURAL; when muscle pain is dominant in association with MD-MUSCLE)
- Joint pain due to viral or protozoic disease (in association with another Guna medical device containing the same type of collagen contained in the joint to be treated)
- Joint pain due to cancer (chronic leukaemia, multiple myeloma) (in association with another Guna medical device containing the same type of collagen contained in the joint to be treated).

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

MD-SHOULDER

Brand Name: MD-SHOULDER
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Iris, NaCl, Water for injection.
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-SHOULDER is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:
- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-SHOULDER is a medical device finalized to help shoulder joint movement. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

Direction for use
Treatment protocol:
1-2 treatments weekly for 10 weeks.
• Periarticular injection technique:
the site of application must be sterile; insert the needle at a 3-6 mm depth.

For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

• Intraarticular injection technique
For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for skin.
- The application of a topical anaesthetic on the skin area to be treated is recommended.
- Needles: sterile 22 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-SHOULDER. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions
Shoulder pain requires differential diagnosis for chronic cervical syndrome, ischemic heart disease (acute/chronic, only on the left side), gallbladder disease (only on the right side), cervical-brachial nerve pain, muscle trigger on the trapezium muscle.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-SHOULDER may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for acute pain, MD-SHOULDER can be associated with MD-NEURAL, MD-POLY and MD-MUSCLE (together with one or more than one of these).
Moreover, when a supportive treatment is needed for the connective tissue matrix or when the physiological aging process should be slowed down, MD-SHOULDER can be associated with MD-MATRIX and MD-TISSUE.
It may also be used as a mechanical support while treating the following diseases:

- Shoulder-arm polyarthritis (in association with MD-POLY)
- Rotator cuff syndrome (in association with MD-MUSCLE)
- Shoulder-arm syndrome (in association with MD-NEURAL and MD-MUSCLE)
- Frozen shoulder (in association with MD-MUSCLE)
- Shoulder pain due to dislocation (therapeutic rest, in association with MD-NEURAL
- Epicondylitis (in association with MD-NEURAL and MD-POLY)

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

Scientific documentation for the exclusive use of qualified staff

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CE 0373

COLLAGEN MEDICAL DEVICES

Instructions for use*

MD-SMALL JOINTS

Brand Name: MD-SMALL JOINTS
CE 0373
Manufacturer: GUNA S.p.a , Via Palmanova 71, 20132 Milano, Italia
Composition: Collagen
Excipients: Viola, NaCl, Water for injection.
For this medical device the following ***packages*** are available:

- Box: 10 ampoules
  (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules
  (single ampoule 2 ml – extraction volume)

Intended use

MD-SMALL JOINTS is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:

- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants.

MD-SMALL JOINTS is a medical device finalized to help movement of small joints, such as foot and hands, ankle. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-SMALL JOINTS is a medical device intended to be used by a qualified staff in private or public health facilities.

Directions for use

Treatment protocol:
1 treatment a week for 10 weeks.

• *Periarticular injection technique:*
the site of application must be sterile; insert the needle at a 2-4 mm depth.

For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Intraarticular injection technique:
For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for skin.
- The application of a topical anaesthetic on the skin area to be treated is recommended.
- Needles: Sterile 22 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Foot joints can be treated via intraarticular injections in the ankle. This treatment can be also applied to the ankle joint.
For medial and lateral approach, the foot is first placed at about a 45-degree angle of plantar flexion.

Contraindications / Side effects

There is no history of hypersensitivity to MD-SMALL JOINTS. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions

Hand/Foot and small joints pain requires differential diagnosis for primary nerve pain, post-traumatic pain, secondary pain due to present or previous bone fractures.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses.

KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance

MD-SMALL JOINTS may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for acute pain, MD-SMALL JOINTS can be associated with MD-NEURAL, MD-POLY and MD-MUSCLE (together with one or more than one of these).
Moreover, when a supportive treatment is needed for the connective tissue matrix or when the physiological aging process should be slowed down, MD-SMALL JOINTS can be associated with MD-MATRIX and MD-TISSUE.
It may also be used as a mechanical support while treating the following diseases:

- Osteoarthritis of fingers pain
- Rhizoarthrosis of the thumb (Forestier disease)
- Arthrosis pain due to hammer toe
- Carpal-tunnel syndrome
  (in association with MD-NEURAL)
- De Quervain disease (in association with MD-NEURAL)
- Metatarsal pain
- Metatarsal pain accompanied by Morton's neuroma (in association with MD-NEURAL)
- Rheumatoid arthritis of hand/foot (in association with MD-POLY)
- Hand/Foot tendon pain due to prolonged immobilization.

Instructions in case of damage to the sterile vials / ampoules

Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected. Do not use if the package is damaged.

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CE 0373

COLLAGEN MEDICAL DEVICES

Instructions for use*

MD-THORACIC

Brand Name: MD-THORACIC
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Cimicifuga, NaCl, Water for injection.
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-THORACIC is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:
- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-THORACIC is a medical device finalized to help movement, specifically the thoracic area of the vertebral spine. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-THORACIC is a medical device intended to be used by a qualified staff in private or public health facilities.

Direction for use
• Periarticular injection technique:
2 treatments for the first 2 weeks, 1 treatment weekly until improvement of symptoms (average 8-10 sessions). For chronic pathologies: go on with 1 treatment weekly for 1 month until improvement of symptoms, then 1 treatment monthly.
The site of application must be sterile; insert the needle at a 2-4 mm depth.

For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-THORACIC. However, patients with a recognized hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

Warnings and precautions
Spinal pain requires differential diagnosis for primary or secondary cancer pain, reflex and referred pain from internal organs.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-THORACIC may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
When a supportive treatment is needed for acute pain, MD-THORACIC can be associated with MD-NEURAL, MD-POLY and MD-MUSCLE (together with one or more than one of these).
Moreover, when a supportive treatment is needed for the connective tissue matrix or when the physiological aging process should be slowed down, MD-THORACIC can be associated with MD-MATRIX and MD-TISSUE.
It may also be used as a mechanical support while treating the following diseases:

- Thoracic pain due to cartilage degenerative thoracic spine disorders (thoracic osteoarthrosis) (in association with MD-POLY)
- Thoracic pain due to scoliosis (in association with MD-MUSCLE and MD-NEURAL)
- Thoracic pain due to thoracic long muscle trigger points (in association with MD-MUSCLE)
- Pain due to thoracic spine osteophytosis (in association with MD-NEURAL)
- Pain from spinal osteoporosis (in association with MD-NEURAL and MD-MUSCLE)
- Mechanical imbalance (costo-vertebral facet joint syndrome) (in association with MD-NEURAL)
- Thoracic spinal ligament syndrome (in association with MD-NEURAL)
- Thoracic spinal nerve root pain (in association with MD-NEURAL).

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

MD-TISSUE

Brand Name: MD-TISSUE
CE 0373
Manufacturer: : GUNA S.p.a , Via Palmanova 71, 20132 Milan, Italy
Composition: Collagen.
Excipients: Ascrobic acid, Magnesium gluconate, Pyridoxin hydrochloride, Riboflavin, Thiamine hydrochloride, NaCl, Water for injection
For this medical device the following ***packages*** are available:
- Box: 10 ampoules (single ampoule 2 ml – extraction volume)
- Box: 50 ampoules (single ampoule 2 ml – extraction volume)

Intended use
MD-TISSUE is a medical device finalized to help movement by limiting a physiological degeneration of joints and tissues as well as by counterbalancing any damage caused by:
- aging
- bad posture
- concomitant chronic diseases
- blows and injuries
- pollutants

MD-TISSUE is a medical device finalized to help movement by counteracting the physiological aging of the connective tissue. Its main therapeutic functions include:
1. a barrier effect
2. a lubricating activity
3. a mechanical support while administering other pharmacological treatments

MD-TISSUE is a medical device intended to be used by a qualified staff in private or public health facilities.

Direction for use
Treatment protocol:
2 treatments for the first 2 weeks, 1 treatment weekly until improvement of symptoms (average 8-10 sessions). It is possible to go on with one treatment every other week for 10 weeks at most. For chronic pathologies: go on with 1 treatment weekly for 1 month until improvement of symptoms, then 1 treatment monthly.

• Intradermic injection technique:
the site of application must be sterile; insert the needle at 1-3 mm depth.
• Periarticular injection technique:
the site of application must be sterile; insert the needle in the joint at 2-4 mm depth.

For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: sterile gloves, Iodine solution, Alcohol solution, sterile gauze pads, Ethyl chloride spray for the skin.
- Needles: Sterile 27 G.
- Syringes: 5 or 10 cc size, according to the volume of the solution to inject.

Contraindications / Side effects
There is no history of hypersensitivity to MD-TISSUE. However, patients with a known hypersensitivity to any ingredients should be tested before use, making a spot injection into one arm and be kept under observation for 1 hour.

Warnings and precautions
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin superficial reaction.
Skin cleansing/disinfection is required before and after application. Saprophytic bacteria may produce injection site abscesses. KEEP AWAY FROM THE REACH AND THE SIGHT OF CHILDREN.
Do not use after the expiration date. The expiration date refers to the product properly stored in an unopened package. Use the product immediately after opening the package.

Performance
MD-TISSUE may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customized treatment according to clinical evolution.
It can be used when patients need a supplementation of collagen or a topical antiaging treatment.

Instructions in case of damage to the sterile vials / ampoules
Do not use if the seal is open or if the vial/ampoule is not perfectly sealed.
Once open, the vial/ampoule must be immediately injected.
Do not use if the package is damaged.

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