MD-HIP

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Calcium Phosphate, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-HIP is a medical device designed 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 action.
3. Mechanical support while administering other pharmacological treatments.

MD-HIP is intended to be used by a qualified staff in private or public health Facilities to:

» Improve the movement of the hip joint.
» Help muscle stretching of the lumbosacral area.
» Support the periarticular muscle tissue.
» Soothe local pain, pain caused by joint movement or bad posture.

DIRECTIONS FOR USE

Therapeutic protocol:
1 treatment weekly for 10 consecutive weeks.

Periarticular injection technique (the site of application must be aseptic; 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: single-use 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: single-use gloves, iodine solution, alcohol solution, sterile gauze pads, ethyl chloride spray for the 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
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. It contains animal-derived collagen from porcine source. Patients with known 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 of 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 reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

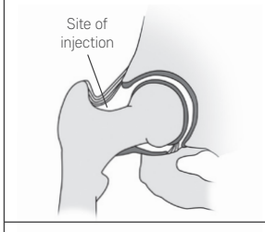
Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE
MD-HIP may be used as a single treatment or mixed with other medical devices of the same range in order to make a customised 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 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
Do not use if the seal is broken or if the vial is not perfectly sealed. Once open, the content of the vial must be immediately injected. Do not use if the package is damaged.



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.

Hip – Intraarticular injection

MD-ISCHIAL

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Rhododendron, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-ISCHIAL is a medical device designed 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 designed to help movement, specifically the low back area of the vertebral spine. Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. Mechanical support while administering other pharmacological treatments.

MD-ISCHIAL is intended to be used by a qualified staff in private or public health Facilities to:

» Improve leg movement.
» Help leg muscle stretching.
» Help to support the leg muscle tissue.
» Soothe leg pain while starting to move legs again, after a period of prolonged inactivity.

DIRECTIONS FOR USE

Therapeutic protocol:
1 treatment weekly for 10 consecutive weeks.

Periarticular injection technique (the site of application must be aseptic; 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: single-use 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. It contains animal-derived collagen from porcine source. Patients with known 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 reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE

MD-ISCHIAL may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised 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 mechanical support while treating the following diseases:

- Sciatic 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

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

MD-LUMBAR

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Hamamelis, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-LUMBAR is a medical device designed 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 designed to help movement, specifically the lumbosacral area of the vertebral spine. Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. 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 to:

» Help lumbar movement.
» Help muscle stretching of the lumbosacral area of the spine.
» Help to support the lumbar muscle tissue.
» Soothe local pain, pain at rest or caused by movement and bad posture.

DIRECTIONS FOR USE

Periarticular therapeutic protocol:
2 treatments weekly 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, then with 1 treatment monthly or – according to individual needs – every 45-50 days.
The site of application must be aseptic. 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: single-use 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. It contains animal-derived collagen from porcine source. Patients with known 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 reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE

MD-LUMBAR may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised 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 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 aches (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

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

MD-KNEE

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Arnica, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-KNEE is a medical device designed 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 designed to help knee movement. Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. Mechanical support while administering other pharmacological treatments.

MD-KNEE is a medical device intended to be used by a qualified staff in private or public health Facilities to:

» Improve the knee movement.
» Help muscle stretching.
» Soothe pain while moving legs and knee.

DIRECTIONS FOR USE

Therapeutic protocol:
1 treatment weekly for 10 consecutive weeks.

Periarticular injection technique (the site of application must be aseptic; 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: single-use 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: single-use gloves, iodine solution, alcohol solution, sterile gauze pads, ethyl chloride spray for the 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. It contains animal-derived collagen from porcine source. Patients with known hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

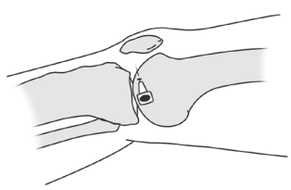
WARNINGS AND PRECAUTIONS
Knee pain requires differential diagnosis for collateral or cruciate ligament injuries, prepatellar bursitis, hip joint pathologies, osteochondritis disseccans, inflammatory arthropathy, gout, pseudo gout, septic arthritis.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE
MD-KNEE may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised 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 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).

INSTRUCTIONS IN CASE OF DAMAGE TO THE STERILE VIALS
Do not use if the seal is broken or if the vial is not perfectly sealed. Once open, the content of the vial must be immediately injected. Do not use if the package is damaged.



The patient should lay supine with the knee comfortably extended. A 22 G needle is inserted in a direction parallel to the plane of the posterior surface of the patella in a medial and lateral position.

Knee – Intraarticular injection technique (internal side)

MD-MATRIX

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Citric acid, Nicotinamide, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

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

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

Due to its special function, MD-MATRIX is also intended for firming the subcutaneous and microvascular connective tissue layer of localized adiposities and cellulite in the connective tissue, especially those at the root of the thighs and in the inner area of the knee.

MD-MATRIX is a medical device designed to help movement, by strengthening the supportive tissue of the joints, and of the skin and its subcutaneous tissue.
Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. 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 to:

» Strengthen the extra-cellular matrix tissues where the collagen is applied.
» Act as a defensive barrier against free radicals.

DIRECTIONS FOR USE

Therapeutic protocol:
2 treatments weekly for the first 2 weeks, 1 treatment weekly until improvement of symptoms (average 8-10 sessions). It is possible to go on with 1 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 and subcutaneous injection technique:* the site of application must be aseptic; insert the needle at 1-3 mm depth and microinject 0.2-0.3 ml into the affected tissue.
- *Periarticular injection technique:* the site of application must be aseptic; 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: single-use gloves, iodine solution, alcohol solution, sterile gauze pads, ethyl chloride spray for the skin.
- Needles: sterile 27 G, 4 mm.
- 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. It contains animal-derived collagen from porcine source. However, patients with known 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 reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE
MD-MATRIX may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised treatment according to clinical evolution.
Concerning its use for the treatment of localized adiposity, and for firming the subcutaneous connective tissue layer, MD-MATRIX should preferably be associated with MD-TISSUE (e.g. MD-MATRIX 2 vials, MD-TISSUE 1 vial/treatment).
It may be used in patients who need a collagen supplementation or a topical antiaging treatment.

INSTRUCTIONS IN CASE OF DAMAGE TO THE STERILE VIALS
Do not use if the seal is broken or if the vial is not perfectly sealed. Once open, the content of the vial must be immediately injected. Do not use if the package is damaged.

MD-MUSCLE

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Hypericum, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-MUSCLE is a medical device designed 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 designed to help muscle and joint movement. Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. Mechanical support while administering other pharmacological treatments.

MD-MUSCLE is a medical device intended to be used by a qualified staff in private or public health Facilities to:

» Help muscle stretching and function.
» Help to support the muscle tissue in bad posture disorders.
» Improve joint movement.
» Soothe local pain, or pain caused by movement and bad posture.

DIRECTIONS FOR USE

Therapeutic protocol:
1-2 treatments weekly for 10 consecutive weeks.

Intramuscular injection technique (the site of application must be aseptic; 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: single-use 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.

Intramuscular injection technique
For this purpose the use of the following materials and accessories is recommended:
- Materials for aseptic skin preparation: single-use 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. It contains animal-derived collagen from porcine source. However, patients with known 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, and deep blood accumulation.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE
MD-MUSCLE may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised 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 associated with MD-MATRIX and MD-TISSUE.

It may also be used as mechanical support while treating the following diseases:
- Pain management: acute, subacute, and 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.

Administration may vary according to individual needs.

INSTRUCTIONS IN CASE OF DAMAGE TO THE STERILE VIALS
Do not use if the seal is broken or if the vial is not perfectly sealed. Once open, the content of the vial must be immediately injected. Do not use if the package is damaged.

MD-NECK

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Silica, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-NECK is a medical device designed 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 designed to help neck movement, specifically the cervical area of the vertebral spine. Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. 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 to:

» Improve the movement of the cervical tract of the spine.
» Help cervical muscle stretching.
» Help to support cervical muscle tissue.
» Help to support cervical muscle tissue in bad posture disorders.
» Soothe pain in cervical column movements.

DIRECTIONS FOR USE

Therapeutic protocol:
1-2 treatments weekly for 10 consecutive weeks.

Periarticular injection technique (the site of application must be aseptic; 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: single-use 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. It contains animal-derived collagen from porcine source. However, patients with known 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 reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE

MD-NECK may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised 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 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).

Administration may vary according to individual needs.

INSTRUCTIONS IN CASE OF DAMAGE TO THE STERILE VIALS

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

MD-NEURAL

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Colocynthis, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-NEURAL is a medical device designed 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 designed to help joint movement, specifically in bad posture disorders. Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. 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.

DIRECTIONS FOR USE

Therapeutic protocol:
1-2 treatments weekly for 10 consecutive weeks.

Periarticular injection technique (the site of application must be aseptic; 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: single-use 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: single-use 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-NEURAL. It contains animal-derived collagen from porcine source. However, patients with known 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 reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE

MD-NEURAL may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised 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 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

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

MD-POLY

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Drosera, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-POLY is a medical device designed 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 designed to help movement, specifically the vertebral spine.
Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. 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 to:

» Improve movement of the joints.
» Help muscle stretching.
» Help to support the muscle tissue in bad posture disorders.
» Soothe local pain, or pain caused by movement and bad posture.

DIRECTIONS FOR USE

Therapeutic protocol:
1-2 treatments weekly for 10 consecutive weeks.

Periarticular injection technique (the site of application must be aseptic; 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: single-use 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: single-use 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: 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. It contains animal-derived collagen from porcine source. However, patients with known hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

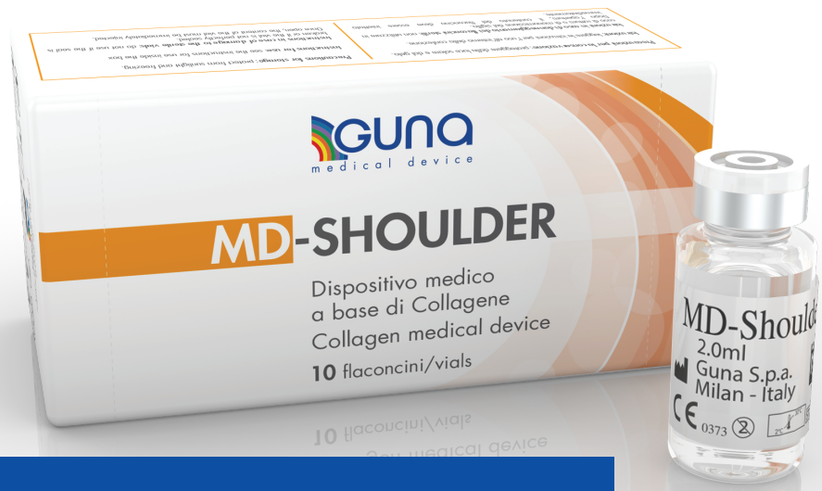
WARNINGS AND PRECAUTIONS
Joint pain requires differential diagnosis for acute or subacute joint viral diseases, pain due to overweight (leg joints), hyperuricemia, gout.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE
MD-POLY may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised 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 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
Do not use if the seal is broken or if the vial is not perfectly sealed. Once open, the content of the vial must be immediately injected. Do not use if the package is damaged.



MD-SHOULDER

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Iris, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-SHOULDER is a medical device designed 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 designed to help joint movement of the shoulder and the arm. Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. Mechanical support while administering other pharmacological treatments.

MD-SHOULDER is a medical device intended to be used by a qualified staff in private or public health Facilities to:

» Improve movement of the shoulder joint and the arm.
» Help muscle stretching.
» Help to support the muscle tissue.
» Soothe local pain and pain caused by movement.

DIRECTIONS FOR USE

Therapeutic protocol:
1-2 treatments weekly for 10 consecutive weeks.

Periarticular injection technique (the site of application must be aseptic; 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: single-use 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: single-use 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: 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. It contains animal-derived collagen from porcine source. However, patients with known hypersensitivity to any ingredient or excipient should be tested before use, making a spot injection into one arm and be monitored for 1 hour.

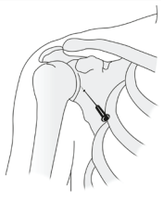
WARNINGS AND PRECAUTIONS
Shoulder pain requires differential diagnosis for chronic cervical syndrome, ischemic heart disease (acute/chronic, only on the left side), gallbladder disease (only on the right side), cervical-brachial nerve pain, muscle trigger in the trapezium muscle.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE
MD-SHOULDER may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised 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.

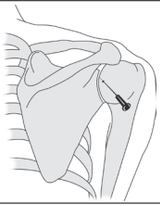
It may also be used as mechanical support while treating the following diseases:
- Shoulder-arm polyarthritis (in association with MD-POLY).
- Rotator cuff syndrome (in association with MD-MUSCLE).
- Shoulder-arm syndrome (in association with MD-NEURAL and MD-MUSCLE).
- Frozen shoulder (in association 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
Do not use if the seal is broken or if the vial is not perfectly sealed. Once open, the content of the vial must be immediately injected. Do not use if the package is damaged.



Anterior approach. With the patient's hand on the thigh and the shoulder muscles relaxed, the glenohumeral joint can be palpated by placing the fingers between the coracoid process and the humeral head. As the shoulder is internally rotated, the humeral head can be felt turning inward and the joint space can be felt as a groove just lateral to the coracoid process. A 22 G needle can be inserted lateral to the coracoid. Insert the needle into the joint space.

Shoulder – Intraarticular injection, anterior approach



Posterior approach. The posterior aspect of the shoulder joint can be identified by making the patient's arm rotate. This position is achieved by placing the patient's ipsilateral hand on the opposite shoulder. The humeral head can be palpated by placing a finger posteriorly along the acromion while the shoulder is rotated. A 22 G needle is inserted about 1 cm inferior to the posterior tip of the acromion and directed anteriorly and medially.

Shoulder – Intraarticular injection, posterior approach

MD-SMALL JOINTS

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Viola, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-SMALL JOINTS is a medical device designed 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 designed to help movement of small joints (such as those of foot, hand and ankle). Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. 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 to:

» Improve movement of the small joints of hand, foot and ankle.
» Help muscle stretching.
» Help to support the muscle tissue.
» Soothe local pain and pain caused by joint movement.

DIRECTIONS FOR USE

Therapeutic protocol:
1 treatment weekly for 10 consecutive weeks.

Periarticular injection technique (the site of application must be aseptic; 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: single-use 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: single-use 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: 5 or 10 cc size, according to the volume of the solution to inject.

ANKLE INTRAARTICULAR APPLICATION
Foot joints can be treated with 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. It contains animal-derived collagen from porcine source. However, patients with known 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 recent or past bone fractures.
A slight reddening at the injection site may be due to a mechanical effect of the needle or to a skin reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE
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 customised 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.

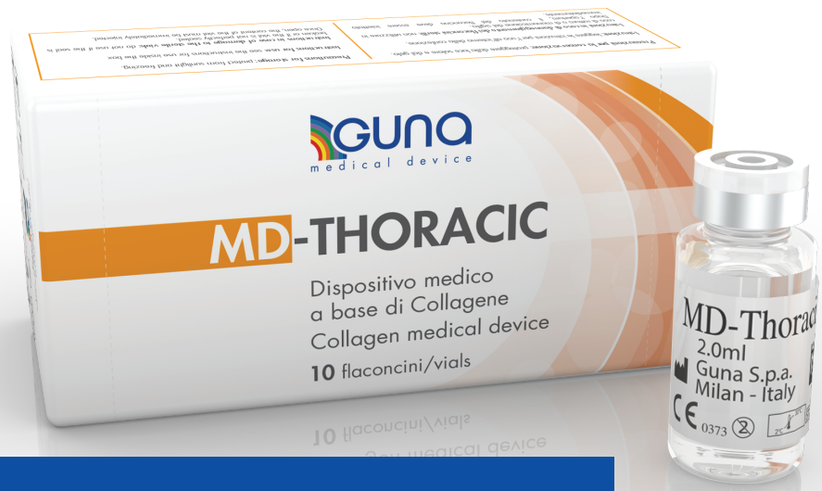
It may also be used as mechanical support while treating the following diseases:
- Osteoarthritis of the fingers.
- Rhizoarthrosis of the thumb (Forestier disease).
- Arthrosis pain due to hammer toe.
- Carpal-tunnel syndrome (in association with MD-NEURAL).
- De Quervain disease (in association with MD-NEURAL).
- Metatarsal pain.
- Metatarsal pain accompanied by Morton's neuroma (in association with MD-NEURAL).
- Rheumatoid arthritis of the hand/foot (in association with MD-POLY).
- Hand/foot tendon pain due to prolonged immobilization.

INSTRUCTIONS IN CASE OF DAMAGE TO THE STERILE VIALS
Do not use if the seal is broken or if the vial is not perfectly sealed. Once open, the content of the vial must be immediately injected. Do not use if the package is damaged.

Medial approach. A 22 G needle is placed about 4 cm proximal and lateral to the distal end of the medial malleolus. The flexor hallucis longus tendon is just lateral to this point. The needle is directed 45 degrees posteriorly, slightly upward, and laterally.

Lateral approach. A 22 G needle is placed about 1 cm proximal and medial to the distal end of the lateral malleolus. The needle should be inserted 45 degrees posteriorly, slightly upward.

Ankle – Intraarticular approach



MD-THORACIC

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Cimicifuga, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE

MD-THORACIC is a medical device designed 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 designed to help movement, specifically the thoracic area of the vertebral spine. Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. 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 to:

» Improve movement of the thoracic tract of the spine.
» Help muscle stretching.
» Help to support the muscle tissue in bad posture disorders.
» Soothe local pain, pain caused by movement and bad posture.

DIRECTIONS FOR USE

Periarticular injection technique:
2 treatments weekly 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 aseptic; 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: single-use 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. It contains animal-derived collagen from porcine source. However, patients with known 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 reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE

MD-THORACIC may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised 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 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

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

MD-TISSUE

Manufacturer: GUNA S.p.a., Via Palmanova 71, 20132 Milano, Italy
Composition: Collagen of porcine origin.
Excipients: Ascorbic acid, Magnesium gluconate, Pyridoxine hydrochloride, Riboflavin, Thiamine hydrochloride, NaCl, Water for injection.
For this medical device the following packages are available:

- Box: 5 vials (single vial 2 ml – extraction volume)
- Box: 10 vials (single vial 2 ml – extraction volume)
- Box: 50 vials (single vial 2 ml – extraction volume)

INTENDED USE
MD-TISSUE is a medical device designed 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.

Due to its special function, MD-TISSUE is also intended to limit the physiological deterioration of the skin and subcutaneous connective tissue, and counterbalance the effects of chrono-ageing and photo-ageing, such as:

- local anti-ageing treatment
- face and neck wrinkles
- firming of the subcutaneous and perivascular connective layer of the face and neck
- alteration of the trophicity of the connective tissue of face and neck induced by airborne pollutants / metabolic disorders.

MD-TISSUE is a medical device designed to help movement by counteracting the physiological aging of the connective tissue. Its main therapeutic functions include:

1. A barrier effect.
2. A lubricating action.
3. 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 to:

» Act as a defensive barrier against free radicals.
» Counteract the physiological aging of the connective tissue.
» Soothe local pain caused by movement.

DIRECTIONS FOR USE

Therapeutic protocol:
2 treatments weekly for the first 2 weeks, 1 treatment weekly until improvement of symptoms (average 8-10 sessions). It is possible to go on with 1 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 aseptic;
  Microinjections: insert the needle at 1-3 mm depth, and inject 0.2-0.3 ml into the affected tissue.
  Tunnelling injection technique: inject 0.3 ml per wrinkle. Insert the needle beneath the skin the full length of the needle, cannulate the wrinkle by moving the needle gently to left and right, while injecting the content of the syringe as the needle is withdrawn.
- *Periarticular injection technique:* the site of application must be aseptic; insert the needle perpendicular to the skin surface at 2-4 mm depth, and perform microinjections of 0.3-0.5 ml.

Preparation for injection
For this purpose the use of the following materials and accessories is recommended:

- Materials for aseptic skin preparation: single-use gloves, iodine solution, alcohol solution, sterile gauze pads, ethyl chloride spray for the skin.
- Needles for microinjections: sterile 27 G, 4 mm.
- Needles for tunnelling injection technique: sterile 30 G, 13 mm.
- 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. It contains animal-derived collagen from porcine source. However, patients with known 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 reaction. The application might cause symptoms of burning/pain at the injection site, that usually solve spontaneously within 5-10 minutes after the treatment.
Skin cleansing/disinfection is required before and after application. Pyogenic bacteria may produce injection site abscesses.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use after the expiration date. The expiration date refers to a product properly stored in its original and undamaged package. Use the product immediately after opening.

INSTRUCTIONS ON USE

MD-TISSUE may be used as a single treatment or mixed with other medical devices of the same range, in order to make a customised treatment according to clinical evolution.
Concerning its use for the treatment of face and neck wrinkles, and for firming the subcutaneous connective tissue layer, MD-TISSUE should preferably be associated with MD-MATRIX (e.g. MD-TISSUE 2 vials, MD-MATRIX 1 vial / treatment).
It may be used in patients who need a collagen supplementation or a topical antiaging treatment.

INSTRUCTIONS IN CASE OF DAMAGE TO THE STERILE VIALS

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