Part No. 030-1370
Rev M

OSTEOMED
KobyGard System
Minimally Invasive Plantar Fasciotomy and Morton's Neuroma Decompression
ESSENTIAL PRESCRIBING INFORMATION

Device Description

The *OSTEOMED KobyGard System* is designed to isolate and cut the transverse metatarsal ligament or plantar fascia through a single small incision. The System is comprised of a tissue locator, a ligament separator, a fascia separator, the KobyGard Flex tip instrument and a calibrated blade. Instrumentation is made from stainless steel and medical grade plastic.

Indications for Use

The *OSTEOMED KobyGard System* is indicated for Plantar Fasciotomy, specifically, chronic plantar fasciitis of the foot unresponsive to conservative therapy; and Intermetatarsal Nerve decompression, specifically, chronic neuroma pain of the foot unresponsive to conservative treatment and in cases requiring decompression of the Intermetatarsal Nerve rather than excising it. *OSTEOMED KobyGard System* blade is intended for single patient use only. OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Maintaining Device Effectiveness

- The Surgeon should have specific training, experience and thorough familiarity with the use of the *OSTEOMED KobyGard System*. Surgeon should familiarize him/her self with the surgical instruction manual.
- All OsteoMed instrumentation may be required for each surgery. Failure to use dedicated, unique OsteoMed instruments for every step of the surgical procedure may compromise the outcome of procedure, leading to subsequent patient injury.
- Carefully inspect the instruments before use to assure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to OsteoMed for disposition.
- OsteoMed recommends the use of OsteoMed products in a sterile environment.

Storage

Sterile packaged blades should be stored at controlled room temperature. Product package should be inspected prior to use for signs of damage or tampering.

Cleaning

- Products must be carefully cleaned prior to sterilization, unless supplied in sterile packaging directly from OsteoMed. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.

Sterility

- Product is supplied non-sterile unless expressly labeled as sterile.
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- *OSTEOMED KobyGard System* blades are packed STERILE (Gamma Sterilized). DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE. DO NOT AUTOCLAVE BLADES.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving). For sterilization of OsteoMed KobyGard System Instrumentation Tray, the following parameters should be used.

Pre-Vacuum Steam Sterilization:
Temperature: 270°F (132°C)
Time: 4 minutes
Dry Time: 20 minutes
Configuration: Tray wrapped with a towel in two layers of 1-ply polypropylene wrap using sequential wrapping techniques.
Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrument tray.

Caution

- Federal Law (USA) restricts this device to sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments. Inspect all components preoperatively to assure utility.

Instructions for Use: Plantar Fasciotomy

Patient Preparation:

The patient is placed in the supine position and local anesthesia is achieved. The patient is prepped and draped in the usual manner. Hemostasis is achieved according to the surgeon's preference.

Surgical Technique:

1. The surgeon palpates the medial calcaneal tubercle. A one centimeter vertical incision is marked one centimeter distal to the palpated tubercle on the medial inferior aspect of the heel. This will avoid the neurovascular bundle.
2. Using a #15 blade, the vertical incision is made at the previously marked incision site.
3. Utilizing small curved Metzenbaum scissors, the incision is deepened to start a plane under the plantar fascia and dorsal to the subcutaneous tissue. This plane is initiated by palpating the underside of the medial aspect of the plantar fascia.
4. The Tissue Locator is used to extend the plane created by the Metzenbaum scissors across to the lateral aspect of the plantar fascia.
5. The Fascia Separator is then introduced to isolate the plantar fascia between the subcutaneous tissue and first layer of intrinsic muscles.
   5a. The Fascia Separator has an upper and lower prong separated by a 5mm gap. The lower prong extends approximately ½ inch further than the upper prong to allow for initial palpation of the underside of the fascia before introduction and capture of the plantar fascia.
6. After removal of the Fascia Separator, the KobyGard instrument is introduced and positioned securely around the plantar fascia using the same palpation technique used previously with the Tissue Locator and Fascia Separator. Care is taken to insert the KOBYGARD into the previously separated tissue planes dorsal and plantar to the fascia.
   6a. The KOBYGARD Flex Tip design allows for isolation of the plantar fascia regardless of it's thickness and protects the surrounding soft tissue structures from damage during the procedure. The longer, lower prong of the KOBYGARD is plantar to the fascia and the short upper prong is dorsal. The KOBY GARD has a slotted channel extending through the handle and passing throughout the length of the device allowing the passage of the blade while incising only the enclosed fascia.
7. The calibrated shaft of the cutting blade is marked with ½ centimeter increments that are used as a reference point to the proximal end of the KOBYGARD handle when the blade is placed on the bottom of the foot in the position needed to make the desired length of the cut. This illustration represents the marking and premeasuring needed to incise ½ the plantar fascia. A surgical pen can be used to mark the blade shaft at the stopping point if desired.
8. The blade is then placed into the KOBYGARD instrument and pushed toward the lateral aspect of the foot as the foot is dorsiflexed to create tension on the plantar fascia. The surgeon can feel the resistance of the plantar fascia as it is incised. When the blade reaches the previously determined calibrated mark, the desired length of cut has been achieved.
9. The KOBYGARD instrument and blade are then removed and the incision is closed with one or two interrupted sutures.

Surgeon's Post-OP Treatment Protocol:

1. A compression dressing is applied to the foot.
2. Immediate ambulation is allowed as tolerable. (A removeable cast boot can be utilized for the first three weeks. This can provide additional protection of the foot during ambulation and keep the fascia stretched in a lengthened position when patients are immobile.)
3. The dressing is removed after 3 to 7 days, and the patient is allowed to return to comfortable shoe gear as tolerable.
4. The sutures are removed after 14 days.
5. Full activity is allowed as tolerable.

NOTE: These are only recommended protocols and each case should be treated independently at the surgeon's discretion.

Instructions for Use: Morton's Neuroma Decompression

Patient Preparation:

The patient is placed in the supine position and local anesthesia is achieved. The patient is prepped and draped in the usual manner. Hemostasis is achieved according to the surgeon's preference.

Surgical Technique:

1. In order to ensure proper alignment of the instrumentation, a line is made with a surgical marker and straight edge that is parallel to the adjacent metatarsals in the appropriate interspaces.
2. Using a #15 blade, a 7mm vertical incision is made in the web space. This incision is made vertically to protect the neurovascular bundle to the toe.
3. A small curved Metzenbaum scissor is then used to palpate and create a small plane on the plantar aspect of the transverse metatarsal ligament (TML).
4. The Tissue Locator is then used to extend the plane across the underside of the TML. Care is taken to ensure that all instruments are introduced in a parallel manner to the adjacent metatarsals.
5. The Ligament Separator is then introduced in order to separate the TML from surrounding tissue and to create planes plantar and dorsal to the TML to assist in the proper placement of the KOBYGARD instrument.
   5a. The Separator has a 5mm gap between the upper and lower prongs. The lower prong extends approximately ½ inch further than the upper prong to allow for initial palpation of the underside of the ligament before introduction and capture of the TML.
6. After removal of the Ligament Separator, the KOBYGARD instrument is introduced and positioned securely around the ligament using the same palpation technique used previously with the Tissue Locator and Separator. Care is taken to insert the KOBYGARD into the previously separated tissue planes dorsal and plantar to the ligament.
   6a. The KOBYGARD Flex Tip design allows for isolation of the TML regardless of it's thickness and protects the nerve and surrounding soft tissue structures from damage during the procedure. The longer, lower prong of the KOBYGARD is plantar to the ligament and the short upper prong is dorsal. The KOBYGARD has a slotted channel extending through the handle and passing throughout the length of the instrument allowing the passage of the blade while incising only the enclosed TML.
7. Once the KOBYGARD instrument is properly positioned, the blade is introduced into the slotted channel until initial resistance of the distal edge of the TML is felt. The blade is advanced proximally within the KOBYGARD instrument incising the TML with a controlled cut. When resistance from the TML is no longer felt, the ligament has been completely incised.
8. The KOBYGARD instrument and blade are then removed. The Tissue Locator can then be reintroduced to palpate between the metatarsal heads for confirmation of a successful release. The incision is closed with one or two interrupted sutures.

Surgeon's Post-OP Treatment Protocol:

1. The patient is placed in a post op shoe for ambulation.
2. Immediate ambulation is allowed as tolerable.
3. The surgical dressing is removed at 48 hours with return to comfortable shoe gear as tolerable.
4. The sutures are removed at one week and full activity is allowed as tolerable.

NOTE: These are only recommended protocols and each case should be treated independently at the surgeon's discretion.

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Symbols and Definitions

Single Use Only		REF	Catalogue Number
Use By (Date)		Do not use if sterile package is damaged	
Batch Code (Lot Number)	LOT	Consult Instructions for Use	
Date of Manufacture (MFG DATE)		Manufacturer (MFR)	
Attention, See Instructions for Use Caution, Consult Accompanying Documents		Authorized Representative in the European Community	EC REP
Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.	Rx ONLY	Sterile, Method of Sterilization Using Irradiation	STERILE R

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