INSTRUCTIONS FOR USE

Haymaker Screw System

Important Information — Please Read Prior to Use

CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of, a physician.

Description:

The Haymaker® screw is a type-II anodized fully threaded titanium screw which provides a dual thread at the proximal end of the screw, increasing engagement with the head and neck of the metacarpal. A tapered design allows the screw to fit more comfortably through the narrowing of the intramedullary canal of the metacarpal. Multiple lengths and diameters offer options for treatment of various shapes and sizes of small bones. Single use supplemental instrumentation is provided sterile packed, consisting of a guide wire, cannulated drill, and T-10 cannulated driver.

Indications:

The Haymaker® Screw System is intended for fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodesis of small joints; bunionectomies and osteotomies, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

Contraindications:

Absolute contraindications include, but are not limited to:

1. Insufficient quality of bone or soft tissue to support fixation;
2. In patients with active local infection or evidence of infection;
3. Any condition not described in the Indications for Use;
4. Not intended for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
5. Any entity or condition that totally precludes the possibility of fusion is a relative contraindication. In addition, the patient's occupation, activity level, or mental capacity may be relative contraindications to this surgery. Relative contraindications include, but are not limited to: cancer, kidney dialysis, osteopenia, obesity, pregnancy, certain degenerative diseases, foreign body sensitivity, mental illness, alcoholism, drug abuse.

Warnings and Precautions

1. The Haymaker® Screw System should only be implanted by surgeons experienced in the use of these implants and the associated extremities surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for the implantation of these devices.
2. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant
3. The Haymaker® Screw System implants are provided as single use only and are not to be reused or reimplanted regardless of an apparent undamaged condition. Any retrieved devices must never be reused under any circumstances.
4. The Haymaker® Screw System implants are provided sterile. Do not clean and/or resterilize sterile implants. Do not use if package is opened or damaged or if expiration date has passed.
5. The Haymaker® Screw System instrumentation is provided sterile and single use only. Instrumentation is not to be reused or resterilized regardless of an apparent undamaged condition.
6. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Sterile implants must be stored in a dry area away from radiation and extreme temperatures and environments such as moisture, air, etc.
7. Patients with previous surgery at the area(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Components of this system should not be used with components of any other system or manufacturer.

9. Prior to inserting the guidewire, check to ensure that it is not bent or damaged.

Possible Adverse Effects:

Potential complications and adverse effects for this system are similar to those of other bone screw instrumentation systems and include, but are not limited to: Bending, fracture or loosening of implant, nonunion or delayed union, fracture of the vertebra, neurological, vascular or visceral injury, metal sensitivity or allergic reaction to a foreign body, infection, decrease in bone density due to stress shielding, pain, discomfort or abnormal sensations due to the presence of the device, nerve damage due to surgical trauma, bursitis, Leak.

MRI Safety Information:

The Haymaker® Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Haymaker® Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

How Supplied:

All Haymaker® Screw System implants and instruments are sterilized via gamma irradiation and are delivered sterile. The implants are for single use only and must not be processed or sterilized again. Haymaker® Screw System instruments are for single use only and must not be processed or sterilized again. Do not use if package is opened or damaged or if expiration date has passed.

Surgical Technique Manual

The Haymaker® Screw System Surgical Technique is available by contacting Customer Service at *888.463.5803*.

Product Complaints:

Any healthcare professional (e.g., a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any Haymaker® implants or instruments should notify OC Medical Devices, or, where applicable, their distributor. In the event of serious incident, or risk of serious incident, having resulted in, or may potentially result in, the death or severe deterioration in the state of health of a patient or user, OC Medical Devices or the distributor must be notified as soon as possible. When filing a complaint, please provide the component(s) reference number, manufacturing lot number(s), your name and address, and the nature of the complaint in full detail, as well as notification of whether a written report is requested.

Symbols and Definitions

REF	Catalog Number		Consult Instructions for Use.
LOT	Batch code		Do not use if package is damaged.
	Date of Manufacture (YYYY-MM-DD)		Single use only. Do not reuse.
	Manufacturer	Rx Only	Prescription use only
	Use by date (YYYY-MM-DD)	UDI	Unique Device Identification
STERILE R	Sterilized using irradiation	NON STERILE	Nonsterile
QTY	Quantity		

For Product Complaints or for additional product information please contact:
OC Medical Devices, 888-463-5803, 15 East Montgomery Crossroads, Suite 3, Savannah, GA 31406