4B Inverness Ct. E., Suite 280
Englewood, CO 80112
USA
(888) 728-1888
CE 0086

Monster® Screw System

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

This booklet is designed to assist in using the Monster® Screw System. It is not a reference for surgical techniques.

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

General Description
The Monster® Screw System is comprised of screws and washers used for bone fixation. The Monster® Screw is a threaded bone screw which is offered in a variety of ranging from 2.0mm to 9.5mm with lengths of 8mm (for smaller diameters) thru 100mm (for larger diameters). Screw washers are also available in four different configurations; flat dome, split flat and bevel. Available screws, washers and instrumentation are packaged as a single system. The system instruments include guide wires, guide wire guide, drill bits, drill guides, tissue protectors, depth gauges, countersinks, bone taps, screw driver shafts, driver handles, small bone distractor & cleaning stylet. These instruments are used to facilitate the placement of the screws.

Implant Materials
All Monster® screws and washers are made from Titanium Alloy (ASTM F136) and Stainless Steel Alloy (ASTM F2229). The instrumentation is made from medical grades of stainless steel, silicone and anodized aluminum.

Indications For Use

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

Contraindications
Use of the Monster® Screw System is contraindicated in cases inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment.

- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

Potential Complications and Adverse Reactions
In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles.
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

A possib[illegible] listed here are not typical of Paragon 28® products but are in principle observed with any implant. Properly inform Paragon 28® as soon as complications occur in connection with implants or instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

Warnings and Precautions
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- The Monster 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 Monster Screw System in the MR Environment is unknown. Scanning a patient who has this device may result in patient injury.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster Screw System.**

Maintaining Device Effectiveness
- The surgeon should have specific training, experience, and thorough familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw

type to use for specific indications.

- The Monster Screws are not intended to endure excessive abnormal functional stresses.
- The Monster Screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Monster Screw System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28 Inc. recommends the use of Paragon 28 Inc. products in a sterile environment.

Cleaning and Decontamination

All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28 ***Monster Screw System - Instrument Reprocessing Instructions for Reusable Instruments*** document P20-CLN-0001. This is also available by calling 888-728-1888.

Sterilization

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap, such as the KimGuard® Sterilization Wrap, is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure	Dry Time
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	45 Minutes

Instructions For Use

The Monster Screw System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques. Refer to the Monster Screw System Surgical Technique P20-STG-0001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28 by phone, 888-728-1888.

Screw Removal (If necessary)

- Locate implant with intra-operative imaging.
- Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
- OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with a medium sized Kern forcep and continue turning driver shaft and Kern forcep counterclockwise while exerting light pressure upwards with the Kern forcep.
- If screw is integrated into bone, core out with appropriate sized trephine drill.

Product Complaints

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28, Inc. immediately. Paragon 28, Inc. should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

Symbol Explanations

EC REP	**Authorized EU Representative**		**Manufacturer**
LOT	**Lot Number**	NON STERILE	**Non-sterile**
REF	**Item Number**		**Do Not Reuse**
	Consult IFU	R_x Only	**USA: Prescription**
	Keep Dry		

P20-IFU-1001 Rev A
Date of Publication: March 14th, 2016
Obsolete Date: March 22nd, 2016

OBSOLETE

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CAUTION
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General Description
The Monster® Screw System is comprised of screws and washers used for bone fixation. The Monster® Screw is a threaded bone screw which is offered in diameters ranging from 3.0mm to 7.5mm with lengths of 8mm (for smaller diameters) thru 200mm (for larger diameters). Screw washers are also available in four different configurations: flat, dome, spot-flat and oval. Available screws, washers and instrumentation are packaged as a single system. The system instruments include guide wires, guide wire guide, drill bits, drill guides, tissue protectors, depth gauges, countersinks, bone taps, screw driver shafts, driver handles, small bone distractor & cleaning stylet. These instruments are used to facilitate the placement of the screws.

Implant Materials
All Monster® screws and washers are made from Titanium Alloy (ASTM F136) and Stainless Steel Alloy (ASTM F2229). The instrumentation is made from medical grades of stainless steel, silicone and anodized aluminum.

Indications For Use

The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

Contraindications
Use of the Monster® Screw System is contraindicated in cases inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment.

- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

Potential Complications and Adverse Reactions
In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles.
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28® Inc. products but are in principle observed with any implants. Promptly inform Paragon 28® as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

Warnings and Precautions

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- The Monster 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 Monster Screw System in the MR Environment is unknown. Scanning a patient who has this device may result in patient injury.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster Screw System.**

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw

type to use for specific indications.

- The Monster Screws are not intended to endure excessive abnormal functional stresses.
- The Monster Screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Monster Screw System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28 Inc. recommends the use of Paragon 28 Inc. products in a sterile environment.

Cleaning and Decontamination

All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28 ***Monster Screw System - Instrument Reprocessing Instructions for Reusable Instruments*** document P20-CLN-0001. This is also available by calling 888-728-1888.

Sterilization

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap, such as the KimGuard® Sterilization Wrap, is recommended,. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	45 Minutes

Instructions For Use

The Monster Screw System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques. Refer to the Monster Screw System Surgical Technique P20-STG-1001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28 by phone, 888-728-1888.

Screw Removal (If necessary)

- Locate implant with intra-operative imaging.
- Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
- OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with a medium sized Kern forcep and continue turning driver shaft and Kern forcep counterclockwise while exerting light pressure upwards with the Kern forcep.
- If screw is integrated into bone, core out with appropriate sized trephine drill.

Product Complaints

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Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

Symbol Explanations

EC REP	**Authorized EU Representative**		**Manufacturer**
LOT	**Lot Number**	NON STERILE	**Non-sterile**
REF	**Item Number**		**Do Not Reuse**
	Consult IFU	**R_x Only**	**USA: Prescription**
	Keep Dry		

EC REP Emergo Europe
Molenstraat 15, 2513 BH
The Hague, The Netherlands

P20-IFU-1001 Rev B

OBSOLETE

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CAUTION
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General Description
The Monster® Screw System is comprised of screws and washers used for bone fixation. The Monster® Screw is a threaded bone screw which is offered in diameters ranging from 2.0mm to 9.5mm with lengths of 8mm (for smaller diameters) thru 200mm (for larger diameters). Screw washers are also available in four different configurations; flat, dome, split-flat and bowl. Available screws, washers and instrumentation are packaged as a single system. The system instruments include guide wires, guide wire guide, drill bits, drill guides, tissue protectors, depth gauges, countersinks, bone taps, screw driver shafts, driver handles, small bone distractor & cleaning stylet. These instruments are used to facilitate the placement of the screws.

Implant Materials
All Monster® screws and washers are made from Titanium Alloy (ASTM F136) and Stainless Steel Alloy (ASTM F2229). The instrumentation is made from medical grades of stainless steel, silicone, anodized aluminum and nitinol.

Indications
The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

Contraindications
Use of the Monster® Screw System is contraindicated in cases inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

Potential Complications and Adverse Reactions
In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles.
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28® Inc. products but are in principle observed with any implant. Promptly inform Paragon 28® as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returned implants. The surgeon is held liable for damages associated with inadequate asepsis, inadequate preparation of the osseous implant bed, in the case of implants, incorrect indication or surgical technique incorrect positioning, information and consequent incorrect patient treatment.

Warnings and Precautions

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- The Monster 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 Monster Screw System in the MR Environment is unknown. Scanning a patient who has this device may result in patient injury.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster Screw System.**

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
- The Monster Screws are not intended to endure excessive abnormal functional stresses.
- The Monster Screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Monster Screw System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28 Inc. recommends the use of Paragon 28 Inc. products in a sterile environment.

Cleaning and Decontamination
All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28 Monster Screw System - Instrument Reprocessing Instructions for Reusable Instruments document P20-CLN-0001. This is also available by calling (855) 786-2828.

Sterilization
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Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Min.	45 Min.

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Screw Removal (If Necessary)

- Locate implant with intra-operative imaging.
- Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
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Symbol Explanations

EC REP	Authorized EU Representative		Manufacturer
LOT	Lot Number		Non-sterile
REF	Item Number		Do Not Reuse
	Consult IFU	**R_x Only**	USA: Prescription
	Keep Dry		

EC REP
Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex St., Sydney, NSW 2000
Australia

CE 0086

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Implant Materials
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Indications
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Contraindications
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- Acute or chronic infections, local or systemic
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- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
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Potential Complications and Adverse Reactions
In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles.
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28® Inc. products but are in principle observed with any implant. Promptly inform Paragon 28® as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

Warnings and Precautions

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster Screw System.**

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

Maintaining Device Effectiveness

- The surgeon should have anatomic training and familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
- The Monster Screws are not intended to endure excessive abnormal functional stresses.
- The Monster Screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Monster Screw System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28 Inc. recommends the use of Paragon 28 Inc. products in a sterile environment.

Handling and Sterilization

NON-STERILE PRODUCT
Product that is presented in a tray is provided non-sterile. All non-sterile implants and instruments should be cleaned using established hospital methods before sterilization and introduction into the sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28®, Inc. ***Instrument Reprocessing Instructions for Reusable Instruments*** (P20-CLN-0001). This is also available by calling (+1) (855) 786-2828.

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap, such as the KimGuard® Sterilization Wrap, is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Min.	45 Min.

STERILE PRODUCT
Paragon28® Monster Screw System implants may be provided sterile. If sterile, product has undergone gamma irradiation. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use implants after expiration date. Packages for implants should be intact upon receipt.

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Product should be stored in a clean and dry environment.

Instructions For Use
The Monster Screw System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques. Refer to the Monster Screw System Surgical Techniques P20-STG-1001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28 by phone, (+1) (855) 786-2828.

Screw Removal (If Necessary)

- Locate implant with intra-operative imaging.
- Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
- OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with a medium sized Kern forcep and continue turning driver shaft and Kern forcep counterclockwise while exerting light pressure upwards with the Kern forcep.
- If screw is integrated into bone, core out with appropriate sized trephine drill.

Product Complaints
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Symbol Definitions

EC REP	Authorized EU Representative		Manufacturer
	Lot Number	NON STERILE	Non-sterile
REF	Item Number		Do Not Reuse
	Consult IFU	**R_x Only**	USA: Prescription
	Keep Dry		Caution, consult accompanying documents
	Use-by date	STERILE R	Sterilized using irradiation
	Do not use if package is damaged		

EC REP
Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex St., Sydney, NSW 2000
Australia

CE 0086

Monster® Screw System

4B Inverness Ct. E, Suite 280
Englewood, CO 80112
USA
(+1) (855) 786-2828

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www.paragon28.com/resources

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General Description
The Monster® Screw System is comprised of screws and washers used for bone fixation. The Monster® Screw is a threaded bone screw which is offered in diameters ranging from 2.0mm to 9.5mm with lengths of 8mm (for smaller diameters) thru 200mm (for larger diameters). Screw washers are also available in four different configurations; flat, dome, split-flat and bowl. Available screws, washers and instrumentation are packaged as a single system. The system instruments include guide wires, guide wire [illegible], drill bits, drill guides, tissue protectors, depth gauges, countersinks, [illegible] taps, screw driver shafts, driver handles, small bone distractor & cleaning stylet. These instruments are used to facilitate the placement of the screws.

Implant Materials
All Monster® screws and washers are made from Titanium Alloy (ASTM F136) and Stainless Steel Alloy (ASTM F2229). The instrumentation is made from medical grades of stainless steel, silicone, anodized aluminum and nitinol.

Indications
The Monster® Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

Contraindications
Use of the Monster® Screw System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

Potential Complications and Adverse Reactions
In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

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Warnings and Precautions

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.**

MR Safety Information
The Monster® Screw System has 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 Monster® Screw System in the MR Environment is unknown. Scanning a patient who has this device may result in patient injury.

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
- The Monster® Screws are not intended to endure excessive abnormal functional stresses.
- The Monster® Screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Monster® Screw System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

Cleaning and Decontamination
All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28® Monster® Screw System - Instrument Reprocessing Instructions for Reusable Instruments document P20-CLN-0001. This is also available by calling (+1) (855) 786-2828.

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Screw [illegible] (If Necessary)

- Locate implant with intra-operative imaging.
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- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
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The Netherlands

Australian Sponsor
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CE 0086

Monster® Screw System

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USA
(+1) (855) 786-2828

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General Description
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Implant Materials
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Contraindications
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All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
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- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
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Warnings and Precautions
- Indication to replace implants may be r… time due to mechanical reasons of device failure. If corrective action is not taken, complications may occur.
- Can undersized screw in areas of high functional… lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together or near the implant site.
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- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.**

MR Safety Information
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Maintaining Device Effectiveness
- The surgeon should have specific training, experience, and thorough familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
- The Monster® Screws are not intended to endure excessive abnormal functional stresses.
- The Monster® Screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Monster® Screw System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

Handling and Sterilization
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CE 0086

Monster® Screw System

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

General Description
The Monster® Screw System is comprised of screws, Monster® BITE Snap-off screws, and washers used for bone fixation. The Monster® Screw is a threaded bone screw which is offered in diameters ranging from 2.0mm to 9.5mm with lengths of 8mm (for smaller diameters) thru 200mm (for larger diameters). Screw washers are also available in four different configurations; flat, dome, split-flat and bowl. Available screws, washers and instrumentation are packaged as a single system. The system instruments include guide wires, guide wire guide, drill bits, drill guides, tissue protectors, depth gauges, countersinks, bone taps, screw driver shafts, driver handles, small bone distractor & cleaning stylet. These instruments are used to facilitate the placement of the screws.

Implant Materials
All Monster® screws and washers are made from Titanium Alloy (ASTM F136) and Stainless Steel Alloy (ASTM F2229). The instrumentation is made from medical grade of stainless steel, silicone, anodized aluminum and Nitinol.

Indications
The Monster® Screw System is indicated for use in bone reconstruction, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges and the joints and ligaments coupling said bones, appropriate for the size of the device.

Contraindications
Use of the Monster® Screw System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

Potential Complications and Adverse Reactions
In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28® as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

Warnings and Precautions

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, or other appliances of dissimilar [illegible] should not be used together near the implant site.
- The implants and guide wires are intended for single use only. Re-use may cause product failure and could lead to disease transmission.
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.**

MR Safety Information
The Monster® Screw System has 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 Monster® Screw System in the MR Environment is unknown. Scanning a patient who has this device may result in patient injury.

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
- The Monster® Screws are not intended to endure excessive abnormal functional stresses.
- The Monster® Screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Monster® Screw System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

Handling and Sterilization
STERILE PRODUCT
Paragon28® Monster® Screw System implants may be provided sterile. If sterile, product has undergone gamma irradiation. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use implants after expiration date. Packages for implants should be intact upon receipt.

Implants in sterile packaging should be inspected to ensure that the package has not been damaged or previously opened. If the inner package integrity has been compromised, DO NOT USE THE IMPLANT. Contact the manufacturer for further instructions. The implants should be opened using the aseptic technique described in document P99-STR-1001. The implant should only be opened after the correct size has been determined. Once the seal of the product is broken, the product should not be re-sterilized.

Product should be stored in a clean and dry environment.

NON-STERILE PRODUCT
Product that is presented in a tray is provided non-sterile. All non-sterile implants and instruments should be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. For manual reusable instrument reprocessing instructions, refer to the Paragon 28® Monster® Screw System – Instrument Reprocessing Instructions for Reusable Instruments document P20-CLN-1001. For automatic reusable instrument reprocessing instructions, refer to the Paragon 28® Automatic Reusable Instrument Reprocessing document P99-CLN-1001. This is also available by calling (+1) (855) 786-2828.

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap, such as the KimGuard® Sterilization Wrap, is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Min.	45 Min.

Instructions For Use
Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Monster® Screw System. Refer to the Monster® Screw System Surgical Techniques P20-STG-1001 and the Monster® BITE Surgical Technique P24-STG-0001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28® by phone, (+1) (855) 786-2828.

Screw Removal (If Necessary)

- Locate implant with intra-operative imaging.
- Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
- OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with a medium sized Kern forcep and continue turning driver shaft and Kern forcep counterclockwise while exerting light pressure upwards with the Kern forcep.
- If screw is integrated into bone, core out with appropriately sized trephine drill.

Product Complaints
The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc. should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

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CE 2797

Monster® Screw System

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Screw Removal (If Necessary)

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- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
- OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with a medium sized Kern forcep and continue turning driver shaft and Kern forcep counterclockwise while exerting light pressure upwards with the Kern forcep.
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Monster® Screw System

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Please check the website, www.paragon28.com/ifus, for the most current instructions for use document.

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CAUTION
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GENERAL DESCRIPTION
The Monster® Screw System is comprised of threaded bone screws which are offered in diameters ranging from 2.0mm to 7.2mm with lengths of 8mm (for smaller diameters) thru 185 mm (for larger diameters), and washers used for bone fixation. Screw washers are available in four different configurations: flat, dome, split-flat and bowl. Available screws, washers and instrumentation are packaged as a single system. The screws of the Monster Screw System provide stable fixation across the fracture / joint / osteotomy site until bone healing occurs.

The Monster® Screw System instruments include guide wires, guide wire guide, drill bits, drill guides, tissue protectors, depth gauges, countersinks, bone taps, screwdriver shafts, driver handles, small bone distractor & cleaning stylet. These instruments are used to facilitate the placement of the screws.

INTENDED/EXPECTED CLINICAL BENEFITS
Intended/Expected Clinical Benefits of the Monster® Screw System include:
- Successful Implantation of Monster® Screw System Devices
- Bone Healing

Paragon 28® has established the safety and performance of the Monster® Screw System, which represents state-of-the-art medical devices for bone fixation. Summary of Safety and Clinical Performance (SSCP) can be found at: https://ec.europa.eu/tools/eudamed by searching for Manufacturer: Paragon 28 (upon Eudamed activation).

Residual Risks identified within the SSCP are included as warnings, precautions Potential complications and adverse reactions.

IMPLANT MATERIALS
The implants of the Monster® Screw System are manufactured from Titanium Alloy (ASTM F136). The elemental composition of the implants is as follows:

Element	% (mass/mass)
Nitrogen	0.05
Carbon	0.08
Hydrogen	0.012
Iron	0.25
Oxygen	0.13
Aluminium	5.5-6.50
Vanadium	3.5-4.5
Titanium	balance

INSTRUMENT MATERIALS
The instrumentation is manufactured from medical grades of stainless steel, silicone, polymers, anodized aluminium and nitinol.

CMR, EPD, PHTHALATES
The Monster® Screw System Implants, guide wires, and drill bits do not contain substances ≥0.1% (w/w) which are classified as carcinogenic, mutagenic or reprotoxic (CMR), substances ≥0.1% (w/w) which have endocrine disrupting properties (EDP) and do not contain phthalates.

INTENDED USE/INTENDED PURPOSE
The Monster® Screw System is intended for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, appropriate for the size of the device.

INDICATIONS FOR USE

System(s)	Indications for Use
Monster® Screws Cannulated Screws and Washers in Diameters: 4.5 mm, 5.5 mm, and 7.0 mm	The Monster® Screws of the Monster® Screw System are indicated for use in the foot for: Bone reconstruction/osteotomy Arthrodesis/joint fusion Fracture repair/fracture fixation The Monster® Screws of the Monster® Screw System are indicated for use in the ankle for: Arthrodesis/joint fusion
Mini-Monster® Screws Canulated Screws and Washers in Diameters: 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, and 4.0 mm	The Mini-Monster® Screws of the Monster® Screw System are indicated for the use in the foot for: Bone reconstruction/osteotomy Arthrodesis/joint fusion Ligament fixation Fracture repair/fracture fixation The Mini-Monster® Screws of the Monster® Screw System are indicated for the use in the ankle for: Fracture repair/fracture fixation
Mini-Monster® Solid Screws Solid Screws and Washers in Diameters: 3.5 mm, and 4.0 mm	The Mini-Monster® Solid Screws of the Monster® Screw System are indicated for use in the foot for: Bone reconstruction Fracture repair/fracture fixation The Mini-Monster® Solid Screws of the Monster® Screw System are indicated for the use in the ankle for: Fracture repair/fracture fixation
Precision® Jones Screws Solid and Cannulated Type II Anodized Screws and Washers in Diameters: 4.0 mm, 4.5 mm, 5.5 mm, and 6.2 mm	The Precision® Jones Screws of the Monster® screw System are indicated for use in the foot for: Fracture repair/fracture fixation
Joust™ Beaming Screws Solid and Cannulated Type II Anodized Screws in 5.0 mm, 5.5 mm, and 7.2 mm	The Joust™ Beaming Screws of the Monster® screw System are indicated for use in the foot for: Bone reconstruction/osteotomy Arthrodesis/joint fusion
Monster® BITE Screws Snap-off Screws in diameters: 2.0 mm and 2.7 mm	The Monster® BITE Screws of the Monster® Screw System are indicated for use in the foot for: Bone reconstruction/osteotomy Arthrodesis/joint fusion

CONTRAINDICATIONS
Use of the Monster® Screw System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis, or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:
- Acute or chronic infections, local or systemic
- Vascular, muscular, or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence, an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status
- Indications not included in the **INDICATIONS FOR USE**

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:
- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS
In any surgical procedure, the potential for complications and adverse reactions exists. The potential complications and adverse reactions with these implants include:
- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles or implant material
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding
- Adverse events include but are not limited to those described in this document

The residual risks with these implants include:
- Using a sterilization cycle outside the validated range of the Monster System can lead to the introduction of microorganisms to the healthcare provider or patient and can result in infection
- Monster BITE implants are designed to be used without pre-drilling or the use of a k-wire. As a result, if hard bone is encountered, the implant may break away from the drive shaft prior to contacting the boney surface, which can lead bone [illegible] when manually inserting the screw
- Movement during the non-load bearing phase can induce an implant break and result in incomplete bone fusion or removal of the implant
- Not following the Surgical Technique Guide when prepping for surgery may lead to incorrect procedural steps being followed, incorrect instruments being selected, and understanding instrument limitations/functionality. This may lead to broken instruments and/or implants resulting in significant OR time delays or serious injury to the patient.
- The use of K-Wires without controlling the insertion points and trajectories can lead to incorrect implant placement or implant intersection and cause significant OR time delays or serious injury to the patient
- Not having visualization of the surgical site when placing screws can lead to unacceptable screw head placement and cause injury to a patient.
- Incorrect interpretation of implant placement anatomy can lead to incorrect implant placement or implant trajectory intersection and lead to significant OR time delays or serious injury to the patient
- Not applying sufficient pressure when attempting to creation bone fusion can lead to a non-union and potential serious injury or revision surgery

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WARNINGS AND PRECAUTIONS
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.

- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants, guide wires, and sterile packaged instruments are intended for single use only. Any single use device which has been used may have come in contact with tissue, bone, blood, or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient and other users
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.**
- **Do not re-sterilize the Monster® Screw System Implants.**

MR SAFETY INFORMATION

MRI Safety Information
A patient with the Monster® Screw System Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Device Name	Monster® Screw System Implant
Static Magnetic Field Strength (B0)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole-Body SAR [W/kg]	2.0W/kg (Normal Operating Mode)
Limits on Scan Duration	All anatomical regions can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 5 minutes of continuous RF (a sequence or back to back series/scan without breaks) with a 20 minute cooling period between scans for an hour long scanning session
	Scanning of the knees and all anatomy superior to the knees can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact extending approximately 20mm from the implant.

MAINTAINING DEVICE EFFECTIVENESS

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- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
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- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon28® non-sterile devices are precision medical devices and must be used and handled with care. Inspect the devices for damage prior to use, and at all stages of handling thereafter. If damage is detected, do not use the device prior to consulting the manufacturer for guidance.
- The surface coating of anodized aluminum devices may degrade due to exposure to highly alkaline cleaning processes and/or inappropriate handling and/or normal use. Such devices may require replacement if they no longer perform as designed.
- If an instrument is damaged, contact Paragon 28® immediately to arrange replacement and/or disposal.
- Devices with cutting functions or sharp points become dull with continuous use. This condition does not indicate a defective device and may indicate normal wear. Any sign of a dull or wearing devices may require replacement if they no longer perform as designed. Inspection prior to use should include verifying the cutting ability and sharpness of these points and edges.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

HANDLING AND STERILIZATION

Sterile Product

Monster® Screw System implants may be provided sterile. If sterile, product has undergone gamma irradiation. Do not re-sterilize. SINGLE USE ONLY Any device labeled as Single Use only must never be reused or reprocessed. Any device opened from its packaging is considered used and may have come in contact with tissue, bone, blood or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient and other users. Do not use implants or instruments after expiration date. Packages for implants and instruments should be intact upon receipt.

Implants and instruments in sterile packaging should be inspected to ensure that the package has not been damaged or previously opened. If the inner package integrity has been compromised, potential for patient harm could occur, DO NOT USE THE IMPLANT or INSTRUMENT. Contact the manufacturer for further instructions. The implants should be opened using the aseptic technique described in document P99-STR-1001. Please check the website, www.paragon28.com/resources/surgical-technical-guides/, for the most current Aseptic Transfer Techniques Document P99-STR-1001. The implant or instrument should only be opened after the correct size has been determined. Once the seal of the product is broken, the product should not be re-sterilized.
All implants and instruments should be stored in a clean, dry environment.

Non-Sterile Product

Product that are presented in a tray are provided non-sterile. All non-sterile implants and instruments should be processed using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. For manual reusable instrument reprocessing instructions, refer to the Monster® Screw System – ***Guidelines for Reprocessing Instructions for Reusable Instruments*** (Manual Method P20-CLN-0001) or Automated Method P99-CLN-0001. For product information or to obtain a copy of the surgical technique manual and/or the Summary of safety and clinical performance, please contact Paragon 28®, Inc. by phone, (+1) (855) 786-2828.

Unless specifically labeled sterile, the implants and instruments supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of 2 layers of sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Min.	45 Min.

INTENDED USERS

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Monster® Screw System. Refer to the Monster®/ Mini-Monster® Screw System Surgical Technique Guide P20-STG-1001, Monster® BITE Surgical Technique P24-STG-1001, Precision® Jones Screw P25-STG-1001, Joust™ Beaming System P26-STG-1001, Precision® MIS Bunion P27-STG-1001 and the Combination Drill Technique Tip P20-STT-1001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28® by phone, (+1) (855) 786-2828.

IMPLANT REMOVAL (IF NECESSARY)

- Locate implant with intra-operative imaging.
- Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
- OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with a medium sized Kern forcep and continue turning driver shaft and Kern forcep counterclockwise while exerting light pressure upwards with the Kern forcep.
- If screw is integrated into bone, core out with appropriately sized trephine drill.

TARGETED POPULATION

The Monster® Screw System is intended for members of the adult general population who are under the care of a doctor who determines the need for bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle requiring screw fixation, appropriate for the size of the device. The population does not include patients that are pregnant except in emergency situations where bone fixation is required; nor does it include patients with conditions listed in the contraindications.

PRODUCT COMPLAINTS The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc. or its EC Representative should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

DISPOSAL OF IMPLANT OR INSTRUMENT

The implant and associated instrumentation will be used in a surgical suite, and thus, any disposal of the implant(s), instrument(s), and/or packaging will occur in the surgical suite by the user.

- The sterile packaged device will be opened in the surgical suite with the packaging disposed of by the user. The outside packaging is not passed onto the operative field and should not be contaminated by human tissue or blood. The outside packaging is disposed of in a standard waste receptacle. If the inner packaging is in contact with human tissue or blood, the inner packaging must be disposed of in a standard biowaste container. If the inner packaging does not come in contact with human tissue or blood, the inner packaging can be disposed of in a standard waste receptacle.
- In the case of an implant removal, or if an implant must be disposed of during surgery, the disposal will occur in the surgical suite by the user. Because the implant has been in contact with human tissue or blood and may have a sharp physical hazard, the implant must be disposed of in a biohazard waste container intended for sharps.
- In the case of instrument disposal, the disposal will occur in the surgical suite by the user. Because the instrument has been in contact with human tissue or blood and may have a sharp physical hazard, the instrument must be disposed of in a biohazard container intended for sharps.

Please contact Paragon 28®, Inc for product inquiries, cleaning instructions and surgical techniques. To report any adverse event, please contact Paragon 28®, Inc or its EC Representative.

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85 Great Portland St.
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CE 2797

Monster® Screw System

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

A FULL SYMBOLS GLOSSARY CAN BE FOUND AT: www.paragon28.com/resources

Please check the website, www.paragon28.com/ifus, for the most current instructions for use document.

This booklet is designed to assist in using the Monster® Screw System. It is not a reference for surgical techniques.

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

GENERAL DESCRIPTION
The Monster® Screw System is comprised of threaded bone screws which are offered in diameters ranging from 2.0mm to 7.2mm with lengths of 8mm (for smaller diameters) thru 185 mm (for larger diameters), and washers used for bone fixation. Screw washers are available in four different configurations: flat, dome, split-flat and bowl. Available screws, washers and instrumentation are packaged as a single system. The screws of the Monster Screw System provide stable fixation across the fracture / joint / osteotomy site until bone healing occurs.

The Monster® Screw System instruments include guide wires, guide wire guide, drill bits, drill guides, tissue protectors, depth gauges, countersinks, bone tap, screwdriver shafts, driver handles, small bone distractor & cleaning stylet. These instruments are used to facilitate the placement of the screws.

INTENDED/EXPECTED CLINICAL BENEFITS
Intended/Expected Clinical Benefits of the Monster® Screw System include:
- Successful Implantation of Monster® Screw System Devices
- Bone Healing

Paragon 28® has established the safety and performance of the Monster® Screw System, which represents state-of-the-art medical devices for bone fixation.
Summary of Safety and Clinical Performance (SSCP) can be found at: https://ec.europa.eu/tools/eudamed by searching for Manufacturer: Paragon 28 (upon Eudamed activation).

Residual Risks identified within the SSCP are included as warnings, precautions Potential complications and adverse reactions.

IMPLANT MATERIALS
The implants of the Monster® Screw System are manufactured from Titanium Alloy (ASTM F136). The elemental composition of the implants is as follows:

Element	% (mass/mass)
Nitrogen	0.05
Carbon	0.08
Hydrogen	0.012
Iron	0.25
Oxygen	0.13
Aluminium	5.5-6.50
Vanadium	3.5-4.5
Titanium	balance

INSTRUMENT MATERIALS
The instrumentation is manufactured from medical grades of stainless steel, silicone, polymers, anodized aluminium and nitinol.

CMR, EPD, PHTHALATES
The Monster® Screw System Implants, guide wires, and drill bits do not contain substances ≥0.1% (w/w) which are classified as carcinogenic, mutagenic or reprotoxic (CMR), substances ≥0.1% (w/w) which have endocrine disrupting properties (EDP) and do not contain phthalates.

INTENDED USE/INTENDED PURPOSE
The Monster® Screw System is intended for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation of the foot and ankle, appropriate for the size of the device.

INDICATIONS FOR USE

System(s)	Indications for Use
Monster® Screws Cannulated Screws and Washers in Diameters: 4.5 mm, 5.5 mm, and 7.0 mm	The Monster® Screws of the Monster® Screw System are indicated for use in the foot for: Bone reconstruction/osteotomy Arthrodesis/joint fusion Fracture repair/fracture fixation The Monster® Screws of the Monster® Screw System are indicated for use in the ankle for: Arthrodesis/joint fusion
Mini-Monster® Screws Canulated Screws and Washers in Diameters: 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm, and 4.0 mm	The Mini-Monster® Screws of the Monster® Screw System are indicated for the use in the foot for: Bone reconstruction/osteotomy Arthrodesis/joint fusion Ligament fixation Fracture repair/fracture fixation The Mini-Monster® Screws of the Monster® Screw System are indicated for the use in the ankle for: Fracture repair/frac
Mini-Monster® Solid Screw Solid Screws and Washers in Diameters: 2.7 mm, 3.5 mm and 4.0 mm	The Mini-Monster® Solid Screws of the Monster® Screw System for use in the foot for: Bone reconstruction/osteotomy Fracture repair/fracture fixation The Mini-Monster® Solid Screws of the Monster® Screw System are indicated for the use in the ankle for: Fracture repair/fracture fixation
Precision® Jones Screws Solid and Cannulated Type II Anodized Screws and Washers in Diameters: 4.0 mm, 4.5 mm, 5.5 mm, and 6.2 mm	The Precision® Jones Screws of the Monster® screw System are indicated for use in the foot for: Fracture repair/fracture fixation
Precision® MIS Bunion Screws Cannulated Type II Anodized Screws in Diameters: 3.0 mm, 3.5 mm, and 4.0 mm	The Precision® MIS Bunion Screws of the Monster® screw System are indicated for use in the foot for: Bone reconstruction/osteotomy
Joust™ Beaming Screws Solid and Cannulated Type II Anodized Screws in 5.0 mm, 5.5 mm, and 7.2 mm	The Joust™ Beaming Screws of the Monster® screw System are indicated for use in the foot for: Bone reconstruction/osteotomy Arthrodesis/joint fusion
Monster® BITE Screws Snap-off Screws in diameters: 2.0 mm and 2.7 mm	The Monster® BITE Screws of the Monster® Screw System are indicated for use in the foot for: Bone reconstruction/osteotomy Arthrodesis/joint fusion

CONTRAINDICATIONS
Use of the Monster® Screw System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis, or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:
- Acute or chronic infections, local or systemic
- Vascular, muscular, or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status
- Indications not included in the **INDICATIONS FOR USE**

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:
- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS
In any surgical procedure, the potential for complications and adverse reactions exists. The potential complications and adverse reactions with these implants include:
- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- [illegible] and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles or implant material
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding
- Adverse events include but are not limited to those described in this document

The residual risks with these implants include:
- Using a sterilization cycle outside the validated range of the Monster System can lead to the introduction of microorganisms to the healthcare provider or patient and can result in infection
- Monster BITE implants are designed to be used without pre-drilling or the use of a k-wire. As a result, if hard bone is encountered, the implant may break away from the drive shaft prior to contacting the boney surface, which can lead bone cracking when manually inserting the screw
- Movement during the non-load bearing phase can induce an implant break and result in incomplete bone fusion or removal of the implant
- Not following the Surgical Technique Guide when prepping for surgery may lead to incorrect procedural steps being followed, incorrect instruments being selected, and understanding instrument limitations/functionality. This may lead to broken instruments and/or implants resulting in significant OR time delays or serious injury to the patient.
- The use of K-Wires without controlling the insertion points and trajectories can lead to incorrect implant placement or implant intersection and cause significant OR time delays or serious injury to the patient
- Not having visualization of the surgical site when placing screws can lead to unacceptable screw head placement and cause injury to a patient.
- Incorrect interpretation of implant placement anatomy can lead to incorrect implant placement or implant trajectory intersection and lead to significant OR time delays or serious injury to the patient
- Not applying sufficient pressure when attempting to creation bone fusion can lead to a non-union and potential serious injury or revision surgery

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc with the explant(s) in a cleaned, disinfected, and sterile condition. Paragon 28®, Inc cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants, guide wires, and sterile packaged instruments are intended for single use only. Any single use device which has been used may have come in contact with tissue, bone, blood, or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient and other users
- Instruments, guide wires and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monster® Screw System.**
- **Do not re-sterilize the Monster® Screw System Implants.**

MR SAFETY INFORMATION

MRI Safety Information
A patient with the Monster® Screw System Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Device Name	Monster® Screw System Implant
Static Magnetic Field Strength (B0)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole-Body SAR [W/kg]	2.0W/kg (Normal Operating Mode)
Limits on Scan Duration	All anatomical regions can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 5 minutes of continuous RF (a sequence or back to back series/scan without breaks) with a 20 minute cooling period between scans for an hour long scanning session
	Scanning of the knees and all anatomy superior to the knees can be safely scanned under the following conditions: 2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact extending approximately 20mm from the implant.

MAINTAINING DEVICE EFFECTIVENESS

- The surgeon should have specific training, experience, and thorough familiarity with the use of screws.
- The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
- The Monster® Screws are not intended to endure excessive abnormal functional stresses.
- The Monster® Screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Monster® Screw System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the screws prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon28® non-sterile devices are precision medical devices and must be used and handled with care. Inspect the devices for damage prior to use, and at all stages of handling thereafter. If damage is detected, do not use the device prior to consulting the manufacturer for guidance.
- The surface coating of anodized aluminum devices may degrade due to exposure to highly alkaline cleaning processes and/or inappropriate handling and/or normal use. Such devices may require replacement if they no longer perform as designed.
- If an instrument is damaged, contact Paragon 28® immediately to arrange replacement and/or disposal.
- Devices with cutting functions or sharp points become dull with continuous use. This condition does not indicate a defective device and may indicate normal wear. Any sign of a dull or wearing devices may require replacement if they no longer perform as designed. Inspection prior to use should include verifying the cutting ability and sharpness of these points and edges.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

HANDLING AND STERILIZATION

Sterile Product

Monster® Screw System implants may be provided sterile. If sterile, product has undergone gamma irradiation. Do not re-sterilize. SINGLE USE ONLY Any device labeled as Single Use only must never be reused or reprocessed. Any device opened from its package is considered contaminated and may have come in contact with blood or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient and other users. Do not use implants or instruments after expiration date. Packages for implants and instruments should be inspected upon receipt.

Implants and instruments in sterile packaging should be inspected to ensure that the package has not been damaged or previously opened. If the inner package integrity has been compromised, the potential for patient harm could exist. DO NOT USE IMPLANT or INSTRUMENT. Contact the manufacturer for further instructions. The implants should be opened using the aseptic technique described in document P99-STR-1001. Please check the website, www.paragon28.com/resources/surgical-technical-guides/, for the most current Aseptic Transfer Techniques Document P99-STR-1001. The implant or instrument should only be opened after the correct size has been determined. Once the seal of the product is broken, the product should not be re-sterilized.
All implants and instruments should be stored in a clean, dry environment.

Non-Sterile Product

Product that are presented in a tray are provided non-sterile. All non-sterile implants and instruments should be processed using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. For manual reusable instrument reprocessing instructions, refer to the Monster® Screw System – ***Instrument Reprocessing Instructions for Reusable Instruments*** (Manual Method P20-CLN-0001) (Automated Method P99-CLN-0001). For product information or to obtain a copy of the surgical technique manual and/or the Summary of safety and clinical performance, please contact Paragon 28®, Inc. by phone, (+1) (855) 786-2828.

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Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 Min.	45 Min.

INTENDED USERS

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Monster® Screw System. Refer to the Monster®/ Mini-Monster® Screw System Surgical Technique Guide P20-STG-1001, Monster® BITE Surgical Technique P24-STG-1001, Precision® Jones Screw P25-STG-1001, Joust™ Beaming System P26-STG-1001, Precision® MIS Bunion Screw P27-STG-1001 and the Combination Drill Technique Tip P20-STT-1001 for surgeon's handbook. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28® by phone, (+1) (855) 786-2828.

IMPLANT REMOVAL (IF NECESSARY)

- Locate implant with intra-operative imaging.
- Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
- OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with a medium sized Kern forcep and continue turning driver shaft and Kern forcep counterclockwise while exerting light pressure upwards with the Kern forcep.
- If screw is integrated into bone, core out with appropriately sized trephine drill.

TARGETED POPULATION

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