Apogee
OrthoSolutions LLC.
2513 Greenview Drive,
Uniontown, OH 44685
(888) 728-1888

Monster Screw System – Cannulated Screws

BEFORE USING PRODUCT, READ THE FO MATION

This booklet is designed to a a reference for surgical techniques.

CAUTION
Federal Law (on the order of, a physician.

General Descri
The Monster Scre prised of screws and washers used for bone fixation. The Monster Screw caded 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 three different configurations; flat, dome and bowl. Available screws, washers and instrumentation are packaged as a single system. The system instruments include guide wires, guide wire drill 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, 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 ther pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the di

Potential Complication
In any surgical p ions exist.
The risks and

- Loose
- Acute p nd late infections with possible sepsis
- Migratio plant with resulting reduction in range of movemen
- Fractures r g 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 Apogee OrthoSolutions products but are in principle observed with any implant. Promptly inform Apogee OrthoSolutions 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 Apogee OrthoSolutions with the explant(s) in a cleaned, disinfected and sterile condition. Apogee OrthoSolutions 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. The Monster Screw System™ has not been tested for heating or migration in the MR environment.
- **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 cannulated 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 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.
- Apogee OrthoSolutions LLC recommends the use of Apogee OrthoSolutions LLC 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 Apogee OrthoSolutions ***Monster Screw System - Reprocessing Instructions for Reusable Instruments*** document P20-CLN-0001. This is als[illegible]e by calling 888-728-1888.

Sterilization

Unless specifically labeled ster[illegible]
NONSTERILE and MU[illegible]n
methods include st[illegible]d
labeling. Prior to [illegible] and unlocked
position within the [illegible] sterilization wrap is
recommended. The [illegible]ycle is recommended:

Method	C[illegible]	[illegible]mperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 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-MST-0001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Apogee OrthoSolutions 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 Apogee OrthoSolutions immediately. Apogee OrthoSolutions 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.

4B Inverness Ct. E., Suite 2
Englewood, CO 8
(888) 7

Obsolete

Monster S Screws

BEFORE U ORTANT INFORMATION

This booklet Monster Screw System™. It is not a reference for surgical techn

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 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 three different configurations; flat, dome and bowl. Available screws, washers and instrumentation are packaged as a single system. The system instruments include guide wires, guide wire drill 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, 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 explain[illegible] other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differenti[illegible]

Potential Complications and A[illegible]
In any surgical procedure[illegible]tions exist. The risks and co[illegible]

- Loos[illegible]
- Acute [illegible]nfections with possible sepsis
- Migrati[illegible]l resulting reduction in range of moveme[illegible]
- Fractures [illegible]nilateral joint loading
- Thrombosi[illegible]mbolism
- 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.
- 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. The Monster Screw System™ has not been tested for heating or migration in the MR environment.
- **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 cannulated 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 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 i ully experienced in the use of such implan echniques. Refer to the Monster Screw S complete instructions for use. F technique manual,

Screw Removal (I

- Locate imp
- Palpate head nding soft tissue to gain maximum exposure.
- Engage screw ppropriate 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.

4B Inverness Ct. E., Suite 280
Englewood, CO 80112
USA
(888) 728-188

Monster® S

BEFORE USING PROD… …MPORTANT INFORMATION

This booklet is design… …using the Monster® Screw System. It is not a reference for surgical t… …ues.

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 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 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, 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 com tentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnor
- Immunos
- Incr pathologies
- Inc
- Pron ount

Potential Compl ions
In any surgical pro for complications and adverse reactions exist. The risks and comp 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.
- 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[illegible]quent patient injury. Failed devices may require re-operation[illegible]
- Carefully inspect the screws prior to u[illegible]efore and after each procedure to assure th[illegible]ion. Instruments which are f[illegible]d.
- Paragon 28 Inc[illegible] sterile environm[illegible]

Cleaning and Dec[illegible]

All implants and ins[illegible]d hospital methods before sterilization ar[illegible]eld. Compliance is required with the manufacturer[illegible]mendations for chemical detergents. Refer to the Paragon 28[illegible]***em - Instrument Reprocessing Instructions for Reusable Instrumen[illegible]*** 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-MST-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**		**Manufa**
LOT	**Lot Number**		
REF	**Item Number**		
	Consult IFU		
	Keep Dry		

EC REP Emerg
Molenstraat 15, 2513 BH
The Hague, The Netherlands

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 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 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, 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 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 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-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		

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

P20-IFU-0001 Rev D

Monster® Screw System

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

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 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 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, 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 Min.	45 Min.

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-0001 and P25-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.

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			

Monster® Screw System

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

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, MonsterBITE 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 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, 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, 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
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
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-0001 and the MonsterBITE 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, (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
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.

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			

Monster® Screw System

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

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

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

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, 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 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, 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, 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 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.

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
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
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-0001 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, (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.