AM Surgical Distal Radius Fracture Repair System

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DESIGN ASSURANCE PLAN / DESIGN HISTORY FILE

I PROJECT SCOPE

Components: See Scope Document
Note: Cases & trays to include existing External Fixation system components.

	AM Surgical Distal Radial Plating System		Set contents
	Set Scope		
Customer Catalog #	Description	Unit	
	Distal Radius Plate System (Full)		
	Volar Plates		
	Volar Plate Narrow Left 3H 20 x 40mm	each	2
	Volar Plate Narrow Left 4H x 20 x 46mm	each	1
	Volar Plate Narrow Galleazzi Left 10H x 20 x 100 mm	each	1
	Volar Plate Narrow Right 3H 20 x 40mm	each	2
	Volar Plate Narrow Right 4H x 20 x 46mm	each	1
	Volar Plate Narrow Galleazzi Right 10H x 20 x 100mm	each	1
	Volar Plate Wide Left 3H 27 x 40 x 1 mm	each	2
	Volar Plate Wide Left 4H x 27 x 46 x 1mm	each	1
	Volar Plate Wide Galleazzi Left 10H x 27 x 100 mm	each	1
	Volar Plate Wide Right 3H 27 x 40 x 1mm	each	2
	Volar Plate Wide Right 4H x 27 x 46 x 1mm	each	1
	Volar Plate Wide Galleazzi Right 10H x 27 x 100mm	each	1
	2.7mm Cortical Screws - Non cannulated		
	2.7mm Cortical Screw X 6mm long	each	5
	2.7mm Cortical Screw X 7mm long	each	5
	2.7mm Cortical Screw X 8mm long	each	5
	2.7mm Cortical Screw X 9mm long	each	5
	2.7mm Cortical Screw X 10mm long	each	5
	2.7mm Cortical Screw X 12mm long	each	5
	2.7mm Cortical Screw X 14mm long	each	5
	2.7mm Cortical Screw X 16mm long	each	5
	2.7mm Cortical Screw X 18mm long	each	5
	2.7mm Cortical Screw X 20mm long	each	5
	2.7mm Cortical Screw X 22mm long	each	5
	2.7mm Cortical Screw X 24mm long	each	5
	2.7mm Cortical Screw X 26mm long	each	5
	2.7mm Cortical Screw X 28mm long	each	5
	2.7mm Cortical Screw X 30mm long	each	5
	2.7mm Cortical Screw X 32mm long	each	2
	2.7mm Cortical Screw X 34mm long	each	2
	2.7mm Cortical Screw X 36mm long	each	2
	2.7mm Cortical Screw X 38mm long	each	2
	2.7mm Cortical Screw X 40mm long	each	2
	2.7mm Cortical Screw X 42mm long	each	2
	2.7mm Cortical Screw X 44mm long	each	2

	2.7mm Cancellous Screws - Cannulated		
	2.7mm Cannulated Cancellous Screw X 10mm long		
	2.7mm Cannulated Cancellous Screw X 12mm long	each	5
	2.7mm Cannulated Cancellous Screw X 14mm long	each	5
	2.7mm Cannulated Cancellous Screw X 16mm long	each	5
	2.7mm Cannulated Cancellous Screw X 18mm long	each	5
	2.7mm Cannulated Cancellous Screw X 20mm long	each	5
	2.7mm Cannulated Cancellous Screw X 22mm long	each	5
	2.7mm Cannulated Cancellous Screw X 24mm long	each	5
	2.7mm Cannulated Cancellous Screw X 26mm long	each	5
	2.7mm Cannulated Cancellous Screw X 28mm long	each	5
	2.7mm Cannulated Cancellous Screw X 30mm long	each	5
	2.7mm Cannulated Cancellous Screw X 32mm long	each	2
	2.7mm Cannulated Cancellous Screw X 34mm long	each	2
	2.7mm Cannulated Cancellous Screw X 36mm long	each	2
	2.7mm Cannulated Cancellous Screw X 38mm long	each	2
	2.7mm Cannulated Cancellous Screw X 40mm long	each	2
	2.7mm Cannulated Cancellous Screw X 42mm long	each	2
	2.7mm Cannulated Cancellous Screw X 44mm long	each	2
	K-wires		
	.045" K-wire Single Trocar Pt, SS, **125mm**, Banded	each	10
	.045" K-wire Single Trocar Pt, SS, **125mm**	each	10
	Volar Plate Drill Guides		
	Volar Plate Narrow Left	each	1
	Volar Plate Narrow Right	each	1
	Volar Plate Wide Left	each	1
	Volar Plate Wide Right	each	2
	Drill Bits		
	Drill Bit, 2.0 mm x 80 mm	each	2
	Drill Bit, 2.4 mm x 80 mm	each	2
	Drill Bit, 2.7 mm x 80 mm	each	2

	Miscellaneous key instruments		
	2.7 mm Screw QC Tap	each	1
	Depth Gauge for 2.7 screws	each	1
	Screw Forceps	each	1
	Screw Holder for 2.7 screws	each	1
	Screwdriver Handle (? with QC)	each	1
	??? Hand Screwdriver Shaft QC	each	2
	Power Screwdriver (with slip torque)	each	2
	Standard Drill Guides		
	Drill Guide Handle with both 2.0 & 2.7 ends	each	1
	Drill guide sleeve for 2.4 mm drill bit	each	1
	Drill guide sleeve for 2.0 mm drill bit	each	1
	Cannulated Screw Instruments		
	Cleaning Stylet		1
	Cleaning Brush		1
	Percutaneous Drill sheath & Trocar Assy with sleeves		1
	Guide wire 1mm x 125 mm	each	10
	Countersink	each	1
	Miscellaneous Instruments (?? Needed ??)		
	Wire Cutter	each	1
	Sharp Hook	each	1
	Screw Forceps	each	1
	Termite Forceps	each	1
	Stag Beetle Reduction Forceps	each	1
	Reduction Forceps with K-wire Guide	each	1
	Mini Verbrugge	each	1
	Generic Cases and Trays		
	Generic Implant Tray	each	1
	Generic Instrument Tray	each	1

Summary Paragraphs:

Executive Summary

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Development Summary: AM Surgical Distal Radius Plating System

Intended use
The Distal Radius Plate system implants are intended for permanent or temporary implantation to repair fractures or reconstruct the anatomical function of the distal radius and distal ulna. In addition, the fixation system may be used in alternative anatomical locations based on physician need.

Indications:
System implants are indicated in the treatment of fractures, non-unions, pseudoarthrosis, and degenerative changes as well as corrective osteotomies geared towards a functionally stable osteosynthesis is small and long bones. This includes: (1) Distal radius fractures; (2) Distal ulna fractures; (3) Radial osteotomies; (4) Radial fusions; (5)Tarsal fractures.

Procedural requirements
The plates, screws and/or k-wires are surgically implanted after an osteotomy or to treat a fracture.

Device requirements
The following implants (plates / screws/k-wires) and instruments are part of the Distal Radius Plating system:

The optimum management of traumatic skeletal fractures may involve the installation of high quality surgical implants by a skilled orthopedic surgeon. Satisfactory clinical results are dependent on the ability to maintain stable fracture fixation. Well designed contemporary implants rely on precise control of material composition and properties to achieve a well tolerated level of biological response. Metallic materials, such as 316L stainless steel, pure titanium, and titanium alloys, demonstrate an acceptable combination of strength, ductility, corrosion resistance, and biocompatibility. Polymers, composites, and biodegradable materials may offer selected opportunities for fracture fixation. An understanding of relevant clinical factors is essential to evaluate potential applications for advanced materials.

Plates: Titanium Alloy, Ti6Al4V

Screws*:* Titanium Alloy, alloy TBD

K-wires*:* 316 LS Stainless Steel Bar & Wire, min YS 896 MPa (reference ASTM F138) or Titanium Alloy, Ti6Al4V

Guide-wires

316 LS Stainless Steel Bar & Wire, min YS 896 MPa (reference ASTM F138) or Wrought CoCr Alloy) *(One of the following based on prototype performance and material availability).*

CoCr alloy with a minimum Yield Strength of 841 MPa (122ksi), Minimum Ultimate Tensile Strength of 1108 MPa (160 ksi). 5% min elongation requirement . Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605) Per ASTM F-90

CoCr alloy with a minimum Yield Strength (YS) of 1172 MPa (170ksi), Maximum YS of 1310 MPa (190 ksi), Minimum Ultimate Tensile Strength (UTS) of 1310 MPa (190 ksi), Maximum UTS of 1586 MPa (230 ksi). 5% min elongation requirement . Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563) per ASTM F-563

❖ Material(s)- Instruments and Sterilization Cases:

The following materials may be used in the Distal Radius Plate system instruments:

- Implant grade wrought Titanium 6-Aluminum 4-Vanadium (Ti6Al4V) alloy (MTL 003) – reference ISO 5832-3

- Other titanium, stainless steel, CoCr or Nitinol implant grade metallic alloys. (See product drawings)
- Surgical grade stainless steels per ASTM F899. the most common alloys used include type 17-4PH per ASTM A564, 420 SS; 13-8 SS, COND H 950;455 SS, COND H950; 304 SS; 301 or 302 SS; 17-7 PH SS, Nitronic 50 & 60, Nitinol.
- Aluminum alloys such as 2024-T3 or T4, 6061-T6, 7075-T66063 T6, N
- USP Class VI polymers, including adhesives and epoxy inks.
- Cadmium free Silver Braze such as Bag 4, 7 or 24.

In addition, materials not mentioned in ISO or ASTM standards for medical devices, which have not fully been characterized as bio-compatible, may only be used on the non-invasive portions of the instruments.

❖ Sterilization Module and Sterilization Case Features

The Distal Radius Plate System will consist of volar plates and screws, k-wires, external fixators and instruments to install and lock the devices.

The sterilization case tray and module breakdown has not yet been determined. However, the instrument tray/module will contain basic and optional instruments plus redundant key instruments such as drill bits, driver shafts. There should be room for adding auxiliary instruments based on surgeon/center preference.

Ideally these can all fit into one outer case for storage. If the weight is above 20 lbs. the plate and screw modules should be in one outer case with instruments in another case.

Screws will be held in a vertical orientation to allow pick up with stick-fit drivers.

The AM Surgical development team's generic screw implant and instrument cases will be used during early clinical evaluations.

❖ Implant , Instrument and Sterilization Module and Sterilization Case Features

Numerous. ***See Spreadsheet below.***

Compatibility with accessories / other devices

Screws must be compatible with:

- Preparation drill bits
- Screwdriver tips
- Holding sleeves and power drivers (as applies)
- Plates
- Sterilization container / modules

Plates must be compatible with:

- Drill guides
- Screws
- .045" diameter K-wires
- Sterilization container / modules
- Depth gages

See product specific features below for instrument specific mating part requirements.

Biocompatibility

Implants:

The implant must be biocompatible (reference ISO 10993-1).

Bioburden testing

For devices sold as 'Sterile', bioburden testing is done as part of sterility validation -- reference 'Gamma radiation sterilization validation and monitoring'.

Biological evaluation & testing: background

ISO 10993-1 defines a process of evaluation and testing medical devices to ensure that the devices are biocompatible. The standard includes two tables (Table 1 and Table 2) that list tests to consider based on the class of device. In addition, ISO 10993-1, Clause 6 states that 'Evaluation may include both a study of relevant experience and actual testing. Such an evaluation may result in the conclusion that no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design.'

The AM Surgical implants are classified in accordance with ISO 10993-1, Table 1 and Table 2 as:

Category: Implant device
Contact: Tissue / bone
Contact duration: 'C' – permanent (>30 days)

Based on the classification listed above, the following tests are to be considered for the initial evaluation of the device:

Table 1: Cytotoxicity
Table 1: Sensitization
Table 1: Irritation or Intracutaneous reactivity
Table 1: Systemic toxicity (acute)
Table 1: Subacute and Subchronic toxicity
Table 1: Genotoxicity
Table 1: Implantation
Table 2: Chronic toxicity
Table 2: Carcinogenicity

Biological evaluation & testing: history of material use

ASTM F138 / F139 states 'The material composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well characterized level of local biological response established by this material, it has been used as a control material in Practice F 981.' It goes on to state 'No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long term clinical experience has shown an acceptable level of biological response can be expected, if the material is used in appropriate applications.

The ISO 5832-3 Introduction states 'No known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body. However, long-term clinical experience of the use of the material referred to in this part of ISO 5832 has shown that an acceptable level of biological response can be expected, when the material is used in appropriate applications.

Stainless Steel (SS) and wrought titanium 6-aluminum 4-vanadium alloy (TiAlV) have a long history of use in the orthopedic industry. These materials are standard materials used in trauma, hip, knee and spinal implants.

Biological evaluation & testing: determination of test requirements

Based on the history of material use (see above), AM Surgical has concluded that the SS & TiAlV raw materials are safe to use and no biocompatibility testing is required for these raw materials.

To ensure that the manufacturing and packaging processes do not cause biocompatibility issues, cytotoxicity testing shall be performed as follows:

Initially (to validate the manufacturing process)

Each calendar quarter (to ensure that the ongoing process is well controlled)

After significant manufacturing process changes

For new designs that are not similar to the existing design

Cytotoxicity testing

Randomly select at least 1 device (size is not critical). The device shall be selected after all production processes have been completed through the completion of the first sterile barrier or non-sterile packaging as applicable.

Additional testing may be performed on devices that have not been through the entire production process. However, such testing does not qualify the device for release.

Cytotoxicity tests shall be conducted in accordance with ISO 10993-5 and USP 87. These standards specify two methods of performing the test: on an extract of the material and/or on the material itself. AM SURGICAL shall perform all cytotoxicity testing on an extract.

The extract of the test article shall be prepared using a single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM). A minimum of three replicates shall be used for test samples and controls.

The USP ratio of 4g: 20ml shall be used to determine the amount of 1X MEM. The preparation shall be extracted and agitated at 37 °C for 24 hours.

After extraction, incubate cultures at 37°C in air with 5% (volume fraction) CO_2 for 24 hours.

Negative, positive and reagent controls shall be used as specified in ISO 10993-5 and USP 87. The preparation of these controls shall be determined by the test labs based on their standard operating procedures.

The cultures shall be evaluated for cellular characteristics and lysis based on the USP 87, Elution Method:

Grade	Reactivity	Cellular characteristics / lysis
0	None	Discrete intracytoplasmic granules; no cell lysis
1	Slight	Not more than 20% of the cells are round, loosely attached, and without intracytoplasmic granules; occasional lysed cells are present
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granules; no extensive cell lysis and empty areas between cells
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed
4	Severe	Nearly complete destruction of the cell layers

The cultures shall be evaluated for cellular characteristics and lysis based on the USP 87, Elution Method:

Test results

If the test results are grade 0 or 1 (reactivity of none or slight), the devices have passed the test

If the test results are grade 2 (reactivity of mild), the devices have passed the test. However, a formal investigation should be considered as AM SURGICAL devices should not have such a high reactivity.

If the test results are grade 3 or higher (reactivity of moderate or severe), the devices have failed the test. Corrective action must be taken and shown to be effective. If the devices are in production, **all production must stop until corrective action has been taken and shown to be effective.**

AM SURGICAL has concluded that the raw material is safe to use with no biocompatibility testing required.

See Quality Plan. Cytotoxicity testing shall be performed on at least one of each type of implant (plate / screw). Test samples shall be selected after all production processes have been completed.

Instruments:

The biocompatibility testing of materials used in single or multi-component medical devices for human use depends to a large degree on the nature of the end-use application. Guidelines for evaluating the safety of materials used in medical devices are available from several sources including the FDA Modified ISO Matrix (Blue Book Memorandum # G95-1, Attachment A), USP, Advamed, American Society for Testing and Materials (ASTM Vol. 13.01, Practice F748-83) and AAMI Standards and Recommended Practices (Volume 4).

AM SURGICAL instruments are classified in accordance with ISO 10993-1, Table 1 and Table 2 as:

Category: Externally communicating device

Contact: Tissue / bone

Contact duration: 'A' – limited (<24 hours)

Note: Portions of instruments (e.g., handles) or some entire instruments are non patient contact.

Metallic instruments used in surgical tools will be of a high quality alloys. Steels will all be stainless alloys. Cobalt chrome, titanium and aluminum alloys with appropriate surface finishes may be used. Care will be taken to assure that wear resistant materials are chosen for any application where debris may be generated during instrument use. Metals will be of implant quality (biocompatible) or will be surgical stainless steels equivalent to one or more of the steels listed in ASTM F899.

Polymeric materials used in instruments will be certified as biocompatible based on their intended application as follows:

INVASIVE PRODUCT APPLICATIONS

All polymers will be certified as biocompatible (i.e. non-toxic, non-pyrogenic (endotoxin free), non-irritating, non-hemolytic, non-sensitizer, and non-mutagenic). The polymer producer or component manufacturer must supply certification from a non-biased independent laboratory such as the North American Science Associates (NAmSA), or Nelson Labs, indicating that the cured paint is in compliance with the requirements for or ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing , or that the material is Class VI per the United States Pharmacopceia (USP) USP 26, "Biological Reactivity Tests, in vivo – Classification of Plastics".

The ISO 10993 tests shall include, at a minimum:

- Cytotoxicity: Mammalian cell culture media (MEM) Elution (ISO/USP)
- Sensitization: Magnusson-Kligman (ISO) (w/2 extracts)
  Or Sensitization: Local Lymph Node assay (ISO) (w/2 extracts)
- Irritation: Intracutaneous Reactivity (ISO) (W/2 extracts)

Refer to 10993-1 and ASTM F748 for a more complete list of tests which may apply depending on the application.

The USP Class VI tests include:

- Acute Systemic Toxicity (T-12),
- Intracutaneous Toxicity (T-13),
- and Muscle Implantation Toxicological Testing (T-14).

In addition to Class VI classification, the polymer will be certified as non-toxic in the in vitro Cytotoxicity Test - MEM Elution MT-023/ ISO 10993-1.

MINIMALLY-INVASIVE PRODUCT APPLICATIONS

The toxicity certification requirements may be lowered for a specific polymer on a specific instrument if the design team documents that the paint may contact surface wounds on the patient for a limited period of time (less than 60 minutes)

In this situation, **the polymer producer or product manufacturer** will submit documentation certifying that :

(1) The polymer has been found to be chemically acceptable by the USDA for use on structural surfaces having indirect contact with food or food products.
(2) Or that it contains no pigments known to be hazardous, and has, at maximum, mild cytotoxicity test reactivity, per USP or ANSI/AAMI/ISO 10993-1 evaluations , and is:
    - Non-hemolytic per ISO 10993-4, in vitro red blood cell hemolysis study
    - Non-irritating per USP Muscle Implantation Toxicological Testing (T-14)

NON-INVASIVE PRODUCT APPLICATIONS

The toxicity certification requirements may be overridden for a specific Epoxy Ink on a specific instrument if the design team documents that the paint (or any subsequent paint debris particles) will not contact the patient, and will not contact open wounds on the patient or those handling the device. **It must be clearly noted on the instrument print whenever the "Toxicity Certification" is not required.**

Sterility

The implants and instruments shall be sold non-sterile.

The implants and instruments must be able to be steam sterilized in accordance with standard hospital cycles (reference AAMI TIR 12 Annex B for examples of sterilization cycles available in health care facilities). Hospital central supply units will verify that the devices can be sterilized in their institutions.

Labeling

Labeling shall consist of:

1. Product label (pouch)
2. Patient labels (*optional*)
3. Instructions for use (IFU)

The product label shall include the following information:

1. Company logo
2. Product logo (*optional*)
3. Manufacturer symbol (EN980, 5.2) & manufacturer name / address
4. Product name and description
5. Symbol: REF (Part number) and part number

6. Bar code with part number (*optional*)
7. Lot number symbol (EN980, 4.4) and lot number
8. Bar code with lot number (*optional*)
9. Symbol: CExxxx (where xxxx is the identification number of the notified body)
10. IFU symbol (EN980, 4.10)
11. Do not reuse symbol (EN980, 4.2)
12. Quantity of devices in package
13. Label part number
14. Other information as desired
15. . See UHS labels in DHF 001 for examples.

If patient labels are used, they shall include the following information:

1. Company name or logo
2. Product logo (*optional*)
3. Product name and description
4. Symbol: REF (Part number) and part number
5. Symbol: LOT (Lot number) and lot number
6. Other information as desired

The Instructions For Use (IFU) shall include the following information:

1. Company logo
2. Product logo *(if applicable)*
3. Manufacturer symbol (EN980, 5.2) & manufacturer name / address
4. EC Representative symbol (EN980, 5.3) & EC representative name / address
5. Description of use by date
6. Description of do not reuse
7. Product name and description
8. Indications for use
9. Operating instructions
10. Warnings and/or precautions
    - One warning shall be to not mix metals that have direct contact for implants (SS with Ti or SS with CoCr)
11. Information on compatibility with other devices / accessories
12. Instructions on sterilization
13. Special storage and/or handling conditions (if applicable)
14. Symbol: CExxxx (where xxxx is the identification number of the notified body)
15. Label part number
16. Other information as desired

Packaging / shipping / storage

The screws and plates shall be sold individually. All implants shall be packaged in a protective bag and labeled as to its contents.

Reliability requirements / goals

There are two basic types of performance requirements: clinically significant and comparative. All voluntary standards (e.g., ASTM and ISO) are comparative in nature and are useful to compare mechanical performance of specific device features in a reproducible fashion. However, these voluntary standards typically do not contain information concerning the clinical significance of the test protocol. The

assignment of *clinical significance* to mechanical tests and results is an important part of establishing the potential safety and efficacy of the devices, and is completed by the design team. The behavior of individual instruments and skeletal components within a reconstructive procedure must be understood before clinically relevant performance requirements can be established for "simple" component comparative tests. Refer to the System Design Rational for a discussion of clinically relevant performance requirements.

Geometry, material and production processes to be selected based on prior successful use in similar orthopaedic products such as other "competitive brand name" system tools. Historical data and experience will be relied upon whenever possible.

System

The system shall be evaluated in one or more animal model, sawbone and cadaver experiments to test the use of the implants and instruments.

Key implant and instrument characteristics to be measured using closed form analytic techniques and FEM/FEA in conjunction with mechanical testing include:

Screws

1. Adequate torsional strength at core diameter, at head-shaft junction, and within drive mechanism.
2. Adequate insertion torque
3. Adequate bone pull out strength

Plates

1. Adequate bend characteristics including appropriate stiffness to facilitate construct stability and flexible tension band applications, and adequate proof or yield load, and ultimate strength
2. Adequate/appropriate bending fatigue strength.

Plates / Screw combination

1. Adequate construct strength - Adequate Screw-Plate interface pull through strength (pull through force to be higher than peak plate bending anticipated load regimes in the intra-or post operative rehabilitation periods, and higher than 1000 N (224 lb).
2. Adequate Screw-Plate interface pull through strength (pull through force is higher than peak compressive force the screws can apply to the plate –bone interface when (A) used to secure or lag two bone surfaces together through the plate or (B) when attaching uni-cortically or bi-cortically to a bone fragment. (Screw-plate pull through force will exceed the force that can be generated at the interface between the screw head and bone plate when securing to high strength cortical bone (6 mm to 8 mm max purchase estimated) . The peak force which can be applied is limited by the bone strength, the frictional properties of the bone-screw and screw head - plate interface, and the torsional strength of the screw and screw-driver mechanisms.

Instruments

1. Adequate torsional strength of the driver shaft, particularly at drive tip. Document service life under anticipated use.

Refer the **Mechanical Validation Master Plan for the Distal Radius Plate** for a comprehensive summary of mechanical test plans.

Statutory and regulatory requirements

Now: USA (510k)
Future: Canada (ISO 13485 certification & Health Canada device license)
Europe (ISO 13485 certification & CE-mark)

Voluntary standards

The applicable voluntary standards are:

- AAMI TIR 12 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: a guide for device manufacturers
- ASTM F86 Standard practice for surface preparation and marking of metallic surgical implants
- ASTM F138 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
- ASTM F139 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)
- F 1314 – 01 Wrought Nitrogen Strengthened 22 Chromium – 13 Nickel – 5 Manganese – 2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)
- ASTM F 1586 – 02 Standard Specification for Wrought Nitrogen Strengthened 21 Chromium—10 Nickel—3 Manganese—2.5 Molybdenum Stainless Steel Alloy Bar for Surgical Implants (UNS S31675)
- ASTM F2229 Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108) (Carpenter Steel BioDur 108)
- ASTM F-90 Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)
- ASTM F-563 Wrought Cobalt-20Nickel-20Chromium-3.5Molybdenum-3.5Tungsten-5Iron Alloy for Surgical Implant Applications (UNS R30563)

- ASTM F382 Standard specification and test method for metallic bone plates
- ASTM F543 Standard specification and test methods for metallic medical bone screws
- ASTM F1839 Standard specification for rigid polyurethane foam for use as a standard material for testing orthopaedic devices and instruments
- EN 980 Graphical symbols for use in the labeling of medical devices
- EN 1041 Information supplied by the manufacturer with medical devices
- ISO 5832 Implants for Surgery – Part 1 – Wrought Stainless Steels
- ISO 10993-1 Biological evaluation of medical devices, part 1: Evaluation and testing
- ISO 10993-5 Biological evaluation of medical devices, part 5: Tests for *in vitro* cytotoxicity
- ISO 11134 Sterilization of health care products – requirements for validation and routine control – Industrial moist heat sterilization
- ISO 13485 Medical devices - Quality management systems – Requirements for regulatory purposes
- ISO 14630 Non-active surgical implants – General requirements
- ISO 14971 Medical devices – Application of risk management to medical devices

Note: many standards reference additional standards. See each standard for these additional references.
The following standards are applicable when used to measure compliance to one or more of the standards listed above. These standards may or may not be maintained by AM SURGICAL as they are maintained by the test facilities.

- ISO 11737-1 Sterilization of medical devices – Microbiology methods – Part 1: Estimation of population of microorganisms on products
- ISO 11737-2 Sterilization of medical devices – Microbiology methods – Part 2: Tests of sterility performed in the validation of a sterilization process

General Quality Requirements

1. Special gauging requirements were not identified at the onset of the project. Special gages will be added as needed. The need for design verification and gauging will be minimized by designing and building parts with tolerances appropriate to the production methods and tooling utilized. Special process studies and 100% inspection *will be considered* for any tolerance requirement below ± .001. The parts will be toleranced appropriately for both manufacturing method selected and functional performance. Electronic data (CAM programs and CAD data, will be built at nominal dimension. Design verification will be accomplished through measurement of critical features on components using standard inspection equipment (+ and - hole gages, calipers, CMM, optical comparitors, and feature specific gauging as is warranted). P-FMEA's will be completed for new and common processes as warranted. *Example*: The quick connect drive end on any power driven tool must match the style desired by the customer.

Manufacturing Processes & Process Validation Requirements:

1. Metallic surface finishes to match roughness and cosmetics found in AM Surgical's standard Surface Finish samples). *Selection of finish to be adequate to assure acceptable function and aesthetics.*

2. No new manufacturing processes requiring validation will be specified for this project. These products will be manufactured using proven machining processes, on existing business unit capital equipment, (or manufactured via AM Surgical approved suppliers).

   Potential Manufacturing Processes:

   - Machining (Mill, Lathe, Broach, Grind): Stainless Steel or CoCr Alloys, Plastics.
   - Wire EDM.
   - Laser Machining.
   - Mechanical Polishing: Stainless Steel Alloys.
   - Electropolishing: Stainless steel instrument materials.
   - Electro-chemical machining or deburring: stainless steels (other than traditional electro-polishing).
   - Passivating: All metals.
   - Electropolishing: Stainless steel materials.
   - Passivating: All metals.
   - Pure glass bead dry blasting.
   - Plastic bead dry blasting.
   - Laser Etching: All metallic components.
   - Electro-chemical etching: Allows for final marking of relatively large metallic. products. Does not weaken thin metallic products.
   - Silk Screening: Plastic instrument handles or sterilization cases.
   - Titanium Nitride Coating
   - ME 92 Chrome Coating
   - Zyglow (inspection process to reveal surface cracks or pits) – N/A.

- Thermoforming: Ultem or Radel plastic sterilization trays.
- Adhesive Assembly using MasterBond EP 42HT (or equivalent) USP Class VI Epoxy Adhesive.
- Injection Molding – RADEL handles (or other *suitable* durable, tough, chemically inert high heat plastic such as Lexan PPC, Ultem, IsoPlast)

Device Classification

Note: Per review of the Medical Device Directives, Annex IX, 93/42/EEC, most Orthopaedic Surgical products are classified as Class I or Class IIa.

Class I: Re-usable surgical instruments or sterilization cases and trays which are non-invasive, or are invasive in a transient fashion (*continuous use for less than 60 minutes*) in a *non-active* fashion are Class I devices.

Class IIa: ***Active*** transient use invasive surgical instruments, ***and*** any transient use invasive surgical instrument which administers body fluids **or removes body substances** (such as bone, cartilage, et cetera) are Class IIa devices. *Active* devices are those which convert power* (typically from electrical or pneumatic sources) into work done on the human body during surgery. However, Medical devices intended to transmit energy, substances or elements between and active medical device and the patient, without any significant change, are NOT considered active medical devices. Typical examples of Class I devices are: patellar clamps, osteotomes, drill bits, non-tissue harvesting reamers, flexible shafts for IM reamers, sawblades, burrs, power driven screws or fixation pins, and power driven clamps. Typical examples of Class IIa devices are bone graft harvesting tools, cartilage or other soft tissue removal tools.

*Power derived solely from gravitational or human forces application is excluded.

II DESIGN INPUTS / Detailed Product Specifications

Note: Drawings, digital photo's, sketches and illustrations to be included when available.

Components: See Scope Section. *Note: *"if possible" and "if practical" requirements may be dropped from the requirements if team determines it cannot be accomplished economically.*

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	General – System		
All	1. Minimize risk to tendons and other soft tissues. * low profile minimal thickness and radius'd or tapered edges * plate contouring, to bone anatomy * To reduce contract stresses on, and minimize damage potential to bone and other soft tissues,. All corners and edges that contact bone, or tissues must be tapered and radius'd . * Retractors and elevators in kits to facilitate adequate visualization , tissue protection and minimal exposure.	See prints and sample parts.	
All	2. The implants and instruments must be compatible with minimally invasive surgical techniques.		
All	3. Minimal number of components to save on inventory costs, development costs, and OR confusion, yet comprehensive enough to cover simple to multi-part & comminuted, juxta-articular fractures.	See scope. (pages 1-5 above)	
All	4. Accurate and reproducible surgical techniques (instrument performance). Surgical technique and instrument function to be reproducible in the hands of hand fellows as well as experienced hand surgeons.	System components similar in size and shape to competitive parts. Surgical technique booklet and sterilization cases outline usage. Parts function as intended without sticking, fracturing or other wise mis-performing.	
All	5. Design and develop to obtain reasonable production costs to make the technology affordable and the products commercially viable.	See component prints. Cost estimated and manufacturing process specification.	
All	6. Peak predicted stresses comply with published safe engineering practice. Materials comply with ISO and ASTM specifications noted above, and any AM Surgical Engineering Specifications noted on applicable prints.	Prints and Mtl Specifications.	
All	7. Individual components rigid enough and strong enough to meet requirements without risk of fracture or other failure under normal use conditions. Worst case and abusive use will be identified, and whenever possible, the products will be designed to withstand these situations. When not possible, product warnings will be included in package inserts and the instructions for use.	N/A	
All	8. In-vitro simulation of end-user environment used to verify and validate design function. Intraoperative / in-vivo use to be followed closely by design team for Beta test sight clinical users.	N/A	

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	General – System –Mechanical Design – Strength Requirements		
All	In general, the peak *analytically predicted* stresses in the devices will comply with published safe engineering practice (*including reasonable safety factors when warranted*) as found in Design or Reference manuals for specific applications. PEAK CYCLIC TENSILE OR COMPRESSIVE STRESSES: <½ YS PEAK CYCLIC SHEAR STRESSES: <¼ YS PEAK SINGLE APPLICATION IMPACT STRESS: <YS Application of a safety factor of ***at least*** 1.5 is ***recommended*** (after all design and material related **correction** factors are included). The safety factor, ***n***, reduces the allowed peak stress by ***1/n***. Refer to ASME/ASSI standards Machinery's Handbook, and other Engineering databases for engineering formulae and recommended peaks stresses for specific applications. **Safety factors and other design factors such as stress concentration, notch sensitivity, and fatigue should be factored into the failure theory equations. General requirement:** Von Mises **Yield Failure Prediction**: $Sy = (((\sigma_1 - \sigma_2)^2 + (\sigma_1 - \sigma_2)^2 + (\sigma_1 - \sigma_2)^2)/2))^{1/2}$ = Yield Stress (YS) ***Maximum*** *Shear Stress Failure Prediction:* $\tau_{max} = S_y/2 = YS$	Peak implant and instrument stresses evaluated for anticipated worst case load scenario's using a combination of closed form analyses, quasi-static and dynamic tests and FEM/FEA as warranted. Testing and analysis reveal that individual components are be rigid enough and strong enough *to adequately withstand* anticipated forces, and to meet all other functional performance requirements without risk of fracture or other failure under normal use conditions. The peak instrument and implant material stresses can be predicted in many ways, including (1) The traditional closed form analyses available in the Machinery's handbook or other engineering design guides; (2) FEM/FEA computations given appropriate models, solvers and boundary conditions; (3) Calculations or analyses which are verified with standardized testing which characterizes the stress/ strain behavior, and the yield or ultimate failure limits of the material or design.	**See Distal Radius Mechanical Validation Master Plan and Master Report** which includes the strength and test results summary documentation as well a spreadsheets and other graphical or CAD/CAE analyses completed during design phases.

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Device Classification & Regulatory Plan		
Regulatory	A 510K will be submitted to the US FDA for the Class II components in this system.	510K submission and FDA's approval notification letter.	

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	General – System		
Component	1. AM Surgical logo, part number and lot number to be marked on every	Logo calls out on implant prints. Final inspection criteria	

Marking	implant or instrument with sufficient surface area to fit characters of at least .4 mm in height.	item to look for correct laser marking including logo.	
Packaging	2. Packaging requirements – Industry standard non-sterile or sterile packaging (sealed labeled polymer bags for non-sterile product, blister packs for sterile products) as applicable. See package specification outputs.	See attached packaging BOM and Transportation Durability test Protocols.	
Label Warning	3. Warnings to stipulate that the 316 LS SS plates must be secured with implant grade SS (ASTM F138, F139, F1314, F1350, F1586, F2181, F 2229, F2257). Similarly, Warnings to stipulate that Ti or Ti Alloy plates must be secured with Ti or Ti Alloy (screws, wires or cables.) "WARNING : GALANIC CORROSION POTNETIAL - Cobalt Chrome , Ti or Ti alloy materials may not be implanted close to 316L SS plates, or vice versa."	See package insert, and other training materials. To be in incorporated into instruction materials, warnings, education materials and possibly labeling.	

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	General Manufacturing Processes & Process Validation & New Technology Requirements		
	1. Certain common processes used throughout the industry do need to be validated for this project if they have not been validated for prior AM Surgical projects. These processes may include electropolish, passivation, blister pack seal, and sterility and cleanability of tools in the sterilization case, non-cytotoxicity of cleaned and processed parts. Otherwise, the Wrist FIT products will be manufactured using proven machining and finishing processes, on existing business unit capital equipment, (or manufactured via AM Surgical suppliers. **The following documents will be included in the Design History File:** ▪ **Final Prints** ▪ **Final Routers/Process Sheets, Final Inspection Criteria/Inspection Instruction Sheets** ▪ **Inspection Results** (from Design Transfer Production Run) ▪ **Special Gage Listing, and copies of overlays** (when used) ▪ **Misc. Labeling & Marketing Information** (Special pre-cautions or warnings, package inserts, indications, contra-indications, surgical techniques, brochures, other literature, cleaning & sterilization methods)	See the Device Manufacturing Record (DMR) for production and quality control documentation such as inspection criteria, process sheets, and routers.	
	2. Implants from new production processes must be documented as non-cyctotoxic.		

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Implants - General		
Plates: XXX	1. Fracture-specific anatomic volar plates designed to facilitate capture and stabilization of the most common fracture fragments under anticipated post operative loads. Fit to Patient & Surgical Wound.	See prints for shapes, length, width and thickness of plates, diameter and length of screws. (See prints, patent application, and images of plates in place on bone anatomy from the Hamman Todd Collection at the Museum of natural History in Cleveland OH.) .	Designed to fit 95% of the population confirmed via literature review and fit to extremes and norms in the Hamman Todd Skeleton Collection – Museum of natural History, Cleveland OH. Evaluated fit on range of bone models, and electronic bone data, and compared sizes and thicknesses to products sold by other manufacturers.
All Implants: XXX	2. Sizes to fit at minimum 95% of the adult population. Mimic dimensions found in ***Prior Art*** (competitive products) that have been used worldwide in tens of thousands of cases. **Fits anatomy** • **Sized to optimize stability** • **Minimal tissue release.** • **Size selection minimizes risk of further bone or trauma due to over/under sized implants**	Fit to Patient & Surgical Wound. Length and width of plates, diameter and length of screws. (See prints, patent application, and images of plates in place on bone anatomy from the Hamman Todd Collection at the Museum of natural History in Cleveland OH.) .	
All Implants: (See Above)	3. Repair methods should have equivalent or greater rigidity and failure loads (when compared to prior constructs under anticipated postoperative load conditions).	Via use of the angled screws, and slightly larger screws, the surgeon can create multi-sided repair constructs equivalent to those previously evaluated for the Hand Innovations System (See ORL test results – AAOS)	(1) Direct comparison to TriMed and Hand Innovation components (in a similar 3D construct) shows that the fixation rigidity will be higher using AM Surgical components due to the higher compressive force and pullout force capability of the individual components and the ability to apply compressive tensioning. (2) Cadaver evaluation shows (videotaped/fluroscopic) shows excellent fixation rigidity post surgeon repair. (3) TBD – Proposing construct stiffness evaluation using tendon pulls to simulate motion and force application.
Implants: (See Above)	4. Device must be easily removed.	Surgeons can remove the screws and plates by reversing the driver torque.	
All Implants: (See Above)	5. AM Surgical logo, part number and lot number to be marked on every implant with sufficient surface area to fit characters of at least .4 mm in height.	Logo call outs are on implant plate prints. (not screws). Final inspection Sheets require inspection for correct laser marking including logo.	
All Implants: (See Above	6. Implants to be packaged non-sterile.	Packaging & labeling specifications	

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Implant Material		
All Implants:	1. Use of Ti Alloy materials with proven fatigue and corrosion resistance • Improved repair construct stiffness and strength over CP Ti and softer /weaker alloys. • Maximize part strength for given low profile geometry by obtaining effective yield strength above 110 ksi,	See Prints and material specifications.	
Plates:	2. **Plates:** Wrought Ti alloy per ASTM F 136, F 1295, F1472, F1713, F1813, F2066 or F2146	See Prints and raw material certifications.	
Screws:	3. **Screws:** Wrought Ti alloy per ASTM F 136, F 1295, F1472, F1713, F1813, F2066 or F2146 Or stronger equivalent Ti alloy material such as biocompatible amorphous alloy.	See Prints and raw material certifications.	
All Implants: (See Above)	4. Metallic implants to be designed to withstand multiple sterilization cycles, and associated chemical and temperature conditions found in typical hospitals or surgery centers.	Prints show use of highly corrosion resistant Titanium alloy as per the list under screw and plate requirements noted above.	
	Implants - Detailed		
All Plates xxxx	5. Sculpted plate profile • Reduces screws hole stress concentration • Reduces disruption of vascular perfusion. • Simplifies contouring to variable anatomy	See prints.	Stress analyses show nearly equivalent section modulii and strength equalization at and between holes in this plate series. (see test results summary sheet).
All Plates: xxxx	6. **Low profile, smooth contours** - The repair must not be too thick (low profile) because there is little soft tissue coverage in many wrists and because vital structures such as tendons, nerves and vessels will be located near or may rub the top of the implants.	Plate cross section thicknesses are 1.0 mm to 1.6 mm. Plates are contoured to hug bones. Edges are radius'd or tapered and radius'd. (See prints and part images). Screw head fits flush, below or within .5 mm above plate. For high angle screws, the screw sides are highly radius'd.	Verified by project team via prototype and print review. Verified by CAD graphical analysis as well as team review of prototype parts. **See nominal fit layouts following this section.**
All Plates: xxxx	7. Maximize plate stiffness, static and dynamic strength characteristics for given the desired low profile geometry.	Use material with Min YS of 827 MPa (120ksi) See part prints, analyses and test results. **See Distal Radius Mechanical Validation Master Plan for performance requirements**.	
Screws: (See Above)	8. The repair must take into account older patients and other individuals with severe osteoporosis where the fixation components can easily cut through the thin cortical and weak cancellous bone.	Plates of varying size and shape provided to allow for use of multiple screws to achieve higher surface contact to distribute load on the weaker bone.	Functional characteristics of screw holding power verified by in-vitro evaluation in bovine or porcine ribs and turkey tibial bones. Functional evaluation in human cadaver tissues planned. Lab not selected.

Screws: (See Above)	9. **Self tapping threads to improve holding power when not pre-tapping in poor quality cortical or cancellous bone.** Screws should not be self drilling. Blunt tip required at end.	See flute and tip geometry on screw prints.	Pull out strength measured in foam bone and turkey bones, performing as anticipated. See Test protocols, report s and test report summaries.

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Implants - Detailed		
Screws: (See Above)	10. Screw tip to be sharp enough to facilitate insertion and yet dull enough to prevent injury to tissue should they protrude beyond the opposing cortex.	As ASSH clinical demonstration, (42 participants Sept 22, 2005) surgeons requested that the screw tips be made slightly sharper to facilitate insertion.	
Screws: (See Above)	11. Screw thread form to comply with ASTM F 543-02. Screw drive mechanism to be Modified Torx to maximize screw and drive mechanism strength in torsion. Modify standard torx to fit in low profile heads.	Print and sample parts.	Verified by design review, lab and functional testing and comparison of screw drawings to ATSM specifications.
Screws: (See Above)	12. Screw torsional and bending strengths comparable to 316 L SS and Ti6al4V screws of similar ISO compliant geometry.	**See Distal Radius Mechanical Validation Master Plan for performance requirements**.	See in vitro test results and screw properties summary sheet. Team reviewed & approved prints design via Design Review Meeting Signatures.
Screws: (See Above)	13. *DRIVE MECHANISM TBD – PROPOSED* - Modified hexalobular socket - driver-socket interface to have full depth line contact in torx mechanism to distribute stresses to prevent torx stripping. . a. Sized similar to Torx plus – proven more durable than Torx b. No ellipsoidal edges – pure arcs. c. Toleranced to be manufactured using drilling and milling.	See Prints & prototypes for design options.	

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Instruments- General		
Instruments & Modules: XXXXX	**Instrumentation & Sterilization Cases** 1. Geometry, material and production processes to be selected ***based on prior successful use in similar orthopaedic products*** such as other "competitive brand name" system tools. Historical data and experience will be relied upon whenever possible. Materials used must comply with ISO and ASTM specifications as noted. Refer to prints for materials selected. ***Biocompatability*****:** The metallic materials used for the instrument parts are commonly used for reusable surgical instruments having transient bodily contact and have been used for surgical instruments in accordance with ISO/DIS 7153/1 as cited in ASTM Volume 13.01, Designation F899, Standard for Medical Devices. **General Surgical Instrument Specifications** ▪ ASTM F565, F700 and F701 - These are care and handling practices for specific types of medical instruments. ▪ ISO 7151 Surgical Instruments – Non-cutting, articulated instruments – General requirements and test methods. ▪ ISO 13402 Surgical and dental hand instruments – Determination of resistance against autoclaving corrosion and thermal exposure.	See prints, material specifications & certifications.	
Instruments: XXXXX	2. To assure durability and functional strength, tools to be primarily manufactured out of higher strength stainless steels (SS) such as 17-4 PH SST, 17-7 PH SST 13-8 Mo SST or 400 series SST (preferably the 420 b series, 455 or 465), or cold worked 302, 316, 304 or Nitronic SS. • All martensitic and precipitation hardened stainless steels will be in the fully heat treated condition. Solution annealing and aging will be done prior to heat treat on weld assemblies requiring maximum strength and toughness. • All stainless steel parts will be passivated. Components in a **Silver Braze** assembly will be passivated prior to assembly, and, at minimum, a citric acid passivation will be completed post assembly.	Standard parts acquired for re-sale. See instrument prints and AM Surgical specifications.	

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Instruments-General		
Instruments: Xxx-xxxx	3. Instruments to be designed to withstand multiple clean and sterilization cycles, and associated chemical and temperature conditions found in typical hospitals or surgery centers.	Cleaning and sterilization test protocols developed to evaluate instrument durability.	
Instruments: Xxx-xxxx	4. Smooth/safe function of implants and instruments, particularly mating parts.	All purchase for resale instruments tested for function. Prints with critical dimensions obtained from suppliers. Graphical CAD or hand written tolerance stack-ups completed to assure design compliance with fits required for smooth /safe function.	
Instruments: Xxx-xxxx	5. Installation system prevents insertion forces or torque which would cause damage to the implant or the implant drive mechanism during implantation. Worst case and abusive use will be identified, and whenever possible, the products will be designed to withstand these situations. When not possible, product warnings will be included in package inserts and the instructions for use.	Prints and specifications, analytic prediction of peak intraoperative stresses, test protocols and test results.	
Instruments: Xxx-xxxx	6. Instruments will be designed and tested to assure that fracture of small or delicate cutting tools and/or tool guides will not be possible under "normal" use situations. Abusive use will be defined for customers to assure proper care and handling of any delicate cutting tools and instruments.	Design Specs and prints. Test protocols and test results summaries. Description of Failure modes to be included in instructions for use, and warnings to be created for customer education and inclusion in package inserts.	
Instruments: Xxx-xxxx	7. Tools to be sized to fit the average male/female adult surgeon's hand.. Size handles and working ends to fit specific use. Tools are primarily for hand or finger tip use. Tools to be light weight and narrow to prevent obstruction of view.	See instrument prints. In many cases, instruments selected are standard parts acquired for re-sale	
Instruments: Xxx-xxxx	8. Create cosmetically appealing and ergonomically optimized (user-friendly) instrumentation, cases, and literature.	Case & tray prints and models, draft surgical technique literature.	
Instruments: Xxx-xxxx	9. Provide instrumentation to facilitate proper placement of juxta-articular screws and k-wires.		

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Instruments - Materials		
Instruments & Modules: :XXXX	**Instrumentation & Sterilization Cases II** 1. The following materials may be used in the Wrist FIT system instruments: • Implant grade wrought Titanium 6-Aluminum 4-Vanadium (Ti6Al4V) alloy (MTL 003) – reference ISO 5832-3 • Other titanium, stainless steel, CoCr or Nitinol implant grade metallic alloys. (See product drawings) • Surgical grade stainless steels per ASTM & ISO specifications noted above. The most common alloys used include type 17-4PH per ASTM A564, 420 SS; 13-8 SS, COND H 950;455 SS, COND H950; 304 SS; 301 or 302 SS; 17-7 PH SS, Nitronic 50 & 60, Nitinol. • Aluminum alloys such as 2024-T3 or T4, 6061-T6, 7075-T66063 T6, N • Steam sterilizable , chemically inert USP Class VI polymers, including adhesives and epoxy inks. (e.g. Acetal Co-Polymers, RADEL R Polyphenylsulfone (Radel R 5000), Masterbond EP 42 HT) et cetera . • Cadmium free Silver Braze such as BAg 4, 7 or 24.		
Instruments & Modules: : XXXX	**2.** Materials not mentioned in ISO or ASTM standards for medical devices, which have not fully been characterized as bio-compatible, may only be used on the non-invasive portions of the instruments.		

NOTE: FINALIZE SCOPE THEN COMPLETE INPUTS FOR ALL ITEMS IN SCOPE.

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Instruments		
XXXX	1. Screwdrivers - Multiple modified torx driver sizes. Torsional strength of driver tip to exceed torsional strength of screw minor diameter. Heat treated 455 or 465 stainless steel to be used for drivers.	See prints. Torsional strength of driver verified by testing.	
XXXX	2. *Torx driver-socket interface to have full depth line contact in torx mechanism to distribute stresses to prevent torx stripping. Drivers must be able to pick a screw out of sterilization case and retain the screw during insertion without use of a holding sleeve.*	Stick fit achieved via 1.5 degree to 3 degree per surface (or up to about 6 degrees if stick is too tight) Morse type taper at base of torx socket. *Taper dimension to be determined via lab evaluation of sample parts.*	
XXXX	3. TBD - Drivers to have AO QC ends.		
All Drill Bits and K-wires	4. LABEL FOR K-WIRES AND DRILL BITS TO SPECIFY NO RE-USE OF DEVICE ALLOWED, ONLY RE-STERILIZATION. "SINGLE USE ONLY" IS ON THE LABEL. ADDED TO PRODUCT LITERATURE AND PACKAGE INSERT.		
xxxx	5. Screw Forceps - Existing Product – No new requirements.		
xxxx	6. Termite Forceps - Existing Product – No new requirements.		
xxxx	7. Stag Beetle Reduction Forceps - Existing Product – No new requirements.		
xxxx	8. Reduction Forceps with K-wire guide - Existing Product – No new requirements.		
xxxx	9. Pickup Forceps, General		
xxxx	10. Mini Verbrugge		
xxxx	11. Cleaning Stylet - Sized to fit through canulations in Wrist FIT drill guides to clear debris.		
xxxx	12. Cleaning Brush (Purchase foe resale - Medical grade reusable polymer brush - sized to fit through canulations in Wrist FIT drill guides to clear debris.)		
xxxx	13. Holding Sleeve for 2.7 Screws		
xxx	14. Screw holder to have surface tension on driver shaft to improve ergonomics during use.		
xxxx	15. **Screw holders needed for each screw size.** Screw holder must allow quick and secure pick up of small screws while assuring the driver stays seated.		
xxxx	16. **Screw holders p**ulls screw to driver. Picks up screw and locks securely with		

	one-hand motion. 17. Small and lightweight.		

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Instruments		

	DESIGN INPUT OR REQUIREMENT CRITICAL PERFORMANCE CHARACTERISTICS & FUNCTIONAL REQUIREMENTS	**DESIGN OUTPUT** (SPECIFICATION, FEATURE OR DIMENSION)	**METHOD/TESTING OF VERIFICATION** (LIST SPECIFIC DOCUMENT OR EVIDENCE OF VERIFICATION)
	Cases and Modules		
Modules: xxxx	36. Continue improved module layout and machined aluminum cases as per our Universal Hand System Project keeping in mind that modules must be light weight and have significant open space and sufficient holes to facilitate steam penetration.		
Modules: xxxx	37. Modules to have graphic artwork of implants and instruments.		
Modules: xxx	38. Modules to have ***COLOR CODING*** per marketing specifications (TBD)		
Modules: xxxx	39. Right and left implants to be stored in the same module.		
Modules: xx	40. Screws to be stored in a vertical position with radius'd edge relief to prevent screw hang up on extraction.		
Case: xxxx	41. A case is required to hold the modules holding the instruments and implants for sterilization. Sterilization requirements of the National Association of Operating Room Nurses (NAON) will be met in addition to requirements specified by the Association for the Advancement of Medial Instrumentation (AAMI) in Technical Report Information (TIR) 12. Sterilization validation to be completed for fully loaded cases and trays under wrapped pre-vacuum OR gravity conditions. Loaded weight to be under 20 lb.		
xxxx	42. Generic cases to be selected from 510k cleared cases from AM Surgical's case manufacturer. Type to be open and simple such that the customer central supply departments can assure sterility of the clinical evaluation tools and implants. Screw caddy to be simple and very open to allow steam flow.		

III RISK ANALYSIS – DESIGN FAILURE MODE EFFECTS ANALYSIS (D-FMEA)

Instructions Summary:

S = Severity Effect	Mil Std 1629A Categories	Rating	Severity Probability
Death	I - Catastrophic	10	1 in every 1000 sold
	I or II	9	
Serious Injury	II - Critical	8	1 in every 2000 sold
	Ii or iii	7	
Injury	Ii or iii	6	1 in every 5000 sold
	Iii - Marginal	5	
Minor Injury	Iii - Marginal	4	1 in every 10,000 sold
	Iii - Marginal	3	
Delay	Iii - Marginal	2	1 in every 20,000 sold
Inconvenience	IV- Minor	1	1 in every 150,000 sold

O = Occurrence Probability	Rating
Very High ≥ 1 in 2	10
Very High ≥ 1 in 3	9
High ≥ 1 in 8	8
High ≥ 1 in 20	7
Moderate ≥ 1 in 80	6
Moderate ≥ 1 in 400	5
Moderate ≥ 1 in 2000	4
Low ≥ 1 in 15000	3
Low ≥ 1 in 150000	2
Remote ≥ 1 in 1500000	1

D = Design Control Detection Probability	Rating
Undetectable ≥ 1 in 1500000	10
Very Remote ≥ 1 in 150000	9
Remote ≥ 1 in 15000	8
Very Low ≥ 1 in 2000	7
Low ≥ 1 in 400	6
Moderate ≥ 1 in 80	5
Moderately High ≥ 1 in 20	4
High ≥ 1 in 8	3
Very High ≥ 1 in 3	2
Almost Certain ≥ 1 in 2	1

RPN = Risk Priority Number = S x O x D

Weighted RPN Rating		
RPN	Risk	Category
1-125	very low	IV
126-250	low	IV
251-500	moderate	III
501-750	high	II
751-850	very high	II
851-1000	extreme	I

C = Class ∇ (Critical) or SC (Significant characteristic)
∇ **if** S ≥ 9 & O ≥ 2 & D ≥ 2

SC **if** 8≥S ≥5 & O ≥4

Product Life Estimate may be

number (#) of uses, cycles, months, years, hours,

PREVENTATIVE ACTIONS TAKEN OR PLANNED TO MINIMIZE FAILURE RISK (ATTACH AS NEEDED)

Itemize Design Features and Design Activities Used to Minimize Failure Risk

Examples:

(1) Geometry & material selection based on structural or stress analysis (attach)

(2) Product meets Functional Performance Specs (see Design Inputs/Outputs)

(3) Graphical CAD or hand written tolerance stack-ups assure design compliance with fits required for smooth /safe function (Attach verification summary)

(4) In-vivo or in-vitro tests verify and validate design function

(5) Geometry, material or process selected based on prior successful use in similar products (historical data and experience)

(6) Rationale for material and process selection included with peer review & team approval. Team approval is based on Design/Development discoveries, or historical data and experience.

Design Teams **must** complete a D-FMEA for each product (system) developed. If needed the team will **revise** the D-FMEA after every formal Design Review. The Design Team must approve/authorize the D-FMEA results for each product prior to Design Transfer Production.
*NOTE: ALL DESIGNS WITH A CLASSIFICATION OF ∇ OR SC & ALL DESIGNS WITH AN RPN ≥ 250 SHOULD BE EVALUATED FOR RE- DESIGN TO MINIMIZE RISK (IF POSSIBLE). IF ANTICIPATED RESULTS ARE NOT ACHIEVED IN ANALYSES, IN PHYSICAL TESTING OR IN OTHER AREAS REDESIGN MAY BE INDICATED.

PRODUCT(S) EVALUATED:

PRODUCT LIFE ESTIMATE: PROTECTED LOADING – 6 MONTHS (UP TO 750,000 CYCLES) NON-LOADED (POST UNION, 1 TO 50 YEARS)

ITEM #	RELIABILITY OR FUNCTIONAL REQUIREMENT	HAZARD - POTENTIAL FAILURE MODE & POTENTIAL CAUSE (S)	POTENTIAL EFFECTS OF FAILURE	S	O	D	RPN *	RPN * CAT	C*	PREVENTATIVE ACTIONS TAKEN OR PLANNED TO MINIMIZE FAILURE RISK (ATTACH AS NEEDED)	**RESULTS VALIDATED ?

3	Tapping effectiveness in cortical bone	Screws can not be inserted into sclerotic cortical bone	Delay of surgery slight loss of holding power in highest density cortical bone due to technique modifications needed to insert screws.	2	3	1	6	IV	--	Screws verified as effective at self tapping in typical phalangeal and metacarpal/metatarsal bone. Difficult to start and high insertion torque in sclerotic bone confirmed via bovine cortical bone testing. Train surgeons – **Surgical tip – Use over-drills in kit to open near side starter hole.** In the rare instance that dense thick sclerotic bone is encountered and the screws will not self-tap, the surgeon can over-drill the near cortex to the major diameter to a depth of by 1 – 3 mm to (1) get through the sclerotic region and/or (2) to assist in stabilizing the screw such that thread-tapping can occur. Taps not provided for screws smaller than 2.7 mm. Per trauma, hand and foot surgeons, a tap is basically not ever used or needed for 1.5, 2.0 or 2.4 mm screws.	

Risk analysis: (prior to risk control / mitigation)								*Risk eval*	*Risk control (risk mitigation)*						
Part description or Product code *	**Hazard code & description**	**Harm**	**SEV**	**Potential Causes of Failure**	**OCC**	**Current measures taken to minimize risk**	**DET**	**RISK**	**Accept? Yes / No**	**Recommended actions or rationale for no mitigation**	**Actions taken & completion date**	**SEV MIT**	**OCC MIT**	**DET MIT**	**RISK MIT**
All Implants	D3a-g, D3i and D3j Cytotoxicity and/or pyrogenicity ; Sensitization ; Irritation / Intracutaneous reactivity; Acute systemic toxicity; Subacute & Subchronic toxicity; Genotoxicity; Implantation; Chronic toxicity; Carcinogenicity	Fevers, allergic reactions, cancers, etc. caused by a biological response to foreign body	5	Base material is not compatible with human body	1	Use of material that is known to be biocompatible	1	5	Yes						
All Implants	D3a-g, D3i and D3j Cytotoxicity and/or pyrogenicity ; Sensitization ; Irritation / Intracutaneous reactivity; Acute systemic toxicity; Subacute & Subchronic toxicity; Genotoxicity; Implantation; Chronic toxicity; Carcinogenicity	Fevers, allergic reactions, cancers, etc. caused by a biological response to foreign body	5	Device is not adequately cleaned in production resulting in residual material that is not compatible with human body	3	All finished implant products go through validated cleaning and passivation processes either at the supplier or at AM Surgical. Via the written purchasing contracts, suppliers agree not to change production processes for implants. Vendors may petition to make a change, and AM Surgical may allow a change, but AM Surgical requires submission of samples for which AM Surgical confirms no cytotoxicity via laboratory testing prior to allowing a change. (See mitigation steps)	3	45	No	Perform cytotoxicity testing on devices after all production steps	See SOP 7-09, & Nelson labs protocol 200529808-01. Results indicate no cytotoxicity plates and screws manufactured at AM Surgical. Similar studies were also completed for products manufactured at supplier locations. Report # _____ Report # _____ Report # _____ (Dec 2005 through March, 2006)	5	1	1	5
All implants	D3a-g, D3i and D3j Cytotoxicity and/or pyrogenicity ; Sensitization ; Irritation / Intracutaneous reactivity; Acute systemic toxicity; Subacute & Subchronic toxicity; Genotoxicity; Implantation; Chronic toxicity; Carcinogenicity	Fevers, allergic reactions, cancers, etc. caused by a biological response to foreign body	5	Device is not adequately cleaned in production resulting in residual material that is not compatible with human body	3	All finished implant products go through validated cleaning and passivation processes either at the supplier or at AM Surgical. Via the written purchasing contracts, suppliers agree not to change production processes for implants. Vendors may petition to make a change, and AM Surgical may allow a change, but AM Surgical requires submission of samples for which AM Surgical confirms no cytotoxicity via laboratory testing prior to allowing a change. (See mitigation	3	45	No	Perform cytotoxicity testing on devices after all production steps.	See SOP 7-09, & Nelson labs protocol 200529808-01. Results indicate no cytotoxicity plates and screws manufactured at AM Surgical. Similar studies were also completed for products	5	1	1	5

						steps)					manufactured at supplier locations. Report # _____ Report # _____ Report # _____ (Dec 2005 through March, 2006)				
All implants	D3n Incorrect chemical composition	Fevers, allergic reactions, cancers, etc. caused by a biological response to foreign body Implant failure due to lack of strength	5	Wrong material is supplied	1	Material is specified and controlled by AM Surgical specifications (MTL 001 through MTL 005) Incoming inspection performed on all raw material	1	5	Yes						
All	D4g Incompatibility with other devices with which it is intended to be used	Surgical delay, minor implant damage compromised fixation	4	Tolerance stack up error, gage error, inspection error, undetected design error	2	DHF review, system design verification.	1	8	Yes						
All	D.3: Biological Hazard a) Cytotoxicity and pyrogenicity	Fevers, allergic reactions, cancers, etc. caused by a biological response to foreign body Post-operative infection or other complications such as pain, loosening, dislocation, and/or loss of motion may require secondary treatment. Possible device removal.	4	The use of materials which are unproven or unknown in the medical device industry. Inadequate cleaning.	2	Raw materials are inspected and accepted per applicable standard. The materials used to fabricate this device are common in the medical device industry. The implant and instrument cleaning process (prior to packaging) have been validated. The cleaning process is described in the product insert accompanying the implant and instrumentation set. It is also included in the Instructions for use (IFU). AM Surgical has validated the sterilization parameters for similar screw and plate implants in other projects. So, for early clinical uses, implant and instrument sterilization will be verified by the participating clinicians and their hospitals. AM Surgical has sent and will send all participating surgeons a letter notifying him/her that they must take responsibility for cleaning and sterilization of the system components at their hospital or institution during early clinical uses. The surgeon must reply in writing that they are taking sterilization responsibility prior to initiating clinical use, (E.g. Dr. Seitz has done so for his institution.) Following design verification through these clinical	1	8	Yes	Perform sterilization validation Provide sterility cycle information in IFU	Sterilization validation to be performed by hospital during early clinical uses. To be repeated by outside lab for AM Surgical on worst case devices – See Nelson labs protocol 200522707-03. Report # _____				

						trials, sterilization validation will be completed by AM Surgical. At that time, the validated steam sterilization parameters are included in the product insert for each instrument set.									
All	D.3: Biological Hazard a) Sensitization b) Irritation/ Intracutaneous Reactivity	Fevers, allergic reactions, cancers, etc. caused by a biological response to foreign body Post-operative infection or other complications such as pain, loosening, dislocation, and/or loss of motion may require secondary treatment. Possible device removal.	4	The use of materials which are unproven or unknown in the medical device industry. Inadequate cleaning.	2	The instructions for use (IFU) and package inserts for the system include cleaning instructions for the case, trays and modules as well as implants and instruments. The sterilization case, trays and/or modules are used away from patient and are much easier to clean than the instruments. The implant and instrument cleaning processes (prior to packaging) have been validated. Testing has also been completed to verify that instruments can be adequately cleaned by hospital. The cleaning process is described in the product insert accompanying the implant and instrumentation set. It is also included in the Instructions for use (IFU). AM Surgical has validated the sterilization parameters for similar cases, trays and modules in other product systems. So, for early clinical uses, implant and instrument and case sterilization will be verified by the participating clinicians and their hospitals. AM Surgical has sent and will send all participating surgeons a letter notifying him/her that he/she must take responsibility for cleaning and sterilization of the system components at their hospital or institution during early clinical uses. The surgeon must reply in writing that they are taking sterilization responsibility prior to initiating clinical use, (E.g. Dr. Seitz has done so for his institution.) Following design verification through these clinical trials, sterilization validation will be completed by AM Surgical. At that time, the validated steam sterilization parameters will be included in the product insert and IFU.	1	8	Yes	Perform sterilization validation. Provide sterility cycle information in IFU. Sterilization is performed by user. It is not possible to prevent user from using a cycle that is not specified in the IFU.	Sterilization validation to To be completed by outside lab for AM Surgical on worst case devices – See Nelson labs protocol 200522707-03 Report #_____				
All	D.3: Biological Hazard (o) Re- and/or Cross Infection	Fevers, allergic reactions, cancers, etc. caused by a biological response to foreign body	4	Insufficient validation parameters for cleaning and steam sterilization which could render the instrument non-sterile	2	The instructions for use (IFU) and package inserts for the system include cleaning instructions for the case, trays and modules as well as implants and instruments.	1	8	Yes	Perform sterilization validation. Provide sterility cycle information in IFU.	Sterilization validation to to be completed by outside lab for AM Surgical on worst case devices – See Nelson labs				

	(cleanability)	Post-operative infection or other complications such as pain, loosening, dislocation, and/or loss of motion may require secondary treatment. Possible device removal.		prior to surgical use.		The sterilization case, trays and/or modules are used away from patient and are much easier to clean than the instruments. The implant and instrument cleaning processes (prior to packaging) have been validated. Testing has also been completed to verify that instruments can be adequately cleaned by hospital. The cleaning process is described in the product insert accompanying the implant and instrumentation set. It is also included in the Instructions for use (IFU). AM Surgical has validated the sterilization parameters for similar cases, trays and modules in other product systems. So, for early clinical uses, implant and instrument and case sterilization will be verified by the participating clinicians and their hospitals. AM Surgical has sent and will send all participating surgeons a letter notifying him/her that he/she must take responsibility for cleaning and sterilization of the system components at their hospital or institution during early clinical uses. The surgeon must reply in writing that they are taking sterilization responsibility prior to initiating clinical use, (E.g. Dr. Seitz has done so for his institution.) Following design verification through these clinical trials, sterilization validation will be completed by AM Surgical. At that time, the validated steam sterilization parameters will be included in the product insert and IFU.				Sterilization is performed by user. It is not possible to prevent user from using a cycle that is not specified in the IFU.	protocol 200522707-03 Report #_____				
Cases, Modules & Trays	D3o Re- and/or cross-infection (cleanability)	Biological response to foreign body	5	Inadequate cleaning of device in the field. Hospitals follow their own, national and/or international standards for cleaning and sterilization implants and surgical tools. Among other things, most hospitals monitor the effectiveness of their steam and other	1	The instructions for use (IFU) and package inserts for the system include cleaning instructions for the case, trays and modules as well as implants and instruments. The sterilization case, trays and/or modules are used away from patient and are much easier to clean than the instruments. The implant and instrument cleaning processes (prior to packaging) have been validated. Testing has also been completed to verify that instruments can be adequately cleaned by hospital.	2	10	Yes	Perform sterilization validation. Provide sterility cycle information in IFU. Sterilization is performed by user. It is not possible to prevent user from using a cycle that is not specified in the IFU.	Sterilization validation to to be completed by outside lab for AM Surgical on worst case devices – See Nelson labs protocol 200522707-03 Report #_____				

				sterilization processes via inoculations (with spores) and measurement of kill rates. For steam sterilization, indicators are frequently used to show that the steam sterilization cycle was held a temperature a sufficient time to kill bacteria, germs and biologic tissues. However, gram negative bacteria may still be toxic.		The cleaning process is described in the product insert accompanying the implant and instrumentation set. It is also included in the Instructions for use (IFU). AM Surgical has validated the sterilization parameters for similar cases, trays and modules in other product systems. So, for early clinical uses, implant and instrument and case sterilization will be verified by the participating clinicians and their hospitals. AM Surgical has sent and will send all participating surgeons a letter notifying him/her that he/she must take responsibility for cleaning and sterilization of the system components at their hospital or institution during early clinical uses. The surgeon must reply in writing that they are taking sterilization responsibility prior to initiating clinical use, (E.g. Dr. Seitz has done so for his institution.) Following design verification through these clinical trials, sterilization validation will be completed by AM Surgical. At that time, the validated steam sterilization parameters will be included in the product insert and IFU.								
All	D.4: Environmental Hazards (f) Storage or Operation Outside Prescribed Environmental Conditions	Storage outside of prescribed environmental conditions may contaminate the instruments and compromise the ability to adequately clean and sterilize the instruments prior to use. Operation outside of prescribed environmental conditions may result in harm to the patient and/or cause damage to the instrument. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device. Post-operative infection	4	Storage of instrument set in an unapproved or incorrect location. Incorrect employment of the surgical technique by the physician.	2	The product insert states that the instruments are packaged clean, not sterile, and should be assumed contaminated. Instruments must be cleaned and sterilized before each use. The product insert states that U.S. Federal Law restricts this device to sale by or on the order of a physician. The product insert also states that the surgical technique should be read and understood prior to use.	1	8	Yes						

		or other complications such as pain, loosening, dislocation, and/or loss of motion may require secondary treatment. Possible device removal.													
All	D4g Incompatibility with other devices with which it is intended to be used	Inability to sterilize as implants do not fit into tray	3	Design error or manufacturing error	2	Fit must be checked for each module.	1	6	Yes						
All	D.4: Environmental Hazards h) Accidental Mechanical Damage	The functional failure and/or reduced functionality of the device may result in harm to the patient and/or cause damage to the instrument. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.	4	Damage to instrument during the shipment. Improper handling of the device by the hospital personnel during the surgical procedure.	2	The product insert states not to use damaged instruments as they may compromise the surgical outcome. The product insert also addresses the proper care and handling as to avoid accidental mechanical damage. For example: Reverse bending and notching of plates should be avoided when contouring bone plates to fit anatomy. Drill bits are labeled disposable, "single use only", or both. Bending forces should not be applied to taps or drills during use. Cutting edged on used taps must be inspected for sharpness. It is critical to obtain anatomic bone fragment alignment and reduction resulting in stable constructs in all cases. When bone apposition is not possible due to fragmentation, grafts should be used to restore bone shape and provide a mechanism for bone to bone load transmission with minimal fracture gapping during anticipated post op load regimes.	1	8	Yes						
All	D4h Accidental mechanical damage	Surgical delay, minor implant damage	3	Part is dropped, compressed in hinged tool, over -torqued during insertion, or other accidental damage	2	DHF review, system design verification	1	6	Yes						
All	D.4: Environmental Hazards (i) contamination From Waste Products/Device Disposal	Infection or contamination of personnel handling non-sterile product that has been returned after use. Medical attention may be required.	4	Improper cleaning and sterilization of the instrumentation by AM Surgical personnel after the instrument set is returned from the hospital.	2	AM Surgical has a procedure that describes the proper and safe handling of contaminated product per SOP III.B.12. Drill bits are labeled as disposable and should be discarded after each use. AM Surgical literature and instructions for use prohibit reuse of surgical implants.	1	8	Yes						

All	D.6: Hazards Related to Device Use a) Inadequate Labeling	Confusion on the order of use or methodologies on the part of the physician and/or assistants resulting in failure to meet physician/patient expectations and requirements. Improper use of the instrument may cause harm to the patient and/or damage to the instrument rendering it unusable or ineffective for implantation of the intended device. This may cause complications such as pain, loosening, dislocation, loss of motion, paralysis, wear debris related lytic responses (such as cysts, local infections, necrosis). These conditions may require secondary treatment and/or revision surgery. Possible device removal.	4	Omission of the product insert in the final packaging of the instrument set, unclear operating instructions and/or surgical technique.	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and Quality Assurance monitoring is performed during the final packaging operation to ensure the completeness. A surgical technique will be provided to the surgeon who requests it or is currently using the device. Tips and trick helpful to assure successful outcomes are presented in AM Surgical educational materials, including AM SURGICAL literature, AM Surgical training manuals, AM Surgical sponsored surgeon continuing education materials and sponsored courses.	1	8	Yes						
All	D6 (a) Inadequate labeling	Labeling does not meet regulatory requirements or does not communicate all necessary information	3	Inadequate review of labeling	1	Quality system requires review and approval of labeling by numerous people Routers & inspection plans reviewed.	1	3	Yes						
All	D6a Inadequate labeling	Labeling does not meet regulatory requirements or does not communicate all necessary information	3	Inadequate review of labeling	1	Quality system requires review and approval of labeling by numerous people Routers & inspection plans reviewed.	1	3	Yes						
All	D.6: Hazards Related to Device Use (b) Inadequate Installation Instructions	Confusion on the order of the physician and/or assistants resulting in failure to meet physician/patient expectations and requirements. Improper use of the instrument may cause harm to the patient and/or damage to the instrument rendering it	4	Omission of the product insert in the final packaging of the instrument set, unclear operating instructions and/or surgical technique.	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and Quality Assurance monitoring is performed during the final packaging operation to ensure the completeness. A surgical technique will be provided to the surgeon who requests it or is currently using the device.	1	8	Yes						

		unusable or ineffective for implantation of the intended device. This may cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.													
All	D.6: Hazards Related to Device Use c) Inadequate Operating Instructions i. inadequate specification of accessories ii. inadequate specification of pre-use checks iii. over complicated operating instructions iv. inadequate specification of service/maintenance	Confusion on the order of the physician and/or assistants resulting in failure to meet physician/patient expectations and requirements. Improper use of the instrument may cause harm to the patient and/or damage to the instrument rendering it unusable or ineffective for implantation of the intended device. This may cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.	4	Omission of the product insert in the final packaging of the instrument set, unclear operating instructions and/or surgical technique.	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and Quality Assurance monitoring is performed during the final packaging operation to ensure the completeness. A surgical technique will be provided to the surgeon who requests it or is currently using the device.	1	8	Yes						
All	D.6: Hazards Related to Device Use (1) Use by Unskilled/Untrained Personnel	Confusion on the order of the physician and/or assistants resulting in failure to meet physician/patient expectations and requirements. Improper use of the instrument may cause harm to the patient and/or damage to the instrument rendering it	4	Illegal sale of devices to non-qualified persons or personnel.	2	The device is intended to be use by a physician in a clean, controlled environment similar to any procedure. The product insert states that it is the surgeon's responsibility to be familiar with the technique, and that U.S. Federal Law Restricts These Devices to Sale By or On the Order of a Physician. To assure that the correct tools are used to prepare for specific screw sizes and specific screw applications, AM Surgical color codes mating	1	8	Yes						

		unusable or ineffective for implantation of the intended device. This may cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.				tools used to prepare holes for and drive screws. AM SURGICAL also provides a wall chart for use in the OR to educate the users on the meaning of color coding schemes, and to facilitate use of the correct screw preparation and driving tools. Cases and trays will be labeled with critical information such as screw length and diameter, drill bit diameters, et cetera. Gages for double check in implant size and length are available in the screw sterilization caddy/case. Labeling in the form of images and part numbers is also planned in the final system cases and trays (post early clinical evaluations) to enhance organization and facilitate inventory count and inspection of required tools prior to surgery.								
Cases, Modules & Trays	D6c Inadequate operating instructions	Patient injury due to infection caused by use of sterilization cycle that does not sterilize devices	5	Inadequate sterilization validation	2	The instructions for use (IFU) and package inserts for the system include cleaning instructions for the case, trays and modules as well as implants and instruments. The sterilization case, trays and/or modules are used away from patient and are much easier to clean than the instruments. The implant and instrument cleaning processes (prior to packaging) have been validated. Testing has also been completed to verify that instruments can be adequately cleaned by hospital. The cleaning process is described in the product insert accompanying the implant and instrumentation set. It is also included in the Instructions for use (IFU). AM Surgical has validated the sterilization parameters for similar cases, trays and modules in other product systems. So, for early clinical uses, implant and instrument and case sterilization will be verified by the participating clinicians and their hospitals. AM Surgical has sent and will send all participating surgeons a letter notifying him/her that he/she must take responsibility for cleaning and sterilization of the system components at their hospital or institution during early clinical uses. The surgeon must reply in writing that they are taking sterilization responsibility prior to initiating clinical	1	8	Yes	Perform sterilization validation. Provide sterility cycle information in IFU. Sterilization is performed by user. It is not possible to prevent user from using a cycle that is not specified in the IFU.	Sterilization validation to to be completed by outside lab for AM Surgical on worst case devices – See Nelson labs protocol 200522707-03 Report #_____				

						use, (E.g. Dr. Seitz has done so for his institution.) Following design verification through these clinical trials, sterilization validation will be completed by AM Surgical. At that time, the validated steam sterilization parameters will be included in the product insert and IFU.									
Cases, Modules & Trays	D6c Inadequate operating instructions	Patient injury due to infection caused by use of sterilization cycle that does not sterilize devices	5	Inadequate sterilization validation. Users do not follow instructions in IFU	2	The instructions for use (IFU) and package inserts for the system include cleaning instructions for the case, trays and modules as well as implants and instruments. The sterilization case, trays and/or modules are used away from patient and are much easier to clean than the instruments. The implant and instrument cleaning processes (prior to packaging) have been validated. Testing has also been completed to verify that instruments can be adequately cleaned by hospital. The cleaning process is described in the product insert accompanying the implant and instrumentation set. It is also included in the Instructions for use (IFU). AM Surgical has validated the sterilization parameters for similar cases, trays and modules in other product systems. So, for early clinical uses, implant and instrument and case sterilization will be verified by the participating clinicians and their hospitals. AM Surgical has sent and will send all participating surgeons a letter notifying him/her that he/she must take responsibility for cleaning and sterilization of the system components at their hospital or institution during early clinical uses. The surgeon must reply in writing that they are taking sterilization responsibility prior to initiating clinical use, (E.g. Dr. Seitz has done so for his institution.) Following design verification through these clinical trials, sterilization validation will be completed by AM Surgical. At that time, the validated steam sterilization parameters will be included in the product insert and IFU.	1	8	Yes	Perform sterilization validation. Provide sterility cycle information in IFU. Sterilization is performed by user. It is not possible to prevent user from using a cycle that is not specified in the IFU.	Sterilization validation to to be completed by outside lab for AM Surgical on worst case devices – See Nelson labs protocol 200522707-03 Report #_____				
All	D.6: Hazards Related to	Improper use of the instrument may result in	4	Misinterpretation of the intended use for the	2	A product insert is provided with each packaged product. A surgical technique will be provided to	1	8	Yes						

Instruments, Case, Trays & Modules	Device Use e) Reasonably Foreseeable Misuse	harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.		instrumentation. Misleading and/or omission of the product insert in the final packaging, unclear operating instructions and/or surgical technique.		the surgeon who requests it or is currently using the device. The product insert and surgical technique are intended to be clear and informative.									
All Instruments	D.6: Hazards Related to Device Use f) Insufficient Warning of Side Effects	Failure to meet physicians/patient expectations and other possible unforeseen long-term complications may occur.	4	Failure to include warnings on the product insert.	2	A product insert is provided with each packaged product. The product insert is intended to be clear and informative and includes a discussion on possible complications.	1	8	Yes						
Cases, Modules & Trays	D6h Incorrect measurement and other metrological aspects	Doctor uses too long of a screw due to measurement error	5	Inaccurate scale	1	Scales are well controlled via prints, processing, and in-house inspection. Drawings were checked to assure that they specify the required accuracy and that inspection plans cover inspection of scale(s). On drawing and on inspection plan. Drawing stack up tolerances (implants, tools and case/tray) are less than +/- 0.25mm, inspection plan has inspection (visual / certification).	1	5	Yes						
All Instruments Cases, Trays & Modules	D.6: Hazards Related to Device Use i) Incompatibility With Consumables/Accessories/ Other Medical Devices	Improper use of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for	4	Inadequate design of instrumentation for compatibility. Instrumentation associated with and/or necessary for the implantation of the intended device is not available.	2	Implants are supplied in a kit (whether consigned or ordered) with an instrument set containing the necessary tools to perform the surgical procedure. Ancillary equipment (sutures, retractors, scalpels, etc…) are to be provided by the hospital or surgery center. A product insert, provided with each packaged product, state that it is the responsibility of the surgeon to be familiar with the surgical procedure prior to using the intended device. A surgical technique will be provided to the surgeon who requests it or is currently using the device.	1	8	Yes						

		the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.				The product insert and surgical technique are intended to be clear and informative. Tools which interface with common power drivers are designed and tested to meet industry standard dimensions to assure interchangeability. (E.g. Stryker-type J-latch features, A./O type small Quick Connects, et cetera).									
All.	D.6: Hazards Related to Device Use j) Sharp Edges or Points	Sharp edges or points may compromise the sterile barrier of the surgical personnel (surgical gloves), cause injury to personnel handling the device (puncture), and/or cause injury to the patient.	4	The instrument and/or the packaging possessing sharp edges or points which are inconsistent with typical instruments or packaging configurations.	2	By design, some of the instruments have sharp edges and/or points. The product insert states warnings about the potential complication if the instruments are mishandled. The instrument tray containing the instruments has been designed with ergonomic consideration, and to prevent damage to sharp edges, when applicable. Instruments with sharp points are initially packaged such than the points are covered to prevent damage as well as handler injury.	1	8	Yes						
All	D6j Sharp edges or points	Skin puncture of users or patient tissue puncture or rupture due to sharp edge of implant.	4	Failure of surgeons to keep sharp edges away from structures including nerves, vessels & moving tendons. Failure to cover implant edges with sheaths of tissues when possible.	1	Provide cases, trays and packaging means to prevent stick or cut risk. Minimize sharp edges when possible in designs.	2	8	Yes						
Cases, Modules & Trays	D7l Movement of device	Device may not be possible to move	3	Poor design	1	Devices have handles or may be easily picked up	1	3	Yes						
All	D.8: Functional Failure, Maintenance, and Aging (b) Lack of, or Inadequate Specification for Maintenance Including Post-Maintenance Functional Checks	The functional failure and/or reduced functionality of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as	4	Omission of the product insert in the final packaging, unclear operating instructions and/or surgical technique.	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and states to not use damaged instruments as they may compromise the surgical outcome and to replace damaged instruments before the next use. The product insert also addresses the proper care and handling as to avoid any mechanical damage. A surgical technique will be provided to the surgeon who requests it or is currently using the device.	1	8	Yes						

		pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.													
All	D.8: Functional Failure, Maintenance, and Aging d) Lack of Adequate Determination of the End of Life of the Medical Device	The functional failure and/or reduced functionality of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.	4	Misinterpretation of the warnings and precautions stated in the product insert and surgical technique.	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and states to not use damaged instruments as they may compromise the surgical outcome and to replace damaged instruments before the next use. The product insert also addresses the proper care and handling as to avoid any mechanical damage. A surgical technique will be provided to the surgeon who requests it or is currently using the device. The functional time span for fracture repair (fracture callous and bone healing and early remodeling stages, or 1 month to about 6 months). The fracture repair device must be able to maintain bone apposition within about 1 mm during anticipated (and reasonable) postoperative loading. NO UNSTABLE FRACTURE REPAIR CONSTRUCT CAN WITHSTAND FULL PHYSIOLOGIC LOADING PRIOR TO CALLUS FORMATION AND/OR FREATURE REPAIR. AM Surgical provides warnings to surgeons and caregiver relative to use bracing and limit therapeutic loading to reasonable post operative stress levels (e.g. less than 20 N of pinch or grip loading of comminuted distal radius fractures prior to objective evidence (radiographic) of callus formation. Motion restrictions may also be advisable for certain fracture repairs.) Surgeon education and instruction is one key to successful clinical outcome. In general, the force transmitted though the wrist is higher than the external grip force measured by a factor ranging from about 2.6 to about 5.2, depending on wrist position and alignment status of the distal radius and ulna.[1] Peak power grip force range is about 250 N to 700 N (56 lb to 157 lb) for adults.[2,3]	1	8	Yes						

						Distal Radius Internal Fixation Methods The treatment of unstable distal radius fractures continues to improve as better methods of skeletal fixation and soft-tissue management are developed. Apart from closed reduction and percutaneous pinning of simpler fracture patterns, the main methods of management are external fixation, dorsal plating, and volar fixed-angle plating, and more recently, combined techniques. Rehabilitation grip force should be limited to ranges appropriate for the stability characteristics of the reconstruction method used. For instance, rehabilitation for patients with single-sided plate reconstructions in complex distal radius fractures should not be allowed to apply active resistance immediately post op and should limit active grip in early rehabilitation protocols to less than about 20 N(4.5 lb).									
All	D.8: Functional Failure, Maintenance, and Aging e) Corrosion	The functional failure and/or reduced functionality of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.	4	Incorrect materials used to fabricate the instrument.	2	The materials specified for the instrument components are common materials used in the medical device industry and have a long history of clinical success. Quality control measures have been taken to insure the proper issuance of material is performed. Particular attention is paid to passivation methods (AM Surgical SOP 7-14) and appropriate passivation post lasermarking. QC evaluations also include assurance of proper heat treat condition of hardenable stainless steels.	1	8	Yes						
All	D8e Corrosion	Implant failure, non-union of fracture fragments, local infection, fevers, or Other biological response to foreign body.	5	Poor hospital cleaning practices.	1	Validated cleaning instructions provided in IFU.	1	5	Yes						
All	D8e Corrosion	Implant failure, non-union of fracture fragments, local infection, fevers, or Other biological response to foreign body.	5	Selection and use of materials which do not have sufficient corrosion resistance to survive the hospital or implant environment.	1	Used highly corrosion resistant implant grade materials.	1	5	Yes						

All	D8e Corrosion	Implant failure, non-union of fracture fragments, local infection, fevers, or Other biological response to foreign body.	5	Mixing metals in an implant	1	Warned about not mixing metals that contact during implantation	1	5	Yes						

All	D.8: Functional Failure, Maintenance, and Aging f) Loss of Mechanical Integrity Due to Fracture or Breakage	The functional failure and/or reduced functionality of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.	4	Misinterpretation of the intended use for the instrumentation. Misleading and/or omission of the product insert in the final packaging, unclear operating instructions and/or surgical technique.	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and states to not use damaged instruments as they may compromise the surgical outcome and to replace damaged instruments before the next use. The product insert also addresses the proper care and handling as to avoid any mechanical damage. A surgical technique will be provided to the surgeon who requests it or is currently using the device.	1	8	Yes						
All	D8f Loss of mechanical integrity – fracture / breakage	Implant failure, non-union of fracture fragments, local infection, fevers, or Other biological response to foreign body. Tendon rupture, progressive deformity, and/or subsequent limb loss.	5	Inadequate reduction or bone grafting resulting in insufficient repair construct stability	1	Devices are only sold to doctors (orthopedic surgeons)	1	5	Yes						
All	D8f Loss of mechanical integrity – fracture / breakage	Implant failure, non-union of fracture fragments, local infection, fevers, or Other biological response to foreign body. Tendon rupture, progressive deformity, and/or subsequent limb loss.	5	Poor healing potential (diabetes, a vascular disease, systemic autoimmune diseases, et cetera)	1	Provide sufficient indications and contraindications Quality system requires review and approval of labeling by numerous people	1	5	Yes						
All	D8f Loss of mechanical integrity – fracture /	Implant failure, non-union of fracture fragments, local infection, fevers, or	5	Inadequate materials used in design.	1	Test parts (see design V&V)	1	5	Yes						

	breakage	Other biological response to foreign body. Tendon rupture, progressive deformity, and/or subsequent limb loss.														
All	D8f Loss of mechanical integrity – fracture / breakage	Implant failure, non-union of fracture fragments, local infection, fevers, or Other biological response to foreign body. Tendon rupture, progressive deformity, and/or subsequent limb loss.	5	Inadequate design for the repair task at hand.	1	Test parts (see design V&V)	1	5	Yes						
Cases, Modules & Trays	D8f Loss of mechanical integrity – fracture / breakage	Equipment damage	2	Dropped case or repeat sterilization causes fatigue failure	1	Material selection	2	4	Yes						
All	D8h Loss of mechanical integrity – wear, fretting, debris	See D8f													
All	D8i Loss of mechanical integrity – fixation failure	See D8f													
All	D8j Inadequate packaging (contamination and/or deterioration of the medical device)	Damaged devices caused by inadequate packaging	2	Inadequate packaging	1	Standard materials used. Implant is metal and resistant to deterioration. Devices must be inspected, cleaned & sterilized by user before use	1	2	Yes						
All	D8g Loss of mechanical integrity – deformation	See D8f													
Cases, Modules & Trays	D8g Loss of mechanical integrity – deformation	Equipment damage	2	Dropped case or repeat sterilization causes fatigue failure	1	Material selection	2	4	Yes						
Cases, Modules & Trays	D8h Loss of mechanical integrity – wear, fretting, debris	Excessive wear causes lid to not fit onto case	3	Usage	2	Correct design & material selection. Use durable proven materials and mechanisms of appropriate geometry with positive track record in the industry. Evaluate clinically to assure performance in hospital or surgi-center environment. See PSpecs and functional performance tests summary in design V&V.	1	6	Yes						
All	D.8: Functional Failure, Maintenance, and Aging g) Loss of Mechanical	The functional failure and/or reduced functionality of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to	4	Misinterpretation of the intended use for the instrumentation. Misleading and/or omission of the product insert in the final packaging, unclear	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and states to not use damaged instruments as they may compromise	1	8	Yes						

	Integrity Due to Deformation	meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.		operating instructions and/or surgical technique.		the surgical outcome and to replace damaged instruments before the next use. The product insert also addresses the proper care and handling as to avoid any mechanical damage. A surgical technique will be provided to the surgeon who requests it or is currently using the device.									
All Instruments, Case, Trays & Modules	D.8: Functional Failure, Maintenance, and Aging h) Loss of Mechanical Integrity Due to Wear, Fretting, Debris	The functional failure and/or reduced functionality of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.	4	Misinterpretation of the intended use for the instrumentation. Misleading and/or omission of the product insert in the final packaging, unclear operating instructions and/or surgical technique.	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and states to not use damaged instruments as they may compromise the surgical outcome and to replace damaged instruments before the next use. The product insert also addresses the proper care and handling as to avoid any mechanical damage. A surgical technique will be provided to the surgeon who requests it or is currently using the device.	1	8	Yes						
All	D.8: Functional Failure, Maintenance,	An inadequate instrument tray could render the instrument unsuitable by	4	Inadequate or insufficient instrument tray design allowing	2	The instruments and instrument trays were designed with consideration to possible damage during shipment. A product insert is provided with	1	8	Yes						

	and Aging j) Inadequate Packaging (Contamination and/or Deterioration of the Medical Device)	permitting physical damage to the instrument. The functional failure and/or reduced functionality of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.		the contents to become damaged during shipment or use.		each packaged instrument set and states to not use damaged instruments as they may compromise the surgical outcome and to replace damaged instruments before the next use. Likewise for implants.								
All	D.8: Functional Failure, Maintenance, and Aging m) Inability For User to Sterilize/Re-sterilize Device	The utilization of a non-sterile instrument. Post-operative infection or other complications such as pain, loosening, dislocation, and/or loss of motion may require secondary treatment. Possible device removal.	4	Insufficient validation parameters for steam sterilization which could render the instrument non-sterile prior to surgical use.	2	The instructions for use (IFU) and package inserts for the system include cleaning instructions for the case, trays and modules as well as implants and instruments. The sterilization case, trays and/or modules are used away from patient and are much easier to clean than the instruments. The implant and instrument cleaning processes (prior to packaging) have been validated. Testing has also been completed to verify that instruments can be adequately cleaned by hospital. The cleaning process is described in the product insert accompanying the implant and instrumentation set. It is also included in the Instructions for use (IFU). AM Surgical has validated the sterilization parameters for similar cases, trays and modules in other product systems. So, for early clinical uses, implant and instrument and case sterilization will be verified by the participating clinicians and their	1	8	Yes	Perform sterilization validation. Provide sterility cycle information in IFU. Sterilization is performed by user. It is not possible to prevent user from using a cycle that is not specified in the IFU.	Sterilization validation to To be completed by outside lab for AM Surgical on worst case devices – See Nelson labs protocol 200522707-03 Report #_____				

						hospitals. AM Surgical has sent and will send all participating surgeons a letter notifying him/her that he/she must take responsibility for cleaning and sterilization of the system components at their hospital or institution during early clinical uses. The surgeon must reply in writing that they are taking sterilization responsibility prior to initiating clinical use, (E.g. Dr. Seitz has done so for his institution.) Following design verification through these clinical trials, sterilization validation will be completed by AM Surgical. At that time, the validated steam sterilization parameters will be included in the product insert and IFU .									
Cases, Modules & Trays	D8m Inability for user to sterilize / re-sterilize device	Patient injury due to infection caused by use of sterilization cycle that does not sterilize devices	5	Inadequate sterilization validation	2	The instructions for use (IFU) and package inserts for the system include cleaning instructions for the case, trays and modules as well as implants and instruments. The sterilization case, trays and/or modules are used away from patient and are much easier to clean than the instruments. The implant and instrument cleaning processes (prior to packaging) have been validated. Testing has also been completed to verify that instruments can be adequately cleaned by hospital. The cleaning process is described in the product insert accompanying the implant and instrumentation set. It also is included in the Instructions for use (IFU). AM Surgical has validated the sterilization parameters for similar cases, trays and modules in other product systems. So, for early clinical uses, implant and instrument and case sterilization will be verified by the participating clinicians and their hospitals. AM Surgical has sent and will send all participating surgeons a letter notifying him/her that he/she must take responsibility for cleaning	1	10	Yes	Perform sterilization validation. Provide sterility cycle information in IFU. Sterilization is performed by user. It is not possible to prevent user from using a cycle that is not specified in the IFU.	Sterilization validation to To be completed by outside lab for AM Surgical on worst case devices – See Nelson labs protocol 200522707-03 Report #_____				

						and sterilization of the system components at their hospital or institution during early clinical uses. The surgeon must reply in writing that they are taking sterilization responsibility prior to initiating clinical use, (E.g. Dr. Seitz has done so for his institution.) Following design verification through these clinical trials, sterilization validation will be completed by AM Surgical. At that time, the validated steam sterilization parameters will be included in the product insert and IFU .									

Cases, Modules & Trays	D8m Inability for user to sterilize / re-sterilize device	Patient injury due to infection caused by use of sterilization cycle that does not sterilize devices	5	Inadequate sterilization validation	2	Recommend cleaning procedure sin IFU. Dr. Seitz has taken responsibility to validate the sterilization at the hospital	1	10	Yes	Perform sterilization validation. Provide sterility cycle information in IFU. Sterilization is performed by user. It is not possible to prevent user from using a cycle that is not specified in the IFU.	Sterilization validation to To be completed by outside lab for AM Surgical on worst case devices – See Nelson labs protocol 200522707-03 Report #_____				
All	D.8: Functional Failure, Maintenance, and Aging n) Re-use and/or Improper Re-use	The functional failure and/or reduced functionality of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary	4	Misinterpretation of the warnings and precautions stated in the product insert and surgical technique.	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and states to not use damaged instruments as they may compromise the surgical outcome and to replace damaged instruments before the next use. The product insert also addresses the proper care and handling as to avoid any mechanical damage. A surgical technique will be provided to the surgeon who requests it or is currently using the device. AM Surgical's trauma system implant instructions , warnings and educational materials clearly and repeatedly stipulate that re-use of implants is prohibited.	1	8	Yes						

		treatment and/or revision surgery. Possible device removal.													
Cases, Modules & Trays	D8n Re-use and/or improper re-use	Equipment damage	2	Repeat sterilization causes fatigue failure	1	Material selection	1	2	Yes						
Cases, Modules & Trays	D8n Re-use and/or improper re-use	User uses cases with sterilization cycle other than that specified in the IFU resulting in equipment damage	2	Users do not read IFU or do not follow instructions	1	None	2	4	Yes						
All	D.8: Functional Failure, Maintenance, and Aging (o) Deterioration in Function (e.g. gradual occlusion of fluid/gas path, or change in resistance to flow, electrical conductivity) as a result of repeated use.	The functional failure and/or reduced functionality of the instrument may result in harm to the patient and/or cause damage to the instrument. Failure to meet physician/patient expectations and requirements. The instrument damage may render the instrument unusable or ineffective for the implantation of the intended device and cause complications such as pain, loosening, dislocation, and loss of motion. These conditions may require secondary treatment and/or revision surgery. Possible device removal.	4	Misinterpretation of the warnings and precautions stated in the product insert and surgical technique. Inappropriate design specifications, failure to complete Mechanical Validation Tests, or inappropriate Mechanical Validation Test protocols. Known failure risks: (1) Drill bit, k-wire or tap fracture due to abusive use, bending, and possibly related to dull surfaces. (2) Screw driver tip wear or yield or "stripping" or Stripping of screw-drive mechanism (3) Plate Bending Fatigue (5) Screw fracture in torsion (during installation) or bending shear (fatigue)	2	Several of the risk reduction measures are in the form of notifications and instructions on the product insert and surgical technique. The product insert and surgical technique are intended to be clear and informative. A product insert is provided with each packaged instrument set and states to not use damaged instruments as they may compromise the surgical outcome and to replace damaged instruments before the next use. The product insert also addresses the proper care and handling as to avoid any mechanical damage. A surgical technique will be provided to the surgeon who requests it or is currently using the device. The product inputs and related product specs stipulate performance requirements were established to minimize the potential for instrument damage or failure as a result of anticipated / normal use and handling. Specific tools and implant interfaces, which are known to be delicate are individually addressed in the product specifications, mechanical performance requirements and related mechanical validation plans. Functional, analytic and laboratory analyses were performed to assure that the final products meet the performance requirements outlined in the Design Inputs and the Product Specifications. ***Refer to the Mechanical Validation Plans and Related test reports.*** Selection of experienced team participants, coupled with: (A) team review of inputs, specifications and test plans; (B) team functional tests in bone/sawbones, and (C) functional tests by key surgeons in cadavers are used to assure	1	8	Yes						

						that the Inputs, Pspecs and Test plans are appropriate. Third party testing, and reputable research lab/clinician product review coupled with regulatory advisor and /or TUV audit s also reinforce that specifications, test protocols and test results are appropriate.									
All	D9a Improper sizing	Surgical delay Inappropriate size selected. Inappropriate size may lead to procedure failure, tissue irritation or tissue damage such as tendon rupture.	5	Untrained user.	1	Devices are only sold to doctors (orthopedic surgeons)	1	5	Yes						

Procedure Failure Modes: (*Red indicates not yet completed.*)

(1) Nonunion or Progressive Deformity – **Effects vary with location of nonunion** (mid shaft verses juxta-articular) **and the damage to soft tissue structures during the initial injury**, but may include : deformity, pain, loss of bone length, reduced function (grip or stepping power loss, joint range of motion loss at one or more joints in the pulley system effected) , other injury to soft tissues including tendon adhesions, vascular compromise, hematoma leading to infection, neuropathies, cartilage injury, joint instability and subsequent joint degeneration or osteoarthritis.

A. Unstable Construct (too much motion under reasonably anticipated loads)
B. Static or dynamic overload of construct components resulting in implant loosening, implant deformation or implant fatigue. May result in loss of correction, instability, non union or soft tissue injury. Implant failures in order of frequency.
    - Implant (screw) loosening - Screw loosening is primarily a consequence of poor quality bone stock as in osteoporotic, fragile or elderly hands and feet.

    (Long term, screw loosening frequently occurs as a result of screw/plate unloading following union. This loosening may require removal operation)
    - Plate fatigue fracture
    - Plate yield or bend
    - Screw fatigue fracture
    - Screw yield or bend
    - Screw-Plate pull-out or pull through

    Prevention: Design the strongest possible lowest profile, snug fitting plates and screws; provide appropriate installation tools ; and provide Sales Force and Surgeon Education regarding:

    - **Methods to achieve, adequate construct stability, and desired healing**
    - **Monitoring and intervention to assure positive outcomes and minimize complications.**

        i. Define acceptable construct stability

            - Fracture Gaps less than 1 mm in small bones. If construct is stable and gaps are less than 1 mm then the likelihood of overload of the plates or screws under typical post operative care/PT programs is low unless a nonunion develops due to other systemic complications such as compromised vasculature, infection or systemic conditions which reduce healing potential.
            - Fracture motion under loading less than 1 mm in small bones.

        ii. Provide tips and caveats for achieving adequate reduction and construct stability in difficult fractures. (Have surgeons advisors edit/improve)

See abstracts from literature following this section.

iii. Provide guidelines/precautions to prevent construct overload (Have surgeons advisors edit/improve)

- Restore alignment and length.
- Graft when gaps are present.
- Limit activity and splint externally when reconstruction is unstable (severe comminution) (Provide Standard PT protocols)

  Example for hand applications: The patient must be adequately protected and no activity against resistance is permitted until healing is assured radiographic. Failure to protect the fracture or osteotomy until healing is confirmed may result in a delayed or non-union and possible plate breakage.

- Monitor for callus formation and stability (in addition to infection). Consider intervention such as grafting if callus formation is not obvious at 3-4 weeks in children and young adults and 6-8 weeks in middle aged and elderly.

(2) Residual Irritants

A. Sharp edges of plates irritate soft tissues in hand, abrading muscle, vessels, nerves, ligaments or, more commonly the flexor or extensor tendons or related pulleys. Hazard – injury to soft tissues including tendon adhesions, tendon ruptures, vascular compromise, hematoma leading to infection, neuropathies, cartilage injury, joint instability and subsequent joint degeneration or osteoarthritis.

- Provide sufficient plate size and shape size selection that intraoperative cutting is kept to a minimum.
- Provide plates shaped to fit anatomy without protruding into the soft tissues.
- Provide plate benders to contour plates to fit the variable anatomy of the human metacarpal, metatarsal and phalanges.
- Designed plate bending characteristics to facilitate contouring to anatomy without creating undue stress risers in the plates.
- Provide means to efficiently create burr free cuts on plates and tines. (Sharp tools with mechanical advantage).
- Provide tools to radius or chamfer or otherwise any cut or sharp edges created in the OR.

(3) Intraoperative Complications or Delay

A. Torsional shear failure of screw head drive or screw driver tip mechanism. Delay of surgery as screw is removed and replaced, or as driver is replaced.
B. Torsional failure of screw in shaft or at head-shaft junction. Delay of surgery as screw is removed and replaced. Possible need to use secondary implant such as a larger screw or k-wire instead of the existing screw.
C. Driver slippage from screw driver or screw falls off of driver – Delay of surgery as screw is retrieved, tissue damage due to driver or screw slippage.
D. Screw holders do not grip screws, screws fall into wound.
E. Drill bit breakage - Delay of surgery as drill bit tip is retrieved, potential tissue damage to facilitate retrieval. – Use of high strength heat-treated SS, single piece manufacture. Limit length of helical flutes. **Make drill bits single use to assure sharpness.** Sharp drills will function with minimal pressure. Size flutes (web) similar to surgical tolls used for decades to achieve sufficient strength and stiffness , yet make flutes deep enough with appropriate helix angle spiral to clear chips. **Warn surgeons NOT to apply bending forces to the drill bits as they insert.**
F. Wrong size drill used for core drilling or over drilling.
G. Quick connect handle sticks. – Prevention - Abusive test shows function possible after body fluids and contaminants dry the mechanisms. Instructions for use should include test of function and application of instrument oil to the mechanisms after cleaning. Proper cleaning , drying and routing application of Surgi-lube and/or Miltex surgical instrument oils recommended maintaining smooth action.

H. Drivers do not fit quick connect handles - Prevent by design and process control. Tolerance stack ups completed and fit checked with mating parts.
I. Screws can not be inserted into sclerotic cortical bone – **Surgical tip – Use over-drills in kit to open near side starter hole.** In the rare instance that dense thick sclerotic bone is encountered and the screws will not self-tap, the surgeon can over-drill the near cortex to the major diameter to a depth of by 1 – 3 mm to (1) get through the sclerotic region and/or (2) to assist in stabilizing the screw such that thread-tapping can occur. (Taps not provided).
J. Dull cutters make cut off of extra plate or tine length difficult. – Delay of surgery. – Provide sharp cutters with replaceable carbide tips. Provide simple and clear instrument maintenance and care instructions to the hospital staff and our distributors and sales force.
K. Mating holes in drill guides inappropriate size. – Delay of surgery. Freehand use of drills required. Slight reduction in accuracy.
L. Drill bit diameters incorrect - Hazard (a) delay of surgery due to fit problem with drill guide, undersized hole making screw insertion difficult; (b) loose fit of screws in hole.

(4) Other

A. **Mis-calibration of drill guide, k-wires or instrument case holding the devices.-** Screw too long (protrudes) or too short (does not capture cortical bone on opposing side). K-wire protrudes.

   Screw or k-wire perforates into soft tissue resulting in tissue irritation. Hazard – injury to soft tissues including tendon adhesions, tendon ruptures, vascular compromise, hematoma leading to infection, neuropathies, cartilage injury, joint instability and subsequent joint degeneration or osteoarthritis. Protruding screws and k-wire tips typically require a second surgery for removal of hardware.

   Wrong screw diameter selected and does not fit in the instrumentation or the prepared hole (too loose or will not start, or fits tight, starts, but screw head does not sit flush in plate. (Surgical Delay while appropriate size is retrieved and installed, or tissue irritation if screw head is left proud.

B. **Patient infection caused by non-sterile implant or non-sterile instrumentation**.

Note that AM Surgical is electing to complete cleaning and sterilization validation to drastically reduce the potential for infection due to contamination of instruments or implants. The severity of injury caused by an infection is dependent on the organism(s) involved and the local and systemic health status of the infected patient. For example, patients with immune system dysfunction, and diabetics with reduced vascular function, and loss of sensation and/or healing problems may loose a limb or even die from an infection. SBi has focused on prevention of infection via validation of cleaning and sterilization processes. The design failure modes and effects rankings below have rated infection as serious (8) as opposed to catastrophic (deadly)

since extenuating disease processes, must also be present (e.g. end stage renal failure in an elderly individual with diabetes and heart disease) to result in death.

Literature Abstracts- Tips and caveats for achieving adequate reduction and construct stability in difficult fractures.

Find references to generate similar information specific to distal radius.

Unstable metacarpal and phalangeal fracture treatment with screws & plates.

Hastings-H 2d Clin-Orthop. 1987 Jan(214): 37-52

Plate and screw fixation of the metacarpals and phalanges has limited indications but can provide crucial assistance to the reconstructive hand surgeon in the treatment of complex fractures. Screws are indicated for unstable, long oblique or spiral fractures of themetacarpals and phalanges, intraarticular fractures with articularsurface involvement in excess of 25% with or without comminution, and intraarticular condylar, T-condylar, and Y-condylar fractures. Plates at the metacarpal level are indicated for segmental defects with substance loss, fractures with extreme comminution, and unstable short oblique or transverse diaphyseal fractures. Plate fixation of phalangeal fractures is seldom necessary but helpful in treatingsegmental defects or extreme comminution of diaphysis or metaphysisas well as intraarticular T- or Y-condylar fractures. Screw and plate fixation at the metacarpal levels, when appropriately applied,renders rigid osteosynthesis while inflicting little to no interference on the surrounding soft tissues. Screws can be applied with little to no soft tissue interference throughout the proximal phalanx and proximal and distal aspects of the middle phalanx. Platefixation for middle phalangeal fractures is limited to salvage situations for preservation of skeletal length. **The essentials for successful use of implants are a hand surgeon well versed in a variety of internal fixation techniques including the Association for the Study of Internal Fixation (ASIF) technique of screw and plate fixation, a meticulous respect for, and protection of, the soft tissues, and a facility for delivery of functional aftercare.**

Rigid fixation of phalangeal and metacarpal fractures.

Melone-C-P-Jr. Orthop-Clin-North-Am. 1986 Jul. 17(3). P 421-35.

Rational use of rigid fixation in hand surgery requires awareness of the advantages as well as the potential pitfalls of this relatively complex method of fracture management. A rational decision also necessitates familiarity with closed techniques of internal fixation which, in most cases, provide superior alternatives for the phalanges and metacarpals. The optimal application of screws, plates, and tension-band wires to small bone fractures can be ascertained only by critical assessment of large series of cases employing these devices and comparisons with similar series using other techniques of internal fixation. Nonetheless, rigid fixation is the logical choice for treatment of unstable fractures when other methods are predictably less effective. **Injuries most suitable for screw or plate fixation include displaced phalangeal condylar fractures, irreducible oblique phalangeal fractures, irreducible transverse metacarpal fractures, disabling malunions, and nonunions requiring multiple adjunctive procedures.** For selective fractures, especially those with established deformity or serious joint contractures, the capacity of rigid fixation to effect immediate skeletal stability and facilitate early digital motion can considerably enhance recovery. **Complications are minimized by precision--in case selection and surgical techniques.**

Complications of plate fixation in the hand skeleton.

Stern-PJ; Wieser-MJ; Reilly-DG, Clin-Orthop. 1987 Jan(214): 59-65

Plate fixation of metacarpal and phalangeal fractures is designed to provide rigid internal fixation in order to facilitate early motion and thereby minimize joint and tendon complications. I**n a series of plate fixations, 16 of 38 (42%) of proximal phalangeal and metacarpal shaft fractures developed complications of stiffness, malunion, nonunion, and tendon rupture.** Complications occurred more frequently for phalangeal than for metacarpal fractures and more frequently when there were associated bone or soft tissue injuries. The technique is demanding and secondary procedures are frequently required.

Influence of fracture pattern on consolidation after metacarpal plate fixation.

Fusetti C, Della Santa DR., Chir Main. 2004 Feb;23(1):32-6.

Consolidation problems may complicate plate fixation of metacarpal fractures. It was our clinical impression that the fracture's morphology and the patient's occupation may influence this complication. METHOD: Retrospective study on 104 extra-articular metacarpal fractures. Time to union, presence of consolidation problems and time to return to work were correlated with fracture pattern (transverse/non-transverse), presence of soft tissue injury, type of patients and type of plate. Twelve patients (15%) experienced consolidations problems: 8 patients within the transverse fracture pattern group (29.6%) and 4 patients (7.4%) within the non-transverse fracture group. The difference was significant ($P = 0.01$). Manual workers were found to be more likely than non-manual workers to have consolidation problems ($p < 0.01$) in both groups of fractures. There was no correlation between consolidation problems and hand dominance ($P = 0.76$), soft tissue injury ($P = 0.24$) or type of plate ($P = 0.34$). **We found a significant correlation between fracture patterns, patients' profession and consolidation problems. Despite technical advances in plate design, management of such fractures by plating remains fraught with complications, demands meticulous handling of soft tissue and does not allow for technical error.**

Metacarpal and phalangeal osteotomy with miniplate fixation.

Sanders RA, Frederick HA. Orthop Rev. 1991 May;20(5):449-56.

We reviewed the results of corrective oseotomies performed with power tools for symptomatic malunions of metacarpal and phalangeal fractures in 10 patients. At an average follow-up of 30 months, all patients had a healed osteotomy with correct alignment and had an average increase of 30 degrees in the flexion arc of the involved digit. We recommend a surgical technique of miniplate fixation over K-wire fixation where possible; it allows precise, intraoperative correction and rigid stabilization. A shortened immobilization time and early motion are significant advantages of plate fixation. **However, plates cannot be used across open growth plates or directly over areas of tendon insertion. A careful preoperative plan should always be prepared prior to any corrective osteotomy.** Problems such as post-operative tendinous adhesions did not occur, nor did nonunions or delayed unions.

IV DESIGN OUTPUTS (SPECIFICATIONS) (Paper & Electronic Files: CAD Models, CAM Programs, Prints, Sketches)

Note: CAD drawings, CAD models and prints are numbered identically. CAD drawing file & CAD model file locations are noted on each print. CAM programs and routers may be otherwise labeled in directories reserved for CUSTOMER process prints, using "XXXXX" process print numbers.

A-size copies of all prints are included in Appendix A of this Design Assurance Plan/Design History File

V DESIGN VERIFICATION SUMMARY – Verification Summary Sheets

V DESIGN VERIFICATION SUMMARY – Quality Control and Process Sheets

Quality Control and Process Verification & Validation

No new manufacturing process requiring validation will be specified for this project. These products will be manufactured using proven machining processes, on existing business unit capital equipment, (or manufactured via AM Surgical suppliers).

The following documents will be included in the final *Design Assurance Plan/Design Dossier* (Design Outputs) as Appendices:

▪ **Final Prints**	**Appendix A**
▪ **Final Routers/Process Sheets, Final Inspection Criteria/Inspection Instruction Sheets**	**Appendix B**
▪ **Inspection Results** (from Design Transfer Production Run)	**Appendix C**
▪ **Special Gage Listing, and copies of overlays** (when used)	**Appendix D**
▪ **Misc. Labeling & Marketing Information** (Special pre-cautions or warnings, package inserts, indications, contra-indications, surgical techniques, brochures, other literature, cleaning & sterilization methods)	**Appendix E**
▪ **Maintenance & Regulatory Documents** (Essential Requirements Safety Questionnaire, Technical file number, change control forms (CUSTOMER ECN's or ORTHOBIOMECH OERC's), Product Complaints)	**Appendix F**

VI Design Review Minutes and Components

VII Reconciliation Form(s) (if applicable)

Summarize alterations made to DESIGN INPUTS or DESIGN OUTPUTS as the project progresses.

Design inputs changed throughout the early CAD and RP prototyping phases of the project. Considerable design refinement was incorporated though the helpful input of the distributor design team and consulting surgeons. Key changes included:

XXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXXXXXX

If DESIGN INPUTS do not meet DESIGN OUTPUTS at the end of this project, provide a plausible rationale why neither the DESING INPUTS or DESIGN OUTPUTS should NOT be updated:

VIII Test Protocols

See Mechanical Validation Master Plan for protocols.

1.1 Screws

1. ***Adequate torsional strength, Stick Fit style screws***

Screw Diameter (mm)	**Minimum** Mean Failure Torque (N-m)
2.7 cortical screws	0.62
2.7 Cancellous Lock Screws	0.62

Acceptance criteria:

- Screw must not fracture during insertion.
- *Each screw should be inserted and removed to a 10 mm depth in virgin core diameter holes of diameter 1.8 mm (next available core drill size) 1 times without stripping the modified torx drive and without fracturing the screw or the driver.*

Recommendations for core drill size to be used in hard bone will be added to the surgical technique and IFU for each Distal Radius Repair screw size. Tapping in hard bone will also be recommended once they are available.

Plates

Bend characteristics *(when loaded in 4 point bending as per ASTM F382)*

Bend Strength

1. *Plate bending strength to be above .41 N-m for the 1.7 to 2.0 mm thick volar plates.*

Stiffness

2. *Mean stiffness to be over 0.075 N-m^2 for the 1.7 to 2.0 mm thick volar plates.*

Yield Point

3. *Mean yield point to be over 63 N for the 1.7 to 2.0 mm thick volar plates.*

4-point bend fatigue strength

4. *Dynamic endurance load in 4 point bending to be greater than 38N for the 1.7 mm to 2.0 mm thick volar plates.*

ASTM 4 Point Bend Test - Analytic (***Minimum Values***)					
Plate Style	Total Yield Force (N)	Bending Structural Stiffness (N-m^2)	Bending Strength (N-m)	Bending Endurance Load (N)	Stiffness (N/mm)
1.7 mm Volar	63.9	0.075	0.415	38.34	82

Calculate for AM Surgical To Alloy parts

Plate / Screw combinations - Adequate Pull Through Strength

Acceptance criteria*: 2.*7 screws: 1000N (224 lb) or greater pull through from screw holes.

Acceptance criteria: *The acceptance criteria will be that (1) screw socket shears, (2) the screw shaft fractures in the core diameter, or (3) the porcine bone strips (shears) prior to plate pull through in this model. If the bone shears, calculate the peak force applied prior to shear and record.* (Use literature values for fresh bovine cortical bone shear strength in the calculation and report the net force.)

Mechanical requirements: Instruments (AM Surgical In-house Functional Tests)

The following tests shall be performed:

1. General Mechanism Assembly – All parts to function as per input requirements
2. Screw Driver & Drill Bit Function – Simulation of typical and worst case or abusive environments.
3. Epoxy paints and assemblies will be tested for adherence and appropriate assembly strength per AM Surgical material specifications for epoxy inks and adhesives.
4. Functional tests include, but are not limited to:
5. Evaluation of self tapping function of flutes on screw tips via insertion into fresh bovine tibial or femoral bone
6. Evaluation of driver-screw function via insertion into fresh bovine tibial or femoral bone.
7. ***Modified Driver Torsional Strength*** *– See functional tests with implants (above)*

Plates / Screw combination – Locked Screws

Locked Screws - *Adequate plate-screw strength in static and fatigue cantilever bending (application point to be near screw causing shear & bending mimicking cortical bone loading at near cortex and unicortical fixation.)*

Acceptance Criteria (Locking mechanism yield moment goal):

Minimal Requirement (Smart lock only)	Desired Requirement Minimal requirement, other locks	Ideal
0.175 Nm (1.55 in-lb)	0.35 Nm (3.1 in-lb)	0.70 Nm (6.2in-lb) (equivalent to a solid tine)
Equivalent load at 8.5 mm moment arm 20 N (4.5 lb)	*Equivalent load at 8.5 mm moment arm* 40 N (9 lb)	*Equivalent load at 8.5 mm moment arm* 80 N (18 lb)
Equivalent load at 4 mm moment arm 43.8 N (9.8 lb)	*Equivalent load at 4 mm moment arm* 87.5 N (19.7 lb)	*Equivalent load at 4 mm moment arm* 175 N (39.4 lb)
Equivalent load at 2.5 mm moment arm 70 N (15.7 lb)	*Equivalent load at 2.5 mm moment arm* 140 N (31.5 lb)	*Equivalent load at 2.5 mm moment arm* 280 N (63 lb)

Cadaver or sawbone construct evaluations:

Lock screw-plate integrity - fatigue performance

Method still TBD with research lab(s) and consulting surgeons. The test model should mimic the ASTM F1798 methodology for sub-construct characterization. However a full construct could be tested using a modified protocol which mimics the Osada publication or the ORL protocol previously submitted to SBi.

Acceptance Criteria: For the cantilever bend sub-construct , the performance requirement is achievement of 50% of the yield performance in fatigue without screw loosening or back out.

Construct performance – Quasi static

Plate Construct Strength and Stiffness at multiple positions. (Qty of 3 to 5 sets)

Method still TBD with research lab(s). Recommend repeating the study by Dodds[4] et al.

Acceptance Criteria: WristFit to provide equivalent or greater stability when compared to the Trimed products under similar test conditions.

IX Test Results Summary

Test Results & Expected Product Performance

• Summaries of all test results, and discussion of results including appropriate theoretical analyses, **conclusions and correlation's between analyses and predicted product performance**.

X Tolerance Stack-up Verification

Following is a BRIEF SUMMARY of when, where and how tolerance analyses were performed to assure component function and interchangeability. Attachment of tolerance stack-ups is acceptable instead of, or in addition to summary statements. Refer to Appendix G.

During CAD modeling and drafting of all components tolerances and fits were evaluated. Parts were all build to nominal. Tolerances were completed to assure .0005 clearance minimum at LMC (***sometimes*** using gage tolerance, as a part of this clearance, to assure clearance in highly critical fit locations). Many graphical evaluations of fit at LMC and MMC were also completed where fit and minimization of angular variation were a concern. Other specific tolerance stack-ups are itemized below.

1.
2.
3.

Reviewed By: Mari Truman_____

Reviewed By: DESIGN ENGINEER_____

XI Design Validation Summary (Sawbones, Cadaver, Field Evaluation Summary)

Validation of Product Performance (using Design Transfer Production Components)

- Summary statement of realized safety and efficacy of devices at the completion of the development phase.
- A brief list of follow-up activities which were completed *post clinical trials* to refine the system prior to initiation of launch for general use. Include copies of engineering change packages as needed.

XI Design Validation Summary

DESIGN ASSURANCE CLOSURE REPORT

Attachments:

x	Scope
x	Design Inputs
x	Risk Analysis – D-FMEA
x	Design Specifications
x	Design Verification Summary
x	Design Review(s) Minutes and Comments
x	Reconciliation Form **(if applicable)**
x	Test Protocols
x	Test Results
x	Tolerance Stack-Up Verification
x	Design Validation Summary **(Sawbones, Cadaver, Field Evaluation Summary)**

Circulate for Approval:

Printed name_____		Printed name_____	
Signature_____	_____	Signature_____	_____
CUSTOMER Development Engineer	Date	ORTHOBIOMECH Design Engineer or CAD Technician	Date
Printed name_____		Printed name_____	
Signature_____	_____	Signature_____	_____
CUSTOMER Development	Date	ORTHOBIOMECH Tool Maker	Date
Printed name_____		Printed name_____	
Signature_____	_____	Signature_____	_____
CUSTOMER Manufacturing	Date	ORTHOBIOMECH Manufacturing	Date
Printed name_____		Printed name_____	
Signature_____	_____	Signature_____	_____
CUSTOMER Quality Assurance	Date	ORTHOBIOMECH Quality Assurance	Date
Printed name_____		Printed name_____	
Signature_____	_____	Signature_____	_____
CUSTOMER Marketing	Date	ORTHOBIOMECH Marketing or Sales	Date

[1] Putnam MD, Meyer NJ, Nelson EW, Gesensway D, Lewis JL.: **Distal radial metaphyseal forces in an extrinsic grip model: implications for postfracture rehabilitation.** J Hand Surg [Am]. 2000 May;25(3):469-75.

[2] **Humanscale 4/5/6 A Portfolio of Information : 4 Human Strength and Safety**; 4 Human Strength, *Henry Dreyfuss Associates*, The MIT Press, Cambridge, MA, 1981.

[3] Sancho-Bru JL, Giurintano DJ, Perez-Gonzalez A, Vergara M: **Optimum tool handle diameter for a cylinder grip.** *J Hand Ther. 200*3 Oct-Dec;16(4):337-42.

[4] Dodds SD, Cornelissen S, Jossan S, Wolfe SW.: A **biomechanical comparison of fragment-specific fixation and augmented external fixation for intra-articular distal radius fractures.** *J Hand Surg [Am].* 2002 Nov;27(6):953-64.