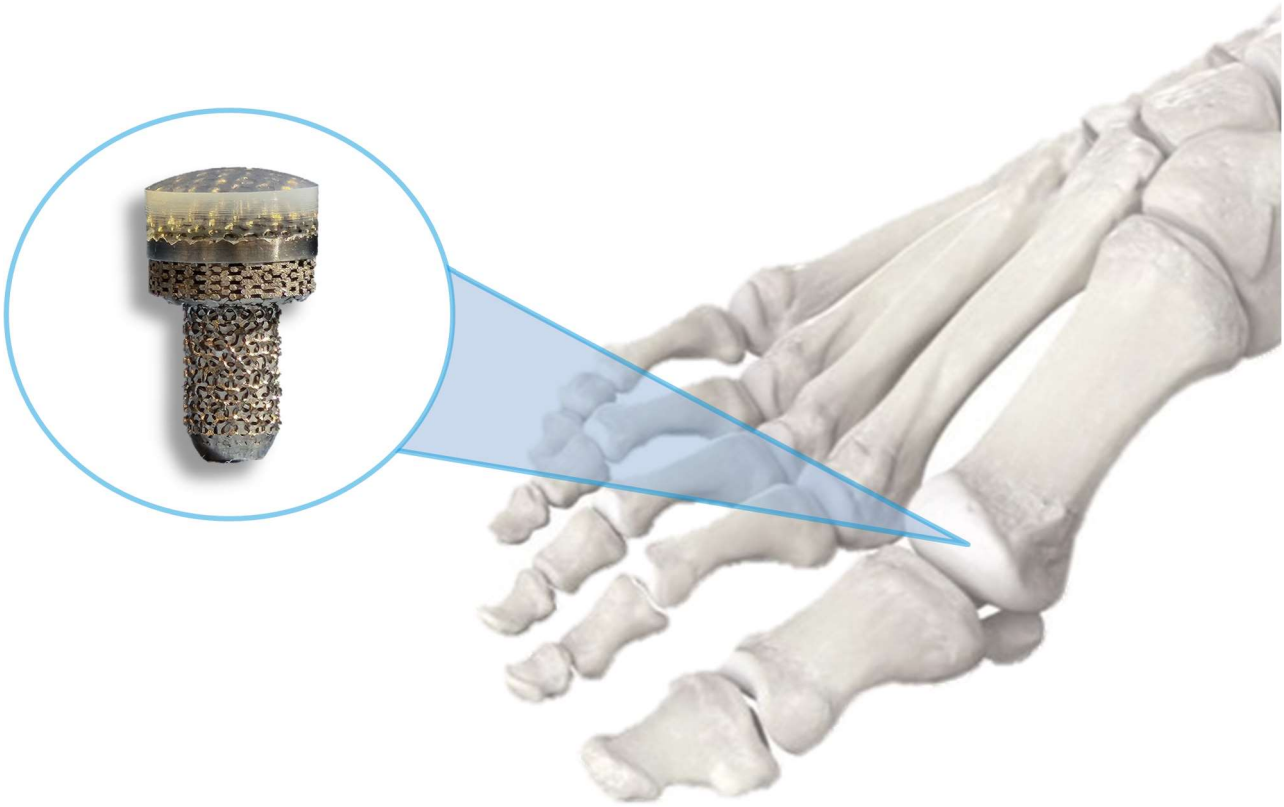
The HYALEX Slalom™ MTP Hemiarthroplasty System Instructions for Use



Caution: Federal law restricts this device to sale by or on the order of a physician.

Contents

Indications for Use

The HYALEX Slalom™ MTP Hemiarthroplasty Implant is intended to be implanted to replace the distal metatarsal surface of the great toe for treatment of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus, hallux limitus, or hallux rigidus, and an unstable or painful metatarsal/phalangeal (MTP) joint. The device is intended for single use and for use without bone cement.

Intended Use

The HYALEX Slalom MTP Hemiarthroplasty System is intended for use in the treatment of patients with degenerative and post-traumatic arthritis in the first metatarsal joint in the presence of good bone stock.

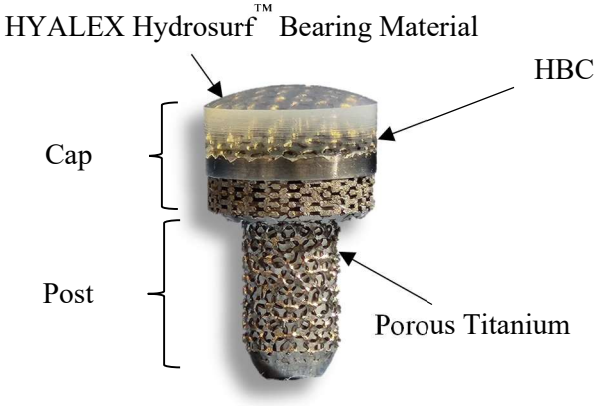
Device Description

The system is composed of the HYALEX Implant and instrumentation. The implant restores the damaged portion of the metatarsal head to relieve pain from degenerative or post-traumatic arthritis. The system is composed of the HYALEX Slalom Implant (Figure 1) and instrumentation.

The implant consists of the HYALEX bearing material (polyurethane and polyacrylic acid) bonded with a titanium coating (Ti6Al4V and commercially pure titanium) using HBC (PMMA and UDMA), a proprietary bonding compound. The device has porous titanium (commercially pure titanium) to allow bone ingrowth. The implant is supplied sterile in two sizes with a cap diameter of 10 and 12mm.

The implant is intended for single use only and should not be re-used or re-sterilized. It should only be implanted by a trained and qualified foot and ankle surgeon.

Figure 1: HYALEX Slalom MTP Hemiarthroplasty Implant



Device Materials

The HYALEX Slalom MTP Hemiarthroplasty implant is made of HYALEX Hydrosurf Bearing Material (polyurethane and polyacrylic acid), HBC (PMMA and UDMA), Ti6Al4V and commercially pure titanium.

Contraindications

The HYALEX Slalom MTP Hemiarthroplasty System is contraindicated in the following conditions:

1. Known allergy to polyurethanes, acrylic bone cement, acrylic, or titanium.
2. Inadequate bone stock.
3. Cartilage lesions on the phalanx of ICRS Grade 3 – 4 opposite the area intended for treatment.
4. Any known systemic cartilage and/or bone disorder, such as but not limited to osteoporosis, chondrodysplasia or osteogenesis imperfecta.

Warnings and Precautions

Implantation of the HYALEX Slalom MTP Hemiarthroplasty System should only be performed by surgeons trained in first metatarsal hemiarthroplasties.

Prior to use, the surgeon should thoroughly read and understand all aspects of the surgical technique to implant the HYALEX Slalom MTP Hemiarthroplasty System.

Caution should be taken if any of the following conditions are present:

- Active Arthritic crystalline or noncrystalline gout of the involved MTP joint.
- Hallux varus to any degree or hallux valgus >20°.
- Chronic instability or deficient soft tissue and other support structures.
- Clinically significant or symptomatic vascular or neurological disorder of the lower extremities which may impair healing including charcot arthopathy.
- Presence of any active systemic or local infection.
- Rheumatological disease including rheumatoid arthritis, Lyme Disease, Fibromyalgia or other forms of inflammatory joint disease or autoimmune disorder.

The implant is sterile and intended for single use only. Do not reuse or resterilize. If the sterile barrier has been compromised in any way or appears damaged DO NOT USE.

Adverse Events

The implant and procedure are both associated with risks. Below is a summary of the expected risks that may occur. They are divided between those events associated with the procedure versus those associated with the HYALEX Slalom MTP Implant. There may be additional risks that are unknown at this time.

- **Device Risks:** Failure to adhere to the HYALEX Slalom MTP Hemiarthroplasty System Surgical Technique Manual and/or Instructions for Use:
    - May lead to implant mispositioning and improper implantation site creation as well as possible bone breakage, damage to neurovascular structures, and bone cyst formation.
    - Failure to insert the HYALEX Slalom MTP Hemiarthroplasty Implant into the prepared site of implantation in a press-fit manner and position could lead to failure due to lack of implant integration.
    - Incorrect orientation and positioning of the HYALEX Slalom MTP Hemiarthroplasty Implant which may lead to improper healing and/or possible need for explantation of the HYALEX Slalom MTP Hemiarthroplasty Implant.
    - Creation of an improper site of implantation for the HYALEX Slalom MTP Hemiarthroplasty Implant could lead to instability, loosening, breakage, and failure of the device.

- If the implant is inserted such that the HYALEX Slalom MTP Hemiarthroplasty Implant articular surface is excessively proud relative to the adjacent articular cartilage, possible damage to the counter surface or adjacent tissue can occur, as well as particulate debris generation and synovitis or improper loading.
- If the opposing phalanx cartilage is of grade 3 or 4, damage to the articular surface of the HYALEX Slalom MTP Hemiarthroplasty Implant may occur causing excessive wear and osteolysis.
- Intra-operative implant resizing or reshaping by the surgeon via manual cutting may lead to injury of nearby tissue and loss of implant integrity and is strictly prohibited.
- Implantation of the HYALEX Slalom MTP Hemiarthroplasty Implant within an area of avascular necrosis and/or cyst may lead to lack of implant integration and/or implant failure.
- Unexpected HYALEX Slalom MTP Hemiarthroplasty Implant migration, subsidence, loosening, and/or inadequate fixation or integration could lead to revision.
- Use of instrumentation not provided by Hyalex may result in damage to the HYALEX Slalom MTP Hemiarthroplasty Implant articular surface, which may lead to high implant wear.
- Use of other instrumentation not provided by Hyalex may result in damage to the surrounding tissue.
- Entrapment of soft tissue between the implant and the bone during implantation may lead to a small gap followed by penetration of synovial fluid, lack of integration, and cyst formation.

- **Procedural Risks:** In addition to the risks of undergoing the procedure, there should be consideration to the risks which are specific to the HYALEX Slalom MTP Hemiarthroplasty Implant. These risks include but are not limited to:
  - Idiosyncratic rejection reaction.
  - Inflammatory response may lead to degeneration of articular surfaces, ligament laxity, and/or joint deformity.
  - Muscle atrophy.
  - Bone fracture and/or breakage.
  - Transient or chronic pain, swelling, synovitis, effusion, and systemic fever may occur due to infection, pseudo-septic or septic reactions, reactive arthritis, or aseptic arthritis.
  - Unwanted and/or suboptimal tissue ingrowth may occur, such as fibrous tissue ingrowth, partial coverage of the HYALEX Slalom MTP Hemiarthroplasty Implant, overgrowth, or partial ingrowth.
  - Transient or chronic pain, including complex regional pain syndrome of the operated joint.
  - Swelling and / or effusion of the operated joint.
  - Catching, locking, or mechanical symptoms.
  - Bone marrow edema.
  - Allergic reaction or pseudo-allergic reaction and/or elevation of acute phase reactants.
  - Pseudo-septic reaction.
  - Reactive arthritis.
  - Bone cyst.
  - Bone deformities.
  - Bone aseptic or avascular necrosis.

- Implant fracture, migration, subsidence, loosening or extrusion, with or without generation of particulate debris.
- Abrasion of counter or nearby tissues.
- Tissue hypertrophy or intra-lesional bone formation.
- Wound infection (superficial or deep).
- Septicemia.
- Wound dehiscence.
- Hematoma.
- Site drainage.
- Intra-articular adhesions.
- Hypertrophic tissue.
- Hypertrophic synovitis.
- Hypertrophic synovium.
- Host reaction(s).
- Inflammation of the joint and surrounding tissues.
- Transient or chronic joint locking and limited range of motion, stiffness, and arthrofibrosis.
- Deep vein thrombosis.
- Infection and related symptoms.
- Upward migration and thickening of the subchondral bone plate.
- Degeneration of the surrounding (adjacent and opposing) cartilage.
- Delamination.
- Development or progression of degenerative changes and osteoarthritis.
- Muscle atrophy.
- Foreign body reaction.
- HYALEX Slalom MTP Hemiarthroplasty Implant migration, subsidence, loosening.
- Erythema along the incision site.
- Incision site pain.
- Inflammatory process.
- Tissue granulation.
- Allergic reaction.
- Adverse reaction to anesthesia.
- Fatigue.
- Fever.
- Hemorrhage.
- Histotoxic reaction.
- Immune rejection.
- Infection.
- Aseptic arthritis.
- Osteophyte formation.
- Ligament laxity.
- Wound complications.
- Perioperative bleeding.
- Post-operative bleeding.
- Skin inflammation.
- Skin irritation.

Key Placement Guidelines

- At least 2mm of healthy bone must be maintained around the implant to ensure stability.

- If a cheilectomy is required, modest removal of bone spurs and excess bone is recommended to ensure adequate bone stock for implant insertion and stability.
- Implant placement must remain dorsal to the sesamoid grooves and should be placed at or above the crista.

Directions for Use

The HYALEX Slalom MTP Hemiarthroplasty System instrumentation must be used to ensure proper fit and alignment of the implant. Refer to the surgical technique (MKT-00011) for specific instructions on the use of the instruments and implantation of the device.

Non-sterile Instruments Care and Instructions for Use

Hyalex Orthopaedics provides non-sterile manual surgical instruments to support the implantation of the HYALEX Slalom MTP Hemiarthroplasty Implant. All of the instruments are intended to be reused. All instruments should be inspected, thoroughly cleaned, sterilized, and stored according to the following instructions.

1. **Preparation after use**
    a. Remove body fluids, tissue, or other debris from internal and external instrument surfaces using a non-shedding cloth or soft-bristled brush.
    b. Place instruments in a basin with distilled water or cover with damp cloth after use. Do not allow blood, bone, or other fluids or tissues to dry on instrument surfaces.
    c. Clean soiled instruments within 30 minutes of use or after removal from solution to minimize the drying of contaminants.
2. **Preparation before cleaning**
    a. Remove all instruments from the instrument case and separate any instruments that remain within others, such as drills from within drill guides or guide pins from within trials, drills, or pin guides.
    b. Pre-rinse all instruments with cool water for 1 minute (minimum); brush surfaces with a soft bristle brush until all visible soil is removed.
    c. All instrument cases should be thoroughly cleaned to remove all visible fluids, tissue or other debris.
3. **Automated Enzymatic Cleaning**

    All reusable instruments must be thoroughly cleaned after use. These instructions require the use of automated washer/disinfector with approved efficacy (e.g., CE mark, FDA approval, and validation according to ISO 15883). Use only cleaning agents/ detergents recommended by the washer/disinfector manufacturer.
    a. Prepare a neutral pH enzymatic detergent according to the manufacturer's instructions.
    b. Place instruments into a mesh basket approved for use with the automated washer system.
    c. Run the automated cleaning cycle with the neutral pH, enzymatic detergent using the following parameters:

Step	Description	Temperature	Cycle Time

1	Pre-Wash	35±5°C (95±9°F)	2 minutes
2	Enzyme Wash (Detergent % per manufacturer)	30±5°C (86±9°F)	4 minutes
3	Wash (Detergent % per manufacturer)	65.5±2°C (149.9±3.5°F)	2 minutes
4	Rinse	30±5°C (86±9°F)	15 seconds
5	Thermal Rinse with no Lubricant using Critical Water per AAMI TIR34	82.2±2°C (180±3.5°F)	1 minute
6	Hot Air Dry	85±5°C (185±9°F)	6 minutes

d. Upon completion, unload the washer/disinfector.
e. Visually inspect the instruments and instrument cases for remaining soil. If a device has any visual contamination, repeat pre-rinse and brushing steps and re-run the automated cleaning for that device.
f. Perform instrument inspection per instructions in Section 6 before replacing instruments into the instrument case.

4. **Sterilization**

a. The HYALEX Slalom MTP Hemiarthroplasty System Instrumentation has been validated for steam sterilization. Use of any other sterilization is not recommended and, if used, must be validated by the end user.
b. Follow all sterilizer manufacturer recommendations and ensure that the manufacturer's maximum load is not exceeded. Instrument cases should not be stacked during steam sterilization.
c. Package and secure the HYALEX Slalom MTP Hemiarthroplasty System Instrumentation set in an approved, FDA-cleared, wrap, pouch, or other method for maintaining sterility for the intended sterilization cycle according to the wrap or pouch manufacturer's instructions.
d. Sterilize the HYALEX Slalom MTP Hemiarthroplasty System Instrumentation using the following cycle parameters:

Recommended cycle parameters			
Cycle	**Temperature**	**Exposure Time**	**Minimum Dry Time**
Prevacuum	132°C / 270°F	4 minutes	30 minutes

5. **Storage**

a. Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/ humidity extremes.
b. Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned, repackaged and sterilized.

6. **Inspection and Maintenance**

   a. Check that all instruments are present within the instrument case. Ensure that all spaces for holding instruments are filled with the device indicated by the markings on the bottom of the case. If any 10 or 12mm instruments are missing, contact Hyalex Orthopaedics.
   b. Inspect with unaided (or corrected 20/20) direct vision at approximately 18 inches all cutting edges and tips for damage, e.g., dents, deformation, worn surfaces, etc.
   c. Inspect all components for structural integrity and ensure there are no signs of fracture, deformation, or excessive wear on any instrument.
   d. Functionally check the fit between mating instruments (e.g., drill incisors/drill guides, pin/drill incisor) to ensure proper function.
   e. If any instrument is damaged or missing, contact Hyalex Orthopaedics.
   f. Specific Instrument Guidance
      i. For drill incisors:
         1. Ensure that the cutting edges are not deformed and are free of burrs or dents; refer to Figure 2 for examples.
         2. Burr test: use a clean gauze pad or similar material and run along the cutting edges (see highlighted edges in the Figure 3). If the material is caught by a burr, do not use the instrument and contact Hyalex Orthopaedics.

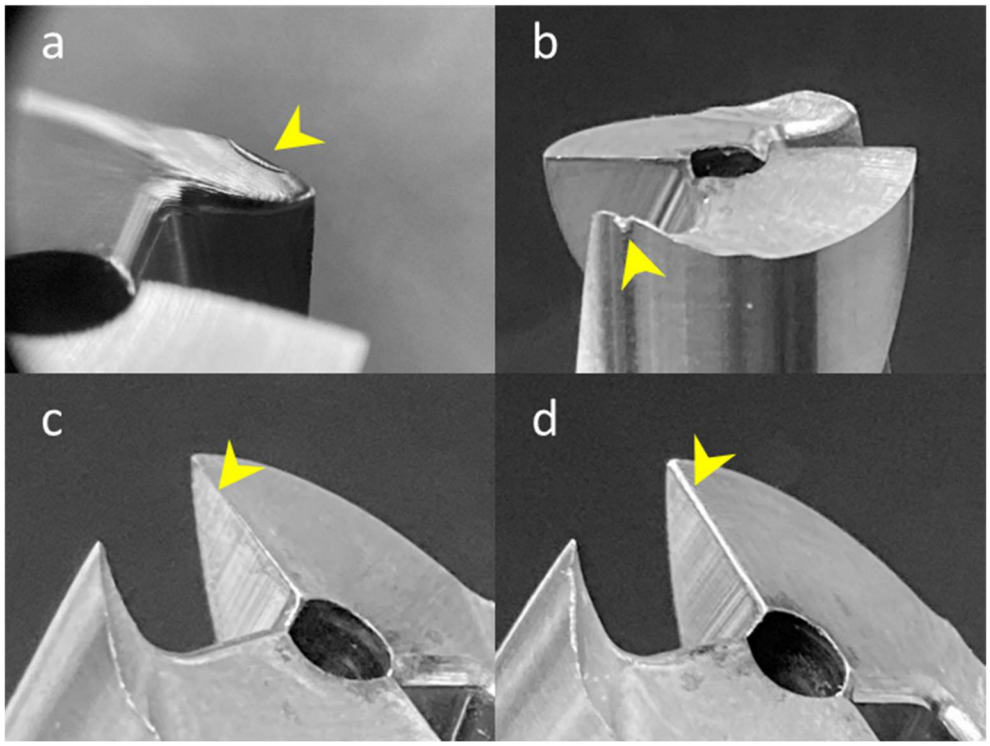


Figure 2 Representative images of a drill incisor with a) a deformed incisor blade; b) damaged incisor blade with a burr; c) sharp cutting blade d) dull cutting blade.

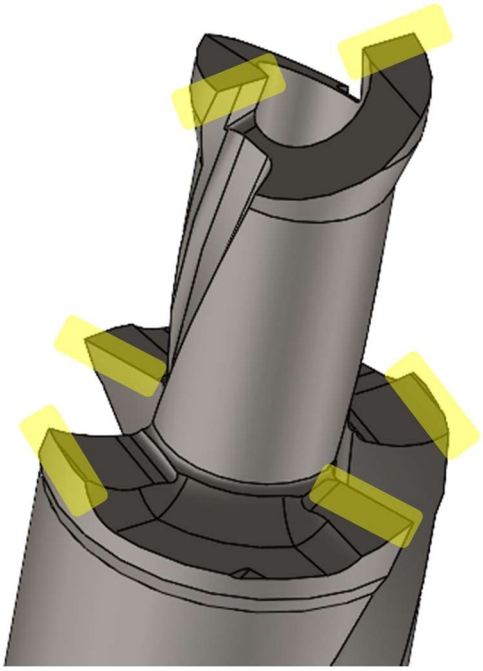


Figure 3: Cutting edges to be checked using a gauze pad or similar material

ii. For pins:

1. Ensure that the tip is not damaged or bent as this may affect cutting performance.
2. Ensure that the pin remains straight. This can be checked by rolling the pin on a flat surface. If the pin wobbles or will not roll, the pin should be replaced.

Magnetic Resonance Imaging

Non-clinical testing demonstrated that the HYALEX Slalom MTP Hemiarthroplasty Implant is MR Conditional. A patient with this implant can be scanned safely in an MR system under the following conditions:

MRI Safety Information  A person with the HYALEX Slalom MTP Hemiarthroplasty Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
Device Name	HYALEX Slalom MTP Hemiarthroplasty Implant
Static Magnetic Field Strength (B_0)	1.5T or 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 Gauss/cm)
RF Excitation	Circularly Polarized
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	2 W/kg
Scan Duration	2.0 W/kg whole body average SAR for 1 hour of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 31mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

How Supplied

The HYALEX MTP Hemiarthroplasty Implant is supplied STERILE using a gamma radiation process.
The packaging is a single sterile barrier. The Tyvek lidded tray provides the sterile barrier while the inner foil lidded tray is provided for sample hydration and protection.
Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.

NOTE: Contents of outer package are STERILE.

Handling and Storage

Store in a dry, dark place at room temperature.

Disposal Information

After use, an explant or instrument is a potential biohazard, since it may be contaminated with blood or other body fluids, bone or other tissue. Handle and dispose of explants in accordance with accepted medical practice and with applicable local, state and national laws and regulations. Explants must be packed in tear-resistant, moisture-proof and sealed containers at the place of collection. If a patient takes possession of the explants, the explants must be clean and disinfected according to national

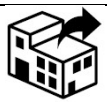
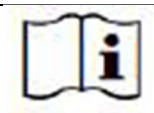
guidelines. Any sharp objects should be disposed immediately after use into a sharps container conforming to EN ISO 23907-1 or equivalent following the requirements in 2010/32/EU directive or equivalent national laws. The sharp object must not be bent, broken or re-sheathed prior to disposal.

Contact Information

	Hyalex Orthopaedics, Inc. 99 Hayden Ave., Bldg. D, Ste. 340 Lexington, MA 02421 USA

Symbols Used In Labeling

All symbols are from ISO 15223.

KEY SYMBOLS			
	Do not use if package is damaged		MR Conditional
	Manufacturer		Use-by date
	Catalog number		Batch code
	Distributor		Sterilized using irradiation
	Do not resterilize		Non-sterile
	Single sterile barrier system with protective inside packaging		Temperature limit
	Do not re-use		Prescription device
	Patient identification		Patient information website
	Health care center or doctor		Date
	Medical device		Date of manufacture
	Consult IFU		