MY3D®PERSONALIZED SOLUTIONS CUSTOM/COMPASSIONATE USE ORTHOPAEDIC PRODUCTS

℞ ONLY

Manufactured in U.S.A.

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Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Description
	Consult instructions for use; indicates the need for the user to consult the instructions for use
	Batch code indicates the manufacturer's batch code so that the batch or lot can be identified
	Manufacturer; indicates the medical device manufacturer
	Date of Manufacture; indicates the date when the medical device was manufactured
	Catalog number indicates the manufacturer's catalogue number so that the medical device can be identified
	Sterilized using irradiation; indicates a medical device that has been sterilized using irradiation
	Sterilized using ethylene oxide; indicates a medical device that has been sterilized using ethylene oxide
	Do not re-use/single use; indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Use-by date; indicates the date after which the medical device is not to be used

℞ only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Do not use if package damaged
	Non-sterile; indicates a medical device that has not been subjected to a sterilization process
	Caution: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	MR unsafe; indicates an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment
	UK Responsible Person

Abbreviation	Material
Ti	Titanium
TiN	Titanium Nitride
Ti6Al4V	Titanium Alloy
CoCr (or Co28Cr6Mo)	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra-High Molecular Weight Polyethylene
PMMA	Polymethylmethacrylate
HA	Hydroxyapatite
Ag	Agluna

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Custom / Specialty Orthopedic Products

As a custom-made product, the enclosed personalized implant device, personalized instrumentation and personalized anatomical models, have been designed according to the operating surgeon's prescription and approval.

Through the advancement of the field of joint replacement, bone fixation prostheses and guided bone preparation instruments, surgeons have been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While custom metal prostheses and personalized instrumentation and personalized anatomical models can also be largely successful in attaining these goals, there can be no guarantee of such. It must be specifically recognized that custom prostheses are manufactured from metal and plastic materials, and, therefore, cannot be expected to withstand the activity levels, loads and as would normal healthy bone. In addition, the system will not be as strong, reliable, or durable as natural human tissue. Finally, given the unique nature of the custom-made metal prosthesis and their accessories, and the personalized instrumentation and personalized anatomical models, the patient should be aware that the device(s) are not cleared or approved for use in patients in the United States or Great Britain, as the USA FDA and Great Britain have not determined the device's safety or efficacy.

In using joint replacement/fixation prostheses, the surgeon should be aware of the following:

A. The correct selection of the prosthesis is extremely important. The potential for success in joint replacement/fixation surgery is increased by selection of the proper size, shape, and the surgeon's design parameters of the prosthesis. Orthopedic prostheses require careful seating and adequate bone support. Smaller sized implants are intended for patients of slight weight and low activity level. Such components could be inappropriate for other patients. Surgeons are encouraged to use their best medical judgement when choosing the proper implant size regardless of the endosteal area of the bone.

B. **In selecting patients for joint replacement/fixation, the following factors can be critical to the eventual success of the procedure:**
    a. **Patient's weight.** An overweight or obese patient can produce loads on a prosthesis which can lead to failure of the prosthesis. This becomes a major consideration when the patient is small boned, and a small size prosthesis must be used.
    b. **Patient's occupation or activity.** If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of fixation, the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
    c. **Condition of senility, mental illness, drug abuse, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.

d. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

DESCRIPTION

This custom device is a non-standard product manufactured to meet the specific needs and requirements for an individual patient and/or the request of a specific surgeon with an approved prescription. All personalized device accessories supplied with the custom device are a non-standard product manufactured to meet the specific needs and requirements for an individual patient. The prescribed device MUST NOT be used for any other patient.

INDICATIONS FOR USE

Custom/specialty devices are typically used in revision cases where failed or loosened prostheses from previous surgery are being replaced.

Another typical reason for use is replacement of a section of bone due to a pathological fracture, non-union, bone tumor and/or any other serious bone defect. These devices are ordered to meet the specific requirements of the patient and surgeon when they cannot be met through the use of a commercially available product.

Custom/specialty device and device accessories, including personalized instrumentation and personalized anatomical models are for use in orthopaedic surgery to aid in the anatomical preparation and implantation of the corresponding custom devices. Capabilities also include a pre-operative software tool for simulating/evaluating surgical treatment options.

Reference pages 7-16 for Metal Custom device IFU information.
&
pages 17-21 for plastic Custom Device & Device Accessory IFU information.

METAL CUSTOM DEVICES

MATERIALS

Custom devices such as joint replacement/fixation components are manufactured from a variety of materials which include cobalt chrome alloy, titanium alloy, unalloyed titanium, titanium nitride, stainless steel, ceramic, hydroxyapatite, polymethylmethacrylate (PMMA), and ultra-high molecular weight polyethylene, all of which conform to ASTM standards.

CONTRAINDICATIONS

Absolute contraindications include:

1) overt infection.
2) distant foci of infections (which may cause hematogenous spread to the implant site).
3) rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram.
4) cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the affected area which would make the procedure unjustifiable; and
5) Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.

Conditions presenting increased risk of failure include:

1) uncooperative patient or patient with neurologic disorders, incapable of following instructions.
2) marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved.
3) metabolic disorders which may impair bone formation.
4) obesity.
5) osteomalacia; and
6) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

PATIENT SELECTION

Factors that should be considered are:

1) Resection of neoplastic or diseased bone.
2) At risk from pathological fracture.
3) Pain relief and improved function.
4) Ability of patient to willingly follow instructions and undergo rehabilitation.

WARNINGS

1. Improper selection, placement, positioning, and fixation of the prosthetic components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic component. The surgeon must be thoroughly familiar with the implant, instruments, and intended surgical procedure prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

2. Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Medical procedures for optimal utilization of the prosthesis should be determined by the physician. However, the physician is advised that there is recent evidence that the potential for deep sepsis following joint replacement/fixation surgery may be reduced by:
    A. Consistent use of prophylactic antibiotics.
    B. Utilizing a laminar flow clean air system.
    C. Having all operating room personnel, including observers, properly attired.
    D. Protecting implants and instruments from airborne contamination; and
    E. Impermeable draping.

3. Complete cleaning prior to site closure (complete removal of bone chips, bone cement fragments, and metallic debris) of the implant site is critical to prevent accelerated wear of the articular surfaces of the implant.

Metal Components

Some of the alloys used to produce orthopedic prostheses may contain some elements that may be carcinogenic in tissue cultures or intact organisms. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic to actual prosthetic recipients. Studies conducted to date to evaluate these questions have not produced convincing evidence of such phenomenon.

Prosthetic Components

Do not mix components of different prosthetic systems or components from different manufacturers without direct instruction from the legal manufacturer of the custom device as outlined in the surgical technique for the subject custom case. Be aware that mixing certain sizes of the same prosthetic system may be inadvisable. Modular components must be assembled securely to prevent disassociation. Avoid repeated assembly and disassembly of modular components which could compromise the locking action of the components. Surgical debris must be cleaned from components before assembly since debris may inhibit proper fit and interfere with the locking mechanisms of modular components, which may lead to early failure of the procedure.

Alignment of Components

Care should be taken to restore proper joint alignment and balance ligamentous tension. Misalignment of the joint can cause excessive wear, loosening of the prosthesis, and pain leading to premature revision of one or more of the prosthetic components.

Press-Fit Application

Tight fixation at the time of surgery is critical to the success of the procedure. Intraoperative fracture of the bone can occur during seating of the prosthesis. Bone stock must be adequate to support the device.

Cemented Application

Care is to be taken to assure complete support of all parts of the device imbedded in bone cement to prevent stress concentrations which may lead to failure of the procedure.

Fixation Screws

Fixation screws, when used, should be fully seated to assure stable fixation and to avoid interference with the proper seating of components. Use only screws recommended by the manufacturer of the specific prosthesis to avoid improper fit, and to avoid improper mixing of metals. Be careful to place screws in the proper position and angle.

HA Coatings

If the implant or HA coating is contaminated or damaged do not use. HA coated interfaces must not come into contact with cement.

PRECAUTIONS

1. The patient must be advised of the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma have been associated with failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.

2. The patient is to be cautioned to limit activities and protect the prosthesis from unreasonable stresses and follow the instructions of the physician with respect to follow-up care and treatment.

3. The patient is to be warned of surgical risks and made aware of possible adverse effects. The patient is to be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity, trauma, or normal use, and has a finite expected service life and may need to be replaced at some time in the future.

Adverse Effects

1. Wear of polyethylene articulating surfaces of prosthetic components has been reported. Higher rates of wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
2. With all custom prostheses affixed to bone, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components such as a consequence of foreign-body reaction to particulate matter. Particulate is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particulate can also be generated by third-body wear. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components. See **Important Physician Information** section for more information.
3. Although rare, metal sensitivity reactions in patients following implantation of custom prostheses affixed to bone have been reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts.
4. Peripheral neuropathies have been reported following implantation of surgery involving custom prostheses affixed to bone. Subclinical nerve damage has been reported and may occur as the result of surgical trauma.
5. Dislocation and subluxation of prosthetic components can result from improper positioning of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
6. Prosthetic components can loosen or migrate due to trauma or loss of fixation.
7. Infection can lead to failure of the custom prostheses affixed to bone.

8. While rare, fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
9. Bone fracture can occur while seating a prosthetic component.

lntraoperative and early postoperative complications can include:

1) perforation or fracture.
2) damage to blood vessels.
3) temporary or permanent nerve damage resulting in pain or numbness of the affected limb.
4) undesirable shortening or lengthening of the limb.
5) traumatic arthrosis from intraoperative positioning of the extremity.
6) cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction.
7) hematoma.
8) delayed would healing; and
9) infection.

Late postoperative complications can include:

1) avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening.
2) non-union due to inadequate reattachment and or early weight bearing.
3) aggravated problems of the affected limb or contralateral extremity by leg length discrepancy, excess femoral medialization, or muscle deficiency.
4) fracture by trauma or excessive loading, particularly in the presence of poor bone stock.
5) periarticular calcification or ossification, with or without impediment to joint mobility.
6) inadequate range of motion due to improper selection or positioning of components, impingement, or periarticular calcification.

Important Physician Information

Bone resorption is a natural consequence of surgery involving custom prostheses affixed to bone due to changes in bone remodeling patterns. Bone remodeling is mediated by the changes in stress distribution caused by implantation. Extensive resorption around the prosthesis may lead to implant loosening and failure. It is generally agreed that osteolysis is the result of localized foreign-body reaction to particulate debris generated by cement, metal, ultra-high molecular-weight polyethylene, and ceramic. Regarding the etiology, it has been hypothesized that particulate debris generated by the components of a prosthesis migrate into the synovial cavity and the bone-implant interface, where they recruit macrophages and stimulate phagocytic action. The degree of recruitment is determined by the size, distribution, and number of particulate debris (rate of debris generation). The phagocytic action results in the release of cytokines and intercellular mediators (IL-I, 2, PE2) which encourage osteoclastic bone resorption. Clinical and basic research is continuing in order to provide scientific basis for the causes of this phenomenon and potential ways to reduce its occurrence.

Osteolysis can be asymptomatic and therefore routine periodic radiographic examination is vital to prevent any serious future complication. Presence of focal lesions which are progressive may necessitate replacement of the prosthetic component(s).

Transport and Storage

The device is individually packed in protective packaging that is labelled according to its contents. Store and transport the device in the original protective packaging. Do not remove the device form the packaging until it is planned to be used. Store the device in standard hospital conditions unless specific requirements are defined and described on the product label.

CLEANING & STERILIZATION:

Unless supplied non-sterile, this product has been sterilized and should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove from package, using accepted sterile technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves and avoid contact with hard objects that may damage the product.

A. This is particularly important in handling porous coated prostheses.
B. Do not allow porous surfaces to come in contact with cloth or other fiber releasing materials.

This product is for single use only. A prosthesis should never be reused. While it may appear undamaged, microscopic imperfections may exist which would reduce the service life of the prosthesis.

A prosthesis should never be resterilized or reused after contact with body tissues or fluids, but rather should be discarded.

Warning: Disassemble components prior to sterilization/resterilization.

Warning: You must **NEVER** steam sterilize/resterilize ceramic, UHMWPE, and/or metal/UHMWPE components. If sterilization/resterilization of the metal component(s) is required, proceed accordingly. The recommended procedures for the sterilization of implant abutments should be closely followed. An implant abutment should only be sterilized once. In the event of unintentional contamination, it may be re-sterilized a single time following thorough cleaning and disinfection.

Warning: If an implant is provided with Agluna® surface treatment and requires sterilization prior to surgery, the implant must **NOT BE** cleaned prior to sterilization. Non-sterile implant(s) provided with Agluna® surface treatment have already been cleaned and cleaning prior to sterilization may affect the efficacy of the treatment. Skip Manual/Automated Cleaning Method and proceed to Sterilization Method / Instructions on Page 14 of this IFU.

Warning: Implants without Agluna® surface treatment may be provided non-sterile and if so, require sterilization prior to surgery.

If the device(s) are not handled after removal from packaging prior to sterilization, additional cleaning of the device(s) are not required prior to sterilization and the devices may proceed according to sterilization method/instructions.

If the device(s) are handled after removal from packaging prior to sterilization, The implant(s) must be cleaned in accordance with the instructions for manual or listed as follows:

Manual Cleaning Method

1. Disassemble as per manufacturer instructions (if appropriate).
2. Each device will be individually rinsed under cold (<16°C) running tap water for one (1) minute to remove gross debris. While rinsing, scrub thoroughly with a soft brush and flush lumens with and blind holes with 60 mL of tap water two (2) times with a syringe.
3. Bathe in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. While completely submerged, scrub thoroughly with a soft brush for one (1) minute per device and flush lumens and blind holes with 60 mL of the prepared enzymatic detergent solution two (2) times with a syringe.
5. Rinse each device individually with cold (<16°C) running tap water for one (1) minute and flush lumens with and blind holes with 60 mL of tap water two (2) times with a syringe.
6. Bathe in a detergent solution prepared per manufacturer directions for 5 minutes.
7. While completely submerged, scrub thoroughly with a soft brush for one (1) minute per device and flush lumens and blind holes with 60 mL of the prepared enzymatic detergent solution two (2) times with a syringe.
8. Thoroughly rinse each device individually under a running stream of deionized water for one (1) minute.
9. While completely submerged, sonicate for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. Thoroughly rinse each device individually under a running stream of deionized water for one (1) minute.
11. Dry with a clean, lint-free cloth and pressurized air at ≤ 40 psi..
12. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary, re-clean until it is visibly clean.

Note: Brushes could be used for cleaning most lumens, however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended.

Automated Cleaning Method

Pre-cleaning:

1. Disassemble as per manufacturer instructions (if appropriate)
2. Rinse under cold (< 16°C) running tap water for one (1) minute to remove gross debris. While rinsing, scrub thoroughly with a soft brush and flush lumens and blind holes with 60 mL of tap water two (2) times with a syringe.
3. While completely submerged, sonicate in an enzymatic detergent solution (prepared per manufacturer directions) for a minimum of 10 minutes.

4. Rinse with cold tap water (< 16°C) for a minimum of one minute; actuate moving parts while rinsing and flush lumens and blind holes with 60 mL of tap water two (2) times with a syringe.
5. Transfer to washer for processing. Orient devices in a manner that will allow maximum access/penetration of water/detergents to hard-to-clean areas (i.e., holes, lumens, mated surfaces, slots, etc.). See table below for cycle parameters.

Washer Parameters:

Phase	Phase Time (Minutes)	Water Temperature	Detergent Type (concentration per manufacturer)
Pre-wash 1	01:00	Cold tap water (approximately 16°C)	N/A
Enzyme Wash	05:00	Hot tap water (approximately 43°C)	Enzymatic Detergent (pH: neutral to slightly basic)
Wash 1	06:00	65°C	Detergent (pH: neutral to slightly basic)
Rinse 1	01:00	Hot tap water (approximately 43°C)	N/A
Pure Water Rinse	00:10	Water (approximately 43°C)	N/A
Drying	07:00	90°C	N/A

6. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary, re-clean until it is visibly clean.

Note: Modifications made to the process beyond what is outlined above should be evaluated to determine the continued effectiveness of the process. Responsibility for this evaluation falls to the entity making the modifications.

Note: Phase times are minimum recommended times. Longer times will not detrimentally affect cleaning.

Sterilization Method / Instructions

Note: All device(s) should be wrapped separately and sterilized in a separate autoclave cycle from any plastic custom device(s) or plastic device accessories.

The following sterilization recommendation has been developed using specific equipment for a SAL of 10^{-6} and may vary depending on processing conditions, wrapping materials, or equipment. The cycle and conditions must be demonstrated to produce sterility in your environment.

1. Disassemble components prior to sterilization (if disassembly is required).
2. Wrap the component in FDA cleared non-woven medical grade wrapping material.
3. Autoclave according to the following parameters:

Method	Cycle	Temperature	Exposure
Steam	Pulsing Vacuum	270ºF (132ºC)	4 minutes
	Dry Time	20 minutes (minimum, in chamber)	

After sterilization, remove the component from its packaging using accepted sterile technique with powder-free gloves. Ensure that the component is at room temperature prior to implantation. Avoid contact with hard objects that may cause damage.

End of Metal Custom Device IFU information.

PLASTIC CUSTOM DEVICE & DEVICE ACCESSORIES

MATERIALS

Custom/specialty device accessories, including personalized instrumentation and personalized anatomical models are manufactured from ISO 10993-1 biocompatible nylon blends, acrylic and epoxy photopolymers.

CONTRAINDICATIONS

1. Patients with a metallic implant at the proposed osteotomy site.
2. Patient with an overt infection.
3. Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.

WARNINGS

Personalized instrumentation and personalized anatomical models manufactured from Nylon 12 (aka DuraForm ProX PA®) and ArthroView®

1. To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the instruments and models prior to use.
2. To avoid serious injury, patient identification on instruments and models must be verified and confirmed against patient identification prior to use.
3. Device(s) are single use only and designed for use with a specific patient only.
4. Instruments manufactured from Nylon 12 may be re-sterilized a single time but may not be re-used for additional surgical procedures.
5. To avoid risk of infection and serious injury, do not attempt to re-clean or re-sterilize or in any way re-use models manufactured from ArthroView®.
6. Personalized instrumentation and personalized anatomical models are designed for a specific patient. To avoid the potential for serious injury, instruments and models should not be modified in any way.
7. Prior to use of any personalized instrumentation and personalized anatomical models the user must thoroughly review this instruction for use and all other labeling provided with the devices.
8. The presence of any moisture on the wrap should be visually monitored. If any moisture is observed after 60 minutes, then the cycle is not considered sterile.

Anatomical models manufactured from Accura ClearVue material

1. Models are not intended to contact the patient or be implanted.
2. Models are single use only and designed for use with a specific patient only. To avoid risk of infection and serious injury, do not attempt to re-clean or re-sterilize or in any way re-use the models manufactured from Accura ClearVue
3. Prior to use of anatomic model, the user must thoroughly review this instruction for use and all other labeling provided with the devices.
4. Models are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before intraoperative use.

PRECAUTIONS

Personalized instrumentation and personalized anatomical models manufactured from Nylon 12 (aka DuraForm ProX PA®) and ArthroView®

1. Personalized instrumentation and personalized anatomical models are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.
2. To ensure that damage has not occurred during shipping and handling, inspect all instrumentation and anatomical models for damage prior to use. Do Not Use if the instrumentation and anatomical models are broken, cracked or otherwise damaged.
3. To avoid material toxicity reactions, contact time for each material should be limited to the time shown below in table 2.
4. Handle models with delicate anatomy, (i.e., nasal bones, orbital floor) cautiously to avoid damage.

Table 2: Contact duration limit per material

Material	Device	Contact Duration	Body Contact
Nylon 12	Guides & Trials	Limited (≤ 24 hours)	Tissue/Bone
ArthroView®	Models	Limited (≤ 24 hours)	Tissue/Bone/ Mucosal Membrane

Anatomical models manufactured from Accura ClearVue material

1. Handle models with delicate anatomy cautiously to avoid damage.
2. Image processing and model fabrication are not to be construed as supplying a medical diagnosis.
3. Anatomic models are to be used by trained professionals only.
4. Anatomic models are created from patient data therefore anatomy may change between manufacture of device and surgery date. For pediatric patients, discretion must be used as anatomy can change rapidly.

Clinician is responsible for ensuring the anatomic model correctly references the patient under care.

CLEANING & STERILIZATION:

Cleaning and sterilization procedures outlined below are applicable for personalized instrumentation and personalized anatomical models manufactured from Nylon 12 (aka DuraForm ProX PA®) and ArthroView®; and anatomical models manufactured from Accura ClearVue material.

The following table defines the basic methods that must be used for cleaning and sterilization of the personalized instrumentation and personalized anatomical models:

Material	Cleaning	Sterilization
Nylon 12	Automatic or Manual	Steam
ArthroView®	Manual	Steam
Accura ClearVue	Manual	Steam

Manual Cleaning Method:

1. Prepare neutral pH enzymatic cleaner per manufacturer's instructions using water less than 25°C. Ensure that enough solution is prepared to completely submerge all devices.
2. Immerse parts in the enzymatic solution and agitate until all surface bubbles have been removed and slots and holes are in contact with the solution. Use a small syringe or soft bristle brush to flush solution into small areas when necessary.
3. Soak five (5) minutes.
4. While immersed, use a soft wipe (such as a cleanroom wiper or 4X4 lap sponge), a soft bristle brush or pipe cleaner (as appropriate) to gently wipe or brush all surfaces, including the small openings for a minimum of one (1) minute. Use a brush or probe that is small enough to access any small openings.
5. Use a syringe to flush the holes or lumens and any difficult to reach areas.
6. Rinse each part under running tap water which is less than 25°C for a minimum of one (1) minute. After the rinse, use a 60-cc syringe filled with tap water which is less than 25°C to aspirate water through all channels, slots, small openings or crevices to remove the enzymatic solution.
7. Soak each part in RO/DI water for a minimum of one (1) minute and then agitate sample for 30 seconds in the rinse water to ensure complete rinsing, repeat two (2) more times using a fresh batch of RO/DI water.
8. Visually inspect surfaces prior to drying, re-rinse if residues and soils are found.
9. Wipe dry with sterilized cloth or wipes.

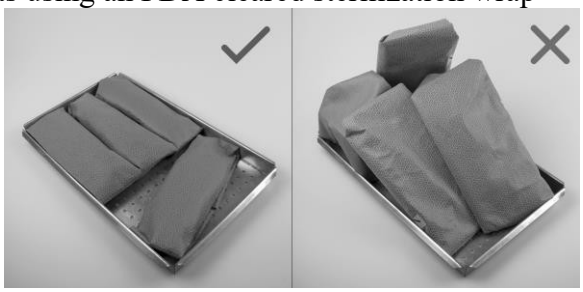
Automated Cleaning Method (Nylon 12 aka DuraForm ProX PA® Only)

1. Complete steps 1 through 6 of the manual cleaning process above.
2. Transfer the test articles onto rack system contained inside the washer for processing.
3. Automatic Cleaning Parameters:

Phase	Recirculation Time (Min)	Temperature	Detergent (Concentration per manufacturer)
Pre-wash 1	02:00	Cold tap water	N/A
Enzyme Wash	02:00	Hot tap water	Neutral pH enzymatic solution
Wash 1	02:00	65.0° C Set Point	Neutral pH enzymatic solution
Rinse 1	02:00	Hot tap water	N/A
Pure Water Rinse	00:10	43° C	N/A
Dry Time	07:00	115° C	N/A

Sterilization Method / Instructions

1. **Packaging:** Wrap parts using an FDA cleared sterilization wrap



2. **Cycle Type:** Dynamic-Air-Removal Sterilization (Pre-Vacuum / Steam)
3. **Cycle Temperature**: 132°C.
4. **Cycle Time:** 4 mins

5. **Dry Time/Cool Time:**

Material	Cycle Time Range
Nylon 12	30-minute dry time, 30-minute cool down time
ArthroView®	60 minutes (NOTE: open sterilization chamber and let cool prior to removal from chamber)
Accura® ClearVue™	60 minutes (NOTE: open sterilization chamber and let cool prior to removal from chamber)

6. **Storage in Sterile State**: Product is intended for use immediately after sterilization only. Do not unwrap until ready for use.

End of plastic custom device and custom device accessory IFU information.

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