MY3D® PERSONALIZED PELVIC RECONSTRUCTION

℞ ONLY

Manufactured in U.S.A.

Instructions for Use: My3D® Personalized Pelvic Reconstruction

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MY3D IFU08.27.21 v3, Effective 31-Jul-2023 (reference ECN 23-038)

Instructions for Use: My3D® Personalized Pelvic Reconstruction

Attention Operating Surgeon
IMPORTANT MEDICAL INFORMATION

DEFINITIONS

Symbols and abbreviations may be used on the package label. Table 1 provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Symbol Title	Explanatory Text	Standard/Law Reference	Standard/Law Title
	Consult instructions for use	Consult instructions for use; indicates the need for the user to consult the instructions for use	ISO 15223-1, Clause 5.4.3	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			Application of ISO 7000-1641	Graphical symbols for use on equipment
	Batch Code	Batch code indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1, Clause 5.1.5	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-2492	Graphical symbols for use on equipment
	Manufacturer	Manufacturer; indicates the medical device manufacturer	ISO 15223-1, Clause 5.1.1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-3082	Graphical symbols for use on equipment
	Date of Manufacture	Date of Manufacture; indicates the date when the medical device was manufactured	ISO 15223-1, Clause 5.1.3	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-2497	Graphical symbols for use on equipment
	Catalogue or model number	Catalog number indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1, Clause 5.1.6	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-2493	Graphical symbols for use on equipment
	Sterilized using irradiation	Sterilized using irradiation; indicates a medical device that has been sterilized using irradiation	ISO 15223-1, Clause 5.2.4	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-2502	Graphical symbols for use on equipment
	Sterilized by ethylene oxide	Sterilized using ethylene oxide; indicates a medical device that has been sterilized using ethylene oxide	ISO 15223-1, Clause 5.2.3	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-2501	Graphical symbols for use on equipment
	Do not re-use	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.	ISO 15223-1, Clause 5.4.2	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-1051	Graphical symbols for use on equipment

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Symbol	Symbol Title	Explanatory Text	Standard/Law Reference	Standard/Law Title
	Use by Date	Use-by date; indicates the date after which the medical device is not to be used	ISO 15223-1, Clause 5.1.4	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-2607	Graphical symbols for use on equipment
	Do not re-sterilize	Do not re-sterilize; indicates the device should not be re-sterilized after it once has been sterilized.	ISO 7000-2608	ISO 7000 — Graphical symbols for use on equipment — Registered symbols
	Prescription use only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.	21 CFR Part 801.1(c)(1)(i)F	Labeling - Medical devices; prominence of required label statements
			21 CFR Part 801.109	Labeling - Prescription devices
	Do not use if package is damaged and consult instructions for use	Do not use if package damaged	ISO 15223-1, Clause 5.2.8	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			Application of ISO 7000-2606	Graphical symbols for use on equipment
	Non-sterile	Non-sterile; indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1, Clause 5.2.7	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			Application of ISO 7000-2609	Graphical symbols for use on equipment
	Caution	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	ISO 15223-1, Clause 5.4.4	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			Application of ISO 7000-0434A G	Graphical symbols for use on equipment
	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed	ISO 15223-1, Clause 5.3.5	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-0534	Graphical symbols for use on equipment
	Keep dry	Indicates a medical device that needs to be protected from moisture. This symbol can also mean "Keep away from rain"	ISO 15223-1, Clause 5.3.4	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-0626	Graphical symbols for use on equipment
	Keep away from sunlight	Indicates a medical device that needs protection from light sources. The symbol can also mean "Keep away from heat"	ISO 15223-1, Clause 5.3.2	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
			ISO 7000-0624	Graphical symbols for use on equipment

Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
SS	Stainless Steel
PMMA	Polymethylmethacrylate

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MY3D® PERSONALIZED PELVIC RECONSTRUCTION SYSTEM

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

The My3D® Personalized Pelvic Reconstruction system is a patient specific combination of single use resection instruments, a pelvic implant, screws, acetabular, and femoral components. The system was developed to address conditions which require reconstruction of the acetabulum and hip joint.

This patient matched device is designed from inputs including imaging, diagnosis, and surgical approach. Together with the surgeon, these inputs are then translated via a design process to create patient specific implants and, if appropriate, instruments to reconstruct the patient’s pelvis. If utilized, the patient specific instruments are used to resect the bone and allow for implantation of the patient matched pelvis. The joint is then reconstructed with a cemented acetabular cup, dual mobility head (POLARCUP Insert), and femoral components.

The implants and resection instruments are single use devices. Reusable instrumentation is provided non-sterile in surgical trays which are to be re-processed per validated instructions.

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INDICATIONS FOR USE

The My3D® Personalized Pelvic Reconstruction system is indicated for use in patients requiring reconstruction of the pelvis and/or hip joint due to disease, deformity, trauma, or revision procedures where other treatments or revisions have failed. The device is a combination of single use guided osteotomy instruments, a pelvic implant, screws, and acetabular/femoral components. The pelvic implant is intended for cementless application in individuals where bone quality or bony defect size cannot support a standard sized acetabular implant. The pelvic implant is intended to be fixed to the remaining pelvic anatomy using compatible bone screws to create a prosthetic acetabulum. The reconstructed prosthetic acetabulum is intended to be used with a compatible cemented acetabular cup, dual mobility head (POLARCUP Insert), and femoral components to restore hip function.

DEVICE COMPATIBILITY

The My3D® Personalized Pelvic Reconstruction system is only compatible with the following devices (Refer to Appendix A for specific Part Numbers):

- Smith and Nephew POLARCUP® Dual Mobility System (Femoral heads, dual mobility heads, and Cemented shells)
- Smith and Nephew POLARSTEM® Cementless hip system including POLARSTEM collar hip system
- Smith and Nephew REDAPT® hip system
- Onkos 6.5mm Cancellous Non-Locking Bone Screws
- Microport 6.5mm Cancellous Non-Locking Bone Screws
- Onkos 5.0mm Cortical Locking Bone Screws

Apical plugs (AP-38016-04M), Trocar Tip Pins (PN-32089-04N), Sterile Modular Drill Bits (DR-43025-04N, DR-43050-04N, and DR-43200-04N), and compatible cemented acetabular cups, dual mobility heads, femoral heads, and hip stems are provided sterile.

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The following devices are provided non-sterile and must be cleaned and sterilized prior to use. Please refer to the IFUs listed (when applicable) for device-specific material information, contraindications, warnings, and precautions.

Section	Device	Related Part/ Tray Number(s)	Ref IFU	Pages
A	My3D® Personalized Pelvic Reconstruction Patient Matched Implants	PV-APRCN-04M PV-ACREC-04M	N/A	16-19
	Non-Sterile Modular Drill Bits	DR-432NS-04N DR-4325N-04N DR-4350N-04N		
B	Re-usable Onkos Surgical Instruments	PV-TRAY1-04T	N/A	20-23
	My3D® Personalized Pelvic Reconstruction Single Use Screws	PV-TRAY2-04T		
C	ArthroView® Models	AM-M3DMD-04N	MM-420 VSP® Orthopedics Models	24-26
	Accura ® ClearVue Anatomic Models	AM-C3DMD-04N	MM-836 ACCURA® CLEARVUE™ ANATOMIC MODELS	
	DuraForm ProX PA®/3D Printed Plastic Guides	PV-GUIDE-04N	MM-694 IFU - VSP® Orthopedics Templates and Guides	

Note: All components in Section A and B should be wrapped separately and sterilized in a separate autoclave cycle from components in Section C.

IMPLANT MATERIALS

The Onkos My3D® Personalized Pelvic Reconstruction Patient Matched Implant, Apical Hole Plugs, and Single Use Screws are manufactured from titanium alloy which conforms to ASTM standards.

CONTRAINDICATIONS

Absolute contraindications include:

1) overt infection, sepsis, or osteomyelitis.
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.

6) use of resection guides is not appropriate for tumors where a specific margin is desired. The My3D Personalized Pelvic Reconstruction instruments and cutting guides have not been evaluated for accuracy to establish any specific desired margin. For more specific details see Warnings section on cutting guide accuracy.

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) osteomalacia
5) poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

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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. The use of My3D Personalized Pelvic Reconstruction instruments and custom cutting guides have not been evaluated for accuracy to establish any specific margin from tumors of the pelvis. The accuracy of the osteotomy location of the patient-specific cutting guides has been evaluated on 4 cadavers. This included 8 peri-acetabular resections. Onkos selected a +/- 5mm positional and +/- 10-degree angular criteria for the acceptable error range of deviation from the desired cut placement. While the average error of all measurements fell within this range, 75% (6/8) of the cadaver operations had individual errors outside the acceptable error range. The worst-case positional deviation was 10mm from the desired cut. The worst-case angular deviation was 14.6 degrees from the planned bony cut (reference Table 2 and Table 3 below). No measurements were calculated distances of the bony cuts from tumors because no cadaver had a tumor or simulated structure to allow measurement of actual margins achieved. For these reasons, use of the My3D Personalized Pelvic Reconstruction patient specific guides should not be used to reproduce any specific margin for oncology cases.

Table 2: Case specific positional and angular error

Error Type	Location		CASE							
			CXX-001	CXX-004	CXX-005	CXX-008	CXX-010	CXX-011	CXX-014	CXX-015
Positional (mm)	Medial/ Lateral	X	6.123	1.916	2.878	-9.105	7.862	-6.252	0.663	-6.903
	Anterior/ Posterior	Y	-3.252	-0.889	-2.100	0.985	8.423	10.063	-2.382	6.828
	Inferior/ Superior	Z	-4.371	-1.865	4.595	-0.659	-1.553	2.207	-7.676	-4.857
Angular (°)	Transverse	XY	-0.418	5.540	5.479	-1.266	-3.218	-12.770	3.569	-9.620
	Sagittal	YZ	-4.022	-3.647	-7.891	-12.451	-0.463	11.676	-4.363	7.117
	Coronal	ZX	5.212	-2.110	2.603	14.587	4.675	2.185	0.895	4.081

Table 3: Average Error Summary

Error Type	Location		Average error (individual Measurements)	STD DEV	Average error (all measurements)	STD DEV
Position (mm)	Medal/ Lateral	X	5.213	2.827	4.350	2.904
	Anterior/ Posterior	Y	4.365	3.332		
	Inferior/ Superior	Z	3.473	2.164		
Angular (°)	Transverse	XY	5.235	3.904	5.411	4.015
	Sagittal	YZ	6.454	3.870		
	Coronal	ZX	4.543	4.033		

Note: Averages calculated using absolute values of measurements.

3. 10% of cases planned for negative margins with the use of the My3D Personalized Pelvic Reconstruction instruments and custom cutting guides were found to have positive margins. A retrospective review of compassionate use oncologic cases with the system was performed. Of the surgeons willing to share data on their tumor margins, 10% (2/20) of those with planned negative margins were found to have positive margins by the pathologist. One of these cases with a positive margin was not in the region of the device's bony cuts. The accuracy of My3D Personalized Pelvic Reconstruction instruments and custom cutting guides should not be relied upon to reproduce a negative margin for oncology cases.
4. Accuracy of planar resections has not been studied in regions outside of the periacetabular pelvis. In the 51 compassionate use cases, 34 reported their pelvic resection region (see table 4 below).

Table 4: Summary of Compassionate Use Resection Types

Pelvic Regions	Total number of cases	In scope regions for My3D Personalized Pelvic Reconstruction
I	0	
I-II	11	✓
II	9	✓
II-III	11	✓
I-II-III	3	✓
III	0	

Displacement and angulation accuracy of implants were not reported for these cases. Planar resection errors by resection region have not been evaluated. The lack of bony landmarks or differences in bony landmarks used for resection guide placement may compromise the accuracy of resection in these cases. The accuracy of the My3D system is limited to a study of 8 cadaver resections performed in the

periacetabular region. The accuracy of My3D system has not been evaluated outside of the periacetabular region and should not be relied upon to reproduce a negative margin for oncology cases.

5. Accuracy of bony resections of the My3D Pelvic Reconstruction system has not been studied in cases where prior hardware from arthroplasty or fracture fixation is present. Prior hardware can create various degrees of artifact that may compromise the surgeon-engineer design team from identifying bone of poor quality. This failure to identify bone of sufficient quality can lead to improper fit of the custom component as well as early loosening if fit or bone quality is inadequate. No evaluation of the accuracy of location or angle of cut has been done in cases with prior implants or hardware.
6. 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.
7. 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.

MRI Safety Information

The My3D Personalized Pelvic Reconstruction system has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the My3D Personalized Pelvic Reconstruction system in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Prosthetic Components

Do not mix components of different prosthetic systems or components from different manufacturers without direct instruction from the legal manufacturer of the patient matched device as outlined in the surgical technique for the subject patient matched 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. Refer to Appendix A for further information on specific part numbers.

Alignment of Components

Care should be taken to restore proper joint alignment and balance soft tissue(s). 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.

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.

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.

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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 patient-matched 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 patient matched 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 patient matched 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 patient matched 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.

Intraoperative 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 patient matched 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).

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CLEANING & STERILIZATION - PART A

My3D Personalized Pelvic Reconstruction Patient Matched Implants
Non-Sterile Modular Drill Bits

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. This includes removing protective caps from drill bits prior to processing through cleaning and sterilization.

Warning: 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.

If the implant is damaged it may NOT be reprocessed and MUST be properly discarded.

The My3D® Personalized Pelvic Reconstruction Patient Matched Implants are provided non-sterile and 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 automated cleaning listed as follows:

Manual Cleaning Method

1. Each device will be individually rinsed under cold (<16°C) running tap water for one (1) minute to remove visual 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.
2. Bathe in an enzymatic detergent solution prepared per manufacturer directions for 5

minutes.
3. 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.
4. 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.
5. Bathe in a detergent solution prepared per manufacturer directions for 5 minutes.
6. 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.
7. Thoroughly rinse each device individually under a running stream of deionized water for one (1) minute.
8. While completely submerged, sonicate for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
9. Thoroughly rinse each device individually under a running stream of deionized water for one (1) minute.
10. Dry with a clean, lint-free cloth and pressurized air at ≤ 40 psi.
11. 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. Rinse under cold (< 16°C) running tap water for one (1) minute to remove visual 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.
2. While completely submerged, sonicate in an enzymatic detergent solution (prepared per manufacturer directions) for a minimum of 10 minutes.
3. 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.
4. 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
RO/DI Water Rinse	00:10	Water (approximately 43°C)	N/A
Drying	07:00	90°C	N/A

5. 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) in Section A and B should be wrapped separately and sterilized in a separate autoclave cycle from components in Section C (see page XX).

The device(s) must be sterilized in accordance with the instructions listed as follows:

1. Wrap the component(s) in FDA cleared non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Method	Cycle	Temperature	Exposure
Moist heat sterilization according to EN ISO 17665 and ANSI / AAMI ST 79	Pre-Vacuum	270ºF (132ºC)	4 minutes
	Dry Time	70 minutes (minimum, in chamber)	
	Open Door Time	30 minutes (minimum)	
	Cool Time	90 minutes (minimum, at room temperature)	

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.

Instructions for Use: My3D® Personalized Pelvic Reconstruction

CLEANING & STERILIZATION - PART B

Onkos Surgical Re-Usable Instrumentation
My3D® Personalized Pelvic Reconstruction Single Use Screws

Onkos Surgical Re-Usable Instrumentation and My3D® Personalized Pelvic Reconstruction Single Use Screws are provided non-sterile and must be steam sterilized prior to surgical use.

Sterilization trays for Onkos Surgical Re-Usable Instrumentation must be cleaned prior to sterilization. Clean and inspect all re-usable instruments within the tray to ensure they are suitable for use. Refer to Section B.1 – Re-Processing Instructions.

Sterilization trays for Onkos Surgical Re-Usable Instrumentation and for Single Use Screws shall be double wrapped using FDA cleared sterilization wrap according to AAMI/CSR technique and steam sterilized using Moist Heat Sterilization per ANSI/AAMI ST-79. Do not stack trays during sterilization.

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 270˚F (132˚C)	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20 minutes (minimum, in chamber)

CAUTION: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

Instructions for Use: My3D® Personalized Pelvic Reconstruction

Manual or Manual/Automatic Cleaning Process:

4a. Manual Cleaning/Disinfection Procedure

Step 1	Completely submerge screws and/or instruments in enzyme solution (temp. 35-40ºC) and soak for a minimum of 15 minutes. Scrub using a soft-bristled, nylon brush until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard to clean areas. Brush all cannula with nylon brush to ensure the inner diameters are clean. Refer to Table 1 for a specific size nylon brush to be used with each cannulated part.
Step 2	Remove the device from the enzyme solution and rinse in tap water (temp. 35-40ºC) for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
Step 3	Place prepared cleaning agents in a sonication unit. Completely submerge device in neutral cleaning solution (pH between 7-9) and sonicate for 10 minutes.
Step 4	Rinse screw and/or instrument in purified water (temp. 35-40ºC) for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
Step 5	Remove visible moisture from the screw and/or instrument with a clean, absorbent, and non-shedding wipe. Flush lumens, holes and other difficult to reach areas with alcohol and/or spray with clean, compressed air.

4b. Manual/Automatic Washer/Disinfector Cycle Procedure

Step 1	Manual pre-cleaning is mandatory. Refer to 4a.
Step 2	Run the automatic wash cycle. (An automatic cleaning process may involve a washer-sterilizer, a washer-sanitizer/disinfector, ultrasonic cleaner. There are many different types of automatic washer systems, each with their own unique instructions that must be followed. Follow the manufacturer's recommendations for proper cleaning and selection of cleaning solutions. Be aware that loading patterns, water temperature and pH of cleaning solutions may change the effectiveness of the equipment.)
Step 3	Check screws and/or instruments for visible soil. Repeat cleaning if soil is visible and re-inspect.

Table 1: Nylon Brush Sizes

Cannula Size Range	Nylon Brush
.040- .053”	4.0Fr x 400mm
.054-.066”	5.0Fr x 360mm
.067 -.079”	6.0Fr x 360mm
.080 -.092”	7.0Fr x 360mm
.093-.105”	8.0Fr x 360mm
.106-.118”	9.0Fr x 360mm
.119-.131”	10.0Fr x 360mm
.159-.170”	13.0Fr x 360mm

*Note: Brushes (i.e. pipe cleaners) 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.

1. Inspection, Functional Testing & Maintenance

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the actuation of moving parts (e.g. hinges, connectors, sliding parts, triggers, etc.) to ensure smooth operation throughout the intended range of motion.
- Where instruments form part of a larger assembly, check that devices assemble readily with mating components.
- Prepare all instruments in proper case and tray configuration (if applicable) to prepare for steam sterilization.

Note: Onkos Surgical does not define the maximum number of uses appropriate for re-usable instruments. The useful life of these devices depends on many factors, including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of serviceable life.

2. Steam Sterilization

Steam autoclave (moist heat) sterilization using a pre-vacuum cycle is recommended. Autoclaves should comply with the requirements of and be validated and maintained in accordance with ANSI/AAMI ST-79.

Onkos Surgical has validated an autoclave cycle for sterilization of complete re-usable Instrumentation and for Single Use Screw cases/trays. Onkos Surgical trays are only validated for use with Onkos Surgical implants and instruments. Screws and/or Instruments shall be sterilized in the assembled state as stored on the tray. Onkos Surgical trays should be double wrapped using FDA cleared sterilization wrap according to AAMI/CSR technique. Do not stack trays during sterilization.

The process parameters shown below are validated and recommended by Onkos Surgical for sterilization.

Method:	**Moist Heat Sterilization per ANSI/AAMI ST-79**
Sterilizer Type:	**Pre-Vacuum**
Exposure Time	**4 minutes**
Minimum Temperature:	**132ºC (270ºF)**
Minimum Dry Time	**20 minutes (minimum, in chamber)**

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

> **Note: These recommendations are consistent with AAMI ST-79 table 5 guidelines and have been validated for use with Onkos Surgical devices and trays. Due to variations in health care user environments and equipment, it remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the reprocessing facility, and achieves sterility. This requires validation and monitoring of the process. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.**

7. Storage

- After sterilization, re-usable instrumentation and single use screw cases/trays should be stored in the sterilization wrap in a dry and dust-free place. The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions and handling. A maximum shelf life for sterilized re-usable instruments before use should be defined by each health care facility.
- Re-usable instrumentation and single use screw cases/trays may be stored between cleaning and sterilization and therefore the devices shall be dried with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet instruments.

Instructions for Use: My3D® Personalized Pelvic Reconstruction

CLEANING & STERILIZATION - PART C

ArthroView® Models
Accura® ClearVue Anatomic Models
DuraForm ProX PA®/3D Printed Plastic Guides

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 orManual	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.

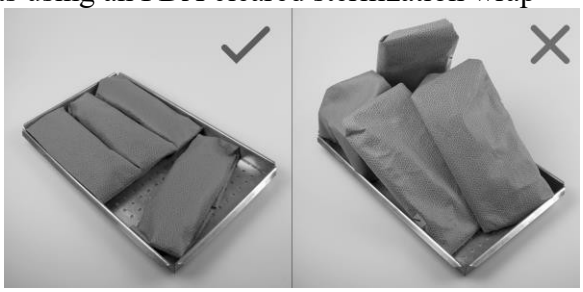
Automated Cleaning Method (Nylon 12 aka DuraForm ProX PA® Only)

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.

Instructions for Use: My3D® Personalized Pelvic Reconstruction

Appendix A: Compatible Prosthetic Components

Manufacturer	Part Number	Description	Material
Microport Orthopedics	7552001000	CANCELLOUS BONE SCREW, 6.5MM DIA x 10MM LENGTH	Ti6Al4V
Microport Orthopedics	7552001500	CANCELLOUS BONE SCREW, 6.5MM DIA x 15MM LENGTH	Ti6Al4V
Microport Orthopedics	7552002000	CANCELLOUS BONE SCREW, 6.5MM DIA x 20MM LENGTH	Ti6Al4V
Microport Orthopedics	7552002500	CANCELLOUS BONE SCREW, 6.5MM DIA x 25MM LENGTH	Ti6Al4V
Microport Orthopedics	7552003000	CANCELLOUS BONE SCREW, 6.5MM DIA x 30MM LENGTH	Ti6Al4V
Microport Orthopedics	7552003500	CANCELLOUS BONE SCREW, 6.5MM DIA x 35MM LENGTH	Ti6Al4V
Microport Orthopedics	7552004000	CANCELLOUS BONE SCREW, 6.5MM DIA x 40MM LENGTH	Ti6Al4V
Microport Orthopedics	7552004500	CANCELLOUS BONE SCREW, 6.5MM DIA x 45MM LENGTH	Ti6Al4V
Microport Orthopedics	7552005000	CANCELLOUS BONE SCREW, 6.5MM DIA x 50MM LENGTH	Ti6Al4V
Microport Orthopedics	7552005500	CANCELLOUS BONE SCREW, 6.5MM DIA x 55MM LENGTH	Ti6Al4V
Microport Orthopedics	7552006000	CANCELLOUS BONE SCREW, 6.5MM DIA x 60MM LENGTH	Ti6Al4V
Microport Orthopedics	7552006500	CANCELLOUS BONE SCREW, 6.5MM DIA x 65MM LENGTH	Ti6Al4V
Microport Orthopedics	7552007000	CANCELLOUS BONE SCREW, 6.5MM DIA x 70MM LENGTH	Ti6Al4V
Microport Orthopedics	7552007500	CANCELLOUS BONE SCREW, 6.5MM DIA x 75MM LENGTH	Ti6Al4V
Microport Orthopedics	7552008000	CANCELLOUS BONE SCREW, 6.5MM DIA x 80MM LENGTH	Ti6Al4V
Smith and Nephew	75018955	Smith and Nephew POLARCUP XLPE Insert Ø28MM ID SIZE47MM	XLPE
Smith and Nephew	75018956	Smith and Nephew POLARCUP XLPE Insert Ø28MM ID SIZE49MM	XLPE
Smith and Nephew	75018957	Smith and Nephew POLARCUP XLPE Insert Ø28MM ID SIZE51MM	XLPE
Smith and Nephew	75018958	Smith and Nephew POLARCUP XLPE Insert Ø28MM ID SIZE53MM	XLPE
Smith and Nephew	75018959	Smith and Nephew POLARCUP XLPE Insert Ø28MM ID SIZE55MM	XLPE
Smith and Nephew	75018960	Smith and Nephew POLARCUP XLPE Insert Ø28MM ID SIZE57MM	XLPE
Smith and Nephew	75018961	Smith and Nephew POLARCUP XLPE Insert Ø28MM ID SIZE59MM	XLPE
Smith and Nephew	75018962	Smith and Nephew POLARCUP XLPE Insert Ø28MM ID SIZE61MM	XLPE
Smith and Nephew	75018942	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE43MM	XLPE

Instructions for Use: My3D® Personalized Pelvic Reconstruction

Manufacturer	Part Number	Description	Material
Smith and Nephew	75018943	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE45MM	XLPE
Smith and Nephew	75018944	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE47MM	XLPE
Smith and Nephew	75018945	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE49MM	XLPE
Smith and Nephew	75018946	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE51MM	XLPE
Smith and Nephew	75018947	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE53MM	XLPE
Smith and Nephew	75018948	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE55MM	XLPE
Smith and Nephew	75018949	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE57MM	XLPE
Smith and Nephew	75018950	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE59MM	XLPE
Smith and Nephew	75018951	Smith and Nephew POLARCUP XLPE Insert Ø22MM ID SIZE61MM	XLPE
Smith and Nephew	75100451	POLARCUP Cemented Stainless Steel 43MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75100452	POLARCUP Cemented Stainless Steel 45MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75100453	POLARCUP Cemented Stainless Steel 47MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75100454	POLARCUP Cemented Stainless Steel 49MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75100455	POLARCUP Cemented Stainless Steel 51MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75100456	POLARCUP Cemented Stainless Steel 53MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75100457	POLARCUP Cemented Stainless Steel 55MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75100458	POLARCUP Cemented Stainless Steel 57MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75100459	POLARCUP Cemented Stainless Steel 59MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75100460	POLARCUP Cemented Stainless Steel 61MM OD	Stainless Steel per- ISO 5832-9/ ASTM F1586
Smith and Nephew	75018400	POLARSTEM - Stem Std. Ti/HA with Collar, Size 0	Ti/HA
Smith and Nephew	75018401	POLARSTEM - Stem Std. Ti/HA with Collar, Size 1	Ti/HA
Smith and Nephew	75018402	POLARSTEM - Stem Std. Ti/HA with Collar, Size 2	Ti/HA
Smith and Nephew	75018403	POLARSTEM - Stem Std. Ti/HA with Collar, Size 3	Ti/HA
Smith and Nephew	75018404	POLARSTEM - Stem Std. Ti/HA with Collar, Size 4	Ti/HA
Smith and Nephew	75018405	POLARSTEM - Stem Std. Ti/HA with Collar, Size 5	Ti/HA
Smith and Nephew	75018406	POLARSTEM - Stem Std. Ti/HA with Collar, Size 6	Ti/HA
Smith and Nephew	75018407	POLARSTEM - Stem Std. Ti/HA with Collar, Size 7	Ti/HA
Smith and Nephew	75018408	POLARSTEM - Stem Std. Ti/HA with Collar, Size 8	Ti/HA
Smith and Nephew	75018409	POLARSTEM - Stem Std. Ti/HA with Collar, Size 9	Ti/HA

Manufacturer	Part Number	Description	Material
Smith and Nephew	75018410	POLARSTEM - Stem Std. Ti/HA with Collar, Size 10	Ti/HA
Smith and Nephew	75018411	POLARSTEM - Stem Std. Ti/HA with Collar, Size 11	Ti/HA
Smith and Nephew	75018412	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 1	Ti/HA
Smith and Nephew	75018413	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 2	Ti/HA
Smith and Nephew	75018414	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 3	Ti/HA
Smith and Nephew	75018415	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 4	Ti/HA
Smith and Nephew	75018416	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 5	Ti/HA
Smith and Nephew	75018417	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 6	Ti/HA
Smith and Nephew	75018418	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 7	Ti/HA
Smith and Nephew	75018419	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 8	Ti/HA
Smith and Nephew	75100463	POLARSTEM - Stem Standard with Ti/HA , Size 0	Ti/HA
Smith and Nephew	75100464	POLARSTEM - Stem Standard with Ti/HA , Size 1	Ti/HA
Smith and Nephew	75100465	POLARSTEM - Stem Standard with Ti/HA , Size 2	Ti/HA
Smith and Nephew	75100466	POLARSTEM - Stem Standard with Ti/HA , Size 3	Ti/HA
Smith and Nephew	75100467	POLARSTEM - Stem Standard with Ti/HA , Size 4	Ti/HA
Smith and Nephew	75100468	POLARSTEM - Stem Standard with Ti/HA , Size 5	Ti/HA
Smith and Nephew	75100469	POLARSTEM - Stem Standard with Ti/HA , Size 6	Ti/HA
Smith and Nephew	75100470	POLARSTEM - Stem Standard with Ti/HA , Size 7	Ti/HA
Smith and Nephew	75100471	POLARSTEM - Stem Standard with Ti/HA , Size 8	Ti/HA
Smith and Nephew	75100472	POLARSTEM - Stem Standard with Ti/HA , Size 9	Ti/HA
Smith and Nephew	75100473	POLARSTEM - Stem Standard with Ti/HA , Size 10	Ti/HA
Smith and Nephew	75100474	POLARSTEM - Stem Lateral with Ti/HA , Size 1	Ti/HA
Smith and Nephew	75100475	POLARSTEM - Stem Lateral with Ti/HA , Size 2	Ti/HA
Smith and Nephew	75100476	POLARSTEM - Stem Lateral with Ti/HA , Size 3	Ti/HA
Smith and Nephew	75100477	POLARSTEM - Stem Lateral with Ti/HA , Size 4	Ti/HA
Smith and Nephew	75100478	POLARSTEM - Stem Lateral with Ti/HA , Size 5	Ti/HA
Smith and Nephew	75100479	POLARSTEM - Stem Lateral with Ti/HA , Size 6	Ti/HA
Smith and Nephew	75100480	POLARSTEM - Stem Lateral with Ti/HA , Size 7	Ti/HA
Smith and Nephew	75100481	POLARSTEM - Stem Lateral with Ti/HA , Size 8	Ti/HA
Smith and Nephew	75100482	POLARSTEM - Stem Lateral with Ti/HA , Size 9	Ti/HA
Smith and Nephew	75100483	POLARSTEM - Stem Lateral with Ti/HA , Size 10	Ti/HA
Smith and Nephew	75100509	POLARSTEM - Stem Standard with Ti/HA , Size 11	Ti/HA
Smith and Nephew	75100510	POLARSTEM - Stem Lateral with Ti/HA , Size 11	Ti/HA
Smith and Nephew	75102072	POLARSTEM - Stem Valgus with Ti/HA , Size 0	Ti/HA
Smith and Nephew	75102073	POLARSTEM - Stem Valgus with Ti/HA , Size 1	Ti/HA
Smith and Nephew	75102074	POLARSTEM - Stem Valgus with Ti/HA , Size 2	Ti/HA
Smith and Nephew	75102075	POLARSTEM - Stem Valgus with Ti/HA , Size 3	Ti/HA
Smith and Nephew	75102076	POLARSTEM - Stem Valgus with Ti/HA , Size 4	Ti/HA
Smith and Nephew	75102077	POLARSTEM - Stem Valgus with Ti/HA , Size 5	Ti/HA
Smith and Nephew	75102078	POLARSTEM - Stem Valgus with Ti/HA , Size 6	Ti/HA
Smith and Nephew	75102079	POLARSTEM - Stem Valgus with Ti/HA , Size 7	Ti/HA
Smith and Nephew	75102209	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 9	Ti/HA
Smith and Nephew	75102210	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 10	Ti/HA

Manufacturer	Part Number	Description	Material
Smith and Nephew	75102211	POLARSTEM - Stem Lat. Ti/HA with Collar, Size 11	Ti/HA
Smith and Nephew	71354461	REDAPT SLVLS MONO STEM 190MM SZ 12 SO	Ti
Smith and Nephew	71354462	REDAPT SLVLS MONO STEM 190MM SZ 13 SO	Ti
Smith and Nephew	71354463	REDAPT SLVLS MONO STEM 190MM SZ 14 SO	Ti
Smith and Nephew	71354464	REDAPT SLVLS MONO STEM 190MM SZ 15 SO	Ti
Smith and Nephew	71354465	REDAPT SLVLS MONO STEM 190MM SZ 16 SO	Ti
Smith and Nephew	71354466	REDAPT SLVLS MONO STEM 190MM SZ 17 SO	Ti
Smith and Nephew	71354467	REDAPT SLVLS MONO STEM 190MM SZ 18 SO	Ti
Smith and Nephew	71354468	REDAPT SLVLS MONO STEM 190MM SZ 19 SO	Ti
Smith and Nephew	71354469	REDAPT SLVLS MONO STEM 190MM SZ 20 SO	Ti
Smith and Nephew	71354471	REDAPT SLVLS MONO STEM 190MM SZ 21 SO	Ti
Smith and Nephew	71354478	REDAPT SLVLS MONO STEM 190MM SZ 12 HO	Ti
Smith and Nephew	71354479	REDAPT SLVLS MONO STEM 190MM SZ 13 HO	Ti
Smith and Nephew	71354481	REDAPT SLVLS MONO STEM 190MM SZ 14 HO	Ti
Smith and Nephew	71354482	REDAPT SLVLS MONO STEM 190MM SZ 15 HO	Ti
Smith and Nephew	71354483	REDAPT SLVLS MONO STEM 190MM SZ 16 HO	Ti
Smith and Nephew	71354484	REDAPT SLVLS MONO STEM 190MM SZ 17 HO	Ti
Smith and Nephew	71354485	REDAPT SLVLS MONO STEM 190MM SZ 18 HO	Ti
Smith and Nephew	71354486	REDAPT SLVLS MONO STEM 190MM SZ 19 HO	Ti
Smith and Nephew	71354487	REDAPT SLVLS MONO STEM 190MM SZ 20 HO	Ti
Smith and Nephew	71354488	REDAPT SLVLS MONO STEM 190MM SZ 21 HO	Ti
Smith and Nephew	71354701	REDAPT SLVLS MONO STEM 240MM SZ 12 SO	Ti
Smith and Nephew	71354702	REDAPT SLVLS MONO STEM 240MM SZ 13 SO	Ti
Smith and Nephew	71354703	REDAPT SLVLS MONO STEM 240MM SZ 14 SO	Ti
Smith and Nephew	71354704	REDAPT SLVLS MONO STEM 240MM SZ 15 SO	Ti
Smith and Nephew	71354705	REDAPT SLVLS MONO STEM 240MM SZ 16 SO	Ti
Smith and Nephew	71354706	REDAPT SLVLS MONO STEM 240MM SZ 17 SO	Ti
Smith and Nephew	71354707	REDAPT SLVLS MONO STEM 240MM SZ 18 SO	Ti
Smith and Nephew	71354708	REDAPT SLVLS MONO STEM 240MM SZ 19 SO	Ti
Smith and Nephew	71354709	REDAPT SLVLS MONO STEM 240MM SZ 20 SO	Ti
Smith and Nephew	71354711	REDAPT SLVLS MONO STEM 240MM SZ 21 SO	Ti
Smith and Nephew	71354712	REDAPT SLVLS MONO STEM 240MM SZ 22 SO	Ti
Smith and Nephew	71354713	REDAPT SLVLS MONO STEM 240MM SZ 23 SO	Ti
Smith and Nephew	71354714	REDAPT SLVLS MONO STEM 240MM SZ 24 SO	Ti
Smith and Nephew	71354715	REDAPT SLVLS MONO STEM 240MM SZ 25 SO	Ti
Smith and Nephew	71354716	REDAPT SLVLS MONO STEM 240MM SZ 26 SO	Ti
Smith and Nephew	71354717	REDAPT SLVLS MONO STEM 240MM SZ 27 SO	Ti
Smith and Nephew	71354718	REDAPT SLVLS MONO STEM 240MM SZ 12 HO	Ti
Smith and Nephew	71354719	REDAPT SLVLS MONO STEM 240MM SZ 13 HO	Ti
Smith and Nephew	71354721	REDAPT SLVLS MONO STEM 240MM SZ 14 HO	Ti
Smith and Nephew	71354722	REDAPT SLVLS MONO STEM 240MM SZ 15 HO	Ti
Smith and Nephew	71354723	REDAPT SLVLS MONO STEM 240MM SZ 16 HO	Ti
Smith and Nephew	71354724	REDAPT SLVLS MONO STEM 240MM SZ 17 HO	Ti

Manufacturer	Part Number	Description	Material
Smith and Nephew	71354725	REDAPT SLVLS MONO STEM 240MM SZ 18 HO	Ti
Smith and Nephew	71354726	REDAPT SLVLS MONO STEM 240MM SZ 19 HO	Ti
Smith and Nephew	71354727	REDAPT SLVLS MONO STEM 240MM SZ 20 HO	Ti
Smith and Nephew	71354728	REDAPT SLVLS MONO STEM 240MM SZ 21 HO	Ti
Smith and Nephew	71354729	REDAPT SLVLS MONO STEM 240MM SZ 22 HO	Ti
Smith and Nephew	71354731	REDAPT SLVLS MONO STEM 240MM SZ 23 HO	Ti
Smith and Nephew	71354732	REDAPT SLVLS MONO STEM 240MM SZ 24 H0	Ti
Smith and Nephew	71354733	REDAPT SLVLS MONO STEM 240MM SZ 25 HO	Ti
Smith and Nephew	71354734	REDAPT SLVLS MONO STEM 240MM SZ 26 H0	Ti
Smith and Nephew	71354735	REDAPT SLVLS MONO STEM 240MM SZ 27 H0	Ti
Smith and Nephew	71354736	REDAPT SLVLS MONO STEM 300MM SZ 12 SO	Ti
Smith and Nephew	71354737	REDAPT SLVLS MONO STEM 300MM SZ 13 SO	Ti
Smith and Nephew	71354738	REDAPT SLVLS MONO STEM 300MM SZ14 SO	Ti
Smith and Nephew	71354739	REDAPT SLVLS MONO STEM 300MM SZ 15 SO	Ti
Smith and Nephew	71354741	REDAPT SLVLS MONO STEM 300MM SZ 16 SO	Ti
Smith and Nephew	71354742	REDAPT SLVLS MONO STEM 300MM SZ 17 SO	Ti
Smith and Nephew	71354743	REDAPT SLVLS MONO STEM 300MM SZ 18 SO	Ti
Smith and Nephew	71354744	REDAPT SLVLS MONO STEM 300MM SZ 19 SO	Ti
Smith and Nephew	71354745	REDAPT SLVLS MONO STEM 300MM SZ 20 SO	Ti
Smith and Nephew	71354746	REDAPT SLVLS MONO STEM 300MM SZ 21 SO	Ti
Smith and Nephew	71354747	REDAPT SLVLS MONO STEM 300MM SZ 22 SO	Ti
Smith and Nephew	71354748	REDAPT SLVLS MONO STEM 300MM SZ 23 SO	Ti
Smith and Nephew	71354749	REDAPT SLVLS MONO STEM 300MM SZ 24 SO	Ti
Smith and Nephew	71354751	REDAPT SLVLS MONO STEM 300MM SZ 25 SO	Ti
Smith and Nephew	71354752	REDAPT SLVLS MONO STEM 300MM SZ 26 SO	Ti
Smith and Nephew	71354753	REDAPT SLVLS MONO STEM 300MM SZ 27 SO	Ti
Smith and Nephew	71354754	REDAPT SLVLS MONO STEM 300MM SZ 12 HO	Ti
Smith and Nephew	71354755	REDAPT SLVLS MONO STEM 300MM SZ 13 HO	Ti
Smith and Nephew	71354756	REDAPT SLVLS MONO STEM 300MM SZ 14 HO	Ti
Smith and Nephew	71354757	REDAPT SLVLS MONO STEM 300MM SZ 15 HO	Ti
Smith and Nephew	71354758	REDAPT SLVLS MONO STEM 300MM SZ 16 HO	Ti
Smith and Nephew	71354759	REDAPT SLVLS MONO STEM 300MM SZ 17 HO	Ti
Smith and Nephew	71354761	REDAPT SLVLS MONO STEM 300MM SZ 18 HO	Ti
Smith and Nephew	71354762	REDAPT SLVLS MONO STEM 300MM SZ 19 HO	Ti
Smith and Nephew	71354763	REDAPT SLVLS MONO STEM 300MM SZ 20 HO	Ti
Smith and Nephew	71354764	REDAPT SLVLS MONO STEM 300MM SZ 21 HO	Ti
Smith and Nephew	71354765	REDAPT SLVLS MONO STEM 300MM SZ 22 HO	Ti
Smith and Nephew	71354766	REDAPT SLVLS MONO STEM 300MM SZ 23 HO	Ti
Smith and Nephew	71354767	REDAPT SLVLS MONO STEM 300MM SZ 24 HO	Ti
Smith and Nephew	71354768	REDAPT SLVLS MONO STEM 300MM SZ 25 HO	Ti
Smith and Nephew	71354769	REDAPT SLVLS MONO STEM 300MM SZ 26 HO	Ti
Smith and Nephew	71354771	REDAPT SLVLS MONO STEM 300MM SZ 27 HO	Ti
Smith and Nephew	71354801	REDAPT SLVD MONO STEM 240MM SZ 12 SO	Ti

Manufacturer	Part Number	Description	Material
Smith and Nephew	71354802	REDAPT SLVD MONO STEM 240MM SZ 13 SO	Ti
Smith and Nephew	71354803	REDAPT SLVD MONO STEM 240MM SZ 14 SO	Ti
Smith and Nephew	71354804	REDAPT SLVD MONO STEM 240MM SZ 15 SO	Ti
Smith and Nephew	71354805	REDAPT SLVD MONO STEM 240MM SZ 16 SO	Ti
Smith and Nephew	71354806	REDAPT SLVD MONO STEM 240MM SZ 17 SO	Ti
Smith and Nephew	71354807	REDAPT SLVD MONO STEM 240MM SZ 18 SO	Ti
Smith and Nephew	71354808	REDAPT SLVD MONO STEM 240MM SZ 19 SO	Ti
Smith and Nephew	71354809	REDAPT SLVD MONO STEM 240MM SZ 20 SO	Ti
Smith and Nephew	71354811	REDAPT SLVD MONO STEM 240MM SZ 21 SO	Ti
Smith and Nephew	71354812	REDAPT SLVD MONO STEM 240MM SZ 22 SO	Ti
Smith and Nephew	71354813	REDAPT SLVD MONO STEM 240MM SZ 23 SO	Ti
Smith and Nephew	71354814	REDAPT SLVD MONO STEM 240MM SZ 24 SO	Ti
Smith and Nephew	71354815	REDAPT SLVD MONO STEM 240MM SZ 25 SO	Ti
Smith and Nephew	71354816	REDAPT SLVD MONO STEM 240MM SZ 26 SO	Ti
Smith and Nephew	71354817	REDAPT SLVD MONO STEM 240MM SZ 27 SO	Ti
Smith and Nephew	71354818	REDAPT SLVD MONO STEM 240MM SZ 12 HO	Ti
Smith and Nephew	71354819	REDAPT SLVD MONO STEM 240MM SZ 13 HO	Ti
Smith and Nephew	71354821	REDAPT SLVD MONO STEM 240MM SZ 14 HO	Ti
Smith and Nephew	71354822	REDAPT SLVD MONO STEM 240MM SZ 15 HO	Ti
Smith and Nephew	71354823	REDAPT SLVD MONO STEM 240MM SZ 16 HO	Ti
Smith and Nephew	71354824	REDAPT SLVD MONO STEM 240MM SZ 17 HO	Ti
Smith and Nephew	71354825	REDAPT SLVD MONO STEM 240MM SZ 18 HO	Ti
Smith and Nephew	71354826	REDAPT SLVD MONO STEM 240MM SZ 19 HO	Ti
Smith and Nephew	71354827	REDAPT SLVD MONO STEM 240MM SZ 20 HO	Ti
Smith and Nephew	71354828	REDAPT SLVD MONO STEM 240MM SZ 21 HO	Ti
Smith and Nephew	71354829	REDAPT SLVD MONO STEM 240MM SZ 22 HO	Ti
Smith and Nephew	71354831	REDAPT SLVD MONO STEM 240MM SZ 23 HO	Ti
Smith and Nephew	71354832	REDAPT SLVD MONO STEM 240MM SZ 24 HO	Ti
Smith and Nephew	71354833	REDAPT SLVD MONO STEM 240MM SZ 25 HO	Ti
Smith and Nephew	71354834	REDAPT SLVD MONO STEM 240MM SZ 26 HO	Ti
Smith and Nephew	71354835	REDAPT SLVD MONO STEM 240MM SZ 27 HO	Ti
Smith and Nephew	71354836	REDAPT SLVD MONO STEM 300MM SZ 12 SO	Ti
Smith and Nephew	71354837	REDAPT SLVD MONO STEM 300MM SZ 13 SO	Ti
Smith and Nephew	71354838	REDAPT SLVD MONO STEM 300MM SZ 14 SO	Ti
Smith and Nephew	71354839	REDAPT SLVD MONO STEM 300MM SZ 15 SO	Ti
Smith and Nephew	71354841	REDAPT SLVD MONO STEM 300MM SZ 16 SO	Ti
Smith and Nephew	71354842	REDAPT SLVD MONO STEM 300MM SZ 17 SO	Ti
Smith and Nephew	71354843	REDAPT SLVD MONO STEM 300MM SZ 18 SO	Ti
Smith and Nephew	71354844	REDAPT SLVD MONO STEM 300MM SZ 19 SO	Ti
Smith and Nephew	71354845	REDAPT SLVD MONO STEM 300MM SZ 20 SO	Ti
Smith and Nephew	71354846	REDAPT SLVD MONO STEM 300MM SZ 21 SO	Ti
Smith and Nephew	71354847	REDAPT SLVD MONO STEM 300MM SZ 22 SO	Ti
Smith and Nephew	71354848	REDAPT SLVD MONO STEM 300MM SZ 23 SO	Ti

Manufacturer	Part Number	Description	Material
Smith and Nephew	71354849	REDAPT SLVD MONO STEM 300MM SZ 24 SO	Ti
Smith and Nephew	71354851	REDAPT SLVD MONO STEM 300MM SZ 25 SO	Ti
Smith and Nephew	71354852	REDAPT SLVD MONO STEM 300MM SZ 26 SO	Ti
Smith and Nephew	71354853	REDAPT SLVD MONO STEM 300MM SZ 27 SO	Ti
Smith and Nephew	71354854	REDAPT SLVD MONO STEM 300MM SZ 12 HO	Ti
Smith and Nephew	71354855	REDAPT SLVD MONO STEM 300MM SZ 13 HO	Ti
Smith and Nephew	71354856	REDAPT SLVD MONO STEM 300MM SZ 14 HO	Ti
Smith and Nephew	71354857	REDAPT SLVD MONO STEM 300MM SZ 15 HO	Ti
Smith and Nephew	71354858	REDAPT SLVD MONO STEM 300MM SZ 16 HO	Ti
Smith and Nephew	71354859	REDAPT SLVD MONO STEM 300MM SZ 17 HO	Ti
Smith and Nephew	71354861	REDAPT SLVD MONO STEM 300MM SZ 18 HO	Ti
Smith and Nephew	71354862	REDAPT SLVD MONO STEM 300MM SZ 19 HO	Ti
Smith and Nephew	71354863	REDAPT SLVD MONO STEM 300MM SZ 20 HO	Ti
Smith and Nephew	71354864	REDAPT SLVD MONO STEM 300MM SZ 21 HO	Ti
Smith and Nephew	71354865	REDAPT SLVD MONO STEM 300MM SZ 22 HO	Ti
Smith and Nephew	71354866	REDAPT SLVD MONO STEM 300MM SZ 23 HO	Ti
Smith and Nephew	71354867	REDAPT SLVD MONO STEM 300MM SZ 24 HO	Ti
Smith and Nephew	71354868	REDAPT SLVD MONO STEM 300MM SZ 25 HO	Ti
Smith and Nephew	71354869	REDAPT SLVD MONO STEM 300MM SZ 26 HO	Ti
Smith and Nephew	71354871	REDAPT SLVD MONO STEM 300MM SZ 27 HO	Ti
Smith and Nephew	71342800	OXINIUM FEM HD 12/14 28MM +0	OXINIUM
Smith and Nephew	71342804	OXINIUM FEM HD 12/14 28MM +4	OXINIUM
Smith and Nephew	71342808	OXINIUM FEM HD 12/14 28MM +8	OXINIUM
Smith and Nephew	71302200	COCR 12/14 FEM HEAD 22 + 0	CoCr per ASTM F799
Smith and Nephew	71302204	COCR 12/14 FEM HEAD 22 + 4	CoCr per ASTM F799
Smith and Nephew	71302803	COCR 12/14 FEM HEAD 28 -3	CoCr per ASTM F799
Smith and Nephew	71302800	COCR 12/14 FEM HEAD 28 +0	CoCr per ASTM F799
Smith and Nephew	71302804	COCR 12/14 FEM HEAD 28 + 4	CoCr per ASTM F799
Smith and Nephew	71302808	COCR 12/14 FEM HEAD 28 + 8	CoCr per ASTM F799