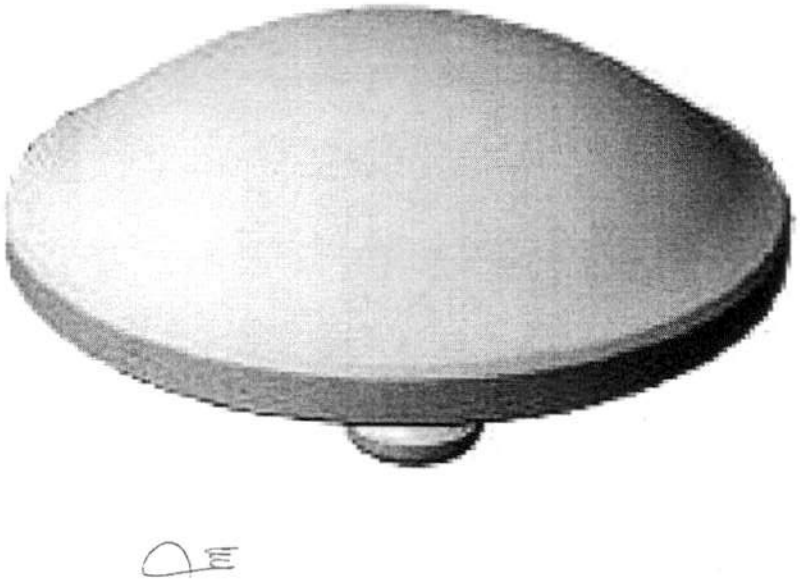
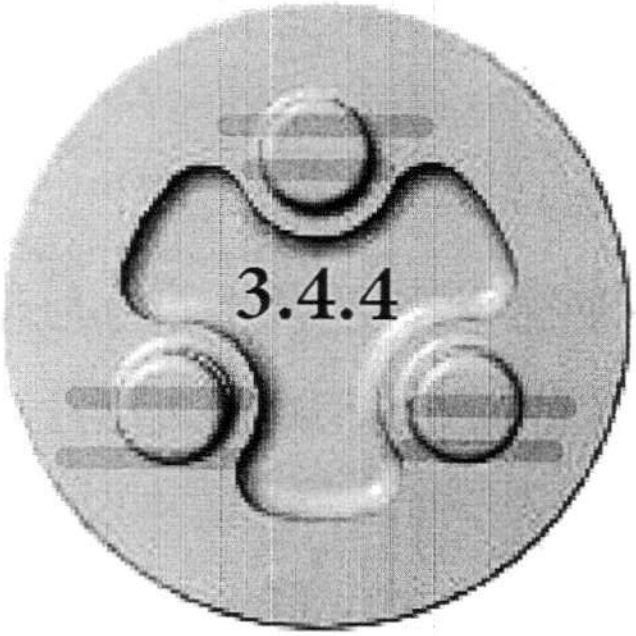
3.3 , 3.3.1

Catalog #	Description	Size
5532-P-509	PS Tibial Insert	# 5 - 9mm
5532-P-511	PS Tibial Insert	# 5 - 11mm
5532-P-513	PS Tibial Insert	# 5 - 13mm
5532-P-516	PS Tibial Insert	# 5 - 16mm
5532-P-519	PS Tibial Insert	# 5 - 19mm
5532-P-522	PS Tibial Insert	# 5 - 22mm
5532-P-525	PS Tibial Insert	# 5 - 25mm
5532-P-609	PS Tibial Insert	# 6 - 9mm
5532-P-611	PS Tibial Insert	# 6 - 11mm
5532-P-613	PS Tibial Insert	# 6 - 13mm
5532-P-616	PS Tibial Insert	# 6 - 16mm
5532-P-619	PS Tibial Insert	# 6 - 19mm
5532-P-622	PS Tibial Insert	# 6 - 22mm
5532-P-625	PS Tibial Insert	# 6 - 25mm

Catalog #	Description	Size
5532-P-709	PS Tibial Insert	# 7 - 9mm
5532-P-711	PS Tibial Insert	# 7 - 11mm
5532-P-713	PS Tibial Insert	# 7 - 13mm
5532-P-716	PS Tibial Insert	# 7 - 16mm
5532-P-719	PS Tibial Insert	# 7 - 19mm
5532-P-722	PS Tibial Insert	# 7 - 22mm
5532-P-725	PS Tibial Insert	# 7 - 25mm
5532-P-809	PS Tibial Insert	# 8 - 9mm
5532-P-811	PS Tibial Insert	# 8 - 11mm
5532-P-813	PS Tibial Insert	# 8 - 13mm
5532-P-816	PS Tibial Insert	# 8 - 16mm
5532-P-819	PS Tibial Insert	# 8 - 19mm
5532-P-822	PS Tibial Insert	# 8 - 22mm
5532-P-825	PS Tibial Insert	# 8 - 25mm

3.4





Catalog #	Description

Symmetric Patella Part Numbers

5550-L-278	Symmetric Patella S27mm x 8mm
5550-L-298	Symmetric Patella S29mm x 8mm
5550-L-319	Symmetric Patella S31mm x 9mm
5550-L-339	Symmetric Patella S33mm x 9mm
5550-L-360	Symmetric Patella S36mm x 10mm
5550-L-391	Symmetric Patella S39mm x 11mm

Symmetric Patella - X3 Part Numbers 3.4.3

5550-G-278	Symmetric Patella - X3 - S27mm x 8mm
5550-G-298	Symmetric Patella - X3 - S29mm x 8mm
5550-G-319	Symmetric Patella - X3 - S31mm x 9mm
5550-G-339	Symmetric Patella - X3 - S33mm x 9mm
5550-G-360	Symmetric Patella - X3 - S36mm x 10mm
5550-G-391	Symmetric Patella - X3 - S39mm x 11mm

Asymmetric Patella Part Numbers

5551-L-299	Asymmetric Patella A29mm (S/I*) x 9mm
5551-L-320	Asymmetric Patella A32mm (S/I*) x 10mm
5551-L-350	Asymmetric Patella A35mm (S/I*) x 10mm
5551-L-381	Asymmetric Patella A38mm (S/I*) x 11mm
5551-L-401	Asymmetric Patella A40mm (S/I*) x 11mm

Asymmetric Patella - X3 Part Numbers

5551-G-299	Asymmetric Patella - X3 - A29mm (S/I*) x 9mm
5551-G-320	Asymmetric Patella - X3 - A32mm (S/I*) x 10mm
5551-G-350	Asymmetric Patella - X3 - A35mm (S/I*) x 10mm
5551-G-381	Asymmetric Patella - X3 - A38mm (S/I*) x 11mm
5551-G-401	Asymmetric Patella - X3 - A40mm (S/I*) x 11mm

Modular Femoral Distal Fixation Peg Part Number

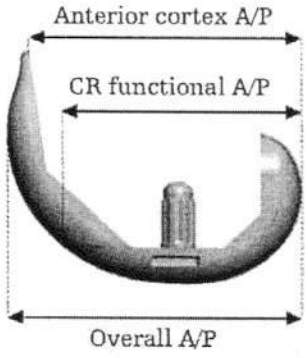
5575-X-000	Modular Femoral Distal Fixation Peg (2 per pack)

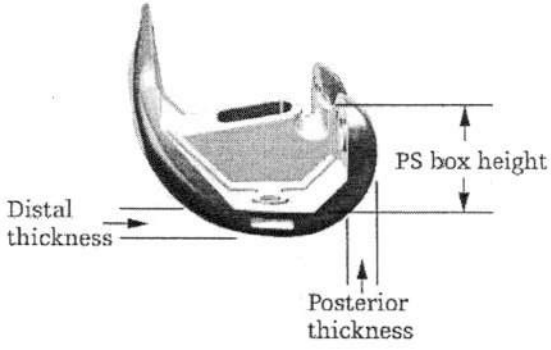
* S/I = Superior/Inferior

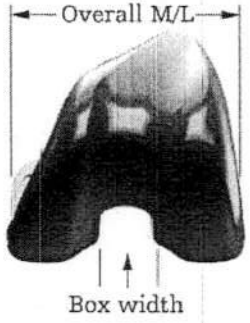
Size

Component and size offering							
Femur	Left/Right, 8 sizes, Size 1-8 3.1.3						
Tibia	8 sizes, Size 1-8 3.2.3						
Insert	CR: 9, 10, 11, 12, 13, 14, 16, 19 CS: 9, 10, 11, 12, 13, 14, 16, 19, 22, 25 PS: 9, 10, 11, 12, 13, 14, 16, 19, 22, 25 TS: 9, 11, 13, 16, 19, 22, 25, 28, 31						
All-Polyethylene Tibia	8 sizes, Size 1-8 9,11,13,16 thickness for CS and PS						
Symmetric Patella 3.4.3		S27 × 8	S29 × 8	S31 × 9	S33 × 9	S36 × 10	S39 × 11
	All-Poly	√	√	√	√	√	√
	Tritanium	–	–	√	√	√	√
Asymmetric Patella		–	A29 × 9	A32 × 10	A35 × 10	A38 × 11	A40 × 11
	All-Poly	–	√	√	√	√	√
	Tritanium	–	√	√	√	√	√
	Beaded PA	–	–	√	√	√	√

Note: Thickness for tibial inserts, all-polyethylene tibiae and patellae are in millimeters.





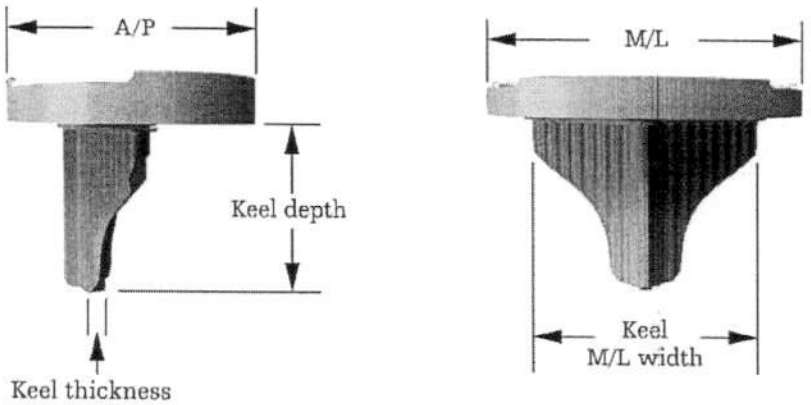


2

Cemented CR and PS Femur | Cementless Beaded PA CR and PS Femur								
3.1.4 Size	1	2	3	4	5	6	7	8
Overall A/P	53	56	59	62	65	68	71	75
Anterior cortex A/P	49	52	54	57	61	64	66	70
Overall M/L	59	62	65	68	71	74	77	80
Posterior thickness	8.5							
Distal thickness	8.5							
Condyle length	32	33	34	35	36	37	38	39
CR functional A/P	45	47	49	50	52	55	56	58
PS box outer width	20.8							
PS box inner width	16.2							
PS box height	20.5							

3.1.4

Note: The bone-facing side of cemented femoral components allows for a cement mantle, and the bone-facing side of cementless femoral components features beads and PA. The beads have peaks and valleys that can protrude out to a maximum of 0.4 mm on a plane. All dimensions are in millimeters.

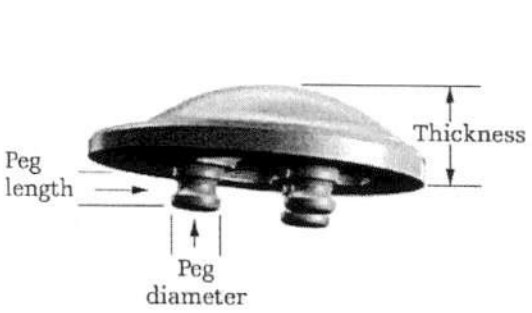


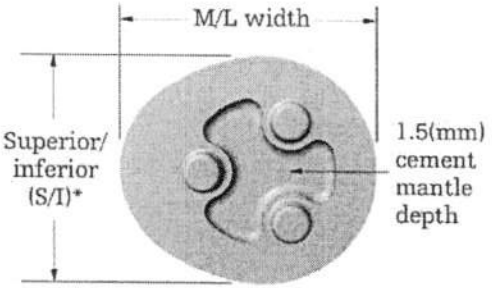
Primary Baseplate |Tritanium Baseplate | Beaded PA Baseplate |Screw-Fixed Baseplate								
3.2.3 Size	1	2	3	4	5	6	7	8
A/P	40	42	44	46	49	52	56	60
M/L	61	64	67	70	74	77	80	85
Keel depth	28	28	28	34	34	34	39	39
Keel M/L width	40	40	40	52	52	52	58	58
Keel thickness	2.6-3.6							

Note: All dimensions are in millimeters.

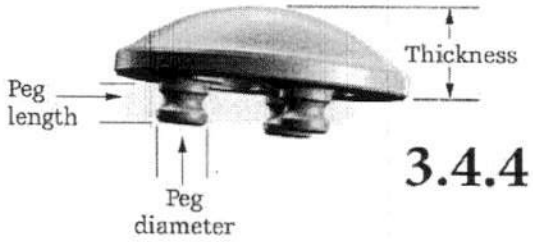
3.4

Asymmetric Patella

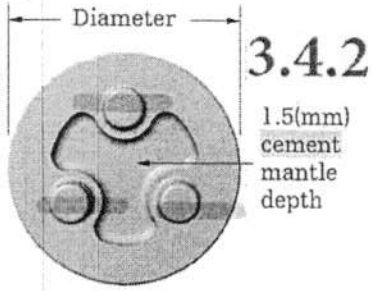




Symmetric Patella



3.4.4



3.4.2

All-Poly Patella dimensions

Asymmetric Patella

Size	A29 × 9	A32 × 10	A35 × 10	A38 × 11	A40 × 11
Superior/inferior (S/I) width	29	32	35	38	40
M/L width	33	36	39	42	44
Thickness	9	10	10	11	11
Peg diameter	5.7				
Peg length					

3.4.3

Symmetric Patella

Size	S27 × 8	S29 × 8	S31 × 9	S33 × 9	S36 × 10	S39 × 11
Patella diameter	27	29	31	33	36	39
Thickness	8	8	9	9	10	11
Peg diameter	5.7					
Peg length	5					

When X3 was developed, we set strict material standards for the product. The patented[2] process for X3 allows for wear resistance while preserving the strength and resistance to oxidative damage.[3,4]

Initially we specified exactly how the material was to be consolidated before treatment, as well as the terminal sterilization. We chose CM as the consolidation method at the outset as CM was considered a reliable method in terms of material consistency. An alternative consolidation method, RE, previously incorporated the additive calcium stearate in the manufacturing process. When calcium stearate was present in the resin, there appeared to be a higher rate of wear-related osteolysis.[5] Advancements in this consolidation method have eliminated the need for the calcium stearate additive. As such, medical device manufacturers have again been turning to this consolidation method[6,11,12] for newer generation polyethylene products. The industry has also started to move to more scalable sterilization methods like Ethylene Oxide (EtO).[6,11,12]

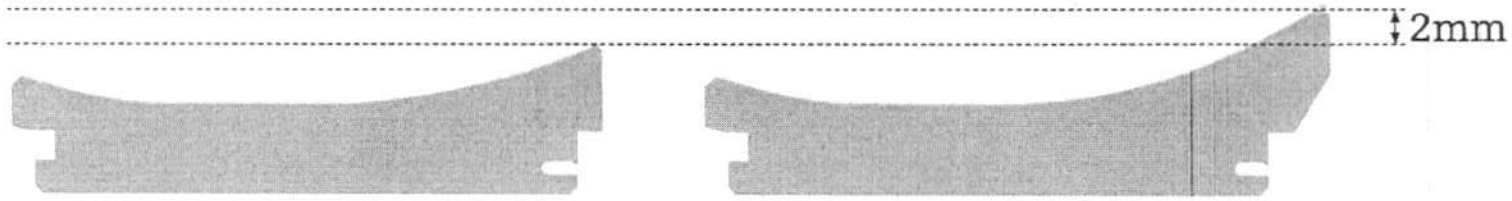
List of consolidation and sterilization methods by company, product, and application[6,11,12]

Company	Product	Resin	Consolidation	Sterilization	Application
DePuy Synthes	Altrx	GUR 1020	RE	GP	Hip
	AOX	GUR 1020	CM	Gamma	Knee
	Marathon	GUR1050	RE	GP	Hip
	XLK	GUR 1020	RE	GP	Knee
Smith & Nephew	XLPE	GUR 1020	CM	EtO	Knee
	XLPE	GUR1050	RE	EtO	Hip
Stryker	Crossfire	GUR 1050	RE	Gamma	Hip
	X3	GUR 1020	CM or RE	GP or Gamma	Knee/Hip
Zimmer Biomet	ArcomXL	GUR 1050	CM	GP	Hip
	Durasul	GUR1050	CM	EtO	Knee/Hip
	E1	GUR 1020/1050	CM	Gamma	Knee/Hip
	Longevity	GUR1050	CM	GP or EtO	Hip
	Prolong	GUR1050	CM	GP	Knee
	Vivacit-E	GUR 1020	CM	EtO	Knee/Hip

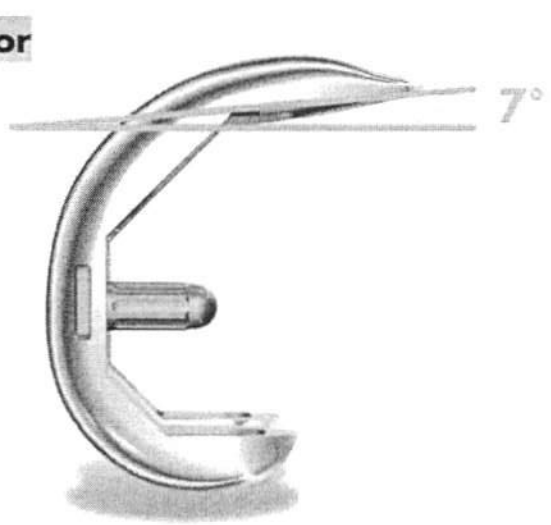
3.4.1

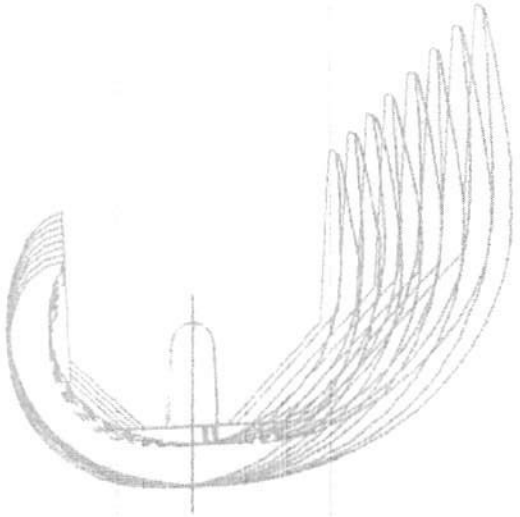
Slope and size incremental

- There is no slope built into CR, CS, PS and TS inserts.
- Triathlon CS insert has approximately 2mm more height in the anterior lip of the insert compared to Triathlon CR.



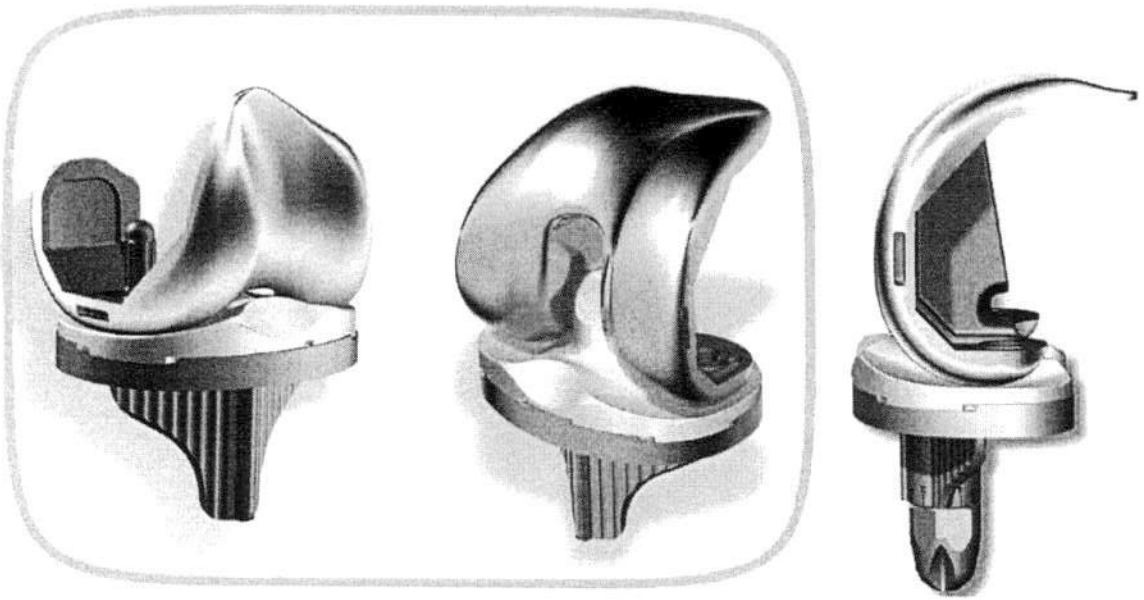
AP dimension increases only anteriorly. For sizes 1-7, size incremental is ≤3mm. For sizes 7-8, size incremental is 4mm.



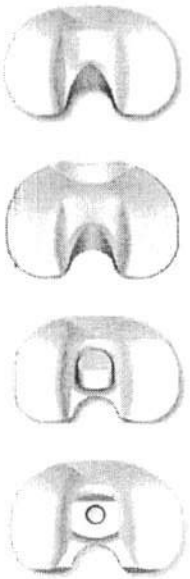


Insert options

3.1.9



3.2.4 , 3.3 , 3.3.3 , 3.3.5



Cruciate Retaining Bearing (CR)

Condylar Stabilized Bearing (CS)

Posterior Stabilized Bearing (PS)

Total Stabilized Bearing* (TS)

*Can only be used with Universal Baseplate

3.3.5

Type	Varus/valgus constraint	Internal/external rotation	Maximum flexion
CR	None	+/- 20°	150°
CS	None	+/- 20°	150°
PS	None	+/- 20°	150°
TS	+/- 2°	+/- 7°	135°

Material

Component	Material	Chemical composition	Weight percentage
3.1 Femoral components, tibial components 3.2	3.1.1 , 3.2.1 Vitallium cobalt chrome alloy conforms to ASTM F75 standard	Nickel (Ni)	0.50 (max.)
		Chromium (Cr)	27.5-28.5
		Carbon (C)	0.20-0.27
		Manganese (Mn)	0.20-0.50
		Phosphorous (P)	0.015 (max.)
		Sulfur (S)	0.01 (max.)
		Silicon (Si)	0.65-0.90
		Molybdenum (Mo)	5.5-6.3
		Iron (Fe)	0.65 (max.)
		Tungsten (W)	0.1 (max.)
		Nitrogen (N)	0.125-0.200
		Oxygen (O)	100 ppm (max.)
		Aluminum (Al)	0.02 (max.)
		Boron (B)	0.01 (max.)
		Cobalt (Co)	Balance

Note: Please refer to Triathlon IFU for more material information.

Material (continued)

Component	Material	Chemical composition	Weight percentage
All-Poly Tibia, All-Poly Patella	3.4 , 3.4.1 UHMWPE		
CR, CS, PS and TS insert (Tibial inserts include locking wire. Please see below for the material composition of insert locking wire)	3.3 , 3.3.2 , 3.3.5 UHMWPE		
Insert locking wire	CoCrWNi alloy conforms to ASTM F90 standard	Nickel (Ni)	9.0-11.0
		Chromium (Cr)	19.0-21.0
		Manganese (Mn)	1.00-2.00
		Phosphorous (P)	0.04 (max.)
		Sulfur (S)	0.03 (max.)
		Silicon (Si)	0.4 (max.)
		Iron (Fe)	3.0 (max.)
		Tungsten (W)	14.0-16.0
		Cobalt (Co)	Balance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2006

4.1

Ms. Tiffani D. Rogers
Specialist, Regulatory Affairs
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K053514
Trade/Device Name: Triathlon® Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: December 15, 2005
Received: December 16, 2005

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman
for

Mark N. Melkerson,
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 Division
D.O.
f/t:PGA:rrr: 1/25/06

510(k) Number (if known): K053514

Device Name: Triathlon® Total Knee System

Indications for Use

General Total Knee Arthroplasty (TKA) Indications

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful uni-knee replacement or other procedure.

Additional Indications for Universal Baseplates and Stem Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Indications for Bone Augments:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful uni-knee replacement or other surgical procedure, accompanied by bone loss.

The Triathlon® Total Knee System components are intended for cemented use only.

Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara C Buch MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053514

bsi.

By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 730261 R000 4.1

Manufacturer: Howmedica Osteonics Corp.

Address:
325 Corporate Drive
Mahwah
New Jersey
07430
USA

Single Registration Number: US-MF-000001881

EU Authorised Representative: Stryker European Operations Ltd.

Address:
Anngrove, IDA Business & Technology Park
Carrigtwohill
County Cork
T45 HX08
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-05-25**

Current Issue Date: **2023-04-04**

Starting Validity Date: **2023-04-04**

Expiry Date: **2026-05-24**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 730261 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	**Intended purpose**
Restoration Anatomic Dual Mobility (ADM) System and Modular Dual Mobility (MDM) System	See MDR 730294
Trident - Crossfire and X3 inserts, and constrained liners	See MDR 730291
Triathlon system (non-coated components)	See MDR 730283
Triathlon system (PA coated components)	See MDR 730285
Accolade II hip stems	See MDR 730270
Exeter® X3® Rimfit® Cup, Exeter® Contemporary™ Flanged Cup, Trident® All Poly Constrained Acetabular Inserts	See MDR 730289
Trident®, Tritanium®, Restoration® and Trident® II Acetabular Shells	See MDR 730277
Cementless Femoral Stems – Restoration Modular & GMRS	See MDR 730275
EXETER® V40™ Femoral Stems	See MDR 730292
ETS Hip Endoprosthesis	See MDR 730293
Triathlon PKR	See MDR 758006
Secur-Fit Advanced, Secur-Fit Max, and Secur-Fit Plus Max hip stems	See MDR 730268

Class IIb, Implantable	**Intended purpose**
Triathlon system (non-coated components)	See MDR 730283

Class IIb, Implantable, Well-established technologies	**Intended purpose**
Knee Prostheses – Augmentation spacers, cones and sleeves	Primary and revision total knee arthroplasty
Knee Prostheses – Accessories - Others	Primary and revision total knee arthroplasty
Hip Prosthesis Augments	Primary and revision total hip arthroplasty
Hip Prosthesis Fixing Screws and Plugs	Primary and revision total hip arthroplasty
Hip Prosthesis Centralizers	Primary and revision partial and total hip arthroplasty
Femoral Intramedullary Caps/Plugs	Primary and revision partial and total hip arthroplasty

First Issue Date: **2021-05-25**

Current Issue Date: **2023-04-04**

Starting Validity Date: **2023-04-04**

Expiry Date: **2026-05-24**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 730261 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Reusable orthopaedic trials	Class IIa
Sterile and non-sterile orthopaedic instruments	Class IIa
Reusable instruments 'Cutting Instruments'	Class Ir
Reusable instruments 'General Surgery Instruments'	Class Ir
Reusable instruments 'Orthopaedic Instruments'	Class Ir
Reusable instruments 'Orthopaedic Instruments'	Class Im, Class Ir
Measurement devices 'Clinical measurement devices'	Class Im, Class Ir
Measurement devices 'Clinical measurement devices'	Class Im
Custom made joint replacements	Custom-made Class III implantable

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

First Issue Date: **2021-05-25**

Current Issue Date: **2023-04-04**

Starting Validity Date: **2023-04-04**

Expiry Date: **2026-05-24**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 730261 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference number	Action
2021-05-25	3320395	Issued
2021-06-22	3220860	Supplemented - Addition of "Trident - crossfire and X3 inserts, and constrained liners to the device schedule. Supplemented – Addition of device categories "Reusable instruments 'Cutting Instruments'" (Class I(r)), "Reusable instruments 'General Surgery Instruments'" (Class I(r)), "Reusable instruments 'Orthopaedic Instruments'" (Class I(r)), "Reusable instruments 'Orthopaedic Instruments'" (Class I(m)/I(r)) and "Measurement devices 'Clinical measurement devices'" (Class I(m)/I(r). Amended – Addition of subcontractor "Isomedix Operations, Inc (South Clifton Avenue)" Update of intended purpose of "Restoration Anatomic Dual Mobility (ADM) System and Modular Dual Mobility (MDM) System" from "Primary and revision total hip arthroplasty" to "See MDR 730294"

First Issue Date: **2021-05-25**

Current Issue Date: **2023-04-04**

Starting Validity Date: **2023-04-04**

Expiry Date: **2026-05-24**

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Date	Reference number	Action
2021-09-03	3505091	Supplemented – Addition of "Triathlon system (non-coated components)" (Class III and Class IIb). Addition of "Triathlon system (PA coated components)". Addition of device groups "Knee Prostheses – Augmentation spacers, cones and sleeves" and "Knee prostheses – Accessories - Others". Amended – Addition of subcontractors "Triangle Manufacturing Company, Inc." and "Caragh Precision" for the activity of "manufacture". Addition of activities "Control of sterilization, Final inspection, Gas plasma sterilization, Packaging" for subcontractor "Howmedica International S de R.L.". Addition of activities "Control of sterilization, Final inspection, Packaging, Surface treatment" for subcontractor "Stryker Ireland Ltd". Amended – Scope "Custom made joint replacements" re-added after erroneous omission at last issue.

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Date	Reference number	Action
2021-11-22	3575652	Supplemented – Addition of "Accolade II hip stems" (Class III) and "Reusable orthopaedic instruments connected to an active device" (Class IIa). Amended – Addition of subcontractors "NGI Instruments, Inc.", "Metal Craft Machine & Engr.", "Oberg Medical Finishing Solutions", "Orchid Unique" and "Symmetry Medical Manufacturing, Inc." for the activity of "manufacture". Addition of subcontractor "Oberg Medical Products Company" for the activities "Manufacture, Final inspection". Amended – Administrative update to device schedule to amend "Class I(r)" to "Class Ir", and "Class I(m)/I(r)" to "Class Im, Class Ir".
2022-01-25	3220854	Supplemented – Addition of "Exeter® X3® Rimfit® Cup, Exeter® Contemporary™ Flanged Cup, Trident® All Poly Constrained Acetabular Inserts" (Class III)
2022-03-08	3622116	Supplemented – Addition of device category "Reusable orthopaedic trials". Amended – Correction of activity for "N2 Biomedical LLC" to "Surface Treatment". Amended – Addition of Subcontractors "Phillips Precision" and "Stryker Suzhou" for activity "Manufacture".

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Date	Reference number	Action
2022-07-11	3659343	Supplemented – Addition of 'Trident®, Tritanium®, Restoration® and Trident® II Acetabular Shells' as Class III Implantable devices Supplemented – Addition of device group 'Hip Prosthesis Augments' as Class IIb Implantable, WET devices Supplemented – Addition of device group 'Hip Prosthesis Fixing Screws and Plugs' as Class IIb Implantable, WET devices Amended – Addition of critical subcontractor "RMS Company" for the activity of "Final Inspection, Manufacture" Amended – Addition of "Stryker Spine Sàrl" for the activity of "Final Inspection, Manufacture" Amended – Addition of critical subcontractor "Croom Precision Medical Ltd" for the activity of "Final Inspection and Manufacture" Amended – Addition of activity "Final Inspection" for subcontractor "NGI Instruments, Inc. dba Avalign Cutting Instruments" Amended – Scope "Exeter® X3® Rimfit® Cup, Exeter® Contemporary™ Flanged Cup,Trident® All Poly Constrained Acetabular Inserts" re-added after erroneous omission at last issue. Amended – correcting spelling error in Device Schedule, from 'Modual Dual Mobility' to 'Modular Dual Mobility'. Amended – correction of date format for all preceding certificate history entries, to align with BSI policy

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