

URGENT FIELD SAFETY NOTICE - Precice IMLL

<u>Date:</u> October 14, 2021

<u>Commercial Name:</u> Precice Intramedullary limb lengthening (IMLL) device system, including the Precice IMLL and Precice Short trade names

Type of Action: Advisory Notice

NuVasive Specialized Orthopedics, Inc. (NSO) voluntarily issues this Field Safety Notice (FSN) to inform healthcare providers of the following, in follow-up from the prior <u>February 2021 Precice</u> <u>FSN</u> and <u>April 2021 - NSO Statement</u> communications:

- In February 2021, NSO informed healthcare providers of gaps in the biological assessments and ongoing additional testing leading to a voluntary removal of Precice Systems devices and recommended user actions.
- In April 2021, NSO alerted healthcare providers to the temporary suspension of the Precice IMLL System Devices CE certificate pending audit of files by DQS Medizinprodukte GmbH (DQS), its notified body, and local regulatory bodies.
- 3. As of 05 October 2021, the CE certificate has been reinstated by DQS. This notice informs users of the immediate availability of the implant along with the following additional information.
- 4. The Precice Intramedullary Limb Lengthening (IMLL) System Instructions for Use (IFU) has been updated and is located at www.nuvasive.com/elFU.

The following are the changes from the prior to the current Precice IMLL system IFU:

IFU Section	Prior IFU Language	Updated IFU Language
Intended Use	The PRECICE Intramedullary Limb Lengthening System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal- unions, non-unions, or bone transport of long bones.	The PRECICE Intramedullary Limb Lengthening System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones in adults.
Warnings	The PRECICE Intramedullary Limb Lengthening System has not been evaluated for biological safety in patients in relation to reproductive	Patients of the PRECICE Intramedullary Limb Lengthening System should not be implanted with more than two devices at a time, and the patient's weight should be a minimum of 50 lbs. Failure to follow these criteria may result

Precice IMLL Field Safety Notice – October 14, 2021



IFU Section	Prior IFU Language	Updated IFU Language
	health or in patients under the age of 18 years of age.	in the potential adverse events and complications described above.
Potential Adverse Events	Did not contain a Potential Adverse Events and Complications section.	Potential Adverse Events and Complications: As this is a major surgical procedure, there are known complications associated with orthopedic surgery such as bone fractures, nonunion, delayed union, malunion, premature healing (consolidation), decrease in bone density due to stress shielding, inadequate screw fixation, difficulty with nail or screw removal, early or late infection that may result in the need for additional surgeries, damage to blood vessels or nerves, deep venous thrombosis or pulmonary embolism, acute local inflammatory response, loss of sensory and/or motor function or paralysis, pain, and/or permanent deformity. The following list of failures and adverse events are possible with the Precice IMLL system. Failure to follow the contraindications, warnings, cautions and precautions listed in this IFU constitute offlabel use and may increase the likelihood of these events. Soft tissue contractures, loss of joint motion, subluxation and/or dislocation Local tissue discoloration (i.e., metallosis), osteolysis, local acute inflammatory response, pain or other harms associated



IFU Section	Prior IFU Language	Updated IFU Language
Potential Adverse Events	Prior IFU Language	with exposure to wear debris, metal nanoparticles, and elevated titanium serum ion levels (including neurological issues and the risks associated with reproductive and developmental toxicity). Exposure to biohazards or non-biocompatible materials potentially leading to immunological response, pain, skin irritation/rash/sensitization, developmental toxicity related harms and/or infection and which may require medical intervention such as revision surgery. Loss of distraction or uncontrolled lengthening which may lead to pain, loss of correction, extension of treatment, progression of deformity, increased limb length discrepancy, over-lengthening, poor regenerate and/or necessitate revision surgery. Implant bending, fracture, loosening, disassociation and/or loss of fixation resulting in medical intervention such as revision surgery. Failure to lengthen which may lead to
		 resulting in medical intervention such as revision surgery. Failure to lengthen which may lead to delays in surgery (leading to additional blood loss and extended exposure to anesthesia), extension of treatment,
		 suboptimal correction, and/or necessitate revision or reoperation. Treatment complications from anatomical compatibility issues due to implant
		configuration selection, implant removals and/or implant sterility which may lead to delays in surgery (leading to additional blood loss and extended exposure to anesthesia), inability to complete the
		procedure and/or cancellation of the procedure, or may result in pain, abnormal sensations and/or suboptimal correction.



Reasons for IFU Updates:

- These changes are a follow up to the prior communications here:
 - o Feb 2021 Precice FSN and April 2021 NSO Statement
- The update clarifies instructions regarding the target patient population based on the latest scientific evidence.
- Further clarify to healthcare providers and patients the potential adverse events that can occur when using the device.

Clinical Impact:

NuVasive continues to monitor all post-market surveillance reports of adverse events as required by the regulations and laws in markets which it operates. To date, there have been no reports of toxicological harms identified. Additional biological assessments are ongoing to determine whether there are potential toxicological risks to patients under 50lbs or for patients with more than two implanted devices. Until that testing is completed, the use of Precice IMLL is not recommended for patients under 50lbs or greater than 2 implanted devices.

Recommended User Action:

This FSN details updates to the IFU document that physicians should consult prior to and during patient care of those being treated with Precice IMLL System devices. This should be consulted for currently implanted and future potential Precice IMLL system patients.

- The IFU should be consulted on an ongoing basis before and throughout patient treatment.
- An NSO representative will be contacting your office or you to help with any questions or concerns.
- Acknowledgement of these changes is critical. Please review, complete, sign and return
 the attached Consignee Confirmation Form in accordance with the directions on the
 form (accompanying this notification).
- Precice IMLL System Devices, for patients currently weighing less than 50 pounds and/or
 with more than two devices implanted should consult their healthcare team for
 assessment of their treatment progression and consider removal of nails promptly at
 the end of treatment in order to minimize the potential for implantation risks while also
 minimizing the risks associated with repetitive surgical interventions and sub-optimal
 conversion to alternative therapies mid-treatment.



Additionally, this is a reminder to reference the existing language within the IFU, including but not limited to:

- The PRECICE Intramedullary Limb Lengthening nail remains implanted until bone consolidation has been completed. Once the physician determines that the nail has achieved its intended use and is no longer required, it is removed using standard surgical techniques
- Device should be removed after implantation time of no more than one year.
- The PRECICE Intramedullary Limb Lengthening device is contraindicated in patients in which the Precice IMLL nail would cross joint spaces or open epiphyseal growth plates.
- The PRECICE Intramedullary Limb Lengthening device is contraindicated in patients unwilling or incapable of following postoperative care instructions.
- The PRECICE Intramedullary Limb Lengthening nail cannot withstand the stresses of full weight bearing for tibia and femur applications.
- The PRECICE Intramedullary Limb Lengthening device is contraindicated for use in patients with metal allergies and sensitivities.
- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Smoking, chronic steroid/drug use and the use of other anti-inflammatory drugs have been
 determined to affect bone healing and could potentially have an adverse effect of the bone
 regenerate during the lengthening process. Additionally, patients should be evaluated for
 narcotic dependencies associated with pain management.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware of it within your organization.

This notice has been reported to all applicable regulatory authorities.

Matthew Collins

Date

Vice President, Global Quality Assurance

101 Enterprise #100

Aliso Viejo, CA 92656



URGENT FIELD SAFETY NOTICE - Precice IMLL

NSO representative, if	applicable	Signature	Date
Name/Title		Signature	Date
l acknowledge receivi	ng and readin	g the October 14, 2021, P	recice IMLL FSN
		(Information required f	or regulatory effectiveness check)
Phone:			
Address:	-		
Customer Nan	ne:		
Your organization's re	eply is the evi	dence we need to monitor	the dissemination of this notice.
have received this FS	N. Please con	nplete and return this forn	ed in this FSN and confirms that you n to NSO per the instructions below.
		onsignee Confirmation F	
Type of Action:	Advisory No	tice	
Commercial Name: Precice IMLL and Pre-	Precice Intramedullary limb lengthening (IMLL) device system, including cice Short trade names		
Date:	October 14, 2021		

Precice IMLL Field Safety Notice - October 14, 2021

Model Number	Item Number	Item Description
CPA1-000	PA0382-001	End Cap
CPA2-000	PA1051-000	PACKAGED END CAP, 8.5/ 10.7MM, +0MM
CPA2-005	PA1051-005	PACKAGED END CAP, 8.5/ 10.7MM, +5MM
CPA2-010	PA1051-010	PACKAGED END CAP, 8.5/10.7MM, +10MM
CPA2-015	PA1051-015	PACKAGED END CAP, 8.5/10.7MM, +15MM
CPA2-020	PA1051-020	PACKAGED END CAP, 8.5/10.7MM, +20MM
CPA3-000	PA1052-000	PACKAGED END CAP, 12.5MM , +0MM
CPA3-005	PA1052-005	PACKAGED END CAP, 12.5MM , +5MM
CPA3-010	PA1052-010	PACKAGED END CAP, 12.5MM , +10MM
CPA3-015	PA1052-015	PACKAGED END CAP, 12.5MM , +15MM
CPA3-020	PA1052-020	PACKAGED END CAP, 12.5MM , +20MM
HEC1-000	PA0709-000	END CAP, OMM HUMERAL NAIL
HEC2-000	PA0709-002	END CAP, 2MM HUMERAL NAIL
HEC3-000	PA0709-005	END CAP, 5MM HUMERAL NAIL
HEC4-000	PA0709-010	END CAP, 10MM HUMERAL NAIL
HEC5-000	PA0709-015	END CAP, 15MM HUMERAL NAIL
LSB3-020	PP1699-020	Locking Screw, 3.5mm x 2 0mm
LSB3-025	PP1699-025	Locking Screw, 3.5mm x 2 5mm
LSB3-030	PP1699-030	Locking Screw, 3.5mm x 3 0mm
LSB3-035	PP1699-035	Locking Screw, 3.5mm x 3 5mm
LSB3-040	PP1699-040	Locking Screw, 3.5mm x 4 0mm
LSB3-045	PP1699-045	Locking Screw, 3.5mm x 4 5mm
LSB3-050	PP1699-050	Locking Screw, 3.5mm x 5 0mm
LSB3-055	PP1699-055	Locking Screw, 3.5mm x 5 5mm
LSB3-060	PP1699-060	Locking Screw, 3.5mm x 6 0mm
LSB3-200-S	PA1220-020	3.5mm x 20mm Screw, Peg
LSB3-250-S	PA1220-025	3.5mm x 25mm Screw, Peg
LSB3-300-S LSB3-350-S	PA1220-030 PA1220-035	3.5mm x 35mm Screw, Peg
LSB3-400-S	PA1220-033 PA1220-040	3.5mm x 35mm Screw, Peg
LSB3-450-S	PA1220-040 PA1220-045	3.5mm x 40mm Screw, Peg 3.5mm x 45mm Screw, Peg
LSB3-500-S	PA1220-045 PA1220-050	3.5mm x 50mm Screw, Peg
LSB3-550-S	PA1220-055	3.5mm x 55mm Screw, Peg
LSB3-600-S	PA1220-053	3.5mm x 60mm Screw, Peg
LSB4-020	PP1425-020	Locking Screw, 4.0mm x 20mm
LSB4-025	PP1425-025	Locking Screw, 4.0mm x 25mm
LSB4-030	PP1425-030	Locking Screw, 4.0mm x 30mm
LSB4-035	PP1425-035	Locking Screw, 4.0mm x 35mm
LSB4-040	PP1425-040	Locking Screw, 4.0mm x 40mm
LSB4-045	PP1425-045	Locking Screw, 4.0mm x 45mm
LSB4-050	PP1425-050	Locking Screw, 4.0mm x 50mm
LSB4-055	PP1425-055	Locking Screw, 4.0mm x 55mm
LSB4-060	PP1425-060	Locking Screw, 4.0mm x 60mm
LSB5-020	PP1426-020	Locking Screw, 5.0mm x 20mm
LSB5-025	PP1426-025	Locking Screw, 5.0mm x 25mm
LSB5-030	PP1426-030	Locking Screw, 5.0mm x 30mm
	20 000	

LSB5-035	PP1426-035	Locking Screw, 5.0mm x 35mm
LSB5-040	PP1426-040	Locking Screw, 5.0mm x 40mm
LSB5-045	PP1426-045	Locking Screw, 5.0mm x 45mm
LSB5-050	PP1426-050	Locking Screw, 5.0mm x 50mm
LSB5-055	PP1426-055	Locking Screw, 5.0mm x 55mm
LSB5-060	PP1426-060	Locking Screw, 5.0mm x 60mm
LSB5-065	PP1426-065	Locking Screw, 5.0mm x 65mm
LSB5-070	PP1426-070	Locking Screw, 5.0mm x 70mm
LSB5-075	PP1426-075	Locking Screw, 5.0mm x 75mm
LSC4-020	PP1794-020	Locking Screw, 4.0mm x 2 0mm
LSC4-025	PP1794-025	Locking Screw, 4.0mm x 2 5mm
LSC4-030	PP1794-030	Locking Screw, 4.0mm x 3 0mm
LSC4-035	PP1794-035	Locking Screw, 4.0mm x 3 5mm
LSC4-040	PP1794-040	Locking Screw, 4.0mm x 4 0mm
LSC4-045	PP1794-040 PP1794-045	•
		Locking Screw, 4.0mm x 4.5mm
LSC4-050	PP1794-050	Locking Screw, 4.0mm x 5 0mm
LSC4-055	PP1794-055	Locking Screw, 4.0mm x 5 5mm
LSC4-060	PP1794-060	Locking Screw, 4.0mm x 6 0mm
LSC4-200-S	PA1221-020	4.0mm x 20mm Screw, Peg
LSC4-250-S	PA1221-025	4.0mm x 25mm Screw, Peg
LSC4-300-S	PA1221-030	4.0mm x 30mm Screw, Peg
LSC4-350-S	PA1221-035	4.0mm x 35mm Screw, Peg
LSC4-400-S	PA1221-040	4.0mm x 40mm Screw, Peg
LSC4-450-S	PA1221-045	4.0mm x 45mm Screw, Peg
LSC4-500-S	PA1221-050	4.0mm x 50mm Screw, Peg
LSC4-550-S	PA1221-055	4.0mm x 55mm Screw, Peg
LSC4-600-S	PA1221-060	4.0mm x 60mm Screw, Peg
LSC5-020	PP1742-020	Locking Screw, 5.0mm x 2 0mm
LSC5-025	PP1742-025	Locking Screw, 5.0mm x 2 5mm
LSC5-030	PP1742-030	Locking Screw, 5.0mm x 3 0mm
LSC5-035	PP1742-035	Locking Screw, 5.0mm x 3 5mm
LSC5-040	PP1742-040	Locking Screw, 5.0mm x 4 0mm
LSC5-045	PP1742-045	Locking Screw, 5.0mm x 4 5mm
LSC5-050	PP1742-050	Locking Screw, 5.0mm x 5 0mm
LSC5-055	PP1742-055	Locking Screw, 5.0mm x 5 5mm
LSC5-060	PP1742-060	Locking Screw, 5.0mm x 6 0mm
LSC5-065	PP1742-065	Locking Screw, 5.0mm x 6 5mm
LSC5-070	PP1742-070	Locking Screw, 5.0mm x 7 0mm
LSC5-075	PP1742-075	Locking Screw, 5.0mm x 7 5mm
LSC5-200-S	PA1222-020	5.0mm x 20mm Screw, Peg
LSC5-250-S	PA1222-025	5.0mm x 25mm Screw, Peg
LSC5-300-S	PA1222-030	5.0mm x 30mm Screw, Peg
LSC5-350-S	PA1222-035	5.0mm x 35mm Screw, Peg
LSC5-400-S	PA1222-040	5.0mm x 40mm Screw, Peg
LSC5-450-S	PA1222-045	5.0mm x 45mm Screw, Peg
LSC5-500-S	PA1222-050	5.0mm x 50mm Screw, Peg
LSC5-550-S	PA1222-055	5.0mm x 55mm Screw, Peg

LSC5-600-S	PA1222-060	5.0mm x 60mm Screw, Peg
LSC5-650-S	PA1222-065	5.0mm x 65mm Screw, Peg
LSC5-700-S	PA1222-070	5.0mm x 70mm Screw, Peg
LSC5-750-S	PA1222-075	5.0mm x 75mm Screw, Peg
P10.7-30H170	PA0676-30H170	Retrograde Feumr 10 Ben d 10.7MM X 170MM
P10.7-30J160	PA0676-30J160	Antegrade Tibia 10 Bend 10.7MM X 160MM
P10.7-30K170	PA0676-30K170	Antegrade Femur Troch 10 Bend 10.7MM X 170MM
P10.7-30U170	PA0676-30U170	Universal Femur 10.7MM X 170MM
P10.7-50A215	PA0411-50A215	Retrograde Femur 10deg, 10.7mm x 215mm
P10.7-50A230	PA0411-50A230	Retrograde Femur 10deg, 10.7mm x 230mm
P10.7-50B215	PA0411-50B215	Ante Femur Piriformis, 1 0.7mm x 215mm
P10.7-50B230	PA0411-50B230	Ante Femur Piriformis, 1 0.7mm x 230mm
P10.7-50C195	PA0411-50C195	Antegrade Tibia, 10.7mm x 195mm
P10.7-50C215	PA0411-50C215	Antegrade Tibia, 10.7mm x 215mm
P10.7-50C230	PA0411-50C230	Antegrade Tibia, 10.7mm x 230mm
P10.7-50D215	PA0411-50D215	Ante Femur (Troch), 10.7 mm x 215mm
P10.7-50D230	PA0411-50D230	Ante Femur (Troch), 10.7 mm x 230mm
P10.7-50E195	PA0411-50E195	Retrograde Femur Straigh t, 10.7mm x 195mm
P10.7-50E215	PA0411-50E215	Retrograde Femur Straigh t, 10.7mm x 215mm
P10.7-50E230	PA0411-50E230	Retrograde Femur Straigh t, 10.7mm x 230mm
P10.7-50H190	PA0676-50H190	Retrograde Femur 10 Ben d 10.7MM X 190MM
P10.7-50J180	PA0676-50J180	Antegrade Tibia 10 Bend 10.7MM X 180MM
P10.7-50K190	PA0676-50K190	Antegrade Femur Troch 10 Bend10.7MM X 190MM
P10.7-50M160	PA0902-50M160	Antegrade Femur Troch 10 Bend 10.7mm X 160mm
P10.7-50M175	PA0902-50M175	Antegrade Femur Troch 10 Bend 10.7mm X 175mm
P10.7-50N160	PA0902-50N160	Universal Femur 10.7mm X 160mm
P10.7-50P160	PA0902-50P160	Retrograde Femur 10 Ben d 10.7mm x 160 mm
P10.7-50P175	PA0902-50P175	Retrograde Femur 10 Bend 10.7mm x 175mm
P10.7-50Q150	PA0902-50Q150	Antegrade Tibia 10 Bend 10.7mm X 150mm
P10.7-50Q155	PA0902-50Q155	Antegrade Tibia 10 Bend 10.7mm X 155mm
P10.7-50U190	PA0676-50U190	Universal Femur 10.7MM X 190MM
P10.7-50V215	PA0411-50V215	Retrograde Femur 10deg, 10.7mm x 215mm
P10.7-50V230	PA0411-50V230	Retrograde Femur 10deg, 10.7mm x 230mm
P10.7-50X215	PA0411-50X215	Retrograde Femur Straigh t, 10.7mm x 215mm
P10.7-50X230	PA0411-50X230	Retrograde Femur Straigh t, 10.7mm x 230mm
P10.7-80A245	PA0411-80A245	Retrograde Femur 10deg, 10.7mm x 245mm
P10.7-80A275	PA0411-80A275	Retrograde Femur 10deg, 10.7mm x 275mm
P10.7-80A305	PA0411-80A305	Retrograde Femur 10deg, 10.7mm x 305mm
P10.7-80A335	PA0411-80A335	Retrograde Femur 10deg, 10.7mm x 335mm
P10.7-80A365	PA0411-80A365	Retrograde Femur 10deg, 10.7mm x 365mm
P10.7-80B245	PA0411-80B245	Ante Femur Piriformis, 1 0.7mm x 245mm
P10.7-80B275	PA0411-80B275	Ante Femur Piriformis, 1 0.7mm x 275mm
P10.7-80B305	PA0411-80B305	Ante Femur Piriformis, 1 0.7mm x 305mm
P10.7-80B335	PA0411-80B335	Ante Femur Piriformis, 1 0.7mm x 335mm
P10.7-80B365	PA0411-80B365	Ante Femur Piriformis, 1 0.7mm x 365mm
P10.7-80C245	PA0411-80C245	Antegrade Tibia, 10.7mm x 245mm
P10.7-80C275	PA0411-80C275	Antegrade Tibia, 10.7mm x 275mm

P10.7-80C305	PA0411-80C305	Antegrade Tibia, 10.7mm x 305mm
P10.7-80C335	PA0411-80C335	Antegrade Tibia, 10.7mm x 335mm
P10.7-80C365	PA0411-80C365	Antegrade Tibia, 10.7mm x 365mm
P10.7-80D245	PA0411-80D245	Ante Femur (Troch), 10.7 mm x 245mm
P10.7-80D275	PA0411-80D275	Ante Femur (Troch), 10.7 mm x 275mm
P10.7-80D305	PA0411-80D305	Ante Femur (Troch), 10.7 mm x 305mm
P10.7-80D335	PA0411-80D335	Ante Femur (Troch), 10.7 mm x 335mm
P10.7-80D365	PA0411-80D365	Ante Femur (Troch), 10.7 mm x 365mm
P10.7-80E245	PA0411-80E245	Retrograde Femur Straigh t, 10.7mm x 245mm
P10.7-80E275	PA0411-80E275	Retrograde Femur Straigh t, 10.7mm x 275mm
P10.7-80E305	PA0411-80E305	Retrograde Femur Straigh t, 10.7mm x 305mm
P10.7-80E335	PA0411-80E335	Retrograde Femur Straigh t, 10.7mm x 335mm
P10.7-80E365	PA0411-80E365	Retrograde Femur Straigh t, 10.7mm x 365mm
P10.7-80V245	PA0411-80V245	Retrograde Femur 10deg, 10.7mm x 245mm
P10.7-80V275	PA0411-80V275	Retrograde Femur 10deg, 10.7mm x 275mm
P10.7-80V305	PA0411-80V305	Retrograde Femur 10deg, 10.7mm x 305mm
P10.7-80V335	PA0411-80V335	Retrograde Femur 10deg, 10.7mm x 335mm
P10.7-80V365	PA0411-80V365	Retrograde Femur 10deg, 10.7mm x 365mm
P10.7-80X245	PA0411-80X245	Retrograde Femur Straigh t, 10.7mm x 245mm
P10.7-80X275	PA0411-80X275	Retrograde Femur Straigh t, 10.7mm x 275mm
P10.7-80X305	PA0411-80X305	Retrograde Femur Straigh t, 10.7mm x 305mm
P10.7-80X335	PA0411-80X335	Retrograde Femur Straight, 10.7mm x 335mm
P10.7-80X365	PA0411-80X365	Retrograde Femur Straight, 10.7mm x 365mm
P10.7-80X303 P12.5-30H170	PA0411-80X303 PA0677-30H170	
		Retrograde Femur 10 Ben d 12.5MM X 170MM
P12.5-30J160	PA0677-30J160	Antegrade Tibia 10 Bend 12.5MM X 160MM
P12.5-30K170	PA0677-30K170	Antegrade Femur Troch 10 Bend 12.5MM X 170MM
P12.5-30U170	PA0677-30U170	Universal Femur 12.5MM 1 70MM
P12.5-50A215	PA0417-50A215	Retrograde Femur 10deg, 12.5mm x 215mm
P12.5-50A230	PA0417-50A230	Retrograde Femur 10deg, 12.5mm x 230mm
P12.5-50B215	PA0417-50B215	Ante Femur Piriformis, 1 2.5mm x 215mm
P12.5-50B230	PA0417-50B230	Ante Femur Piriformis, 1 2.5mm x 230mm
P12.5-50C195	PA0417-50C195	Antegrade Tibia, 12.5mm x 195mm
P12.5-50C215	PA0417-50C215	Antegrade Tibia, 12.5mm x 215mm
P12.5-50C230	PA0417-50C230	Antegrade Tibia, 12.5mm x 230mm
P12.5-50D215	PA0417-50D215	Ante Femur (Troch), 12.5 mm x 215mm
P12.5-50D230	PA0417-50D230	Ante Femur (Troch), 12.5 mm x 230mm
P12.5-50E215	PA0417-50E215	Retrograde Femur Straigh t, 12.5mm x 215mm
P12.5-50E230	PA0417-50E230	Retrograde Femur Straigh t, 12.5mm x 230mm
P12.5-50H190	PA0677-50H190	Retrograde Femur 10 Ben d, 12.5MM X 190MM
P12.5-50J180	PA0677-50J180	Antegrade Tibia 10 Bend 12.5MM X 180MM
P12.5-50K190	PA0677-50K190	Antegrade Femur Troch 10 Bend 12.5MM X 190MM
P12.5-50U190	PA0677-50U190	Universal Femur 12.5MM X 190MM
P12.5-50V215	PA0417-50V215	Retrograde Femur 10deg, 12.5mm x 215mm
P12.5-50V230	PA0417-50V230	Retrograde Femur 10deg, 12.5mm x 230mm
P12.5-50X215	PA0417-50X215	Retrograde Femur Straigh t, 12.5mm x 215mm
P12.5-50X230	PA0417-50X230	Retrograde Femur Straigh t, 12.5mm x 230mm
P12.5-80A245	PA0417-80A245	Retrograde Femur 10deg, 12.5mm x 245mm

P12.5-80A275	PA0417-80A275	Retrograde Femur 10deg, 12.5mm x 275mm
P12.5-80A305	PA0417-80A305	Retrograde Femur 10deg, 12.5mm x 305mm
P12.5-80A335	PA0417-80A335	Retrograde Femur 10deg, 12.5mm x 335mm
P12.5-80A365	PA0417-80A365	Retrograde Femur 10deg, 12.5mm x 365mm
P12.5-80B245	PA0417-80B245	Ante Femur Piriformis, 1 2.5mm x 245mm
P12.5-80B275	PA0417-80B275	Ante Femur Piriformis, 1 2.5mm x 275mm
P12.5-80B305	PA0417-80B305	Ante Femur Piriformis, 1 2.5mm x 305mm
P12.5-80B335	PA0417-80B335	Ante Femur Piriformis, 1 2.5mm x 335mm
P12.5-80B365	PA0417-80B365	Ante Femur Piriformis, 1 2.5mm x 365mm
P12.5-80C245	PA0417-80C245	Antegrade Tibia, 12.5mm x 245mm
P12.5-80C275	PA0417-80C275	Antegrade Tibia, 12.5mm x 275mm
P12.5-80C305	PA0417-80C305	Antegrade Tibia, 12.5mm x 305mm
P12.5-80C335	PA0417-80C335	Antegrade Tibia, 12.5mm x 335mm
P12.5-80C365	PA0417-80C365	Antegrade Tibia, 12.5mm x 365mm
P12.5-80D245	PA0417-80D245	Ante Femur (Troch), 12.5 mm x 245mm
P12.5-80D275	PA0417-80D275	Ante Femur (Troch), 12.5 mm x 275mm
P12.5-80D305	PA0417-80D305	Ante Femur (Troch), 12.5 mm x 305mm
P12.5-80D335	PA0417-80D335	Ante Femur (Troch), 12.5 mm x 335mm
P12.5-80D365	PA0417-80D365	Ante Femur (Troch), 12.5 mm x 365mm
P12.5-80E245	PA0417-80E245	Retrograde Femur Straigh t, 12.5mm x 245mm
P12.5-80E275	PA0417-80E275	Retrograde Femur Straigh t, 12.5mm x 275mm
P12.5-80E305	PA0417-80E305	Retrograde Femur Straigh t, 12.5mm x 305mm
P12.5-80E335	PA0417-80E335	Retrograde Femur Straigh t, 12.5mm x 335mm
P12.5-80E365	PA0417-80E365	Retrograde Femur Straightt, 12.5mm x 365mm
P12.5-80U303	PA0417-80U303	Retrograde Femur 10deg, 12.5mm x 245mm
P12.5-80V245	PA0417-80V243 PA0417-80V275	Retrograde Femur 10deg, 12.5mm x 275mm
P12.5-80V275	PA0417-80V273	Retrograde Femur 10deg, 12.5mm x 305mm
P12.5-80V303		
	PA0417-80V335	Retrograde Femur 10deg, 12.5mm x 335mm
P12.5-80V365 P12.5-80X245	PA0417-80V365 PA0417-80X245	Retrograde Femur 10deg, 12.5mm x 365mm
		Retrograde Femur Straigh t, 12.5mm x 245mm
P12.5-80X275	PA0417-80X275	Retrograde Femur Straigh t, 12.5mm x 275mm
P12.5-80X305	PA0417-80X305	Retrograde Femur Straigh t, 12.5mm x 305mm
P12.5-80X335	PA0417-80X335	Retrograde Femur Straigh t, 12.5mm x 335mm
P12.5-80X365	PA0417-80X365	Retrograde Femur Straigh t, 12.5mm x 365mm
P8.5-30H170	PA0675-30H170	Retrograde Femur 10 Ben d 8.5MM X 170MM
P8.5-30J160	PA0675-30J160	Antegrade Tibia 10 Bend 8.5MM X 160MM
P8.5-30K170	PA0675-30K170	Antegrade Femur Troch 10 Bend 8.5MM X 170MM
P8.5-30U170	PA0675-30U170	Universal Femur 8.5MM X 170MM
P8.5-50A215	PA0465-50A215	Retrograde Femur 10deg, 8.5mm x 215mm
P8.5-50A230	PA0465-50A230	Retrograde Femur 10deg, 8.5mm x 230mm
P8.5-50B215	PA0465-50B215	Ante Femur Piriformis, 8 .5mm x 215mm
P8.5-50B230	PA0465-50B230	Ante Femur Piriformis, 8 .5mm x 230mm
P8.5-50C195	PA0465-50C195	Antegrade Tibia, 8.5mm x 195mm
P8.5-50C215	PA0465-50C215	Antegrade Tibia, 8.5mm x 215mm
P8.5-50C230	PA0465-50C230	Antegrade Tibia, 8.5mm x 230mm
P8.5-50D215	PA0465-50D215	Ante Femur (Troch), 8.5m m x 215mm
P8.5-50D230	PA0465-50D230	Ante Femur (Troch), 8.5m m x 230mm

P8.5-50E215	PA0465-50E215	Retrograde Femur Straigh t, 8.5mm x 215mm
P8.5-50E230	PA0465-50E230	Retrograde Femur Straigh t, 8.5mm x 230mm
P8.5-50H190	PA0675-50H190	Retrograde Femur 10 Ben d 8.5mm x 190 mm
P8.5-50J180	PA0675-50J180	Antegrade Tibia 10 Bend 8.5MM X 180MM
P8.5-50K190	PA0675-50K190	Antegrade Femur Troch 10 Bend 8.5MM X 190MM
P8.5-50M160	PA0901-50M160	Antegrade Femur Troch 10 Bend 8.5mm X 160mm
P8.5-50M165	PA0901-50M165	Antegrade Femur Troch 10 Bend 8.5mm x 165mm
P8.5-50N150	PA0901-50N150	Universal Femur 8.5mm x 150mm
P8.5-50P165	PA0901-50P165	Retrograde Femur 10 Bend 8.5mm x 165 mm
P8.5-50Q150	PA0901-50Q150	Antegrade Tibia 10 Bend 8.5mm X 150mm
P8.5-50Q155	PA0901-50Q155	Antegrade Tibia 10 Bend 8.5mm x 155mm
P8.5-50U190	PA0675-50U190	Universal Femur 8.5MM X 190MM
P8.5-50V215	PA0465-50V215	Retrograde Femur 10deg, 8.5mm x 215mm
P8.5-50V213	PA0465-50V230	Retrograde Femur 10deg, 8.5mm x 230mm
P8.5-50X215	PA0465-50X215	Retrograde Femur Straigh t, 8.5mm x 215mm
P8.5-50X230	PA0465-50X230	Retrograde Femur Straigh t, 8.5mm x 230mm
P8.5-80A245	PA0465-80A245	Retrograde Femur 10deg, 8.5mm x 245mm
P8.5-80A275	PA0465-80A275	Retrograde Femur 10deg, 8.5mm x 275mm
P8.5-80A305	PA0465-80A305	Retrograde Femur 10deg, 8.5mm x 305mm
P8.5-80A335	PA0465-80A335	Retrograde Femur 10deg, 8.5mm x 335mm
P8.5-80B245	PA0465-80B245	Ante Femur Piriformis, 8 .5mm x 245mm
P8.5-80B275	PA0465-80B275	Ante Femur Piriformis, 8 .5mm x 275mm
P8.5-80B305	PA0465-80B305	Ante Femur Piriformis, 8 .5mm x 305mm
P8.5-80B335	PA0465-80B335	Ante Femur Piriformis, 8 .5mm x 335mm
P8.5-80C245	PA0465-80C245	Antegrade Tibia, 8.5mm x 245mm
P8.5-80C275	PA0465-80C275	Antegrade Tibia, 8.5mm x 275mm
P8.5-80C305	PA0465-80C305	Antegrade Tibia, 8.5mm x 305mm
P8.5-80C335	PA0465-80C335	Antegrade Tibia, 8.5mm x 335mm
P8.5-80D245	PA0465-80D245	Ante Femur (Troch), 8.5m m x 245mm
P8.5-80D275	PA0465-80D275	Ante Femur (Troch), 8.5m m x 275mm
P8.5-80D305	PA0465-80D305	Ante Femur (Troch), 8.5m m x 305mm
P8.5-80D335	PA0465-80D335	Ante Femur (Troch), 8.5m m x 335mm
P8.5-80E245	PA0465-80E245	Retrograde Femur Straigh t, 8.5mm x 245mm
P8.5-80E275	PA0465-80E275	Retrograde Femur Straigh t, 8.5mm x 275mm
P8.5-80E305	PA0465-80E305	Retrograde Femur Straigh t, 8.5mm x 305mm
P8.5-80E335	PA0465-80E335	Retrograde Femur Straigh t, 8.5mm x 335mm
P8.5-80V245	PA0465-80V245	Retrograde Femur 10deg, 8.5mm x 245mm
P8.5-80V275	PA0465-80V275	Retrograde Femur 10deg, 8.5mm x 275mm
P8.5-80V305	PA0465-80V305	Retrograde Femur 10deg, 8.5mm x 305mm
P8.5-80V335	PA0465-80V335	Retrograde Femur 10deg, 8.5mm x 335mm
P8.5-80V365	PA0465-80V365	Retrograde Femur 10deg, 8.5mm x 365mm
P8.5-80X245	PA0465-80X245	Retrograde Femur Straigh t, 8.5mm x 245mm
P8.5-80X275	PA0465-80X275	Retrograde Femur Straightt, 8.5mm x 275mm
P8.5-80X305	PA0465-80X305	Retrograde Femur Straightt, 8.5mm x 305mm
P8.5-80X335	PA0465-80X335	Retrograde Femur Straightt, 8.5mm x 335mm
P8.5-80X365	PA0465-80X365	Retrograde Femur Straightt, 8.5mm x 365mm
PR10.5-50C195	PA0656-50C195	Antegrade Tibia, 10.5 x 195
1 WTO'D-DOCT2D	I WOODO-DOCTAD	Antegrade Hold, 10.3 A 133

PR10.5-80B245	PA0656-80B245	Ante Femur Piriformis, 10.5 x 245
PR10.5-80C245	PA0656-80C245	Antegrade Tibia, 10.5 x 245
PR10.5-80D305	PA0656-80D305	Antegrade Femur, 10.5 x 305
PR11.5-80B245	PA0657-80B245	Ante Femur Piriformis, 11.5 x 245
PR11.5-80C245	PA0657-80C245	Antegrade Tibia, 11.5 X 245
PR12.5-80B245	PA0663-80B245	Ante Femur Piriformis, 12.5 x 245 (R)
PR12.5-80C245	PA0663-80C245	Antegrade Tibia, 12.5 x 245 (R)
PR9.0-50A215	PA0654-50A215	Retrograde Femur 9.0 x 215
PR9.0-50A230	PA0654-50A230	Retrograde Femur 9.0 x 230
PR9.0-50B215	PA0654-50B215	Ante Femur Piriformis 9.0 x 215
PR9.0-50B230	PA0654-50B230	Ante Femur Piriformis 9.0 x 230
PR9.0-50C195	PA0654-50C195	Antegrade Tibia 9.0 x 195
PR9.0-50C215	PA0654-50C215	Antegrade Tibia 9.0 x 215
PR9.0-50C230	PA0654-50C230	Antegrade Tibia 9.0 x 230
PR9.0-50D215	PA0654-50D215	Antegrade Femur 9.0 x 215
PR9.0-50D230	PA0654-50D230	Antegrade Femur 9.0 x 230
PR9.0-50E215	PA0654-50E215	Retrograde Fem Straight 9.0 x 215
PR9.0-50E230	PA0654-50E230	Retrograde Fem Straight 9.0 x 230
PR9.0-80A245	PA0654-80A245	Retrograde Femur 9.0 x 245
PR9.0-80A275	PA0654-80A275	Retrograde Femur 9.0 x 275
PR9.0-80A305	PA0654-80A305	Retrograde Femur 9.0 x 305
PR9.0-80A335	PA0654-80A335	Retrograde Femur 9.0 x 335
PR9.0-80A365	PA0654-80A365	Retrograde Femur 9.0 x 365
PR9.0-80B245	PA0654-80B245	Ante Femur Piriformis 9.0 x 245
PR9.0-80B275	PA0654-80B275	Ante Femur Piriformis 9.0 x 275
PR9.0-80B305	PA0654-80B305	Ante Femur Piriformis 9.0 x 305
PR9.0-80B335	PA0654-80B335	Ante Femur Piriformis 9.0 x 335
PR9.0-80B365	PA0654-80B365	Ante Femur Piriformis 9.0 x 365
PR9.0-80C245	PA0654-80C245	Antegrade Tibia 9.0 x 245
PR9.0-80C275	PA0654-80C275	Antegrade Tibia 9.0 x 275
PR9.0-80C305	PA0654-80C305	Antegrade Tibia 9.0 x 305
PR9.0-80C365	PA0654-80C365	Antegrade Tibia 9.0 x 365
PR9.0-80D245	PA0654-80D245	Antegrade Femur 9.0 x 245
PR9.0-80D275	PA0654-80D275	Antegrade Femur 9.0 x 275
PR9.0-80D305	PA0654-80D305	Antegrade Femur 9.0 x 305
PR9.0-80D335	PA0654-80D335	Antegrade Femur 9.0 x 335
PR9.0-80D365	PA0654-80D365	Antegrade Femur 9.0 x 365
PR9.0-80E245	PA0654-80E245	Retrograde Fem Straight 9.0 x 245
PR9.0-80E275	PA0654-80E275	Retrograde Fem Straight 9.0 x 275
PR9.0-80E305	PA0654-80E305	Retrograde Fem Straight 9.0 x 305
PR9.0-80E335	PA0654-80E335	Retrograde Fem Straight 9.0 x 335
PR9.0-80E365	PA0654-80E365	Retrograde Fem Straight 9.0 x 365
PR9.5-50A230	PA0655-50A230	Retrograde Femur 10deg, 9.5 x 230
SSA1-000	PA0335-001	PKG PRECICE #6-32 SETSCR EW 10.7mm
SSA2-000	PA0335-002	PKG PRECICE #6-32 SETSCR EW 12.5mm
TSA4.5-020	PP2662-200	4.5MM X 20MM LOCKING SCREW, FULLY THREADED
TSA4.5-022.5	PP2662-225	4.5MM X 22.5MM LOCKING SCREW, FULLY THREADED

TSA4.5-025	PP2662-250	4.5MM X 25MM LOCKING SCREW, FULLY THREADED
TSA4.5-027.5	PP2662-275	4.5MM X 27.5MM LOCKING SCREW, FULLY THREADED
TSA4.5-030	PP2662-300	4.5MM X 30MM LOCKING SCREW, FULLY THREADED
TSA4.5-032.5	PP2662-325	4.5MM X 32.5MM LOCKING SCREW, FULLY THREADED
TSA4.5-035	PP2662-350	4.5MM X 35MM LOCKING SCREW, FULLY THREADED
TSA4.5-037.5	PP2662-375	4.5MM X 37.5MM LOCKING SCREW, FULLY THREADED
TSA4.5-040	PP2662-400	4.5MM X 40MM LOCKING SCREW, FULLY THREADED
TSA4.5-042.5	PP2662-425	4.5MM X 42.5MM LOCKING SCREW, FULLY THREADED
TSA4.5-045	PP2662-450	4.5MM X 45MM LOCKING SCREW, FULLY THREADED
TSA4.5-047.5	PP2662-475	4.5MM X 47.5MM LOCKING SCREW, FULLY THREADED
TSA4.5-050	PP2662-500	4.5MM X 50MM LOCKING SCREW, FULLY THREADED
TSA4.5-055	PP2662-550	4.5MM X 55MM LOCKING SCREW, FULLY THREADED
TSA4.5-060	PP2662-600	4.5MM X 60MM LOCKING SCREW, FULLY THREADED
TSA4.5-065	PP2662-650	4.5MM X 65MM LOCKING SCREW, FULLY THREADED
TSA4.5-070	PP2662-700	4.5MM X 70MM LOCKING SCREW, FULLY THREADED
TSA4.5-075	PP2662-750	4.5MM X 75MM LOCKING SCREW, FULLY THREADED
TSA4.5-080	PP2662-800	4.5MM X 80MM LOCKING SCREW, FULLY THREADED
TSA4.5-085	PP2662-850	4.5MM X 85MM LOCKING SCREW, FULLY THREADED
TSA4.5-090	PP2662-900	4.5MM X 90MM LOCKING SCREW, FULLY THREADED
TSA4.5-095	PP2662-950	4.5MM X 95MM LOCKING SCREW, FULLY THREADED
TSA4.5-100	PP2662-100	4.5MM X 100MM LOCKING SCREW, FULLY THREADED
TSA4-000-S	PA1223-000	•
TSA4-200-S	PA1223-000 PA1223-200	4.0mm x 100mm Screw, Fully Threaded
TSA4-200-3	PA1223-200 PA1223-225	4.0mm x 20mm Screw, Fully Threaded
TSA4-250-S	PA1223-225 PA1223-250	4.0mm x 22.5mm Screw, Fully Threaded
TSA4-250-5 TSA4-275-S	PA1223-230 PA1223-275	4.0mm x 25mm Screw, Fully Threaded
		4.0mm x 27.5mm Screw, Fully Threaded 4.0mm x 30mm Screw, Fully Threaded
TSA4-300-S	PA1223-300	•
TSA4-325-S	PA1223-325	4.0mm x 32.5mm Screw, Fully Threaded
TSA4-350-S	PA1223-350	4.0mm x 35mm Screw, Fully Threaded
TSA4-375-S	PA1223-375	4.0mm x 37.5mm Screw, Fully Threaded
TSA4-400-S	PA1223-400	4.0mm x 40mm Screw, Fully Threaded
TSA4-425-S	PA1223-425	4.0mm x 42.5mm Screw, Fully Threaded
TSA4-450-S	PA1223-450	4.0mm x 45mm Screw, Fully Threaded
TSA4-475-S	PA1223-475	4.0mm x 47.5mm Screw, Fully Threaded
TSA4-500-S	PA1223-500	4.0mm x 50mm Screw, Fully Threaded
TSA4-550-S	PA1223-550	4.0mm x 55mm Screw, Fully Threaded
TSA4-600-S	PA1223-600	4.0mm x 60mm Screw, Fully Threaded
TSA4-650-S	PA1223-650	4.0mm x 65mm Screw, Fully Threaded
TSA4-700-S	PA1223-700	4.0mm x 70mm Screw, Fully Threaded
TSA4-750-S	PA1223-750	4.0mm x 75mm Screw, Fully Threaded
TSA4-800-S	PA1223-800	4.0mm x 80mm Screw, Fully Threaded
TSA4-850-S	PA1223-850	4.0mm x 85mm Screw, Fully Threaded
TSA4-900-S	PA1223-900	4.0mm x 90mm Screw, Fully Threaded
TSA4-950-S	PA1223-950	4.0mm x 95mm Screw, Fully Threaded
TSA5-000-S	PA1225-000	5.0mm x 100mm Screw, Fully Threaded
TSA5-200-S	PA1225-200	5.0mm x 20mm Screw, Fully Threaded
TSA5-225-S	PA1225-225	5.0mm x 22.5mm Screw, Fully Threaded

TSA5-250-S	PA1225-250	5.0mm x 25mm Screw, Fully Threaded
TSA5-275-S	PA1225-275	5.0mm x 27.5mm Screw, Fully Threaded
TSA5-300-S	PA1225-300	5.0mm x 30mm Screw, Fully Threaded
TSA5-325-S	PA1225-325	5.0mm x 32.5mm Screw, Fully Threaded
TSA5-350-S	PA1225-350	5.0mm x 35mm Screw, Fully Threaded
TSA5-375-S	PA1225-375	5.0mm x 37.5mm Screw, Fully Threaded
TSA5-400-S	PA1225-400	5.0mm x 40mm Screw, Fully Threaded
TSA5-425-S	PA1225-425	5.0mm x 42.5mm Screw, Fully Threaded
TSA5-450-S	PA1225-450	5.0mm x 45mm Screw, Fully Threaded
TSA5-475-S	PA1225-475	5.0mm x 47.5mm Screw, Fully Threaded
TSA5-500-S	PA1225-500	5.0mm x 50mm Screw, Fully Threaded
TSA5-550-S	PA1225-550	5.0mm x 55mm Screw, Fully Threaded
TSA5-600-S	PA1225-600	5.0mm x 60mm Screw, Fully Threaded
TSA5-650-S	PA1225-650	5.0mm x 65mm Screw, Fully Threaded
TSA5-700-S	PA1225-700	5.0mm x 70mm Screw, Fully Threaded
TSA5-750-S	PA1225-750	5.0mm x 75mm Screw, Fully Threaded
TSA5-800-S	PA1225-800	5.0mm x 80mm Screw, Fully Threaded
TSA5-850-S	PA1225-850	5.0mm x 85mm Screw, Fully Threaded
TSA5-900-S	PA1225-900	5.0mm x 90mm Screw, Fully Threaded
TSA5-950-S	PA1225-950	5.0mm x 95mm Screw, Fully Threaded