INSTRUCTIONS FOR USE

Important Information – Please Read Prior to Use

Rx Only

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(MDSS)
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This supplementary Instructions for Use pertains to European Medical Device Regulations 2017/745 (MDR) Class I devices associated with the Orthofix medical device systems listed below. For full prescribing information please reference the device system Instructions for Use:

FORZA XP Expandable Spacer System	Firebird Spinal Fixation Systems
FORZA PTC Spacer System	Navigated Instrument System
FORZA Spacer System	NewBridge Laminoplasty Fixation System
FORZA Ti Spacer System	Unity Lumbosacral Fixation System
Centurion Posterior Occipital Cervico-Thoracic (POCT) System	Connector System
Cetra Anterior Cervical Plate System	CONSTRUX Mini Spacer System
LONESTAR Cervical Stand Alone System	CONSTRUX Mini PTC Spacer System
TDX Posterior Dynamic Stabilization System	CONSTRUX Mini Ti Spacer System
InSWing Interspinous Spacer	ProView Minimal Access Portal (MAP) System
FIREBIRD SI Fusion System	Reliant Anterior Cervical Plating System
SKYHAWK Lateral Plate System	Hallmark Anterior Cervical Plate System
SKYHAWK Lateral Interbody Fusion System	3° Anterior Cervical Plating System
PILLAR SA PEEK Spacer System	Ascent (POCT) System
PILLAR SA PTC Spacer System	Ascent LE (POCT) System
PILLAR PEEK Spacer System	NGage Surgical Mesh System
Spinal Fixation System	

Labeling pertaining to Serious Incidents

Any serious incident that has occurred in relation to the devices subject of the supplementary Instructions for Use should be reported to Orthofix Inc., 3451 Plano Parkway, Lewisville, TX 75056, USA, by telephone at 1-214-937-3199 or 1-888-298-5700 or by e-mail at complaints@orthofix.com and the competent authority of the Member State in which the user and/or patient is established.

NEW MDR SYMBOLS USED ON LABELING FOR CLASS I DEVICES

MD	Medical device		Quantity or packaging unit