PURPOSE: The purpose of this document is to record a symbols glossary

1. **Symbols Table:** This table describes the symbols that are utilized in Orthofix M6-C and M6-L product labeling, which includes device Product Labels, Instructions for Use, Operative Technique Manuals, and Patient Implant Cards.

Index	Symbol	Description	Source of Symbol	Comments/ Special Instructions
1	CE 0123	Communauté Européenne (CE Mark)	EU MDR/ Notified Body	Indicates that Class II and Class III products conform to EU MDR General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations. NOTE: Attachment of the mark indicates that the products have been certified by the referenced Notified Body TÜV SÜD Product Service GmbH (identified by registration number 0123).
2	CE	Communauté Européenne (CE Mark)	EU MDR/ Notified Body	Indicates that Class I products conform to EU MDR General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations. NOTE: Attachment of the mark indicates that the products have been self-certified according to the manufacturer's Declaration of Conformity.
3		Manufacturer	ISO 15223-1 5.1.1	Indicates the *medical device manufacturer.*
4		Date of manufacture	ISO 15223-1 5.1.3 ISO 7000 2497	Indicates the date when the *medical device* was manufactured.
5		Use-by date YYYY/MM/DD (date required)	ISO15223-1 5.1.4 ISO 7000 2607	Indicates the date after which the *medical device* is not to be used. NOTE: Synonyms for "use-by date" are "use by", "expiry date" and "expiration date".
6		Catalog Number	ISO 15223-1 5.1.6 ISO 7000 2493	Indicates the *manufacturer's catalogue number* so that the *medical device* can be identified. NOTE: Synonyms for "*catalog number*" are "*commercial product name", "commercial product code", stock keeping unit,* "reference number" and "reorder number".
7		Batch Code	ISO 15223-1 5.1.5 ISO 7000	Indicates the *manufacturer's batch code* so that the batch or lot can be identified. NOTE: Synonyms for "*batch code*" are "*lot number*", "lot code" and "*batch number*".

Index	Symbol	Description	Source of Symbol	Comments/ Special Instructions
			2492	
8		Serial Number	ISO 15223-1 5.1.7 ISO 7000 2498	Indicates the *manufacturer's serial number* so that a specific *medical device* can be identified.
9		Sterilized using ethylene oxide	ISO 15223-1 5.2.3 ISO 7000 2501	Indicates a *medical device* that has been sterilized using ethylene oxide.
10		Do not resterilize	ISO 15223-1 5.2.6 ISO 7000 2608	Indicates a *medical device* that is not to be resterilized.
11		Non-Sterile	ISO 15223-1 5.2.7 ISO 7000 2609	Indicates a *medical device* that has not been subjected to a sterilization process.
12		Do not use if package is damaged and consult instructions for use	ISO 15223-1 5.2.8 ISO 7000 2606	Indicates that a *medical device* that should not be used if the package has been damaged or opened and that the user should consult the i*nstructions for use* for additional information. NOTE 1 This *symbol* can also mean "Do not use if the product *sterile* barrier system or its packaging is compromised".
13		Single sterile barrier system	ISO 15223-1 5.2.11 ISO 7000 3707	Indicates a single *sterile* barrier system. NOTE 1: A solid line identifies a *sterile* barrier system. NOTE 2: Additional information on *sterile* barrier systems can be found in ISO 11607-1 and ISO 11607-2.
14		Double sterile barrier system	ISO 15223-1 5.2.12 ISO 7000 3704	Indicates two *sterile* barrier systems. NOTE 1 A double solid line indicates a double *sterile* barrier system. NOTE 2 Additional information on *sterile* barrier systems can be found in ISO 11607-1 and ISO 11607-2.

Index	Symbol	Description	Source of Symbol	Comments/ Special Instructions
15		Do not re-use	ISO 15223-1 5.4.2 ISO 7000 1051	Indicates a *medical device* that is intended for one *single use* only. NOTE: Synonyms for "*Do not re-use*" are "*single use*" and "*use only once*".
16	 eifu.orthofix.com	Consult electronic instructions for use	ISO 15223-1 5.4.3 ISO 7000 1641	Indicates the need for the user to consult the *instructions for use* and provides the website address to locate the electronic instructions for use. NOTE 1: Synonym for "Consult *instructions for use*" is "Consult operating instructions". NOTE 2: See also ISO 20417 and the safety sign ISO 7010-M002.
17		Caution	ISO 15223-1 5.4.4 ISO 7000-0434A	Indicates that caution is necessary when operating the device or control close to where the *symbol* is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
18		Non-pyrogenic	ISO 15223-1 5.6.3 ISO 7000 2724	Indicates a *medical device* that is non-pyrogenic.
19		MR Conditional	ASTM F2503	Indicates that the item has been demonstrated to pose no known hazard in a ***specified MRI environment*** *(specific field strength, special gradient, RF pulse limitations, and specific absorption rate).* NOTE: Yellow background of symbol indicates that a specific hazard could occur and warns the user to take caution.
20		Authorized representative in the European Community/ European Union	15223-1 5.1.2	Indicates the authorized representative in the European Community/ European Union.
21		Authorized representative in CH (Switzerland)	Swissmedic MU600_00_016e	Indicates the authorized representative in CH (Switzerland).
22		Package contents (quantity)	ISO 7000 2794	Indicates the quantity of units in package. Quantity to be displayed on symbol – see example.

Index	Symbol	Description	Source of Symbol	Comments/ Special Instructions
23		Medical device	ISO 15223-1 5.7.7	Indicates the item is a medical device. For the purposes of the Patient Implant Card, this symbol indicates "Device Type", as defined in MDCG 2019-8. NOTE For use in Europe the full definition of "*medical device*" is given in EU Regulation 2017/745. Other jurisdictions can have unique definitions.
24		Unique Device Identifier	ISO 15223-1 5.7.10	Indicates a carrier that contains unique device identifier information. NOTE This *symbol* identifies the UDI carrier, including the AIDC and human readable information.
25		Prescription use symbol	21 CFR 801.109	Indicates that, for products distributed in the USA, the medical device is intended for prescription use only. Symbol replaces the statement "*Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.*"
26		Peel Here	N\A	Indicates the location where the package can be opened.
27		Patient Identification	ISO 15223-1 5.7.3	For Patient Implant Cards, provides a field for healthcare staff to enter the Patient Name or Patient ID #.
28		Date of Implantation	ISO 15223-1 5.7.6	For Patient Implant Cards, provides a field for healthcare staff to enter the Date of Implantation of the Device.
29		Health Care Center or Doctor	ISO 15223-1 5.7.5	For Patient Implant Cards, indicates that adjacent fields are provided for healthcare staff entry of the names of the Physician and Healthcare Center, and Address and Telephone Number for the Healthcare Center.

Index	Symbol	Description	Source of Symbol	Comments/ Special Instructions
30		Information website for patients	ISO 15223-1 5.7.4	For Patient Implant Cards, indicates the website address for critical patient information.
31		Keep Dry	ISO 15223-1 5.3.4	Indicates a medical device that needs to be protected from moisture.
32		Sterilized using irradiation	ISO 15223-1 5.2.4	Indicates a medical device that has been sterilized using radiation.