	ANNEX 6.1	
	Rev.1	Page 1 di 7

Label of the first code of each kind of device described in this Design Dossier is following reported. For each label, all the information which changes in the other labels of the same device is showed.

The information about the sterilization method for the device is reported on the labels. The external cardboard box (first label in each of the following pages) indicates only the possible sterilization methods:

STERILE R

- **STERILE R:** sterilization by **irradiation** (Beta rays or Gamma rays according to the applicable sterilization method).

STERILE EO

- **STERILE EO:** sterilization by **ETO**

Labels provided below are here included as example. For the sterilization method applicable to each product refer to Chapter 1.2 of the Design Dossier.

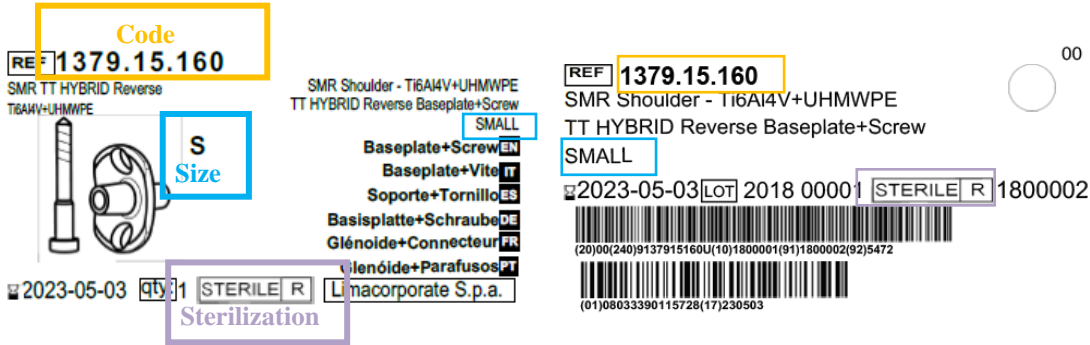
The labels are reported as follows:

- Paragraph 1** Example of labels for SMR TT Hybrid Glenoid Reverse Baseplate
- Paragraph 2** Example of labels for SMR TT Hybrid Glenoid
- Paragraph 3** Example of labels for SMR TT Augmented 360 Baseplate
- Paragraph 4** Example of labels for SMR Lateralized Connector with Screw
- Paragraph 5** Example of labels for SMR Cementless Finned Short Stem

1. Example of labels for SMR TT Hybrid Glenoid Reverse Baseplate

Data Legend

(the information which changes in the other labels of devices of the same product family is squared and showed in the table below).



Code
REF 1379.15.160

SMR TT HYBRID Reverse
Ti6Al4V+UHMWPE

S
Size

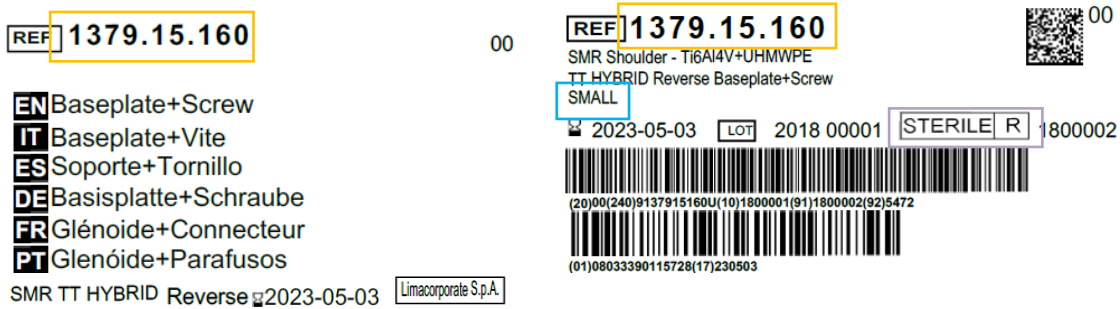
SMR Shoulder - Ti6Al4V+UHMWPE
TT HYBRID Reverse Baseplate+Screw

SMALL

Baseplate+Screw EN
Baseplate+Vite IT
Soporte+Tornillo ES
Basisplatte+Schraube DE
Glénoïde+Connecteur FR
Glénoïde+Parafusos PT

2023-05-03 Qty: 1 STERILE R Limacorporate S.p.A.

Sterilization



REF 1379.15.160

SMR Shoulder - Ti6Al4V+UHMWPE
TT HYBRID Reverse Baseplate+Screw

SMALL

EN Baseplate+Screw
IT Baseplate+Vite
ES Soporte+Tornillo
DE Basisplatte+Schraube
FR Glénoïde+Connecteur
PT Glénoïde+Parafusos

2023-05-03 LOT 2018 00001 STERILE R 1800002

Limacorporate S.p.A.



WARNING

USE ONLY WITH
SMR TT HYBRID
GLENOID SYSTEM

Single use
Do not use if package is damaged
Keep away from sunlight
Temperature limit

Use By
Reference Number
Keep dry

LOT Lot Number
Caution
Sterilized using Ethylene Oxide

IFU Consult instructions for use
Manufacturer
Sterilized using irradiation

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33038 Villanova di San Daniele - Udine - Italy

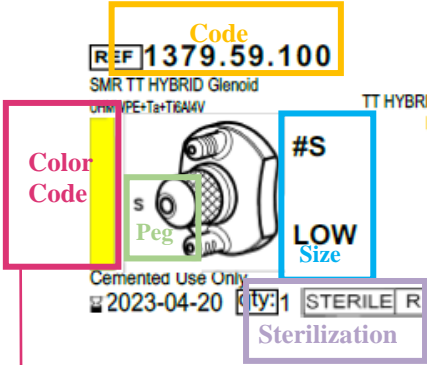
CE 0426

Code	Size
1379.15.160	S
1379.15.170	STD

2. Example of labels for SMR TT Hybrid Glenoid

Data Legend

(the information which changes in the other labels of devices of the same product family is squared and showed in the table below).

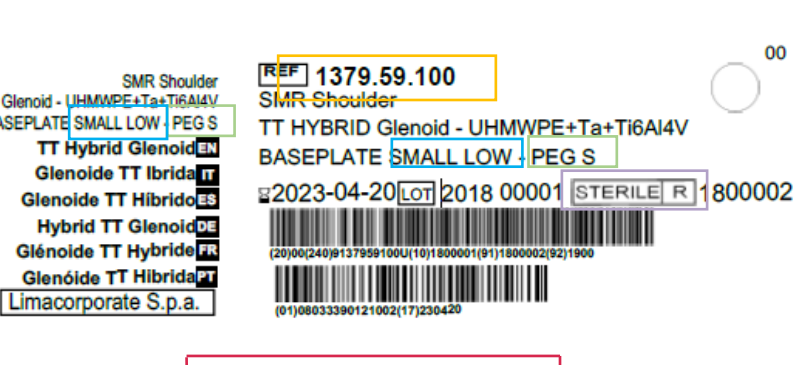


Code
REF 1379.59.100

Color Code

#S
LOW Size

Sterilization
STERILE R



REF 1379.59.100

REF 1379.59.100

STERILE R

Color code introduced to easily identify the color of the related trial instrument.
 Colors applied are Orange, Yellow, Grey, Magenta. Some sizes do not have a colored bar on labels. Color code is currently present only on the labels of the devices that LimaCorporate intends to commercialize in the imminent future.

Single use	Do not use if package is damaged	Keep away from sunlight	Temperature limit
Use By	Reference Number	Keep dry	
Lot Number	Caution	Sterilized using Ethylene Oxide	
IFU Consult instructions for use	Manufacturer	Sterilized using Irradiation	

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 33038 Villanova di San Daniele - Udine - Italy

CE 0426

		Peg Size	
		Peg #S	Peg #L
Baseplate Size	Small LOW	1379.59.100	1379.59.120
	Small LOW +1	1379.59.101	1379.59.121
	Small LOW +2	1379.59.102	1379.59.122
	Small LOW +3	1379.59.103	1379.59.123
	Small LOW +4	1379.59.104	1379.59.124
	Small	1379.59.110	1379.59.130
	Small +1	1379.59.111	1379.59.131
	Small +2	1379.59.112	1379.59.132
	Small +3	1379.59.113	1379.59.133
	Small +4	1379.59.114	1379.59.134
	Std LOW	1379.59.200	1379.59.220
	Std LOW +1	1379.59.201	1379.59.221
	Std LOW +2	1379.59.202	1379.59.222
	Std LOW +3	1379.59.203	1379.59.223
	Std LOW +4	1379.59.204	1379.59.224
	Std	1379.59.210	1379.59.230
	Std +1	1379.59.211	1379.59.231
	Std +2	1379.59.212	1379.59.232
	Std +3	1379.59.213	1379.59.233
	Std +4	1379.59.214	1379.59.234
	Large LOW	1379.59.300	1379.59.320
	Large LOW +1	1379.59.301	1379.59.321
	Large LOW +2	1379.59.302	1379.59.322
	Large LOW +3	1379.59.303	1379.59.323
	Large LOW +4	1379.59.304	1379.59.324
	Large	1379.59.310	1379.59.330
	Large +1	1379.59.311	1379.59.331
	Large +2	1379.59.312	1379.59.332
	Large +3	1379.59.313	1379.59.333
	Large +4	1379.59.314	1379.59.334

3. Example of labels for SMR TT Augmented 360 Baseplate

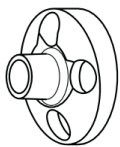
Data Legend

(the information which changes in the other labels of devices of the same product family is squared and showed in the table below).

Code

REF 1375.15.507

SMR Shoulder
TT Augm. 360 MR
Ti6Al4V



Size
7°
S-R
Ø27

Sterilization

Augmented Glenoid EN
Glèna Aumentata IT
Glenoide Aumentada ES
Augmentierte Glenoid DE
Glène Compensée FR
Glenó de Aumentada PT

For Pegs SMALL-F


2024-03-31 Qty 1 [STERILE R] Limacorporate S.p.a.

Code


REF 1375.15.507

SMR Shoulder
TT Augmented 360 Baseplate - Ti6Al4V
7°;S-R;Ø27mm

2024-03-31 [LOT] 2019 00001 [STERILE R] 1900002



(20)00(240)91375155070(10)1900001(91)1900002(92)4659




(01)08033390161459(17)240331


REF 1375.15.507

SMR Shoulder
TT Augmented 360 Baseplate - Ti6Al4V
7°;S-R;Ø27mm

2024-03-31 [LOT] 2019 00001 [STERILE R] 1900002



(20)00(240)91375155070(10)1900001(91)1900002(92)4659



(01)08033390161459(17)240331

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33038 Villanova di San Daniele - Udine - Italy

CE 0426

403

WARNING

DEVICE INTENDED FOR REVERSE USE ONLY

<p>COUPLE ONLY WITH PEG:</p> <p style="text-align: center;">1375.14.652 1375.14.653 1375.14.654</p>	<p>COUPLE ONLY WITH CONNECTOR+SCREW:</p> <p style="text-align: center;">1374.15.305</p>
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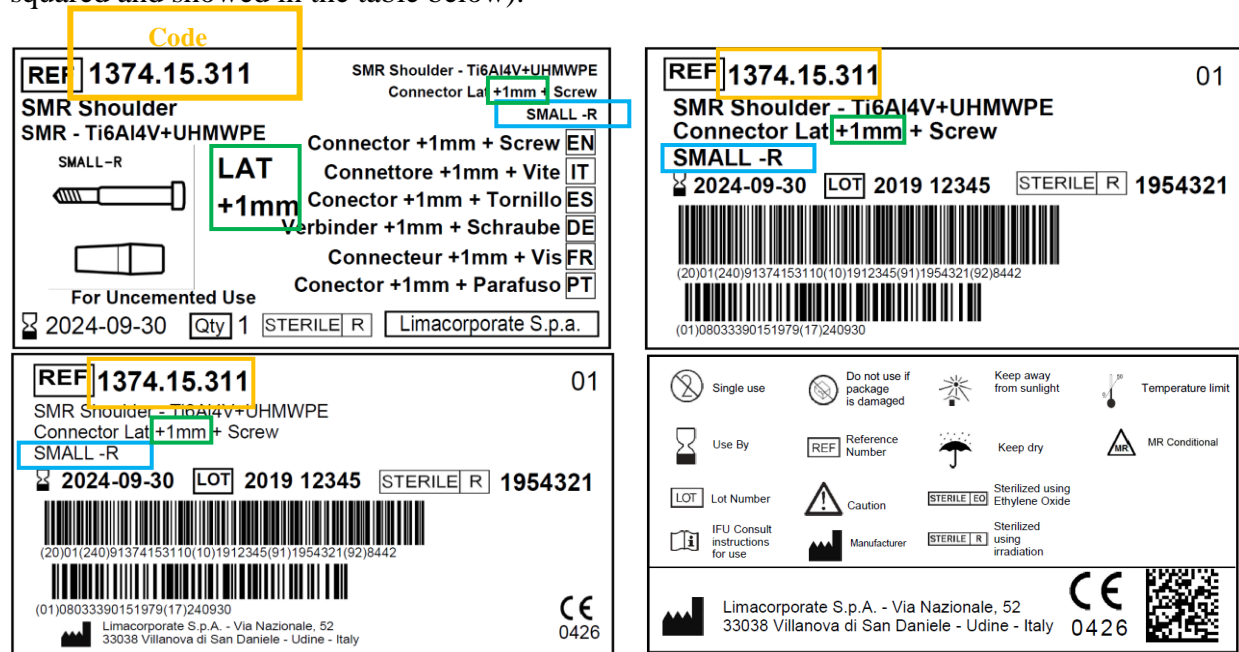
Single use	Do not use if package is damaged	Keep away from sunlight	Temperature limit
Use By	Reference Number	Keep dry	MR Conditional
Lot Number	Caution	Sterilized using Ethylene Oxide	
IFU Consult instructions for use	Manufacturer	Sterilized using irradiation	
Limacorporate S.p.A. - Via Nazionale, 52 33038 Villanova di San Daniele - Udine - Italy		CE 0426	

Code	Size
1375.15.507	S-R 7°
1375.15.510	S-R 10°
1375.15.515	S-R 15°
1375.15.519	S-R 19°
1375.15.522	S-R +2mm
1375.15.524	S-R +4mm

4. Example of labels for SMR Lateralized Connector with Screw

Data Legend

(the information which changes in the other labels of devices of the same product family is squared and showed in the table below).



The image shows four examples of product labels for SMR Lateralized Connector with Screw. The labels are arranged in a 2x2 grid. The top-left label shows the product name 'SMR Shoulder - Ti6Al4V+UHMWPE Connector Lat +1mm + Screw' and 'SMALL - R'. The top-right label shows the product name 'SMR Shoulder - Ti6Al4V+UHMWPE Connector Lat +1mm + Screw' and 'SMALL - R'. The bottom-left label shows the product name 'SMR Shoulder - Ti6Al4V+UHMWPE Connector Lat +1mm + Screw' and 'SMALL - R'. The bottom-right label shows the product name 'SMR Shoulder - Ti6Al4V+UHMWPE Connector Lat +1mm + Screw' and 'SMALL - R'. The labels include the code 'REF 1374.15.311', lot number '2019 12345', expiration date '2024-09-30', and manufacturer information 'Limacorporate S.p.a.'. The labels also include a barcode and a QR code.



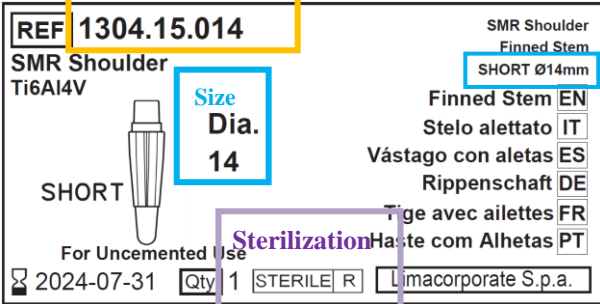
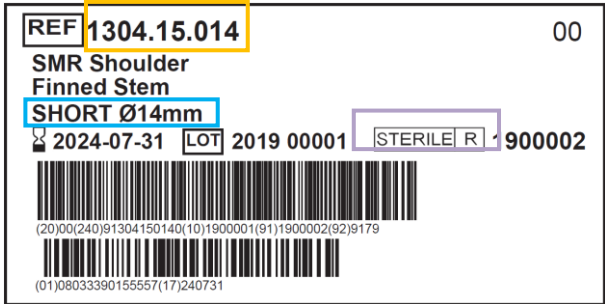

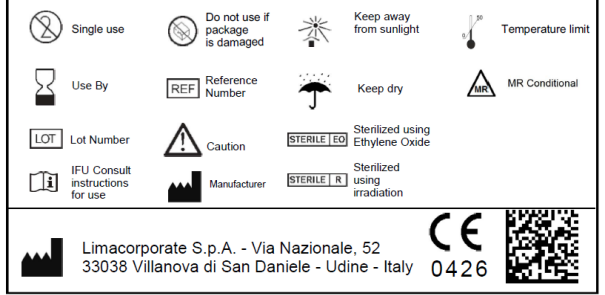
WARNING
 COUPLE ONLY WITH CONCENTRIC GLENOSPHERE 38mm, 40mm OR 44mm
 DO NOT USE WITH ECCENTRIC GLENOSPHERES

Code	Connector Size	Lateralization
1374.15.311	SMALL-R	1mm
1374.15.312	SMALL-R	2mm
1374.15.313	SMALL-R	3mm
1374.15.314	SMALL-R	4mm
1374.15.315	SMALL-R	5mm
1374.15.321	SMALL / STD	1mm
1374.15.322	SMALL / STD	2mm
1374.15.323	SMALL / STD	3mm
1374.15.324	SMALL / STD	4mm
1374.15.325	SMALL / STD	5mm

5. Example of labels for SMR Cementless Finned Short Stem

Data Legend

(the information which changes in the other labels of devices of the same product family is squared and showed in the table below).

Code	Size
1304.15.014	Dia. 14mm
1304.15.015	Dia. 15mm
1304.15.016	Dia. 16mm
1304.15.017	Dia. 17mm
1304.15.018	Dia. 18mm
1304.15.019	Dia. 19mm
1304.15.020	Dia. 20mm
1304.15.021	Dia. 21mm
1304.15.022	Dia. 22mm
1304.15.023	Dia. 23mm
1304.15.024	Dia. 24mm
1304.15.025	Dia. 25mm
1304.15.026	Dia. 26mm