

EXAMPLE OF LABELS OF SMR STEMLESS SYSTEM

An example of label for each kind of device belonging to SMR Stemless System is reported in the following paragraph. For each label, all the information which changes in the other labels of the same type of device is showed.

The labels are reported as follows:

Section 1	Example of labels for SMR Stemless Core
Section 2	Example of labels for SMR Stemless Adaptor with screws
Section 3	Example of labels for SMR Stemless Adaptor screw
Section 4	Example of labels for SMR Stemless Reverse Liner

STERILIZATION – DATA ON THE LABELS

The information about the sterilization method for the devices 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:** sterilization by **irradiation** (Beta rays or Gamma rays according to the applicable sterilization method).

Always refer to device labels for information about the sterilization method.

SECTION 1 – EXAMPLE OF LABELS FOR SMR STEMLESS CORE
Data Legend

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

REF **1355.14.131**
 SMR STEMLESS - Ti6Al4V
 Ti6Al4V **Code**



XS Size

SHORT
 For Uncemented Use
 2022-05-31 qty: 1 STERILE R Limacorporate S.p.a.

SMR STEMLESS - Ti6Al4V
 Stemless Core
 #X-SMALL SHORT
 Stemless Core EN
 Nucleo Stemless IT
 Núcleo Stemless ES
 Stemless Core DE
 Noyau Stemless FR
 Nucleo Stemless PT

Codes	Sizes
1355.14.033	SMALL
1355.14.035	MEDIUM
1355.14.038	LARGE
1355.14.131	X-SMALL SHORT
1355.14.231	X-SMALL
1355.14.133	SMALL SHORT
1355.14.233	SMALL
1355.14.135	MEDIUM SHORT
1355.14.235	MEDIUM
1355.14.138	LARGE SHORT
1355.14.238	LARGE
1355.14.140	X-LARGE SHORT
1355.14.240	X-LARGE

REF **1355.14.131** 00
 SMR STEMLESS - Ti6Al4V
 Stemless Core
 #X-SMALL SHORT

2022-05-31 LOT 2016 07964 STERILE R 1700160



(20)00(240)91355141310(10)1607964(91)1700160(92)1881
 01410001995004077964171990634


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

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
REF **1355.14.131** 00
 SMR STEMLESS - Ti6Al4V
 Stemless Core
 #X-SMALL SHORT

2022-05-31 LOT 2016 07964 STERILE R 1700160



(20)00(240)91355141310(10)1607964(91)1700160(92)1881
 (01)08033390107785(17)220531

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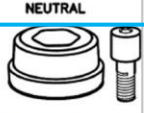
SECTION 2 – EXAMPLE OF LABELS FOR SMR STEMLESS ADAPTOR WITH SCREW AND ADAPTOR SCREW

Data Legend

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

REF **1335.15.200**
SMR STEMLESS
T6AI4V **Code**

NEUTRAL **Type**



SMR STEMLESS - Ti6Al4V
NEUTRAL Adaptor with Screw

Neutral Adaptor **EN**
Adattatore Neutro **IT**
Adaptador Neutral **ES**
Neutraler Adapter **DE**
Adaptateur Neutre **FR**
Adaptador Neuro **PT**

For Uncemented Use
2021-07-31 **qty:** 1 **STERILE R** Limacorporate S.p.a.

Codes	Types
1335.15.100	Neutral Adaptor with Screw
1335.15.102	2 mm Eccentric Adaptor with Screw
1335.15.104	4 mm Eccentric Adaptor with Screw
1335.15.200	Neutral Adaptor with Screw
1335.15.202	2 mm Eccentric Adaptor with Screw
1335.15.204	4 mm Eccentric Adaptor with Screw

REF **1335.15.200**
SMR STEMLESS - Ti6Al4V
NEUTRAL Adaptor with Screw

2021-07-31 **LOT** 2016 07018 **STERILE R** 1600191



(20)00(240)91335152000(10)1607018(91)1600191(92)1864
(01)08033390107723(17)210731

Single use Do not use if package is damaged Keep away from sunlight Temperature limit
Use By REF Reference Number Keep dry
LOT Lot Number Caution **STERILE EO** Sterilized using Ethylene Oxide
IFU Consult instructions for use Manufacturer **STERILE X** Sterilized using irradiation

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REF **1335.15.200**
SMR STEMLESS - Ti6Al4V
NEUTRAL Adaptor with Screw

2021-07-31 **LOT** 2016 07018 **STERILE R** 1600191



(20)00(240)91335152000(10)1607018(91)1600191(92)1864
(01)08033390107723(17)210731

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SECTION 3 – EXAMPLE OF LABELS FOR SMR STEMLESS ADAPTOR SCREW

Data Legend

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

REF 1335.15.001
SMR STEMLESS
Ti6AlV




SMR STEMLESS - Ti6AlV
Adaptor Screw / Vite per Adattatore

Adaptor Screw **EN**
Vite per Adattatore **IT**
Tornillo Adattatore **ES**
Adapterschraube **DE**
Vis pour Adaptateur **FR**
Parafuso Adaptador **PT**

For Uncemented Use
2000-00-00 **qty:**1 **STERILE R** Limacorporate S.p.a.

REF 1335.15.001
SMR STEMLESS - Ti6AlV
Adaptor Screw / Vite per Adattatore








2000-00-00 **LOT** 2018 00000 **STERILE R** 1800001




(20)00(240)91335150010(10)1800000(91)1800001(92)9219



(01)08033390094184(17)000000

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

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REF 1335.15.001
SMR STEMLESS - Ti6AlV
Adaptor Screw / Vite per Adattatore



2000-00-00 **LOT** 2018 00000 **STERILE R** 1800001



(20)00(240)91335150010(10)1800000(91)1800001(92)9219



(01)08033390094184(17)000000

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SECTION 4 – EXAMPLE OF LABELS FOR SMR STEMLESS REVERSE LINER

Data Legend

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

REF **1365.09.405**
SMR STEMLESS - CoCrMo
CoCrMo **Code**



D=40
#S **Size and Diameter**

SMR STEMLESS - CoCrMo
Reverse Liner
SHORT Dia.40mm
Reverse Liner **EN**
Inserto Inverso **IT**
Inserto Inverso **ES**
Inverses Inlay **DE**
Insert Inverse **FR**
Inserto Invertido **PT**

For Uncemented Use
2021-04-30 **Qty:** 1 **STERILE R** **Limacorporate S.p.a.**

Codes	Sizes and Diameters
1365.09.401	SHORT Dia 40 mm
1365.09.402	MEDIUM Dia 40 mm
1365.09.403	LONG Dia 40 mm
1365.09.441	SHORT Dia 44 mm
1365.09.442	MEDIUM Dia 44 mm
1365.09.443	LONG Dia 44 mm
1365.09.405	SHORT Dia 40 mm
1365.09.406	MEDIUM Dia 40 mm
1365.09.407	LONG Dia 40 mm
1365.09.445	SHORT Dia 44 mm
1365.09.446	MEDIUM Dia 44 mm
1365.09.447	LONG Dia 44 mm

REF **1365.09.405**
SMR STEMLESS - CoCrMo
Reverse Liner
SHORT Dia.40mm

2021-04-30 **LOT:** 2015 19725 **STERILE R** 1600098



(20)00(240)91365094050(10)1519725(91)1600098(52)2000
(01)08033390108379(17)210430

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

Use By REF Reference Number Keep dry

LOT Lot Number Caution STERILE EO Sterilized using Ethylene Oxide

IFU Consult instructions for use Manufacturer STERILE R Sterilized using irradiation

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REF **1365.09.405**
SMR STEMLESS - CoCrMo
Reverse Liner
SHORT Dia.40mm

2021-04-30 **LOT:** 2015 19725 **STERILE R** 1600098



(20)00(240)91365094050(10)1519725(91)1600098(52)2000
(01)08033390108379(17)210430

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