



**DECLARATION OF CONFORMITY**

Manufacturer:	Sol-Millennium Medical, Inc. 1735 North Brown Road Suite 120 Lawrenceville, GA 30043
Classification rule:	Class IIa per Rule 6 in accordance of the Council Directive MDD 93/42/EEC
Management Representative:	Jim Barley, RA Director
European Authorized Representative:	Registered Address: Obelis s.a. Bd. Général Wahis 53 B-1030 Brussels, Belgium Phone: 32.2.732.59.54 Fax: 32.2.732.60.03 E-mail: mail@obelis.net Representative: Mr. Gideon ELKAYAM
Medical Device(s):	SOL-CARE™ Insulin Safety Syringe U-100 Insulin Only, SOL-CARE™ Luer Lock Safety Syringe without needle, SOL-CARE™ Luer Lock Safety Syringe with exchangeable needle, SOL-CARE™ TB Safety Syringe with fixed needle, SOL-CARE™ Luer Lock Syringe with Safety Needle, SOL-CARE™ Safety Needle, SOL-M™ Hypodermic Needle, SOL-M™ Luer Lock Syringe with exchangeable needle, SOL-M™ Syringe with fixed needle SOL-M™ Insulin Syringe with exchangeable needle, SOL-M™ Insulin Syringe with fixed needle, SOL-M™ Luer Lock Syringe without needle, SOL-M™ TB Slip Tip Syringe with exchangeable needle, SOL-M™ Slip Tip Syringe without needle, SOL-M™ Catheter Tip Syringe without needle, SOL-GUARD™ Insulin Safety Syringe U-100 Insulin Only, SOL-GUARD™ TB Safety Syringe with fixed needle. See the attached product details.

We hereby declare that the distributed CE marked product SOL-CARE™ Insulin Safety Syringe U-100 Insulin Only, SOL-CARE™ Luer Lock Safety Syringe without needle, SOL-CARE™ Luer Lock Safety Syringe with exchangeable needle, SOL-CARE™ TB Safety Syringe with fixed needle, SOL-CARE™ Luer Lock Syringe with Safety Needle, SOL-CARE™ Safety Needle, SOL-M™ Hypodermic Needle, SOL-M™ Luer Lock Syringe with exchangeable needle, SOL-M™ Syringe with fixed needle, SOL-M™ Insulin Syringe with exchangeable needle, SOL-M™ Insulin Syringe with fixed needle, SOL-M™ Luer Lock Syringe without needle, SOL-M™ TB Slip Tip Syringe with exchangeable needle, SOL-M™ Slip Tip Syringe without needle, SOL-M™ Catheter Tip Syringe without needle, SOL-GUARD™ Insulin Safety Syringe U-100 Insulin Only, SOL-GUARD™ TB Safety Syringe with fixed needle conform to the type(s) covered by Certificate of Registration, Quality System Management – ISO 13485:2003, Certificate Number FM 576929 issued on October 11, 2011 by BSI, 12950 Worldgate Drive, Suite 800, Herndon, VA 20170.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, meet the provisions of the EC-Directive that apply to them.

This declaration is based on Annex VII and Annex V according to Article 11 of the Council Directive 93/42/EEC.

This declaration is based on the application of the Quality System approved for the manufacturer and final inspection of the products concerned, in accordance with Annex VII of the EC Directive. The conformity of

Effective

B. Braun Meisingen AG - Document No.: NA - Version: 1.0 - Document ID: DC-RA-IVA-000003 - Effective Date: 2020-11-04 - Title: Declaration of Conformity - DoC-001 - SOL-CARE Safety Needle



# SOL-MILLENNIUM<sup>®</sup> Effective

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the production quality assurance set out in Annex VII, coupled with the procedure set out in Annex V, is described in the CE Marking of Conformity Certificate, reference number CE 584545 issued for the first time on August 22 2012, reissued on December 20, 2015, and delivered by BSI Healthcare located at Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK.

This Declaration of Conformity covers the SOL-CARE<sup>™</sup> Insulin Safety Syringe U-100 Insulin Only, SOL-CARE<sup>™</sup> Luer Lock Safety Syringe without needle, SOL-CARE<sup>™</sup> Luer Lock Safety Syringe with exchangeable needle, SOL-CARE<sup>™</sup> TB Safety Syringe with fixed needle, SOL-CARE<sup>™</sup> Luer Lock Syringe with Safety Needle, SOL-CARE<sup>™</sup> Safety Needle, SOL-M<sup>™</sup> Hypodermic Needle, SOL-M<sup>™</sup> Luer Lock Syringe with exchangeable needle, SOL-M<sup>™</sup> Syringe with fixed needle, SOL-M<sup>™</sup> Insulin Syringe with fixed needle, SOL-M<sup>™</sup> Insulin Syringe with exchangeable needle, SOL-M<sup>™</sup> Luer Lock Syringe without needle, SOL-M<sup>™</sup> TB Slip Tip Syringe with exchangeable needle, SOL-M<sup>™</sup> Slip Tip Syringe without needle, SOL-M<sup>™</sup> Catheter Tip Syringe without needle, SOL-GUARD<sup>™</sup> Insulin Safety Syringe U-100 Insulin Only, SOL-GUARD<sup>™</sup> TB Safety Syringe with fixed needle. This declaration is valid for all products concerned bearing the CE marking and manufactured at the above location entitled "Manufacturer".

**Issued:** Lawrenceville, GA on July 16, 2016



Mark Stoppenbach, President

B. Braun Meisungen AG - Document No.: NA - Version: 1.0 - Document ID: DC-RA-IVA-000003 - Effective Date: 2020-11-04 - Title: Declaration of Conformity - DoC-001 - SOL-CARE Safety Needle

Effective



<b>SOL-M™ Luer Lock Syringe with exchangeable needle</b>			
<b>Product REF</b>	<b>Product Description</b>		<b>GMDN Code</b>
1812010	10ml	20Gx1"	47017
1812015	10ml	20Gx1-1/2"	47017
1812110	10ml	21Gx1"	47017
1812115	10ml	21Gx1-1/2"	47017
1812210	10ml	22Gx1"	47017
1831815	3ml	18Gx1-1/2"	47017
1832010	3ml	20Gx1"	47017
1832015	3ml	20Gx1-1/2"	47017
1832110	3ml	21Gx1"	47017
1832115	3ml	21x1-1/2"	47017
1832210	3ml	22Gx1"	47017
1832215	3ml	22Gx1-1/2"	47017
1832310	3ml	23Gx1"	47017
1832510	3ml	25Gx1"	47017
1832515	3ml	25Gx1-1/2"	47017
1832558	3ml	25Gx5/8"	47017
1852010	5ml	20Gx1"	47017
1852015	5ml	20Gx1-1/2"	47017
1852110	5ml	21Gx1"	47017
1852115	5ml	21Gx1-1/2"	47017
1852210	5ml	22Gx1"	47017
1852215	5ml	22Gx1-1/2"	47017
18012010	1ml	20Gx1"	47017
18012912	1ml	29Gx1/2"	47017
012912PC	1ml	29Gx1/2" (PC)	47017
18322125	3ml	22Gx1-1/4"	47017
1831815B	3ml	18Gx1-1/2"	47017
1851815B	5ml	18Gx1-1/2"	47017
1811815B	10ml	18Gx1-1/2"	47017
1832110T	3ml	21Gx1"	47017
1832210T	3ml	22Gx1"	47017
1832310T	3ml	23Gx1"	47017
1852010T	5ml	20Gx1"	47017
1852110T	5ml	21Gx1"	47017
110101120011	10ml	20Gx1"	47017
110101120012	10ml	21Gx1"	47017

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<b>SOL-M™ Syringe with fixed needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
180527	0.5ml	27Gx1/2"	38501
181027	1ml	27Gx1/2"	38501
180526IDB	0.5ml	26Gx3/8"	38501
180527IDBT	0.5ml	27Gx3/8"	38501
180527T	0.5ml	27Gx1/2"	38501
181023T	1ml	23Gx1/2"	38501
181026IDB	1ml	26Gx3/8"	38501
181026IDBT	1ml	26Gx3/8"	38501
181026T	1ml	26Gx1/2"	38501
181027IDBT	1ml	27Gx3/8"	38501
181027SNT	1ml	27Gx3/8"	38501
181027T	1ml	27Gx1/2"	38501
181126IDBT	1ml	26Gx1/2"	38501
<b>SOL-M™ Insulin Syringe with exchangeable needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
505037	1ml	25Gx1"	38501
505038	1ml	29Gx1/2"	38501
505039	1ml	30Gx1/2"	38501
505040	1ml	30Gx5/16"	38501
<b>SOL-M™ Insulin Syringe with fixed needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
1612912	1ml	29Gx1/2"	38501
1613012	1ml	30Gx1/2"	38501
1632912	0.3ml	29Gx1/2"	38501
1633012	0.3ml	30Gx1/2"	38501
1652912	0.5ml	29Gx1/2"	38501
1653012	0.5ml	30Gx1/2"	38501
16130516	1ml	30Gx5/16"	38501
16330516	0.3ml	30Gx5/16"	38501
16530516	0.5ml	30Gx5/16"	38501
012558S	1ml	25Gx5/8"	38501
1612912B	1ml	29Gx1/2"	38501
1613012B	1ml	30Gx1/2"	38501
1613051B	1ml	30Gx5/16"	38501
1613151B	1ml	31Gx5/16"	38501
1632612B	0.3ml	29Gx1/2"	38501

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1633012B	0.3ml	30Gx1/2"	38501
1633051B	0.3ml	30Gx5/16"	38501
1633151B	0.3ml	31Gx5/16"	38501
1632912B	0.3ml	29Gx1/2"	38501
1652912B	0.5ml	29Gx1/2"	38501
1653012B	0.5ml	30Gx1/2"	38501
1653051B	0.5ml	30Gx5/16"	38501
1653151B	0.5ml	31Gx5/16"	38501
<b>SOL-M™ Luer Lock Syringe without needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
180001	1ml	--	47017
180002	2ml	--	47017
180003	3ml	--	47017
180005	5ml	--	47017
180010	10ml	--	47017
180011	1ml	--	47017
180020	20ml	--	47017
180030	30ml	--	47017
180060	60ml	--	47017
307005	5ml	--	47017
308003	10ml	--	47017
309003	20ml	--	47017
313001	2ml	--	47017
180001PP	1ml	--	47017
180001T	1ml	--	47017
180001TPC	1ml	--	47017
180010ET	10ml	--	47017
180020ET	20ml	--	47017
180030ET	30ml	--	47017
180060ET	60ml	--	47017
<b>SOL-M™ TB Slip Tip Syringe with exchangeable needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
181025S	1ml	25Gx5/8"	47017
181027S	1ml	27Gx1/2"	47017
<b>SOL-M™ Slip Tip Syringe without needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
180011	1ml	--	47017



180003ST	3ml	--	47017
180005ST	5ml	--	47017
180010ST	10ml	--	47017
180020ST	20ml	--	47017
180030ST	30ml	--	47017
180050ST	50ml	--	47017
<b>SOL-M™ Catheter Tip Syringe without needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
180060CT	60ml	--	47017
<b>SOL-CARE™ Insulin Safety Syringe U-100 Insulin Only</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
100001IM	0.5ml	30Gx1/2"	34973
100002IM	0.5ml	29Gx1/2"	34973
100017IM	1ml	29Gx1/2"	34973
100020IM	1ml	30Gx5/16"	34973
100071IM	1ml	28Gx1/2"	34973
100081IM	1ml	30Gx1/2"	34973
100089IM	0.5ml	30Gx5/16"	34973
100091IM	1ml	31Gx5/16"	34973
100094IM	1ml	30Gx15/64"	34973
100095IM	0.5ml	30Gx15/64"	34973
<b>SOL-CARE™ TB Safety Syringe with fixed needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
100006IM	0.5ml	23Gx1"	45042
100007IM	0.5ml	25Gx1"	45042
100008IM	0.5ml	26Gx1/2"	45042
100009IM	0.5ml	27Gx1"	45042
100010IM	0.5ml	30Gx1/2"	45042
100011IM	0.5ml	26Gx3/8"	45042
100018IM	1ml	25Gx5/8"	45042
100019IM	1ml	27Gx1/2"	45042
100023IM	0.5ml	23Gx3/8"	45042
100026IM	1ml	27Gx3/8"	45042
100029IM	1ml	29Gx1/2"	45042
100032IM	1ml	27Gx1/2"	45042
100033IM	0.5ml	27Gx1/2"	45042
100034IM	1ml	25Gx1"	45042

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100035IM	0.5ml	26Gx3/8"	45042
100040IM	1ml	22Gx1-1/2"	45042
100067IM	1ml	28Gx1/2"	45042
100069IM	1ml	26Gx3/8"	45042
100070IM	1ml	26Gx3/8"	45042
100082IM	1ml	30Gx1/2"	45042
100088IM	1ml	25Gx1"	45042
100090IM	0.5ml	27Gx1/2"	45042
<b>SOL-CARE™ Luer Lock Safety Syringe without needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
120002IM	2ml	--	47017
120006IM	3ml	--	47017
120007IM	5ml	--	47017
120008IM	10ml	--	47017
120009IM	20ml	--	47017
<b>SOL-CARE™ Luer Lock Safety Syringe with exchangeable needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
100059IM	3ml	18Gx1-1/2"	45042
100060IM	3ml	21Gx1-1/4"	45042
100061SIM	3ml	21Gx1-1/2"	45042
100062IM	3ml	22Gx1-1/4"	45042
100062SIM	3ml	22Gx1-1/4"	45042
100063SIM	3ml	23Gx1"	45042
100064IM	3ml	23Gx1-1/4"	45042
100065SIM	3ml	23Gx1-1/4"	45042
100066IM	3ml	23Gx1-1/2"	45042
100068IM	3ml	25Gx1-1/4"	45042
100072IM	3ml	21Gx1-1/2"	45042
100074IM	3ml	20Gx1"	45042
100075IM	3ml	21Gx1"	45042
100076IM	3ml	22Gx1-1/2"	45042
100077IM	3ml	23Gx1"	45042
100078IM	3ml	25Gx5/8"	45042
100079IM	3ml	25Gx1"	45042
100084IM	3ml	20Gx1-1/2"	45042
100085IM	3ml	22Gx1"	45042
140060IM	5ml	21Gx1-1/4"	45042

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140061SIM	3ml	21Gx1-1/2"	45042
140062IM	5ml	22Gx1-1/4"	45042
140065IM	5ml	23Gx1-1/4"	45042
140072IM	5ml	21Gx1-1/2"	45042
140075IM	5ml	21Gx1"	45042
140076IM	5ml	22Gx1-1/2"	45042
140076SIM	5ml	22Gx1-1/2"	45042
140077IM	5ml	23Gx1"	45042
140084IM	5ml	20Gx1-1/2"	45042
140085IM	5ml	22Gx1"	45042
150085IM	3ml	22Gx1"	45042
160061SIM	10ml	21Gx1-1/2"	45042
160062IM	10ml	22Gx1-1/4"	45042
160065IM	10ml	23Gx1-1/4"	45042
160072IM	10ml	21Gx1-1/2"	45042
160075IM	10ml	21Gx1"	45042
160076IM	10ml	22Gx1-1/2"	45042
160077IM	10ml	23Gx1"	45042
160084IM	10ml	20Gx1-1/2"	45042
160085IM	10ml	22Gx1"	45042
190061IM	20ml	21Gx1-1/2"	45042
190072IM	20ml	21Gx1-1/2"	45042
190075IM	20ml	21Gx1"	45042
190085IM	20ml	22Gx1"	45042
<b>SOL-GUARD™ Insulin Safety Syringe U-100 Insulin Only</b>			
Product Ref	Product Description		GMDN Code
200002SG	0.5ml	29GX1/2"	34973
200003SG	0.3ml	29GX1/2"	34973
200017SG	1ml	29GX1/2"	34973
200091SG	1ml	31GX5/16"	34973
233105SG	0.3ml	31Gx1/2"	34973
2331516SG	0.3ml	31GX5/16"	34973
253105SG	0.5ml	31Gx1/2"	34973
2531516SG	0.5ml	31GX5/16"	34973
<b>SOL-GUARD™ TB Safety Syringe with fixed needle</b>			
23316SG	0.3ml	31Gx15/64"	34973
23303SG	0.3ml	30Gx15/64"	34973

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25315SG	0.5ml	31Gx15/64"	34973
25306SG	0.5ml	30Gx15/64"	34973
200018SG	1ml	25GX5/8"	34973
200019SG	1ml	27GX1/2"	34973
200034SG	1ml	25GX1"	34973
200067SG	1ml	28GX1/2"	34973
200092SG	1ml	31Gx1/2"	34973
200093SG	1ml	31Gx15/64"	34973
200094SG	1ml	30Gx15/64"	34973
2102215SG	1ml	22Gx1-1/2"	34973
2131516SG	1ml	31Gx5/16"	34973
2152215SG	1.5ml	22GX1-1/2"	34973
110101040008	1ml	25Gx1"	34973
<b>SOL-M™ Hypodermic Needle</b>			
Product Ref	Product Description		GMDN Code
111810	--	18Gx1"	59230
111815	--	18Gx1-1/2"	59230
111915	--	19Gx1-1/2"	59230
111915F	--	19Gx1-1/2" w/Filter	59230
112010	--	20Gx1"	59230
112015	--	20Gx1-1/2"	59230
112110	--	21Gx1"	59230
112115	--	21Gx1-1/2"	59230
112210	--	22Gx1"	59230
1122125	--	22Gx1-1/4"	59230
112215	--	22Gx1-1/2"	59230
112310	--	23Gx1"	59230
112334	--	23Gx3/4"	59230
112410	--	24Gx1"	59230
112506	--	25Gx5/8"	59230
112510	--	25Gx1"	59230
112515	--	25Gx1/5"	59230
112612	--	26Gx1/2"	59230
112638	--	26Gx3/8"	59230
112705	--	27Gx1/2"	59230
112734	--	27Gx3/4"	59230
112905	--	29Gx1/2"	59230

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113005	--	30Gx1/2"	59230
113112	--	31Gx1/2"	59230
1123125	--	23Gx1-1/4"	59230
<b>SOL-CARE™ Luer Lock Syringe with Safety Needle</b>			
<b>Product Ref</b>	<b>Product Description</b>		<b>GMDN Code</b>
102010SN	10ml	20Gx1"	45042
102015SN	10ml	20Gx1-1/2"	45042
102110SN	10ml	21Gx1"	45042
102115SN	10ml	21Gx1-1/2"	45042
102210SN	10ml	22Gx1"	45042
102215SN	10ml	22Gx1-1/2"	45042
12558SS	1ml	25Gx5/8"	45042
12638SS	1ml	26Gx3/8"	45042
12638SST	1ml	26Gx3/8"	45042
13005SS	1ml	30Gx1/2"	45042
13005SN	1ml	30Gx1/2"	45042
12734SS	1ml	27Gx3/4"	45042
12734SN	1ml	27Gx3/4"	45042
12705SS	1ml	27Gx1/2"	45042
12705SN	1ml	27Gx1/2"	45042
12558SN	1ml	25Gx5/8"	45042
12510SS	1ml	25Gx1"	45042
12510SN	1ml	25Gx1"	45042
12338SN	1ml	23Gx3/8"	45042
12705SST	1ml	27Gx1/2"	45042
22310SN	2ml	23Gx1"	45042
32010SN	3ml	20Gx1"	45042
32015SN	3ml	20Gx1-1/2"	45042
32110SN	3ml	21Gx1"	45042
32115SN	3ml	21Gx1-1/2"	45042
32210SN	3ml	22Gx1"	45042
32215SN	3ml	22Gx1-1/2"	45042
32310SN	3ml	23Gx1"	45042
323125SN	3ml	23Gx1-1/4"	45042
32315SN	3ml	23Gx1-1/2"	45042
32510SN	3ml	25Gx1"	45042
32558SN	3ml	25Gx5/8"	45042

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32558SS	3ml	25Gx5/8"	45042
32510SS	3ml	25Gx1"	45042
32310SS	3ml	23Gx1"	45042
323125SS	3ml	23Gx1-1/4"	45042
32315SS	3ml	23Gx1-1/2"	45042
32210SS	3ml	22Gx1"	45042
32215SS	3ml	22Gx1-1/2"	45042
32110SS	3ml	21Gx1"	45042
32115SS	3ml	21Gx1-1/2"	45042
32010SS	3ml	20Gx1"	45042
32015SS	3ml	20Gx1-1/2"	45042
110101060109	3ml	22Gx1-1/4"	45042
52010SN	5ml	20Gx1"	45042
52015SN	5ml	20Gx1-1/2"	45042
52110SN	5ml	21Gx1"	45042
52115SN	5ml	21Gx1-1/2"	45042
52210SN	5ml	22Gx1"	45042
52215SN	5ml	22Gx1-1/2"	45042
523125SN	5ml	23Gx1-1/4"	45042
52215SS	5ml	22Gx1-1/2"	45042
52110SS	5ml	21Gx1"	45042
52115SS	5ml	21Gx1-1/2"	45042
52010SS	5ml	20Gx1"	45042
52015SS	5ml	20Gx1-1/2"	45042
110101060110	5ml	22Gx1-1/4"	45042
102215SS	10ml	22Gx1-1/2"	45042
102110SS	10ml	21Gx1"	45042
110101060111	10ml	21Gx1-1/2"	45042
102010SS	10ml	20Gx1"	45042
102015SS	10ml	20Gx1-1/2"	45042
<b>SOL-CARE™ Safety Needle</b>			
Product Ref	Product Description		GMDN Code
SN1810	--	18G X 1"	59230
SN1815	--	18G X 1-1/2"	59230
SN1820	--	18G X 2"	59230
SN1910	--	19G X 1"	59230
SN1915	--	19G X 1-1/2"	59230

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SN1920	--	19Gx2"	59230
SN2005	--	20G X 2"	59230
SN2010	--	20G X 1"	59230
SN2015	--	20G X 1-1/2"	59230
SN2105	--	21G X 2"	59230
SN2110	--	21G X 1"	59230
SN21125	--	25G X 1 1/4"	59230
SN2115	--	21G X 1-1/2"	59230
SN2158	--	21G X 5/8"	59230
SN2205	--	22G X 2"	59230
SN2210	--	22G X 1"	59230
SN22125	--	22G X 1 1/4"	59230
SN2215	--	22G X 1-1/2"	59230
SN2310	--	23G X 1"	59230
SN23125	--	23G X 1-1/4"	59230
SN2315	--	23G X 1-1/2"	59230
SN2358	--	23G X 5/8"	59230
SN2410	--	24G X 1"	59230
SN2415	--	24G X 1-1/2"	59230
SN2420	--	24G X 2"	59230
SN2510	--	25G X 1"	59230
SN2512	--	25G X 1/2"	59230
SN2515	--	25G X 1-1/2"	59230
SN2558	--	25G X 5/8"	59230
SN2610	--	26G X 1"	59230
SN2612	--	26G X 1/2"	59230
SN2638	--	26G X 3/8"	59230
SN2712	--	27G X 1/2"	59230
SN27125	--	27Gx1/2"	59230
SN2715	--	27Gx1-1/2"	59230
SN2734	--	27G X 3/4"	59230
SN2758	--	27Gx5/8"	59230
SN2812	--	28G X 1/2"	59230
SN2912	--	29G X 1/2"	59230
SN3012	--	30G X 1/2"	59230