

Product List – Class I

Tech File # 1750010 Revision AU

Ref #	Description	Class	Rule	Sterile	Initial date	O* date
013105	O* 5.5 mm Interference Screwdriver, Large Handle	I	6	N/A	6/1997	12/2001
013106	O* 7.0 mm Interference Screwdriver	I	6	N/A	6/1997	12/2001
013107	O* 9.0 mm Interference Screwdriver	I	6	N/A	6/1997	12/2001
013124	Fixation Post Driver w/Holder	I	6	N/A	6/1997	
013177	Fixation Post, Tap	I	6	N/A	6/1997	
013190	TAG Arthroscopic Driver, 3.7mm Wedge	I	6	N/A	6/1997	
013191	TAG Arthroscopic Driver, 3.7mm Rod II	I	6	N/A	6/1997	
013194	TAG Driver, 3.7mm Rod II (open procedure)	I	6	N/A	6/1997	
013351	SURETAC Driver	I	6	N/A	6/1997	
013446	TAG Driver, 3.7mm Wedge (open procedure)	I	6	N/A	6/1997	
013472	SpreadLocTool	I	6	N/A	9/1997	
013582	ISOTAC Driver	I	6	N/A	6/1997	
013629	PCL, Screw Driver	I	6	N/A	6/1997	
014270	Cannu-Flex Silk Screw Driver, 7mm, Cannulated	I	6	N/A	6/1997	
014271	Cannu-Flex Silk Screw Driver, 9mm, Cannulated	I	6	N/A	6/1997	
014331	Driver, for Mini-TAG 3.0mm Wedge Style	I	6	N/A	6/1997	
014333	Driver, for Mini-TAG 2.0mm Wedge Style	I	6	N/A	6/1997	
014338	Arthroscopic TAG Driver, 3.0mm Wedge Style	I	6	N/A	6/1997	
014419	O* Adjustable Screw Holder	I	6	N/A	9/1997	1999
014432	Bone Block Remover	I	6	N/A	7/1997	
014511	O*Cannu-Flex Silk Screw Driver, 7mm Non-Cannulated	I	6	N/A	6/1997	5/2009
014542	O*EndoFix Tap, 7.0mm	I	6	N/A	6/1997	5/2012
014543	O*EndoFix Tap, 9.0mm	I	6	N/A	6/1997	5/2012
014607	O*EndoFix Driver	I	6	N/A	6/1997	5/2009
014626	Redux Screw Retainer	I	6	N/A	2/1995	
014627	Redux Screw Extractor	I	6	N/A	6/1995	
014766	Redux Driver, 1.9mm	I	6	N/A	2/1995	
014767	Redux Driver, A2.3mm	I	6	N/A	2/1995	
014768	Redux Driver, 2.4mm	I	6	N/A	2/1995	
014769	Redux Driver, 2.7mm	I	6	N/A	2/1995	
014770	Redux Driver, 3.4mm	I	6	N/A	2/1995	
014815	Driver, 1.5mm Cannulated, 3.5mm Hex	I	6	N/A	8/1995	
014924	Driver, Tibial Anchor	I	6	N/A	5/1999	
3134003	Cannu-Flex Silk Screw Driver	I	6	N/A	3/1999	
3134010	O* EndoFix Tap, 7mm	I	6	N/A	5/1999	2000
3134011	O* EndoFix Tap, 9mm	I	6	N/A	5/1999	2000
3134014	O* Endo-Fix Driver with Hudson Adaptor	I	6	N/A	3/2001	7/2012
3134015	O*Endo-Fix 9mm Tap with Hudson Adaptor	I	6	N/A	3/2001	7/2012
3134016	O*Endo-Fix 7mm Tap with Hudson Adaptor	I	6	N/A	3/2001	6/2012
3134108	O* Cannu-Flex Silk Screw Driver, 7mm Non-Cannulated	I	6	N/A	5/1999	10/2010
3134214	O*Tapered Driver 3.5mm Hex, Non-Cannulated	I	6	N/A	6/2000	7/2012
3134295	Driver, BIORCI with Hudson Adaptor	I	6	N/A	11/2000	
3134299	MTO, 3.5mm Driver, 1.5mm Cannulation w/Hudson Adaptor	I	6	N/A	6/2000	
6900840	O*Heavy Knurled Handle, SLAP Hammer	I	6	N/A	5/2001	1/2010
6900876	T-Handle, Dilator System	I	6	N/A	6/6/11	
6900963	10.5mm Dilator	I	6	N/A	7/2002	
6900964	11.5mm Dilator	I	6	N/A	7/2002	
6901012	Driver, BioRCI, with Hudson Adaptor, Extended 3 Inches	I	6	N/A	2/2010	
6901038	TwinFix Ti 3.5 Threaded Dilator, Reusable	I	6	N/A	6/2003	



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6901046	Dilator w/T-Handle 6.0mm	I	6	N/A	4/2003	
6901047	Dilator w/T-Handle 6.5mm	I	6	N/A	4/2003	
6901048	Dilator w/T-Handle 7.0mm	I	6	N/A	4/2003	
6901049	Dilator w/T-Handle 7.5mm	I	6	N/A	4/2003	
6901050	Dilator w/T-Handle 8.0mm	I	6	N/A	4/2003	
6901051	Dilator w/T-Handle 8.5mm	I	6	N/A	4/2003	
6901052	Dilator w/T-Handle 9.0mm	I	6	N/A	4/2003	
6901053	Dilator w/T-Handle 9.5mm	I	6	N/A	4/2003	
6901054	Dilator w/T-Handle 10.0mm	I	6	N/A	4/2003	
6901055	Dilator w/T-Handle 11.0mm	I	6	N/A	4/2003	
6901056	Dilator w/T-Handle 12.0mm	I	6	N/A	4/2003	
7207031	2.0 Cannulated Driver, w/3.5 mm hex	I	6	N/A	6/1997	
7207193	Acufex RCI Driver	I	6	N/A	10/1996	
7207268	Driver, 2.0mm Cannulated, w/3.5 mm hex	I	6	N/A	4/1998	
7207358	O*Endo-Fix L Driver	I	6	N/A	5/1999	5/2009
7207359	ACUFEX Screw Starter	I	6	N/A	5/1999	
7207586	O*Awl, RotorLoc	I	6	N/A	4/2000	2/2003
7207639	Slap Hammer	I	6	N/A	1/2001	
7207640	6.0mm Dilator	I	6	N/A	1/2001	
7207641	6.5mm Dilator	I	6	N/A	1/2001	
7207642	7.0mm Dilator	I	6	N/A	1/2001	
7207643	7.5mm Dilator	I	6	N/A	1/2001	
7207644	8.0mm Dilator	I	6	N/A	1/2001	
7207645	8.5mm Dilator	I	6	N/A	1/2001	
7207646	9.0mm Dilator	I	6	N/A	1/2001	
7207647	9.5mm Dilator	I	6	N/A	1/2001	
7207648	10.0mm Dilator	I	6	N/A	1/2001	
7207649	11.0mm Dilator	I	6	N/A	1/2001	
7207650	12.0mm Dilator	I	6	N/A	1/2001	
7207704	Driver, 1.5mm Cann, 3.5mm Hex, w/Hudson Adaptor	I	6	N/A	4/2000	
7207705	Driver, 2.0mm Cann., 3.5mm Hex w/Hudson Adaptor	I	6	N/A	4/2000	
7207706	O*Endo-Fix L Driver w/Hudson Adaptor	I	6	N/A	4/2000	7/2006
7207754	Driver BioRCI w/Hudson Adaptor	I	6	N/A	6/2000	
7207755	Tap, BioRCI, 7mm w/Hudson Adaptor	I	6	N/A	6/2000	
7207756	Tap, BioRCI, 8mm w/Hudson Adaptor	I	6	N/A	6/2000	
7207757	Tap, BioRCI, 9mm w/Hudson Adaptor	I	6	N/A	6/2000	
7207758	Tap, BioRCI, 10mm w/Hudson Adaptor	I	6	N/A	6/2000	
7207759	Starter, ACUFEX Screw w/Hudson Adaptor	I	6	N/A	6/2000	
7208656	BioRCI Driver	I	6	N/A	2/2000	
7208661	BioRCI Tap, 7mm	I	6	N/A	2/2000	
7208662	BioRCI Tap, 8mm	I	6	N/A	2/2000	
7208663	BioRCI Tap, 9mm	I	6	N/A	2/2000	
7208664	BioRCI Tap, 10mm	I	6	N/A	2/2000	
7208667	O*Endo-Fix L Tap, 8mm	I	6	N/A	11/1999	5/2009
7208669	O*Absorbable Screw Extractor	I	6	N/A	6/2000	1/2010
7208681	Acufex Spiked Washer Stabilizer	I	6	N/A	1/2001	
7209119	Cannulated Inserter, PeBA	I	6	N/A	4/2001	
7209120	5" Inserter Shaft, PeBA 2.8mm	I	6	N/A	4/2001	
7209121	8" Inserter Shaft, PeBA 2.8mm	I	6	N/A	4/2001	
7209122	Inserter w/o Stop PeBA C Anchor	I	6	N/A	4/2001	





DECLARATION OF CONFORMITY
for Class I Products

Manufacturer's Name: Smith & Nephew, Inc., Endoscopy Division, 150 Minuteman Road, Andover, MA 01810 USA

Name: **Non Invasive Preparation Devices**

Product Code(s): See attached Product List

Technical File Reference Number: 1750095 Rev. V

We, being the manufacturer, declare that the products covered by this declaration conform to the provisions of EC Directive 93/42/EEC Annex VII. This declaration is supported by the self-declaration route to conformance.

Sve Dahlqvist Sve Dahlqvist 28 APR 2015
Printed Name Signature Date of Issue
Regulatory Affairs

Authorized European Representative:

Smith & Nephew Inc.
York Science Park
Heslington, York
YO105DF
United Kingdom

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Ref #	Description	Class	Rule	Sterile	Initial Date	O* Date
013522	6mm Sizing Tube	I	1	N/A	12/1997	
013523	7mm Sizing Tube	I	1	N/A	12/1997	
013524	8mm Sizing Tube	I	1	N/A	12/1997	
013525	9mm Sizing Tube	I	1	N/A	12/1997	
013526	10mm Sizing Tube	I	1	N/A	12/1997	
013527	11mm Sizing Tube	I	1	N/A	12/1997	
013528	12mm Sizing Tube	I	1	N/A	12/1997	
013529	13mm Sizing Tube	I	1	N/A	12/1997	
013540	O*14mm Sizing Tube	I	1	N/A	12/1997	5/2009
013675	O* 9mm Tendon Template	I	1	N/A	5/1997	10/2001
013676	O* 10mm Tendon Template	I	1	N/A	5/1997	10/2001
013677	O* 11mm Tendon Template	I	1	N/A	5/1997	10/2001
014408	O* GraftMaster ACL Preparation Board	I	1	N/A	3/1998	8/2003
014409	O* GraftMaster Preparation Board	I	1	N/A	3/1998	8/2003
014410	O*GraftMaster Preparation Block	I	1	N/A	3/1998	10/2004
014411	GraftMaster Sliding Base	I	1	N/A	3/1998	
014412	GraftMaster, Tissue Graspers	I	1	N/A	4/1997	
014413	GraftMaster Suture Vise	I	1	N/A	4/1997	
014414	GraftMaster Suture Vise w/Tensiometer	I	1	N/A	4/1997	
014415	GraftMaster EndoButton Holder	I	1	N/A	3/1998	
014467	O* GraftMaster ACL Prep Board	I	1	N/A	3/1996	12/1997
014949	GraftMaster II Graft Prep Board	I	1	N/A	4/1997	
014950	GraftMaster II Board. Slide Base	I	1	N/A	4/1997	
014951	O* GraftMaster II EndoButton Holder	I	1	N/A	4/1997	2/1999
014953	GraftMaster II, Cutting Strip	I	1	N/A	4/1997	
313266	O* MTO, GraftMaster Tissue Grasper	I	1	N/A	5/1999	4/2000
313254	O* MTO, 11mm Slotted Sizing Tube	I	1	N/A	1999	1/2004
313331	O*MTO Sizing Tube, 5.5mm	I	1	N/A	1999	1/2004
3134163	SOD, 6mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
3134164	SOD, 6.5mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
3134165	SOD, 7mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
3136166	SOD, 7.5mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
3134167	SOD, 8mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
3134168	SOD, 8.5mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
3134169	SOD, 9mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
3134170	SOD, 9.5mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
3134171	SOD, 10mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
3134173	SOD, 10.5mm Sizing Tube, Slotted 2mm	I	1	N/A	6/1999	
6900849	O*MTO, 4mm Sizing Tube	I	1	N/A	6/2001	1/2010
7207163	6.5mm Sizing Tube	I	1	N/A	12/1997	
7207164	7.5mm Sizing Tube	I	1	N/A	12/1997	



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Ref #	Description	Class	Rule	Sterile	Initial Date	O* Date
7207165	8.5mm Sizing Tube	I	1	N/A	12/1997	
7207342	GraftMaster Tensioning Post	I	1	N/A	5/1999	
7207499	5mm Sizing Tube	I	1	N/A	3/2000	
7207500	5.5mm Sizing Tube	I	1	N/A	3/2000	
7207501	9.5mm Sizing Tube	I	1	N/A	3/2000	
7207502	10.5mm Sizing Tube	I	1	N/A	3/2000	
7207503	11.5mm Sizing Tube	I	1	N/A	3/2000	
7207504	12.5m Sizing Tube	I	1	N/A	3/2000	
7207505	13.5mm Sizing Tube	I	1	N/A	3/2000	
7207638	Graft Sizing Block	I	1	N/A	1/2001	
7207692	GraftMaster II Cutting Strip	I	1	N/A	9/2001	
7207111	O* 4.5 Bone Plug Compressor	I	6	N/A	3/1998	2001
7209214	MTO, Slotted Graft Sizing Block	I	1	N/A	2/2001	
7209281	MTO, Bone Graft Compressor, 9.0mm	I	1	N/A	5/2001	
7209282	MTO, Bone Graft Compressor, 10.0mm	I	1	N/A	5/2001	
7209283	MTO, Bone Graft Compressor, 11.0mm	I	1	N/A	5/2001	
7209440	O* 6mm Compaction Pliers	I	1	N/A	2002	11/2003
7209441	7mm Compaction Pliers	I	1	N/A	5/2002	
7209442	8mm Compaction Pliers	I	1	N/A	5/2002	
7209443	9mm Compaction Pliers	I	1	N/A	5/2002	
7209446	10mm Compaction Pliers	I	1	N/A	5/2002	
7209447	11mm Compaction Pliers	I	1	N/A	5/2002	
7209448	12mm Compaction Pliers	I	1	N/A	5/2002	
7209449	O* Compaction Pliers, Set	I	1	N/A	5/2002	8/2002
7209721	GraftMaster II Scale Extender, EB Holder	I	1	N/A	1/2004	
7209862	GraftMaster II Tensioning Device Holder	I	1	N/A	1/2004	
7209926	GraftMaster II Tensioning Device	I	1	N/A	10/2004	
72201212	Endobutton Direct Holder	I	1	N/A	12/2007	
72201600	Endobutton Direct Ruler	I	1	N/A	12/2007	
72201710	10mm Compaction Pliers with 2mm Center Hole	I	1	N/A	10/2007	
72201852	8mm Compaction Pliers with 2mm Center Hole	I	1	N/A	2/2008	
72201853	9mm Compaction Pliers with 2mm Center Hole	I	1	N/A	2/2008	
72201880	O*8mm Bone Graft Compressor	I	1	N/A	2/2008	5/2012
72202303	Patella Tendon Template, 9mm	I	I	N/A	5/2009	
72202304	Patella Tendon Template, 10mm	I	I	N/A	5/2009	
72202315	GraftMaster III Tissue Grasper	I	1	N/A	12/2009	
72202316	GraftMaster III Sliding Base	I	1	N/A	12/2009	
72202317	GraftMaster III Cutting Strip	I	1	N/A	12/2009	
72202319	GraftMaster III Slotted Sizing Block	I	1	N/A	12/2009	
72202326	Handle, Tensioning Device	I	I	N/A	6/2009	
72202452	Acufex GraftMaster III, Preparation Board	I	1	N/A	12/2009	
72202453	GraftMaster III BTB Holder	I	1	N/A	12/2009	
72202663	5mm x 9mm Oval Sizing Tube	I	I	N/A	10/2009	



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Ref #	Description	Class	Rule	Sterile	Initial Date	O* Date
72202754	BIOSURE SYNC Tensioner	I	1	N/A	3/2010	
72202910	6mm x 11mm Oval Sizing Tube	I	I	N/A	01/2010	
72202912	7mm x 13mm Oval Sizing Tube	I	I	N/A	01/2010	
72203093	HEALICORE Compaction Pliers	I	1	N/A	4/2015	
72203507	8mm Oval Sizing Tube	I	I	N/A	05/2011	
72203508	8.5mm Oval Sizing Tube	I	I	N/A	05/2011	
72203509	9mm Oval Sizing Tube	I	I	N/A	05/2011	
72203510	9.5mm Oval Sizing Tube	I	I	N/A	05/2011	
72203511	10mm Oval Sizing Tube	I	I	N/A	05/2011	
72203512	10.5mm Oval Sizing Tube	I	I	N/A	05/2011	
72203513	11mm Oval Sizing Tube	I	I	N/A	05/2011	
72203514	11.5mm Oval Sizing Tube	I	I	N/A	05/2011	
72203515	12mm Oval Sizing Tube	I	I	N/A	05/2011	
72203877	HEALICORE Transfer Block	I	1	N/A	4/2015	
72203882	HEALICORE Plunger, 6mm	I	1	N/A	4/2015	
72203883	HEALICORE Plunger, 7-8mm	I	1	N/A	4/2015	
72203884	HEALICORE Plunger, 9-10mm	I	1	N/A	4/2015	
72204324	HAT-TRICK Suture Tensioner	I	I	N/A	07/2014	

