



## EC Declaration of Conformity

We

CIVCO Medical Instruments Co., Inc. dba CIVCO Medical Solutions  
102 First Street South  
Kalona, Iowa 52247 United States  
Phone: 319.248.6757  
Fax: 319.656.4451

declare under our sole responsibility that the medical imaging accessory product described hereafter...

Sterile and Non-sterile Needle Guides and Non-sterile Brackets  
*as specified in master list ML 000003*

is in conformity with the general safety and performance requirements and provisions of *Council Directive 93/42/EEC* for Medical Devices,


as a *Class IIa* product following *Rule 5 (body orifice invasive, short-term use)* and *Rule 7 (surgically invasive, short-term use)* from *Annex IX of Council Directive 93/42/EEC*,

and is subject to the procedure set out in *Annex II (excluding Section 4) of Directive 93/42/EEC as amended by 2007/47/EC* under the supervision of *Notified Body number 1639, SGS Belgium NV, SGS House-Noorderlaan 87, Antwerp 2030 Belgium.*

Kalona, Iowa USA *December 2019*

European Regulatory Representative:

MPS  
Medical Product Service GmbH  
Borngasse 20  
35619 Braunfels, Germany  
Phone: 49 6442 32370  
Fax: 49 6442 32578

			Date: <u>Dec-20/19</u>
Person Responsible for Regulatory Compliance (PRRC)			
Date	Rev	Description	Issued By
1 Nov 2019	1	Release new Declaration of Conformity, notified body SGS Belgium	kg

# Master List ML 000003

Technical File Number: 000003

Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
E8385MG	STARTER KIT SINGLE-ANGLE-3.5C (348C) 548C AC2-5 UP II GUIDE W/COVERS
E8385MJ	GUIDE KIT ENDO-E721 STERILE W/ LATEX COVERS
E8385MY	GUIDE ENDO-E721 STERILE
E8385MZ	STARTER KIT MULTI-ANGLE-M3S 3S UPII GUIDE W/COVERS
E8385N	STARTER KIT MULTI-ANGLE-8L, 8L-RS UPII GUIDE W/COVERS
E8385NA	STARTER KIT MULTI-ANGLE-4C UP II GUIDE
E8385RF	STARTER KIT MULTI-ANGLE-M6C AMA, M6C-D, M7C, M7C-H UPII GUIDE W/COVERS
H40432LC	STARTER KIT MULTI-ANGLE 12L-RS UPII GUIDE
H40432LE	STARTER KIT MULTI-ANGLE C1-5-D UPII GUIDE
H40432LJ	STARTER KIT MULTI-ANGLE ML6-15-D UPII GUIDE
H40442LR	STARTER KIT SINGLE-ANGLE 3CRF UP II GUIDE
H40462LB	GUIDE ENDO - E8C QUICK RELEASE STERILE
H40462LD	GUIDE ENDO KIT - E8C QUICK RELEASE STERILE W/LATEX COVERS
H40482LK	C2-7-D UPII MULTI-ANGLE BRACKET STARTER KIT
H40482LL	C2-7 STAINLESS STEEL NEEDLE GUIDE STARTER KIT
H40482LP	Starter Kit Multi Angle 4VC UPII
H42742LH	GUIDE ENDO KIT BE9C STERILE
H42742LJ	GUIDE ENDO KIT - BE9C QUICK RELEASE STERILE
H44901AM	Starter Kit L2-9 Verza
H44901AV	VERZA GUIDANCE SYSTEM -ML4-20 VERZA NEEDLE GUIDE W/CIV-FLEX COVER
H44901AW	Needle Guide - Endocavity RIC10 Sterile
H44901AX	Needle Guide - Endocavity RIC10 w/ Latex Covers Sterile
H45201BLF	VERZA GUIDANCE SYSTEM - L4-20T VERZA NEEDLE GUIDE W/CIV-FLEX COVER
H45281BL	Starter Kit Single-Angle 9L Infiniti Plus Needle Guide
H45561FC	STARTER KIT MULTI-ANGLE M5S-D UPII GUIDE
H46222LC	STARTER KIT MULTI-ANGLE 3Sp UPII GUIDE
H46332LY	GUIDE KIT - INTEG GDE STERILE WITH CIV-FLEX 17.8x147cm
H46701AE	STARTER KIT SINGLE ANGLE RAB2-5-D,RAB4-8-D,RAB4-8L,4D3CL UPII GUIDE
H46721R	Guide Endocavity RIC5-9 SS

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Part Number:	Description:
H48302AA	BRACKET MULTI-ANGLE L3-12
H48392LL	STARTER KIT SINGLE-ANGLE 12L-RS ACCUSITE GUIDE
H48392LT	STARTER KIT SINGLE-ANGLE 12L-RS INFINITI GUIDE
H48681AT	STARTER KIT MULTI-ANGLE C4-8-D UPII GUIDE
H48681GF	GUIDE ENDO RIC5-9 STERILE
H48681MK	STARTER KIT MULTI-ANGLE EeM6C UPII GUIDE W/COVERS
H48681ML	STARTER KIT MULTI-ANGLE RAB6-D ULTRA-PRO II GUIDE
H48691YW	IC9-RS Disposable Guide w/Covers Sterile
H48691YX	IC9-RS Disposable Guide only Sterile
H48691Z	GUIDE ENDO KIT RIC5-9 STERILE
H48701MN	Guide Endocavity IC9
H48701MP	eM6C-G2 UPII Starter Kit
H4906BK	STARTER KIT MULTI-ANGLE 9LUPII GUIDE
H4908SD	STARTER KIT MULTI-ANGLE S1-5 UPII GUIDE
H4913BA	STARTER KIT MULTI-ANGLE GE C2-9-D ULTRA-PRO II GUIDE
H4913BB	STARTER KIT MULTI-ANGLE GE C1-6-D ULTRA-PRO II GUIDE
H4917VB	C1-6 Verza Bracket Starter Kit
P01300-08	STARTER KIT SINGLE-ANGLE L38 UPII GUIDE
P01882-08	STARTER KIT SINGLE-ANGLE C60 UPII GUIDE
P03372-04	GUIDE ENDO KIT C8
p03883-06	NEEDLE GUIDE - EDOCAVITY ICT W/LATEX COVER
P04999-04	STARTER KIT SINGLE-ANGLE P17 UPII GUIDE
P05187-04	STARTER KIT SINGLE ANGLE P10 UPII GUIDE
P05649-04	GUIDE ENDO KIT C8 STERILE W/LATEX COVERS
P07873-02	STARTER KIT SINGLE ANGLE P21 UPII GUIDE
P09072-01	GUIDE KIT L25 STERILE W/CIV-FLEX 10.2 X 147CM 18GA
P09073-01	GUIDE KIT L25 STERILE W/CIV-FLEX 10.2 X 147CM 21GA
P09074-01	GUIDE KIT L25 STERILE W/CIV-FLEX 10.2 X 147CM 22GA
P12051-02	STARTER KIT SINGLE-ANGLE HFL50 UPII GUIDE

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Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
P12868-03	Starter Kit Multi-Angle L38XI UPII Guide
P12920-03	Starter Kit Multi-Angle L25 18ga
P12922-03	Starter Kit Multi-Angle L25 21ga
P12924-03	Starter Kit Multi-Angle L25 22 ga
P15679-01	STARTER KIT MULTI-ANGLE C60xp UPII GUIDE W/COVERS
P18708-01	STARTER KIT MULTI-ANGLE C35XP UPII
P18710-01	STARTER KIT MULTI-ANGLE C60XF UPII
P22244-02	RP19X Starter Kit Ultra-Pro II
P27060-01	NEEDLE GUIDE STARTER KIT - C5-1 INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P27062-01	NEEDLE GUIDE STARTER KIT - C10-3 INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P27064-01	NEEDLE GUIDE STARTER KIT - L12-3 INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P27066-01	NEEDLE GUIDE STARTER KIT - L19-5 INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P27068-01	NEEDLE GUIDE STARTER KIT - L15-4 INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P27070-01	BIOPSY STARTER KIT - L19-5 ACCUSITE NEEDLE GUIDE W/CIV-FLEX COVER
P28639-01	NEEDLE GUIDE STARTER KIT - C35xp INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P28642-01	NEEDLE GUIDE STARTER KIT - C60 INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P28643-01	NEEDLE GUIDE STARTER KIT - C60xf INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P28645-01	NEEDLE GUIDE STARTER KIT - C60xp INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P28662-01	NEEDLE GUIDE STARTER KIT - L38 INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P28664-01	NEEDLE GUIDE STARTER KIT - L38xp INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P28773-01	NEEDLE GUIDE STARTER KIT - HFL50 SERIES INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
P28775-01	NEEDLE GUIDE STARTER KIT - L25 SERIES INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
UA0013	GUIDE-UP3 STERILE
UA1341	STARTER KIT SINGLE-ANGLE 8820E/8823 UP3 GUIDE
04392143	NEEDLE GUIDE - ENDOCAVITY 6.5EV13, EV9-4 SST
04838723	STARTER KIT MULTI-ANGLE C5-2, CX5-2 UPII GUIDE
04838749	STARTER KIT MULTI-ANGLE VF10-5, VF7-3, VFX9-4 UPII GUIDE
04838756	STARTER KIT SINGLE-ANGLE VF13-5, VFX13-5 UPII GUIDE
07472314	STARTER KIT MULTI-ANGLE-CH4-1, CH5-2 UPII GUIDE

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Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
07472322	STARTER KIT SINGLE ANGLE CH6-2 UPII GUIDE
07472330	STARTER KIT MULTI-ANGLE PH4-1 UPII GUIDE
07843159	STARTER KIT MULTI-ANGLE C5F1,UPII GUIDE
07848141	GUIDE ENDO- 6.5EC10
08256947	STARTER KIT SINGLE-ANGLE-5C2G, 6C2 UPII GUIDE
08256950	STARTER KIT MULTI-ANGLE-4V1 UPII GUIDE
08260150	STARTER KIT MULTI-ANGLE-4C1 UPII GUIDE
10041822	GUIDE ENDO KIT- EC9-4 (G40, X150, X300) STERILE
10041823	GUIDE ENDO- EC9-4 (G40)
10044200	STARTER KIT MULTI-ANGLE 18L6 HD UPII GUIDE
10136145	STARTER KIT MULTI-ANGLE 8C3 HD UPII GUIDE
10136306	GUIDE ENDO KIT EV-8C4 STERILE
10563771	GUIDE ENDO KIT-BP9-4 STERILE
10563772	GUIDE ENDO-BP9-4 CURVED SS
10658470	STARTER KIT- VF12-4 W/ULTRA-PRO II
10658731	GDE ENDO KIT BP9-4 STRAIGHT STERILE
10658732	GDE ENDO KIT-BP9-4 STRAIGHT PATH
10658880	GUIDE ENDO KIT- EC9-4W STERILE
10659481	GUIDE ENDO- EC9-4W
10659482	GUIDE ENDO KIT- EC9-4W STERILE
10787043	STARTER KIT SINGLE-ANGLE VF16-5 INFINITI PLUS GUIDE
10787045	ENDOCAVITY GUIDE EV9F3
10787095	ENDOCAVITY GUIDE ONLY EV10-5 QUICK RELEASE STERILE
10787096	GUIDE ENDO EV10-5
11001906	STARTER KIT SINGLE-ANGLE L8-3 INFINITI
11001907	STARTER KIT SINGLE-ANGLE L13-5 ACCUSITE
11002748	Starter Kit Freestyle L8-3
11002759	Freestyle L13-5 Infiniti Starter Kit
11003205	CH-2 Infiniti Starter Kit

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Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
11003356	Freestyle C5-2 Infiniti Starter Kit
11014271	ENDOCAVITY GUIDE KIT EV10-5 QUICK RELEASE STERILE
11287650	14L5 Verza Starter Kit
11291775	L10-5 Ultra-Pro II Starter Kit
11291776	C5-2V Ultra-Pro II Starter Kit
11336181	Guide Endo Kit BP10-3 Sterile
11336182	Guide Endo BP10-3 Sterile
11336183	Guide Endo SS BP10-3
11343996	Endocavity Guide Kit 10MC3 Sterile Disposable
11343997	Endocavity Guide 10MC3 SS
11502761	VERZA GUIDANCE SYSTEM - 13L4 VERZA NEEDLE GUIDE W/ CIV-FLEX COVER 14x91.5cm
11504106	VERZA GUIDANCE SYSTEM - 14L4 VERZA NEEDLE GUIDE W/ CIV-FLEX COVER 14x91.5cm
11504339	NEEDLE GUIDE - ENDOCAVITY 10EV3 w/ LATEX COVERS STERILE
11504340	Needle Guide – Endocavity 10EV3 SST
11506901	NEEDLE GUIDE - ENDOCAVITY 9VE4 W/ LATEX COVERS STERILE
11575442	Needle Guide - Endocavity 9EV4 w/ Latex Cover Sterile
11652961	Needle Guide - Endocavity 9EV4 Sterile
610-1017	GUIDE KIT ACCUSITE STERILE W/CIV-FLEX 14 X 147CM 18GA
610-1018	GUIDE KIT ACCUSITE STERILE W/CIV-FLEX 14 X 147CM 20GA
610-1019	GUIDE KIT ACCUSITE STERILE W/CIV-FLEX 14 X 147CM 21GA
610-1083	ULTRA-PRO e REPLACEMENT KIT 16ga ULTRA-PRO e VARIABLE ANGLE W/ CIV-FLEX COVER
610-1089	ULTRA-PRO e REPLACEMENT KIT 14 gaULTRA-PRO e VARIABLE ANGLE W/ CIV-FLEX COVER
610-1093	GUIDE ENDO D6C12L
610-1123	GUIDE KIT ACCUSITE STERILE W/CIV-FLEX 14 X 147CM 18GA
610-1124	GUIDE KIT ACCUSITE STERILE W/CIV-FLEX 14 X 147CM 20GA
610-1125	GUIDE KIT ACCUSITE STERILE W/CIV-FLEX 14 X 147CM 21GA
610-1134	ULTRA-PRO e REPLACEMENT KIT 18ga ULTRA-PRO e VARIABLE ANGLE W/ CIV-FLEX COVER
610-1137	ULTRA-PRO e REPLACEMENT KIT 20ga ULTRA-PRO e VARIABLE ANGLE W/ CIV-FLEX COVER
610-1144	GUIDE ENDO VR5-9 STERILE

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Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
610-1145	GUIDE ENDO KIT VR5-9 STERILE
610-1214	GUIDE KIT INFINITI+ SM STERILE W/CIV-FLEX 14X29CM
610-1215	GUIDE KIT INFINITI+ LG STERILE W/CIV-FLEX 14X29CM
610-1216	GUIDE KIT ACCUSITE STERILE W/CIV-FLEX 14X29CM 18GA
610-1217	GUIDE KIT ACCUSITE STERILE W/CIV-FLEX 14X29CM 20GA
610-1218	GUIDE KIT ACCUSITE STERILE W/CIV-FLEX 14X29CM 21GA
610-1231	GUIDE KIT INFINITI PLUS STERILE W/CIV-FLEX 14 X 91.5CM
610-1232	GUIDE KIT INFINITI PLUS STERILE W/CIV-FLEX 14 X 147CM
610-1235	GUIDE KIT INFINITI PLUS STERILE W/CIV-FLEX 14 X 91.5CM
610-1236	GUIDE KIT INFINITI PLUS STERILE W/CIV-FLEX 14 X 147CM
610-1274	GUIDE ENDO KIT SE12-3 STERILE
610-1275	GUIDE ENDO SE12-3 STERILE
610-1296	GUIDE KIT UPII STERILE W/ CIV-FLEX 9x91.5CM
610-139	GUIDE ENDO-OMNI STERILE
610-1429	Guide only EndocavitySterile EC7
610-1430	Guide Endocavity Sterile EC7
610-1431	Guide Endocavity SS EC7
610-1500-24	Replacement Kit Verza
610-1501-24	Verza Replacement Kit 5.5x58" CIV-Flex (24)
610-1502-24	Replacement Kit Verza Needle Guide
610-1504-24	Verza Replacement Kit 5.5x58" PEELSafe (24)
610-2342	AccuSITE Replacement Kit 18GA with Envision Cover
610-2343	AccuSITE Replacement Kit 20GA with Envision Cover
610-2344	AccuSITE Replacement Kit 21/22GA with Envision Cover
610-2345	Infiniti Replacement Kit Small GA with Envision Cover
610-2346	Infiniti Replacement Kit Large GA with Envision Cover
610-543	GUIDE ENDO KIT- STERILE W/ LATEX COVERS
610-579	GUIDE KIT UPII STERILE W/ CIV-FLEX 14 x 61CM
610-588	GUIDE ENDO KIT- E6509 STERILE W/CIV-FLEX COVER

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Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
610-590	GUIDE ENDO- E6509 STERILE
610-604	GUIDE ENDO STERILE
610-605	GUIDE ENDO KIT-STERILE W/ LATEX COVERS
610-608	GUIDE KIT UPII STERILE W/ CIV-FLEX 14 X 91.5CM
610-609	GUIDE KIT UPII STERILE W/ CIV-FLEX 17.8 X 91.5CM
610-666	GUIDE ENDO- EC7
610-693	GUIDE ENDO KIT- E6509/ STERILE W/ LATEX COVERS
610-711	GUIDE ENDO KIT- T/V STERILE W/ LATEX COVERS
610-842	GUIDE ENDO- T/V STERILE
610-854	GUIDE ENDO- ERW7-10AK STERILE
610-901	GUIDE KIT UP3 STERILE W/ CIV-FLEX 14 X 91.5CM
610-904	GUIDE KIT UPII STERILE W/ CIV-FLEX 14 X 147CM
610-917	GUIDE KIT UP II STERILE W/ CIV-FLEX 17.8 X 147CM
610-919	GUIDE KIT UP3 STERILE W/ CIV-FLEX 17.8 X 91.5CM
610-958	GUIDE ENDO- BP10-5EC STERILE
610-959	GUIDE ENDO KIT- BP10-5EC STERILE
610-982	GUIDE ENDO KIT- e6509 STERILE W/LATEX COVERS
610-987	GUIDE ENDO- EC9-5 STERILE
610-988	GUIDE ENDO KIT- EC9-5 STERILE W/LATEX COVERS
612-051	GUIDE ENDO KIT- EC7, EC10C5, EC9-4 STERILE W/ LATEX COVERS
612-055	GUIDE ENDO KIT-EC7, EC10C5, EC9-4 STERILE W/LATEX COVERS
612-058	GUIDE KIT QUIK-CLIP STERILE W/ LATEX 5 X 30CM
612-061	GUIDE ENDO- EC7, EC10C5, EC9-4 STERILE
612-062	GUIDE QUIK-CLIP STERILE
612-068	GUIDE KIT QUIK-CLIP STERILE W/CIV-FLEX 14 X 61CM
612-085	STARTER KIT SINGLE-ANGLE-L5, L7, 6L3, 8L5 UPII GUIDE
613-198	GUIDE ENDO- C8-4V
613-209	STARTER KIT MULTI-ANGLE-L12-5 50MM
613-229	STARTER KIT SINGLE-ANGLE- C8-5 UP GUIDE



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Technical File Number: 000003

Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
613-242	GUIDE ENDO C9-5ICT
613-244	STARTER KIT MULTI-ANGLE-C9-4 UPII GUIDE W/COVERS
613-245	GUIDE ENDO KIT- C9-5 STERILE W/ LATEX COVER
613-246	GUIDE ENDO- C9-5 STERILE
613-247	STARTER KIT MULTI-ANGLE-L17-5 INFINITI GUIDE W/COVERS
614-079	GUIDE ENDO- UST-945 STERILE
614-089	GUIDE KIT ENDO- UST-670P-5 STERILE W/ LATEX COVERS
614-090	GUIDE ENDO KIT- UST-9118, UST-9124 BRACKET
614-094	GUIDE ENDO- UST-670P-5 STERILE
614-095	GUIDE ENDO- UST-9118, UST-9124 STERILE
614-096	GUIDE ENDO KIT- UST-9118, UST-9124 STERILE W/ CIV-FLEX COVER
614-100	STARTER KIT SINGLE-ANGLE UST-987 UPII GUIDE
614-102	STARTER KIT SINGLE-ANGLE UST-979 UPII GUIDE
614-106	STARTER KIT MULTI-ANGLE UST-5410 UPII GUIDE
614-110	GUIDE ENDO- UST-676LP STERILE
614-111	GUIDE ENDO KIT- UST-676LP STERILE W/LATEX COVERS
614-112	STARTER KIT MULTI-ANGLE UST-52105 UPII GUIDE
614-114	NEEDLE GUIDE - ENDOCAVITY UST-677P STERILE
614-115	NEEDLE GUIDE - ENDOCAVITY UST-677P W/ LATEX COVER STERILE
620-116	STARTER KIT SINGLE-ANGLE 8870 INFINITI GUIDE
639-012	GUIDE ENDO EC1123 STERILE
639-013	GUIDE ENDO KIT EC1123 STERILE W/LATEX COVERS
639-014	BIOPSY STARTER KIT - CA421, CA430, CA431 INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER
639-015	STARTER KIT MULTI-ANGLE LA332 UPII GUIDE
639-016	STARTER KIT SINGLE-ANGLE LA523 INFINITI GUIDE
639-018	STARTER KIT MULTI-ANGLE CA430 UPII GUIDE
639-019	STARTER KIT MULTI-ANGLE CA631 UPII GUIDE
639-020	STARTER KIT MULTI-ANGLE BC431 UPII GUIDE
639-021	BIOPSY STARTER KIT - LA435, SL2325 INFINITI PLUS NEEDLE GUIDE W/CIV-FLEX COVER

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Part Number:	Description:
639-022	STARTER KIT MULTI-ANGLE LA523 UPII GUIDE
639-023	STARTER KIT MULTI-ANGLE LA435 UPII GUIDE
639-024	STARTER KIT SINGLE-ANGLE CA631 INFINITI GUIDE
639-025	STARTER KIT SINGLE -ANGLE SL3323 INFINITI GUIDE
639-026	STARTER KIT SINGLE-ANGLE LA332 INFINITI GUIDE
639-027	STARTER KIT SINGLE-ANGLE SC3421 INFINITI GUIDE
639-028	STARTER KIT MULTI-ANGLE CA123 UPII GUIDE
639-032	STARTER KIT MULTI-ANGLE CA541 UPII GUIDE
639-033	STARTER KIT SINGLE-ANGLE CA541 INFINITI GUIDE
639-034	STARTER KIT MULTI-ANGLE LA533 UPII GUIDE
639-035	STARTER KIT SINGLE-ANGLE LA533 INFINITI GUIDE
639-036	STARTER KIT MULTI-ANGLE AL2442 ULTRA-PRO II GUIDE
639-037	Starter Kit Single-Angle AL2442 Infiniti Plus Guide
639-045	STARTER KIT MULTI-ANGLE SC3123 ULTRA-PRO II GUIDE
639-047	STARTER KIT SINGLE-ANGLE AC2541 INFINITI GUIDE
639-049	STARTER KIT MULTI-ANGLE AC2541 ULTRA-PRO II GUIDE
639-053	LA533 Needle Guide Starter Kit
639-054	C1-8 Needle Guide Kit
639-058	C1-8 Needle Guide Only
639-059	LA533 Guide Only Kit
639-060	Verza Guidance System – LMX 4-20 Verza Needle Guide w/ CIV-Flex Cover
639-062	Verza Guidance System – CX 1-8 Verza Needle Guide w/ CIV-Flex Cover
644-068	GUIDE ENDO- CC531 STERILE
644-069	GUIDE ENDO KIT- CC531 STERILE W/LATEX COVERS
644-073	STARTER KIT MULTI-ANGLE UST-9147 UPII GUIDE
644-075	STARTER KIT MULTI-ANGLE UST-5415 UPII GUIDE
644-077	STARTER KIT MULTI-ANGLE EUP-C532 UPII GUIDE
644-079	STARTER KIT MULTI-ANGLE EUP-L52 UPII
644-082	STR KIT MULTI-ANGLE C251/C35 UPII GUIDE

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Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
644-092	Needle Guide - Transvaginal C41V1 Sterile
644-093	Needle Guide - Transvaginal C41V1 Sterile w/ Latex Covers Sterile
644-094	BX2 NEEDLE GUIDE - C23 W/CIV-FLEX COVER
644-095	Starter Kit - C23, C23RV Verza Needle Guide w/ CIV-Flex Cover
644-101	Needle Guide - Endocavity CC41R2 Sterile
644-102	Needle Guide - Endocavity CC41R2 w/ Latex Cover Sterile
645-068	STARTER KIT SINGLE-ANGLE-L12-3 UPII GUIDE W/COVERS
657-014	GUIDE ENDO- STERILE
657-024	GUIDE ENDO- NEV4-9ES, NER4-9ES
657-025	GUIDE ENDO- V9-4V
657-029	STARTER KIT MULTI-ANGLE L4-7 UPII GUIDE
657-033	STARTER KIT MULTI-ANGLE P4-12 UPII GUIDE
657-034	DISPOSABLE ENDOCAVITY GUIDE E3-12A
657-035	ENDOCAVITY GUIDE KIT E3-12A STERILE W/LATEX COVERS
657-042	STARTER KIT LA4-18B UPII
657-050	CA3-10A Starter Kit
657-052	Starter Kit LM4-15B/LM4-15BD Ultra-Pro II
657-057	STARTER KIT - CA1-7A ULTRA-PRO II NEEDLE GUIDE w/CIV-FLEX COVER
657-064	Guide Endocavity TR SS EA2-11AR/EA2-11AV
657-065	Guide Endocavity TV SS EA2-11AR/EA2-11AV
657-066	Guide Endocavity SS V5-9
657-067	Guide only Endocavity TV Sterile EA2-11AR/EA2-11AV
657-068	Guide Endocavity TV Sterile EA2-11AR/EA2-11AV
657-069	Guide only Endocavity TR Sterile EA2-11AR/EA2-11AV
657-070	Guide Endocavity TR Sterile EA2-11AR/EA2-11AV
657-071	Guide Endocavity E3-12A SS
657-072	Endocavity Guide Kit E3-12A Sterile Disposable
657-073	Endocavity Guide Kit E3-12A Sterile Disposable w/ covers
657-078	Verza Guidance System - LA418-A Verza Needle Guide w/CIV-Flex Cover

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Technical File Number: 000003

Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
657-080	VERZA GUIDANCE SYSTEM - CA1-7S VERZA NEEDLE GUIDE W/CIV-FLEX COVER
657-088	Verza Guidance System - LM2-18 Verza Needle Guide w/CIV-Flex Cover
657-090	VERZA GUIDANCE SYSTEM - PA1-5A VERZA NEEDLE GUIDE W/CIV-FLEX COVER
657-094	Verza Guidance System - LA2-9S Verza Needle Guide w/CIV-Flex Cover
658-001	STARTER KIT SINGLE-ANGLE L14-6Ns INFINITI PLUS GUIDE
658-002	STARTER KIT MULT-ANGLE C5-2S UPII GUIDE
667-066	GUIDE ENDO KIT-3D9-3V STERILE W/ CIV-FLEX COVERS
667-069	STARTER KIT SINGLE-ANGLE-PA4-2 S4-2 UPII GUIDE W/COVERS
667-070	STARTER KIT MULTI-ANGLE-L9-3 UPII GUIDE W/COVERS
667-071	STARTER KIT MULTI-ANGLE ERGO C5-2 UPII GUIDE
667-074	STARTER KIT MULTI-ANGLE V6-2 UPII GUIDE
667-075	STARTER KIT MULTI-ANGLE C6-3 UPII GUIDE
667-077	STARTER KIT MULTI-ANGLE C5-1 UPII GUIDE
667-089	GUIDE ENDO- C8-4V STERILE
667-090	GUIDE ENDO KIT- C8-4V STERILE W/LATEX COVERS
667-091	STARTER KIT MULTI-ANGLE CXL12-3 UPII GUIDE
667-095	GUIDE MULTI-ANGLE C5-2
667-097	GUIDE MULTI ANGLE C8-5
667-099	GUIDE MULTI ANGLE S5-1,S5-2
667-101	STARTER KIT MULTI ANGLE VL13-5 UPII GUIDE
667-102	STARTER KIT MULTI-ANGLE S5-1 UPII GUIDE
667-103	STARTER KIT MULTI-ANGLE C8-5 UPII GUIDE
667-105	STARTER KIT MULTI-ANGLE X6-1 UPII GUIDE
667-106	STARTER KIT SINGLE-ANGLE L12-4 INFINITI GUIDE
667-107	GUIDE ENDO - C8-4V,C10-3V QUICK-RELEASE STERILE
667-108	GUIDE ENDO KIT - C8-4V, C10-3V QUICK RELEASE STERILE W/LATEX COVERS
667-109	STARTER KIT MULTI-ANGLE C5-2 ULTRA-PRO II GUIDE W/COVERS
667-111	STARTER KIT MULTI-ANGLE S4-1 ULTRA-PRO II GUIDE W/COVERS
667-112	GUIDE ENDO KIT-C9-4V STERILE W/LATEX COVERS

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Technical File Number: 000003

Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
667-113	GUIDE ENDO-C9-4V STERILE
667-114	GUIDE ENDO KIT-C9-4V STERILE W/LATEX COVERS
667-115	GUIDE ENDO KIT-C9-4V
667-116	GUIDE ENDO KIT-C9-4V STERILE W/LATEX COVERS
667-117	GUIDE ENDO-C9-4V STERILE
667-118	GUIDE ENDO KIT-C9-4V STERILE W/LATEX COVERS
667-119	GUIDE MULTI-ANGLE C5-2
667-121	GUIDE ENDO KIT-C9-4V
667-124	GUIDE ENDO-C9-4V QUICK-RELEASE STERILE
667-125	GUIDE ENDO KIT-C9-4V QUICK-RELEASE STERILE W/LATEX COVERS
667-126	Starter Kit Single-Angle L12-4 AccuSITE
667-127	Starter Kit Single-Angle C5-1 Infiniti Plus Guide
667-128	STARTER KIT MULTI-ANGLE C9-3IO UPII GUIDE
667-129	STARTER KIT MULTI-ANGLE CLEARVUE L12-4 ULTRA-PRO II GUIDE W/COVERS
667-133	GUIDE ENDO C10-4EC STERILE
667-134	GUIDE KIT ENDO C10-4EC STERILE W/LATEX COVERS
667-135	GUIDE ENDO C10-4EC W/CLEANING BRUSHES
667-139	STARTER KIT C9-2 Guide Guide SST w/covers
667-141	STARTER KIT MULTI-ANGLE C9-2 UP II GUIDE W/COVERS
667-142	Starter Kit XL14-3 Ultra Pro II
667-143	EL18-4 INFINITI BRACKET STARTER KIT
667-144	Starter Kit EL8-4 Ultra Pro II
667-153	STARTER KIT MULTI-ANGLE L12-5 39MM GUIDE
667-161	C5-1 Verza Starter Kit
667-162	X6-1 Verza Starter Kit
667-164	C9-2 Verza Starter Kit
667-166	L12-5 50mm Verza Starter Kit
667-168	EL18-4 Verza Needle Guide Starter Kit
667-170	L18-5 Verza Needle Guide Starter Kit

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Technical File Number: 000003

Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
667-172	L12-3 Verza Starter Kit
667-174	XL14-3 Verza Starter Kit
667-177	VERZA NEEDLE GUIDANCE SYSTEM - V9-2 VERZA NEEDLE GUIDE W/CIV-FLEX COVER
667-178	Starter Kit C5-2 Ultra-Pro II
668-001	HBG-882MT UPII Starter Kit
670-036	EV5C Verza Starter Kit
671-002	AccuSITE Needle Guide Starter Kit
672-001	STARTER KIT SINGLE-ANGLE SL15-4 INFINITI GUIDE
672-002	STARTER KIT MULTI-ANGLE SC6-1 UPII GUIDE
674-015	GUIDE ENDO- C8 STERILE
674-030	STARTER KIT SINGLE-ANGLE L25 INFINITI GUIDE
674-030-T	STARTER KIT TETHER SINGLE-ANGLE L25 INFINITI PLUS
674-031	STARTER KIT SINGLE-ANGLE L38 INFINITI GUIDE
674-031-T	STARTER KIT TETHER SINGLE-ANGLE L38 INFINITI PLUS
674-035	STARTER KIT SINGLE-ANGLE L38XI INFINITI GUIDE
674-036	STARTER KIT SINGLE-ANGLE C60 INFINITI GUIDE
674-037	STARTER KIT MULTI-ANGLE L25 SERIES GUIDE
674-038	STARTER KIT MULTI-ANGLE L25 SERIES GUIDE
674-039	STARTER KIT MULTI-ANGLE L25 SERIES GUIDE
674-040	GUIDE ENDO KIT - ICT SERIES STERILE W/LATEX COVERS
674-044	STARTER KIT SINGLE-ANGLE HFL50 INFINITI GUIDE
674-050	GUIDE ENDO - ICT SERIES STERILE
674-052	STARTER KIT SINGLE-ANGLE C60XP INFINITI PLUS GUIDE W/COVERS
674-054	STARTER KIT SINGLE-ANGLE C60xp INFINITI PLUS GUIDE
674-059	STARTER KIT C35XP INFINITI PLUS
674-061	STARTER KIT SINGLE-ANGLE C60XF INFINITI PLUS GUIDE
674-068	STARTER KIT SINGLE-ANGLE L38 ACCUSITE
674-070	Starter Kit Single-Angle C11 Infiniti Plus Guide
676-110	GUIDE ENDO KIT- BE9-4 STERILE W/ LATEX COVERS

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Technical File Number: 000003

Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
676-112	GUIDE ENDO- BE9-4 STERILE
676-132	GUIDE ENDO-EC9-4 (G40, X150, X300) STERILE
676-133	GUIDE ENDO KIT EC9-4 (G40, X150, X300) STERILE W/LATEX COVERS
676-144	GUIDE ENDO KIT-BP9-4 STERILE W/LATEX COVERS
676-150	GUIDE ENDO-BP9-4 STERILE
676-154	Guide Endo EV-8C4 Sterile
676-155	GUIDE ENDO KIT-EV8-C4 STERILE W/LATEX COVERS
676-157	GUIDE ENDO EC9-4W STERILE
676-167	GUIDE ENDO- BP9-4 STRAIGHT STERILE
676-206	Endocavity Guide 10MC3 Sterile Disposable
677-043	GUIDE ENDO KIT-UB10R-065U STERILE W/ LATEX COVERS
677-044	GUIDE ENDO KIT- UB10R-065U STERILE W/ LATEX COVERS
677-057	GUIDE ENDO- UB10R-065U STERILE
678-002	STARTER KIT MULTI-ANGLE-L6-12IS UPII GUIDE W/COVERS
680-062	BIOPSY BRACKET - L006A
680-092	GUIDE ENDO KIT- PVT-740RT STERILE W/LATEX COVERS
680-093	BRACKET ENDOCAVITY- 740RT
680-102	STARTER KIT SINGLE ANGLE TG-4 UPII GUIDE
680-104	STARTER KIT MULTI-ANGLE PSK-37CT UPII GUIDE
680-105	STARTER KIT MULTI ANGLE TG-1 UPII GUIDE
680-106	STARTER KIT MULTI ANGLE PST-25BT UPII GUIDE
680-107	STARTER KIT MULTI-ANGLE TG-3 UPII GUIDE
680-109	STARTER KIT MULTI-ANGLE TG-6 UPII GUIDE
680-110	BX2 BIOPSY BRACKET - PVT382BT
680-112	GUIDE KIT BX2 STERILE W/CIV-FLEX 8.9 X 91.5CM
680-113	GUIDE ENDO-PVT-681MV STERILE
680-114	GUIDE ENDO KIT-PVT-681MV STERILE
680-115	GUIDE ENDO- PVT-740RT STERILE
680-116	GUIDE ENDO PVU-770ST STERILE
680-117	GUIDE ENDO PVU-770ST STERILE W. LATEX COVERS

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Technical File Number: 000003

Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
680-120	GUIDE PVT-781VT AND PVU-781VT STERILE
680-121	GUIDE KIT PVT-781VT AND PVU-781VT STERILE
680-123	STARTER KIT SINGLE-ANGLE PLT-1204BT INFINITI PLUS GUIDE W/COVERS
680-125	STARTER KIT SINGLE-ANGLE PLT-805AT INFINITI PLUS GUIDE W/COVERS
680-127	STARTER KIT MULTI-ANGLE PVT-712BT UPII GUIDE
680-129	PLT-705BT STARTER KIT
680-130	ENDO GUIDE ONLY PVU-681MVL STERILE
680-131	ENDO GUIDE KIT PVU-681MVL STERILE W/LATEX COVERS
680-132	Starter Kit I18LX5 AccuSite
680-134	PLI-2004BX AccuSite Starter Kit
680-137	PLI-2004BX UPII Starter Kit
680-139	PLI-1205BX UPII Starter Kit
680-143	PVI-475BX UPII Starter Kit
680-145	PVI-475BT UPII Starter Kit
680-147	Starter Kit I24LX8 Verza
680-149	Starter Kit I18LX5 Verza
680-150	PLI-705BX Verza Starter Kit
680-153	Starter Kit I8CX1 Verza
680-155	Starter Kit I8C1 Verza
680-156	Verza Guidance System - PSI-40VX/PSI-30VX Verza Needle Guide w/CIV-Flex Cover
680-158	Verza Guidance System - 6C2 Verza Needle Guide w/CIV-Flex Cover
680-160	STARTER KIT 11L4/18L7 VERZA NEEDLE GUIDE
680-162	Biopsy Starter Kit - 11L4/18L7 AccuSITE Needle Guide w/CIV-Flex Cover
680-164	Biopsy Starter Kit - i11LX3 AccuSITE Needle Guide w/CIV-Flex Cover
680-166	Starter Kit PVI-574BX Verza Needle Guide
680-168	Starter Kit PVT-574BT Verza Needle Guide
680-170	Biopsy Starter Kit - PLT/U-1204BT AccuSITE Needle Guide w/CIV-Flex Cover
680-172	INTEGRATED NEEDLE GUIDE - PVI-450BXP W/CIV-FLEX COVER
680-174	Verza Needle Guidance System - i9LX2 Verza Needle Guide w/CIV-Flex Cover



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Technical File Number: 000003

Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
680-176	Biopsy Starter Kit - i9LX2 AccuSITE Needle Guide w/CIV-Flex Cover
683-002	STARTER KIT SINGLE-ANGLE- 12L5V ACCUSITE GUIDE W/COVERS
688-002	STARTER KIT MULTI-ANGLE SC1-6 UPII GUIDE W/COVERS
688-003	STARTER KIT MULTI-ANGLE L3-12 UPII GUIDE W/COVERS
693-003	STARTER KIT MULTI-ANGLE C5-2 UPII GUIDE
693-004	STARTER KIT MULTI-ANGLE L18-4 UPII GUIDE
693-005	L14-4 UPII Starter Kit
693-006	L11-3 Starter Kit
698-001	STARTER KIT MULTI ANGLE P4-1 UPII GUIDE
698-002	GUIDE ENDO- E9-4
698-003	STARTER KIT SINGLE-ANGLE C5-2 UPII GUIDE
698-004	STARTER KIT SINGLE-ANGLE L10-5 UP II GUIDE
698-005	STARTER KIT SINGLE ANGLE L8-3 ACCUSITE GUIDE
698-006	STARTER KIT SINGLE-ANGLE L14-5SP ACCUSITE GUIDE
698-007	STARTER KIT SINGLE-ANGLE L14-5 INFINITI GUIDE
698-009	STARTER KIT SINGLE ANGLE C9-3 INFINITI GUIDE
698-010	GUIDE ENDO- E9-4 STERILE
698-011	GUIDE ENDO KIT- E9-4 STERILE W/LATEX COVERS
698-012	STARTER KIT SINGLE-ANGLE L14-5W ACCUSITE GUIDE
698-013	STARTER KIT SINGLE-ANGLE C4-1 INFINITI GUIDE
698-014	GUIDE ENDO KIT E9-4 WITH CIV-FLEX STERILE
698-015	STARTER KIT SINGLE-ANGLE L10-5 INFINITI GUIDE
698-019	STARTER KIT MULTI ANGLE C4-1 UPII GUIDE
742-042	GUIDE ENDO- 618E STERILE LONG
742-052	GUIDE ENDO- 618E STERILE MEDIUM
742-252	GUIDE ENDO- 7.5 ENDORECTAL STERILE
742-270	GUIDE KIT ENDO- E721 STERILE W/ LATEX COVERS
742-306	GUIDE ENDO- E721 STERILE
742-337	GUIDE ENDO KIT BE9-C STERILE W/LATEX COVERS

# Master List ML 000003

Technical File Number: 000003

Device: Sterile and Non-sterile Needle Guides and Non-Sterile Brackets

Part Number:	Description:
742-338	GUIDE ENDO BE9-C STERILE
742-378	GUIDE ENDO - RIC5-9 STERILE
742-379	GUIDE ENDO KIT - RIC5-9 STERILE W/LATEX COVERS
742-397-T	STARTER KIT TETHER-SINGLE ANGLE 11L, 11L-D, 12L-RS, 12L-SC INFINITI PLUS
742-400	GUIDE ENDO BE9C QUICK RELEASE STERILE
742-415	GUIDE ENDO KIT E8-C STERILE W/LATEX COVERS
742-416	STARTER KIT SINGLE-ANGLE 9L, 9L-D, 9L-RS INFINITI PLUS GUIDE W/COVERS
742-427	GUIDE ENDO KIT-E8C QUICK-RELEASE STERILE W/LATEX COVERS
742-428	GUIDE ENDO KIT-BE9C QUICK-RELEASE STERILE W/LATEX COVERS