

Briennon, 19th June 2023

Subject: FSN - SAFETY DATA SHEET FOR A MEDICAL DEVICE – Reusable instruments

Ref : AQ2048

Letter sent by email.

For the attention of the materiovigilance correspondent, distributor, doctor and director of healthcare establishment.

Identification of medical devices:

The medical devices concerned is all reusable instruments (all batches).

Reason for Safety Data Sheet:

EVOLUTIS deemed it necessary to inform you about a change in the **sterilization cycle** for its ancillary instruments.

We bring the following information to your attention: Instruments are now sterilized according to a validated cycle of **134°C/18 min** instead of 132°C/4min.

For normative reasons, we had to update our cleaning/disinfection and sterilization validations. Only the sterilization conditions have changed.

We consider it necessary to inform all users of this change.

The potential risk to the patient from an unsterile instrument is infection.

However, the risks associated with the use of the old cycle during the post-validation period have been measured (the old cycle had been validated) and do not present any major risks.

Behaviour:

- Acknowledge receipt of this safety data sheet by returning the page 2
- Send this safety data sheet to your customers
- Sterilize instruments using the validated 134°C/18 min cycle instead of 132°C/4min cycle.

Contact person:

For any questions, you can contact Mrs. Laure Oliver 04-77-60-79-99, qualite@evolutis42.com

This information has been declared to the French authority competent (ANSM) and distributed to distributors.

Best regards

Jean Michel PEGUET
President



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ACKNOWLEDGMENT

I..... the undersigned representative of the company / establishment....., declare that I have read and understood this safety data sheet. I certify that I have sent this safety data sheet to all users of the medical devices concerned.

Date :

Visa :

This acknowledgment of receipt must be returned to Evolutis by email, fax or post:

EVOLUTIS
Service qualité
10 place des tuiliers
42720 BRIENNON (France)
Fax : +33(0)4 77 60 79 90
commercial@evolutis42.com

REF	DESIGNATION	Code GMDN	Code UDI	CLASSE
H01 007	Calcar reamer	36249	03701271018295	C2a
H01 009	Rasp handle quick-click posterior approach	47829	03701271018271	C1r
H01 021	Femoral stem carrier with conical nozzle	59009	03701271018165	C1r
H01 023	Spherical Stem Impactor	32878	03701271018158	C1r
H01 029	Definitive stem impactor Spade tip	32878	03701271018110	C1r
H01 033	Extraction sledge mass	12696	03701271018080	C1r
H02 001	Impaction / Extraction nozzle for heads D28	32856	03701271017717	C1r
H02 2220	Trial head Ø22.2 -2mm 12/14	58479	03701271017472	C2a
H02 2221	Trial head Ø22.2 0mm 12/14	58479	03701271017465	C2a
H02 2222	Trial head Ø22.2 +2mm 12/14	58479	03701271017458	C2a
H02 2280	Trial head Ø28 -3.5mm 12/14	58479	03701271017427	C2a
H02 2281	Trial head Ø28 0mm 12/14	58479	03701271017403	C2a
H02 2282	Trial head Ø28 +3.5mm 12/14	58479	03701271017380	C2a
H02 2283	Trial head Ø28 +7mm 12/14	58479	03701271017366	C2a
H02 2284	Trial head Ø28 +10.5mm 12/14	58479	03701271017342	C2a
H02 2320	Trial head Ø32 -4mm 12/14	58479	03701271017335	C2a
H02 2321	Trial head Ø32 0mm 12/14	58479	03701271017311	C2a
H02 2322	Trial head Ø32 +4mm 12/14	58479	03701271017298	C2a
H02 2323	Trial head Ø32 +8mm 12/14	58479	03701271017274	C2a
H02 2360	Trial head Ø36 -4mm 12/14	58479	03701271017250	C2a
H02 2361	Trial head Ø36 +0mm 12/14	58479	03701271017236	C2a
H02 2362	Trial head Ø36 +4mm 12/14	58479	03701271017212	C2a
H02 2363	Trial head Ø36 +8mm 12/14	58479	03701271017199	C2a
H03 013	Ø 18 clip orientation device	47900	03701271016802	C1r
H03 0346	Trial cage 46 mm Ext 50, int 46	58480	03701271016536	C2a
H03 0350	Trial cage 50 mm Ext 54, int 50	58480	03701271016512	C2a
H03 0354	Trial cage 54 mm Ext 58, int 54	58480	03701271016505	C2a
H03 0358	Trial cage 58 mm Ext 62, int 58	58480	03701271016499	C2a
H03 036	Impaction shaft	47829	03701271016482	C1
H03 0362	Trial cage 62 mm Ext 66, int 62	58480	03701271016475	C2a
H03 037	Cup impaction tip M10 connection	32878	03701271016468	C1r
H03 043	M6 impaction handle	47829	03701271016390	C1r
H03 0445	Trial Cup Ø45 Solid shell	58480	03701271016376	C2a
H03 0447	Trial Cup Ø47 Solid shell	58480	03701271016352	C2a
H03 0449	Trial Cup Ø49 Solid shell	58480	03701271016338	C2a
H03 0451	Trial Cup Ø51 Solid shell	58480	03701271016314	C2a
H03 0453	Trial Cup Ø53 Solid shell	58480	03701271016291	C2a
H03 0455	Trial Cup Ø55 Solid shell	58480	03701271016277	C2a
H03 0457	Trial Cup Ø57 Solid shell	58480	03701271016253	C2a
H03 0459	Trial Cup Ø59 Solid shell	58480	03701271016239	C2a
H03 0461	Trial Cup Ø61 Solid shell	58480	03701271016215	C2a
H03 0463	Trial Cup Ø63 Solid shell	58480	03701271016192	C2a
H03 0465	Trial Cup Ø65 Solid shell	58480	03701271016178	C2a
H03 200212	AO reamer shaft	59009	03701271016154	C2a
H28 001	Reamer S10	45115	03701271015379	C2a
H28 002	Reamer S12	45115	03701271015362	C2a
H28 003	Reamer S14	45115	03701271015355	C2a
H28 004	Reamer S16	45115	03701271015348	C2a
H28 005	Reamer S18	45115	03701271015331	C2a
H28 010	Junction reamer	45115	03701271015317	C2a
H28 012	Curved rasp S12	35559	03701271015300	C2a
H28 013	Curved rasp S14	35559	03701271015294	C2a
H28 014	Curved rasp S16	35559	03701271015287	C2a
H28 015	Curved rasp S18	35559	03701271015270	C2a
H28 016	Curved rasp S20	35559	03701271015263	C2a
H28 018	Ø21 metaphyseal reamer	45115	03701271015256	C2a
H28 022	Left proximal frame	59009	03701271015225	C1r
H28 023	Right proximal frame	59009	03701271015218	C1r
H28 025	Ø6 Abutment Drill	32390	03701271015201	C2a
H28 027	Ø6 sleeve for drill	47815	03701271015195	C1r
H28 037	Right drilling jig Distal Locking S12 to 20	59009	03701271015133	C1r
H28 038	Assembly screw Targeting jig PRIUS	47779	03701271015126	C1r
H28 039	Left drilling jig Distal locking S12 to 20	59009	03701271015119	C1r
H28 040	Combined impaction handle	32878	03701271015102	C1r
H28 041	PRIUS trial metaphysis H65	58481	03701271015096	C2a
H28 042	PRIUS trial metaphysis H75	58481	03701271015089	C2a
H28 043	PRIUS trial metaphysis H85	58481	03701271015072	C2a
H28 044	Sleeve for screw holder	47815	03701271015065	C1r
H28 050	Trial diaphysis S10 lg115	58481	03701271015034	C2a
H28 051	Trial diaphysis S10 lg145	58481	03701271015027	C2a
H28 052	Trial diaphysis S10 lg175	58481	03701271015010	C2a
H28 054	Trial diaphysis S12 lg115	58481	03701271015003	C2a
H28 055	Trial diaphysis S12 lg145	58481	03701271014990	C2a

REF	DESIGNATION	Code GMDN	Code UDI	CLASSE
H28 056	Trial diaphysis S12 lg175	58481	03701271014983	C2a
H28 058	Trial diaphysis S14 lg115	58481	03701271014976	C2a
H28 059	Trial diaphysis S14 lg145	58481	03701271014969	C2a
H28 060	Trial diaphysis S14 lg175	58481	03701271014952	C2a
H28 062	Trial diaphysis S16 lg115	58481	03701271014945	C2a
H28 063	Trial diaphysis S16 lg145	58481	03701271014938	C2a
H28 064	Trial diaphysis S16 lg175	58481	03701271014921	C2a
H28 066	Trial diaphysis S18 lg115	58481	03701271014914	C2a
H28 067	Trial diaphysis S18 lg145	58481	03701271014907	C2a
H28 068	Trial diaphysis S18 lg175	58481	03701271014891	C2a
H28 9000	Basis PRIUS tray Straight diaphysis	12143	03701271014679	C1
H28 9001	Complementary PRIUS tray Curved diaphysis	12143	03701271014662	C1
H28 9002	Trial diaphysis S20 Lg 175 PRIUS	12143	03701271014655	C1
H36 001	Head measurement	32845	03701271013931	C1m
H36 002	Pusher tip for Bipolar cup	32878	03701271013924	C1r
H36 003	Caliper for femoral head for Ø 43 to 59	46479	03701271013917	C1r
H36 2239	Bipolar acetabular trial liner Ø22.2/39	58480	03701271013900	C2a
H36 2241	Bipolar acetabular trial liner Ø22.2/41	58480	03701271013894	C2a
H36 2243	Bipolar acetabular trial liner Ø 22.2/43	58480	03701271013887	C2a
H36 2841	Bipolar acetabular trial liner Ø 28/41	58480	03701271013863	C2a
H36 2843	Bipolar acetabular trial liner Ø28/43	58480	03701271013849	C2a
H36 2845	Bipolar acetabular trial liner Ø28/45	58480	03701271013825	C2a
H36 2847	Bipolar acetabular trial liner Ø 28/47	58480	03701271013801	C2a
H36 2849	Bipolar acetabular trial liner Ø28/49	58480	03701271013788	C2a
H36 2851	Bipolar acetabular trial liner Ø28/51	58480	03701271013764	C2a
H36 2853	Bipolar acetabular trial liner Ø28/53	58480	03701271013740	C2a
H36 2855	Bipolar acetabular trial liner Ø 28/55	58480	03701271013726	C2a
H36 2857	Bipolar acetabular trial liner Ø28/57	58480	03701271013702	C2a
H36 2859	Bipolar acetabular trial liner Ø 28/59	58480	03701271013696	C2a
H36 9001	MOONSTONE with locking ring tray	12143	03701271013672	C1
H38 020	Femoral stem carrier with ergots	59009	03701271013634	C1r
H38 022	Femoral implant holder screw	47779	03701271013627	C1r
H46 003	Assembling screw for stem & Targeting device STEMSYS	47779	03701271012842	C1r
H46 021	3,5mm Long screwdriver For jig	33968	03701271023633	C1r
H46 022	Sleeve for screw holder	47815	03701271012699	C1r
H46 023	Ø4,5 drill lg 233 mm	32390	03701271012682	C2a
H46 024	Main sleeve	47815	03701271012675	C1r
H46 025	Ø4,5 Sleeve for drill	35095	03701271012668	C1r
H46 026	Depth gauge	32845	03701271012651	C1m
H46 027	Jig for Stemsys locking stems Size 12 to 20	59009	03701271012644	C1r
H46 028	Jig extension for 12L-12XL Stemsys locking stems	13180	03701271012637	C1r
H46 029	Long nut for jig extension	47779	03701271012620	C1r
H46 030	T- screwdriver 8mm	33968	03701271020687	C1r
H46 9001	STEMSYS slotted revision tray	12143	03701271012491	C1
H46 9008	tray for STEMSYS revision kit	12143	03701271032345	C1
H46 9009	tray for STEMSYS revision kit complement for locked stem	12143	03701271032338	C1
H46 9058	Lid for STEMSYS revision tray	12143	03701271032321	C1
H46 9059	Lid for STEMSYS revision tray complement for locked stem	12143	03701271032314	C1
H46 R010	STEMSYS Revision rasp S10 Toothed rasp	35559	03701271012262	C2a
H46 R012	STEMSYS Revision rasp S12 Toothed rasp	35559	03701271012255	C2a
H46 R012L	STEMSYS Revision rasp S12L Toothed rasp	35559	03701271012248	C2a
H46 R012XL	STEMSYS Revision rasp S12XL Toothed rasp	35559	03701271012231	C2a
H46 R014	STEMSYS Revision rasp S14 Toothed rasp	35559	03701271012224	C2a
H46 R016	STEMSYS Revision rasp S16 Toothed rasp	35559	03701271012217	C2a
H46 R018	STEMSYS Revision rasp S18 Toothed rasp	35559	03701271012200	C2a
H46 TR10	STEMSYS revision trial stem Slotted S10	58481	03701271012194	C2a
H46 TR12	STEMSYS revision trial stem Slotted S12	58481	03701271012187	C2a
H46 TR14	STEMSYS revision trial stem Slotted S14	58481	03701271012170	C2a
H46 TR16	STEMSYS revision trial stem Slotted S16	58481	03701271012163	C2a
H46 TR18	STEMSYS revision trial stem Slotted S18	58481	03701271012156	C2a
H46 TR20	STEMSYS revision trial stem Slotted S20	58481	03701271012149	C2a
H50 003	Hactiv trial neck 12/14 Standard	58481	03701271012132	C2a
H50 AC10	Distal reamer Ø10x200	45115	03701271011692	C1r
H50 AC11	Distal reamer Ø11x200	45115	03701271011685	C1r
H50 AC12	Distal reamer Ø12x200	45115	03701271011678	C1r
H50 AC13	Distal reamer Ø13x200	45115	03701271011661	C1r
H50 AC14	Distal reamer Ø14x200	45115	03701271011654	C1r
H50 R020	Reactiv toothed rasp size 20	35559	03701271011609	C2a
H52 007	Outer body impactor handle for dual mobility cups	59009	03701271011524	C1r
H52 008	Inner shaft impactor for dual mobility cups	47779	03701271011517	C1r
H52 010	Cup positioner & impactor end piece	32856	03701271011500	C1r
H52 011	Straight impactor for pegs	32878	03701271011494	C1r
H52 017	Straight screw length measurer	32845	03701271011470	C1m

REF	DESIGNATION	Code GMDN	Code UDI	CLASSE
H52 018	Flange bender	13180	03701271011463	C1r
H52 020	Impaction ball	32856	03701271011456	C1r
H52 028	Washer for head centralizer for press	13180	03701271011401	C1r
H52 030	Threaded inserter of heads into inserts (part of press)	47779	03701271011395	C1r
H52 031	10/12 head positioning cone for press	13180	03701271011388	C1r
H52 033	Insert press	13180	03701271011364	C1r
H52 035	Mobile insert adaptator for press	32856	03701271011340	C1r
H52 037	Curved impactor for pegs for tripod cup	32878	03701271011326	C1r
H52 038	Extractor for tripod pegs with universal joint	12696	03701271011319	C1r
H52 2228	Trial insert adaptor For 22.2 heads	13180	03701271011296	C1r
H52 2245	Cup impaction tip Ø44-45	32856	03701271011289	C1r
H52 2247	Cup impaction tip Ø46-47	32856	03701271011272	C1r
H52 2249	Cup impaction tip Ø48-49	32856	03701271011265	C1r
H52 2251	Cup impaction tip Ø50-51	32856	03701271011258	C1r
H52 2253	Cup impaction tip Ø52-53	32856	03701271011241	C1r
H52 2255	Cup impaction tip Ø54-55	32856	03701271011234	C1r
H52 2257	Cup impaction tip Ø56-57	32856	03701271011227	C1r
H52 2259	Cup impaction tip Ø58-59	32856	03701271011210	C1r
H52 2261	Cup impaction tip Ø60-61	32856	03701271011203	C1r
H52 2263	Cup impaction tip Ø62-63	32856	03701271011197	C1r
H52 2265	Cup impaction tip Ø64-65-66	32856	03701271011180	C1r
H52 3250	Drill guide for pegs & screws	35095	03701271011173	C1r
H52 9002	Expanding cup holder end piece Ø44-45	12143	03701271011159	C1
H52 9003	Capitole lower tray	12143	03701271011142	C1
H52 9050	Capitole upper tray	12143	03701271032208	C1
H52 M2245	Ø 22/44-45 trial mobile insert	58480	03701271011104	C2a
H52 M2847	Ø 28/46-47 trial mobile insert	58480	03701271011098	C2a
H52 M2849	Ø 28/48-49 trial mobile insert	58480	03701271011081	C2a
H52 M2851	Ø 28/50-51 trial mobile insert	58480	03701271011074	C2a
H52 M2853	Ø 28/52-53 trial mobile insert	58480	03701271011067	C2a
H52 M2855	Ø 28/54-55 trial mobile insert	58480	03701271011050	C2a
H52 M2857	Ø 28/56-57 trial mobile insert	58480	03701271011043	C2a
H52 M2859	Ø 28/58-59 trial mobile insert	58480	03701271011036	C2a
H52 M2861	Ø 28/60-61 trial mobile insert	58480	03701271011029	C2a
H52 M2863	Ø 28/62-63 trial mobile insert	58480	03701271011012	C2a
H52 M2865	Trial mobile insert Ø 28/64-65-66	58480	03701271011005	C2a
S01 006	Ring forceps	13180	03701271008890	C1r
S01 009	Screwdriver For targeting device	33968	03701271012613	C1r
S01 011	Screw holder	12696	03701271008852	C1r
S01 014	Ø3,2 drill, length 145mm AO connection	32390	03701271008845	C2a
S01 015	Hexagonal 3,5 mm screwdriver	33968	03701271008906	C1r
S01 041	Ø5 Drill with pin length 23mm	32390	03701271008661	C2a
S01 042	AO T handle	47829	03701271008654	C1r
S02 012	Stainl. steel lid 522x248 x20 INOMED with printing	12143	03701271008616	C1
S02 017	S. Steel tray 245x244x66 INOMED	12143	03701271008562	C1
S02 018	S. STEEL lid 245x244x20 INOMED	12143	03701271008555	C1