

## URGENT – FIELD SAFETY NOTICE

### Medical devices sold by Victory between May 30, 2017 and July 3, 2017

<b>PRODUCTS CONCERNED</b>	Medical devices sold by Victory after May 29, 2017 until July 3, 2017 : implants, abutments, cutters, drills, etc. (cf attached list)
<b>DESCRIPTION OF THE PROBLEM</b>	Products were sold after expiration of our CE certificates (expiry date May 29, 2017), resulting in non-compliance with regulatory requirements.
<b>RELATED RISKS</b>	The risks associated with this non-conformity were evaluated and Victory did not identify any particular risk or recommendation concerning the follow-up of patients in whom these products may have been implanted/used prior to issuance of this product recall. In particular, no sanitary / health risk was identified because all of the products had been certified compliant prior to May 29, 2017.
<b>HOW TO IDENTIFY THE PRODUCTS CONCERNED</b>	Attached Annex 2 lists all of the products sold during this period. We are sending you a copy of your invoice(s) concerning this period to help you identify the products.
<b>MEASURES TO BE TAKEN BY THE CLIENT / USER</b>	Please fill out attached document Annex 1 to confirm that you have received this information about our voluntary product recall. Do not forget to check the square indicating whether or not you still have any of these products in stock. If you do have some or all of these products in stock, do not use them. Fill out the Product Return Form, sign and date it and send it to us so that we can arrange for return of the products.
<b>ACTIONS SCHEDULED BY VICTORY</b>	This Field Safety Notice is destined to alert clients who received products concerned by this voluntary recall. These products will be replaced as soon as possible or a credit slip will be issued. The appropriate Competent Authority has been informed of this notification.
<b>ADDITIONAL INFORMATION</b>	Should you have any questions or desire any additional information about this voluntary recall, please do not hesitate to contact Victory by telephone (04 93 62 21 01).

Victory	Victory	Anthogyr	Victory
N° REF.	Désignation / Commercial name	LOT/Batch	Code barre
06211	Diskimplant Monobloc 7G2-DDM	13 001 773	1311
06241	Diskimplant Monobloc 7G5-DDM	14 027 724	1412
06410	Diskimplant Monobloc 9G2-DM	15 062 841	1510
06411	Diskimplant Monobloc 9G2-DDM	14 027 725	1412
06420	Diskimplant Monobloc 9G3-DM	14 029 784	1412
062110	Diskimplant Monobloc 7G2-DDM/5	13 313 822	1307
064102	Diskimplant Monobloc 9G2-DM/7	14 033 049	1412
064102	Diskimplant Monobloc 9G2-DM/7	14 027 726	1412A
064202	Diskimplant Monobloc 9G3-DM/7	15 045 489	1509
068104	Diskimplant Monobloc 11G2-DM/9	13 309 550	1305
080100	Implant cylindrique à plaque 33x9/9G2-DP	13 008 310	1401A
083100	Implant cylindrique à plaque 43x7/7G2-DP	15 045 491	1509A
083100	Implant cylindrique à plaque 43x7/7G2-DP	15 062 564	1509
083110	Implant cylindrique à plaque 43x9/9G2-DP	15 045 492	1509A
10031	Cutter 5-DDC	15 038 816	1504
10201	Cutter 7L22	09 213098	0912
10220	Cutter 7L28	12 293 561	1209
10231	Cutter 7-DDC	11 272 596	1112
10420	Cutter 9L28	15 045 488	1509
10431	Cutter 9DDC	16 094 329	1603
21032	Fractal Octocone OI 3.3H11-OF1	13 309 657	1305
21071	Fractal Monobloc 3.3H16-MF4	15 044 776	1506
21091	Fractal Monobloc 3.3H19-MF4	15 046 801	1506
21091	Fractal Monobloc 3.3H19-MF4	15 044 189	1505A
21110	Fractal Monobloc 3.75H8-MF1	14 027 719	1412A
21112	Fractal Octocone OI 3.75H8-OF1	14 027 722	1411A
21130	Fractal Monobloc 3.75H11-MF1	16 094 320	1603B
21130	Fractal Monobloc 3.75H11-MF1	14 027 714	1412C
21130	Fractal Monobloc 3.75H11-MF1	16 094 318	1603A
21132	Fractal Octocone OI 3.75H11-OF1	17 158 637	1702A
21132	Fractal Octocone OI 3.75H11-OF1	15 036 988	1505C
21150	Fractal Monobloc 3.75H13-MF1	16 094 324	1603
21152	Fractal Octocone OI 3.75H13-OF1	17 158 628	1702A
21152	Fractal Octocone OI 3.75H13-OF1	17 158 627	1702
21312	Fractal Plus Octocone OI 4.75H8-OF1	16 094 326	1603
22010	Fratex Octocone 3.3H12-OFX	17 151 120	1611
24112	Fractal Plus Octocone OI 3.75H8-FPO	17 151 128	1611
24112	Fractal Plus Octocone OI 3.75H8-FPO	14 027 718	1411
24132	Fractal Plus Octocone OI 3.75H11-FPO	17 158 647	1702
24132	Fractal Plus Octocone OI 3.75H11-FPO	17 151 121	1611
24132	Fractal Plus Octocone OI 3.75H11-FPO	15 062 808	1510A

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24312	Fractal Plus Octocone OI 4.75H8-FPO	16 105 818	1603
24332	Fractal Plus Octocone OI 4.75H11-FPO	15 047 855	1509
30032	Foret pilote court	538765	1207
30032	Foret pilote court	16 121 919	1608
30063	Foret pilote long	13 315 271	1307
30075	Foret pilote FPXL	13 315 684	1307
31000	Foret fractal 8L30 FR-8L30	15 055 960	1509
31010	Foret fractal FR-8L40	15 056 027	1509
31100	Foret fractal FR-11L30	13 005 102	1312
31110	Foret fractal 11L40 FR-11L40	13 004 695	1312
31200	Foret fractal 13L30 FR-13L30	13 315 268	1307
403220	Pilier de cicatrisation OI pour 3.3 PCIC-3.3OI	15 038 827	1504
403221	Pilier cicatrisation OI pour 3.75 PCIC-3.75OI	16 127 319	1609
40421	Pilier de cicatrisation M1.4 PCICM-3	15 038 137	1504
40461	Pilier large monobloc PLM-3.5	13 308 050	1304T
40461	Pilier large monobloc PLM-3.5	16 130 985	1610
40461	Pilier large monobloc PLM-3.5	16 127 321	1609
40461	Pilier large monobloc PLM-3.5	14 033 812	1501A
40651	Faux moignon transvissé FMT-7	15 038 319	1503
40681	Faux moignon transvissé FMT-5	15 072592	1511T
40713	Pilier Monobloc Axiom H2 PMAX-2	16 094 333	1603
40723	Pilier Monobloc Axiom H2 PMAX-3	16 094 334	1603
40733	Pilier Monobloc Axiom H2 PMAX-4	16 094 335	1603
40812	Pilier Monobloc OI 2mm/M2-0.40 PMOI-2	16 108 539	1605A
40822	Pilier Monobloc OI 2mm/M2-0.40 PMOI-3	15 041 998	1504A
40832	Pilier Monobloc OI 2mm/M2-0.40 PMOI-4	15 045 481	1507A
40832	Pilier Monobloc OI 2mm/M2-0.40 PMOI-4	13 309 701	1305
41514	Faux moignon OI FMOI-5	15 036 989	1504
41534	Faux moignon OI FMOI-7	16 127 321	1609
42122	Attachement bouton pression DB/0.5-M1.4	16 123 598	1608
42162	Attachement bouton pression DB/2.5-M1.4	14 027 732	1411
50016	Vis de fixation titane M1.4 VFT- M1.4	16 123 604	1609C
50214	Vis de fixation or M1.4 VFO-M1.4	311402	1608
50312	Vis de fixation or M2-0.25 VFO-M2	29263	0304
50547	Vis osteosynthese autoforante 5mm VOAF-4	13 313 958	1306
50557	Vis osteosynthese autoforante 5mm VOAF-5	16 094 540	1605A
50557	Vis osteosynthese autoforante 5mm VOAF-5	16 105 820	1605
50567	Vis osteosynthese autoforante 5mm VOAF-6	16 094 344	1605
50613	Vis de fixation titane OI VFT-OI	15 057 154	1509D

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50613	Vis de fixation titane OI VFT-OI	16 149 470	1702A
50616	Vis de fixation titane OI VFT-OI	15 057 155	1509B
60040	Tr-préf pilier large / implant Monobloc TPPL	16 108 538	1605B
60040	Tr-préf pilier large / implant Monobloc TPPL	16 105 946	1605C
60040	Tr-préf pilier large / implant Monobloc TPPL	16 094 341	1603A
60050	Tr-pref hexa implant M2 TPHI	06 103493	0610
60053	Tr-pref unitaire TPMU	16 091 030	1602
60065	Tr-pref octocone OI 3.3 TPOI-3.3C	10 238 151	1010
60090	Tr-pref octocone bridge OI TPOI-3.75C	1 694 338	1603
60090	Tr-pref octocone OI 3.75 TPOI-3.75C	16 105 945	1605
60097	Tr-pref octogone AR TPOI-AR	15 045 480	1509
70340	Bague de collage Ti BCOL	15 048 449	1509E
70340	Bague de collage Ti BCOL	15 060 407	1509D
70346	Bague de collage Ti BCOL-OI	14 027 730	1412
80102	Tournevis CA puits court TCPC	01ACEQ	0107
80104	Tournevis CA puits pliable TCPP	09 193342	0903
80112	Tournevis CA fente court TCFC	13 313 778	1306
81143	Clé hexa creuse contre-angle long CHCAL	14 033 814	1501
81600	Mandrin porte-pilier PP	10 230 943	1007
83410	Mandrin entraîneur court MEC	13 315 625	1307
83420	Mandrin entraîneur long MEL	10 220 035	1002