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CooperSurgical®

June 4, 2021

URGENT FIELD SAFETY NOTICE
COOPERSURGICAL OXYGEN SENSORS

Dear Valued CooperSurgical Customer,

CooperSurgical has issued a Field Safety Notice for 526 lot numbers of its Oxygen Sensors supplied for use in the following incubator and work chamber products; G185 Standard 110V, G185 SensorTech 110V, G185 Standard 230V, G185 SensorTech 230V, G210 InviCell Standard, G210 InviCell Standard US, G210 Invicell Plus Optional pH and External Monitoring, G603 Work Chamber 115V, & G603 Work Chamber 230V. [CooperSurgical part numbers K22400-110, K22200-110, K22400-230, K22200-230, K59500, K59700, K60000, 3.641.831.153, & 3.641.832.153]. The G185 & G210 Incubators provide an environment with controlled temperature at or near body temperature and gas level (CO₂, O₂ and N₂), for the development of human gametes and embryos during in vitro fertilization (IVF) treatment. While the G603 is a laboratory device which is intended to be used and operated in IVF laboratories. This appliance is designed for continuous use in within ambient conditions listed in the product manual.

CooperSurgical is issuing this Notice because the Incubator units are displaying output readings that differ from the measurements taken using a Gas Analyzer. When the display is reading a target setting of 5%, an external meter is reading between 3% and 12% and the Incubator does not alarm. The nonconformity was detected during complaint investigations and a corrective action has been initiated to prevent future recurrence. **The oxygen saturation level may be verified with the use of a gas analyzer or external probe to set oxygen levels to 5%, even if the incubator display shows a different value.** No adverse events have been reported to CooperSurgical due to this potential issue.

This Notice affects 526 lot numbers (Table 1) procured from December 1, 2020 to April 26, 2021 and our records indicate that you have purchased the affected product from CooperSurgical. If the affected product at your facility is displaying any of the above characteristics, please complete the attached **Acknowledgement and Receipt Form** to arrange for an onsite field service call at CooperSurgical's expense. Otherwise, this issue will be addressed at your next onsite routine service at no expense for the correction. Please be advised that we are expecting the Oxygen Sensor replacement to be approximately an extra 2.5 hours during this service. If you do not have affected Oxygen Sensors in inventory, please use the same enclosed Form to indicate that and return it to CooperSurgical so that we may document receipt of this Field Safety Notice.

The relevant regulatory authorities have been notified of this field safety notice. We sincerely apologize for any inconvenience caused by this Field Safety Notice. CooperSurgical is committed to high quality, safe and effective products. Please feel free to reach us at +001.203.601.5200 ext. 3300 with any questions regarding this notice.

Sincerely,

Peter Niziolek
Product Surveillance Manager

**COOPERSURGICAL OXYGEN SENSORS WITHIN
G185 & G210 INCUBATORS & G603 WORK CHAMBERS**

Table 1- Affected Lot Numbers

531540	531541	531542	531543	531544	531545	531546	531547	531548	531549
531550	531551	531552	531553	531554	531555	531556	531557	531558	531559
531560	531561	531562	531563	531564	531565	531566	531567	531568	531569
531570	531571	531572	531573	531574	531575	531576	531577	531578	531579
531580	531581	531582	531583	531584	531585	531586	531587	531588	531589
531590	531591	531597	531598	531599	531600	531601	531602	531603	531604
531605	531606	531607	531608	531609	531610	531611	531612	531613	531614
531615	531616	531617	531618	531619	531620	531621	531622	531623	531624
531625	531626	531627	531628	531629	531630	531631	531632	531633	531634
531635	531636	531637	531638	531639	531640	531641	531642	531643	531644
531645	531646	531647	531648	531649	531650	531651	531652	531653	531654
531655	531656	531657	531658	531659	531660	531661	531662	531663	531664
531665	531667	531668	531669	531670	531671	531672	531673	531674	531675
531676	531677	531678	531679	531690	531691	531692	531693	531694	531695
531696	531697	531698	531699	531700	531701	531702	531703	531704	531705
531706	531707	531708	531709	531710	531711	531712	531713	531714	531715
531716	531717	531718	531719	531721	531722	531723	531724	531725	531726
531727	531728	531729	531730	531731	531732	531733	531734	531735	531736
531737	531738	531739	531740	531741	531742	531743	531744	531745	531746
531747	531748	531749	532001	532034	532035	532036	532037	532038	532039
532040	532041	532042	532043	532044	532045	532046	532047	532048	532052
532053	532054	532070	532071	532072	532073	532074	532075	532076	532077
532079	532080	532081	532082	532083	532084	532085	532086	532087	532088
532089	532090	532091	532092	532103	532104	532105	532106	532107	532108
532109	532110	532111	532112	532113	532114	532115	532116	532117	532118
532119	532120	532121	532122	532123	532124	532125	532126	532127	532128
532129	532130	532131	532132	532134	532135	532136	532137	532138	532139
532140	532141	532142	532143	532144	532145	532146	532147	532148	532149
532150	532151	532152	540659	540660	540661	540662	540663	540665	540666
540667	540668	540669	540670	540671	540672	540673	540674	540675	540676
540677	540678	540679	540680	540681	540682	540683	540684	540685	540686
540687	540688	540689	540691	540692	540693	540694	540695	540696	540697
540698	540699	540700	540701	540702	540708	540710	540711	540712	540713
540714	540715	540716	540717	540718	540719	540720	540721	540723	540724
540725	540726	540727	540730	540731	540732	540733	540734	540735	540736
540737	540738	540739	540740	540741	540742	540743	540744	540745	540746
540747	560830	560831	560900	560901	560930	560952	560953	560954	560967
560968	560969	560970	560971	560972	560973	560974	560975	560976	560977
560978	560979	560980	560981	560983	560984	560985	560986	560987	560988
560989	560990	560991	560992	560993	560994	560995	560996	560997	560998

561000	561001	561002	561003	561004	561005	561006	561007	561008	561009
561010	561011	561012	561019	561025	561026	561027	561028	561030	561031
561032	561033	561034	561035	561036	561040	582528	582531	582533	582534
582535	582537	582538	582539	582541	582542	582543	582544	582545	582547
582553	582554	582555	582556	582557	582558	582559	582560	582561	582562
582563	582564	582566	582567	582568	582569	582570	582571	582572	582574
582576	582578	582579	582580	582581	582582	589268	589269	589270	589272
589273	589274	589275	589276	589277	589278	589279	589280	589281	589282
589283	589284	589285	589286	589287	589288	589289	589290	589291	589292
589293	589294	589295	589296	589297	589298	589299	589300	589301	589302
589303	589304	589305	589306	589307	589308	589309	589310	589311	589312
589313	589314	589315	589316	589317	589318	589319	589320	589321	589322
589323	589324	589325	589326	589327					

Acknowledgement and Receipt Form: Response is required

Please complete this form and return it via email: recall@coopersurgical.com or fax to **+001.203.601.9870** **ATTN: Product Surveillance.**

CooperSurgical will arrange for a product field service at your facility after this form has been received.

Customer Account #: _____ Account Name: _____

Street Address: _____ Town, State, Zip Code: _____

Contact Name: _____ Phone Number: _____

Email address: _____

I have read and understand the Notice instructions provided in the June 4, 2021 letter. Yes ____ No ____

Any adverse events associated with product subject to this Notice? Yes __ No ____

If yes, please explain: _____

Please check the appropriate boxes below and complete the table if applicable.

- We have no inventory within the scope of this Notice.
- We have the following affected product at our facility. We have identified the affected product and will need the following lot numbers serviced onsite.

Lot Number	Quantity to be Serviced

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at **+001.203.601.5200 ext. 3300** or email us at recall@coopersurgical.com. Adverse reactions or quality problems experienced with the use of this product may be reported to the respective Competent Authority's Adverse Event Reporting program either online, by regular mail or by fax.

Acknowledgement and Receipt Form: Response is required

Please complete this form and return it via email: recall@coopersurgical.com or fax to +001.203.601.9870 **ATTN: Product Surveillance.**

FOR DISTRIBUTORS ONLY:

Customer Account #: _____ Account Name: _____

Contact Name/Title: _____ Phone Number: _____

Email address: _____

Please complete the appropriate information below if applicable.

I have read and understand the Notice instructions provided in the June 4, 2021 letter. Yes ___ No___

I have checked my stock and have quarantined inventory consisting of _____ units

Lot Number shipped to Customer : _____ Quantity Shipped: _____

I have identified and notified my customers that were shipped or may have been shipped this product by _____ (Specify date and method of notification)

Or

Please notify the attached is a list of customers who received/may have received this product.

Signature of Receipt: _____