

PRODIMED
6 rue Louis Armand
95130 Le Plessis Bouchard

At Plessis-Bouchard,
August 3rd 2020

URGENT: FIELD SAFETY NOTICE Bacth recall – PRODIMED RA#20_002
LETTER SENT BY PRODIMED ONLY TO CONCERNED EXPORT DISTRIBUTORS

To the attention of concerned Distributor:

Recipients: Quality Manager & Director

Subject:

Identification PRODIMED FSN : Recall of products # RA20_002

ANSM registry number: R2010762

Legal manufacturer: PRODIMED

Description of the product: - Commercial references - Batch number: Single use surgical instruments and sets of the range One Shot®. The complete list of products, references and batch numbers concerned is available on the ANSM website: Safety information -Withdrawal of batches and products in Appendix 2.

Inventory of products delivered within your establishment or medical office: Specific Customer Listing to each establishment, see Appendix 1 of the notice sent by PRODIMED only to concerned health establishments

Dear Sir or Madam,

We inform you that PRODIMED has initiated a voluntary recall on manufactured batches of single use surgical instruments and sets **of the range One Shot®**. As far as you are concerned, the details can be found in Appendix 1 attached to this letter.

1) Description of the product

The description of the medical devices concerned and the complete list of references and batch numbers are available on the ANSM website: Safety information - Withdrawal of batches and products.

2) Reason of the voluntary recall of products

PRODIMED has observed a change in bioburden in its subcontractors of the One Shot® range that could challenge the efficiency of the ethylene oxide sterilization cycle.

Therefore, an undetermined portion of the devices in the concerned batches may not have reached a Sterility Assurance Level of 10^{-6} required for sterile products.

The sterile condition of the products may not be guaranteed.

No incident reports related to this risk have been reported to PRODIMED to date.

As a precautionary principle for patient safety, PRODIMED has decided to recall the concerned batches, in agreement with the National Agency for the Safety of Medicines and Health Products.

3) Potential risk for patients

In addition to the normal risk of infection associated with any intervention, there is an additional potential risk: if a potentially affected product is used in intervention.

In case of infection, medical treatment may be required.

4) Origin of the problem

During the annual review of the sterilization cycle with ethylene oxide for the range One Shot®, PRODIMED has highlighted an evolution of bioburden of the products at its subcontractors that can challenge the efficiency of the sterilization process.

5) Corrective and preventive actions

As a precautionary principle for patient safety, PRODIMED decided to recall the concerned batches on the market.

In parallel with this decision, PRODIMED has started a corrective and preventive action plan to ensure the sterile condition of future manufacturing batches that should be available within 6 months.

6) Action to be taken by the customer / user

Our records indicate that you have received at least one of the above mentioned devices. Therefore, you are concerned by this action.

Please read this notice carefully and take the steps outlined below:

Kindly:

1. Immediately check your inventory and quarantine any device affected by the product recall according to Customer listing attached in appendix #1.
2. Disseminate this notice to all relevant individuals within your organization
3. Remain internally vigilant against this notice until all required actions are taken within your organization.
4. Recall the products in the territories under your responsibility according to the same instructions, and according to the terms of the QTA established with PRODIMED (if applicable). A translation of this letter into your local language will be provided by Prodimed to enable you to communicate with your customers.
5. Complete the Field Safety Notice RA20_002 response form and attach it to the completed, dated and signed inventory, regardless of the level of your stock (even zero). Indeed, your confirmation will allow PRODIMED to carry out a complete traceability of this recall and avoid any unnecessary reminder.
6. Send back the response form and the completed, dated and signed inventory by email to: customer-service@prodimed.com, or by fax: +33 23746388.
7. After receipt the response, our Export Customer Service will contact you to define the next steps to manage the products quarantined.

We would be much obliged if you could reply to this notice before August 31st, 2020 about product in your inventory. Relating products recovered from your customers, you could reply later.

To assist you in recall management, your PRODIMED's Sales Manager in charge of your account will revert to you. Support provided by PRODIMED will be studied, on a case-by-case basis, with said Sales Manager. The effective management process will be done after prior agreement and upon presentation of supporting documents.

Our customer service is closed between August 3rd to 7th 2020. For further questions, please contact the customer service by email serviceclients@ccdlab.com who will fail to come back to you as soon as possible, or by phone at ++ 33 2 37 65 86 20. from August 17th 2020.

In accordance with the recommendations of the Meddev Vigilance Guidance ref. 2.12-1, this safety notice has been communicated to all relevant health authorities and the notified body.

Please inform PRODIMED in case of an undesirable effects observed in relation to the product and the batch concerned. We remind you of the need to report any undesirable effect observed with these devices to PRODIMED and to the health authority in your country.

The safety and well-being of patients and healthcare professionals is the priority of PRODIMED and we want to ensure that only quality products are used by our customers.

We apologize for the inconvenience and thank you in advance for helping us to resolve this issue as quickly and efficiently as possible.

Please accept the expression of my distinguished greetings.

Jean Christophe STERN

Site director of Plessis Bouchard
Materiovigilance Correspondant

Product Code	Product name	Lot #
OS2PHM	SET DE 2 PINCES	50035460
		50037237
OSACCOUCH	SET ACCOUCHEMENT	50034273
		50034328
		50034385
		50034444
		50037801
		50040536
OSCCBB1	SET DE SUTURE CCBB	50034227
		50034279
		50034336
		50034400
		50036142
		50036812
OSCHIRESTH1	SET CHIRURGIE ESTHETIQUE	50037238
		50034280
		50034401
OSDENTADULT1S	SET DENTAIRE ADULTE 1 SACHET	50035456
		50034220
		50034271
		50034326
		50034383
		50034442
		50036140
		50036837
		50037262
OSEPISIO	SET EPISIOTOMIE	50037806
		50034272
		50034327
		50034384
		50034443
OSLA	SET DE SUTURE/LIPO	50037800
		50034228
		50034740
OSLA2	SET DE SUTURE	50035896
		50034191
OSLC	SET DE SUTURE FINE	50034192
		50034229
		50034281
		50034337
		50034403
		50036813
OSNRPHM	SET NRP HENRI MONDOR	50034338
		50040514
OSSTERILET	SET POSE STERILET	50034193
		50034230
		50034282
		50034339
		50034404
		50036144
		50036814
		50037240
SAT0804-3	MANCHE DE BISTOURI NO 3	50037770
		50034283
		50036145

Product Code	Product name	Lot #
SAT0905-16	STYLET OLIVAIRE 16CM 2MM	50034231
		50034340
		50034405
		50035200
		50036815
		50037241
		50040516
		50041790
SAT0915-16	SONDE CANNELEE 16CM	50035201
SAT10	PINCE DE PRECELLE 16,5CM	50034284
		50034342
SAT1001-15	CISEAUX DAUPHIN POINTU MOUSSE 15CM	50034194
		50034232
		50034285
		50034343
		50034407
		50036130
		50036147
		50037773
		50039219
		50040517
SAT1002-20	CISEAUX DAUPHIN MOUSSE MOUSSE 20CM	50034233
		50034344
		50035202
		50036148
		50037242
SAT1016-17	CISEAUX MAYO DROIT 17CM	50034195
		50034234
		50034286
		50034348
		50035461
SAT1017	CISEAUX MAYO COURBE 17CM	50034287
		50036149
		50036817
		50037243
SAT1026-15	CISEAUX METZENBAUM DROIT 15CM	50035203
SAT1027-15	CISEAUX METZENBAUM COURBE 15CM	50034235
		50034288
		50034345
SAT1027-17	CIS METZENBAUM 17CM COURBES B15	50034225
		50034277
		50034398
SAT1027-25	CISEAUX METZENBAUM COURBE 25CM	50034236
		50034289
		50034346
		50034410
		50036150
		50036818
		50037244
		50037777
SAT1036	CISEAUX RAGNEL-KILNER	50040518
		50039221

Product Code	Product name	Lot #
SAT1038	CISEAUX IRIS DROIT 11.5CM	50034237
		50034290
		50034347
		50034411
		50036819
		50036842
		50037245
		50037778
		50041791
SAT1039	CISEAUX IRIS COURBE 11.5CM	50034198
		50034238
		50034291
		50034349
		50034412
		50036131
		50036151
		50036820
		50037246
		50037779
		50039220
		50040519
SAT11	SONDE DENTAIRE 15CM	50034239
		50034292
		50034350
SAT1153	PINCE ADSON SANS GRIFFES 12CM	50034199
		50034240
		50034293
		50034351
		50034414
		50036153
		50036821
		50037247
SAT1154	PINCE ADSON MICRO SANS GRIFFES 12CM	50037781
		50034241
SAT1156	PINCE ADSON A GRIFFES 12CM	50034294
		50036125
SAT1157	PINCE ADSON MICRO A GRIFFES 12CM	50037782
		50034201
		50034295
		50034415
		50036155
SAT1171	PINCE MC INDOE SANS GRIFFE 15CM	50036823
		50034353
SAT12	SPATULE DE HEIDEMANN ADULTE 17CM	50035204
		50034224
		50034242
		50034296
		50034354
		50034416
		50036133
SAT1217	PINCE HALSTED COURBE SANS GRIFFES 12.5CM	50036156
		50036824
		50034243
		50034297
		50034355
		50034417
		50036157
		50036825
		50037250
		50037784
		50039222

Product Code	Product name	Lot #
SAT1219-12	PINCE HALSTED COURBE A GRIFFES 12.5CM	50034244
		50034356
		50035205
SAT1244	PINCE DE KOCHER DROITE A GRIFFES 14CM	50034202
		50034245
		50034298
		50034357
		50034418
SAT128-16	PINCE STANDARD A GRIFFES 14CM	50034203
		50035206
SAT128-17	PINCE STANDARD A GRIFFES 16CM	50034299
SAT129-03	PINCE STAND SANSGRIF 14CMB25	50034189
		50034226
		50034335
		50034399
		50036123
		50037236
		50040513
SAT13	SPATULE DE HEIDEMANN ENFT 16.5CM	50038513
		50039227
SAT1401	ECARTEUR DE FARABEUF 15CM 15MM	50039223
SAT1457	ECARTEUR DE DESMARRES 16MM	50034246
SAT15	MIROIR LARYNGE 16CM DIA 24MM	50034247
		50034300
		50036826
SAT16	SONDE PARODONTALE GRADUEE	50037252
		50038512
SAT1603-13	PORTE AIGUILLE HALSEY 13CM	50034248
		50034301
		50034361
		50034419
		50039225
		50040522
SAT1603-15	PORTE AIGUILLE HALSEY 15CM	50034249
		50034302
		50034362
		50034420
		50040523
SAT1605	PORTE AIGUILLE BAUMGARTNER 14CM	50034250
		50034421
SAT164	PINCE KELLY DROITE SANS GRIFFES 14CM	50034251
		50034303
		50034363
		50036158
		50037253
		50040524

Product Code	Product name	Lot #
SAT167-02	PINCE BENGOLEA COURBE SANS GRIFFES 20CM	50034252
		50034304
		50034364
		50034422
		50036134
		50036159
		50036827
SAT17	DOUBLE SPATULE A CIMENT	50034206
		50034253
		50034305
		50034365
		50034423
		50036135
		50036160
		50036828
SAT225-03	PINCE LONGUETTE COLLIN 25CM	50036835
		50034207
		50034254
		50034306
		50034366
		50034424
		50036136
		50036161
		50036829
SAT225-05	PINCE DE CHERRON 25CM	50036836
		50034208
		50034255
		50034307
		50034367
		50034425
		50036126
		50036137
		50036162
		50037257
		50037788
SAT2515	CROCHET DE GILLIS PETIT	50039226
		50040525
		50034256
		50034308
		50034368
		50034426
		50036163
		50037258
		50037789
SAT47-10	CISEAU REYNOLDS COURBE 18CM	50039230
		50040526
		50037790
		50034257
		50034309
SAT479-44	CURETTE VOLKMANN 17CM 0.50CM	50034369
		50034427
		50040527
		50034310
SAT479-45	CURETTE VOLKMANN 17CM 0.65CM	50034310
SAT569	PINCE A ECHARDES 10CM	50034311

Product Code	Product name	Lot #
SAT569-09	PINCE MAGIL ENFANT 15CM	50034210
		50034258
		50034312
		50034370
		50034429
		50036830
SAT569-10	PINCE MAGIL ADULTE 20CM	50034211
		50034259
		50034313
		50034371
		50034430
		50035459
SAT569-11	PINCE MAGIL ADULTE 25CM	50040528
		50034212
		50034260
		50034314
		50034372
		50034431
SAT607-05	DILATATEUR TRACHEAL LABORDE 14CM	50035458
		50035899
		50036128
		50036165
SAT617-15	SPECULUM DE VOLTOLINI MEDIUM	50036834
		50034213
		50034261
		50034373
SAT671-23	PINCE DE POLITZER SANS GRIFFES	50034432
		50037794
		50034214
		50034262
		50034316
		50034374
SAT672-05	MICRO PINCE DE HARTMANN 7.4MM	50034433
		50039231
		50040529
		50034215
		50034263
		50034317
		50034375
		50034434
SAT680-09	SPECULUM DE HARTMANN 4.5CM	50037259
		50037795
		50039232
		50040530
SAT680-10	SPECULUM DE HARTMANN 5.5CM	50034264
		50034318
		50034376
		50037260
SAT7003	PINCE DEBAKEY 15CM	50034319
		50035898
		50036832
		50037797
SAT7003	PINCE DEBAKEY 15CM	50034265
		50034320
		50034377
		50034436
SAT7003	PINCE DEBAKEY 15CM	50040531
		50040531

Product Code	Product name	Lot #
SAT881-04	PINCE DE POZZI 25CM	50034216
		50034266
		50034321
		50034378
		50034437
		50037798
		50039233
		50040532
SAT907-32	CURETTE DE NOVAK POUR BIOPSIE 23CM 2MM	50034217
		50034267
		50034322
		50034379
SAT907-33	CURETTE DE NOVAK POUR BIOPSIE 23CM 3MM	50034218
		50034268
		50034323
		50034380
		50034439
		50036127
		50036139
		50036833
		50037261
SATE40-041	ECARTEUR DE PAUPIERE SUPERIEURE	50040533
		50034269
		50034324
		50034381
SATE40-042	ECARTEUR DE PAUPIERE INFERIEURE	50034440
		50034270
		50034325
		50034382
		50034441
		50039234
		50041839